JUDGMENT OF THE COURT (Fifth Chamber)
7 December 1993 *

In Case C-83/92,

REFERENCE to the Court under Article 177 of the EEC Treaty by the Consiglio di Stato (Italy) for a preliminary ruling in the proceedings pending before that court between

Pierrel SpA and Others

and

Ministero della Sanità

on the interpretation of Council Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ, English Special Edition 1965-1966, p. 20), as amended,

THE COURT (Fifth Chamber),

composed of: J. C. Moitinho de Almeida, President of the Chamber, R. Joliet and G. C. Rodríguez Iglesias, Judges,

Advocate General: C. O. Lenz,
Registrar: H. von Holstein, Deputy Registrar,

* Language of the case: Italian.

after considering the written observations submitted on behalf of:

— the Italian Government, represented by Professor Luigi Ferraro Bravo, Head of the Department for Contentious Diplomatic Affairs at the Ministry of Foreign Affairs, acting as Agent, and by Francesco Guicciardi, Avvocato dello Stato,

— the Portuguese Government, represented by Maria Luisa Duarte, Legal Adviser at the Directorate-General for the European Communities at the Ministry for Foreign Affairs, Luis Ines Fernandes, director of the Legal Department of the Directorate-General for the European Communities at the same Ministry, and Cláudio Monteiro, Legal Adviser at the Directorate-General for Medicinal Products, acting as Agents,

— the Commission of the European Communities, represented by Antonio Aresu, of its Legal Service, and Virginia Melgar, a national officer seconded to the Legal Department, acting as Agents,

having regard to the Report for the Hearing,

after hearing the oral observations of the Italian Government, represented by Professor Luigi Ferraro Bravo, Head of the Department for Contentious Diplomatic Affairs at the Ministry of Foreign Affairs, assisted by Oscar Fiumara, Avvocato dello Stato, the Portuguese Government and the Commission at the hearing on 24 June 1993,

after hearing the Opinion of the Advocate General at the sitting on 15 July 1993,

gives the following

Judgment

1 By order of 20 December 1991, received at the Court on 16 March 1992, the Consiglio di Stato referred to the Court pursuant to Article 177 of the EEC Treaty two questions concerning the interpretation of Council Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ, English Special Edition 1965-1966, p. 20, 'Directive 65/65'), as amended.

2 Those questions arose in the context of an application for a stay of execution lodged by the companies Pierrel, Serpero, Impresa Alba Intes Officina Oftalmoterapica and Radimfarma against various orders adopted by the Italian Ministry of Health ('the Ministry') declaring that the registration of certain of their proprietary medicinal products had lapsed.

3 Article 19(11) of Italian Law No 67 of 11 March 1988 ('Law No 67', Supplemento Ordinario GURI, 61, 14 March 1988) provides as follows:

'Failure to place medicinal products on the market within a period of eighteen months following the issue of the authorization relating thereto shall cause the authorization to lapse. For medicinal products which are already authorized, the eighteen-month period shall begin to run from the date of entry into force of this Law.'

4 Pursuant to that provision, the Ministry made a number of orders declaring that the registration of various proprietary medicinal products manufactured by the four abovementioned companies had lapsed.

5 The companies brought an action before the Tribunale Amministrativo Regionale per il Lazio seeking a stay of execution of those orders. As the application was not granted, they lodged an appeal with the Consiglio di Stato.

6 Since that court was in doubt as to the interpretation to be given to the rules of Community law governing the matter, it referred the following questions to the Court pursuant to Article 177 of the Treaty:

'1. Must Article 11 in conjunction with Article 21 of Council Directive 65/65/EEC of 26 January 1965, as amended, be interpreted as meaning that the grounds for suspension or revocation are definitive and that the national authorities are therefore precluded from introducing additional grounds for suspension or revocation?

2. If so, must the abovementioned provisions be understood as prohibiting the national authorities not only from introducing additional grounds for suspension and revocation, but also from providing for the lapse of an authorization, which is a very different matter from revocation, in so far as, unlike revocation, it does not involve a reassessment of the benefits of the product but is the automatic consequence of failure to make use of the authorization for a certain period (in the present case, eighteen months, pursuant to Article 19(11) of Law No 67 of 11 March 1989)?'

7 As a preliminary point, it should be observed that, in Community law, proprietary medicinal products are the subject of a series of highly detailed harmonization directives aiming at the gradual attainment of the free movement of these products in the Community, while at the same time safeguarding public health.

8 The bases for that harmonization were laid down by Council Directive 65/65/EEC.

9 In the area to which the present case relates, that directive has been amended and supplemented by:

— the second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ 1975 L 147, p. 13, 'Directive 75/319');

— Council Directive 83/570/EEC of 26 October 1983 amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ 1983 L 332, p. 1, 'Directive 83/570');

— Council Directive 92/27/EEC of 31 March 1992 on the labelling of medicinal products for human use and on package leaflets (OJ 1992 L 113, p. 8, 'Directive 92/27').

10 Additional provisions and derogations have been laid down for high-technology medicinal products by Council Directive 87/22/EEC of 22 December 1986 on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology (OJ 1987 L 15, p. 38, 'Directive 87/22').

11 With regard to marketing authorizations, the general system is laid down by Directive 65/65. Pursuant to Article 3 of that directive, no proprietary medicinal products may be placed on the market in a Member State unless an authorization has been issued by the competent authority of that Member State. Articles 4 to 6 of the same Directive, as subsequently amended, provide in effect that such authorization will be issued only if the manufacturer proves, on the basis of specified scientific documentation, that the product is not harmful in the normal conditions of use, that it is of therapeutic efficacy and that its qualitative and quantitative composition is as declared.

12 According to Article 10 of Directive 65/65, as amended by Article 1(5) of Directive 83/570,

'An authorization shall be valid for five years and be renewable for five-year periods on application by the holder at least three months before expiry.'

13 The Community provisions in force concerning the grounds for the suspension and revocation of marketing authorizations may be summarized as follows.

14 The basic provision is Article 11 of Directive 65/65, the first paragraph of which provides as follows:

'The competent authorities of the Member States shall suspend or revoke an authorization to place a proprietary medicinal product on the market where that product proves to be harmful in the normal conditions of use, or where its therapeutic efficacy is lacking, or where its qualitative and quantitative composition is not as declared. ...'

15 The second paragraph of Article 11 was first amended by Article 36 of Directive 75/319, and then by Article 1(6) of Directive 83/570. According to that provision, an authorization is also to be suspended or revoked where the particulars supporting the application are incorrect or have not been amended to take account of scientific and technical progress in respect of control methods and the quality of the product, or when the controls on the finished product have not been carried out.

16 Subsequently a ground of temporary suspension of a marketing authorization was added by Article 11(1) of Directive 92/27. Where the provisions of that directive concerning labelling and package leaflets are not complied with, and a notice served on the person concerned has remained without effect,

'The competent authorities of the Member States may suspend the authorization to place the medicinal product on the market, until the labelling and the package leaflet of the medicinal product in question have been made to comply with the requirements of this Directive.'

17 Finally, in spite of the amendments to certain provisions of Directive 65/65, Article 21 remains unchanged and provides as follows:

'An authorization to market a proprietary medicinal product shall not be refused, suspended or revoked except on the grounds set out in this Directive.'

18 It should also be observed that, in the special sector of high-technology medicinal products, suspension or withdrawal are authorized on grounds which are not exhaustively listed, but subject to the opinion of the Committee for Proprietary Medicinal Products (Articles 1 and 2(4) of Directive 87/22).

19 Reference is made to the Report for the Hearing for a fuller account of the facts of the main action, the procedure and the written observations submitted to the Court, which are mentioned or discussed hereinafter only in so far as is necessary for the reasoning of the Court.

First question

20 It is apparent from the order making the reference that the Consiglio di Stato seeks to ascertain, firstly, whether the combined provisions of Articles 11 and 12 of

Directive 65/65, as amended, must be interpreted as meaning that the grounds to which they refer are the only grounds which can justify the revocation or suspension of a marketing authorization and, consequently, whether they prevent the Member States from introducing others.

21 For the purposes of the reply to this question, it should be noted that, in its judgment in Case 301/82 *Clin-Midy* v *Belgian State* [1984] ECR 251, paragraph 11), the Court has already interpreted Article 21 of Directive 65/65 as meaning that authorization to market a proprietary medicinal product may not be refused, suspended or revoked save on the ground of the protection of public health as referred to by that directive.

22 Since that judgment, Community law on medicinal products has been enriched by new provisions upon which such measures may be based. However, it does not follow from this that national legislatures are empowered to provide for grounds of suspension or revocation other than those which are exhaustively set out by the Community directives.

23 The reply to the first question from the national court must therefore be that, as the provisions relating to proprietary medicinal products now stand, Article 21 of Directive 65/65 must be interpreted as meaning that the suspension or revocation of a marketing authorization may be decided only on the grounds laid down in that directive or other relevant provisions of Community law.

Second question

24 By the second question the national court asks in effect whether the abovementioned provisions of Directive 65/65 prevent the national authorities, not only from introducing grounds for suspension or revocation other than those laid down by Community law, but also from providing for the lapse of marketing authorizations in certain circumstances.

25 On this point the Italian Government contends that the exhaustive nature of the grounds for the suspension or revocation of marketing authorizations does not prevent the Member States from providing for the lapse of those authorizations because lapse cannot in any event be treated as comparable to the circumstances entailing revocation specified in Article 11 of Directive 65/65.

26 It is not disputed that, according to the national law applicable, lapse is differs from revocation in that it does not entail a reassessment of the benefits of the product. It is in effect an automatic sanction punishing the failure by a private person who has obtained an authorization for a given period to exercise within that period the powers attaching to the authorization.

27 However, the effects of such lapse are the same as those of revocation within the meaning of Directive 65/65 because in both cases an existing authorization is terminated.

28 The harmonized framework set up by the directives relating to proprietary medicinal products and the effectiveness of those directives would be impaired if the Member States were permitted not only to prescribe circumstances entailing revocation other than those contemplated by the directives but also other grounds for the termination of authorizations.

29 In this connection it should be observed that no provision of Community law applicable in the matter lays down that an authorization must be used within a specified period. Article 10 of Directive 83/570 merely limits the validity of the authorization to five years, which is renewable on application by the holder within the three months preceding expiry.

30 It follows that the provisions of national law according to which marketing authorizations which are not used within a specified period are to lapse are not compatible with Directive 65/65/EEC, as amended.

31 That finding is not open to objection by the Italian Government on the ground that Article 19(11) of Law No 67 was repealed subsequent to the order making the reference and was replaced by Article 11(4) of Legislative Decree No 178 of 29 May 1991 (GURI 139, 15 June 1991). That article provides that the holder of an authorization must pay a second time the State fee prescribed for the issue of the authorization if he does not place the medicinal product on the market within 18 months of the date of issue or renewal of authorization, but it does not provide for the authorization to lapse.

32 It should be borne in mind that Article 177 confers jurisdiction on the Court to interpret Community law and that therefore changes in national legislation after the order making the reference cannot influence that interpretation.

33 The reply to the question from the national court must therefore be that the provisions of Directive 65/65, as amended, preclude national authorities not only from introducing grounds for suspension or revocation other than those laid down by Community law but also from providing for the lapse of authorizations to market medicinal products.

Costs

34 The costs incurred by the Portuguese Government, which has submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to the main proceedings, a step in the proceedings pending before the national court, the decision on costs is a matter for that court.

On those grounds,

THE COURT (Fifth Chamber),

in answer to the questions referred to it by the Consiglio di Stato by order of 20 December 1991, hereby rules:

1. **Article 21 of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products must be interpreted as meaning that the suspension or revocation of an authorization to market medicinal products may be decided only on the grounds laid down in that directive or other applicable provisions of Community law.**

2. **Directive 65/65/EEC, as amended, precludes national authorities not only from introducing grounds for suspension or revocation other than those laid down by Community law but also from providing for the lapse of authorizations to market medicinal products.**

Moitinho de Almeida Joliet Rodríguez Iglesias

Delivered in open court in Luxembourg on 7 December 1993.

J.-G. Giraud — Registrar

J. C. Moitinho de Almeida — President of the Fifth Chamber