COUNCIL DIRECTIVE

of 16 September 1985

concerning the coordination of provisions laid down by law, regulation or administrative action in respect of certain activities in the field of pharmacy

(85/432/EEC)

THE COUNCIL OF THE EUROPEAN

COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Articles 49 and 57 thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas persons who hold a diploma, certificate or other formal qualification in pharmacy are for that reason specialists in the field of medicinal products and, in principle, must have access in all the Member States to a minimum range of activities in that field; whereas, in defining that minimum range, this Directive does not have the effect of limiting the activities accessible in the Member States to pharmacists, in particular with regard to medical biology analyses, and does not give them any monopoly, since the creation of a monopoly continues to be a matter for the Member States alone;

Whereas, moreover, this Directive does not ensure coordination of all conditions of access to and pursuit of activities in the field of pharmacy; whereas, in particular, the geographical distribution of pharmacies and the monopoly of the supply of medicinal products continue to be matters for the Member States;

Whereas, with a view to achieving mutual recognition of diplomas, certificates and other evidence of formal qualifications in pharmacy, as required by Council Directive 85/433/EEC of 16 September 1985 concerning the mutual recognition of diplomas, certificates and other evidence of formal qualifications in pharmacy, including measures to facilitate the effective exercise of the right of establishment relating to certain activities in the field of pharmacy (4), the broad comparability of training courses in the Member States enables coordination in this field to be confined to the requirement that minimum standards be observed, thus leaving the Member States freedom of organization as regards teaching;

Whereas this Directive does not prevent the Member States from requiring supplementary conditions of training for access to activities not included in the coordinated minimum range of activities; whereas for this reason a host Member State which lays down such conditions may subject thereto nationals of Member States who hold one of the diplomas referred to in Article 4 of Directive 85/433/EEC;

Whereas the coordination provided for by this Directive covers professional qualifications; whereas, as regards such qualifications, most Member States do not at present distinguish between professional persons who pursue their activities as employed persons and those who are self-employed; whereas, for this reason, it appears necessary to extend the application of this Directive to employed professional persons;

Whereas further training is being developed in the Member States in certain aspects of pharmacy which is intended to extend certain areas of knowledge acquired during the training of pharmacists; whereas, therefore, with a view to mutual recognition of diplomas, certificates and other evidence of formal qualifications in pharmacy specialities and in order to put all members of the profession who are nationals of the Member States on an equal footing within the Community, some coordination of the requirements for training in pharmacy specialities is necessary where there are specialized forms of training common to several Member States which can entitle a person to use a specialist title, without such training being a condition of access to the activities included in the coordinated minimum range of activities; whereas such coordination does not seem possible at this stage, but constitutes an objective to be attained as soon as possible together with the relevant mutual recognition,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. Member States shall ensure that holders of a diploma, certificate or other university or equivalent qualification in pharmacy which meets the conditions laid down in Article 2 shall be entitled at least to access to the activities mentioned in paragraph 2 and to pursue such activities subject, where appropriate, to the requirement of additional professional experience.

2. The activities referred to in paragraph 1 are:

- 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 the of medicinal of 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.

3. Where at the time of adoption of this Directive a system of competition based on tests exists in a Member State for the purpose of selecting from among the holders referred to in paragraph 1 those to be appointed to control the new pharmacies to be set up under a national geographical distribution system, that Member State may, by way of derogation from paragraph 1, retain this competition system and may oblige nationals of the Member States

holding the diplomas, certificates and other formal qualifications in pharmacy referred to in Article 2 (1) and Article 6 of Directive 85/433/EEC to take part in such a competition.

Article 2

Member States shall subordinate the award of the diplomas, certificates and other formal qualifications referred to in Article 1 to the following minimum conditions:

1. Training leading to the award of the diploma, certificate or other formal qualification shall ensure:

(a) adequate knowledge of medicines and the substances used in the manufacture of medicines;

(b) adequate knowledge of pharmaceutical technology and the physical, chemical, biological and microbiological testing of medicinal products;

(c) adequate knowledge of the metabolism and the effects of medicinal products and of the action of toxic substances, and of the use of medicinal products;

(d) adequate knowledge to evaluate scientific data concerning medicines in order to be able to supply appropriate information on the basis of this knowledge;

(e) adequate knowledge of the legal and other requirements associated with the practice of pharmacy.

2. In order to be accepted for such training, the candidate must have a diploma or a certificate which entitles him to be admitted for the course of study concerned to the universities of a Member State or to higher education institutions recognized as having equivalent status.

3. The diploma, certificate or other formal qualification shall testify to the completion of a course of training covering a period of at least five years and comprising:

- at least four years of full-time theoretical and practical training in a university, in a higher education institution of a level recognized as having equivalent status, or under the supervision of a university,

- at least six months of in-service training in a pharmacy open to the public or in a hospital under the supervision of the pharamaceutical department of that hospital. 4. By way of derogation from point 3:

(a) if at the time of the adoption of this Directive two courses of training coexist in a Member State, one of which lasts five years and the other four years, the diploma, certificate or other formal qualification testifying to the completion of the four-year course of training, shall be considered to fulfil the condition concerning duration referred to in point 3 provided that the diplomas, certificates or other formal qualifications testifying to the completion of the two courses of training are recognized as equivalent by that State;

(b) if, because, there are insufficient places in pharmacies open to the public and in hospitals near training establishments, a Member State is unable to provide six months of in-service

training, it may, for a period of five years following the expiry of the time limit laid down in Article 5, make provision for no more than half of that training period to involve activities as a pharmacist in an undertaking which manufactures medicinal products.

5. The course of training referred to in point 3 shall comprise as a minimum theoretical and practical training in the following subjects:

- Plant and animal biology,

- Physics,

- General and inorganic chemistry,

- Organic chemistry,

- Analytical chemistry,

- Pharmaceutical chemistry, including analysis of medicinal products,

- General and applied biochemistry (medical),

- Anatomy and physiology; medical terminology,

- Microbiology,

- Pharmacology and pharmacotherapy,

- Pharmaceutical technology,

- Toxicology,

- Pharmacognosy,

- Legislation and, where appropriate, professional ethics.

The balance between theoretical and practical training shall, in respect of each subject, give sufficient importance to theory to maintain the university character of the training.

Article 3

Not more than three years after the expiry of the time limit laid down in Article 5, the Commission shall submit to the Council appropriate proposals on specializations in pharmacy and in particular hospital pharmacy. The Council shall examine these proposals within one year.

Article 4

This Directive shall also apply to nationals of Member States who, in accordance with Council Regulation (EEC) No 1612/68 of 15 October 1968 on freedom of movement for

workers within the Community (1), are pursuing or will pursue, as employed persons, one of the activities referred to in Article 1 of Directive 85/433/EEC.

Article 5

1. Member States shall take the measures necessary to comply with this Directive before 1 October 1987. They shall forthwith inform the Commission thereof.

2. Member States shall communicate to the Commission the texts of the main provisions of national law which they adopt in the field covered by this Directive.

Article 6

Where a Member State encounters major difficulties in certain fields when applying this Directive, the Commission shall examine these difficulties in conjunction with that State and shall request the opinion of the Pharmaceutical Committee set up by Council Decision 75/320/EEC (2).

Where necessary, the Commission shall submit appropriate proposals to the Council.

Article 7

This Directive is addressed to the Member States.

Done at Luxembourg, 16 September 1985.

For the Council

The President

M. FISCHBACH

(1) OJ No C 35, 18. 2. 1981, p. 3.

(2) OJ No C 277, 17. 10. 1983, p. 160.

(3) OJ No C 230, 10. 9. 1981, p. 10.

(4) See page 37 of this Official Journal.

(1) OJ No L 257, 19. 10. 1968, p. 2.

(2) OJ No L 147, 9. 6. 1975, p. 23.