Reports of Cases

OPINION OF ADVOCATE GENERAL
CAMPOS SÁNCHEZ-BORDONA
delivered on 30 January 2025 [1]

Case C-618/23

SALUS Haus Dr. med. Otto Greither Nachf. GmbH & Co. KG
v
Astrid Twardy GmbH

(Request for a preliminary ruling from the Oberlandesgericht Düsseldorf (Higher Regional Court, Düsseldorf, Germany))

(Reference for a preliminary ruling – Medicinal products for human use – Labelling of organic products – Indications on the outer packaging of a medicinal herbal tea based on organically grown plants)

1. In 1991, the European Union adopted Regulation (EEC) No 2092/91 [2] on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs. That regulation, which was amended on numerous occasions, was succeeded by Regulation (EC) No 834/2007 [3] and the latter, from 1 January 2021, by Regulation (EU) 2018/848, which repeals the preceding regulation. [4]

2. In 2001, Directive 2001/83/EC, [5] establishing the Community code relating to medicinal products for human use, was also adopted and was subsequently amended.

3. Regulation 2018/848 and Directive 2001/83 are the legislative acts the interpretation of which has been requested by the referring court.

1 Original language: Spanish.

2 Council Regulation of 24 June 1991 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs (OJ 1991 L 198, p. 1).

3 Council Regulation of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 (OJ 2007 L 189, p. 1).

4 Regulation of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 (OJ 2018 L 150, p. 1). Some provisions of Regulation No 834/2007 remain in force by virtue of Article 56 et seq. of Regulation 2018/848.

5 Directive of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67). The version applicable is that resulting from the amendments introduced by Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 (OJ 2004 L 136, p. 85) and Directive 2004/27/EC of the European Parliament and of the Council of the same date (OJ 2004 L 136, p. 34).

4. While the Court has already ruled with regard to Regulation 2018/848,[6] new questions are raised in this case. Against a backdrop of increased supply of, and demand for, organic products,[7] the relationship between the labelling of medicinal products for human use and that of organic products is considered.

5. Indeed, in addition to the rules on organic *production*, Regulation 2018/848 contains those relating to the *labelling* of organic products. The debate revolves around the application of the latter rules to traditional herbal medicinal products.

I. Legal context

A. European Union law

1. Directive 2001/83

6. In Title I ('Definitions'), Article 1(29) states:

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

…

29. Traditional herbal medicinal product: a herbal medicinal product that fulfils the conditions laid down in Article 16a(1);'

7. In Title II ('Scope') Article 2 provides, in paragraph 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.'

8. In Chapter 2a ('Specific provisions applicable to traditional herbal medicinal products') of Title III ('Placing on the market'), Article 16a(1) states:

'A simplified registration procedure (hereinafter "traditional-use registration") is hereby established for herbal medicinal products which fulfil all of the following criteria:

(a) they have indications exclusively appropriate to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment;

(b) they are exclusively for administration in accordance with a specified strength and posology;

[6] Judgments of 26 February 2019, *Oeuvre d'assistance aux bêtes d'abattoirs* (C-497/17, EU:C:2019:137), and of 4 October 2024, *Herbaria Kräuterparadies* (C-240/23, EU:C:2024:852).

[7] The increasing importance and rapid evolution of the sector is confirmed by the information contained in the Market Brief on organic farming published by the European Commission in January 2023, the most recent to date, available at: https://agriculture.ec.europa.eu/news/organic-farming-eu-decade-growth-2023-01-18_es?etrans=es#more. I refer to that brief in footnote 5 to my Opinion in *AFAÏA* (C-228/23, EU:C:2024:364).

(c) they are an oral, external and/or inhalation preparation;

(d) the period of traditional use as laid down in Article 16c(1)(c) has elapsed;

(e) the data on the traditional use of the medicinal product are sufficient; in particular the product proves not to be harmful in the specified conditions of use and the pharmacological effects or efficacy of the medicinal product are plausible on the basis of long-standing use and experience.'

9. Article 62, in Title V ('Labelling and package leaflet'), states:

'The outer packaging and the package leaflet may include symbols or pictograms designed to clarify certain information mentioned in Articles 54 and 59(1) and other information compatible with the summary of the product characteristics which is useful for the patient, to the exclusion of any element of a promotional nature.'

2. Regulation 2018/848

10. Recital 10 reads:

'Experience gained so far with the application of Regulation (EC) No 834/2007 shows the need to make clear to which products this Regulation applies. Primarily, it should cover products originating from agriculture, including aquaculture and beekeeping, as listed in Annex I to the Treaty on the Functioning of the European Union (TFEU). Moreover, it should cover processed agricultural products for use as food or feed because the placing of such products on the market as organic products provides a major outlet for agricultural products and ensures that the organic nature of the agricultural products from which they are processed is visible to the consumer. Likewise, this Regulation should cover certain other products which are linked to agricultural products in a similarly close way as processed agricultural products for use as food and feed because those other products either constitute a major outlet for agricultural products or form an integral part of the production process. … For reasons of clarity, such other products not listed in Annex I to the TFEU should be listed in an Annex to this Regulation.'

11. Recital 16 states:

'This Regulation should apply without prejudice to related legislation, in particular in the fields of safety of the food chain, animal health and welfare, plant health, plant reproductive material, labelling and the environment.'

12. In Chapter I ('Subject matter, scope and definitions'), Article 2 ('Scope') states:

'1. This Regulation applies to the following products originating from agriculture, including aquaculture and beekeeping, as listed in Annex I to the TFEU and to products originating from those products, where such products are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union:

(a) live or unprocessed agricultural products, including seeds and other plant reproductive material;

(b) processed agricultural products for use as food;

(c) feed.

This Regulation also applies to certain other products closely linked to agriculture listed in Annex I to this Regulation, where they are, or are intended to be, produced, prepared, labelled, distributed, placed on the market, imported into or exported from the Union.

…

4. Except where otherwise provided, this Regulation applies without prejudice to related Union legislation, in particular, legislation in the fields of safety of the food chain, animal health and welfare, plant health and plant reproductive material.

5. This Regulation applies without prejudice to other specific Union law relating to the placing of products on the market and, in particular, to Regulation (EU) No 1308/2013 of the European Parliament and of the Council and to Regulation (EU) No 1169/2011.

…'

13. Article 30 ('Use of terms referring to organic production'), in Chapter IV ('Labelling'), states:

'1. For the purposes of this Regulation, a product shall be regarded as bearing terms referring to organic production where, in the labelling, advertising material or commercial documents, such a product, its ingredients or feed materials used for its production are described in terms suggesting to the purchaser that the product, ingredients or feed materials have been produced in accordance with this Regulation. In particular, the terms listed in Annex IV and their derivatives and diminutives, such as "bio" and "eco", whether alone or in combination, may be used throughout the Union and in any language listed in that Annex for the labelling and advertising of products referred to in Article 2(1) which comply with this Regulation.

2. For the products referred to in Article 2(1), the terms referred to in paragraph 1 of this Article shall not be used anywhere in the Union, in any language listed in Annex IV, for the labelling, advertising material or commercial documents of a product which does not comply with this Regulation.

Furthermore, no terms, including terms used in trademarks or company names, or practices shall be used in labelling or advertising if they are liable to mislead the consumer or user by suggesting that a product or its ingredients comply with this Regulation.

…'

14. Also in Chapter IV, Article 32 ('Compulsory indications') provides:

'1. Where products bear terms as referred to in Article 30(1), including products labelled as in-conversion products in accordance with Article 30(3):

(a) the code number of the control authority or control body to which the operator that carried out the last production or preparation operation is subject shall also appear in the labelling; and

(b) in the case of prepacked food, the organic production logo of the European Union referred to in Article 33 shall also appear on the packaging, except in cases referred to in Article 30(3) and points (b) and (c) of Article 30(5).

2. Where the organic production logo of the European Union is used, an indication of the place where the agricultural raw materials of which the product is composed have been farmed shall appear in the same visual field as the logo and shall take one of the following forms, as appropriate:

…'

15. Article 33 ('Organic production logo of the European Union'), also in Chapter IV, states:

'1. The organic production logo of the European Union may be used in the labelling, presentation and advertising of products which comply with this Regulation.

…'

16. Annex I ('Other products referred to in Article 2(1)') contains the entry:

'– plant-based traditional herbal preparations.'

17. Annex V ('Organic production logo of the European Union and code numbers') contains detailed provisions on the presentation of the logo and the format of the code numbers.

B. German law

18. In accordance with Paragraph 10(1), fifth sentence, of the Arzneimittelgesetz (Law on medicinal products),[8] transposing Article 62 of Directive 2001/83:

'Additional information which is not provided for in a regulation of the European Community or European Union or which is not already permitted pursuant to such a regulation shall be permitted in so far as it is related to the use of the medicinal product, is useful for the patient's health education and does not conflict with the information referred to in Paragraph 11a.'

II. Facts, dispute and questions referred for a preliminary ruling

19. Astrid Twardy GmbH ('Twardy') and SALUS Haus Dr. med. Otto Greither Nachf. GmbH & Co. KG ('SALUS') market, inter alia, traditional herbal medicinal products.

20. SALUS's product portfolio currently includes the 'Salus sage leaf medicinal tea'. The company also plans to bring to market an 'organic nerve-calming tea' and an 'alchemilla' tea.

21. Appearing on the outer packaging of the 'Salus sage leaf medicinal tea' is the official logo of the European Union, in accordance with Annex V to Regulation 2018/848, the code number of the control body and the indication 'non-EU Agriculture'. The packaging of the 'organic nerve-calming tea' will carry the official logo, a 'bio' (organic production) logo belonging to

[8] In the version published on 12 December 2005 (BGBl. 2005 I, p. 3394), as amended by the Law of 20 July 2007 (BGBl. 2007 I, p. 1574) ('the Law on Medicinal Products'). The law was amended again in 2024, but that amendment does not affect the present case.

SALUS, the code number of the control body and the indication 'from organic farming'. The 'alchemilla' tea will also carry the official logo and the code number of the control body on its packaging, as well as the indication 'EU Agriculture'.

22. Twardy maintains that placing those elements on the outer packaging of the products at issue constitutes an infringement of Paragraph 10(1), fifth sentence, of the Law on medicinal products. It therefore brought an action against SALUS seeking an injunction, information, determination of the obligation to pay damages and reimbursement of the expenses for the formal notice served.

23. SALUS contested the claim, relying on the provisions of Regulation 2018/848.

24. On 7 June 2023, the Landgericht Düsseldorf (Regional Court, Düsseldorf, Germany) ordered SALUS to refrain, in the course of trade, from marketing the products at issue [9] and to pay the expenses for the formal notice served. With regard to the infusion 'sage leaf medicinal tea', it ordered SALUS to provide certain information. The judgment also ordered the payment of damages.

25. For the court of first instance:

– All of the indications at issue are unlawful pursuant to Paragraph 10(1), fifth sentence, of the Law on medicinal products.

– The term 'regulation of the European Community or European Union', appearing in the first alternative of that provision, only refers to regulations relating to medicinal products, which is not the case with Regulation 2018/848.

– The question of whether Regulation 2018/848 is applicable in this case remains open, as the provisions on labelling in the legislation on medicinal products take precedence over it – even more so when the indications which it regulates are not mandatory.

– SALUS cannot rely on the second alternative in Paragraph 10(1), fifth sentence, of the Law on medicinal products, as the indications referred to in Regulation 2018/848 are not directly connected with the taking of the medicinal product by the patient and are, therefore, not useful for the patient's health.

26. SALUS has lodged an appeal against the judgment at first instance, arguing that:

– The material scope of Regulation 2018/848 has been extended, in comparison with the previous legislation, to include certain non-food or feed products, namely 'plant-based traditional herbal preparations', as 'other products closely linked to agriculture', provided for in Article 2(1) thereof, read together with Annex I. Consequently, the herbal teas at issue are included in it.

[9] Specifically, it ordered it to refrain from: (i) marketing the 'sage leaf' herbal tea, or causing it to be marketed, if the packaging includes the following indications: (a) the organic production logo of the European Union, in accordance with Annex V to Regulation 2018/848, and/or (b) the control body code number DE-ÖKO-003, and/or (c) 'non-EU Agriculture', as they appear on the packaging of the 'sage leaf' herbal tea; and/or (ii) marketing the 'organic nerve-calming tea', or causing it to be marketed, if the packaging includes the following indications: (a) the organic production logo of the European Union, in accordance with Annex V to Regulation 2018/848, and/or (d) the company's own 'Salus bio' organic production logo, and/or (e) the control body code number DE-ÖKO-003, and/or (f) 'organic nerve-calming tea', and/or (g) 'from organic farming', as they appear on the packaging of the 'organic nerve-calming tea in teabags'; and/or (iii) marketing 'alchemilla' herbal tea, or causing it to be marketed, if the packaging includes the following indications: (a) the organic production logo of the European Union, in accordance with Annex V to Regulation 2018/848, and/or (b) the control body code number DE-ÖKO-003, and/or c) 'EU Agriculture', as they appear on the packaging of the 'alchemilla' herbal tea.

– The provisions on labelling in Regulation 2018/848 and Directive 2001/83 apply simultaneously.

– In any event, Article 62 of Directive 2001/83 and Paragraph 10(1), fifth sentence, of the Law on medicinal products should be interpreted as meaning that the labelling permitted by Regulation 2018/848 is 'useful for the patient'.

27. Twardy submits that the appeal should be dismissed. In its view, even if the material scope of Regulation 2018/848 also extended to 'plant-based traditional herbal preparations', which are to be classified as medicinal products, Article 62 of Directive 2001/83 and Paragraph 10(1), fifth sentence, of the Law on medicinal products would take precedence. In order to protect the customer from excessive information on the outer packaging and in advertising, Article 62 of Directive 2001/83 must be interpreted restrictively, especially since there is no obligation to indicate the organic origin of the plants.

28. Against that backdrop, the Oberlandesgericht Düsseldorf (Higher Regional Court, Düsseldorf, Germany), which has to determine the appeal, has referred the following questions to the Court of Justice for a preliminary ruling:

'(1) Are herbal medicinal teas which are to be classified as "traditional herbal medicinal products" within the meaning of point 29 of Article 1 and Article 16a of [Directive 2001/83] ("the Community code") to be regarded as "plant-based traditional herbal preparations" within the meaning of Article 2(1) of, in conjunction with Annex I to, [Regulation 2018/848] …?

(2) If the first question is answered in the affirmative:

Can the labelling provided for in Chapter IV of Regulation 2018/848, in particular,

– the official organic production logo of the European Union (Article 33 of, in conjunction with Annex V to Regulation 2018/848),

– the company's own organic production logo (Article 33(5) of Regulation 2018/848),

– the code number of the control body (Article 32(1)(a) of Regulation 2018/848),

– the place of production, "EU Agriculture" or "non-EU Agriculture" (Article 32(2) of Regulation 2018/848),

– the term "bio" (Article 30(2) of Regulation 2018/848), and

– the reference 'from organic production' (Article 30(1) of Regulation 2018/848),

be affixed on the outer packaging of a medicinal product without the conditions of Article 62 of the Community code having to be fulfilled?

(3) If the first or second question is answered in the negative:

Is the labelling that is specified in the second question labelling that is "useful for the patient" and is not "of a promotional nature" within the meaning of Article 62 of the Community code?'

III. Procedure before the Court

29. The request for a preliminary ruling was received at the Court on 6 October 2023.

30. Written observations have been submitted by Twardy, SALUS, the French and Italian Governments, and also the European Commission. All of them, with the exception of the Italian Government, attended the hearing held on 27 November 2024.

IV. Analysis

31. For the purposes of this Opinion, I shall accept the premiss underlying the order for reference: the disputed herbal teas fit the definition of 'traditional herbal medicinal product', within the meaning of Article 1(29) of Directive 2001/83.

32. As *medicinal products*, those herbal teas are subject to the provisions on marketing laid down in Directive 2001/83.

33. Starting from that premiss, the referring court asks whether the herbal teas at issue would be able to make use of the rules on the specific labelling of products from organic farming (assuming, of course, that they satisfy the requirements of Regulation 2018/848):

– because they are capable of being classified among the *traditional herbal preparations* included in the scope of Regulation 2018/848 and the provisions of that regulation should take precedence over those of Directive 2001/83;

– or, alternatively, because the logos and particulars which, pursuant to Regulation 2018/848, the manufacturer intends to place on the packaging of the herbal teas comply with the labelling requirements of Directive 2001/83.

A. First question referred

34. The referring court wishes to know whether a 'traditional herbal medicinal product', within the meaning of Directive 2001/83, may, at the same time, be regarded as a 'plant-based traditional herbal preparation', for the purposes of Regulation 2018/848.

35. In my opinion, the answer is that it cannot. Regulation 2018/848 does not apply to traditional preparations based on (organically grown) plants that are 'medicinal products' within the meaning of Directive 2001/83.

36. I accept that there are arguments which, at first glance, might support the opposite opinion to the one that I have just expressed:

– Recital 10 of Regulation 2018/848 refers to 'other products' as a distinct category from those 'listed in Annex I to the Treaty on the Functioning of the European Union' and to 'processed agricultural products for use as food or feed',[10] whereby it extends the scope of Regulation 2018/848.

[10] It would equate, in Article 2(1) of Regulation 2018/848, to the category 'certain other products closely linked to agriculture listed in Annex I to this Regulation …'.

– The similarity between the phrasing of the final indent of Annex I to Regulation 2018/848 and that of Article 1(32) of Directive 2001/83 [11] could be another indication supporting the view that Regulation 2018/848 applies to medicinal products.

37. I do not, however, believe that either of those two arguments is conclusive. For one thing, recital 10 of Regulation 2018/848 does not, of necessity, require the inclusion of medicinal products in that regulation. [12] For another, a 'plant-based traditional herbal preparation', within the meaning of Regulation 2018/848, will only be a 'traditional herbal medicinal product' for the purposes of Directive 2001/83 if it also satisfies the conditions of Article 1(2) [13] and (29) of that directive.

38. The desire that Regulation 2018/848 should also include medicinal products was clearly expressed in the preparatory work, but it did not ultimately come about.

39. The draft European Parliament legislative resolution on the proposal drawn up by the Commission [14] accepted amendments 255 to 275, such that:

– certain entries, relating to 'other products referred to in Article 2(1)' were removed from Annex I to the proposal, given that they would already be covered by the definition of 'food' in Article 3(21) of that same proposal, and

– other entries, which, conversely, would not be encompassed by that definition, were added. According to amendment 275, one of them would be that relating to 'plant-based raw materials for traditional herbal medicinal products'.

40. The final version of the text, however, did not include the reference to those medicinal products. The documents available record that the Council objected to that reference, precisely because the medicinal products in question were outside the scope of Regulation 2018/848. [15]

[11] In Spanish, 'preparaciones vegetales tradicionales a base de plantas' and 'preparados vegetales', respectively; in English, 'plant-based traditional herbal preparations' and 'herbal preparations'; in French 'préparations traditionnelles à base de plantes' and 'préparations à base de plantes'; in German 'traditionelle pflanzliche Zubereitungen auf pflanzlicher Basis' and 'Pflanzliche Zubereitungen'.

[12] The Commission, in its proposal of 24 March 2014 for a Regulation of the European Parliament and of the Council on organic production and labelling of organic products, amending Regulation (EU) No XXX/XXX of the European Parliament and of the Council [Official controls Regulation] and repealing Council Regulation (EC) No 834/2007, COM(2014) 180 final, included a recital 9 identical to recital 10 of the current regulation. Medicinal products did not appear in Annex I to the proposal, which, in addition to foods, only mentioned natural gums and resins and beeswax.

[13] In this paragraph, 'medicinal product' is defined, on a general basis, as: 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.

[14] Document A8-0311/2015, of 5 November 2015.

[15] Document 13436/15, of 27 October 2015, containing the responses suggested by the Presidency of the Council to the Parliament's amendments to the Commission's proposal. The Council's reaction to the entry 'plant-based raw materials for traditional herbal medicinal products' was: 'Acceptable if "medicinal" is deleted because outside of the scope of the Regulation, and if limited to food purposes.'

41. A later suggestion by the Parliament (to modify amendment 275, replacing the reference to 'medicinal products' with the formula 'plant-based raw materials for traditional herbal treatments') was also rejected by the Council, as the term 'treatment' implied a medical use for the product. [16]

42. The formula 'plant-based traditional herbal preparations', appearing in Annex I to Regulation 2018/848, reflects an interinstitutional compromise. [17] That formula is certainly generic in nature, but, in the light of what I have set out, it does not include preparations which, fitting the definition given in Article 1(2) of Directive 2001/83, are medicinal products (specifically, plant-based medicinal products).

43. The interpretation which I propose is also consistent with the European approach to regulating medicinal products, which tends to reject the double legal classification of products (and the consequent diversity of regimes) which fit the description of 'medicinal product'. To that end, the legislature:

– Defines the scope of the rules applicable to different products, expressly excluding medicinal products from instruments regulating other types of product. [18]

– Article 2(2) of Directive 2001/83 [19] provides for the application of that directive to 'borderline' products, except where there is no doubt that they belong to another category. [20]

44. Similarly, the Court:

– Has observed that, when the same product falls within the definition of a medical product and that of another product, the more rigorous rules relating to medicinal products apply. [21]

[16] Document 15269/15 (from General Secretariat of the Council to Delegations), of 15 December 2015, on the state of play following the first two trilogues. At page 3, it refers to three products on which there was still disagreement with the Parliament, one of them being plant-based raw materials for traditional herbal treatments. Because of its association with medicinal products, the Council took the view that the term 'treatment' 'therefore falls outside the scope of application of the Regulation, which does not cover pharmaceutical products.'

[17] In Document 6699/16, of 3 March 2016, informing on the outcome of the fourth trilogue, this compromise formula already appears.

[18] See, in relation to medical devices, Article 1(5)(c) of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ 1993 L 169, p. 1), now repealed. In relation to cosmetics, recital 6 of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ 2009 L 342, p. 59); previously, recital 5 of Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (OJ 1976 L 262, p. 169). Medicinal products are excluded from the definition of food according to Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ 2002 L 31, p. 1). See also Article 2(2)(c) of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ 2012 L 167, p. 1). Regulation 2018/848 does not make any express clarification of that kind; however, it applies without prejudice to other EU legislation, which could include Directive 2001/83, as I note later on.

[19] According to the wording resulting from Article 2(2) of Directive 2004/27: '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.' In my opinion, that rule endorses the case-law of the Court prior to 2007, to which I refer in footnotes 21 and 22 to this Opinion.

[20] The adjective 'borderline' is applied by recital 7 of Directive 2004/27 to products which, while fully falling within the definition of a medicinal product, may also fall within the definition of other regulated products. That recital refers, in particular, to food, food supplements, medical devices, biocides and cosmetics. It adds that, where a product *clearly* falls within one of those categories, those descriptions are to take precedence. The statement is not intended to question the rule on Directive 2001/83 taking precedence: see judgment of 19 January 2023, *Bundesrepublik Deutschland (Nasal drops)* (C-495/21 and C-496/21, EU:C:2023:34, paragraph 32).

[21] Judgments of 21 March 1991, *Delattre* (C-369/88, EU:C:1991:137, paragraph 21), and *Monteil and Samanni* (C-60/89, EU:C:1991:138, paragraph 16) (medicinal product or cosmetic product); of 16 April 1991, *Upjohn* (C-112/89, EU:C:1991:147, paragraph 31); of 28 October 1992, *Ter Voort* (C-219/91, EU:C:1992:414, paragraphs 19 and 20) (foodstuff or medicinal product); and of 15 November 2007, *Commission* v *Germany* (C-319/05, EU:C:2007:678, paragraph 38) (foodstuff or medicinal product).

– Has ruled that the application of those more rigorous rules (those relating to medicinal products) is *exclusive*.[22]

45. In short, in my view, the scope of Regulation 2018/848 does not include organically produced herbal teas having the status of 'traditional herbal medicinal products', within the meaning of Articles 1(29) and 16a of Directive 2001/83.

B. Second question referred

46. The referring court poses its second question in the event that the preceding question is answered in the affirmative. As I have already proposed answering the first question in the negative, as I understand it, it would not be necessary to address the second.

47. If, despite everything, the expression 'plant-based traditional herbal preparations' were interpreted to include 'medicinal products',[23] it would still be necessary to examine whether such an interpretation implied that Regulation 2018/848 and its rules on the labelling of organic products should displace Directive 2001/83.

48. In that hypothetical situation, my answer would also be in the negative.

49. Medicinal products are not like other products. They are not sold or consumed in the same way that organically grown products are sold and consumed. The way in which medicinal products are used is specific and their use is subject to special precautions relating to efficacy and safety.

50. For the EU legislature, the peculiar nature of medicinal products resides in the objective of making their free movement compatible with that of ensuring a high level of human and public health protection (Article 168 TFEU). That statement is equally valid for all medicinal products, including traditional herbal medicinal products, whether they are organically grown or not.

51. In view of the particular risks which they may pose, medicinal products are subject to a strict legal regime, which is more rigorous than that for other regulated products, such as, for example, food or cosmetics.[24]

52. In justifying the application of the legislation on medicinal products to products that, a priori, could also fall within another definition and be subject to other rules, the Court refers explicitly to the greater rigour of that legislation.[25]

53. For its part, the legislature modified Article 2(2) of Directive 2001/83, as I have already noted, such that, in cases of doubt as to the classification of a product with attributes of a medicinal product and of another class of products, only that directive applies.

[22] Judgments of 9 June 2005, *HLH Warenvertrieb and Orthica* (C-211/03, C-299/03 and C-316/03 to C-318/03, EU:C:2005:370, paragraph 43) (medicinal product and foodstuff); of 15 November 2007, *Commission* v *Germany* (C-319/05, EU:C:2007:678, paragraph 63) (medicinal product and food supplement); of 3 October 2013, *Laboratoires Lyocentre* (C-109/12, EU:C:2013:626, paragraph 41) (medicinal product and medical device); of 27 October 2022, *Orthomol* (C-418/21, EU:C:2022:831, paragraph 37) (medicinal product, food, food for special medical purposes); and of 2 March 2023, *Kwizda Pharma* (C-760/21, EU:C:2023:143, paragraph 27) (medicinal product and food for special medical purposes).

[23] Or be capable of including products that are also medicinal products.

[24] See the case-law cited in footnote 21.

[25] See footnote 21.

54. It is not plausible that that exclusive preference underlying Directive 2001/83, intended to support the objective of ensuring the protection of public health, should be altered by the fact that a medicinal product is obtained from organically grown plants.

55. In my opinion, Regulation 2018/848 does not preclude the above.

56. It is true that Regulation 2018/848, adopted years after Directive 2001/83, does not explicitly preserve the priority of the rules on the labelling of medicinal products contained in Directive 2001/83. However:

– In accordance with Article 2(4) of that regulation, except where otherwise provided, it is to apply without prejudice to related EU legislation. It then lists fields in which legislation with those characteristics exists. Moreover, it does so in a manner that is not intended to be exhaustive, as may be deduced from the use of the expression 'in particular'.

– In Article 2(5), it states that it applies without prejudice to other specific provisions of EU law relating to the placing of products on the market. The paragraph makes express reference to two regulations: again, with the expression 'in particular', it makes it clear that it does so merely by way of example.

– According to recital 16, Regulation 2018/848 'should apply without prejudice to related legislation, in particular in the fields of safety of the food chain, animal health and welfare, plant health, plant reproductive material, labelling and the environment.'

57. With regard to the placing of products on the market, Regulation 2018/848 is, then, not conceived to prevent the application of other preferable provisions of EU law. Among those provisions is, precisely, Directive 2001/83, which establishes the legal regime for medicinal products, including traditional herbal medicinal products.

C. Third question referred

58. The third question referred is posed in the event that the first or (as I have proposed) the second question is answered in the negative. It must, therefore, be addressed.

59. The referring court wishes to know whether the indications referred to in the labelling elements appearing in Chapter IV of Regulation 2018/848 satisfy the requirements of Article 62 of Directive 2001/83 and may, consequently, be placed on the outer packaging of the herbal teas at issue.

60. According to Article 62 of Directive 2001/83, medical information may only be included in the package leaflet or placed on the outer packaging of a medicinal product if, cumulatively, that information:

– is compatible with the summary of the product characteristics;

– is useful for the patient;

– is not of a promotional nature.

61. Given those conditions,[26] it is my view that the third question referred must also be answered in the negative.

1. Compatibility with the summary of product characteristics

62. Article 11 of Directive 2001/83 provides for the *summary* of product characteristics which, pursuant to Article 8(3)(j), is to accompany the application for authorisation to market medicinal products.[27]

63. The application for the simplified registration of a traditional herbal medicinal product, regulated in Chapter 2a of Title III ('Placing on the market') of Directive 2001/83, must also include that summary.[28]

64. I am inclined to think that the elements at issue in the dispute are not compatible with the summary of the medicinal product's characteristics. The reason for that is not that those elements do not appear as such among the information required for that summary,[29] but rather that the summary is to state the 'qualitative and quantitative composition in terms of the active substances and constituents of the excipient, knowledge of which is essential for proper administration of the medicinal product'.[30]

65. By themselves, details regarding whether the plants on which the medicinal product is based[31] are organically grown or not, or regarding where they were obtained, or the other indications at issue in the dispute (logos and code numbers of control bodies), do not correspond materially to the information referred to in Article 11(2) of Directive 2001/83.[32]

66. It is not necessary to know any of those indications in order to administer the medicinal product correctly. On the other hand, their presence on the packaging of the product could suggest or evoke the impression of a higher quality product and, to that same extent, mislead (the user) regarding its therapeutic properties or serve to promote the product, contrary to the requirements of Article 62 of Directive 2001/83.

[26] I shall deal with each of those conditions separately, despite the indivisible relationship between them.

[27] Literally, for authorisations not provided for in the procedure established by Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization 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). That reference should, however, be construed as a reference to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1), in accordance with Article 88 of the latter regulation.

[28] Article 16c(1)(a)(iii). The content of the summary is provided for in Article 11, except as regards the information specified in point 4 of that article (clinical data).

[29] The Commission appears to suggest as much in paragraph 39 of its written observations: 'Keine dieser Angaben betrifft die ökologische/biologische Produktion.' The compatibility of information on the medicinal product with the summary of its characteristics should not imply exact correspondence or the possibility of subsuming that information under one of the categories listed in Article 11, but rather the absence of conflict. Any other interpretation would make it practically impossible to advertise the medicinal products, even where that is authorised, since all parts of the advertising 'must comply with the particulars listed in the summary of product characteristics,' as required by Article 87(2) of Directive 2001/83. For examples of indications considered acceptable under Article 62 of Directive 2001/83, I refer to the annex to the Commission's own document 'Guideline on the Packaging Information of Medicinal Products for Human Use Authorised by the Union', footnote 43 below.

[30] Article 11(2) of Directive 2001/83.

[31] I recall that, in accordance with Article 16g(2)(a) of Directive 2001/83, the statement to the effect that the product is a traditional herbal medicinal product is, on a mandatory basis, to appear in the package leaflet and on the labelling.

[32] At the hearing, the Commission insisted that particulars such as the origin of the plants or the way in which they were grown are not 'product characteristics', within the meaning of Article 11 of Directive 2001/83, except where they are assessed to be such by the competent authorities, in the light of scientific studies which prove that the product has a different quality or efficacy that is attributable to precisely those elements. There is no record, in the present case, of an assessment having been made in that regard.

2. Usefulness for the patient

67. The medical information authorised by Article 62 of Directive 2001/83 must be 'useful for the patient'.

68. Asked regarding that expression, the Court ruled out the inclusion, in the package leaflet of a homeopathic medicinal product, of indications relating to posology, considering them capable of misleading the user regarding the characteristics of the product. [33]

69. In a negative sense, information capable of confusing him or her about the properties of the medicinal product would not be 'useful for the patient'.

70. The presence on the outer packaging of the medicinal product of information such as that at issue here (organic production logos and other similar logos) could produce such a confusing effect: the patient would be confronted with an *inflation* or excess of information, with references of various kinds, among which he or she would hardly be able distinguish the relevant information, in therapeutic terms, from that with no bearing on his or her health. [34]

71. Placing the indications at issue here on the packaging of the medicinal product could, moreover, give rise to the risk of two other errors on the part of the patient: [35] that of equating the medicinal products with organic consumer products on which, generally speaking, those particulars appear; [36] and that of believing the preparation to have greater therapeutic efficacy. [37] It should not, in this context, be forgotten that purchasing a traditional herbal medicinal product is possible (and usually occurs) without a prescription, [38] that is, without the prior involvement of a healthcare professional. [39]

[33] Judgment of 23 April 2020, *DHU Arzneimittel* (C-101/19 and C-102/19, EU:C:2020:304): see the second question referred. In those cases, the medicinal product, in order to be placed on the market, required an authorisation or was subject to a simplified registration procedure. The Court did not focus its observations specifically on Article 62 of Directive 2001/83, beyond paragraph 41 of the judgment. In paragraph 46, however, the judgment refers to the authorisation of the inclusion in the package leaflet of particulars in addition to the mandatory information listed in Article 69, which would only be possible pursuant to Article 62.

[34] The Committee on Herbal Medicinal Products (HMPC) of the European Medicines Agency expresses that concern in the document, mentioned by the Commission at the hearing, entitled 'Regulatory questions and answers on herbal medicinal products', reference number EMA/HMPC/345132/2010 – Rev. 5, in response to question 5 ('Is reference to "organic farming" acceptable in either the labelling or the package leaflet of a herbal medicinal product?'). That response reads: 'Having regard to the position adopted by the Pharmaceutical Committee in March 2000 on this matter, the HMPC is of the opinion that "accreditation logos" … or the "organic farming" logo *are not acceptable as they cannot … be considered as "health information*" and as the risk of an inflation of additional items on the packaging requires a restrictive interpretation of the provisions of Article 62.' Emphasis added.

[35] The legislature itself reflects both risks: Article 90(g) and (h) of Directive 2001/83 prohibits the inclusion in advertising aimed at the general public of any material which 'suggests that the medicinal product is a foodstuff, cosmetic or other consumer product' or 'suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural', respectively.

[36] The labelling of organic products has its own purposes, described in recital 73 of Regulation 2018/848. The specific provisions relating to the labelling of organic products 'should protect both the interests of operators in having their products correctly identified on the market and in enjoying conditions of fair competition, and the interests of consumers in being able to make informed choices.'

[37] Recital 2 of Regulation 2018/848 explains that 'the observance of high standards for health, the environment and animal welfare in the production of organic products is intrinsic to the high quality of those products.' The 'jump', in the mind of the patient, from that high quality of the basic ingredients of the product to the product having greater preventative or curative efficacy is perfectly easy to imagine.

[38] See Article 1(29), read together with Article 16a(1)(a) of Directive 2001/83.

[39] In the judgment of 22 December 2022, *EUROAPTIEKA* (C-530/20, EU:C:2022:1014, paragraph 65), in analysing the advertising of medicinal products which do not require a medical prescription, the Court acknowledged that the patient does not necessarily have the specific and objective knowledge enabling him or her to evaluate their therapeutic value. It added that advertising may, therefore, exercise a particularly strong influence on the evaluation and choice made by the patient, both as regards the quality of the medicinal product and the amount to purchase. As I set out in the main body of the text, I believe the elements at issue in the dispute to be of a promotional nature.

72. In a positive sense, in the light of recital 40 of Directive 2001/83, it is my view that information that is 'useful for the patient' is that which illustrates how to use the product correctly. The objective stated in that recital [40] is to protect the patient, offering him or her 'full and comprehensible' indications, with a specific purpose – that of ensuring the medicinal product is used correctly. The purchaser, I repeat, is considered in the capacity of patient, which is not the same as that of any other consumer.

73. The original wording of Article 62 of Directive 2001/83 required additional information in the package leaflet or on the outer packaging to be useful 'for health education', [41] as opposed to the current 'useful for the patient'. Taking into account the preparatory work done in relation to that amendment, I believe the reformulation of that point is only intended to improve the wording of the text: it did not alter its purpose of informing the patient, in his or her capacity as such. [42]

74. In my opinion, it is not useful for the patient, in therapeutic terms, to know whether or not the plants on which the medicinal product is based are organically grown or where they were obtained.

3. Absence of elements of a promotional nature

75. Article 62 of Directive 2001/83 authorises the placing of certain indications on the outer packaging and in the package leaflet of the medicinal product '[excluding] any element of a promotional nature'.

76. In my opinion, the addition of an indication to the labelling that is not useful for the correct use of the medicinal product by the patient suggests that that indication is probably of a promotional nature. [43]

[40] 'The provisions governing the information supplied to users should provide a high degree of consumer protection, in order that medicinal products may be used correctly on the basis of full and comprehensible information.'

[41] That expression already appeared in Council Directive 92/27/EEC of 31 March 1992 on the labelling of medicinal products for human use and on package leaflets (OJ 1992 L 113, p. 8). It was used in Article 2(2), for the outer packaging of medicinal products, and in Article 7(3), for the package leaflet, in the context of a change of orientation with regard to the person for whom the package leaflet was principally intended, which becomes the user: see document A3-0126/91, of 8 May 1991, containing the Parliament's report on the Commission's proposal for a directive (COM(89) 607 final – C3-0050/90 – SYN 231). Previously, Article 7 of the 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), provided that '… Member States may require that the proprietary medicinal product shall be labelled so as to indicate on the container and/or outer packaging and/or on the package leaflet other requirements essential to safety or for the protection of public health, including any particular precautions to be taken in using the product and any other warnings based on the results of the clinical trials and pharmacological tests mentioned in point 8 of Article 4, second paragraph, of Directive 65/65/EEC, or resulting from experience in the course of use of the proprietary medicinal product after marketing.'

[42] The new wording, which is incorporated into Directive 2001/83 by means of Directive 2004/27, comes from Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, COM(2001) 404 final, of 26 November 2001. It was not accompanied by any explanation. However, of the nine appearing in the section 'Detailed content of the proposal', the only one that could fit is that in point A, 'Adaptation of definitions, terminology and certain concepts'. At the hearing, the Commission explained that, with the new text, it aimed to emphasise that the usefulness or otherwise of the information has to be assessed from the point of view of the patient and not with the general objective of health education.

[43] I exclude from that any indications that are mandatory under national rules. See, in that regard, the annex to the Commission document 'Guideline on the Packaging Information of Medicinal Products for Human Use Authorised by the Union', (last revised in September 2023, accessible online at: 2018_packaging_guidelines_en_1.pdf), intended to assist applicants and marketing authorisation holders when drawing up the labelling and package leaflet for medicinal products. That annex contains, for each Member State, expressions, symbols or pictograms that have become established in the different Member States and are in accordance with Article 62 of Directive 2001/83. None of those at issue in this case appear among those for Germany.

77. In order to clarify what constitutes that (promotional) nature, it seems relevant to consider the provisions of Directive 2001/83 that, with a view to securing its essential objective of safeguarding public health, define and regulate the advertising of medicinal products.

78. Article 86(2) of Directive 2001/83 states that Title VIII ('Advertising') does not cover either labelling or the package leaflet. That exclusion is logical, as labelling and the package leaflet are governed by Title V, which specifically prohibits placing promotional information on them. [44]

79. However, the case-law established with regard to the provisions of Title VIII may be useful in relation to Article 62 of Directive 2001/83, for the sole purpose of clarifying what messages or content are promotional in relation to medicinal products. [45]

80. Article 86(1) of Directive 2001/83 defines advertising as 'any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products'.

81. The definition applies to all medicinal products. However, the rules relating to advertising aimed at the general public vary: advertising medicinal products only available on prescription to the general public is prohibited; medicinal products available without a prescription may be advertised, although subject to conditions and restrictions. [46] The difference is justified on the basis of the different risks inherent in the consumption of the different types of product, which are lower in the case of those dispensed without a prescription, albeit not non-existent. [47]

82. Among the judgments given with regard to Article 86(1) of Directive 2001/83, the judgment in *MSD Sharp & Dohme* seems to me to be particularly illustrative for the purposes of this request for a preliminary ruling. [48]

83. In that judgment, after noting that purely objective information may also have promotional intent, [49] the Court observed that, in order to classify the dissemination of information as 'promotional', the following were useful indicators: the identity of the person disseminating the information; the purpose of the communication; its content; possibly other factors, such as the media used in order to disseminate the information and the groups addressed. [50]

[44] The dissemination by other means (for example, on the manufacturer's website) of information identical to that appearing on the labelling or in the package leaflet does not appear to be promotional in nature: judgment of 5 May 2011, *MSD Sharp & Dohme* (C-316/09, EU:C:2011:275; 'the judgment in *MSD Sharp & Dohme*'), paragraph 43.

[45] I insist that, having established the promotional nature of a particular element, that element would not be authorised, either in the package leaflet or on the outer packaging of a traditional herbal medicinal product: that is laid down in Article 62 of Directive 2001/83. However, if it satisfies the conditions laid down in Titles VIII and VIIIa of that directive, it would be able to appear in the advertising for the product.

[46] Article 88(1) and (2) and recital 45 of Directive 2001/83.

[47] As the Court has emphasised, inter alia, in the judgments of 11 June 2020, *ratiopharm* (C-786/18, EU:C:2020:459, paragraph 36); of 1 October 2020, *A (Advertising and sale of medicinal products online)* (C-649/18, EU:C:2020:764, paragraph 94); and of 22 December 2022, *EUROAPTIEKA* (C-530/20, EU:C:2022:1014, paragraph 43).

[48] That case, relating to prescription-only medicinal products, concerned whether the faithful reproduction of the packaging of the product on the manufacturer's website, or a literal and complete reproduction of the package leaflet or the summary of the product's characteristics approved by the authorities with competence in relation to medicinal products, is advertising, where such information is only available according to the system of 'pull' services.

[49] The judgment in *MSD Sharp & Dohme*, paragraph 32.

[50] It also noted that such a classification requires a detailed examination of all the relevant circumstances of the case, which is for the national court: the judgment in *MSD Sharp & Dohme*, paragraph 33, and judgment of 22 December 2022, *EUROAPTIEKA* (C-530/20, EU:C:2022:1014, paragraph 54).

84. Its analysis of those indicators led to the following conclusions:

– With regard to the person disseminating the information, if it is the manufacturer of the product, that points to a promotional purpose. There may, however, by explanations other than an interest in increasing sales: for example, a general communication policy on the part of an undertaking to publish information on the medicinal products, aimed at the patients concerned, in order to avoid as far as possible the risks to health from self-medication. [51]

– With regard to the purpose, as a general rule, objective information relating to medicinal products requiring a prescription does not have a promotional purpose. The requirement for a medical prescription is able to ensure that any interest aroused by that information 'cannot lead directly to a decision to purchase' and that 'the final decision as to the medicinal product to be taken by the patient remains with his doctor.' [52]

– With regard to the content, the dissemination of information has a promotional purpose when it is 'selected or rewritten by the manufacturer', in comparison with that appearing in the package leaflet or in the summary of the product's characteristics. 'Such manipulation of information can be explained only by an advertising purpose.' [53]

– With regard to the media used and the groups addressed, information which, while being accessible to anyone on the Internet, is only obtained by means of a system requiring 'active research steps by the Internet user' is not regarded as advertising. [54]

85. In the light of the above, and without prejudice to the fact that the assessment of the specific circumstances of the present case is a matter for the referring court, I am of the opinion that placing labelling elements provided for in Chapter IV of Regulation 2018/848 on the packaging of a traditional herbal medicinal product is promotional in nature when:

– those elements or indications have no value in healthcare terms. They could, therefore, hardly be explained by a non-commercial interest on the part of the manufacturer, such as better protecting the patient against the risks of self-medication;

– purchasing the medicinal product is possible without a prescription. In that eventuality, the information is addressed to and reaches the patient without the intermediation of a healthcare professional, such that it could lead, directly, to a decision to purchase on the part of the patient;

– the elements provided for in Chapter IV of Regulation 2018/848 do not equate to any of those provided for in the summary of the product characteristics, but are in addition to them;

– the information is easily accessed by the general public. Whoever gets hold of the product will find it immediately, without the need for any particular research on his or her part.

86. In short, it is my view that the labelling elements regulated in Chapter IV of Regulation 2018/848 do not satisfy the conditions laid down in Article 62 of Directive 2001/83 and cannot, therefore, be placed on the outer packaging of a traditional herbal medicinal product.

[51] The judgment in *MSD Sharp & Dohme*, paragraphs 34 and 35.

[52] Ibid., paragraph 36.

[53] Ibid., paragraphs 43 and 44.

[54] Ibid., paragraph 47.

V. Conclusion

87. In the light of the foregoing, I propose that the response to the Oberlandesgericht Düsseldorf (Higher Regional Court, Düsseldorf, Germany) should be as follows:

'Article 2(1), read together with Annex I, of Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007, Chapter IV of that regulation, and also Articles 1(29), 16a and 62 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use,

must be interpreted as meaning that:

(1) Herbal teas classified as "traditional herbal medicinal products" within the meaning of Articles 1(29) and 16a of Directive 2001/83 cannot be regarded as 'plant-based traditional herbal preparations' for the purposes of Article 2(1), read together with Annex I to Regulation 2018/848.

(2) The rules on labelling set out in Chapter IV of Regulation 2018/848 do not take precedence over the provisions on labelling in Directive 2001/83.

(3) The labelling elements provided for in Chapter IV of Regulation 2018/848 do not satisfy the conditions laid down in Article 62 of Directive 2001/83.'