interpreted as meaning that the suspension or revocation of an authorization to market medicinal products may be decided only on the grounds laid down by that directive or other applicable provisions of Community law.

The provisions of the aforesaid directive, as amended, also 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, the effects of such lapse being the same as those of revocation since in both cases an existing authorization is terminated.

REPORT FOR THE HEARING
in Case C-83/92 *

I — Facts

Article 19(11) of Italian Law No 67 of 11 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.'

Pursuant to this provision, the Italian Ministry of Health made a number of orders declaring that the registration of various proprietary medicinal products which had not been placed on the market within eighteen months of authorization had lapsed.

The pharmaceutical companies Pierrel SpA, Serpero SpA, Impresa Alfa Intes officina oftalmoterapica and Radiumfarma Srl brought an action before the Administrative Court, Latium, seeking a stay of execution of these orders.

As this application was not granted, the four abovementioned companies lodged an appeal with the Italian Council of State.

II — Questions referred to the Court

By order of 20 December 1991, received at the Court on 16 March 1992, the Council of

* Language of the case: Italian.

State referred the following two questions to the Court:

'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 1988)?'

III — Community law

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.

The basis for harmonization was laid down by 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 (OJ, English Special Edition 1965-1966, p. 20, 'Directive 65/65'). In the area to which the present case relates, this 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').

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).

A — General system

1. *Authorization for placing on the market*

Pursuant to Article 3 of Directive 65/65, 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,

— that its qualitative and quantitative composition is as declared.

Pursuant 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.'

2. *Suspension and revocation of marketing authorizations*

The suspension and revocation of marketing authorizations are regulated by Article 11 of Directive 65/65 and Article 11 of Directive 92/27.

Pursuant to the first paragraph of Article 11 of Directive 65/65:

'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. Therapeutic efficacy is lacking when it is established that therapeutic results cannot be obtained with the proprietary product.'

The second paragraph of of the same Article 11 was amended, first, by Article 36 of Directive 75/319, and then by Article 1(6) of Directive 83/570. As amended, it reads as follows:

'An authorization shall also be suspended or revoked where the particulars supporting the application as provided for in Articles 4 and 4a are incorrect or have not been amended in accordance with Article 9a, or when the controls referred to in Article 8 of this Directive or in Article 27 of 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 have not been carried out.'

Finally, an authorization may be withdrawn if the rules relating to labelling are not observed. In this connection the first paragraph of Article 20 of Directive 65/65 provided as follows:

'Where the provisions of this Chapter [concerning the labelling of proprietary medicinal products] are not observed and an order addressed to the person concerned has remained without effect, the competent authorities of the Member States may suspend or revoke the authorization to place the proprietary medicinal product on the market.'

This provision was repealed by Article 13 of Directive 92/27 on labelling, which ought to have been implemented by the Member States before 1 January 1993. Article 11(1) of this directive, which relates to the same problem, is at present worded as follows:

'Where the provisions of this Directive 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.'

With regard to procedure, the first paragraph of Article 12 of Directive 65/65, and Article 11(2) of Directive 92/27 require the national authorities to state in detail the reasons for decisions on suspension or revocation and to notify them to the party concerned, informing him of the remedies available to him under the laws in force and of the time limit allowed for the exercise of such remedies.

Finally, Article 21 of Directive 65/65 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.'

3. *Other measures*

In addition to the revocation and suspension of authorization, Article 28(1) of Directive 75/319 permits the Member States, 'notwithstanding the measures provided for in Article 11 of Directive 65/65/EEC', to take

'all appropriate measures to ensure that the supply of the proprietary medicinal product shall be prohibited and the proprietary medicinal product withdrawn from the market if:

(a) the proprietary medicinal products proves to be harmful under normal conditions of use;

(b) it is lacking in therapeutic efficacy;

(c) its qualitative and quantitative composition is not as declared;

(d) the controls on the finished product and/or on the ingredients and the controls at an intermediate stage of the manufacturing process have not been carried out or if some other requirement or obligation relating to the grant of the authorization referred to in Article 16 has not been fulfilled.'

B — The system applicable to high-technology medicinal products

Pursuant to Articles 1 and 2 of Directive 87/22, before taking a decision on suspension or withdrawal in respect of a high-technology medicinal product, Member States' authorities must refer the matter for an opinion to the Committee for Proprietary Medicinal Products. This Committee, set up by Article 8 of Directive 75/319, consists of representatives of the Member States and of the Commission.

The grounds justifying the suspension or revocation of authorization in relation to products of this kind are not specified in Directive 87/22. Furthermore, Article 4(2) provides as follows:

'When a proposal to suspend or withdraw a marketing authorization is referred to it, the Committee shall fix an appropriate time limit for issuing its reasoned opinion, having regard to the requirements for the protection of public health. However, in cases of urgency, the Member States may suspend the marketing authorization in question without waiting for the opinion of the Committee provided that they forthwith inform the Committee thereof, indicating the reasons for the suspension and justifying the urgency of this measure.'

IV — Procedure before the Court

The order from the Council of State was received by the Court Registry on 16 March 1992.

In accordance with Article 20 of the Protocol on the Statute of the Court of Justice of the EEC, written observations were submitted on 27 July 1992 by

— the Italian Government, represented by F. Guicciardi, Avvocato dello Stato,

— the Portuguese Government, represented by L. Fernandes, Director of the Department for Foreign Affairs of the Directorate-General for the European Communities, M. L. Duarte, Legal Adviser at the Directorate-General for the European Communities at the Ministry for Foreign Affairs, and Cl. Monteiro, Legal Adviser at the Directorate-General for Medicinal Products, as Agents,

— the Commission, represented by A. Aresu, a member of its Legal Department, and Mme V. Melgar, a national officer seconded to the Legal Department, as Agents.

Upon hearing the report of the Judge-Rapporteur and the views of the Advocate General, the Court decided to open the oral procedure without any preparatory enquiry.

By decision of 26 April 1993, the Court decided, in accordance with Article 95(1) and

(2) of the Rules of Procedure, to assign the case to the Fifth Chamber of the Court.

V — Written observations submitted to the Court

A — First question

For the *Portuguese Government* the Community provisions applicable to medicinal products do not preclude the national authorities from laying down other grounds of revocation than those set out by those provisions.

Although the wording of Article 21 of Directive 65/65 appears to mean that the grounds of suspension and revocation given in Article 5 of that directive are exhaustive, it must be borne in mind that this directive was amended by Directive 75/319, Article 28 of which provides for other grounds on which proprietary medicinal products may be withdrawn from the market. Consequently the later directive should serve as the reference framework for interpreting the legislative framework of the first directive.

The Portuguese Government adds that the directives concerning proprietary medicinal products leave room for the principle of the revocability of unlawful administrative measures, a principle of national law which is illustrated by Article 19(11) of Italian Law No 67. According to the preamble to Directive 65/65, the relevant directives have two objectives: to safeguard public health while promoting the development of the pharmaceutical industry and trade in medicinal products within the Community. This objective means that administrative decisions must be subject to certain requirements with regard to their substantive content and the method of preparing them, but not that there should be a bar on the application of the principles governing administrative activity in the different Member States, one of which is the rule of the free revocability of unlawful administrative measures, as the Court stated in the judgment in Cases 7/56 and 3 to 7/57 *Algera* v *Common Assembly* [1957-58] ECR 81. If the directive allows the revocation of an authorization which was issued lawfully on the ground of its incompatibility with the interests of public health, revocation must be allowed *a fortiori* where an authorization is issued unlawfully by reason of the violation of rules which have no connection with the substance of the measure. The Government adds that, in Portuguese law, the principle that unlawful measures are freely revocable is a corollary of the principle of administrative legality, which is the true foundation of a State governed by the rule of law, enshrined in Article 266 of the Constitution and expressly set out in Articles 138 and 141 of the Portuguese Code of Administrative Procedure.

On the other hand, the *Italian Government* considers that the grounds of revocation and suspension of the marketing authorization set out by Directive 65/65 are exhaustive.

The *Commission*, for its part, begins by saying that it understands the reasons which prompted the Italian authorities to adopt measures such as Article 19(11) of Italian Law No 67.

According to the Commission, measures of this kind permit a reduction in the extent of the controls to be carried out on proprietary medicinal products which are already on the market. All medicinal products which have been lawfully placed on the market should be subject to supervision, even if they are used by very limited categories of individuals and if they are in practice no longer in circulation. On this point it should be observed that Article 39(2) of Directive 75/319 required the Member States to carry out a complete reassessment of all proprietary medicinal products already on the market within 15 years expiring in May 1990. In Italy these operations were complicated by the fact that Directives 65/65 and 75/319 were not implemented until a Law of 11 March 1988 and a ministerial order of 28 April 1988, so that the Italian health authorities had to reassess more than 5 000 proprietary medicinal products in the space of one and a half years. The failure to fulfil this obligation was established by the Court in its judgment in Case 145/82 *Commission* v *Italy* [1983] ECR 711.

In spite of these difficulties the Commission considers that Article 19(11) of Italian Law No 67 is incompatible with Community law. Its position is based on two main reasons.

First, the harmonized framework set up by the relevant directives and their effectiveness would be altered if the Member States were authorized to lay down other grounds of revocation than those provided for by the directives.

Secondly, the Italian provision concerning the lapse of an authorization is unfair and disproportionate to the objective pursued. In the first place, the application for authorization is not the only formality which the undertaking concerned has to carry out in order to market its product. After obtaining the authorization in question, it must also arrange for the administrative price to be fixed and apply for the registration of the product in a register. In the second place, the undertaking may be prevented from placing the product on the market within 18 months of the issue of authorization for reasons beyond its control, such as the scarcity of raw materials or technical difficulties arising during the production process.

The Commission points out that the rule that the specified grounds are exhaustive has already been accepted by the Court in the judgment in Case 301/82 *Clin-Midy* v *Belgian State* [1984] ECR 251. In that judgment the Court held that Article 21 of Directive 65/65 'must be interpreted 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 referred to in the directive'. In the present case, the reasons justifying the lapse of the authorization are unconnected with the area of public health.

Finally, the Commission states that an exception must be allowed for the special sector of high-technology medicinal products regulated by the abovementioned Directive 87/22, Articles 1 and 2(4) of which authorize measures of suspension or withdrawal on any grounds whatever, subject to the obligation to obtain the opinion of the Committee for Proprietary Medicinal Products beforehand.

B — Second question

The *Italian and Portuguese Governments* consider that Articles 11 and 21 of Directive 65/65 do not prevent the national authorities from introducing in their legislation grounds for the lapse of an authorization for marketing a proprietary medicinal product. The *Commission* takes the opposite view.

For the *Portuguese Government* this question must be clearly distinguished from the first because a declaration that an authorization has lapsed is an instrument which differs considerably from revocation. In nullifying a previous legal measure and producing new legal effects, revocation entails an assessment by the authorities of the conduct of the undertaking concerned or of the benefits of the product. A declaration that an authorization has lapsed, on the other hand, is a declaratory measure by means of which the authorities record, on the basis of an objective fact such as failure to place a product on the market within a specified period, that a measure has ceased to produce effect. In the latter case the authorities do not have a power of assessment.

The Portuguese Government considers that the existence of such a principle in national law does not conflict with any provision of the directives applicable to medicinal products and that it is not contrary to the objectives of the harmonization of laws which has been undertaken in this field, particularly that of the free movement of medicinal products in the Community.

Firstly, as it is entirely automatic and does not entail an assessment by the national administrative authorities, it does not have the effect of enlarging their decision-making powers.

Secondly, a declaration that an authorization has lapsed provides an adequate safeguard for public health by ensuring that the documents and information supplied in support of an application for authorization are always up-to-date at the time when a proprietary medicinal product is actually placed on the market. Such declaration also permits the various control mechanisms set up by the directive to be put into effect. In this connection, the Portuguese Government considers that Article 10 of Directive 65/65, which limits the duration of validity of an authorization to five years, is insufficient.

Finally, the obligation to market the product laid down by Article 19 of Italian Law No 67 serves to frustrate schemes consisting in applying for an authorization in one Member State in order to market a product in another Member State where the administrative authorities in question are less strict. With a view to facilitating the movement of medicinal products in the Community, the so-called 'multi-State' procedure set up by Directive 83/570, amending Directive 75/319, permits an undertaking which has obtained a marketing authorization from one Member State pursuant to Community law to apply for an extension to two or more Member States.

The *Italian Government* also emphasizes the distinction between a declaration of lapse and revocation. Whereas the latter entails a new, different assessment of the benefits of the product, the former is the automatic consequence of failure to use the authorization for a certain period of time. The difference is shown in the effects produced by the two instruments. In the case of revocation, the product can only be placed on the market again if the undertaking concerned proves,

on the basis of new documentation, that the product fulfils the conditions laid down by the Community directives, whereas if an authorization lapses the technical and scientific documentation which was produced to obtain the authorization retains its entire validity. Then an undertaking which actually wishes to market its product is only required to pay the fiscal charges prescribed by Italian law.

The Italian Government goes on to inform the Court that Article 19(11) of Italian Law No 67 of 11 March 1988 was repealed by Article 26(6) of Decree-law No 178 of 29 May 1991, Article 11(4) of which provides that if, after the issue or renewal of an authorization, a proprietary medicinal product is not placed on the market within 18 months, the holder of the authorization is liable to pay once again the Government fee for the issue of the authorization.

The *Commission* considers that, on the contrary, the provision for authorizations to lapse under Italian law is incompatible with Community law.

Like the Italian and Portuguese Governments, the Commission begins by stressing the difference between the 'declaration of lapse' and revocation or suspension. In the Commission's opinion, the declaration of lapse may be described as a sanction punishing the failure of a private person who has obtained an authorization for a fixed period to exercise the powers attached to it within that period. Unlike revocation, it applies automatically as soon as two objective facts are established, namely the expiry of the period and the omission by the holder of the authorization, and it is unnecessary for the authorities to exercise any kind of power of assessment.

The Commission then distinguishes between theory and practice. In theory, the declaration of lapse is compatible with Community law, but it is not so in practice.

If it is theoretically compatible with Community law, there are two reasons.

Firstly, it is a strong incentive to make actual, rapid use of the authorizations issued by the authorities and to reduce the number of medicinal products which exist only on paper. Thus it reduces the control tasks of the national authorities.

Secondly, it conforms to the principle of the efficacy of legal situations, which means that rights which are not exercised tend to become extinguished. This forms the basis of Article 10 of Directive 65/65. It may be recalled that this provision, as amended by Article 1(5) of Directive 83/570, fixes the period of validity of a marketing authorization at five years and provides for renewal only on application by the holder at least three months before expiry.

On the other hand, the Commission considers that in practice Article 19(11) of Italian Law No 67 is incompatible with Community law. It interferes with the harmonized

system set up by the abovementioned directives. Under this system States are allowed to take only the measures provided for by the directives and, furthermore, only on the grounds which they specify. In addition, the measures must be justified by reasons inherent in the protection of public health and can be adopted only after careful scientific assessment of the medical dossier in question. As the contested Italian measure is not connected with the situations envisaged by Community law, is not justified on grounds of health and does not entail reassessment of the scientific dossier relating to the medicinal product in question, it falls outside the scope of the relevant directives and may therefore have unfair, discriminatory consequences for the free movement of medicinal products.

Accordingly, the Commission suggests that the two questions from the national court be answered together to the effect that the Community measures in force concerning the marketing of proprietary medicinal products, particularly Council Directive 65/65 of 26 January 1965, as amended and supplemented, must be interpreted as meaning that the provisions of Article 19(11) of Italian Law No 67 of 11 March 1988 are incompatible with those measures.

R. Joliet

Judge-Rapporteur