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Press and Information

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Judgment of the Court of Justice in Case C-212/03

European Commission v French Republic

THE AUTHORISATION PROCEDURE FOR IMPORTATION INTO FRANCE OF MEDICINAL PRODUCTS FOR PERSONAL USE NOT EFFECTED BY PERSONAL TRANSPORT IS INCOMPATIBLE WITH THE TREATY RULES CONCERNING THE FREE MOVEMENT OF GOODS

France has not shown that grounds of health protection require a prior authorisation procedure for the importation of a homeopathic medicinal product lawfully placed on the market in the Member State of exportation

The French Public Health Code [1] requires a prior authorisation procedure for the importation of medicinal products for personal use, not effected by personal transport. Following a complaint, the Commission examined the compatibility of that procedure with Community law and took the view that it could obstruct the free movement of goods. It then brought these proceedings before the Court of Justice of the European Communities, referring to three situations involving imports.

In respect of medicinal products authorised in France and in the Member State of purchase, the French Government conceded that under administrative practice an import authorisation is required for certain products which have a marketing authorisation in France, but that that procedure concerned applications from nationals of Member States in only 1% of cases. The Court held that the mere fact that those authorisations were required constitutes a restriction on the free movement of goods.

In respect of a homeopathic medicinal product lawfully placed on the market in the Member State of exportation, the Court held that requiring a prior authorisation constitutes a restriction on the free movement of goods which, however, could be justified by the need to protect the health of humans.

[1] Articles R 5142-12, R 5142-13 and R 5142-14 of the French Public Health Code in the version in force at the relevant time.

Directive 92/73 [2] lays down rules for the harmonisation of the manufacture, control and inspection of those medicinal products. It draws a distinction between homeopathic medicinal products placed on the market without therapeutic indications (subject to a special, simplified registration procedure), and those with therapeutic indications (which must be authorised in accordance with the rules applicable to medicinal products other than homeopathic medicinal products). For medicinal products in the latter group the Member States may introduce or retain specific rules for the pharmacological and toxicological tests and clinical trials of medicinal products in accordance with the principles and characteristics of homeopathy as practised in that Member State. In this case, the Commission's complaint refers, however, only to medicinal products which have been manufactured, controlled and inspected in accordance with the harmonised rules and have a sufficient degree of dilution to guarantee their safety. The Court held that **France has not shown that grounds of health protection require a prior authorisation procedure in respect of personal imports of such medicinal products.**

In respect of medicinal products not authorised in France but authorised in the Member State where they were purchased, the Court held that the French regulations exempt from authorisation importation by means of personal transport, whereas the general rules on authorisations for commercial imports generally apply when the importation is not effected by personal transport. In that respect, the Court states that although grounds of health protection may justify restrictions on the free movement of goods, those measures must comply with the principle of proportionality in relation to the objective pursued of ensuring the safeguarding of public health.

The French Government has not demonstrated the need in this case to make those imports subject to the authorisation procedure applied to commercial imports.

It is for the French authorities to adopt an authorisation procedure adapted to the specific nature of those imports and the restrictive effects on intra-Community trade of which do not go beyond what is necessary to attain the objective pursued, and which is easily accessible and capable of being brought to completion within a reasonable period. In the absence of those specific rules, **the Court held that France has failed in its obligations.**

Accordingly, the Court concludes that France has failed to fulfil its obligations.

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

Languages available: FR DE EN

The full text of the judgment may be found on the Court's internet site
http://curia.eu.int/jurisp/cgi-bin/form.pl?lang=en
It can usually be consulted after midday (CET) on the day judgment is delivered.

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[2] Council Directive 92/73/EEC of 22 September 1992 widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products and laying down additional provisions on homeopathic medicinal products (OJ 1992 L 297, p. 8).