JUDGMENT OF THE COURT (Fourth Chamber)

2 April 2009 *

In Joined Cases C-352/07 to C-356/07, C-365/07 to C-367/07 and C-400/07,

REFERENCES for a preliminary ruling under Article 234 EC from the Tribunale amministrativo regionale del Lazio (Italy), made by decisions of 14 February, 28 March and 26 April 2007, received at the Court on 31 July, 2 and 29 August 2007, in the proceedings

A. Menarini Industrie Farmaceutiche Riunite Srl and Others (C-352/07)

v

Ministero della Salute,

Agenzia Italiana del Farmaco (AIFA),

* Language of the case: Italian.

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,

THE COURT (Fourth Chamber),

composed of K. Lenaerts, President of the Chamber, T. von Danwitz, R. Silva de Lapuerta (Rapporteur), E. Juhász and G. Arestis, Judges,

Advocate General: V. Trstenjak,
Registrar: C. Strömholm, Administrator,

having regard to the written procedure and further to the hearing on 10 September 2008,

after considering the observations submitted on behalf of:

— A. Menarini Industrie Farmaceutiche Riunite Srl and Others, by S. Grassi, avvocato,

— Sanofi Aventis SpA, by S. Romano, M. Siragusa and G.C. Rizza, avvocati,

— IFB Stroder Srl and Schering Plough SpA, by P. Vaiano, D. Vaiano and R. Izzo, avvocati,

— Baxter SpA, by C.A. Piria and F. Setti, avvocati,

— Bayer SpA, by A. Lirosi and C. Guglielmello, avvocati,

— Simesa SpA, by G. Ferrari, avvocato,

— SALF SpA, by A. Astolfi and S. Selletti, avvocati,

— the Italian Government, by I.M. Braguglia, acting as Agent, assisted by G. De Bellis, avvocato dello Stato,

— the Polish Government, by M. Dowgielewicz, acting as Agent,

— the Commission of the European Communities, by D. Recchia, M. Šimerdová and C. Zadra, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 13 November 2008,

gives the following

Judgment

1 These references for a preliminary ruling concern the interpretation of Article 4 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 (OJ 1989 L 40, p. 8).

2 The references were made in proceedings between A. Menarini Industrie Farmaceutiche Riunite Srl and Others, Sanofi Aventis SpA, IFB Stroder Srl, Schering Plough SpA, Bayer SpA, Simesa SpA, Abbott SpA, Baxter SpA and SALF SpA, on the one hand, and the Agenzia Italiana del Farmaco (Italian Medicines Agency, 'the AIFA') and, in five of the nine actions, the Ministero della Salute (Ministry of Health) also, on the other hand, concerning measures reducing the prices of medicinal products paid for by the Servizio Sanitario Nazionale (National Health Service, 'the SSN'), adopted by the AIFA.

Legal context

Community legislation

3 The second to sixth recitals in the preamble to Directive 89/105 are worded as follows:

'Whereas Member States have adopted measures of an economic nature on the marketing of medicinal products in order to control public health expenditure on such products; …

Whereas the primary objective of such measures is the promotion of public health by ensuring the availability of adequate supplies of medicinal products at a reasonable cost; whereas, however, such measures should also be intended to promote efficiency in the production of medicinal products and to encourage research and development into new medicinal products, on which the maintenance of a high level of public health within the Community ultimately depends;

Whereas disparities in such measures may hinder or distort intra-Community trade in medicinal products and thereby directly affect the functioning of the common market in medicinal products;

Whereas the objective of this Directive is to obtain an overall view of national pricing arrangements, including the manner in which they operate in individual cases and all the criteria on which they are based, and to provide public access to them for all those involved in the market in medicinal products in the Member States; …

Whereas, as a first step towards the removal of these disparities, it is urgently necessary to lay down a series of requirements intended to ensure that all concerned can verify that the national measures do not constitute quantitative restrictions on imports or exports or measures having equivalent effect thereto; whereas, however, these requirements do not affect the policies of those Member States which rely primarily upon free competition to determine the price of medicinal products; whereas these requirements also do not affect national policies on price setting and on the determination of social security schemes, except as far as it is necessary to attain transparency within the meaning of this Directive'.

4 Article 1(1) of that directive provides:

'Member States shall ensure that any national measure, whether laid down by law, regulation or administrative action, to control the prices of medicinal products for human use or to restrict the range of medicinal products covered by their national health insurance systems complies with the requirements of this Directive.'

5 Article 4 of that directive provides:

'1. In the event of a price freeze imposed on all medicinal products or on certain categories of medicinal products by the competent authorities of a Member State, that Member State shall carry out a review, at least once a year, to ascertain whether the macro-economic conditions justify that the freeze be continued unchanged. Within 90 days of the start of this review, the competent authorities shall announce what increases or decreases in prices are being made, if any.

2. In exceptional cases, a person who is the holder of a marketing authorisation for a medicinal product may apply for a derogation from a price freeze if this is justified by

particular reasons. The application shall contain an adequate statement of these reasons. Member States shall ensure that a reasoned decision on any such application is adopted and communicated to the applicant within 90 days. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of what detailed additional information is required and take their final decision within 90 days of receipt of this additional information. Should the derogation be granted, the competent authorities shall forthwith publish an announcement of the price increase allowed.

Should there be an exceptional number of applications, the period may be extended once only for a further 60 days. The applicant shall be notified of such extension before the expiry of the initial period.'

National legislation

6 According to the referring court, the provisions of the national legislation applicable to the main proceedings are the following.

7 In the context of reform and control of public health expenditure, Article 48(1) of Decree-Law No 269 of 30 September 2003 laying down urgent provisions for promoting development and correcting the situation of the public finances, converted into law, after amendment, by Law No 326 of 24 November 2003 ('Decree-Law No 269/2003'), sets the upper limit on pharmaceutical expenditure paid for by the SSN at 16% of planned health expenditure.

8 In that regard, Article 48(5) defines the AIFA's functions and powers, particularly as regards the monitoring of medicinal product consumption and pharmaceutical

expenditure by the SSN and the reduction of the share accruing to the producer if the upper limit set in Article 48(1) is exceeded.

9 The effects of the measures monitoring pharmaceutical expenditure, adopted by the AIFA under Article 48 of Decree-Law No 269/2003, were confirmed pursuant to Article 1(796)(f) of Law No 296 of 27 December 2006 relating to the provisions for drawing up the annual and pluriennial budget of the State, which entered into force on 1 January 2007.

The main proceedings and the questions referred for a preliminary ruling

10 The applicants in the main proceedings market medicinal products the costs of which are paid entirely by the SSN.

11 During 2005 and 2006, the AIFA adopted, on the basis of Article 48(1) and (5) of Decree-Law No 269/2003, measures reducing the prices of the medicinal products paid for by the SSN in order to ensure compliance with the upper limit on expenditure set in Article 48(1).

12 It is apparent from the decisions making the references that those measures were adopted on the basis of a predicted, but not actual, excess over that limit.

13 The referring court observes that the past, present, and future effects of those measures were confirmed in Article 1(796)(f) of Law No 296/2006.

14 Uncertain of the conformity of the system for pricing medicinal products under the legislation in question in the main proceedings with the requirements of Directive 89/105, the Tribunale amministrativo regionale del Lazio (Regional Administrative Court for Lazio) decided to stay the proceedings in Cases C-352/07, C-354/07 to C-356/07, C-365/07 to C-367/07 and C-400/07 and to refer the following questions to the court for a preliminary ruling:

'1. In that it refers to "decreases in prices …, if any", is [Article 4(1) of Directive 89/105] 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, or of certain specific categories, of medicinal product, or must "decreases in prices …, 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 macro-economic conditions justify continuing that price freeze, may Article 4(1) [of Directive 89/105] be interpreted as meaning that, if the reply to Question 1 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 [such] Article 4 … — read in the light of the preamble [to Directive 89/105] 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 the requirement to prevent "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, paragraph by paragraph, 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], of transparency and of 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]) and for genuine participation by the applicant company, with the consequent need for the administrative authorities to state the reasons for any refusal?'

15 In Case C-353/07, the first to third and fifth questions are identical to those referred in the eight cases specified in the preceding paragraph of this judgment. As regards the fourth question, it is worded as follows:

'May the requirements relating to the indication of criteria which are objective and transparent, and of such a nature that the intervention of the relevant competent authorities (as regards the period up to 31 December 2006) and of the legislature (as from 1 January 2007) is verifiable be taken to be fully satisfied by the indication of the requirements relating to the ceiling for pharmaceutical expenditure which each Member State is competent to determine and to the containment of that expenditure and, in particular, by data relating to health expenditure overall or, more specifically, to pharmaceutical expenditure alone?'

16 By order of 23 October 2007, the President of the Court ordered Cases C-352/07 to C-356/07, C-365/07 to C-367/07 and C-400/07 to be joined for the purposes of the written and oral procedure.

17 It is expedient, because of their connection, that they be joined also for the purposes of the judgment.

The questions referred for a preliminary ruling

The first question

18 By its first question, the referring court is asking, in essence, whether Article 4(1) of Directive 89/105 is to be interpreted as meaning that it allows recourse to a general measure reducing the prices of all, or of certain categories of, medicinal products or whether that provision is to be interpreted as meaning that such a measure may be adopted only as regards medicinal products which have been the subject of a 'price freeze' within the meaning of that provision.

19 It must be noted, as a preliminary point, that Community law does not detract from the power of the Member States to organise their social security systems and to adopt, in particular, provisions intended to govern the consumption of pharmaceutical products in order to promote the financial stability of their health-care insurance schemes (Case 238/82 *Duphar and Others* [1984] ECR 523, paragraph 16; Case C-249/88 *Commission* v *Belgium* [1991] ECR I-1275, paragraph 31; Joined Cases C-159/91 and C-160/91 *Poucet and Pistre* [1993] ECR I-637, paragraph 6; Case C-70/95 *Sodemare and Others* [1997] ECR I-3395, paragraph 27; Case C-158/96 *Kohll* [1998] ECR I-1931, paragraph 17; Case C-245/03 *Merck, Sharp & Dohme* [2005] ECR I-637, paragraph 28; and Case C-141/07 *Commission* v *Germany* [2008] ECR I-6935, paragraph 22).

20 However, in exercising that power the Member States must comply with Community law (see *Kohll*, paragraph 19, and *Commission* v *Germany*, paragraph 23).

21 Under Article 4(1) of Directive 89/105, in the event of a price freeze imposed on all medicinal products or on certain categories of medicinal products by the competent authorities of a Member State, that Member State is to carry out a review, at least once a year, to ascertain whether the macro-economic conditions justify that the freeze be continued unchanged.

22 Under that same provision, within 90 days of the start of that review, the competent authorities are to announce what increases or decreases in prices are being made, if any.

23 It follows from the wording of that provision that the competent authorities of a Member State may adopt measures freezing the prices of all, or of certain categories of, medicinal products and, as part of the review procedure provided for by that same provision, measures increasing or reducing those prices.

24 However, the wording of Article 4(1) of Directive 89/105 does not state whether a measure reducing the prices of medicinal products may or may not be adopted unless it was preceded by a measure freezing those prices.

25 Consequently, that provision is to be interpreted by reference to the purpose and general scheme of that directive.

26 The purpose of Directive 89/105, according to Article 1 thereof, is to ensure that any national measure to control the prices of medicinal products for human use or to restrict the range of medicinal products covered by their national sickness insurance

systems complies with the requirements of that directive (Case C-424/99 *Commission* v *Austria* [2001] ECR I-9285, paragraph 30; Case C-229/00 *Commission* v *Finland* [2003] ECR I-5727, paragraph 37; Case C-317/05 *Pohl-Boskamp* [2006] ECR I-10611, paragraph 25; and judgment of 17 July 2008 in Case C-311/07 *Commission* v *Austria*, paragraph 29).

27 According to the fifth recital in its preamble, the main purpose of Directive 89/105 is to ensure transparency of pricing, including the manner in which it operates in individual cases and the criteria on which it is based (*Pohl-Boskamp*, paragraph 29).

28 Moreover, according to the sixth recital in its preamble, ensuring the effectiveness of the directive requires that the persons concerned can verify that the official entry of medicinal products on the list corresponds to objective criteria and that there is no discrimination between national medicinal products and those from other Member States (*Commission* v *Finland*, paragraph 39).

29 It follows that the meaning of a 'price freeze … on all medicinal products or on certain categories of medicinal products' in Article 4(1) of Directive 89/105 encompasses all national measures controlling the prices of medicinal products even if those measures are not preceded by a freeze on those prices.

30 National measures, such as those at issue in the main proceedings, reducing the prices of all, or of certain categories of, medicinal products are national measures to control the prices of medicinal products, within the meaning of Article 1(1) of Directive 89/105.

31 Consequently, under that provision, such measures must comply with the requirements of that directive.

32 In particular, such measures must, in the same way as measures freezing the prices of all medicinal products or of certain categories of medicinal products, satisfy the requirements laid down by Article 4 of Directive 89/105.

33 The fact that the adoption of measures reducing the prices of all, or of certain categories of, medicinal products was not preceded by a freeze on those prices, within the meaning of that provision, is irrelevant to that determination.

34 Indeed, a contrary interpretation would be tantamount to excluding from that provision's scope measures reducing the prices of all, or of certain categories of, medicinal products, if such measures are not preceded by a freeze on those prices.

35 As regards the general scheme of Directive 89/105, it must be noted that, under the sixth recital in its preamble, the requirements arising from that directive affect neither the Member States' policies for determining the prices of medicinal products nor national policies on price setting or the determination of social security schemes, except as far as it is necessary to attain transparency for the purposes of that directive.

36 It follows that Directive 89/105 has as its underlying principle the idea of minimum interference in the organisation by Member States of their domestic social security policies (see *Merck, Sharp & Dohme*, paragraph 27).

37 An interpretation according to which the adoption of measures reducing the prices of all, or of certain categories of, medicinal products must be preceded by a freeze on those prices would affect the Member States' price-setting policies to an extent going beyond what is necessary to ensure transparency for the purposes of Directive 89/105, since its

effect would be to constrain them to adopt measures freezing the prices of the medicinal products before reducing those prices.

38 In those circumstances, the reply to the first question must be that 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 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.

The second question

39 By its second question, the referring Court is asking, in essence, whether Article 4(1) of Directive 89/105 is to be interpreted as meaning that 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.

40 In that regard, it is to be recalled that, under that provision, in the event of a price freeze imposed on all medicinal products or on certain categories of medicinal products by a Member State, that Member State is to carry out a review, at least once a year, to ascertain whether the macro-economic conditions justify the freeze being continued unchanged.

41 It therefore follows from the wording of Article 4(1) of Directive 89/105 that the annual review of the macro-economic conditions required by that provision is a minimum requirement which does not preclude a Member State from carrying out such a review more than once a year, or, if the results of those reviews justify it, from deciding to

maintain a price freeze on all, or on certain categories of, medicinal products or to adopt measures increasing or reducing those prices.

42 Likewise, if those results also justify it, that provision does not prevent a Member State deciding to adopt or continue such measures for several years.

43 Consequently, the reply to the second question must be that 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.

The third question

44 By its third question, the referring Court is asking, in essence, whether Article 4(1) of Directive 89/105 is to be interpreted as meaning that it precludes the adoption of measures controlling the prices of medicinal products on the basis of predicted rather than actual expenditure.

45 In that respect, it is to be noted that that provision contains no indication as regards the data on the basis of which such measures must be adopted.

46 That being so, it cannot be ruled out that the adoption of measures controlling the prices of all, or of certain categories of, medicinal products on the basis of predicted expenditure complies with Article 4(1) of that directive.

47 A contrary interpretation would constitute interference in the organisation by Member States of their domestic social security policies and affect the Member States' policies for pricing medicinal products to an extent going beyond what is necessary to ensure transparency for the purposes of Directive 89/105.

48 Again, however, the requirements laid down by Article 4(1) of that directive must be met and such predicted expenditure must guarantee transparency for the purposes of that directive, that is to say that those predictions must be based on objective and verifiable data.

49 In those circumstances, the reply to the third question must be that 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.

The fourth question

50 By its fourth question in Cases C-352/07, C-354/07 to C-356/07, C-365/07 to C-367/07 and C-400/07, and by its fourth question in Case C-353/07, which it is appropriate to examine together, the referring court is asking, in essence, whether Article 4(1) of Directive 89/105 is to be interpreted as meaning that, for the purposes of setting the upper limit on pharmaceutical expenditure in order to control public health

expenditure on medicinal products, the competent authorities of a Member State, if they decide to continue measures freezing the prices of all, or of certain categories of, medicinal products or to adopt measures increasing or reducing those prices because of that limit being exceeded, must take account of pharmaceutical expenditure alone, or whether those authorities may take account of health expenditure overall.

51 In that regard, it must be noted that that provision gives no indication as to what type of expenditure is to be taken into consideration by the Member States if they decide to continue measures freezing the prices of all, or of certain categories of, medicinal products or to adopt measures increasing or reducing those prices.

52 While Article 4(1) of Directive 89/105 provides that the Member States are, at least once a year, to review the macro-economic conditions, it does not specify the criteria on the basis of which that review is to be conducted.

53 Failing such criteria, it is for the Member States to determine those criteria in compliance with the objective of transparency pursued by Directive 89/105 and the requirements laid down by Article 4(1) thereof.

54 In that regard, Member States can take account of pharmaceutical expenditure alone, health expenditure overall or even other types of relevant expenditure.

55 Accordingly, the reply to the fourth question in Joined Cases C-352/07, C-354/07 to C-356/07, C-365/07 to C-367/07 and C-400/07, and to the fourth question in Case C-353/07, must be that 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.

The fifth question

56 By its fifth question, the referring court is asking, in essence, whether 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 and for genuine participation by that undertaking, and whether that entails, for the competent administrative authorities, an obligation to state the reasons for refusing such an application.

57 In that regard, Article 4(2) of Directive 89/105 provides that, in exceptional cases, a person who is the holder of a marketing authorisation for a medicinal product may apply for a derogation from a price freeze, if that is justified by particular reasons.

58 It is clear therefore from that provision 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, on the basis that such possibility is without prejudice to the ascertainment, by the competent authorities of the Member States, that it is an exceptional case and that there are particular reasons, within the meaning of that provision.

59 As regards the genuine participation of the undertaking concerned, it takes the form of the obligations upon it under Article 4(2) of Directive 89/105, which consist, 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.

60 As regards the obligation, for the competent authority, to state the reasons for refusal of such an application for derogation, it is sufficient to state that such obligation is expressly imposed by Article 4(2) of Directive 89/105 since, in the terms of that provision, Member States are to ensure that a reasoned decision on any such application is adopted and communicated to the applicant within 90 days.

61 In those circumstances, the reply to the fifth question must be that 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.

Costs

62 Since these proceedings are, for the parties to the main proceedings, a step in the actions pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Fourth Chamber) hereby rules:

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.

[Signatures]