Evaluation of the Professional Qualifications Directive 2005/36/EC

Experience reports from national authorities with regard to pharmacists

Evaluating the Professional Qualifications Directive
Experience reports from competent authorities

QUESTIONNAIRE FOR PHARMACISTS

A. RECOGNITION PROCEDURE IN CASE OF MIGRATION ON A PERMANENT BASIS

1. Please describe the government structure of the competent authority or authorities in charge of the recognition and of sanctions/restriction to practice.

2. To what extent have the system of automatic recognition and the general system been a success? How do you see the costs and benefits for patients and for your organisation? Can you give concrete examples. Specify in particular whether automatic recognition based on diploma, Annex V and the current notification system represent an efficient way to facilitate automatic recognition.

Please submit comments for:

- automatic recognition based on diploma
- automatic recognition based on acquired rights

3. Is the general system (as described in article 10) applied in your country each time the conditions for automatic recognition are not met? Are there major difficulties in the recognition procedure under the general system? Please include any comments you may have on the implementation of compensation measures.

4. What is your experience with the recognition procedure for EU citizens with professional qualifications obtained in a third country and already recognised in a first Member State (see Articles 2(2) and 3(3))?

5. Do you accept applications from EU citizens for the recognition of foreign diplomas sent by email or requests made on line? Under which conditions can they send documents and declarations electronically? What are your experiences in this respect?

6. What is the yearly number of applications for recognition from 2000 to 2009? Please submit specific data for applications for automatic recognition based on diplomas, automatic recognition based on acquired rights (as from 2005), and recognition based on the general system[1].

[1] Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

B. TEMPORARY MOBILITY (OF A SELF-EMPLOYED OR AN EMPLOYED WORKER)

7. Are EU citizens interested in using the provisions for exercising their professional activities on a temporary and occasional basis in your Member State? How many citizens used this new system since the directive has been transposed in your country (can you provide any statistics per month, per year) [2]?

8. How are the provisions of Directive 2005/36/EC concerning temporary mobility applied by the competent authorities in practice taking into account the relevant provisions of the Code of Conduct? For instance:

   - How is the "legal establishment" criteria foreseen by Article 5(1) (a) interpreted in practice? What conditions does a migrant need to fulfil in his home Member State in order to be able to provide services?

   - How are the "temporary and occasional basis" criteria foreseen by Article 5.2 interpreted in practice? Do Member States assess duration, frequency, regularity and continuity of an activity and if so according to which criteria?

9. Why is a prior declaration system necessary? What do competent authorities do with the information received? Are other possibilities conceivable?

10. Do you have concrete examples of abuse or misuse of this new possibility for pharmacists? Have you been confronted to problems with regards to patient safety on this issue?

C MINIMUM TRAINING REQUIREMENTS

11. To what extent are the common minimum training requirements set out in Title III Chapter III of Directive 2005/36/EC and the compulsory training subjects as defined in Annex V in line with scientific progress and professional needs? Furthermore, are the knowledge and skills required by the directive still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

12. To what extent are the common minimum requirements for training set out in Title III Chapter III of Directive 2005/36/EC in line with scientific progress and professional needs in the last ten years? Are the knowledge and skills outlined in Article 24.3 still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

13. The Directive is based on mutual trust between Member States. To what extent is such trust actually achieved? Are training programmes accredited in your country? Does accreditation of a training program in another Member State enhance trust or is it not relevant?

14. To what extent are the existing Directive provisions (see recital 39 and Article 22(b) on continuous professional development (continuous training) adequate? What is your

[2] Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

definition of CPD/continuous training? Is continuous training mandatory in your country and what are the exact conditions?

D. ADMINISTRATIVE COOPERATION (THIS SECTION APPLIES TO ESTABLISHMENT AS TO PROVISION OF SERVICES)

15. To which extent does administrative cooperation, as outlined in Articles 8, 50, and 56 of the Directive, simplify procedures for the migrant professionals? Can you give your own experience?

16. Is the competent authority in your country registered with IMI? Under which circumstances does your competent authority use IMI? If not registered, why not and what would be the conditions for changing this situation?

17. How could a professional card (see Recital 32 of the Directive) facilitate recognition of professional qualifications and provision of temporary services? Under which conditions could it be issued by a competent authority?

18. How do you share information about suspensions/restrictions with competent authorities in other Member States? Could more be done in this respect?

E. OTHER OBSERVATIONS

19. How and when are the necessary language skills of migrants checked after recognition of the professional qualifications? Are you aware of any complaints (especially from patients/clients/employers) about insufficient language skills of migrants?

20. Please fill free to add any comment you want on the directive 2005/36/EC

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Bureau de Bruxelles

SYNTHESIS OF THE NATIONAL EXPERIENCE REPORTS ON THE DIRECTIVE 2005/36/EC RELATIVE TO THE RECOGNITION OF QUALIFICATIONS FOR PHARMACISTS

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The European Commission has launched an assessment of the existing system of recognition of professional qualifications, in the perspective of the revision of directive 2005/36/EC.

In this context, DG MARKT would like competent authorities in the Member States to prepare national reports presenting their practical experience in applying this directive. Mr Patrick Fortuit has been charged to coordinate this process for pharmacists at European level (see letter attached).

Consistently with the approach proposed by the Commission, 3 meetings of the competent authorities for pharmacists were organised:

- On the 7th of June 2010, in Brussels: This meeting aimed at discussing the questionnaire proposed by the Commission, adapting it to pharmacists' issues, and validating it as a basis for national experience reports.
- On the 9th of July 2010, in Brussels: During this meeting, projects linked to the European directive (IMI, HPRO) were presented and a debate was organised on the several parts of the questionnaire in order to exchange on the situation in various countries (on recognition in case of migration on a permanent basis, on temporary mobility, on minimum training requirements and on cooperation between competent authorities).
- On 3rd September 2010 in Paris, a draft synthesis of the national reports was presented and debates organised according to the several parts of the questionnaire. Malta was in charge of commenting the answers to part A (with exception of the first question) of the questionnaire, Denmark in charge of part B, France in charge of part C and Belgium in charge of parts D and E.

The questionnaire validated on 7 June 2010 was sent out to competent authorities in the 27 member states, answers to the questionnaire are annexed to the present document.

This document intends to give an overview of the answers received.

This synthesis was elaborated thanks to the contribution of competent authorities from Malta, Denmark, France and Belgium.

PART A: RECOGNITION PROCEDURE IN CASE OF MIGRATION ON A PERMANENT BASIS

Question 2: To what extent have the system of automatic recognition and the general system been a success? How do you see the costs and benefits? Specify in particular whether automatic recognition based on diploma, Annex V and the current notification system represent an efficient way to facilitate automatic recognition. Please submit comments for: automatic recognition based on diploma; acquired rights and on the general system

Question 3: Is the general system (as described in article 10) applied in your country each time the conditions for automatic recognition are not met? Are there major difficulties in the recognition procedure under the general system? Please include any comments you might have concerning the implementation of compensatory measures.

Question 4 : What is your experience with the recognition procedure for EU citizens with professional qualifications obtained in a third country and already recognised in a first Member State (See Articles 2(2) and 3(3))?

Question 5: Do you accept applications from EU citizens for the recognition of foreign diplomas sent by email or requests made on line? Under which conditions can they send documents and declarations electronically? What are your experiences in this respect?

Part A of the questionnaire is relative to the recognition procedure in case of migration on a permanent basis. It has to be noted that the analyse will only be on question 2 to 5, because it was seen as not relevant to make such an analyse on question 1 on government structure of every competent authority as each answer can be looked at in the annexes.

Automatic registration based on diploma

The majority of those that replied declared that **this system is effective and fast and facilitates the recognition process since the qualifications are listed in the annex.** Another positive note is that this system reduces documentation.

On the negative side, this permits pharmacists to be registered even if they have not practiced for a number of years. From the patients' point of view, since language is not a barrier, this might create problems. Germany also mentioned the fact that specification regarding diploma have to be kept up to date (in particular the wording in German is not accurate anymore).

Recognition based on acquired rights

There are a couple of countries such as Malta who have not yet experienced this type. The majority said that this is a fast and effective way for recognition.

Automatic recognition based on acquired rights is an advantage since the person can benefit from automatic recognition only if has the certificate of working experience. But because Directive doesn't specify how many hours person has to work in order to get the certificate of working experience, person can get it also if he works part time. However the Netherlands explained they experiences socme problems with this possibility in particular when certificates are issued wrongly.

The UK raised the issue that there is no mention of the validity of the acquired rights document and feels that this should also have a validity of 3 months from issue.

There was also an issue raised by Hungary on the amount of hours of work that will be valid for acquired rights since there is no mention in the Directive.

Hungary has also raised an issue about the interpretation of 'effective and lawful practice'. The language issue is also of concern to most countries.

Recognition based on general system

The majority agree that this is the **most time consuming of all three systems.** However, it is very exact as the education programme is compared with the programme valid for the particular country in which the applicant is applying. This is more costly for the applicant and administratively more resource intensive but public safety can be taken into account to a certain extent as if the comparison reveals substantial differences can require a period of adaptation training with assessments. The benefits of this system are that it provides the Member State with an assurance of an applicant's current knowledge and competence.

Come country also presented the problem related to the timeframe of 3 months in which a Member State is obliged to reply to the applicants. Germany raised the difficulty to define proper compensation measures. The Netherlands pointed out the costs of organising tests.

The majority of replies indicated that yes, the general system is used when the conditions for automatic recognition are not met.

The UK indicated that the general system of recognition is only applied within the limits permitted by the Directive i.e. within the parameters of Article 10(b) and 10(g). Applicants not entitled to automatic recognition and not covered by the General Systems provisions of 10(b) and 10(g) are considered under the provisions of the EU Treaty and ECJ jurisprudence.

In the case of Belgium, the provisions of the general system have not been trasposed into Belgian law.

There were a couple of countries such as Cyprus, Lithuania and Slovenia who have no experience of applying these conditions.

With regards to difficulties encountered, the majority of those that replied indicated that this system creates many difficulties since an application has to be assessed and evaluated in a short period of time.

Many countries also pointed out that this system creates a financial burden, whilst the applicants also find it difficult to undergo compensatory measures due to language restrictions.

Difficulties were also encountered in providing adaptation period and conducting training.

Recognition procedure for EU citizens with professional qualifications obtained in a third country and already recognised in a first Member State (See Articles 2(2) and 3(3))

This instance seems to be not so common in the Member States. Those who have experienced such cases said that they apply the Hocsman case. Some countries declared that this system is used by applicants who try to find easier routes for registration and then come back to their Home MS to register on the basis of their first recognition in another MS.

Applications sent by email or requests made on line

The majority have declared that they do not accept applications by email or online since the presentation of the physical documents is needed. Most countries provide details as well as registration packs and information by email and online.

Those that declared that they accept applications online or via email, still need the applicants to present their certificates in physical format.

Denmark, Luxembourg and Hungary have replied that they recieve applications online even though their experience is limited and that from their experience it transpires that applicants like the physical contact when applying. Most respondents declared that they do recieve applications via post just as long as all documents are certified, translated and in order. In teh Netehrlands only additional information can be sent out by e-mail. Some countries replied that an on-line facility is likely to be introduced in the near future.

PART B: TEMPORARY MOBILITY (OF A SELF-EMPLOYED OR AN EMPLOYED WORKER)

In this part the following questions were asked:

Question 7: Are EU citizens interested in using the provisions for exercising their professional activities on a temporary and occasional basis in your Member State? How many citizens used this new system since the directive has been transposed in your country (can you provide any statistics per month, per year)[1]?

Question 8: How are the provisions of Directive 2005/36/EC concerning temporary mobility applied by the competent authorities in practice taking into account the relevant provisions of the Code of Conduct? For instance:

- How is the "legal establishment" criteria foreseen by Article 5(1) (a) interpreted in practice? What conditions does a migrant need to fulfil in his home Member State in order to be able to provide services?
- How are the "temporary and occasional basis" criteria foreseen by Article 5.2 interpreted in practice? Do Member States assess duration, frequency, regularity and continuity of an activity and if so according to which criteria?

Question 9: Why is a prior declaration system necessary? What do competent authorities do with the information received? Are other possibilities conceivable?

Question 10: Do you have concrete examples of abuse or misuse of this new possibility for pharmacists? Have you been confronted to problems with regards to patient safety on this issue?

Experience to date

In general most countries have little or no experience with pharmacists whom wish to exercise their professional activity on a temporary and occasional basis in another Member State. In the Netherlands, it is interesting to not that there is another possibility for pharmacists to work on a temporary basis; pharmacists can work on order of a Dutch pharmacist. This is to say that the Dutch pharmacist is responsible of the foreign pharmacist.

The United Kingdom[1] has had two inquiries to date – the applicants choose to apply for establishment instead when they realised they did not have the right to automatic recognition. Denmark, France and Spain have had a few inquiries and one declaration.

Italy has very few pharmacists that exercise their professional activity on a temporary and occasional basis, while in the Czech Republic they had 7 applications in 2009 and have registered an increasing interest from pharmacists who wish to exercise their professional activity on a temporary and occasional basis.

[1] *The Competent Authority for England, Scotland and Wales will be referred to as the UK in this document.*

Hungary has believes that the reason why the number of the declaration concerning temporary mobility is very low is due to the fact that the service providers do not always inform the authorities about their service or that they do not know about this obligation or find that the procedure is too complicated. Spain is of the opinion that applicants prefer to apply for permanent recognition, which means that they do not need to renew their application and which does not require prior declaration of the provision of services they intend to carry out.

Spain has pointed out that the relatively low number of declarations might be explained by the fact that the procedure relating to establishment is virtually the same as the procedure for temporary provision of service and furthermore pharmacists might choose establishment in order not to have to renew their declaration annually.

Practice in general

In general Member States require the service provider to submit information in accordance to article 7 of the directive 2005/36 EC and the code of conduct.

The Czech Republic operates with two types of declarations for temporary provision of service. The most common declaration is the announcement of the visiting person for the medical profession performance, which is time-limited for one year. Another possibility is the so called one-time performance announcement when it is only needed to submit to the Ministry of Health a letter declaring that the applicant has been invited by a health institution for a "one-time performance".

In Italy the information received is forwarded to the competent Order of Pharmacists that is responsible for the territory in which the migrant will be provisionally enrolled during his performance.

In Denmark, Ireland and Slovenia the service provider is entered into a register.

Furthermore, the Slovenian authorities collect information for statistical and analytical purposes, and the information is also used for annual reports to the European Commission.

Interpretation of legal establishment

Legal establishment is interpreted in Denmark as meaning that the applicant has an education automatically recognised under title III chapter III of the directive 2005/36 EC. In cases where the service provider does not have an education which benefits from automatic recognition, the professional qualifications must be verified. Finally the service provider has to document that he or she has not been prohibited from practicing as a pharmacist.

In Ireland the term "establishment" is defined as being the actual pursuit of an economic activity, as referred to in Article 43 of the Treaty, by the provider for an indefinite period and through a stable infrastructure from where the business of providing services is actually carried out.

Legal establishment is in Belgium interpreted as being the obligation to be registered with the Pharmacists Organisation in the Member State and to be authorised to exercise the profession without restrictions or being subject to sanctions.

In Cyprus the migrant must be a registered pharmacist of good professional standing in the country of origin in order to be eligible to either provide services or be established permanently in Cyprus.

France has the understanding that pharmacists are required to be registered by a competent authority in order to constitute "legal establishment".

In Luxembourg the criteria is analysed individually for every application. The migrant must hold an authorization to practice in his country

The UK states that 'Legal establishment' for the sectoral professions appears to be interpreted as the right to practise in the home Member State without the need for evidence that the individual does indeed practise – i.e. evidence of a subsisting contract for services or contract of employment. Legislation must provide for a clearer definition of what is meant by the practitioner being 'legally established'. According to the UK it should be more than being qualified to practise with no prohibition from practice (even temporarily). The UK also does not believe that the directive is sufficiently robust to protect members of the public and patients. The Directive only requires the applicant to demonstrate that they are 'legally established' in a Member State for the practice of their profession. Persons wishing to avoid disciplinary proceedings or who have been removed from practice in one Member State may move from one jurisdiction to another, continuing to rely on 'legal establishment' in a Member State which maybe unaware of any fitness to practise allegations or history of such proceedings in other Member States.

As a 'risk based' regulator, the UK sees this as an area where any person wishing to circumvent reasonable regulatory process may target.

Furthermore the Directive only requires the person to be legally established for the purpose of pursuing the 'activities concerned'. It provides no safeguards in cases of dually qualified persons in circumstances for example where a practitioner who is dually qualified as a doctor and pharmacist, and who has been prohibited from practising as a doctor in his home Member State nevertheless relies on establishment in a Member State as a pharmacist to continue to provide services as a pharmacist in other Member States. Furthermore, the UK remains concerned that they cannot require prospective temporary service providers to complete the same fitness to practise declarations prior to registration as we require of national or European registrants applying to either join the Register or to renew their registration annually. Finally the UK is of the opinion that it would be very helpful if in a review of the Directive the role of the Competent Authority charged with recognition could be clarified in relation to the process that can exist for the authorisation of temporary service provision in a host MS.

Spain interprets "legal establishment" as the applicants' submission of a supporting certificate issued by the relevant authority of the Member State of establishment.

Conclusion

Member States do not have a common interpretation of the notion "legal establishment" apart from the service provider not being prohibited from practicing as a pharmacist in the Member State of Establishment or other Member States.

Interpretation of "temporary and occasional basis" criteria in practice

In Denmark "temporary and occasional basis" is interpreted as a visit or a stay of a period of up to max. 12 months. The applicant is not required to inform the authorities about the duration of his or her stay, as the applicant is not required to give information about contracts.

The Czech Republic has two types of applications for the limited period of time. Most common is the announcement of the visiting person for the medical profession performance that is time-limited for

one year. Another possibility is a so called one-time performance announcement with a maximum time of two months.

"Temporary and occasional basis" has not been defined in Ireland. The Council of the Pharmaceutical Society of Ireland is required to assess, on a case by case basis, the temporary and occasional nature of the provision of the professional services of a registered pharmacist by a visiting pharmacist form another State, having regarded in particular to its duration, its frequency, its regularity and its continuity. Since the question has not yet arisen, no criteria have been laid down.

The applicant must inform the Slovenian authorities about the duration and how often the applicant intends to perform services in Slovenia. The authorities decide in each case on the basis of the information given by the applicant whether or not the service is "temporary and occasional".

The criteria are reviewed on a case-by-case basis in Luxembourg and France, by taking into account the individual characteristics of the declaration made by the service provider. France is of the opinion that the term 'temporary and occasional' is ambiguous and would appreciate further clarification about these notions. France considers that a length of time should not be specified, but it would be appreciated if some specific indications could be defined.

In Spain, service providers shall describe the services to be provided in their prior declaration, with particular reference to their continuity or temporality, as well as to their periodicity.

Conclusion interpretation - "temporary and occasional basis" criteria

The majority of the Member States requires that the service provider is authorised to exercise the profession without restrictions or being subject to sanctions. Besides there is no common interpretation of the notion of "legal establishment".

In general the Member States do not have a common view on the duration of the in order for it to be *"temporary and occasional".* The duration seems to be interpreted as being somewhere within one day and 12 months.

Most Member States asses the *temporary and occasional basis* on a case by case basis. They do so by applying the information given in the declaration by the service provider.

Why is a prior declaration system necessary?

Austria points to the fact that temporary mobility may lead to abuse through by-passing the recognition formalities.

In Cyprus, a prior declaration is necessary to determine the professional qualifications, nationality and indemnities of the applicant as well as to allocate responsibility in the case of false statements and professional misconduct.

Belgium finds that the preliminary statement allows the competent authority to verify with the Member State where the professional is based, whether the latter is legally authorised to exercise his profession.

Hungary is of the opinion that prior declaration/notification is essential because that is the only guarantee the service provider can be supervised by the national authorities in the Member States. The system could work more efficiently, if common sanctions in case of non compliance with the requirement of prior declaration were developed.

Denmark is of the opinion that the declaration system is needed in order to avoid that applicants bypass the procedure concerning establishment under Title III Chapter III of directive 2005/36 EC.

According to Spain a prior declaration is necessary since it replaces the application for recognition and specifies the temporality of services.

Italy, Ireland and the UK find that a prior declaration system is necessary in order to secure patient and public safety. With a prior system of declaration the competent authority has the opportunity intervene before service provider causes damage to patients or public. Furthermore, the UK is of the opinion that prior notification will enable the Member States to verify migrants' identity and qualifications. If the migrants are not entitled to automatic recognition there can be a prior check of their qualifications before the first provision of services is permitted in the interests of public and patient safety. Under UK legislation before anyone can call themselves a pharmacist or practice as a pharmacist they must be registered with the competent authority. A prior declaration is necessary in order to ensure that only eligible individuals are placed on the register before they can provide a service.

France is of the opinion that a prior declaration system is pertinent in order for the competent authority to organize test for declarations within in the general system. The temporary provision of services should not be used by professionals whose diplomas do not meet the criteria for automatic recognition to benefit from this principle to practice in another country.
Furthermore, France points out that it is necessary for the national authorities to receive information on pharmacists practicing on national territory – e.g. in relation to a health crisis or professional misconduct leading to a disciplinary actions.
Finally, France stresses that the temporary provision of services should not offer the opportunity for professionals prohibited from practicing in one Member State to practice in another Member State.

France proposes that the service provider in the future should be obligated to add information about on the first practice place in the host Member State in order to facilitate the internal administrative processing of prior declarations. In cases of professional misconduct the case should be registered with the competent disciplinary chamber.

Conclusion

The prior declaration system is necessary in order to ensure patient and public safety. Furthermore, the system enables the competent authority to check service providers without an education automatically recognised under the directive and to register service providers acting on national territory. Finally the declaration system is pertinent in order to avoid that migrants bypass the automatic and general recognition of establishment procedure as well as avoiding that pharmacists prohibited from practising in other Member States become a service provider in another Member State in order to circumvent a national prohibition to practice.

Examples of abuse or misuse of the right to provide service on a *"temporary and occasional basis"*

The Member States have no examples of misuse.

PART C: MINIMUM TRAINING REQUIREMENTS – DRAFT SYNTHESIS OF THE ANSWERS RECEIVED

The four following questions were asked to competent authorities:

Question 11: To what extent are the common minimum training requirements set out in Title III Chapter III of Directive 2005/36/EC and the compulsory training subjects as defined in Annex V in line with scientific progress and professional needs? Furthermore, are the knowledge and skills required by the directive still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

Question 12: To what extent are the common minimum requirements for training set out in Title III Chapter III of Directive 2005/36/EC in line with scientific progress and professional needs in the last ten years? Are the knowledge and skills outlined in Article 24.3 still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

Question 13: The Directive is based on mutual trust between Member States. To what extent is such trust actually achieved? Are training programmes accredited in your country? Does accreditation of a training program in another Member State enhance trust or is it not relevant?

Question 14: To what extent are the existing Directive provisions (see recital 39 and Article 22(b) on continuous professional development (continuous training) adequate? What is your definition of CPD/continuous training? Is continuous training mandatory in your country and what are the exact conditions?

In general Part C of the questionnaire relative to minimum training requirements seems to be one of the most difficult parts to complete. This could be explained by the fact that competent authorities as identified together with the European Commission on the evaluation of the directive for pharmacists have few responsibilities in this area. In fact it appears that competent authorities are in charge of the recognition of the diploma and not of the content of it. It appears also that at a European level faculties have the power to define programmes for pharmacists' education. The independence of faculties in order to define their own programmes could be seen as an explanation for fewer comments to this area of the questionnaire.

It has to be noted that the directive specifies (both in articles and annexes) the knowledge and skills required for pharmacists. These knowledge and skills were not modified since 1985 when the directive was first drafted. Competent authorities where asked to identify if the knowledge and skills listed in the directive were still adequate.

Even if as explained earlier most of the respondents felt it difficult to answer these questions. The majority felt that the knowledge and skills listed were still adequate (Austria, Czech Republic, Denmark, Italy, Lithuania, Portugal, Slovenia, Spain). In fact the topics listed are so general that even if there were evolutions these evolutions still fits in the text. However, some countries found that the knowledge and skills had to be adapted in order to take into account the evolutions of our society (Ireland, Cyprus, Belgium, Hungary, and France). In particular recent developments in the pharmacists' role known as "pharmaceutical care" are cited as an example in several responses to the questionnaire.

Suggestions were made in particular by Cyprus, Belgium, Germany and France). The purpose of the suggestions is to add some topics to the training subjects, knowledge and skills and not to delete anyone. The Netherlands in particular suggested detailing more the theoretical and practical courses. It was suggested to add the following topics to the pharmaceutical knowledge and skills:

- Clinical pharmacy: therapeutics, pharmacokinetics and communication
- Pharmaceutical care
- Behavioral sciences,
- Pharmaceutical care/Medicines management,
- Pharmacy management and leadership, Medical informatics,
- Complementary and alternative medicines,
- Business studies,
- Legislation, Professional conduct and ethics,
- Dietetics,
- Pathology,
- Biochemistry and molecular biology,
- Immunology,
- Biopharmaceutics,
- Biotechnology,
- Clinical chemistry,
- Clinical pharmacy,
- Pharma-coepidemiology and economics,
- Medical devices and quality assurance during the production and testing of drugs.

It was also suggested to add the following topics to the pharmaceutical activities:

- Pharmaceutical care
- Adequate capability to provide health and medicine information efficiently and effectively
- Adequate knowledge, skills and attitudes that will enable the provision of a safe, high quality service in all healthcare settings within a clinical governance framework that is focused on patient safety.

In the previous version of the directive (Directive 85/432/EEC), it was referred to further training that was being developed in Member States in certain aspects of pharmacy and to possible mutual recognition of qualifications in pharmacy specialities following co-ordination of training. Discussions to date have not led to agreement among Member States on co-ordination of training. Developments in aspects of pharmacy practice are, however, continuing. In the answers given it was felt important to recognise these developments. They are designed to improve further the high quality of pharmaceutical services provided to citizens and to encourage free movement by suggesting mutual recognition of specialities such as hospital pharmacy and clinical laboratory medicine. The possibility for pharmacists to specialise in some area (biology or hospital pharmacy for instance) represent a great opportunity to evolve on the employment market.

These answers reflect the current trends in the pharmaceutical sector. Indeed the traditional role of pharmacists to manufacture and supply medicines is changing. Recently, pharmacists have been faced with new health demands and in particular had to evolve into a more patient centred approach (known as pharmaceutical care). The shortage of some health professionals (in particular doctors) represent also an opportunity for pharmacists which were given some tasks that were used to be done by others. This is why pharmacists have a more direct role in counselling patients, supplying them information and even review, monitor and adapt the therapeutic when needed according to an appropriate plan.

N.B : During the FIP (international Pharmaceutical Federation) annual congress that took place from August 30th 2010 to September 2nd 2010, the FIP presented a study that was organised in 8 countries among which five are European ones (Australia, France, Germany, Italy, Portugal, Turkey, the UK and the U.S.) between April and June 2010.

The international survey on pharmacists' view on their changing roles" In this study, pharmacists had to pronounce themselves on their changing roles. 76% of pharmacists think that the most favourable part of their job is helping patients and patients contact because it increases patients' outcomes and increases the visibility of pharmacists. According to this survey 93% of pharmacists think more information and advice is expected that ever before. Moreover 78% of pharmacists think they are expected to provide additional services to patients. One of the questions asked in this survey is particularly relevant to the training of pharmacists. 2/3 of pharmacists estimate that their training does not prepare them for their current role. When asked what the critical success factors for the next generation of pharmacists are, pharmacists are most likely to volunteer:

- more and better services oriented towards patients;
- increasing and securing competences through initial and continuing education;
- increased knowledge (including specialisation);
- communication skills, patient interaction and counselling;
- disease management;
- Providing new services.

As far as the length of the training is concerned, all the respondents think the duration is fine. However, France and Ireland point out that the training period of 6 months **should be in block** in order to allow pharmacists to have the best possible training.

⇨ Mutual trust:

Most of the answers point out that mutual trust is achieved. The directive dates back to 1985 and the principle there exist for more than 20 years now. The case of Luxemburg is a bit special as no faculty exist and all the pharmacists have to be trained elsewhere. However some member states (mainly new ones) think that trust is not enough and ask for certificates (Slovenia and Lithuania).

In general the accreditation of programs is made by faculties. Ireland suggests in its answer that there should be an obligation for accreditation in each Member State. This obligation coupled with transparent accreditation criteria and transparent processes used to accredit the pharmacist qualification would greatly enhance the established relationships of trust across all Member States.

⇨ Continuing education:

At the meetings organised for this evaluation process there was general agreement that lifelong learning dimension is important due to the evolution of sciences and the changing role of pharmacists. However no clear definition does exist at European level, so it is not sure that every one understands the same with this concept (words lifelong learning, continuing education and CPD are all used).

CPD is becoming more and more mandatory (moral or legal obligation): According to the answers received Slovenia, Austria, Denmark, Hungary, Ireland, Italy, Cyprus, France and Belgium have obligations for continuous professional developments in their laws. In Spain and in Malta discussions ion this issue are going on.

Hungary, Ireland and France suggested going further by offering the possibility of validation of credits all over European. Some member state pointed out the interest of harmonisation in respect of national specificities. The creation of European cards for health professionals could be seen as a possibility to validate continuing education credits in all the European Union.

PART D: ADMINISTRATIVE COOPERATION

Question 15: To which extent does administrative cooperation simplify procedures for the migrant professionals?

Administrative cooperation improved since the IMI system has come into use (Belgium & Italy).
This tool has also cut down the response time.
Administrative cooperation simplifies the procedure for the migrant as relevant information is exchanged between authorities. (Denmark & Italy)
Trough a network of competent authorities, experience and information about legislations could be shared. (France)
The establishing of an informal network for pharmacists would be welcomed. This cooperation could simplify the situation of the applicants. (Hungary)
Administrative cooperation facilitates and fastens the recognition procedure. (Luxembourg & Slovenia
Administrative cooperation guarantees the safety of the recognition process. (Portugal)

Question 16: Is the competent authority in your country registered with IMI? Under which circumstances does your competent authority use IMI? If not registered, why not and what would be the conditions for changing the situation?

All countries answered that their competent authorities are registered with IMI.
IMI is used to reply to inquiries from other Member States and to contact and to request information from other Member States. (Portugal)
Some countries uses the IMI system to verify whether or not education is automatically recognised by the directive, when for instance the education is dated before the country's accession to the directive (Denmark). It is also used in case of doubt on the diploma or the degree or on some certifications presented by professionals (Italy & Luxembourg).
The IMI system is mostly used to exchange information concerning doctors and nurses, and not so much for pharmacists.

Various remarks made about the IMI system:

1. Getting translations of official documents is still a problem. (Austria)
2. Additional comments or information or an extra question is often needed. (Belgium)
3. The validation of the questions raised by a competent authority by the national coordinator delays the exchange. (France)
4. A current weakness in the IMI system is relating to the identification of just one competent authority in a Member State where the separate functions of confirmation of qualifications, and the information regarding current professional status, are carried out by separate authorities. (Ireland)
5. Direct contact between competent authorities for pharmacists has already been established and is already on-going, which reduces the need to use the IMI system (Ireland)
6. The use of IMI should be compulsory for all the Member States' competent authorities. The fact that this is not an obligatory system makes it less effective. (Hungary, Malta and the Netherlands)
7. There should be a time limit for countries to answer (The Netherlands)
8. IMI could be used more efficiently, if strict deadlines were built into the mechanism, as in some cases (and from some authorities) the answer arrives very slowly. (Hungary)
9. The questions specified are unsuitable for individual cases (Germany)

Question 17: How could a professional card facilitate recognition of professional qualifications of temporary services? Under which conditions could it be issued by a competent authority?

Most Member States are positive towards a professional card which can allow the qualified professionals to work in another EU country without having to provide many documents to the competent authority. Only the Netherlands does not see any added value of the card for the recognition of diplomas.

The card contains the essential elements to contact the competent authority in the migrants' country of origin, thus limiting the administrative procedures for the migrant. The card will bear a microchip that will work as a key to access the database of the competent authority of the country of origin and to know at any time the registration status of the health professional. (France)

A professional card enhances mutual trust. (Austria).

The card facilitates the recognition of professional qualifications and is also useful to give access to information about possible disciplinary sanctions pronounced by the competent authority of the country of origin. (Belgium)

Issuing a professional card demands a large number of migrant workers to be cost-effective. (Denmark)

However the card must be supported by an appropriate organisational procedural a technical infrastructure. (Ireland)

The information accessed by using the card, or printed on the card, has to be up-to-date and reliable. (Hungary, Portugal and Lithuania)

The card has to be issued by a national competent authority. (Luxembourg, Lithuania)

Professional associations issue the card if they are competent authority. (Slovenia)

For professions with a high level of mobility the professional card is important. (Austria).

The card could be used to submit certain documents, but it has to be standardised at European level (Germany)
The question of data protection has to be considered (Germany)

Question 18: How do you share information about suspensions / restrictions with competent authorities in other Member States? Could more be done in this respect?

At this moment information about suspensions and restrictions is exchanged through direct and personal contacts between competent authorities, mainly under request (Austria), or by using the IMI system (Denmark).

However the professional card could improve the communication of this information in real time (Belgium).

Concerns exist in some Member States about the authority to share this type of information arising out of the need to comply with data protection laws and these concerns exist notwithstanding the obligation towards that end that are contained in Article 56.2 of the Directive. It is noted that the Construction of Article 56.2 of the Directive, in providing that the data protection legislation be

respected, has left the door open to this particular (mis) interpretation. It is therefore suggested that Article 56.2 should be re-examinated so as to remove any such ambiguity.

The concerns for patient safety that would arise if this form of essential information were not to be shared, for whatever reason, are too great to be ignored and an appropriate amendment to the text would therefore seem to be necessary. (Ireland)

Two types of information sharing can be identified: reactive information sharing on case-by-case basis, and proactive information sharing. Some countries can only share information reactively because of the national data protection legislation. (Hungary)

It would be useful to identify the competent authority in each Member State in this field. (Luxembourg)

Some Member States requires a certificate of Current Professional Status and Fitness to Practise History (known as a "Letter of Good Standing) (UK and Spain).

Question 19: How and when are the necessary language skills of migrants checked after recognition of the professional qualifications? Are you aware of any complaints about insufficient language skills of migrants?

In most Member States the language skills of the migrant professional are not checked by public authorities after recognition. (Belgium, France, Denmark, Luxembourg

Only in case of doubt the health professional is asked to meet with representatives of the competent authority for an interview. This interview comprises an assessment test on the pharmacists' ability to communicate in the native language. (France, Portugal)

In other countries (Italy) language skills are checked after recognition.

In some countries the Code of Ethics or the Act provides that where an EU applicant for registration lacks the linguistic competence to be a registered pharmacist in the State, he or she must provide an undertaking to acquire it. (Ireland)

In Germany the applicant is asked to provide a certificate from a recognised language institute or in individual cases there is a personal interview with the migrant.

Most Member States consider that it is the employer's duty to ensure that the pharmacist has the required competence to communicate fluently with patients in the language of the country and that he has sufficient language skills. The Netherlands considers it incomprehensible that there is a possibility to be recognised and to register with insufficient knowledge of language.

Sometimes the applicant is asked to make a self-declaration concerning his language knowledge when he applies for registration.

All Member States believe that it is essential to ensure that health professionals who are in contact with the patients have sufficient language skills.

Complaints about insufficient language skills were made in Italy and Luxembourg. In Ireland concerns have been expressed about the limited ability in certain circumstances to communicate effectively with patients and their carers in the necessary counselling of patients on their usage of medicines.

CONCLUSION

This synthesis is the first step of the evaluation of the application of the directive 2005/36/EC on the mutual recognition of qualifications. The European Commission envisage to adopt a legislative proposal in order to review the above mentioned directive in 2012 based on the work done until 2011, in order to facilitate the mobility of workers and in particular pharmacists and to adapt education and skills to the needs of today's employment market and patients' needs.

Citizens and patients, when benefiting from cross-border services, should not have their health or safety put at risk and they should be assured of obtaining the highest level of quality and consumer protection. As a consequence, the provision of services should be subject to strict rules. Both host and home country rules and proper registration requirements should apply.

In the answers received it is clearly said that the system of automatic recognition for establishment can be considered as a success as it facilitates the procedure for both competent authorities and pharmacists. As far as temporary provision of services is concerned, competent authorities have only few experiences and it is difficult to draw conclusions at this stage.

The other main messages that have been identified are the following:

- Regarding minimum training requirements and compulsory training, skills and knowledge, the subjects defined in the directive are still in accordance because they are very general. However interesting suggestions are made by competent authorities in order to add new items and in particular to take into consideration the changing role of pharmacists;
- The duration of the training seems to be adequate, but the directive may suggest a number of hours as well and precise that the stage has to be in a block;
- Competent authorities are quite satisfied with the IMI system, even if some improvements need to be made (to become more user friendly and have all the competent authorities participating in the project);
- The question of languages skills is still a concern for competent authorities;
- Continuing professional development and continuing education are becoming more and more mandatory in the various member states, the directive should reflect this move and the possibility to validate continuing education credits in the entire European Union should be further explored;
- The use of professional cards (both for national and European purposes) issued by competent authorities represent an added value for the recognition of diplomas and facilitate the conditions of mobility for health professionals both for establishment and temporary provision of services.

LIST OF ANNEXES

1. Mission Letter from the European Commission
2. Questionnaire
3. List of Competent authorities contacted
4. Answers received

Evaluating the Professional Qualifications Directive
Experience reports from competent authorities

QUESTIONNAIRE FOR PHARMACISTS

A. RECOGNITION PROCEDURE IN CASE OF MIGRATION ON A PERMANENT BASIS

1. Please describe the government structure of the competent authority or authorities in charge of the recognition and of sanctions/restriction to practice.

2. To what extent have the system of automatic recognition and the general system been a success? How do you see the costs and benefits for patients and for your organisation?
Can you give concrete examples. Specify in particular whether automatic recognition based on diploma, Annex V and the current notification system represent an efficient way to facilitate automatic recognition.

Please submit comments for:

- automatic recognition based on diploma
- automatic recognition based on acquired rights

3. Is the general system (as described in article 10) applied in your country each time the conditions for automatic recognition are not met? Are there major difficulties in the recognition procedure under the general system? Please include any comments you may have on the implementation of compensation measures.

4. What is your experience with the recognition procedure for EU citizens with professional qualifications obtained in a third country and already recognised in a first Member State (see Articles 2(2) and 3(3))?

5. Do you accept applications from EU citizens for the recognition of foreign diplomas sent by email or requests made on line? Under which conditions can they send documents and declarations electronically? What are your experiences in this respect?

6. What is the yearly number of applications for recognition from 2000 to 2009? Please submit specific data for applications for automatic recognition based on diplomas, automatic recognition based on acquired rights (as from 2005), and recognition based on the general system[1].

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1 Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

B. TEMPORARY MOBILITY (OF A SELF-EMPLOYED OR AN EMPLOYED WORKER)

7. Are EU citizens interested in using the provisions for exercising their professional activities on a temporary and occasional basis in your Member State? How many citizens used this new system since the directive has been transposed in your country (can you provide any statistics per month, per year) [2]?

8.How are the provisions of Directive 2005/36/EC concerning temporary mobility applied by the competent authorities in practice taking into account the relevant provisions of the Code of Conduct? For instance:

- How is the "legal establishment" criteria foreseen by Article 5(1) (a) interpreted in practice? What conditions does a migrant need to fulfil in his home Member State in order to be able to provide services?

- How are the "temporary and occasional basis" criteria foreseen by Article 5.2 interpreted in practice? Do Member States assess duration, frequency, regularity and continuity of an activity and if so according to which criteria?

9. Why is a prior declaration system necessary? What do competent authorities do with the information received? Are other possibilities conceivable?

10. Do you have concrete examples of abuse or misuse of this new possibility for pharmacists? Have you been confronted to problems with regards to patient safety on this issue?

C MINIMUM TRAINING REQUIREMENTS

11. To what extent are the common minimum training requirements set out in Title III Chapter III of Directive 2005/36/EC and the compulsory training subjects as defined in Annex V in line with scientific progress and professional needs? Furthermore, are the knowledge and skills required by the directive still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

12. To what extent are the common minimum requirements for training set out in Title III Chapter III of Directive 2005/36/EC in line with scientific progress and professional needs in the last ten years? Are the knowledge and skills outlined in Article 24.3 still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

13. The Directive is based on mutual trust between Member States. To what extent is such trust actually achieved? Are training programmes accredited in your country? Does accreditation of a training program in another Member State enhance trust or is it not relevant?

14. To what extent are the existing Directive provisions (see recital 39 and Article 22(b) on continuous professional development (continuous training) adequate? What is your 2 Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports. definition of CPD/continuous training? Is continuous training mandatory in your country and what are the exact conditions ?

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2 Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

D. ADMINISTRATIVE COOPERATION (THIS SECTION APPLIES TO ESTABLISHMENT AS TO PROVISION OF SERVICES)

15. To which extent does administrative cooperation, as outlined in Articles 8, 50, and 56 of the Directive, simplify procedures for the migrant professionals? Can you give your own experience?

16. Is the competent authority in your country registered with IMI? Under which circumstances does your competent authority use IMI? If not registered, why not and what would be the conditions for changing this situation?

17. How could a professional card (see Recital 32 of the Directive) facilitate recognition of professional qualifications and provision of temporary services? Under which conditions could it be issued by a competent authority?

18. How do you share information about suspensions/restrictions with competent authorities in other Member States? Could more be done in this respect?

E. OTHER OBSERVATIONS

19. How and when are the necessary language skills of migrants checked after recognition of the professional qualifications? Are you aware of any complaints (especially frompatients/clients/employers) about insufficient language skills of migrants?

20. Please fill free to add any comment you want on the directive 2005/36/EC

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LIST OF COMPETENT AUTHORITIES CONTACTED

Austria	Österreichische Apothekerkammer
Belgium	• SPF Service Public, Sécurité de la Chaîne alimentaire et Environnement, DG Soins de santé primaires et Gestion de crise • Ordre des pharmaciens, Conseil national
Bulgaria	• Ministry of Health • български фармацевтичен съюз (Bulgarian Pharmaceutical Union)
Cyprus	Pharmacists Registration Board
Czech Republic	• Ministerstvo zdravotnictví - oddělení lékařských povolání a uznávání odborných kvalifikac • Česká lékárnická komora (Czech Chamber of Pharmacists)
Germany	• National subdivisions exist. For the purpose of this evaluation it was decided to contact Bayern region who was in charge to coordinate with the other regional chambers • Bayern Landesapothekerkammer
Denmark	• Københavns Universitet - Det Farmaceutiske Fakultet • Laegemiddelstyrelsen
Estonia	Health Board (Terviseamet)
Spain	• Ministerio de Sanidad y Política Social (Subdirección General de Ordenación Profesional) • Consejo General de Colegios Oficiales de Farmaceuticos España
Finland	• National Supervisory Authority for Welfare and Health (Sosiaali- ja terveysalan lupa- ja valvontavirasto, Valvira)
France	• Conseil National de l'Ordre des Pharmaciens • Ministère de la santé et des sports (DGHOS)
Greece	Ministry of Health and Social Solidarity, Directorate for Health Professions
Hungary	• Egészségügyi Engedélyezési és Közigazgatási Hivatal (Office of Health Authorisation and Administrative Procedures)

Ireland	• The Pharmaceutical Society of Ireland
Italy	• Ministero del lavoro, della salute e delle politiche sociali • Federazione Ordini Farmacisti Italiani (FOFI) (Federation of the Order of Italian Pharmacists)
Lithuania	• Sveikatos apsaugos ministerija (Ministry of Health) • Farmacijos departamentas Department of Pharmacy (Ministry of health)
Luxemburg	• Ministère de la santé- service professions de santé, professions médicales et pharmaciens
Latvia	• Latvijas Farmaceitu biedrība (Pharmacists Society of Latvia)
Malta	Pharmacy Council, Health Division
The Netherlands	• Registratie en Informatie Beroepsbeoefenaren in de Zorg (RIBIZ) (Ministry department) • Registration and Information Health Care Professionals (Ministry departement), RIBIZ
Poland	• 20 regional chambers but the national level aggregates all regional chambers • Naczelna Izba Aptekarska (national pharmaceutical chamber)
Portugal	• Ministério do Trabalho e da Solidariedade Social • Ordem dos Farmaceuticos (College of pharmacists)
Romania	• Ministry of Public Health • The Romanian College of Pharmacists
Sweden	• Socialstyrelsen (The National Board of Health and Welfare)
Slovenia	• Ministrstvo za zdravje (Ministry of Health)
Slovakia	• Slovenská lekárnická komora (Slovak Chamber of Pharmacists)
United Kingdom	• Royal Pharmaceutical Society of Great Britain • The Pharmaceutical Society of Northern Ireland

ANSWERS RECEIVED

Cf. zip file for the answers received

BELGIUM

Federal Public Service of Health of Belgium
Order of Pharmacists of Belgium

Questionnaire for sectoral profession : pharmacists

A. Recognition procedure in case of migration on a permanent basis

1. The Federal Minister for Public Health is competent for recognising the qualifications of health professionals. S/he is assisted in this task by the Administration, the Federal Public Service of Health and more specifically, by the Cell for International Mobility of Health Professionals.

   The Order of Pharmacists of Belgium is the competent authority which gives access to the profession. An inscription as a member at the board of the Order of Pharmacists is mandatory for all pharmacists wishing to exercise the profession in community pharmacies, hospital pharmacies and clinical biology laboratories. The Order of Pharmacists is the legal body for disciplinary matters, including sanctions or restrictions to practice.

2. The automatic system (classic or based on acquired rights) speeds up and facilitates the recognition process, also in legal terms. There is no difference in the treatment of the applications based on automatic system (classic or acquired rights).

   A general system for pharmacists does not exist as of now.

   The notification system for academic titles in order to modify appendix V is not easy in Belgium as academic titles and training courses fall under the competence of linguistic Communities, whereas access to the profession is one of the competences of the Federal Minister for Public Health. It is therefore the federal government that should coordinate the notifications of the 2 linguistic Communities (There is no pharmacist training in the German Community) in the each one of which applies its own legislation, thus making harmonisation impossible.

3. The general system has not been transcribed into Belgian Law for sectoral health professionals. According to law, the answer to an application is either positive or negative.

When the application is rejected, the applicant is asked to apply for academic equivalence from one of the competent linguistic Communities of Belgium for pharmacist training.

4. When the pharmacist's degree has been obtained in a third State and has been recognized in a 1st Member State and if the pharmacist is authorized to exercise his profession in the 1st Member State without any restrictions, then the degree is automatically recognized in Belgium by virtue of Hocsman jurisprudence, the 3 years of experience mentioned in article 3§3 not being mandatory.

5. We do not accept applications made through email. Documents must be sent by post. We ask certified copies of the main documents.

6. See appendix

B. Temporary mobility

7. We have never had any application for temporary exercise of the profession of pharmacist.

8. - We interpret "legal establishment" as being the obligation of the professional to be registered with the Pharmacist Association in this Member State and to be authorised to exercise the profession without any restrictions, and, consequently, that he is not subject to any sanctions when applying for authorization to exercise the profession temporarily in Belgium.

- Each application is examined individually. In general, temporary exercise of profession is not accepted if it lasts longer than 3 months on a full-time basis.

These criteria had not been defined when this provision was transcribed into Belgian law.

9. This preliminary statement allows the competent authority to verify with the Member State where the professional is based, whether the latter is legally authorised to exercise his profession. The Order of Pharmacists and the National Social Security Institute are informed of this temporary exercise of profession through this preliminary statement.

10. No

C. Minimum training requirements

11. *Answer of The Order of pharmacists* : During the last year of the academic course a practical training of 6 months in a community pharmacy or hospital pharmacy is required to obtain the diploma

12. *Answer of The Order of pharmacists :* The list of knowledge and skills contained in Article 44.3 has to be updated.
As the profession of pharmacist is in constant progress and evolution an adequate level of knowledge and skills is necessary to assure the competency of the pharmacist to provide pharmaceutical care to his patients, to give correct scientific information about the delivered medicines, and to assure good pharmaceutical practices in general. A new Royal Decree of 21.01.2009 contains a guide of "good pharmaceutical practices" which contains the requirements for quality in the professional exercise.

13. *Answer of The Order of pharmacists*: As diplomas of other European Member States are accepted, the training programmes are also accepted

14. *Answer of The Order of pharmacists*: Continuous training was not mandatory in a legal way, but only as a deontological obligation.
However the Royal Decree of 21.01.2009 requires in the "Manual of Good Pharmaceutical Practices" that pharmacists :
- have to be concerned for the health and the quality of life of the patients, and the wellbeing of the population in general,
- have to give information to patients when they deliver drugs and other health products
- have to respect the legislation.
This is why pharmacists :
- have to follow continuous training concerning the actual aspects and the expected evolutions of the pharmaceutical profession,
- are due to keep there competence up to date.

D. Administrative cooperation

15. Administrative cooperation improved by leaps and bounds ever since the IMI system, through which most applications are

submitted, has come into use. This tool has also cut down the response time.

16. The Federal Public Health Service is registered with IMI and put in requests very regularly (several times a month) through the IMI system. Requests may concern files that are complete but need additional information or incomplete files. Questions that already exist in IMI often need to be completed by a comment or an extra question.

We also receive requests several times a month.

We do not receive or ask a lot of requests about the pharmacists. We mostly use IMI for the nurses and doctors.

The Order of Pharmacists is also registered with IMI.

17. *Answer of the Order of pharmacists:* A professional card could definitely facilitate the recognition of professional qualifications. It can also be a useful tool to give access to information about possible disciplinary sanctions pronounced by the competent authority in the country of origin of the professional.

18. *Answer of the Order of pharmacists:* For the moment the competent authority of the country of origin is questioned about possible sanctions. However a professional card could improve the communication of this information in real time.

E. Other observations

19. As of now, no language test is conducted by public authorities after professional recognition. It is up to the employer to evaluate the linguistic abilities of the pharmacists that they intend to employ.

20. *Answer of the Order of pharmacists*: We hope that the European Commission will consider to adopt the principle of a health professional card in the Directive

BULGARIA

Evaluating the Professional Qualifications Directive
Experience reports from competent authorities

QUESTIONNAIRE FOR PHARMACISTS

A. RECOGNITION PROCEDURE IN CASE OF MIGRATION ON A PERMANENT BASIS

1. Please describe the government structure of the competent authority or authorities in charge of the recognition and of sanctions/restriction to practice.

   The recognition of professional qualifications of pharmacists is conducted by the Ministry of Health of Bulgaria which is the competent authority for all health professions. There is an expert committee by the Minister of Health which examines the documents of the applicants and submits to the Minister of Health a motivated proposal for recognition or refusal of recognition of professional qualification.
   The procedure of recognition of a qualification is initiated by a candidate's application.
   After the receipt of the application, the competent authority informs the candidate about any missing documents and asks for additional information if necessary. After the receipt of all documents required the competent authority must take a decision within three months on the basis of the expert committee's proposals.

2. To what extent have the system of automatic recognition and the general system been a success? How do you see the costs and benefits for patients and for your organisation? Can you give concrete examples. Specify in particular whether automatic recognition based on diploma, Annex V and the current notification system represent an efficient way to facilitate automatic recognition.

Please submit comments for:

- automatic recognition based on diploma
- automatic recognition based on acquired rights

The system of automatic recognition is the fastest way for recognition of qualifications but is leading to recognition of different levels of knowledge as equal. We consider the absence of language test is a problem.
On the other hand the recognition based on the general system gives the opportunity for thorough analysis of the applicant's training and setting a compensation measure thus decreasing the differences in knowledge level and actually testing the language knowledge.

3. Is the general system (as described in article 10) applied in your country each time the conditions for automatic recognition are not met? Are there major difficulties in the recognition procedure under the general system? Please include any comments you may have on the implementation of compensation measures.

   The general system is applied in our country each time the conditions for automatic recognition are not met. There aren't major difficulties in the recognition procedure under

the general system. The Bulgarian legislation doesn't allow the choice of compensation measure to be made by the applicant in case of pharmacists. The decision for the compensation measure is made by the competent authority – the Ministry of Health.

4. What is your experience with the recognition procedure for EU citizens with professional qualifications obtained in a third country and already recognised in a first Member State (see Articles 2(2) and 3(3))?

   We haven't had the case.

5. Do you accept applications from EU citizens for the recognition of foreign diplomas sent by email or requests made on line? Under which conditions can they send documents and declarations electronically? What are your experiences in this respect?

   The Ministry of Health in Bulgaria doesn't accept applications from EU citizens for the recognition of foreign diplomas sent by email or requests made on line.

6. What is the yearly number of applications for recognition from 2000 to 2009? Please submit specific data for applications for automatic recognition based on diplomas, automatic recognition based on acquired rights (as from 2005), and recognition based on the general system[1].

   For 2007 – 1 – automatic recognition (positive)
   For 2008 – 8 of which:
   - 2 – automatic recognition (positive);
   - 4 – general system;
   - 2 – suspended

   For 2009 – 9 of which:
   - 7 – automatic recognition (positive);
   - 2 – suspended

B. TEMPORARY MOBILITY (OF A SELF-EMPLOYED OR AN EMPLOYED WORKER)

7. Are EU citizens interested in using the provisions for exercising their professional activities on a temporary and occasional basis in your Member State? How many citizens used this new system since the directive has been transposed in your country (can you provide any statistics per month, per year)[2]?

   We haven't had a case of pharmacist using the provisions for exercising the professional activities on a temporary and occasional basis in Bulgaria.

8. How are the provisions of Directive 2005/36/EC concerning temporary mobility applied by the competent authorities in practice taking into account the relevant provisions of the Code of Conduct? For instance:

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1 Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

2 Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

- How is the "legal establishment" criteria foreseen by Article 5(1) (a) interpreted in practice? What conditions does a migrant need to fulfil in his home Member State in order to be able to provide services?

The applicant has to submit a certificate issued by the competent authority of the relevant member-state that he/she is legally established on its territory for the pursuing the relevant activities and is not subject of any prohibition from practising, including temporary, at the moment of delivering the certificate.

- How are the "temporary and occasional basis" criteria foreseen by Article 5.2 interpreted in practice? Do Member States assess duration, frequency, regularity and continuity of an activity and if so according to which criteria?

According to the national legislation (art. 11, para 2 of the Law of recognition of professional qualifications) the duration, frequency, regularity and continuity of an activity is accessed on case-by-case basis.

9. Why is a prior declaration system necessary? What do competent authorities do with the information received? Are other possibilities conceivable?

On principal the Ministry of Health collects the information for statistical and analytical purposes. On the basis of the information we supervise the professionals delivering services in our country.

10. Do you have concrete examples of abuse or misuse of this new possibility for pharmacists? Have you been confronted to problems with regards to patient safety on this issue?

No.

C MINIMUM TRAINING REQUIREMENTS

11. To what extent are the common minimum training requirements set out in Title III Chapter III of Directive 2005/36/EC and the compulsory training subjects as defined in Annex V in line with scientific progress and professional needs? Furthermore, are the knowledge and skills required by the directive still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

We consider the minimum training requirements for pharmacists as given in Article 44 and Annex V, point 5.6.1 still relevant and up to date. We consider specifying the minimum hours for pharmacists' training in Directive 2005/36/EC advisable.

12. The Directive is based on mutual trust between Member States. To what extent is such trust actually achieved? Are training programmes accredited in your country? Does accreditation of a training program in another Member State enhance trust or is it not relevant?

We consider mutual trust between Member States is not fully achieved.

13. To what extent are the existing Directive provisions (see recital 39 and Article 22(b) on continuous professional development (continuous training) adequate? What is your

definition of CPD/continuous training? Is continuous training mandatory in your country and what are the exact conditions?

According to the Bulgarian national legislation continuous medical training of pharmacists is organized, coordinated, carried out and registered by the professional organisation of pharmacists.

D. ADMINISTRATIVE COOPERATION (THIS SECTION APPLIES TO ESTABLISHMENT AS TO PROVISION OF SERVICES)

14. To which extent does administrative cooperation, as outlined in Articles 8, 50, and 56 of the Directive, simplify procedures for the migrant professionals? Can you give your own experience?

The administrative cooperation can reduce the duration of the procedure of recognition of professional qualification.

15. Is the competent authority in your country registered with IMI? Under which circumstances does your competent authority use IMI? If not registered, why not and what would be the conditions for changing this situation?

Yes.

16. How could a professional card (see Recital 32 of the Directive) facilitate recognition of professional qualifications and provision of temporary services? Under which conditions could it be issued by a competent authority?

We consider that a professional card will not facilitate the recognition of professional qualifications and provision of services. In case of questions or need of additional information the IMI-system can be used.

17. How do you share information about suspensions/restrictions with competent authorities in other Member States? Could more be done in this respect?

IMI is a suitable tool for asking and giving information about suspensions/restrictions.

E. OTHER OBSERVATIONS

18. How and when are the necessary language skills of migrants checked after recognition of the professional qualifications? Are you aware of any complaints (especially from patients/clients/employers) about insufficient language skills of migrants?

According to the Bulgarian legislation all pharmacists who pursue their profession have to be members of the professional association of pharmacists. The employer (in case of employed pharmacists) decides if the language skills of the migrant are sufficient to perform the relevant activities.

19. Please fill free to add any comment you want on the directive 2005/36/EC

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CZECH REPUBLIC

Evaluating the Professional Qualifications Directive
Experience reports from competent authorities

QUESTIONNAIRE SECTORAL PROFESSION

A. RECOGNITION PROCEDURE IN CASE OF MIGRATION ON A PERMANENT BASIS

1. Do you accept applications from EU citizens for the recognition of foreign diplomas sent by email or requests made on line? Under which conditions can they send documents and declarations electronically? What are your experiences in this respect? **For the time bring, the submission of applications on time is not possible. However, this issue is bring solved.**

2. What is the yearly number of applications for recognition from 2000 to 2009? Please submit specific data for applications for automatic recognition based on diplomas, automatic recognition based on acquired rights (as from 2005), and recognition based on the general system[1]. **There is not statistic available from 2000 to 2004. The data are not archivated. The statistic from 2005 to 2009 is not structured according these criteria, so it is not possible to isolate the number of qualification recognition based on diplomas, acquired rights or the general system. Generally, in previsious years 80% qualifications were recognised on the basis of diplomas, 15 % general system, 5 % acquired rights.**

Year	2005	2006	2007	2008	2009
The number of medical workers:	**292**	**225**	**105**	**159**	**112**

3. To what extent have the system of automatic recognition and the general system been a success? How do you see the costs and benefits? Specify in particular whether automatic recognition based on diploma, Annex V and the current notification system represent an efficient way to facilitate automatic recognition. Please submit comments for:

- automatic recognition based on diploma
- automatic recognition based on acquired rights
- recognition based on the general system.

[1] Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

When the diploma issued in another Member State contains all the necessary formalities (the verification, apostila, the conformity of education verified by competent authorities of the state, where the applicant received his education) then this recognition system is unambiguously the less financially demanding and time-consuming. The recognition based on required rights is as demanding and effective as the conformity. The recognition based on the general system is the most demanding and time-consuming, to however, it is very exact as the education programme is compared with the programme valid for the Czech Republic on the basis of the index and logbook (the list of practice and performances in case of specialist training) submission.

4. Is the general system applied in your country each time the conditions for automatic recognition are not met? Are there major difficulties in the recognition procedure under the general system? Please include any comments you may have on the implementation of compensation measures. **Yes, the general system is applied everytime when the conditions of automatic recognition are not fulfilled. It is predominantly specialist training in a field that is not included in the Directive 2005/36/EC in appendix 5.1.3. but exist in the Czech Republic. There are difficulties only with the time-consumption genrally the assessing books 2-3 months) and financial demandingness.**

5. What is your experience with the recognition procedure for EU citizens with professional qualifications obtained in a third country and already recognised in a first Member State (see Articles 2(2) and 3(3))? **This type of recognition is not common in the Czech Republic. If such a case of recognition occurs, problems are always incountered in submitting of documents issued in the first Member state of EU. The applicants often have to undergo the process of qualification as the applicants that received their education in so called Third World.**

6. Please describe the government structure of the competent authority or authorities in charge of the recognition. **Ministry of Health of the Czech Republic → Department of Education and Science → Section of medical professions and qualification recognition.**

B. TEMPORARY MOBILITY (OF A SELF-EMPLOYED OR AN EMPLOYED WORKER)

7. Are EU citizens interested in using the provisions for exercising their professional activities on a temporary and occasional basis in your Member State? How many citizens used this new system in 2008 **(no applicant)** and 2009 **(7 applicants)** (per month, per year) [2]? **Yes, EU citizens areincreasingly interested in this type of the profession performance, but at this time not in the past.**

8. How are the provisions of Directive 2005/36/EC concerning temporary mobility applied by the competent authorities in practice taking into account the relevant provisions of the Code of Conduct? For instance:

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[2] Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

- How is the "legal establishment" criteria foreseen by Article 5(1) (a) interpreted in practice? What conditions does a migrant need to fulfil in his home Member State in order to be able to provide services?

- How are the "temporary and occasional basis" criteria foreseen by Article 5.2 interpreted in practice? Do Member States assess duration, frequency, regularity and continuity of an activity and if so according to which criteria? **In the Czech Republic, there are two types of applications for the limited period of time. Most common is the announcement of the visiting person for the medical profession performance, that is time-limited for one year and the applicant has so submit** copy of an identification card, copy of document confirming nationality; officially verified copy of a document concerning the authorization to perform the medical profession within the EU; officially verified copy of legal performing of the medical profession in the member state of origin, (document certifying the fact that authorization was not revoked or temporarily suspended); document confirming basic qualification; officially verified copy of a document of insurance concerning the responsibility for any harm caused during the performance of the medical profession. **Another possibility is so called one-time performance announcement when it is only needed to send the Ministry of Health a letter declaring that the applicant had been invited by a health institution for one-time performances. Maximum time for the medical profession performance is two months and the medical institution advises the Ministry of Health the name, nationality, date of birth, kind of specialty training and the address of the institution where the applicant will be employed.**

9. Why is a prior declaration system necessary? What do competent authorities do with the information received? Are other possibilities conceivable? **The recognition unit is in charge of the archivation of all the applications submitted to the Ministry of Health. If the same applicant submits another application, only the documents whose validity is time-limited are reguired.**

C MINIMUM TRAINING REQUIREMENTS

10. To what extent are the common minimum training requirements set out in Title III Chapter III of Directive 2005/36/EC and the compulsory training subjects as defined in Annex V in line with scientific progress and professional needs? Furthermore, are the knowledge and skills required by the directive still relevant and up to date? Please specify. What about the conditions relating to the duration of training? **The common minimum training requirements set out in Title III Chapter III of Directive 2005/36/EC are very general, but The Czech Republic has no problem with it. For example the minimum training programme of specialties is longer than introduced by the Directive 2005/36/EC.**

11. To what extent are the common minimum requirements for training set out in Title III Chapter III of Directive 2005/36/EC in line with scientific progress and professional needs in the last ten years? Are the knowledge and skills outlined in Article 24.3 still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

12. The Directive is based on mutual trust between Member States. To what extent is such trust actually achieved? **Yes, we trust every statement issued by competent authorities.** Are training programmes accredited in your country? Does accreditation of a training program in another Member State enhance trust or is it not relevant? **No, it is not relevant.**

13. To what extent are the existing Directive provisions (see recital 39 and Article 22(b) on continuous professional development (continuous training) adequate? Is continuous training mandatory in your country and what are the exact conditions? **A physician, who had finished his University studies and has started (zařadit se) his specialist training, is obliged to study (celoživotně se vzdělávat) to receive a Certificate of specialist training. Long life education is organized and arranged by the Institut of Postgradual Education, medical faculties and the Czech Medical Council. The Institut of Posrgradual Education gets every information about long life education . Contact person is Mrs. Řeháková; www.ipvz.cz**

D. Administrative cooperation

14. To which extent does administrative cooperation, as outlined in Articles 8, 50, and 56 of the Directive, simplify procedures for the migrant professionals? **Administrative cooperation is very beneficial and useful, mainly email corespondence and IMI system. But sometimes not fast and sufficient enough.**

15. Is the competent authority in your country registered with IMI? Under which circumstances does your competent authority use IMI? If not registered, why not and what would be the conditions for changing this situation? **The IMI System is used by the Ministry of Health, mainly to answear the inquiries of other Member States.**

16. How could a professional card (see Recital 32 of the Directive) facilitate recognition of professional qualifications and provision of temporary services? Under which conditions could it be issued by professional associations? **Yes, I think this service could be beneficial – mostly if it is important to check professional practice, suspension or sanction.**

17. How do you share information about suspensions/restrictions with competent authorities in other Member States? Could more be done in this respect? **Our department is not in charge of suspensions/restrictions. The Czech Medical Council, The Czech Dentist Council, The Czech farmacist Council are competent to this issue.**

E. OTHER OBSERVATIONS

18. How and when are the necessary language skills of migrants checked after recognition of the professional qualifications? Are you aware of any complaints (especially from patients/clients/employers) about insufficient language skills of migrants? **If an applicant does not have minimum knowledge of Czech language (secondary school or University studies in czech language, Certificate of Czech language from a language school), Ministry of Health is going to test the**

applicant´s language knowledge. The applicant is advised the term 1 month prior to the examination. The applicant has to understand a printed specialist text and spoken word. The applicant´s response in communication is important to find out whether he is able to understand the patient and specialist terminology in czech language.

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DENMARK

Evaluating the Professional Qualifications Directive
Experience reports from competent authorities

QUESTIONNAIRE FOR PHARMACISTS

A. RECOGNITION PROCEDURE IN CASE OF MIGRATION ON A PERMANENT BASIS

1. Please describe the government structure of the competent authority or authorities in charge of the recognition and of sanctions/restriction to practice.

In Denmark, there is no authorisation system for pharmacists. Thus, it is not possible for a pharmacist in Denmark to lose his or her authorization to practice pharmacy or the right to work as Pharmacist.

A pharmacist from another Member State can seek employment in the pharmaceutical industry without permission from the Danish Medicines Agency (DMA).

A pharmacist from another Member State needs the permission from the DMA to work in a Danish Pharmacy. The owner of a Pharmacy can loose his or her license to operate the Pharmacy. The DMA is the competent authority in Denmark to grant permission to pharmacists who holds a degree in pharmacy in another country to work in a Danish Pharmacy. The DMA is an agency placed directly under the Ministry of the Interior and Health. The DMAs' aim is that medicinal products used in Denmark are of satisfactory quality, are safe to use and that they have the desired effect. We do so by administering the Danish legislation on e.g. medicinal products, reimbursement, pharmacies, medical, devices and euphoriants.

In relation to the administration of legislation concerning Pharmacies one of the tasks carried out by The DMA is the organization of the structure in the area and the appointment of Pharmacist to operate a pharmacy.
The owner a Pharmacy is responsible for the daily running of a Pharmacy, including all matters relating to personnel such as training and linguistic skills etc. The DMA controls that the pharmacies operate in line with current legislation.

In Denmark the Ministry of Education is the competent authority with regard to the composition of educations offered by e.g. the universities.

2. To what extent have the system of automatic recognition and the general system been a success? How do you see the costs and benefits for patients and for your organisation? Can you give concrete examples. Specify in particular whether automatic recognition based on diploma, Annex V and the current notification system represent an efficient way to facilitate automatic recognition.

The DMA is of the opinion that the current system works to our satisfaction and is relatively efficient with the support of IMI. The system facilitates the harmonization and the processing of the application.

Please submit comments for:

- automatic recognition based on diploma

see above

- automatic recognition based on acquired rights

see above

3. Is the general system (as described in article 10) applied in your country each time the conditions for automatic recognition are not met? Are there major difficulties in the recognition procedure under the general system? Please include any comments you may have on the implementation of compensation measures.

   The general system is applied each time the conditions for automatic recognition are not met.

4. What is your experience with the recognition procedure for EU citizens with professional qualifications obtained in a third country and already recognised in a first Member State (see Articles 2(2) and 3(3))?

   To date we have only received one application. The applicant's education was automatically recognised due to the first Member States recognition.

5. Do you accept applications from EU citizens for the recognition of foreign diplomas sent by email or requests made on line? Under which conditions can they send documents and declarations electronically? What are your experiences in this respect?

   Yes. We have no experience in this aspect as the DMA has never received an application electronically.

6. What is the yearly number of applications for recognition from 2000 to 2009? Please submit specific data for applications for automatic recognition based on diplomas, automatic recognition based on acquired rights (as from 2005), and recognition based on the general system[1].

[1] Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

	The yearly number of applications for recognition from 2000 to 2009:	Automatic recognition based on diplomas 2000 to 2009:	Automatic recognition based on acquired rights 2000 to 2009	Recognition based on the general system 2000 to 2009
2000	2	0		1
2001	6	5		
2002	6	2		
2003	2	1		
2004	2	2		1
2005	3	2		
2006	2	3		
2007	5	2	1	1
2008	2	2		
2009	10	4		

* In the year 2004 and 2006 there has been given a permission on an application from a previous year.

B. TEMPORARY MOBILITY (OF A SELF-EMPLOYED OR AN EMPLOYED WORKER)

7. Are EU citizens interested in using the provisions for exercising their professional activities on a temporary and occasional basis in your Member State? How many citizens used this new system since the directive has been transposed in your country (can you provide any statistics per month, per year) [2]?

   The DMA has received several inquiries concerning the provisions for exercising their professional activities on a temporary and occasional basis. To date we have only received one application.

8. How are the provisions of Directive 2005/36/EC concerning temporary mobility applied by the competent authorities in practice taking into account the relevant provisions of the Code of Conduct? For instance:

   - How is the "legal establishment" criteria foreseen by Article 5(1) (a) interpreted in practice? What conditions does a migrant need to fulfil in his home Member State in order to be able to provide services?

     "Legal establishment" is interpreted as meaning that the applicant has an education automatically recognised under Titel III Chapter III of the Directive and the applicant is not prohibited from practicing as a pharmacist .

[2] Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

- How are the "temporary and occasional basis" criteria foreseen by Article 5.2 interpreted in practice? Do Member States assess duration, frequency, regularity and continuity of an activity and if so according to which criteria?

  "temporary and occasional basis" is interpreted as one stay of a period of up to max. 12 months or numerous shorter stays with a total maximum 12 months.

9. Why is a prior declaration system necessary? What do competent authorities do with the information received? Are other possibilities conceivable?

   The declaration system is needed in order to avoid that applicants bypass the procedure concerning establishment under Titel III Chapter III of the Directive

10. Do you have concrete examples of abuse or misuse of this new possibility for pharmacists? Have you been confronted to problems with regards to patient safety on this issue?

    We have no examples of misuse or abuse.

C MINIMUM TRAINING REQUIREMENTS

11. To what extent are the common minimum training requirements set out in Title III Chapter III of Directive 2005/36/EC and the compulsory training subjects as defined in Annex V in line with scientific progress and professional needs? Furthermore, are the knowledge and skills required by the directive still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

12. To what extent are the common minimum requirements for training set out in Title III Chapter III of Directive 2005/36/EC in line with scientific progress and professional needs in the last ten years? Are the knowledge and skills outlined in Article 24.3 still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

13. The Directive is based on mutual trust between Member States. To what extent is such trust actually achieved? Are training programmes accredited in your country? Does accreditation of a training program in another Member State enhance trust or is it not relevant?

14. To what extent are the existing Directive provisions (see recital 39 and Article 22(b) on continuous professional development (continuous training) adequate? What is your definition of CPD/continuous training? Is continuous training mandatory in your country and what are the exact conditions?

    Point 11 -13; With regard to the content and duration of University educations, such as the pharmacists' education, the Danish Ministry of Education is the responsible authority. As regards pharmacists taking employment in a Pharmacy the DMA has no specific comments to the training requirements as well as the training subjects.

To point point 13 in particular; The DMA have very applications, and thus it is difficult to generalise.

Point 14; In Denmark the pharmacist who owns the pharmacy is responsible for hiring and planning training and courses for the employees at the pharmacy. By law the pharmacist is required to insure that the employees has the necessary training in order to carry out his or her job in a responsible manner. Failure to comply this provision in Danish law is subject to penalty.

D. ADMINISTRATIVE COOPERATION (THIS SECTION APPLIES TO ESTABLISHMENT AS TO PROVISION OF SERVICES)

15. To which extent does administrative cooperation, as outlined in Articles 8, 50, and 56 of the Directive, simplify procedures for the migrant professionals? Can you give your own experience?

In practice the administrative cooperation simplify the procedure for the migrant as the authorities by direct contact can supply each other with relevant information instead of asking the applicant to produce further documentation.

The experience of the Danish Medicines Agency is that, by using IMI, we can acquire relevant information without having to involve the applicant.

16. Is the competent authority in your country registered with IMI? Under which circumstances does your competent authority use IMI? If not registered, why not and what would be the conditions for changing this situation?

The Danish Medicines Agency is registered with IMI.

We use the system in order to verify whether or not an education is automatically recognised by the directive. E.g. when the education is dated before the country's accession to the directive.

17. How could a professional card (see Recital 32 of the Directive) facilitate recognition of professional qualifications and provision of temporary services? Under which conditions could it be issued by a competent authority?

The Danish Medicines Agency is positive towards professional cards – however, in our opinion, IMI is just as efficient and safe – issuing a professional card demands a large number of migrant workers to be cost-effective.

18. How do you share information about suspensions/restrictions with competent authorities in other Member States? Could more be done in this respect?

By using IMI – please note that in Denmark a Pharmacist cannot be subject to sanctions or restrictions to practice.

E. OTHER OBSERVATIONS

19. How and when are the necessary language skills of migrants checked after recognition of the professional qualifications? Are you aware of any complaints (especially from patients/clients/employers) about insufficient language skills of migrants?

    We do not check the language skills of the applicant after the recognition. Whether or not the migrant posses the necessary language skills to work in a Danish Pharmacy is a decision made by the hiring Pharmacy.

    To date we have not received any formal complaint with regard to language skills.

20. Please fill free to add any comment you want on the directive 2005/36/EC

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GERMANY

Evaluating the Professional Qualifications Directive
Experience reports from competent authorities
GERMANY

QUESTIONNAIRE FOR PHARMACISTS

A. RECOGNITION PROCEDURE IN CASE OF MIGRATION ON A PERMANENT BASIS

1. Please describe the government structure of the competent authority or authorities in charge of the recognition and of sanctions/restriction to practice.

   The competent authorities in charge of professional recognition are usually medium-level authorities subordinate to the supreme *Land* (federal state) authority, or upper-level *Land* authorities; the competent authority in federal city states is in part the supreme *Land* authority. Professional regulation is also the responsibility of the authority in charge of recognition, or the relevant state chamber of pharmacists.

2. To what extent have the system of automatic recognition and the general system been a success? How do you see the costs and benefits for patients and for your organisation? Can you give concrete examples. Specify in particular whether automatic recognition based on diploma, Annex V and the current notification system represent an efficient way to facilitate automatic recognition.

   Please submit comments for:

   - automatic recognition based on diploma
   - automatic recognition based on acquired rights

   All in all, the system of automatic recognition can be considered a success as it facilitates the procedure for authorities and applicants. To this extent the cost-benefit ratio can therefore be assessed as positive.

   It is important, however, that the specifications regarding diplomas in Annex 5.6.2. of the Directive are always kept up-to-date. For Germany, the current designation of the diploma as "Zeugnis über die Staatliche Pharmazeutische Prüfung" is wrong. Correctly, it should read: "Zeugnis über die Pharmazeutische Prüfung".

3. Is the general system (as described in article 10) applied in your country each time the conditions for automatic recognition are not met? Are there major difficulties in the recognition procedure under the general system? Please include any comments you may have on the implementation of compensation measures.

   If the conditions for automatic recognition are not met, the general system is applied. The problem here is how to establish any possible qualification deficits that the applicant might have. The authorities in charge of recognition lack the appropriate expertise, which therefore needs to be provided from external sources (e.g. from ex-

perts at universities). There are also no explicit specifications about the subjects and the quantitative deficits that are to be considered as "substantial" within the meaning of the Directive and the Federal Ordinance of Pharmacists to justify compensation measures.

Under German law the only compensation measure that is applied is the aptitude test (in the form of a "deficit test").

4. What is your experience with the recognition procedure for EU citizens with professional qualifications obtained in a third country and already recognised in a first Member State (see Articles 2(2) and 3(3))?

   No experience.

5. Do you accept applications from EU citizens for the recognition of foreign diplomas sent by email or requests made on line? Under which conditions can they send documents and declarations electronically? What are your experiences in this respect?

   As a rule, applications and documents can be submitted electronically in advance, but originals (or certified copies) must then be submitted afterwards in the course of the procedure. At the moment, applications or documents submitted only electronically cannot be accepted on account of the lack of proof of authenticity. So far we are not aware of any problems in this respect as the documents are usually submitted in paper form anyway.

6. What is the yearly number of applications for recognition from 2000 to 2009? Please submit specific data for applications for automatic recognition based on diplomas, automatic recognition based on acquired rights (as from 2005), and recognition based on the general system[1].

   The Commission has already been provided with the number of applications for recognition. On average the procedures takes between two and eight weeks, depending on the quality and completeness of the submitted documents.

B. TEMPORARY MOBILITY (OF A SELF-EMPLOYED OR AN EMPLOYED WORKER)

7. Are EU citizens interested in using the provisions for exercising their professional activities on a temporary and occasional basis in your Member State? How many citizens used this new system since the directive has been transposed in your country (can you provide any statistics per month, per year) [2]?

   No interest shown by EU citizens so far, so no experience.

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1 Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

2 Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

8. How are the provisions of Directive 2005/36/EC concerning temporary mobility applied by the competent authorities in practice taking into account the relevant provisions of the Code of Conduct? For instance:

   - How is the "legal establishment" criteria foreseen by Article 5(1) (a) interpreted in practice? What conditions does a migrant need to fulfil in his home Member State in order to be able to provide services?

   - How are the "temporary and occasional basis" criteria foreseen by Article 5.2 interpreted in practice? Do Member States assess duration, frequency, regularity and continuity of an activity and if so according to which criteria?

   No practical experience so far. In our view, the "legal establishment" criterion is to be understood as authorisation to practise the profession of pharmacist without any restriction in one's home Member State. In other words the evidence to be submitted has to fulfil this requirement. This means that the diploma in particular needs to be submitted as evidence of training in conformity with EU regulations as well as a certificate of good standing as proof of professional and personal integrity in the home Member State.

9. Why is a prior declaration system necessary? What do competent authorities do with the information received? Are other possibilities conceivable?

   No practical experience so far. A prior declaration system is necessary, however, in order to be able to check whether an authorisation exists for the temporary provision of services. The declaration also serves as information for the competent authorities, enabling if necessary appropriate professional monitoring.

10. Do you have concrete examples of abuse or misuse of this new possibility for pharmacists? Have you been confronted to problems with regards to patient safety on this issue?

    No.

C MINIMUM TRAINING REQUIREMENTS

11. To what extent are the common minimum training requirements set out in Title III Chapter III of Directive 2005/36/EC and the compulsory training subjects as defined in Annex V in line with scientific progress and professional needs? Furthermore, are the knowledge and skills required by the directive still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

    The – rather more generally formulated – knowledge and skills mentioned in Art. 44 Para. 3 of the Directive are essentially still in accordance with the current state of the scientific art. The catalogue could, however, be supplemented to include the following fields: dietetics, pathology, biochemistry and molecular biology, immunology, biopharmaceutics, biotechnology, clinical chemistry, clinical pharmacy, pharmacoepidemiology and economics, and also with regard to medical devices and quality assurance during the production and testing of drugs.
    The duration of the training is adequate.

12. The Directive is based on mutual trust between Member States. To what extent is such trust actually achieved? Are training programmes accredited in your country? Does accreditation of a training program in another Member State enhance trust or is it not relevant?

There is basically mutual trust between the Member States.
Courses of study are usually not accredited, but established on the basis of the higher education laws of the *Länder* (federal states) within the scope of the universities' autonomy. Whether a course of study is accredited in another Member State is irrelevant. Rather, what is important is that the relevant evidence of formal qualifications listed in Annex 5.6.2. of the Directive is submitted. The *Länder* assume that the minimum training requirements have been checked by the EU Commission before notification. An accreditation of the course of study in the home Member State is thus irrelevant.

13. To what extent are the existing Directive provisions (see recital 39 and Article 22(b) on continuous professional development (continuous training) adequate? What is your definition of CPD/continuous training? Is continuous training mandatory in your country and what are the exact conditions?

To the extent that the *Länder* stipulate a duty for pharmacists to take part in continuous training, this is usually provided for in the respective professional codes of the state chambers of pharmacists (*Landesapothekerkammer*). The provisions in the Directive are adequate.

D. ADMINISTRATIVE COOPERATION (THIS SECTION APPLIES TO ESTABLISHMENT AS TO PROVISION OF SERVICES)

14. To which extent does administrative cooperation, as outlined in Articles 8, 50, and 56 of the Directive, simplify procedures for the migrant professionals? Can you give your own experience?

Provided there is direct cooperation between the Member States (e.g. via IMI), this can simplify the procedure for migrants.

15. Is the competent authority in your country registered with IMI? Under which circumstances does your competent authority use IMI? If not registered, why not and what would be the conditions for changing this situation?

The competent authorities of the *Länder* are usually registered with IMI. So far, however, little use has been made of the system. The questions specified are often unsuitable for individual cases.

16. How could a professional card (see Recital 32 of the Directive) facilitate recognition of professional qualifications and provision of temporary services? Under which conditions could it be issued by a competent authority?

Whether and how a professional card could facilitate recognition is not clear. It would at best be conceivable if the card could reliably replace certain evidence that would otherwise have to be submitted (e.g. the diploma). To this extent, the card

would have to be standardised throughout the EU. There would also have to be an absolute guarantee in terms of data-protection and that the card is forgery-proof. This seems scarcely feasible.

17. How do you share information about suspensions/restrictions with competent authorities in other Member States? Could more be done in this respect?

For reasons of data protection, there is currently no regular or automatic exchange of information with other Member States about sanctions and other circumstances that are relevant under professional legislation. Information is most likely to be provided by way of a "certificate of good standing" in specific individual cases.
What might be examined is the establishment of a central database of sanctions imposed upon professionals, to be managed by the Commission. Its operation and use would have to meet the highest data-protection requirements.

E. OTHER OBSERVATIONS

18. How and when are the necessary language skills of migrants checked after recognition of the professional qualifications? Are you aware of any complaints (especially from patients/clients/employers) about insufficient language skills of migrants?

As part of the procedure to grant the licence to practice as a pharmacist, the competent authorities normally request B2-level language skills based on the Common European Framework of Reference for Languages. Proof of language skills can be provided by means of a language certificate from a recognised language institute or, in individual cases, by means of a personal interview with the migrant or a technical discussion.
So far we have not been aware of any complaints about insufficient language skills of migrants.

19. Please feel free to add any comment you want on the directive 2005/36/EC

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Evaluierung der Richtlinie 2005/36/EG
Erfahrungsberichte der zuständigen Behörden
DEUTSCHLAND

FRAGEBOGEN FÜR DEN BERUF „APOTHEKER“

A. ANERKENNUNGSVERFAHREN BEI DAUERHAFTER NIEDERLASSUNG/ WOHNSITZÄNDERUNG

1. Geben Sie bitte die Stellung der zuständigen Behörde(n) im Staatsaufbau an (z. B. staatliche Mittelbehörde, sonstige Körperschaft des öffentlichen Rechts), die in Ihrem Land für die Anerkennungen einerseits und für die Berufsaufsicht andererseits verantwortlich ist (sind).

   Zuständige Berufszulassungsbehörden sind in der Regel unterhalb der obersten Landesbehörde stehende Mittelbehörden oder obere Landesbehörden; in Stadtstaaten ist z. T. die oberste Landesbehörde zuständig. Die Berufsaufsicht obliegt entweder ebenfalls der Berufszulassungsbehörde oder der jeweiligen Landesapothekerkammer.

2. Inwieweit waren das System der automatischen Anerkennung und die allgemeine Regelung bisher ein Erfolg (aus Sicht der Behörde(n) und der Antragsteller)? Wie schätzen Sie Kosten und Nutzen für die Behörde(n) und für die Antragsteller ein? Bitte äußern Sie sich insbesondere dazu, ob die automatische Anerkennung auf der Grundlage von Diplomen, Anhang V und das derzeitige System der Notifizierung die automatische Anerkennung wirksam erleichtern. Bitte machen Sie Angaben zur

   - automatischen Anerkennung auf der Grundlage von Diplomen,
   - automatischen Anerkennung auf der Grundlage erworbener Rechte.

   Das System der automatischen Anerkennung ist im Großen und Ganzen als Erfolg zu werten, da es das Verfahren für Behörden und Antragsteller erleichtert. Das Kosten- und Nutzenverhältnis ist daher, soweit dies beurteilt werden kann, positiv.

   Wesentlich ist allerdings, dass die Angaben zu den Diplomen in Anhang 5.6.2. der Richtlinie stets auf dem aktuellen Stand sein müssen. Für Deutschland lautet die Bezeichnung des Diploms bisher fälschlicherweise „Zeugnis über die Staatliche Pharmazeutische Prüfung“. Richtigerweise muss es heißen: „Zeugnis über die Pharmazeutische Prüfung“.

3. Wird in Ihrem Land in allen Fällen, in denen die Bedingungen für die automatische Anerkennung nicht erfüllt sind, die allgemeine Regelung angewendet (Art. 10 der Richtlinie)? Gibt es größere Probleme mit dem Anerkennungsverfahren nach der allgemeinen Regelung? Machen Sie gegebenenfalls Angaben zur Anwendung der Ausgleichsmaßnahmen.

   Soweit eine automatische Anerkennung nicht in Betracht kommt, wird die allgemeine Regelung angewendet. Das Problem hierbei ist die

Feststellung etwaiger Ausbildungsdefizite des Antragstellers. Bei den Berufszulassungsbehörden fehlt entsprechender Sachverstand, der somit extern gesucht werden muss (z. B. durch Gutachter aus dem Hochschulbereich). Zudem fehlen explizite Vorgaben, welche Fächer und welches quantitative Defizit als „wesentlich" im Sinne der Richtlinie und der Bundes-Apothekerordnung anzusehen sind und damit Ausgleichsmaßnahmen rechtfertigen.

Als Ausgleichsmaßnahme kommt nach deutschem Recht nur die Eignungsprüfung (in Form einer „Defizitprüfung") zur Anwendung.

4. Welche Erfahrungen haben Sie mit dem Anerkennungsverfahren für EU-Bürger mit in Drittländern erworbenen Berufsqualifikationen gemacht, die bereits in einem anderen Mitgliedstaat anerkannt wurden, (s. Art. 2 Abs. 2 und Art. 3 Abs. 3 der Richtlinie)?

   Keine Erfahrungen.

5. Akzeptieren Sie Anträge von EU-Bürgern auf Anerkennung ausländischer Diplome, die per E-Mail oder online gestellt werden? Unter welchen Bedingungen können Unterlagen und Meldungen elektronisch übermittelt werden? Welche Erfahrungen haben Sie in diesem Zusammenhang gemacht?

   Anträge und Unterlagen können in der Regel vorab elektronisch eingereicht werden, müssen allerdings im Laufe des Verfahrens im Original (oder in beglaubigter Kopie) nachgereicht werden. Wegen des fehlenden Authentizitätsnachweises können ausschließlich elektronisch eingereichte Anträge oder Unterlagen derzeit nicht akzeptiert werden. Probleme sind in dieser Hinsicht bisher nicht bekannt geworden, da die Unterlagen in der Regel ohne Weiteres in Papierform eingereicht werden.

6. Wie viele Anerkennungsanträge wurden im Zeitraum 2000 bis 2009 jährlich gestellt? Bitte übermitteln Sie uns anhand der beiliegenden Tabelle Angaben zu Anträgen auf automatische Anerkennung auf der Grundlage von Diplomen, auf der Grundlage erworbener Rechte (ab 2005) und Anerkennung nach der allgemeinen Regelung (Gleichwertigkeits- bzw. Defizitprüfung). Soweit möglich, geben Sie bitte die durchschnittliche Dauer der jeweiligen Anerkennungsverfahren an.

   Die Zahl der Anerkennungsanträge liegt der Kommission bereits vor. Die durchschnittliche Verfahrensdauer beträgt zwischen zwei und acht Wochen, abhängig von der Qualität und der Vollständigkeit der eingereichten Unterlagen.

B. VORÜBERGEHENDE MOBILITÄT (SELBSTÄNDIGER ODER ABHÄNGIG BESCHÄFTIGTER)

7. Zeigen die EU-Bürger Interesse an der Nutzung der Bestimmungen für die vorübergehende oder gelegentliche Ausübung ihres Berufes in Ihrem Mitgliedstaat? Wie viele Bürger haben dieses neue System in den Jahren 2008 und 2009 genutzt (monatlich, jährlich)?

   Bisher kein Interesse der EU-Bürger, daher keine Erfahrungen.

8. Wie wenden die zuständigen Behörden – unter Berücksichtigung der relevanten Bestimmungen des Verhaltenskodex – die Bestimmungen der Richtlinie 2005/36/EG zur vorübergehenden Mobilität in der Praxis an? Geben Sie z. B. an,

   - wie das in Artikel 5 Absatz 1 Buchstabe a vorgesehene Kriterium der „rechtmäßigen Niederlassung" in der Praxis ausgelegt wird und welche Bedingungen ein Migrant in seinem Herkunftsmitgliedstaat erfüllen muss, um in Ihrem Land Dienstleistungen erbringen zu dürfen,

   - wie die in Artikel 5 Absatz 2 vorgesehenen Kriterien für den "vorübergehenden und gelegentlichen" Charakter der Berufsausübung in der Praxis ausgelegt werden und ob die Behörde(n) Dauer, Häufigkeit, regelmäßige Wiederkehr und Kontinuität der Tätigkeit prüfen (wenn ja, anhand welcher Kriterien).

   Bisher keine praktischen Erfahrungen. Das Kriterium der „rechtmäßigen Niederlassung" ist u. E. zu verstehen als die Berechtigung, den Apothekerberuf im Herkunftsstaat uneingeschränkt ausüben zu dürfen. Die Nachweise sind demnach hierauf abzustellen. Vorzulegen sind damit vor allem das Diplom als Nachweis der EU-konformen Ausbildung und ein „certificate of good standing" als Nachweis der beruflichen und persönlichen Unbescholtenheit im Herkunftsstaat.

9. Ist ein System der vorherigen Meldung notwendig? Wie verwenden die zuständigen Behörden die eingegangenen Informationen? Gäbe es andere Möglichkeiten?

   Bisher keine praktischen Erfahrungen. Ein System der vorherigen Meldung ist aber erforderlich, um überprüfen zu können, ob eine Berechtigung zur Erbringung von vorübergehenden Dienstleistungen besteht. Die Meldung dient auch der Information der zuständigen Behörden und ermöglicht bei Bedarf eine entsprechende berufsaufsichtliche Überwachung.

10. Gibt es konkrete Fälle, in welchen die neuen Regelungen durch Apotheker missbraucht oder umgangen wurden? Gab es in dem Zusammenhang Anzeichen für eine Gefährdung der Patientensicherheit?

    Nein.

C. MINDESTAUSBILDUNGSANFORDERUNGEN

11. Inwieweit entsprechen die in Titel III Kapitel III der Richtlinie 2005/36/EG enthaltenen gemeinsamen Mindestanforderungen an die Ausbildung für Apotheker noch dem wissenschaftlichen Fortschritt der letzten zehn Jahre und den beruflichen Erfordernissen? Sind die in Artikel 44 Absatz 3 enthaltenen Kenntnisse und Fähigkeiten noch relevant und aktuell? (Bitte machen Sie hierzu spezifische Angaben aufgrund Ihrer praktischen Erfahrung). Was ist zu den Bestimmungen betreffend die Dauer der Ausbildung zu bemerken?

Die in Art. 44 Abs. 3 der Richtlinie aufgeführten - eher allgemein formulierten - Kenntnisse und Fähigkeiten entsprechen im Wesentlichen noch dem wissenschaftlichen Stand. Ergänzt werden könnte der Katalog allerdings um folgende Gebiete: Ernährungslehre, Krankheitslehre, Biochemie und Molekularbiologie, Immunologie, Biopharmazie, Biotechnologie, Klinische Chemie, Klinische Pharmazie, Pharmaoekoepidemiologie und Ökonomie sowie zu Medizinprodukten und zur Qualitätssicherung bei der Herstellung und Prüfung von Arzneimitteln.
Die Dauer der Ausbildung ist adäquat.

12. Grundlage der Richtlinie ist das Vertrauen zwischen den Mitgliedstaaten. Inwieweit existiert dieses Vertrauen wirklich? Werden in Ihrem Land Studiengänge zugelassen (akkreditiert)? Fördert es das Vertrauen, wenn ein Studiengang in einem anderen Mitgliedstaat zugelassen (akkreditiert) ist oder ist dies ohne Bedeutung?

Das Vertrauen zwischen den Mitgliedstaaten ist grundsätzlich gegeben.
Studiengänge werden in der Regel nicht akkreditiert, sondern nach dem Hochschulrecht der Länder im Rahmen der Autonomie der Hochschulen eingerichtet. Ob ein Studiengang in einem anderen Mitgliedstaat akkreditiert ist, ist unerheblich. Wesentlich ist vielmehr, dass jeweils der in Anhang 5.6.2. der Richtlinie genannte Ausbildungsnachweis vorgelegt wird. Die Länder gehen dabei davon aus, dass die Mindestausbildungsanforderungen von der EU-Kommission vor der Notifizierung geprüft wurden. Eine Akkreditierung des Studiengangs im Herkunftsstaat ist damit nicht relevant.

13. Inwieweit sind die derzeitigen Bestimmungen der Richtlinie zur beruflichen Fortbildung (Erwägungsgrund 39 und Artikel 22 Buchstabe b) angemessen? Ist kontinuierliche Fortbildung für Apotheker in Ihrem Land vorgeschrieben und wie sehen die Bestimmungen hierzu im Einzelnen aus?

Sofern in den Ländern eine Pflicht zur Fortbildung für Apotheker vorgeschrieben ist, erfolgt dies in der Regel in den jeweiligen Berufsordnungen der Landesapothekerkammern. Die Regelungen in der Richtlinie sind adäquat.

D. VERWALTUNGSZUSAMMENARBEIT

14. Inwieweit vereinfacht die Verwaltungszusammenarbeit gemäß den Artikeln 8, 50 und 56 der Richtlinie das Verfahren für Migranten?

Soweit eine unmittelbare Zusammenarbeit zwischen den Mitgliedstaaten erfolgt (z. B. über IMI), kann dies das Verfahren für die Migranten vereinfachen.

15. Ist die zuständige Behörde in Ihrem Land im IMI (Binnenmarktinformationssystem) registriert? Unter welchen Bedingungen nutzt Ihre zuständige Behörde das IMI? Welche praktischen Erfahrungen bestehen mit dem System? Falls Ihre Behörde nicht registriert ist: warum nicht und unter welchen Bedingungen könnte sich dies ändern?

Die zuständigen Behörden der Länder sind in der Regel in IMI registriert. Das System wird bisher aber noch wenig genutzt. Die vorgegebenen Fragen sind für den konkreten Fall oftmals ungeeignet.

16. Könnte ein Berufsausweis (siehe Erwägungsgrund 32 der Richtlinie) die Anerkennung von Berufsqualifikationen oder die Erbringung von Dienstleistungen erleichtern? Unter welchen Bedingungen könnte ein solcher Ausweis ausgestellt werden?

Es ist nicht ersichtlich, ob und wie ein Berufsausweis das Anerkennungsverfahren erleichtern könnte. Das wäre allenfalls vorstellbar, wenn der Ausweis bestimmte Nachweise, die ansonsten vorzulegen wären, zuverlässig ersetzen könnte (z. B. das Diplom). Insofern müsste der Ausweis EU-weit standardisiert sein. Die Fälschungssicherheit und der Datenschutz müssten zudem absolut gewährleistet sein. Dies erscheint kaum praktikabel.

17. Wie tauschen Sie Informationen mit anderen Mitgliedstaaten über disziplinarische oder strafrechtliche Sanktionen oder über sonstige Umstände aus, die sich auf die Ausübung der von der Richtlinie 2005/36/EG erfassten Tätigkeiten auswirken könnten? Könnte hier mehr getan werden?

Aus datenschutzrechtlichen Gründen erfolgt derzeit kein regelmäßiger oder automatischer Austausch mit anderen Mitgliedstaaten über Sanktionen und andere berufsrechtlich relevante Umstände. Eine Information erfolgt am ehesten im Wege eines „certificate of good standing" in konkreten Einzelfällen.
Geprüft werden könnte die Einrichtung einer zentralen Datenbank für Sanktionen gegen Berufsangehörige, die von der Kommission verwaltet wird. Der Betrieb und die Nutzung müssten dabei höchsten datenschutzrechtlichen Anforderungen genügen.

E. SONSTIGE ANMERKUNGEN

18. Wie und zu welchem Zeitpunkt werden die erforderlichen Sprachkenntnisse der Migranten geprüft, nachdem ihre Berufsqualifikation anerkannt wurde? Liegen Ihnen Informationen über Beschwerden (insbesondere von Patienten/Kunden/Arbeitgebern) über ungenügende Sprachkenntnisse von Migranten vor?

In der Regel verlangen die zuständigen Behörden im Zuge des Verfahrens zur Erteilung der Approbation einen Sprachnachweis auf dem Niveau B2 des Europäischen Referenzrahmens. Der Sprachnachweis kann durch ein Sprachzertifikat eines anerkannten Spracheninstituts oder im Einzelfall auch durch eine persönliche Vorsprache des Migranten oder ein Fachgespräch erbracht werden.
Offizielle Beschwerden über ungenügende Sprachkenntnisse von Migranten sind bisher nicht bekannt geworden.

19. Haben Sie sonstige Erfahrungen mit der Anwendung der Richtlinie 2005/36/EG oder weitere Anmerkungen?

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ESTONIA

Evaluating the Professional Qualifications Directive
Experience reports from competent authorities

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QUESTIONNAIRE FOR PHARMACISTS (Estonia)

A. RECOGNITION PROCEDURE IN CASE OF MIGRATION ON A PERMANENT BASIS

1. Please describe the government structure of the competent authority or authorities in charge of the recognition and of sanctions/restriction to practice.

The Health Board is a governmental authority of the Estonian Ministry of Social Affairs, which is empowered by a legal order of the Government of the Republic. Estonia is a small country with a small population. There are no local authorities. The Health Board is the leading, coordinating and consulting agency in the field of public health, also dealing with the recognition of health care professionals' qualifications.
The Health Board holds the national registers of health care professionals (doctors, dentists, midwives, nurses, pharmacists and assistant pharmacists), issues and revokes registration certificates, appropriate certificates to Estonian health care professionals who wish to work in EU/EEA member states or in Switzerland, issues and revokes activity licenses to health care providers.
• Compares, in line with legislation, foreign professional qualifications of applicants applying for regulated healthcare posts in Estonia, and makes recognition decisions;
• Cooperates and exchanges information with competent authorities on disciplinary decisions that may affect the recognition of an applicant's professional qualification;
• Monitors the number of recognition applications and submits relevant reports to the Ministry of Education and Research;
• Issues certificates and documents that are necessary for the recognition of the professional qualifications in Estonia or in another country.
The responsible unit for dealing with healthcare qualifications is
the Unit of Registers and Licences. Head: Ms Evi Lindmäe (evi.lindmae@terviseamet.ee),
The Health Board, Gonsiori 29,
15157 Tallinn, Estonia http://www.terviseamet.ee.

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2. To what extent have the system of automatic recognition and the general system been a success? How do you see the costs and benefits for patients and for your organisation? Can you give concrete examples. Specify in particular whether automatic recognition based on diploma, Annex V and the current notification system represent an efficient way to facilitate automatic recognition.

Please submit comments for:

- automatic recognition based on diploma

No experience.

- automatic recognition based on acquired rights

No experience.

3. Is the general system (as described in article 10) applied in your country each time the conditions for automatic recognition are not met? Are there major difficulties in the recognition procedure under the general system? Please include any comments you may have on the implementation of compensation measures.

   No experience.

4. What is your experience with the recognition procedure for EU citizens with professional qualifications obtained in a third country and already recognised in a first Member State (see Articles 2(2) and 3(3)?

   No experience.

5. Do you accept applications from EU citizens for the recognition of foreign diplomas sent by email or requests made on line? Under which conditions can they send documents and declarations electronically? What are your experiences in this respect?

   At present we do not accept documents which have been sent by e-mail. Emails, however, can be used to give a provisional assessment. We do accept documents that have sent and signed electronically (digital signature). However, we have had no cases where an EU citizen has submitted an application electronically.

6. What is the yearly number of applications for recognition from 2000 to 2009? Please submit specific data for applications for automatic recognition based on diplomas, automatic recognition based on acquired rights (as from 2005), and recognition based on the general system[1].

   None.

B. TEMPORARY MOBILITY (OF A SELF-EMPLOYED OR AN EMPLOYED WORKER)

7. Are EU citizens interested in using the provisions for exercising their professional activities on a temporary and occasional basis in your Member State? How many citizens used this new system since the directive has been transposed in your country (can you provide any statistics per month, per year)[2]?

   No experience.

8. How are the provisions of Directive 2005/36/EC concerning temporary mobility applied by the competent authorities in practice taking into account the relevant provisions of the Code of Conduct? For instance:

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[1] Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

[2] Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

How is the "legal establishment" criteria foreseen by Article 5(1) (a) interpreted in practice? What conditions does a migrant need to fulfil in his home Member State in order to be able to provide services?

He/she must be registered in the home country and have a legal right to practice in the home country.

How are the "temporary and occasional basis" criteria foreseen by Article 5.2 interpreted in practice? Do Member States assess duration, frequency, regularity and continuity of an activity and if so according to which criteria?

According to the law, the frequency and duration of temporary provision of services is assessed case by case.

9. Why is a prior declaration system necessary? What do competent authorities do with the information received? Are other possibilities conceivable?

Prior declaration is necessary to make sure that the person is indeed qualified to provide the planned service as a pharmacist or assistant pharmacist.

10. Do you have concrete examples of abuse or misuse of this new possibility for pharmacists? Have you been confronted to problems with regards to patient safety on this issue?

No experience.

C MINIMUM TRAINING REQUIREMENTS

11. To what extent are the common minimum training requirements set out in Title III Chapter III of Directive 2005/36/EC and the compulsory training subjects as defined in Annex V in line with scientific progress and professional needs? Furthermore, are the knowledge and skills required by the directive still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

The minimum training requirements are at present sufficient to ensure that there is at least a satisfactory level of competence.

12. To what extent are the common minimum requirements for training set out in Title III Chapter III of Directive 2005/36/EC in line with scientific progress and professional needs in the last ten years? Are the knowledge and skills outlined in Article 24.3 still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

The professional associations have been asked their opinion on this topic but have not yet provided comments.

13. The Directive is based on mutual trust between Member States. To what extent is such trust actually achieved? Are training programmes accredited in your country? Does accreditation of a training program in another Member State enhance trust or is it not relevant?

Yes, training programmes in Estonia undergo international accreditation. Yes, such accreditations do enhance trust.

14. To what extent are the existing Directive provisions (see Article 22(b) on continuous professional development (continuous training) adequate? What is your definition of CPD/continuous training? Is continuous training mandatory in your country and what are the exact conditions?

The continuous training of health care professionals is mandatory in Estonia and there are clear requirements in law (mandatory 60 academic hours per year). It is the duty of the employer to finance the continuous training of employees (same conditions for self-employed persons).

D. ADMINISTRATIVE COOPERATION (THIS SECTION APPLIES TO ESTABLISHMENT AS TO PROVISION OF SERVICES)

15. To which extent does administrative cooperation, as outlined in Articles 8, 50, and 56 of the Directive, simplify procedures for the migrant professionals? Can you give your own experience?

Administrative cooperation between competent authorities is essential. However, cooperation is much easier with a single institution per country as compared to federal states where every state / region has their own competent authority or branch.

16. Is the competent authority in your country registered with IMI? Under which circumstances does your competent authority use IMI? If not registered, why not and what would be the conditions for changing this situation?

Yes. We have used IMI both ways – for making enquiries and replying to questions.

17. How could a professional card (see Recital 32 of the Directive) facilitate recognition of professional qualifications and provision of temporary services? Under which conditions could it be issued by a competent authority?

In the case of temporary provision of services, it could be useful.

18. How do you share information about suspensions/restrictions with competent authorities in other Member States? Could more be done in this respect?

The sharing of information about suspensions and restrictions depends on the basic principles of the legal system – it sets limits as to whether proactive or reactive information exchange is possible, and determines how the disciplinary measures are regulated. Since it is the employer who sets disciplinary penalties, the Health Board may not be aware of minor breaches. The Health Board does share information about suspensions and restrictions if needed.

E. OTHER OBSERVATIONS

19. How and when are the necessary language skills of migrants checked after recognition of the professional qualifications? Are you aware of any complaints (especially from patients/clients/employers) about insufficient language skills of migrants?

According to Estonian law, it is the duty of the employer to ensure sufficient language skills when dealing with the public. The Estonian Language Board carries out inspections and responds to complaints from the public.

20. Please fill free to add any comment you want on the directive 2005/36/EC

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IRELAND

Evaluating the Professional Qualifications Directive
Experience reports from competent authorities

QUESTIONNAIRE FOR PHARMACISTS

Response by the Competent Authority in Ireland

A. RECOGNITION PROCEDURE IN CASE OF MIGRATION ON A PERMANENT BASIS

1. Please describe the government structure of the competent authority or authorities in charge of the recognition and of sanctions/restriction to practice.

Response: *The Pharmaceutical Society of Ireland (the Society) is the competent authority in Ireland for the purposes of the mutual recognition of pharmacy qualifications obtained in or recognised by Member States for the purposes of the Professional Qualification Directive*[1].

The Society was established by the Pharmacy Act 2007 (No. 20 of 2007) as an independent statutory body for the purpose of regulating the profession of pharmacy in the State and one of the duties assigned to it in the Act is to act as the competent authority for the purposes of the Directive (as amended).

Under the Pharmacy Act the Society is required to establish and to maintain registers of pharmacists and of retail pharmacy businesses and it is an offence under the Act to carry on a retail pharmacy business unless the business is registered and the sale and supply of medicinal products is conducted by or under the personal supervision of a registered pharmacist. Penal sanctions are laid down for breeches of the Act.

The principal functions of the Society are set out in section 7(1) of the Act as follows:

> *"(a) to regulate the profession of pharmacy in the State having regard to the need to protect, maintain and promote the health and safety of the public,*
> *(b) to promote and ensure a high standard of education and training for persons seeking to become pharmacists,*
> *(c) to ensure that those persons and pharmacists obtain appropriate experience,*
> *(d) to ensure that pharmacists undertake appropriate continuing professional development, including the acquisition of specialisation, and*

[1] "Professional qualifications Directive" means Directive 2005/36/EC of 7 September 2005 .....as amended by Council Directive 2006/100/EC of 20 November 2006.....

(e) otherwise to supervise compliance with the Act and the instruments made under it."

The powers available to the Society to secure compliance with the Act include powers of investigation, powers to prosecute for offences under the Act (and related medicines laws) and the imposition of disciplinary sanctions by way of complaints and inquiries which in extreme situations may result in the registration of a pharmacist, or of a retail pharmacy business, being cancelled.

2. To what extent have the system of automatic recognition and the general system been a success? How do you see the costs and benefits for patients and for your organisation? Can you give concrete examples? Specify in particular whether automatic recognition based on diploma, Annex V and the current notification system represent an efficient way to facilitate automatic recognition.

   Please submit comments for:

   - automatic recognition based on diploma
   - automatic recognition based on acquired rights

Response: *The automatic recognition system as set out in the Directive and as has been implemented and operated in the State to date has been a considerable success. It should be noted that this system has now been effectively in place since 1987 when the original 1985 pharmacist Directives were implemented in the Member States.*

Ireland has had considerable experience with both the diploma based and the acquired rights based systems and no difficulties of significance have emerged over the years. The acquired rights based system has always been recognised as being essentially transitional.

It remains the view of the Society that the automatic recognition of pharmacists should continue to be based on the diploma and Annex V that currently forms part of the Directive. Our experience has shown that it continues to be necessary for the various diplomas, documentation, professional standing, etc of applicants to be checked prior to recognition. This is particularly important where patient and public safety considerations are at issue and where in a notification system, the facility for intervention may arise too late and after considerable damage to patients or the public may have arisen.

3. Is the general system (as described in article 10) applied in your country each time the conditions for automatic recognition are not met? Are there major difficulties in the recognition procedure under the general system? Please include any comments you may have on the implementation of compensation measures.

Response: *Yes, but the initiative to proceed with the general system application rests with the applicant.*

The legal procedures for the operation of the general system only became available with the implementation of the Directive in October 2007 and for that reason experience is very limited.

Of necessity, the general system requires that a detailed assessment be carried out in each case with the possibility of requiring an adaptation period. This is difficult and time consuming and invariably involves evaluations by external experts. This presents considerable difficulties particularly where time deadlines must be met and this has been found to be the case notwithstanding the extra month provided for such applications in Article 51.2 of the Directive.

4. What is your experience with the recognition procedure for EU citizens with professional qualifications obtained in a third country and already recognised in a first Member State (see Articles 2(2) and 3(3))?

Response: *For the reasons set out in 3 above, experience under this heading is limited. The comments under 3 above are also relevant here.*

5. Do you accept applications from EU citizens for the recognition of foreign diplomas sent by email or requests made on line? Under which conditions can they send documents and declarations electronically? What are your experiences in this respect?

Response: *Yes. While applications may be made and may be processed on-line, certain documentation that must be submitted in the form of "statutory declarations" etc are required to be presented in hard-copy format before the application is determined.*

6. What is the yearly number of applications for recognition from 2000 to 2009? Please submit specific data for applications for automatic recognition based on diplomas, automatic recognition based on acquired rights (as from 2005), and recognition based on the general system[2].

Response: *The numbers for automatic recognition are set out in the following Table:*

Based on diplomas		***Based on acquired rights***		***Based on General System***	
Year	***No of Applications***	***Year***	***No of Applications[3]***	***Year***	***No of Applications***
2000	*151*	*2000*	-	*2000*	-
2001	*113*	*2001*	-	*2001*	-
2002	*136*	*2002*	-	*2002*	-
2003	*186*	*2003*	-	*2003*	-
2004	*183*	*2004*	-	*2004*	-
2005	*229*	*2005*	-	*2005*	*1*

[2] Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

[3] This information is currently not readily available. All recognition based on acquired rights has therefore been included in the figure given for recognitions based on diplomas for the period 2000-2007.

2006	*286*	*2006*	*-*	*2006*	*1*
2007	*306*	*2007*	*-*	*2007*	*-*
2008	*226*	*2008*	*11*	*2008*	*4*
2009	*100*	*2009*	*4*	*2009*	*1*

B. TEMPORARY MOBILITY (OF A SELF-EMPLOYED OR AN EMPLOYED WORKER)

7. Are EU citizens interested in using the provisions for exercising their professional activities on a temporary and occasional basis in your Member State? How many citizens used this new system since the directive has been transposed in your country (can you provide any statistics per month, per year) [4]?

Response: *To date, no interest has been shown in this form of temporary mobility where pharmacists are concerned.*

8. How are the provisions of Directive 2005/36/EC concerning temporary mobility applied by the competent authorities in practice taking into account the relevant provisions of the Code of Conduct? For instance:

   - How is the "legal establishment" criteria foreseen by Article 5(1) (a) interpreted in practice? What conditions does a migrant need to fulfil in his home Member State in order to be able to provide services?

   - How are the "temporary and occasional basis" criteria foreseen by Article 5.2 interpreted in practice? Do Member States assess duration, frequency, regularity and continuity of an activity and if so according to which criteria?

Response: *The relevant provisions of the Directive are applied on the basis of creating a specific division of the Register of Pharmacists for visiting European Pharmacists and once a notification (in the form of a declaration) is received, the name of the pharmacist is immediately entered in that Part of the Register.*

The declaration is required in advance of providing the service for the first time. It must include details of any insurance cover or other means of personal or collective protection with regard to professional liability and the declaration must be renewed annually if the person intends to provide temporary or occasional services during that year. Evidence of qualification as a pharmacist, and an attestation from the competent authority in the other Member State certifying that he or she is lawfully established in that State for the purpose of providing services as a pharmacist, and that he or she is not prohibited from providing such services in that State.

The authority to provide services ceases if the pharmacist concerned becomes established in the State, is prohibited from practising in the other State, fails to make a renewal declaration as required or is found to have infringed the disciplinary rules applicable to pharmacists in the State.

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[4] Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

The term "establishment" is defined as being the actual pursuit of an economic activity, as referred to in Article 43 of the Treaty, by the provider for an indefinite period and through a stable infrastructure from where the business of providing services is actually carried out.

While the concept of a "temporary and occasional basis" has not been defined, the Council of the Society is required to assess, on a case by case basis, the temporary and occasional nature of the provision of the professional services of a registered pharmacist by a visiting pharmacist form another State, having regard in particular to its duration, its frequency, its regularity and its continuity. Since the question has not yet arisen, no criteria have been laid down.

9. Why is a prior declaration system necessary? What do competent authorities do with the information received? Are other possibilities conceivable?

Response: *Prior declarations are essential in all of those areas where patient and public safety considerations are at issue and where the procedures and actions that may be carried out could present immediate and irreversible damage to patients or the public if not carried out competently and in accordance with the highest professional standards. The absence of a system of prior declarations, would deny the opportunity of intervention until after considerable damage to patients or the public may have arisen.*

It is a duty of competent authorities to the citizens of their respective Member States to competently examine any declarations received from visiting pharmacists and to satisfy themselves that the pharmacists concerned are genuine, of good professional standing in the other Member States concerned and that, insofar as can possibly be established, there are no patient or public safety concerns surrounding the services that are likely to be offered on a temporary and occasional basis by such pharmacists.

No conceivable alternatives to prior notifications are currently known that would meet the safety objectives concerned.

10. Do you have concrete examples of abuse or misuse of this new possibility for pharmacists? Have you been confronted to problems with regards to patient safety on this issue?

Response: *Since no interest in this form of movement on a temporary and occasional basis has been shown, no examples are available.*

C MINIMUM TRAINING REQUIREMENTS

11. To what extent are the common minimum training requirements set out in Title III Chapter III of Directive 2005/36/EC and the compulsory training subjects as defined in Annex V in line with scientific progress and professional needs? Furthermore, are the knowledge and skills required by the directive still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

Response: *In view of the changes in pharmacy practice since Annex V.6 was first proposed, the Society would suggest that consideration be given to the addition of the following subject areas:*

- *Behavioural sciences*
- *Pharmaceutical care/Medicines management*
- *Pharmacy management and leadership*
- *Medical informatics*
- *Complementary and alternative medicines*
- *Business studies*

The Society would also suggest that the subject area that currently reads 'Legislation and, where appropriate, professional ethics' be amended to read as:

- *Legislation*
- *Professional conduct and ethics.*

With regard to the conditions relating to the duration of training, the Society is convinced of the need to retain the requirement that the education and training required should be of a duration that is not less than 5 years of full-time (or its equivalent) education and training, with a minimum of 'four years of full-time theoretical and practical training at a university or at a higher institute of a level recognised as equivalent, or under the supervision of a university'.

Regarding the clinical training component which is currently a 'six-month traineeship in a pharmacy which is open to the public or in a hospital, under the supervision of that hospital's pharmaceutical department', the Society would suggest that the Directive should make explicit the requirement that this formal six months traineeship should be a continuous block of six months that occurs in the final stages of the training. The Society would also suggest that the Directive should include a requirement for an additional period of six months of in-service practical training to be carried out by the student across a range of practice settings throughout the course of the five-year training.

It should be noted that the current Article 44.2.(b) of the Directive (at least in the English language version) appears to contain an error in that there should be no comma after the word "hospital". The implications of the current text are significant in that, with the comma, all the pharmacies open to the public that may be used for traineeship purposes would have to be under the supervision "of that hospital's pharmaceutical department" (which was never the intention even if it were practical).

12. To what extent are the common minimum requirements for training set out in Title III Chapter III of Directive 2005/36/EC in line with scientific progress and professional needs in the last ten years? Are the knowledge and skills outlined in Article 24.3 still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

Response: *Taking into account the developments in scientific progress and professional needs in the last ten years, the Society would suggest that the following should be*

added to the list of knowledge and skills contained in Article 44.3 and that the term 'knowledge and skills' should be expanded to read as 'knowledge, skills, attitudes, values and behaviours':

- *adequate capability to provide health and medicine information efficiently and effectively*
- *adequate knowledge, skills and attitudes that will enable the provision of a safe, high quality service in all healthcare settings within a clinical governance framework that is focussed on patient safety.*

The point under 11 above with regard to duration of training is also relevant here.

13. The Directive is based on mutual trust between Member States. To what extent is such trust actually achieved? Are training programmes accredited in your country? Does accreditation of a training program in another Member State enhance trust or is it not relevant?

Response: *The Society is required under the Pharmacy Act 2007 to 'determine, approve and keep under review programmes of education and training suitable to enable persons applying for registration to meet those criteria (...)'. To give effect to this provision, the Society is required to draw up criteria/standards against which the five years of education and training are evaluated. A review of all accredited programmes is required to be undertaken by the Society at least once in every five year period with an annual report required to be submitted to the Society by the head of each of the schools of pharmacy during the accredited period.*

A mandatory requirement for accreditation in each Member State coupled with transparent accreditation criteria and transparent processes used to accredit the pharmacist qualification would greatly enhance the established relationships of trust across all Member States.

14. To what extent are the existing Directive provisions (see recital 39 and Article 22(b) on continuous professional development (continuous training) adequate? What is your definition of CPD/continuous training? Is continuous training mandatory in your country and what are the exact conditions?

Response: *Recital 39 and Article 22(b) make clear reference to the need for certain professions to maintain their competence post-qualification to the extent necessary to maintain safe and effective practice.*

It is important that the procedures to implement such requirements remain specific to each Member State but the Directive should make a clear statement as to the requirement for each Member State to have in place a system of mandatory continuing professional development (CPD) for each of the healthcare professions.

The Society defines CPD as an ongoing cyclical process of continuous quality improvement which allows pharmacists to learn and develop to meet their own

personal and professional needs, the needs of the health service and the needs of patients.

The Pharmacy Act 2007 places a clear and unambiguous requirement for all registered pharmacists to undertake appropriate CPD, including the acquisition of specialisation and therefore there is a mandatory requirement for CPD. At each application for continued registration that a pharmacist must make for the annual renewal of their certificates of registration (which are only valid for 12 months), the pharmacist must provide a statement setting out how she/he ensures the maintenance of appropriate experience in the practice of pharmacy and how she/he keeps abreast of continuing education and continuing professional developments in the profession of pharmacy.

The Council of the Society has only recently approved a model for mandatory CPD for pharmacists in Ireland. The model will be rolled-out on an incremental basis with immediate effect. The system will require the maintenance by each registered pharmacist of a reflective learning portfolio that documents their learning needs, how they address those needs and a reflection on the impacts of their learning on their practice and on patient outcomes. Pharmacists may address their learning needs through a range of learning activities, ranging from informal (i.e. workplace-based), non-formal to formal (structured, quality assured and assessed programmes) learning activities. A rolling practice review that incorporates an evaluation of the learning needs portfolio will take place for 20% of those on the Register of Pharmacists on an annual basis. This will be followed by a peer developed and peer assessed review of competency that encompasses a clinical knowledge assessment with a number of simulated standardised patient interviews.

D. ADMINISTRATIVE COOPERATION (THIS SECTION APPLIES TO ESTABLISHMENT AS TO PROVISION OF SERVICES)

15. To which extent does administrative cooperation, as outlined in Articles 8, 50, and 56 of the Directive, simplify procedures for the migrant professionals? Can you give your own experience?

Response: *Articles 8, 50 and 56 are essential to the free movement provisions of the Directive. The points made under section 18 below are also relevant to the effective functioning of the Directive.*

16. Is the competent authority in your country registered with IMI? Under which circumstances does your competent authority use IMI? If not registered, why not and what would be the conditions for changing this situation?

Response: *The Society is registered with IMI. It is used to obtain contact and other information about other competent authorities.*

A current weakness in the IMI system is relating to the identification of just one competent authority in a Member State where the separate functions of (i) confirmation of qualifications and (ii) the information regarding current professional status, are carried out by separate authorities.

It should also be borne in mind that in the case of the competent authorities relating to pharmacists, the fact that direct contact between most of those authorities has already been established and are already on-going, reduces the need to use the IMI system.

17. How could a professional card (see Recital 32 of the Directive) facilitate recognition of professional qualifications and provision of temporary services? Under which conditions could it be issued by a competent authority?

Response: *The Society believes a professional card can contribute to the process of qualifications recognition and the provision of temporary services. However it must be supported by an appropriate organisational, procedural and technical infrastructure. Such a card can support the requirements on this front but pending other developments cannot be solely relied on to provide the necessary guarantees.*

The comments in point 18 below are also relevant to this point.

18. How do you share information about suspensions/restrictions with competent authorities in other Member States? Could more be done in this respect?

Response: *The authority to suspend or restrict a registered pharmacist in Ireland has only recently become available to the Society under the Act and for that reason, the occasion has not arisen.*

It is understood that concerns exist in some Member States about the authority to share this type of personal information arising out of the need to comply with data protection laws and that these concerns exist notwithstanding the obligation towards that end that are contained in Article 56.2 of the Directive. It is noted that the construction of Article 56.2 of the Directive, in providing that the data protection legislation be respected, has left the door open to this particular (mis) interpretation.

It is suggested, therefore, that this Article 56.2 should be re-examined so as to remove any such ambiguity. The concerns for patient safety that would arise if this form of essential information were not to be shared, for whatever reason, are too great to be ignored and an appropriate amendment to the text would therefore seem to be necessary.

E. OTHER OBSERVATIONS

19. How and when are the necessary language skills of migrants checked after recognition of the professional qualifications? Are you aware of any complaints (especially from patients/clients/employers) about insufficient language skills of migrants?

Response: *In light of the strict requirement of the Directive, the Act provides that where an EU applicant for registration as a pharmacist lacks the linguistic competence to be a registered pharmacist in the State, he or she must provide an undertaking to acquire it. The applicant concerned is then registered as a pharmacist and it then, in the first instance, becomes a matter for employers. If concerns were subsequently to arise in the course of their professional practice as pharmacists*

arising out of their not having the necessary linguistic competence, the possibility exists of the matter being considered on the basis of a complaint under Part 6 of the Act (relating to fitness to practice). This procedure could result in the registered pharmacist concerned being removed from the Register of Pharmacists.

To date, while no such complaints have been made, we are aware that concerns have been expressed about the matter and in particular, about the limited ability in certain instances to communicate effectively with patients and their carers in the necessary counselling of patients on their usage of medicines.

20. Please fill free to add any comment you want on the directive 2005/36/EC

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SPAIN

Evaluating the Professional Qualifications Directive

Experience reports from competent authorities

QUESTIONNAIRE FOR PHARMACISTS

Preliminary notes:

The General Council of Pharmacists of Spain is the representative, coordinating and executive body of the Regional Councils of Pharmacists of Spain, at national and at international level and is, to all effects, a corporation of Public law.

Not being the competent authority for titles' recognition, we will only answer **Section C concerning Minimum Training Conditions.**

C MINIMUM TRAINING REQUIREMENTS

1. To what extent are the common minimum training requirements set out in Title III Chapter III of Directive 2005/36/EC and the compulsory training subjects as defined in Annex V in line with scientific progress and professional needs? Furthermore, are the knowledge and skills required by the directive still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

We consider that the minimum training requirements continue being adequate and are in line with scientific progress and professional needs. We verify that although new structures and courses have been elaborated by means of the construction of the European Higher Education Area, that in our country has finalised in 2010 (and that has demanded a review of all requirements to adapt them to the current professional needs), the courses and competences as defined in the Directive and the ones included in the national programs are coincidental in the basis.

At national level, more topics and competences have been added, being the Directive only referred to minimum, does not restrict the establishment of supplementary conditions of access, and because it is considered that in a world where the multidisciplinarity is the rule, pharmacists due to their university education, are qualified to exercise complementary activities in the fields of the analysis, food, environment and others.

Five years are considered to be the minimum to acquire the 300 European credits (ECTS).

2. To what extent are the common minimum requirements for training set out in Title III Chapter III of Directive 2005/36/EC in line with scientific progress and professional needs in the last ten years? Are the knowledge and skills outlined in Article 24.3 still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

   As mentioned, all objectives defined as competences have been recently checked in the light of the new professional needs on the occasion of the adjustment to the European Higher Education Area (EHEA). This review and adjustment has finished in 2010, so that 2011 will be the first year with the new structure.

3. The Directive is based on mutual trust between Member States. To what extent is such trust actually achieved? Are training programmes accredited in your country? Does accreditation of a training program in another Member State enhance trust or is it not relevant?

   In principle, the system of European credits was designed to ensure this trust. So we trust the veracity of the certificates issued by the relevant authorities for the EU recognition, and assume that the requirements as regards training have undergone prior harmonisation for automatic recognition.

   Yes, there is a unit of the Ministry of Health that accredits postgraduate training programmes presented on a voluntary basis.

   We consider that accreditation of a training program in another Member State by a competent authority enhance trust.

1. To what extent are the existing Directive provisions (see recital 39 and Article 22(b) on continuous professional development (continuous training) adequate? What is your definition of CPD/continuous training? Is continuous training mandatory in your country and what are the exact conditions?

We consider them to be adequate. Every Member state must guarantee that the persons who have completed their studies are kept up to date of the professional development in a way to support professional, safe and effective services.

From our point of view the continuous training, is that of provides competences and knowledge updated and of confirmed quality and should contemplate, on the one hand, the new scientific advances and, on the other, the welfare and adviser role that the society demands of the pharmacists.

It is not mandatory. According to the legislation, continuous training is a right and obligation of health professionals; and it is taken into account both in terms of selective tests and for professional career and development.

As mentioned before, there is a unit of the Ministry of Health and Social Policy that assess the proposed programs and accredits them, if pertinent, ensuring the application of standard quality criteria.

One example is the National Plan of Continuous Training developed by the General Council of Pharmacists, born with aim of independence and national homogeneity. This Plan is integrated by different courses at distance (by means of a platform of e- learning) responding to the objective of keeping update the knowledge related to the profession and facilitating the role of the pharmacist as health advisor. All courses are proposed for accreditation to the Ministry of Health. The participation of pharmacists is voluntary.

Evaluación de la Directiva relativa a las cualificaciones profesionales
Informes de las autoridades competentes sobre su experiencia práctica

POSIBLE CUESTIONARIO PARA CADA PROFESIÓN SECTORIAL

C CONDICIONES MÍNIMAS DE FORMACIÓN

1. ¿En qué medida las condiciones mínimas de formación comunes establecidas en el título III, capítulo III, de la Directiva 2005/36/CE, así como las materias de formación obligatorias definidas en el anexo V, están en consonancia con el progreso científico y las necesidades profesionales? Es más, ¿siguen siendo pertinentes y estando actualizados los conocimientos y las cualificaciones que exige la Directiva? Especifíquese. ¿Y en cuanto a las condiciones relativas a la duración de la formación?

Las condiciones mínimas de formación comunes establecidas en el título III, capítulo III son:
Art. 44 Formación del Farmacéutico.

1. La admisión a la formación de farmacéutico supondrá la posesión de un **título o certificado** que permita el acceso, para la realización de esos estudios, a los centros universitarios de un Estado miembro o a sus instituciones superiores de nivel reconocido como equivalente.

2. El título de formación de farmacéutico sancionará una formación de una duración de por lo menos **cinco años**, en los que se habrán realizado como mínimo:

a) **cuatro años de enseñanza teórica y práctica** a tiempo completo en una universidad, en un instituto superior con nivel reconocido como equivalente o bajo el control de una universidad;

b) **seis meses de período de prácticas** en una oficina de farmacia abierta al público o en un hospital bajo la supervisión del servicio farmacéutico de dicho hospital.

Las materias de formación obligatorias definidas en el Anexo V (punto 5.6.1) son:

1. Botánica y zoología
2. Física
3. Química general e inorgánica
4. Química orgánica
5. Química analítica
6. Química farmacéutica, incluyendo el análisis de medicamentos
7. Bioquímica general y aplicada (médica)
8. Anatomía y fisiología; terminología médica
9. Microbiología

10. Farmacología y farmacoterapia
11. Tecnología farmacéutica
12. Toxicología
13. Farmacognosia
14. Legislación y, en su caso, deontología

La distribución entre enseñanza teórica y práctica en cada materia debe dar suficiente importancia a la teoría para conservar el carácter universitario de la enseñanza.

Marco Normativo en España

En España, el **Real Decreto 1837/2008** traspone al ordenamiento jurídico español la Directiva 2005/36/CE relativa al reconocimiento de cualificaciones profesionales. Según este Decreto, los requisitos mínimos son una formación de cómo mínimo 5 años, un programa de materias y una lista de conocimientos y competencias tales como las mencionadas anteriormente.

Por otro lado, en España se ha promulgado el **Real Decreto 1393/2007 de 29 de Octubre** por el que se establece la ordenación de las enseñanzas universitarias oficiales como resultado de la progresiva armonización de los sistemas universitarios que exige el proceso de construcción del Espacio Europeo de Educación Superior (el llamado Proceso de Bolonia). Cabe recordar que el EEES tiene como objetivo principal la armonización de los títulos universitarios de los países miembros de la UE y está organizado sobre los principios de calidad, movilidad, diversidad y competitividad. En España todas las enseñanzas deben estar adaptadas a la nueva estructura del proceso de en el 2010, comenzando los nuevos planes de estudio en el 2011.

Según lo expuesto en este Real Decreto, dicho Proceso de Bolonia profundiza en la concepción y expresión de la autonomía universitaria de modo que son las propias universidades las que crean y proponen, de acuerdo con las reglas establecidas, las enseñanzas y títulos que hayan de impartir, sin sujeción a un catálogo previo establecido por el Gobierno, como era obligado hasta ese momento.

Por último, el Real Decreto también destaca que los planes de estudio deberán tener en el centro de sus objetivos la adquisición de competencias, ampliando sin excluir, el tradicional enfoque basado en contenidos y horas lectivas. Para evaluar la adquisición de estas competencias se proponen los créditos europeos ECTS, tal y como se definen en el Real Decreto 1125/2003 de 5 septiembre.

Así pues, el Gobierno promulga la **Orden CIN/2137/2008** que desarrolla el marco normativo establecido en el anterior Real Decreto 1393/2007 de 29 de Octubre respecto a los **planes de estudio conducentes a la obtención del Grado que habilite para la profesión de farmacéutico**. En el Anexo de esta Orden se detallan las materias y las competencias que han de adquirirse en cada una las materias que deben estar incluidas en los planes de estudio para la obtención del título de Farmacéutico.

Dicha Orden recoge las competencias que los estudiantes de Farmacia deberán adquirir, y lista un total de **15 competencias**, a saber:

1. Identificar, diseñar, obtener, analizar, controlar y producir fármacos y medicamentos, así como otros productos y humano o veterinario.
2. Evaluar los efectos terapéuticos y tóxicos de sustancias con actividad farmacológica.

3. Saber aplicar el método científico y adquirir habilidades en el manejo de la legislación, fuentes de información, bibliografía, elaboración de protocolos y demás aspectos que se consideran necesarios para el diseño y evaluación crítica de ensayos preclínicos y clínicos.

4. Diseñar, preparar, suministrar y dispensar medicamentos y otros productos de interés sanitario.

5. Prestar consejo terapéutico en farmacoterapia y dietoterapia, así como en el ámbito nutricional y alimentario en los establecimientos en los que presten servicios.

6. Promover el uso racional de los medicamentos y productos sanitarios, así como adquirir conocimientos básicos en gestión clínica, economía de la salud y uso eficiente de los recursos sanitarios.

7. Identificar, evaluar y valorar los problemas relacionados con fármacos y medicamentos, así como participar en las actividades de farmacovigilancia.

8. Llevar a cabo las actividades de farmacia clínica y social, siguiendo el ciclo de atención farmacéutica.

9. Intervenir en las actividades de promoción de la salud, prevención de enfermedad, en el ámbito individual, familiar y comunitario; con una visión integral y multiprofesional del proceso salud-enfermedad.

10. Diseñar, aplicar y evaluar reactivos, métodos y técnicas analíticas clínicas, conociendo los fundamentos básicos de los análisis clínicos y las características y contenidos de los dictámenes de diagnóstico de laboratorio.

11. Evaluar los efectos toxicológicos de sustancias y diseñar y aplicar las pruebas y análisis correspondientes.

12. Desarrollar análisis higiénico-sanitarios, especialmente los relacionados con los alimentos y medioambiente.

13. Desarrollar habilidades de comunicación e información, tanto orales como escritas, para tratar con pacientes y usuarios del centro donde desempeñe su actividad profesional. Promover las capacidades de trabajo y colaboración en equipos multidisciplinares y las relacionadas con otros profesionales sanitarios.

14. Conocer los principios éticos y deontológicos según las disposiciones legislativas, reglamentarias y administrativas que rigen el ejercicio profesional, comprendiendo las implicaciones éticas de la salud en un contexto social en transformación.

15. Reconocer las propias limitaciones y la necesidad de mantener y actualizar la competencia profesional, prestando especial importancia al autoaprendizaje de nuevos conocimientos basándose en la evidencia científica disponible.

Asimismo se establece que el plan de estudios deberá recoger como mínimo un conjunto de módulos, especificándose para cada uno las competencias que deben adquirirse (se adjunta en Anexo 1).

Se considerará que se han cumplido los objetivos designados en forma de competencias si se alcanzan los 300 créditos europeos.

Es importante hacer notar que la Conferencia Nacional de Decanos de Facultades de Farmacia de España, creada en 1991 y que agrupa a todas las facultades de Farmacia públicas y privadas españolas, ha logrado el consenso para homogeneizar los contenidos de los planes de estudio de Farmacia en un 75%.

Además, la característica pluridisciplinar de los estudios de Farmacia permite preparar a los licenciados para ejercer en diversos ámbitos:

1. Oficina de farmacia
2. Farmacia Hospitalaria
3. Distribución Farmacéutica
4. Industria Farmacéutica
5. Industria Alimentaria
6. Sanidad Ambiental
7. Análisis clínicos
8. Análisis de Medicamentos y Drogas
9. Salud Pública
10. Administración Pública
11. Investigación
12. Docencia

De los mencionados, únicamente los tres primeros son específicos del farmacéutico. En los restantes ámbitos, se ha de competir con otros licenciados para conseguir un puesto de trabajo.

Volviendo a la Directiva de Reconocimiento de Cualificaciones Profesionales y a la pregunta de si las materias de formación obligatorias definidas en el Anexo V (punto 5.6.1) están de acuerdo con el progreso científico, consideramos que siguen siendo pertinentes y estando actualizados los conocimientos y las cualificaciones que exige la Directiva. Comprobamos que si bien se han elaborado nuevas estructuras y planes de estudios para su adaptación al Espacio Europeo de Educación Superior que en nuestro país ha culminado en el 2010 (lo que ha exigido una nueva revisión de los requisitos para adecuarlos a las necesidades profesionales), las materias y competencias definidas en la Directiva Europea y las incluidas en los planes de estudio coinciden en lo básico. En los planes de estudio a nivel nacional se han añadido más materias y competencias, ya que la Directiva al tratar de mínimos, no restringe el establecimiento de condiciones suplementarias de acceso, y porque se considera que en un mundo donde la pluridisciplinariedad es la regla, el farmacéutico por su formación universitaria, está capacitado para ejercer actividades complementarias en los campos del análisis, de la alimentación, medio ambiente y otros.

¿Y en cuanto a las condiciones relativas a la duración de la formación? Se considera que cinco años como mínimo son necesarios para conseguir los 300 ECTS. En todos los países europeos la duración de la carrera de farmacéutico es de al menos 5 años aunque en algunos países se divida en dos o más ciclos.

2. ¿En qué medida las condiciones mínimas de formación comunes establecidas en el título III, capítulo III, de la Directiva 2005/36/CE están en consonancia con el progreso científico y las necesidades profesionales en los últimos 10 años?¿siguen siendo pertinentes y estando actualizados los conocimientos y las cualificaciones señalados en el artículo 24.3. Especifíquese. ¿Y en cuanto a las condiciones relativas a la duración de la formación?

Como ya se ha mencionado, todos los objetivos curriculares definidos en clave de competencias han sido recientemente revisados a la luz de las nuevas necesidades profesionales con motivo de la adaptación al EEES. Esta revisión y adaptación ha culminado en el 2010, de manera que el 2011 será el primer año con los nuevos planes de estudio.

3. La Directiva está basada en la confianza mutua entre los Estados miembros. ¿En qué medida se consigue de hecho esa confianza? ¿Se reconocen programas de formación en su país? El reconocimiento de un programa de formación en otro Estado miembro, ¿mejora la confianza o es irrelevante?

   El sistema de créditos europeos fue diseñado precisamente para asegurar esa confianza.

   Sí, hay un organismo dependiente del Ministerio de Sanidad que acredita estos programas de formación.

   Consideramos que el reconocimiento de un programa de formación en otro Estado miembro mejora la confianza.

4. ¿Hasta qué punto son adecuadas las disposiciones actuales de la Directiva (véanse el considerando 39 y el artículo 22, letra b), sobre el desarrollo profesional continuo y la formación continuada)? Cuál es la definición de CPD/Formación continuada en su país? ¿Es la formación continuada obligatoria en su país? ¿Cuáles son exactamente las condiciones que se le aplican?

   Nos parecen adecuadas. Cada Estado Miembro debe garantizar que las personas que han completado sus estudios se mantengan al día de las novedades profesionales en la medida necesaria para mantener unas prestaciones profesionales, seguras y eficaces.

   Desde nuestro punto de vista la formación continuada es la formación e información actualizadas y de calidad contrastada que contemple, por un lado, los nuevos avances científicos y, por otro, la labor asistencial y de asesoramiento que la sociedad demanda de los profesionales farmacéuticos.

   No es obligatoria

   Existe una Comisión dependiente del Ministerio de Sanidad que evalúa los programas de formación propuestos y los acredita en su caso, asegurando así la aplicación de unos criterios de calidad uniformes.

   Un ejemplo es el Plan Nacional de Formación Continuada que ha puesto en marcha el Consejo General de Colegios de Farmacéuticos, que nace con una vocación de independencia y uniformidad a nivel nacional. Dicho Plan está integrado por cursos a distancia (plataforma de e-learning) que responden a los objetivos prioritarios de actualizar los conocimientos relacionados con la profesión y facilitar al farmacéutico su tarea como informador sanitario. Todos los cursos son propuestos para su acreditación por el Ministerio de Sanidad. La participación es voluntaria.

   En el ámbito de la farmacia existen además incentivos especiales para la formación continuada y es que ésta puntúa de cara a los concursos de adjudicación de oficinas de farmacia.

SPAIN

AÑO_ORD	PAIS	TOTAL
2000	Italia	2
2000	Bélgica	1
2000	Alemania	5
2000	Portugal	2
2000	Reino Unic	3
2001	Italia	2
2001	Alemania	5
2001	Reino Unic	1
2002	Italia	3
2002	Austria	1
2002	Bélgica	1
2002	Francia	4
2002	Alemania	4
2002	Reino Unic	2
2003	Italia	5
2003	Bélgica	3
2003	Francia	4
2003	Noruega	1
2003	Alemania	5
2003	Reino Unic	3
2004	Italia	4
2004	Francia	2
2004	Alemania	3
2004	Portugal	2
2004	Países Baj	1
2005	Grecia	1
2005	Italia	9
2005	Bélgica	1
2005	Francia	4
2005	Hungría	1
2005	Irlanda	1
2005	Alemania	5
2005	Portugal	2
2005	Dinamarca	1
2005	Reino Unic	3
2005	Países Baj	1
2006	Suiza	1
2006	Italia	5
2006	Bélgica	2
2006	Francia	9
2006	Alemania	5
2006	Portugal	1
2006	Reino Unic	2
2007	Italia	10
2007	Francia	4
2007	Polonia	2
2007	Alemania	6
2007	Dinamarca	1
2007	Reino Unic	3
2007	Países Baj	1
2007	República	2

2008	Italia	9
2008	Austria	1
2008	Bélgica	1
2008	Francia	5
2008	Noruega	1
2008	Polonia	2
2008	Alemania	2
2008	Portugal	3
2008	República	1
2009	Italia	18
2009	Bélgica	1
2009	Francia	6
2009	Hungría	2
2009	Rumanía	3
2009	Alemania	3
2009	Bulgaria	1
2009	Portugal	8
2009	Eslovenia	1
2009	Reino Unic	1
2009	República	1
2010	Polonia	2

AÑO	PAIS	TOTAL
2000	Italia	4
2000	Austria	1
2000	Bélgica	1
2000	Alemania	5
2000	Portugal	2
2000	Reino Unic	1
2001	Italia	5
2001	Francia	2
2001	Alemania	9
2001	Reino Unic	2
2002	Italia	6
2002	Austria	1
2002	Bélgica	1
2002	Francia	3
2002	Alemania	5
2002	Reino Unic	4
2003	Italia	7
2003	Bélgica	3
2003	Francia	4
2003	Noruega	2
2003	Alemania	5
2003	Reino Unic	1
2003	Países Baj	1
2004	Italia	6
2004	Francia	2
2004	Hungría	1
2004	Letonia	1
2004	Alemania	4
2004	Portugal	3
2004	Reino Unic	4
2005	Grecia	1
2005	Italia	10
2005	Bélgica	2
2005	Francia	7
2005	Hungría	1
2005	Irlanda	1
2005	Polonia	1
2005	Alemania	5
2005	Portugal	2
2005	Dinamarca	1
2005	Reino Unic	3
2005	Países Baj	1
2006	Suiza	1
2006	Italia	11
2006	Bélgica	1
2006	Francia	7
2006	Polonia	2
2006	Alemania	7
2006	Portugal	2
2006	Reino Unic	2
2006	República	1

2007	Italia	10
2007	Francia	5
2007	Rumanía	5
2007	Alemania	6
2007	Portugal	2
2007	Dinamarca	1
2007	Reino Unic	2
2007	Países Baj	1
2007	República	2
2008	Italia	15
2008	Suecia	1
2008	Austria	1
2008	Bélgica	2
2008	Francia	4
2008	Hungría	2
2008	Noruega	1
2008	Polonia	6
2008	Rumanía	2
2008	Alemania	4
2008	Bulgaria	2
2008	Portugal	8
2008	Reino Unic	1
2009	Italia	9
2009	Suecia	1
2009	Francia	6
2009	Polonia	1
2009	Rumanía	2
2009	Alemania	1
2009	Bulgaria	1
2009	Portugal	6
2009	Eslovenia	1
2009	Reino Unic	1
2009	República	1

FRANCE

Evaluating the Professional Qualifications Directive
Experience report from the French competent authorities for pharmacists: National Council of Pharmacists and Ministry of health

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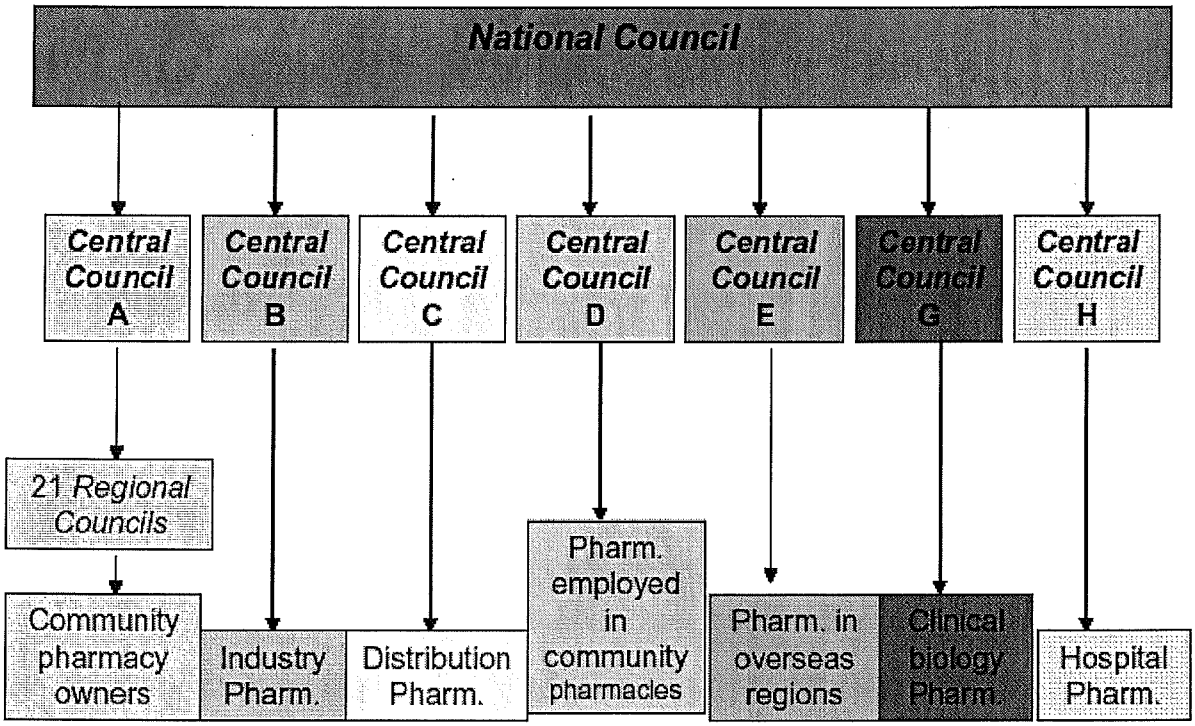
A. RECOGNITION PROCEDURE IN CASE OF MIGRATION ON A PERMANENT BASIS

1. Please describe the government structure of the competent authority or authorities in charge of the recognition and of sanctions/restriction to practice.

In France, the National Council of Pharmacists directly registers professionals who fit in the automatic recognition part of the directive. For the general system, professionals must first obtain an authorization to practice from the Ministry of health.

- Governance of the National Council of Pharmacists (automatic recognition)

The National Council coordinates the actions of 7 sections:
-**'Section A'** for community pharmacy owners
-**'Section B'** for industry pharmacists
- **'Section C'** for pharmacists working for wholesalers
- **'Section D'** for pharmacists employed in community pharmacies and social pharmacies (+others)
-**'Section G'** for clinical biology pharmacists
-**'Section H'** : a new Section, for hospital pharmacists
- **'Section E'** for all pharmacists in overseas regions
Each Section has a *Central council* to administer its affairs. Section A has 21 *Regional Councils (+ a Central Council* to co-ordinate them).
Each section registers the pharmacists it is in charge of (*Regional Councils for section A, central Councils for the others).*



Disciplinary role

In case of professional misconduct or infringement to the ethics code, a pharmacist may be suspended, or even removed, from the Council's register.
We have a 2-level Disciplinary Chambers system (both are courts composed of elected health professionals):

- 1st level: Regional Council (for Section A only) or Central Council
- Appeals: to the National Council
- Possibility of cassation (Conseil d'Etat)

Procedure:

- A member of the relevant Council is appointed to report on the case
- Disciplinary Chambers are chaired by a professional judge
- Disciplinary hearings are open to the public

➢ Governance of the department of the Health Ministry in charge of delivering the authorizations to practice (general system)

When the general system set in the Directive applies, it is the ministry of Health, through the "Centre national de gestion" (CNG) who receives the application of the migrant and takes the decision to authorise the migrant to practise.
The ministry is also responsible for the organisation of the commissions, which are composed by several and different professionals and will assess the competencies of the applicant. This commission will decide if it's necessary to require a compensating measure.

2. To what extent have the system of automatic recognition and the general system been a success? How do you see the costs and benefits for patients and for your organisation? Can you give concrete examples. Specify in particular whether automatic recognition based on diploma, Annex V and the current notification system represent an efficient way to facilitate automatic recognition.

Please submit comments for:

- automatic recognition based on diploma

The automatic recognition based on diploma is a success but it already worked well before directive 2005/36 thanks to directive 85/432 and 433/CEE. For the patient, this system is a guarantee that he will have in front of him a competent health professional, whatever the country in the EU where he obtained his diploma. For our organisation, this system is simple and easy to use, even more thanks to IMI.

- automatic recognition based on acquired rights

This system is very useful for applicants: it simplifies a number of cases of "old" diplomas listed in the directive.

As a competent authority, we feel the system is efficient since the competent authority of the Member state of origin is the most able to check that the professional actually practiced 3 years during the last 5 years prior to the delivery of the certificate.

The problem is when the migrant asks for this proof more than 2 years after having left his country. Another problem could appear in a few years: is it compulsory for the host country to accept a migrant holding a 10 years old certificate of acquired rights ?

3. Is the general system (as described in article 10) applied in your country each time the conditions for automatic recognition are not met? Are there major difficulties in the recognition procedure under the general system? Please include any comments you may have on the implementation of compensation measures.

The general system is applied when the conditions for the automatic recognition are not met.
Difficulties have been experienced to compare properly the qualifications in order to understand the very large scope of practice of the profession within the EU.
The problem to identify the competent authority that can deliver diplomas and qualifications or to determine the validity of documents the applicant has to produce is also common and delays the recognition process. A database with the different qualifications and titles, and specially the scope of the attached rights, would help the process of recognition.
The evaluation of the training always raises interrogations and is hard to determine. The problem is to determine how to recognize the experience, with no specification of its duration, of a migrant that in fact would have had only part time jobs. A provision in the directive should allow member states to require this kind of detail. An insufficient experience would increase the risk for patient safety.

4. What is your experience with the recognition procedure for EU citizens with professional qualifications obtained in a third country and already recognised in a first Member State (see Articles 2(2) and 3(3))?

It could be useful for competent authorities to have some information about the different agreements and mechanisms of recognition of the professional or academic qualification, as every member-state will then have to recognise the qualifications of a migrant from a third country who also has the European citizenship. Sometimes, the recognition of the qualifications does not allow practising as another national practitioner but only to gain access to the educational system and those cases should be communicated.
The experience and rights acquired in a third country and the verification from the member-state of recognition is sometimes complicated, especially when there isn't enough information to assess the professional experience. A safe net mechanism should be set in the directive to allow the second member state to require some information about the experience and the professional qualifications from the first member state of recognition. It would avoid that an honest mistake in the application of the directive would be supported by all member states.

5. Do you accept applications from EU citizens for the recognition of foreign diplomas sent by email or requests made on line? Under which conditions can they send documents and declarations electronically? What are your experiences in this respect?

The registration form can be downloaded on the website www.ordre.pharmacien.fr .

Requests can be made by email but, for practical reasons, the current practice is still based on paper files. Moving to electronic files would be possible, with some organizational changes.

To avoid frauds, it would be safer to exchange the documents issued by competent authorities - such as the professional qualifications, the certificate of acquired rights, or certificates on professional experience- from competent authority to competent authority. We already had the case, for instance, of a false conformity attestation: the document issued by the competent authority had been changed, and the translation into French also altered the meaning of the document.

6. What is the yearly number of applications for recognition from 2000 to 2009? Please submit specific data for applications for automatic recognition based on diplomas, automatic recognition based on acquired rights (as from 2005), and recognition based on the general system[1].

To answer this question, we used the statistics of our two organizations:
- The Council provided the number of European pharmacists with an EU diploma registered in France per year
- The Ministry provided the number of general system cases

When subtracting the « general system » figures to the global number of pharmacists registered, we obtain the automatic recognition figures. We are not able to provide figures on acquired rights (these people will be included in the automatic recognition global figures).

[1] Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

YEAR	Number of EU pharmacists with an EU diploma registered	General system	Automatic recognition
2000	21		
2001	39		
2002	45		
2003	43		
2004	61		
2005	72	48	24
2006	55	49	6
2007	74	66	8
2008	51	4	47
2009	60	34	26

B. TEMPORARY MOBILITY (OF A SELF-EMPLOYED OR AN EMPLOYED WORKER)

7. Are EU citizens interested in using the provisions for exercising their professional activities on a temporary and occasional basis in your Member State? How many citizens used this new system since the directive has been transposed in your country (can you provide any statistics per month, per year) [2]?

The provisions on temporary provision of services were transposed into French law for pharmacists only in August 2009 (decree n° 2009-958 of 29 July 2009) and February 2010 (Arrêté dated 20 January 2010 setting the prior declaration form). Therefore, we only had one case until now (June 2010) and we are not in a position to stand back and comment on the temporary provision of services.

Besides temporary provisions of services, we know that there are a number of cross-border workers, who work (not on a temporary and occasional basis) on both sides of the border and who are therefore registered in two countries. It is difficult to assess the extent of this phenomenon since no comparative study with border countries was ever done.

8. How are the provisions of Directive 2005/36/EC concerning temporary mobility applied by the competent authorities in practice taking into account the relevant provisions of the Code of Conduct? For instance:

   - How is the "legal establishment" criteria foreseen by Article 5(1) (a) interpreted in practice? What conditions does a migrant need to fulfil in his home Member State in order to be able to provide services?

As explained earlier, we have very little experience. Our understanding is that the "legal establishment" means the country where the professional is registered by a competent authority.

[2] Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

- How are the "temporary and occasional basis" criteria foreseen by Article 5.2 interpreted in practice? Do Member States assess duration, frequency, regularity and continuity of an activity and if so according to which criteria?

We did not have to assess these criteria until now since we were not confronted with renewals. Our understanding is that these criteria should be assessed on a case by case basis.

9. Why is a prior declaration system necessary? What do competent authorities do with the information received? Are other possibilities conceivable?

The prior declaration system is necessary for three reasons:

- first, for the general system, the competent authority will sometimes have to organize a test; The temporary provision of services should not be used by professionals whose diploma does not meet the criteria for automatic recognition to benefit from this principle to practice in another country.
- second, to know the professionals practicing in our country; this is necessary for authorities to know who they could use in case of a health crisis for instance; it is also necessary to know the person in case of any professional misconduct leading to a disciplinary actions;
- third, temporary provision of services should not give the opportunity for professionals prohibited from practicing in a country to practice abroad. If there was no prior declaration, accompanied with "an attestation [from the competent authority in the country of origin] certifying that the holder is legally established in a Member State and that he is not prohibited from practicing, even temporarily", the competent authority of the host country would never know that the professional is prohibited to practice, and patients would be put at risk.

In addition, the prior declaration neither delays nor represents additional expenses for the migrant.

In the future, we believe it would be useful to add to the prior declaration the first practice place in the host country. This information would be useful for two reasons:

- Our institution is organized in sections corresponding to the different pharmacy practices/ outlets (hospital, community pharmacy, etc, see question 1). It would facilitate the internal administrative treatment of the prior declaration to know where the professional wants to practice. This would help us meeting the short deadlines imposed.
- In case of professional misconduct, the disciplinary chamber competent to judge the pharmacist is the one of the section corresponding to his practice (see question 1).

10. Do you have concrete examples of abuse or misuse of this new possibility for pharmacists? Have you been confronted to problems with regards to patient safety on this issue?

Not yet in France, cf little experience.
But some interrogations remain *in abstracto*.
It is still not clear under what circumstances a provision of services or renewal would be considered to be temporary and occasional and there's a lack of specifications on the means available to make a control *ex-post*.
The fact that there's no registration fee for this type of registration, can also be appealing.

The term 'temporary and occasional' is ambiguous and we would welcome further clarification about these notions. We don't think a length of time should be specified, but we would appreciate some specific indications, while we wait for an E.C's case-law. A forum where the competent authorities could discuss their experience would help specifying these notions reducing the discrepancies in the interpretation and the implementation of the directive.
Even if there is still no experience in the temporary mobility, it would be safer for the patients to solve these issues, common to all member-states.

C MINIMUM TRAINING REQUIREMENTS

11. To what extent are the common minimum training requirements set out in Title III Chapter III of Directive 2005/36/EC and the compulsory training subjects as defined in Annex V in line with scientific progress and professional needs? Furthermore, are the knowledge and skills required by the directive still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

- Compulsory training subjects (annex V)

We believe it would be useful to **introduce pharmaceutical care** as a new subject area in the general pharmacy curriculum. Pharmaceutical care reflects the modern pharmacy practice and there is a universally agreed definition of this concept, which would facilitate the implementation of the subject at the higher education institution level. To us, pharmaceutical care includes **therapeutic education,** which is a crucial point today.

Additionally, introduction of the more generic subjects such as information technology, management, gerontology, etc., can support the future pharmacy workforce to take a more active role in the multidisciplinary health care team.

- Duration of studies (art 44.2)

In all EU Member States, pharmacists are acquiring new roles and responsibilities. New services that go beyond traditional dispensing role of pharmacists require pharmacy education and training to be adequate to support the development of the relevant competencies.

In France for instance, following the adoption in July 2009 of a new law (known as HPST), some tasks of physicians will be delegated to other health care professionals. This law officially expands Community pharmacists' missions.
Beyond dispensing and compounding medicines, community pharmacists are expected to take part in therapeutic education and disease management actions, and to put into place "organised cooperations" based on protocols with other health professionals. This law further provides for the creation of a "liaising pharmacist" function: At the request of a patient's doctor or with his consent, this community pharmacist, chosen by the patient, will be allowed to renew chronic treatments, adjust dosages if necessary, and make medication use reviews.
These new missions outline the need for a solid initial training, for which 5 years is a reasonable minimum to us.

In addition to this 5 years duration, it could be useful to set a minimum number of hours as it is the case for doctors in the directive, because 5 years can have a very different meaning in

EU countries. But this new criteria should be complementary to the "5years" one, it could not replace it.

To us, the combination of theoretical studies with practical experience (internship) is necessary. In France, a 6 months training period in a hospital is mandatory in 5th year. This training allows students to concretely know the hospital environment, which will encourage later a better coordination between hospital and ambulatory care.
Regarding this traineeship, we believe it would be useful that the Directive requires it should be a continuous block of six months.

Equally to this traineeship, a theoretical training is all the more necessary today: medicines become more and more complex (genomics, personalized medicines) and patients are encouraged to be treated at home when possible ("maintien à domicile" et "hospitalisation à domicile").

- Towards pharmacy specializations in clinical biology and hospital pharmacy

In Europe, clinical biology is practiced both by physicians and by pharmacists. In France for instance, 80% of clinical biologists are pharmacists working in private and public laboratories. The directive recognizes clinical biology as a specialization only for physicians. It would be more consistent for this specialization to be recognized for pharmacists as well. Such a change would facilitate the mobility of clinical biologists in Europe. Other European countries are interested in this request.

The idea to have a hospital pharmacy specialization recognized in the directive should also be considered. Hospital pharmacists' professional practice require more advanced and specialised knowledge in pharmaceuticals and pharmacotherapy, as well as more practice skills than are included in the average basic curriculum of pharmaceutical training. Such a specialization would guarantee the right level of quality for patient, as well as safety and efficiency in health care provision in European hospital structures.

12. The Directive is based on mutual trust between Member States. To what extent is such trust actually achieved? Are training programmes accredited in your country? Does accreditation of a training program in another Member State enhance trust or is it not relevant?

We fully trust the declaration of the competent authorities in the member states of origin. It is a guarantee for us, and we fully rely on the information provided by our partners. Therefore, to us, the objective of mutual trust is achieved.

13. To what extent are the existing Directive provisions (see recital 39 and Article 22(b) on continuous professional development (continuous training) adequate? What is your definition of CPD/continuous training? Is continuous training mandatory in your country and what are the exact conditions?

Continuing pharmaceutical education became compulsory in France in 2002, with a checking each 5 years. However, these provisions were not really enforced.

The concept of Continuous professional development was introduced in French law in July 2009 (law n° 2009-879 du 21 juillet 2009 portant réforme de l'hôpital et relative aux patients, à la santé et aux territoires, article 59). In that law, CPD is defined as follows :
«The aims of CPD are to assess professional practices, to improve knowledge, to improve quality and security of care and to take into account public health priorities and objectives of containing health costs. It is mandatory for all pharmacists" (art L 4236-1 of the French public health code).
Application decrees setting the practical modalities are currently under negotiation.

The French provisions on CPD are consistent with the provisions of the directive.
However, in the context of a growing health professionals' mobility in Europe (establishment and free provision of services), it could be useful to introduce a CPD obligation in the directive, Member States remaining free to set the modalities and the items to be trained according to national health priorities and health care systems.
We consider that in the future, when moving across Europe, a pharmacist should be asked to prove that he complied with his continuing professional education obligations, by providing a certificate from his competent authority or via the European health professional card (see question 16).

D. ADMINISTRATIVE COOPERATION (THIS SECTION APPLIES TO ESTABLISHMENT AS TO PROVISION OF SERVICES)

14. To which extent does administrative cooperation, as outlined in Articles 8, 50, and 56 of the Directive, simplify procedures for the migrant professionals? Can you give your own experience?

It's a gain of time for the migrants. In case of doubt, we can ask questions (or give answers) to the other member state through IMI or by mail (e or post), (though we never encountered a migrant pharmacist with a disciplinary problem).

It would be useful for competent authorities to share their experience and legislations more often and more easily, through a network of competent authorities for pharmacists. A comparative perspective would definitely help the process of recognition.

15. Is the competent authority in your country registered with IMI? Under which circumstances does your competent authority use IMI? If not registered, why not and what would be the conditions for changing this situation?

The French Council of Pharmacists is registered within IMI. To us, this system is useful and works well.
Our services use the system when necessary, although they do not need it very frequently since there are few migrants for the pharmacy profession, and even less problematic cases.

16. How could a professional card (see Recital 32 of the Directive) facilitate recognition of professional qualifications and provision of temporary services? Under which conditions could it be issued by a competent authority?

We think that the creation of a European card is a solution for the migration of professionals. This card would allow an easier control of the qualifications in the framework of free provisions of services and establishments within the European Union. This identity card would allow the qualified professionals to work in another EU country without having to provide many documents to the competent authority. Besides, thanks to this card, the host country would have the essential elements to contact the competent authority in the migrant's country of origin, thus limiting the administrative procedures for the migrant.

The card will bear a microchip that will work as a key to access the database of the competent authority of the country of origin and to know at any time the registration status of the health professional. The card will be based on existing cards at national level and keep all national functions.

Further application of the card could be envisaged : access to patients records, validation of continuing professional education credits ...

17. How do you share information about suspensions/restrictions with competent authorities in other Member States? Could more be done in this respect?

In French law, two principles are essential: the presumption of innocence and privacy. Equally, once a sentence has been served, a professional is considered fit to practice again. This creates a number of legal constraints limiting the possibility for competent authorities to exchange freely and pro-actively whatever information on health professional's fitness to practice.

In this context, the French Council of Pharmacists communicates on final decisions regarding disciplinary sanctions or suspensions for medical reasons which are currently in force.
We send this information on demand (from another competent authority) and not proactively.
We do not mention past sanctions.

E. OTHER OBSERVATIONS

18. How and when are the necessary language skills of migrants checked after recognition of the professional qualifications? Are you aware of any complaints (especially from patients/clients/employers) about insufficient language skills of migrants?

Consistently with the directive, our role is limited to the cases where we have a doubt in the registration process. In case of doubt, there is no specific procedure in place: we call the pharmacist or meet him.

For employed pharmacists, we believe that the employer is allowed to check the language skills but this control could also be made by the competent authority to avoid any conflict of interests.

Until now, we did not experience particular difficulties regarding the language skills.
In only one case we refused to register a pharmacist for language reasons. This pharmacist was registered a few months later after having improved his French.

In the future, we can expect more migrants than today. We believe it is essential to ensure that health professionals who are in contact with the patients have sufficient language skills.

19. Please feel free to add any comment you want on the directive 2005/36/EC

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Version du 8 juin 2010

ITALY

Evaluating the Professional Qualifications Directive
Experience reports from competent authorities

QUESTIONNAIRE FOR PHARMACISTS

A. RECOGNITION PROCEDURE IN CASE OF MIGRATION ON A PERMANENT BASIS

1. Please describe the government structure of the competent authority or authorities in charge of the recognition and of sanctions/restriction to practice The Ministry of Health is the only competent Authority in charge of the recognition of pharmacist qualifications and of sanctions/restriction to practice.

2. To what extent have the system of automatic recognition and the general system been a success? How do you see the costs and benefits for patients and for your organisation? Can you give concrete examples. Specify in particular whether automatic recognition based on diploma, Annex V and the current notification system represent an efficient way to facilitate automatic recognition.

Please submit comments for:

- automatic recognition based on diploma
- automatic recognition based on acquired rights

3. From the point of view of our organization, the automatic recognition does not create problems, if the qualifications are those that are set in Annex V and if the acquired rights are accompanied by the certificate of the competent Authority.From the point of view of patients, lack of knowledge of Italian language creates communication problems in a sensitive area such as health.Is the general system (as described in article 10) applied in your country each time the conditions for automatic recognition are not met? Are there major difficulties in the recognition procedure under the general system? Please include any comments you may have on the implementation of compensation measures. The general system is applied each time the conditions for automatic recognition are not met. Yes, there are many difficulties in the recognition procedure under the general system. In particular, there are some difficulties in comparing trainings and in organizing the compensatory measures (examination or adaptation).

4. What is your experience with the recognition procedure for EU citizens with professional qualifications obtained in a third country and already recognised in a first Member State (see Articles 2(2) and 3(3))? Our experience with the recognition procedure for EU citizens with professional qualifications obtained in a third country and already recognised in a first Member State is very bad. In fact, in many cases this system is used in order to circumvent the rules set in the directive and in the italian law. In particular, there are many cases of Italian citizens who have obtained the degree

in a third Country without a regular course of study and who have obtained a first EU recognition. Then, these citizens come to the Italian Ministry of Health for a second recognition (pharmacist degrees irregularly achived in Moldavia, with a first ricognition in Romania).

5. Do you accept applications from EU citizens for the recognition of foreign diplomas sent by email or requests made on line? Under which conditions can they send documents and declarations electronically? What are your experiences in this respect? No, the Italian Ministry of Health never accept applications from EU citizens for the recognition of foreign diplomas sent by email or requests made on line We can only give information by e-mail or by telephone.

6. What is the yearly number of applications for recognition from 2000 to 2009? Please submit specific data for applications for automatic recognition based on diplomas, automatic recognition based on acquired rights (as from 2005), and recognition based on the general system[1].

B. TEMPORARY MOBILITY (OF A SELF-EMPLOYED OR AN EMPLOYED WORKER)

7. Are EU citizens interested in using the provisions for exercising their professional activities on a temporary and occasional basis in your Member State? How many citizens used this new system since the directive has been transposed in your country (can you provide any statistics per month, per year) [2]? In Italy, there are very few pharmacists that exercise their professional activities on a temporary and occasional basis

8. How are the provisions of Directive 2005/36/EC concerning temporary mobility applied by the competent authorities in practice taking into account the relevant provisions of the Code of Conduct? For instance:

   - How is the "legal establishment" criteria foreseen by Article 5(1) (a) interpreted in practice? What conditions does a migrant need to fulfil in his home Member State in order to be able to provide services?

How are the "temporary and occasional basis" criteria foreseen by Article 5.2 interpreted in practice? Do Member States assess duration, frequency, regularity and continuity of an activity and if so according to which criteria? The Italian Ministry of Health apply the directive in a strict way. Why is a prior declaration system necessary? What do competent authorities do with the information received? Are other possibilities conceivable? A prior declaration system is necessary because, expecially in the case of pharmacist qualification, is necessary to protect public health. In fact, pharmacists must have all the necessary skills to carry out their activities. The information received is forwarded to the competent Order of Pharmacists that is responsible for the territory in which the migrant will be provisionally enrolled during his performance.

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1 Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

2 Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

9. Do you have concrete examples of abuse or misuse of this new possibility for pharmacists? Have you been confronted to problems with regards to patient safety on this issue? It doesn't result that in the last years pharmacist use the provisions for exercising their professional activities on a temporary and occasional basis.

C MINIMUM TRAINING REQUIREMENTS

10. To what extent are the common minimum training requirements set out in Title III Chapter III of Directive 2005/36/EC and the compulsory training subjects as defined in Annex V in line with scientific progress and professional needs? Furthermore, are the knowledge and skills required by the directive still relevant and up to date? Please specify. What about the conditions relating to the duration of training? In scientific professions, training must be constantly updated and it must be in line with new knowledge However, we think that the knowledge and skills required by the directive are still relevant and up to date.

11. To what extent are the common minimum requirements for training set out in Title III Chapter III of Directive 2005/36/EC in line with scientific progress and professional needs in the last ten years? Are the knowledge and skills outlined in Article 24.3 still relevant and up to date? Please specify. What about the conditions relating to the duration of training? As far as duration of training is concerned, the Italian Ministry of Health think that the pharmacist course has to last 5 years or more. In fact, this minimal duration is necessary to garantee a basic professionality, according to the basic requirements set in the directive (article 44)

12. The Directive is based on mutual trust between Member States. To what extent is such trust actually achieved? Are training programmes accredited in your country? Does accreditation of a training program in another Member State enhance trust or is it not relevant? Yes, the training programmes are accredited in Italy. The mutual trust between Member States is actually achieved

To what extent are the existing Directive provisions (see recital 39 and Article 22(b) on continuous professional development (continuous training) adequate? The existing Directive provisions (see recital 39 and Article 22(b) on continuous professional development (continuous training) are adequate. In Italy, continuous training is mandatory for health professions. What is your definition of CPD/continuous training? **Educazione Continua in Medicina (ECM)** is a national program of educational activities, since 2002. The ECM provides for maintaining a high level of knowledge about theory, practice and communication in medicine (art. 16 bis, decreto lgs. N. 502/1992) Is continuous training mandatory in your country and what are the exact conditions? Yes, continuous training is mandatory in Italy and it is organized by a specific national law.

D. ADMINISTRATIVE COOPERATION (THIS SECTION APPLIES TO ESTABLISHMENT AS TO PROVISION OF SERVICES)

13. To which extent does administrative cooperation, as outlined in Articles 8, 50, and 56 of the Directive, simplify procedures for the migrant professionals? Yes, administrative cooperation simplify procedures for the migrant professionals. Can you give your

own experience? The IMI system is very useful to solve quickly some problems about professionals who wish to migrate.

14. Is the competent authority in your country registered with IMI? Yes, it is. Under which circumstances does your competent authority use IMI? In case of doubt on the degree or on some certifications presented by professionists. If not registered, why not and what would be the conditions for changing this situation?

15. How could a professional card (see Recital 32 of the Directive) facilitate recognition of professional qualifications and provision of temporary services? Under which conditions could it be issued by a competent authority? We don't know this subject in a deep way.

16. How do you share information about suspensions/restrictions with competent authorities in other Member States? Could more be done in this respect? If there are suspensions/restrictions, the Italian Ministry of Health share this information with competent authorities in other Member States

E. OTHER OBSERVATIONS

17. How and when are the necessary language skills of migrants checked after recognition of the professional qualifications? In Italy, the necessary language skills of migrants are checked by the competent Order of Pharmacists, after the recognition of the professional qualifications opered by Ministry of Health. Are you aware of any complaints (especially from patients/clients/employers) about insufficient language skills of migrants? Yes, the Italian Ministry of Health is aware of complaints from patients about insufficient language and skills of migrants.

18. Please fill free to add any comment you want on the directive 2005/36/EC

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CYPRUS

Evaluating the Professional Qualifications Directive
Experience reports from competent authorities

PHARMACY

POSSIBLE QUESTIONNAIRE FOR EACH SECTORAL PROFESSION

A. RECOGNITION PROCEDURE IN CASE OF MIGRATION ON A PERMANENT BASIS

1. Do you accept applications from EU citizens for the recognition of foreign diplomas sent by email or requests made on line? Under which conditions can they send documents and declarations electronically? What are your experiences in this respect?

   As a matter of general internal procedure, applications form EU citizens are not accepted by email. It is required that hard copies of original documents are submitted.

2. What is the yearly number of applications for recognition from 2000 to 2009? Please submit specific data for applications for automatic recognition based on diplomas, automatic recognition based on acquired rights (as from 2005), and recognition based on the general system[1].

   Since 2000, the Pharmacy Board registered 241 pharmacists. It should be indicated that since there is no pharmacy school in Cyprus, all pharmacists are holders of degrees and professional qualifications from other countries, mainly member states. Holders of degrees and professional qualifications from third countries are screened in order to establish that the curricula of the universities attended, comply with the requirements of the provisions of Directive 2005/36/EC relating to the minimum qualifications for pharmacists.

   Cyprus introduced the acquis on the profession of pharmacy (Directives 85/432/EC and 85/434/EC in 2003 as part of the pre-accession negations and acceded to the EU on 2004.

   As a result of the above, all pharmacy school graduates are subject to either recognition of professional qualifications or for recognition based on acquired rights.

   Holders of pharmacy degrees that do not benefit from the automatic recognition (either from member states or third countries) must undertake the Forensic Pharmacy Examination and succeed in order to be eligible for registration.

   All pharmacists eligible for registration, who held degrees and qualifications that did not appear in Appendix V of Directive 2005/36/EC at the time of the adoption of the acquis, were granted the right to register. This provision was applicable up to 2007.

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[1] Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

3. To what extent have the system of automatic recognition and the general system been a success? How do you see the costs and benefits? Specify in particular whether automatic recognition based on diploma, Annex V and the current notification system represent an efficient way to facilitate automatic recognition. Please submit comments for:

   - automatic recognition based on diploma

   The automatic recognition based on the diploma offers a good opportunity for professionals to enhance their employment options in other member states other than their own.

   - automatic recognition based on acquired rights

   Acquired rights are of great importance for professionals that at the time of the introduction of a new requirement may not possess them. This was of particular importance for the registered and to be registered pharmacists in Cyprus, at the time of the introduction of the acquis.

   - recognition based on the general system.

   For the profession of pharmacy there are specific requirements since it has been a sectoral profession.

4. Is the general system applied in your country each time the conditions for automatic recognition are not met? Are there major difficulties in the recognition procedure under the general system? Please include any comments you may have on the implementation of compensation measures.

   Not applicable.

5. What is your experience with the recognition procedure for EU citizens with professional qualifications obtained in a third country and already recognised in a first Member State (see Articles 2(2) and 3(3))?

   In such case, the Hocsman ECJ decision applies.

6. Please describe the government structure of the competent authority or authorities in charge of the recognition.

   The Competent Authority for the recognition of the qualifications of pharmacists in Cyprus is the Pharmacy Board. The Pharmacy Board established under the Pharmacy and Poisons Law (Cap. 254) is the legal instrument for the regulation of the profession of pharmacy. Pursuant to Section 4 of the Law, the Pharmacy Board consists of three registered pharmacists employed in the public sector appointed by the Council of Ministers and four registered pharmacists nominated by the council of the pharmaceutical body and appointed by the Council of Ministers, as well. The Pharmacy Board advises the Minister of Health on matters relating to the profession of pharmacy registers pharmacists and maintains a record of registered pharmacists.

B. TEMPORARY MOBILITY (OF A SELF-EMPLOYED OR AN EMPLOYED WORKER)

7. Are EU citizens interested in using the provisions for exercising their professional activities on a temporary and occasional basis in your Member State? How many citizens used this new system in 2008 and 2009 (per month, per year) [2]?

   Even though the legal provisions for the temporary and occasional basis of exercising professional activities are in place, to date there has been no interest from pharmacists from other member states to provide them in Cyprus.

8. How are the provisions of Directive 2005/36/EC concerning temporary mobility applied by the competent authorities in practice taking into account the relevant provisions of the Code of Conduct? For instance:

   - How is the "legal establishment" criteria foreseen by Article 5(1) (a) interpreted in practice? What conditions does a migrant need to fulfil in his home Member State in order to be able to provide services?

     The migrant must be a registered pharmacist on good professional standing at the country of origin in order to be eligible to either provide services or establish permanently in Cyprus.

   - How are the "temporary and occasional basis" criteria foreseen by Article 5.2 interpreted in practice? Do Member States assess duration, frequency, regularity and continuity of an activity and if so according to which criteria?

     Even though the legislation provides for the Pharmacy Board to determine the actual nature of "temporary and occasional basis", such cases did not present, so that an opportunity would arise to further define the issue.

9. Why is a prior declaration system necessary? What do competent authorities do with the information received? Are other possibilities conceivable?

   A prior declaration is necessary to determine the professional qualifications, nationality and indemnities of the applicant as well as allocate responsibility in the case of false statements and professional misconduct. Alternative schemes cannot be foreseen at this time.

C MINIMUM TRAINING REQUIREMENTS

10. To what extent are the common minimum training requirements set out in Title III Chapter III of Directive 2005/36/EC and the compulsory training subjects as defined in Annex V in line with scientific progress and professional needs? Furthermore, are the knowledge and skills required by the directive still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

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[2] Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

Pharmacy is a dynamic profession that needs to be constantly updated. As new medicinal products enter the market, attitudes toward illness shift along with the needs of the pharmaceutical industry, pharmacists are called upon to meet the new challenges. It may be argued that the profession of pharmacy at least at the community and hospital level is moving more into the clinical domain and away from the traditional "mortar and pestle" image. It is suggested that curricula acknowledge this and place more emphasis on courses that are more oriented towards clinical pharmacy such as therapeutics, pharmacokinetics as well as communication skills at the undergraduate level.

11. To what extent are the common minimum requirements for training set out in Title III Chapter III of Directive 2005/36/EC in line with scientific progress and professional needs in the last ten years? Are the knowledge and skills outlined in Article 24.3 still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

    The requirements as laid down in article 24.3 remain current at this time. Title III may in time encourage the harmonization of curricula throughout the EU o produce a high standard of professionals able to cope with the challenges of their profession.

12. The Directive is based on mutual trust between Member States. To what extent is such trust actually achieved? Are training programmes accredited in your country? Does accreditation of a training program in another Member State enhance trust or is it not relevant?

    Since Cyprus has no pharmacy school, all pharmacy graduates come from foreign universities. It is trusted that the authorities adequately accredit pharmacy schools in member states.

13. To what extent are the existing Directive provisions (see recital 39 and Article 22(b) on continuous professional development (continuous training) adequate? Is continuous training mandatory in your country and what are the exact conditions?

    There are currently no statutory requirements for pharmacists to acquire continuous education during their professional career. Should such requirements be put in place, the appropriate administrative structures must be established in order to facilitate their implementation.

D. ADMINISTRATIVE COOPERATION

14. To which extent does administrative cooperation, as outlined in Articles 8, 50, and 56 of the Directive, simplify procedures for the migrant professionals?

    It is estimated that it is early to fully evaluate the system of administrative cooperation. In theory, it is intended to simplify the procedures, not only for the migrant workers but also for the competent authorities.

15. Is the competent authority in your country registered with IMI? Under which circumstances does your competent authority use IMI? If not registered, why not and what would be the conditions for changing this situation?

The Pharmacy Board is registered with the IMI. The IMI has been so far and on a few occasions utilised in order to determine the validity of the credentials of a pharmacist applying for registration as well as good professional status.

16. How could a professional card (see Recital 32 of the Directive) facilitate recognition of professional qualifications and provision of temporary services? Under which conditions could it be issued by professional associations?

A professional card is an acceptable form of identification of a professional provided it contains the information in such a way in order to determine professional good standing.

17. How do you share information about suspensions/restrictions with competent authorities in other Member States? Could more be done in this respect?

Such information is divulged only if a member state places an official query to the Pharmacy Board.

E. OTHER OBSERVATIONS

18. How and when are the necessary language skills of migrants checked after recognition of the professional qualifications? Are you aware of any complaints (especially from patients/clients/employers) about insufficient language skills of migrants?

The Pharmacy Board maintains the right to determine the language skills of an applicant for registration as a pharmacist. Good communication skills are of paramount importance for the practice of pharmacy, especially for providing patient advice and counselling at the community setting. No complaints have come to the attention of the Pharmacy Board up to now.

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LITHUANIA

Evaluating the Professional Qualifications Directive
Experience reports from competent authorities
PHARMACISTS
LITHUANIA

QUESTIONNAIRE FOR PHARMACISTS

A. RECOGNITION PROCEDURE IN CASE OF MIGRATION ON A PERMANENT BASIS

1. Please describe the government structure of the competent authority or authorities in charge of the recognition and of sanctions/restriction to practice.

The Ministry of Health (MoH) is the competent authority in the Republic of Lithuania in charge of the recognition of pharmacist.

Applicants shall submit documents to the MoH → Department of Pharmacy of the MoH examines submitted documents and takes decision to recognize or not to recognize formal qualification→ order of MoH.

The State Medicines Control Agency (SMCA) is the competent authority in the Republic of Lithuania of sanctions/restriction to practice as a pharmacist.

2. To what extent have the system of automatic recognition and the general system been a success? How do you see the costs and benefits for patients and for your organisation? Can you give concrete examples. Specify in particular whether automatic recognition based on diploma, Annex V and the current notification system represent an efficient way to facilitate automatic recognition.

We have no experience in automatic recognition based on diploma and (or) on acquired rights, but we think that the automatic recognition is the fastest way for employment of qualified persons. In Lithuania there are no state fees (taxes) for evaluation of submitted documents (i.e. recognition is free of charge). The knowledge of language is one of the biggest problem and barrier to the mobility on internal market.

Please submit comments for:

- automatic recognition based on diploma
- automatic recognition based on acquired rights

3. Is the general system (as described in article 10) applied in your country each time the conditions for automatic recognition are not met? Are there major difficulties in the recognition procedure under the general system? Please include any comments you may have on the implementation of compensation measures.

We have no experience in the recognition of EU citizens, but according to the law the general system is applied each time when the conditions for automatic recognition are not met.

In comparison with the automatic recognition the recognition procedure under the general system is more complicated and longer because of compensation measures which are applied.

4. What is your experience with the recognition procedure for EU citizens with professional qualifications obtained in a third country and already recognised in a first Member State (see Articles 2(2) and 3(3))?

We have no experience.

5. Do you accept applications from EU citizens for the recognition of foreign diplomas sent by email or requests made on line? Under which conditions can they send documents and declarations electronically? What are your experiences in this respect?

We do not accept documents or declarations electronically. . Applicant shall submit an application and other required documents himself or sent by post.

6. What is the yearly number of applications for recognition from 2000 to 2009? Please submit specific data for applications for automatic recognition based on diplomas, automatic recognition based on acquired rights (as from 2005), and recognition based on the general system[1].

No applications were received until now.

B. TEMPORARY MOBILITY (OF A SELF-EMPLOYED OR AN EMPLOYED WORKER)

7. Are EU citizens interested in using the provisions for exercising their professional activities on a temporary and occasional basis in your Member State? How many citizens used this new system since the directive has been transposed in your country (can you provide any statistics per month, per year)[2]?

We do not have received any questions or declarations of applicants concerning the exercising their professional activities on a temporary and occasional basis.

8. How are the provisions of Directive 2005/36/EC concerning temporary mobility applied by the competent authorities in practice taking into account the relevant provisions of the Code of Conduct? For instance:

We do not have previous experience.

- How is the "legal establishment" criteria foreseen by Article 5(1) (a) interpreted in practice? What conditions does a migrant need to fulfil in his home Member State in order to be able to provide services?

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1 Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

2 Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

"Legal establishment" is interpreted as an authorisation under which the applicant is legally entitled to practice as a pharmacist without any restrictions in the Member State, as well as the absence of any disciplinary or criminal sanctions of a professional nature.

- How are the "temporary and occasional basis" criteria foreseen by Article 5.2 interpreted in practice? Do Member States assess duration, frequency, regularity and continuity of an activity and if so according to which criteria?

In order to prove "legal establishment" an applicant shall submit following documents:

- **copy of passport,**
- **evidence of formal qualifications,**
- **certificate from competent authority about legal establishment in Member State,**
- **Certificate of good standing.**

Each application is examined individually.

9. Why is a prior declaration system necessary? What do competent authorities do with the information received? Are other possibilities conceivable?

The declaration system is important for patient safety reasons. The national supervisory authority is aware of persons who have the right to practice in Lithuania. There are no other possibilities.

10. Do you have concrete examples of abuse or misuse of this new possibility for pharmacists? Have you been confronted to problems with regards to patient safety on this issue?

We do not have previous experience.

C MINIMUM TRAINING REQUIREMENTS

11. To what extent are the common minimum training requirements set out in Title III Chapter III of Directive 2005/36/EC and the compulsory training subjects as defined in Annex V in line with scientific progress and professional needs? Furthermore, are the knowledge and skills required by the directive still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

The training requirements and the duration of training fully comply with the requirements set out in the Directive. Furthermore programmes of the studies are continually evaluated in order to ensure the compliance of the study programme with scientific progress and professional needs.

12. To what extent are the common minimum requirements for training set out in Title III Chapter III of Directive 2005/36/EC in line with scientific progress and professional needs in the last ten years? Are the knowledge and skills outlined in Article 24.3 still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

Diplomas issued from 2006 fully complies the minimum training requirements set out in the Directive. Diplomas issued before above-mentioned data did not satisfy the minimum training requirements: animal biology was not included *per se* in study programme of pharmacists.

In the last ten years the duration of training comply the training duration requirements referred in paragraph 2 of Article 44, Directive 2005/36/EC.

13. The Directive is based on mutual trust between Member States. To what extent is such trust actually achieved? Are training programmes accredited in your country? Does accreditation of a training program in another Member State enhance trust or is it not relevant?

MoH always requires certificate of obtained qualification, issued by competent authority. Trust is obvious when the qualification is based on the Annex V.

Training programme (Pharmacy) is accredited by external bodies.

14. To what extent are the existing Directive provisions (see recital 39 and Article 22(b) on continuous professional development (continuous training) adequate? What is your definition of CPD/continuous training? Is continuous training mandatory in your country and what are the exact conditions?

According to the law a pharmacist can perform the functions of the pharmacist in a public pharmacy, preparation public pharmacy, hospital pharmacy, preparation hospital pharmacy, university pharmacy and charity pharmacy only if he/she has the license to practice as a pharmacist. A license to practice as a pharmacist is issued for unlimited time. Specialists are obliged to improve his/her professional qualification in accordance with the procedure defined by the Minister of Health (At least 120 hours every 5 years). A pharmacist is obliged to notify State Medicines Control Agency about improvement of his/her professional qualification pursuant to the procedure defined by regulations for licensing pharmacist's practice.

D. ADMINISTRATIVE COOPERATION (THIS SECTION APPLIES TO ESTABLISHMENT AS TO PROVISION OF SERVICES)

15. To which extent does administrative cooperation, as outlined in Articles 8, 50, and 56 of the Directive, simplify procedures for the migrant professionals? Can you give your own experience?

Administrative cooperation is provided by IMI system or directly by email.

16. Is the competent authority in your country registered with IMI? Under which circumstances does your competent authority use IMI? If not registered, why not and what would be the conditions for changing this situation?

MoH is registered with IMI. We use IMI when we need clarifications from a competent authority concerning the application.

17. How could a professional card (see Recital 32 of the Directive) facilitate recognition of professional qualifications and provision of temporary services? Under which conditions could it be issued by a competent authority?

A professional card could facilitate recognition of professional qualification in case if the competent authorities were sure that the information on the card is reliable and up to date.

Furthermore, the issue of such cards has to be ensured in the context of strict respect of data protection.

The professional card could be issued by the national competent authorities.

18. How do you share information about suspensions/restrictions with competent authorities in other Member States? Could more be done in this respect?

MoH does not have an experience in such cases. The major document which provides information about suspensions/restrictions is Certificate of Good standing issued by Member States competent authorities.

E. OTHER OBSERVATIONS

19. How and when are the necessary language skills of migrants checked after recognition of the professional qualifications? Are you aware of any complaints (especially from patients/clients/employers) about insufficient language skills of migrants?

MoH have no experience in the recognition of EU citizens so we are not aware of any complaints about the insufficient language skills of migrants. According to the law professionals, whose professional qualifications are recognised, shall have adequate language skills on purpose to be engaged in pharmacy activities.

20. Please fill free to add any comment you want on the directive 2005/36/EC.

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Version du 8 juin 2010

LUXEMBOURG

Evaluating the Professional Qualifications Directive
Experience reports from competent authorities

QUESTIONNAIRE FOR PHARMACISTS

A. RECOGNITION PROCEDURE IN CASE OF MIGRATION ON A PERMANENT BASIS

Please describe the government structure of the competent authority or authorities in charge of the recognition and of sanctions/restriction to practice.
The Ministry of Health in Luxembourg is the competent authority to recognize pharmacist's diplomas.

1.

2. To what extent have the system of automatic recognition and the general system been a success? How do you see the costs and benefits for patients and for your organisation? Can you give concrete examples. Specify in particular whether automatic recognition based on diploma, Annex V and the current notification system represent an efficient way to facilitate automatic recognition.

Please submit comments for:

- automatic recognition of diplomas:

We had no major problems applying the automatic recognition of diplomas It allows persons with diplomas mentioned in annexe V of the directive to be recognized in a short time Problems appear only when member states changed diplomas without notifying this change to the Commission at all or in due time.

- automatic recognition based on acquired rights

Until now we had no major problems applying the recognition based on acquired rights.

- Recognition based on the general system

The Luxembourg authorities are unable to make recognitions based on the general system as we have no pharmaceutical education and thus no criteria to evaluate in the frame of the general system. Thus we are unable to offer compensation measures.

3. Is the general system (as described in article 10) applied in your country each time the conditions for automatic recognition are not met? Are there major difficulties in the

recognition procedure under the general system? Please include any comments you may have on the implementation of compensation measures.

Luxembourg does not apply the general system for the reasons mentioned above.

4. What is your experience with the recognition procedure for EU citizens with professional qualifications obtained in a third country and already recognised in a first Member State (see Articles 2(2) and 3(3))?

   Luxembourg accepts diplomas issued in a third country if the diploma has been recognized in an other member state and if the holder of the diploma has a professional experience of three years in the country that has recognized the diploma.

5. Do you accept applications from EU citizens for the recognition of foreign diplomas sent by email or requests made on line? Under which conditions can they send documents and declarations electronically? What are your experiences in this respect?

   We accept applications sent on line or by email. However some documents have to be send as originals such as the signed request, the police record or the certificate of good standing issued by the Medical Council. Until now we had no negative experiences.

6. What is the yearly number of applications for recognition from 2000 to 2009? Please submit specific data for applications for automatic recognition based on diplomas, automatic recognition based on acquired rights (as from 2005), and recognition based on the general system[1].

   Luxembourg can only give data on the number of positive recognitions. All the recognitions are based on diplomas or acquired rights as we are unable to make recognitions based on the general system. (cf question 3). The average duration of the recognition process is about one to two months.

2000 15
2001 31
2002 13
2003 26
2004 21
2005 22
2006 35
2007 23
2008 18
2009 28

[1] Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

B. TEMPORARY MOBILITY (OF A SELF-EMPLOYED OR AN EMPLOYED WORKER)

7. Are EU citizens interested in using the provisions for exercising their professional activities on a temporary and occasional basis in your Member State? How many citizens used this new system since the directive has been transposed in your country (can you provide any statistics per month, per year) [2]?

Until now no EU citizen was interested in using the provisions for exercising their professional activities on a temporary and occasional basis.

8. How are the provisions of Directive 2005/36/EC concerning temporary mobility applied by the competent authorities in practice taking into account the relevant provisions of the Code of Conduct? For instance:

   - How is the "legal establishment" criteria foreseen by Article 5(1) (a) interpreted in practice? What conditions does a migrant need to fulfil in his home Member State in order to be able to provide services?

The criteria is analysed individually for every application. The migrant must hold an authorization to practice in his country

   - How are the "temporary and occasional basis" criteria foreseen by Article 5.2 interpreted in practice? Do Member States assess duration, frequency, regularity and continuity of an activity and if so according to which criteria?

These criteria are reviewed on a case-by-case basis, by taking into account the individual characteristics of the service provision

9. Why is a prior declaration system necessary? What do competent authorities do with the information received? Are other possibilities conceivable?

The prior declaration system is necessary for the patient's safety. A copy of the declaration is send to the social security administration.

10. Do you have concrete examples of abuse or misuse of this new possibility for pharmacists? Have you been confronted to problems with regards to patient safety on this issue?

Luxembourg has no examples of abuse of this new possibility.

C MINIMUM TRAINING REQUIREMENTS

11. To what extent are the common minimum training requirements set out in Title III Chapter III of Directive 2005/36/EC and the compulsory training subjects as defined in Annex V in line with scientific progress and professional needs? Furthermore, are the knowledge and skills required by the directive still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

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[2] Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

As Luxembourg has no pharmaceutical education we are unable to judge the level of knowledge and duration of training.

12. To what extent are the common minimum requirements for training set out in Title III Chapter III of Directive 2005/36/EC in line with scientific progress and professional needs in the last ten years? Are the knowledge and skills outlined in Article 24.3 still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

    As Luxembourg has no pharmaceutical education we are unable to judge the level of knowledge and duration of training.

13. The Directive is based on mutual trust between Member States. To what extent is such trust actually achieved? Are training programmes accredited in your country? Does accreditation of a training program in another Member State enhance trust or is it not relevant?

    As we have no pharmaceutical education we rely on the expertise of other member states. For instance as we do not apply the general system, we recommend the holder of a diploma not mentioned in Annexe V to ask a recognition of his diploma in another member state. This recognition will then be used in his application.

14. To what extent are the existing Directive provisions (see recital 39 and Article 22(b) on continuous professional development (continuous training) adequate? What is your definition of CPD/continuous training? Is continuous training mandatory in your country and what are the exact conditions?

    Continuous training is mandatory in Luxembourg but until now it is not evaluated and there is no supervision of this training.

D. ADMINISTRATIVE COOPERATION (THIS SECTION APPLIES TO ESTABLISHMENT AS TO PROVISION OF SERVICES)

15. To which extent does administrative cooperation, as outlined in Articles 8, 50, and 56 of the Directive, simplify procedures for the migrant professionals? Can you give your own experience?

    The administrative cooperation between member states is of great importance for the migrant professional and the competent authorities. It facilitates and fastens the recognition procedure

16. Is the competent authority in your country registered with IMI? Under which circumstances does your competent authority use IMI? If not registered, why not and what would be the conditions for changing this situation?

Our competent authority is registered to IMI. It is used if there are any doubts about a diploma or another certificate.

17. How could a professional card (see Recital 32 of the Directive) facilitate recognition of professional qualifications and provision of temporary services? Under which conditions could it be issued by a competent authority?

    A professional card on EU level could improve and facilitate the recognition of professional qualifications. However this card should be issued by the competent authority.

18. How do you share information about suspensions/restrictions with competent authorities in other Member States? Could more be done in this respect?

    Luxembourg gives information in case of disciplinary actions to the competent authorities of the neighbouring countries.

    In our opinion improvements in this field have to be done. For instance it would be useful to identify the competent authority in each member state in this field.

E. OTHER OBSERVATIONS

19. How and when are the necessary language skills of migrants checked after recognition of the professional qualifications? Are you aware of any complaints (especially from patients/clients/employers) about insufficient language skills of migrants?

    The language skills of migrants are not checked on a regular base but only if there is a doubt. We had some complaints from patients about insufficient language skills.

20. Please fill free to add any comment you want on the directive 2005/36/EC

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HUNGARY

National implementation report for EU Directive 2005/36/EC

Pharmacists

Country: **Hungary**

Organisation: Office of Health Authorisation and Administrative Procedures

The Office is responsible for the recognition of the foreign healthcare diplomas and qualifications and the registration of all the healthcare professionals.

The Office's website: www.eekh.hu

Contact details: Dr. András Zsigmond
Head of department
zsigmond.andras@eekh.hu / recognition@eekh.hu
0036-1-235-79-65

Evaluating the Professional Qualifications Directive
Experience reports from competent authorities

QUESTIONNAIRE FOR PHARMACISTS

A. RECOGNITION PROCEDURE IN CASE OF MIGRATION ON A PERMANENT BASIS

1. Please describe the government structure of the competent authority or authorities in charge of the recognition and of sanctions/restriction to practice.

A) In Hungary the **competent authority in charge of the recognition** is the Office of Health Authorisation and Administrative Procedures. It was founded on 1st April 2003 by the Government in accordance with Hungary's preparation to join the European Union. The Office is an independent centralised national authority, with national competences regarding different administrative matters. Our Office works under the supervision of the Minister of Health.

The Department of Migration and Monitoring works - amongst others - as the Hungarian competent authority with regards to 2005/36/EC Directive on the recognition of professional qualifications for medical professional qualifications:

- this department is responsible for the recognition of most of the foreign medical professional qualifications (EEA countries and non EEA countries)
- it issues different kinds of certificates that are necessary for the recognition of the Hungarian medical professional qualifications in other countries
- it shares information concerning the conditions of the recognition and registration with other competent authorities.

The Office is also responsible for the registration: we have a so-called basic register (diploma register) and an operational registry.

A healthcare professional can only practice his/her medical activities in Hungary without supervision, if he/she holds a valid operational registration, otherwise he/she can only practise the activities under supervision.

Our **National Contact Point** and **National Coordinator** is the Educational Authority Hungarian Equivalence and Information Centre.

B) In charge of sanctions or restrictions there are two competent authorities in Hungary. If the pharmacist is a member of the Hungarian Pharmaceutical Chamber ('Magyar Gyógyszerészi Kamara') in case of breaching some ethical rules that is the competent authority on first level. In cases on non-Chamber Members the Office of the Chief Medical Officer of State ('Országos Tisztifőorvosi Hivatal') has the right to decide about sanctions or restrictions.

The Office of Health Authorisation and Administrative Procedures registers the sanctions/restrictions from all the abovementioned authorities.

2. **To what extent have the system of automatic recognition and the general system been a success? How do you see the costs and benefits for patients and for your organisation? Can you give concrete examples. Specify in particular whether automatic recognition based on diploma, Annex V and the current notification system represent an efficient way to facilitate automatic recognition.**

Please submit comments for:

- **automatic recognition based on diploma**

This possibility simplifies the procedures also for the applicants, but for the competent authorities as well. It is a very simple procedure, if the denomination, reference date and other conditions are met.

- **automatic recognition based on acquired rights**

Though the Directive's general aspect is built on the mutual trust between the competent authorities, we find the most problems concerning the certificate of acquired rights, mostly in the cases where the professional's residence MS (or his/her pursue of the medical activity) has changed several times during the last five years period.

In the Directive, it is not regulated that during the three consecutive years in the last five years in how many hours the applicant has to work in order to be able to apply for the certificate of acquired rights. (it is an extreme example, but it is possible to benefit the acquired rights even if the professional pursues his/her activities just 1 hour monthly).

We also had some problems with the interpretation of the criteria "effective and lawful practice" laid down in Article 23.1.

According to Articles 110-113. of Act CLIV of 1997 on Health (our national legislation), we have two registers of the healthcare professionals: basic register and operational registry.

Basic register functions as a register of the qualifications, which means that all the healthcare qualifications obtained/recognised (or formerly nostrificated) in Hungary are registered automatically in the basic register.

It is a requirement in case of all the regulated professions that the professional (and his/her qualification) is registered in the basic register (which means he/she holds a valid qualification).It is in accordance with Article 1 of the Directive.

The healthcare activity concerned can be pursued in Hungary with or without supervision.

The registration into the operational registry is upon the application of the professional. The registration period is valid for 5 years and can be renewed if the professional satisfies the requirements (collect points on practical and theoretical CPD activities etc.)

The valid operational registration is a condition on the pursuit of the healthcare activity without supervision. But according to the abovementioned legislation it is also possible

to practise the healthcare activity with supervision if the professional does not hold a valid operational legislation.

The Commission has informed us, that according to their interpretation if in Hungary only professionals who are registered in the so called "operational registry" can exercise independently all the activities of the profession in question, only their professional experience can be considered as an "effective and lawful practice" of a profession in the sense of Article 23(1) of the Directive, and only they can receive a certificate on the effective and lawful exercise of the profession.

It can also cause problems that the certificate issued by the MS of the origin doesn't include in which activities the applicant have been engaged effectively and lawfully according to Article 44 of the 2005/36/EC Directive.

3. **Is the general system (as described in article 10) applied in your country each time the conditions for automatic recognition are not met? Are there major difficulties in the recognition procedure under the general system? Please include any comments you may have on the implementation of compensation measures.**

In all cases where not all the conditions for the automatic recognition are met we apply the general system for the procedures. When it is necessary we ask our national experts to examine the training requirements/professional experiences of the applicant, and we decide in a preliminary decision (in aware of the expert's opinion) about the conditions of the recognition. We always put a deadline to complete the conditions and inform the applicant about all the necessary information in the decision itself.

We haven't got any negative feedback concerning nor the aptitude test nor the adaptation period, in some cases the applicant's had problems with their completion because they didn't have the sufficient knowledge of language.

4. **What is your experience with the recognition procedure for EU citizens with professional qualifications obtained in a third country and already recognised in a first Member State (see Articles 2(2) and 3(3))?**

We do not have too many experiences with the application of Article 2 (2) and 3 (3).

We've some experiences in case of applicants with EU citizenship who obtained their qualifications in non member states, but recognised/nostificated them in Hungary and wish to move to another MS. e usually issue them certificates which attest the lawful and effective pursuit of the activity concerned.

5. **Do you accept applications from EU citizens for the recognition of foreign diplomas sent by email or requests made on line? Under which conditions can they send documents and declarations electronically? What are your experiences in this respect?**

The application form can be submitted electronically as well.
The certified copies and official translations of the documents should be submitted by post, or personally. According to our experiences, our clients like the possibility of the personal consult at least when they do their application.

6. **What is the yearly number of applications for recognition from 2000 to 2009? Please submit specific data for applications for automatic recognition based on diplomas, automatic recognition based on acquired rights (as from 2005), and recognition based on the general system[1].**

Applications					
2007		2008		2009	
EEA	3rd countries	EEA	3rd countries	EEA	3rd countries
6	1	12	0	5	0

Positive decisions					
2007		2008		2009	
EEA	3rd countries	EEA	3rd countries	EEA	3rd countries
3	0	7	1	8	0

Negative decisions					
2007		2008		2009	
EEA	3rd countries	EEA	3rd countries	EEA	3rd countries
0	0	0	0	0	0

B. TEMPORARY MOBILITY (OF A SELF-EMPLOYED OR AN EMPLOYED WORKER)

7. **Are EU citizens interested in using the provisions for exercising their professional activities on a temporary and occasional basis in your Member State? How many citizens used this new system since the directive has been transposed in your country (can you provide any statistics per month, per year)[2]?**

We haven't had any queries or applications from pharmacists concerning the temporary provision of services yet.

8. **How are the provisions of Directive 2005/36/EC concerning temporary mobility applied by the competent authorities in practice taking into account the relevant provisions of the Code of Conduct? For instance:**

   - **How is the "legal establishment" criteria foreseen by Article 5(1) (a) interpreted in practice? What conditions does a migrant need to fulfil in his home Member State in order to be able to provide services?**

   - **How are the "temporary and occasional basis" criteria foreseen by Article 5.2 interpreted in practice? Do Member States assess duration, frequency, regularity and continuity of an activity and if so according to which criteria?**

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1 Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

2 Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

We do not have experiences concerning temporary mobility.

9. Why is a prior declaration system necessary? What do competent authorities do with the information received? Are other possibilities conceivable?

As the number of the notifications concerning temporary mobility is very low, we think that the service providers do not always inform us about their service. The reason might be that they do not know about this obligation, or they find that the procedure is too complicated.

In case of healthcare I think the prior declaration/notification would be essential, because it could only guarantee the supervision of the service, and all the information could be provided concerning it later on, in case of any problems with it.

The system could work more efficiently, if its enforcement was more efficient, like developing some kind of common sanctions in case of not complying with the requirement of prior declaration.

10. Do you have concrete examples of abuse or misuse of this new possibility for pharmacists? Have you been confronted to problems with regards to patient safety on this issue?

We do not have any concrete example concerning pharmacists.

C MINIMUM TRAINING REQUIREMENTS

11. To what extent are the common minimum training requirements set out in Title III Chapter III of Directive 2005/36/EC and the compulsory training subjects as defined in Annex V in line with scientific progress and professional needs? Furthermore, are the knowledge and skills required by the directive still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

This regulation is out of date, as it was taken over from the Directives 85/432/EEC and 85/433/EEC, revision would be much welcomed.

12. To what extent are the common minimum requirements for training set out in Title III Chapter III of Directive 2005/36/EC in line with scientific progress and professional needs in the last ten years? Are the knowledge and skills outlined in Article 24.3 still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

This regulation is out of date, as it was taken over from the Directives 85/432/EEC and 85/433/EEC, revision would be much welcomed.

13. The Directive is based on mutual trust between Member States. To what extent is such trust actually achieved? Are training programmes accredited in your country? Does accreditation of a training program in another Member State enhance trust or is it not relevant?

When we ask or provide information concerning the recognition of professional qualifications we have experienced that the mutual trust exists. We found that the competent authorities can work effectively together mostly on a case-by-case basis.

We just had some problems concerning the certificates of acquired rights as mentioned previously.

We also have some problems with countries where the competent authorities are organized on territorial basis because it is sometimes very hard to find out who to ask to get the relevant information.

We exchange information concerning state accredited trainings and qualifications.

14. To what extent are the existing Directive provisions (see recital 39 and Article 22(b) on continuous professional development (continuous training) adequate? What is your definition of CPD/continuous training? Is continuous training mandatory in your country and what are the exact conditions?

Requirement of the continuous professional development exists in Hungary, all the healthcare professionals who want to practise their activities without supervision, are to have a valid operational registration. The registration is valid for five years, and one of the conditions of the renewal is to collect enough credits on CPD activities.

It would be useful, if the CPD elements could be mutually recognized or transferred in each Member States national system because the professionals could benefit a lot from this possibility. We would welcome the introduction of a common framework of the CPD in the Directive.

D. ADMINISTRATIVE COOPERATION (THIS SECTION APPLIES TO ESTABLISHMENT AS TO PROVISION OF SERVICES)

15. To which extent does administrative cooperation, as outlined in Articles 8, 50, and 56 of the Directive, simplify procedures for the migrant professionals? Can you give your own experience?

The establishing of an Informal Network for pharmacist would be welcomed. There are good experiences in the other professional sectors such as nurses or doctors.

This cooperation could simplify the situation of the applicants.

16. Is the competent authority in your country registered with IMI? Under which circumstances does your competent authority use IMI? If not registered, why not and what would be the conditions for changing this situation?

The Office is registered in the IMI system we send and receive answers and questions very often.

We find it a very useful tool to communicate amongst the competent authorities, and we would warmly welcome to make the use of the IMI compulsory for all the MS's competent authorities.

We found that using the pre-formulated questions and also the free text common boxes it is very easy to understand the individual applicant's situations, and we also have very good

feedbacks from the applicants, because we are dealing these matters on a fast and effective ways, and they are not obliged to gather all the information personally.

IMI could be used more efficiently, if strict deadlines were built into the mechanism, because in some cases (and from some authorities) the answer arrives very slowly.

We'd also welcome the introduction of the alert mechanism into the IMI system also for PQ modul as it already exists for services.

17. How could a professional card (see Recital 32 of the Directive) facilitate recognition of professional qualifications and provision of temporary services? Under which conditions could it be issued by a competent authority?

In Hungary a professional card exists with regards all the healthcare professionals but this card does not give any information about their training requirements.

A sophisticated system should be developed to ensure that the information accessed by using the card, or printed on the card are up-to-date.

We find that Europass CVs and certificates of good standing/current professional status are the best source to get the relevant information.

18. How do you share information about suspensions/restrictions with competent authorities in other Member States? Could more be done in this respect?

The Healthcare Professionals Crossing Borders initiative (HPCB) has launched some surveys and consultations on this matter to clearly see the national settings on the information sharing.

They identified two types of information sharing: reactive information sharing on case-by-case basis, and proactive information sharing.

Some countries (like Hungary) can only share information reactively, because of the national data protection legislation, until the requirement of proactive information sharing would not be introduced in the Directive itself.

Some other countries sends the information (mostly concerning fitness to practice issues) proactively, and we find it very useful to have these information, when it affects some of our registrants.

If we are informed about a case, we can investigate directly whether it has any effect on the registrant under our national law.

The HPCB has a memorandum of understanding on this matter.

We think that the IMI system could also be used as an alert mechanism in this field (it would be similar to the application of the tool with regards the services directive) if proactive information sharing would be compulsory, which would be the fastest and more secured way to inform other authorities.

E. OTHER OBSERVATIONS

19. How and when are the necessary language skills of migrants checked after recognition of the professional qualifications? Are you aware of any complaints (especially from patients/clients/employers) about insufficient language skills of migrants?

The sufficient language knowledge is not a condition to examine during the recognition procedure, though in cases falling under the effect of the general system, when the applicant is to complete a compensation measure (adaptation period, aptitude test) the knowledge of the language is necessary.

The sufficient knowledge of language would be a condition during the registration, but we can not systematically check it, nor ask any formal evidences of the applicant's language knowledge.

The applicants are to make a self-declaration concerning their language knowledges when they apply for the registration, and their former employers can interview them.

20. Do you charge any fee for the recognition process? If so, how much?

The fee of the recognition procedure is laid down in Act C of 2001, it is based on the minimum wages (3/4 of a monthly minimum wage).

The fee of the procedure in 2010 is 55125 HUF (approximately 200 euros).

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MALTA

PHARMACY COUNCIL – MALTA
MR JOSEPH BUSUTTIL

The level of incoming mobility from EU nationals with regards to pharmacists has been very low and therefore our experience with regards to the Directive is still in its infancy. Despite this the Council received training together with the other competent authorities in Malta with regards to healthcare professions, on Directive 2005/36. This was done under a Twinning Light Project which was undertaken with the Netherlands.

One can evaluate thoroughly and effectively when a directive has been put into practice and experienced in several cases. Even though, I can provide some evaluations, considerations and comments with regards to this directive.

The Council accepts applications from EU citizens generally in physical format, i.e. they either hand it in personally or they send it via mail. Generally the email system is used for queries and request for information by the applicants. At the moment we do not have a system in place whereby they can send docs electronically since we generally require original translated documents and qualifications. The yearly number of requests varies between 2 and 5.

Generally the automatic recognition system is used for the evaluation of EU qualifications listed in the Annex. With regards to those qualifications that do not reach the requirements of automatic recognition, the general system is used.

The Directive stipulates administrative cooperation and this is a positive step towards good regulation of the profession in the EU. The Pharmacy Council is registered with the IMI and has contributed in the setup and the design of the questions. Even though the IMI system is a step in the right direction, the fact that this is not an obligatory system makes it less effective. We utilise IMI system generally to search for our counterparts in other countries. Given the low mobility to Malta and also out of Malta, the IMI system has been rarely used.

Pharmacists in Malta possess a professional card and they have done so for the past 4years. This card helps people identify the pharmacists especially in a pharmacy open to the public. This card serves also as their portable registration certificate. The possession of a valid professional card could also guarantee that the practitioner is a registered and licenced pharmacist. Having this card as an electronic card would also assist competent authorities to get information with regards to the pharmaceutical activity of the practitioner in different countries.

I hope that this information is satisfactory for the submissions for Malta with regards to what is expected from us in respect of Directive 2005/36. Should you need further information do not hesitate to contact me. This evaluation is based mainly on my experience and views on the Directive. Should you require a more detailed view from the Council please ask us. We will only be in a position to provide this once the Council has been entirely set up.

The Netherlands
15-09-2010

THE NETHERLANDS

Evaluating the Professional Qualifications Directive
Experience reports from competent authorities

QUESTIONNAIRE FOR PHARMACISTS

A. RECOGNITION PROCEDURE IN CASE OF MIGRATION ON A PERMANENT BASIS

1. Please describe the government structure of the competent authority or authorities in charge of the recognition and of sanctions/restriction to practice.

   The competent authority in cases of registration of professionals with a basic qualification is the Minister of Health Welfare and Sport. The procedure of recognition of professional qualifications is carried out by the BIG-register, that is a part of the government executive agency CIBG (Central Information point Professions in Health Care).

   In cases of registration of professionals with a specialist qualification the authority is in hands of Specialist Registration Committees. These committees exercise this authority by order of the Ministry of Health, Welfare and Sport in the Netherlands.

   In The Netherlands there is one recognised register for specialised pharmacists: hospital pharmacists. The central pharmacists organisation KNMP organises the Specialist Registration Committee (SRC) that takes decisions about registration of hospital pharmacists.

2. To what extent have the system of automatic recognition and the general system been a success? How do you see the costs and benefits for patients and for your organisation? Can you give concrete examples. Specify in particular whether automatic recognition based on diploma, Annex V and the current notification system represent an efficient way to facilitate automatic recognition.

Please submit comments for:

- automatic recognition based on diploma

  The system is fast, simple and cost effective.

  There are major differences in the education systems of the member states. In some states the level of education is far above the minimum standards while in other states it is not. Language proficiency is essential to be able to function well in a profession.

  Since the system of automatic recognition is based on recognition of the primary qualification there is no assurance that the current knowledge and skills of the migrating professional are up to date.

- automatic recognition based on acquired rights

We have experienced problems concerning interpretation of the rules for automatic recognition based on acquired rights.

In case of automatic recognition based on acquired rights it is in principle not possible to verify whether a certificate for automatic recognition was issued rightly and according to Directive 2005/36/EC. However, occasionally verification is possible using a former application file if the migrant applied in the past (before accession of the country of origin) or using information provided by the migrant unasked, like a curriculum vitae. Several times it turned out that certificates for automatic recognition were issued wrongly and not according to Directive 2005/36/EC. For example: the migrant had not been engaged in the activities in question for at least three during the five years preceding the award of the certificate; the migrant had not been engaged in the activities in question effectively and lawfully, as he had been working under supervision; the migrant had been engaged in the activities in question in a third country.
This means that the total number of wrongly issued certificates for automatic recognition must be much higher.

3. Is the general system (as described in article 10) applied in your country each time the conditions for automatic recognition are not met? Are there major difficulties in the recognition procedure under the general system? Please include any comments you may have on the implementation of compensation measures.

   The option of a test is extremely expensive for professions in the health care system. For some of these professions the test would only be used in approx. ten applications per year. Therefore, in situations that there are few recognition requests, aptitude tests are not available. The choice between an aptitude test and an adaptation period should be made not by the migrating professional, but by the host member state's competent authority.

4. What is your experience with the recognition procedure for EU citizens with professional qualifications obtained in a third country and already recognised in a first Member State (see Articles 2(2) and 3(3))?

   The Netherlands does not simply follow another member state in its recognition of a third country diploma. The case law supports this practice. Each state has its own recognition procedures.

   There are immigrants that will file a request for recognition of their qualifications in multiple member states. There is a concern that these individuals try to use a recognition from a member state where they do not wish to settle, to get recognition in another member state.

   Some member states issue ill defined declarations concerning the (educational) recognition of third country diplomas. Migrants rely on these declarations in the process of recognition.

   Where third country diplomas are the issue, member states should clearly specify in their declarations whether it is a declaration as meant in article 2 (2) or article 3 (3) of the Directive.

The procedure for EU citizens with third country diplomas and at least three years professional experience in the member state that recognized the third country diploma, is clear: according to article 10(g) the general system is applicable in these cases. That is not the case if there is less than three years professional experience in the home member state: in those cases the general system is not applicable and the competent authority in the host member state can apply national law, but has to deal with the request considering the Hocsman verdict. This should be more clear by the directive, for example with an article 42c of Directive 93/16/EEC.

5. Do you accept applications from EU citizens for the recognition of foreign diplomas sent by email or requests made on line? Under which conditions can they send documents and declarations electronically? What are your experiences in this respect?

Applications for the recognition of foreign diplomas sent by e-mail or otherwise electronically submitted are not accepted. Only original diplomas or certified copies of the diploma are accepted. The application form needs to be signed by the applicant, a copy is not accepted.
These conditions are almost always met.
Only additional information can be submitted by e-mail.

6. What is the yearly number of applications for recognition from 2000 to 2009? Please submit specific data for applications for automatic recognition based on diplomas, automatic recognition based on acquired rights (as from 2005), and recognition based on the general system[1].

These are the data we can give to you.

Automatic Recognition pharmacist:

2000	*00*
2001	*18*
2002	*18*
2003	*23*
2004	*12*
2005	*16*
2006	*20*
2007	*16*
2008	*29*
2009	*12*
2010	*11 (till September).*

Otherwise:

2000	*09*
2001	*22*
2002	*23*

[1] Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

2003	*25*
2004	*12*
2005	*17*
2006	*20*
2007	*16*
2008	*29*
2009	*13*
2010	*11 (till September).*

For applications for automatic recognition, the duration of the recognition process is 15 days on average. For recognition based on acquired rights the process takes 30 days on average. For recognition based on the general system the process takes longer because advice by an independent professional body needs be asked. This process takes 90 days on average.

B. TEMPORARY MOBILITY (OF A SELF-EMPLOYED OR AN EMPLOYED WORKER)

7. Are EU citizens interested in using the provisions for exercising their professional activities on a temporary and occasional basis in your Member State? How many citizens used this new system since the directive has been transposed in your country (can you provide any statistics per month, per year) [2]?

In the Netherlands there is another possibility for professionals who wish to exercise their activities on a temporary and occasional basis. A pharmacist can work by order of a Dutch pharmacist. This Dutch pharmacist is fully responsible for the foreign pharmacist.

Because of this, EU citizens do not use the 'temporary mobility' provisions to work in The Netherlands. In 2008 and 2009 there were no pharmacists who used these provisions.

The only instances known to us are the following; in 2006 doctors in service of the Tour de France asked about the provisions. In 2008 a doctor specialist from Czech Republic asked about the possibility, but he did not decide to use the provisions.

We agree with the answer of the General Medical Council of the UK. For "United Kingdom", you also can read "the Netherlands" for "doctor" you can read "pharmacist":
"We firmly believe that members of the public have a right to expect that the protection afforded to them by the regulatory system should be the same regardless of whether the doctor practises in the United Kingdom temporarily or permanently. We would wish to require them to provide the same information as other applicants, i.e. asking the applicant to complete a fitness to practice declaration, which enables us to follow-up any issues in relation to potential impairment. There is anecdotal information to suggest that Section 18 is seen as a 'back route' to gaining registration."

[2] Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

8. How are the provisions of Directive 2005/36/EC concerning temporary mobility applied by the competent authorities in practice taking into account the relevant provisions of the Code of Conduct? For instance:

   - How is the "legal establishment" criteria foreseen by Article 5(1) (a) interpreted in practice? What conditions does a migrant need to fulfil in his home Member State in order to be able to provide services?

     The migrant has to provide all the information as mentioned in Article 7 of the Directive. In The Netherlands there is an easier method in place; working under the direction of a Dutch pharmacist. Many migrants prefer this to the process of temporary mobility.

   - How are the "temporary and occasional basis" criteria foreseen by Article 5.2 interpreted in practice? Do Member States assess duration, frequency, regularity and continuity of an activity and if so according to which criteria?

     The temporary and occasional nature of the provision of services is assessed case by case.

     As mentioned above, the situation rarely occurs, so we have no experience to base our answer on.

9. Why is a prior declaration system necessary? What do competent authorities do with the information received? Are other possibilities conceivable?

   We prefer a system where a prior announcement is in place. The system in the Directive is very complicated. There are no cases in The Netherlands where the pharmacists have sent the declaration after the provision of services has taken place.

10. Do you have concrete examples of abuse or misuse of this new possibility for pharmacists? Have you been confronted to problems with regards to patient safety on this issue?

    No

C MINIMUM TRAINING REQUIREMENTS

11. To what extent are the common minimum training requirements set out in Title III Chapter III of Directive 2005/36/EC and the compulsory training subjects as defined in Annex V in line with scientific progress and professional needs? Furthermore, are the knowledge and skills required by the directive still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

    We agree with the answer of the CMC of the UK. For "UK" you can read "the Netherlands" and for "NHS" "Dutch healthcare system":
    "The minimum times for training set out in the Directive are useful, but the lack of overall consistency of approach between member states means that the level of assurance that states can draw from the training obtained by migrants is limited. We have an example of a specialist who gained recognition in the UK under the Directive but subsequently found

they requires a further four years of experience to gain employment as a specialist consultant in the NHS in the UK."
(We have the same problem in the Netherland with pharmatists.)

12. To what extent are the common minimum requirements for training set out in Title III Chapter III of Directive 2005/36/EC in line with scientific progress and professional needs in the last ten years? Are the knowledge and skills outlined in Article 24.3 still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

The Netherlands fully concurs with the point of view of Denmark and the UK. It is very important that the content of the theoretical and practical courses are detailed. Otherwise it is impossible to make a comparison.

We agree with the answer of Denmark. For "Denmark" you can read "the Netherlands".

"The overall intentions stated in Article 24.3 a – d are still highly relevant. We find it of importance, that the hours of theory and hours of practical training in all basic and clinical subjects are well described.

Denmark could recommend, that the trans-national and/or the European dimension is more visualised in accordance with declarations from the Bologna process, i.e. the Loeven communiqué."

We also agree with the answer of the CMC of the UK. For "UK" you can read "the Netherlands", and for" medical practise" you can read "pharmaceutical practise".

"There is a lack of any information about the nature and content of medical training, and of the skills, knowledge, and competencies required of trained doctors in other member states. Without this information we cannot be assured of the quality of education elsewhere, not least given the very general nature of the standards on curriculum content and delivery required in the Directive, and the lack of information about how those standards are quality assured. In addition, comparability is largely based on length of training rather than training content or the range of competencies that medical education develops.

The overall result is a climate in which competent authorities cannot have full confidence in each other's medical training and education.

In addition, the scope of medical practice can differ between member states. What is routine treatment or procedure for a General Practitioner in the UK, for example, may not be within the normal scope of a doctor trained from another EEA country. Moreover, in some member states graduates may have strong theoretical training but less clinical experience than is deemed desirable in other member states. This can give rise to a patient safety risk where the expectations placed upon a doctor working in one jurisdiction, but trained in another, are not met.

In our view the abolition of the Advisory Committee on Medical Training (ACMT), when the Directive was revised in 2005, has lead to a situation where there is currently no European forum for the co-ordination of control of training and no satisfactory route by

which the formal views of competent authorities can be made available to the Commission.

We believe there is a need for an urgent audit of basic and specialist medical qualifications in Europe as a means of identifying and confirming 'content comparability'. The findings should be used as a basis from which to develop the minimum training requirements. These should be developed in terms of learning outcomes rather than inputs (hours and length of study)".

13. The Directive is based on mutual trust between Member States. To what extent is such trust actually achieved? Are training programmes accredited in your country? Does accreditation of a training program in another Member State enhance trust or is it not relevant?

Trust will be achieved when competent authorities correctly implement the Directive as well as proper safeguards to prevent abuse of such trust.

Misinterpretation of the Directive can harm bilateral trust. Implementation of the Directive and its effective use is made difficult due to vast differences between national law, which can cause miscommunication between member states.

Training programmes are accredited in the Netherlands. Accreditation in other Member States could enhance bilateral trust when the legal grounds and conditions in Member States are identical. Especially relevant in this regard is that the accreditation institute checks the training programmes regularly and consistently at the at the same (high) level.

14. To what extent are the existing Directive provisions (see recital 39 and Article 22(b) on continuous professional development (continuous training) adequate? What is your definition of CPD/continuous training? Is continuous training mandatory in your country and what are the exact conditions?

Continuous professional training is not mandatory in the Netherlands. In 2009 a system was introduced requiring renewal of registration every five years. This requirement was introduced for basic professions: nurses, midwives and physiotherapists. The same system will be introduced other professions in installments over the next years, requiring professionals to meet minimum working condition every five years. The professional that does not meet the minimum conditions is required to follow training before renewed registration.

For specialists a system of recertification was instated years ago. The registration of all specialists, including general practitioners, is valid for five years. After five years, the specialist has to prove that he/she actually did work in his/her profession for at least 16 hours per week during the period of five years and took part in accredited CME activities for at least 40 hours per year.

We agree with the answer of the CMC of the UK.

"The Directive as it currently stands does not allow competent authorities to assure themselves that the doctors and healthcare professionals they register have kept their skills and competence up to date since the award of their professional qualifications. The inability of member states to obtain such assurance at the point at which they register or

license a doctor to practice inevitably weakens the level of confidence that competent authorities can have in the fitness to practice of doctors entering the host state."

D. ADMINISTRATIVE COOPERATION (THIS SECTION APPLIES TO ESTABLISHMENT AS TO PROVISION OF SERVICES)

15. To which extent does administrative cooperation, as outlined in Articles 8, 50, and 56 of the Directive, simplify procedures for the migrant professionals? Can you give your own experience?

Administrative cooperation will likely speed up and simplify the procedure, and allows competent authorities to exchange information directly and safely – without any need for the migrant to send in his/her personal documents.

We also refer to our answer to question 16.

We prefer the direct communication between competent authorities, without involving the migrant in question. Especially where pending restrictions are concerned the IMI can perform a vital function.

16. Is the competent authority in your country registered with IMI? Under which circumstances does your competent authority use IMI? If not registered, why not and what would be the conditions for changing this situation?

Yes, the BIG-register and the specialist registration committees – the Dutch competent authorities - are registered with IMI. In case of doubt or when additional information is needed, we refer to IMI.

Our opinion is that the IMI is a useful and reliable tool to communicate with other competent authorities. Use of IMI can speed up procedures and often negates the need for further correspondence with the migrant, or for the migrant having to submit documents; IMI allows communication with competent authorities that otherwise would be difficult to reach, that would not respond within certain time limits, or with whom no communication would be possible due to language barriers.

On the other hand, IMI is not always user-friendly, and national law and discrepancies between systems of recognition (many national competent authorities exist for one profession) sometimes make the use of IMI challenging.

<u>Suggestions for improvement of the IMI</u>:

1. Registration with IMI should be mandatory for all competent authorities.

2. All competent authorities should be required to use IMI and respond within a given time limit.

3. IMI could be made more user-friendly, by (i) improving the interface (clustering and highlighting questions - some questions are used more often than others); (ii) implementing a system to monitor incoming and outgoing requests; (iii) improving the

translation tool; (iv) implementing the option to identify competent authorities by profession (in all languages).

17. How could a professional card (see Recital 32 of the Directive) facilitate recognition of professional qualifications and provision of temporary services? Under which conditions could it be issued by a competent authority?

In our opinion, a "professional card" does not have any added value to facilitate recognition of professional qualifications. The development of such a system would be very expensive, while keeping the information contained in the card up-to-date would be nearly impossible. Furthermore, developing a European database would be difficult and expensive when taking into account that every professional would need to get a card while only a few would practice their profession in another Member State.

It seems that professional cards are meant mainly to address problems at a national level that are not prevalent in all Member States. In the Netherlands, a public, online, current directory is made available: a professional may demonstrate his/her qualifications by submitting a registration number.

Two professional card systems are imaginable with regard to recognition of professional qualifications:
1. A card that contains data, or:
2. a card that provides access to a database.

With a card that contains data, the problem arises that data may not always beup-to-date. Also, this system would be more susceptible to data fraud. With a card that provides access to a database, the problem arises that competent authorities must maintain such a database. With a European database, a few problems would likely arise, such as: language barriers, the effort of keeping the data up-to-date, and differences in interpretation with regard to data. Furthermore, there is no added value when the card is meant to be used to access data through a closed network, because of the existence of the IMI. Member States are able to provide each other with information through use of the IMI, and may incorporate such data in a national database. Subsequently, employers and civilians or patients would be able to refer to such a national database.

Even a professional card will not prevent fraud and abuse. Furthermore, the card may imply the holder of that card to be qualified when this is not actually the case.

When taking into account the number of migrants vis-à-vis the number of residents, the costs versus the benefits of introducing and maintaining a card system linked to a European database would seem disproportionate.

Maintaining both a professional card system and a public online up-to-date database would be confusing and inefficient. Employers and civilians or patients should use the register, while competent authorities should exchange information through IMI directly.

From the viewpoint of cost reductions and efficiency, we feel it would make more sense to invest in the development of public, central databases in each Member State, while using IMI for the direct exchange of data between Member States.

18. How do you share information about suspensions/restrictions with competent authorities in other Member States? Could more be done in this respect?

The General Medical Council of England and the Medical Council of Ireland inform us about disciplinary action or criminal sanctions taken.

Other Member States only inform us incidentally in this regard.

Other Member States do not inform us about pharmacists.

Dutch decisions with regard to disciplinary action or criminal sanctions are made available online, at: www.bigregister.nl.

The Netherlands are a partner in the Health Care Professionals Crossing Borders (HCPB) partnership. The Netherlands therefore issue Certificates of Current Professional Status (CCPS) according to the HCPB agreement. The CCPS, issued by the competent authority of the home member state, should be made a compulsory document to be carried by a migrant health professional within the EEA.

E. OTHER OBSERVATIONS

19. How and when are the necessary language skills of migrants checked after recognition of the professional qualifications? Are you aware of any complaints (especially from patients/clients/employers) about insufficient language skills of migrants?

Language skills are considered an essential part of the work quality of a professional. When a doctor, dentist, nurse, midwife or pharmacist has received recognition from the government, he or she may immediately start working in the Netherlands.

Complaints have been received by the BIG-register and the specialist registration committees about insufficient language skills of migrating health professionals who were granted registration under the Directive on a regular basis. It is incomprehensible to employers and insurance agencies that a migrant can be recognized and registered even though he or she does not speak the Dutch language.

20. Please fill free to add any comment you want on the directive 2005/36/EC

HJS
2010-09-15.

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Version du 8 juin 2010

AUSTRIA

Evaluating the Professional Qualifications Directive
Experience reports from competent authorities

QUESTIONNAIRE FOR PHARMACISTS

A. RECOGNITION PROCEDURE IN CASE OF MIGRATION ON A PERMANENT BASIS

1. Please describe the government structure of the competent authority or authorities in charge of the recognition and of sanctions/restriction to practice.

The Chamber of Austrian Pharmacists (ÖAK) has been given the authority (through § 2a (1) Z 4 Apothekerkammer Gesetz) to act in-lieu of the responsible authorities in these matters. The Chamber is the only organisation which is responsible for the recognition in Austria. As a matter of fact transparency and quick completion of the applications is guaranteed.

2. To what extent have the system of automatic recognition and the general system been a success? How do you see the costs and benefits for patients and for your organisation? Can you give concrete examples. Specify in particular whether automatic recognition based on diploma, Annex V and the current notification system represent an efficient way to facilitate automatic recognition.

The effects on patients have been negligible with few language related exceptions mainly in border areas.

Please submit comments for:

- automatic recognition based on diploma

For the Chamber the system of automatic recognition constitutes a simplification, as testing of job-specific capabilities is no longer part of the process: On the positive side this (through Annex V) guarantees a certain level of job specific knowledge/training as a pharmacist. On the negative side the fact that automatic recognition is a mere formalism without any job specific testing/examinations raises concerns as the institution as well as the quality of prior training remains unknown.

- automatic recognition based on acquired rights

This way of recognition seems to be rather insecure. Concerns exist concerning e.g. the institution certifying the practical experience (who is allowed to certify?), the practical experience itself (§ 3c Abs. 4 Austrian Pharmacy Act: duration, full-time employment).

3. Is the general system (as described in article 10) applied in your country each time the conditions for automatic recognition are not met? Are there major difficulties in the recognition procedure under the general system? Please include any comments you may have on the implementation of compensation measures.

So far there are no practical cases in which the directive has been applied. However, there are concerns that the general quality of service/advice might decrease, which is the more worrisome as the profession of a pharmacist touches on sensitive areas ie health.

4. What is your experience with the recognition procedure for EU citizens with professional qualifications obtained in a third country and already recognised in a first Member State (see Articles 2(2) and 3(3))?

So far there are very few practical cases except one case of a Ukrainian pharmacist seeking official recognition of her professional diploma in CR. In many cases the length of practical work experience constitutes problems. It is mainly the traceability that causes problems.

5. Do you accept applications from EU citizens for the recognition of foreign diplomas sent by email or requests made on line? Under which conditions can they send documents and declarations electronically? What are your experiences in this respect?

According § 13 AVG (general administration act) applications may be submitted electronically. In any event the originals (ie original document and translated and certified copy) also need to be presented thereafter.

6. What is the yearly number of applications for recognition from 2000 to 2009? Please submit specific data for applications for automatic recognition based on diplomas, automatic recognition based on acquired rights (as from 2005), and recognition based on the general system[1].

Year	Applications
2003	52
2004	36
2005	20
2006	29
2007	30
2008	31
2009	37

B. TEMPORARY MOBILITY (OF A SELF-EMPLOYED OR AN EMPLOYED WORKER)

7. Are EU citizens interested in using the provisions for exercising their professional activities on a temporary and occasional basis in your Member State? How many citizens used this new system since the directive has been transposed in your country (can you provide any statistics per month, per year)[2]?

No requests have been registered since the Directive 2005/36/EC. Consequently we do not have any experience in this regard.

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1 Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

2 Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

8. How are the provisions of Directive 2005/36/EC concerning temporary mobility applied by the competent authorities in practice taking into account the relevant provisions of the Code of Conduct? For instance:

   - How is the "legal establishment" criteria foreseen by Article 5(1) (a) interpreted in practice? What conditions does a migrant need to fulfil in his home Member State in order to be able to provide services?

   - How are the "temporary and occasional basis" criteria foreseen by Article 5.2 interpreted in practice? Do Member States assess duration, frequency, regularity and continuity of an activity and if so according to which criteria?

9. Why is a prior declaration system necessary? What do competent authorities do with the information received? Are other possibilities conceivable?

10. Do you have concrete examples of abuse or misuse of this new possibility for pharmacists? Have you been confronted to problems with regards to patient safety on this issue?

No experience as of yet. Additionally, we point to the fact that temporary mobility may lead to abuse through by-passing the recognition formalities, e.g. concatenation of holiday replacements.

C MINIMUM TRAINING REQUIREMENTS

11. To what extent are the common minimum training requirements set out in Title III Chapter III of Directive 2005/36/EC and the compulsory training subjects as defined in Annex V in line with scientific progress and professional needs? Furthermore, are the knowledge and skills required by the directive still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

From our point of view a minimum training of 6 months in the job is required in order to be able to give qualified advice/recommendations to patients. Austrian university graduates need to attend a one year on the job training upon graduation. On top of this they need to attend obligatory classroom trainings given by practising pharmacists.

12. To what extent are the common minimum requirements for training set out in Title III Chapter III of Directive 2005/36/EC in line with scientific progress and professional needs in the last ten years? Are the knowledge and skills outlined in Article 24.3 still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

Knowledge and skills as set out in Art 44 represent an accurate job description of a pharmacist in Austria (subsect to ongoing change).

13. The Directive is based on mutual trust between Member States. To what extent is such trust actually achieved? Are training programmes accredited in your country? Does accreditation of a training program in another Member State enhance trust or is it not relevant?

In the process of adopting Annex V mutual trust requirements between memberstates have been sufficiently fulfilled/achieved. According to the Austrian code of conduct for pharmacists (Berufsordnung) pharmacists are obliged to keep themselves abreast of new developments in their line of work. Mutual recognition and accrediation of training programs further enhances the creation of trust. Furthermore the content of (accredited) training programs should be exchanged.

14. To what extent are the existing Directive provisions (see recital 39 and Article 22(b) on continuous professional development (continuous training) adequate? What is your definition of CPD/continuous training? Is continuous training mandatory in your country and what are the exact conditions?

Provisions as stated in the directive are considered adequate. Continuous training, however, is required by Art. 3 of the Austrian Code of Conduct:
"Fortbildung
§ 3. (1) Der Apotheker hat sich laufend beruflich fortzubilden und sich über die für die Berufsausübung geltenden Vorschriften zu unterrichten.
(2) Ziel der Fortbildung ist es, die in der Aus- und allenfalls Weiterbildung erworbenen Kenntnisse zu erhalten, weiter zu entwickeln und den neuen Erkenntnissen anzupassen. Der zur Berufsausübung berechtigte Apotheker ist grundsätzlich selbst dafür verantwortlich, dass er die Verpflichtung zur kontinuierlichen fachlichen Fortbildung im Rahmen seines Berufslebens erfüllt.
(3) Mittel der Fortbildung sind insbesondere
a) die Teilnahme an Fortbildungsveranstaltungen,
b) praktische Übungen im Rahmen von Seminarveranstaltungen,
c) Studium von Fachliteratur,
d) EDV-unterstützte Lerntechnologien oder audiovisuelle Lehrmittel und
e) Lehr-, Forschungs- oder Vortragstätigkeit."

D. ADMINISTRATIVE COOPERATION (THIS SECTION APPLIES TO ESTABLISHMENT AS TO PROVISION OF SERVICES)

15. To which extent does administrative cooperation, as outlined in Articles 8, 50, and 56 of the Directive, simplify procedures for the migrant professionals? Can you give your own experience?

See below question 16.

16. Is the competent authority in your country registered with IMI? Under which circumstances does your competent authority use IMI? If not registered, why not and what would be the conditions for changing this situation?

The Austrian Chamber of Pharmacists is registered with IMI. This is particularly helpful when dealing with EE states, where it is notoriously difficult to find contact persons. Getting translations of official documents automatically is still a problem.

17. How could a professional card (see Recital 32 of the Directive) facilitate recognition of professional qualifications and provision of temporary services? Under which conditions could it be issued by a competent authority?

The professional card then enhances mutual trust when the conditions for issuing are trustworthy. Before release a careful examination of the applicant's qualification is required. At the moment no additional value is evident for pharmacists. In other professional guilds with a high level of mobility this function of the professional card is important.

18. How do you share information about suspensions/restrictions with competent authorities in other Member States? Could more be done in this respect?

Mainly based on personal contacts.

E. OTHER OBSERVATIONS

19. How and when are the necessary language skills of migrants checked after recognition of the professional qualifications? Are you aware of any complaints (especially from patients/clients/employers) about insufficient language skills of migrants?

In case of reasonable doubt applicants are asked to provide documentation of their language skills (eg. Aptitude tests). In order to facilitate language aptitude exams such as the GER the Austrian Chamber has also initiated cooperation with a language institute.

20. Please fill free to add any comment you want on the directive 2005/36/EC

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Naczelna Izba Aptekarska

POLAND

Warszawa, 9 September 2010

EVALUATING THE PROFESSIONAL QUALIFICATION DIRECTIVE

Experience report

Polish Pharmaceutical Chamber has been competent authority for recognition professional qualifications of pharmacists since May 1, 2004.

Experience of the Chamber in recognition qualifications of pharmacists from Member States of EU applying to perform profession in Poland is rather limited as during past 6 years the Chamber has received only 9 applications:

in 2005 – 2 applications (Austria and Switzerland),
in 2006 – 2 applications (Germany and Czech Republic),
in 2007 – 2 applications (Germany),
in 2008 – 1 application (Austria),
in 2009 – 2 applications (Spain and Germany)

All cases were rather simple and the qualifications of all applicants have been recognized without the need to contact competent authorities in the countries of origin of applicants. All of them has been recognized on the basis of automatic recognition of diplomas.

The Chamber accepts foreign diplomas sent as authorized copies send by regular mail and as far we do not use electronic way.

Polish Pharmaceutical Chamber have had not any experience with temporary mobility, as there were not any applications during last 5 years.

In our opinion the common minimum training requirements set out in Title III Chapter III of Directive 2005/36/EC and compulsory training subjects defined in Annex V are in line with scientific progress and professional needs. As concern scientific progress and professional needs in the last ten years , the requirements should be regularly periodically updated to reflect actual progress in pharmaceutical sciences and practice.

We consider that we have achieved a high mutual trust with competent authorities in other Member States (it concerns Polish pharmacists migrating to these countries), especially a very good cooperation exists between Polish Pharmaceutical Chamber and Royal Pharmaceutical Society of Great Britain and Pharmaceutical Society of Ireland.

Polish Pharmaceutical Chamber is registered with IMI, but we do not use it as there is not a real need to do it. Only several times (5-6 cases) we have got specific question from other competent authorities. In everyday practice we communicate by e-mail which is simpler and quicker.

Polish Pharmaceutical Chamber

ul. Długa 16, 00-238 WARSZAWA

Telefon: 022 635-92-85, 022 6350670, Faks: 022 887-50-32

http://www.nia.org.pl, e-mail: nia@nia.org.pl

Continuous training for pharmacists is mandatory in Poland. The cycle of this training lasts 5 years during which pharmacists should gain 100 educational points. The training is regulated by the governmental regulation and is provided by accredited units (pharmaceutical faculties, scientific societies, and chambers). It would be very important to solve the problem of continuous education on the international level and to harmonize the curricula. It would facilitate recognition them after the return of pharmacist to his host country.

Polish Pharmaceutical Chamber demands of applicants to declare in writing that they know Polish language in the extent allowing them to perform the profession of pharmacist. 6 of 9 applicants were of Polish origin and their knowledge of Polish was perfect.

As concerns information about suspension/restrictions we ask applicants to present a certificate of good professional standing issued by competent authority of their host Member State or the State were they performed the profession of pharmacist during last 5 years.

In our opinion professional card would be a valuable document facilitating recognition professional qualification when it would contain information about competent authority, suspension/restrictions in performing the profession and obligatory continuous training and professional specialization. It should be issued to the all members of the Chamber, or another competent authority, who have an actual Right to Perform the Profession, and in the future could limit bureaucracy in recognition qualifications.

Prezes
Naczelnej Rady Aptekarskiej
dr Grzegorz Kucharewicz

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PORTUGAL

Evaluating the Professional Qualifications Directive
Experience reports from competent authorities

QUESTIONNAIRE FOR PHARMACISTS

A. RECOGNITION PROCEDURE IN CASE OF MIGRATION ON A PERMANENT BASIS

1. Please describe the government structure of the competent authority or authorities in charge of the recognition and of sanctions/restriction to practice.

   Ordem dos Farmacêuticos (Portuguese Pharmaceutical Society) is the official body representing Portuguese pharmacists (practising pharmacy in Portugal) with administrative and regulatory competencies conferred upon by the Government, according to the Decree-Law 288/2001, the new Statute of the Portuguese Pharmaceutical Society (PPS).
   Nevertheless, the Directive was transposed to the internal law without the appointment of the Portuguese competent authority. This is to be regulated in the subsequent governmental decree, to be published.

2. To what extent have the system of automatic recognition and the general system been a success? How do you see the costs and benefits for patients and for your organisation? Can you give concrete examples. Specify in particular whether automatic recognition based on diploma, Annex V and the current notification system represent an efficient way to facilitate automatic recognition.

   We haven't had any problems with the automatic recognition based on diploma. It has many benefits to all EU citizens, because it facilitates the cultural exchange between EU countries, and it also simplifies many administrative processes.

Please submit comments for:

- automatic recognition based on diploma Until now, all the situations are based on automatic recognition based on diploma. No special remarks to be done about them.

- automatic recognition based on acquired rights We have no experience on this type of recognition so far.

3. Is the general system (as described in article 10) applied in your country each time the conditions for automatic recognition are not met? Are there major difficulties in the recognition procedure under the general system? Please include any comments you may have on the implementation of compensation measures.

   Yes, but until now we never had any situation in which we had applied the recognition procedure under the general system.

4. What is your experience with the recognition procedure for EU citizens with professional qualifications obtained in a third country and already recognised in a first Member State (see Articles 2(2) and 3(3))?

   So far we only had one case of a pharmacist from Brasil with Spanish nationality. She asked for the recognition of her Brazilian qualifications in pharmacy near the Spanish competent authorities. The authorities had approved the request and then she came to Portugal and asked the same near our Institution. We had recognized her qualifications because she had Spanish nationality and a diploma recognized by the Spanish competent authorities.

5. Do you accept applications from EU citizens for the recognition of foreign diplomas sent by email or requests made on line? Under which conditions can they send documents and declarations electronically? What are your experiences in this respect?

   It's possible to start the recognition procedure with a request made on-line or by e-mail, but the candidates have always to present a hard copy of the documents in our Institution. Until now we don't have much experience in this kind of requests.

6. What is the yearly number of applications for recognition from 2000 to 2009? Please submit specific data for applications for automatic recognition based on diplomas, automatic recognition based on acquired rights (as from 2005), and recognition based on the general system[1].

   This is data for EU citizens only:

   2000 – Automatic Recognition based on the diploma – 5
   Automatic Recognition based on acquired rights – 0
   Automatic Recognition based on the general system – 0

   2001 – Automatic Recognition based on the diploma – 9
   Automatic Recognition based on acquired rights – 0
   Automatic Recognition based on the general system - 0

   2002 – Automatic Recognition based on the diploma – 8
   Automatic Recognition based on acquired rights – 0
   Automatic Recognition based on the general system - 0

   2003 – Automatic Recognition based on the diploma – 5
   Automatic Recognition based on acquired rights – 0
   Automatic Recognition based on the general system - 0

   2004 – Automatic Recognition based on the diploma – 6
   Automatic Recognition based on acquired rights – 0
   Automatic Recognition based on the general system - 0

   2005 – Automatic Recognition based on the diploma – 10

[1] Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

Automatic Recognition based on acquired rights – 0
Automatic Recognition based on the general system - 0

2006 – Automatic Recognition based on the diploma – 11
Automatic Recognition based on acquired rights – 0
Automatic Recognition based on the general system - 0

2007 – Automatic Recognition based on the diploma – 12
Automatic Recognition based on acquired rights – 0
Automatic Recognition based on the general system - 0

2008 – Automatic Recognition based on the diploma – 8
Automatic Recognition based on acquired rights – 0
Automatic Recognition based on the general system - 0

2009 – Automatic Recognition based on the diploma – 7
Automatic Recognition based on acquired rights – 0
Automatic Recognition based on the general system - 0

B. TEMPORARY MOBILITY (OF A SELF-EMPLOYED OR AN EMPLOYED WORKER)

7. Are EU citizens interested in using the provisions for exercising their professional activities on a temporary and occasional basis in your Member State? How many citizens used this new system since the directive has been transposed in your country (can you provide any statistics per month, per year) [2]? Until now, we didn't have any solicitations in this subject, so we don't have any information about citizens that used this new system.

8. How are the provisions of Directive 2005/36/EC concerning temporary mobility applied by the competent authorities in practice taking into account the relevant provisions of the Code of Conduct? For instance:

   We haven't experience concerning temporary mobility.

   - How is the "legal establishment" criteria foreseen by Article 5(1) (a) interpreted in practice? What conditions does a migrant need to fulfil in his home Member State in order to be able to provide services?

   - How are the "temporary and occasional basis" criteria foreseen by Article 5.2 interpreted in practice? Do Member States assess duration, frequency, regularity and continuity of an activity and if so according to which criteria?

9. Why is a prior declaration system necessary? What do competent authorities do with the information received? Are other possibilities conceivable?

   We haven't experience in this field.

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[2] Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

10. Do you have concrete examples of abuse or misuse of this new possibility for pharmacists? Have you been confronted to problems with regards to patient safety on this issue?

    No.

C MINIMUM TRAINING REQUIREMENTS

11. To what extent are the common minimum training requirements set out in Title III Chapter III of Directive 2005/36/EC and the compulsory training subjects as defined in Annex V in line with scientific progress and professional needs? Furthermore, are the knowledge and skills required by the directive still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

    They are adequate.

12. To what extent are the common minimum requirements for training set out in Title III Chapter III of Directive 2005/36/EC in line with scientific progress and professional needs in the last ten years? Are the knowledge and skills outlined in Article 24.3 still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

    They are adequate.

13. The Directive is based on mutual trust between Member States. To what extent is such trust actually achieved? Are training programmes accredited in your country? Does accreditation of a training program in another Member State enhance trust or is it not relevant?

    Until 2007, professional organizations like Ordem dos Farmacêuticos had the power to perform the accreditation of the Pharmaceutical Sciences Degrees conferred by Pharmacy Schools in Portugal. After 2007, the government decided to create an 'Agency for the evaluation and accreditation of the Higher Education' who is responsible for that process. Ordem dos Farmacêuticos is represented in the Agency' Advisory Council.
    Anyway, an accredited training program in another Member State is relevant to enhance trust in the recognition process.

14. To what extent are the existing Directive provisions (see recital 39 and Article 22(b) on continuous professional development (continuous training) adequate? What is your definition of CPD/continuous training? Is continuous training mandatory in your country and what are the exact conditions?

    In November 2001, the Portuguese Parliament approved as Decree-Law 288/2001, the new Statute of the Portuguese Pharmaceutical Society (PPS). Among other innovations, the approved Statute moves towards requiring demonstration of participation in Continuing Professional Development (CPD), as a pre-requisite for the revalidation of the right to practise.
    The approved model defined as mandatory the renewal of pharmacists' professional license, on a five year basis, subject to a pre-defined number of credit units obtainable through continuous professional development (CPD) activities (15 CDP credits).

D. ADMINISTRATIVE COOPERATION (THIS SECTION APPLIES TO ESTABLISHMENT AS TO PROVISION OF SERVICES)

15. To which extent does administrative cooperation, as outlined in Articles 8, 50, and 56 of the Directive, simplify procedures for the migrant professionals? Can you give your own experience?

    The administrative cooperation simplifies the requests and guarantees the safety of the recognition process. Particularly in regard of the language issues, and problems in the translation processes of the citizens.

16. Is the competent authority in your country registered with IMI? Under which circumstances does your competent authority use IMI? If not registered, why not and what would be the conditions for changing this situation?

    Yes, Ordem dos Farmacêuticos is listed on IMI, but we use IMI to answer or to request information from other competent authorities.
    We are emailed every time we have a new request in the platform.

17. How could a professional card (see Recital 32 of the Directive) facilitate recognition of professional qualifications and provision of temporary services? Under which conditions could it be issued by a competent authority?

    We think it has the potential to be a good tool in providing all EU citizens a manageable mean of being recognized in other Member-Stares.
    Nevertheless, we have to be careful to find out a perfect system that allows the professional card to always be up-to-date regarding the information of that professional, specially in what concerns the possible regulatory punishments/suspensions/restrictions.

18. How do you share information about suspensions/restrictions with competent authorities in other Member States? Could more be done in this respect?

    At the moment we just share information under request.

E. OTHER OBSERVATIONS

19. How and when are the necessary language skills of migrants checked after recognition of the professional qualifications? Are you aware of any complaints (especially from patients/clients/employers) about insufficient language skills of migrants?

    After the recognition request, the competent authority' responsible person schedule an interview with the applicant. This interview comprises an assessment test on the pharmacists' ability to communicate in the native language. This test aims to prove the applicant's knowledge about the Portuguese pharmaceutical legislation and code of conduct.
    No we don't have any complaints until now.

20. Please fill free to add any comment you want on the directive 2005/36/EC

    No further comments.

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SLOVENIA

Evaluating the Professional Qualifications Directive
Experience reports from competent authorities

QUESTIONNAIRE FOR PHARMACISTS

A. RECOGNITION PROCEDURE IN CASE OF MIGRATION ON A PERMANENT BASIS

1. Please describe the government structure of the competent authority or authorities in charge of the recognition and of sanctions/restriction to practice.

For the coordination of the implementation and the uniform application for the procedures of recognizing and regulations issued for the implementation of the directives is responsible the Ministry of Labour, Family and Social Affairs of the Republic of Slovenia.
The procedures for recognising qualifications of pharmacist is conducted by Ministry of Health of Republic of Slovenia which is competent authority for all of health professions. The procedure of recognition of a qualification is initiated by a candidate lodging an application with the competent authority for a particular regulated profession or professional activity.

After the receipt of the application, the competent authority informs the candidate about any missing certificates and asks for additional documentation, as necessary. After the receipt of a complete application, the competent authority must issue a decision within two months.
In the course of the procedure, the competent authority may request a competent professional chamber or organisation to submit their opinion; if the latter is not provided, the competent authority shall issue its decision without it. An opinion of a competent professional chamber or organisation shall not be binding for a decision issued by the competent authority.

In the case of an automatic recognition procedure the applicant's documents are compared with the evidence requested in Annex V and if they meet the qualification is automatically recognized.

In the procedure, the competent ministry compares written documentation on the applicant's professional qualifications with the professional qualifications required by regulations in the Republic of Slovenia for the pursuit of the regulated profession or professional activity. If based on the comparison, the competent authority assesses that the applicant's professional qualifications are not adequate, it issues a provisional decision and calls on the applicant to take one of the following supplementary actions, depending on the circumstances, in order to obtain recognition of his/her professional qualifications:
– an aptitude test; or
– an adaptation period, during which the applicant will satisfy the conditions for recognition of professional qualifications which he/she initially failed to meet.

The competent authority issues a decision on the recognition of the candidate's professional qualification regarding the pursuit of a particular regulated profession or activity in the Republic of Slovenia:
a) when it is assessed –based on the application – that the candidate's professional qualifications comply with the qualifications required for the pursuit of a particular regulated profession or professional activity in the Republic of Slovenia;

b) when the candidate submits evidence of a successfully completed adjustment period or aptitude test
c) in case of automatic recognition on the basis of evidence that meets the evidence in Annex V.

On the basis of a decision on the recognition of professional qualifications, the candidate is enabled to pursue a regulated profession for which he/she has been qualified in a Member State of the EU, EEA or the Swiss Confederation under the same conditions that apply to Slovenian nationals, provided that the activities covered by that profession are comparable.

2. To what extent have the system of automatic recognition and the general system been a success? How do you see the costs and benefits for patients and for your organisation? Can you give concrete examples. Specify in particular whether automatic recognition based on diploma, Annex V and the current notification system represent an efficient way to facilitate automatic recognition.

Please submit comments for:

- automatic recognition based on diploma

The system of automatic recognition works very well. In our view automatic recognition is a very effective way of recognition, and saves time and costs. Actually is the fastest way for employment of qualified persons.

- automatic recognition based on acquired rights

Also the automatic recognition based on acquired rights is an advantage, while person can benefit from automatic recognition only if has the certificate of working experience. But because Directive doesn't specify how many hours person has to work in order to get the certificate of working experience, person can get it also if he works part time.

3. Is the general system (as described in article 10) applied in your country each time the conditions for automatic recognition are not met? Are there major difficulties in the recognition procedure under the general system? Please include any comments you may have on the implementation of compensation measures.

Up till now all applicants were recognized on the basis of automatic recognition.
We noticed that applicants were Slovene citizens, who obtained qualification of pharmacist in other EU country (Italy).

4. What is your experience with the recognition procedure for EU citizens with professional qualifications obtained in a third country and already recognised in a first Member State (see Articles 2(2) and 3(3))?

We have no experience with professional qualifications obtained in a third country and already recognised in a first Member State.

5. Do you accept applications from EU citizens for the recognition of foreign diplomas sent by email or requests made on line? Under which conditions can they send documents and declarations electronically? What are your experiences in this respect?

In the procedure of professional qualification an application can be also sent by email. The certificated copies and official translations of documents should be submitted by post or personally.

6. What is the yearly number of applications for recognition from 2000 to 2009? Please submit specific data for applications for automatic recognition based on diplomas, automatic recognition based on acquired rights (as from 2005), and recognition based on the general system[1].

Ministry of Health is competent authority for recognition of qualification from November 2008. We have only few cases (2 cases) in year 2009.

B. TEMPORARY MOBILITY (OF A SELF-EMPLOYED OR AN EMPLOYED WORKER)

7. Are EU citizens interested in using the provisions for exercising their professional activities on a temporary and occasional basis in your Member State? How many citizens used this new system since the directive has been transposed in your country (can you provide any statistics per month, per year)[2]?

Ministry of Health has not received declaration from pharmacists for exercising their professional activities on a temporary and occasional basis Slovenia.

8. How are the provisions of Directive 2005/36/EC concerning temporary mobility applied by the competent authorities in practice taking into account the relevant provisions of the Code of Conduct? For instance:

   - How is the "legal establishment" criteria foreseen by Article 5(1) (a) interpreted in practice? What conditions does a migrant need to fulfil in his home Member State in order to be able to provide services?

For attesting legal establishment the migrant has to attach next documents:
- certificate from competent authority,
- certificate of the professional licence,
- certificate of good standing,
- registration certificate

   - How are the "temporary and occasional basis" criteria foreseen by Article 5.2 interpreted in practice? Do Member States assess duration, frequency, regularity and continuity of an activity and if so according to which criteria?

For determination of "temporary services" in declaration the migrant has to indicate how much time and how often will perform services. And than the Ministry of Health decides whether it is "temporary and occasional basis" or not.

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[1] Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

[2] Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

9. Why is a prior declaration system necessary? What do competent authorities do with the information received? Are other possibilities conceivable?

The competent authority collects information for statistical and analytical purposes., they are also used for annual reports to the European Commission.
On the basis of the information we supervise the professionals pursuing services in our country.

After receiving complete declaration Ministry of Health temporary registers migrant in the register.

10. Do you have concrete examples of abuse or misuse of this new possibility for pharmacists? Have you been confronted to problems with regards to patient safety on this issue? No experience in this field.

C MINIMUM TRAINING REQUIREMENTS

11. To what extent are the common minimum training requirements set out in Title III Chapter III of Directive 2005/36/EC and the compulsory training subjects as defined in Annex V in line with scientific progress and professional needs? Furthermore, are the knowledge and skills required by the directive still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

We have not received any information that minimum training requirements set out in Title III Chapter III of Directive 2005/36/EC and the compulsory training subjects as defined in Annex V are not in line with scientific progress and professional needs, nor that. knowledge and skills required by the directive are not relevant and up to date.

12. To what extent are the common minimum requirements for training set out in Title III Chapter III of Directive 2005/36/EC in line with scientific progress and professional needs in the last ten years? Are the knowledge and skills outlined in Article 24.3 still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

We have not received any information that minimum training requirements set out in Title III Chapter III of Directive 2005/36/EC are not in line with scientific progress and professional needs, nor that. knowledge and skills required by the directive are not relevant and up to date.

13. The Directive is based on mutual trust between Member States. To what extent is such trust actually achieved? Are training programmes accredited in your country? Does accreditation of a training program in another Member State enhance trust or is it not relevant?

The mutual trust is not achieved completely. The compulsory training subjects as defined in Annex V do strengthen the mutual trust, but in spite of that in the procedure of professional qualification Ministry of Health always requires certificate of obtained qualification, issued by competent authority.

Training programmes are accredited by Ministry of higher education.

14. To what extent are the existing Directive provisions (see recital 39 and Article 22(b) on continuous professional development (continuous training) adequate? What is your definition of CPD/continuous training? Is continuous training mandatory in your country and what are the exact conditions?

Continuous professional development is mandatory in Slovenia. According to national law all (Health service act) health workers and health associates have the right and obligation of further professional training, thus an institution must enable them to:

- regularly to follow the development of health sciences;
- occasional practical further training in appropriate health institutions;
- occasional verifying of theoretical and practical knowledge.

D. ADMINISTRATIVE COOPERATION (THIS SECTION APPLIES TO ESTABLISHMENT AS TO PROVISION OF SERVICES)

15. To which extent does administrative cooperation, as outlined in Articles 8, 50, and 56 of the Directive, simplify procedures for the migrant professionals? Can you give your own experience?

Administrative cooperation simplifies and fastens procedure for the migrant professionals, while some information about migrants qualifications can be obtained directly from competent authority.

16. Is the competent authority in your country registered with IMI? Under which circumstances does your competent authority use IMI? If not registered, why not and what would be the conditions for changing this situation?

Ministry of Heath is registered in IMI. Till now we only replied to inquires of another Member State.

17. How could a professional card (see Recital 32 of the Directive) facilitate recognition of professional qualifications and provision of temporary services? Under which conditions could it be issued by a competent authority?

A professional card could be a useful tool to facilitate the free movements of health personal. It can only work if information contained in cars are is secured by chip, and if the information are up to date. The professional card could be issued by professional associations if they are competent authority.

18. How do you share information about suspensions/restrictions with competent authorities in other Member States? Could more be done in this respect?

We are not alerted and we don't share this kind of information with other countries, because we don't have obvious registration for pharmacists.

E. OTHER OBSERVATIONS

19. How and when are the necessary language skills of migrants checked after recognition of the professional qualifications? Are you aware of any complaints (especially from patients/clients/employers) about insufficient language skills of migrants?

According to The act on the performance of medical professions in the Republic of Slovenia by citizens of other Member States of the European Union the employer specify in its employment regulations the level of knowledge of the Slovene languages and the method of its assessment, that are required in relation to individual work posts. The Government has set the standards for the level of Slovene language skills for typical work posts.

20. Please fill free to add any comment you want on the directive 2005/36/EC

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Version du 8 juin 2010

FINLAND

Evaluating the Professional Qualifications Directive
Experience reports from competent authorities

QUESTIONNAIRE FOR PHARMACISTS

A.Recognition procedure in case of migration on a permanent basis

1. Please describe the government structure of the competent authority or authorities in charge of the recognition and of sanctions/restriction to practice.

When the recognition and of sanctions/restriction to practice concerns healthcare professionals according to the Finnish Act on Healthcare Professionals, the competent authority is Valvira. Valvira is an independent office under the Ministry Of Social Affairs and Health.

2. To what extent have the system of automatic recognition and the general system been a success? How do you see the costs and benefits for patients and for your organisation? Can you give concrete examples. Specify in particular whether automatic recognition based on diploma, Annex V and the current notification system represent an efficient way to facilitate automatic recognition.
Please submit comments for:
automatic recognition based on diploma
automatic recognition based on acquired rights

Automatic recognition based on diploma is a simple procedure and a fast way to get a recognition.

Automatic recognition based on acquired rights is also a simple procedure and a fast way to get a recognition.

3. Is the general system (as described in article 10) applied in your country each time the conditions for automatic recognition are not met? Are there major difficulties in the recognition procedure under the general system? Please include any comments you may have on the implementation of compensation measures.

No experience.

4. What is your experience with the recognition procedure for EU citizens with professional qualifications obtained in a third country and already recognised in a first Member State (see Articles 2(2) and 3(3))?

No experience.

5. Do you accept applications from EU citizens for the recognition of foreign diplomas sent by email or requests made on line? Under which conditions can they send documents and declarations electronically? What are your experiences in this respect?

The Finnish National Supervisory Authority for Welfare and Health (Valvira) accepts only applications for the recognition of foreign diplomas that have been signed by the applicant. Valvira accepts only certified copies of diplomas and other official documents. No documents or declarations are accepted electronically.

6. What is the yearly number of applications for recognition from 2000 to 2009? Please submit specific data for applications for automatic recognition based on diplomas, automatic recognition based on acquired rights (as from 2005), and recognition based on the general system1.

The yearly number of positive decisions:

2000	5
2001	1
2002	2
2003	2
2004	3
2005	8
2006	5
2007	5
2008	4
2009	8

Negative decisions have not been made.

The information whether the decision has been based on automatic recognition (diplomas, acquired rights) or general system is not available.

B. Temporary mobility (of a self-employed or an employed worker)

7. Are EU citizens interested in using the provisions for exercising their professional activities on a temporary and occasional basis in your Member State? How many citizens used this new system since the directive has been transposed in your country (can you provide any statistics per month, per year) 2?

No experience.

8. How are the provisions of Directive 2005/36/EC concerning temporary mobility applied by the competent authorities in practice taking into account the relevant provisions of the Code of Conduct? For instance:

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[1] Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

[2] Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

How is the "legal establishment" criteria foreseen by Article 5(1) (a) interpreted in practice? What conditions does a migrant need to fulfil in his home Member State in order to be able to provide services?
How are the "temporary and occasional basis" criteria foreseen by Article 5.2 interpreted in practice? Do Member States assess duration, frequency, regularity and continuity of an activity and if so according to which criteria?

No experience.

9. Why is a prior declaration system necessary? What do competent authorities do with the information received? Are other possibilities conceivable?

It is important for patient safety reasons that the national supervisory authority is aware of who plans to practice in Finland.

10. Do you have concrete examples of abuse or misuse of this new possibility for pharmacists? Have you been confronted to problems with regards to patient safety on this issue?

No.

C Minimum training requirements

11. To what extent are the common minimum training requirements set out in Title III Chapter III of Directive 2005/36/EC and the compulsory training subjects as defined in Annex V in line with scientific progress and professional needs? Furthermore, are the knowledge and skills required by the directive still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

It has not come to Valviras knowlegde that the minimum training requirements would not be in line with the provisions of the Directive. The Ministry of Education and Culture is the competent authority when it comes to educational requirements.

12. To what extent are the common minimum requirements for training set out in Title III Chapter III of Directive 2005/36/EC in line with scientific progress and professional needs in the last ten years? Are the knowledge and skills outlined in Article 24.3 still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

See question number 11. The duration of training is appropriate.

13. The Directive is based on mutual trust between Member States. To what extent is such trust actually achieved? Are training programmes accredited in your country? Does accreditation of a training program in another Member State enhance trust or is it not relevant?

Valvira does not question the authenticity of proofs issued by other competent authorities according to Annex VII 2.

14. To what extent are the existing Directive provisions (see recital 39 and Article 22(b) on continuous professional development (continuous training) adequate? What is your definition of CPD/continuous training? Is continuous training mandatory in your country and what are the exact conditions?

Continuous professional development (continuous training) is mandatory in Finland. According to Section 18 of the Act on Health Care Professionals (559/1994) health care professionals must maintain and improve their professional knowledge and skills required to carry on their professional activity and familiarise themselves with the provisions and regulations concerning them. Employers of health care professionals shall create opportunities for participation in necessary further training for the profession.

D. Administrative cooperation (this section applies to establishment as to provision of services)

15. To which extent does administrative cooperation, as outlined in Articles 8, 50, and 56 of the Directive, simplify procedures for the migrant professionals? Can you give your own experience?

Active administrative cooperation is crucial for the functioning of the Directive. Administrative cooperation simplifies and quickens the procedure.

16. Is the competent authority in your country registered with IMI? Under which circumstances does your competent authority use IMI? If not registered, why not and what would be the conditions for changing this situation?

Valvira is registered with IMI. Valvira uses IMI whenever it needs clarifications from a competent authority concerning an application.

17. How could a professional card (see Recital 32 of the Directive) facilitate recognition of professional qualifications and provision of temporary services? Under which conditions could it be issued by a competent authority?

A professional card can only work if the competent authority could be sure that the information on the card is reliable and up to date.

18 . How do you share information about suspensions/restrictions with competent authorities in other Member States? Could more be done in this respect?

Valvira shares information about suspensions/restrictions with the competent authorities of the other Nordic countries.

E. Other observations

19. How and when are the necessary language skills of migrants checked after recognition of the professional qualifications? Are you aware of any complaints (especially from patients/clients/employers) about insufficient language skills of migrants?

According to the Act on Health Care Professionals health care professionals must have the language skills required for the performance of their duties. The official languages of Finland are Finnish and Swedish. Citizens EU/EEA countries are not required to provide evidence of their knowledge of Finnish or Swedish for the Valvira. However, employers may require a language certificate as a proof of language skills.

20. Please fill free to add any comment you want on the directive 2005/36/EC

SWEDEN

Evaluating the Professional Qualifications Directive
Experience reports from competent authorities

QUESTIONNAIRE FOR PHARMACISTS

A. RECOGNITION PROCEDURE IN CASE OF MIGRATION ON A PERMANENT BASIS

1. Please describe the government structure of the competent authority or authorities in charge of the recognition and of sanctions/restriction to practice.

   The National Board of Health and Welfare (Socialstyrelsen) is an authority under the Ministry of Health and Social Affairs. The Board is responsible for the recognition and supervision of all regulated health care professionals in Sweden. The Medical Responsibility Board (HSAN) is in charge of restriction to practice.

2. To what extent have the system of automatic recognition and the general system been a success? How do you see the costs and benefits for patients and for your organisation? Can you give concrete examples. Specify in particular whether automatic recognition based on diploma, Annex V and the current notification system represent an efficient way to facilitate automatic recognition.

Please submit comments for:

- automatic recognition based on diploma

  When the applicant has the qualification listed in Annex V and the training began after the reference date the recognition process is quick and cost-effective.

  The information in Annex V is not always up to date. The process of recognition could be quicker if the Annex was updated more frequently. It would also be useful to include historical information, including the denomination of the documents that have been issued in the past and when they have been issued.

- automatic recognition based on acquired rights

  In some cases we have received certificates stating that the applicant has been working in the Member State of origin when the CV shows that the applicant has been residing in Sweden during that time.

  We have also experienced difficulties in certifying professional experience in Sweden since the applicants sometimes do not provide us with the relevant documentation.

3. Is the general system (as described in article 10) applied in your country each time the conditions for automatic recognition are not met? Are there major difficulties in the recognition procedure under the general system? Please include any comments you may have on the implementation of compensation measures.

The general system has never been used regarding pharmacists. It would be applied if the conditions for automatic recognition are not met.

4. What is your experience with the recognition procedure for EU citizens with professional qualifications obtained in a third country and already recognised in a first Member State (see Articles 2(2) and 3(3))?

   When the professional qualifications obtained in a third country are recognised in a Member State they are automatically recognized in Sweden, thus the three years of experience is not mandatory.

   We have experienced difficulties in certifying professional experience in Sweden since the applicants sometimes do not provide us with the relevant documentation.

5. Do you accept applications from EU citizens for the recognition of foreign diplomas sent by email or requests made on line? Under which conditions can they send documents and declarations electronically? What are your experiences in this respect?

   We accept applications sent by email, but most applicants send in an application form by post. We demand that certified copies of diplomas and other official documents are sent in by post.

6. What is the yearly number of applications for recognition from 2000 to 2009? Please submit specific data for applications for automatic recognition based on diplomas, automatic recognition based on acquired rights (as from 2005), and recognition based on the general system[1].

   Yearly number of applications with positive decisions 2003-2009

2003	2004	2005	2006	2007	2008	2009
14	16	10	11	7	16	17

   In 2009 there were 2 negative decisions.

   We can at present not submit specific data for applications for automatic recognition based on diplomas, automatic recognition based on acquired rights and recognition based on the general system.

[1] Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

B. TEMPORARY MOBILITY (OF A SELF-EMPLOYED OR AN EMPLOYED WORKER)

7. Are EU citizens interested in using the provisions for exercising their professional activities on a temporary and occasional basis in your Member State? How many citizens used this new system in 2008 and 2009 (per month, per year) [2]?

   No one has yet used this system. We believe that they instead apply for permanent recognition. There might also be persons exercising their professional activities on a temporary and occasional basis in Sweden that are unaware of the procedure or for other reasons refrain from informing The National Board of Health and Welfare.

8. How are the provisions of Directive 2005/36/EC concerning temporary mobility applied by the competent authorities in practice taking into account the relevant provisions of the Code of Conduct? For instance:

   - How is the "legal establishment" criteria foreseen by Article 5(1) (a) interpreted in practice? What conditions does a migrant need to fulfil in his home Member State in order to be able to provide services?

   We do not have any practise since no one has used the provisions. In the regulation incorporating the provisions it is stated that the applicant has to meet all the conditions for practising that profession in the host Member State and is not prohibited from practising that profession.

   - How are the "temporary and occasional basis" criteria foreseen by Article 5.2 interpreted in practice? Do Member States assess duration, frequency, regularity and continuity of an activity and if so according to which criteria?

9. Why is a prior declaration system necessary? What do competent authorities do with the information received? Are other possibilities conceivable?

   To ensure patient safety it is important for the supervisory authority to know when health care professionals are exercising professional activities in Sweden.

10. Do you have concrete examples of abuse or misuse of this new possibility for pharmacists? Have you been confronted to problems with regards to patient safety on this issue?

    We do not have any experience of abuse or misuse of these provisions.

C MINIMUM TRAINING REQUIREMENTS

11. To what extent are the common minimum training requirements set out in Title III Chapter III of Directive 2005/36/EC and the compulsory training subjects as defined in Annex V in line with scientific progress and professional needs? Furthermore, are the knowledge and skills required by the directive still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

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[2] Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

It has not come to the attention of The National Board of Health and Welfare that the minimum training requirement would not be in line with scientific progress and professional needs.

12. The Directive is based on mutual trust between Member States. To what extent is such trust actually achieved? Are training programmes accredited in your country? Does accreditation of a training program in another Member State enhance trust or is it not relevant?

Mutual trust is achieved when competent authorities correctly implement the directive. Misinterpretation of the directive and wrongly issued certificates can harm bilateral trust.

Training programmes are not formally accredited in Sweden, but they must follow nationally regulated curricula, supervised by the Swedish National Agency for Higher Education. There are also regulations stating the responsibility of every caregiver to secure that all their employees have adequate competence and training. Those regulations are supervised by the National Board of Health and Welfare. The high specialization of health-care and the various conditions in the different countries makes it necessary to have this local training. All newly employed health-care personnel should therefore get an introduction to secure that he or she is adequately skilled.

13. To what extent are the existing Directive provisions (see recital 39 and Article 22(b) on continuous professional development (continuous training) adequate? What is your definition of CPD/continuous training? Is continuous training mandatory in your country and what are the exact conditions?

All health-care personnel have a responsibility to maintain and improve their professional knowledge and skills required to carry out their profession. As stated under 13 it is also the responsibility of every caregiver to secure that all their employees have adequate competence and training.

D. ADMINISTRATIVE COOPERATION (THIS SECTION APPLIES TO ESTABLISHMENT AS TO PROVISION OF SERVICES)

14. To which extent does administrative cooperation, as outlined in Articles 8, 50, and 56 of the Directive, simplify procedures for the migrant professionals? Can you give your own experience?

Active administrative cooperation simplifies the procedure considerably. The process is quicker and simpler for the applicant as well as for the competent authority.

15. Is the competent authority in your country registered with IMI? Under which circumstances does your competent authority use IMI? If not registered, why not and what would be the conditions for changing this situation?

Yes the National Board of Health and Welfare is registered with IMI. We use it when we need clarification concerning an application. It is a useful tool to communicate with other competent authorities. However not all professions are included in the IMI system and

some competent authorities are not in the system. Registration with IMI should be mandatory and more widely used. IMI could be improved to be more user-friendly.

We would also welcome the introduction of an alert mechanism in the IMI system. The system could also be used to proactively share information about suspension/prohibition to pursuit the profession.

16. How could a professional card (see Recital 32 of the Directive) facilitate recognition of professional qualifications and provision of temporary services? Under which conditions could it be issued by a competent authority?

In order for a European card for health care professionals to work effectively the competent authorities must be sure that the information on the card is reliable and up to date. We believe that public registers, e.g. web-based searchable lists of authorisation/registrations and/or exchange of information via IMI would be better tools.

17. How do you share information about suspensions/restrictions with competent authorities in other Member States? Could more be done in this respect?

We believe that the administrative cooperation in this regard could be improved. At present we inform the Nordic countries when a registered health personnel has been suspended, disqualified or prohibited from practicing the profession.

E. OTHER OBSERVATIONS

18. How and when are the necessary language skills of migrants checked after recognition of the professional qualifications? Are you aware of any complaints (especially from patients/clients/employers) about insufficient language skills of migrants?

It is the employer that is responsible for checking the necessary language skills. We have gotten complaints from employers and patients regarding insufficient language skills.

In order to ensure patient safety we believe that it should be possible, when appropriate, to require minimum language skills as part of the recognition procedure regarding health care personnel.

19. Please fill free to add any comment you want on the directive 2005/36/EC

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UNITED KINGDOM

Evaluating the Professional Qualifications Directive
Experience reports from competent authorities

QUESTIONNAIRE FOR PHARMACISTS

The response which follows is provided by the Competent Authority for England, Scotland and Wales. A separate response will be provided by the Competent Authority for Northern Ireland, the Pharmaceutical Society of Northern Ireland.

A. RECOGNITION PROCEDURE IN CASE OF MIGRATION ON A PERMANENT BASIS

1. Please describe the government structure of the competent authority or authorities in charge of the recognition and of sanctions/restriction to practice.

The Royal Pharmaceutical Society of Great Britain (RPSGB) is currently the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians.

However the UK government is harmonizing the arrangements for the regulation of health professionals to ensure that regulation is independent and to avoid any conflict of interest created by combining regulation and professional leadership in one body. We are therefore setting up

- A new independent regulator - the General Pharmaceutical Council (GPhC) for pharmacists, pharmacy technicians and pharmacy premises in England, Scotland and Wales and
- A new professional body for pharmacy – the Royal Pharmaceutical Society (RPS).

The 2 new organisations should be in place from 27 September 2010 (subject to parliamentary process) and on that date the RPSGB's regulatory role will be transferred to the GPhC. From then on anyone (including EEA pharmacists) who wishes to practise as a pharmacist and use the restricted title 'pharmacist' in Great Britain must be registered with the GPhC. All pharmacists and pharmacy technicians currently on the RPSGB practising register will be automatically transferred to the GPhC register.

Further information on the GPhC can be found at www.pharmacyregulation.org.

From the 27 September 2010 (subject to parliamentary process) the GPhC will be the competent authority for pharmacists and pharmacy technicians in Great Britain. The GPhC is a statutory corporation established under the Pharmacy Order 2010 (Statutory Instrument 2010/231) http://www.legislation.gov.uk/uksi/2010/231/contents/made .

The GPhC is governed by a Council of 14 members, including the Chair. The Council has equal numbers of lay and registrant members who are independently appointed.

2. **To what extent have the system of automatic recognition and the general system been a success? How do you see the costs and benefits for patients and for your organisation? Can you give concrete examples. Specify in particular whether automatic recognition based on diploma, Annex V and the current notification system represent an efficient way to facilitate automatic recognition.**

Please submit comments for:

- **automatic recognition based on diploma**

Automatic recognition is a success for EU applicants. It provides EU pharmacists with certainty that they are entitled to have their qualification recognised and, if there are no outstanding fitness to practise issues, they can be registered and permitted to practise. The application procedure is relatively inexpensive and if documents are submitted in the format required by our registration rules registration can be completed in about a month from initial enquiry.

However following A10 and A2 accession many applicants from these Member States assumed that as they held a qualification which was now listed in the Directive (initially in the Annex to Directive 85/433/EC) they had rights to automatic recognition irrespective of the fact that in most cases their qualification had not been awarded in accordance with the Directive minimum training requirements (MTR).

From a patient safety perspective automatic recognition based on diploma compliance with the MTR takes no account of whether an applicant has maintained their professional competence since qualification or of the steps they have taken to keep their knowledge and skills up-to-date. An EU national with a qualification listed in the Annex and started after 1 October 1987 reference date and awarded in 1992 for example, which complies with the MTR of Article 44 is entitled to automatic recognition of that qualification and registration (provided they satisfy health and character requirements) even though they may have not practised at all in their home or any other Member State since qualification. In the interests of patient safety such individuals following recognition that they do hold a qualification which entitles them to automatic recognition should also be required to satisfy the national competent authority's 'return to practice' requirements before being granted registration and a licence to practise in exactly the same way as a UK qualified person who had completed a degree in 1992 and had not practised as a pharmacist since qualification would have to do.

We would strongly recommend that any review of the Directive addresses this patient safety issue and that it is reviewed in accordance with statements contained in current recitals 3 and 44.

- **automatic recognition based on acquired rights**

In the case of EU applicants relying on automatic recognition based on acquired rights there is some assurance of current professional competence as such applicants must have worked as pharmacists for at least 3 consecutive years in the last 5 years. Difficulties however arise when applicants who had practised in the past in a MS but had stopped over 2 or more years ago, attempt to rely on acquired rights certificates which have been issued by their

Competent Authority many months or even years earlier. Such certificates although correctly attesting to the fact that the applicant has indeed practised as a pharmacist for 3 consecutive years in the last 5 years from the date of issue of the certificate as required by the Directive do not attest that the applicant has at least 3 consecutive years of practice within the 5 years preceding the date of request for recognition in a host MS.

We would strongly recommend that consideration be given in the review to limiting the validity of an 'acquired rights' certificate and stipulating that such certificates should be no more than 3 months old by the date on which they are submitted to the regulator. This will bring the validity of acquired rights certificates in line with the requirements for certificates attesting to an applicant's health and good character as provided for in Article 50(1).

- **Recognition based on general systems**

This involves a comparison of an applicant's pharmacy qualifications, including CPD and work experience against the current UK requirements for registration. This comparative assessment is undertaken by expert assessors who are either academics or senior pharmacy practitioners. This process is more costly for the applicant as they need to provide us with details of the curriculum for each pharmacy qualification studied together with details of their work experience and evidence of any CPD completed which they wish the assessors to consider. Applicants must also pay a fee to cover the cost of the comparative assessment. This is set in our fees rules and is currently in the order of £360. The fee is set on a 'cost recovery basis'.

This route to registration is also more resource intensive for us as the competent authority. Each comparative assessment is completed by two expert independent assessors. One assessor must be an academic currently involved in undergraduate teaching of prospective pharmacy students on the UK Masters degree in Pharmacy (MPharm) course and the other must be a senior level pharmacy practitioner who must be in active pharmacy practice. The assessors compare the information provided by the applicant against the syllabus for the current MPharm degree, the performance standards which pre-registration pharmacy trainees must achieve during the period of in-service training and the syllabus of our registration assessment. If the comparative assessment of an applicant's qualification and work experience including any evidence submitted of the applicant's continuing professional development since first qualification reveals 'substantially different matters' then the applicant is required to complete a period of adaptation with assessments before re-applying to register. The adaption period is a period of paid employment under the supervision of a pharmacist tutor who provides training and assessment of the applicant's knowledge and competence in the areas identified as missing.

The benefits of this system are that it provides us with an assurance of an applicant's current knowledge and competence (as this has been compared against the current national requirements for registration) and also of their English language skills. Applicants would not be able to successfully complete the period of adaptation if they had insufficient English language skills to practise as a pharmacist in GB.

However as the comparison is against the current national requirements for registration, if an applicant has obtained their pharmacy qualification over 10 to 15 years ago and has no

recent practice in their home MS or evidence of any CPD, limiting the compensation measure to an adaptation period may be insufficient to bring their knowledge up to date. Such applicants may benefit from additional formal education and training together with a period of supervised work experience to ensure that they can satisfactorily address the shortfalls identified. A provision in a revised Directive to offer such applicants a period of structured additional education in the form of a return to practice course for example as well as a period of adaptation training with assessments would be beneficial.

3. **Is the general system (as described in article 10) applied in your country each time the conditions for automatic recognition are not met? Are there major difficulties in the recognition procedure under the general system? Please include any comments you may have on the implementation of compensation measures.**

No. The General System of recognition is only applied within the limits permitted by the Directive. For pharmacists this is within the parameters of Article 10(b) and 10(g). Applicants not entitled to automatic recognition and not covered by the General Systems provisions of 10(b) and 10(g) are considered under the provisions of the EU Treaty and ECJ jurisprudence.

For pharmacy technicians the General System of recognition would be applied in the majority of cases. The only situation where we would follow the EU Treaty and ECJ jurisprudence is where a pharmacy technician had a third country pharmacy technician qualification, that had been recognised for practice in a MS but had not worked as a pharmacy technician in the recognising MS for at least 3 years.

We have not experienced any major difficulties with the application of the recognition procedure under either the General System or EU Treaty and ECJ jurisprudence. Under both of these routes the application process requires the applicant to self-assess their qualifications/ knowledge/work experience/CPD against an assessment framework based on the current national requirements for registration and provide evidence to support their self assessment. The completed self-assessment and supporting evidence is then submitted to the assessors to evaluate – see answer to question 2.

For pharmacists, the GB implementing legislation of the General Systems process has applied the derogation from an applicant's ability to choose between an aptitude test or a period of adaptation with assessments. Where the comparative assessment reveals 'substantially different matters' a period of adaptation with assessments is required. The adaptation period must be completed in either hospital or community pharmacy at pharmacy premises which have been approved by us as suitable training premises and under the supervision of a registered pharmacist who has likewise been approved by us as a tutor.
Following the comparative assessment applicants are provided with a Notice of Decision which informs applicants of the following:

- The topics where substantial differences have been identified from the national requirements for registration
- The length of adaptation period with assessments that the assessors consider appropriate to address the gaps identified
- The learning resources available to applicants and how these can be accessed
- How to apply to complete the adaptation period

- How to apply to register once the adaptation period has been successfully completed
- How to appeal to the Registration Appeals Committee (RAC) if the applicant disagrees with the assessors' decision.

To date the Registration Appeals Committee has only heard one appeal from a European qualified pharmacist. The applicant was a Spanish national with a Spanish pharmacy qualification started in October 1986 and completed in 1992. The qualification did not include the 6 month period of in-service training and the applicant only had a total of 2 years work experience as a pharmacist in Spain over a period of 17 years. Following the comparative assessment the assessors recommended a minimum 12 month period of adaptation. The applicant appealed this decision but his appeal was dismissed. The full decision of the Registration Appeals Committee is available on the Society's website at http://www.rpsgb.org/pdfs/ftpracdet0907pallares.pdf

As stated in response to question 2 we do have concerns that certain applicants who possess old qualifications and no recent work experience would benefit from a formal return to practice course in addition to an adaptation period.

4. What is your experience with the recognition procedure for EU citizens with professional qualifications obtained in a third country and already recognised in a first Member State (see Articles 2(2) and 3(3))?

From our experience applicants tend to choose to obtain first recognition in a Member State (MS) where recognition of their third country qualification is easier to obtain. Each year we receive a number of applications from individuals with third country pharmacy qualifications who, having obtained recognition of their qualification in another MS, immediately apply for recognition and registration with us with no or very limited work experience in the recognising MS. Having acquired a Community element their application falls under the comparative assessment route to registration as opposed to our standard registration route for internationally qualified pharmacists. The standard registration route for internationally qualified pharmacists is completion of a one year Overseas Pharmacists Assessment Programme (OSPAP), successful completion of 12 months pre-registration training and a pass of a registration examination conducted by us. A recent example is an EU national with a third country qualification who applied to register with us as the MS of first recognition. As this was first recognition we required the applicant to complete the standard international route to registration. Unfortunately the applicant failed to pass the OSPAP and also failed all available re-sit attempts. The individual then applied for first recognition in another MS following which they immediately enquired about registration with us as an EU national with EU Treaty rights.

We are also seeing an increasing number of enquiries from EU nationals with qualifications obtained from countries such as Moldova or Croatia. These individuals obtain recognition of their qualification in an adjacent MS to their country of qualification and then apply to us for registration on the basis of that recognition. Some applicants are under the mistaken belief that recognition gives them automatic rights to registration with us, others assume that without any work experience as a pharmacist in the recognising MS they are entitled to a

comparative assessment of their qualification in accordance with the General Systems provisions.

5. **Do you accept applications from EU citizens for the recognition of foreign diplomas sent by email or requests made on line? Under which conditions can they send documents and declarations electronically? What are your experiences in this respect?**

We accept requests for information from applicants via e-mail and provide applicants with electronic versions of our application packs. Our registration procedures require Competent Authorities and Professional Associations to submit relevant certificates of compliance/acquired rights and certificates of current professional status (formerly known as certificates of good standing) on behalf of applicants directly to us. We accept these documents electronically if sent to our dedicated e-mail address.
Applicants can provide documents in electronic format but our registration procedures do require us to have sight of either the original document or a solicitor/notary certified photocopy of the original document depending on the nature of the document concerned before we can complete their registration.
At present applicants cannot apply on-line. Processes are currently being reviewed and an on-line application facility is likely to be introduced in the near future. If such a facility is introduced our legislation and procedures would still require sight of original documents for purposes of verification of an applicant's identity, and qualifications before registration is granted.

6. **What is the yearly number of applications for recognition from 2000 to 2009? Please submit specific data for applications for automatic recognition based on diplomas, automatic recognition based on acquired rights (as from 2005), and recognition based on the general system[1].**

The information we have extracted from our records is provided in Annex A.

In the past we have not separated EEA pharmacists who register via compliance with the minimum training requirements from those registering in accordance with the acquired rights provisions.
Likewise currently we do not differentiate between EEA pharmacists registering under the General Systems provisions from those registering under the EU Treaty and ECJ jurisprudence.
The databases which support our register information will be updated in the next year or two and we will endeavour to ensure that this level of analysis will be available going forwards.

[1] Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

B. TEMPORARY MOBILITY (OF A SELF-EMPLOYED OR AN EMPLOYED WORKER)

7. Are EU citizens interested in using the provisions for exercising their professional activities on a temporary and occasional basis in your Member State? How many citizens used this new system since the directive has been transposed in your country (can you provide any statistics per month, per year) [2]?

We have only had 2 enquiries. Both of these individuals had pharmacy qualifications which did not entitle them to mutual automatic recognition of their qualification in accordance with Article 44 or Article 23. (Their applications fell under Article 10(b)). These enquirers appeared to be seeking to circumvent the comparative assessment route to the register contending that they should be permitted to provide services because they were legally established to practise in their home MS.
When we informed them that should they apply as temporary service providers we would wish to check their qualifications before the first provision of services (in accordance with Art 7(4)) and if a substantial difference was identified we would require them to pass an aptitude test before permitting them to provide services on a temporary and occasional basis both individuals made applications for establishment instead. Following the comparative assessment of their qualifications and successful completion of the required adaptation period both applicants have now registered as established practitioners.

8. How are the provisions of Directive 2005/36/EC concerning temporary mobility applied by the competent authorities in practice taking into account the relevant provisions of the Code of Conduct? For instance:

- **How is the "legal establishment" criteria foreseen by Article 5(1) (a) interpreted in practice? What conditions does a migrant need to fulfil in his home Member State in order to be able to provide services?**

As stated above we have only had 2 enquiries and no substantive applications.

We do however have the following concerns:

- <u>The Interpretation of 'legal establishment'</u>

'Legal establishment' for the sectoral professions appears to be interpreted as the right to practise in the home MS without the need for evidence that the individual does indeed practise – ie evidence of a subsisting contract for services or contract of employment. Legislation must provide for a clearer definition of what is meant by the practitioner being 'legally established'. Our view is that it should be more than being qualified to practise with no prohibition from practice (even temporarily).

We also do not believe that the Directive provisions relating to the applicant being 'legally established' in a Member State are sufficiently robust to protect members of the public and patients. The Directive only requires the applicant to demonstrate that they are 'legally

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[2] Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

established' in a MS for the practice of their profession. Persons wishing to avoid disciplinary proceedings or who have been removed from practice in one MS may move from one jurisdiction to another, continuing to rely on 'legal establishment' in a MS which maybe unaware of any fitness to practise allegations or history of such proceedings in other MSs. As a 'risk-based' regulator, we see this as an area where any person wishing to circumvent reasonable regulatory process may target.
Furthermore the Directive only requires the person to be legally established for the purpose of pursuing the 'activities concerned'. It provides no safeguards in cases of dually qualified persons in circumstances for example where a practitioner who is dually qualified as a doctor and pharmacist, and who has been prohibited from practising as a doctor in his home MS nevertheless relies on establishment in a MS as a pharmacist to continue to provide services as a pharmacist in other MSs.

- <u>The restricted nature of the fitness to practise checks we can undertake</u>

We remain concerned that we cannot require prospective temporary service providers to complete the same fitness to practise declarations prior to registration as we require of national or European registrants applying to either join the Register or to renew their registration annually.

A recipient of services from a temporary service provider would expect us, as the regulator, to subject a temporary service provider to the same level of fitness to practise scrutiny as we apply to other prospective registrants before permitting them to provide services here. This unfortunately is not the case. A prospective temporary service provider's right to provide services outside their home MS is determined by the fitness to practise regime in the home MS, not that of the host MS where services are to be provided.

- <u>The national legislation implementing temporary service provisions</u>

National legislation implementing the Directive provisions on temporary service provision gives persons the right to provide services from the date we receive their declaration and supporting documents. If the applicant's qualification/work experience satisfies either Article 44 or Article 23 then their registration is automatic and effective for one calendar year from the date of receipt of the declaration and supporting documents. Implementing legislation does not permit verification of the documents or even checking that a right to provide services does indeed exist prior to registration with us.

The provisions described in Articles 6 and 7 of the Directive appear to address the concerns raised by the ECJ case of Corsten C58/98.

The Directive appears to acknowledge that a 2 stage process can exist for the authorisation of temporary service provision in a host MS.

- Stage 1

An application by the prospective visiting EEA practitioner to a Competent Authority, the 'recognition' body with the declaration and supporting documents (Article 7) which must be authenticated and checked by the Competent Authority.

Followed by

- Stage 2

The sending of the declaration and supporting documents by the Competent Authority (once all administrative checks are completed) to the professional organisation for the purposes of registration (Article 6). It is this process which according to the Directive should not delay or complicate in any way the provision of services nor entail any additional costs for the service provider

It is our view that in the UK context, regulators as both the competent authority for recognition and registration/authorisation must be able to administratively check the declaration and documents provided. There would appear to be no point in requiring a declaration and documents or providing for co-operation between Competent Authorities if it was not envisaged that the documents submitted by a prospective temporary service provider would be checked by the Competent Authority in the host MS.
Only once the declaration and supporting documents had been verified would authorisation by virtue of registration be automatic.

It would be very helpful if in a review of the Directive the role of the Competent Authority charged with recognition could be clarified.

- **How are the "temporary and occasional basis" criteria foreseen by Article 5.2 interpreted in practice? Do Member States assess duration, frequency, regularity and continuity of an activity and if so according to which criteria?**

We have no experience of this in practice as we have not received or processed any declarations.
We have however produced draft 'Frequently asked Questions' in preparation for enquiries. In this we propose assessing the 'temporary and occasional' nature of service provision within the first year of authorisation to provide such services.

9. Why is a prior declaration system necessary? What do competent authorities do with the information received? Are other possibilities conceivable?

The professions of pharmacist and pharmacy technician are regulated professions with public health and safety implications. A prior declaration system is necessary because as a regulator we need to be aware of persons who intend to provide temporary and occasional services before they start to do so.
Prior notification will enable us to verify their identity and qualification and if they are not entitled to automatic recognition there can be a prior check of their qualifications before the first provision of services is permitted in the interests of public and patient safety.

Under our legislation before anyone can call themselves a pharmacist or practise as a pharmacist they must be registered with us. A prior declaration is necessary so that we can ensure that only eligible individuals are placed on the register before they can provide a service.

10. Do you have concrete examples of abuse or misuse of this new possibility for pharmacists? Have you been confronted to problems with regards to patient safety on this issue?

We have very little experience other than that described in our response to question 8.

C MINIMUM TRAINING REQUIREMENTS

11. To what extent are the common minimum training requirements set out in Title III Chapter III of Directive 2005/36/EC and the compulsory training subjects as defined in Annex V in line with scientific progress and professional needs? Furthermore, are the knowledge and skills required by the directive still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

Compulsory Training Subjects

The knowledge and skills in the Directive represent part of the scientific basis of the discipline but do not adequately reflect the current state of pharmacy as a clinical, healthcare profession in the UK. In summary, we would argue that the full basis of the discipline would be:

- Practise safely & effectively
- Practise ethically and lawfully
- Understand and apply biomedical and pharmaceutical science principles, method and knowledge (covered in the Directive)
- Understand and apply psychological and social principles, method and knowledge
- Understand and apply population and improvement science principles, method and knowledge

Annex V is a reflection of the restricted scope of pharmacy described in Title III Chapter III. The list in the Annex is an elaboration of biomedical and pharmaceutical science but little else. The UK's new education standards have addressed the broad base of pharmacy by designing a syllabus in three parts: 1. How medicines work, 2. How people work and 3. How systems work. Added to this are core/transferable skills and attitudes & values. The attitudes & values shape the professional use of the knowledge & skills base and the core/transferable skills provide the flexibility for pharmacists to work in a variety of contexts.

In addition, pharmacists in the UK work frequently in inter-professional teams with doctors, nurses, pharmacy technicians and others. Inter-professional learning is, therefore, compulsory in initial education and training from 2011.

Conditions relating to the duration of training

The conditions do not reflect the *modus operandi* of a modern higher education system, certainly not one which has applied the principles of the Bologna Declaration. For example, duration is an imperfect proxy measure for achievement: a better one is learning outcomes, one of the axiomatic principles of Bologna. Rather than requiring four years of full-time

training, a more flexible alternative would be to require four years of full-time training or a minimum of 4800 hours of study. (1200 hrs equates to one year of full time study in the UK.) This would allow other modes of delivery based on patterns of study other than the traditional undergraduate route. Not all pharmacy students are 18-19-year-old post-compulsory education students and not all pharmacy students need the traditional undergraduate experience (especially those who may be graduates already).

If one applied the hours principle to the whole five years of the minimum training the result would be:

> Five years or 6000 hours of initial education and training, including a six-month traineeship in a pharmacy which is open to the public or in a hospital, under the supervision of that hospital's pharmaceutical department. The six-month traineeship should be positioned towards the end of the five years.

This liberalisation is not a threat to the integrity of the discipline and using learning outcomes to define competence would ensure that whatever pattern of delivery is used, students would be fit to enter the workforce at the end of their minimum training period (subject to fitness to practise and health checks). The sheer spread of knowledge and skills necessary to be a pharmacist means that a liberalisation of conditions would not lessen the amount of work a student would have to do. As an example of how liberalisation might assist with flexibility of delivery, the UK undergraduate model is helpful. The basic pattern is three terms with an extended Easter break and a very long Summer break. If the Easter break was shortened and the Summer break was reduced from three-four months to three weeks, what is now taught in four academic years could be taught in three calendar years. This would not reduce contact time at all but the pattern of delivery would be better suited to some students. Both models could co-exist.

The caveat in this proposal is that education systems fully understand and have applied Bologna principles. Specifically, this means that education is credit rated, properly quantified and based on learning outcomes.

12. To what extent are the common minimum requirements for training set out in Title III Chapter III of Directive 2005/36/EC in line with scientific progress and professional needs in the last ten years? Are the knowledge and skills outlined in Article 44.3 still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

These points have been covered in the previous answer.

13. The Directive is based on mutual trust between Member States. To what extent is such trust actually achieved? Are training programmes accredited in your country? Does accreditation of a training program in another Member State enhance trust or is it not relevant?

The trust has to based on member states accepting the Directive as being legally binding, which the UK does. Trust is achieved by accepting that documents provided by member states are correct and querying them when there appears to be a discrepancy or if

something is unclear. If a member state is a signatory, we trust it will act in accordance with the Directive.

Accreditation is relevant to quality assurance in a given jurisdiction but does not form part of our recognition process.

Linking this question and the following one, we would be interested to explore how CPD could be integrated into the minimum training requirement and how it could form part of the mutual recognition process. Article 22(b) is appropriately worded but we are unsure how it could be checked. Being able to reassure ourselves that all EEA applicants had undertaken continuing education (or CPD) that enabled them to 'keep abreast of professional developments to the extent necessary to maintain safe and effective practice' would be just as valuable (perhaps more valuable in some cases) than checking an applicant had a compliant qualification.

14. To what extent are the existing Directive provisions (see recital 39 and Article 22(b) on continuous professional development (continuous training) adequate? What is your definition of CPD/continuous training? Is continuous training mandatory in your country and what are the exact conditions?

Existing provisions

We challenge the basis of recital 39, which cites only 'technological change' and 'scientific progress' as the basis for ongoing training. Certainly, they are good reasons for ongoing training but equally significant ones are professional developments and societal needs. Indeed, for practising community and hospital pharmacists (the majority of pharmacists in the UK), societal needs and professional developments are far more likely to inform changes in practice directly than technological change and scientific progress.

Definitions

We use the term continuing professional development (CPD) in pharmacy regulation (as defined below) but in parts of the pharmacy profession – for example, hospital pharmacy – continuous training is also used. CPD is defined in our CPD document *Plan and Record*: 'CPD is a continual process of life long learning. It follows a cycle of four stages: reflection, planning, action and evaluation. It includes everything that a pharmacist or pharmacy technician learns which makes him or her better able to do his or her job'.

Conditions

Continuous training is not mandatory but CPD is. The conditions are:

- Nine entries per year. The entries comprise the CPD record
- Entries must reflect the context and scope of a registrant's practice
- Entries must comply with the good practice criteria for CPD recording
- Entries must record how they have contributed to the quality or development of a registrant's practice
- Records must be submitted to the regulator on request for assessment and feedback

We have chosen to require CPD not continuous training because in the UK context continuous training is more generic than CPD and an older model of development. Our position is that ongoing developmental needs should be self defining, within a general professional context defined by the regulator. CPD is based on scope of practice, which will vary between individuals. As patterns of employment are no longer delineated by sector alone, CPD has to be sufficiently flexible to accommodate a wide range of developmental needs.

D. ADMINISTRATIVE COOPERATION (THIS SECTION APPLIES TO ESTABLISHMENT AS TO PROVISION OF SERVICES)

15. To which extent does administrative cooperation, as outlined in Articles 8, 50, and 56 of the Directive, simplify procedures for the migrant professionals? Can you give your own experience?

In our experience the implementation of the Internal Market Information (IMI) system has improved administrative co-operation between ourselves and home MS Competent Authorities when EU nationals apply for recognition and registration with us.

We have however encountered a reticence by Competent Authorities and Professional Associations in home MS to disclose information concerning sanctions which they had previously applied to an applicant's right to practise under their jurisdiction. Competent authorities will very often only confirm the applicant's current status and the current absence of disciplinary proceedings or sanctions.

We have an example where we received a certificate from a professional association confirming the absence of any disciplinary history only to subsequently discover that the same professional authority had imposed a period of suspension from practice on the applicant. The suspension from practice was relatively recent. The matter of the suspension was raised with the Competent Authority responsible for issuing the applicant with an 'acquired rights' certificate. Following investigation of the matter the Competent Authority annulled the 'acquired rights' certificate as the applicant, in his application for the 'acquired rights' certificate, had failed to inform them of his earlier suspension. At present the applicant is continuing with his application under the General Systems provisions. When assessing the applicant's fitness to practise to register with us we took account of his failure to disclose to his home Competent Authority the period of suspension when applying for the 'acquired rights' certificate.

We believe it would assist administrative co-operation if in any future review of the Directive consistent terminology was used to describe the range of fitness to practise information which Competent Authorities should exchange.

Article 8 limits the information which can be exchanged between us and the Competent Authority in the Member State of establishment, to information concerning the legality of the service provider's establishment in a Member State, his good conduct and *'disciplinary matters or criminal sanctions of a professional nature'.*

Article 56 on the other hand states that Competent Authorities
'shall exchange information regarding disciplinary action or criminal sanctions taken or any other serious, specific circumstances which are likely to have consequences for the pursuit of activities under this Directive'.

Irrespective of whether an EU national applies to us to provide temporary or occasional services or for purposes of establishment the Directive should permit us to require full fitness to practise disclosure from the home MS. This should include a complete disciplinary history of current or historic sanctions imposed on the individual by the Competent/professional authority, any criminal sanctions imposed, (not just those limited to criminal sanctions of a professional nature) and matters relating to poor performance or health of the applicant.

Our new legislation requires all applicants to our register to request the regulatory authority in their home country to provide us with the following information:

- full details of any conditions to which the applicant's entry in a register or part of a register is subject and of any restrictions on the applicant's practice;
- full details of any fitness to practise matters in relation to the applicant including any warnings or advice given by, or undertakings agreed with, the relevant competent authority or authorities; and
- such other relevant information as the Registrar may reasonably request in relation to the applicant in the particular circumstances of the applicant's case.

On the application for registration form, applicants are also required to disclose if they have any problems with their mental or physical health that may impair their fitness to practise and whether or not they have any previous conviction or cautions in the British Islands or elsewhere.

In future, administrative co-operation between Competent Authorities may be enhanced by the activities of the Council for Healthcare Regulatory Excellence (CHRE) International Observatory on the Regulation of Health Professionals. This is a new initiative which is being established by CHRE, which oversees the work of the nine healthcare regulatory bodies in the UK, in collaboration with LSE Health, an academic research centre of the London School of Economics. The Observatory, which will formally launch in early 2011, aims to support regulatory improvement around the world and to develop a central store of information on how health professionals are regulated in different countries and enable cross-country learning. Improved understanding of our individual regulatory processes can enhance mutual trust and co-operation.

16. Is the competent authority in your country registered with IMI? Under which circumstances does your competent authority use IMI? If not registered, why not and what would be the conditions for changing this situation?

Yes, the RPSGB is registered as the Competent Authority for pharmacists with IMI. We are making the necessary arrangements to ensure that the GPhC will be registered with IMI as the Competent Authority for pharmacists and pharmacy technicians from 27 September 2010 onwards.

We currently use IMI to check with the relevant home Competent Authority if we have any queries with applications for initial recognition and registration only. It would be very helpful if use of IMI were made mandatory and its use extended to enable us to utilise it for exchange of documents between Competent Authorities and for both reactive and proactive information exchange on Fitness to Practise matters from the time that an EU national first applies to register with us and throughout his registration with us and beyond if relevant.

17. How could a professional card (see Recital 32 of the Directive) facilitate recognition of professional qualifications and provision of temporary services? Under which conditions could it be issued by a competent authority?

Our legislation requires us to issue a notice of entry on the Register which states the registrant's name, their registration number, the part of the register in which they are entered and the validity of their entry.
Employers and members of the public should not rely on notices of entry (whether originals or copies) as confirmation that someone is registered with us, as all such a notice would tell them is that the person was registered on the date the notice was issued. The same would apply in relation to a professional card. The information would only be accurate at the time such a card was issued. To be sure that someone is currently registered and has no restrictions on their practice, it is necessary to check the online register on our website: www.pharmacyregulation.org/ (from 27 September 2010 parliamentary process permitting).

18. How do you share information about suspensions/restrictions with competent authorities in other Member States? Could more be done in this respect?

With the increasing movement of healthcare professionals around Europe there is clearly an increasing risk that some health practitioners may seek registration in other parts of Europe when they have been erased or suspended from the register or in order to avoid disciplinary action in their home country. The RPSGB is therefore a signatory of the Healthcare Professionals Crossing Borders: General Memorandum of Understanding Covering the Proactive and Case-by-Case Exchange of Disciplinary Information. We have also actively encouraged other European Pharmacy Competent Authorities to sign the memorandum in the interests of public and patient safety.
The agreement covers the exchange of information on healthcare professions crossing borders and was developed by competent authorities to ensure a common and effective approach to fulfil obligations resulting from Article 56 of the Directive. It introduces case-by-case and proactive information sharing in a form that will be acceptable to as many EU Competent Authorities as possible. It therefore describes a minimum level of information exchange. There is no requirement for MS to share information relating to matters under investigation or previous fitness to practise history.

How we share information

Information about outcomes of all public hearings of our Disciplinary Committee is available on the Disciplinary Committee page of our website. This information includes decisions regarding suspensions. Decisions imposing an interim suspension order or conditions on registration can be accessed via a search of the on-line register where there is a link to the decision against the relevant registrant's name on the register. This information and outcomes of any Health Committee hearings (which are usually held in private) are also provided to the relevant international regulator if our registration records indicate that the individual had been previously registered in another country before applying to register with us.

Pharmacists currently registered in Great Britain who wish to apply for registration to practise in another country will normally require us to send a Certificate of Current Professional Status and Fitness to Practise History (CCPS) (formerly known as a 'Letter of Good Standing') to the relevant registration and/or regulatory authority in the jurisdiction in which they intend to practise.

The information in the CCPS is extracted from the Society's Register and its fitness to practise files. Therefore, the CCPS may include information which is not in the public domain.

The CCPS will include details of the registrant's full name, registered address, date of birth, details of their pharmacy education, current registration status and concluded and outstanding fitness to practise matters

If a registrant has previously been the subject of a fitness to practise allegation(s) a summary of the case(s) and the outcome of the investigation or hearing will be disclosed in the CCPS. If at the time of the application for a CCPS, the registrant is subject to an ongoing investigation by us or has had an allegation referred to either the Investigating Committee or Disciplinary/Health Committee a summary of the outstanding matters (s) will also be provided in the CCPS.

E. OTHER OBSERVATIONS

19. How and when are the necessary language skills of migrants checked after recognition of the professional qualifications? Are you aware of any complaints (especially from patients/clients/employers) about insufficient language skills of migrants?

As the number of healthcare professionals choosing to work in other European countries (from that in which they qualified) increases it is necessary that regulators efficiently manage the registration process in accordance with domestic and EC law. Regulators also need to be assured that the professionals they register are fit to practise and will not put patient safety at risk.

From a patient perspective communication is key to building trust in the patient-practitioner relationship. It also goes without saying that clinical information and advice must be communicated clearly and accurately to patients.

We accept that language competency is not a relevant consideration when determining whether an applicant holds a qualification which entitles them to mutual automatic recognition because, for example, the qualification complies with the minimum training requirements and is listed in the Directive. (The 'recognition stage' of an application).

Similarly, the standard of an applicant's language competency is not a factor to be considered when comparing an applicant's qualification with the national requirements for registration under the General System of recognition to ascertain whether compensation measures such as an aptitude test or a period of adaptation training with assessment(s) is required prior to registration.

However once we are satisfied that the applicant holds a qualification which complies with the requirements of the Directive (or following completion of any compensation measure) an applicant will move to the second stage – the registration stage.

According to Article 53 of the Directive such an applicant would have benefited from the recognition of professional qualifications and *'shall have knowledge of languages necessary for practising the profession in the host Member State'.*

We are therefore firmly of the view that following recognition but prior to registration, we should be able to require applicants to provide evidence of their language competency necessary for safe and effective practice in the UK in an appropriate and proportionate manner. It would be very helpful if a review of the Directive could clarify the role of the host Competent Authority in determining an EU healthcare practitioner's competency in the host MS language following recognition of their professional qualification but before authorisation to practise.

We currently have a prohibition in our governing legislation that prevents us requiring 'exempt persons' (i.e. EEA nationals) from meeting any requirements to demonstrate that they have reached an adequate standard of proficiency in the knowledge and use of English. This provision does not however apply to non-EEA Nationals.

Current Department of Health (DH) policy is that it is the responsibility of employers to ensure that the persons they employ have the necessary language and communication skills. However a particular issue of concern for us is that many pharmacists work as self-employed locums and do not have 'employers' as such.

To determine the extent of language testing by employers of EEA qualified pharmacists we administered an employer survey during May and June 2009.

The survey was completed by 162 employers. (A further 81 employers indicated that the survey had not been completed as they had not employed any EEA qualified pharmacists). 63% of 162 employers reported that they do not routinely check the language competency of European applicants and nearly 40% reported having encountered problems that were potentially related to the language proficiency of employees. The survey results were reported in the Pharmaceutical Journal. Please see:

http://www.pjonline.com/news/communication_is_key
http://www.pjonline.com/news/english_language_skills_european_pharmacists

We have also conducted a review of our recent fitness to practise cases and have identified two cases that demonstrate our inability to prevent a lack of English language proficiency posing a risk to patients. These are summarised below. (A more comprehensive review of fitness to practise records has not been possible within existing resources because of the difficulty of identifying historical cases which may have included language deficiency as an allegation).

Case 1

In October 2004 Mr Y was given a reprimand by the Society's Statutory Committee for acting as a Superintendent Pharmacist (SI) in circumstances where he was not sufficiently competent in the use and understanding of English and his failure to understand the responsibilities of a SI pharmacist and/or those of a pharmacist providing professional services and/or to discharge them. (It was alleged in the case that there were also three other pharmacists that worked in the pharmacy from time to time while Mr Y was the SI and none of them were competent in English. Furthermore, when the Inspector visited the premises Mr Y had difficulty in understanding English and he required an interpreter during subsequent interviews. Arabic was also found handwritten on boxes of medication).

The Committee however required undertakings from him. One of them was:

Within 3 years to demonstrate that he had attained a standard of English such that he can undertake the role of SI, such standard to Level 6 of IELTS or equivalent.

On 22 August 2007, the Society's inspector visited Pharmacy Y Ltd and purchased a P medicine from Mr Y when no SI was appointed for the company. At an interview under caution on 23 August 2007 Mr Y admitted that he did not have an SI on 22 August 2007. At that interview Mr Y produced a copy of an IELTS certificate to the inspector as evidence that he had attained level 6 following a test on 8 July 2007. It was suspected that the certificate had been falsified and the police were notified.

At a further interview under caution on 27 November 2007 Mr Y produced the 'original' of the IELTS certificate for 8 July 2007. Full investigations were undertaken and it was discovered that it was indeed a forgery. The time for obtaining IELTS level 6 pursuant to the Committee's undertakings expired on 19 October 2007 without any further (genuine) certificate being submitted.

Mr Y has subsequently been prosecuted by the CPS and he had a trial at the Crown Court as he pleaded not guilty to the count of fraud. He defence was that he did not know the document was a forgery. The jury rejected his account and convicted him.

Mr Y is due back before the Disciplinary Committee for the substantive hearing to take place for the fraud allegation in the near future.

Case 2

The case of Mr M concerns allegations of a number of dispensing errors and of a lack of competency in the English language. The case has only recently concluded with the Disciplinary Committee directing Mr M's removal from the Register of Pharmacists. The language allegations were that he accepted employment as a locum pharmacist at three pharmacies when he did not have the requisite skills and fitness for the task to be performed, contrary to part 2A1(a) of the code, in that he lacked sufficient competency in the English language. The evidence of lack of competency was provided by his colleagues and one patient; one colleague said that, in her view, Mr. M had difficulty in making himself understood, a patient said that Mr. M's command of English was not very good; another colleague said that Mr. M's English would be best described as broken, and there were gaps when he spoke while he appeared to think what he was going to say; another colleague said "I do not think that his English was very good. I sometimes found him difficult to understand".

There were however evidential difficulties in establishing that the registrant's command of English was so deficient that he was guilty of misconduct by virtue of having accepted locum work as a community pharmacist. The committee did not find any of the language allegations proved, on the ground that Mr M had been interviewed before being offered work and the interviewers had considered Mr M's English language skills to be sufficient.

20. Please fill free to add any comment you want on the directive 2005/36/EC

- Definition of activities which qualify for 'acquired rights'

Under the former Directives the activities which would enable a European pharmacist to benefit from acquired rights were clearly defined. According to Article 6 of Directive 85/433/EEC a person had to be *"effectively and lawfully engaged in one of the activities referred to in Article 1 (2) of Directive 85/432/EEC in a MS for at least 3 consecutive years preceding the award of the certificate provided that this activity is regulated in that State".*

Thus, in order for a competent authority to issue a certificate of acquired rights, the person concerned must have been effectively and lawfully engaged in one of the activities mentioned under Article 1 (2) of Directive 85/432/EEC:
- the preparation of the pharmaceutical form of medicinal products
- the manufacture and testing of medicinal products - the testing of medicinal products in a laboratory for medicinal products
- the storage, preservation and distribution of medicinal products at the wholesale stage
- the preparation, testing, storage and supply of medicinal products in pharmacies open to the public
- the preparation, testing, storage and dispensing of medicinal products in hospitals
- the provisions of information and advice on medicinal products

In Directive 2005/36/EC it is unclear what activities would qualify a European pharmacist to an acquired rights certificate.

For example in order to obtain an 'acquired rights' certificate under Article 23 (1) the European pharmacist must have been effectively and lawfully engaged in the 'activities in question' .

Whereas the special 'acquired rights provisions' relating to qualifications awarded by states which no longer exist such as the former Czechoslovakia in Article 23 (3) for example limits the qualifications to those giving access to and pursuit of the activities in Article 45(2) (previously Article 1(2) of Directive 85/432/EEC).

It would be very helpful if in any review it would be possible to clarify whether the 'activities in question' in both cases are limited to those listed in Article 45(2)?

- The derogation provided by Article 21(4)

The derogation provided by Article 21(4) has been implemented by sections 70 and 71 of the Medicines Act 1968. This places a prohibition on pharmacists registered by virtue of a qualification in pharmacy awarded in a relevant European State from being the responsible pharmacist of pharmacy premises that have been registered for less than three years in Great Britain. This is commonly referred to as the 'Three year Rule'.

We believe that the prohibition may have been inserted into national legislation in the 1980s for economic reasons rather than as a patient safety or public protection measure. The prohibition is not linked to the expertise and competence of the European pharmacist or the length of time that they have been registered with us and have worked in Great Britain but is instead linked to the date of registration of the premises. Therefore, irrespective of how long a European qualified pharmacist has been on our register they can never be the responsible pharmacist of pharmacy premises which have been on the register for less than 3 years.

This is demonstrated, and is particularly problematic, if a pharmacy relocates to a new premises sometimes even in the same street. A pharmacy, which has the same staff and serves the same population, is considered to be a new entity after the move. If the owner/ pharmacist, who may have been practising in the pharmacy for many years, has a European qualification then they are unable to work in the pharmacy as the responsible pharmacist after the move.

A review of the Directive would be an opportunity to determine whether this derogation should be continued.

Question 6 **Annex A**

Yearly number of applications for recognition from 2001* to 2009

Numbers of EEA Applicants Registered – automatic recognition based on diplomas and 'acquired rights' 2001 - 2009

MEMBER STATE	2001	2002	2003	2004	2005	2006	2007	2008	2009
AUSTRIA	0	0	1	0	3	2	3	0	3
BELGIUM	1	4	1	0	1	2	2	1	1
BULGARIA	nms	nms	nms	nms	nms	nms	3	16	28
CYPRUS	0	0	0	0	0	0	0	0	0
CZECH REPB	nms	nms	nms	nms	4	6	7	13	12
DENMARK	4	5	11	6	5	0	6	4	3
ESTONIA	nms	nms	nms	nms	0	3	2	3	4
FINLAND	1	1	1	3	0	2	0	2	0
FRANCE	11	14	12	6	3	5	7	9	7
GERMANY	19	30	36	27	17	23	16	12	20
GREECE	0	2	3	2	5	5	6	2	1
HUNGARY	nms	nms	nms	nms	2	11	2	13	17
ICELAND	1	0	0	0	0	2	1	1	1
IRELAND	2	4	8	3	19	20	1	7	4
ITALY	9	24	21	23	24	35	48	40	52
LATVIA	nms	nms	nms	nms	1	2	5	3	0
LIECHTENSTEIN	0	0	0	0	0	0	0	0	0
LITHUANIA	nms	nms	nms	nms	4	7	5	13	16
LUXEMBURG	0	0	0	0	0	0	0	0	0
MALTA	nms	nms	nms	nms	6	8	5	5	1
NETHERLANDS	3	3	2	5	0	2	2	3	1
NORWAY	2	5	0	1	1	0	0	1	0
POLAND	nms	nms	nms	nms	124	171	207	118	65
PORTUGAL	1	7	9	4	9	8	15	13	27
ROMANIA	nms	nms	nms	nms	nms	nms	6	26	30
SLOVAKIA	nms	nms	nms	nms	0	8	9	10	9
SLOVENIA	nms	nms	nms	nms	0	2	1	0	1
SPAIN	159	291	323	158	85	148	107	91	125
SWEDEN	4	13	13	9	14	25	5	6	7
SWITZERLAND	0	1	0	0	1	1	0	1	1
TOTAL	217	404	441	247	328	498	471	413	436

KEY:
nms - Not Member State
n/r - Not Recorded

* Unfortunately statistics for 2000 are not available

Numbers of EEA applicants for registration based on the General System/EU Treaty

2007 - Positive after adaptation - none

2008 - Positive after adaptation

Country of qualification	MS of first recognition	Number
Hungary		2
Lithuania		3
Poland		1
Slovak Republic		1
Spain		2
Total		**9**

2009 - Positive after adaptation

Country of qualification	MS of first recognition	Number
Czech Republic		1
Italy		1
Lithuania		3
Romania		2
Argentina	Spain	1
Iraq	Sweden	1
Australia	Ireland	1
Total		**10**

2009 - Undergoing adaptation

Country of qualification	MS of first recognition	Number
Czech Republic		1
Latvia		2
Hungary		1
Malta		1
Poland		2
Portugal		1
Romania		1
Argentina	Spain	1
Columbia	Spain	1
Venezuela	Spain	1
Total		**12**

2009 - Decision made to require adaptation period – but adaptation not started

Country of qualification	MS of first recognition	Number
Czech		1
Lithuania		1
Poland		1
Peru	Spain	1
Total		**4**

2009 - Being examined

Country of qualification	MS of first recognition	Number
Bulgaria		1
Italy		1
Malta		1
Lithuania		4
Poland		2
Romania		1
Spain		1
Argentina	Spain	2
Venezuela	Spain	1
Total		**14**

2009 - Appeal

Country of qualification	MS of first recognition	Number
Spain		1

Evaluating the Professional Qualifications Directive
Experience reports from competent authorities

PHARMACEUTICAL SOCIETY OF NORTHERN IRELAND

A. RECOGNITION PROCEDURE IN CASE OF MIGRATION ON A PERMANENT BASIS

1. Please describe the government structure of the competent authority or authorities in charge of the recognition and of sanctions/restriction to practice.

The Pharmaceutical Society of Northern Ireland is the regulatory and professional body for pharmacists in Northern Ireland. www.psni.org.uk

It protects public safety in pharmacy by:

- setting and promoting standards for pharmacists' admission to the register and for remaining on the register;
- maintaining a publicly accessible register of pharmacists, and pharmacy premises, in Northern Ireland;
- handling concerns about the Fitness to Practise of registrants, acting as a complaints portal and taking action to protect the public; and
- Ensuring high standards of education and training for pharmacists in Northern Ireland.

As the professional body it seeks to develop the pharmacy profession in Northern Ireland in the public interest.

2. To what extent have the system of automatic recognition and the general system been a success? How do you see the costs and benefits for patients and for your organisation? Can you give concrete examples. Specify in particular whether automatic recognition based on diploma, Annex V and the current notification system represent an efficient way to facilitate automatic recognition.

Please submit comments for:

- automatic recognition based on diploma
- automatic recognition based on acquired rights

We consider that the system of automatic recognition has been a success and has protected the public in the recognition of professionals moving within states.

In relation to automatic recognition it is also our view that any process needs to reflect both the diploma and Annex V. The requirement for 3/5 years within the acquired rights does insure in

some manner the competency of the professional to work in the same field of practise in transferring member state. This assurance is not evident in those registrants moving with diploma rights and therefore patient safety cannot be assured.

3. Is the general system (as described in article 10) applied in your country each time the conditions for automatic recognition are not met? Are there major difficulties in the recognition procedure under the general system? Please include any comments you may have on the implementation of compensation measures.

No there is not an automatic process the applicant must apply for consideration under the general system. Our experience of the General System is somewhat limited due to small numbers of applicants..

4. What is your experience with the recognition procedure for EU citizens with professional qualifications obtained in a third country and already recognised in a first Member State (see Articles 2(2) and 3(3))?

We have had no experience of this to date.

5. Do you accept applications from EU citizens for the recognition of foreign diplomas sent by email or requests made on line? Under which conditions can they send documents and declarations electronically? What are your experiences in this respect?

Applications can be made by email to prime the process and speed applications but cannot be made online as yet. The original documentation must be provided in full before any registration will be implemented

6. What is the yearly number of applications for recognition from 2000 to 2009? Please submit specific data for applications for automatic recognition based on diplomas, automatic recognition based on acquired rights (as from 2005), and recognition based on the general system[1].

year	diploma	acquired rights	general system
2000	1	0	0
2001	1	0	0
2002	0	0	0
2003	2	0	0
2004	3	0	0
2005	2	0	0
2006	3	0	0
2007	4	0	0
2008	2	0	0
2009	1	0	0

[1] Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

B. TEMPORARY MOBILITY (OF A SELF-EMPLOYED OR AN EMPLOYED WORKER)

7. Are EU citizens interested in using the provisions for exercising their professional activities on a temporary and occasional basis in your Member State? How many citizens used this new system since the directive has been transposed in your country (can you provide any statistics per month, per year) [2]?

Currently we have had no applications

8. How are the provisions of Directive 2005/36/EC concerning temporary mobility applied by the competent authorities in practice taking into account the relevant provisions of the Code of Conduct? For instance:

The legal enactment is legislated by **The European Qualifications (Pharmacy) Regulations (Northern Ireland) 2008 (No. 192)** We require that there is • an advance of service application to join the register of temporary service providers • a declaration of indemnity insurance • an annual declaration

- How is the "legal establishment" criteria foreseen by Article 5(1) (a) interpreted in practice? What conditions does a migrant need to fulfil in his home Member State in order to be able to provide services?

Legal establishment is not defined in specific criteria but would bee interpreted as the right to practise unrestricted in the home state

- How are the "temporary and occasional basis" criteria foreseen by Article 5.2 interpreted in practice? Do Member States assess duration, frequency, regularity and continuity of an activity and if so according to which criteria?

This will be assessed on a case by case basis

9. Why is a prior declaration system necessary? What do competent authorities do with the information received? Are other possibilities conceivable?

This is necessary to ensure public safety and provide clinical governance and accountability by practitioners not normally registered in the MS. We do not see any other options at this time

10. Do you have concrete examples of abuse or misuse of this new possibility for pharmacists? Have you been confronted to problems with regards to patient safety on this issue?

No evidence as we have had no applicants

[2] Please provide this information unless it has already been provided to the Commission in the Database or the implementation reports.

C MINIMUM TRAINING REQUIREMENTS

11. To what extent are the common minimum training requirements set out in Title III Chapter III of Directive 2005/36/EC and the compulsory training subjects as defined in Annex V in line with scientific progress and professional needs? Furthermore, are the knowledge and skills required by the directive still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

We would align our response to that of the Royal Pharmaceutical Society of Great Britain

Compulsory Training Subjects

The knowledge and skills in the Directive represent part of the scientific basis of the discipline but do not adequately reflect the current state of pharmacy as a clinical, healthcare profession in the UK. In summary, we would argue that the full basis of the discipline would be:

- Practise safely & effectively
- Practise ethically and lawfully
- Understand and apply biomedical and pharmaceutical science principles, method and knowledge (covered in the Directive)
- Understand and apply psychological and social principles, method and knowledge
- Understand and apply population and improvement science principles, method and knowledge

Annex V is a reflection of the restricted scope of pharmacy described in Title III Chapter III. The list in the Annex is an elaboration of biomedical and pharmaceutical science but little else. The UK's new education standards have addressed the broad base of pharmacy by designing a syllabus in three parts: 1. How medicines work, 2. How people work and 3. How systems work. Added to this are core/transferable skills and attitudes & values. The attitudes & values shape the professional use of the knowledge & skills base and the core/transferable skills provide the flexibility for pharmacists to work in a variety of contexts.

In addition, pharmacists in the UK work frequently in inter-professional teams with doctors, nurses, pharmacy technicians and others. Inter-professional learning is, therefore, compulsory in initial education and training from 2011.

Conditions relating to the duration of training

The conditions do not reflect the *modus operandi* of a modern higher education system, certainly not one which has applied the principles of the Bologna Declaration. For example, duration is an imperfect proxy measure for achievement: a better one is learning outcomes, one of the axiomatic principles of Bologna. Rather than requiring four years of full-time training, a more flexible alternative would be to require four years of full-time training or a minimum of 4800 hours of study. (1200 hrs equates to one year of full time study in the UK.) This would allow other modes of delivery based on patterns of study other than the traditional undergraduate route. Not all pharmacy students are 18-19-year-old post-compulsory education students and not all pharmacy students need the traditional undergraduate experience (especially those who may be graduates already).

If one applied the hours principle to the whole five years of the minimum training the result would be:

Five years or 6000 hours of initial education and training, including a six-month traineeship in a pharmacy which is open to the public or in a hospital, under the supervision of that hospital's pharmaceutical department. The six-month traineeship should be positioned towards the end of the five years.

This liberalisation is not a threat to the integrity of the discipline and using learning outcomes to define competence would ensure that whatever pattern of delivery is used, students would be fit to enter the workforce at the end of their minimum training period (subject to fitness to practise and health checks). The sheer spread of knowledge and skills necessary to be a pharmacist means that a liberalisation of conditions would not lessen the amount of work a student would have to do. As an example of how liberalisation might assist with flexibility of delivery, the UK undergraduate model is helpful. The basic pattern is three terms with an extended Easter break and a very long Summer break. If the Easter break was shortened and the Summer break was reduced from three-four months to three weeks, what is now taught in four academic years could be taught in three calendar years. This would not reduce contact time at all but the pattern of delivery would be better suited to some students. Both models could co-exist.

The caveat in this proposal is that education systems fully understand and have applied Bologna principles. Specifically, this means that education is credit rated, properly quantified and based on learning outcomes.

12. To what extent are the common minimum requirements for training set out in Title III Chapter III of Directive 2005/36/EC in line with scientific progress and professional needs in the last ten years? Are the knowledge and skills outlined in Article 24.3 still relevant and up to date? Please specify. What about the conditions relating to the duration of training?

See above

13. The Directive is based on mutual trust between Member States. To what extent is such trust actually achieved? Are training programmes accredited in your country? Does accreditation of a training program in another Member State enhance trust or is it not relevant?

There are good levels of trust exhibited in our experiences to date. Accreditation of training programmes is a positive influence in decision making

14. To what extent are the existing Directive provisions (see recital 39 and Article 22(b) on continuous professional development (continuous training) adequate? What is your definition of CPD/continuous training? Is continuous training mandatory in your country and what are the exact conditions?

CPD has been a professional requirement of pharmacists since 2005 in Northern Ireland.
Portfolios must be kept annually and record 30 hours of accredited CPD. Portfolios are randomly sampled by the regulator and assessed by a group of trained assessors. Portfolios which are sub standard will enter a process of remediation and re assessment of new cycles of evidence.
The legislation to make CPD mandatory in law and allow removal for non compliance is currently under construction and will be implemented in the coming months

D. ADMINISTRATIVE COOPERATION (THIS SECTION APPLIES TO ESTABLISHMENT AS TO PROVISION OF SERVICES)

15. To which extent does administrative cooperation, as outlined in Articles 8, 50, and 56 of the Directive, simplify procedures for the migrant professionals? Can you give your own experience?

Administrative cooperation is essential to allow certification of peripatetic practitioners within EEA

16. Is the competent authority in your country registered with IMI? Under which circumstances does your competent authority use IMI? If not registered, why not and what would be the conditions for changing this situation?

Our experience of IMI has been good and the Pharmaceutical Society of Northern Ireland is registered with IMI

17. How could a professional card (see Recital 32 of the Directive) facilitate recognition of professional qualifications and provision of temporary services? Under which conditions could it be issued by a competent authority?

Professional card have a limited validity as they can be easily reproduced and have a limited life. They may have some value if the technology can be developed to protect the information and link if in a way to the individual so that it cannot be misused by others
But allows a light touch verification by a competent authority

18. How do you share information about suspensions/restrictions with competent authorities in other Member States? Could more be done in this respect?

All fitness to practise proceedings and outcomes are on our website. We proactively supply information of fitness to practise on certificates of current professional status. We are a co signature to the health professionals crossing borders initiative.

E. OTHER OBSERVATIONS

19. How and when are the necessary language skills of migrants checked after recognition of the professional qualifications? Are you aware of any complaints (especially from patients/clients/employers) about insufficient language skills of migrants?

Language skills are checked by employers. It is a requirement of pharmacists contracted to provide NHS services in Northern Ireland to be competent in language this is employer led.

We have no evidence of language difficulties but have few non UK qualified registrants.

20. Please fill free to add any comment you want on the directive 2005/36/EC

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