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White paper regarding legal forms of establishment of pharmacies and pharmacy services in the European Union

VERBAND DER EUROPAÏSCHEN SOZIALEN APOTHEKEN
EUROPEAN UNION OF THE SOCIAL PHARMACIES
UNION EUROPEENNE DES PHARMACIES SOCIALES
UNIONE EUROPEA DELLE FARMACIE SOCIALI
EUROPESE UNIE VAN DE SOCIALE APOTHEKEN
EUROPEJSKA UNIA APTEK SOCIALNYCH
UNIÃO EUROPEIA DAS FARMÁCIAS SOCIAIS

A. INTRODUCTION

Over the last few years, the European Union of the Social Pharmacies (EUSP) has been thoroughly discussing the **profession of pharmacist and the role taken on** thereby in the first years of this century. In particular, we have been focusing on the criteria that should be satisfied in order for pharmacists and pharmacies to guarantee their function in the healthcare industry[1].

We now wish to deal with another issue related to said profession: rather than focusing on its merely social-healthcare role, we will look at a wider scenario pertaining to **the legal, economic and financial context of the profession**. We have already dealt with the economic conditions related to the profession[2] when analysing the system of payments for pharmaceutical services. We will now focus on the same issue though in a wider perspective, i.e. concentrating on the topical (and controversial) issue of access to pharmacy ownership, which is intertwined with the right of establishment.

Such a comprehensive discussion of the legal and economic issues related to the said profession will be carried out:

> by looking at the different situations in the many European countries;

> by examining European law;

> by supplementing this analysis with previous remarks made by our Union.

B. NATIONAL REGULATIONS ON THE FIELD OF PHARMACY

1. **The field of pharmacy is regulated in every EU Member State.** Indeed, a plethora of issues pertaining to the profession in question is regulated, at times quite strictly. Laws and regulations cover the following matters:

   > access to the profession (academic and professional qualifications, etc.);

   > (total or partial) monopoly on the sale of medicines;

   > qualitative limits to pharmacy ownership (pharmacy ownership reserved exclusively to given professional figures);

   > quantitative limits to pharmacy ownership and pharmacy running (number of pharmacies);

   > limits to vertical integration (incompatibility);

   > demographic and geographic limits (closed-number ranges, distance, etc.);

   > commercial practices (advertising, pharmacy infrastructures, opening hours, online sales, etc.);

   > price policies, profit margins, etc.

2. The laws and regulations in force in the many Member States are roughly **comparable** with respect to certain matters, e.g. access to the profession, demographic and geographic criteria for the establishment of pharmacies, the monopoly on the sale of prescription drugs. However, there remain notable **differences** on other issues, particularly on the conditions for access to pharmacy ownership and multi-ownership.

3. Moreover, the national laws of some Member States have recently and significantly **developed**. Said laws concern the past monopoly of pharmacies on the sale of given over-the-counter drugs, commercial practices, distance sales of drugs, and the criteria for access to pharmacy ownership.

   Said legal changes, together with the currently undergoing debates, are sometimes caused by and, in any event, spring from Member States' **interaction** with **European authorities**.

1 *Six commitments for quality pharmaceutical services – EUSP 2001*
Recommendations for Patient Medication Records – EUSP 2005
Recommendations for the Development of Standards for Good Practice in Pharmacy – EUSP 2007

2 *Recommendations for an appropriate system of payments for pharmaceutical service – EUSP 2003*

C. THE ESTABLISHMENT OF PHARMACIES AND PHARMACEUTICAL SERVICES IN ACCORDANCE WITH EUROPEAN LAW

1. The **field of pharmacy** is subject to specific European rules pertaining to **drugs marketing, manufacturing, importing, labelling,** the drafting of **information leaflets**, as well as to drug **classification, wholesale distribution, advertising, pharmacovigilance**, etc.

   Said Directives have now been **codified**: on 6th November 2001, the European Parliament and the Council enacted a Directive laying down a *Community code relating to medicinal products for human use*[3].

   Though the manufacturing, marketing and wholesale distribution of medicines are regulated by European provisions, drug dispensing to patients, i.e. the last link of the chain, is not regulated by any European law or regulation. **Hence, there are no specific legal instruments (i.e. Directives) regulating pharmacies and pharmaceutical services**.

2. However, the application of **European law** to pharmacies and pharmaceutical services is just as compelling as in any other field.

   The European **legal source** we first need to refer to is the Treaty establishing the European Community, which guarantees the **fundamental freedoms** underpinning the Community itself.

   The first text to refer to is, quite obviously, Art. 14(2), which establishes the *free movement of goods, persons, services and capital* within the Union.

   The second text deals with the freedom of establishment and thus the free movement of persons: *»[…] restrictions on the freedom of establishment of nationals of a Member State in the territory of another Member State are prohibited. Freedom of establishment shall include the right to take up and pursue activities as self-employed persons and to set up and manage undertakings, in particular companies […]»* (art. 43).

   The law on the free movement of persons further extends to the free movement of services: *«[…] restrictions on freedom to provide services within the Community shall be prohibited in respect of nationals of Member States who are established in a State of the Community […]»* (art. 49), as well as to the free movement of capital: *«[…] all restrictions on the movement of capital between Member States and between Member States and third countries shall be prohibited»* (art. 56), and to the free movement of goods: *«Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States»* (art. 28).

3. The **EC Treaty** also lays down specific provisions on the healthcare field.

   Derogations from the freedom of establishment and from the free movement of services are allowed on grounds of public policy, public security and public health (art. 46): *«Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care.»*[4] (art. 152.5).

4. Other than primary law sources, there also apply legislative, regulatory and administrative provisions included in **secondary law sources**.

   Let us first mention Directive 2006/123/EC on services in the internal market, which states that *«it shall not apply […] to healthcare services, whether or not they are provided via healthcare facilities, and regardless of the ways in which they are organised and financed at national level or whether they are public or private»* (art. 2.f.)

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3 *Directive 2001/83/EC of the European Parliament and of the Council of 6th November 2001, on a Community Code relating to medicinal products for human use, O.J. n. Law 311 of 28th November 2001, p. 67, amended by Directives 2002/98/EC, 2003/63/EC, 2004/24/EC, 2004/27/EC and by Regulation no. 1901/2006*

4 *See also the Watts judgement of 16.05.2006, case C-372/04, points 146 and 147: "Next, it should be noted that, according to Article 152(5) EC, Community action in the field of public health is to fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care. That provision does not, however, exclude the possibility that the Member States may be required under other Treaty provisions, such as Article 49 EC, or Community measures adopted on the basis of other Treaty provisions, such as Article 22 of Regulation No 1408/71, to make adjustments to their national systems of social security. It does not follow that this undermines their sovereign powers in the field.»*

Moreover, Premise 22 of the same Directive states: «*The exclusion of healthcare from the scope of this Directive should cover healthcare and pharmaceutical services provided by health professionals to patients to assess, maintain or restore their state of health where those activities are reserved to a regulated health profession in the Member State in which the services are provided*».

Lastly, Directive 2005/36/EC, on the recognition of professional qualifications, states that «*Member States shall not be obliged to give effect to evidence of formal qualifications […] for the setting up of new pharmacies open to the public*» (art. 21.4.).

Premise 26 of the Directive also states that it «*does not coordinate all the conditions for access to activities in the field of pharmacy and the pursuit of these activities. In particular, the geographical distribution of pharmacies and the monopoly for dispensing medicines should remain a matter for the Member States. This Directive leaves unchanged the legislative, regulatory and administrative provisions of the Member States forbidding companies from pursuing certain pharmacists' activities or subjecting the pursuit of such activities to certain conditions.*»

5. Hence, it can be seen that **the EU authorities have paid special attention to the field of pharmacy** over the last few years, with particular focus on the **restrictions to fundamental freedoms encountered in the field**.

   Several **problems pertaining to the internal market** have been pointed out and have called for serious measures.

   5.1. The relevant Authorities have gathered information in the field, drawing from several **sources**:

   > legal actions (brought by companies, healthcare professionals, private citizens, etc.);
   > questions referred to the European Court of Justice for preliminary rulings;
   > parliamentary questions;
   > interpellations;
   > studies.

   5.2. In short, the restrictions in question may be divided into the following **categories**:

   > Restrictions to pharmacy ownership:
   - ownership reserved exclusively to pharmacists;
   - ownership reserved exclusively to national pharmacists;
   - quantitative limits to pharmacy ownership;
   - incompatibility between running a pharmacy and pursuing other activities.

   > Restrictions to the free establishment of pharmacies:
   - limited number of pharmacies, proportionately to the number of inhabitants;
   - minimum distance between pharmacies;
   - presence of a physician in the Municipality where a pharmacy is to be set up;
   - priority given to local pharmacists.

   > Restrictions to free medicine dispensing:
   - no on-line sales of medicines;
   - sales monopoly of pharmacies located in the Municipality and neighbouring areas;
   - no drug advertising;
   - no "foreign" prescriptions.

   5.3. The currently pending **proceedings** concern different Member States[5].

   5.3.1. On 22nd December 2006, the European Commission (EC) took **Italy** to the Court of Justice on account of the alleged infringement by its national legislation of the freedom of establishment (art. 43 EC Treaty) and the free movement of capital (art. 56 EC Treaty)[6].

   Firstly, Italian legislation is criticised for granting the right to own a private pharmacy to Pharmacy graduates only, and to legal entities made up exclusively of associate pharmacists. Hence, no other

5 *A list of pending proceedings as of the date of approval of the present document (i.e. 25th September 2008) is herein provided.*

6 *Case C-531/06.*

professional (other than Pharmacy graduates) can hold investments in pharmacies or establish pharmacies, especially if s/he comes from another Member State.

Secondly, the EC criticises the fact that Italian law forbids enterprises involved in the distribution of pharmaceutical products from holding investments in companies running Municipal pharmacies.

5.3.2. The EC has also criticised **Spain**, by sending a reasoned opinion on 28th June 2006, on account of the fact that its national rules require community pharmacies to comply with healthcare planning rules, laid down according to the population and to the distance between pharmacies.

The EC deems it more suitable to take alternative measures, e.g. establishing that a new pharmacy may be opened in an area where there is already a significant number of pharmacies only when at least one pharmacy is opened in an area where there are no pharmacies.

Moreover, the EC criticises the criteria used by Spain[7] for the granting of administrative licences[8], as well as the country's regulatory provisions which allow pharmacists only to own a pharmacy and which forbid pharmacists from owning or co-owning more than one pharmacy at any given time.

5.3.3. Concurrently, the EC asked **Austria** to amend some of its regulatory provisions which have introduced limits to the number of pharmacies (according to the number of inhabitants and to minimum distances between pharmacies), as well as to the legal status of pharmacies, to the running of more than one pharmacy, etc.

5.3.4. An infringement procedure was also instituted against **France** (formal notice of failure of 21st March 2007).

The action concerns the incompatibility of several provisions of the French Public Health Code with art. 43 EC Treaty on the freedom of establishment.

The criticised provisions concern:

> the need to be a Pharmacy graduate to run a pharmacy;

> the circumstance that a pharmacist cannot own (or co-own) more than one pharmacy;

> the circumstance that non-pharmacists cannot hold investments in companies running pharmacies;

> the incompatibility between running a pharmacy and pursuing another activity;

> the need to refer to the Pharmacists' Association in order to either open or transfer a pharmacy.

5.3.5. A declaration of failure against **Belgium** has been object of a formal intimation (17th October 2007).

The declaration concerns several Belgium law provisions governing the dispensing of medicines, through intermediaries, to citizens within a specific community. Pharmacists are forbidden from dispensing medicines through intermediaries (agents or representatives) to private customers not resident in the same Municipality where the pharmacy is based or in a neighbouring Municipality. According to the EC, said provisions are in contrast with article 43 (no restrictions on freedom of establishment), 49 (no restrictions on the freedom to provide services within the EC) and 28 (no quantitative restrictions on imports).

5.3.6. The EC has recently decided (September 2008) to formally request **Germany** to reviews its rules on ownership of pharmacies. In fact, current national legislation reserves pharmacy ownership to pharmacists or partnerships consisting solely of pharmacists.

Moreover, the German legislation prohibits ownership of more than one main pharmacy and three branch offices. Finally, the legislation requires proximity between the main pharmacy and the branch offices. The Commission considers that these measures are incompatible with the freedom of establishment, enshrined in Article 43 of the EC Treaty, since they cannot be justified for reasons of health protection.

7 *European Commission, Press releases, Brussels, 28th June 2006, IP/06/858, http://europa.eu/rapid/pressReleasesAction.do?reference=IP/06/858&format=HTML&aged=1&language=FR&guiLanguage=en.*

8 *In Spain, some autonomous communities give priority to pharmacists with professional experience in the same Community.*

A similar matter had already been referred to the **European Court of Justice** on 30th March 2007 by the **Administrative Court of the Saar Region** for a preliminary ruling[9].

5.3.7. Lastly, in September 2008, the EC decided to formally request **Portugal** to review its rules on ownership of pharmacies.

Under Portuguese national rules, companies active in the wholesaling of medicines are not allowed to own or manage pharmacies. Moreover, the Portuguese legislation establishes a ban on owning more than four pharmacies. Again, in the Commission's view, these requirements are disproportionate to guaranteeing the protection of health and therefore are not compatible with the freedom of establishment, enshrined in Article 43 of the EC Treaty.

6. Said actions and measures are evidence precisely of the same concern expressed by European Authorities: without prejudice to the fact that the field of national pharmacy, as well as other fields concerning healthcare services, fall within **the responsibility of each Member State** (principle of subsidiarity), said power must nonetheless be exerted **in accordance with the fundamental freedoms** laid down by the EC Treaty.

Such a stand has been repeatedly confirmed, especially by Commissioner Charlie McCREEVY, in response to questions raised by members of the European Parliament. Here is the full text of the third point of the Commissioner's answer of 03.07.2007 to Anne FERREIRA, a member of the European Parliament:

«I wish to assure you that both the Commission and myself are perfectly aware of the fundamental importance of healthcare services, especially pharmaceutical services, to European citizens. We do not question the responsibility of each Member State to organise its national healthcare system and, in particular, the field of pharmacy, in accordance with its own national policies and traditions. However, the measures taken by Member States must be in accordance with the fundamental freedoms laid down by the EC Treaty, such as the freedom of establishment, which may be implemented directly within national legal systems. Without prejudice to the fact that the evaluation of healthcare provisions cannot be grounded on merely economic considerations related to the freedom of movement laid down by the Treaty, it is nonetheless underlined that national laws protecting public interests, such as public health, must be in accordance with the principles of non-discrimination and proportionality. For instance, with respect to pharmaceutical services, national laws that grant pharmacists only the right to run a pharmacy, or that require companies running pharmacies to take on a specific legal status, may be replaced by regulatory measures guaranteeing the control of said services, or the professional responsibility of those providing said services; this would ensure the quality of pharmaceutical services, and thus serve the public interest, without infringing fundamental freedoms.»

In this scenario, the different proceedings pending against Italy, Germany, Austria, Spain, France and Portugal, all deal with the same issue: **pharmacy ownership**.

The aforementioned Member States all share the same belief: the compulsory link between pharmacy ownership and pharmacy management; the requirement to be a Pharmacist in order to own a pharmacy; the principle whereby a pharmacist can own one pharmacy only, thus prohibiting multi-ownership. All of these factors are deemed vital in order to guarantee a pharmacist's independence in performing his/her tasks and to ensure the quality of pharmaceutical services.

In response to such contentions, the EC raises the following question: is the (totally or partially) compulsory link between pharmacy ownership and Pharmacy graduation for the pharmacy owner, as well as the (total or partial) prohibition of multi-ownership, compatible with freedom of establishment and free movement of capital? Are said legal provisions necessary and proportionate to ensure public health protection? Wouldn't it be sufficient to require the presence of a pharmacist engaged in managing the stock of medicines and dispensing medicines to patients? This is the central core of the debate raised by the European Authorities.

The other issue which different pending proceedings are grounded on (Spain, Austria, France, Belgium) concerns national laws **on the establishment of pharmacies and pharmaceutical services** and, in particular, the compatibility of said laws with freedom of establishment and with the free provision of services in the European Union.

9 *Case C-172/07: Reference for a preliminary ruling from the Administrative Court (Verwaltungsgericht) of the Saar Region (Germany) lodged on 30th March 2007 — Helga Neumann-Seiwert, pharmacist (Plaintiff) v. the Saar Region and the Ministry of Justice, Public Health and Social Affairs (Defendants): DocMorris N.V., G.U. 140, 23rd June 2007, p. 0011 – 0012.*

7. The increasing interest in pharmacy and pharmaceutical services has been confirmed by a **study carried out** in late 2005 by the company **ECORYS** Nederland B.V **for the European Commission**, DG Internal Market and Services. The results of the study, called **"Study of regulatory restrictions in the field of pharmacies"**, were delivered on 22nd June 2007 and published by the EC in January 2008.

   The aim of the study was to **evaluate how the various rules in force in the different Member States impact on the quality of pharmaceutical services** and on internal market trends, and therefore on the **performance of the field of pharmacy** as a whole.

   The level of regulation was measured according to seven categories.

   Said seven regulatory categories were then split into two groups: the first five entries referred to the structure and organization of the market ("structure"), while the last two concerned behaviours, practices and conducts of the firms directly concerned ("conduct»).

   As for the performance of the field of pharmacy across the Member States, this was measured according to indicators related to three different points:

   - productivity,
   - performance in terms of "allocative efficiency", i.e. the relationship between the allocation of means and benefits to consumers,
   - performance examined in the light of the relationship between quality and product variety.

   The data were then cross-examined to ascertain whether there was a link between a high/low level of regulation and performance, evaluated according to the above three indicators.

   ECORYS's study showed that:

   - there is a strong negative correlation between a high regulation of structures and performance in terms of productivity and allocative efficiency;
   - there is a positive correlation between a high regulation of conducts and performance in terms of allocative efficiency and quality/product variety;
   - more specifically, there is a positive correlation between the variety of services offered and high educational requirements, as well as the regulation of prices and profit margins;
   - conversely, there is a negative correlation between product variety and high requirements on registration or obligatory membership of a professional organization.

D. EUSP'S STAND

1. The **Member States' regulations** on the establishment of pharmacies and pharmaceutical services are similar on certain matters and different on others, and at times even conflict with European law.

   This has prompted the **European Authorities** to intervene in specific cases, though only for the purpose of checking that national laws complied with the EC Treaty. In this respect, since the European Authorities have deemed it appropriate to introduce Directives harmonising and coordinating the manufacturing and wholesale distribution of medicines, **wouldn't it be equally appropriate for medicine dispensing to be covered by a specific Directive**?

2. **Medicines are subject to a European regulation prior to "entering" pharmacies.**

   Therefore, medicine dispensing should be seen as an **extension** of the above regulations.

   Indeed, it would be quite paradoxical if the manufacturing, marketing and wholesale distribution of medicines were subject to strict regulations guaranteeing quality, safety and efficacy, whilst medicine dispensing were not subject to a similar and equally strict regulation. It would be like breaking the final link of a chain whose first stages, instead, are strictly coordinated and regulated.

   It is worth mentioning the 35th Premise of the Community Code relating to medicinal products for human use: «*It is necessary to exercise control over the entire chain of distribution of medicinal products, from their manufacture or import into the Community through to supply to the public, so as to guarantee that such products are stored, transported and handled in suitable conditions […]*» (sentence underlined by ourselves).

3. Whether the EU enacts a Directive or takes specific action against single Member States, requiring them to amend their national legislative, regulatory and administrative frameworks, the European Authorities should always draw inspiration from the **principles that our Union deems essential** and, more precisely, from the following four principles.

PRINCIPLES

1. The patient's interest as a fundamental objective

Any approach to pharmacy and pharmaceutical services should be driven by a fundamental and primary objective: the patient's interest.

- The law on pharmacy and pharmaceutical services should be drafted and developed in the **patient's interest**, both by the EU and by single Member States.

  This is the first principle to refer to and is certainly the primary one. It is a basic principle which cannot be side-stepped or derogated from.

- The main goal is to guarantee the **quality**, **safety**, **efficacy** and **accessibility** of pharmaceutical services to patients.

  The *recognised efficacy* of medicines and their acceptable safety standards should be both required prior to their marketing. Said **requisites** will be increasingly complied with if they are demanded also after the manufacturing and marketing stage, i.e. at the time of **medicine dispensing**.

  Similarly, product accessibility can be guaranteed (at a fair price) to all patients across the EU only if **pharmaceutical services are accessible** (not so much in economic as in geographic terms).

  According to the European Commission, *the key public health objective in the field of pharmacy is to manufacture readily accessible, effective, high-quality and safe medicines – including the most recent and innovative medicines – for all those needing them, regardless of their income and social status*[10].

  Manufacture, but also **distribute** medicines in full observance of the same requirements – we would add.

2. The necessary role of pharmacists

Pharmacists are the only professional figures that are suitably qualified to dispense medicines while offering information and suitable advice to patients.

- Medicine dispensing must go hand in hand with the provision of **professional consultancy services**, as well as **information** and a **pharmacotherapeutic follow-up**, guaranteeing the safety and effectiveness of treatment.

  Said requirements are fulfilled by a **figure who is suitably qualified for such a purpose**, i.e. the **pharmacist**, who takes on full responsibility for the role so performed.

  By virtue of his qualification, the pharmacist is a **medicine specialist**. By reason of the tasks performed thereby, the pharmacist develops a **privileged relationship** with his/her patients, who trust him/her just like they would trust their doctor during the anamnesis, diagnosis and therapy prescription stages.

- We believe that the intervention of a pharmacist is compelling for dispensing both **prescription drugs and over-the-counter drugs**. In fact, a pharmacist is all the more needed when dispensing and managing over-the-counter drugs if the patient has not visited his/her doctor beforehand. Indeed, the Community Code relating to medicinal products for human use establishes that all drugs (whether they be medicinal products on renewable or non-renewable medical prescription or over-the-counter drugs) are to be subject to the same limits and restrictions on manufacturing, marketing and wholesale distribution. Once a product falls within the **definition of "medicinal product", as laid down by European law**, said product should be introduced into a circuit which guarantees quality, safety, efficacy and accessibility, at all levels of the process.

  The sole relevant distinction regarding the required intervention of a pharmacist is that between a medicinal and a non medicinal product. According to the Community Code, a product is either a medicinal product or it is not. A medicinal product is any product which, by reason of its presentation, function and composition, is designed to restore one's health. Hence, it must be introduced into a protected circuit. Otherwise, there is no reason to require a special circuit, as long as the product is not presented as a healthcare substance.

10 *Communication from the Commission to the Council, to the European Parliament, to the European Economic and Social Committee and to the Committee of the Regions, called "A Stronger European-based Pharmaceutical Industry for the Benefit of the Patient – A Call for Action" (01.07.2001)*

In the preliminary considerations of the Community Code relating to medicinal products for human use, the EC rightfully states that the classification of a "medicinal product" may need to be changed to take innovative therapies into account, as well as the increasing number of products "on the borderline" between pharmacy and other fields.

3. The necessary compliance with standards for good dispensing practices

The pharmacist's role should be viewed and defined by standards for good practice in medicine dispensing, which are vital to ensure its effectiveness.

Said standards must be **mandatory** and **binding**.

The pharmacist and his/her assistants should work in an environment that allows them to make the best of their work. The pharmacist should thus implement a **system that guarantees pharmaceutical quality**, and should rely on specific **instruments** and suitable **procedures** supporting and guiding his/her activity.

Such a *third* principle cannot be separated from the aforementioned *second* principle (necessary role of pharmacists) **if the conditions for the *first* principle** (quality, safety and efficacy of pharmaceutical services) **are to be satisfied**.

It is a principle of the utmost importance, it being a **key element** for the actual implementation of the entire system, which otherwise would result incomplete.

Nonetheless, this topic is not analysed in depth in this document, as a previous EUSP's publication was entirely dedicated thereto.

For a further insight into the matter, please refer to our previous publication, ***Recommendations for the Development of Standards for Good Practice in Pharmacy*** (September 2007).

4. The enforcement of the fundamental principles of European law and the public interest

The field of pharmacy and pharmaceutical services should be structured so as not to conflict with the fundamental freedoms laid down by the EC Treaty, whilst also guaranteeing the public interest or, more specifically, public health.

- The above three principles guarantee an ideal setting within which pharmacies can perform their **social-healthcare role** and help safeguard and promote public health.

  Yet, pharmacies also have an **economic role** and, as such, they are part of a process which starts with manufacturers and ends with the recipients of pharmaceutical services, i.e. patients.

  As **economic agents**, the pharmacist and the pharmacy must comply with the **fundamental principles of European law**.

  The free movement of persons, goods, services and capital, as well as freedom of establishment, should be ensured by taking the specific features of the field into account, i.e. ensuring that the public interest, i.e. **public health**, is protected and safeguarded.

  Nonetheless, the patient's interest and the protection of public health cannot serve as an excuse to justify any unwarranted, disproportionate and unjustified infringement of the fundamental freedoms guaranteed by the EC Treaty.

  The respect for **fundamental freedoms** and the protection of the **public interest** should be interpreted and applied in a balanced, harmonised, consistent and cautious way.

  This balance can only be achieved by implementing correctly the principles of **subsidiarity** and **proportionality**.

- It follows that the above principles, aimed at protecting the patient's interest and public health, take priority over the **issue of pharmacy ownership**. Rather, it is important to make a **distinction between access to profession and access to ownership**. As long as medicines are dispensed by a pharmacist (Pharmacy graduate) in accordance with standards for good practice, the specific qualifications of the pharmacy owner are irrelevant – whether the latter is an individual or a legal entity, whether or not a pharmacist, etc. – as

the pharmacy owner himself is bound to comply with the implementation system devised to guarantee the independence of the pharmacist and the quality of pharmaceutical services.

In any event, in order to avoid conflicts of interests, it is certainly feasible to lay down specific **incompatibilities** between a given category of natural or legal persons and pharmacy ownership. Said incompatibilities may be justified only on grounds of public interest and only if they are necessary and proportionate to achieve said objective.

The same applies to **multi-ownership**. As long as the compulsory presence of a pharmacist is guaranteed, as well as compliance with standards for good practice, there is no reason why a person (whether a natural or legal person, whether or not a Pharmacy graduate) **should not own more than one pharmacy**.

- The regulations on the **establishment and geographical distribution of pharmacies** should equally and fully comply with freedom of establishment.

  However, the application of said principles may be subject to certain limits.

  Indeed, pharmaceutical services are linked to the objective of public health, which implies accessibility to pharmaceutical services. Therefore, **pharmacies must be adequately distributed** (and comply with quality standards) so as to satisfy the public demand for medicines. However, the measures taken to ensure said adequate territorial distribution of pharmacies should be necessary and proportionate to the public interest to be pursued.

- Lastly, since European citizens, as patients, are entitled to have access to safe and good pharmaceutical services, they are equally entitled, as recipients of said services, to have the latter performed to their benefit. This may only occur if **free competition rules**, as laid down by European law, are fully honoured.

  In the field of **pharmacy**, competition should be allowed only when it is beneficial to patients. Hence, free competition should not produce results that are opposite to said interest.

  It follows that free competition between pharmacies may be subject to limits; however, once again, they must be necessary and proportionate to the public health objective.

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