OPINION OF ADVOCATE GENERAL LENZ

delivered on 15 July 1993 *

Mr President,
Members of the Court,

A — Introduction

1. In the area of the law relating to medicinal products there has been considerable activity by the Community with the aim of the gradual attainment of the free movement of medicinal products while at the same time safeguarding public health. Of fundamental importance in this area are 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 [1] and 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. [2] Some of the most important further directives in this area are listed in the Report for the Hearing. [3]

2. Article 3 of Directive 65/65 provides that a proprietary medicinal product may be placed on the market in a Member State only when the competent authority of that State has issued an authorization.

3. Pursuant to Article 10 of Directive 65/65, this authorization is valid for five years. It may be renewed for five-year periods on application by the holder.

4. The question of the circumstances under which such authorization may be suspended or revoked is regulated in Article 11 of Directive 65/65 and Article 11 of Directive 92/27/EEC of 31 March 1992 on the labelling of medicinal products for human use and on package leaflets. [4]

According to the last-mentioned provision, an authorization may be suspended under certain conditions if the labelling provisions of the directive are not complied with. This possibility is not relevant to the present case.

5. The first sentence of the first paragraph of Article 11 of Directive 65/65 is worded 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

* Original language: German.

1 — OJ, English Special Edition 1965-1966, p. 20.

2 — OJ 1975 L 147, p. 13.

3 — See also now Council Directive 92/73/EEC of 22 September 1992 on the extension of the scope of application of Directives 65/65/EEC and 75/319/EEC to the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products and on additional provisions for homeopathic medicinal products (OJ 1992 L 297, p. 8). This Directive is the subject of the action pending before the Court in Case C-437/92 *Guna* v *Council*.

4 — OJ 1992 L 113, p. 8.

where its qualitative and quantitative composition is not as declared.'

Other cases in which an authorization may be 'suspended or revoked' are set out in the second paragraph of Article 11 of the directive.

6. It is clear from the provision cited above that an authorization may also be annulled in cases where it was unlawful, i. e. where the conditions laid down by the directive for issuing the authorization were not fulfilled. According to the customary terminology in Germany, the annulment of unlawful administrative measures is referred to as 'Rücknahme' ('withdrawal'). However, as the directive uses the term 'Widerruf' ('revocation'), this is the word I shall use below, in the wider sense for the purposes of the Directive as covering cases of the withdrawal of illegal authorizations.

7. 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.'

8. On 11 March 1988 the Italian legislature passed Law No 67. [5] Article 19(11) of this Law provides that an authorization for marketing medicinal products shall lapse if it is not used within 18 months of issue.

5 — The text of this Law is reproduced in the Supplemento Ordinario of the Official Journal of the Italian Republic (GURI) 61, 14.3.88.

9. On the basis of this provision the Italian Minister of Health adopted a number of decrees declaring that the authorizations for marketing several products of Pierrel SpA and other undertakings had lapsed. The undertakings concerned challenged these decrees before the Tribunale Amministrativo per il Lazio, which however dismissed the applications for a stay of execution of the decrees. The undertakings then lodged an appeal against this decision with the Consiglio di Stato.

10. The Consiglio di Stato referred the following questions to the Court for a preliminary ruling pursuant to Article 177 of the EEC 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)?'

B — Analysis

First question

11. The wording of Article 21 itself shows that this provision aimed to regulate exhaustively the grounds on which an authorization for marketing a proprietary medicinal product may be refused, suspended or revoked. In the judgment of 26 January 1984 in Case 301/82, *Clin-Midy* v *Belgium*, the Court confirmed that the Council 'intended to restrict the grounds for the refusal, suspension or revocation of authorization to market proprietary medicinal products solely to the considerations of public health expressly mentioned in the directive'. [6]

12. Italy and the Commission concur in this interpretation. The Portuguese Government also considers that the relevant provisions of Community law constituted an exhaustive rule so far as the *substantive* requirements for the refusal, suspension or revocation of authorization are concerned. However, relying on the principle that administrative measures must be based on law, the Portuguese Government takes the view that unlawful authorizations may be withdrawn if their illegality arises from the infringement of provisions or principles applying to administrative measures, i. e. on *formal* grounds. Here the Portuguese Government refers in particular to the provisions concerning competence and concerning the form of the decision.

13. There is much to be said in favour of the Portuguese Government's argument. The Community law provisions leave it to the Member States to determine the competent authorities for the issue of authorizations in the individual Member States and also, to a large extent, the detailed organization of the administrative procedure. Therefore it seems only consistent in principle to leave the law of the Member State concerned to decide on the consequences of contravening the relevant provisions concerning competence or procedure.

If, for example, under the law of a Member State an authority or body has to be consulted before such authorization is issued and if failure to consult renders the authorization illegal under the law of that State, annulment of the authorization *on that ground* would in principle undoubtedly be compatible with the rules of Community law, which makes exhaustive provision for annulment on grounds relating to public health.

14. Of course, it might be pointed out that this could result in making it more difficult or impossible to attain the objectives of the Community measures. As we have already seen, one of these is to bring about the free movement of medicinal products. If the authorities of a Member State could temporarily prevent the marketing of such a product by annulling a marketing authorization, which fulfils all the requirements of Community law, on grounds relating to lack of competence or to procedural defects, the attainment of this objective might be jeopar-

6 — [1984] ECR 251, paragraph 10.

dized. [7] On this point it should be observed that, as the Court has previously held, 'the Member States' obligation arising from a directive to achieve the result envisaged by the directive and their duty under Article 5 of the EEC Treaty to take all appropriate measures, whether general or particular, to ensure the fulfilment of that obligation, is binding on all the authorities of Member States'. [8]

15. In the present case, however, it seems to me that this question does not call for further discussion. The Italian provision in issue here does not deal with the withdrawal of unlawful authorizations, but has as its consequence a reduction in the period of validity of lawfully issued authorizations.

16. Article 21 of Directive 65/65 provides that an authorization may be refused, suspended or revoked only on the grounds set out 'in this Directive'. However, there are now other provisions on which such measures may be based. For example, as already mentioned, under certain circumstances an authorization may be suspended if the labelling provisions of Directive 92/27/EEC are not complied with. [9] Therefore the Commission is right to suggest that the reply to the first question from the national court should not be limited to Directive 65/65, but should include all the relevant measures of Community law. This appears appropriate also because the question itself refers to the amendments of Directive 65/65.

17. Therefore the reply to be given to the first question is that Article 21 of Directive 65/65 must be interpreted as meaning that the suspension or revocation of an authorization to market medicinal products may be effected only on the grounds laid down in that directive or other relevant provisions of Community law.

Second question

18. The Italian provision has the consequence that a marketing authorization lapses unless it is used within 18 months of issue. Therefore the effects of this provision are the same as those of revocation within the meaning of Directive 65/65. In both cases an existing authorization is discontinued.

19. The Italian and Portuguese Governments claim, however, that lapse ('decadenza') differs from revocation in that, in the framework of the revocation procedure, the authorities reassess the benefits of the product, whereas lapse is the automatic consequence of the expiry of the fixed period. I am not persuaded by this view, which is confined to the activity of the administrative authorities. Directive 65/65, with its prohibition on annulling an authorization on grounds other than those stated in the directive, is addressed not only to the administrative authorities, but to *all* authorities and

7 — See the similar problem raised by Advocate General Jacobs in his opinion of 16 June 1993 in Case C-212/91 *Angelopharm* (not yet published in ECR), at paragraph 70. There the question was whether a national court could treat as invalid a national provision which was adopted in order to implement a directive, if the grounds of invalidity arise from national law.

8 — Judgment in Case C-106/89 *Marleasing* v *La Comercial Internacional de Alimentación* [1990] ECR I-4135, at paragraph 8; settled case-law.

9 — See paragraph 4 above. It should be observed that this directive replaced the labelling provisions which were originally included in Directive 65/65 (see Articles 13 to 20).

bodies of the Member State. [10] Therefore a provision of a Member State permitting or even prescribing the revocation of authorizations on grounds other than those specified in the Community directives is just as contrary to Community law as a measure of the administrative authorities adopting a decision to that effect.

20. The Italian Government points out that Article 19(11) of Law no 67 has in the meantime been repealed and replaced by Article 11(4) of Legislative Decree No 178 of 29 May 1991. [11] The latter 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 market the proprietary medicinal product within 18 months. On the other hand, there is no mention of the authorization lapsing. It cannot be denied that the reference from the national court was made on the basis of the previous law, so that this new rule cannot be examined in detail here. However, it may be observed that this amendment — which, according to the submissions of the Italian Government, only confirms the 'ratio' of the former provision — does not seem apt to support the Portuguese Government's view that the Italian provision serves to safeguard public health. It is more likely that fiscal considerations also played a part when the measure was adopted.

21. In my opinion it is unnecessary to examine more closely the legal nature of 'lapse' in Italian law. [12] In any case it is clear that, under Italian administrative law, a right granted by statute or by administrative measure will lapse in accordance with the respective provisions if it is not exercised within a specified period.

In the present case this period is 18 months. However, Article 10 of Directive 65/65 provides that an authorization for marketing proprietary medicinal products is valid for *five years*. The directive does not require the authorization to be used within a particular period. The Commission also correctly points out that there are circumstances which may delay the marketing of such a product for which the holder of the authorization could not be held responsible. The Italian provision is manifestly incompatible with Article 10.

22. Furthermore, there appear to be no grounds which would dictate that the Italian provision be regarded as nevertheless compatible with Community law. In particular, it cannot be alleged that this provision is necessary to safeguard public health. It is not clear what risks there may be to public health from a product which has been authorized for marketing, but which has not yet been placed on the market.

23. However, it should not be overlooked that the Italian provision may have entirely positive effects. It creates a strong incentive

10 — See the judgment in the *Marleasing* case cited above (paragraph 14).

11 — GURI 139, 15.6.91, p. 3.

12 — See A. M. Sandulli, *Manuale di Diritto Amministrativo*, 14th edition, Naples 1984, p. 162 ff.; P. Virga, *Diritto Amministrativo*, Volume 2, 2nd edition, Milan 1992, p. 162 ff..

for the rapid marketing of medicinal products and therefore serves the public interest. At the same time it reduces the number of products which exist only on paper and thereby relieves the national authorities in respect of their control tasks.

For these reasons it is perfectly possible that the Community legislative authority may introduce such a measure, as the Commission observes, but it is not open to the Member States themselves to do so, on the grounds which have been stated.

C — Conclusion

24. I therefore propose that the following replies be given to the questions from the Italian Consiglio di Stato:

(1) Article 21 of Directive 65/65/EEC must be interpreted as meaning that the suspension or revocation of an authorization to market medicinal products may be effected only on the grounds laid down in that directive or other relevant provisions of Community law.

(2) A national provision to the effect that, if an authorization to market medicinal products is not used within a specified period, it shall lapse is incompatible with the provisions of Directive 65/65/EEC.