Community pharmacy in Europe: Overview of key aspects of regulation

Javne lekarne v Evropi: ključni regulatorni vidiki

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1. Introduction: Public interest considerations in the pharmacy sector

When examining the pharmacy sector we must put it in the right context, which is under the framework of healthcare systems. Too often, we have seen attempts to legislate the pharmacy profession without taking due account of public health considerations.

Community pharmacists are part of national health systems and are among the health professionals that citizens visit most often. They play a key role in providing information to patients on the use of medicines and on minor health issues. By guaranteeing the supply of medicines, they are essential for social security reimbursement schemes.

The Pharmacist is a highly qualified health professional, he is expert in medicines, he operates in a highly computerised system and he is very accessible and trusted by the citizens. We have many statistics, both at a European level and also several national surveys showing that the pharmacist is at the top of the most trusted professionals in Europe. So pharmacists are a huge resource for national healthcare systems which we believe should be more valued and used by legislators and governments.

Cost containment for medicines and health services is one of the main priorities for all Member States and in particular in the new Member States. Research has demonstrated that pharmacist's activities in the control of patients' medication, in advising patients on the safe and effective use of medicines, and in carrying on health promotion campaigns contribute to reducing costs for national health systems and at improving public health.

From the amount of legislation and obligations which pharmacist are asked to fulfil it is also clear that the profession provide services that are of general interest for the community. They are obliged to fulfil a number of obligations imposed by national law to ensure patient safety and adequate accessibility to medicines. All Member States have these kind of obligations. Examples are the obligations to keep sufficient medicinal products in stock or to provide night services.

This special character of the pharmacy services and the role that the profession plays in the healthcare system has been well described and highlighted in a Resolution of 1999 by the Council of Europe, signed by all health ministers of member countries. The Council recognised not only the role of the pharmacists in achieving public health objectives but also their contribution to the financial balance of health systems.

If we look that at the pharmacist as a profession, so as a liberal profession active in the health, it is also important to underline that the ECJ in several rulings has underlined the importance of public interest considerations in the provision of professional services. In the to Wouters Case[1], on of the key rulings in the field of professional regulations, the Court recognised that certain professional rules and regulations are inherent to a particular profession and necessary for the correct delivery of the services and therefore outside the scope of EU competition law.

In this context it is worth mentioning that another EU Institution, the European Parliament (EP), approved on 16th December 2003 a resolution on the role of liberal profession and competition rules. The EP in its resolution recognised the specificity of professional services, the importance of the professional associations, to ensure an appropriate delivery of services, the importance of maintaining appropriate regulation in professional services and the key message of putting public interest and public health before competition and Internal market issues. The Resolution the European Parliament also clearly recognised the specificity of liberal professions active in healthcare.

2. The European and the national dimension

In order to better understand the legal framework of the pharmacy sector in Europe it is necessary to make a distinction between the legislation coming from the European Union and that established at national level.

2.1 The European dimension

Essential aspects of the pharmacy framework are set out at EU level as the legislation on pharmaceutical products[2] and the education and training requirements for pharmacists[3].

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1 Case C-309/99 (J.C.J. Wouters)
2 Directive 2004/27 on the Community Code relating to medicinal products for human use
3 Directive 2005/36 on the recognition of professional qualifications

In relation to pharmaceutical products, EU law covers mainly the quality, safety and efficacy of medicinal products; the classification of medicines; rules on advertising of medicines and wholesale distribution.

As for training requirements, the EU legislation has harmonised the length of the study of the university title for pharmacist, the list of subjects and a minimum range of activities that pharmacists can carry out. This system establishes an automatic recognition of the title of pharmacist which allows the person holding it to work in any country of the EU.

2.2 The national dimension

The delivery and the organisation of health services is, according to the EC Treaty, a national responsibility. Therefore other fundamental aspects for the provision of pharmacy services such as the distribution of medicines, the rules governing the opening of new pharmacies (establishment rules) and the rules on the ownership of pharmacies are stipulated at national level.

Distribution of medicines

In most European countries the distribution of prescription (POM) and non-prescription medicines (NPM) is done mainly through community pharmacies. Some countries such as Switzerland, Denmark, Ireland, Latvia, Norway, Portugal and the United kingdom have established a what is known as a "general sales list" with a number of NPM such as analgesics and cough syrups that can be sold outside pharmacies.

However, in the PGEU's view, a move aiming at dispensing certain medicines outside pharmacies and without the supervision of a highly qualified professional expert is against the principle of rational and appropriate use of medicines. Furthermore, experience shows that this move is not without consequences to public health.

This can be easily concluded by the analysis of data from those countries that have notification procedures of admissions in hospital emergency services related to the overuse or misuse of medicines.

We should keep in mind that the way you get a medicine is a key element in the perception citizens have of medicinal products. As evidence shows, overuse from easily accessible medicines is a common phenomenon that should be appropriately addressed.

As more and more effective and therefore potent medicines are reclassified from prescription-only control to non-prescription status, this will be an even more important consideration.

In addition, a limited number of European countries allow the distance selling of medicines through the internet. In a recent judgment, the DocMorris Case (11 December 2003)[4], the ECJ has ruled that "*a national prohibition on mail order sales of medicinal products available only on prescription can be justified*". The court, however, allowed the sale of non-prescription medicines through the Internet. It is important to highlight that the Court agreed with the distance sale of NPM on the basis that the activities were carried out by a legally constituted pharmacy, subject to controls and public service obligations and where a pharmacist was always available to answer possible questions on the use of medicines.

Requirements for the opening of new pharmacies

All Member States have, by one means or another, criteria for the establishment of new pharmacies (criteria include geographical or population criteria, the need to obtain a service contract with an insurer in the area (the Netherlands), or a contract with a social security body (UK), etc).

These criteria have proven to be important in guaranteeing that pharmacy services and medicines are conveniently accessible to all citizens. Even in countries with a rather liberalised pharmacy system, the authorities have recognised the importance on these rules and have decided to maintain it.

For example, in the beginning of 2003, the British government decided not to follow a recommendation by the Office of Fair Trading (OFT) to sweep away this type of control. When the UK government announced its decision, it said that *"Community pharmacies play a vital role, particularly in rural and poorer areas, and we will do nothing to jeopardize their position. Pharmacists are trained clinicians, not simply shopkeepers and they will have an even greater role in the NHS of the future".*

Ownership structure of pharmacies

Another aspect, which is a key part of the way pharmacy is organised, is the ownership of pharmacies.

All EU Member States have looked at this aspect at a certain point in time. These analyses have, in the great majority of cases, considered and recognised the importance of the independent ownership of the individual pharmacist as a value.

In the majority European countries pharmacies must be owned by pharmacists or by companies owned by pharmacists. However, today a number of countries (Belgium, Netherlands Ireland, UK, Croatia, Check Republic, Estonia, Lithuania, Latvia, Poland and Romania) have decided to open up ownership to persons other than pharmacists.

Rules on the ownership are established by national legislation to guarantee:

- the independence of the profession from major market entities,
- that decisions are not taken solely for commercial reasons, and
- the provision of high quality pharmacy services.

For example, restrictions on doctors owning pharmacies contribute to ensuring that prescribing is based only on clinical need. Attempts made to weaken the separation of role between the doctor and the pharmacists, which are a key guarantee in the delivery on pharmaceuticals, could be a great problem ,especiallyin some new EU Member States.

Last but not least, legislation on the ownership of pharmacies also contributes to the promotion of small and medium size enterprises which are the pillar of the European economy.

Too see the practical consequences of total deregulation in the pharmacy sector, what has happened in Norway is a good example.

After strong pressure from big pharmaceutical wholesalers, the pharmacy sector, including pharmacy ownership, was liberalised from 2001. In just over a year, the number of independent pharmacies has gone from 356 to 78.

[4] Judgment of the Court of 11 December 2003 In Case C-322/01, Deutscher Apothekerverband eV and 0800 DocMorris NV,

In addition, in Norway, there has recently been a fight between supermarkets and big pharmacy chains over the sale of some branded non-prescription medicines.

The reasons for this confrontation are of a commercial nature, as both parties want to sell branded products which are the ones more attractive to the customers.

This situation has brought the attention of the media and a bad image for the pharmacy sector. The action of market forces can lead to purely commercial decisions which disregard the public health aspects involved.

On the other hand, it is interesting to note that some countries have considered the possibility of opening up ownership rules. In the end most of these countries have decided to maintain the status quo on the basis of public health considerations.

In Europe, for example, the German Government has very recently (legislation adopted on October 2003) undertaken a reform of the health sector. The question of pharmacy ownership was widely debated. It was finally decided to maintain the previous system whereby only pharmacists can own pharmacies. This political decision was taken after a deep analysis of the experiences in other countries like Norway and in response to the demands of German citizens.

In fact, it should be noted that research across Europe shows that citizens trust and support "their local pharmacist" and highly appreciate the pharmacy profession.

It is worth highlighting the importance of the personal contact with the pharmacist. In the traditional, independent pharmacy, the pharmacist has a continuous presence facilitating the building up of a personal relationship with the patient which is very beneficial for the adequate use of medicines.

3. Recent EU trends to influence the national dimension of pharmacy systems

In the last few years we have seen different attempts by the EU institutions, mainly the European Commission, to influence the pace in the introduction of liberalising measures in different service sectors, including pharmacy services. The most important initiatives in this sense are the Directorate General for Competition revision on regulation in professional services (the Monti initiative) and the Commission proposal on services in the internal Market.

DG Competition revision of the compliance of professional rules with EU competition rules covers among other liberal professions, the pharmacists. After an independent study carried out during 2002 on regulation in the professions, and a consultation with stakeholders, the Commission concluded that there is too much regulation in the liberal professions. PGEU was very active in following the developments in relation to this initiative. However, the Commission's action in this area is rather limited as most of the rules in the pharmacy sector are established by national legislation and not by the professional bodies. Recent reports indicate that the Commission is mainly concerned with rules limiting the advertising of pharmacy services.

On February 2004 the European Commission, put forward a proposal for a Directive for services in the Internal Market.

The proposal aims at facilitating the administrative requirements needed to provide services in another Member State by trying to fight against legal barriers to the freedom of establishment and free movement of services.

Besides establishing a list of forbidden requirements to the access to a service activity, the Directive will oblige Member States to assess the adequacy of a number of requirements to access service activities with the provisions of the Directive. Examples of these requirements are:

- quantitative or territorial restrictions,
- particular legal forms for the service provider or
- bans of having more than one establishment on the same national territory

This exercise could have some impact on national laws on business structure of pharmacies as the original Commission proposal covered all services except financial, transport and electronic communications (covered by existing community legislation) and thus included social services such as healthcare and social care, and of course pharmacy services.

Since the outset of the legislative procedure, this proposal has been subject to strong controversy and has been used by politicians to encourage a debate on what kind of European Union European citizens want in the future: an EU which is mainly a free trade-area or an EU sustained on the European social model.

After two years of work, the European Parliament adopted 16 February 2006, by 391 votes in favour, 213 against and 34 abstentions, the first-reading report on the proposed Directive. The EP has substantially modified essential aspects of the proposal as its field of application. The effective action of the different health stakeholders, including the PGEU, has lead to a wide majority (434 votes in favour; 207 against and 5 abstentions) of Members of European Parliament supporting the exclusion of health services. In addition, the coordinated action of PGEU and its members has also resulted in the clarification of the concept of health services in terms of the scope of the exclusion. The EP has adopted a new recital which clarifies which health services will be considered excluded and refers to healthcare services and pharmaceutical services provided by professionals to patients.

The modified proposal presented by the Commission on 4 April 2006 has accepted the exclusion of health services from the scope. The proposal will be now be discussed by the Council of Ministers but it is very likely that health services will remain outside the scope of the future directive.

The Member states are generally in favour of the adoption of the proposed Directive and consider it necessary to boost the European economy. The maintenance of the principle of county of origin is essential for some countries in order to make the Directive work in practice. 6 more liberal-minded Member States (UK, Spain, Netherlands, Poland, Hungary and Czech Republic) recently wrote to

the Commission to warn against any significant watering down of the text. However, regarding the exclusion of health, there is a general support among member states to exclude both private and public health services.

4. Conclusion

It is worth mentioning here that a comprehensive study entitled "Community pharmacy in Europe: Lessons from deregulation–case studies" was presented at the March 2006 PGEU General Assembly meeting.

The study, which examines pharmacy legislation and quantitative and qualitative indicators in six European countries, has been carried out by the Austrian Health Institute (OBIG) a research institute specialising in health and economic issues, based in Vienna. The authors of the study have carried out exhaustive research including assessment of national legislation through the development of a detailed questionnaire, contacts with stakeholders involved in the pharmacy sector, patient groups, national authorities and professional associations. The study outlines a comprehensive picture of the sector quantifying when possible economic and quality related aspects of the services provide to citizens.

From the study it comes out that pharmacy systems are high quality systems in all countries examined and there is also a clear recognition of the need of an adequate legal framework for the pharmacy sector, which however may differ from country to country. The study demonstrates that in the pharmacy sector the public payer (the National healthcare systems) and the private operators (in most case pharmacists) ensure effective and well-developed services throughout the national territories. Clearly, the study shows that adequate regulation is an additional guarantee to ensure good, effective, sustainable and accessible services.

As a conclusion, therefore, it should be said that that when considering any legislative initiative both at EU or national level in the area of pharmacy services, the promotion of public interest should be the first priority and the final objective.

European and National Institutions already recognise that medicines are special products, and must not be treated as ordinary consumer goods. Citizens do not usually choose the product and do not have all the relevant information and prices are controlled by the State. This leads to a special market in which conventional economic theory cannot always be strictly applied.