It is important therefore that an **adequate distribution** of pharmacies (in keeping with qualitative norms) make it possible to meet the population's need for medicines. However, such rules must be necessary and **proportionate to this objective of general interest**.

The result is, therefore, that the criteria put in place must favour a good territorial coverage. These criteria must be objective, non-discretionary, non-discriminatory (e.g. geographic and/or demographic criteria) and linked to the sole objective of ensuring adequate coverage, and must not have any other hidden or implicit aim such as preserving existing situations unchanged.

2.3. Access in terms of opening hours, home delivery, use of e-commerce techniques, etc., must be ensured, as must economic accessibility, by **healthy competition** in the sector (see 3.2.), in compliance with the rules of good practice (see 1.1.2.).

3. ECONOMIC ACCESSIBILITY OF PHARMACEUTICAL SERVICES

3.1. As regards the **economic accessibility** of pharmaceutical services, three preliminary remarks may be made.

First, **quality has a cost** and the provider of quality services must be remunerated for those services.

Secondly, **quality is profitable**, with regard to savings of expenses caused by lack of quality.

Thirdly, we emphasise that existing medical **insurance systems** in the various Member States are intended to give patients access to health care, and thus among other things to medicines and pharmaceutical services.

3.2. In light of these preliminary remarks, if citizens have a right to high quality and safe pharmaceutical services, they also have the right, as consumers of these services, to benefit from the **free competition** enshrined in European law.

We defend a **mandatory circuit** for medicines, a circuit that is, moreover, **secure**. But within that circuit, **competition must come into play** whenever it serves the interests of patients, and notably to make pharmaceutical services affordable.

We therefore argue, in this case as well, for a **reduction in restrictions** that may currently exist in national legislation or in the rules imposed by professional organisations in which membership is mandatory.

However, competition can in some cases have an effect that is contrary to the interests of patients. In such cases **limits** may placed on free competition between pharmacies, but once again only to the extent necessary and in proportion to the true objectives of quality in public health. These limits are found set out in the rules of good practice (see 1.1.2.).

EUROPEAN UNION OF SOCIAL PHARMACIES

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Position of the European Union of the Social Pharmacies (EUSP)

Workshop on **Access** to **High Quality Pharmacy Services**

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Wednesday, 15 October 2008

European Commission
Internal Market and Services DG

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The European Union of Social Pharmacies (EUSP) has over the past few months conducted an in-depth reflection on the questions relating to the **legal framework for pharmacies and pharmaceutical services**.

This framework naturally has an impact on the exercise of the profession not only in social and health terms but also in economic and financial terms.

This reflection was carried out by the EUSP:

> starting from the existing situation in the various countries within the European Economic Area,
> taking into account Community law,
> including it within the continuity of its earlier work.

At its most recent Annual General Meeting (TORUN, PL - 26.09.2008), the EUSP adopted a *White Paper regarding the legal forms of establishment of pharmacies and pharmacy services in the European Union*.

Clearly it is by reference to this document that the EUSP sets forth its position today and responds to the three questions placed on the agenda, namely:

> How to guarantee the independence of the pharmacist in exercising his or her profession?
> How to ensure access to pharmaceutical services?
> How to provide citizens with high quality and affordable pharmaceutical services?

We reply to these questions by addressing these points in a slightly different order.

First, we address (1) jointly the questions of the **independence of the pharmacist** and that of **the quality of pharmaceutical services**, as it seems to us that the same means are used to respond to these two demands.

We then examine (2) the question of **access** to pharmaceutical services.

Finally, we treat separately (3) the need to make pharmaceutical services **affordable**.

The development of each of these points is fairly brief, as requested by the organisers of the workshop.

EUROPEAN UNION OF SOCIAL PHARMACIES

1. THE INDEPENDENCE OF THE PHARMACIST AND THE QUALITY OF PHARMACEUTICAL SERVICES

1. The independence of the pharmacist and the quality of pharmaceutical services must be guaranteed by **one and the same provision consisting of three elements** that make up a whole in which each element supports the others: initial and ongoing training of the pharmacist, rules of good practice in pharmacy, and the continued distribution of medicines via a secure circuit.

1.1.1. The technical independence of the pharmacist in practising his/her profession is guaranteed first of all by the pharmacist's **initial training**.

The first condition guaranteeing the autonomy of the pharmacist is to reserve access to the profession solely to qualified persons, and to maintain the requirement for a **high level of qualification**.

The pharmacist must, of course, supplement that initial training over the years by means of a constant investment in **continuing professional education**.

The **expertise** of the pharmacist is a guarantee of his/her independence of judgment in making decisions.

If the pharmacist's qualification guarantees his/her independence, it also leads quite naturally to the quality of the services the pharmacist provides.

1.1.2. There is a second principle that supplements the above, namely that the **intrinsic competence** of the pharmacist is in effect a necessary but **not a sufficient** condition for his/her effectiveness and full technical independence, and for the quality of the pharmaceutical services he/she provides.

The activity of the pharmacist must be governed by **rules of good practice in dispensing (GPD)**, and these rules must be **binding**.

The EUSP has issued a publication on this question: *Recommendations for the development of standards for good practice in pharmacy*.

These rules of good practice should cover the entire range of activities in pharmacy, and especially the principal process of **responsible dispensing** of medicines as well as all associated and supporting processes, and should concern both activities of an intellectual, intangible nature (e.g. the design, creation and maintenance - updating - of the patient's pharmaceutical record) and activities relating to the material management of medicines and other products or arrangements (e.g. the organisation of inventory and storage of products).

The **industrial manufacture** of medicines has, for many years, been subjected by the European authorities to the **Principles and Guidelines of Good Manufacturing Practice in Respect of Medicinal Products** (Directive 2003/94/EC). Similarly, **Guidelines on Good Distribution Practice of Medicinal Products for Human Use** have been drawn up (former 94/C 63/03).

We consider that just as the European authorities have adopted directives on the manufacture and wholesale distribution of medicines, it would be timely to enshrine in a directive the **dispensing of medicines to the patient**.

The chain the links the medicine from the producer to the consumer must offer a high level of guarantees in terms of quality, effectiveness and safety. It is paradoxical that measures were taken in this regard at various stages of that chain except for the very last link before the consumer, namely the pharmacy. The entire process having been protected by rules of good practice upstream from the pharmacy itself, it is important now to close that final gap.

Mandatory compliance with the GPD guarantees the safety of European patients thanks to the quality and effectiveness of the actions of the pharmacist, which he or she carries out with full autonomy in his/her sphere of competence.

EUROPEAN UNION OF SOCIAL PHARMACIES

1.1.3. To these two principles, an **indispensable corollary** must be added: the **sale of medicines must be reserved to the channel that has thus been secured**. Medicine must be administered to the patient by means of the pharmacist, who exercises his/her profession in compliance with the GPD.

To allow the patient to access medicines by other means would render meaningless the measures for global safety that have been put in place.

1.2. For the EUSP, the **three principles set out above are indispensable for guaranteeing the independence of the pharmacist** in exercising his/her profession, and thus for guaranteeing that consumers have access to pharmaceutical services that meet **requirements for quality, safety and efficiency**. All three are jointly necessary, and are also sufficient.

1.3. Thus the EUSP does not consider the link between ownership of the pharmacy and the exercise of the profession to be necessary in order for that exercise to be carried out under the best possible conditions of responsibility, independence and high quality service provision. The question of the ownership does not seem to be of prime importance.

If medicines are dispensed by a diploma-holding pharmacist and in accordance with the GPD, the specific characteristics of a proprietor (natural or legal person, pharmacist or other, etc.) are not of key importance, since the owner is in turn bound by the arrangements put in place to guarantee the independence of the pharmacist and the quality of pharmaceutical services.

In order to avoid potential conflicts of interest, **incompatibilities** between certain natural or legal persons and the role of proprietor of a pharmacy may need to be defined. Such incompatibilities can only be justified by objectives of general interest, and on condition that they are necessary and **proportionate to achieving those objectives**.

As regards **multiple ownership**, the same reasoning should be applied. As long as the mandatory intervention of the pharmacist and the application of the rules of good practice are respected, there is no reason to prohibit a person (natural or legal, pharmacist or other) from owning several pharmacies, in accordance with the rules of free competition.

1.4. The EUSP stresses that its proposals are in line with certain conclusions of the study conducted by **ECORYS** on behalf of the Commission.

We suggest maintaining and reinforcing, at European level, regulations on *conduct* and to loosen and reduce regulations pertaining to *structure*.

Indeed, according to ECORYS, their analysis demonstrates:

> a negative correlation between a high rate of regulation of *structure* and the performance of the sector in terms of productivity and efficient use of the resources available;
> a positive correlation between a high rate of regulation of *conduct* and the performance of the sector in terms of efficient use of the resources available and in terms of the quality and diversity of the services offered.

2. ACCESS TO PHARMACEUTICAL SERVICES

2.1. The organisation of the right to open, close and move pharmacies must, in the first instance, follow the principle of **freedom of establishment**.

2.2. However, Member States are responsible for ensuring that their citizens have access to pharmaceutical services. It is no use putting in place an arrangement that guarantees the quality of pharmaceutical services if these services are not accessible locally to those who need them.