COMMUNITY PHARMACY IN EUROPE

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PGEU (PHARMACEUTICAL GROUP OF THE EUROPEAN UNION)
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Lessons from deregulation – case studies

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Foreword

It is a great pleasure for me to have opportunity of introducing this study on legislation in the pharmacy sector. The EESC is the EU Institution which represents organized civil society, and as its President and also because of my background, I am very interested in all issues related to liberal professions and particularly in research looking at regulation and the public interest.

I am convinced of the importance of organized civil society, and I think that liberal professions play a key role in civil society. I am convinced that the services provided by liberal professions have been and will continue to be essential for the proper functioning of our society.

In recent years, the EU Institutions have taken a great deal of interest in this sector. For example, the recent Communication from the European Commission entitled “Report on Competition in Professional Services”, the responses from the other institutions to this Communication, including the activities that the EESC has undertaken and is continuing to do on the subject, confirm that this sector is a key one to society and therefore a major contributor to the achievement of the Lisbon objectives.

At the end of 2003 the European Parliament adopted a Resolution on this subject. In that document the Parliament outlined very well the relation between competition in the areas of liberal professions and the need to ensure adequate regulation to protect the public interest. The European Parliament also clearly recognized the additional specificity of liberal professions active in the health sector, something which I think it is important to underline in the context of this study.

The study by the OBIG Institute highlights very well how the pharmacy sector, which is an integral part of healthcare systems, is an area in which, even though there are different models and different levels of regulation, the common objective is the protection of the public interest. This is achieved by ensuring convenient access to pharmacy services and thus contributing to a high level of public health protection. In addition, 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.

The authors of the study have carried out exhaustive research including contacts with many stakeholders involved in the pharmacy sector, patient groups and national authorities and the development of a comprehensive questionnaire aiming to provide a balanced picture of the sector.

In my view, the key factor in analysing any area of professional services is to make sure that all aspects of the services and moreover the objectives that the service aims to ensure, are taken into account. It would be incomplete to base any analysis of such a complex sector only on merely economic data. This study is certainly an important step towards providing a comprehensive picture of a complex and essential sector like the pharmacy sector.

I am pleased to conclude that this study makes very interesting reading and offers very useful and up to date information. I would recommend it without reservation to those interested in getting to know more about how pharmacy services are organised and provided nowadays in several countries in Europe.

Anne-Marie Sigmund
President of the European Economic and Social Committee
Executive Summary

In the last few years, deregulation of public services has taken place in several Member States of the European Union. One of the sectors targeted is health care, and, among others, the pharmacy business. Pharmacy is, by tradition a strictly regulated sector, in order to guarantee high quality of and broad accessibility to pharmaceuticals. Typical regulations in the pharmacy sector concern the establishment of new pharmacies (often based on the assessment of the public's needs), ownership issues (pharmacies owned by independent pharmacists, prohibition of pharmacy chains), as well as the quality of the training of pharmacists and other staff working in community pharmacies.

The rationale behind deregulation in the pharmacy sector is the expectation that liberalisation will increase competition and thus succeed in lowering, or at least containing, (public) expenditure, while accessibility to and quality of pharmacy services will be, at least, kept stable or even be improved by the opening of new outlets. By now, scientific evidence has not been provided for the arguments in favour of deregulation especially in the pharmacy sector, as no detailed investigation has yet been carried out on this particular issue in Europe.

The Pharmaceutical Group of European Union (PGEU) commissioned the Vienna-based, independent research institute ÖBIG (Österreichisches Bundesinstitut für Gesundheitswesen/ Austrian Health Institute) to survey and analyse possible effects of deregulation in the pharmacy sector, with a special focus on the accessibility to, the quality of, and the expenditure of pharmacy services. Performance indicators of pharmacy services were developed, analysed and ranked, based on data gathered in selected European countries, analysed and ranked. In addition, to examine the assumption of cost-containment triggered by deregulation, the ÖBIG team performed a single-price comparison of OTC blockbusters.

The outcome of the analysis is this ÖBIG report “Community Pharmacy in Europe: lessons from deregulation - case studies”, submitted to the PGEU in February 2006.
Highlighting pharmacy deregulation in case studies

In order to study in detail the impact of deregulation for community pharmacies, three European countries, which have undergone liberalisation in the pharmacy sector, were selected for an in-depth investigation and analysis. After having collected the necessary data in a next step, they were subject to a cross-country comparison and benchmarking, comparing their performance to reference countries whose pharmacy sector is still highly regulated.

The three deregulated “case study” countries are Ireland, the Netherlands, and Norway.

The pharmacy sector in Ireland has always been a very liberal one, with quite a few regulations. One of the current challenges in drafting a new Pharmacy Act is to include modern “fitness-to-practice” rules, which, among others, will enable the Pharmaceutical Society of Ireland, a statutory body, to sanction pharmacists. As a general rule, in Ireland in principal any individual or legal person could own one or more pharmacies. In reality, pharmacy chains, often owned by pharmacists have started to be set up in the mid-1990s; all three Irish wholesalers are involved in the pharmacy business. In 1996, needs-based establishment criteria for opening of pharmacies were introduce for the first time and were again revoked in 2002, leading to a rise of the number of pharmacies afterwards. In general, the provision with pharmacies, complemented by self-dispensing doctors, is rather good, compared to the other countries under survey. However, there are indications for a clustering of pharmacies in economically attractive urban places, whereas the satisfactory provision with dispensaries of prescription-only medicines in rural areas seems to be one of the challenges of the future.

In the Netherlands, the pharmacy sector has likewise been traditionally rather liberal. The sale of over-the-counter (OTC) products outside pharmacies has been allowed for more than a century, leading to a dichotomy between the dispensing of prescription-only medicines (POM) in Dutch community pharmacies and the sale of OTC products in drugstores. In the late 1990s, establishment and ownership rules, which had
never been statutory, but determined by the Royal Dutch Pharmaceutical Society, were abolished. Since then, the increase in the number of pharmacies (especially in attractive urban places) as well as the rise of pharmacy chains has been observed. A major difference to pharmacies in other European countries concerns the composition of pharmacy personnel in the Netherlands. While Dutch pharmacies are, in general, well staffed, there is a comparatively low number of pharmacists per pharmacy, and pharmacy assistants, having received a secondary vocational education, are allowed to perform tasks, that are exclusively reserved to pharmacists in other countries (e.g. filling prescriptions or providing counselling to customers). The matter of qualified staff in Dutch pharmacies continues to be a burning issue: Under the new Pharmacy Act, which is currently drafted, pharmacists might be entitled to act as supervising pharmacists in more than one pharmacy, thus no longer guaranteeing the constant presence of a pharmacist in a pharmacy.

The Norwegian case is often quoted as the key example for deregulation of pharmacy services. Before liberalisation in 2001, the pharmacy sector in Norway was a very strictly regulated one, with a five-year state plan on the establishment of new pharmacies and the prohibition of multiple and non-pharmacist ownership. After the removal of the establishment rules in March 2001, there has been a sharp increase in the openings of new pharmacies. This development, on the one hand, is considered as a positive one because there was an under-supply of pharmacies before 2001, but, on the other hand, it has been, observed with concern due to an obvious trend for urban clustering. Even if, according to an agreement between the Norwegian Ministry of Health and pharmacy chains, no pharmacies have been closed in rural areas in the past few years, every second Norwegian municipality still has no pharmacy, as new pharmacies were mainly opened in municipalities where pharmacy services were already available. Another problem arises from the fact that the number of community pharmacists and other pharmacy staff could not keep track with the major increase in the number of pharmacies. Apart from this, vertical integration is the other major effect of the deregulation process in the Norwegian pharmacy sector. Within a surprisingly short period of time, pharmacy chains have been established, which are
mainly owned by the three large European pharmaceutical wholesalers, thus dominating the market. Only four years after deregulation, four out of five pharmacies in Norway are part of a pharmacy chain owned by a wholesaler.

In addition to the increase in the number of pharmacies, Norway has also seen a considerable emergence of so-called LUA-shops (now around 6,000), which have been, since 2003, allowed to sell a small range of OTC blockbusters.

Besides the country-specific analysis of these three case study countries to identify possible changes arising from deregulation, their current pharmacy sectors were assessed in comparison to the ones of a control group. As reference countries Austria, Finland and Spain were chosen a reference countries, whereas France and Portugal acted as back-up countries, providing additional information if necessary.

These selected countries are characterised by several regulations in the pharmacy sector: They all have statutory establishment criteria as prerequisite for the opening of new pharmacies, providing for the ownership of community pharmacies only by pharmacists and prohibiting multiple ownership.

**Urban clustering and accessibility concerns for rural areas**

Accessibility is a key indicator for assessing pharmacy services in a country. It is mainly reflected not only in a sufficient number of POM-dispensaries reachable within reasonable time, but also in the range of products and services available.

Deregulation on establishment rules for pharmacies may lead, as evidenced in Norway after liberalisation, to a strong increase in the number of pharmacies. Within the group of the six countries surveyed, Norway, however, still lacks behind with regard to the pharmacy density (8,500 inhabitants per prescription-only medicines (POM) dispensary, The lowest ratio of inhabitants per POM-dispensary was found in Spain (2,050); followed by Ireland (3,000) and Austria (3,700). The development of the pharmacy density has been rather stable in Spain and Austria.
The removal of establishment rules for pharmacies usually leads to more pharmacies, but the new openings take place, for the most part, in attractive places, mainly city centres, as observed in the case study countries in this report. Besides the possible negative impact from a business perspective (excessive growth within a small area may damage the economic viability of the pharmacies), there are concerns from a public health perspective: With the focus on uncontrolled urban clustering, sparsely populated rural areas may be neglected.

Concerning the accessibility to pharmaceuticals, most of the surveyed countries (including the deregulated ones) provide for an immediate availability of frequently asked pharmaceuticals in their legislation or self-regulation. Among the countries studied, an immediate availability of pharmaceuticals is best guaranteed in Austria and Finland, followed by Spain and the Netherlands. This has also to be seen in connection with a high frequency of wholesale deliveries (on average three deliveries a day in Austria and Spain).

**Market dominance resulting from vertical integration**

In the regulated countries (Austria, Finland, and Spain), due to the regulations on ownership, every community pharmacy is owned by an independent pharmacist. In Ireland and in the Netherlands, respectively 90% and 77% of the pharmacies respectively are owned by pharmacists, who in some cases co-operate and form pharmacy chains in response to the market dominance by other actors. This market power of (mainly) pharmaceutical wholesalers in the pharmacy sector is excessive in Norway, where big pharmaceutical wholesale companies bought many pharmacies within short time after deregulation, leaving only 19% of the pharmacies owned by pharmacists. In the meantime only 2% of all Norwegian pharmacies are not part of a pharmacy chain, while the respective numbers for Ireland and the Netherlands are about 25% and 70% respectively.

The Norwegian case evidences quite well that deregulation does not automatically lead to a boost in competition, because, without providing for safe-guards in the legal framework (e. g. excluding or limiting certain
actors with regard to the ownership of community pharmacies), actors will utilise loop-holes to gain market dominance.

Another assumption is that the deregulation of community pharmacies may contribute to cost-containment, especially through a decrease of pharmaceutical prices. In this ÖBIG report the price development of four OTC blockbusters has been analysed from 1995 to 2005 (paracetamol tablets, ibuprofen tablets, diclofenac cream/gel and aciclovir cream/ointment) in the six countries under survey. The focus was put on OTC products, as in the prescription segment prices are usually determined by or negotiated with the state, while the development of free-priced OTC products could give an indication of the impact of deregulation on cost-containment. However, in none of the six countries clear price reductions for at least two of the OTC products selected could be observed, with Austria and Finland having the most stable price development, and Ireland and Norway showing the highest price fluctuations and growth rates respectively.

In addition, the three regulated countries (particularly in Finland) and the Netherlands had, in the last decade, lower growth rates in pharmaceutical expenditure compared to Ireland and Norway, whose runaway pharmaceutical expenditure needs to be seen in connection with the boosting economy of these countries.

**Be aware of false expectations**

Pharmacists are key health professionals, and community pharmacies in Europe play an important role in health care promotion and disease prevention, as patients do not only have their prescriptions screened and filled, but receive tailor-made preparations and pharmaceutical services (such as health checks or health related information, e. g. for Diabetes, Asthma or smoking cessation). Community pharmacists provide advice and counselling, and may, particularly in sparsely populated areas, even act as first contact point for patients.

The quality of pharmacy services in Europe is, in general, on a high level. This positive evaluation on the pharmacy sector is, according to
the results gained in this survey, substantially true for all six countries analysed (Austria, Finland, Ireland, the Netherlands, Norway, and Spain).

However, when benchmarking the indicators on accessibility, quality, and expenditure, some countries (to a larger extent. the ones of the control group with a stricter regulatory framework) rank better than the others, whose performance is, nevertheless, still more than satisfactory. Every system – and thus, also the pharmacy sector – has its particularities, which reflect historical developments, cultural patterns and traditions. Therefore, the assessment of the pharmacy sector in this report was not limited to the impact of liberalisation in the deregulated countries, as each country's “policy culture” has been taken into account. For example, despite indications that tailor-made services may disappear after deregulation, the low relevance of magistral preparations in the deregulated countries under survey was contributed to traditional reasons, as these preparations have never played a major role in such countries.

The report “Community Pharmacy in Europe: lessons from deregulation - case studies” comes to the conclusion that deregulation in the pharmacy sector has not met the expectations, provided that these have explicitly been defined beforehand. In the three deregulated countries in this survey, liberalisation in the pharmacy system “happened” as one part of an overall deregulation process targeting several sectors like energy supply or telecommunications.

Assuming that increasing competition and cost-containment as the two key aims of deregulation, the research undertaken in this study could not provide any evidence that these goals have been achieved through deregulation of community pharmacies. On the contrary, unfavourable side-effects could be observed, such as extreme market power by other players dominating the pharmacy sector and therefore causing concern in relation to competition, or the uneven spread of new openings of pharmacies with disregard for rural areas. Thus, if deregulation is on the agenda for political reasons, modifications in the legislation should be well-prepared and include mechanisms, incentives and rules to prevent adverse effects for the citizens.
Conclusions

Based on the analysis of the situation in the case study countries (Ireland, the Netherlands and Norway) and the comparison of the case study countries with the three control group countries (Austria, Finland and Spain) we have drawn the following conclusions.

Consequences of deregulation on the ownership of pharmacies

Total freedom in ownership of pharmacies (i.e. non-pharmacists allowed to own pharmacies) leads most likely to **vertical integration** in the pharmacy sector. In this case, the ownership of pharmacies shifts from pharmacists to other actors within the pharmaceutical distribution system, which very often seem to be, besides pharmacists, wholesalers. This is likely to put a restriction on the professional freedom of pharmacists, in that, as employees, they have to follow the objectives of their superiors, which might include turnover targets and strict regulations on ordering, processing and "promoting" selected products. In addition, vertical integration in the pharmacy sector can also cause other problems.

Firstly, vertical integration can become a threat if it leads to a **conflict of interests**. To avoid this, most countries have decided not to allow doctors and manufacturers of pharmaceuticals to own pharmacies.

Secondly, the penetration of large companies into the pharmacy sector can make it very **difficult for independent pharmacists to buy pharmacies** themselves, as companies are willing and able to pay large amounts of money for pharmacies.

In addition, a change in ownership rules for pharmacies will cause a split between the ownership and the professional responsibility, which can create uncertainty with regard to **liability** in case of misconduct or negligence in a pharmacy. Clear legislation is needed in order to prevent this situation from happening.

Allowing multiple ownership of pharmacies results in the formation of **pharmacy chains**. Pharmacies in these chains are being owned by the
holder of the chain, and supervised by one or more pharmacists. Some pharmacy chains give to supervising pharmacists the opportunity to partly own the pharmacy.

This horizontal integration can decrease the pharmacists' professional freedom and lead to a higher fluctuation of personnel. The independence of the profession and the continuous presence of the pharmacist in the community pharmacy is an important factor to create a personal and strong relationship with patients that will result in a higher level of compliance with the prescribed treatment and further safety for patients.

In combination with vertical integration, horizontal integration can become a threat if (one of the) actors in the pharmaceutical distribution system becomes very large and gains too much market power, i.e. leading to oligopoly or monopoly situations, still with still high barriers for market entry. This needs to be prevented by putting limits to the growth of pharmacy chains. For example, in Norway the number of pharmacies in a pharmacy chain is restricted to 40 percent of all Norwegian pharmacies.

**Consequences of deregulation on the establishment of pharmacies**

Removal of criteria for the establishment of new pharmacies leads to a growth of the number of newly established pharmacies and thus, most likely, to an increase of the pharmacy density. The extent of the increase depends on the situation before the liberalisation. The growth in the number of pharmacies will be larger if the provision of pharmacies was formerly relatively low, as it occurred in Norway.

Still, in a liberal pharmacy sector, without establishment criteria for pharmacies and with increased competition, the growing number of community pharmacies does not imply improved accessibility for all inhabitants, because newly established pharmacies tend to cluster in urban areas at the expense of the less densely populated rural areas, and some existing pharmacies choose to leave the rural areas and move to economically more attractive urban areas. This way, deregulation can
lead to a relatively bad provision of pharmacy services in rural areas, compared to the larger cities in country.

However, one should realize that, besides an improved accessibility of pharmacies, a growing number of community pharmacies can also have negative impacts.

For example, excessive growth of the number of pharmacies in a region can damage the economic viability of individual pharmacies, which in turn might lead to a reduced variety of available pharmaceuticals in pharmacies and customers having to visit multiple pharmacies in order to get their prescriptions filled. Furthermore, the quality of the services provided may be affected in a negative way.

In addition, due to the growing number of pharmacies, in combination with increased competition in the pharmacy sector the number of pharmacists and other pharmacy staff per pharmacy will decrease, as the available pharmacy personnel needs to be spread over more pharmacies and pharmacy owners try to keep the costs for personnel as low as possible. A smaller number of staff per pharmacy can lead to an increase of the workload for pharmacy personnel, especially pharmacists, and possibly also to a lower quality of the services provided. It has been observed that the overall work satisfaction of pharmacy staff is lessening in some deregulated countries, as they experience a much higher workload and somehow have been cut in their former total freedom of choice of products to dispense and sell.

Thus it seems, that regulation leads to higher involvement in professional practice and that deregulation leads to increased relevance of reaching business targets, thus leading to a reduction of (expensive) pharmacy staff and services, which is more or less true for all analysed countries.

**False expectations**

Apart from these possible consequences of deregulation in the pharmacy sector, the analysis of the three chosen deregulated countries has also shown that deregulation does not always lead to what was intended to be accomplished through deregulation.
Apparently, liberalisation of the pharmacy sector *does not necessarily lead to more competition*, as can be seen in Norway, where there are currently only three large pharmacy-wholesale chains that own, together, more than 80 percent of all pharmacies practically leaving no chance for other new pharmacies to enter the market. As mentioned previously, precautions need to be taken in order to prevent this scenario from happening.

Deregulation *does not necessarily reduce the price of OTC medicines*, as these are more connected to the statutory framework than to the pharmacy system. Thus, liberalisation of the pharmacy sector alone will not decrease the prices of pharmaceuticals.

In general, liberalisation and increased competition in the pharmacy sector do *not guarantee cost-containment* in the pharmaceutical sector. Obviously, there are more factors, apart from the financial stimulation (induced by increased competition) of pharmacists to dispense cheaper pharmaceuticals.

**General conclusions**

Besides the possible consequences and the false expectations of deregulation, conclusions on a more general level can also be drawn.

First of all, it is apparent that *historical developments, traditions and culture have a large influence* on the way how issues are regulated and how systems are organised in a country, which is reflected in the health care and pharmacy policy. Several EU Member States have seen deregulation initiatives with regard to public services in the course of the last 10 to 15 years, often due to pressure by European authorities. Deregulation focused on several sectors (like telecommunication or energy supply), of which the health care and pharmacy sector were “just” further areas being deregulated.

This deregulation process “by chance” and the historical background of the underlying system, makes it difficult to link some developments to specific deregulation initiatives. For example, there are indications that liberalisation and increased competition in the pharmacy sector leads to
pharmacies focussing more on the blockbusters at the costs of specific tailor-made services. However, in the deregulated countries that were analysed in this report, these customized services seem to have never played a large role in the pharmacy sector. Thus the observed differences with regard to the preparations of magistral formulae are also likely to be the result of different historical backgrounds.

Based on the benchmarking analysis of the pharmaceutical sectors in the six examined countries, we can state that, with regard to the accessibility of pharmaceutical services, the regulated countries perform quite better than the deregulated countries, as community pharmacies and other POM dispensaries in these countries are not only sufficient in number, but they are also evenly spread throughout the country. The quality of services offered by pharmacies seems to be sufficient in all countries surveyed. Nonetheless, the benchmarking analysis has provided indications that the quality of the pharmaceutical services in countries where the pharmacy sector is regulated is somewhat superior to that in countries with a liberalised pharmacy sector, with regard to the extent to which the dispensing of pharmaceuticals in pharmacies, and especially in other medicines dispensaries, is supervised by pharmacists, and with regard to the participation of pharmacies in public health tasks. Concerning the pharmaceutical expenditure in the six countries, the growth in pharmaceutical expenditure was more moderate and the prices of OTC medicines tended to be more stable in the regulated countries.

In general, the analysis of the developments in the deregulated countries have made clear that reforms need to be well-prepared in order to have the impact envisaged and that possible negative consequences must be tackled. A good example of this is the Norwegian agreement which prevents the closure of pharmacies in rural areas. In preparation of any reform (deregulation initiatives or any other), the consequences should be assessed thoroughly, and side-effects and loop-holes for some of the actors affected should be anticipated. In addition, it should be evaluated whether the situation in a country justifies liberalisation. For example, insufficient accessibility and quality of pharmacy services might
be reasons for liberalisation of the pharmacy sector, as can be seen in Norway. On the other hand, in this view, the liberalisation of, for example, the Spanish pharmacy market would not appear to be justified at this moment.

Furthermore, it has once more become clear that health care is a special issue and needs regulations, which is reflected by the fact that even in the countries considered as very much deregulated, regulations do exist for pharmacies, for example, with regard to the availability of pharmaceuticals or the tasks and duties of community pharmacies. Even if some changes are taking place a regulatory framework, be it statutory or not, is always necessary to guarantee a good quality of care. In this context, we would like to point to the fact that in the guaranteeing the good quality of pharmacy services and of professional pharmaceutical expertise lies an important role for regulatory bodies and professional associations in the pharmaceutical sector.