JUDGMENT OF THE COURT (First Chamber)

5 March 2009 *

In Case C-88/07,

ACTION under Article 226 EC for failure to fulfil obligations, brought on 15 February 2007,

Commission of the European Communities, represented by S. Pardo Quintillán and A. Alcover San Pedro, acting as Agents, with an address for service in Luxembourg,

applicant,

v

Kingdom of Spain, represented by J. Rodríguez Cárcamo, acting as Agent, with an address for service in Luxembourg,

defendant,

* Language of the case: Spanish.

THE COURT (First Chamber),

composed of P. Jann, President of Chamber, M. Ilešič (Rapporteur), A. Tizzano, A. Borg Barthet and E. Levits, Judges,

Advocate General: J. Mazák,
Registrar: M. Ferreira, Principal Administrator,

having regard to the written procedure and further to the hearing on 25 June 2008,

after hearing the Opinion of the Advocate General at the sitting on 16 October 2008,

gives the following

Judgment

1 By its action, the Commission of the European Communities asks the Court to declare that:

— by withdrawing from the market a number of herbal products lawfully produced and/or marketed in another Member State, under an administrative practice

consisting in withdrawing from the market any product with herbal constituents not included in the annex to the Ministerial Order on the creation of a special register of medicinal herb-based preparations (Orden Ministerial por la que se establece el registro especial para preparados a base de especies vegetales medicinales) of 3 October 1973 (BOE No 247 of 15 October 1973, p. 19866), as amended ('the 1973 Order') on the ground that it is deemed to be a medicinal product marketed without the requisite authorisation, and

— by not communicating that measure to the Commission,

the Kingdom of Spain has failed to fulfil its obligations under Articles 28 EC and 30 EC and Articles 1 and 4 of Decision No 3052/95/EC of the European Parliament and of the Council of 13 December 1995 establishing a procedure for the exchange of information on national measures derogating from the principle of the free movement of goods within the Community (OJ 1995 L 321, p. 1).

2 The Commission states that its action relates to the marketing of products based on medicinal herbs, in other words products containing one or more herbs which, because of their properties and their physiological effects, can be used as ingredients in medicinal products or in other types of products, such as food supplements.

Legal context

Community legislation

Directive 2001/83/EC

3 Article 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 Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 (OJ 2004 L 136, p. 34, 'Directive 2001/83'), provides:

'For the purposes of this Directive, the following terms shall bear the following meanings:

…

2. Medicinal product:

(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis;

3. Substance:

Any matter irrespective of origin which may be:

…

— vegetable, e.g:

micro-organisms, plants, parts of plants, vegetable secretions, extracts,

…

…

29. Traditional herbal medicinal product:

A herbal medicinal product that fulfils the conditions laid down in Article 16a(1);

30. Herbal medicinal product:

Any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations;

31. Herbal substances:

All mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried, form, but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author);

32. Herbal preparations:

Preparations obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or

fermentation. These include comminuted or ground herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.'

4 Article 2(1) and (2) of Directive 2001/83 provide:

'1. This Directive shall apply to medicinal products for human use intended to be placed on the market in Member States and either prepared industrially or manufactured by a method involving an industrial process.

2. In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a "medicinal product" and within the definition of a product covered by other Community legislation the provisions of this Directive shall apply.'

5 The first subparagraph of Article 6(1) of Directive 2001/83 provides that '[n]o medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with this Directive or unless an authorisation has been granted 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)]'.

6 Title III of Directive 2001/83 contains a Chapter 2a, headed 'Specific provisions applicable to traditional herbal medicinal products', which contains Articles 16a to 16i. That chapter establishes, under certain conditions, a simplified registration procedure for traditional herbal medicinal products.

7 To qualify for such a procedure, a traditional herbal medicinal product must have been in medicinal use throughout a period of at least 30 years preceding the date of the application for registration, including at least 15 years within the European Community (Articles 16a(1)(d) and 16c(1)(c) of Directive 2001/83).

8 It is also necessary that the data on the traditional use of the medicinal product be sufficient; in particular the product must prove not to be harmful in the specified conditions of use and the pharmacological effects or efficacy of the medicinal product must be plausible on the basis of longstanding use and experience (Article 16a(1)(e) of Directive 2001/83).

9 Article 16f(1) and (2) of Directive 2001/83 provide:

‘1. A list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products shall be established in accordance with the procedure referred to in Article 121(2). The list shall contain, with regard to each herbal substance, the indication, the specified strength and the posology, the route of administration and any other information necessary for the safe use of the herbal substance as a traditional medicinal product.

2. If an application for traditional-use registration relates to a herbal substance, preparation or a combination thereof contained in the list referred to in paragraph 1, the data specified in Article 16c(1)(b), (c) and (d) do not need to be provided. Article 16e(1)(c) and (d) shall not apply.’

Decision No 3052/95

10 The third to sixth recitals in the preamble to Decision No 3052/95 are worded as follows:

'… the transparency of national measures banning products may make it easier to deal quickly and at the appropriate level with problems which may jeopardize the free movement of goods, inter alia by approximating such measures in good time or adjusting them pursuant to Article [28 EC];

… in order to facilitate such transparency, a simple and pragmatic procedure should be established for the exchange of information between Member States and with the Commission so that any problems that may arise in connection with the operation of the internal market can be settled satisfactorily for both businesses and consumers;

… the main purpose of this procedure is to enhance knowledge concerning the implementation of the free movement of goods in non-harmonised sectors and to identify the problems encountered with a view to finding appropriate solutions to them;

… such a procedure should cover only those cases in which a Member State takes steps to prevent, on grounds of non-conformity with its own national rules, the free movement or placing on the market of goods lawfully produced or marketed in another Member State'.

11 Article 1 of Decision No 3052/95 provides:

‘Where a Member State takes steps to prevent the free movement or placing on the market of a particular model or type of product lawfully produced or marketed in another Member State, it shall notify the Commission accordingly where the direct or indirect effect of the measure is:

— a general ban on the goods,

— a refusal to allow the goods to be placed on the market,

…

or

— withdrawal of the goods from the market.’

12 Article 4(2) of Decision No 3052/95 states that ‘[t]he information referred to in paragraph 1 shall be communicated within 45 days of the date on which the measure referred to in Article 1 is taken’.

National legislation

13 Article 8(1) of Law No 25/1990 on medicinal products (Ley 25/1990 del Medicamento) of 20 December 1990 (BOE No 306 of 22 December 1990, p. 38228), provides:

'For the purposes of this legislation, the following terms have the following meanings … "medicinal product": any medicinal substance and any association or combination of such substances intended for use by human beings or animals which is presented as having properties which facilitate the prevention, diagnosis, treatment, relief or cure of diseases or illnesses, or which affect physical functions or mental state. Medicinal substances or combinations of such substances which can be administered to human beings or animals for the above purposes, even if they are offered for sale without explicit reference to those purposes, are also deemed to be medicinal products.'

14 Under Article 9(1) of Law No 25/1990,'no proprietary medicinal product or any other medicinal product for human use manufactured industrially may be placed on the market without prior marketing authorisation from the Spanish Medicines Agency and inclusion in the register of proprietary medicinal products, or without a Community authorisation in accordance with the provisions of Regulation... No 2309/93'.

15 Article 42 of Law No 25/1990, headed 'Herbal medicinal products', provides:

'1. Herbs and mixtures of them and any preparations obtained from herbs in the form of extracts, lyophilisates, distillations, tinctures, decoctions or any other galenic preparation, which are presented as having a therapeutic, diagnostic or preventive value will be subject, as appropriate, to the rules relating to magistral formulas, officinal formulas or proprietary medicinal products, and in accordance with the specific requirements laid down by legislation.

2. The Ministry of Health and Consumer Affairs shall establish a list of herbs the sale of which to the public is restricted or prohibited because of their toxicity.

3. Herbs which are traditionally regarded as medicinal and which are offered for sale without reference to therapeutic, diagnostic or preventive properties may be freely sold to the public, but door-to-door selling of them is prohibited.'

16 The list referred to in Article 42(2) of Law No 25/1990 is to be found in the annex to Order SCO/190/2004 of the Ministry of Health and Consumer Affairs establishing the list of plants sale of which to the public is prohibited or restricted because of their toxicity (Orden SCO/190/2004 por la que se establece la lista de plantas cuya venta al público queda prohibida o restringida por razón de su toxicidad) of 28 January 2004 (BOE No 32 of 6 February 2004, p. 5061, 'the 2004 Order').

17 Article 1 of the 2004 Order states that 'sale [of the plants listed] and sale of preparations based on them to the public is prohibited because of their toxicity' and that 'their use and their placing on the market are limited to the production of proprietary medicinal products, magistral formulas, officinal preparations and homeopathic strains, and to the purposes of research'. The annex in question lists 197 herbs.

18 Article 1 of the 1973 Order provides:

'Preparations the constituents of which are exclusively one or more medicinal herbs, whole parts of such herbs, or such herbs in crushed or ground form shall be listed in a special register by the appropriate departments of the Directorate General for Health.'

19 Article 2 of the 1973 Order provides:

'There shall not be listed in that special register:

(a) preparations for immediate use which contain a single medicinal herb — or parts of it — listed in the annex and which state that fact clearly on the external packaging of the product;

(b) preparations for immediate use based on extracts, tinctures, distillations, decoctions or any other galenic preparation, obtained from medicinal herbs, in which case they shall in all circumstances be treated as proprietary medicinal products.'

20 The 1973 Order has annexed to it the list of medicinal herbs referred to in Article 2(a) of that order. That list was last updated in 1976 and extends to 119 herbs.

21 It is common ground that 'herbs which are traditionally regarded as medicinal', within the meaning of Article 42(3) of Law No 25/1990 are treated by the competent Spanish authorities in the same way as the medicinal herbs listed in the annex to the 1973 Order, with the result that preparations which, first, satisfy the conditions of Article 2(a) of the 1973 Order and, secondly, are offered for sale without reference to therapeutic, diagnostic or preventive properties may be freely sold to the public, in accordance with Article 42(3) of Law No 25/1990.

22 Law No 25/1990 was repealed by Law No 29/2006 on the guarantees and rational use of medicines and health products (Ley 29/2006 de garantías y uso racional de los medicinal productos y productos sanitarios) of 26 July 2006 (BOE No 178 of 27 July 2006, p. 28122), which came into force on 28 July 2006. Article 51 of the latter law essentially reproduces Article 42 of Law No 25/1990.

Pre-litigation procedure

23 In several letters sent in 2004 to departments of the Commission, three Spanish companies, Ynsadiet SA ('Ynsadiet'), Laboratorios Tregor SL ('Tregor') and Laboratorios Taxón SL ('Taxón') complained that, between 2002 and 2003, the Agencia española de medicamentos y productos sanitarios (Spanish Drugs and Health Products Agency, 'AEMPS') had withdrawn from the Spanish market more than 200 products based on medicinal herbs on the ground that they were medicinal products without any authorisation to be placed on the market ('marketing authorisation'), although those products were lawfully marketed in other Member States as food supplements or dietary products. Other complaints on the same ground were made to the Commission in 2005 and 2006.

24 According to those complaints, the classification by AEMPS of those products as medicinal products was often based on the fact that the products withdrawn from the market contained medicinal herbs which were not listed in the annex to the 1973 Order.

25 The Commission considered that the abovementioned decisions to withdraw goods from the market were contrary to Article 28 EC and that the failure to communicate those decisions was an infringement of Articles 1 and 4 of Decision No 3052/95, and accordingly on 21 March 2005 sent a letter of formal notice asking the Spanish authorities to clarify the matter.

26 The Commission was not satisfied with the responses of the Spanish authorities and sent on 10 April 2006 to the Kingdom of Spain a reasoned opinion, requesting that the necessary measures for compliance be taken within a period of two months from the date of receipt of the opinion.

27 Since the Spanish authorities do not accept that the Commission's criticism is well founded, the Commission has brought this action.

The alleged failure to fulfil obligations under Articles 28 EC and 30 EC

Arguments of the parties

28 The Commission claims that there is at present no harmonisation at Community level either as regards herbs and herbal extracts used in the composition of food supplements or as regards the classification of products based on medicinal herbs as medicinal products or food supplements. The Commission states in particular that Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ 2002 L 183, p. 51) postponed to a later stage the adoption of specific rules concerning nutrients, other than vitamins and minerals, or other substances with a nutritional or physiological effect, such as various herbs and herbal extracts.

29 In the absence of such harmonisation, products based on medicinal herbs lawfully marketed in one Member State ought, as a general rule, to move freely pursuant to the principle of the free movement of goods set out in Article 28 EC, unless it is properly demonstrated that they carry a risk to human health, in accordance with Article 30 EC.

30 First, the Commission claims that the Spanish authorities have adopted a consistent administrative practice, which involves the systematic classification of products based on medicinal herbs which are not listed in the annex to the 1973 Order as medicinal products by function, without first submitting each of those products to detailed analysis, and, consequently, in the absence of marketing authorisation, the withdrawal of those products from the Spanish market.

31 However, according to the Court's case-law, in order to determine whether or not a product is a medicinal product by function, it is appropriate to have regard to its composition, its pharmacological properties, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail. Products can be described as medicinal products by function only on a case-by-case basis, taking account of their pharmacological properties.

32 Accordingly, the mere presence in a product lawfully produced or marketed in another Member State of medicinal herbs not listed in the annex to the 1973 Order is not a criterion which can justify treating such a product as a medicinal product and withdrawing it from the Spanish market in the absence of marketing authorisation.

33 Consequently, the practice of the Spanish authorities is a measure having equivalent effect to a quantitative restriction, prohibited by Article 28 EC.

34 The Commission does not accept the assertion by the Kingdom of Spain that, before the decision to withdraw a product from the market is taken, a detailed examination, product by product, is carried out. The Commission claims, first, that the reality of the practice complained of is clear from the complaints submitted to it by businesses whose products based on medicinal herbs have been withdrawn from the market, from the Report on the marketing of various products based on medicinal herbs (Informe sobre la comercialización de diversos productos a base de plantas medicinas) dated 26 March 2004 issued by AEMPS, and from the court judgments rejecting actions brought by those businesses against the decisions to withdraw their products from the market, in particular the judgment of the contentious administrative division of the Audiencia Nacional of 30 June 2004 in relation to the action brought by Tregor. The Commission

emphasises, secondly, that the Kingdom of Spain makes no reference to any individual withdrawal decisions and the reasons for them, with the result that the Kingdom of Spain has not proved that a case-by-case examination is made prior to the classification of a product containing medicinal herbs as a medicinal product.

35 Secondly, in the Commission's opinion, the practice of the Spanish authorities cannot be justified on the basis of Article 30 EC.

36 Contrary to the requirements laid down by the Court's case-law in relation to Article 30 EC, the systematic nature of the Spanish administrative practice makes it impossible either to identify or evaluate any actual risk to public health, when there is no thorough evaluation, on a case-by-case basis, of the negative effects on human health which consumption of the products in question might entail. The practice is based on a presumption of danger going beyond what is necessary and proportionate for the protection of public health.

37 First, the Kingdom of Spain denies that there is a practice such as described by the Commission.

38 The decision to submit the marketing of a product containing medicinal herbs to the rules applicable to medicinal products is the result of an analysis of that product in relation to its composition, the properties which the producer associates with it and the form in which it is offered for sale. As part of that analysis, investigation is also made into whether herbs prohibited under the 2004 Order or authorised under the 1973 Order are constituents of the product. Only when, as a result of that analysis, the conclusion is unavoidable that the marketing of the product in question ought to have been monitored in the way required for the marketing of medicinal products is that product withdrawn from the market.

39 Such a withdrawal is therefore not systematic, but is prompted by the dangerousness of the product examined. There are moreover many herbal products marketed freely in Spain which are categorised as food supplements.

40 As regards, more particularly, the products the withdrawal of which from the market led to the complaints which initiated the pre-litigation procedure, the Kingdom of Spain states that a detailed individual analysis of each of those products was carried out, which consisted of identifying the substances present as constituents and also examining their presentation and the properties associated with those substances. The principal objective of that analysis was to evaluate both the capacity of those products to correct or modify physiological functions and the risks to health, actual or potential, entailed in their consumption.

41 In respect of each of the products concerned, the withdrawal decision was not based exclusively on the fact that medicinal herbs not listed in the annex to the 1973 Order were among its constituents, but was founded on the results of that analysis.

42 According to the Kingdom of Spain, all the products the withdrawal of which from the market led to the complaints which initiated the pre-litigation procedure fell under the harmonised definition of 'herbal medicinal product' within the meaning of Directive 2001/83, since they were either products presented as associated with therapeutic, curative or preventive properties in respect of human health, or products associated with purposes unrelated to health, but in any event likely to cause in human beings some modification of physiological functions by pharmacological action.

43 All those products contained one or more substances derived from medicinal herbs whose possible effects on human health and medical uses regarded by other European health authorities as acceptable had been established by a scientific study by AEMPS.

44 Furthermore, most of those substances are to be found in a provisional list of medicinal herbs dated 11 January 2007 and published by the Working Party on Community Monographs and Community Lists of the Committee on Herbal Medicinal Products set up by Article 16h of Directive 2001/83, which shows that that committee has already taken the decision to classify those substances as medicinal herbs. It follows, according to the Kingdom of Spain, that products composed of those substances necessarily fall under the definition of 'herbal medicinal product' within the meaning of that directive.

45 The Kingdom of Spain adds that, under Article 2(2) of Directive 2001/83, in cases of doubt, when a product may fall within the definition of a medicinal product within the meaning of that directive and also within the definition of a product covered by other Community legislation, classification as a medicinal product must prevail.

46 The Kingdom of Spain considers that the legislation and practice in Spain are consistent with the Court's case-law on medicinal products, from which it is clear in particular that the national authorities have some discretion in relation to the classification of a product as a medicinal product.

47 Secondly, if the Court were to consider that the practice complained of by the Commission exists, that the products withdrawn from the market were not medicinal products, and that those withdrawals constituted a restriction on the free movement of goods within the meaning of Article 28 EC, the Kingdom of Spain contends that such a withdrawal is justified by the exception, provided for by Article 30 EC, concerning the protection of public health.

48 First, in the current state of scientific research, there is uncertainty as regards the harmlessness of the products withdrawn from the market that justifies their withdrawal under the precautionary principle, in accordance with the case-law of the Court and in particular Case C-24/00 *Commission* v *France* [2004] ECR I-1277, paragraph 56.

49 Products based on medicinal herbs are almost always products the safety of which has not been thoroughly examined. On many occasions, preparations based on medicinal herbs have had undesirable, and sometimes serious effects. Moreover, there is a risk that such preparations may interact with other medicinal products.

50 The mere presence in a product of substances which present a risk to public health undeniably constitutes a reason for the health authorities, on the basis of available scientific and technical knowledge, to withdraw that product from the market.

51 The Kingdom of Spain considers moreover that the analysis made by the Court in Case C-150/00 *Commission* v *Austria* [2004] ECR I-3887 is not transposable to the present case. In that judgment, which concerned a consistent and generalised practice of classifying foodstuffs containing vitamins as medicinal products, the Court's finding that there was a failure to fulfil obligations was based on the fact that as a general rule vitamins are harmless. On the other hand, in the present case, most of the products concerned could have serious consequences for human health, especially since the Commission has provided no data to suggest that the harmlessness of those products has been established.

52 Secondly, a decision to withdraw goods from the market is always taken by the Spanish authorities on an ad hoc, case-by-case, basis, taking into account a complex set of circumstances, in which the role of the 1973 Order is secondary, and the undertakings concerned always have the possibility of bringing proceedings before the courts which would review all aspects of the withdrawal decision. Furthermore, it is always open to those undertakings to apply for a marketing authorisation as a medicinal product. Consequently, the withdrawal decisions appear proportionate.

53 Alternatively, the Kingdom of Spain considers that the withdrawal from the market of the products concerned was justified by the overriding requirement of consumer protection, recognised in the case-law of the Court.

Findings of the Court

Whether there is an administrative practice

54 It is settled case-law that an administrative practice can be made the object of an action for failure to fulfil obligations when it is, to some degree, of a consistent and general nature (see, inter alia, Case C-135/05 *Commission* v *Italy* [2007] ECR I-3475, paragraph 21).

55 It is clear from the Commission's pleadings that its criticism of the Spanish authorities relates to an administrative practice which consists of systematically classifying as medicinal products by function and, in the absence of marketing authorisation, withdrawing from the Spanish market products based on medicinal herbs lawfully produced and/or marketed as food supplements or dietary products in other Member States, where, and solely because, the herbs they contain are not listed in the annex to the 1973 Order.

56 The Kingdom of Spain contends that there is no such administrative practice.

57 In that regard, first, the Kingdom of Spain correctly submits that some of the products the withdrawal of which from the Spanish market led to the complaints received by the Commission were not withdrawn from the market for the reason that the medicinal

herbs they contained were not listed in the annex to the 1973 Order, but because those medicinal herbs were listed in the annex to the 2004 Order. The latter annex, which corresponds to the list referred to in Article 42(2) of Law No 25/1990, refers to herbs whose toxicity in the opinion of the Spanish authorities precludes their use in products other than medicinal products.

58 Accordingly, the withdrawal of such herbal products follows from Article 42(2) of Law No 25/1990, read in conjunction with the 2004 Order; those provisions of national law prohibit sale to the public of those herbs and of preparations containing them other than as medicinal products, because of their toxicity.

59 The Commission, which did not refer to the 2004 Order either in the letter of formal notice, the reasoned opinion, or its pleadings before the Court, does not claim that those provisions might be incompatible with Community law.

60 Secondly, as is contended by the Kingdom of Spain and confirmed by the judgment of the Audiencia Nacional of 30 June 2004 referred to in paragraph 34 of this judgment, the marketing of some of the products based on medicinal herbs which are not listed in either the annex to the 1973 Order or in the annex to the 2004 Order is not subject to obtaining a marketing authorisation. It is clear from Article 1 of the 1973 Order that the marketing of preparations the constituents of which are exclusively medicinal herbs, whole parts of such herbs, or crushed or ground parts of such herbs, requires merely that those preparations be included in the special register provided for by that order.

61 On the other hand, as regards other products based on medicinal herbs not listed in the annex to the 1973 Order, the reality and consistency of their systematic classification as medicinal products and the need to obtain marketing authorisation if they are to be marketed are established in the AEMPS report referred to in paragraph 34 of this judgment. It is clear from that report that, apart from products based on herbs traditionally considered to be medicinal and listed in the annex to the 1973 Order,

products based on medicinal herbs are subject to the legislation on medicinal products as regards their manufacture, their marketing, their distribution and their sale.

62 That practice has been validated by the national courts. In its judgment of 30 June 2004 referred to in paragraph 34 of this judgment, the contentious administrative division of the Audiencia Nacional made the finding that the classification of products based on medicinal herbs marketed by Trégor as medicinal products was a consequence of 'the fact that they contain herbs not listed in the annex to the 1973 Order'.

63 It must moreover be observed, first, that the Kingdom of Spain has provided no evidence, such as individual withdrawal decisions, to establish that any case-by-case examination, going beyond a simple check whether the medicinal herbs contained in a given product are or are not listed in either the annex to the 1973 Order or in the annex to the 2004 Order, is carried out prior to the classification of that product as a medicinal product. Next, the Kingdom of Spain has offered no instance of a product based on medicinal herbs not listed in the annex to the 1973 Order which is marketed freely. Lastly, it is clear that the Kingdom of Spain does not contend that, between 2004 and the date of expiry of the period allowed in the reasoned opinion, there was any change in the national legislation or in the practices of AEMPS.

64 It must be added that the Kingdom of Spain does not submit, and it is in no way suggested in the court file, that the practice of systematically classifying products based on medicinal herbs not listed in the Annex to the 1973 Order as medicinal products does not apply to products lawfully produced and marketed in other Member States. Consequently, it is clear that no distinction is made on the basis of the origin of the products.

65 It follows from the above considerations that, when the period allowed in the reasoned opinion expired, the administrative practice complained of was established in relation to products based on medicinal herbs which are not listed in either the annex to the 1973 Order or in that of the 2004 Order, other than preparations the constituents of

which are exclusively medicinal herbs or whole parts of such herbs, or crushed or ground parts of such herbs, and that that practice had a sufficient degree of consistency and generality to justify an action for failure to fulfil obligations.

66 In the remainder of this judgment, reference to products based on medicinal herbs not listed in the Annex to the 1973 Order will refer exclusively to those products based on medicinal herbs which are not listed either in the annex to the 1973 Order or in the annex to the 2004 Order, other than preparations the constituents of which are exclusively medicinal herbs or whole parts of such herbs, or crushed or ground parts of such herbs.

Classification as medicinal product by function

67 It is clear from Articles 2 and 6(1) of Directive 2001/83 that no medicinal product manufactured industrially can be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authority of that Member State or unless an authorisation has been issued in accordance with Regulation No 2309/93.

68 It follows that, if a product manufactured industrially comes within the definition of medicinal product in Article 1(2) of Directive 2001/83, the obligation on the importer of that product to obtain a marketing authorisation in accordance with that directive prior to marketing it in the Member State of importation cannot, in any event, constitute a restriction on trade between Member States prohibited by Article 28 EC (Case C-319/05 *Commission* v *Germany* [2007] ECR I-9811, paragraph 35).

69 Moreover, as the harmonisation of national legislation in relation to the production and distribution of medicinal products currently stands, the fact that a product is classified as a foodstuff in another Member State cannot prevent it from being classified as a

medicinal product in the Member State of importation, if it displays the characteristics of such a product (see Joined Cases C-211/03, C-299/03 and C-316/03 to C-318/03 *HLH Warenvertrieb and Orthica* [2005] ECR I-5141, paragraph 56, and *Commission* v *Germany*, paragraphs 36 and 37).

70 As regards, more particularly, products based on medicinal herbs, as stated by the Commission, in the Community legislation there is no harmonisation as regards classification of such products either as medicinal products or as food products.

71 The Court must therefore determine, first, whether products based on medicinal herbs not listed in the annex to the 1973 Order are necessarily medicinal products by function within the meaning of Article 1(2)(b) of Directive 2001/83.

72 In order to determine whether a product falls under the definition of medicinal product by function within the meaning of Directive 2001/83, the national authorities, subject to review by the courts, must decide on a case-by-case basis, taking account of all the characteristics of the product, in particular its composition, its pharmacological, immunological and/or metabolic properties, to the extent to which they can be established in the present state of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail (*HLH Warenvertrieb and Orthica*, paragraph 51; *Commission* v *Germany*, paragraph 55, and Case C-140/07 *Hecht-Pharma* [2009] ECR I-41, paragraph 32).

73 As clarified by the Commission itself, medicinal herbs are plants which, because of their properties and physiological effects, can be used as ingredients in medicinal products or in other types of products, such as food supplements.

74 However, the mere fact that one or more medicinal herbs are among the constituents of a product is not sufficient to permit the conclusion that that product contributes to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action or to making a medical diagnosis, within the meaning of Article 1(2)(b) of Directive 2001/83.

75 It is possible that, having regard, in particular, to the small amount of the active substance contained in it and/or the manner in which it is used, a product based on medicinal herbs will have no effect on physiological functions or that its effects will not suffice for it to be a medicinal product by function (see, by analogy, as regards preparations containing vitamins or minerals, *Commission* v *Austria*, paragraph 63; see also, to that effect, *Hecht-Pharma*, paragraph 42). In that regard, the Court has held that substances which, while having an effect on the human body, do not significantly affect the metabolism and thus do not strictly modify the way in which it functions should not be classified as medicinal products by function (see *Commission* v *Germany*, paragraph 60, and *Hecht-Pharma*, paragraph 41).

76 A consequence of the Spanish administrative practice complained of, in so far as it is applied systematically to all products based on medicinal herbs not listed in the annex to the 1973 Order, may therefore be that some of those products are classified as medicinal products, even when they are not capable of restoring, correcting or modifying human physiological functions.

77 That conclusion is not invalidated by the results of the scientific study referred to in paragraph 43 of this judgment, from which it emerges, according to the Kingdom of Spain, that all the products of Ynsadiet, Tregor and Taxón withdrawn from the market in 2002 and 2003 contained herbs which can be harmful to human health. As was stated by the Advocate General in points 40 to 42 of his Opinion, that scientific study relates to the harmfulness of the medicinal herbs themselves, but not to the pharmacological, immunological or metabolic properties of the products withdrawn from the market or to the risks which their use might entail. Furthermore, that study relates to only 34 herbs, whereas the practice complained of is applied to all products based on medicinal herbs not listed in the annex to the 1973 Order, the number of which is potentially unlimited.

78 The Court must also reject the argument of the Kingdom of Spain that, in accordance with Article 2(2) of Directive 2001/83, and given the doubt on the matter, products based on medicinal herbs other than those listed in the annex to the 1973 Order must be classified as medicinal products by function.

79 Article 2(2) of Directive 2001/83 must be interpreted as meaning that that directive does not apply to a product in respect of which it has not been scientifically established that it is a medicinal product by function, without its being possible to exclude that possibility (*Hecht-Pharma*, paragraph 29). Moreover, given the systematic nature of the Spanish administrative practice, it is possible that products based on medicinal herbs other than those listed in the annex to the 1973 Order will be classified as medicinal products by function although that is clearly not the case.

80 It follows from the foregoing that the Spanish administrative practice complained of in the present case cannot be defended on the basis of Directive 2001/83.

Whether there is a restriction

81 It is accordingly necessary to consider, secondly, whether the requirement of marketing authorisation for products based on medicinal herbs not listed in the annex to the 1973 Order, imposed by the Spanish administrative practice, constitutes a measure having equivalent effect to a quantitative restriction on imports, prohibited by Article 28 EC.

82 The prohibition on measures having equivalent effect to quantitative restrictions set out in Article 28 EC covers all measures which are capable of hindering, directly or

indirectly, actually or potentially, intra-Community trade (see, in particular, Case 8/74 *Dassonville* [1974] ECR 837, paragraph 5; Case C-192/01 *Commission* v *Denmark* [2003] ECR I-9693, paragraph 39; *Commission* v *France*, paragraph 22; and *Commission* v *Germany*, paragraph 80).

83 In the present case, the Spanish administrative practice creates an obstacle to intra-Community trade in so far as a product based on medicinal herbs not listed in the annex to the 1973 Order, lawfully produced and/or marketed in another Member State as a food supplement or dietary product, can be marketed in Spain only after going through the marketing authorisation procedure (see, by analogy, *Commission* v *Austria*, paragraph 82, and *Commission* v *Germany*, paragraph 81).

84 The Spanish administrative practice complained of in the present case therefore constitutes a measure having equivalent effect to a quantitative restriction, within the meaning of Article 28 EC.

Whether there is justification

85 It must therefore be determined, thirdly, whether, as contended by the Kingdom of Spain, the practice in question can be justified by the need to protect human health, referred to in Article 30 EC, or by the overriding requirement of consumer protection, established in the Court's case-law.

86 In accordance with the Court's case-law, it is for the Member States, in the absence of harmonisation and to the extent that uncertainties continue to exist in the current state of scientific research, to decide on the level of protection of human health and life they wish to ensure and on whether to require prior authorisation for the marketing of foodstuffs, always taking into account the requirements of the free movement of goods within the Community (see *Commission* v *Denmark*, paragraph 42; *Commission* v *France*, paragraph 49; and *Commission* v *Germany*, paragraph 86).

87 It follows that Community law does not therefore, in principle, preclude a Member State from prohibiting, unless there is prior authorisation, the marketing of foodstuffs to which nutrients, such as vitamins or minerals other than those whose use is lawful under Community legislation, have been added (*Commission* v *Denmark*, paragraph 44; *Commission* v *France*, paragraph 51; and *Commission* v *Austria*, paragraph 87).

88 However, in exercising their discretion relating to the protection of public health, the Member States must comply with the principle of proportionality. The means which they choose must therefore be confined to what is actually necessary to ensure the safeguarding of public health or to meet overriding requirements such as, for example the protection of consumers; they must be proportional to the objective thus pursued, which could not have been attained by measures which are less restrictive of intra-Community trade (see *Commission* v *Denmark*, paragraph 45; *Commission* v *France*, paragraph 52; *Commission* v *Austria*, paragraph 88; and *Commission* v *Germany*, paragraph 87).

89 Furthermore, since Article 30 EC provides for an exception, to be interpreted strictly, to the rule of free movement of goods within the Community, it is for the national authorities which invoke it to show in each case, in the light of national nutritional habits and in the light of the results of international scientific research, that their rules are necessary to give effective protection to the interests referred to in that provision and, in particular, that the marketing of the products in question poses a real risk to public health (*Commission* v *Denmark*, paragraph 46; *Commission* v *France*, paragraph 53; *Commission* v *Austria*, paragraph 89; and *Commission* v *Germany*, paragraph 88).

90 That case-law, which was developed in relation to foodstuffs enriched with nutrients such as vitamins and minerals, is also applicable to products based on medicinal herbs intended for human consumption.

91 In the present case, while, as was stated in paragraph 87 of this judgement, Community law does not, in principle, preclude a system of prior authorisation, it remains however clear that the issuing of marketing authorisation pursuant to Article 8 of Directive 2001/83 is subject to particularly strict requirements (*Commission* v *Germany*, paragraph 89). In that regard, it must be observed that the Kingdom of Spain has not contended that all or some of the products withdrawn from the market in 2002 and 2003 could take advantage of a simplified registration procedure such as that established by Articles 16a to 16i of that directive for traditional herbal medicinal products.

92 In those circumstances, the obligation to obtain marketing authorisation before being able to market products based on medicinal herbs on Spanish territory may be regarded as in accordance with the principle of proportionality only if it is actually necessary, in each case, to safeguard public health (see, to that effect, *Commission* v *Austria*, paragraph 94, and *Commission* v *Germany*, paragraph 90).

93 Such a restriction on the free movement of goods must therefore necessarily be based on a detailed assessment, on a case-by-case basis, of the risk alleged by the Member State invoking Article 30 EC (see, to that effect, *Commission* v *Austria*, paragraph 96, and *Commission* v *Germany*, paragraph 91).

94 However, the criterion used by the Spanish authorities for requiring marketing authorisation, namely the fact that the medicinal herb on which the manufactured product is based is not listed in the Annex to the 1973 Order, does not allow, on the basis of the most recent scientific data, account to be taken of the actual risk to public health presented by such products.

95 It follows from the foregoing that the Spanish administrative practice complained of in this plea does not meet the requirements of Community law, as set out in the case-law of the Court referred to in paragraphs 89 to 93 of this judgment, and in particular the

requirement that there be a detailed assessment, on a case-by-case basis, of the risk to public health which the marketing of a product based on medicinal herbs might entail.

96 It cannot be argued that traders have the option of applying for the inclusion of the herb contained in their product in the annex to the 1973 Order. As clarified by the Kingdom of Spain itself, a trader can have a herb included in that annex only if he proves that it has been traditionally used. The fact that a product contains a medicinal herb which has not been traditionally used does not necessarily imply that that product presents a risk to public health.

97 Moreover, as regards effective consumer protection, to which the Kingdom of Spain also refers, it is naturally legitimate to seek to ensure that consumers are properly informed about the products which they consume (*Commission* v *France*, cited above, paragraph 74).

98 However, the Kingdom of Spain has not explained why appropriate labelling, informing consumers of the nature, the ingredients and the characteristics of products based on medicinal herbs, would not adequately meet that objective where the classification of those products as medicinal products is not justified on grounds of public health (see, by analogy, *Commission* v *France*, paragraph 75).

99 Consequently, the first complaint, alleging infringement of Articles 28 EC and 30 EC, is well founded.

The alleged failure to fulfil obligations under Articles 1 and 4 of Decision No 3052/95

Arguments of the parties

100 The Commission considers that the Kingdom of Spain ought to have notified it of the market withdrawal measures taken in 2002 and 2003 in respect of products of Ynsadiet, Tregor and Taxón, within a period of 45 days from the date when each of those measures was taken. By failing to do so, the Kingdom of Spain has infringed Articles 1 and 4 of Decision No 3052/95.

101 The Commission claims that the products based on medicinal herbs withdrawn from the market by the Spanish authorities were lawfully marketed in other Member States, generally as food supplements or dietary products.

102 The Commission claims that the Spanish authorities had been made aware of that fact. First, the undertakings whose products were involved had stated to those authorities that some of those products were lawfully produced or marketed in other Member States. Secondly, the Commission had previously noted that fact in its reasoned opinion sent to the Kingdom of Spain, which did not challenge the truth of the matter.

103 The Kingdom of Spain contends, first, that some of the products withdrawn from the market were manufactured in Spain and that, on no occasion did Ynsadiet, Tregor and Taxón submit to the Spanish authorities documents establishing that those products were lawfully marketed in another Member State. Second, the defendant Member State maintains that it was not informed that some of the products withdrawn from the market had been imported from another Member State where they were lawfully produced. Also, the Commission has not so far provided any detailed information on that matter.

104 Consequently, in accordance with Article 1 of Decision No 3052/95, since the procedure laid down by that decision was not applicable, the Kingdom of Spain was not obliged to notify the abovementioned withdrawal decisions.

Findings of the Court

105 Under Article 1 of Decision No 3052/95,'[w]here a Member State takes steps to prevent the free movement or placing on the market of a particular model or type of product lawfully produced or marketed in another Member State, it shall notify the Commission accordingly where the direct or indirect effect of the measure is', in particular,'a general ban on the goods','a refusal to allow the goods to be placed on the market' or 'withdrawal of the goods from the market'.

106 Decision No 3052/95 defines 'measure' as any measure taken by a Member State, except for judicial decisions, which has the effect of restricting the free movement of goods lawfully produced or marketed in another Member State, regardless of its form or the authority from which it emanates (Joined Cases C-388/00 and C-429/00 *Radiosistemi* [2002] ECR I-5845, paragraph 68, and Case C-432/03 *Commission* v *Portugal* [2005] ECR I-9665, paragraph 57).

107 The wording 'a particular model or type of product lawfully produced or marketed in another Member State' of Article 1 of Decision No 3052/95 indicates that the obligation to notify laid down by that provision falls on the Member State concerned not only where products produced or marketed in another Member State are withdrawn from the market, but also where products produced in its own territory are withdrawn from the market while products of the same model or of the same type are lawfully produced and/or marketed in another Member State and would also be subject to withdrawal from the market if they were imported into the Member State concerned.

108 That interpretation is also consistent with the purpose of Decision No 3052/95. The mere existence of legislation or of a practice in a Member State applicable without distinction to domestic and imported products is likely to deter traders from importing into that Member State goods lawfully produced or marketed in another Member State and therefore has the effect of restricting the free movement of those goods.

109 However, the obligation to notify laid down in Article 1 of Decision No 3052/95 falls on the Member State concerned only if it knows, or could reasonably be expected to know, that the measure adopted by it has the effect of hindering the marketing in its territory of products lawfully produced or marketed in another Member State. The onus is on the Commission to provide evidence to that effect.

110 In the present case, it must therefore be ascertained, first, whether, when the Spanish authorities withdrew in 2002 and 2003 the products of Ynsadiet, Tregor and Taxón from the Spanish market, there were products based on medicinal herbs not listed in the annex to the 1973 Order that were lawfully produced and/or marketed in another Member State and, secondly, whether the Spanish authorities were aware of that fact.

111 In that regard, the Kingdom of Spain contends that it was the Commission itself, in the reasoned opinion, that informed it that some of the products marketed by Ynsadiet in Spain and withdrawn from the Spanish market had been lawfully produced by Biover NV in Belgium, where the products were certified by the Belgian Ministry of Health and Social Affairs.

112 However, as the Commission correctly points out, immediately after the inspection which was carried out on 15 and 16 July 2003 at the premises of Ynsadiet, that company informed the Spanish authorities that the products in the Biover range were imported from Belgium, where they were lawfully produced and marketed, and repeated that information in its action against the decision to withdraw its products from the Spanish market.

113 The Commission has also correctly stated that the Belgian origin of those products was not disputed by the Spanish authorities, since it was mentioned in a fax sent on 21 November 2003 by AEMPS to Ynsadiet.

114 It must also be observed that the objective of the procedure for the exchange of information between the Member States themselves and the Commission established by Decision No 3052/95 is not to protect the rights of any specific trader, but, as is clear from the fifth recital of the preamble to that decision, to identify the problems encountered in the implementation of the free movement of goods with a view to finding appropriate solutions to them. Accordingly, when the Spanish authorities were informed that products in the Biover range had been imported from Belgium, it was their duty, if they considered the evidence that those products were lawfully produced and/or marketed in Belgium to be insufficient, to check the facts with the Belgian authorities, in accordance with the duty of genuine cooperation laid down in Article 10 EC, and they could not take refuge behind any failings on the part of Ynsadiet.

115 Consequently, the second ground of complaint, that there was an infringement of Articles 1 and 4 of Decision No 3052/95, is also well founded.

116 In light of all of the foregoing, it must be held that:

— by withdrawing from the market products based on medicinal herbs lawfully produced and/or marketed in another Member State, under an administrative practice consisting in withdrawing from the market any product containing medicinal herbs not included either in the annex to the 1973 Order or in the annex to the 2004 Order, other than a preparation the constituents of which are exclusively one or more medicinal herbs or whole parts of such herbs, or crushed or powdered parts of such herbs, on the ground that that product is deemed to be a medicinal product marketed without the requisite marketing authorisation, and

— by not communicating that measure to the Commission,

the Kingdom of Spain has failed to fulfil its obligations under Articles 28 EC and 30 EC and Articles 1 and 4 of Decision No 3052/95.

Costs

117 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 and the Kingdom of Spain has been unsuccessful, the Kingdom of Spain must be ordered to pay the costs.

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

1. Declares that,

— **by withdrawing from the market products based on medicinal herbs lawfully produced and/or marketed in another Member State, under an administrative practice consisting in withdrawing from the market any product based on medicinal herbs not included either in the annex to the Ministerial Order on the creation of a special register of medicinal herb-based preparations (Orden Ministerial por la que se establece el registro especial para preparados a base de especies vegetales) of 3 October 1973, as amended, or in the annex to the Order SCO/190/2004 of the Ministry of Health and Consumer Affairs, establishing the list of plants sale of which to the public is prohibited or restricted because of their toxicity (Orden SCO/190/2004 por la que se establece la lista de plantas cuya venta al público queda prohibida o restringida por razón de su toxicidad) of 28 January 2004, other than a preparation the constituents of which are**

exclusively one or more medicinal herbs or whole parts of such herbs, or crushed or powdered parts of such herbs, on the ground that that product is deemed to be a medicinal product marketed without the requisite marketing authorisation, and

— **by not communicating that measure to the Commission of the European Communities,**

the Kingdom of Spain has failed to fulfil its obligations under Articles 28 EC and 30 EC and Articles 1 and 4 of Decision No 3052/95/EC of the European Parliament and of the Council of 13 December 1995 establishing a procedure for the exchange of information on national measures derogating from the principle of the free movement of goods within the Community.

2. **Orders the Kingdom of Spain to pay the costs.**

[Signatures]