JUDGMENT OF THE COURT (Second Chamber)

20 January 2005 *

In Case C-296/03,

REFERENCE for a preliminary ruling under Article 234 EC by the Conseil d'État (Belgium) by decision of 27 June 2003, received at the Court on 8 July 2003, in the proceedings

Glaxosmithkline SA

v

État Belge,

THE COURT (Second Chamber),

composed of C.W.A. Timmermans, President of the Chamber, R. Silva de Lapuerta (Rapporteur), C. Gulmann, P. Kūris 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:

— Glaxosmithkline SA, by S. Callens and S. Brillon, avocats,

— the Belgian Government, by E. Dominkovits, 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 and A. Guimaraes-Purokoski, acting as Agents,

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

— the Commission of the European Communities, by B. Stromsky, acting as Agent,

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 Glaxosmithkline SA ('Glaxosmithkline') and the Belgian State in respect of an implied decision of the Minister for Social Affairs and Pensions ('the Minister') refusing to admit the proprietary medicinal product Infanrix Henra for reimbursement under the compulsory health care insurance and benefits. That decision was taken following the annulment by the Conseil d'État of an earlier decision of the Minister. Glaxosmithkline seeks annulment of the decision on the ground, essentially, that the Minister was no longer competent *ratione temporis* to take it.

Legal framework

Community rules

3 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

4 On the date on which the application for admission in issue was submitted, entry on the list of reimbursable proprietary medicinal products was governed by the coordinated Law of 14 July 1994 on health care insurance and benefits, in the version amended by the Law of 10 August 2001 introducing health care measures, which entered into force on 1 January 2002 and transposed the Directive into Belgian law. The Royal Decree of 21 December 2001 laying down the procedures, time-limits and conditions concerning assistance from compulsory health insurance completes the national legal framework.

5 Article 35 *bis* of the coordinated Law of 14 July 1994 provides:

'...

Where no decision is adopted within 180 days of the date communicated by the Secretariat of the [Commission de remboursement des médicaments] to which the file has been submitted, the decision [relating to the application for entry on the list of reimbursable proprietary medicinal products] shall be deemed to be positive as regards the basis for reimbursement for the medicinal products, the conditions for reimbursement and the category of reimbursement proposed by the applicant ...'

6 Article 22(3) of the Law of 10 August 2001 provides:

'Applications seeking a subsidy duly submitted before 1 January 2002 and in respect of which the file has already been deemed to be complete shall continue to be dealt with in accordance with the rules in force before 1 January 2002, provided that they are examined within 90 days from the date of communication of the price, as determined by the Minister whose portfolio includes Economic Affairs, or from the date of communication of the opinion of the Commission de transparence, whichever is later.

As regards applications in respect of which the applicant has already communicated by 1 January 2002 the price determined by the Minister whose portfolio includes Economic Affairs and the opinion of the Commission de transparence, the period of 90 days shall be calculated as from 1 January 2002.

Where no decision has been taken within the 90-day periods referred to in the first and second subparagraphs, the file shall be transmitted to the [Commission de remboursement des médicaments].

The King shall determine the rules concerning such reference and the procedure to be followed.'

7 As regards the applications referred to in Article 22(3) of the Law of 10 August 2001, Article 100(3) of the Royal Decree of 21 December 2001 provides:

'...

Where no decision is adopted in respect of those files within the 90-day period referred to in Article 22(3) of the Law of 10 August 2001 ..., the Chairman of the [Conseil technique des spécialités pharmaceutiques] shall transmit them to the Secretariat of the [Commission de remboursement des médicaments].

...

Where no decision has been taken by the Minister within a period of 90 days from the date of transmission, the official designated by the Minister shall inform the applicants concerned forthwith that no decision has been taken. That notification must be accompanied by the applicant's proposal to amend the most recent list and the entry or entries to be amended, with effect from the first day of the month after expiry of a period of 10 days following its publication in the [*Moniteur belge*].'

Main proceedings and question referred to the Court

8 On 3 December 2001, Glaxosmithkline applied to the Institut national d'assurance maladie-invalidité ('INAMI') for 'approval for reimbursement for the proprietary medicinal product Infanrix Hexa, an absorbed combined diphtheria-tetanus-acellular pertussis, hepatitis B, inactivated poliovirus and Haemophilus influenzae type B vaccine ...'.

9 Glaxosmithkline completed its file before 1 January 2002. On 22 January 2002 it sent the Conseil technique des spécialités pharmaceutiques ('the CTSP') a memorandum stating, in particular, that it sought reimbursement for that vaccine in Category A (reimbursement in full).

10 On 7 May 2002, the CTSP informed Glaxosmithkline that, as it had not made a definitive proposal within the period allowed under the national rules, it had forwarded the application for reimbursement to the Commission de remboursement des médicaments ('the CRM'), which had delivered a provisional reasoned opinion on the date of that letter, 7 May 2002, in favour of reimbursement for the vaccine according to the 'B-nouveau' criterion, on certain conditions.

11 On 21 May 2002, after Glaxosmithkline had expressed its views on that proposal, the CRM issued a definitive reasoned proposal confirming its provisional proposal.

12 On 29 May 2002, the CRM notified that proposal to Glaxosmithkline. It stated that the definitive proposal had been sent to the Minister, who would adopt a reasoned

decision within 90 days from the date on which the file was transferred from the CTSP to the CRM.

13 By letter of 27 June 2002, the Minister informed Glaxosmithkline that he had decided to refuse to enter the Infanrix Hexa vaccine on the list of reimbursable medicinal products, for the following reasons:

'[t]he components of that vaccine are already reimbursed individually. The interministerial conference on public health has stated that it is in favour of a uniform basic vaccination policy to be drawn up between the Communities and the Federal Government. In order to avoid influencing future negotiations, I am not giving a favourable reply to your application ...'

14 Glaxosmithkline brought an action before the Conseil d'État for annulment of that decision and applied for its suspension.

15 By judgment of 11 December 2002, the Conseil d'État annulled the contested decision. It held, in substance:

— first, that the Minister could depart from the CRM's definitive proposal only on the basis of social or budgetary factors, or on the basis of a combination of those two factors,

— second, that the grounds of the contested decision were materially incorrect in part and, for the remainder, did not constitute sufficient justification based on social or budgetary arguments.

16 By letter of 7 January 2003, Glaxosmithkline requested INAMI to enter the Infanrix Hexa vaccine on the list of proprietary medicinal products in accordance with the most recent proposal for approval. It claimed that it was no longer possible to take a lawful decision concerning the application for approval of reimbursement for that vaccine, as the time-limits laid down by national law for a determination of the application for reimbursement had expired and national law provided that in such a situation the application for entry must be automatically granted.

17 On 17 January 2003, the Minister informed Glaxosmithkline that he refused to enter the Infanrix Hexa vaccine on the list of reimbursable medicinal products for social or budgetary reasons, the terms of which he stated. The Minister further maintained that, contrary to Glaxosmithkline's contention, the judgment of the Conseil d'État opened a new period of 30 days from notification of that judgment within which to determine the application and that he was not required automatically to enter the proprietary medicinal product on the positive list of medicinal products eligible for reimbursement.

18 Glaxosmithkline applied to the Conseil d'État for annulment of the decision of 17 January 2003, on the ground, essentially, that the Minister was no longer competent *ratione temporis* to take such a decision.

19 In those circumstances, the Conseil d'État (Sixth Chamber) 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, referred to 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 prices of medicinal products for human use and their inclusion in the scope of national health insurance systems be considered to be a strict time-limit precluding, upon expiry, the adoption of any decision, even where an initial decision adopted in good time has been annulled?'

The question referred to the Court

Admissibility

20 As a preliminary point, Glaxosmithkline disputes the admissibility of the reference for a preliminary ruling on the ground that the question is not relevant to the outcome of the main proceedings. That outcome is clear from Article 35*bis*(3) of the coordinated Law of 14 July 1994, which not only prescribes a mandatory time-limit but also states that failure to comply with that time-limit entails automatic entry of the medicinal product on the list of reimbursable products. Accordingly, there is no need to seek in the Directive a solution which in reality is already clear from national law.

21 However, that argument cannot be accepted.

22 It is settled case-law that the Court has no jurisdiction to answer a question raised by a national court where it is quite obvious that the interpretation or the appraisal of the validity of a rule of Community law sought by the national court bears no relation to the actual facts of the main action or its purpose, where the problem is hypothetical, or where the Court does not have before it the factual or legal material necessary to give a useful answer to the questions submitted (see Case C-379/98 *PreussenElektra* [2001] ECR I-2099, paragraph 39, and Case C-390/99 *Canal Satélite Digital* [2002] ECR I-607, paragraph 19).

23 Those conditions are not satisfied in the present case. In this case, the purpose of the main proceedings relates to the meaning to be ascribed to the procedural period prescribed in Article 6 of the Directive, transposed into the Belgian legal order by the coordinated Law of 14 July 1994. The interpretation of the Community provision therefore clearly has a bearing on the purpose of the main proceedings.

24 It follows that the request for a preliminary ruling is admissible.

Substance

25 In order to provide a useful answer to that question, the Court must determine, first, the nature of the time-limit laid down in the first subparagraph of Article 6(1) of the Directive and, second, the consequences envisaged by the Directive should that time-limit be exceeded and, in particular, whether the fact that that time-limit is exceeded prevents the competent authority from adopting a new decision where it adopted an initial decision in good time and that decision was then annulled in court proceedings.

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

26 As to whether the time-limit laid down in the first subparagraph of Article 6(1) of the Directive is indicative or mandatory, it should be observed that, 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.

27 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.

28 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.

29 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).

30 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 where a previous decision adopted in good time has been annulled

31 Regard being had to the mandatory nature of the time-limit laid down in Article 6(1) of the Directive, the question arises whether the fact that that time-limit is exceeded precludes the adoption by the national authorities of a new decision confirming an earlier decision adopted within the prescribed time-limit but annulled in court proceedings.

32 In that regard, it must be recalled, first, that Article 6(1) of the Directive determines clearly and precisely the time-limit for adoption and communication of the decision relating to the application for entry of the medicinal products on the list of medicinal products covered by the sickness insurance scheme and defines the circumstances in which that time-limit may be suspended or extended. Second, Article 6(2) lays down an obligation to state the reasons for the decision and states that it is for the national legislation to determine the remedies available to the applicant and the relevant time-limits.

33 However, the Directive does not govern the situation in which a new decision must be taken following annulment by a court of an earlier decision adopted within the prescribed time-limit.

34 All of the parties which have submitted observations in the present case maintained that such a situation would be governed by national law. However, their views differ on the procedures for the adoption of such a new decision. The plaintiff in the main proceedings maintains that the annulment of a decision in court proceedings precludes the adoption of any new decision and therefore constitutes an implied acceptance of the application for entry on the list of reimbursable medicinal products. The Belgian and Finnish Governments, on the other hand, contend that if the consequences where the time-limit is exceeded are governed by national law, there is nothing to prevent a new statutory period from being opened, allowing the competent authorities to determine the application for entry on the list of reimbursable medicinal products. The Commission submits that it is for the Member States to regulate the remedies against the decisions in issue and the consequences of the decisions annulling them.

35 In that regard, it may be inferred from both the terms and the objectives pursued by the Directive that the latter seeks to ensure effective judicial protection. It follows that every person whose initial application for entry has been rejected by a decision which was then annulled must be guaranteed the right for a new decision to be taken in respect of that application for entry on the list, whether an implied decision that the product in question must be entered on the list purely because the initial time-limit has expired or a new formal decision.

36 In the former case, it is then necessary to determine the time-limit within which such a decision must be adopted.

37 Although the Directive does not govern that question, it follows from the abovementioned requirements for effective judicial protection that Community law sets a limit to Member States' freedom in that regard, in that the new decision cannot be adopted within an indefinite period, but must be taken within a reasonable time which does not in any event exceed the time-limit laid down in Article 6 of the Directive.

38 In the absence of that limit, the exercise of the applicant's right to obtain a reasoned decision within the mandatory 90-day time-limit, which may be extended by a further 90 days, would be excessively difficult (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). In effect, the Member States could impose a longer time-limit for implementation of the decision annulling the initial decision than that which the Directive prescribes for the closure of the administrative procedure. In that case, the decision of annulment would not protect the applicant's right.

39 The answer to the second part of the question referred to the Court must be that it is for the Member States to determine whether the fact that the time-limit laid down in the first subparagraph of Article 6(1) of the Directive is exceeded precludes the competent authorities from formally adopting a new decision when the previous decision has been annulled in court proceedings, although such a possibility can be exercised only within a reasonable time which may not in any event exceed the time-limit laid down in that article.

Costs

40 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. **It is for the Member States to determine whether the fact that the time-limit laid down in the first subparagraph of Article 6(1) of Directive 89/105 is exceeded precludes the competent authorities from formally adopting a new decision when the previous decision has been annulled in court proceedings, although such a possibility can be exercised only within a reasonable time which may not in any event exceed the time-limit laid down in that article.**

[Signatures]