JUDGMENT OF THE COURT (First Chamber)

28 October 2010 *

In Case C-350/08,

ACTION under Article 226 EC for failure to fulfil obligations, brought on 29 July 2008,

**European Commission,** represented by A. Steiblytė and M. Šimerdová, acting as Agents, with an address for service in Luxembourg,

applicant,

v

**Republic of Lithuania,** represented by D. Kriaučiūnas and R. Mackevičienė, acting as Agents,

defendant,

* Language of the case: Lithuanian.

THE COURT (First Chamber),

composed of A. Tizzano (Rapporteur), President of the Chamber, J.-J. Kasel, A. Borg Barthet, M. Ilešič and M. Berger, Judges,

Advocate General: E. Sharpston,
Registrar: C. Strömholm, Administrator,

having regard to the written procedure and further to the hearing on 3 December 2009,

after hearing the Opinion of the Advocate General at the sitting on 22 April 2010,

gives the following

**Judgment**

1 By its application, the Commission of the European Communities (now the European Commission) requests the Court to declare that, by maintaining in force the national marketing authorisation for the medicinal product Grasalva, the Republic of

Lithuania has failed to fulfil its obligations under Article 6(1) 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 Commission Directive 2003/63/EC of 25 June 2003 (OJ 2003 L 159, p. 46), and under Article 3(1) of Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ 1993 L 214, p. 1), and under Article 3(1) of 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).

## Legal context

### *European Union legislation*

#### The 2003 Accession Treaty and the 2003 Act of Accession

2 The Treaty concerning the accession to the European Union of 10 new Member States, including the Republic of Lithuania, was signed in Athens on 16 April 2003 (OJ 2003 L 236, p. 17; 'the 2003 Treaty of Accession') and, in accordance with Article 2(2) thereof, entered into force on 1 April 2004. As is apparent from Article 1(2) of the Treaty, the conditions of admission are set out in the Act concerning the conditions of accession to the European Union of the Czech Republic, the Republic of Estonia, the

Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded (OJ 2003 L 236, p. 33; 'the 2003 Act of Accession').

3 Under Article 2 of the 2003 Act of Accession:

'From the date of accession, the provisions of the original Treaties and the acts adopted by the institutions and the European Central Bank before accession shall be binding on the new Member States and shall apply in those States under the conditions laid down in those Treaties and in this Act.'

4 Article 10 of the 2003 Act of Accession provides:

'The application of the original Treaties and acts adopted by the institutions shall, as a transitional measure, be subject to the derogations provided for in this Act.'

5 The fourth part of the 2003 Act of Accession, Title I of which deals with the transitional measures, contains an Article 24 which provides:

'The measures listed in Annexes V, VI, VII, VIII, IX, X, XI, XII, XIII and XIV to this Act shall apply in respect of the new Member States under the conditions laid down in those Annexes.'

6 Under Article 54 of the 2003 Act of Accession:

'The new Member States shall put into effect the measures necessary for them to comply, from the date of accession, with the provisions of directives and decisions within the meaning of Article 249 of the EC Treaty and of Article 161 of the Euratom Treaty, unless another time-limit is provided for in the Annexes referred to in Article 24 or in any other provisions of this Act or its Annexes.'

7 With regard to the Republic of Lithuania, Annex IX, Chapter 1, paragraph 2, of the 2003 Act of Accession provides, as regards Directive 2001/83:

'By way of derogation from the requirements of quality, safety and efficacy laid down in Directive [2001/83 in the original version], marketing authorisations for the pharmaceutical products on the list (in Appendix A to this Annex as provided by Lithuania in one language) issued under Lithuanian law prior to the date of accession, shall remain valid until they are renewed in compliance with the acquis and in accordance with the timeframe set out in the abovementioned list, or until 1 January 2007, whichever is the earlier. …'

8 Appendix A referred to in Chapter 1 of Annex IX (OJ 2003 C 227 E, p. 115; 'Appendix A') states:

'List as provided by Lithuania in one language of pharmaceutical products for which a marketing authorisation issued under Lithuanian law prior to the date of accession shall remain valid until it is renewed in compliance with the acquis or until 31 December 2006, whichever is the earlier.

Mention on this list does not prejudge whether or not the pharmaceutical product in question has a marketing authorisation in compliance with the acquis.'

European Union legislation on pharmaceutical products

9 Article 6(1) of Directive 2001/83, in the original version, was worded as follows:

'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 … No 2309/93.'

10 Article 8 of that directive provided:

'1. In order to obtain an authorisation to place a medicinal product on the market regardless of the procedure established by Regulation … No 2309/93, an application shall be made to the competent authority of the Member State concerned.

…

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

…

(i) Results of:

— physico-chemical, biological or microbiological tests,

— toxicological and pharmacological tests,

— clinical trials.

…’

11 Article 10 of that directive provided:

‘1. In derogation of Article 8(3)(i), and without prejudice to the law relating to the protection of industrial and commercial property:

(a) The applicant shall not be required to provide the results of toxicological and pharmacological tests or the results of clinical trials if he can demonstrate:

…

(iii) … that the medicinal product is essentially similar to a medicinal product which has been authorised within the Community, in accordance with Community provisions in force, for not less than six years and is marketed in the Member State for which the application is made. …

…'

12 Article 126 of Directive 2001/83, in the original version, stated:

'An authorisation to market a medicinal product shall not be refused, suspended or revoked except on the grounds set out in this directive.

No decision concerning suspension of manufacture or of importation of medicinal products coming from third countries, prohibition of supply or withdrawal from the market of a medicinal product may be taken except on the grounds set out in Articles 117 and 118.'

13 Pursuant to the first paragraph of Article 2 of Directive 2003/63, which was adopted on 25 June 2003 and entered into force on 1 July 2003, Member States were to bring into force the laws, regulations and administrative provisions necessary to comply with that directive by 31 October 2003 at the latest.

14 Annex I, Part II, point 4, to Directive 2001/83, as amended by Directive 2003/63, is worded as follows:

'The provisions of Article 10(1)(a)(iii) may not be sufficient in the case of biological medicinal products. If the information required in the case of essentially similar products (generics) does not permit the demonstration of the similar nature of two biological medicinal products, additional data, in particular, the toxicological and clinical profile, shall be provided.

When a biological medicinal product … is submitted for a marketing authorisation by an independent applicant …, the following approach shall be applied.

— Information to be supplied shall not be limited to Modules 1, 2 and 3 (pharmaceutical, chemical and biological data), supplemented with bio-equivalence and bio-availability data. The type and amount of additional data (i.e. toxicological and other non-clinical and appropriate clinical data) shall be determined on a case-by-case basis in accordance with relevant scientific guidelines.

— Due to the diversity of biological medicinal products, the need for identified studies foreseen in Modules 4 and 5, shall be required by the competent authority, taking into account the specific characteristic of each individual medicinal product.

…'

15 The second paragraph of Article 2 of Regulation No 2309/93 provided:

'The person responsible for placing the medicinal products covered by this Regulation on the market must be established in the Community.'

16 Article 3(1) of that regulation provided:

'No medicinal product referred to in Part A of the Annex may be placed on the market within the Community unless a marketing authorisation has been granted by the Community in accordance with the provisions of this Regulation.'

17 Regulation No 2309/93 was repealed and replaced by Regulation No 726/2004, of which the second paragraph of Article 2 and Article 3(1), applicable with effect from 20 November 2005, are drafted in essentially identical terms to those of the second paragraph of Article 2 and of Article 3(1) of Regulation No 2309/93.

18 In the same way, the annexes to both those regulations concern, in particular, medicinal products developed by means of biotechnological processes such as recombinant DNA technology.

*National law*

19 Decree No 669 of the Minister for Health of 22 December 2001 on the general rules for registration of medicinal preparations ('Decree No 669') transposes the provisions of Directive 2001/83, in the original version, into Lithuanian national law, with a view to the accession of the Republic of Lithuania to the European Union.

20 Article 18, third paragraph, of Decree No 669 provides that the applicant for a marketing authorisation in Lithuania may not be obliged to provide the results of preclinical trials or of clinical investigations provided that:

'the medicinal preparation does not differ by its active medicinal ingredients either qualitatively or quantitatively or by the form of the medicinal product from a medicinal preparation meeting the two following requirements:

— registration in at least one Member State of the European Union in compliance with the requirements of the European Community for a period of at least 6 years, and of 10 years for high-technology medicinal preparations,

— registration in the Republic of Lithuania.

...'

**Background to the dispute and the pre-litigation procedure**

21 The application for marketing authorisation of Grasalva, which was submitted to the Lithuanian authorities on 8 May 2003, asserted that it is a biological medicinal product analogous to another medicinal product, Neupogen, for which a marketing authorisation had already been issued in the Community.

22 On the basis of that application, by virtue of Article 18, third paragraph, of Decree No 669, on 2 July 2003 those authorities issued a marketing authorisation for Grasalva in Lithuania, without requiring the applicant to supply the results of preclinical and clinical trials. That authorisation was granted for a period of five years and thus expired on 2 July 2008.

23 Grasalva is not included in the list in Appendix A.

24 After an exchange of correspondence which began on 14 April 2004, by letter of 15 February 2006, the Commission informed the Republic of Lithuania that the marketing authorisation for Grasalva could not be regarded as complying with European Union law. Since it did not contain the results of preclinical and clinical trials, the application did not meet the requirements laid down for biological medicinal products in Annex I, Part II, point 4, to Directive 2001/83, as amended by Directive 2003/63. The Lithuanian authorities were therefore requested to withdraw that authorisation.

25 On 15 December 2006, the Commission sent the Republic of Lithuania a letter of formal notice in which it stated that, with effect from the date of its accession to the European Union, national authorities no longer had power to issue marketing authorisations for medicinal products from biotechnical processes, such as Grasalva.

In accordance with Regulation No 2309/93 and, with effect from 20 November 2005, with Regulation No 726/2004, that power was held by the Commission.

26 On 5 March 2007, the Republic of Lithuania replied to that letter of formal notice and submitted, firstly, that at the time when Grasalva was registered, all the information required under Article 10(1)(a)(iii) of Directive 2001/83, in the original version, had been provided, in particular concerning the quality, safety and efficacy of that medicinal product. Next, that Member State submitted that the competent Lithuanian authorities were not bound by Directive 2003/63. It had not been adopted until 25 June 2003, that is to say after signature of the 2003 Treaty of Accession by the Republic of Lithuania on 16 April 2003, and the period for the transposition into national law of that directive, which expired on 31 October 2003, had not yet expired when, on 2 July 2003, Grasalva obtained its marketing authorisation. Finally, the Republic of Lithuania also referred to the fact that Regulation No 2309/93 applied in the new Member States only from 1 May 2004 for all newly registered medicinal products and that it did not apply to medicinal products registered prior to that date.

27 In its reasoned opinion of 29 June 2007, the Commission reminded the Republic of Lithuania that all the provisions of Directive 2001/83, as amended by Directive 2003/63, were to be applied by it with effect from 1 May 2004 and that, consequently, from that date, the marketing authorisation for Grasalva should have met the requirements set out in Annex I, Part II, point 4, of that directive. By maintaining in force an authorisation which did not comply with those requirements, that Member State had not fulfilled its obligations under European Union law. The Commission therefore called on the Republic of Lithuania to comply with European Union law within two months of receiving the reasoned opinion.

28 On 5 September 2007, the Republic of Lithuania replied to the reasoned opinion. Taking the view that that reply was unsatisfactory, the Commission decided to bring the present action.

## The action

### *Admissibility*

29 The Republic of Lithuania submits, in essence, that the Commission has committed a number of infringements of the principle of sound administration which, as a whole, render the action inadmissible. More specifically, the action is devoid of purpose, since the marketing authorisation granted for Grasalva expired on 2 July 2008, namely almost a month before the Commission brought the present action on 29 July 2008. In addition, the Commission excessively delayed initiation of the administrative proceedings provided for in Article 226 EC. It did not send the letter of formal notice to that Member State until 15 December 2006 although, according to the Commission, the alleged failure to fulfil obligations had existed since 1 May 2004. Moreover, the action was not brought until 11 months after expiry of the period laid down in the reasoned opinion.

30 In that regard, it must be borne in mind, firstly, that, in accordance with established case-law, the subject-matter of an action for failure to fulfil obligations is determined by the Commission's reasoned opinion (Case 39/72 *Commission* v *Italy* [1973] ECR 101, paragraph 9, and Case C-236/05 *Commission* v *United Kingdom* [2006] ECR I-10819, paragraph 10 and the case-law cited). Consequently, whether a Member State has failed to fulfil its obligations must be determined by reference to the situation prevailing in the Member State at the end of the period laid down in the reasoned opinion, and the Court cannot take account of any subsequent changes (Case

C-161/02 *Commission* v *France* [2003] ECR I-6567, paragraph 6, and Case C-158/09 *Commission* v *Spain*, paragraph 7).

31 It is clear from the documents before the Court that, as the Advocate General observed in point 74 of her Opinion, Grasalva continued to be marketed in Lithuania until the expiry on 2 July 2008 of the marketing authorisation which had been granted for that medicinal product, that is to say, until considerably later than 29 August 2007, the date set in the reasoned opinion.

32 Since the date on which the Commission brought the present action is not at all relevant in that regard, it must be concluded that this action cannot be regarded as being without purpose.

33 Next, with regard to the alleged delay in bringing the proceedings under Article 258 TFEU, the rules of that provision must be applied without any obligation on the Commission to act within a specific period (Case 324/82 *Commission* v *Belgium* [1984] ECR 1861, paragraph 12, and Case C-333/99 *Commission* v *France* [2001] ECR I-1025, paragraph 25) and it is for the Commission to choose when it will bring an action for failure to fulfil obligations before the Court; the considerations which determine its choice of time cannot affect the admissibility of the action (Case C-317/92 *Commission* v *Germany* [1994] ECR I-2039, paragraph 4, and Case C-40/00 *Commission* v *France* [2001] ECR I-4539, paragraph 23).

34 Indeed, in certain situations, the excessive duration of the pre-litigation procedure is capable of making it more difficult for the Member State concerned to refute the Commission's arguments and of thus infringing the rights of defence of that Member

State. Nevertheless, it is for the Member State concerned to show that it has been so affected (Case C-96/89 *Commission* v *Netherlands* [1991] ECR I-2461, paragraph 16, and Case C-546/07 *Commission* v *Germany* [2010] ECR I-439, paragraph 22).

35 However, the fact remains that, as the Commission argues, in the present case the Republic of Lithuania has not advanced any evidence to that effect and that, accordingly, the action for failure to fulfil obligations cannot be regarded as having been brought with excessive delay.

36 Finally, to the extent that the Republic of Lithuania submits that the present action is inadmissible since the Commission has infringed the principle of sound administration, clearly that Member State bases that argument only on lack of purpose of the action and on delay in bringing the proceedings under Article 258 TFEU.

37 It follows from paragraphs 32 and 35 of this judgment that the Commission's action is neither without purpose nor brought with excessive delay.

38 In those circumstances, there are no grounds for the conclusion that the Commission infringed the principle of sound administration in such a way as to call into question the admissibility of the action.

39 Having regard to the foregoing considerations, the action must be regarded as admissible.

*Substance*

The first complaint

— Arguments of the parties

40 In order to substantiate, by its first complaint, the allegation that the Republic of Lithuania has infringed Directive 2001/83, as amended by Directive 2003/63, the Commission submits that, pursuant to Article 6 of that directive, read in conjunction with Article 2 of the 2003 Act of Accession, that Member State was, upon its accession to the European Union, to ensure that only medicinal products with marketing authorisations which comply with the requirements of European Union law in force at the date of that accession are placed on the market.

41 The only derogation from that obligation is that provided for in Annex IX, Chapter 1, paragraph 2, to the 2003 Act of Accession, according to which marketing authorisations for the pharmaceutical products in Appendix A 'issued under Lithuanian law prior to the date of accession, shall remain valid until they are renewed in compliance with the acquis … or until 1 January 2007, whichever is the earlier'.

42 However, the Republic of Lithuania permitted the biological medicinal product Grasalva to continue to be marketed after the accession of that Member State to the European Union, despite the fact that its marketing authorisation had not been issued in accordance with European Union law in force at the date of that accession.

43 That authorisation did not comply with Annex I, Part II, point 4, of Directive 2001/83, as amended by Directive 2003/67, in that it was issued on the basis of an abridged application, which did not contain the results of preclinical and clinical trials. Nor, since Grasalva was not on the list in Appendix A, was that authorisation covered by the derogations laid down in Annex IX to the 2003 Act of Accession.

44 The Commission adds in that regard that, contrary to the principle that exceptions must be strictly interpreted, maintenance of the marketing authorisation for Grasalva after the accession of the Republic of Lithuania to the European Union amounts to extending the scope of the derogation laid down in that annex.

45 However, the Republic of Lithuania takes the view that it was possible for Grasalva to be marketed in Lithuania even after accession and until expiry of the marketing authorisation for that medicinal product, that is to say, until 2 July 2008.

46 Firstly, the Lithuanian legislation under which the authorisation had been issued on 2 July 2003 had already been amended in preparation for accession, to comply with the requirements of Directive 2001/83 in the original version. When that authorisation was issued, the period for transposition of Directive 2003/63, which ran until 31 October 2003, had not yet expired. Consequently, in the view of the Republic of Lithuania, given that Grasalva met all the requirements of quality, safety and efficacy laid down by Directive 2001/83, in force when the marketing authorisation for that medicinal product was issued, that authorisation remained valid even beyond the date of accession, without it being necessary to renew it to ensure its compliance with the acquis.

47 Next, the Lithuanian authorities were entitled to presume that it was not necessary either for Grasalva to be included in the list in Appendix A for it to be able to be marketed after the accession, given that that list contains only those medicinal products which do not meet the requirements laid down by Directive 2001/83. In addition, in the view of the Republic of Lithuania, when that list was drawn up, Directive 2003/63 had not yet been adopted, so that the Lithuanian authorities were not in a position to know that the marketing authorisation granted for that medicinal product would not comply with European Union law, as it was likely to be drafted following a future amendments to the relevant legislation. Furthermore, the new Member States are required to grant marketing authorisations in compliance with the new requirements laid down by Directive 2003/63 only for medicinal products for which an application for authorisation has been made after their accession to the European Union.

48 In addition, since the marketing authorisation for Grasalva was issued in accordance with the European Union law in force when it was issued, withdrawal of that authorisation would have infringed the principle of legality, particularly since no data have been submitted to show that the risk/benefit assessment of that medicinal product was not positive.

49 The Lithuanian Government also relies on the case-law of the Court in environmental matters and, in particular, on Case C-209/04 *Commission* v *Austria* [2006] ECR I-2755, paragraphs 53 to 63, pursuant to which the obligation on a Member State which has acceded to the European Union to apply the entire acquis, even if that entails amending earlier legislation under which that Member State issued an administrative authorisation, does not require the annulment of that authorisation.

50 Finally, the Commission's interpretation constitutes discrimination between the Member States which acceded to the European Union on 1 May 2004 and the other 15 Member States. The latter had to apply the new requirements laid down by Directive 2003/63 only to medicinal products for which an application for marketing authorisation was made after expiry of the period laid down for transposition of that directive, that is to say, 31 October 2003. However, the new Member States were

obliged to ensure, with effect from 1 May 2004, that all medicinal products whose marketing authorisations did not comply with Directive 2001/83, as amended by Directive 2003/63, were withdrawn from the market.

— Findings of the Court

51 By its first complaint, the Commission claims, in essence, that the Republic of Lithuania maintained the marketing authorisation for Grasalva after the date of its accession to the European Union, although, on that date, that authorisation did not meet the requirements laid down by Directive 2001/83, as amended by Directive 2003/63.

52 It must be borne in mind from the outset that it is common ground between the parties that the marketing authorisation which had been granted for that medicinal product did not, on the date of accession of the Republic of Lithuania to the European Union, meet the requirements of Directive 2001/83, as amended by Directive 2003/63. The authorisation had been issued before accession by the Lithuanian authorities on the basis of an abridged application, which did not contain the results of preclinical and clinical trials, whereas, with effect from 1 May 2004, the date of accession, marketing authorisations for medicinal products from biotechnical processes, such as Grasalva, could no longer be issued on the basis of such an abridged application, having regard to the amendments made by Directive 2003/63 to Annex I, Part II, point 4, to Directive 2001/83.

53 Nevertheless, the Republic of Lithuania submits that, since that authorisation complied with Directive 2001/83, as it was in force on 2 July 2003, the date of issue of that authorisation, it remained valid even beyond the date of accession.

54 It is therefore necessary to establish whether, with effect from the date of its accession to the European Union, the Republic of Lithuania was required to comply with Directive 2001/83, not in the original version but in that which followed its amendment by Directive 2003/63.

55 In that regard, it is apparent from Articles 2 and 10 of the 2003 Act of Accession that the Act is based on the principle that the provisions of European Union law apply *ab initio* and *in toto* to new Member States, derogations being allowed only in so far as they are expressly provided for by transitional provisions (see, by analogy, Case 258/81 *Metallurgiki Halyps* v *Commission* [1982] ECR 4261, paragraph 8; Case C-233/97 *KappAhl* [1998] ECR I-8069, paragraph 15; and Case C-420/07 *Apostolides* [2009] ECR I-3571, paragraph 33).

56 It follows that, with effect from 1 May 2004, the date of accession of the Republic of Lithuania to the European Union, that Member State was bound by the provisions of primary law and by the measures adopted before its accession, in particular, by the institutions, such that it was required, in accordance with Article 54 of the 2003 Act of Accession, to bring into force the measures necessary to comply, in particular, with the provisions of directives within the meaning of the third paragraph of Article 249 EC.

57 With regard to the derogations under that Act of Accession, it must be borne in mind that, Article 24, read in conjunction with Annex IX, Chapter 1, paragraph 2, thereto, provides for a transitional period during which marketing authorisations granted under its national legislation by the Republic of Lithuania, before the date of its accession to the European Union, for pharmaceutical products in the list in Appendix A remained valid even after that date and until 1 January 2007 at the latest.

58 In other words, by way of derogation from the obligations following from Article 2 of the 2003 Act of Accession and only in respect of medicinal products in that list, the Republic of Lithuania was not required, upon accession, to comply with Directive 2001/83, as amended by Directive 2003/63.

59 It is established that Grasalva is not included in the list in Appendix A.

60 Consequently, since the marketing authorisation granted for that medicinal product was not covered by the derogation laid down in Annex IX, Chapter 1, paragraph 2, of the 2003 Act of Accession, it should, with effect from 1 May 2004, have been made compliant with the European Union legislation in force on that date.

61 The arguments which the Republic of Lithuania has submitted in support of its contrary interpretation of that Act are not capable of affecting this finding.

62 In particular, firstly, the fact that that authorisation complied with European Union law in force at the date of its issue, that is to say, Directive 2001/83 in the original version, cannot be relevant.

63 Firstly, Article 54 of the 2003 Act of Accession requires the Member States to put into effect the measures necessary for them to comply with European Union law only from the date of their accession. Secondly, since Directive 2003/63 set as 31 October 2003 the end of the period in which Member States were to transpose that directive, it was an integral part of the acquis with which, pursuant to Article 2 of the 2003 Act of Accession, the Republic of Lithuania was required to comply with effect from 1 May 2004.

64 Next, that Member State incorrectly argues that the Lithuanian authorities were entitled to presume that it was not necessary for Grasalva to be included in the list in Appendix A in order to satisfy themselves that the marketing authorisation for that medicinal product would remain valid after the accession.

65 On the contrary, it cannot be deduced from the fact that Annex IX, Chapter 1, paragraph 2, of the 2003 Act of Accession refers to Directive 2001/83 in the original version that any authorisation complying with that version could, without the medicinal product in question being included in the list in Appendix A, benefit from a derogation from the requirements laid down in European Union law in force at the date of accession. The same is true even where those requirements have been amended during the period between the date of signature of that Act of Accession and the date on which accession occurred.

66 Firstly, that annex could not refer to Directive 2003/63, since that directive was not adopted until 25 June 2003, after signature of the 2003 Act of Accession. Secondly, the provisions of that annex must be interpreted in the light of those of that Act, of which that annex is an integral part, and, in particular, of Article 2 thereof, under which the new Member States are bound by all directives adopted by the institutions of the European Union before their accession.

67 The insertion of a medicinal product into the list in Appendix A was accordingly to permit the maintenance on the market not only of medicinal products whose authorisations did not comply with European Union law when that appendix was drawn up, but also those whose authorisations were likely to become invalid because of successive amendments to European Union legislation.

68 In those circumstances, at the date when Appendix A was drawn up, the Republic of Lithuania could, as a precaution, have added Grasalva to the list which it supplied for inclusion in that appendix, given that the Lithuanian authorities were in a position to know what amendments Directive 2003/63 would make to Directive 2001/83.

69 In that regard, it is apparent from the documents placed before the Court that the Republic of Lithuania took part, although only in the role of observer to which it was entitled as an acceding State, in the negotiations commenced in 2002 with a view to the adoption of Directive 2003/63 and that, consequently, the Lithuanian authorities were in a position to assess the potential impact that failing to add a medicinal product developed from biotechnical processes to the list which was to appear in the Appendix A was likely to have on the validity of the marketing authorisation for that medicinal product.

70 Even if, as the defendant Member State submits, the Lithuanian authorities learned of the existence of Grasalva only when the application for marketing authorisation was filed, that is to say, on 8 May 2003, and that it was therefore impossible for them to request an amendment to Appendix A – which had been annexed to the 2003 Act of Accession, signed on 16 April 2003 – the Republic of Lithuania then had not only the possibility of requesting an amendment of Directive 2003/63, which was not adopted until 25 June 2003, but also of requesting such an amendment after its definitive adoption.

71 Once the 2003 Treaty of Accession was signed, and subject to the application of the particular procedures provided for in that Treaty for deciding on certain types of transitional measures, such as, for example, those established by Articles 41 or 42 of the 2003 Act of Accession, there is no objection in principle to secondary legislation adopted after that signature and before the entry into force of the 2003 Treaty of Accession containing temporary derogations in favour of a future Member State being adopted directly on the basis of the provisions of the EC Treaty (Case C-413/04 *Parliament* v *Council* [2006] ECR I-11221, paragraph 62).

72 Consequently, as regards measures that must be thus adopted during the period between the date of signature of the Treaty of Accession and the date when the accession takes effect, the institutions are fully aware of the imminent accession of new Member States, and the latter have the opportunity to assert their interests where necessary, in particular through the information and consultation procedure (see, to that effect, Joined Cases 39/81, 43/81, 85/81 and 88/81 *Halyvourgiki and Helleniki Halyvourgia* v *Commission* [1982] ECR 593, paragraph 10, and *Parliament* v *Council*, paragraph 66).

73 It is therefore, in principle, in the framework of that procedure and by making use of their observer status in the Council of the European Union, with the opportunities for dialogue and cooperation which those special mechanisms afford them, that the future Member States may, once informed of the future adoption of new measures of secondary legislation, assert their interest in obtaining the necessary transitional derogations, having regard, for example, to the fact that it would be impossible to ensure immediate application of those measures on accession, or to major socio-economic problems to which such application might give rise (*Parliament* v *Council*, paragraph 67).

74 In the present case, the Republic of Lithuania has merely argued that it was practically impossible for it to negotiate transitional periods, but has not provided any evidence to show that it actually availed itself of the rights conferred on it by those procedures and that those procedures bore no fruit.

75 In addition, with regard to the alleged infringement of the principle of legality and of Article 126 of Directive 2001/83, it is sufficient to note that, as the Advocate General observed in point 138 of her Opinion, such arguments rest on the premiss that the marketing authorisation for Grasalva was issued validly and in compliance with European Union law.

76 That is not the situation in the present case, given that, on the date of accession of the Republic of Lithuania to the European Union, the authorisation did not meet the requirements laid down in that law, as in force at that date.

77 In the same way, contrary to the Member State's allegations, the conclusion set out in paragraph 63 of this judgment cannot in any way infringe the principle of non-discrimination given that, as the Advocate General observed in point 123 of her Opinion, the situation of a future Member State with regard to the obligations under the Treaty of Accession and that of Member States with regard to the transposition of a directive within the period prescribed cannot be regarded as being comparable.

78 Finally, with regard to the approach adopted by the Court in the case of *Commission* v *Austria*, it is sufficient to note that that approach was justified in particular by the fact, described in paragraph 60 of that judgment, that the Act of Accession did not provide, with respect to the Republic of Austria, for any derogation or transitional period in respect of the directives in question in the case which gave rise to that judgment.

79 Clearly, that is not the case as regards Directive 2001/83, given that the 2003 Act of Accession expressly provided, in Annex IX thereto, for derogation from the applicability of that directive in Lithuania.

80 In the light of the foregoing conclusions, the Court holds that the Commission's first complaint in support of its action is well founded.

The second complaint

— Arguments of the parties

81 By its second complaint, the Commission submits that, given that the marketing authorisation for Grasalva was no longer valid after 1 May 2004 because of its non-compliance with Directive 2001/83, as amended by Directive 2003/63, that medicinal product could not be marketed after that date except on the basis of an authorisation issued by the Commission in accordance with the centralised authorisation procedure laid down by Regulation No 2309/93. That regulation, applicable in the Republic of Lithuania upon its accession to the European Union, made biological medicinal products developed by means of recombinant DNA technology, such as Grasalva, subject to that procedure.

82 The Lithuanian authorities, after having pointed out that this second plea is closely linked to the first, reiterate that the marketing authorisation for Grasalva was issued on 2 July 2003, when the Republic of Lithuania was not yet a Member State of the European Union. Under the second paragraph of Article 2 of Regulation No 2309/93, '[t]he person responsible for placing the medicinal products covered by this Regulation on the market must be established in the Community'.

83 Consequently, according to those authorities, it was not possible on 2 July 2003 for the author of the application for a marketing authorisation for Grasalva to take advantage of the centralised procedure laid down in Regulation No 2309/93, given that he was established in Lithuania, that is to say, outside the Community. In addition, it would not be reasonable, having regard to the length of the procedures in question, to require, as the Commission does, the national marketing authorisation to be withdrawn on 1 May 2004, when, before that date, it would not have been possible for an

operator established in Lithuania to make an application for authorisation under the centralised procedure laid down in that regulation.

— Findings of the Court

84 In response to this second complaint, it must first be pointed out that, as is clear from the analysis of the first complaint, the national marketing authorisation for Grasalva was not granted in compliance with the European Union law applicable to medicinal products.

85 Consequently, in accordance with Article 6(1) of Directive 2001/83, that marketing authorisation was not sufficient, from accession of the Republic of Lithuania to the European Union, to permit the marketing of Grasalva in Lithuania.

86 It also follows from Article 6(1) of Directive 2001/83, from Article 3(1) of and the Annex to Regulation No 2309/93, and from Article 3(1) of and the Annex to Regulation No 726/2004 that, since it was not included in the list in Appendix A, Grasalva, as a medicinal product developed from biotechnical processes, could not be marketed in the Community after that accession except on the basis of an authorisation issued by the Commission under the centralised procedure laid down in Regulation No 2309/93 and, with effect from 20 November 2005, Regulation No 726/2004.

87 It is sufficient to note in that regard that, as the Republic of Lithuania itself accepts, Grasalva was marketed in Lithuania after accession of that Member State to the European Union and until 2 July 2008.

88 In those circumstances, it must be held that the Republic of Lithuania has infringed Articles 3(1) of Regulations Nos 2309/93 and 726/2004.

89 Consequently, the second complaint advanced by the Commission in support of its action is also well founded.

90 Accordingly, it must be held that, by maintaining in force the national marketing authorisation for the medicinal product Grasalva, the Republic of Lithuania has failed to fulfil its obligations under Article 6(1) of Directive 2001/83, as amended by Directive 2003/63, under Article 3(1) of Regulation No 2309/93, and under Article 3(1) of Regulation No 726/2004.

**Costs**

91 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the Commission has applied for costs to be awarded against the Republic of Lithuania and the latter has been unsuccessful, the Republic of Lithuania must be ordered to pay the costs.

On those ground, the Court (First Chamber) hereby:

1. **Declares that, by maintaining in force the national marketing authorisation for the medicinal product Grasalva, the Republic of Lithuania has failed to fulfil its obligations under Article 6(1) 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 Commission Directive 2003/63/EC of 25 June 2003, under Article 3(1) of Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products, and under Article 3(1) of 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;**

**2. Orders the Republic of Lithuania to pay the costs.**

[Signatures]