OPINION OF ADVOCATE GENERAL

BOT

delivered on 10 July 2008 [1]

1. In this reference for a preliminary ruling, the High Court of Justice of England and Wales, Queen's Bench Division (Administrative Court) (United Kingdom), requests the Court to interpret Article 28 of Directive 2001/83/EC [2] ('Directive 2001/83' or 'the Directive') which establishes a procedure for the mutual recognition of marketing authorisations for medicinal products.

2. The Court is asked, essentially, to rule on the scope of the discretion enjoyed by a Member State when it receives an application for mutual recognition of a marketing authorisation ('the Member State concerned') issued by another Member State ('the reference Member State') under the abridged procedure provided for in Article 10(1)(a)(iii) of Directive 2001/83. This procedure exempts the applicant from the requirement to provide in support of his application the results of appropriate toxicological and pharmacological tests and clinical trials where he can show that the medicinal product is 'essentially similar' to a medicinal product already authorised within the Community and marketed in the Member State concerned by the application. [3]

3. The questions referred for a preliminary ruling have been raised in a dispute between Synthon BV [4] and the Licensing Authority of the Department of Health, the competent United Kingdom authority, [5] which rejected its application for mutual recognition of the marketing authorisation issued by the competent Danish authority for Varox, on the ground that that product was not, in its view, essentially similar to the reference product.

4. In this Opinion I shall set out the reasons why I consider that the rejection of the application for mutual recognition in circumstances such as those in the main proceedings contravenes Article 28 of Directive 2001/83 and may accordingly constitute a sufficiently serious infringement of Community law.

1 — Original language: French.

2 — Directive of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67), in the version applicable at the material time of the facts in the main proceedings. In this Opinion the expression 'medicinal product(s)' refers only to medicinal products for human use.

3 — 'The reference product'.

4 — 'Synthon' or 'the applicant'.

5 — The 'Licensing Authority'.

I — Legal background

A — *Community law*

5. The questions referred by the national court seek an interpretation of Article 28 of Directive 2001/83. That directive was in fact in force when, on 21 November 2002, the applicant lodged its second application for mutual recognition of the marketing authorisation issued by the Danish authority. [6]

6. None the less, it is plain from the decision for reference that the provisions of Directives 65/65/EEC [7] and 75/319/EEC [8] also apply.

7. Authorisation to market Varox was in fact issued by the competent Danish authority under the abridged procedure originally referred to in Article 4, second paragraph, point 8(a)(iii), of Directive 65/65.

8. I also understand that the first application for mutual recognition of this authorisation was lodged by Synthon with the Licensing Authority pursuant to Article 9 of Directive 75/319. [9]

9. None the less, in the context of this Opinion I shall — in the interests of clarity — refer only to the applicable provisions of Directive 2001/83. In fact each of the provisions of Directives 65/65 and 75/319 mentioned in the preceding paragraphs has been consolidated in almost identical terms in Articles 10(1)(a)(iii) and 28 of Directive 2001/83.

10. This directive continues the approximating of national laws begun in Directives 65/65, 75/318/EEC [10] and 75/319, in order to eliminate obstacles to trade in

6 — Decision for reference (paragraph 14).

7 — Council Directive 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, *Series I 1965-1966 p. 24*), as amended by Council Directives 87/21/EEC of 22 December 1986 (OJ 1987 L 15, p. 36) and 93/39/EEC of 14 June 1993 (OJ 1993 L 214, p. 22) ('Directive 65/65'). Directive 87/21 laid down the requirements applicable to the issue of marketing authorisations in the specific case of an abridged procedure. Directive 93/39 introduced into the existing Community legislation a procedure for the mutual recognition of national marketing authorisations together with a Community consultation and arbitration procedure.

8 — Second Council Directive 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), as amended by Directive 93/39 ('Directive 75/319').

9 — The decision for reference does not specify the exact date on which Synthon filed that application.

10 — Council Directive of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products (OJ 1975 L 147, p. 1).

medicinal products in the common market. It consolidates the abovementioned laws in a more structured whole.

11. Under Article 6(1) of Directive 2001/83, no medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued.

12. Such authorisation may be granted either by the competent authorities of a Member State or, since the entry into force of Regulation No 2309/93, [11] by the Commission of the European Communities.

13. Articles 8 to 12 of Directive 2001/83 lay down the conditions for the grant of marketing authorisations.

14. Under Article 8(1) and (2) of the Directive, an application is to be made to the competent authority of the Member State concerned by an applicant established in the Community. The application must be accompanied by the information and documentation referred to in Article 8(3) of that directive. Among those documents are mentioned, in subparagraph (i), the results of physico-chemical, biological, microbiological, toxicological and pharmacological tests and of clinical trials of the product. The application must also be accompanied by a copy of any marketing authorisation already obtained for the medicinal product in another Member State (subparagraph l).

15. Next, Article 10 of Directive 2001/83 lays down the situations in which an abridged procedure may be used.

16. By virtue of Article 10(1)(a)(iii), first subparagraph, of the Directive, [12] the applicant is not to be required to provide the results of toxicological and pharmacological tests or clinical trials if he can demonstrate that the medicinal product at issue is essentially similar to a product already authorised in the Community for not less than six years and marketed in the Member State concerned

11 — Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ 1993 L 214, p. 1). This regulation institutes a centralised procedure for marketing authorisations at Community level having uniform legal effects in the whole of the territory of the European Union as well as a European Agency for the Evaluation of Medicinal Products whose role is to coordinate existing scientific resources available to the Member States with a view to the evaluation, supervision and pharmacological vigilance of medicinal products.

12 — Former Article 4, second paragraph, point 8(a)(iii), of Directive 65/65, as amended by Directive 87/21.

by the application. [13] That provision does not cover the case where the product is intended for a different therapeutic use or is to be administered by different routes or in different doses, as compared with the other medicinal products marketed. In that case, the results of those tests must be provided.

17. Article 18 of Directive 2001/83 establishes a procedure for the mutual recognition of marketing authorisations where a Member State is informed by way of the particulars and documents attached to an application for authorisation that the medicinal product at issue has already been authorised by another Member State. [14]

18. The Member State concerned must recognise that authorisation within 90 days of receipt of the assessment report drawn up by that other Member State, unless it considers that there are grounds for believing that that authorisation may present a risk to public health. [15] In such a case the procedures for Community consultation and arbitration referred to in Articles 29 to 34 apply.

19. Directive 2001/83 then includes a Chapter 4, entitled 'Mutual recognition of authorisations'. This chapter, which encompasses Articles 27 to 39, occupies a central place in these preliminary reference proceedings.

20. Article 27 of that Directive establishes a Committee for Proprietary Medicinal Products in order to facilitate the adoption of common decisions by Member States on marketing authorisations of medicinal products within the Community. [16] It is specifically charged with examining any question relating to the granting, variation, suspension or withdrawal of marketing authorisations.

21. Article 28 of the Directive relates, next, to the situation where a Member State is

13 — Under that same provision, that period may be extended to 10 years in the case of high-technology medicinal products or where a Member State, by a single decision covering all the medicinal products marketed on its territory, considers this necessary in the interest of public health. None the less, that provision does not appear to affect the obligation to provide information relating to the physico-chemical nature of the product.

14 — That procedure, in force since 1 January 1998, was inserted by Directive 93/39 as Article 7a of Directive 65/65. Article 18, first paragraph, of Directive 2001/83 specifically relates to the documents and information attached to the title of Article 8(3)(l) of that directive, which is to say, inter alia, a copy of any marketing authorisation obtained for that product in the other Member States, a list of the Member States in which an application is being examined and a copy summary of the characteristics of the product.

15 — The concept of 'risk to public health' is defined in Article 1(28), of Directive 2001/83 as '[a]ll risks with regard to the quality, safety and efficacy of the medicinal product'.

16 — This committee, which was created by Directive 75/319, is part of the European Agency for the Evaluation of Medicinal Products.

formally seised of an application for mutual recognition. [17]

22. In order to obtain the recognition by a Member State of a marketing authorisation issued by another Member State, the holder of the authorisation must, under Article 28(2) of Directive 2001/83, submit an application for marketing authorisation to the competent authority of the Member State concerned, together with the information and documentation referred to in Articles 8 (normal authorisation procedure), 10(1) (abridged authorisation procedure), and 11 of that directive. He must attest that the dossier is identical to that accepted by the reference Member State, or identify any additions or amendments where appropriate.

23. Article 28(4) of the Directive is worded as follows:

'Save in the exceptional case provided for in Article 29(1), each Member State shall recognise the marketing authorisation granted by the reference Member State within 90 days of receipt of the application and the assessment report.[[18]] …'

24. The reservation provided for in Article 29(1) of Directive 2001/83 relates to the situation where 'a Member State considers that there are grounds for supposing that the marketing authorisation of the medicinal product concerned may present a risk to public health'. [19] In this situation the Member State concerned must immediately inform the applicant, the reference Member State, the other Member States affected by the application and the European Agency for the Evaluation of Medicinal Products. It must also state its reasons in detail and indicate what action may be necessary to correct any defect in the application.

25. Article 29(2) of the Directive then provides for a procedure for consultation between the Member States concerned which must enable them to reach agreement on the action to be taken in respect of the application. In the event of disagreement between the Member States on the quality, security and efficacy of a medicinal product, this provision provides for a Community arbitration procedure, the detailed rules of which are laid down in Article 32 of the Directive. This procedure, in which the committee plays a central role, must make it possible to undertake a scientific evaluation of the

17 — This procedure was introduced by Directive 93/39 in Article 9 of Directive 75/319.

18 — Under Article 28(1), second subparagraph, of Directive 2001/83, a holder of a marketing authorisation is to request the reference Member State to draw up an assessment report for the product in question or, if need be, to update such report if it exists.

19 — See footnote 15.

matter so that a single decision on the areas of disagreement, binding on the Member States concerned, may be reached. [20]

II — Facts and main proceedings

28. Synthon is a Netherlands company operating in the pharmaceutical sector. It is dedicated to the development, registration, marketing and distribution of a wide range of products.

B — *National law*

26. Under section 6 of the Medicines Act 1968, and Regulation 2 of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994, the Licensing Authority is responsible for issuing marketing authorisations for pharmaceutical products in the United Kingdom.

27. All applications for marketing authorisations for medicinal products in the United Kingdom must comply with the provisions of the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994. The third to fifth regulations state that since an application for authorisation to market a medicinal product in the United Kingdom, as well as the issue of such authorisation by the competent national authority, falls within the scope of Directive 2001/83, these procedures must comply with the applicable Community provisions.

A — *Marketing authorisation for the product issued in Denmark under the abridged procedure*

29. On 23 October 2000, Synthon obtained a marketing authorisation in Denmark for a medicinal product called Varox. This product contains paroxetine mesylate. The authorisation was issued by the Danish Medicines Agency under the abridged procedure referred to at the time of the main proceedings in Article 4, second paragraph, point (8)(a)(iii), of Directive 65/65 (consolidated in Article 10(1)(a)(iii) of Directive 2001/83).

30. With a view to obtaining that authorisation, Synthon demonstrated, in accordance with the aforementioned provisions, that the product in question was essentially similar to

20 — See recital 12.

a product already authorised in the Community for at least six years and marketed by the pharmaceuticals company SmithKline Beecham plc ('SmithKline') under the name Seroxat (paroxetine hydrochloride hemihydrate). Both products contain the same active substance, namely paroxetine, and accordingly Synthon took Seroxat as the reference product.

31. The Danish Medicines Agency found that the condition of essential similarity between the two products was indeed satisfied and therefore granted Synthon authorisation to market Varox.

32. On 30 October 2000, SmithKline challenged the validity of that marketing authorisation, in particular the Danish Medicines Agency's assessment as to the essential similarity of the two products, before the Østre Landsret (Eastern Regional Court, Denmark). By decision of 19 February 2003, the court stayed proceedings and requested the Court of Justice to give a preliminary ruling on the question whether two medicinal products containing the same active substance, but in different salt forms, could none the less be regarded as essentially similar.

33. In its judgment in *SmithKline Beecham*, [21] the Court of Justice held that an application for a marketing authorisation for a medicinal product may be dealt with under the abridged procedure where the product contains the same therapeutic moiety as the reference product, even though combined with another salt.

B — *The application for a marketing authorisation for the product in the United Kingdom under the mutual recognition procedure*

34. While the procedure initiated by SmithKline was pending, Synthon applied to the Licensing Authority for a marketing authorisation in relation to Varox in the United Kingdom under the mutual recognition procedure provided for in Article 28 of Directive 2001/83. The applicant based its application on the authorisation issued by the Danish Medicines Agency.

35. By letter dated 19 January 2001, the Licensing Authority rejected the application for mutual recognition lodged by Synthon on the ground that different salts of the same active moiety (in this case paroxetine

21 — Case C-74/03 [2005] ECR I-595.

mesylate and paroxetine hydrochloride hemihydrate) have a different qualitative and quantitative composition and cannot therefore be regarded as essentially similar.

36. On 12 February 2001, Synthon informed the Licensing Authority that the Kingdom of Spain, the Portuguese Republic and the Kingdom of Norway had also refused to recognise the marketing authorisation issued by the Danish authorities owing to discrepancies as to the legal basis of the application.

37. On 21 November 2002, the applicant brought a second application for mutual recognition, which the Licensing Authority once again rejected.

38. On 28 February 2003, Synthon brought before the High Court of Justice an application for annulment of that decision.

39. The applicant maintained, in particular, that the Licensing Authority was, under Directive 2001/83, bound to recognise the marketing authorisation issued by the Danish Medicines Agency within 90 days unless it considered that there was a risk to public health, which it did not claim in this case. Furthermore, Synthon claimed that the administrative practice of the Licensing Authority, in taking the view that different salts of the same active moiety could not, as such, be regarded as essentially similar, was contrary to Community law. In this regard the applicant argues that the refusal by the United Kingdom authorities to recognise the marketing authorisation issued by the reference Member State amounted to a sufficiently serious breach of Community law within the meaning of the judgment of the Court of Justice in *Brasserie du pêcheur and Factortame* [22] and has, accordingly, applied for damages.

40. It is clear from the summary of the facts established by the national court that the Licensing Authority did not reject the applicant's applications for the reason referred to in Article 29 of Directive 2001/83, namely, risk to public health.

III — The questions referred for a preliminary ruling

41. Having doubts as to the interpretation of Community law, the national court has

22 — Joined Cases C-46/93 and C-48/93 [1996] ECR I-1029.

decided to stay proceedings and to refer the following questions to the Court for a preliminary ruling:

'(1) Where:

— [the Member State concerned] receives an application pursuant to Article 28 of [Directive 2001/83] for mutual recognition in the [Member State concerned] of a marketing authorisation of a medicinal product granted by [the reference Member State];

— such marketing authorisation was granted by the reference Member State pursuant to the abridged application procedure in Article 10(1)(a)(iii) of [Directive 2001/83] on the grounds that the [product concerned] is essentially similar to the reference product;

— the [Member State concerned] operates a procedure for validation of the application during which it checks that the application contains the particulars and documents required by Articles 8, 10(1)(a)(iii) and 28 of [Directive 2001/83], including that the particulars provided are compatible with the legal basis upon which the application is submitted;

(a) is it compatible with [that] Directive and in particular Article 28 for the [Member State concerned] to check that the [product concerned] is essentially similar to the [reference product] (without carrying out any substantive assessment), to refuse to accept and review the application and not proceed to recognise the marketing authorisation granted by the reference Member State on the grounds that in its opinion the [product concerned] is not essentially similar to the [reference product]? or

(b) is the [Member State concerned] obliged to recognise the marketing authorisation granted by the reference Member State within 90 days of receipt of the application and the assessment report pursuant to Article 28(4) of [Directive 2001/83] unless the

[Member State concerned] invokes the procedure set out in Articles 29 to 34 of [that] Directive (which is applicable where there are grounds for supposing that the marketing authorisation of the product may present a risk to public health within the meaning of Article 29 of [that] Directive)?

(3) Where the failure of the [Member State concerned] to recognise the marketing authorisation granted by the reference Member State as set out in Question 1 above is based on a general policy adopted by the [Member State concerned] that different salts of the same active moiety cannot, as a matter of law, be considered essentially similar, does the failure by the [Member State concerned] to recognise the marketing authorisation granted by the reference Member State in the circumstances referred to above amount to a sufficiently serious breach of Community law within the meaning of the second condition in the judgment in [*Brasserie du pêcheur and Factortame*]? Alternatively, what factors ought the national court to take into consideration when it comes to determine whether such failure amounts to a sufficiently serious breach?'

(2) If the answer to Question 1(a) is no and the answer to Question 1(b) is yes, where the [Member State concerned] rejects the application at the validation stage on the grounds that the [product concerned] is not essentially similar to the [reference product], and thereby fails to recognise the marketing authorisation granted by the reference Member State or to invoke the procedure set out in Articles 29 to 34 of [Directive 2001/83], does the failure by the [Member State concerned] to recognise the marketing authorisation granted by the reference Member State in the circumstances referred to above amount to a sufficiently serious breach of Community law within the meaning of the second condition in the judgment in [*Brasserie du pêcheur and Factortame*]? Alternatively, what factors ought the national court to take into consideration when it comes to determine whether such failure amounts to a sufficiently serious breach?

42. Since the submission of this reference for a preliminary ruling, it appears that the Licensing Authority has altered its decision-making practice as a result of the amendments made to Directive 2001/83 by Commission Directive 2003/63/EC of 25 June 2003. [23] The authority now allows applications claiming essential similarity between products containing different salt forms of the same active moiety.

23 — OJ 2003 L 159, p. 46.

43. Synthon, therefore, in April 2005 made a third application for mutual recognition of the marketing authorisation issued by the Danish authorities for Varox. The Licensing Authority authorised the marketing of Varox on 6 February 2006.

IV — Analysis

44. I shall begin by examining the first question referred for a preliminary ruling and then go on to deal with the second and third questions referred by the national court.

A — *Concerning the first question*

45. By its first question, the national court in essence asks the Court to determine whether a Member State which receives an application for mutual recognition of a marketing authorisation pursuant to Article 28 of Directive 2001/83 issued by the reference Member State under the abridged procedure may reject the application on the ground that the product in question is not, in its view, essentially similar to the reference product.

46. The Court is therefore requested to rule on the scope of the discretionary power enjoyed by a Member State in the context of the mutual recognition procedure laid down in Article 28 of Directive 2001/83.

1. Observations of the parties

47. In addition to Synthon, SmithKline, the Commission, the Republic of Poland, the United Kingdom of Great Britain and Northern Ireland and the Kingdom of Norway have submitted observations on the questions referred by the national court.

48. Synthon, the Commission and the Republic of Poland essentially argue that it is contrary to Article 28 of Directive 2001/83 for a Member State to reject an application for mutual recognition of a marketing authorisation issued by another Member State on the basis of the abridged procedure provided for in Article 10(1)(a)(iii) of the Directive on the ground that the product in question is not

essentially similar to the reference product. On the contrary, they take the view that any Member State is bound to recognise within a period of 90 days a marketing authorisation granted by another national authority unless it invokes the exception provided for in Article 29(1) of the Directive.

49. As the Commission and the Republic of Poland acknowledge, the Member State concerned certainly has the option under Article 28 of Directive 2001/83 of applying a 'validation' procedure to verify the administrative correctness of the dossier submitted by the applicant. However, that procedure is merely formal in nature and does not permit a Member State concerned to repeat the evaluation carried out by another Member State in order to determine whether the product authorised is in fact essentially similar to the reference product.

50. Furthermore, Synthon points out that the approach adopted by the Licensing Authority also runs counter to the objectives pursued by the establishing of a procedure for mutual recognition of marketing authorisations and, in particular, to the objective of avoiding the fruitless repetition of the toxicological and pharmacological tests and clinical trials for the purpose of evaluating the product in question.

51. The United Kingdom of Great Britain and Northern Ireland and the Kingdom of Norway do not share that view. They observe first of all that, in order to obtain mutual recognition of a marketing authorisation under Article 28 of Directive 2001/83, the applicant must submit an application accompanied by the 'particulars and documents required by Articles 8, 10(1) and 11' of that directive. Therefore it is necessary in their view for the Member State concerned to verify the legal validity of that application. Accordingly, in the context of an abridged procedure, they consider that the Member State concerned ought to check whether the product in question is essentially similar to the reference product. If not, the application will then not comply with the conditions laid down in Article 28(2) of that directive and will accordingly be invalid.

52. SmithKline for its part emphasises the distinction between the in-depth scientific evaluation of the product which precedes the grant of a marketing authorisation, and the validation procedure which, in contrast, forms part of the procedure for the mutual recognition of the marketing authorisation. With regard to the latter procedure, SmithKline considers that, notwithstanding the many legislative amendments, and also the various instructions published by the Commission, the mutual recognition procedure retains the essential characteristics of a national approval system. It follows from this that the Member States concerned remain free to assess whether authorisations issued by other national authorities are well founded.

2. Analysis

53. Like Synthon, the Commission and the Republic of Poland, I believe that a Member State which receives an application for mutual recognition of a marketing authorisation pursuant to Article 28 of Directive 2001/83, issued by another Member State under an abridged procedure, may not reject that application on the ground that the product in question is not essentially similar to the reference product.

54. I base my assessment not only on the wording of Article 28 of the Directive, but also on the broad logic and purpose of the procedure for mutual recognition referred to in that provision.

55. Before embarking on an examination of that provision, I should like to point out that Article 28 of Directive 2001/83, like Article 18 thereof, is based on the principle of mutual recognition of national marketing authorisations. However, these two procedures must be distinguished from one another.

56. In fact, Article 18 of the Directive applies to the situation in which a national authority, having received an application for a marketing authorisation for a medicinal product, finds by means of an examination of the documents and information appended to the dossier by the applicant that an authorisation has already been issued for that product by another national authority. This situation was covered by Article 7a of Directive 65/65. It is not the case here.

57. Article 28 of Directive 2001/83 applies to a situation in which a Member State is *formally seised* of an application for a marketing authorisation. That is the position in this case. The scope and detailed rules for applying the procedure were laid down in Articles 9 and 10 of Directive 75/319, before being consolidated in almost identical terms in Articles 28 and 29 of Directive 2001/83.

(a) The wording of Article 28 of Directive 2001/83, in conjunction with the scheme of the procedure established by that provision

58. I would point out that Article 28 of Directive 2001/83 forms part of Chapter 4, entitled 'Mutual recognition of authorisations'. It lays down the circumstances in which a marketing authorisation issued by

one Member State may be recognised by another Member State.

59. Article 28(4) of the Directive, I would point out, states that '[s]ave in the exceptional case provided for in Article 29(1), each Member State shall recognise the marketing authorisation granted by the reference Member State within 90 days of receipt of the application and the assessment report'.

60. The exception referred to in Article 29(1) of the Directive is, as we shall see, based on the existence of a potential risk to public health.

61. Article 28(4) of Directive 2001/83 is couched in general terms favouring the mutual recognition of marketing authorisations.

62. Its wording is unequivocal. As the Community judicature has pointed out, this is a binding mechanism. [24]

24 — Case T-273/03 *Merck Sharp & Dohme and Others* v *Commission* [2006] ECR II-141, paragraph 87 and case-law cited.

63. So, unless it raises the exception referred to in Article 29(1) of Directive 2001/83, a Member State receiving an application for mutual recognition is bound to recognise the marketing authorisation issued by the reference Member State.

64. In order to understand a Member State's obligations flowing from the implementation of a mutual recognition procedure, it is necessary to explain the basis of the procedure.

65. The mutual recognition procedure is based, first of all, on the unity of the law. In order for a marketing authorisation to be recognised, the various national regimes for marketing authorisations must in point of fact be concordant. The Community pharmaceutical legislation fully harmonises the conditions for marketing medicinal products, and in particular the conditions for issuing marketing authorisations. It fixes the rules relating to analytical, toxico-pharmacological and clinical norms and protocols which the Member States are to follow in order to enable the competent authorities to make assessments on the basis of uniform tests and according to common criteria. It also lays down the conditions in which medicinal products must be manufactured, imported and labelled.

66. Next, the procedure for mutual recognition is based on mutual confidence between the Member States.

67. Under this procedure, a marketing authorisation is no longer a decision handed down on the basis of the law of the Member State concerned. That Member State must in fact rely on the scientific examination and assessment conducted by the competent authorities of the reference Member State.

68. In this spirit, the Member State concerned has very limited discretion. Under the wording of Article 28 of Directive 2001/83, its role is limited to verifying that the application for mutual recognition satisfies the requirements laid down in Article 28(2).

69. The Member State concerned must therefore satisfy itself that the dossier submitted to it contains the documents and particulars referred to in Articles 8 and 10 of the Directive and a summary of the characteristics of the product. It must also check that the dossier is identical with that accepted by the reference Member State, and that any additions or amendments it contains have been identified by the applicant.

70. Contrary to the role it plays in the context of examination of an application for marketing authorisation under Article 19 of Directive 2001/83, the powers of the Member State dealing with an application for mutual recognition are therefore reduced to the strictly legal aspect of the application. It cannot therefore, in my view, make a fresh examination of the substance of the application for marketing authorisation or repeat the investigations already conducted in this connection by the reference Member State. Nor can it decide to submit the product to additional verifications or require the applicant to supplement the dossier beyond the requirements laid down in Article 28(2) of the Directive.

71. Finally, the mutual recognition procedure limits the grounds on which a Member State may refuse to recognise a marketing authorisation, which prevents it exercising any discretionary power.

72. Thus, under Article 28(4) of Directive 2001/83, the Member State concerned may rely on the exception in Article 29(1) of the Directive only in order not to recognise within the time-limit the marketing authorisation issued by the reference Member State. It must therefore show that 'there are grounds for supposing that the marketing authorisa-

tion of the medicinal product concerned may present a risk to public health'. [25]

73. That proviso is the only exception to the principle of the mutual recognition of marketing authorisations.

74. It must, like any derogation from a principle, be interpreted strictly.

75. The concept of 'risk to public health' within the meaning of Article 1(28) of Directive 2001/83 covers risks connected with the quality, safety, and efficacy of the product. [26] The Member State concerned is not bound to show that there is a danger to public health. It need only, under Article 29(1) of the Directive, show that there are 'grounds' for supposing that to be the case. In the words of the recital 12 in the preamble to the Directive, the grounds must none the less be 'serious'.

76. The Member State concerned may thus challenge the findings made by the reference Member State in assessing the product [27] if there are scientific facts showing that it does not fulfil the required conditions of safety, efficacy or quality. It is only in this context that, in my view, a Member State which receives an application for mutual recognition may challenge the assessment made by the reference Member State, based on the precautionary principle. Pursuant to Article 29(1) of Directive 2001/83, the Member State concerned must therefore give reasons for its point of view in a detailed manner and, I believe, produce the scientific data on the basis of which it considers that the marketing of the product might entail a risk to public health.

77. Where the Member State concerned has doubts as to the efficacy, quality or safety of the product, the Community legislature has not made provision for it to reject an application for mutual recognition on its own initiative. On the contrary, it has laid down, in Article 29 of Directive 2001/83, a procedure

25 — That exception is an expression of the principle of precaution. It is also a legitimate ground under Article 30 EC.

26 — See also guideline adopted by the Commission in March 2006 on the definition of potential serious risk to public health in the context of Article 29(1) and (2) of Directive 2001/83 (OJ 2006 C 133, p. 5). The guideline refers to Article 29(1) and (2) of the Directive, as amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 (OJ 2004 L 136 p. 34).

27 — Under Article 28(1) of Directive 2001/83, the reference Member State is bound to establish, to update and to communicate to the Member State concerned an assessment report in relation to the product. Under Article 21(4) of the Directive, the report is to contain the comments of the reference Member State on the results of the analytical and pharmaco-toxicological tests and clinical trials of the product and is further to be updated 'whenever new information becomes available which is of importance for the evaluation of the quality, safety or efficacy of the medicinal product concerned'.

for consultation between the Member States concerned and for Community arbitration. [28]

78. That procedure must enable the Member States to adopt a common approach with regard to marketing authorisations. It is, therefore, only under that procedure that the scientific evaluation of the area of disagreement is undertaken and the action to be taken in response to the application for mutual recognition is decided. [29]

79. As the Community judicature has observed, this is also a binding procedure. [30]

80. Having regard to the foregoing, a Member State receiving an application for mutual recognition of a marketing authorisation pursuant to Article 28 of Directive 2001/83 has only very limited discretion. It cannot but be observed that that provision does not give the Member State concerned the option of making the recognition of an authorisation subject to conditions other than that referred to in Article 29(1) of the Directive.

81. In my view, that interpretation of Article 28 of the Directive is valid, whether the marketing authorisation was issued by the reference Member State under the normal procedure referred to in Article 8 of Directive 2001/83 or under the abridged procedure laid down in Article 10(1) of the Directive. [31]

82. The latter procedure, I would note, relieves the applicant from the need to provide the results of toxicological and pharmacological tests and clinical trials, if it is shown that the relevant product is 'essentially similar' to a product already authorised for at least 6 or 10 years in the Community and marketed in the Member State to which the application is made. In this situation the competent authority must refer to the toxicological and pharmacological tests and clinical trials of the reference product. The procedure reduces the period for preparing an application for authorisation, by relieving the applicant of the obligation to perform some of the tests provided for in Article 8(3)(i) of Directive 2001/83. In accordance

28 — In accordance with that provision, the Member States concerned must first of all use their best endeavours to reach agreement on the action to be taken in respect of the application. If they fail to do so, the matter is to be referred to the Committee for Proprietary Medicinal Products in order for it to issue a reasoned opinion on the question raised in accordance with Article 32 of Directive 2001/83. The final decision is to be adopted by the Commission at the end of the procedure laid down in Articles 33 and 34 of the Directive.

29 — See recital 12 in the preamble to Directive 2001/83.

30 — *Merck Sharp & Dohme and Others* v *Commission*, paragraph 87 and case-law cited.

31 — It is to be borne in mind that in this case the marketing authorisation issued to Synthon by the Danish Medicines Agency was issued in the context of the abridged procedure set out at the time of the facts in the main proceedings in Article 4, second paragraph, point 8(a)(iii), of Directive 65/65 (consolidated in Article 10(1)(a)(iii) of Directive 2001/83).

with recital 10 in the preamble to the Directive, the abridged procedure also makes it possible to avoid, on public policy grounds, repetitive testing on humans or animals without overriding cause.

83. This procedure is expressly referred to in Article 28(2) of Directive 2001/83, which, I would recall, lays down the conditions in which an application for mutual recognition may be made. In the words of that provision, the holder of the authorisation must append to his application for mutual recognition 'the information and particulars referred to in Articles 8, *10(1)* and 11'. [32] By so providing, the Community legislature intended, therefore, to enable the applicant to obtain recognition of a marketing authorisation that it had acquired under either the normal or the abridged procedure.

84. Next, in Article 28(4) of Directive 2001/83, the Community legislature makes no distinction, in the laying-down of the mutual recognition procedure, depending on whether the authorisation was issued under the normal or the abridged procedure.

85. This may be explained by the fact that a marketing authorisation issued under an abridged procedure offers the same guarantees in terms of safety and efficacy as an authorisation granted under a normal procedure. As the Court has stated, the abridged procedure does not relax the requirements of safety and efficacy which must be met by medicinal products. [33]

86. In fact, although the applicant may be relieved of the requirement to provide the results of the toxicological and pharmacological tests and clinical trials for the product, he is none the less required to demonstrate that the product is 'essentially similar' to a product which has already been authorised according to the Community provisions in force for at least 6 or 10 years in the Community and is marketed in the Member State to which the application is made.

87. The concept of an 'essentially similar' medicinal product has not been defined by the Community legislature, but was defined by the Court in its judgment in *Generics (UK) and Others*. [34]

32 — My emphasis.

33 — Case C-440/93 *Scotia Pharmaceuticals* [1995] ECR I-2851, paragraph 17.

34 — Case C-368/96 [1998] ECR I-7967, paragraph 24.

88. In the light of that case-law, an applicant relying on the essential similarity of two medicinal products must show that the product in question has the same qualitative and quantitative composition of active substances as well as the same pharmaceutical form as the reference product. He must also prove that the two products are bioequivalent [35] and that the product in respect of which he applies for marketing authorisation does not differ significantly from the reference product in terms of safety or efficacy.

89. In the light of the foregoing, and in particular of the wording of Article 28 of Directive 2001/83, I am of the view that a Member State receiving an application for mutual recognition of a marketing authorisation issued under an abridged procedure must examine the application in the same way as it examines an application for marketing authorisation issued under the normal procedure.

90. The examination which it conducts must therefore be confined to ascertaining whether the application has satisfied the requirements set out in Article 28(2) of the Directive. In such a case, the Member State concerned cannot have recourse to fresh scientific evaluations of the product. Nor, in my view, can it repeat tests already carried out by the reference Member State or, in this connection, carry out a fresh examination of the essential similarity of the product to the reference product. Such conduct would, by its very nature, run counter to the principle of mutual recognition. It would, furthermore, render nugatory the consultation and arbitration procedure established by the Community legislature which seeks to ensure that scientific evaluation of areas of disagreement should be performed at Community level.

91. In addition, the Member State to which such an application is made remains bound to recognise that authorisation unless it is able to invoke an objective reason concerning the protection of public health. In that case, Directive 2001/83 offers it no choice other than to initiate the procedure provided for in Article 29 of the Directive.

92. That is why I am of the view that it is incompatible with Article 28 of the Directive not only for a Member State, receiving an application for mutual recognition of a marketing authorisation issued by the reference Member State under the abridged procedure, to make a fresh examination of the essential similarity of the two products but also for it to reject the application on the ground that the product in question is not essentially similar to the reference product.

35 — Two medicinal products are bioequivalent if they are pharmaceutically equivalents or alternatives and if their bioavailability (level and speed) after administration, in the same molar dose, is so similar that their effects both from the point of view of their efficacy and from that of their safety are essentially the same (see *The Rules governing medicinal products in the European Union*, EudraLex, Vol. 3C, Guidelines on medicinal products for human use — Efficacy, 1998 Edition, p. 235).

93. That interpretation of Article 28 of Directive 2001/83 is corroborated by the broad logic and purpose of the procedure for mutual recognition established by the Community legislature.

(b) The scheme and purpose of the mutual recognition procedure.

94. Article 28 of Directive 2001/83 must also be construed in the light of the objectives pursued by the Community legislature. [36]

95. As I have indicated, this provision forms part of Chapter 4 of Directive 2001/83, which is entitled 'Mutual recognition of authorisations'. In putting in place a procedure named 'mutual recognition', the Community legislature pursues various objectives.

96. The system in place must first of all make it possible to ensure the highest level of protection in the administration of marketing authorisations for medicinal products. [37] It must guarantee to European citizens that the medicinal products authorised to be marketed have been subjected to an evaluation based on strict scientific rules with regard to quality, safety and efficacy, and that the products will be used in the same conditions in the whole of the European Union. The exception in Article 29(1) of Directive 2001/83, on the ground of protection of public heath, makes it possible, where there is scientific uncertainty, to rely on a scientific evaluation common to the Member States. That procedure thus makes it possible to guarantee the uniformity of decisions authorising marketing throughout the Union.

97. Beyond protecting public health, the procedure for mutual recognition is intended, next, to facilitate the free movement of medicinal products in the common market and to encourage the growth of the pharmaceutical industry. [38] To that end, this procedure is designed to harmonise national marketing authorisations by eliminating repeated assessments and varying evaluations as between the competent national authorities. Thus it allows pharmaceutical companies more rapid access to the single European market, by shortening national

36 — For a recent application by the Court of this method of interpretation, see Case C-268/06 *Impact* [2008] ECR I-2483, paragraph 110 and case-law cited.

37 — I would point out that, under recital 12 in the preamble to Directive 2001/83, the protection of public health is classed as an 'essential objective'.

38 — Recital 3 in the preamble to Directive 2001/83.

administrative procedures and rationalising the use of resources required for the authorisation and supervision of medicinal products. [39]

98. In the light of the objectives of Article 28 of Directive 2001/83, I cannot agree with the interpretation proposed by the United Kingdom to the effect that a Member State which receives an application for mutual recognition could make a fresh examination of the application and reject it for a reason other than a potential risk to public health.

99. That interpretation would render meaningless the principle of mutual recognition, which constitutes the keystone of Article 28 of Directive 2001/83.

100. In fact, if we were to allow the Member State concerned to examine and assess the application for mutual recognition in the same way as it examines an application for marketing authorisation, that would deprive the mutual recognition procedure of all meaning. On that interpretation we would run the risk of divergent assessments by national authorities. Furthermore, recourse by the Member State concerned to fresh scientific evaluations of the product could be interpreted as a sign of mistrust with regard to the checks already carried out by the competent authorities of the reference Member State. Such an approach would therefore destroy the vital mutual confidence between the Member States.

101. Furthermore, if the Member State concerned could on its own initiative reject an application for mutual recognition, there would be no uniformity of national marketing authorisations, and such an approach would negate the effectiveness of the consultation and arbitration procedure established for this purpose by the Community legislature.

102. Finally, if we were to allow the Member State concerned to rely on a ground other than that expressly referred to in Article 29(1) of Directive 2001/83, in order not to recognise a marketing authorisation, such an approach would have the effect of limiting the scope of the obligation set out in Article 28(4) of the Directive.

103. In the light of all of the foregoing, I therefore propose that the Court should find that Article 28 of Directive 2001/83 must be interpreted as meaning that a Member State, receiving an application for mutual recognition of a marketing authorisation issued by the reference Member State

39 — Recital 15 in the preamble to the Directive.

under the abridged procedure referred to in Article 10(1)(a)(iii) of the Directive, is bound to recognise that authorisation within a period of 90 days following receipt of the application and of the assessment report, unless it invokes the exception set out in Article 29(1) of the Directive, based on the existence of a potential risk to public health.

104. Accordingly, I take the view that it is contrary to Article 28 of Directive 2001/83 for the Member State concerned, in the context of the examination of the application for mutual recognition, to investigate afresh the essential similarity of the two medicinal products and to reject the application in question on the ground that the two products are not essentially similar within the meaning of Article 10(1)(a)(iii) of the Directive.

105. Next, the national court seeks to know whether, in circumstances such as those in the main proceedings, the Member State concerned has committed a sufficiently serious breach of Community law.

106. In the comments that follow, I shall examine together the second and third questions referred for a preliminary ruling.

B — *Concerning the second and third questions*

107. By its second and third questions, the national court seeks, essentially, to ascertain whether a Member State which has rejected an application for mutual recognition of a national marketing authorisation on the ground that the product in question is not essentially similar to the reference product, thus not recognising the authorisation in accordance with the conditions fixed by Article 28 of Directive 2001/83, has committed a sufficiently serious breach of Community law within the meaning of the second condition laid down by the Court of Justice in *Brasserie du pêcheur and Factortame*.

108. The national court asks, in addition, whether that condition is satisfied when that Member State's refusal of recognition is based on a general practice in that State whereby different salts of the same therapeutic moiety cannot in law be regarded as being essentially similar.

1. Observations of the parties

109. Synthon and the Republic of Poland argue that, having regard to the clarity and precision of the wording of Article 28 of Directive 2001/83, and to the limited discretion enjoyed by the Licensing Authority, the latter's refusal to allow an application for mutual recognition of the marketing authorisation already delivered in another Member State constitutes a sufficiently serious breach of Community law.

110. Furthermore, Synthon claims that the administrative practice of the Licensing Authority, on which the refusal to accept the application for mutual recognition in question was based, in itself represents a serious and manifest breach of Community law such as to justify the award of damages.

111. The Commission and the United Kingdom, on the other hand, consider that, in accordance with the case-law of the Court, the factors to be taken into account in order to determine whether the breach of Community law is 'sufficiently serious', namely, the discretion enjoyed by the Member States, whether the breach was intentional or involuntary, and whether the error of law was excusable or inexcusable, fall within the sole jurisdiction of the national court. Therefore, in the context of the main proceedings, the Court ought not to determine this issue.

112. In the alternative, the Commission and the United Kingdom consider that the infringement ought not to be regarded as a serious breach of Community law, as the concepts of 'essentially similar product' and 'generic product' are complex and extremely difficult to discern, so that the Licensing Authority's approach was not unreasonable.

113. Furthermore, the United Kingdom adds that the infringement was not committed deliberately. The national authority acted in good faith, given that there was no consolidated Community case-law on this point.

2. Analysis

114. I would point out that the principle of State liability for damage caused to individuals by infringements of Community law attributable to the State was established by the Court in its judgment in *Francovich and Others*. [40] According to the Court, '[this prin-

40 — Joined Cases C-6/90 and C-9/90 [1991] ECR I-5357, paragraph 37.

ciple] is inherent in the system of the [EC] Treaty'. [41]

115. The principle has been the subject of numerous developments since *Brasserie du pêcheur and Factortame*, relating to State liability attributable to the legislature or the administration. The principle of State liability — because it is inherent in the system of the Treaty — is valid for any situation in which there is a breach of Community law and whatever the organ of the State may be whose act or omission was responsible for the breach. [42]

116. It is to be pointed out to the national court that, where a breach of Community law by a Member State is attributable to a public authority, the individuals who suffer damage have a right to compensation if three conditions are met: the rule infringed is intended to confer rights on them; the breach is sufficiently serious; and there is a causal link between the breach and the damage sustained by the individuals. [43] Subject to that reservation, it is under the national law of liability for tort or delict that the State must make good the consequences of the harm caused by the infringement of Community law attributable to it, provided that the conditions laid down by national law are not less favourable than those relating to similar claims under domestic law or organised in such a way as to render it virtually impossible or excessively difficult to obtain compensation.

117. In the case in the main proceedings, it is clear from the decision for reference and from the wording of the question that the latter is limited to the second condition laid down in the case-law. The two other conditions were not the subject of any question from the High Court of Justice.

118. The nature of the breach at issue was clarified by the Court of Justice in *Brasserie du pêcheur and Factortame*. The Court distinguished two situations.

41 — Ibid., paragraph 35. This formula has invariably been repeated by the Court, in particular in *Brasserie du pêcheur and Factortame*, paragraph 31; Case C-392/93 *British Telecommunications* [1996] ECR I-1631, paragraph 38; C-5/94 *Hedley Lomas* [1996] ECR I-2553, paragraph 24; Joined Cases C-178/94, C-179/94 and C-188/94 to C-190/94 *Dillenkofer and Others* [1996] ECR I-4845, paragraph 20; Joined Cases C-283/94, C-291/94 and C-292/94 *Denkavit and Others* [1996] ECR I-5063, paragraph 47; Case C-319/96 *Brinkmann* [1998] ECR I-5255, paragraph 24; Case C-424/97 *Haim* [2000] ECR I-5123, paragraph 26; Case C-150/99 *Stockholm Lindöpark* [2001] ECR I-493, paragraph 36; Case C-118/00 *Larsy* [2001] ECR I-5063, paragraph 34; and Case C-224/01 *Köbler* [2003] ECR I-10239, paragraph 30.

42 — *Brasserie du pêcheur and Factortame*, paragraphs 31 and 32. This formula was in particular repeated and extended by the Court in Case C-302/97 *Konle* [1999] ECR I-3099, paragraph 62; and in *Haim*, paragraph 27; *Larsy*, paragraph 35; and *Köbler*, paragraph 36.

43 — See, in particular, Case C-278/05 *Robins and Others* [2007] ECR I-1053, paragraph 69 and case-law cited.

119. First, if, when it committed the infringement, the Member State in question was not called upon to make any legislative choices and had no, or considerably reduced or non-existent discretion, the mere infringement of Community law may be sufficient to establish the existence of a sufficiently serious breach. That is the case, for example, where Community law requires the national legislature in a field governed by Community law to achieve a particular result or to take action [44] or refrain from taking action. That wide concept of State liability has been applied on many occasions by the Court, particularly in the event of non-transposition of a directive, [45] or where a directive has been transposed in a manner that disregards its temporal effects, [46] or where the administrative authorities have refused to issue an export licence even though the grant of such licence ought to have been more or less automatic having regard to the fact that there were harmonising directives in the field concerned. [47]

120. Secondly, the Court considers that when a Member State acts in a field in which it has broad discretion, it can incur liability only if the breach is sufficiently serious, that is to say, when, in the exercise of its legislative functions, it has manifestly and gravely disregarded the limits on the exercise of its powers. [48]

121. None the less, it appears that this distinction is no longer relevant in the light of the manner in which the case-law has developed. In fact, the Court now uses the same criteria to assess whether there has been a sufficiently serious breach in either situation.

122. Therefore, in order to determine whether an infringement of Community law constitutes a sufficiently serious breach, the Court takes the view that the national court must take account of all the factors which characterise the situation put before it. [49]

123. Those factors include, in particular, in addition to the clarity and precision of the rule infringed and the discretion left to the national authorities by that rule, whether

44 — See *Francovich and Others*, paragraph 46, referring to the situation where a directive has not been transposed.

45 — See *Dillenkofer and Others*, paragraph 26.

46 — See Case C-140/97 *Rechberger and Others* [1999] ECR I-3499, paragraph 51.

47 — See *Hedley Lomas*, paragraphs 18, 28 and 29.

48 — See *Brasserie du pêcheur and Factortame*, paragraphs 45, 47, 51 and 55.

49 — See *Robins and Others,* paragraph 76 and case-law cited.

the infringement or the damage caused was intentional or involuntary, whether any error of law was excusable or inexcusable, and the fact that the position taken by a Community institution may have contributed towards the adoption or maintenance of national measures or practices contrary to Community law. [50]

124. At this point it should be noted that in *Brasserie du pêcheur and Factortame*, the Court took the view that it 'cannot substitute its assessment for that of the national courts, which have sole jurisdiction to find the facts in the main proceedings and decide how to characterise the breaches of Community law at issue'. [51]

125. It stated, none the less, that it '[would] be helpful to indicate a number of circumstances which the national courts might take into account'. [52] That case-law has been confirmed on several occasions. [53] It applies in full in the case of an action involving State liability as a result of a breach of Community law by a public authority. In accordance with that case-law, I shall make some observations on this case in the light of the information available.

126. As I was able to establish in the examination of the first question, Article 28 of Directive 2001/83 leaves to the competent national authority a particularly narrow discretion.

127. As I have said, the wording of Article 28(4) of the Directive is in my view very clear and precise. It requires the Member State receiving an application for mutual recognition of a marketing authorisation to recognise it within a period of 90 days from receipt of the application and of the assessment report, unless it can rely on the exception expressly set out in Article 29(1)

50 — Ibid., paragraph 77 and case-law cited. I should point out that the Court does not establish any hierarchy for these different criteria.

51 — Paragraph 58. Confirmed since in settled case-law (see, in particular, *British Telecommunications,* paragraph 41; *Brinkmann*, paragraph 26; and *Stockholm Lindöpark*, paragraph 38).

52 — *Brasserie du pêcheur and Factortame*, paragraph 58.

53 — See, in particular, *Konle*, paragraph 59; *Haim*, paragraph 44; *Stockholm Lindöpark*, paragraph 38; and recently, *Robins and Others*, paragraphs 78 to 82. None the less, I would point out that in some judgments the Court itself assessed whether there was a sufficiently serious breach of Community law. I refer in this connection to *British Telecommunications*, paragraph 41; *Brinkmann*, paragraph 26; and *Larsy*, paragraph 40. In this case I shall confine myself to laying down some guidelines which the national court could take into account in its assessment, by reason of the spirit prevailing in which the mechanism for judicial cooperation of the reference for a preliminary ruling operates.

of the Directive, namely, the existence of a potential risk to public health.

128. Furthermore, I am of the view that Article 29 of Directive 2001/83 describes with all necessary clarity the procedure which a Member State is to initiate when it has any doubt as to the quality, safety or efficacy of a medicinal product.

129. The Commission and the United Kingdom point out that the concept of an 'essentially similar' medicinal product mentioned in Article 10(1)(a)(iii) of Directive 2001/83 is complex and difficult to grasp, with the result that the infringement committed by the Licensing Authority was not unreasonable.

130. That argument does not seem to me to be relevant. That the concept might have given rise to problems of interpretation may certainly create difficulties with regard to the issue by the reference Member State of a marketing authorisation under the abridged procedure, but it cannot, in my view, entail consequences with regard to recognition of that authorisation by the Member State concerned. I have in fact demonstrated that the implementation of the mutual recognition procedure is unambiguous and does not allow any challenge to the assessment made by the reference Member State on any ground other than that of risk to public health.

131. Consequently, it does not appear to me to be possible to accept the United Kingdom's interpretation of Article 28(4) of Directive 2001/83.

132. In conducting *a novo* an examination which the reference Member State had already conducted, thereby rejecting the application for mutual recognition on a ground other than that expressly set out in Directive 2001/83, and in failing to initiate the procedure for consultation and mutual assistance provided for to this end, the United Kingdom by its interpretation in my view renders meaningless and nugatory the principle of mutual recognition and the consultation and arbitration procedures established in Articles 28 and 29 of Directive 2001/83.

133. The effect of such an interpretation is therefore to diminish the effectiveness of Community law, which is incompatible with the requirements inherent in the very nature of Community law.

134. Accordingly, it is open to us to consider that in circumstances such as those in the main proceedings the interpretation made by the Member State concerned of the meaning and scope of Article 28 of Directive 2001/83 is capable of constituting a serious breach of Community law.

V — Conclusion

135. In the light of all of the foregoing considerations, I propose that the Court reply in the following terms to the questions referred for a preliminary ruling by the High Court of Justice:

(1) Article 28 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use must be interpreted as meaning that a Member State, receiving an application for mutual recognition of a marketing authorisation issued by another Member State under the abridged procedure referred to in Article 10 (a)(iii) of Directive 2001/83, is bound to recognise that authorisation within a period of 90 days following receipt of the application and of the assessment report, unless it invokes the exception set out in Article 29(1) of Directive 2001/83, based on the existence of a potential risk to public health.

(2) It is contrary to Article 28 of Directive 2001/83 for a Member State, receiving an application for mutual recognition of a marketing authorisation issued by another Member State under the abridged procedure referred to in Article 10(1)(a)(iii) of Directive 2001/83, to investigate afresh the essential similarity of the two medicinal products and to reject the application in question on the ground that the two products are not essentially similar within the meaning of that provision.

(3) In circumstances such as those in the main proceedings, the interpretation of the meaning and scope of Article 28 of Directive 2001/83 adopted by the Member State receiving such an application is capable of constituting a serious breach of Community law.