JUDGMENT OF THE COURT (Fifth Chamber)

26 October 2006 *

In Case C-317/05,

REFERENCE for a preliminary ruling under Article 234 EC, by the Sozialgericht Köln (Germany), made by decision of 8 August 2005, received at the Court on 17 August 2005, in the proceedings

G. Pohl-Boskamp GmbH & Co. KG

v

Gemeinsamer Bundesausschuss,

intervening parties:

AOK-Bundesverband KdöR,

IKK-Bundesverband,

* Language of the case: German.

Bundesverband der Betriebskrankenkassen (BKK),

Bundesverband der landwirtschaftlichen Krankenkassen,

Verband der Angestellten-Krankenkassen eV,

AEV-Arbeiter-Ersatzkassen-Verband eV,

Bundesknappschaft,

Seekrankenkasse,

Bundesrepublik Deutschland,

THE COURT (Fifth Chamber),

composed of J. Klučka, President of the Seventh Chamber, acting for the President of the Fifth Chamber, R. Silva de Lapuerta (Rapporteur) and J. Makarczyk, Judges,

Advocate General: P. Mengozzi,
Registrar: B. Fülöp, Administrator,

having regard to the written procedure and further to the hearing on 28 June 2006,

after considering the observations submitted on behalf of:

— G. Pohl-Boskamp GmbH & Co. KG, by W. Kozianka and N. Hussman, Rechtsanwälte,

— the Gemeinsamer Bundesausschuss, by M. Grüne, Rechtsanwalt,

— AOK-Bundesverband KdöR, by K.-H. Mühlhausen and J. Ihle, acting as Agents,

— IKK-Bundesverband, by S. Reitzenstein, acting as Agent,

— the Bundesverband der Betriebskrankenkassen (BKK), by K.-P. Adelt and P. Kraftberger, acting as Agents,

— the German Government, by M. Lumma, acting as Agent,

— the Commission of the European Communities, by B. Schima and B. Stransky, acting as Agents,

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

gives the following

Judgment

1 This reference for a preliminary ruling concerns the interpretation of Article 6 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 This reference was made in the course of proceedings between G. Pohl-Boskamp GmbH & Co. KG ('Pohl-Boskamp') and the Gemeinsamer Bundesausschuss (Joint Federal Committee) regarding the latter's refusal to include two ready-to-use medicinal products belonging to the applicant in the main proceedings on a list of non-prescription medicinal products which can, by way of exception, be prescribed and thus covered by the compulsory health insurance scheme.

Legal context

Community legislation

3 Article 6 of Directive 89/105 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 system 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.

...

5. Any decision to exclude a product from the list of products covered by the health insurance system shall contain a statement of reasons based on objective and verifiable criteria. Such decisions, including, if appropriate, any expert opinions or recommendations on which the decisions are based, shall be communicated to the person responsible, who shall be informed of the remedies available to him under the laws in force and the time-limits allowed for applying for such remedies.

6. Any decision to exclude a category of medicinal products from the list of products covered by the health insurance system shall contain a statement of reasons based on objective and verifiable criteria and be published in an appropriate publication.'

4 Article 7 of Directive 89/105 provides:

'The following provisions shall apply if the competent authorities of a Member State are empowered to adopt decisions to exclude individual or categories of medicinal products from the coverage of its national health insurance system (negative lists).

1. Any decision to exclude a category of medicinal products from the coverage of the national health insurance system shall contain a statement of reasons based upon objective and verifiable criteria and be published in an appropriate publication.

...'

National legislation

5 The statutory provisions governing the compulsory health insurance scheme in Germany are set out, in essence, in Book V of the German Social Law Code (Sozialgesetzbuch, 'the SGB V').

6 According to the first sentence of Paragraph 31(1) of the SGB V, insured persons are entitled, inter alia, to be provided with medicinal products obtainable only in pharmacies in so far as such medicinal products are not excluded pursuant to Paragraph 34 thereof or pursuant to national directives adopted under the second sentence, heading (6), of Paragraph 92(1) of the SGB V.

7 Under Paragraph 34(1) of the SGB V:

'Non-prescription medicinal products are excluded from provision under Paragraph 31. The Gemeinsamer Bundesausschuss is to determine by way of national directives under the second sentence, heading (6), of Paragraph 92(1), initially no later than 31 March 2004, which non-prescription medicinal products, constituting standard therapy for the treatment of serious illnesses, may exceptionally be prescribed for use in treating such illnesses where reasons are provided by the contracting doctor.'

The main proceedings and the questions referred for a preliminary ruling

8 Pohl-Boskamp is a pharmaceutical company which manufactures and markets, inter alia, the phytotherapeutical products Gelomyrtol and Gelomyrtol forte. Their active ingredient is myrtol standardised and they are used to treat acute and chronic bronchitis and sinusitis. Those preparations may be dispensed for end use only in pharmacies, but they do not require a doctor's prescription.

9 Pursuant to the second sentence of Paragraph 34(1) of the SGV V, the Gemeinsamer Bundesausschuss proposed a list of non-prescription medicinal products which can, by way of exception, be prescribed and thus covered by the compulsory health insurance scheme. It submitted that list on 11 December 2003 and opened a hearings procedure to enable associations of pharmaceutical undertakings to express their views.

10 As the ready-to-use medicinal products Gelomyrtol and Gelomyrtol forte were not on the abovementioned list, Pohl-Boskamp submitted a request, in January 2004, that the medicinal products in question be included on the list.

11 On 16 March 2004, the Gemeinsamer Bundesausschuss finally adopted the list of the exempted medicinal products which was approved by the Federal Minister for Health and Social Security on the same day.

12 On 23 April 2004, that list was published in the German Official Journal (*Bundesanzeiger* No 77 of 23 April 2004, p. 8905). That list sets out as standard therapeutic products for the purposes of the second sentence of Paragraph 34(1) of the SGB V, active ingredients, and groups and combinations of active ingredients as well as, in part, products associated with specific types of intervention. The various serious illnesses for the treatment of which the therapeutic products may be prescribed also appear on that list. The active ingredient in the Gelomyrtol and Gelomyrtol forte preparations, namely myrtol standardised, cannot be classified under any of the standard therapeutic products listed.

13 As Pohl-Boskamp did not receive any explanation regarding the decision of the Gemeinsamer Bundesausschuss not to include its medicinal products on the list, it brought an action before the Sozialgericht Köln (Social Court, Cologne) on 19 May 2004.

14 It is against that background that the Sozialgericht Köln decided to stay proceedings and refer the following questions to the Court for a preliminary ruling:

'(1) Is Council Directive 89/105 ... to be interpreted as precluding rules of a Member State which, following the exclusion of non-prescription medicinal products from the range of benefits provided by the national health system,

empower an authority under that system to adopt rules derogating from that exclusion in respect of certain medicines without making provision for a procedure under Article 6(1), second sentence, and 6(2) of Directive 89/105?

(2) Is Directive 89/105 ... to be interpreted as granting the manufacturers of the medicinal products referred to in point 1 above a subjective right vis-à-vis the public authorities, in particular a right to a decision, containing a statement of reasons and information as to the available avenues of appeal, on the inclusion of one of their medicinal products on a list of the type mentioned above, even though the rules of the Member State make no provision for any corresponding decision-making or appeal procedures?'

The questions referred for a preliminary ruling

The first question

15 In order to answer the first question, it is first of all necessary to analyse whether the provisions adopted pursuant to the second sentence of Paragraph 34(1) of the SGB V constitute an act covered by Article 6 of Directive 89/105.

16 In that regard, the Gemeinsamer Bundesausschuss submits that its decisions do not have the legal status of a positive list as only positive authorisation decisions by the Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Medicinal and Medical Products) have that function under the German system.

17 Article 6 of the directive applies 'if a medicinal product is covered by the national health insurance system only after the competent authorities have decided to include [it] in a positive list of medicinal products covered by [that system]'.

18 Admittedly, it is apparent from the description of the German system set out by the national court that the inclusion of a medicinal product on the list of those which can be issued subject to prescription and thus prescribed at the expense of the compulsory health insurance scheme entails, at the initial stage, a positive authorisation decision by the Bundesinstitut für Arzneimittel und Medizinprodukte.

19 However, the Gemeinsamer Bundesausschuss is entitled to determine, at a second stage, which non-prescription medicinal products can, by way of exception, be prescribed and thus covered. The list of those medicinal products must be approved subsequently by the Federal Minister for Health and Social Security.

20 It follows that if the Bundesinstitut für Arzneimittel und Medizinprodukte does not decide, at the initial stage, to include a medicinal product on the list of medicinal products which are covered by the national health insurance system, the later decision by the Gemeinsamer Bundesausschuss to include certain active ingredients in the scheme of coverage by way of exception necessarily has the consequence of making ready-to-use medicinal products which contain such ingredients subject to that scheme.

21 Moreover, on the basis of that decision by the Gemeinsamer Bundesausschuss, medicinal products which contain an active ingredient to which that decision applies qualify for coverage.

22 The Court has already ruled that a decision like that adopted by the Gemeinsamer Bundesausschuss, even if it covers only the acceptance for coverage of a series of active ingredients, constitutes a bundle of individual decisions on the inclusion of certain medicinal products in one of the social security schemes, so as to bring it within the provisions of Article 6 of Directive 89/105 (see, to that effect, Case C-229/00 *Commission* v *Finland* [2003] ECR I-5727, paragraph 34).

23 As regards the argument submitted by the German Government that Article 6(1) of Directive 89/105 applies only to applications submitted by the holder of a marketing authorisation, it is sufficient to note that, according to the interpretation given by the Court in *Commission* v *Finland*, a decision such as that at issue in the main proceedings constitutes a body of individual decisions affecting several interested parties. The fact that they are affected entitles the holders of marketing authorisations for medicinal products containing the active ingredients concerned to claim the rights accorded by that article.

24 In the context of the application of Article 6 of Directive 89/105, the Gemeinsamer Bundesausschuss added that guidelines do not constitute measures for the purposes of controlling the prices of medicinal products, which appears to be the requirement for the application of Directive 89/105, in particular Article 6 thereof.

25 According to settled case-law, 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 (see, to that effect, Case C-424/99 *Commission* v *Austria* [2001] ECR I-9285, paragraph 30, and *Commission* v *Finland*, paragraph 37).

26 The Court also pointed out that the decisions pursuant to which certain medicinal products qualify for higher-rate cover constitute a means of determining the extent of the range of medicinal products covered by the sickness insurance scheme and likely to be used in the treatment of such or such an illness. Moreover, according to the sixth recital in the preamble to Directive 89/105, ensuring the effectiveness of the directive also requires that the persons concerned can verify that the 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 (see, to that effect, *Commission* v *Finland*, paragraphs 38 and 39).

27 According to that case-law, those objectives would be compromised if a Member State were able to introduce a dual procedure for the establishment of a list of medicinal products qualifying for reimbursement, one pursuant to the obligations laid down by Article 6(1) of Directive 89/105, namely, for Germany, that set out by the Bundesinstitut für Arzneimittel und Medizinprodukte, the other being exempt in part from those obligations and, in part, not complying with the objectives laid down by that directive, namely that established by the Gemeinsamer Bundesausschuss (see, to that effect, *Commission* v *Finland*, paragraph 40).

28 Furthermore, that finding is in no way affected by the claim of the Gemeinsamer Bundesausschuss that the decision at issue in the main proceedings does not distort intra-Community trade, thus respecting the purpose of Directive 89/105.

29 In that regard, it is sufficient to state that, even if possible detriment to intra-Community trade was taken into consideration during the drawing up of Directive 89/105, its main purpose, according to its fifth recital, is to ensure transparency of pricing, including the manner in which it operates in individual cases and the

criteria on which it is based, and to provide public access to pricing arrangements for all those involved in the market in medicinal products in the Member States. A barrier to intra-Community trade does not constitute a requirement for the application of that directive.

30 It is apparent from the above that the decisions adopted pursuant to the second sentence of Paragraph 34(1) of the SGB V constitute an act covered by Article 6 of Directive 89/105.

31 Article 6(2) of Directive 89/105 requires that any decision not to include a medicinal product in the list of products covered by the health insurance system is to contain a statement of reasons based upon objective and verifiable criteria and information as regards the remedies available to the person requesting the inclusion under the laws in force and the time-limits allowed for applying for such remedies.

32 It is apparent from the information submitted by the national court that the decision of 16 March 2004, by which the Gemeinsamer Bundesausschuss finally adopted the list of medicinal products which could be covered by way of exception, was not communicated to Pohl-Boskamp, which received no statement of the reasons for the decision. That list was published in the German Official Journal and included a statement of the main grounds for the inclusion of the active ingredients accepted.

33 The failure of the Gemeinsamer Bundesausschuss to communicate the list of medicinal products to Pohl-Boskamp and also its failure to state the reasons for the decision and to mention in the decision the remedies which were available prove difficult to reconcile with the requirements set out in Article 6(2) of Directive 89/105 as regards decisions not to include a medicinal product in the list of products covered by the health insurance system.

34 In connection with the first question, the German Government has submitted that the decisions at issue in the main proceedings, which give rise to the exclusion of a 'category of medicinal products', fall more within the scope of Articles 6(6) or 7 of Directive 89/105.

35 It is sufficient to point out, in that regard, that those articles relate to circumstances where a category of medicinal products which is on the list of products covered by the national health insurance system is excluded. That is not the situation at issue in the main proceedings as it does not concern a decision to exclude medicinal products which are already covered, but a decision to include medicinal products in the scheme of cover provided by the health insurance system.

36 In view of what has already been stated, the answer to the first question referred for a preliminary ruling must be that Directive 89/105 is to be interpreted as precluding rules of a Member State which, following the exclusion of non-prescription medicinal products from the range of benefits provided by the national health system, empower an authority under that system to adopt rules derogating from that exclusion in respect of certain medicines without making provision for a procedure under Article 6(1) and (2) of that directive.

The second question

37 By its second question, the national court seeks to ascertain, in essence, whether Article 6(2) of Directive 89/105 is deemed to have direct effect, that is to say whether it must be interpreted as meaning that it confers on the manufacturers of medicinal products affected by a decision which allows the coverage by the health insurance system of certain medicinal products containing certain active ingredients the right to a reasoned decision mentioning the remedies to which recourse may be had, even

though the rules of the Member State make no provision for any corresponding procedure or remedies.

38 As regards the question whether Article 6(1) and (2) of Directive 89/105 may have a direct effect which can be relied on in the context of the case in the main proceedings, the applicant and the Commission of the European Communities maintain that the provision in question is clear and univocal, that is to say sufficiently precise, unconditional and comprehensive and that for it to apply no new legal measure on the part of the Member State is required. Therefore, it ought to be capable of being relied on directly.

39 The Gemeinsamer Bundesausschuss disputes that direct effect, having regard to the answer which it proposes that the Court should give to the first question, and raises the problem of the application of Directive 89/105 to the circumstances at issue in the main proceedings on account of the fact that the decisions to which the case relates are legally applicable only to the relations between the health insurance fund and those insured, so that they do not affect the legally protected positions of manufacturers of pharmaceutical products.

40 As regards the issue of the direct application of Article 6 of Directive 89/105, it is clear from the settled case-law of the Court that, 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 upon 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, inter alia, Joined Cases C-397/01 to C-403/01 *Pfeiffer and Others* [2004] ECR I-8835, paragraph 103).

41 A Community provision is unconditional where it sets forth an obligation which is not qualified by any condition, or subject, in its implementation or effects, to the taking of any measure either by the Community institutions or by the Member States. Moreover, a provision is sufficiently precise to be relied on by an individual and applied by a national court where it sets out an obligation in unequivocal terms (see Joined Cases C-246/94 to C-249/94 *Cooperativa Agricola Zootecnica S. Antonio and Others* [1996] ECR I-4373, paragraphs 18 and 19).

42 Article 6(2) of Directive 89/105 exhibits precisely those characteristics, in so far as it describes with precision and in unequivocal terms an obligation, namely that of stating reasons for the refusal and informing the applicant of the remedies available, which is not qualified by any condition, or subject, in its implementation or effects, to the taking of a subsequent measure. Its wording thus appears to be unconditional and sufficiently precise so that it can be relied on by interested parties in their relations with the Member State concerned.

43 Lastly, as regards the argument of the Gemeinsamer Bundesausschuss that the decision at issue in the main proceedings is legally applicable only to relations between the health insurance fund and those insured, it is sufficient to note that that decision has the effect of allowing the coverage of a body of medicinal products containing the active ingredients referred to therein. Accordingly, that decision falls within the scope of Article 6 of Directive 89/105. In that connection it is of little importance that the decisions at issue in the main proceedings can be relied on only by the insured in their relations with the health insurance funds, since what determines whether that article applies is whether or not a medicinal product is covered by the health insurance system.

44 On those grounds, the answer to the second question referred must be that Article 6 (2) of Directive 89/105 is to be interpreted as meaning that it confers on the manufacturers of medicinal products affected by a decision which allows the coverage by the health insurance system of certain medicinal products containing active ingredients referred to therein the right to a reasoned decision mentioning remedies, even though the rules of the Member State make no provision for any corresponding procedure or remedies.

Costs

45 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 (Fifth Chamber) hereby rules:

1. **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 precluding rules of a Member State which, following the exclusion of non-prescription medicinal products from the**

range of benefits provided by the national health system, empower an authority under that system to adopt rules derogating from that exclusion in respect of certain medicines without making provision for a procedure under Article 6(1) and (2) of that directive.

2. **Article 6(2) of Directive 89/105 is to be interpreted as meaning that it confers on the manufacturers of medicinal products affected by a decision which allows the coverage by the health insurance system of certain medicinal products containing active ingredients referred to therein the right to a reasoned decision mentioning remedies, even though the rules of the Member State make no provision for any corresponding procedure or remedies.**

[Signatures]