V

(Announcements)

COURT PROCEEDINGS

COURT OF JUSTICE

Reference for a preliminary ruling from the Tribunale Amministrativo Regionale del Lazio (Italy) lodged on 4 June 2009 — IFB Stroder Srl v Agenzia Italiana del Farmaco (AIFA)

(Case C-198/09)

(2009/C 233/02)

Language of the case: Italian

Referring court

Tribunale Amministrativo Regionale del Lazio

Parties to the main proceedings

Applicant: IFB Stroder Srl

Defendant: Agenzia Italiana del Farmaco (AIFA)

Question(s) referred

1. After the provisions contained in Articles 2 and 3 [of Directive 89/105/EC] which modulate the relationship between the public authorities of a Member State and the pharmaceutical companies — by allowing the pricing of a medicinal product or the raising of its price to be determined on the basis of information provided by the [latter], but only in so far as is acceptable to the competent authority, and thus on the basis of dialogue between the undertakings themselves and the authorities competent to supervise pharmaceutical expenditure — Article 4(1) [of that Directive] concerning '*price freeze[s] imposed on all medicinal products or on certain categories of medicinal products*' characterises a price freeze as a general instrument, the continuing use of which is conditional upon a review which must be carried out, at least once a year, with reference to the macro-economic conditions existing in the Member State in question. That provision allows the competent authorities a period of 90 days in which to take a final decision, requiring them, on expiry of that period, to announce what increases or decreases in prices are being made, if any. On a proper construction of the reference to 'decreases in prices … being made, if any', is that provision to be interpreted as meaning that, as well as the general remedy of freezing the prices of all categories, or certain specific categories, of medicinal product, another general remedy may be applied in the form of a reduction in the prices of all categories, and of certain specific categories, of medicinal product, or must 'decreases …, if any' be interpreted as referring exclusively to the medicinal products which are already subject to the price freeze?

2. In requiring the competent authorities of a Member State to verify, at least once a year, in the case of price freezes, whether the macroeconomic conditions justify continuing that price freeze, may Article 4(1) [of Directive 89/105/EC] be interpreted as meaning that, if the reply to Question I is that a price reduction is permissible, it is possible to have recourse to such a measure even more than once in the course of a single year, and to do that again for many years (from 2002 until 2010)?

3. Under the terms of Article 4 [of Directive 89/105/EC] — read in the light of the preamble emphasising that the principal aim of measures controlling the prices of medicinal products is 'the promotion of public health by ensuring the availability of adequate supplies of medicinal products at a reasonable cost' and preventing 'disparities in such measures [which] may hinder or distort intra-Community trade in medicinal products' — is it compatible with the Community rules to adopt measures which refer to economic values attributed to that expenditure on the basis of 'predictions' rather than values which have been 'ascertained' (this question relates to both situations)?

4. Must the requirements relating to compliance with the ceilings for pharmaceutical expenditure which each Member State is competent to determine be linked, point by point, to pharmaceutical expenditure alone, or is it within the powers of the Member States to take account also of data relating to other health expenditure?

5. Must the principles, to be inferred from … Directive [89/105/EC], of transparency and of shared participation on the part of the undertakings with an interest in measures freezing the prices of pharmaceutical products or reducing them across the board be interpreted as requiring provision to be made, always and in any circumstances, for the possibility of derogation from the price imposed (Article 4(2) [of Directive 89/105/EC]) and for genuine participation by the applicant company, with the consequent need for the administrative authorities to state the reasons for any refusal?