Court of Justice EU, 14 February 2019, De Staat v Warner Lambert

PATENT LAW

In a marketing authorisation procedure, a communication of the package leaflet or summary of the product characteristics of a generic medicinal product, which does not include indications or dosage forms which were still covered by patent law at the time that medicinal product was placed on the market (carve out), constitutes a request to limit the scope of the marketing authorisation of the generic medicinal product in question

- **The second paragraph of Article 11 of Directive 2001/83 must be interpreted** as meaning that, in a marketing authorisation procedure such as that at issue in the main proceedings, communication to the competent national authority by the applicant or holder of a marketing authorisation for a generic medicinal product of the package leaflet or summary of the product characteristics of that medicinal product which does not include any reference to indications or dosage forms which were still covered by patent law at the time that medicinal product was placed on the market constitutes a request to limit the scope of the marketing authorisation of the generic medicinal product in question.

44. Even though all the parties which submitted observations to the Court agree on that point, the Netherlands Government maintains that if the marketing authorisation holder of a generic product decides to make use of the option provided for in the second paragraph of Article 11 of Directive 2001/83, that decision has no effect on the scope of the marketing authorisation of the generic medicinal product.

45. However, such an interpretation of Directive 2001/83 is incompatible with the principle recalled in paragraph 34 of this judgment, according to which any medicinal product placed on the market must comply with marketing authorisation conditions, which must be reflected in the summary of product characteristics. In accordance with that principle, in circumstances such as those set out by the Netherlands Government, it will be for the competent national authority to amend the marketing authorisation in order to ensure it reflects the summary of product characteristics. The communication of a summary of product characteristics which does not include certain marketing authorisation indications constitutes the removal of therapeutic indications covered by minor type IB variations which are subject to the procedure laid down in Article 9 of Regulation No 1234/2008.

46. Contrary to the Netherlands Government's claims, that interpretation is not invalidated by the fact that it imposes on the marketing authorisation holder the responsibility of requesting a new variation of the authorisation when, upon expiry of the protection period by a patent of an indication covered by the marketing authorisation of the reference medicinal product, the holder wishes to add that indication to those already authorised for the generic product. In such a situation, the marketing authorisation holder may request a type II variation, in accordance with the procedure provided for in Article 10 of Regulation No 1234/2008.

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Court of Justice EU, 14 February 2019

(A. Arabadjiev, C.G. Fernlund (Rapporteur) and S. Rodin)

JUDGMENT OF THE COURT (Sixth Chamber)

14 February 2019 (*)

(Reference for a preliminary ruling — Medicinal products for human use — Directive 2001/83/EC — Article 11 — Generic medicinal products — Summary of product characteristics — Exclusion of references referring to indications or dosage forms still covered by patent law at the time when the generic medicine was marketed)

In Case C‑423/17,

REQUEST for a preliminary ruling under Article 267 TFEU from the Gerechtshof Den Haag (Regional Court of Appeal, The Hague, Netherlands), made by decision of 4 July 2017, received at the Court on 13 July 2017, in the proceedings

Staat der Nederlanden

v

Warner-Lambert Company LLC,

THE COURT (Sixth Chamber),

composed of A. Arabadjiev, President of the Second Chamber, acting as President of the Sixth Chamber, C.G. Fernlund (Rapporteur) and S. Rodin, Judges,

Advocate General: J. Kokott,

Registrar: M. Ferreira, Principal Administrator,

having regard to the written procedure and further to the hearing on 14 June 2018,

after considering the observations submitted on behalf of:

– Warner-Lambert Company LLC, by C. Schoonderbeek, avocate, and by S. Dack, J.A. Dullaart and P. van Schijndel, advocaten,

– the Netherlands Government, by M. Gijzen and M.K. Bulterman, acting as Agents,

– the European Commission, by E. Manhaeve and A. Sipos, acting as Agents,

after hearing the **Opinion** of the Advocate General at the sitting on 4 October 2018,

gives the following

Judgment

1. This request for a preliminary ruling concerns the interpretation of Article 11 and Article 21(3) 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 (OJ 2001 L 311, p. 67), as amended by Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 (OJ 2012 L 299, p. 1) ('Directive 2001/83').

2. The request has been made in proceedings between the Staat der Nederlanden (Netherlands State) and Warner-Lambert Company LLC ('WLC') concerning the publication of information on the patented uses of a reference medicinal product during the decentralised marketing authorisation procedure for a generic medicinal product provided for in Article 28 of Directive 2001/83.

Legal context

Directive 2001/83

3. Article 6(1) of Directive 2001/83 provides:

'No medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with this Directive or an authorisation has been granted in accordance with Regulation (EC) No 726/2004 [of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1),] …

When a medicinal product has been granted an initial marketing authorisation in accordance with the first subparagraph, any additional strengths, pharmaceutical forms, administration routes, presentations, as well as any variations and extensions shall also be granted an authorisation in accordance with the first subparagraph or be included in the initial marketing authorisation. All these marketing authorisations shall be considered as belonging to the same global marketing authorisation, in particular for the purpose of the application of Article 10(1).'

4. Article 8(3)(i) and (j) of that directive is worded as follows:

'The application shall be accompanied by the following particulars and documents, submitted in accordance with Annex I:

…

(i) Results of:

– pharmaceutical (physico-chemical, biological or microbiological) tests,

– pre-clinical (toxicological and pharmacological) tests,

– clinical trials;

…

(j) A summary, in accordance with Article 11, of the product characteristics, a mock-up of the outer packaging, containing the details provided for in Article 54, and of the immediate packaging of the medicinal product, containing the details provided for in Article 55, together with a package leaflet in accordance with Article 59'.

5. Under Article 10(1) of that directive:

'By way of derogation from Article 8(3)(i), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised under Article 6 for not less than eight years in a Member State or in the Community.

A generic medicinal product authorised pursuant to this provision shall not be placed on the market until ten years have elapsed from the initial authorisation of the reference product.

The first subparagraph shall also apply if the reference medicinal product was not authorised in the Member State in which the application for the generic medicinal product is submitted. In this case, the applicant shall indicate in the application form the name of the Member State in which the reference medicinal product is or has been authorised. At the request of the competent authority of the Member State in which the application is submitted, the competent authority of the other Member State shall transmit, within a period of one month, a confirmation that the reference medicinal product is or has been authorised together with the full composition of the reference product and if necessary other relevant documentation.

…'

6. Article 10(2) of Directive 2001/83 defines a 'generic medicinal product' as a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated.

7. The first paragraph of Article 11 of that directive lists the information knowledge of which is essential for proper administration of the medicinal product and which must be listed in the summary of product characteristics of the pharmaceutical product. The second paragraph of that article provides:

'For authorisations under Article 10, those parts of the summary of product characteristics of the reference medicinal product referring to indications or dosage forms which were still covered by patent law at the time when a generic medicine was marketed need not be included.'

8. Article 21(2) and (3) of the directive provides:

'2. The competent authorities shall take all necessary measures to ensure that the information given in the summary is in conformity with that accepted when the marketing authorisation is issued or subsequently.

3. The national competent authorities shall, without delay, make publicly available the marketing authorisation together with the package leaflet, the summary of the product characteristics and any conditions established in accordance with Articles 21a,

22 and 22a, together with any deadlines for the fulfilment of those conditions for each medicinal product which they have authorised.'

9. Article 59(1) of Directive 2001/83 provides that the package leaflet is to be drawn up in accordance with the summary of the product characteristics.

Regulation No 726/2004

10. Article 3(3) of Regulation No 726/2004, as amended by Regulation (EU) No 1027/2012 of the European Parliament and of the Council of 25 October 2012 (OJ 2012 L 316, p. 38) ('Regulation No 726/2004') provides as follows:

'A generic medicinal product of a reference medicinal product authorised by the Community may be authorised by the competent authorities of the Member States in accordance with Directive 2001/83/EC and Directive 2001/82/EC [of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ 2001 L 311, p. 1),] under the following conditions:

(a) the application for authorisation is submitted in accordance with Article 10 of Directive 2001/83/EC or Article 13 of Directive 2001/82/EC;

(b) the summary of the product characteristics is in all relevant respects consistent with that of the medicinal product authorised by the Community except for those parts of the summary of product characteristics referring to indications or dosage forms which were still covered by patent law at the time when the generic medicine was marketed, …

…'

Regulation (EC) No 1234/2008

11. Article 4(1) of Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ 2008 L 334, p. 7), as amended by Commission Regulation (EU) No 712/2012 of 3 August 2012 (OJ 2012 L 209, p. 4) ('Regulation No 1234/2008'), provides that the European Commission is to draw up guidelines on the details of the various categories of variations, on the operation of the procedures laid down in Chapters II, IIa, III and IV of that regulation, as well as on the documentation to be submitted pursuant to those procedures.

12. Article 9 of Regulation No 1234/2008, which is in Chapter II thereof, defines the notification procedure for minor type IB variations. Article 10 of that regulation, which is in the same chapter, establishes the notification procedure for minor type II variations.

13. In accordance with Article 4(1) of Regulation No 1234/2008, the Commission has adopted the guidelines on the details of the various categories of variations, on the operation of the procedures laid down in Chapters II, IIa, III and IV of Regulation No 1234/2008 and on the documentation to be submitted pursuant to those procedures (OJ 2013 C 223, p. 1). It is apparent from point C.I.6(a) and (b) of the annex to those guidelines, first, that the addition of a new therapeutic indication or the variation of an approved indication constitutes a major type II variation and, second, that the deletion of a therapeutic indication constitutes a minor type IB variation.

The dispute in the main proceedings and the questions referred for a preliminary ruling

14. It is apparent from the explanation provided by the referring court that WLC is a company belonging to the Pfizer pharmaceutical group, which markets the medicinal product Lyrica, whose active ingredient is pregabalin. That medicinal product is intended for the treatment of epilepsy, generalised anxiety disorder and neuropathic pain.

15. On 6 July 2004, Lyrica obtained a marketing authorisation under the centralised procedure.

16. At the material time in the main proceedings, use of pregabalin for the treatment of epilepsy and generalised anxiety disorder was no longer covered by a patent. WLC was, however, the holder of European Patent EP 0 934 061 B3, granted on 28 May 2003 ('Patent EP 061'), which covered the used of pregabalin for the treatment of, inter alia, neuropathic pain. That patent expired on 17 July 2017.

17. In the Netherlands, the College ter Beoordeling van Geneesmiddelen (Medicinal Product Evaluation Board, 'the CBG') is the autonomous administrative body responsible for monitoring and assessing the efficacy, risks and quality of medicinal products. The CBG publishes on its website, inter alia, the terms of the marketing authorisation, the package leaflet and the summary of product characteristics for each medicinal product.

18. The referring court notes that producers of generic medicinal products sometimes fail to mention on the package leaflet and in the summary of the product characteristics information on a reference medicinal product relating to indications or dosages which are still covered by a patent. Until 2009, it was the CBG's practice to publish on its website the package leaflets and summaries of product characteristics not mentioned by marketing authorisation holders or applicants for generic medicinal products.

19. During 2009, the CBG abandoned that policy and decided to systematically publish all the information on the reference medicinal product, even when the applicant informed the CBG of its intention to omit certain information.

20. During 2015, several producers of generic medicinal products obtained marketing authorisation for pregabalin from the CBG under the decentralised procedure. One of those producers, Aurobindo, informed the CBG, before placing its medicinal product on the market, that it intended not to include the package leaflet and the summary of product characteristics in the information relating to the treatment of neuropathic pain. That company asked if it could publish only part of the package leaflet and of the summary of product characteristics, but the CBG refused.

21. WLC brought an action before the rechtbank Den Haag (District Court, The Hague, Netherlands) seeking, in essence, an order that CBG abandon its practice of

publishing in full on its website package leaflets and summaries of product characteristics of generic medicinal products and instead publish the edited version of those documents. WLC maintains, inter alia, that the CBG's policy of full publication constitutes a direct infringement of Patent EP 061 as it offers pregabalin for sale for a patented indication and an indirect infringement in that it encourages third parties to engage in infringements. WLC also claims that the CBG's policy is contrary to Article 11 of Directive 2001/83.

22. By judgment of 15 January 2016, the rechtbank Den Haag (District Court, The Hague) upheld WLC's action concerning pregabalin and rejected the claims concerning other medicinal products due to insufficient interest. That court found that full publication of the package leaflet and the summary of product characteristics of a medicinal product does not constitute an infringement of Patent EP 061, and is incompatible with the CBG's duty of care.

23. On 11 February 2017, the Netherlands State filed an appeal against that judgment with the referring court. WLC also lodged a cross-appeal with that court.

24. After delivery of that judgment, the CBG changed its administrative practice. It publishes the full version of the package leaflet and the summary of product characteristics in its medicinal products database. However, when the holder of a marketing authorisation for a generic medicinal product informs the CBG that certain indications have been omitted, the CBG indicates this by means of an asterisk, together with the following text:

' This indication is protected by a patent … of another marketing authorisation holder. Further information in this regard may be found on the CBG website, www.cbg-meb.nl.'*

25. The referring court takes the view that the outcome of the dispute in the main proceedings depends on the interpretation of EU legislation on medicinal products, in particular, that of Article 11 of Directive 2001/83.

26. The parties to the main proceedings agree that that provision allows the applicant for marketing authorisation in respect of a generic medicinal product not to mention indications that are still covered by a patent in the package leaflet and the summary of product characteristics. On the other hand, their positions differ as to the consequences for the national authority of a declaration whereby a marketing authorisation applicant indicates that it intends to avail itself of that option and to opt for publication of an edited version.

27. In the first place, the parties in the main proceedings are in dispute as to whether notification of the intention to publish an edited version aims to limit the marketing authorisation in so far as it will not cover patented indications or dosage forms. If this is so, then the CBG should limit the marketing authorisation and publish the package leaflet and the summary of product characteristics in accordance with the applicant's wishes, in their edited version.

28. In the second place, WLC maintains that, in any event, notification of the intention to publish an edited version requires the national authority to publish the package leaflet and the summary of product characteristics omitting the redacted information, because their full publication is contrary to the objective of the EU legislature, which is to protect the interests of patent holders. Full publication would encourage general practitioners to prescribe generic versions of medicinal products for indications or dosage forms which are still patented.

29. In those circumstances, the Gerechtshof Den Haag (Regional Court of Appeal, The Hague, Netherlands) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) Must Article 11 of Directive [2001/83] or any other provision of EU law be interpreted as meaning that a communication whereby the marketing authorisation applicant or holder for a generic medicinal product, within the meaning of Article 10 of [that directive], notifies the competent authority that he does not intend to include in the summary of product characteristics or the package leaflet those parts of the summary of product characteristics of the reference medicinal product which refer to indications or dosage forms covered by the patent of a third party should be regarded as a request to limit the marketing authorisation, which must result in the marketing authorisation not applying, or no longer applying, to the patented indications or dosage forms?

(2) If the answer to Question 1 is in the negative, do Articles 11 and 21(3) of Directive [2001/83] or any other provisions of EU law preclude the competent authority from making public, by means of an authorisation granted under Article 6 in conjunction with Article 10 of [that directive], the summary of product characteristics and the package leaflet, including those parts which refer to indications or dosage forms covered by the patent of a third party, where the marketing authorisation applicant or holder has notified the authority that he does not intend to include in the summary of product characteristics or the package leaflet those parts of the summary of product characteristics of the reference medicinal product which refer to indications or dosage forms covered by the patent of a third party?

(3) Does it make any difference to the answer to Question 2 that the competent authority requires the authorisation holder to include in the package leaflet which the authorisation holder must insert in the packaging of the medicinal product a reference to the authority's website on which the summary of product characteristics is published, including the parts which refer to indications or dosage forms covered by the patent of a third party, even though, under Article 11 of Directive 2001/83, those parts to not have to be included in the package leaflet?'

Consideration of the questions referred

The first question

30. By its first question, the referring court asks, in essence, whether the second paragraph of Article 11 of Directive 2001/83 must be interpreted as meaning that, in a marketing authorisation procedure such as that at issue in the main proceedings, communication to the competent national authority by the applicant or holder of a marketing authorisation for a generic medicinal product of the package leaflet or summary of the product characteristics of that medicinal product which does not include any reference to indications or dosage forms which were still covered by patent law at the time that medicinal product was placed on the market constitutes a request to limit the scope of the marketing authorisation of the generic medicinal product in question.

31. It must be noted at the outset that, in accordance with the essential aims of Directive 2001/83, inter alia, that of safeguarding public health, Article 6(1), first subparagraph, of that directive provides that no medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that State in accordance with that directive or an authorisation has been issued in accordance with the centralised procedure provided for in Regulation No 726/2004 for the medicinal products referred to in the annex to that regulation (judgments of 29 March 2012, Commission v Poland, C‑185/10, EU:C:2012:181, paragraph 26, and of **23 January 2018, F. Hoffmann-La Roche and Others, C‑179/16, EU:C:2018:25, paragraph 53**).

32. The principle of a mandatory marketing authorisation also applies, according to the second subparagraph of Article 6(1) of Directive 2001/83, when a medicinal product has been granted an initial marketing authorisation in accordance with the first subparagraph of that provision, in so far as, in that case, any additional strengths, pharmaceutical forms, administration routes, presentations, as well as any variations and extensions are also to be granted an authorisation in accordance with that first subparagraph or be included in the initial marketing authorisation (judgment of 21 November 2018, Novartis Farma, C‑29/17, EU:C:2018:931, paragraph 70).

33. Additionally, in order to verify whether a medicinal product meets the information needs of patients and health professionals, Article 8(3)(j) of Directive 2001/83 requires that the application for authorisation to place a medicinal product on the market be accompanied, inter alia, by a summary of the product characteristics, whose content is defined in Article 11 of that directive together with the package leaflet for the medicinal product concerned, which should be drawn up, under Article 59(1) of the directive, in accordance with the summary of the product characteristics. In that regard, Article 21(2) of Directive 2001/83 provides that *'the competent authorities shall take all necessary measures to ensure that the information given in the summary is in conformity with that accepted when the marketing authorisation is issued or subsequently'*.

34. It follows from those provisions, first, that the package leaflet and the summary of product characteristics form part of the marketing authorisation, second, that the medicinal product placed on the market must fulfil the conditions of the marketing authorisation, which must be reflected in the summary of product characteristics and, third, that the marketing authorisation holder may not amend the package leaflet or the summary of product characteristics without notifying the competent authority in order to obtain its approval.

35. In addition, in order to encourage the market entry of generic medicinal products, Article 10 of Directive 2001/83 provides for an abridged marketing authorisation procedure, by exempting marketing authorisation applicants for generic medicinal products, subject to compliance with certain conditions, of the duty to submit the results of pre-clinical tests and clinical tests.

36. Article 10(2)(b) of Directive 2001/83 requires that generic medicinal products have the same quantitative and qualitative composition in active substances and the same pharmaceutical form as the reference medicinal product and that its bioequivalence with the reference medicinal product has been demonstrated.

37. Taking into account that requirement that the reference medicinal product and the generic medicinal product covered by the abridged marketing authorisation procedure should be the same, the application for marketing authorisation of a generic medicinal product may not go beyond the indications covered by the marketing authorisation of the reference product, but must, in principle, be limited to those indications. Consequently, the summary of product characteristics accompanying the application for a marketing authorisation of a generic medicinal product cannot cover indications or dosage forms which are not consistent with those covered by the wording of the marketing authorisation of the reference product.

38. Those factors are corroborated by the fact that when, as in the case in the main proceedings, the marketing authorisation procedure for a generic medicinal product laid down in Article 10 of Directive 2001/83 concerns a reference medicinal product authorised by the centralised procedure provided for by Regulation No 726/2204, Article 3(3)(b) of that regulation expressly states that *'the summary of the product characteristics is in all relevant respects consistent with that of the medicinal product authorised by the [Union]'*.

39. As an exception to that principle that the marketing authorisation of a generic medicinal product and that of a reference product must tally, the second paragraph of Article 11 of Directive 2001/83 provides, as regards applications for marketing authorisation of generic medicinal products, that *'those parts of the summary of product characteristics of the reference medicinal product referring to indications or dosage forms which were still covered by patent law at the time when a generic medicine was marketed need not be included'*.

40. That provision therefore confers on the applicant for a marketing authorisation of a generic medicinal product the option of derogating from the principle that the marketing authorisation of a generic medicinal product and that of a reference product must tally by reducing the scope of its application to indications or dosage forms which are not covered by patent law.
41. The rationale behind this exception is not to delay entry on the market of generic medicinal products until expiry of all patents which may include several indications or dosage forms of the reference medicinal product, without any relaxation of the requirements of safety and efficacy which must be met by generic medicinal products (see, to that effect, judgment of 23 October 2014, Olainfarm, C‑104/13, EU:C:2014:2316, paragraphs 27 and 28).
42. Under a decentralised procedure, such as that at issue in the main proceedings, if the marketing authorisation applicant or holder for a generic product avails himself of the option provided for in Article 11 of Directive 2001/83, then the marketing authorisation for that product covers only the indications and dosage forms which are not patented.
43. It is clear from a combined reading of Article 8(3)(j) and the second paragraph of Article 11 of Directive 2001/83 that failure to include in the summary of product characteristics of a generic medicinal product certain indications or dosage forms of the marketing authorisation for the reference medicinal product means that those indications or dosage forms are not covered by the marketing authorisation application. By making use of the option given by the second paragraph of Article 11, the marketing authorisation applicant thus limits the scope of his application and the competent national authority does not have any discretion in that respect, as the Advocate General stated in point 57 of her **Opinion**.
44. Even though all the parties which submitted observations to the Court agree on that point, the Netherlands Government maintains that if the marketing authorisation holder of a generic product decides to make use of the option provided for in the second paragraph of Article 11 of Directive 2001/83, that decision has no effect on the scope of the marketing authorisation of the generic medicinal product.
45. However, such an interpretation of Directive 2001/83 is incompatible with the principle recalled in paragraph 34 of this judgment, according to which any medicinal product placed on the market must comply with marketing authorisation conditions, which must be reflected in the summary of product characteristics. In accordance with that principle, in circumstances such as those set out by the Netherlands Government, it will be for the competent national authority to amend the marketing authorisation in order to ensure it reflects the summary of product characteristics. The communication of a summary of product characteristics which does not include certain marketing authorisation indications constitutes the removal of therapeutic indications covered by minor type IB variations which are subject to the procedure laid down in Article 9 of Regulation No 1234/2008.
46. Contrary to the Netherlands Government's claims, that interpretation is not invalidated by the fact that it imposes on the marketing authorisation holder the responsibility of requesting a new variation of the authorisation when, upon expiry of the protection period by a patent of an indication covered by the marketing authorisation of the reference medicinal product, the holder wishes to add that indication to those already authorised for the generic product. In such a situation, the marketing authorisation holder may request a type II variation, in accordance with the procedure provided for in Article 10 of Regulation No 1234/2008.
47. In the light of all the foregoing considerations, the answer to the first question is that the second paragraph of Article 11 of Directive 2001/83 must be interpreted as meaning that, in a marketing authorisation procedure such as that at issue in the main proceedings, communication to the competent national authority by the applicant or holder of a marketing authorisation for a generic medicinal product of the package leaflet or a summary of the product characteristics of that medicinal product which does not include any reference to indications or dosage forms which were still covered by patent law at the time that medicinal product was placed on the market constitutes a request to limit the scope of the marketing authorisation of the generic medicinal product in question.

The second and third questions

48. By its second and third questions, the referring court asks, in the event that the first question is answered in the negative, whether Article 11 of Directive 2001/83 must be interpreted as precluding publication by a national authority of a full version of the package leaflet or the summary of product characteristics of a generic medicinal product in respect of which the marketing authorisation holder has made use of the option given by that provision not to include certain indications or dosage forms in the package leaflet or summary of product characteristics of the medicinal product in question.
49. Having regard to the positive answer given to the first question, there is no need to answer those questions.

Costs

50. Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Sixth Chamber) hereby rules:

The second paragraph of Article 11 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, as amended by Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012,

must be interpreted as meaning that, in a marketing authorisation procedure such as that at issue in the main proceedings, communication to the competent national authority by the applicant or holder of a marketing authorisation for a generic medicinal product of the package leaflet or a summary of the product characteristics of that medicinal product which does not include any reference to indications or dosage forms which were still covered by patent law at the time that medicinal product was placed on the market constitutes a request to limit the scope of the marketing authorisation of the generic medicinal product in question.

OPINION OF ADVOCATE GENERAL KOKOTT
delivered on 4 October 2018 (1)
Case C‑423/17
Staat der Nederlanden
v
Warner-Lambert Company LLC
(Request for a preliminary ruling
from the Gerechtshof Den Haag (Court of Appeal, The Hague, Netherlands)
(Reference for a preliminary ruling — Medicinal products for human use — Directive 2001/83/EC — Generic medicinal products — Summary of product characteristics — Carve-out for still patented indications of the reference medicinal product — Scope of the marketing authorisation for the generic medicinal product — Publication of the summary of product characteristics)

I. Introduction

1. The rules of EU law on the marketing of medicinal products, in particular Directive 2001/83/EC on medicinal products for human use, (2) which is at issue in the present case, and Regulation (EC) No 726/2004, (3) balance various, sometimes conflicting interests. It is thus necessary, on the one hand, to offer innovative pharmaceutical companies adequate incentives to develop medicinal products. On the other hand, the marketing of generic medicinal products is also to be promoted because they ease the financial burden on the health system and help to avoid excessive testing on humans and animals. (4)

2. Accordingly, generic medicinal products, that is to say, ‘copies’ of reference medicinal products, (5) can be authorised and placed on the market without providing the results of pre-clinical tests and clinical trials. However, this is possible only after a period of 10 years has elapsed, during which studies of the reference medicinal product are subject to data exclusivity. This means that manufacturers of generic medicinal products cannot rely on the documents submitted for the authorisation of the reference medicinal product, such that the manufacturer of the reference medicinal product is guaranteed time-limited exclusive distribution rights. (6)

3. After the data exclusivity period has expired, the marketing of generic medicinal products, which is then possible under EU law, may still be precluded, however, by patent rights of manufacturers of reference medicinal products which are not regulated in EU law. In such cases, Directive 2001/83 seeks once again to reconcile the various interests and to prevent patent rights relating to only certain indications or dosage forms of a reference medicinal product — patents for a second or further medical indication — from frustrating the distribution of a generic medicinal product in its entirety. (7)

4. In order to allow the possibility of a generic medicinal product being placed on the market only for indications and dosage forms of the reference medicinal product which are no longer patented, Directive 2001/83 permits an exception to the principle of the uniformity of the reference medicinal product and the generic medicinal product: manufacturers of generic medicinal products can introduce a ‘carve-out’, whereby still patented indications or dosage forms of the reference medicinal product are deleted from the summary of characteristics of the generic medicinal product. (8) The summary of characteristics is part of the authorisation documentation and contains information inter alia on applications and dosage of the medicinal product. It is aimed primarily at healthcare professionals, but also forms the basis for the package leaflet. (9) A carve-out therefore means, in particular, that the still patented indications or dosage forms of the reference medicinal product do not appear in the package leaflet for the generic medicinal product, even though, from a purely medical point of view, that product — which is identical to the reference medicinal product (10) — can also be used and thus prescribed for the indications in question and in the dosage forms in question.

5. It is not expressly regulated what effects the introduction of a carve-out in the summary of characteristics of a generic medicinal product has on the scope of the marketing authorisation for that generic medicinal product. In particular, it is unclear whether, if a carve-out is introduced after a marketing authorisation has already been granted for the generic medicinal product concerned, this marketing authorisation still applies to the indications or dosage forms which were deleted from the summary of characteristics by the carve-out or whether, in contrast, the subsequent notification of a carve-out means that the marketing authorisation must be limited to the remaining indications and dosage forms not affected by the carve-out.

6. That is the central question in this request for a preliminary ruling. It arises against the background of the practice of the Netherlands College ter Beoordeling van Geneesmiddelen (CBG), the Netherlands authority responsible for authorising medicinal products, of publishing on its website the summary of characteristics of generic medicinal products in its full label version, without taking into consideration a subsequently introduced carve-out. This practice is consistent with the position adopted by the Netherlands Government in this case, according to which at least a subsequent carve-out has no effect on the scope of a

previously granted marketing authorisation. Warner-Lambert Company (WLC) contends, as a manufacturer of a reference product, that through its practice the CBG is encouraging the prescription of generic medicinal products for a still patented indication of its reference medicinal product, which deprives the carve-out arrangement under Directive 2001/83 of its effectiveness.

7. This argument illustrates that, against the initially seemingly technical background of the main proceedings, the fundamental question is that of the spirit and purpose of the carve-out arrangement and thus of the relationship between the law on medicinal products and patent law. The Court must therefore clarify which course taken by the legislature forms the basis for the carve-out arrangement: is it intended only to eliminate obstacles to the marketing of generic medicinal products by permitting manufacturers of generic medicinal products to avoid infringements of patent rights, while the generic medicinal product in question continues to be approved for the still patented indications and dosage forms? Or did the legislature wish for effective protection of the patents concerned, thereby at the same time accepting a greater burden on national health systems? This would be the case if it were assumed that the carve-out limits the marketing authorisation for the generic medicinal products concerned as, in all likelihood, they would then no longer be prescribed for the patented indications or dosage forms of the reference medicinal product.

II. Legal framework

A. EU law

8. In addition to the purely national authorisation procedure, which is not relevant here, a marketing authorisation for a medicinal product can be obtained in the centralised procedure, the decentralised procedure (11) and the mutual recognition procedure. Directive 2001/83 lays down the legal framework for authorisations by national authorities. Regulation No 726/2004, on the other hand, governs the Commission's centralised authorisation procedure at European level. Lastly, Regulation (EC) No 1234/2008 (12) sets out the procedural steps for the examination of variations to the marketing authorisation both by the Commission and by national authorities.

1. Directive 2001/83

9. Under Article 6(1) of Directive 2001/83, *'[n]o medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with [the] Directive ...'*.

10. Article 8(3)(i) and (j) of Directive 2001/83 provides that the application for the marketing authorisation is to be accompanied in particular by the following particulars and documents:

'(i) Results of:

– pharmaceutical (physico-chemical, biological or microbiological) tests,

– pre-clinical (toxicological and pharmacological) tests,

– clinical trials; …

(j) [a] summary, in accordance with Article 11, of the product characteristics ...'

11. Article 10 of Directive 2001/83 permits the following simplified application procedure for generic medicinal products:

'1. By way of derogation from Article 8(3)(i), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised under Article 6 for not less than eight years in a Member State or in the Community.

A generic medicinal product authorised pursuant to this provision shall not be placed on the market until 10 years have elapsed from the initial authorisation of the reference product. ...'

12. With regard to the necessary information in the summary of product characteristics, the second sentence of Article 11 of Directive 2001/83 provides:

'For authorisations under Article 10, those parts of the summary of product characteristics of the reference medicinal product referring to indications or dosage forms which were still covered by patent law at the time when a generic medicine was marketed need not be included.' (13)

13. In connection with the authorisation procedure, Article 21(2) and (3) of Directive 2001/83 imposes the following duties on the authorities:

'2. The competent authorities shall take all necessary measures to ensure that the information given in the summary is in conformity with that accepted when the marketing authorisation is issued or subsequently.

3. The national competent authorities shall, without delay, make publicly available the marketing authorisation together with the package leaflet, the summary of the product characteristics and any conditions established in accordance with Articles 21a, 22 and 22a, together with any deadlines for the fulfilment of those conditions for each medicinal product which they have authorised.'

14. In the case of the amendment of the applicant's particulars, Article 23(2) of Directive 2001/83 provides:

'The marketing authorisation holder shall forthwith provide the national competent authority with any new information which might entail the amendment of the particulars or documents referred to in Article 8(3), Articles 10, 10a, 10b and 11, or Article 32(5), or Annex I. ...'

15. A refusal of the marketing authorisation is possible under Article 26 of Directive 2001/83 only if:

'1. … after verification of the particulars and documents listed in Articles 8, 10, 10a, 10b and 10c, it is clear that:

(a) the risk-benefit balance is not considered to be favourable; or

(b) its therapeutic efficacy is insufficiently substantiated by the applicant; or

(c) its qualitative and quantitative composition is not as declared.
2. Authorisation shall likewise be refused if any particulars or documents submitted in support of the application do not comply with Articles 8, 10, 10a, 10b and 10c. ...'
16. With regard to the mutual recognition procedure and the decentralised application procedure, Article 28 of Directive 2001/83 provides:
'1. With a view to the granting of a marketing authorisation for a medicinal product in more than one Member State, an applicant shall submit an application based on an identical dossier in these Member States. The dossier shall contain the information and documents referred to in Articles 8, 10, 10a, 10b, 10c and 11. The documents submitted shall include a list of Member States concerned by the application.
The applicant shall request one Member State to act as "reference Member State" and to prepare an assessment report on the medicinal product in accordance with paragraphs 2 or 3.
2. Where the medicinal product has already received a marketing authorisation at the time of application, the concerned Member States shall recognise the marketing authorisation granted by the reference Member State. ...'
17. Article 35(1) of Directive 2001/83 permits an application to vary an authorisation:
'Any application by the marketing authorisation holder to vary a marketing authorisation … shall be submitted to all the Member States which have previously authorised the medicinal product concerned.'
18. Article 116 of Directive 2001/83 regulates the powers of variation of the competent authorities and provides, in particular, that *'[a] marketing authorisation may … be suspended, revoked or varied where the particulars supporting the application as provided for in Articles 8, 10, 10a, 10b, 10c or 11 are incorrect or have not been amended in accordance with Article 23 ...'*.

2. Regulation No 726/2004

19. With regard to the centralised authorisation procedure, Article 3(3) of Regulation No 726/2004 provides:
'A generic medicinal product of a reference medicinal product authorised by the Community may be authorised by the competent authorities of the Member States in accordance with Directive 2001/83/EC … under the following conditions:
(a) the application for authorisation is submitted in accordance with Article 10 of Directive 2001/83/EC …,
(b) the summary of the product characteristics is in all relevant respects consistent with that of the medicinal product authorised by the Community except for those parts of the summary of product characteristics referring to indications or dosage forms which were still covered by patent law at the time when the generic medicine was marketed ...'
20. With regard to multiple authorisations, Article 82(1) of Regulation No 726/2004 makes the following provision:
'Only one authorisation may be granted to an applicant for a specific medicinal product.
However, the Commission shall authorise the same applicant to submit more than one application to the Agency for that medicinal product when there are objective verifiable reasons relating to public health regarding the availability of medicinal products to healthcare professionals and/or patients, or for co-marketing reasons.'

3. Regulation No 1234/2008

21. Regulation No 1234/2008, which was adopted in particular on the basis of the original version of Article 35(1) of Directive 2001/83, (14) contains, in Article 9, rules on the notification procedure for minor variations of type IB. Under Article 2(5) of Regulation No 1234/2008, this is a catch-all term for variations which do not come under the other categories. The deletion of a therapeutic indication is classified in the Commission Guidelines on Regulation No 1234/2008 as a 'minor variation of type IB'. (15)
22. Article 9 of Regulation No 1234/2008 reads as follows:
'1. The holder shall submit simultaneously to all relevant authorities a notification …
2. If within 30 days following the acknowledgement of receipt of a valid notification, the competent authority of the reference Member State has not sent the holder an unfavourable opinion, the notification shall be deemed accepted by all relevant authorities.
Where the notification is accepted by the competent authority of the reference Member State, the measures provided for in Article 11 shall be taken.
3. Where the competent authority of the reference Member State is of the opinion that the notification cannot be accepted, it shall inform the holder and the other relevant authorities, stating the grounds on which its unfavourable opinion is based. ...'
23. The addition of a therapeutic indication is classified in the Commission Guidelines on Regulation No 1234/2008 as a 'major variation of type II'. (16) For such major variations of type II, Article 10 of Regulation No 1234/2008 provides for a 'prior approval' procedure:
'1. The holder shall submit simultaneously to all relevant authorities an application …
2. Within 60 days following the acknowledgement of receipt of a valid application, the competent authority of the reference Member State shall prepare an assessment report and a decision on the application, which shall be communicated to the other relevant authorities. …
5. Where the decision referred to in paragraph 2 has been recognised by all relevant authorities in accordance with paragraph 4, the measures provided for in Article 11 shall be taken. ...'
24. Article 11 of Regulation No 1234/2008 provides, with regard to the closure of the procedure, inter alia, of Articles 9 and 10:
'1. Where reference is made to this Article, the competent authority of the reference Member State shall take the following measures:

(a) it shall inform the holder and the other relevant authorities as to whether the variation is accepted or rejected;
(b) where the variation is rejected, it shall inform the holder and the other relevant authorities of the grounds for the rejection;
(c) it shall inform the holder and the other relevant authorities as to whether the variation requires any amendment to the decision granting the marketing authorisation.
2. Where reference is made to this Article, each relevant authority shall, where necessary and within the time limit laid down …, amend the decision granting the marketing authorisation in accordance with the accepted variation.'

B. National law

25. Under Article 40 of the Geneesmiddelenwet (Netherlands Law on medicines), it is prohibited to place a medicinal product on the market without a marketing authorisation.

26. Article 42 of the Law on medicines provides that the marketing authorisation will be granted by the CBG only upon application by a natural or legal person.

III. Facts and main proceedings

27. WLC is part of the Pfizer group, which markets worldwide the medicinal product Lyrica, with the active substance pregabalin, for the indications epilepsy, generalised anxiety disorder and neuropathic pain. On 6 July 2004, the Commission granted a marketing authorisation for Lyrica under the centralised procedure.

28. WLC is the holder of the European Patent EP 0 934 061 B3 for the active substance isobutyl-GABA and its derivatives for the indication neuropathic pain, which was granted to it on 28 May 2003 and subsequently limited to the active substance pregabalin.

29. That patent expired on 17 July 2017. It had been granted for the discovery of a 'second medical indication', supplementing the original indications. An earlier patent for the original indications epilepsy and generalised anxiety disorder expired some time ago.

30. After the data exclusivity period for the medicine Lyrica had expired in 2015 pursuant to Article 10 of Directive 2001/83, several manufacturers of generic medicinal products, including Aurobindo, applied to the CBG under the decentralised procedure for a marketing authorisation for a generic medicinal product with the active substance pregabalin. The reference Member State for the decentralised procedure was Portugal. The original application by Aurobindo in the decentralised authorisation procedure did not contain a carve-out for the indication neuropathic pain, but a full label version of the summary of product characteristics, which also included the still patented indication. However, patent protection still applied in the Netherlands at that time from the abovementioned patent EP 0 934 061 B3 for the indication neuropathic pain.

31. After the marketing authorisation had been granted, but before its generic pregabalin-based medicinal product had been placed on the market, Aurobindo notified the CBG that it would subsequently introduce a carve-out, that is, in the case at hand, delete from the summary of product characteristics the still patented indication neuropathic pain. Aurobindo requested the CBG to publish the summary in accordance with the subsequent carve-out. The CBG did not comply with that request, however, but published the full label version of the summary.

32. Thereupon, WLC made an application for interim measures at the Rechtbank Den Haag (District Court, The Hague, Netherlands), claiming that the Netherlands State should be ordered to instruct the CBG to replace the published full label version of the summary of product characteristics with the carve-out version. WLC contended that the practice of the CBG would encourage the prescription of generic medicinal products for the still patented indication and thus infringements of patent rights. The court hearing the application for interim measures allowed WLC's claims in part. In the appeal proceedings before the Gerechtshof Den Haag (Court of Appeal, The Hague, Netherlands), the Netherlands State is now requesting that the judgment of the Rechtbank Den Haag (District Court, The Hague) be set aside.

IV. Request for a preliminary ruling and procedure before the Court

33. By order of 4 July 2017, received on 14 July 2017, the Gerechtshof Den Haag (Court of Appeal, The Hague) made a reference to the Court pursuant to Article 267 TFEU for a preliminary ruling on the following questions:

'(1) Must Article 11 of Directive 2001/83 or any other provision of European Union law be interpreted as meaning that a communication whereby the marketing authorisation applicant or holder for a generic medicine, within the meaning of Article 10 of Directive 2001/83, notifies the authority that he is not including in the Summary of Product Characteristics and the package leaflet those parts of the Summary of Product Characteristics for the reference medicine which refer to indications or dosage forms covered by the patent right of a third party, should be considered as a request to limit the marketing authorisation which must result in the marketing authorisation not applying, or no longer applying, to the patented indications or dosage forms?
(2) If the answer to question 1 is in the negative, do Articles 11 and 21(3) of Directive 2001/83 or any other provisions of EU law preclude the competent authority from making public, in the context of an authorisation granted under Article 6 in conjunction with Article 10 of Directive 2001/83, the Summary of Product Characteristics and the package leaflet, including those parts which refer to indications or dosage forms which fall under the patent rights of a third party, in a situation where the marketing authorisation applicant or holder has notified the authority that he is not including in the Summary of Product Characteristics and the package leaflet those parts of the Summary of Product Characteristics for the reference medicine

which refer to indications or dosage forms covered by the patent right of a third party?
(3) Does it make any difference to the answer to question 2 that the competent authority requires the authorisation holder to include in the package leaflet which the authorisation holder must insert in the packaging of the medicine a reference to the authority's website on which the Summary of Product Characteristics is published, including the parts which refer to indications or dosage forms covered by the patent rights of a third party, whereas those parts, pursuant to Article 11 of Directive 2001/83, are not included in the package leaflet?'
34. In the preliminary ruling proceedings before the Court, WLC, the Netherlands Government and the European Commission submitted written observations and answered questions posed by the Court. The same parties took part in the hearing on 14 June 2018.

V. Substantive assessment of the questions referred

35. By its first question, the referring court would like to know what effects a carve-out has on the scope of the marketing authorisation for a medicinal product (see under A). The second and third questions relate to the publication of the summary of product characteristics by the authorising authority (see under B).

A. Effects of a carve-out on the scope of the marketing authorisation for a medicinal product (first question)

36. The parties to the present proceedings are in dispute as to how the introduction of a carve-out under the second sentence of Article 11 of Directive 2001/83, that is to say, the deletion of a still patented indication or dosage form of the reference medicinal product from the summary of characteristics of the generic medicinal product, affects the scope of the marketing authorisation for such a generic medicinal product.
37. According to the Netherlands Government, the effects of a carve-out on the scope of the marketing authorisation for a medicinal product depend on the time when and the manner in which the carve-out is introduced. If a manufacturer of a generic medicinal product deletes a still patented indication or dosage form of the reference medicinal product from the summary of characteristics of the generic medicinal product which accompanies its application for authorisation and if it does not include that indication or dosage form in the list of indications and dosage forms to be drawn up for that application, the patented indication or dosage form in question is not part of its application for authorisation and a marketing authorisation will not therefore be granted in that regard.
38. If, on the other hand, a manufacturer of a generic medicinal product submits a full label application for authorisation which includes all indications and dosage forms of the reference medicinal product and if it introduces a carve-out only subsequently by submitting to the competent authorities a new version of the summary of characteristics of the generic medicinal product from which the still patented indication or dosage form has been deleted, this does not, in the view of the Netherlands Government, result in the limitation of the marketing authorisation originally granted in full.
39. In this connection, the Netherlands Government draws a distinction between the draft summary of product characteristics originally submitted and the printed version of that summary subsequently produced, which accompanies the medicine. This would appear to mean the package leaflet to be drawn up pursuant to Article 59 of Directive 2001/83, that is to say, the leaflet containing information for the user which accompanies the medicinal product. Consequently, a carve-out made solely in the printed version of the summary of product characteristics after the marketing authorisation has been granted would have no effect on the scope of the marketing authorisation for that medicinal product.
40. The Commission and WLC take the view, on the other hand, that not only an original carve-out, but also a subsequently introduced carve-out must result in the marketing authorisation for the medicinal product being limited to the indications and dosage forms not affected by that carve-out. In particular, the Commission relies in this regard on a fundamental principle of the law on medicinal products according to which the version of a medicinal product placed on the market must be identical to the authorised version of that medicinal product as described in the summary of characteristics. Thus, an authorisation holder may not under any circumstances modify its medicinal product subsequently without notifying the authorising authority. Accordingly, a subsequently introduced carve-out would constitute an application to limit the previously granted marketing authorisation for a generic medicinal product to the indications and dosage forms not affected by the carve-out.
41. This argument is compelling. The marketed version of a medicinal product must be the same as the authorised version. This is not only essential in order to guarantee legal certainty and transparency, but it is also consistent with the spirit and purpose of the carve-out arrangement in the second sentence of Article 11 of Directive 2001/83. Not only the initial introduction of a carve-out (2) but also the subsequent introduction of a carve-out must therefore result in the limitation of the marketing authorisation for a medicinal product (3). Before this is discussed, it is helpful to consider briefly the status of the carve-out in the authorisation system under Directive 2001/83 (1).

1. The carve-out in the authorisation system under Directive 2001/83

42. As has already been mentioned, the carve-out arrangement in the second sentence of Article 11 of Directive 2001/83, whereby still patented indications or dosage forms of the reference medicinal product need not be included in the summary of characteristics of a generic medicinal product, permits an exception to the principle of the uniformity of the reference medicinal product and the generic medicinal product. This is necessary so that generic medicinal products can be placed on the market after the data exclusivity period

for reference medicinal products has expired, even if individual indications or dosage forms of the reference medicinal product are still patented. (17)

43. It is not apparent from the wording of the second sentence of Article 11 of Directive 2001/83 whether a carve-out can be introduced only at the time of submission of the application for a marketing authorisation for a generic medicinal product or also subsequently, that is, after the grant of the marketing authorisation but before the actual introduction on the market. (18)

44. Under Article 8(3)(j) of Directive 2001/83, the application for the marketing authorisation is to be accompanied by a summary, in accordance with Article 11, of the product characteristics. This shows that a carve-out under the second sentence of Article 11 can at least be introduced at the stage of the application for the marketing authorisation for a generic medicinal product. However, this does not give any indication as to whether it is also possible to introduce a carve-out after the marketing authorisation has been granted.

45. As the Commission states in its reply to the questions posed by the Court, it may be necessary to introduce a carve-out after authorisation has been granted in particular if the authorisation holder becomes aware only subsequently that an indication or dosage form of the reference medicinal product is still patented in the Member State concerned. It would also be conceivable that, upon an application by the patent holder, a national court orders an authorisation holder to introduce a carve-out.

46. Furthermore, the parties disagree on the importance of the subsequent introduction of a carve-out in the decentralised authorisation procedure and in the mutual recognition procedure.

47. The decentralised authorisation procedure laid down in Article 28(1), (3), (4) and (5) of Directive 2001/83 is applicable where a marketing authorisation does not yet exist for the medicinal product and is being sought for a number of Member States at the same time. In that procedure, the applicant selects a reference Member State whose assessment is approved by the other Member States concerned before each Member State concerned then grants a marketing authorisation. The mutual recognition procedure under Article 28(1), (2), (4) and (5) of Directive 2001/83 is applicable, on the other hand, where a marketing authorisation already exists in one Member State, which is to be recognised in one or more other Member States before they then each grant a marketing authorisation.

48. According to the Commission and the Recommendations of the Coordination Group referred to in Article 27 of Directive 2001/83, (19) in the decentralised authorisation procedure and in the mutual recognition procedure, an application is typically — though not necessarily — made initially for a full authorisation for all indications and dosage forms of a generic medicinal product, which is then, if necessary, adjusted to the patent law situations in the various Member States concerned, even before the authorisations are granted by those Member States, by means of carve-outs as appropriate.

49. The Netherlands Government takes the view, on the other hand, that in the decentralised procedure and in the mutual recognition procedure an identical marketing authorisation must in any event be granted initially in all the Member States concerned. Accordingly, any carve-outs in the Member States in which that is necessary could be introduced only after the marketing authorisation has been granted.

50. In any case, it seems likely, in view of the procedures provided for in Directive 2001/83 for recognition of marketing authorisations for medicinal products granted in other Member States and the different patent law situations in the various Member States, that situations will regularly arise where a carve-out is introduced only after a marketing authorisation has been granted.

51. This also appears to have been the case in the main proceedings. The present case thus falls under the decentralised authorisation procedure, where the Netherlands is a Member State concerned and Portugal acted as the reference Member State within the meaning of Article 28(1) of Directive 2001/83. According to the referring court and the Netherlands Government, the carve-out was introduced in the Netherlands only after the marketing authorisation had been granted for the generic medicinal product in question.

52. The referring court in any case expressly refers, in its first question and in its statements, both to the situation where a carve-out is introduced in the application procedure (‘initial carve-out’) and to the situation where a carve-out is introduced only after the marketing authorisation has been granted (‘subsequent carve-out’). Both situations will therefore be considered below.

2. Initial carve-out

53. As all the parties to the present proceedings agree, it is relatively clear from the provisions of Directive 2001/83 that a carve-out introduced at the stage of the application for a marketing authorisation for a medicinal product limits the scope of that application, and also therefore the scope of the authorisation to be granted.

54. Thus, under Article 6(1) of Directive 2001/83, the marketing of a medicinal product is subject to an authorisation which, under Article 8(1), is granted only on application.

55. It is also clear from Article 8(3) of the directive, which lists the particulars and documents to accompany the application, that the applicant determines the scope of its application by the claims it makes and the documents submitted, which include, under Article 8(3)(j), the summary of product characteristics. If an indication or dosage form is not mentioned in the summary of product characteristics accompanying the application as a result of a carve-out pursuant to the second sentence of Article 11 of Directive 2001/83, it is not therefore covered by the application. This is consistent with the fact that, under Article 8(3)(e) and

(f) of the directive, the application must list the therapeutic indications and posology of the medicinal product for which an application is made. As the Netherlands Government rightly notes, in the case of a carve-out in the summary of characteristics of a medicinal product accompanying the application for authorisation, a still patented indication or dosage form will logically also not be included in the list to be drawn up pursuant to Article 8(3)(e) and (f) of Directive 2001/83.

56. By introducing a carve-out, the manufacturer of a generic medicinal product thus reduces, at its own request, the number of indications or dosage forms for which its medicinal product is to be approved. There is no obligation to introduce a carve-out; rather it is an option which the directive offers manufacturers of generic medicinal products in order to avoid infringements of patent rights. The manufacturer of a generic medicinal product must itself assess whether there is a risk of an infringement of patent rights in the absence of a deletion of still patented indications or dosage forms, since it is for the manufacturer of the generic medicinal product to determine autonomously the indications and dosage forms for which it wishes to place its generic medicinal product on the market.

57. By contrast, the examination of the application by the authorising authority extends, under Article 10(1) in conjunction with the second paragraph of Article 26 of Directive 2001/83, only to the expiry of the data exclusivity period, but not to any conflicting patent rights. As Article 26 exhaustively lists the grounds for refusal and does not make any reference to considerations of patent law, the authorities may not reject an application because it contains a carve-out; conversely, the authorities also cannot require the applicant to introduce a carve-out because they do not examine conflicting patent rights. The authorities are thus bound by the scope of the application submitted and would have neither any reason nor any power to grant a marketing authorisation that also covered indications or dosage forms excluded by the applicant by means of the carve-out.

58. The above interpretation is also confirmed by the Commission's practice in the centralised authorisation procedure. In this regard, the particular nature of multiple authorisations shows that the scope of the marketing authorisation corresponds to the scope of the summary of product characteristics. Thus, under Article 82(1) of Regulation No 726/2004, in principle only one marketing authorisation is granted for a medicinal product in all Member States. Exceptionally, however, the Commission grants multiple authorisations pursuant to that provision, as the patent protection of certain indications and dosage forms can have a different scope in the various Member States. (20) If a carve-out in the summary of product characteristics did not limit the scope of the authorisation, there would be no need for multiple authorisations, but multiple summaries of product characteristics could simply be published. Moreover, it is assumed in the case-law on the centralised authorisation procedure that the scope of the marketing authorisation corresponds to the summary of product characteristics submitted. (21) Because the centralised and decentralised procedures cannot be viewed in isolation from one another, (22) the observations on the centralised procedure are also relevant to the decentralised procedure.

3. Subsequent carve-out

59. As has already been mentioned, (23) the wording of the second sentence of Article 11 of Directive 2001/83 is unclear in respect of whether a carve-out can also be introduced after the marketing authorisation has been granted for a medicinal product. As has also been explained, (24) however, the subsequent carve-out proves to be essential in any case in the complex system of authorisation of medicinal products under Directive 2001/83. Even though patent protection differs in the various Member States, the directive nevertheless provides for parallel application for a marketing authorisation for a medicinal product in all or several Member States or application for recognition of a marketing authorisation granted in one Member State in other Member States.

60. Against this background, it seems logical to interpret the second sentence of Article 11 of Directive 2001/83 to the effect that it is also possible to introduce a carve-out after the marketing authorisation has been granted for a medicinal product. In order to ensure that the authorised version of a medicinal product corresponds to the version placed on the market (a), a subsequent carve-out of this nature must be regarded as an application to limit the marketing authorisation (b).

(a) The need for the authorised version of a medicinal product to correspond to the version placed on the market

61. The Netherlands Government's view that a subsequent carve-out does not affect the scope of the previously granted marketing authorisation for a medicinal product is not persuasive, as this would lead to a discrepancy between the authorised version of a medicinal product and the version placed on the market.

62. As the Commission rightly argues, however, it is a fundamental principle of the law on medicinal products that the authorised version of a medicinal product and the version placed on the market must be identical. Consequently, the authorisation holder may not under any circumstances autonomously and without the consent of the competent authorities modify the summary of characteristics and the package leaflet for a medicinal product. The summary of characteristics is an integral part of the marketing authorisation for a medicinal product and defines the characteristics of the medicinal product as approved. (25) Furthermore, the need for the authorised summary of characteristics to correspond to the version of a medicinal product placed on the market, including the package leaflet, follows from a number of provisions of Directive 2001/83. (26)

63. If an authorisation holder were permitted to place a medicinal product on the market with a summary of characteristics that was modified compared with the authorised version, this would jeopardise the

effectiveness of the authorisation procedure and legal certainty and transparency for healthcare professionals and patients.

64. Furthermore, the time when a carve-out is introduced — before or after the marketing authorisation is granted — is not an aspect that would justify the view that only an initial carve-out affects the scope of the authorisation. Regardless of the time when a carve-out is introduced, any discrepancy between the scope of the marketing authorisation and the summary of product characteristics must be avoided.

65. A subsequently introduced carve-out must therefore result in the limitation by the competent authorities of the authorisation granted. Because the marketing of a medicinal product requires official authorisation, a subsequent carve-out does not automatically vary a previously granted authorisation, but requires an official act of variation. The variation procedures provided for by Directive 2001/83 and Regulation No 1234/2008, which will be discussed immediately below, (27) also suggest in this connection that a subsequent carve-out must result in the variation of the previously granted authorisation.

66. The notification of a subsequent carve-out must therefore be regarded as an application to limit the previously granted marketing authorisation for a medicinal product. It is irrelevant in this connection whether by the carve-out the authorisation holder merely wishes to avoid infringements of patent rights or is intentionally seeking to limit the marketing authorisation. The deletion of an indication or dosage form from the summary of product characteristics objectively limits the scope of that summary. As the latter determines the scope of the marketing authorisation, the carve-out must therefore also result in the limitation of that authorisation.

67. In accordance with this interpretation, both holders of marketing authorisations for generic medicinal products and national health authorities must accept that, after the introduction of a carve-out and the related limitation of the marketing authorisation, generic medicinal products will not be prescribed, or at least will no longer be prescribed as often, for the still patented indications or dosage forms of the reference medicinal product which are now no longer covered by the authorisation.

68. This consequence is nevertheless consistent with the spirit and purpose of the carve-out arrangement in the second sentence of Article 11 of Directive 2001/83, as that provision was introduced not only to promote quick market entry for generic medicinal products, (28) but also to encourage innovative manufacturers to conduct research into new indications and dosage forms of known active substances. (29) To that end, the protection of patents granted for a second or further medical indication of a known active substance must be guaranteed. For this aim to be achieved, the carve-out for still patented indications and dosage forms of the reference medicinal product must also result in a reduction of the scope of the marketing authorisation for the generic medicinal product in question.

69. The carve-out arrangement in the second sentence of Article 11 of Directive 2001/83 is thus also consistent with the fact that EU law on medicinal products is without prejudice to the patent law of the Member States, (30) but takes account of existing patent rights.

70. The effect of carve-outs introduced in various Member States concerned is that the marketing authorisation for a single medicinal product differs in extent in the Member States concerned. This cannot be avoided, however, in the absence of uniform Union-wide patent protection, as the same indication or dosage form can be protected in various Member States with a different scope and for different periods of time. In the light of this, the carve-out arrangement provided for in the second sentence of Article 11 of Directive 2001/83 and in Article 3(3)(b) of Regulation No 726/2004 is an essential instrument, as it is the only possible means, after the expiry of the data exclusivity period for a reference medicinal product, which is uniformly regulated in EU law, to have a generic medicinal product authorised in a single procedure in all or several Member States and, at the same time, to take account of the potentially different patent protection in those Member States.

(b) Possibilities for the subsequent limitation of the marketing authorisation for a medicinal product

71. It follows from the above considerations that the notification of a subsequent carve-out is to be construed as an application to limit the previously granted marketing authorisation for a medicinal product. In this connection, Directive 2001/83 and Regulation No 1234/2008 lay down various provisions which give an authority the right to vary the previously granted authorisation.

(1) Application to vary the marketing authorisation

72. First, an explicit application by the authorisation holder to vary the marketing authorisation is possible under Article 35 of Directive 2001/83. However, no such application was made in the main proceedings, as the Government of the Netherlands confirmed at the hearing.

(2) Variation of the marketing authorisation after notification of the carve-out

73. Second, an authorisation holder may comply with its duty under Directive 2001/83 to notify the competent authorities of amendments of the summary of product characteristics. The authorities then have the power under Regulation No 1234/2008 to vary a previously granted authorisation. Such a situation could have occurred in the present case when Aurobindo notified the CBG of the subsequent carve-out.

74. Article 23(2) of Directive 2001/83 thus requires the marketing authorisation holder in particular to provide the competent authority with any new information which may entail the amendment of the particulars referred to in Article 11. The introduction of a carve-out pursuant to the second sentence of Article 11 thus represents new information to which the notification obligation applies.

75. This is confirmed by the drafting history of Article 23(2) of Directive 2001/83. This provision was introduced to clarify the responsibilities of authorisation holders, to encourage them to inform the authorities of any changes that might impact on the marketing authorisation and to ensure that the product information is kept up to date. (31)
76. Under Article 9(1) of Regulation No 1234/2008, to which Article 23b of Directive 2001/83 refers, the authorisation holder is also required to notify the competent authorities of each Member State concerned (32) and of the reference Member State (33) of 'minor variations of type IB', which include the deletion of an indication. (34) The notification of a carve-out falls under the category 'deletion of an indication', as the manufacturer of the generic medicinal product thereby deletes an indication from the summary of product characteristics. (35)
77. If the competent authorities of the reference Member State do not explicitly refuse the variation made by the authorisation holder, it is deemed to be authorised pursuant to Article 9(2) of Regulation No 1234/2008. On the other hand, Article 9(3) of Regulation No 1234/2008 gives the competent authority of the reference Member State the power to refuse the notified variation. In the present case, however, the refusal by the CBG to publish the summary of product characteristics in the carve-out version would not appear to constitute such refusal. First of all, the Netherlands is not the reference Member State in this case, but Portugal. Second, the authority responsible for authorising medicinal products does not have any power of review under patent law on which a refusal of the deletion of an indication by means of the carve-out could be based. (36) It is for the referring court to examine whether the notification of the carve-out was not accepted on other grounds.
78. Article 11(2) of Regulation No 1234/2008, lastly, gives the relevant authority the power to vary the authorisation, after the conclusion of the notification procedure, if the notified variation so requires. In accordance with the view taken in this Opinion, this is the case with the deletion of an indication by means of a carve-out in the summary of product characteristics in order to ensure the necessary correspondence between the scope of the summary of product characteristics and the marketing authorisation. (37) This holds even where the authorisation holder does not expressly apply to vary its marketing authorisation. (38)
79. Contrary to the submission made by the Netherlands, the interpretation to the effect that the notification of a carve-out makes it necessary to vary the marketing authorisation is not precluded by the fact that, as a result of this, the manufacturer of the generic medicinal product must apply again to supplement its authorisation by the indication or dosage form deleted by the carve-out after the relevant protection under patent law has expired.
80. The addition of an indication may, according to the Commission Guidelines on Regulation No 1234/2008, constitute a major variation of type II which must be authorised in the procedure provided for in Article 10 of that regulation (and not merely notified under Article 9). (39) However, a variation procedure of this kind also does not delay unnecessarily the marketing of the generic medicinal product for an indication which is no longer patented, as the addition of a new indication may be applied for, under Article 10(2) of Regulation No 1234/2008, 60 days before the protection under patent law expires. Marketing of the generic medicinal product is thus made possible immediately after the protection under patent law has expired.

(3) Variation of the marketing authorisation after the determination of the existence of a carve-out by the competent authorities

81. Lastly, according to the statements made by WLC at the hearing, a third situation is conceivable, where a manufacturer of a generic medicinal product introduces a carve-out by simply amending the package leaflet for its medicinal product, but does not make a notification pursuant to Article 23(2) of Directive 2001/83. In this case, the authorities have the right to vary the marketing authorisation under the second paragraph of Article 116 of Directive 2001/83. However, this does not appear to be the case in the main proceedings, as the CBG was informed of the introduction of the carve-out.

4. Interim conclusion

82. In the light of the foregoing, Articles 10 and 11 of Directive 2001/83 must be interpreted as meaning that a communication whereby the marketing authorisation applicant or holder for a generic medicine, within the meaning of Article 10, notifies the authority that he is not including in the summary of product characteristics and the package leaflet, pursuant to the second sentence of Article 11, those parts of the summary of product characteristics for the reference medicine referring to indications or dosage forms covered by the patent right of a third party should be considered as a request to limit the marketing authorisation for that generic medicinal product to the remaining indications or dosage forms.

B. Publication of the summary of product characteristics and carve-out (second and third questions)

83. By its second question, the referring court would like to know whether the competent authorities may publish a full label version of the summary of product characteristics even though a carve-out has been notified. The third question seeks to ascertain whether it makes any difference that the authority requires the authorisation holder to refer in the package leaflet for the medicinal product, which does not contain the indication affected by the carve-out, to the authority's website, on which the full label version of the summary of product characteristics can be found.
84. The answer to the second and third questions follows from the proposed answer to the first question since, under Article 21(3) of Directive 2001/83, the competent authorities must make publicly available the summary of the product characteristics for each

medicinal product which they have authorised. If a carve-out limits the scope of the marketing authorisation and the marketing authorisation and the summary of product characteristics thus have the same scope, there is therefore no reason to publish a summary of product characteristics going beyond the scope of the marketing authorisation.

85. The view taken by the Netherlands Government that it is also necessary to publish the full label version of the summary of product characteristics in the case of a subsequent carve-out for patient information reflects the risk of confusion that would exist if the subsequent notification of a carve-out had no effect on the marketing authorisation granted and there was thus a discrepancy in the scopes of the marketing authorisation and of the package leaflet. If, however, the marketing authorisation is varied in accordance with the carve-out and there is no discrepancy in the scopes of the marketing authorisation and of the package leaflet, the problem of inadequate patient information does not arise at all. In accordance with the Recommendations of the Coordination Group referred to in Article 27 of Directive 2001/83, moreover, the Member States may require manufacturers of generic medicinal products, in the case of a carve-out, to include a statement in the package leaflet which explains that the active substance of the medicinal product in question is authorised for other conditions which are not mentioned in the package leaflet, and patients may ask their doctor or pharmacist if they have questions. (40)

86. Accordingly, Article 11 and Article 21(3) of Directive 2001/83 must be interpreted as precluding the competent authority from making public the summary of characteristics and the package leaflet of a medicinal product, including those parts referring to indications or dosage forms which are covered by patent law, in a situation where the marketing authorisation applicant or holder has notified the authority that, in accordance with the second sentence of Article 11 of the directive, he is not including such indications or dosage forms in the summary of characteristics and the package leaflet.

VI. Conclusion

87. In light of the foregoing, I propose that the Court answer the request for a preliminary ruling from the Gerechtshof the Haag (Court of Appeal, The Hague, Netherlands) as follows:

(1) Articles 10 and 11 of Directive 2001/83/EC on the Community code relating to medicinal products for human use, as amended by Directive 2012/26/EU, must be interpreted as meaning that a communication whereby the marketing authorisation applicant or holder for a generic medicine, within the meaning of Article 10, notifies the authority that he is not including in the summary of product characteristics and the package leaflet, pursuant to the second sentence of Article 11, those parts of the summary of product characteristics for the reference medicine referring to indications or dosage forms covered by the patent right of a third party should be considered as a request to limit the marketing authorisation for that generic medicinal product to the remaining indications or dosage forms.

(2) Article 11 and Article 21(3) of Directive 2001/83 must be interpreted as precluding the competent authority from making public the summary of characteristics and the package leaflet of a medicinal product, including those parts referring to indications or dosage forms which are covered by patent law, in a situation where the marketing authorisation applicant or holder has notified the authority that, in accordance with the second sentence of Article 11 of the directive, he is not including such indications or dosage forms in the summary of characteristics and the package leaflet.

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1 Original language: German.

2 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 (OJ 2001 L 311, p. 67), as amended by Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 (OJ 2012 L 299, p. 1).

3 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1), as amended by Regulation (EU) No 1027/2012 of the European Parliament and of the Council of 25 October 2012 (OJ 2012 L 316, p. 38).

4 See recital 10 of Directive 2001/83 and judgment of the General Court of 15 September 2015, Novartis Europharm v Commission (T‑472/12, EU:T:2015:637, paragraph 62).

5 See the definition in Article 10(2) of Directive 2001/83.

6 See Article 10 of Directive 2001/83 and judgments of 23 October 2014, Olainfarm (C‑104/13, EU:C:2014:2316, paragraph 37), and of 14 March 2018, Astellas Pharma (C‑557/16, EU:C:2018:181, paragraph 34). See also Opinion of Advocate General Bot in Synthon (C‑452/06, EU:C:2008:393, point 82).

7 See, with regard to the background to patent protection for a further indication, decision of the Enlarged Board of Appeal of the European Patent Office of 19 February 2010, G 2/08, ECLI:EP:BA:2010:G000208.20100219, in particular paragraph 7.1. The grant of patent protection for a further indication does not extend data exclusivity unless the situation comes under the fourth subparagraph of Article 10(1) of Directive 2001/83.

8 See the second sentence of Article 11 of Directive 2001/83 and Article 3(3)(b) of Regulation No 726/2004 for the centralised authorisation procedure.

9 See, in particular, Article 8(3)(j), Article 11, Article 21 and Article 59 of Directive 2001/83 and paragraph 115 of the judgment of the General Court of 11 June

2015, Laboratoires CTRS v Commission (T‑452/14, EU:T:2015:373).
10 See again the definition in Article 10(2) of Directive 2001/83.
11 See in this regard judgment of 14 March 2018, Astellas Pharma (C‑557/16, EU:C:2018:181, paragraph 23).
12 Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ 2008 L 334, p. 7), as amended by Commission Regulation (EU) No 712/2012 of 3 August 2012 (OJ 2012 L 209, p. 4).
13 This footnote is not relevant for the English-language version of this Opinion.
14 Only Article 23b of Directive 2001/83 now refers to the adoption of an implementing regulation.
15 Annex C.I.6(b) of the Guidelines on the details of the various categories of variations, on the operation of the procedures laid down in Chapters II, IIa, III and IV of Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products and on the documentation to be submitted pursuant to those procedures (OJ 2013 C 223, p. 1).
16 Annex C.I.6(a) of the Commission Guidelines on Regulation No 1234/2008 (footnote 15 above).
17 See points 3 and 4 of this Opinion.
18 The tenses of this provision are unclear, as the Commission rightly states. On a literal reading (in the German, French, English and Bulgarian versions at least), the actual introduction on the market would precede the grant of authorisation (‘those parts of the summary of product characteristics of the reference medicinal product referring to indications or dosage forms which were still covered by patent law at the time when a generic medicine was marketed need not be included’ (emphasis added)). However, this would be contrary to Article 6(1) of Directive 2001/83, which requires the existence of an authorisation for introduction to the market.
19 See Questions 4 and 5 in the Recommendations of the Co-ordination Group for Mutual Recognition and Decentralised Procedures (CMDh) on patented indications (http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Questions_Answers/CMDh-279-2012-Rev0-2012_10.pdf).
20 See the Commission Note on Handling of Duplicate Marketing Authorisation Applications, Ref. Ares(2011)1044649 of 3 October 2011, p. 8, available at: https://ec.europa.eu/health/sites/health/files/files/latest_news/2011_09_duplicates_note_upd_01.pdf
21 See judgment of the General Court of 11 June 2015, Laboratoires CTRS v Commission (T‑452/14, EU:T:2015:373, paragraph 68).
22 Opinions of Advocate General Sharpston in Commission v Lithuania (C‑350/08, EU:C:2010:214, point 90 et seq.), and Novartis Pharma (C‑535/11, EU:C:2013:53, point 47); see also judgment of the General Court of 15 September 2015, Novartis Europharm v Commission (T‑472/12, EU:T:2015:637, paragraph 73 et seq.).
23 See point 43 of this Opinion.
24 See point 44 et seq. of this Opinion.
25 See judgment of the General Court of 11 June 2015, Laboratoires CTRS v Commission (T‑452/14, EU:T:2015:373, paragraph 115).
26 See in particular Article 21(2), Article 59(1), Article 61(2), Article 62, Article 87(2), Article 91(1) and Article 92 of Directive 2001/83.
27 See point 71 et seq. of this Opinion.
28 See in particular recital 14 of Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83 (OJ 2004 L 136, p. 34), to which the current version of the second sentence of Article 11 of Directive 2001/83 goes back.
29 The 2004 legislative package (Directive 2004/27 and Regulation No 726/2004) thus not only introduced the carve-out arrangement in the second sentence of Article 11 of Directive 2001/83, but also amended Article 10 of Directive 2001/83 and created Article 14(11) of Regulation No 726/2004 in order to provide an additional year of protection if, within the original data exclusivity period, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which are considered to bring a significant clinical benefit in comparison with existing therapies. See also, with regard to the promotion of innovation and generic medicinal products, the Commission Proposal for a Regulation of the European Parliament and of the Council 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, COM(2001) 404 final.
30 See in particular Article 10(1) of Directive 2001/83 and Article 14(11) of Regulation No 726/2004.
31 See recital 12 of Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ 2010 L 348, p. 74).
32 Article 9(1) of Regulation No 1234/2008 refers to ‘all relevant authorities’. According to Article 2(7)(a) of Regulation No 1234/2008, the relevant authority is the competent authority of each Member State concerned. Under Article 2(6) of Regulation No 1234/2008, the Member State concerned is any Member State whose competent authority has granted a marketing authorisation for the medicinal product in question.
33 According to WLC at the hearing, in this case, Aurobindo informed the Portuguese authorities accordingly about the introduction of a carve-out for the Netherlands.

34 See Annex C.I.6(b) of the Commission Guidelines on Regulation No 1234/2008 (point 21 and footnote 15 of this Opinion).
35 According to Annex C.I.7(a) and (b) of the Commission Guidelines, the deletion of a 'pharmaceutical form' or a 'strength' also falls under the category 'minor variations of type IB'. This appears to correspond to 'dosage form' in the second sentence of Article 11 of Directive 2001/83. The terminology of the different language versions of the directive and of the Guidelines is somewhat inconsistent here: for example, the German version of the directive uses the term 'Dosierung' and the German version of the Guidelines the terms 'Darreichungsform' and 'Stärke'; the English version of the directive uses the term 'dosage forms' and the English version of the Guidelines the terms 'pharmaceutical form' and 'strength'; the French version of the directive uses the term 'formes de dosage' and the French version of the Guidelines the terms 'forme pharmaceutique' and 'dosage'.
36 See point 57 of this Opinion.
37 See point 61 et seq. of this Opinion.
38 See point 66 of this Opinion.
39 See Annex C.I.6(a) of the Commission Guidelines on Regulation No 1234/2008 (point 23 and footnote 16 of this Opinion); where no submission of further data is required, the addition of an indication for a generic medicinal product under Annex C.I.2 of the Guidelines could, however, constitute a minor variation of type IB for which the simple notification procedure under Article 9 of Regulation No 1234/2008 would be sufficient. See also Question 6 of the CMDh information on patented indications (http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Questions_Answers/CMDh-279-2012-Rev0-2012_10.pdf).
40 See Question 3 of the CMDh Questions and Answers on patented indications (http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Questions_Answers/CMDh-279-2012-Rev0-2012_10.pdf).