JUDGMENT OF THE COURT (Second Chamber)

20 January 2005 *

In Case C-245/03,

REFERENCE for a preliminary ruling under Article 234 EC by the Conseil d'État (Belgium), by decision of 9 May 2003, received at the Court on 10 June 2003, in the proceedings

Merck, Sharp & Dohme BV

v

État belge,

THE COURT (Second Chamber),

composed of C.W.A. Timmermans, President of the Chamber, R. Silva de Lapuerta (Rapporteur), C. Gulmann, R. Schintgen and G. Arestis, Judges,

* Language of the case: French.

Advocate General: A. Tizzano,
Registrar: M. Múgica Arzamendi, Principal Administrator,

having regard to the written procedure and further to the hearing on 14 July 2004,

after considering the observations submitted on behalf of:

— Merck, Sharp & Dohme BV, by R. Subiotto, Solicitor, and T. Graf, avocat,

— the Belgian Government, by A. Snoecx, acting as Agent, and by L. Levi and L. Depré, avocats,

— the Danish Government, by J. Molde, acting as Agent,

— the Netherlands Government, by H.G. Sevenster, acting as Agent,

— the Finnish Government, by T. Pynnä, acting as Agent,

— the Norwegian Government, by A. Enersen and F. Platou Amble, acting as Agents,

— the Commission of the European Communities, by H. Stovlbaek and B. Stromsky, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 30 September 2004,

gives the following

Judgment

1 The reference for a preliminary ruling concerns the interpretation of the first subparagraph of Article 6(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; 'the Directive').

2 The reference was made in proceedings between Merck, Sharp & Dohme BV ('Merck') and the Belgian State in respect of an implied decision of the Minister for Social Affairs and Pensions ('the Minister') refusing to accept the proprietary medicinal product Proscar for reimbursement under the compulsory health care and compensation.

Legal framework

Community rules

3 The fifth and sixth recitals of the preamble to the Directive 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 this information should be public;

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 6 of the Directive provides:

'The following provisions shall apply if a medicinal product is covered by the national health insurance system only after the competent authorities have decided to include the medicinal product concerned in a positive list of medicinal products covered by the national health insurance system.

1. Member States shall ensure that a decision on an application submitted, in accordance with the requirements laid down in the Member State concerned, by the holder of a marketing authorisation to include a medicinal product in the list of medicinal products covered by the health insurance systems is adopted and communicated to the applicant within 90 days of its receipt. Where an application under this Article may be made before the competent authorities have agreed the price to be charged for the product pursuant to Article 2, or where a decision on the price of a medicinal product and a decision on its inclusion within the list of products covered by the health insurance system are taken after a single administrative procedure, the time-limit shall be extended for a further 90 days. The applicant shall furnish the competent authorities with adequate information. If the information supporting the application is inadequate, the time-limit shall be suspended and the competent authorities shall forthwith notify the applicant of what detailed additional information is required.

   Where a Member State does not permit an application to be made under this Article before the competent authorities have agreed the price to be charged for the product pursuant to Article 2, the Member State concerned shall ensure that the overall period of time taken by the two procedures does not exceed 180 days. This time-limit may be extended in accordance with Article 2 or suspended in accordance with the provisions of the preceding subparagraph.

2. Any decision not to include a medicinal product in the list of products covered by the health insurance system shall contain a statement of reasons based upon objective and verifiable criteria, including, if appropriate, any expert opinions or recommendations on which the decision is based. In addition, the applicant shall be informed of the remedies available to him under the laws in force and of the time-limits allowed for applying for such remedies.'

National rules

5 On the date of the application for approval of reimbursement for the medicinal product Proscar, 2 February 1993, entry on the list of reimbursable proprietary pharmaceutical products was governed by the Law of 9 August 1963 and by the Royal Decree of 2 September 1980. Those provisions made no reference to the legal effects of exceeding the time-limit for responding to an application for entry on the list.

6 The Royal Decree of 2 September 1980 was amended by the coordinated Law of 14 July 1994 on health insurance and compensation, in the version amended by the Law of 10 August 2001 laying down measures on health care, which entered into force on 1 January 2002 and transposed the Directive into Belgian law ('the Law of 14 July 1994'). Those provisions introduced a system whereby failure to reply constitutes a positive response (automatic entry) where the time-limit for responding to an application for entry of a medicinal product on the list of reimbursable proprietary medicinal products is exceeded.

Main proceedings and question referred to the Court

7 On 2 February 1993, Merck applied to the Institut national d'assurance maladie invalidité ('INAMI') for approval of reimbursement for the proprietary medicinal product Proscar, which is indicated in the treatment and control of benign prostatic hyperplasia. Merck enclosed with that application a file containing, in particular, the opinion of the Commission de transparence des médicaments drawn up on 3 January 1993 and containing an assessment of the therapeutic value of the medicinal product within the pharmacological group to which it belongs and also of the packaging of the medicinal product in relation to the dosage in the medical conditions referred to in relation to the cost of health.

8 On 1 July 1993, INAMI's Conseil technique des spécialités pharmaceutiques (Technical committee for proprietary medicinal products) ('the CTSP') delivered a reasoned opinion unfavourable to the approval of reimbursement for Proscar. That reasoned opinion was notified to Merck by letter of 8 July 1993.

9 On 11 August 1993, Merck sent INAMI a memorandum setting out its comments on the unfavourable opinion of the CTSP. On 2 September 1993, the CTSP decided, before reaching a definitive decision, to obtain the opinions of a number of experts 'as to the cases in which the use of a medicinal product of that type would be absolutely essential and, in the case of a positive response, the means of proving it objectively'.

10 On 12 January 1994, the experts delivered a negative opinion on reimbursement for Proscar. They considered that Proscar was a palliative medicinal product rather than a therapeutic medicinal product.

11 On 10 February 1994, the CTSP therefore delivered a new opinion unfavourable to reimbursement for Proscar.

12 On 25 February 1994, Merck wrote to INAMI amending its application for approval of reimbursement for Proscar. It proposed reimbursement in category C, by inclusion of the medicinal product in Chapter IV of Annex I to the Royal Decree of 2 September 1980. On 1 April 1994, Merck suggested, in the alternative, that Proscar should be approved for reimbursement in Category Cs.

13 On 14 April 1994, the CTSP considered those new proposals and concluded that they were not such as to alter the unfavourable opinion which it had previously given.

14 On 8 July 1994, INAMI's Commission des conventions pharmaciens, organismes assureurs (committee on agreements between pharmacists and insurers) did not comment on the CTSP's unfavourable opinion. On 17 October 1994, INAMI's insurance committee also gave an opinion unfavourable to the approval of reimbursement for Proscar.

15 On 27 February 1995, the Minister informed Merck that he was not approving the proprietary product Proscar for reimbursement under the compulsory insurance for health care and benefits.

16 That decision was challenged by Merck and was eventually annulled by the Conseil d'État on 7 June 1996 on the ground that the decision to enter or refuse to enter a proprietary product on the list of reimbursable proprietary medicinal products falls within the competence of the King and not within that of the Minister.

17 On 3 July 1996, Merck gave the defendant formal notice to comply with that judgment and to approve reimbursement for Proscar as requested in the application lodged on 2 February 1993. The competent administration remained silent for four months and the request was rejected by implication. That implied rejection forms the subject-matter of the main proceedings.

18 In those circumstances, the Conseil d'État decided to stay proceedings and to refer the following question to the Court for a preliminary ruling:

'Must the time-limit of 90 days, which may be extended for a further 90 days, mentioned in the first subparagraph of Article 6(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, be regarded as a merely indicative time-limit or as a mandatory time-limit and, if the time-limit is mandatory, what are the consequences of exceeding it as regards the response to be given to the application for inclusion of a medicinal product in the list of medicinal products covered by the health insurance scheme?

Must exceeding the time-limit be deemed to constitute inclusion in the abovementioned list?'

The question referred to the Court

19 In order to give a useful reply to that question, the Court must determine, first, the nature of the time-limit fixed in the first subparagraph of Article 6(1) of the Directive and, second, the consequences envisaged by the Directive where that time-limit is exceeded.

The indicative or mandatory nature of the time-limit referred to in the first subparagraph of Article 6(1) of the Directive

20 As to whether the time-limit in the first subparagraph of Article 6(1) of the Directive is indicative or mandatory, it should be observed, as the Advocate General did at point 36 of his Opinion, that it follows from both the wording and the scheme of that provision that the time-limit in question must be regarded as mandatory.

21 First, the use of the verb 'ensure' in its indicative form, and the precise definition of the method of calculating the time-limit in issue, show that the competent authorities are required to comply with the prescribed time-limit when adopting their decisions.

22 Second, the first subparagraph of Article 6(1) of the Directive also determines with precision the circumstances in which the time-limit in issue may be extended or suspended. The precise indication of those circumstances would be pointless if Member States were free not to comply with that time-limit.

23 That interpretation of the first subparagraph of Article 6(1) of the Directive is corroborated by the objective of the Directive, which, as stated in the sixth recital, is to allow the persons concerned to ensure that the administrative entry of medicinal products satisfies objective criteria and that there is no discrimination between national medicinal products and those from other Member States (see Case C-229/00 *Commission* v *Finland* [2003] ECR I-5727, paragraph 39).

24 In the light of those considerations, the answer to the first part of the question must be that the time-limit laid down in the first subparagraph of Article 6(1) of the Directive is a mandatory time-limit which the national authorities are not entitled to exceed.

The consequences of exceeding the time-limit within which the competent authority is to respond

25 It should be noted at the outset that Article 6(1) of the Directive gives no indication of the consequences of exceeding the time-limit within which the administration is to respond to an application for inclusion of a medicinal product on the positive list

of medicinal products for which reimbursement is made. In particular, that article does not state whether the product concerned is automatically entered on the list when the time-limit is exceeded.

26 In so far as that information is not disclosed by any other provision of the Directive, the Court must examine the purpose and the structure of the Directive in order to determine whether the Directive must be interpreted as meaning that it entails the automatic entry of a medicinal product on the positive list of medicinal products for which reimbursement is made when the time-limit laid down in the first subparagraph of Article 6(1) is exceeded.

27 In that regard, the sixth recital of the preamble to the directive states that the transparency requirements deriving from the Directive 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 the Directive. It follows that the Directive has as its underlying principle the idea of minimum interference in the organisation by Member States of their domestic social security policies.

28 It follows from settled case-law, moreover, that Community law does not detract from the power of the Member States to organise their social security systems (see, in particular, Case 238/82 *Duphar and Others* [1984] ECR 523, paragraph 16, and Case C-70/95 *Sodemare and Others* [1997] ECR I-3395, paragraph 27), and that, in the absence of harmonisation at Community level, it is for the laws of each Member State to determine the circumstances in which social security benefits are granted (see, in particular, Case 110/79 *Coonan* [1980] ECR 1445, paragraph 12; Case C-349/87 *Paraschi* [1991] ECR I-4501, paragraph 15; and Joined Cases C-4/95 and C-5/95 *Stöber and Piosa Pereira* [1997] ECR I-511, paragraph 36).

29 Therefore, in the absence of a specific provision in the Directive, it is for the Member States to determine the effects of exceeding the time-limit, on condition that the rules which it adopts are not less favourable than those concerning similar

situations (principle of equivalence) and that they do not render the rights conferred by the Community legal order impossible or difficult in practice to exercise (see Case C-255/00 *Grundig Italiana* [2002] ECR I-8003, paragraph 33, and Case C-129/00 *Commission* v *Italy* [2003] ECR I-14637, paragraph 25).

30 That interpretation is confirmed by the difference in treatment which the Directive reserves for applications for approval of the marketing price or for an increase in that price by comparison with applications for inclusion of medicinal products on a positive list.

31 It should be noted that where the Directive means to penalise failure to observe a time-limit by automatic acceptance of the application, it expressly states so.

32 Thus, Article 2(1) of the Directive, on applications for approval of the marketing price of medicinal products, states that '[i]n the absence of such a decision within the abovementioned period or periods, the applicant shall be entitled to market the product at the price proposed'.

33 Likewise, the third subparagraph of Article 3(1) of the Directive, on applications for approval of an increase in the price of a medicinal product which is already being marketed, states that '[i]n the absence of such a decision within the abovementioned period or periods, the applicant shall be entitled to apply in full the price increase requested'.

34 In the light of those considerations, the answer to the second part of the question must be that the Directive is to be interpreted as meaning that it does not impose the automatic entry of a medicinal product on the list of proprietary medicinal products covered by the sickness insurance system where the time-limit laid down in the first subparagraph of Article 6(1) is exceeded.

Costs

35 Since these proceedings are, for the parties to the main proceedings, a step in the action 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 (Second Chamber) rules as follows:

1. **The time-limit laid down in the first subparagraph of Article 6(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 is a mandatory time-limit which the national authorities are not entitled to exceed.**

2. **The first subparagraph of Article 6(1) of Directive 89/105 does not impose the automatic entry of a medicinal product on the list of proprietary medicinal products covered by the sickness insurance system where the time-limit laid down in that article is exceeded.**

[Signatures]