JUDGMENT OF THE COURT

16 December 1999 (1)

(Medicinal products - Marketing authorisation - Parallel imports)

In Case C-94/98,

REFERENCE to the Court under Article 177 of the EC Treaty (now Article 234 EC) by the High Court of Justice of England and Wales, Queen's Bench Division, United Kingdom, for a preliminary ruling in the proceedings pending before that court between

The Queen

and

The Licensing Authority established by the Medicines Act 1968

(represented by the Medicines Control Agency),

ex parte: **Rhône-Poulenc Rorer Ltd,**

May & Baker Ltd,

on the interpretation 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 medicinal products (OJ, English Special Edition 1965-1966, p. 20), as amended, in particular, by Council Directive 93/39/EEC of 14 June 1993 (OJ 1993 L 214, p. 22), and of the provisions of Community law relating to the grant of parallel import licences for medicinal products,

THE COURT,

composed of: G.C. Rodríguez Iglesias, President, D.A.O. Edward, L. Sevón, R. Schintgen (Presidents of Chambers), C. Gulmann (Rapporteur), J.-P. Puissochet, G. Hirsch, P. Jann and H. Ragnemalm, Judges,

Advocate General: A. La Pergola,

Registrar: D. Louterman-Hubeau, Principal Administrator,

after considering the written observations submitted on behalf of:

-Rhône-Poulenc Rorer Ltd and May & Baker Ltd, by G. Hobbs QC and J. Stratford, Barrister, instructed by R. Freeland and M. Farquharson, Solicitors,

-the United Kingdom Government, by J.E. Collins, Assistant Treasury Solicitor, acting as Agent, assisted by R. Drabble QC and P. Saini, Barrister,

-the French Government, by K. Rispal-Bellanger, Head of Subdirectorate in the Legal Affairs Directorate of the Ministry of Foreign Affairs, and R. Loosli-Surrans, Head of Mission in that directorate, acting as Agents,

-the Commission of the European Communities, by R.B. Wainwright, Principal Legal Adviser, and H. Støvlbæk, of its Legal Service, acting as Agents,

having regard to the Report for the Hearing,

after hearing the oral observations of Rhône-Poulenc Rorer Ltd and May & Baker Ltd, represented by G. Hobbs and J. Stratford, of the United Kingdom Government, represented by R. Drabble and P. Saini, of the French Government, represented by R. Loosli-Surrans, of the Swedish Government, represented by A. Kruse, DepartementsrÊad in the Legal Affairs Secretariat (EU) of the Ministry of Foreign Affairs, acting as Agent, and of the Commission, represented by R.B. Wainwright and H. Støvlbæk, at the hearing on 9 March 1999,

after hearing the Opinion of the Advocate General at the sitting on 19 May 1999,

gives the following

Judgment

1. By order of 31 July 1997, received at the Court on 1 April 1998, the High Court of Justice of England and Wales, Queen's Bench Division, referred to the Court for a preliminary ruling under Article 177 of the EC Treaty (now Article 234 EC) two questions on the interpretation 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 medicinal products (OJ, English Special Edition 1965-1966, p. 20), as amended, in particular, by Council Directive 93/39/EEC of 14 June 1993 (OJ 1993 L 214, p. 22) ('the Directive'), and of the provisions of Community law relating to the grant of parallel import licences for medicinal products.

2. Those questions were raised during proceedings between Rhone-Poulenc Rorer Ltd ('RPR') and May & Baker Ltd ('M & B'), and the Licensing Authority established by the Medicines Act 1968, represented by the Medicines Control Agency ('the MCA'), concerning decisions taken by the MCA on parallel import licences for a medicinal product called 'Zimovane'.

The relevant provisions

3.

Article 30 of the EC Treaty (now, after amendment, Article 28 EC) states that quantitative restrictions on imports and measures having equivalent effect are prohibited between Member States. However, Article 36 of the EC Treaty (now, after amendment, Article 30 EC) provides that prohibitions and restrictions on imports between Member States which are justified on grounds of, *inter alia*, the protection of health of humans are permitted, so long as they do not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

4.

Under Article 3 of the Directive, no medicinal product may be placed on the market of a Member State unless an authorisation has been issued by the competent authorities of that State.

5.

Article 4 of the Directive defines the procedure, documents and information required in order to obtain a marketing authorisation. Under point 3 of Article 4 of the Directive, an application for a marketing authorisation must be accompanied by qualitative and quantitative particulars of all the constituents of the medicinal product. Under point 8 of Article 4 of the Directive, the application must be, in particular, accompanied by the results of physico-chemical, biological or microbiological tests, pharmacological and toxicological tests, and clinical trials. Under point 9 of the same article, the application must be accompanied by a summary of the product characteristics and one or more specimens or mock-ups of the sales presentation of the medicinal product. Article 4a of the Directive, which was inserted by Council Directive 83/570/EEC of 26 October 1983 (OJ 1983 L 332, p. 1), specifies the information that must be included in the summary of the product characteristics.

6.

Article 5 of the Directive provides that the authorisation will be refused if, after verification of the particulars and documents listed in Article 4, it proves that the medicinal product is harmful in the normal conditions of use, or that its therapeutic efficacy is lacking or is insufficiently substantiated by the applicant, or that its qualitative and quantitative composition is not as declared.

7. Article 10 of the Directive provides that authorisation is to be valid for five years and is to be renewable for five-year periods after consideration by the competent authority of a dossier containing details of the data on pharmacovigilance and other information relevant to the monitoring of the medicinal product.

8. Article 29a of Second Council Directive 75/319/EEC of 20 May 1975 (OJ 1975 L 147, p. 13), inserted by Directive 93/39, provides that the Member States are to establish a pharmacovigilance system which, in particular, imposes obligations on the holder of the marketing authorisation in respect of recording and reporting all adverse reactions to the medicinal product. Thus, records must be submitted to the competent authorities at regular intervals and must be accompanied by a scientific evaluation.

9. In 1984, on the basis of a Commission communication published on 6 May 1982 (OJ 1982 C 115, p. 5), which is based on Case 104/75 *De Peijper* [1976] ECR 613, the MCA issued a document entitled 'Notes on Application for Product Licences (Parallel Importing) (Medicines for Human Use)' ('MAL 2 (PI)').

10. An import of medicinal products is treated as a 'parallel import' for the purpose of MAL 2 (PI) where a product is the subject of a United Kingdom marketing authorisation and an applicant wishes to import from the European Community a version of that product which already has a marketing authorisation issued by another Member State. In accordance with MAL 2 (PI), applications for parallel import licences are examined and assessed according to a 'simplified' procedure under which the applicant needs to provide less information than is required for an application for a marketing authorisation made in accordance with the Directive.

11. Paragraph 4 of MAL 2 (PI) provides that:

> '*All* the following conditions must be met before an application can be considered under these arrangements i.e. the product concerned must be -

(a)A product which is to be imported from a Member State of the European Community;

(b)a proprietary medicinal product (as defined in Article 1 of EC Directive 65/65) for human use ...;

(c)covered by a currently valid marketing authorisation granted, in accordance with Article 3 of EC Directive 65/65, by the regulatory authority of an EC Member State;

(d)... have no differences, having therapeutic effect, from a product covered by a UK product licence (PL) ...;

(e)made by, or under licence to:

(i)the manufacturer who made the product covered by the UK product licence or;

(ii)a member of the same group of companies as the manufacturer who made the product covered by the UK product licence.

If any of these conditions is not met the applicant will be invited to apply for a PL in the normal way under the MAL 2 procedures.'

12. Paragraph 12 of MAL 2 (PI) provides that an authorisation for parallel imports continues in force only so long as both the United Kingdom licence and the Community marketing authorisation to which it relates are in force. If either ceases to be valid for any reason (for example, through expiry or revocation) the parallel import licence also ceases to be valid.

13. Paragraph 21 of MAL 2 (PI) provides that the normal arrangements apply with regard to variations to a parallel import licence made at the request of the licence holder. The

licensing authority needs to ensure that the licence is kept in line with the relevant provisions of the appropriate product licence. The licensing authority will notify the parallel import licence holder of any action necessary as the result of a variation to the United Kingdom product licence. The parallel import licence holder is required to notify the licensing authority of any variation to the Community marketing authorisation that comes to his attention. He must seek approval to market the varied product by asking for a variation to that parallel import licence. No batch of a varied product may be marketed in the United Kingdom until the variation has been approved by the licensing authority.

The main proceedings

14. In 1989 and 1993, M & B, a member of a group of companies which operate in the research-based pharmaceutical industry, obtained marketing authorisations issued by the MCA covering various forms of tablets and capsules of the product called 'Zimovane', which is used for the treatment of insomnia and whose generic name is zopiclone. M & B appointed RPR as its agent to manufacture and market that product.

15. After more than three years of research, RPR developed a new version of Zimovane. It contains the same active ingredients and has the same therapeutic effect as the old version, but is manufactured by a different manufacturing process and using different excipients which provide a particular benefit to public health compared with the old version of Zimovane.

16. RPR submitted the required relevant data to the MCA in order to establish the safety, efficacy and quality of the new version and, on 11 July 1996, the MCA granted a variation to some of the existing marketing authorisations relating to Zimovane. The variations allow RPR to market its new version of Zimovane in the United Kingdom. On 31 July 1996, at the request of RPR, the MCA revoked the authorisations under which the old version of Zimovane had been marketed.

17.

Accordingly, RPR has no longer marketed the old version of Zimovane in the United Kingdom. However, RPR continued to market that version of Zimovane in the other Member States, its new version only being marketed in the United Kingdom.

18. Before the authorisations relating to the old version of Zimovane were revoked, parallel import licences for that version were granted to several companies, in accordance with MAL 2 (PI). When the parent authorisation upon which they depended was revoked by the MCA, they lapsed under paragraph 12 of MAL 2 (PI). The holders of the parallel import licences were informed by the MCA that, if they wished to maintain their licences, they had to apply for variations to those licences in order to determine a new appropriate reference product. After examining the applications made to this effect, the MCA, by a number of decisions taken between November 1996 and May 1997, decided to treat the parallel import licences as still valid, those licences then being appended to the marketing authorisation issued for the new version of Zimovane. The MCA also, with effect from 1 August 1996, issued three new parallel import licences for the old version of Zimovane.

19. On 14 February and 5 June 1997, M & B and RPR lodged applications for judicial review of the MCA's decisions claiming that, in the absence of any subsisting marketing authorisations for the old version of Zimovane in the United Kingdom, imports of that version into the United Kingdom were not parallel imports, so it was contrary both to the legislation applicable in the United Kingdom and to Community law to treat them as such.

20. During those proceedings, the MCA contended, in particular, that had it treated the two versions of Zimovane as different products and required the parallel importers of the old version of that product to apply for marketing authorisations under the Directive, it would have created an unjustifiable restriction on imports contrary to Article 30 of the Treaty.

21. In those circumstances, the national court decided to stay proceedings and to refer the following questions to the Court for a preliminary ruling:

'1.In a case where medicinal product X is sought to be imported from Member State A into Member State B, is it permissible for the person who proposes to place the imported product upon the market in Member State B to seek and obtain a marketing authorisation from the competent authority in Member State B without complying with the requirements of Council Directive 65/65/EEC (as amended) if:

(a) medicinal product X is the subject of a marketing authorisation granted in Member State A and was the subject of a marketing authorisation which has ceased to have effect in Member State B; and

(b) medicinal product X has the same active ingredients and therapeutic effect as medicinal product Y, but is not manufactured according to the same formulation as medicinal product Y; and

(c)medicinal product Y is the subject of a marketing authorisation granted in Member State B, but is not the subject of a marketing authorisation granted in Member State A; and

(d)the marketing authorisations referred to in (a) and (c) above were granted to different members of the same group of companies and the manufacturers of medicinal products X and Y are also members of that group of companies; and

(e)companies within the same group as the holder of the marketing authorisation for product X continue to manufacture and market product X in Member States other than Member State B?

2.To what extent is it relevant to the answer to Question 1 that:

(a)the marketing authorisation for medicinal product X ceased to have effect in Member State B as a result of voluntary surrender on the part of the person to whom it had been granted; and/or

(b)the formulation of medicinal product Y was developed and introduced in order to provide a benefit to public health which medicinal product X (manufactured according to a different formulation) does not provide; and/or

(c)that benefit to public health would not be achieved if product X and product Y are both on the market in Member State B at the same time; and/or

(d)the differences between the formulations of medicinal product X and medicinal product Y are such that neither product may lawfully be marketed under the marketing authorisation applicable to the other; and/or

(e)the competent authority possesses the relevant data required under Directive 65/65 in relation to both product X and product Y; and/or

(f)the competent authority considers that the prohibition on imports of product X from Member State A would have the effect of partitioning the market; and/or

(g)the competent authority considers that there are no grounds within

Article 36 of the EC Treaty which would justify a prohibition on imports and sales of product X?'

The questions referred for a preliminary ruling

22.

In order to answer the questions referred for a preliminary ruling, which may be examined together, it is necessary to ascertain whether imports of the old version of Zimovane may in fact be treated as parallel imports, in which case the normal procedure under the Directive relating to the issue of marketing authorisations does not apply.

23.

The first point to note is that notwithstanding the Treaty rules on the free movement of goods no medicinal product may be placed on the market in a Member State unless a marketing authorisation has been issued in accordance with the Directive by the competent authority of that State. An application for a marketing authorisation for a medicinal product submitted by the person responsible for placing it on the market must contain the information and be accompanied by the documents listed in Article 4 of the Directive even where the medicinal product concerned is already the subject of an authorisation issued by the competent authority of another Member State.

24. However, those principles are subject to exceptions arising, on the one hand, from the Directive itself and, on the other, from the Treaty rules relating to the free movement of goods.

25. Accordingly, point 8 of Article 4 of Directive 65/65/EEC, as amended by Council Directive 87/21/EEC of 22 December 1986 (OJ 1987 L 15, p. 36), establishes an 'abridged' procedure which, subject to certain conditions, relieves the manufacturers of medicinal products which are essentially similar to medicinal products already authorised from having to provide the results of pharmacological and toxicological tests and of clinical trials, thus saving the time and expense necessary to assemble such data, and avoiding the repetition of tests on humans or

> animals where these are not absolutely necessary (see Case C-368/96 *Generics (UK) and Others* [1998] ECR I-7967, paragraphs 2 to 4).

26. The other exception, which is relevant in this case, is defined in *De Peijper*. In that case, the Court held, at paragraphs 21 and 36, in the context of Articles 30 and 36 of the Treaty, that if, as a result of importation on a previous occasion which gave rise to the grant, by them, of a marketing authorisation, the public health authorities of the Member State of importation are already in possession of all the particulars necessary for checking that the product is effective and safe, it is not necessary, for the purpose of protecting the health and life of humans, for those authorities to require a second trader who has imported a medicinal product which is in every respect the same or which has no differences altering the therapeutic effect, to submit the abovementioned particulars to them again.

27. In Case C-201/94 *Smith & Nephew and Primecrown* [1996] ECR I-5819, paragraph 21, the Court stated again that the Directive cannot apply to a medicinal product covered by a marketing authorisation in one Member State which is being imported into another Member State as a parallel import of a product already covered by a marketing authorisation in that other Member State, because the imported medicinal product cannot, in such a case, be regarded as being placed on the market for the first time in the Member State of importation.

28. The Court went on to state, in paragraphs 25 and 26 of that judgment, that in order to ascertain whether imports of a medicinal product constitute parallel imports the competent authority in the Member State of importation must verify that the two medicinal products have a common origin and, if not identical in all respects, have at least been manufactured according to the same formulation, using the same active ingredient, and have the same therapeutic effect.

29. In the light of that case-law, it is important to note that in the present case it is common ground that the medicinal products at issue in the main proceedings contain the same active ingredients and have the same therapeutic effect and a common origin, since they come from manufacturers belonging to the same group of companies.

30. However, it is clear from the observations submitted to the Court that there are other particular circumstances of the case which might cast doubt on the compliance with Community law of the decisions of the United Kingdom authorities at issue.

31. M & B and RPR claim that the provisions of Community law relating to the parallel importation of medicinal products apply only for so long as the product concerned is covered by marketing authorisations which are simultaneously in force in the Member State of exportation and the Member State of importation. In this case, it would therefore have been unlawful to apply the procedure set out in MAL

> 2 (PI) with a view to authorising imports into the United Kingdom of the old version of Zimovane. First, the parent authorisation of the old version of the medicinal product was revoked and, second, the condition established by the Court in *Smith & Nephew and Primecrown* of 'manufacture according to the same formulation' was not met. According to M & B and RPR, this latter condition includes both active ingredients and excipients. They add that their decision to distribute only the new version of Zimovane in the United Kingdom and to surrender the authorisations relating to the old version is explained by the need to achieve, primarily in that Member State, a particular benefit for public health - a benefit which could not be achieved if the old and new versions of the product were both available on the United Kingdom market at the same time.

32. The French Government observes that, even if the excipient is not relevant to the therapeutic effect, it is considered to be a part of the qualitative and quantitative particulars of the product as referred to in the Directive, since it is part of the formulation of the product. Therefore, unless a new marketing authorisation is obtained in accordance with the provisions of the Directive, imports of the old version of Zimovane cannot be treated as parallel imports within the meaning of the case-law of the Court.

33. The Commission observes that, according to Articles 3 and 4 of the Directive, marketing authorisations are given for a specific medicinal product, which has been evaluated by means of a stringent authorisation procedure, taking into account the product as a whole, including the excipients. The composition of a medicinal product includes both the active ingredients and the excipients. All the constituents of a medicinal product are of importance to the quality, efficacy and safety of the product and form part of the summary of product characteristics of a medicinal product required by Article 4a of the Directive. That summary is an integral part of the authorisation for any medicinal product. In this case, the differences between the old and new versions are therefore not without importance. The Commission adds that, if the marketing authorisation for a medicinal product is revoked, there is no obligation to submit information regularly in connection with renewal of the authorisation, in accordance with the pharmacovigilance system established by Directive 75/319. As a result, the competent authorities in the State of importation cannot be sure that the use of the old product imported in parallel is still safe, according to the latest scientific data.

34. According to the United Kingdom Government, in circumstances such as those of this case, the MCA is required, under Article 30 of the Treaty, to allow parallel imports of the old version of Zimovane onto the United Kingdom market. There is no reason to treat the two versions of the product as different medicinal products. That would require parallel importers of the old version of Zimovane to obtain a marketing authorisation within the meaning of the Directive, if indeed that were actually possible (given the insuperable difficulty of repeating the chemical, pharmaceutical and biological tests required by the Directive). The old and new products are, from the therapeutic point of view, in normal conditions of use,

> equivalent versions of a product with a common origin and the same active ingredient. Changes in the excipients of a medicinal product do not, in general, alter the therapeutic effect.

35. Whilst acknowledging that RPR did not consciously attempt to isolate the United Kingdom market from the rest of the Community market, the United Kingdom Government observes that, if RPR's arguments were accepted, the voluntary surrender of the marketing authorisation for the old version of Zimovane would have precisely the effect of thus partitioning the market. Notwithstanding the formal revocation of the parent authorisation, the MCA is in possession of all the data, documents and details required by Article 4 of the Directive for the purpose of monitoring the efficacy and safety of the medicinal product which is to be the subject of a parallel importation. It is also in a position, in the future, by virtue of the rules that exist in relation to pharmacovigilance, to acquire the information needed to be sure that the old version of Zimovane does not pose a problem for public health, so long as there are marketing authorisations in other Member States.

36. The United Kingdom Government observes, finally, that the general interest in safeguarding public health, even if it were understood in the sense relied upon by M & B and RPR, does not require a measure such as a complete ban on parallel imports of the old version of the product.

37. The Swedish Government submits that the two versions of Zimovane are sufficiently alike for them to be treated as the same product. If the obligation for the formulation to be identical were to be understood as meaning the whole formulation of the medicinal products, this would create unjustified obstacles to intra-Community trade.

38. It appears, therefore, that the criticism of the contested decisions of the United Kingdom authorities is based, in particular, on the fact that those decisions could be contrary to Community law for the following three reasons:

-the two versions of Zimovane are not manufactured according to the same formulation, the new version being manufactured using different excipients and by a different manufacturing process;

-the pharmacovigilance system will not work because after the parent marketing authorisation is revoked the holder of the marketing authorisation is no longer obliged to submit information regularly in relation to the old version of the medicinal product; and

-the particular benefit for public health which is provided by the new version of Zimovane as compared with the old version could not be achieved if the

old and new versions of the medicinal product were both available on the United Kingdom market at the same time.

39. Before examining each of those three grounds for criticising the parallel import licences at issue, it is important to note that it is not necessary to rule on the question of lawfulness in the light of the free movement of goods of the automatic revocation of parallel import licences as a result of the revocation of a parent authorisation at the request of the holder of that authorisation. That question does not arise in this case because the United Kingdom authorities have acknowledged that the parallel import licences for the old version of Zimovane are appended to the marketing authorisation issued for the new version.

40. Next, it should be noted that although, as the Court held in *De Peijper* and *Smith & Nephew and Primecrown*, it follows from Articles 30 and 36 of the Treaty that national authorities must not obstruct parallel imports by requiring parallel importers to satisfy the same requirements as those which are applicable to undertakings applying for the first time for a marketing authorisation for a medicinal product, that principle is subject to the condition that an exception of that kind to the rules normally applicable to marketing authorisations for medicinal products does not undermine the protection of public health. As is clear from the first recital in the preamble to the Directive, the primary purpose of any rules concerning the production and distribution of medicinal products must be to safeguard public health. The criteria which must be met by a product imported as a parallel import for the parallel importer to be under no obligation to supply the particulars referred to in the Directive must not, therefore, lead to a relaxation of safety requirements (see, to that effect, *Generics (UK)*, paragraph 22).

41. It must also be borne in mind that there would be a real obstacle to intra-Community trade if importers of the old version of Zimovane, which is still authorised in other

Member States and lawfully marketed there, were not able to use the simplified procedure open to parallel importers in accordance with MAL 2 (PI).

42. As is clear from paragraph 35 of this judgment, the competent authorities in the United Kingdom considered it possible to authorise the placing on the market of those medicinal products imported as parallel imports by using as a parent marketing authorisation the authorisation for the new version of Zimovane and they have taken the view that, on the basis of the information in their possession, in spite of the different excipients used, the old version of Zimovane clearly remained effective and safe.

43. Although, as the United Kingdom Government has submitted, differences in the excipients used in medicinal products do not normally have any effect on safety, it is not disputed that such effects can exist. It is possible for a medicinal product imported as a parallel import, which contains the same active ingredients and has the same therapeutic effect but does not use the same excipients as the medicinal

> product which is the subject of the marketing authorisation in the Member State of importation, to show significant differences from the authorised product in terms of safety, given that modifications to the formulation of a medicinal product in respect of the excipients may have an effect on the shelf-life and the bioavailability of the product, for example in relation to the rates at which the medicinal product dissolves or is absorbed (see also, to that effect, *Generics (UK)*, paragraph 32).

44. However, the possibility of such effects on safety does not mean that as a consequence of differences relating to the excipients used the national authorities may never resort to simplified procedures for the licences granted to parallel importers.

45. The national authorities are required to authorise, in accordance with the rules relating to parallel imports, a medicinal product imported as a parallel product where they are convinced that that product, in spite of differences relating to the excipients, does not pose a problem for public health. Accordingly, the competent authorities of the Member State of importation must ensure, at the time of import and on the basis of information

in their possession, that the medicinal product imported as a parallel product, even if not identical in all respects to that already authorised by them, has the same active ingredient and the same therapeutic effect and does not pose a problem of quality, efficacy or safety (see, to that effect, Case C-100/96 *British Agrochemicals Association* [1999] ECR I-1499, paragraph 40).

46. As regards the problem raised in relation to pharmacovigilance, it is sufficient that pharmacovigilance satisfying the relevant requirements of Directive 75/319 as amended can be ensured for medicinal products imported as parallel imports, like those in this case, through cooperation with the national authorities of the other Member States by means of access to the documents and data, produced by the manufacturer or other companies in the same group, relating to the old version in the Member States in which that version is still marketed on the basis of a marketing authorisation still in force. In addition, it is possible to compel the holder of the marketing authorisation in the Member State of importation, who belongs to the group of companies which is in possession of the marketing authorisations for the old version in the other Member States, to supply the necessary information (see, to that effect, *De Peijper*, paragraphs 26 and 27).

47. Finally, it is necessary to examine the argument put forward by M & B and RPR that the particular benefit to public health provided by the new version of Zimovane as compared with the old version would not be achieved if the old version of Zimovane were present on the United Kingdom market. In that regard, it is sufficient to state that, even if the argument were well founded, it does not follow that, in circumstances such as those of the main case, the national authorities are compelled to require parallel importers to follow the procedure laid down in the Directive if they take the view that, in normal conditions of use, as referred to

> in Article 5 of the Directive, the medicinal product imported as a parallel import does not pose a risk as to quality, efficacy or safety.

48. In the light of the foregoing, the answer to the questions referred for a preliminary ruling must be that where it is sought to import medicinal product X from Member State A into Member State B, it is permissible for the person who proposes to place the imported product upon the market in Member State B to seek and obtain a parallel import licence from the competent authority in Member State B without complying with all the requirements of the Directive if:

-medicinal product X is the subject of a marketing authorisation granted in Member State A and was the subject of a marketing authorisation which has ceased to have effect in Member State B;

-medicinal product Y is the subject of a marketing authorisation granted in Member State B, but is not the subject of a marketing authorisation granted in Member State A;

-medicinal product X has the same active ingredients and therapeutic effect as medicinal product Y, but does not use the same excipients and is manufactured by a different manufacturing process, where the competent authority in Member State B is in a position to verify that medicinal product X complies with the requirements relating to quality, efficacy and safety in normal conditions of use and is in a position to ensure normal pharmacovigilance;

-the marketing authorisations referred to above were granted to different members of the same group of companies and the manufacturers of medicinal products X and Y are also members of that group of companies; and

-companies within the same group as the holder of the marketing authorisation for product X which has been withdrawn in Member State B continue to manufacture and market product X in Member States other than Member State B.

In such a situation, the competent authority is not required to take into consideration the fact that medicinal product Y was developed and introduced in order to provide a particular benefit to public health which medicinal product X does not provide and/or that that particular benefit to public health would not be achieved if product X and product Y were both on the market in Member State B at the same time.

Costs

49. The costs incurred by the United Kingdom, French and Swedish Governments and by the Commission, which have 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,

in answer to the questions referred to it by the High Court of Justice of England & Wales, Queen's Bench Division, by order of 31 July 1997, hereby rules:

Where it is sought to import medicinal product X from Member State A into Member State B, it is permissible for the person who proposes to place the imported product upon the market in Member State B to seek and obtain a parallel import licence from the competent authority in Member State B without complying with all the requirements 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 medicinal products (OJ, English Special Edition 1965-1966, p. 20), as amended by Council Directive 93/39/EEC of 14 June 1993, if:

-medicinal product X is the subject of a marketing authorisation granted in Member State A and was the subject of a marketing authorisation which has ceased to have effect in Member State B;

-medicinal product Y is the subject of a marketing authorisation granted in Member State B, but is not the subject of a marketing authorisation granted in Member State A;

-medicinal product X has the same active ingredients and therapeutic effect as medicinal product Y, but does not use the same excipients and is manufactured by a different manufacturing process, where the competent authority in Member State B is in a position to verify that medicinal product X complies with the requirements relating to quality, efficacy and safety in normal conditions of use and is in a position to ensure normal pharmacovigilance;

-the marketing authorisations referred to above were granted to different members of the same group of companies and the manufacturers of medicinal products X and Y are also members of that group of companies; and

-companies within the same group as the holder of the marketing authorisation for product X which has been withdrawn in Member State B continue to manufacture and market product X in Member States other than Member State B.

In such a situation, the competent authority is not required to take into consideration the fact that medicinal product Y was developed and introduced in order to provide a particular benefit to public health which medicinal product X does not provide and/or that that particular benefit to public health would not be achieved if product X and product Y were both on the market in Member State B at the same time.

Rodríguez Iglesias

Edward

Sevón

Schintgen

Gulmann

Puissochet

Hirsch

Jann

Ragnemalm

Delivered in open court in Luxembourg on 16 December 1999.

R. Grass G.C. Rodríguez Iglesias

Registrar President

1: Language of the case: English.