Judgment of the Court (Fourth Chamber) of 2 April 2009 (Reference for a preliminary ruling from the Tribunale amministrativo regionale del Lazio (Italy)) — A. Menarini Industrie Farmaceutiche Riunite Srl, Laborati Guidotti SpA, Istituto Lusofarmaco d'Italia SpA, Malesi Istituto Farmacobiologico SpA, Menarini International Operations Luxembourg SA (C-352/07) v Ministero della Salute, Agenzia Italiana del Farmaco (AIFA), third party: Sanofi Aventis SpA, Sanofi Aventis SpA (C-353/07) v Agenzia Italiana del Farmaco (AIFA), IFB Stroder Srl (C-354/07) v Agenzia Italiana del Farmaco (AIFA), Schering Plough SpA (C-355/07) v Agenzia Italiana del Farmaco (AIFA), third party: Baxter SpA, Bayer SpA (C-356/07) v Agenzia Italiana del Farmaco (AIFA), Ministero della Salute, Simesa SpA (C-365/07) v Ministero della Salute, Agenzia Italiana del Farmaco (AIFA), third party: Merck Sharp & Dohme (Italia) SpA, Abbott SpA (C-366/07) v Ministero della Salute, Agenzia Italiana del Farmaco (AIFA), Baxter SpA (C-367/07) v Agenzia Italiana del Farmaco (AIFA), third party: Merck Sharp & Dohme (Italia) SpA, and SALF SpA (C-400/07) v Agenzia Italiana del Farmaco (AIFA), Ministero della Salute

(Joined Cases C-352/07 to C-356/07, C-365/07 to C-367/07 and C-400/07) [1]

(Directive 89/105/EEC — Transparency of measures regulating the prices of medicinal products for human use — Article 4 — Price freeze — Price reduction)

(2009/C 141/09)

Language of the case: Italian

Referring court

Tribunale amministrativo regionale del Lazio

Parties to the main proceedings

Applicants: A. Menarini Industrie Farmaceutiche Riunite Srl, FIRMA Srl, Laboratori Guidotti SpA, Istituto Lusofarmaco d'Italia SpA, Malesi Istituto Farmacobiologico SpA, Menarini International Operations Luxembourg SA (C-352/07), Sanofi Aventis SpA (C-353/07), IFB Stroder Srl (C-354/07), Schering Plough SpA (C-355/07), Bayer Spa (C-356/07), Simesa SpA (C-365/07), Abbott SpA (C-366/07), Baxter SpA (C-367/07), SALF SpA (C-400/07)

Defendants: Ministero della Salute, Agenzia Italiana del Farmaco (AIFA)

Re:

Reference for a preliminary ruling — Tribunale amministrativo regionale del Lazio — Interpretation of Article 4(1) and (2) of Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems (OJ 1989 L 40, p. 8) — Price freeze imposed on medicinal products — Procedures to follow in the case of a price reduction

Operative part of the judgment

1. *Article 4(1) of 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 is to be interpreted as meaning that, provided the requirements laid down by that provision are met, the competent authorities of 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.*

2. *Article 4(1) of Directive 89/105 is to be interpreted as meaning that, provided the requirements laid down by that provision are met, the adoption of measures reducing the prices of all, or of certain categories of, medicinal products is possible more than once a year and for several years.*

3. *Article 4(1) of Directive 89/105 is to be interpreted as meaning that it does not preclude measures controlling the prices of all, or of certain categories of, medicinal products from being adopted on the basis of predicted expenditure, provided that the requirements laid down by that provision are met and that the predictions are based on objective and verifiable data.*

4. *Article 4(1) of Directive 89/105 is to be interpreted as meaning that it is for the Member States to determine, in compliance with the objective of transparency pursued by that directive and the requirements laid down by that provision, the criteria on the basis of which the review of the macro-economic conditions referred to in that provision is to be conducted and that those criteria may consist in pharmaceutical expenditure alone, in health expenditure overall or even in other types of expenditure.*

5. *Article 4(2) of Directive 89/105 is to be interpreted as meaning:*

   — *that the Member States must, in all cases, provide for the possibility for an undertaking, which is concerned by a measure freezing or reducing the prices of all, or of certain categories of, medicinal products, of applying for a derogation from the price imposed pursuant to such measure;*

   — *that they are to ensure that a reasoned decision on any such application is adopted, and*

   — *that the genuine participation of the undertaking concerned consists, first, in the submission of an adequate statement of the particular reasons justifying its application for derogation and, second, in the provision of detailed additional information if the information supporting the application is inadequate.*

[1] OJ C 247, 20.10.2007.
OJ C 269, 10.11.2007.