Reports of Cases

JUDGMENT OF THE COURT (Eighth Chamber)

16 April 2015 *

(Reference for a preliminary ruling — Medicinal products for human use — Directive 89/105/EEC — Article 6(3) and (5) — Removal of medicinal products from a list of pharmaceutical proprietary products covered in addition to fixed payments in respect of hospital treatment — Obligation to state reasons)

In Joined Cases C-271/14 and C-273/14,

REQUEST for a preliminary ruling under Article 267 TFEU from the Conseil d'État (France), made by decisions of 14 May 2014, received at the Court on 4 and 5 June 2014, in the proceedings

LFB Biomédicaments SA,

Association des déficitaires en Alpha 1 Antitrypsine (Association ADAAT Alpha 1-France) (C-271/14)

and

Pierre Fabre Médicament SA (C-273/14)

v

Ministre des Finances et des Comptes publics,

Ministre des Affaires sociales et de la Santé,

THE COURT (Eighth Chamber),

composed of A. Ó Caoimh, President of the Chamber, C. Toader and C.G. Fernlund (Rapporteur), Judges,

Advocate General: N. Jääskinen,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

— LFB Biomédicaments SA, by J. Robert, A. Regniault, E. Nigri and F. Thiriez, avocats,

— Pierre Fabre Médicament SA, by C. Smits, avocat,

* Language of the case: French.

— the French Government, by D. Colas and R. Coesme, acting as Agents,

— the Spanish Government, by L. Banciella Rodríguez-Miñón, acting as Agent,

— the European Commission, by O. Beynet and P. Mihaylova, acting as Agents,

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

gives the following

Judgment

1 These requests for a preliminary ruling concern the interpretation of Article 6(3) and (5) 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 requests have been made in proceedings between, in one case, LFB Biomédicaments SA ('LFB') and the Association des déficitaires en Alpha 1 Antitrypsine (Association ADAAT Alpha 1-France) and, in the other, Pierre Fabre Médicament SA ('PFM'), and the ministre des Finances et des Comptes publics (Minister for Finance and Public Accounts) and the ministre des Affaires sociales et de la Santé (Minister for Social Affairs and Health) concerning the removal of medicinal products from the list of proprietary medicinal products covered by compulsory health insurance schemes in addition to services relating to hospital treatment covered by fixed payments in respect of periods of hospitalisation and hospital care.

Legal context

European Union law

Directive 89/105

3 The fifth recital in the preamble to Directive 89/105 states that:

'… 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; … this information should be public'.

4 The sixth recital in the preamble to Directive 89/105 states that 'as a first step …, 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'.

5 Under Article 1(1) of Directive 89/105:

'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.'

6 Article 6 of that 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.

...

(3) Before the date referred to in Article 11(1), Member States shall publish in an appropriate publication and communicate to the Commission the criteria which are to be taken into account by the competent authorities in deciding whether or not to include medicinal products on the lists.

...

(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.

...’

7 Article 11(1) of Directive 89/105 reads as follows:

‘Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 December 1989 at the latest. They shall forthwith inform the Commission thereof.’

French law

8 Article L. 162-22-7 of the Code de la sécurité sociale (French Social Security Code), in the version thereof applicable to the dispute in the main proceedings, is worded as follows:

‘The State shall establish the list of proprietary medicinal products authorised to be placed on the market and to be provided to inpatients in health establishments referred to in Article L. 162-22-6 which may be covered, upon presentation of invoices, by the compulsory health insurance schemes in addition to services relating to hospital treatment referred to in paragraph 1 therein, and the conditions under which certain products and services referred to in Article L. 165-1 may be covered in addition to the abovementioned services relating to hospital treatment.

Establishments which have joined the contract for proper use of medicinal products and services drawn up jointly by the director-general of the regional health agency and the health insurance scheme under terms defined by decree shall receive full reimbursement for the share covered by the compulsory health insurance schemes.

Where the member establishment has not complied with the stipulations of that contract and has been put on formal notice to submit its observations, the reimbursement may be reduced by up to 30% of the share covered by the health insurance scheme, according to the breaches established.

Establishments which have not joined the contract for proper use of medicinal products and services shall be reimbursed up to 70% of the share covered by the compulsory health insurance schemes.

Under no circumstances may the difference between the reimbursable amount and the reimbursed amount be billed to patients.

…’

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

9 LFB and PFM market medicinal products under the names Alfalastin and Javlor respectively.

10 By Decree of 21 February 2012 amending the list of proprietary medicinal products covered in addition to services relating to hospital treatment which is referred to in Article L. 162-22-7 of the French Social Security Code (JORF of 28 February 2012, p. 3486) (‘the Decree of 21 February 2012’), those medicinal products were removed from the list at issue.

11 By applications received at the Conseil d’État on 13 April and 24 April 2012, LFB and the Association ADAAT Alpha 1-France each brought an action for annulment of the Decree of 21 February 2012, in so far as it removed the medicinal product Alfalastin from the list at issue in the main proceedings. By application received at the Conseil d’État on 1 October 2012, PFM brought an action for annulment of that decree, in so far as it removed the medicinal product Javlor from that list.

12 The referring court is uncertain as to whether the Decree of 21 February 2012 is compatible with Article 6(3) and (5) of Directive 89/105. It observes that the decree has not had the effect of excluding the medicinal products at issue in the main proceedings from the list of proprietary products covered by health insurance. The coverage is henceforth provided for by fixed payments in respect of periods of hospitalisation and inpatient care established in accordance with a classification of diagnosis-related groups and no longer, on the presentation of invoices, in addition to services relating to hospital treatment.

13 In those circumstances, the Conseil d’État decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

‘In Case C-271/14:

Does Article 6(5) of [Directive 89/105] require that a statement of reasons be given for a decision to remove a proprietary medicinal product from the list of medicinal products provided to inpatients in health establishments which may be covered by compulsory health insurance schemes in addition to services relating to hospital treatment covered by fixed payments in respect of periods of hospitalisation and hospital care determined in accordance with diagnosis-related groups?

In Case C-273/14:

Does [Article 6(3) and (5) of Directive 89/105] apply to decisions to remove a proprietary medicinal product from the list of medicinal products provided to inpatients in health establishments which may be covered by compulsory health insurance schemes in addition to services relating to hospital treatment covered by fixed payments in respect of periods of hospitalisation and hospital care determined in accordance with diagnosis-related groups?’

14 By decision of the President of the Court of 2 July 2014, Cases C-271/14 and C-273/14 were joined for the purposes of the written and oral procedure and the judgment.

Consideration of the questions referred

15 By its questions, the referring court asks, in essence, whether Article 6 of Directive 89/105 must be interpreted as meaning that the obligation to state reasons provided for in Article 6(3) and (5) is applicable to a decision by which a pharmaceutical product is removed from a list of medicinal products covered in addition to fixed payments in respect of hospital treatment.

16 LFB and PFM submit that the obligation to state reasons provided for in Article 6(5) of Directive 89/105 concerns all measures for covering medicinal products under the health insurance scheme. The Court's case-law has established the principle that Article 6 of that directive is to be interpreted broadly (judgments in *Commission* v *Austria*, C-424/99, EU:C:2001:642 and *Commission* v *Finland*, C-229/00, EU:C:2003:334). LFB and PFM observe that the Decree of 21 February 2012 leads to a lower level of coverage and, correlatively, a reduction in the demand for the medicinal products removed from the list in question.

17 PFM makes an analogous argument concerning the interpretation of Article 6(3) of Directive 89/105.

18 The French Government submits that the scope of Article 6(3) and (5) of Directive 89/105 is limited to decisions having the effect of excluding coverage of a medicinal product from the health insurance scheme. However, although the medicinal products at issue in the main proceedings were removed from the list referred to in the first paragraph of Article L. 162-22-7 of the French Social Security Code, they remain covered by the health insurance scheme. Accordingly, a decision such as that at issue in the main proceedings does not come within the scope of Article 6(3) and (5) of that directive.

19 The French Government observes that the removal of a medicinal product from the list in question entails no negative consequences for hospitals. The reinstatement of a medicinal product in the fixed payment in respect of hospital treatment is effected on the basis of the average cost of the services provided in respect of hospitalisation, adjusted annually. After a medicinal product has been removed from the list, the total amount corresponding to the health insurance scheme's coverage in respect of that list is transferred to the total amount corresponding to the rate of the 'diagnosis-related hospitalisation group' to which that medicinal product relates. Consequently, removals of this nature have no impact on the treatment of patients and any ensuing cost increases for hospitals are not passed on to patients.

20 The French Government adds that the publication referred to in Article 6(3) of Directive 89/105 was to have occurred by 31 December 1989 but that, on that date, the list referred to in the first paragraph of Article L. 162-22-7 of the French Social Security Code had not yet been adopted. Moreover it cannot be inferred from the wording or objectives of that directive that it required the French authorities to effect such notification or publication.

21 The Spanish Government submits that, should it be held that the medicinal products at issue in the main proceedings were, by effect of the Decree of 21 February 2012, removed from the list of products covered by the health insurance scheme, the conclusion must be that a statement of reasons had to be provided for that decree, as required by Article 6(5) of Directive 89/105. However, the French Government did comply with the requirement to state reasons in respect of those medicinal products although, with respect to Javlor, the decree does not specify whether it was adopted on the basis of any expert recommendations or opinions, which it is for the referring court to verify.

22 On the other hand, should it be established that the Decree of 21 February 2012 has not had the effect of excluding the medicinal products at issue in the main proceedings from coverage under the health insurance scheme, the Spanish Government takes the view that that decree has merely made a change of entry, which does not come within the scope of Article 6(3) and (5) of Directive 89/105.

23 The Commission, relying on a purposive interpretation of Directive 89/105, submits that the obligation to state reasons provided for in Article 6 thereof must be interpreted broadly (see judgments in *Commission* v *Austria*, C-424/99, EU:C:2001:642, paragraphs 24 to 32; *Commission* v *Finland*, C-229/00, EU:C:2003:334, paragraphs 37 to 40; *Pohl-Boskamp*, C-317/05, EU:C:2006:684, and *Commission* v *Austria*, C-311/07, EU:C:2008:431, paragraph 29). It submits that Article 6(3) to (5) of that directive is accordingly applicable to a decision such as the Decree of 21 February 2012.

24 It should be remembered that, under Article 6(3) of Directive 89/105, '[b]efore the date referred to in Article 11(1), Member States shall publish in an appropriate publication and communicate to the Commission the criteria which are to be taken into account by the competent authorities in deciding whether or not to include medicinal products on the lists'. It should also be noted that Article 6(5) 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'.

25 In the present case, the decision at issue in the main proceedings does not have the effect of excluding the medicinal products in question from coverage under the health insurance scheme. Nevertheless, that decision does change the terms or level of reimbursement for those medicinal products and may thus restrict the conditions of reimbursement or reduce the level of coverage of those medicinal products under the health insurance scheme.

26 It should be noted that 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 the national health insurance systems complies with the requirements of that directive (judgment in *Commission* v *Finland*, C-229/00, EU:C:2003:334, paragraph 37 and the case-law cited).

27 According to the sixth recital in the preamble to Directive 89/105, ensuring the effectiveness of that directive also 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 (judgment in *Commission* v *Finland*, C-229/00, EU:C:2003:334, paragraph 39).

28 According to the fifth recital in the preamble to Directive 89/105, its main purpose 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 (see, to that effect, judgment in *Pohl-Boskamp*, C-317/05, EU:C:2006:684, paragraph 29).

29 The Court has also held 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 health insurance scheme and likely to be used in the treatment of such or such an illness (judgment in *Commission* v *Finland*, C-229/00, EU:C:2003:334, paragraph 38).

30 In view of the foregoing, it would be contrary to the objective of transparency to accept that a decision such as that at issue in the main proceedings may be exempt from the obligation to state reasons provided for in Article 6(3) and (5) of Directive 89/105, which requirement seeks to allow interested parties to verify whether decisions relating to the pricing of medicinal products and their inclusion in national health insurance systems are taken on the basis of objective and verifiable criteria and do not discriminate in any way between national medicinal products and those originating in other Member States.

31 In the light of the foregoing considerations, the answer to the questions referred is that Article 6 of Directive 89/105 must be interpreted as meaning that the obligation to state reasons provided for in Article 6(3) and (5) is applicable to a decision which restricts the conditions of reimbursement or reduces the level of coverage of a medicinal product by excluding it from the list of proprietary medicinal products covered by compulsory health insurance schemes in addition to services relating to hospital treatment covered by fixed payments in respect of periods of hospitalisation and hospital care.

Costs

32 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 (Eighth Chamber) hereby rules:

Article 6 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 the obligation to state reasons provided for in Article 6(3) and (5) is applicable to a decision which restricts the conditions of reimbursement or reduces the level of coverage of a medicinal product by excluding it from the list of proprietary medicinal products covered by compulsory health insurance schemes in addition to services relating to hospital treatment covered by fixed payments in respect of periods of hospitalisation and hospital care.

[Signatures]