

Pharmacy education & training in

MOLDOVA

2013

PHARMINE (PHARMacy education IN Europe) is a project funded by the European Commission (LLL programme, Erasmus). Its aims and objectives are to survey the present state of pharmacy education and training in Europe, and on the basis of this survey, formulate recommendations for new competence curricula for pharmacy education and training in the EU. A model for pharmacy education and training for candidate member states and other countries will be proposed. The opportunities for a quality assurance and accreditation scheme for EU pharmacy courses will be investigated.

PHARMINE will take into account two important issues, (i) the EU directive 2005/36/EC on the recognition of professional qualifications and, (ii) the Bologna declaration. PHARMINE will focus both on recommendations for core education and training and for activities such as industrial and hospital pharmacy.

The PHARMINE consortium consists of universities which are members of the European Association of Faculties of Pharmacy (EAFP) and EU partner associations representing community, hospital or industrial pharmacy, together with the European Pharmacy Students' Association and other interested bodies.

In order to reach the objectives of the PHARMINE project, a work-plan was set up and divided into 7 work-packages (WP).

The aims and objectives of PHARMINE WP7 are to:

1. Survey European higher education institutions (HEIs)
2. Produce a databank of pharmacy education and training courses in Europe leading to core pharmacist qualifications and to qualifications required for industrial and hospital pharmacy
3. Survey to what extent the "Bologna" (based on the principles enumerated in the Bologna declaration) and the "Sectoral profession" (based on 2005/36/EC) models for pharmacy education and training are compatible.

PHARMINE WP7 will produce several documents including a WP7 survey by country. **Such surveys are intended for the use of students and staff interested in mobility and/or contacts with the country in questions as well as educationalists working on pharmacy education and training in Europe.**

(see:http://enzu.pharmine.org/media/filebook/files/PHARMINE_Paradigm.pdf)

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Introduction.

From the the WHO country survey at:

<http://www.euro.who.int/en/what-we-do/health-topics/Health-systems/medicines/country-work2/a-selection-of-country-profiles/republic-of-moldova-2008>

Almost all pharmacies were privatized in 1993, except those in large hospitals, which are generally still state owned. The state, however, remains a shareholder in a number of privatized enterprises, so the country has a mixed system of state and private pharmacies. The large-scale privatization was undertaken to try to ensure an adequate and regulated drug supply in the face of an economic collapse and the state's consequent difficulties in running a centralized drug supply and distribution system immediately following independence. The weaknesses in the state drug supply and regulatory system that arose shortly after independence led to the formation of a large and unregulated illegal market in pharmaceuticals, alongside a collapse in the national prescription system. Today, the illicit supply of pharmaceuticals is considered insignificant, and regulation of sales through privatized pharmacies is helping to ensure the quality of the pharmaceutical supply. With the exception of a few restricted items, however, most drugs continue to be available for sale from all pharmacies without a prescription, although this is technically illegal.

Privatization drastically improved the reliability of drug supply in urban areas, but it has also made drugs much more expensive, thus reducing access. One review of paediatric care services found that having multiple privately run pharmacies that practised shared price fixing within an individual hospital resulted in inflated rather than competitive drug costs. Drugs were much more expensive in the rural areas than in the cities, and hospitals that had maintained their own non-privatized pharmacies seemed to have the least problems with the availability of essential drugs.^[1]

Moldova has one main generic drug production company, Farmaco, which manufactures a limited range of products, and approximately 12 smaller drug production companies. However, approximately 95% of all drugs used in the country are imported.^[2] Prior to independence, the Republic of Moldova was able to obtain and distribute drugs through the centralized Soviet pharmaceutical system. However, post-independence it became clear that this approach to drug purchasing was not sustainable. As part of the health reform process, the Republic of Moldova moved to a system of local hospital-level purchasing. Exceptions to this new system included certain drugs such as insulin and haemophilia drugs, which were supposed to be supplied directly to the hospitals by the state. The state was often unable to provide these items and the shortfall had to be met by international nongovernmental organizations such as *Pharmaciens sans Frontières*. Under the local purchasing scheme, hospitals were supposed to receive money for specified drugs and prepare tenders to purchase these competitively. However, the money from the state budget for these drugs purchases was often inadequate.^[3]

Following the introduction of mandatory social health insurance, different mechanisms for paying for pharmaceuticals were introduced. To help to rationalize prescribing and encourage doctors to prescribe effective but inexpensive drugs, an essential drugs list was drawn up in 1998, based on WHO recommendations. This essential drugs list is reviewed and revised on a regular basis. The reimbursement of prescribed medicines included on the essential drugs list depends on the level of care and geographical location. Doctors working in primary care can prescribe medicines on the reimbursed list, and the National Health Insurance Company (NHIC) contracts with pharmacies in order to reimburse them directly for medicines dispensed to patients. Consequently, while primary care providers do not receive any direct funding for pharmaceuticals, they have an indicative prescribing budget. However, there is a payment mechanism for use in the rayon hospitals, as they have their own pharmacies. Because of the absence of an alternative network for the supply of pharmaceuticals in rural communities, the rayon hospital pharmacies are also allowed to dispense drugs prescribed by family doctors. This is a part of the contract between rayon hospitals and the NHIC. Since 2005, when the system was introduced, this mechanism has worked quite well, and contrary to the problem of overconsumption encountered in other countries, the problem has been one of under-consumption of the resources allocated.^[4]

Officially, pharmaceuticals prescribed as part of inpatient care are free of charge for certain vulnerable groups (pensioners, children, registered disabled, etc.); however, drugs prescribed as part of outpatient care are generally charged at full cost, and this is a significant barrier to accessing health care for low-income households. Most out-of-pocket payments for health care are spent on pharmaceuticals.^[5] For patients with chronic conditions, such as diabetes, the situation can be precarious. Although under the minimum package most drugs for children under 5 years are supposed to be free of charge, the mechanism for this is unclear and it is unlikely that many children are benefiting from this arrangement. Also, although pharmaceutical treatment in hospital is meant to be free of charge for certain groups, in practice families often have to purchase expensive drugs.^[6] The costs for families are made even higher by the practice of giving many drugs at once under cumbersome treatment protocols, many of which were written under the old regime.^[7] Poly-pharmacy is also the result of financial incentives and parental or patient expectations; indeed some clinical guidelines were brochures sponsored by drug companies.^[8] Since 2004, drugs included on the essential drug list were also free of charge when prescribed for outpatient care; however, the essential drug list is very limited, covering just 32 products in 2005. Given the high level of out-of-pocket payments dedicated to the purchase of pharmaceuticals, it is critical to carefully expand the drug benefit package covered by the NHIC.

Key aspects of pharmaceutical regulation in the Republic of Moldova are governed by the Law on Pharmaceutical Activity (1993, amended 1998), which outlines who can perform pharmaceutical duties and the importing, production and registration of drugs, and the Law on Pharmaceuticals (December 1997), which covers quality control issues of pharmaceuticals, manufacturing and trials. Regulation of the pharmaceutical sector is a responsibility of the health ministry. It has set profit limits (40% on wholesale price) on pharmacies and also regulates which drugs may be sold in the country.^[9] In recent years, significant progress has been made towards the accreditation and medical auditing of pharmacies in order to establish and enforce quality standards in the country. In 2002, the Law on Evaluation and Accreditation in Health Care (No. 552-XIII) was approved, and between 2002 and 2003 the National Council for Evaluation and Accreditation in Health Care accredited 67 pharmaceutical facilities. However, little information on the accreditation process is available and very few of the drugs supplied by pharmacies are actually quality controlled. There are currently no licensing procedures for nonmedical, medical or pharmaceutical activities. Nevertheless, a Pharmaceuticals Agency has now been set up in the health ministry for the market authorization and licensing of new pharmaceuticals. As part of an action plan with the European Union, the Republic of Moldova has also been actively moving towards compliance with the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which is also a compulsory aspect of the country's membership of WTO.^[10]

The number of pharmacies in the country has been expanding rapidly, and there were 1111 pharmacies in the country in 2005, the equivalent of 33 per 100 000 population. Since 2002, when there were 53.4 pharmacists per 100 000 population, the number of pharmacists working in the system has also been growing rapidly, and in 2006 it was 79.0. While this may indicate that there is excessive capacity in the pharmacy network, the pharmacies and pharmacists are not evenly distributed across the country. For example, there are less than 16 pharmacies per 100 000 inhabitants in the rural rayons of Cimislia, Nisporeni and Causeni, while in Basarabasca rayon and the municipalities of Chisinau and Balti there are more than 45 pharmacies per 100 000 inhabitants – overall, 68% of pharmacies are located in Balti and Chisinau.

Total drug spending in Moldova was 1223.7 lei (US\$ 95.8 million) during 2005 and it grew at an average rate of 8% per year between 2000 and 2005. This growth in drug expenditures can be partially explained by the introduction of reimbursement of pharmaceuticals by the NHIC under the State Drug Policy approved by parliament on 3 October 2002. However, given the use of private pharmacies to distribute the drug benefit package under health insurance, it is important that the NHIC develops adequate mechanisms to guard against fraudulent overbilling. This is particularly important as many doctors bought pharmacies under the privatization programme, which are often in the clinic or hospital where they work. Unscrupulous professionals might, therefore, be interested in prescribing expensive or even inappropriate drugs to patients to increase their own pharmacy profits.^[11]

[1] Duke T et al. (2006). Quality of hospital care for children in Kazakhstan, Republic of Moldova, and Russia: systematic observational assessment. *Lancet*,367:919–925.

[2] WHO (2006). *Country cooperation strategy at a glance: Republic of Moldova*. Geneva, World Health Organization

[3] MacLehose L (2002). *Health care systems in transition: Republic of Moldova*. Copenhagen, European Observatory on Health Care Systems (<http://www.euro.who.int/document/e81265.pdf>).

[4] Shishkin S, Kacevicius G, Ciocanu, M (2006). *Evaluation of health financing reform in the Republic of Moldova*. Copenhagen, WHO Regional Office for Europe.

[5] Ibid.

[6] Duke T et al. (2006). Quality of hospital care for children in Kazakhstan, Republic of Moldova, and Russia: systematic observational assessment. *Lancet*,367:919–925.

[7] Ibid.

[8] Ibid.

[9] MacLehose L (2002). *Health care systems in transition: Republic of Moldova*. Copenhagen, European Observatory on Health Care Systems (<http://www.euro.who.int/document/e81265.pdf>).

[10] Government of the Republic of Moldova and European Union (2005). *EU/Moldova Action Plan 2005*. Chisinau, Government of the Republic of Moldova (http://ced.pca.md/files/Action_Plan_EU-Moldova.pdf).

[11] MacLehose L (2002). *Health care systems in transition: Republic of Moldova*. Copenhagen, European Observatory on Health Care Systems (<http://www.euro.who.int/document/e81265.pdf>).

A Country Pharmaceutical Profile can be accessed to have more relevant and wide data on pharmaceutical sector in Moldova: http://www.who.int/medicines/areas/coordination/Moldova_PSCPNarrativeQuestionnaire_23052011.pdf

Chapter 1. Organization of the activities of pharmacists, professional bodies

	Y/N, number or %	Comments.
Community pharmacy		
Community pharmacists	≈1500	Pharmacists (graduates from USMF after 5 years of study with a diploma qualification of pharmacist)
Community pharmacies	1014 (+ pharmacy outlets)	
Competences and roles of community pharmacists		Pharmacists work as pharmacy owners, managers, responsible pharmacists, competences include administrative issues, customer service, medication review, marketing.
Is ownership of a community pharmacy limited to pharmacists?	N	Any person can own a pharmacy, but a pharmacist must be engaged in pharmacy in order to obtain license.
Are there rules governing the geographical distribution of community pharmacies?	Y	250 m around existing community pharmacy and 500 m around compounding pharmacy (rule introduced in 2011)
Are drugs and healthcare products available to the general public by channels other than pharmacies?	N	
Are persons other than pharmacists involved in community practice?	Y	<i>Laborant</i> -pharmacists are allowed to dispense OTC medication under the supervision of a pharmacist
Their titles and number(s)	≈1150	<i>Laborant</i> –pharmacist (≈pharmacy assistant)
Their qualifications		
Organisation providing and validating the E&T		National college of Medicine and Pharmacy http://www.cnmf.md/
Duration of studies (years)	3	
Subject areas		Pharmaceutical chemistry, biochemistry, technology of medicines, pharmacology, hygiene, microbiology, marketing and management, etc.
Competences and roles		Mainly <i>laborant</i> -pharmacists are prepared for extemporaneous compounding of medicines, preparing of demands and labelling procedures, ensure proper storage and handling of medicines etc.
Hospital pharmacy		
Does such a function exist?	Y	
Number of hospital pharmacists	≈160	
Number of hospital pharmacies	76	
Competences and roles of hospital pharmacists		Hospital pharmacists used to have logistic role in hospitals and healthcare centres. The role is now starting to change and some pharmacists are working in the wards.
Pharmaceutical and related industries		
Number of companies with production, R&D and distribution	96	www.farmaprim.md www.farmaco.md www.balcanpharmaceuticals.com www.rnp.md www.tetis.md

		www.rpgf.md www.becor.md www.vinamex.md
Number of companies with production only	25	
Number of companies with distribution only	71	
Number of companies producing generic drugs only	25	
Industrial pharmacy		
Number of pharmacists working in industry	≈100	
Competences and roles of industrial pharmacists		Their competencies are not clear stated in official documents. Mainly industrial pharmacists are involved in supervision of production process in industrial settings and quality assurance activities.
Other sectors		
Number of pharmacists working in other sectors	194	
Sectors in which pharmacists are employed		A) Academic sector, e.g. pharmacists working in Universities and research organizations B) Administration, e.g. pharmacists working in national authorities (National Agency of Medicines, Ministry of Health) C) Other/Un-specified
Competences and roles of pharmacists employed in other sectors		A) Teaching, research, administration, management and leadership B) Varying roles and competencies: specialist pharmacists (pharmacists specialized in some specific issues for example marketing authorizations, pricing and re-imbursments of medical products, IT-issues such as e-prescriptions and databases, medicines information), researchers, managers.
Roles of professional associations		
Registration of pharmacists	N	Pharmacists are not registered in Republic of Moldova, since we don't have a national pharmacy chamber which regulates pharmacy practice. There is only the Association of Pharmacists, which a non-profit organization and doesn't have any regulatory power. Licences for pharmaceutical activity are issued by Licensing Chamber, as for any other domain of economy. www.licentiere.gov.md Other regulatory institutions in pharmaceutical sector are: Agency of Medicines: www.amed.md Ministry of Health: www.ms.gov.md
Creation of community pharmacies and control of territorial distribution	N	
Ethical and other aspects of professional conduct	N	
Quality assurance and validation of HEI courses for pharmacists	N	The State University of Medicine and Pharmacy Nicolae Testemitanu is providing continuing pharmacy education and has its own quality handbooks and quality assurance procedures.

Chapter 2. Pharmacy HEIs, students and courses

	Y/N, number or %	If you wish to expand your answer, please add your comments below.
Total number of HEIs in Moldova	1 public	
Organisation of HEIs		
Independent faculty	Y	State University of Medicine and Pharmacy “Nicolae Testemitanu” , Faculty of Pharmacy
Do HEIs offer B + M degrees?	Y	State University of Medicine and Pharmacy “Nicolae Testemitanu” , Faculty of Pharmacy offers 5 years B.Sc. Pharm. compulsory for pharmacy practice, and an optional 2 years Master
On a national level		
Teaching staff		
Number of teaching staff (nationals)	72	
Students		
Number of places at traditional entry (beginning of S1 of B1, following secondary school)	100	
Number of applicants for entry	600	
Number of graduates that become registered / professional pharmacists.	100	
Number of international students (from EU member states)	4	
Number of international students (non EU)	8	
Entry requirements (beginning of S1 of B1, following secondary school)		
Specific pharmacy-related, national entrance examination	Y	
Other form of entry requirement at a national level	N	
Is there a national <i>numerus clausus</i> ?	Y	Each institution sets its individual numerus clausus.
Specific requirements for international students (EU or non EU).		Language skills requirements.
Fees per year		
For home students	1140 €	
For EU MS students	2600- 3500 €	

For non EU students	2600- 3500 €	
Length of course	5 years	
Specialization		
Do HEIs provide specialized courses?	N	
Past and present changes in E&T		
Have there been any major changes since 1999?	Y	
Are any major changes envisaged before 2019?	N	

Chapter 3. Teaching and learning methods

Student hours						
Method	Year 1	Year 2	Year 3	Year 4	Year 5	Total
HEIs courses						
Lecture	17 hours per student for a week	22	22	19	9	89
Tutorial	21	20	9	16	14	80
Practical	20	21	34	29	7	111
Traineeship						
Hospital					360 hours (12 weeks)	360
Community	60 hours (2 weeks)	60 hours (2 weeks)		60 hours (2 weeks)	180 hours (6 weeks)	360
Industrial (academic or industrial)					180 hours (6 weeks)	180
Other (please specify) Botany and Pharmacognosy	60 hours (2 weeks)		60 hours (2 weeks)			120
Total traineeship	120	60	60	60	720	1020
Electives						
Optional		60 hours	30 hours	60 hours	60 hours	210

Chapter 4. Subject areas

Student hours						
Subject area	Year 1	Year 2	Year 3	Year 4	Year 5	Total
CHEMSCI	10 ETCS 300 h	30 ETCS 900 h	16 ETCS 480 h	21 ETCS 630 h	10 ETCS 300 h	2610 28.4%
PHYSMATH	12 ETCS 360 h					360 3.9%
BIOLSCI	14 ETCS 420 h		6 ETCS 180 h			600 6.5%
PHARMTECH			8 ETCS 240 h	10 ETCS 300 h	7 ETCS 210 h	750 8.2%
MEDISCI	6 ETCS 180 h	18 ETCS 540 h	22 ETCS 660 h	14 ETCS 420h	6 ETCS 180 h	1980 21.6%
LAWSOC		8 ETCS 240 h	2 ETCS 60 h	12 ETCS 360 h	9 ETCS 330 h	990 10.8%
GENERIC	11 ETCS 750 h	4 ETCS 120 h				870 9.5%
Subtotal	2010	1800	1620	1710	1020	8160
Traineeship	120	60	60	60	720	1020 11.1%
Total plus traineeship	2130	1860	1680	1770	1740	9180 = 100%

The hours calculated in every column, is the time scheduled for lectures, assignments and group works in the B.Sc. The time student use for individual work is not calculated here.

Chapter 5. Impact of the Bologna principles

Bologna principle	Is the principle applied? Y/N or partially	How is it applied? Does your HEI have multilateral recognition and agreements? Other comments.
1. Comparable degrees / Diploma Supplement	Partially	State University of Medicine and Pharmacy “Nicolae Testemitanu”, Faculty of Pharmacy offers 5 years B. compulsory and 2 years residency. Each graduating student receives a diploma supplement.
2. Two main cycles (B and M) <u>with entry and exit at B level</u>	Y	Entrance is permitted each year for 100 students (B.Sc.). Bachelors graduate after 5 years and Masters after 2. Bachelors in Pharmacy are employed in Republic of Moldova in community pharmacies, hospital pharmacies, industry etc. They constitute the main work force in Moldova’s community pharmacies. In Europe the degree is recognized, after examination for confirmation.
3. ECTS system of credits / links to LLL	Y	All our courses are built according to the ECTS system. We accept ECTSs obtained in other European countries to the full.
4. Obstacles to mobility	Y	The biggest obstacle to student mobility is obtaining visa and the strictly organized curriculum, which does not easily allow students to move. This means, that most of our exchange students select to their Master’s project abroad, because at that point they don’t have so many compulsory courses.
5. European QA	N	

Chapter 6. Impact of EC directive 2005/36/EC

The directive states	How does / will this directive statement affect pharmacy E&T?
“Evidence of formal qualifications as a pharmacist shall attest to training of at least <u>five years' duration...</u> ”	Our Faculty of Pharmacy offers 5 years B. compulsory and 2 years residency.
“ <u>...four years of full-time theoretical and practical training</u> at a university or at a higher institute of a level recognised as equivalent, or under the supervision of a university;”	Students study 5 years at the university, so this requirement is fulfilled.
“ <u>...six-month traineeship in a pharmacy</u> which is open to the public or in a hospital, under the supervision of that hospital's pharmaceutical department.”	Bachelor students perform the six-month traineeship.
“The balance between theoretical and practical training shall, in respect of each subject, give <u>sufficient importance to theory to maintain the university character of the training.</u> ”	We need to place emphasis on both theoretical knowledge and practical training in order to prepare the students for further studies (Ph.D.) and also for future pharmaceutical activity.
Directive annex	
V.6. PHARMACIST 5.6.1. Course of training for pharmacists 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. All these aspects are taught	



Lifelong Learning Programme



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