



Press and Information

Court of Justice of the European Union

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Judgment in Case C-62/09

Association of the British Pharmaceutical Industry v Medicines and
Healthcare Products Regulatory Agency

Public authorities may offer financial incentives to induce doctors to prescribe cheaper medicinal products

However, those authorities are required, first, to ensure that the incentive scheme is based on non-discriminatory objective criteria and, second, to make public, inter alia, the therapeutic evaluations relating to the scheme

The directive relating to medicinal products for human use¹ prohibits, where medicinal products are being promoted to doctors or pharmacists, pecuniary advantages or benefits in kind from being supplied, offered or promised to such persons.

To reduce public expenditure on medicinal products, the national public health authorities in England and Wales introduced schemes providing doctors with financial incentives to prescribe to their patients medicinal products cheaper than other medicinal products in the same therapeutic class. However, choosing cheaper medicinal products with a different active substance might, in certain cases, have adverse consequences for the patient. The prescription of statins, which are cholesterol reducing substances, is primarily at issue in this case.

The High Court of Justice of England and Wales has asked the Court of Justice whether the prohibition on financial incentives in the directive precludes the system applied in England and Wales.

In today's judgment, the Court finds that the prohibition in the directive concerns primarily the promotional activities carried out by the pharmaceutical industry and seeks to prevent promotional practices which may induce doctors to act in accordance with their economic interests when prescribing medicinal products.

By contrast, that prohibition does not apply to national public health authorities which, themselves, have competence for ensuring that the directive is applied for defining and to define the priorities for action in relation to public health policy, in particular so far as concerns the rationalisation of the public expenditure allocated to that policy.

In that regard, the Court notes that the health policy defined by a Member State and the public expenditure in that field do not pursue any profit-making or commercial aim. Therefore, the financial incentive scheme examined, which forms part of such a policy, cannot be regarded as seeking the promotion of commercial promotion of medicinal products. In addition, as regards that scheme, no danger to public health can be established in so far as the therapeutic value of the medicinal products favoured is constantly reviewed by the public authorities.

In those circumstances, it is permissible for those authorities to determine, on the basis of evaluations of the therapeutic qualities of the medicinal products by reference to their cost for the public budget, whether certain medicinal products containing a given active substance are, from the point of view of public finances, preferable to other medicinal products containing a different active substance, but falling within the same therapeutic class.

¹ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67), as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 (OJ 2004 L 136, p. 34).

The Court points out, none the less, that the public authorities are required to make available to professionals in the pharmaceutical industry information showing that the scheme at issue is based on objective criteria and that there is no discrimination between national medicinal products and those from other Member States. In addition, those authorities must make such a scheme public and make available to those professionals the evaluations establishing the therapeutic equivalence of the active substances available belonging to the same therapeutic class covered by the scheme.

In the light of all the above findings, **the Court holds that the financial incentive system examined is compatible with the directive and that, furthermore, it does not prejudice the objectivity of prescribing doctors.**

NOTE: A reference for a preliminary ruling allows the courts and tribunals of the Member States, in disputes which have been brought before them, to refer questions to the Court of Justice about the interpretation of European Union law or the validity of a European Union act. The Court of Justice does not decide the dispute itself. It is for the national court or tribunal to dispose of the case in accordance with the Court's decision, which is similarly binding on other national courts or tribunals before which a similar issue is raised.

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The [full text](#) of the judgment is published on the CURIA website on the day of delivery.

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