JUDGMENT OF THE COURT (Third Chamber)

14 January 2010 *

In Joined Cases C-471/07 and C-472/07,

REFERENCES for a preliminary ruling under Article 234 EC from the Conseil d'État (Belgium), made by decisions of 15 October 2007, received at the Court on 24 October 2007, in the proceedings

Association générale de l'industrie du médicament (AGIM) ASBL (C-471/07 and C-472/07),

Bayer SA (C-471/07 and C-472/07),

Pfizer SA (C-471/07 and C-472/07),

Servier Benelux SA (C-471/07 and C-472/07),

Janssen Cilag SA (C-471/07),

* Language of the case: French.

Sanofi-Aventis Belgium SA, formerly Sanofi-Synthelabo SA (C-472/07),

v

État belge,

intervener:

Sanofi-Aventis Belgium SA (C-471/07),

THE COURT (Third Chamber),

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

Advocate General: V. Trstenjak,
Registrar: R. Grass,

having regard to the written procedure,

after considering the observations submitted on behalf of:

— Association générale de l'industrie du médicament (AGIM) ASBL, Bayer SA, Janssen Cilag SA, Pfizer SA, Sanofi-Aventis Belgium SA and Servier Benelux SA, by X. Leurquin, avocat,

— the Belgian Government, by T. Materne, acting as Agent, assisted by J. Sohier and P. Hofströssler, avocats,

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

— the Commission of the European Communities, by M. Šimerdová and R. Troosters, acting as Agents,

having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,

gives the following

Judgment

1 These references for a preliminary ruling concern the interpretation of Article 4(1) 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).

2 The references have been made in the context of actions brought by Association générale de l'industrie du médicament (AGIM) ASBL, Bayer SA, Pfizer SA, Servier Benelux SA, Janssen Cilag SA and Sanofi-Aventis Belgium SA, formerly Sanofi-Synthelabo SA (together, 'the applicants in the main actions') against État belge (the Belgian State) in respect of measures adopted by the Belgian Government freezing the prices of medicinal products.

Legal context

Community law

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

'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 4(1) of Directive 89/105 provides:

'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.'

National legislation

5 Adopted pursuant to the Framework Law of 22 December 1989 (*Moniteur belge* of 30 December 1989, p. 21382), the ministerial decree of 29 December 1989 on the prices of refundable medicinal products (*Moniteur belge* of 6 January 1990, p. 162), as amended by the ministerial decrees of 20 January 2003 (*Moniteur belge* of 11 February 2003, p. 6877) and 13 June 2005 (*Moniteur belge* of 1 July 2005, p. 30399), imposed a price freeze on medicinal products from 1 January 2003 to 31 December 2003 and from 1 July 2005 to 31 December 2005.

The actions in the main proceedings and the questions referred for a preliminary ruling

6 In Case C-471/07, the applicants in the main actions, by means of an application made before the referring court on 11 April 2003, sought the annulment of Article 3 of the ministerial decree of 20 January 2003, in so far as that article provided for a price freeze on medicinal products from 1 January to 31 December 2003.

7 In Case C-472/07, the applicants in the main actions, with the exception of Janssen Cilag SA, by an application made before the referring court on 31 August 2005, sought the annulment of Article 1 of the ministerial decree of 13 June 2005 in so far as that article imposed a price freeze on medicinal products from 1 July to 31 December 2005.

8 In both instances, the applicants in the main actions claim, in particular, that Article 4(1) of Directive 89/105 has been infringed. In essence, they submit that the measures freezing prices were adopted without the review provided for in Article 4(1) actually having been conducted to ascertain whether the macro-economic conditions justified such a freeze.

9 In those circumstances, the Conseil d'État (Council of State) decided, as regards Case C-417/07, to stay proceedings and to refer the following questions to the Court for a preliminary ruling:

'(1) Is the review of macro-economic conditions referred to in Article 4(1) of … Directive [89/105] to be understood as meaning only review as to whether

healthcare expenditure is manageable, or must it also extend to other macro-economic conditions, in particular to those in the pharmaceutical industry sector whose products are liable to be made subject to a price freeze?

(2) May the review of macro-economic conditions referred to in Article 4(1) of Directive [89/105] be based on a general trend or trends, such as, for example, ensuring balance in healthcare, or must it be based on more specific criteria?'

10 In Case C-472/07, the third and fourth questions are identical to the questions referred in Case C-471/07. As for the first two questions, they are worded as follows:

'(1) Since the period for transposition of … Directive [89/105] expired on 31 December 1989, must Article 4(1) of that directive be considered to be directly applicable in the domestic legal systems of the Member States?

(2) May Article 4(1) of Directive [89/105] be interpreted as meaning that the resumption for one year, after an absence of 18 months, of a general price freeze in respect of refundable medicinal products which had lasted eight years exempts the Member State from carrying out a review, when the freeze is resumed, of the macro-economic conditions affected by that freeze?'

11 By order of the President of the Court of 4 December 2007, Cases C-471/07 and C-472/07 were joined for the purposes of the written and oral procedures and of the judgment.

12 By decision of the President of the Court of 3 March 2008, proceedings in Cases C-471/07 and C-472/07 were stayed until the delivery, which took place on 2 April 2009, of the judgment in Joined Cases C-352/07 to C-356/07, C-365/07 to C-367/07 and C-400/07 *A. Menarini Industrie Farmaceutiche Riunite and Others* [2009] ECR I-2495.

13 That judgment having been delivered, the President of the Court decided on 5 June 2009 that proceedings in Cases C-471/07 and C-472/07 should be resumed.

The questions referred for a preliminary ruling

The questions in Case C-471/07 and the third and fourth questions in Case C-472/07

14 By its questions in Case C-471/07 and the third and fourth questions in Case C-472/07, which it is appropriate to examine together, the referring court is asking, in essence, whether:

— the review of macro-economic conditions provided for in Article 4(1) of Directive 89/105 involves only review as to whether healthcare expenditure is manageable, or whether it must extend to other macro-economic conditions, in particular to those in the pharmaceutical industry sector whose products are liable to be made subject to a price freeze;

— that review may be based on a general trend or trends, such as the need to ensure balance in healthcare, or whether it must be based on more specific criteria.

15 It must be recalled, first, that 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 (Case C-317/05 *Pohl-Boskamp* [2006] ECR I-10611, paragraph 29, and *A. Menarini Industrie Farmaceutiche Riunite and Others*, paragraph 27) and, second, that according to the sixth recital in its preamble, the requirements arising from Directive 89/105 affect neither the Member States' policies for determining the prices of medicinal products nor national policies on price setting or on the determination of social security schemes, except as far as it is necessary to attain transparency for the purposes of that directive (see *A. Menarini Industrie Farmaceutiche Riunite and Others*, paragraph 35).

16 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 (Case C-245/03 *Merck, Sharp & Dohme* [2005] ECR I-637, paragraph 27, and *A. Menarini Industrie Farmaceutiche Riunite and Others*, paragraph 36).

17 Furthermore, it must be noted that Article 4(1) of Directive 89/105 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 (*A. Menarini Industrie Farmaceutiche Riunite and Others*, paragraph 51).

18 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 carried out (*A. Menarini Industrie Farmaceutiche Riunite and Others*, paragraph 52).

19 Consequently, 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 (*A. Menarini Industrie Farmaceutiche Riunite and Others*, paragraph 53).

20 In that respect, Member States can take account of healthcare expenditure alone or of other macro-economic conditions, such as those in the pharmaceutical industry sector (see, to that effect, *A. Menarini Industrie Farmaceutiche Riunite and Others*, paragraph 54).

21 Equally, Article 4(1) of Directive 89/105 does not preclude the annual review of macro-economic conditions provided for in that provision from being based on a general trend or trends, such as the financial balance of national healthcare systems.

22 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 (*A. Menarini Industrie Farmaceutiche Riunite and Others*, paragraph 47).

23 None the less, the criteria on the basis of which that review is carried out must guarantee transparency for the purposes of that directive, that is to say they must be based on objective and verifiable factors (see, to that effect, *A. Menarini Industrie Farmaceutiche Riunite and Others*, paragraph 48).

24 In those circumstances, the answer to the questions in Case C-471/07 and to the third and fourth questions in Case C-472/07 is that Article 4(1) of Directive 89/105 must 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 macro-economic conditions which is referred to in that provision is to be carried out, provided that those criteria are based on objective and verifiable factors.

The first question in Case C-472/07

25 By its first question in Case C-472/07, the referring court is asking, in essence, whether, following the expiry of the period for transposition of Directive 89/105, Article 4(1) of that directive must be considered to have direct effect for the purposes of the domestic legal systems of the Member States.

26 According to settled case-law, whenever the provisions of a directive appear, so far as their subject-matter is concerned, to be unconditional and sufficiently precise, they may be relied on before the national courts by individuals against the State where the latter has failed to implement the directive in domestic law by the end of the period prescribed or where it has failed to implement the directive correctly (see Case 152/84 *Marshall* [1986] ECR 723, paragraph 46, and Joined Cases C-397/01 to C-403/01 *Pfeiffer and Others* [2004] ECR I-8835, paragraph 103).

27 Although, in the event of a price freeze imposed on all medicinal products or on certain categories of medicinal products, Article 4(1) of Directive 89/105 requires Member States unconditionally to carry out a review, at least once a year, to ascertain whether the macro-economic conditions justify that the freeze be continued, that provision

contains no indication as regards the matters on the basis of which measures to control the prices of medicinal products must be adopted and does not specify either the criteria in the light of which such an annual review is to be carried out (see *A. Menarini Industrie Farmaceutiche Riunite and Others*, paragraphs 45 and 52) or the method or procedure for that review.

28 Consequently, Article 4(1) of Directive 89/105 cannot be considered, so far as its subject-matter is concerned, to be sufficiently precise for an individual to be able to rely on it before a national court against a Member State.

29 In those circumstances, the answer to the first question in Case C-472/07 is that Article 4(1) of Directive 89/105 must be interpreted as not being, so far as its subject-matter is concerned, sufficiently precise for an individual to be able to rely on it before a national court against a Member State.

The second question in Case C-472/07

30 By its second question in Case C-472/07, the referring court is asking, in essence, whether Article 4(1) of Directive 89/105 may be interpreted as meaning that a Member State may, 18 months after the end of a general price freeze in respect of refundable medicinal products which lasted eight years, adopt a new measure freezing the prices of medicinal products without carrying out the review of macro-economic conditions which is provided for in that provision.

31 Article 4(1) of Directive 89/105 provides that, 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.

32 The wording of Article 4(1) of Directive 89/105 thus shows that the purpose of the Member States' obligation to carry out an annual review of macro-economic conditions is to ensure that, where the prices of medicinal products have been frozen, those macro-economic conditions justify that the freeze be continued.

33 Therefore, once a measure freezing the prices of medicinal products has been adopted by a Member State, that review must be carried out every time the Member State proposes to continue that price freeze unchanged.

34 By contrast, Article 4(1) of Directive 89/105 does not require Member States to conduct such a review when a measure freezing prices is adopted, even where, as in the main proceedings, it is adopted 18 months after the end of an earlier measure freezing the prices of medicinal products.

35 In those circumstances, the answer to the second question in Case C-472/07 is that Article 4(1) of Directive 89/105 must be interpreted as meaning that a Member State may, 18 months after the end of a general price freeze in respect of refundable medicinal products which lasted eight years, adopt a new measure freezing the prices of medicinal products without carrying out the review of macro-economic conditions which is provided for in that provision.

Costs

36 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 (Third 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 pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems must 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 macro-economic conditions which is referred to in that provision is to be carried out, provided that those criteria are based on objective and verifiable factors.**

2. **Article 4(1) of Directive 89/105 must be interpreted as not being, so far as its subject-matter is concerned, sufficiently precise for an individual to be able to rely on it before a national court against a Member State.**

3. **Article 4(1) of Directive 89/105 must be interpreted as meaning that a Member State may, 18 months after the end of a general price freeze in respect of**

refundable medicinal products which lasted eight years, adopt a new measure freezing the prices of medicinal products without carrying out the review of macro-economic conditions which is provided for in that provision.

[Signatures]