

Brussels, 28 June 2006

Internal market: infringement proceedings concerning Italy, Austria and Spain with regard to pharmacies

The European Commission today decided to take Italy to the Court of Justice on account of restrictions imposed by its national legislation on the acquisition of holdings in and ownership of retail pharmacies. According to the Commission, the Italian legal provisions, as interpreted by the Constitutional Court and as amended in April 2006, are not consistent with Articles 43 and 56 of the EC Treaty concerning freedom of establishment and free movement of capital within the EU. The Commission has also decided to make a formal request to Austria and Spain to amend their national rules relating to the setting-up of pharmacies. The Commission's requests take the form of reasoned opinions, the second stage of the infringement procedure under Article 226 of the EC Treaty. If there is no satisfactory reply within two months, the Commission may refer the matter to the European Court of Justice. These three infringement procedures concern a series of existing national restrictions relating to the opening and running of pharmacies, such as: incompatibility between the distribution and the retail sale of pharmaceutical products; ownership of pharmacies reserved for pharmacists; exclusion of non-national pharmacists from new pharmacies; preference for pharmacists with local experience; territorial and demographic limits to the setting-up of pharmacies; ban on owning more than one pharmacy; mandatory legal forms for pharmacies.

Italy: acquisition of holdings in and setting-up of retail pharmacies

The Commission has decided to take Italy to the Court of Justice on account of the incompatibility of the Italian rules with freedom of establishment (Article 43 of the EC Treaty) and freedom of movement of capital (Article 56 of the EC Treaty). The Commission contests :

a) the ban on the acquisition of holdings by enterprises active in the distribution of medicines (or having links with companies active in this area) in private pharmaceutical companies or community pharmacies. Under the Italian rules, as interpreted by the Constitutional Court and as recently amended by Decree 591/2006 of 26 April 2006 (Article 100(2)), the distribution and the retail sale of pharmaceutical products are mutually incompatible. This entails, in particular, a ban on enterprises active in the distribution of pharmaceuticals (or having links with companies active in this area) from acquiring holdings in companies operating community pharmacies as part of the process of privatising community pharmacies which started in Italy in the 1990s and which would be affected by this legal incompatibility rule.

b) ownership of pharmacies reserved for pharmacists or legal entities consisting of pharmacists. Italian law prohibits individuals without a pharmacist's diploma or legal entities not consisting of pharmacists from having holdings in pharmacies. This prevents the acquisition of holdings or the setting-up of retail pharmacies by operators, in particular those from other Member States, without a pharmacist's diploma.

Such restrictions cannot be considered compatible with the EC Treaty unless they are justified by objectives of general interest and are necessary and proportionate to achieve those objectives. The Italian authorities justify the restrictions reported on the grounds of public health protection objectives consisting in particular (where the former restriction is concerned) of avoiding conflicts of interest and (where the latter restriction is concerned) ensuring greater control over those who dispense medicines to patients.

The Commission considers that the restrictions in question go beyond what is necessary to achieve the objective of health protection.

On the one hand, possible risks of conflicts of interest can be avoided by measures other than an outright ban on enterprises having a link with enterprises active in the pharmaceutical distribution sector from acquiring holdings in retail pharmacies. In Italy, numerous cases of pursuit of the activity of distribution or of participation in pharmaceutical distribution companies by pharmacists in charge of private pharmacies have been reported to the Commission.

On the other, prohibiting non-pharmacists or legal entities not consisting of pharmacists from having holdings in pharmacies also goes beyond what is necessary to achieve the objective of public health protection, since it would be sufficient to require the presence of a pharmacist to dispense medicines to patients or for stock management. Moreover, under the Italian legislation, members of a deceased pharmacist's family who are not themselves pharmacists can take charge of their relative's pharmacy for up to ten years, which goes to show that this professional qualification condition is not absolutely essential and a matter of priority for the purposes of owning a pharmacy.

Spain: territorial planning rules and ban on owning more than one pharmacy

The Commission has decided to send a reasoned opinion to Spain on account of the following legislative restrictions on the setting-up of pharmacies:

- territorial planning rules

Community pharmacies are subject to health planning rules based on population (minimum module between 2 800 and 4 000 inhabitants) and the distance (minimum 250 metres) between community pharmacies, with the possibility of smaller population modules in rural, tourist, mountain areas, etc. This system of limiting the number of pharmacies seems disproportionate or even counterproductive in relation to the objective of ensuring a good supply of medicines to the area concerned: it would, for example, be more appropriate, as an alternative, to specify that no additional pharmacy can be opened in an area that is well-off for pharmacies until such time as an area without pharmacies has at least one. This is in fact confirmed by the experience of certain Autonomous Communities (such as Navarre) which stipulate that pharmacies may be authorised beyond the limit of one pharmacy per 2 800 inhabitants.

- *criteria applied in the administrative licensing procedures.*

In the context of the licensing procedures for community pharmacies, certain Autonomous Communities (such as Valencia) give priority to pharmacists with professional experience in the same Community. These criteria are discriminatory.

- *ownership rules*

Under the Spanish legislation, only pharmacists can own and run a community pharmacy open to the public. It is also forbidden for one and the same pharmacist to have a holding or a joint holding in more than one pharmacy at any one time. These too are excessive restrictions in relation to the legitimate requirement to ensure that relations between patients and the pharmacy are exclusively entrusted to professionals qualified in pharmacy. Restrictions on ownership of pharmacies or on owning more than one pharmacy are not necessary to achieve that objective.

Austria: national discrimination clause and other restrictions on opening pharmacies

The Commission has decided to send a reasoned opinion to Austria on account of the incompatibility of the following restrictions in its legislation on pharmacies with the freedom of establishment enshrined in Article 43 of the EC Treaty:

- *discrimination on the basis of nationality for the purposes of obtaining a licence to operate a pharmacy* (non-Austrians cannot be authorised to operate a pharmacy that has been open for less than three years);

- *ban on opening a pharmacy in areas without a doctor's surgery*; this cannot be justified by the objective of guaranteeing public health and the supply of medicines.

- *limitations on the number of pharmacies according to the number of inhabitants and the minimum distance between pharmacies* (see the above considerations about the disproportionate nature of such quantitative restrictions);

- *limiting the choice of legal form for a pharmacy* by prohibiting companies from being in charge of pharmacies; the quality and supervision of the service offered by a pharmacy should be assured by means of control and forms of professional responsibility rather than through the legal form of a pharmacy, as indicated by the Court of Justice in its Judgement of 21 April 2005 in Case C-140/03 concerning similar restrictions in the case of opticians' shops in Greece;

- *ban on operating more than one pharmacy*, thus preventing any individual or legal entity from having more than one place of establishment in the Community, which is contrary to the case-law of the Court of Justice.

The latest information on infringement proceedings concerning all Member States is available at:

http://ec.europa.eu/community_law/eulaw/index_en.htm