Regulation of Professional Services
28 October 2003
PGEU Presentation

Introduction
Commissioner, ladies and gentlemen, good morning,

I would like to thank the Commission for giving us the opportunity to address this distinguished audience.

Let me briefly introduce to you the Pharmaceutical Group of the European Union. PGEU represents Community pharmacists in the 29 European Countries, overall PGEU represents over 400.000 Community pharmacies in Europe through their professional bodies and pharmacists associations. PGEU's main objective is to promote the role of the pharmacist as a key player in delivery of healthcare to European citizens.

Comments on the Austrian Study and Commission consultation
I have to say that we were surprised to be invited to take part in this conference and moreover to have been part of the analysis of the study carried out by the Austrian Institute for Advance Studies last year. Our surprise and concern arose from the fact that in the study, and in the subsequent Commission consultation, no account was taken of the fact that community pharmacy is a liberal profession operating within the healthcare sector, to which very special considerations apply.

In my contribution I will highlight and provide examples of such special considerations. Before, however, I would like to make some comments on the Austrian study. I will not repeat the concerns and criticisms expressed by previous speakers in relation to inaccuracies and faults in methodology. However, I will just like to mention here that we have detected several inaccuracies in the pharmacy sector and we believe that the study does not reflect the reality of our profession.

We are concerned that the Commission will attempt to assess the compliance of professional rules with competition law on the basis of what we consider to be unreliable facts. We trust that the Commission will listen to the views expressed here today and will view the conclusions reached by the study in a more critical manner, taking into consideration other aspects rather than pure economics when analysing all professions and in particular pharmacists.

Overview of pharmacy professional rules
In the next few minutes, I will give you an overview of professional rules for pharmacy services and, more importantly, the reasons behind them. I have been asked to address rules on opening new pharmacies, on ownership and on distribution of medicines.

I will start by highlighting why examining pharmacists out of the context of the healthcare system does not give a full and realistic picture of the profession.

Community pharmacists are part of national health systems under the framework of social security reimbursement schemes. Their activities and professional responsibilities have a direct impact on the provision of health care. Member States recognise and value that impact by imposing on the profession clear rules aiming at meeting public health objectives.

In addition, pharmacists provide services of general interest. Members States recognise this by imposing legal obligations on the profession to ensure patient safety and adequate accessibility to medicines. A clear example of this kind of requirement is for instance the obligation to ensure the proper and timely supply of medicinal products to the population.

Article 152 of the EC Treaty (and Article 179 of the draft constitutional text, which did not changed the wording) establishes Member States' responsibility for provision of health care services and also states that all Community policies must ensure a high level of public health protection.

In light of this we think it is important that any consideration of pharmacy services and the way they are organised at Member State level is undertaken from an appropriate perspective.

Cost containment for medicines and health services is one of the key priorities for all Member States and EU applicant countries. Any rules that contribute to achieve this important objective should not be jeopardised, especially if the reason for proposed changes is based solely on the desire to increase competition rather than on the protection of public health and the public interest.

Let me give an example, Iceland liberalised pharmacy services in 1996 with the aim of increasing competition, cutting down costs and improving the service to citizens. The result was that national expenditure in pharmaceuticals increased and pharmacies became concentrated in areas with high population density to the detriment of rural areas. Since the liberalization it is no longer possible in Iceland to get medicines at night. Obviously, providing pharmacy services at night is not profitable enough. I am not so sure if the liberalisation met the objective of improving services to citizens and surely it did not contribute to reducing pharmaceutical expenditure, rather the contrary. Well, yes, it might have increased competition but at what costs? I leave the judgment to you.

In the pharmacy sector we have rules specifying, geographic and demographic requirements for the opening of new pharmacies. As we have seen from the example these have proven to be important to guarantee that pharmacy services and medicines are conveniently accessible to all citizens and to avoid the

situation where pharmacies are concentrated in highly populated urban areas. All Member States have, by one means or another, criteria for the establishment of new pharmacies.

At national level, some developments are relevant to this debate. In 1998 the Austrian High Constitutional Court concluded that the requirement of a license for the establishment of a new pharmacy ensures the proper supply of medicines to the public and thus the public interest.

More recently, in the beginning of 2003, similar conclusions have been reached by the British government in response to a recommendation by the Office of Fair Trading (OFT) to sweep away these controls. The Parliament in Scotland and the equivalent assemblies in Wales and Northern Ireland had also rejected this proposal outright. When the UK government announced that it would not implement the recommendation of the OFT, 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".*

Requirements for the opening of new pharmacies are associated with legislation limiting the ownership through pharmacies. Rules on the ownership are established by national legislation to guarantee the independence of the profession, to ensure that decisions are not taken solely for commercial reasons and to guarantee the provision of high quality pharmacy services.

Pharmacists must be independent from major market entities or other parties that might influence professional decisions. For example, restrictions on doctors owning pharmacies contribute to ensure that prescribing is based only on clinical need.

Only very recently, the Italian Constitutional Court has confirmed the importance of this independence of pharmacies from other operators in the pharmaceutical sector in order to achieve public health objectives.

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 European economy. For example, in Norway, after strong pressure from big pharmaceutical wholesalers, pharmacy ownership was liberalised from 2001. In just over a year, the number of independent pharmacies has gone from 356 to 78.

It is interesting to note that 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 of 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. This is a clear indication that the profession as it is currently organised responds to the needs of citizens and fulfils their expectations.

In the time I have left, I would like to briefly refer to the last aspect relevant to our sector which I was asked to cover, the sales of medicines only in pharmacies. A few countries as, for example, the United Kingdom and Ireland, have adopted legislation allowing for certain medicinal products to be sold in non-pharmacy outlets.

Even common medicinal products, such as paracetamol and aspirin, can be dangerous if they are not taken in appropriate quantities and in the appropriate way.

Let me give you an example. According to a study entitled ‘Paracetamol Availability and Overdose in Ireland” carried out by the Irish public health authorities, paracetamol remains the most common form of overdose requiring hospital treatment in Ireland with admissions increasing in the last few years. The researchers concluded that poisoning was directly related to availability of paracetamol. It was also found that paracetamol was wrongly displayed at the selling point and too accessible for buyers in many non-pharmacy outlets. We should keep in mind that the way you get a medicine is a key element which contributes to the perception citizens have of medicinal products. As evidence shows overuse from easily accessible medicines is a common phenomenon that should be adequately 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 contrast, the existence of a network of community pharmacies guarantees that, at the point of delivery, there is always a pharmacist available, who, can provide all necessary information on a specific product. In addition, the network of pharmacies ensures that the medicines are stored correctly, that they are available at all times, and when problems are identified, a quick recall is implemented or advice on precautions is given to citizens without delay.

Let me conclude here. I believe that when considering pharmacy services the promotion of public interest should be kept in mind. The Wouters Case, mentioned earlier, has clearly stated the importance of promoting the general interest in the context of other professional services. I believe the same conclusion, can be equally applied to pharmacy services. The public health

element, which is a full part of pharmacy services, makes this principle even more relevant.

European and National Institutions already recognise, that medicines are special products, and must not be treated as ordinary consumer goods. In addition the peculiar situation of the pharmaceutical market in which the entity who pays for the medicines, the one who uses it and the one who actually buys it are normally three different “persons” underlines the specificity of this sector which leads to a special market in which conventional economic theory cannot always be strictly applied.

Therefore the EU has indeed the obligation of making sure that competition rules are enforced, however Public Health protection, also an obligation of the EU, should be the first priority and the final objective of any national and Community policy in relation to pharmacy services.

With this in mind I wish to close by quoting the Regulation 1/2003 relevant to the implementation of Articles 81 and 82 of the Treaty, the Regulation clearly establishes that the application of its provisions do not “*preclude Member States from implementing on their territory national legislation, which protects other legitimate interests...”*

I wonder which interests are more legitimate than health protection.

Thank you very much for your attention.