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Advocate General's Opinions in Case C-531/06 and Joined Cases C-171/07 and C-172/07

Commission v Italy / Apothekerkammer des Saarlandes and Others

**ACCORDING TO ADVOCATE GENERAL BOT, THE OWNERSHIP AND
OPERATION OF A PHARMACY MAY BE RESERVED EXCLUSIVELY TO
PHARMACISTS**

The Advocate General considers that Italian and German laws laying down such a rule are justified by the objective of seeking to guarantee an appropriate supply of medicinal products to the public

Today, Advocate General Yves Bot delivered his Opinions in two sets of cases relating to the rules governing the ownership of pharmacies.

The cases relate, principally, to the issue of whether the Treaty provisions on the freedom of establishment preclude provisions contained in Italian and German laws which provide that only pharmacists may own and operate a pharmacy.

Joined Cases C-171/01 and C-172/07 (*Apothekerkammer des Saarlandes and Others*) arise from the authorisation granted by the competent ministry in the Saarland to a Netherlands limited liability company, Doc Morris, to operate a branch pharmacy in Saarbrücken from 1 July 2006. Before the Administrative Court of the Saarland, several pharmacists and their professional associations contested the ministry's decision for not complying with German legislation which reserves the right to own and operate a pharmacy exclusively to pharmacists.

The Administrative Court referred questions to the Court of Justice to determine whether the Treaty provisions on the freedom of establishment must be interpreted as precluding such a law.

In addition, in Case C-531/06 (*Commission v Italy*), the Commission seeks, inter alia, a declaration from the Court that by reserving the ownership and operation of private pharmacies exclusively to pharmacists, the Italian Republic has failed to fulfil its obligations under Community law.

In his Opinions, the Advocate General begins by noting that the European Community has not been conferred full and complete competence in the field of public health. That competence is therefore still shared between the Community and the Member States.

He notes that the retention of national competence in the field of public health is expressly provided for in Article 152(5) EC, which states that ‘Community action in the field of public health shall fully respect the responsibilities of Member States for the organisation and delivery of health services and medical care’.

Nevertheless, in the Advocate General’s view, in the exercise of their retained competence, the Member States are not released from their Community obligations. A national law which provides that pharmacies may be owned and operated exclusively by pharmacists must, therefore, be consistent with the Treaty provisions on the freedom of establishment if it is to be upheld.

The fact that such a law operates in an area of retained national competence expressly protected by Article 152(5) EC nevertheless has consequences for the assessment of whether that law is consistent with the freedom of establishment.

In the context of an assessment of the justification for the Italian and German laws under an imperative requirement of public interest, such as the protection of public health, it is necessary, the Advocate General explains, to take into account the fact that the Member State can decide what level of protection of public health it seeks to ensure and the means by which that level should be attained.

The existence of a restriction on the freedom of establishment

The Advocate General finds that the national provisions at issue have the effect of preventing Member State nationals, who are not pharmacists, from owning and operating a pharmacy in Italy and Germany. Whilst, according to the Advocate General, those provisions constitute, on the whole, a restriction on the freedom of establishment in so far as they hinder access to the market for natural and legal persons wishing to open a pharmacy in those Member States, they are, in the present case, justified.

The justification of the established restriction on the freedom of establishment

The Advocate General takes that view that **the obstacle thus established does not breach Community law because the restriction on the freedom of establishment is justified by the objective of protecting public health.**

According to him, the prohibition on owning or operating a pharmacy, for those who are not pharmacists, is suitable for achieving that objective since it is such as to ensure **a supply to the public of medicinal products, the quality and variety of which are sufficiently guaranteed.**

He points out that an individual owning a pharmacy, who is both proprietor and employer, inevitably has an influence on the policy followed by that pharmacy in relation to the dispensing of medicinal products. Therefore, the choice made by the Italian and German legislatures to link the professional qualification and the economic ownership of the pharmacy is justified under the objective of protecting public health.

He emphasises the importance of ensuring that medicinal advice be neutral, that is to say, that it be competent and objective. In his view, **the quality of the service of dispensing medicinal products is closely linked to the independence which a pharmacist is required to exhibit in carrying out his duties.**

By deciding to reserve the ownership and operation of pharmacies exclusively to pharmacists, the Italian and German legislatures thus wanted to guarantee the independence of pharmacists, by making the economic structure of pharmacies impervious to outside influences, for example from manufacturers of medicinal products or wholesalers.

In that regard, the Advocate General asserts that the free exercise of the profession guarantees that independence. A pharmacist who has full control over his work apparatus can therefore carry out his profession with the independence which characterises the liberal professions, being both a business manager close to the economic realities associated with the management of his pharmacy, and a health professional taking care to balance the economic imperatives against public health considerations, which sets him apart from a simple investor.

Moreover, reserving the ownership and operation of pharmacies exclusively to pharmacists does not go beyond what is necessary to ensure a high level of public health protection.

The Advocate General takes the view that the establishment of rules governing liability of both non-pharmacist operators and salaried pharmacists, and a system establishing penalties against both, is not sufficient to ensure such a high level of protection of public health since it essentially involves measures intended subsequently to correct abuses, once they have actually occurred.

In addition, he considers that the mere requirement of having a salaried pharmacist present to carry out tasks involving a relationship with third parties is not such as to ensure, to the same degree in terms of quality and neutrality in the service of dispensing medicinal products, the appropriate supply of medicinal products to the public. In so far as he is not in control of the commercial policy of the pharmacy, and as he is in fact required to carry out the instructions of his employer, the possibility cannot be excluded that a salaried pharmacist, working in a pharmacy run by a non-pharmacist, might be led to prioritise the economic interests of the pharmacy over the demands linked to carrying out a pharmaceutical activity.

Lastly, linking the authorisation for the operation of a pharmacy to the pharmacist is an efficient way to ensure the appropriate supply of medicinal products to the public, in particular because the practising pharmacist would, in a case of professional negligence, be subject to the withdrawal not only of his practising licence, but also of his authorisation to run a pharmacy, with the onerous financial consequences which follow therefrom.

Consequently, the Advocate General considers that **the requirement that the person who has economic control over the pharmacy** and, on that basis, determines its commercial policy, **be a pharmacist is consistent with the Treaty provisions on the freedom of establishment.**

IMPORTANT: The Advocate General's Opinion is not binding on the Court. It is the role of the Advocates General to propose to the Court, in complete independence, a legal solution to the cases for which they are responsible. The Judges of the Court of Justice are now beginning their deliberations in this case. Judgment will be given at a later date.

Unofficial document for media use, not binding on the Court of Justice.

Languages available: ES, DE, EL, EN, FR, HU, IT, NL, PL, PT, RO

The full text of the Opinion may be found on the Court's internet site

<http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=EN&Submit=rechercher&numaff=C-531/06>

<http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=EN&Submit=rechercher&numaff=C-171/07>

It can usually be consulted after midday (CET) on the day of delivery.

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*Pictures of the delivery of the Opinion are available on Ebs "Europe by Satellite",
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