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Judgment of the Court of Justice in Case C-352/07

A. Menarini Industrie Farmaceutiche Riunite Srl and Others v Ministero Della Salute and Agenzia Italiana del Farmaco

THE MEMBER STATES MAY REDUCE MEDICINAL PRODUCT PRICES MORE THAN ONCE A YEAR AND ON THE BASIS OF PREDICTED EXPENDITURE

They may organise their social security systems and regulate the consumption of pharmaceutical products in the interests of the financial stability of their health-care insurance schemes

The object of Directive 89/105[1] is to ensure the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems.

During 2005 and 2006, the Italian Medicines Agency (Agenzia Italiana del Farmaco, 'the AIFA'), which is responsible for monitoring consumption of medicinal products and pharmaceutical expenditure borne by the Italian National Health Service ('the SSN'), adopted certain measures reducing the prices of medicinal products in order to ensure compliance with the upper limit of pharmaceutical expenditure borne by the SSN.

Menarini and other companies which market medicinal products, the costs of which are wholly borne by the SSN, sued the Ministero Della Salute and the AIFA in respect of those measures before the Tribunale amministrativo regionale del Lazio (Regional Administrative Court for Lazio). The Court of Justice is asked whether the Italian system for pricing medicinal products complies with Directive 89/105.

The Court notes, as a preliminary point, that Community law does not detract from Member States' **powers** to organise, in compliance with Community law, their social security systems and to adopt, in particular, provisions intended to govern the consumption of pharmaceutical products in the interests of the financial stability of their health-care insurance schemes.

The Court decides, first of all, **that a Member State may adopt general measures reducing the prices of all, or of certain categories of, medicinal products, even if the adoption of those measures is not preceded by a freeze on those prices**.

[1] Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems (OJ 1989 L 40, p. 8).

In the event of a price freeze imposed on medicinal products by a Member State, it must review, at least once a year, whether the macro-economic conditions justify that freeze being continued. That review is, under the directive, a minimum requirement. According to the results of such review, a Member State may decide to continue a freeze on the prices of medicinal products, or to adopt measures increasing or reducing those prices. The Court decides that, provided that such minimum requirement is met, **measures reducing prices may be adopted more than once a year and for several years.**

The Court declares, next, that the directive does not preclude measures controlling medicinal product prices from being adopted **on the basis of predicted expenditure**, provided **that the predictions are based on objective and verifiable data**. A contrary interpretation would constitute interference in the organisation by the Member States of their domestic social security policies and affect their policies for pricing medicinal products to an extent going beyond what is necessary to ensure transparency for the directive's purposes.

Further, in the absence of any indication, in the directive, as to the types of expenditure which Member States may take into account in order to continue a price freeze or to increase or reduce medicinal product prices, the Court confirms **that it is for the Member States to determine the criteria** on the basis of which they are to review the macro-economic conditions. They may thus, in compliance always with the objective of transparency, **take account of pharmaceutical expenditure alone, health expenditure overall or even other types of relevant expenditure**.

Finally, if, in exceptional cases and for particular reasons, an undertaking, which is the holder of a marketing authorisation for a medicinal product and concerned by a measure freezing or reducing medicinal product prices, applies for a derogation from the price imposed pursuant to such measure, it must set out the particular reasons justifying its application. The Court notes that the directive imposes on Member States the obligation to ensure that a reasoned decision is adopted on any such application.

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