OPINION OF ADVOCATE GENERAL FENNELLY
delivered on 6 February 1997 *

I — Introduction

1. The present request for a preliminary ruling raises the question of whether Article 19 of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (hereinafter 'the [SPC] Regulation') [1] derogates from the substantive conditions for the granting of a supplementary protection certificate (hereinafter 'SPC' or 'certificate'), or whether the derogation is merely temporal in character.

II — Facts and legislative background

(a) The SPC Regulation

2. The Court is already familiar with the SPC Regulation, which survived a challenge to its validity in *Spain* v *Council*; [2] certain provisions of the same Regulation were the subject of a request for a preliminary ruling in *Biogen*, [3] in which the Court delivered judgment on 23 January 1997.

3. In *Spain* v *Council*, the Court explained the factual situation, as described in the preamble to the Regulation, which led the Council to adopt the Regulation, in the following terms:

'medicinal products, especially those that are the result of long, costly research, will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research ... at the moment, the period that elapses between the filing of an application for a patent for a new medicinal product and authorization to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research. That situation leads to a lack of protection which penalizes pharmaceutical research.' [4]

* Original language: English.

1 — OJ 1992 L 182, p. 1.

2 — Case C-350/92 [1995] ECR I-1985.

3 — Case C-181/95 *Biogen Inc.* v *Smithkline Beecham Biologicals* [1997] ECR I-357; see also paragraphs 2 to 11 of my Opinion of 3 October 1996.

4 — Paragraph 2 of the judgment.

4. The conditions for the grant of an SPC are set out in Article 3, which provides as follows:

'A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:

(a) the product is protected by a basic patent in force;

(b) a valid authorization to place the product on the market as a medicinal product has been granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC, as appropriate;

(c) the product has not already been the subject of a certificate;

(d) the authorization referred to in (b) is the first authorization to place the product on the market as a medicinal product.'

5. Article 7 provides that the application for an SPC must be submitted within six months of the granting of the authorization to place the product on the market (hereinafter 'market authorization'), unless the authorization is granted before the basic patent has been granted.

6. Article 19 of the Regulation, which is central to the present case, is one of a number of 'Transitional provisions', and reads as follows:

'1. Any product which, on the date on which this Regulation enters into force, is protected by a valid basic patent and for which the first authorization to place it on the market as a medicinal product in the Community was obtained after 1 January 1985 may be granted a certificate.

In the case of certificates to be granted in Denmark and in Germany, the date of 1 January 1985 shall be replaced by that of 1 January 1988.

In the case of certificates to be granted in Belgium and in Italy, the date of 1 January 1985 shall be replaced by that of 1 January 1982.

2. An application for a certificate as referred to in paragraph 1 shall be submitted within six months of the date on which this Regulation enters into force.'

7. In accordance with Article 23, the Regulation entered into force on 2 January 1993.

8. Paragraph 5 of Annex 15 to Decision No 7/94 of the EEA Joint Committee [5] provides for the following adaptations of the Regulation in the context of the Agreement on the European Economic Area of 2 May 1992 (hereinafter 'the [EEA] Agreement'): [6]

'(a) in Article 3(b) the following shall be added:

"; for the purpose of this subparagraph and the Articles which refer to it, an authorization to place the product on the market granted in accordance with the national legislation of the EFTA State shall be treated as an authorization granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC, as appropriate.";

(b) Article 19(1) shall be replaced by the following:

"1. Any product which on 2 January 1993 is protected by a valid patent and for which the first authorization to place it on the market as a medicinal product within the territories of the Contracting Parties was obtained after 1 January 1985 may be granted a certificate.

... (omissis)."

(c) the following paragraphs shall be added to Article 19:

"3. If a basic patent in an EFTA State lapses, due to the expiry of its lawful term, between 2 January 1993 and the date of entry into force of this Regulation under this Agreement, the certificate shall take effect only with respect to the time following the date of publication of the application for the certificate. However, Article 13 shall apply as to the calculation of the duration of the certificate.

5 — OJ 1994 L 160, p. 1.
6 — OJ 1994 L 1, p. 1.

4. In the case of paragraph 3, the application for a certificate shall be lodged within two months of the date on which the Regulation enters into force in the EFTA State concerned.

5. A certificate applied for in accordance with paragraph 3 shall not prevent any third party who, between the lapse of the basic patent and the publication of the application for a certificate, in good faith has commercially used the invention or made serious preparations for such use, to continue such use."'

9. 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 [7] to which Article 3(b) refers, does not provide for a Community authorization procedure for the marketing of proprietary medicinal products. Article 3 of the Directive establishes that no such product may be placed on the market without an authorization issued by the competent Member State authority, while subsequent provisions lay down the rules governing the grant, suspension and revocation of market authorizations. Council Directive 81/851/EEC relates to veterinary medicinal products and is therefore not relevant to the present proceedings.

7 — OJ, English Special Edition 1965-66 (I), p. 20.

(b) The factual background

10. On 18 January 1973, Yamanouchi Pharmaceutical Co. Ltd (hereinafter 'the applicants') obtained United Kingdom Patent No 1415256 in respect of α-aminomethylbenzyl alcohol derivatives, referred to hereinafter for convenience as 'eformoterol'. In 1982 the applicants licensed the patent to Ciba-Geigy, which has sought to develop eformoterol in tablet and aerosol form for use in the treatment of asthma. On 29 June 1990, Ciba-Geigy was granted an authorization to market a solution aerosol formulation of eformoterol in France, the first such marketing authorization in the Community. Authorization to market both a solution aerosol formulation and a tablet formulation in the United Kingdom submitted in June 1989 was refused; authorization for a dry powder formulation was, however, granted by the United Kingdom authorities on 17 August 1995.

11. On 15 January 1993, two days before the United Kingdom patent was due to expire, Ciba-Geigy lodged an application, on the applicants' behalf, for an SPC in respect of an eformoterol-based product, Formoterol Fumarate (hereinafter 'the product'). This was refused by the United Kingdom Patent Office on 8 September 1993, essentially on the ground that no valid authorization to place the product on the market as a medicinal product had been granted in the United Kingdom.

12. On appeal, the High Court of Justice, Patents Court, London, decided on 30 October 1994 to refer the following question to the Court for a preliminary ruling:

'In the case of an application for a certificate under Council Regulation (EEC) No 1768/92 in a particular Member State (in casu the United Kingdom) in circumstances where:

— a medicinal product was (on 2nd January 1993) the subject of a first marketing authorization in the Community (in casu, in France) which was obtained pursuant to EC Directive 65/65 (as amended) after 1st January 1985;

— the medicinal product was (on 2nd January 1993) protected by a valid basic patent in the Member State;

— at the date of submission of such application, marketing authorization in the Member State had still to be obtained;

— application for a certificate as referred to in paragraph 1 of Article 19 was submitted to the relevant national authority (viz. the UK Patent Office) within 6 months of 2nd January 1993, as laid down in paragraph 2 of Article 19;

is Council Regulation (EEC) No 1768/92, and in particular Article 19 thereof, to be interpreted so as to allow the grant of an SPC to the patentee in that Member State or must the provisions of Articles 3(b), 8 and 9 concerning a valid marketing authorization in the Member State also be complied with?'

13. Written observations were submitted by the applicants, the Kingdom of Belgium, the Federal Republic of Germany, the Kingdom of the Netherlands and the United Kingdom of Great Britain and Northern Ireland and the Commission. The applicants, the United Kingdom and the Commission were represented at the oral hearing. All those who submitted observations, except the applicants, argued that Article 19 derogates only from Article 7, and that the material conditions laid down in Article 3 of the Regulation must be fulfilled for an SPC to be granted.

III — Analysis

14. In the applicants' view, Article 19 of the Regulation provides for the (obligatory) grant of a transitional SPC when three conditions are satisfied, to wit, that the product be protected by a valid basic patent on the date on which the Regulation enters into force, that the first authorization to place the

product on the market in the Community have been obtained after 1 January 1985, and that the application for an SPC be submitted within six months of the entry into force of the Regulation. As the three conditions are admittedly fulfilled in the present case, the applicants contend that the SPC applied for must be granted.

15. The applicants rely on the general scheme, wording, purposes and legislative history of the Regulation. As to the first, they argue on the basis of the structure of the Regulation that the transitional provisions are distinct from the 'ordinary provisions', and that Article 19(1) is the equivalent in the transitional provisions of Article 3, while Article 19(2) is the equivalent of Article 7. They rely for support for this view on the corresponding EEA provisions, Article 19 of which is, in their submission, expressly stated to operate independently of Article 3.

16. The applicants contend that it is clear from the wording of the Regulation that Article 19(1) does not incorporate expressly the ordinary provisions of the Regulation; had this been the Council's intention, there would have been an explicit reference back to Article 3 and the necessity to fulfil the conditions it lays down. Nor is such a reference implicit, as Article 19(1) 'can operate sensibly and effectively so as to achieve the objectives of the Regulation without reference to Article 3'. In their view, the Regulation draws a very clear distinction between the first authorization to place a product on the market in the Community, the date of which determines the duration of the SPC (Article 13(1)), and the first authorization to place a product on the market, which refers to the first marketing authorization granted for a particular Member State, whether or not this is the first marketing authorization anywhere in the Community (compare Article 8(1)(a)(iv) and (c)). As the wording of Articles 3 and 19(1) reflect this difference, these provisions should be differently interpreted. Furthermore, unlike Article 3, Article 19 does not require that the basic patent be valid when the application for an SPC is made but only requires that it be valid on the date the Regulation came into force, a point of view they suggest is reinforced by the inclusion in the EEA version of the Regulation of specific provisions governing the situation where a patent expires before an application under Article 19 is made.

17. The applicants identify two purposes of the Regulation: a general purpose, that new medicinal products should not be deprived of adequate patent protection (or its equivalent) as a result of the length of time taken to process applications for marketing authorizations, and a more specific purpose (of the transitional provisions), to allow the Community pharmaceutical industry to catch up, to some extent, with its main non-Community competitors while taking account of other legitimate objectives in the area of public health. The refusal of the SPC would, in their view, conflict with each of these purposes, in that no protection would

be provided in the Member State where the investment and research effort was greatest, and that it would not enable the European pharmaceutical industry to catch up with its competitors. Had the Council intended merely to extend the deadline for submitting applications fixed by Article 7(1), it would have been differently worded to reflect the limited character of the derogation accorded. The applicants further argue that the granting of an SPC would not imply that the product could be marketed in the United Kingdom without a United Kingdom authorization, nor that the effect of the United Kingdom patent would be extended beyond the expiry of its lawful term, as the SPC only covers products covered by the marketing authorization.

18. The applicants rely finally on the legislative history of the Regulation, as going to show that 'the intention was to allow SPCs to be obtained under the transitional provisions for medicinal products which had been authorized to be placed on the market *anywhere* in the Community'.

19. The only matter of substance raised by the present request for a preliminary ruling is the interpretation of Article 19(1) of the Regulation, and in particular whether the phrase 'the first authorization to place [a product] on the market as a medicinal product in the Community' replaces the basic conditions for the grant of an SPC found principally in Article 3(a) and (b). The applicants' contentions in this regard are based essentially on a literal construction of the first subparagraph of this provision without regard to its legislative context. I find them wholly unconvincing.

20. In my opinion, Article 19 does no more than open, for a six-month period, the possibility of obtaining an SPC for products which were still protected on 2 January 1993 by a basic patent in the Member State of application, and for which a marketing authorization had been issued in that Member State between 1 January 1985 (or 1 January 1988 in the case of Denmark and Germany and 1 January 1982 in the case of Belgium and Italy) and the date of submitting the application under Article 19(2). [8] The requirement that the product still be protected by a basic patent arises from the very nature of the SPC, which, in accordance with Article 5 of the Regulation, extends for a limited period the legal protection hitherto provided by the patent. [9] Article 19 constitutes a derogation from the requirement of Article 7(1) that the application for a certificate be submitted within six months of the granting of the market authorization; Article 19(2) consequently fixes a new deadline for the lodging of an application for an

8 — The situation of products for which a marketing authorization was issued in the period after the Regulation was adopted and before the expiry of the transitional period fixed by Article 19(2) is considered at paragraph 27, below.

9 — On the equivalent provisions of the EEA version of the Regulation, which in certain circumstances allow the grant of an SPC for a product whose basic patent has expired, see paragraphs 30 to 33, below.

SPC for a certain category of such products which have failed, for obvious reasons, to meet the deadline fixed by Article 7(1).

21. Nothing in the general scheme, wording, objectives or legislative history of Article 19, or of the Regulation as a whole, supports the view put forward by the applicant. Article 19 seeks to apply the 'ordinary provisions' of the Regulation, including Article 3, for a transitional period, to products which would have benefited from an SPC but for the impossibility of respecting the deadline for submitting an application set by Article 7(1). To a temporal limitation, Article 19 provides a temporal derogation; to extend the scope of this derogation to the material conditions for acceding to an SPC, in the absence of any textual support, would, as the Commission observed at the oral hearing, contravene the general principle of construction of Community law that exceptions should be strictly interpreted. The general scheme of the Regulation relies on a basic patent, which can be European or national, and a marketing authorization, which in the present state of Community law as it applies to the facts of these proceedings, is national in character. The applicants are seeking to give the marketing authorization a pan-Community effect which, as they expressly recognize, it does not have, except as regards the calculation of the duration of the SPC.

22. Nor does the wording of the Regulation support the applicants' view. Unlike Article 3, Article 19(1) does not define the conditions of eligibility for an SPC but identifies a category of products, otherwise temporally excluded, for which an application for an SPC may be made. Nothing in this provision suggests that the substantive criteria for eligibility are any different from those laid down in Article 3; Article 19 makes no cross-reference to Article 3 simply because such a reference would have been superfluous.

23. It cannot seriously be maintained, in my view, that Article 19(1) is capable of operating autonomously without regard to Article 3. In the explanatory memorandum to its 1990 proposal which, subject to certain amendments, subsequently became the Regulation, the Commission noted that '[as] the certificate is a national document, compliance with [the] conditions [of Article 3] must be examined with respect to the Member State in which the certificate application is submitted at the application date'. [10] This view is borne out by the remaining provisions of the Regulation, and in particular Article 4, which limits the protection of the SPC to the product covered by the national market authorization and 'any use of the product as a medicinal product that has been authorized before the expiry of the certificate'.

24. Articles 8(1)(a)(iv), 8(1)(b), 9(1), 9(2)(d), and 11(1)(d), concerning, respectively, the content, notification and publication of an application, each require information

10 — COM(90) 101 final — SYN 255, 11 April 1990, comments on draft Article 3, explanatory memorandum, paragraph 32, p. 18.

concerning the 'authorization [...] referred to in Article 3(b)', that is, the national marketing authorization; they each imply the existence of a marketing authorization in the Member State of application and are clearly intended to be of general application. The applicants' case requires them to be ignored. It also appears somewhat anomalous that an SPC granted in one Member State could lapse as a result of the withdrawal of a marketing authorization in another Member State, always presuming of course that Article 14(d) does, under the applicants' interpretation, apply to transitional SPCs. By the same token, as the Netherlands has pointed out, Article 15(1)(a) could not apply to transitional SPCs, as it expressly only refers to certificates which were 'granted contrary to the provisions of Article 3', with no reference to Article 19(1).

25. The anomalies to which the applicants' interpretation gives rise do not stop at the impossibility of applying most of the procedural provisions of the Regulation. As the United Kingdom has pointed out, under this view the holder of a basic patent valid *anywhere* in the Community on 2 January 1993 could apply in *any* Member State for an SPC for a product which has received a marketing authorization *anywhere* in the Community after the date set by Article 19(1). Faced with this striking anomaly, the applicants, at the oral hearing, departed from a literal interpretation and sought a common-sense one, based on Articles 4 and 5, which would require the basic patent to exist in the Member State of application.

26. Equally, the applicants' interpretation would mean that the rule laid down in Article 3(d), that the marketing authorization relied upon in the Member State of application be the first such authorization in that Member State, would not apply; multiple SPCs could therefore be obtained in a given Member State in respect of the same patent on the basis of multiple marketing authorizations, which is not the case for other SPCs, and was clearly not the intention of the Commission when it submitted its proposal. [11]

27. Furthermore, where a national marketing authorization was delivered in the period after the adoption of the Regulation and the expiry of the transitional period fixed by Article 19(2), the applicant for an SPC could choose between the more restrictive 'ordinary provisions' of the Regulation (Articles 2 to 18) and the free-for-all provisions of Article 19 as interpreted by the applicants in the present case. Thus, for example, where the marketing authorization was granted on, say, 1 October 1992, an application lodged on 1 February 1993 would comply with both Articles 7(1) and 19(2); the same is true of

11 — 'It occurs very often that one and the same product is successfully granted several authorizations to be placed on the market, namely each time a modification is made affecting the pharmaceutical form, dose, composition, indications, etc. In such a case, *only the first authorization* ... is taken into account' (Commission proposal, cited in preceding footnote, explanatory memorandum, paragraph 35, p. 19, emphasis added).

an application lodged, say, on 1 May 1993 where the authorization was granted on 1 February 1993. I find it difficult to accept that the Council intended either to provide such a discriminatory regime in favour of patent-holders of medicinal products authorized before the Regulation came into force, who are in essentially the same position as those applying for an SPC under the 'ordinary provisions', or to create such an overlap between entirely different regimes.

28. While it is true that the Regulation draws a distinction between, on the one hand, the first marketing authorization in the Community and, on the other hand, the first marketing authorization in an individual Member State, and that the former is used as the basis for calculating the duration of the SPC in accordance with Article 13, I do not see how this can afford any assistance to the applicants; indeed, it is clear from Articles 13 and 19(1) that the function of the first marketing authorization in the Community is temporal in character. Their affirmation that 'Article 19(1) operates by reference to the first marketing authorization granted in the Community' assumes that Article 19(1) defines a substantive criterion of eligibility for an SPC, rather than identifying the category of products which can benefit from the temporal derogation it provides. The difference in wording in Articles 3 and 19(1) reflects the differences in their function in the system set up by the Regulation, and not the imposition of different criteria of eligibility for an SPC under the transitional arrangements.

29. The applicants further argue that, unlike Article 3, Article 19 does not require that the basic patent be valid at the date of the application, in order to demonstrate that Article 19 cannot be read subject to Article 3. This argument begs, rather than resolves, the question of whether Article 19 is a material, or merely a temporal, derogation from the remainder of the Regulation. It adds nothing to the other arguments of the applicants I have already rejected. Rather it draws further attention to the anomaly which would thereby be created. Such anomalies are carefully avoided in the EEA version, which I will now discuss.

30. The applicants have sought to rely on the EEA version of the Regulation set out in paragraph 5 of Annex 15 to Decision No 7/94 of the EEA Joint Committee. [12] None of the parties to the present proceedings addressed the issue of whether it is appropriate to interpret a measure based on the EEC/EC Treaty in the light of a later measure which was based on an international agreement concluded by the Community, the Member States and a number of third countries. In my view, resort to such a technique of interpretation should be approached with caution; even if the provisions in question had been identical, the differences in character between the EEC/EC Treaty and the EEA Agreement are notorious. [13]

12 — Cited at paragraph 8 of the present Opinion, above.

13 — Opinion 1/91 *Draft Agreement relating to the creation of the European Economic Area* [1991] ECR I-6079, paragraphs 13 to 22.

31. Here the applicants are relying on certain amendments made to the text of the Regulation with a view to applying it as part of the common rules which apply to products and services by virtue of Article 65(2) of the Agreement. They rely in particular on the fact that the EEA version of the Regulation contains specific provisions covering the situation where the patent expires before an application under Article 19 is made. From this they conclude that '[in] the EEA version, Article 19 *must* operate independently of Article 3[, and that it] follows that the same applies in the case of the EC version'; the fact that the (original) EEC version contains no such provisions is dismissed as 'not material'.

32. This argument seems to be based on a misunderstanding of the legal effect and function of the amendments in question. Article 19(1) of the EEA Regulation provides in effect that an SPC may be granted in the EFTA States for products protected by a valid patent on 2 January 1993 and for which a marketing authorization has been granted after 1 January 1985. Under Article 19(2), applications for such transitional EFTA-SPCs must be made within six months of the coming into force of the EEA Regulation, on 1 July 1994 (Article 3 of Decision No 7/94 of the EEA Joint Committee). Article 19(3) provides for the special situation of products in respect of which the basic patent has expired between the coming into force of the EEC Regulation and that of the EEA Regulation; an SPC may be granted for such products, in accordance with Article 19(1), but only with effect from the date of publication of the application for the certificate (Article 19(3)) and only if the application is made within two months of the entry into force of the EEA Regulation (Article 19(4)). These provisions therefore seek at the same time to harmonize the arrangements regarding SPCs in all the EEA Member States, while avoiding any retroactive effect for SPCs granted for products whose basic patent had expired before the entry into force of the EEA Regulation (Article 19(3)), and safeguarding the interests of third parties acting in good faith after the basic patent has expired (Article 19(5)).

33. The applicants' submission that Article 19 of the EEA Regulation operates independently of Article 3 of the same Regulation is therefore, in my view, completely unfounded, and their suggested interpretation of the EEC Regulation in the light of these provisions must be rejected.

34. The interpretation of Article 19 put forward by the applicants would not, in my view, advance the purposes of the transitional provisions. These were outlined in the tenth recital in the preamble as being to 'enable the Community pharmaceutical industry to catch up to some extent with its main competitors who, for a number of years, have been covered by laws guaranteeing them more adequate protection, while making sure that the arrangements do not compromise the achievement of other legitimate objectives concerning the health policies pursued both at national and

Community level'. It seems to me that the interpretation of Article 19 as a temporal derogation to Article 7 of the Regulation corresponds perfectly well with the objectives of the former provision set out in this recital. Nor is there any indication in the Regulation that the balance between the interests of the pharmaceutical industry and those promoted by Community and national health policies should be so vastly different under the transitional, as compared to the definitive, regime. Furthermore, the net effect of the applicants' thesis would be to extend SPC protection to patent-holders in Member States where they have not obtained a marketing authorization; I do not see how such an interpretation could be said to foster research and innovation in the pharmaceutical sector, which the applicants identified as the underlying purpose of the Regulation.

35. Given the overwhelming evidence that Article 19 of the Regulation should be treated as a temporal derogation only, it does not seem necessary or appropriate to refer to its legislative history, which the applicants take to comprise only a preliminary draft proposal considered by a group of government experts in September 1989 and the Commission proposal of April 1990. The first I would exclude in this case, as any contribution the experts made to the preparation of the proposal was superseded by the proposal itself which, furthermore, originated in a Community institution. I shall examine the latter briefly, should this be of assistance to the Court.

36. It would take a remarkably eclectic reading of the Commission proposal to derive any support for the applicants' thesis. In describing the 'Details and characteristics of the proposed system' at page 7 of the explanatory memorandum, [14] the Commission notes that the SPC 'will be granted by the patent office in each Member State ... relating to a product authorized to be marketed in the State concerned'; as neither Article 3 nor Article 19 is mentioned, the statement was presumably intended to cover both. In discussing the duration of the certificate, the purpose of the cut-off point (established by Article 13(2) of the Regulation) is identified as being 'to penalize against authorizations obtained at a very late date (more than 15 years after the filing of the patent)'. In its commentary on the conditions established by Article 3, the Commission states that as the certificate is 'a national document, compliance with these conditions must be examined with respect to the Member State in which the certificate application is submitted'; no exception is made for transitional SPCs, either here or in the comments on the draft of those provisions. In commenting on Article 4, the Commission describes the SPC as being 'linked to ... an authorization to place the product on the market (the first chronologi-

14 — Cited in footnote 10 above.

cally given in the State concerned)', again no exception being made here or elsewhere for transitional certificates. Finally, nothing in the Commission's comments on the draft transitional provisions gives any hint of an indication that these were to set up a radically different regime to that which applied to ordinary SPCs.

IV — Conclusion

37. In the light of the foregoing, I recommend that the question referred by the High Court of Justice, Patents Court, London, be answered as follows:

Article 19 of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products should be interpreted as meaning that a supplementary protection certificate may only be granted if, in the Member State in which the application is submitted and at the date of that application, a valid authorization to place the product on the market as a medicinal product has been granted, in accordance with Council Directive 65/65/EEC or Council Directive 81/851/EEC, as appropriate.