JUDGMENT OF THE COURT OF FIRST INSTANCE (Fifth Chamber)
31 January 2006 *

In Case T-273/03,

Merck Sharp & Dohme Ltd, established in Hoddesdon (United Kingdom),

Merck Sharp & Dohme BV, established in Haarlem (Netherlands),

Laboratoires Merck Sharp & Dohme-Chibret, established in Paris (France),

MSD Sharp & Dohme GmbH, established in Haar (Germany),

Merck Sharp & Dohme (Italia) SpA, established in Rome (Italy),

Merck Sharp & Dohme, L^da^, established in Paço de Arcos (Portugal),

Merck Sharp & Dohme de España, SA, established in Madrid (Spain),

Merck Sharp & Dohme GmbH, established in Vienna (Austria),

Vianex SA, established in Nea Erythrea (Greece),

represented by G. Berrisch and P. Bogaert, lawyers,

applicants,

* Language of the case: English.

Commission of the European Communities, represented by L. Flynn and B. Stromsky, acting as Agents, with an address for service in Luxembourg,

defendant,

ACTION for annulment of Commission Decision C(2003) 1752 of 21 May 2003 on the marketing of medicinal products for human use containing the substance enalapril,

THE COURT OF FIRST INSTANCE
OF THE EUROPEAN COMMUNITIES (Fifth Chamber),

composed of M. Vilaras, President, E. Martins Ribeiro and K. Jürimäe, Judges,

Registrar: K. Andová, Administrator,

having regard to the written procedure and further to the hearing on 13 September 2005,

gives the following

Judgment

Legal context

1 The legislation on the marketing of medicinal products for human use in the European Union has been codified by Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67, the 'HUM code' or 'HUM'). In accordance with Article 129 thereof, the HUM code entered into force on 18 December 2001.

2 The HUM code codifies, inter alia, the provisions of Second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ 1975 L 147, p. 13, 'Directive 75/319'), as amended, inter alia, by Council Directive 83/570/EEC of 26 October 1983 (OJ 1983 L 332, p. 1) and Council Directive 93/39/EEC of 14 June 1993 (OJ 1993 L 214, p. 22) ('Directive 75/319, as amended').

3 It follows from Article 6 HUM 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 Member State in accordance with the HUM code, or by the Community in accordance with 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). In accordance with Article 74 thereof, Regulation No 2309/93 entered into force on 1 January 1995.

Marketing authorisation procedures

4 There are three procedures for marketing authorisation for medicinal products for human use: the decentralised Community procedure, the centralised Community procedure and the national procedure.

5 The decentralised Community procedure was established by Directive 93/39, with effect from 1 January 1995. It is governed by Articles 28 and 29 HUM (corresponding to Articles 9 and 10 of Directive 75/319, as amended) and is based on the principle of mutual recognition.

6 This procedure begins with an application for a national marketing authorisation made to a Member State (the 'reference Member State'). The issuing of this marketing authorisation takes place at national level, in conditions originally harmonised by Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ, English Special Edition 1965-1966, p. 20), those conditions having since been codified, essentially, in Chapters 1 ('Marketing authorisation') and 3 ('Procedures relevant to the marketing authorisation') of Title III HUM ('Placing on the market').

7 The holder of the national marketing authorisation thus issued then applies for its recognition in one or more other Member States, in accordance with Article 28

HUM in Chapter 4 ('Mutual recognition of authorisations') of Title III HUM ('Chapter 4 of Title III HUM' or 'Chapter 4 HUM'). That Member State or those Member States may refuse recognition only on grounds of risk to public health (Articles 28(4) and 29(1) HUM). If such a risk is alleged and the Member States concerned do not agree on the action to be taken in respect of the application for recognition, the matter is referred for an opinion to the Committee for Proprietary Medicinal Products ('the CPMP'), which is part of the European Agency for the Evaluation of Medicinal Products ('the EMEA') (Articles 29(2) and 32 HUM), following which the Commission or the Council is required to take a decision (Articles 33, 34 and 121(2) HUM).

8 The centralised Community procedure was instituted by Regulation No 2309/93. Under this procedure, the marketing authorisation application is sent to the EMEA and leads to the grant of a marketing authorisation by decision either of the Commission or of the Council, taken on the advice of the CPMP. This procedure is obligatory for medicinal products developed by means of certain biotechnological processes and optional for other innovative medicinal products. It does not concern this action.

9 The national procedure is the result of the approximation of national legislation initiated by Directive 65/65 and continued by Directive 75/319. The only procedure in existence before the entry into force, on 1 January 1995, of the centralised and decentralised Community procedures, it has no longer applied since 1 January 1998 except where the medicinal product is intended to be marketed in only one Member State (Article 7a of Directive 65/65, corresponding to Article 18 HUM, as added by Article 1(7) of Directive 93/39). Since then, the lodging, in respect of a medicinal product already authorised in one Member State, of an application for a marketing authorisation in another Member State automatically sets in motion the mutual recognition procedure. The issue of a marketing authorisation as part of the national procedure is carried out in the harmonised conditions referred to in paragraph 6 above.

Provisions at issue in this case

10 Chapter 4 ('Mutual recognition of authorisations') of Title III HUM ('Placing on the market') contains the following provisions:

'Article 27 [corresponding to Article 8 of Directive 75/319, as amended]:

1. In order to facilitate the adoption of common decisions by Member States on the authorisation of medicinal products on the basis of the scientific criteria of quality, safety and efficacy, and to achieve thereby the free movement of medicinal products within the Community, a [CPMP] is hereby set up. The [CPMP] shall be part of the [EMEA].

2. In addition to the other responsibilities conferred upon it by Community law, the [CPMP] shall examine any question relating to the granting, variation, suspension or withdrawal of the marketing authorisation which is submitted to it in accordance with this Directive.

...

Article 28 [corresponding to Article 9 of Directive 75/319, as amended]

1. Before submitting the application for recognition of a marketing authorisation, the holder of the authorisation shall inform the Member State which granted the

authorisation on which the application is based (hereinafter "reference Member State"), that an application is to be made in accordance with this Directive and shall notify it of any additions to the original dossier; ...

In addition the holder of the authorisation shall request the reference Member State to prepare an assessment report in respect of the medicinal product concerned, or, if necessary, to update any existing assessment report. ...

At the same time as the application is submitted in accordance with paragraph 2, the reference Member State shall forward the assessment report to the Member State or Member States concerned by the application.

2. In order to obtain the recognition according to the procedures laid down in this Chapter in one or more of the Member States of a marketing authorisation issued by a Member State, the holder of the authorisation shall submit an application to the competent authorities of the Member State or Member States concerned, together with the information and particulars referred to in Articles 8, 10(1) and 11. He shall testify that the dossier is identical to that accepted by the reference Member State, or shall identify any additions or amendments it may contain. ...

3. The holder of the marketing authorisation shall communicate the application to the [EMEA], inform it of the Member States concerned and of the dates of submission of the application and send it a copy of the authorisation granted by the reference Member State. He shall also send the [EMEA] copies of any such authorisation which may have been granted by the other Member States in respect of the medicinal product concerned, and shall indicate whether any application for authorisation is currently under consideration in any Member State.

4. Save in the exceptional case provided for in Article 29(1), each Member State shall recognise the marketing authorisation granted by the reference Member State within 90 days of receipt of the application and the assessment report. It shall inform the reference Member State which granted the initial authorisation, the other Member States concerned by the application, the [EMEA], and the marketing authorisation holder.

Article 29 [corresponding to Article 10 of Directive 75/319, as amended]

1. Where a Member State considers that there are grounds for supposing that the marketing authorisation of the medicinal product concerned may present a risk to public health, it shall forthwith inform the applicant, the reference Member State which granted the initial authorisation, any other Member States concerned by the application and the [EMEA]. The Member State shall state its reasons in detail and shall indicate what action may be necessary to correct any defect in the application.

2. All the Member States concerned shall use their best endeavours to reach agreement on the action to be taken in respect of the application. ... However, if the Member States have not reached agreement within the time limit referred to in Article 28(4) they shall forthwith refer the matter to the [EMEA] with regard to the [CPMP's] reference for the application of the procedure laid down in Article 32.

3. Within the time limit referred to in Article 28(4), the Member States concerned shall provide the [CPMP] with a detailed statement of the matters on which they have been unable to reach agreement and the reasons for their disagreement. ...

Article 30 [formerly Article 11 of Directive 75/319, as amended]

If several applications submitted in accordance with Articles 8, 10(1) and Article 11 have been made for marketing authorisation for a particular medicinal product, and Member States have adopted divergent decisions concerning the authorisation of the medicinal product or its suspension or withdrawal, a Member State, or the Commission, or the marketing authorisation holder may refer the matter to the [CPMP] for application of the procedure laid down in Article 32.

The Member State concerned, the marketing authorisation holder or the Commission shall clearly identify the question which is referred to the [CPMP] for consideration and, where appropriate, shall inform the holder.

The Member State and the marketing authorisation holder shall forward to the [CPMP] all available information relating to the matter in question.

Article 31 [corresponding to Article 12 of Directive 75/319, as amended]

The Member States or the Commission or the applicant or holder of the marketing authorisation may, in specific cases where the interests of the Community are involved, refer the matter to the [CPMP] for the application of the procedure laid down in Article 32 before reaching a decision on a request for a marketing authorisation or on the suspension or withdrawal of an authorisation, or on any other variation to the terms of a marketing authorisation which appears necessary, in particular to take account of the information collected in accordance with Title IX.

The Member State concerned or the Commission shall clearly identify the question which is referred to the [CPMP] for consideration and shall inform the marketing authorisation holder.

The Member States and the marketing authorisation holder shall forward to the [CPMP] all available information relating to the matter in question.

Article 32 [corresponding to Article 13 of Directive 75/319, as amended]

1. When reference is made to the procedure described in this Article, the [CPMP] shall consider the matter concerned and issue a reasoned opinion within 90 days of the date on which the matter was referred to it.

...

3. In the cases referred to in Articles 29 and 30, before issuing its opinion, the [CPMP] shall provide the marketing authorisation holder with an opportunity to present written or oral explanations.

In the case referred to in Article 31, the marketing authorisation holder may be asked to explain himself orally or in writing.

...

4. The [EMEA] shall forthwith inform the marketing authorisation holder where the opinion of the [CPMP] is that:

— the application does not satisfy the criteria for authorisation, or

— the summary of the product characteristics proposed by the applicant in accordance with Article 11 should be amended, or

— the authorisation should be granted subject to conditions, with regard to conditions considered essential for the safe and effective use of the medicinal product including pharmacovigilance, or

— a marketing authorisation should be suspended, varied or withdrawn.

... [T]he marketing authorisation holder may notify the [EMEA] in writing of his intention to appeal. ... [The CPMP] shall consider whether its opinion should be revised, and the conclusions reached on the appeal shall be annexed to the assessment report referred to in paragraph 5.

5. Within 30 days of its adoption, the [EMEA] shall forward the final opinion of the [CPMP] to the Member States, the Commission and the marketing authorisation holder together with a report describing the assessment of the medicinal product and stating the reasons for its conclusions.

...

Article 33 [corresponding to Article 14(1) of Directive 75/319, as amended]

Within 30 days of the receipt of the opinion, the Commission shall prepare a draft of the decision to be taken in respect of the application, taking into account Community law.

...

Where, exceptionally, the draft decision is not in accordance with the opinion of the [EMEA], the Commission shall also annex a detailed explanation of the reasons for the differences.

The draft decision shall be forwarded to the Member States and the applicant.

Article 34 [corresponding to Article 14(2) to (4) of Directive 75/319, as amended]

1. A final decision on the application shall be adopted in accordance with the procedure referred to in Article 121(2).

...

3. A decision as referred to in paragraph 1 shall be addressed to the Member States concerned by the matter and reported to the marketing authorisation holder. The Member States shall either grant or withdraw marketing authorisation, or vary the terms of a marketing authorisation as necessary to comply with the decision within 30 days of its notification. They shall inform the Commission and the [EMEA] thereof.

Article 35 [corresponding to Article 15 of Directive 75/319, as amended]

1. Any application by the marketing authorisation holder to vary a marketing authorisation which has been granted in accordance with the provisions of this Chapter shall be submitted to all the Member States which have previously authorised the medicinal product concerned.

...

2. In case of arbitration submitted to the Commission, the procedure laid down in Articles 32, 33 and 34 shall apply by analogy to variations made to marketing authorisations.

Article 36 [corresponding to Article 15a of Directive 75/319, as amended]

1. Where a Member State considers that the variation of a marketing authorisation which has been granted in accordance with the provisions of this Chapter or its suspension or withdrawal is necessary for the protection of public health, the Member State concerned shall forthwith refer the matter to the [EMEA] for the application of the procedures laid down in Articles 32, 33 and 34.

2. Without prejudice to the provisions of Article 31, in exceptional cases, where urgent action is essential to protect public health, until a definitive decision is adopted a Member State may suspend the marketing and the use of the medicinal product concerned on its territory. It shall inform the Commission and the other Member States no later than the following working day of the reasons for its action.'

Background to the dispute

11 The applicants, all (with the exception of Vianex SA) members of the Merck Sharp & Dohme group ('MSD'), are holders of marketing authorisations issued under the national procedure in respect of medicinal products for human use marketed under the name Renitec and related trade names ('Renitec').

12 By letter of 31 October 2000, the Agence française de sécurité sanitaire des produits de santé (French Agency for safety of health products) (the 'Afssaps') submitted to the CPMP a notification for a referral relating to Renitec under Article 11 of

Directive 75/319, as amended (corresponding to Article 30 HUM), concerning Renitec. The subject-matter of the referral to the CPMP was the fact that Renitec did not have the same summary of product characteristics ('SPC') in all the Member States and that, in the opinion of the Afssaps, harmonisation of the SPCs for Renitec at Community level was necessary for reasons of public health.

13 By fax of 23 February 2001 the Afssaps submitted to the EMEA an official referral by the French Republic for arbitration concerning Renitec pursuant to Article 11 of Directive 75/319, as amended.

14 On 19 September 2002 the CPMP adopted the opinion provided for in Article 32(1) HUM. In that opinion, the CPMP suggested certain amendments to the SPC for Renitec, in particular relating to the wording of section 4.1 ('Therapeutic Indications').

15 On 3 October 2002 MSD notified the EMEA of its intention to appeal against that opinion to the CPMP pursuant to the final subparagraph of Article 32(4) HUM. By letter of 15 November 2002 MSD sent the CPMP the detailed grounds of its appeal.

16 On 18 December 2002 the CPMP, after re-examining its original opinion, adopted its final opinion which confirmed, apart from some minor amendments, the wording of section 4.1 suggested in its original opinion. The final opinion was then sent to the Commission

17 On 21 May 2003 the Commission adopted, pursuant to Articles 33 and 34 HUM, Decision C(2003) 1752 concerning the placing on the market of medicinal products for human use containing the substance enalapril ('the contested decision'). By that

decision, the Commission ordered the Member States concerned, listed in Article 5 of the decision, to amend the SPCs of the national marketing authorisations for Renitec, listed in Annex I to the decision. The Commission informed MSD of that decision by electronic mail of 26 May 2003.

Procedure and forms of order sought

18 By application lodged at the Registry of the Court of First Instance on 1 August 2003 the applicants brought the present action.

19 The applicants have requested measures of organisation of procedure with a view to the production by the Commission of various documents.

20 Upon hearing the Report of the Judge-Rapporteur the Court of First Instance (Fifth Chamber) decided to open the oral procedure without adopting any measures of organisation of procedure.

21 The parties presented oral arguments and their replies to the questions asked by the Court of First Instance at the hearing on 13 September 2005.

22 The applicants claim that the Court should:

— annul the contested decision;

— order the Commission to pay the costs.

23 The Commission contends that the Court should:

— dismiss the action as unfounded;

— order the applicants to pay the costs.

Law

24 The applicants put forward four pleas in law supporting the claim for annulment. The first alleges that the referral to the CPMP pursuant to Article 30 HUM was unlawful and that there was a misuse of powers. The second, alleging that the Commission was incompetent to adopt the contested decision, falls into three parts. The first part is based on the Commission's lack of competence to adopt a decision pursuant to Articles 33 and 34 HUM following a referral under Article 30 HUM. The second part alleges that it is impossible for the CPMP to propose an SPC in its opinion when the grant or maintenance of the marketing authorisation is not at issue. The third part alleges that there are, in the circumstances of the case, no public health grounds making it possible to adopt the contested decision. The third plea in law claims that the 'clean indication policy' is unlawful, and alleges infringement of the principle of equal treatment and a manifest error of assessment. The fourth plea alleges infringement of procedural rules.

25 The Court of First Instance considers it appropriate to begin by examining the first part of the second plea, which alleges that the Commission lacked competence to adopt a decision pursuant to Articles 33 and 34 HUM following a referral under Article 30 HUM.

Arguments of the parties

26 The applicants submit that it follows from the judgment of the Court of First Instance in Joined Cases T-74/00, T-76/00, T-83/00, T-84/00, T-85/00, T-132/00, T-137/00 and T-141/00 *Artegodan and Others* v *Commission* [2002] ECR II-4945 ('the judgment in *Artegodan*'), the findings of which were not, in their view, invalidated by the Court of Justice's judgment in Case C-39/03 P *Commission* v *Artegodan and Others* [2003] ECR I-7885, that the Commission was incompetent to adopt the contested decision following a referral to the CPMP under Article 30 HUM. In that regard, the applicants point out that the judgment in *Artegodan* concerns not only Article 12 of Directive 75/319, as amended, but also Article 11 of that directive (corresponding to Article 30 HUM), which is relevant to the present case.

27 Contrary to what the Commission maintains, the fact that, in its judgment *Commission* v *Artegodan and Others*, paragraph 26 above, the Court of Justice did not address the relevant grounds of the judgment in *Artegodan* does not make of those findings obiter dicta. Nor, what is more, did the Court challenge those findings.

28 In the applicants' view, the history of the harmonisation process, ignored in the Commission's arguments, shows that the procedure under Article 30 HUM can contribute to the protection of public health and the free movement of medicinal products even if it cannot lead to a binding Commission decision. Article 30 HUM, as it stood before codification, was already intended to promote those interests. It is not at all illogical that those procedures under Articles 30 and 31 HUM should be purely consultative. They concern older medicinal products that were previously

subject to consultative procedures and that will de facto become less and less relevant in the overall category of medicinal products as more and more new products are approved under the decentralised and centralised procedures that entered into force in 1995.

29 In addition, the fourth recital in the preamble to Directive 93/39 (now the 12th recital in the preamble to the HUM) refers specifically to the need for a binding decision in case of disagreement between Member States under the mutual recognition procedure. There is no similar recital, however, concerning the procedures under Articles 30 and 31 HUM.

30 With regard to Article 27 HUM, the Commission stresses the reference to the adoption of common decisions, but overlooks the fact that the purpose of establishing the CPMP was to facilitate the adoption of common positions by Member States, which does not require or imply binding decisions by the Commission.

31 The second and third recitals in the preamble to the HUM code, to which the Commission refers also, are almost identical to the two first recitals in the preamble to Directive 65/65, which contains no reference to consultations between Member States, let alone to binding decisions.

32 The Commission's argument that it would be illogical that only marketing authorisation holders could start a procedure resulting in a binding decision, that is to say, by starting a mutual recognition procedure for an old product, is an argument de lege ferenda and in any event refers to a highly theoretical situation.

33 With regard to the Commission's argument that non-binding harmonisation efforts in respect of decisions on individual products would be incompatible with harmonisation legislation based on Article 95 EC, the applicants note that before the HUM code the directives were all based on Article 95 EC, yet did not provide for binding decisions. It is not uncommon for harmonisation legislation in complex areas, such as marketing authorisations, to lay down harmonised criteria that the Member States have to apply to individual cases. It is also common for the Member States, in making individual decisions, to take into account opinions from scientific Community bodies.

34 The Commission submits, first, that the judgment in *Artegodan* concerned decisions adopted on the basis of Community interest referrals (Article 12 of Directive 75/319, as amended, corresponding to Article 31 HUM), rather than on the basis of the divergent decisions process (Article 11 of Directive 75/319, as amended, corresponding to Article 30 HUM).

35 The Commission argues, second, that the appeal against the judgment in *Artegodan* was decided by the Court of Justice in its judgment in *Commission* v *Artegodan and Others*, paragraph 26 above, on a point of law concerning the interpretation to be given to Article 15a of Directive 75/319, as amended (corresponding to Article 36 HUM). The Court did not rule on whether the Commission could base a binding decision on Article 12 of that directive. The *Artegodan* case related to a different procedure with which the Court of First Instance is not at all concerned in the present proceedings. The reasoning in the judgment in *Artegodan* concerning the procedure under the abovementioned Article 12 and more generally concerning the scheme of Chapter III of Directive 75/319, as amended, is thus obiter dictum.

36 In addition to those arguments concerning the relevance of the judgment in *Artegodan* to this case, the Commission invites the Court of First Instance to depart from the approach adopted in that judgment.

37 In that judgment the Court examined the question of the interpretation of Article 12 of Directive 75/319, as amended, through the prism of competence. Such an examination, according to the defendant, must be undertaken only with the greatest care. It is not the Member States, despite the fact that they are the most likely to wish to retain their powers, which have raised this question of competence in the present case but holders of marketing authorisations affected by the contested decision. In fact, the holders of authorisations seek indirectly to reserve to themselves the right to decide if and when a SPC is to be harmonised.

38 Relying on the second and third recitals in the preamble to the HUM code, and on Article 27(1) HUM which it describes as the central provision of Chapter 4 HUM, the Commission notes that the purpose of the HUM code is not only to safeguard public health but also to achieve the free movement of medicinal products within the Community.

39 The common decisions the adoption of which by the Member States is to be facilitated, in accordance with Article 27(1) HUM, are not only those taken under the mutual recognition procedure. Nothing in Article 27(1) HUM indicates that for certain procedures under Chapter 4 HUM (Articles 28, 29, 35 and 36 HUM) the Community authorities deemed it necessary to provide for the adoption by the Commission of a binding decision, whereas for other procedures under the same chapter (Articles 30 and 31 HUM) a common decision could not be required, but merely aspired to. The verb 'facilitate', used in Article 27(1) HUM, does not, as the applicants suggest, mean that CPMP opinions are not to be followed automatically by a binding decision, but simply reflects the fact that it is not the CPMP that adopts the binding decision.

40 In reliance on considerations relating to the codification mechanism, the Commission suggests that the heading of Chapter 4 HUM, namely, 'Mutual recognition of authorisations', which replaced the former heading 'Committee for

Proprietary Medicinal Products', must, like that former heading, be understood in a broad sense, that is to say, as not covering solely the procedure under Article 28 HUM which is no more than a particular mechanism of mutual recognition triggered by the holder of the marketing authorisation, but also the other procedures under Chapter 4 HUM, including that under Article 30 HUM.

41 What is more, the Commission fails to see how the effectiveness of the Community interest procedure can be ensured by an interpretation that limits its scope to the consultation of the CPMP, leaving each Member State free to decide what action to take on the basis of the CPMP's opinion. The Commission takes the view that there will be numerous cases where the Member States will have different ideas as to the measures to be taken. The Commission questions whether the concept of 'voluntary harmonisation' is compatible with an instrument, based on Article 95 EC, whose object is the establishment and functioning of the internal market.

42 For all those reasons, the Commission takes the view that the practical effectiveness of the procedure under Article 30 HUM requires it to be accompanied by a binding decision. The considerations which led the Court of First Instance to rule in the judgment in *Artegodan* that, in order to be effective, the mutual recognition procedure needed to be accompanied by a binding decision apply precisely to the procedure under Article 30 HUM.

43 With regard to the applicants' argument relating to the history of the harmonisation process, the Commission considers that the indisputable fact that before 1995 harmonisation was carried out by means of the fixing of common standards to be implemented by the Member States cannot be interpreted as preventing any evolution of Community law in the direction of harmonisation by way of binding decisions.

44 In another respect, the applicants' contention that it is logical that the procedures under Articles 30 and 31 HUM should be merely consultative because they refer to older products is without foundation. These procedures are not limited to older marketing authorisations but apply equally to authorisations approved under the mutual recognition system.

45 Furthermore, it is not possible to infer the consultative nature of the procedure under Article 30 HUM from the absence of a recital in the HUM code referring to the binding nature of referrals made under that article. The reference in Article 27 HUM to the CPMP's being established in order to facilitate the adoption of common decisions does not imply that the outcome of an arbitration is not binding.

46 The applicants' puzzlement in the face of the Commission's unease regarding legislation which, although based on Article 95 EC, reduces harmonisation to a coincidence is the result of the applicants' failure to appreciate that the HUM code is intended to mark a progression in relation to the situation before 1995.

Findings of the Court

47 By the first part of the second ground of annulment, the applicants claim that the Commission had no power, following a referral to the CPMP under Article 30 HUM, to adopt pursuant to Articles 33 and 34 HUM a decision binding on the Member States.

48 It is to be noted that that point was the subject of consideration in the judgment in *Artegodan* and in Case T-147/00 *Laboratoires Servier* v *Commission* [2003] ECR II-85 ('*Servier*') in proceedings similar to those in the present case.

49 In the judgment in *Artegodan* the Court of First Instance annulled three decisions of the Commission ordering the withdrawal of marketing authorisations, granted in accordance with the national procedure, for certain anorectic medicinal products.

50 That judgment particularly concerned Directive 75/319, as amended.

51 The national marketing authorisations granted in that case had been amended by the Member States concerned, as a result of a decision of the Commission of 9 December 1996, based on Article 14 of Directive 75/319, as amended (corresponding to Articles 33 and 34 HUM) and taken after consultation of the CPMP under Article 12 of that directive (corresponding to Article 31 HUM) ('the decision of 9 December 1996') (the judgment in *Artegodan*, paragraphs 17 and 20 to 25).

52 Taking the view that those marketing authorisations had been harmonised in part by the decision of 9 December 1996 (the judgment in *Artegodan*, paragraphs 107 and 120), the Commission considered that they no longer fell within the exclusive competence of the Member States and that that decision had had the effect of transferring to the Community competence to decide, henceforth, on their withdrawal, variation or suspension.

53 Thus it was that by several decisions of 9 March 2000 ('the decisions of 9 March 2000'), which were those at issue in the proceedings giving rise to the judgment in *Artegodan*, the Commission, acting on the basis of referrals by Member States under

Article 15a of Directive 75/319, as amended, and following the procedure governed by Articles 13 and 14 of that directive (corresponding to Article 32 HUM and Articles 33 and 34 HUM, respectively), ordered the withdrawal of those marketing authorisations on grounds of public health.

54 The Court of First Instance annulled those decisions in its judgment in *Artegodan*.

55 The Court noted, first of all, that it was common ground between the parties that the marketing authorisations of the medicinal products referred to by the decisions of 9 March 2000 had been granted, and in some cases renewed, in accordance with the national procedures applicable in the various Member States concerned, and not in accordance with the mutual recognition procedure coupled with arbitration procedures, provided for in Chapter III of Directive 75/319, as amended (the judgment in *Artegodan*, paragraph 113).

56 The Court concluded therefrom that, 'leaving aside the decision of 9 December 1996, those authorisations were thus purely national' and that 'the suspension, variation or withdrawal of those authorisations therefore came, at the time when the contested decisions were adopted [9 March 2000], within the exclusive competence of the Member States concerned, a competence which, following the introduction of the mutual recognition procedure by Directive 93/39, is essentially residual' (judgment in *Artegodan*, paragraph 114). According to the interpretation of the Community legislation given by the Court, 'since 1 January 1995 that exclusive competence [of the Member States] has been restricted to, first, the grant and management of marketing authorisations for medicinal products marketed solely in a single Member State and, second, the management of purely national marketing authorisations granted before that date or during the transitional period from 1 January 1995 to 31 December 1997' (judgment in *Artegodan*, paragraph 116).

57 The Court went on to examine the question whether, following their amendment pursuant to the decision of 9 December 1996, the marketing authorisations for the

medicinal products at issue fell within the ambit of Article 15a(1) of Directive 75/319, as amended, which constitutes the legal basis on which the Commission adopted the decisions of 9 March 2000. Finding that that provision referred only to marketing authorisations granted in accordance with the provisions of Chapter III of that directive, that is to say, in accordance with the mutual recognition procedure, the Court interpreted it as meaning that 'the variation, suspension or withdrawal of such marketing authorisations, on the initiative of a Member State with a view to the protection of public health, falls within the exclusive competence of the Commission, when adopting a decision following a CPMP opinion in accordance with the procedures laid down in Articles 13 and 14 of Directive 75/319[, as amended]' whereas, '[c]onversely, the variation, suspension and withdrawal of marketing authorisations which do not fall within the ambit of Article 15a remain, in principle, subject to the exclusive competence of the Member States' (judgment in *Artegodan*, paragraph 121).

58 The Court considered that, the wording of Articles 12 and 15a of Directive 75/319 providing no clear guidance, it was necessary to consider whether, in the scheme of Chapter III of that directive and in the light of the aims of that directive, Article 15a(1), in conjunction with Article 12, could be construed as also applying to national marketing authorisations which had been harmonised under Article 12 (judgment in *Artegodan*, paragraph 125).

59 To that end, the Court examined the question of which authority is competent to adopt a decision following an opinion of the CPMP under Article 12 of Directive 75/319, as amended, an article which does no more than provide expressly for the application of the consultative procedure governed by Article 13 of that directive and does not refer to Article 14 of that directive also. It held, in this regard, that Article 12 of Directive 75/319, as amended, 'is intended to apply in the residual field of exclusive competence of the Member States, or when the initial marketing authorisation of a medicinal product is granted by the reference Member State' (judgment in *Artegodan*, paragraph 142), and that it 'cannot be interpreted as implicitly empowering the Commission to adopt a binding decision under the procedure set out in Article 14' of that directive (judgment in *Artegodan*, paragraph 147), unlike Article 10(2) which, although also referring to the consultative procedure laid down in Article 13, nevertheless forms part of a different context,

that of the mutual recognition procedure (judgment in *Artegodan*, paragraphs 130 to 133). The Court reached these conclusions by means of an interpretative approach based on the scheme of Chapter III of Directive 75/319, as amended, and on the objectives sought by that directive.

60 With regard to Article 11 of Directive 75/319, as amended (corresponding to Article 30 HUM), at issue in the instant case, the Court reached the same conclusion (judgment in *Artegodan*, paragraphs 140 and 146). Article 11 of Directive 75/319, as amended, just like Article 12 thereof, opens only a purely consultative procedure.

61 Taking notice of the fact that the decision of 9 December 1996 had been complied with by the Member States concerned, the Court considered it necessary to establish whether, in the scheme of Chapter III of Directive 75/319, as amended, authorisations harmonised by the Member States following consultation of the CPMP under Article 12 of Directive 75/319 could nevertheless be placed on the same footing as marketing authorisations granted in accordance with the provisions of Chapter III (judgment in *Artegodan*, paragraph 148).

62 In this connection, the Court found that, 'in the absence of an express provision, the principle, set out in the first paragraph of Article 5 EC, that the Community is to act within the limits of the powers conferred upon it, precludes an interpretation of Article 15a(1) of Directive 75/319[, as amended,] to the effect that the harmonisation of certain marketing authorisations, in accordance with a non-binding opinion of the CPMP under Article 12 of that directive, can have the effect of depriving the Member States concerned of their powers, by triggering the application of the arbitration procedure provided for in Article 15a in respect of the adoption of any subsequent decision regarding the suspension or withdrawal of such authorisations' (judgment in *Artegodan*, paragraph 150). It held therefore that, 'in the scheme of Directive 75/319[, as amended,] the concept of a marketing authorisation granted in accordance with the provisions of Chapter III of that directive, referred to in Article 15a(1), cannot be interpreted as also including authorisations harmonised following consultation of the CPMP under Article 12' (judgment in *Artegodan*, paragraph 155).

63 The Court accordingly concluded that the decisions of 9 March 2000 had no legal basis and that the plea in law alleging that the Commission lacked competence was well founded.

64 In *Servier*, the Court applied to a similar situation the solution adopted in its judgment in *Artegodan* (see, in particular, paragraphs 57 to 63, which refer to the judgment in *Artegodan*).

65 The Commission appealed against the judgments in *Servier* and *Artegodan*, complaining that the Court had denied that it was competent to adopt a decision pursuant to Article 14 of Directive 75/319, as amended, following a procedure initiated under Article 12 of that directive.

66 In its judgment in *Commission* v *Artegodan and Others*, paragraph 26 above, the Court of Justice, sitting as a full court, dismissed the appeal, basing its assessment not on Article 12 of Directive 75/319, as amended, but on Article 15a thereof, which constitutes the legal basis for the decisions of 9 March 2000. The Court held:

'44 ... [I]t should be noted that the decisions at issue were adopted solely on the basis of Article 15a of Directive 75/319.

45 According to its wording, Article 15a of Directive 75/319[, as amended,] applies to marketing authorisations which have been granted in accordance with the provisions of Chapter III of that directive.

46 The Court of First Instance found, and this was not contested by the Commission, that the marketing authorisations whose withdrawal was ordered by the decisions [of 9 March 2000] were initially granted under purely national procedures.

47 Assuming that the purpose of Article 15a of Directive 75/319[, as amended,] is to be interpreted broadly and the provision can thus be held to apply to marketing authorisations which have not been granted under Chapter III but which have been the subject of another harmonisation procedure, it becomes necessary in the present case to determine whether the 1996 decision can be regarded as having brought about such harmonisation.

48 It is common ground that the ... decision [of 9 December 1996] merely ordered the amendment of certain terms of the initial marketing authorisations, namely the clinical particulars which, along with other data, must be included in the summary of product characteristics in accordance with point 5 of Article 4a of Directive 65/65.

49 A partial amendment of that kind cannot amount to an authorisation granted in accordance with the provisions of Chapter III of Directive 75/319[, as amended].

50 It is therefore of no importance whether that partial amendment of the marketing authorisations of the medicinal products in question was the result of compliance with a binding decision or of voluntary harmonisation by the Member States.

51 It follows that Article 15a of Directive 75/319[, as amended,] could not be used as a legal basis for the decisions [of 9 March 2000].

52 In those circumstances, and without its being necessary to rule on the other pleas and arguments put forward by the Commission, the Court finds that the Court of First Instance was right to hold that the Commission lacked the competence to adopt the decisions [of 9 March 2000] and that, accordingly, those decisions had to be annulled.'

67 In its order of 1 April 2004 in Case C-156/03 P *Commission* v *Laboratoires Servier*, not published in the European Court Reports, the Court of Justice, following the line of reasoning adopted in its judgment in *Commission* v *Artegodan and Others*, paragraph 26 above, dismissed, for the same reasons, the appeal against the judgment in *Servier* as manifestly unfounded (paragraphs 38 to 48 of the order).

68 The Court of First Instance finds, first, that the judgment in *Artegodan* has been rendered definitive by the dismissal of the appeal brought against it. It is apparent from the grounds of that judgment that referrals to the CPMP under Articles 30 and 31 HUM cannot lead to binding decisions of the Commission under Articles 33 and 34 HUM, but only to an opinion of the CPMP.

69 The Court of First Instance finds, however, that the Court of Justice did not explicitly adopt a position on those grounds of the judgment in *Artegodan*.

70 That is the context in which the Commission contends that the approach adopted in the judgment in *Artegodan* is irrelevant to the present case and argues that it is in any event necessary to reverse the position adopted in that judgment.

71 It is appropriate, first, to consider the Commission's argument that the judgment in *Artegodan* has no bearing on the instant case because the procedure at issue in that

judgment related to Article 15a of Directive 75/319, as amended, and not to Article 12 thereof.

72 It is, admittedly, true that the decisions of 9 March 2000, challenged in the *Artegodan* case, were taken on the basis of Article 15a of Directive 75/319, as amended, and that the Court of Justice did not tackle the question of the Commission's competence to adopt the decision of 9 December 1996 following a referral under Article 12 of that directive.

73 Nevertheless, although that may mean that, for the Court of Justice, the grounds of the judgment in *Artegodan* relating to the Commission's lack of decision-making competence in the context of Article 12 of Directive 75/319, as amended, were not essential to the outcome of the dispute in the *Artegodan* case, but rather constituted obiter dicta, that does not mean that those grounds were regarded by the Court as incorrect or indeed that they are irrelevant to the present case.

74 The fact that in paragraph 50 of the judgment in *Commission* v *Artegodan and Others*, paragraph 26 above, the Court of Justice stated that it 'is therefore of no importance whether that partial amendment of the marketing authorisations of the medicinal products in question (carried out following the decision of 9 December 1996) was the result of compliance with a binding decision or of voluntary harmonisation by the Member States' does not mean that the Court challenged the Court of First Instance's reasoning with regard to the Commission's lack of competence to take a final decision following a referral to the CPMP under Article 12 of Directive 75/319, as amended. That statement by the Court means only that it had not, in examining the appeal, dealt with that issue.

75 The fact that in paragraph 47 of its judgment, the Court of Justice contemplated, beside the marketing authorisations granted under Chapter III of Directive 75/319, as amended, the possibility that a marketing authorisation should be the subject of 'another harmonisation procedure' does not imply that the Court departed from the Court of First Instance's reasoning. After finding that the marketing authorisations at issue in the case giving rise to the judgment in *Artegodan* had not been granted under Chapter III of Directive 75/319, as amended (paragraph 46 of the Court's judgment), the Court confined itself to the pure supposition that the purpose of Article 15a of Directive 75/319 could be interpreted broadly, which would enable that provision to apply to marketing authorisations which had not been granted under Chapter III but which had been the subject of another harmonisation procedure. By so doing, the Court did not in any way intend to depart from the Court of First Instance's reasoning.

76 The Commission's argument that the judgment in *Artegodan* dealt with decisions taken on the basis of a Community interest referral (Article 12 of Directive 75/319, as amended, corresponding to Article 31 HUM) and not on the basis of divergent decisions (Article 11 of Directive 75/319, as amended, corresponding to Article 30 HUM) cannot render that judgment irrelevant. As a matter of fact, the Court of First Instance considered that Article 11 of Directive 75/319, as amended, like Article 12 of that directive, 'is not one of the provisions providing the framework for the mutual recognition procedure' (judgment in *Artegodan*, paragraph 140) and that the procedure established by Article 11, like that under Article 12, is purely consultative (judgment in *Artegodan*, paragraph 146). The Court of First Instance therefore placed the two procedures on the same footing. At the very most those statements in the judgment in *Artegodan* relating to Article 11 of Directive 75/319, as amended, are to be regarded as constituting mere obiter dicta.

77 It would therefore appear that the grounds of the judgment in *Artegodan*, obiter dicta as they may be (as regards Article 11 of Directive 75/319, as amended), or as they may seem to be in the light of the judgment in *Commission* v *Artegodan and*

Others, paragraph 26 above (as regards Article 12 of that directive), are not shaken by the latter judgment and that they are relevant to the instant case.

78 The Commission's argument that the judgment in *Artegodan* is irrelevant to this case must therefore be rejected.

79 Second, it falls to be examined whether, as the Commission would have it, Article 30 HUM (corresponding to Article 11 of Directive 75/319, as amended) must be interpreted as allowing that institution to adopt, under Articles 33 and 34 HUM (corresponding to Article 14 of Directive 75/319, as amended), a decision binding on the Member States concerning purely national marketing authorisations.

80 In its judgment in *Artegodan*, the Court of First Instance replied that it must not, stating that it was not apparent from the wording or the purpose of Article 12 of Directive 75/319, as amended (corresponding to Article 31 HUM), or even from the system established by Chapter III of that directive (corresponding to Chapter 4 HUM) that the Commission was competent to take a decision following a referral procedure initiated under Article 12. The Court noted that that provision was intended to apply in the residual field of the exclusive competence of the Member States, that is to say, with regard to purely national marketing authorisations, and that consequently it made sense that that article should provide for it to be possible to consult the CPMP only under Article 13 of Directive 75/319, as amended (corresponding to Article 32 HUM) (judgment in *Artegodan*, paragraph 142). The Court of First Instance considered that the same was true of Article 11 of Directive 75/319, as amended (corresponding to Article 30 HUM) (judgment in *Artegodan*, paragraph 146).

81 The Court of First Instance sees no reason to cast any doubt on that interpretation.

82 First of all, the amendments made by Directive 93/39 to the wording of Article 11 of Directive 75/319, as amended by Directive 83/570, do not permit the inference that that article, thus amended, established an arbitration procedure.

83 In point of fact, the amendments to Article 11 of Directive 75/319 (corresponding to Article 30 HUM) involve, in addition on the one hand to the extension of the right of referral to the CPMP to 'the person responsible for placing the medicinal product on the market' ('the marketing authorisation holder' in the codified version, Article 30 HUM) and on the other hand to the statement that the person making the referral must clearly identify the question referred for consideration, what are essentially no more than drafting amendments. Those amendments in no way indicate that any transfer of decision-making power has been made in the Commission's favour.

84 Having regard to the foregoing considerations, from which it is clear that the amendments to the wording of Directive 75/319 made by Directive 93/39 do not lead to the conclusion that there has been any transfer of competence to the Community so far as purely national marketing authorisations are concerned, it must be considered, in the same way as in the findings made by the Court of First Instance in the judgment in *Artegodan* (paragraph 139 of the judgment), that such competence can be given to the Commission only if it is clearly apparent from the purpose of Article 30 HUM (corresponding to Article 11 of Directive 75/319 of Directive 75/319, as amended) or is expressly provided for in the system established by Chapter 4 HUM (corresponding to Chapter III of that directive).

85 In this connection, the Court considers, as it has earlier indicated in the judgment in *Artegodan* with regard to Directive 75/319, as amended (paragraph 140 of the judgment in *Artegodan*), that, unlike Article 29(2) HUM (corresponding to Article 10(2) of Directive 75/319, as amended), which relates to the mutual recognition procedure and must accordingly be interpreted in accordance with the purpose of that procedure, as specifically defined in recital 12 in the preamble to the Code, Article 30 HUM, just like Article 31 HUM, is not one of the provisions providing the framework for the mutual recognition procedure. That procedure is in fact expressly governed by Articles 28 and 29 HUM (corresponding to Articles 9 and 10 of Directive 75/319, as amended) on the grant of marketing authorisations, and Articles 35 and 36 HUM (corresponding to Articles 15 and 15a of Directive 75/319, as amended) on their management.

86 That finding of the Court in respect of the scope of Article 30 HUM is not shaken by the Commission's argument based on considerations concerning the codification mechanism and the meaning to be given, in this connection, to the title of Chapter 4 HUM (see paragraph 40, above).

87 The wording of the title of Chapter 4 HUM, of which Article 30 HUM forms part, and the fact that that title replaces an earlier title to which it was supposedly accepted that a broad interpretation would be given, in no way compel the conclusion suggested by the Commission, that the procedure under Article 30 HUM must lead to the adoption of a binding decision by the Commission. Indeed, it does not follow from the fact that Article 30 HUM appears in a chapter entitled 'Mutual recognition of authorisations' that that provision is a mechanism for mutual recognition, based on an obligation to recognise if the conditions for such recognition are satisfied. While the procedure under Articles 28 and 29 HUM does constitute such a binding mechanism (see paragraph 85 above and paragraph 140 of the judgment in *Artegodan*), Article 30 HUM merely provides a mechanism intended to make it easier for the Member States to adopt common decisions in the sphere of their exclusive competence in respect of purely national marketing authorisations and in the case of divergent decisions.

88 Nor can the Court's finding as to the scope of Article 30 HUM be put in issue by the Commission's considerations relating to the scope of Article 27 HUM (corresponding to Article 8 of Directive 75/319, as amended) (see paragraphs 38 and 39 above).

89 On this point the Court considers, first, and as in its findings made earlier in its judgment in *Artegodan* (in paragraph 141 of that judgment), that Article 27 HUM does not support an interpretation of Article 30 HUM, as of Article 31 HUM, to the effect that it establishes a Community arbitration procedure or that the opinion issued by the CPMP is binding on the Member States. In point of fact, Article 27 HUM does no more than state that the CPMP has been set up in order to make it easier for the Member States to adopt common decisions so far as marketing authorisations for medicinal products are concerned.

90 Second, the Court considers that those submissions of the Commission can detract nothing from the fact that the HUM code, although it does in fact seek to protect public health by means that do not hinder the development of the industry or trade in medicinal products between Member States, cannot for all that, in the absence of express provisions to that effect and having regard to the principle set out in the first paragraph of Article 5 EC that the Community is to act within the limits of the powers conferred on it, deprive the Member States of their exclusive competence as regards marketing authorisations granted under purely national procedures. Thus, in the absence of such express provisions, Article 30 HUM is to be understood not to affect the Member States' exclusive competence but rather to be intended, by means of the consultative procedure which it makes it possible to implement, at Community level, to guide the exercise of the various national competences in a common direction.

91 According to the Commission, the effectiveness of the procedure under Article 30 HUM cannot be ensured by an interpretation that limits its scope to the consultation of the CPMP, leaving each Member State free to decide what action to take following the CPMP's opinion (see paragraph 41 above).

92 It is true that it is possible to suppose that the Commission is competent to take a binding decision even though initiating that procedure is simply an option, and one that may be exercised not only by the Member States but also by the Commission itself, or again by the holder of the marketing authorisation at issue.

93 However, having regard to the consequences of that approach, in particular to the circumstance that the procedure under Article 30 HUM would lead to the transfer of competence to the Commission in conditions that might completely escape the Member States, the Court of First Instance considers that at the very least express provisions to that effect would be necessary. There being no such provisions, the Member States cannot be divested of their exclusive competence in unforeseeable fashion by the effect of a consultative reference made by the Commission or the holder of the marketing authorisation.

94 That consideration is borne out by the fact that, in the procedure under Article 30 HUM and unlike the mutual recognition procedure (see Article 29(2) HUM), reference to the CPMP is not preceded by any prior consultation that might enable the Member States to agree amongst themselves and by so doing avoid recourse to the Commission's binding arbitration.

95 In addition, the fact that Directive 93/39 and the HUM code were adopted on the basis of the Treaty provisions relating to the approximation of the laws of the Member States and the purpose of which is the establishment and functioning of the internal market, namely, for Directive 93/39, Article 100a of the EC Treaty (now, after amendment, Article 95 EC), added to the Treaty by the Single European Act in 1987, and for the HUM code, Article 95 EC, does not in any way mean, in itself, that the Commission must be recognised to possess decision-making power following a referral to the CPMP under Article 30 HUM. The reply to the question whether such power exists depends on the actual wording of the provisions of Directive 93/39 and the HUM code. The Court notes, moreover, that Directives 75/319 and 83/570, while based on Article 100 of the EC Treaty (now Article 94 EC), relating to the approximation of the laws of the Member States, have not introduced such Community competence either.

96 Finally, the Court notes that to follow the Commission's approach and therefore give it power to take a binding decision at the end of the procedure under Article 30 HUM would entail the consequence that the Commission, being itself entitled to make a reference to the CPMP under that provision, might draw within the sphere of Community competence all those cases of national marketing authorisations with regard to which it found that divergent decisions existed.

97 That approach infringes the exclusive residual competence of the Member States in the sphere of purely national marketing authorisations.

98 In short, the objective of the HUM code, which is to protect public health by means that do not hinder the development of the industry or trade in medicinal products

within the Community, is reconciled with the maintenance, in the absence of express provision to the contrary, of the exclusive residual competence of the Member States in the grant and management of purely national marketing authorisations.

99 In the light of the foregoing considerations, it is to be concluded that Article 30 HUM may not be interpreted as impliedly enabling the Commission to adopt a binding decision in accordance with the procedure laid down in Articles 33 and 34 HUM.

100 In consequence, it was unlawfully that the Commission, in this case, following a referral to the CPMP under Article 11 of Directive 75/319, as amended (corresponding to Article 30 HUM), adopted the contested decision on the basis of Articles 33 and 34 HUM.

101 The first part of the second ground of annulment must therefore be upheld, and the contested decision annulled, and there is no need to consider the other grounds of annulment.

Costs

102 Under Article 87(2) of the Rules of Procedure of the Court of First Instance, 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 defendant has been unsuccessful, it must, in accordance with the form of order sought by the applicants, be ordered to pay the costs.

On those grounds,

THE COURT OF FIRST INSTANCE (Fifth Chamber)

hereby:

1. **Annuls Commission Decision C(2003) 1752 of 21 May 2003 on the marketing of medicinal products for human use containing the substance enalapril;**

2. **Orders the Commission to pay the costs.**

Vilaras Martins Ribeiro Jürimäe

Delivered in open court in Luxembourg on 31 January 2006.

E. Coulon M. Vilaras

Registrar President