

European Court Rules that Restriction on Pharmacy Ownership is Justified



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The European Court of Justice (ECJ) has ruled that, while restrictions on ownership and operation of pharmacies constitute a restriction on freedom of establishment and the free movement of capital, these restrictions can be justified by the objective of ensuring that the provision of medicinal products to the public is reliable and of good quality (*Joined Cases C 171/07 and C 172/07 Commission v Italy and Apothekerkammer des Saarlandes and Others*, 19 May 2009). This is in line with the Advocate General’s opinion (one of the court’s senior legal advisers) in these cases which issued in December 2008.

Background

Under Article 43 of the EC Treaty “restrictions on the freedom of establishment of nationals of a Member State in the territory of another Member State shall be prohibited. Such prohibition shall also apply to restrictions on the setting-up of agencies, branches or subsidiaries by nationals of any Member State established in the territory of any Member State.”

Under Article 48 of the EC Treaty “companies or firms formed in accordance with the law of a Member State and having their registered office, central administration or principal place of business within the Community shall, for the purposes of this Chapter, be treated in the same way as natural persons who are nationals of Member States.”

These provisions prohibit EU Member States from introducing or maintaining unjustified restrictions on the exercise of the freedom of establishment and the free movement of capital. In this context, provisions intended to govern the organisation of health services, such as pharmacies, may be restrictive and in violation of the EC Treaty. However, such restrictions may be allowed provided they are justifiable for overriding reasons in the public interest.

Facts of the case

German and Italian legislation restrict the right to own and operate a pharmacy exclusively to licensed pharmacists and a challenge was mounted in both jurisdictions arguing that the legislation was in breach of Articles 43 and 48 of the EC Treaty and the principles of Community law.

The German case involved several pharmacists and their professional associations challenging a decision to allow a Netherlands public limited company to operate a branch pharmacy in Germany.

The Italian case was an action brought by the European Commission alleging that Italy has failed to fulfill its obligations under Community law.

Decision

The ECJ acknowledged that the German and Italian rules constitute a restriction on the freedom of establishment and the free movement of capital under Articles 43 and 48 because they only allow pharmacists to

operate pharmacies. However, it went on to say that such restrictions, if imposed without discrimination on grounds of nationality, may be justified by overriding reasons in the public interest.

The protection of public health and the objective of ensuring that the provision of medicinal products to the public is reliable and of good quality were both held to be justifications for restrictions on the freedoms of movement guaranteed by the EC Treaty. In this context, the court drew attention to the particular nature of medicinal products, whose therapeutic effects distinguish them from other products. If medicinal products are consumed unnecessarily or incorrectly they may cause serious harm to health, and the patient may not realise this when the products are administered.

The ECJ also noted that a Member State should be able to take protective measures, such as measures that reduce public health risks, without having to wait until the reality of the risks become apparent. As a result, a Member State may, at its discretion, take steps to prohibit the operation of a pharmacy by a non-pharmacist, if it considers such operation by a non-pharmacist to be a risk to public health.

While the ECJ acknowledged the argument that a pharmacist has an

interest in making a profit through his pharmacy business like any business owner, it went on to say that that is not the pharmacist's sole objective as it is tempered by the pharmacist's training, professional experience and the responsibility he or she owes. The ECJ held that, unlike pharmacists, non-pharmacists by definition lack training, experience and equivalent responsibilities. Accordingly, they do not provide the same safeguards as pharmacists. Therefore, a Member State may take the view that the operation of a pharmacy by a non-pharmacist may represent a risk to public health in light of the fact that the pursuit of profit by the non-pharmacist owner is not moderated by his training, experience and responsibility.

The ECJ held that the restrictions in the German and Italian legislation are appropriate for attaining the objective of protection of public health and do not go beyond what is necessary for reaching that objective and therefore may be justified. As a result a Member State may take the view, in the exercise of its discretion, that the operation of a pharmacy by a non-pharmacist may represent a risk to public health, in particular, to the reliability and quality of the supply of medicinal products at retail level. The court concluded,

however, that each EU Member State has discretion to determine its own level of protection of public health.

Implications

It is important to note that this ruling does not say that pharmacy ownership must be restricted to pharmacists. Each of the 27 EU Member States has discretion in this regard. In Ireland, like the majority of EU Member States, there are no restrictions on third party ownership of pharmacies and this continues to be the case unless the Irish Government decides to introduce legislation to change this position.

This article has been written by Judy Goldman, a solicitor in Beauchamps Solicitors. She advises primarily on public, regulatory and sport law. This article is merely intended to highlight issues and is not to be regarded as legal advice on any particular matter. Specialist advice should be sought in all circumstances. If you would like to discuss any of the issues raised do not hesitate to contact Judy at Beauchamps Solicitors, Riverside Two, Sir John Rogerson's Quay, Dublin 2. Tel: 01-4180600 or email to securemail@beauchamps.ie