JUDGMENT OF THE COURT

15 July 2021[*]

(*Directive 2001/83/EC – Directive 2011/62/EU – Medicinal products – Wholesale distribution of medicinal products – Brokering of medicinal products – Freedom of establishment*)

In Case E-7/20,

REQUEST to the Court under Article 34 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice by the Princely Court of Appeal (*Fürstliches Obergericht*) in criminal proceedings against

M and X AG

concerning the interpretation 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 and Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products,

THE COURT,

composed of: Páll Hreinsson, President, Per Christiansen and Bernd Hammermann (Judge-Rapporteur), Judges,

Registrar: Ólafur Jóhannes Einarsson,

having considered the written observations submitted on behalf of:

– M and X AG, represented by Sabine Mohr-Egger, advocate;

[*] Language of the request: German. Translations of national provisions are unofficial and based on those contained in the documents of the case.

– the Liechtenstein Government, represented by Dr Andrea Entner-Koch and Thomas Bischof, acting as Agents;

– Ireland, represented by Maria Browne and Tony Joyce, acting as Agents, and assisted by David Fennelly, Barrister-at-Law;

– the EFTA Surveillance Authority ("ESA"), represented by Ewa Gromnicka, James Stewart Watson, Catherine Howdle and Carsten Zatschler, acting as Agents; and

– the European Commission ("the Commission"), represented by Ken Mifsud-Bonnici and Attila Sipos, acting as Agents,

having regard to the Report for the Hearing,

having heard oral argument of M and X AG, represented by Sabine Mohr-Egger; the Liechtenstein Government, represented by Thomas Bischof; Ireland, represented by David Fennelly; ESA, represented by Ewa Gromnicka; and the Commission, represented by Ken Mifsud-Bonnici at the remote hearing on 10 December 2020;

gives the following

Judgment

I Legal background

EEA law

1 Article 31 of the Agreement on the European Economic Area ("the EEA Agreement" or "EEA") reads:

> *1. Within the framework of the provisions of this Agreement, there shall be no restrictions on the freedom of establishment of nationals of an EC Member State or an EFTA State in the territory of any other of these States. This shall also apply to the setting up of agencies, branches or subsidiaries by nationals of any EC Member State or EFTA State established in the territory of any of these States.*
>
> *Freedom of establishment shall include the right to take up and pursue activities as self-employed persons and to set up and manage undertakings, in particular companies or firms within the meaning of Article 34, second paragraph, under the conditions laid down for its own nationals by the law of the country where such establishment is effected, subject to the provisions of Chapter 4.*
>
> *2. Annexes VIII to XI contain specific provisions on the right of establishment.*

2 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67) ("the Directive") was incorporated into the EEA Agreement by Decision of the EEA Joint Committee No 82/2002 of 25 June 2002 (OJ 2002 L 266, p. 32), inserting it as point 15q of Chapter XIII of Annex II to the EEA Agreement (Technical regulations, standards, testing and certification). No constitutional requirements were indicated and the decision entered into force on 26 June 2002. Unless otherwise indicated, the following provisions are quoted with the wording applicable, subject to Protocol 1 to the EEA Agreement and the adaptions contained in Annex II, at the time when the facts giving rise to the main proceedings took place.

3 Recital 2 of the Directive reads:

> *The essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health.*

4 Recital 3 of the Directive reads:

> *However, this objective must be attained by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the Community.*

5 Recital 14 of the Directive reads:

> *This Directive represents an important step towards achievement of the objective of the free movement of medicinal products. Further measures may abolish any remaining barriers to the free movement of proprietary medicinal products will be necessary in the light of experience gained, particularly in the abovementioned Committee for Proprietary Medicinal Products.*

6 Recital 35 of the Directive reads:

> *It is necessary to exercise control over the entire chain of distribution of medicinal products, from their manufacture or import into the Community through to supply to the public, so as to guarantee that such products are stored, transported and handled in suitable conditions. The requirements which must be adopted for this purpose will considerably facilitate the withdrawal of defective products from the market and allow more effective efforts against counterfeit products.*

7 Recital 36 of the Directive reads:

> *Any person involved in the wholesale distribution of medicinal products should be in possession of a special authorization. Pharmacists and persons authorized to supply medicinal products to the public, and who confine themselves to this activity, should be exempt from obtaining this authorization. It is however*

necessary, in order to control the complete chain of distribution of medicinal products, that pharmacists and persons authorized to supply medicinal products to the public keep records showing transactions in products received.

8 Recital 37 of the Directive reads:

Authorization must be subject to certain essential conditions and it is the responsibility of the Member State concerned to ensure that such conditions are met; whereas each Member State must recognize authorizations granted by other Member States.

9 Article 1 of the Directive reads, in extract:

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.

...

17. Wholesale distribution of medicinal products:

All activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public. Such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorized or entitled to supply medicinal products to the public in the Member State concerned.

17a. Brokering of medicinal products:

All activities in relation to the sale or purchase of medicinal products, except for wholesale distribution, that do not include physical handling

and that consist of negotiating independently and on behalf of another legal or natural person.

...

10 Article 2 of the Directive reads, in extract:

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.

...

11 Article 3 of the Directive reads, in extract:

This Directive shall not apply to:

1. Any medicinal product prepared in a pharmacy in accordance with a medical prescription for an individual patient (commonly known as the magistral formula).

2. Any medicinal product which is prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and is intended to be supplied directly to the patients served by the pharmacy in question (commonly known as the officinal formula).

...

12 Article 6(1) of the Directive forms part of Title III headed "Placing on the market" and reads, in extract:

No medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State in accordance with this Directive or an authorisation has been granted in accordance with Regulation (EC) No 726/2004, read in conjunction with Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and Regulation (EC) No 1394/2007.

...

13 Articles 76, 77, 79, 80, 81, 83, 85a and 85b of the Directive form part of Title VII, headed "Wholesale Distribution and Brokering of Medicinal Products".

14 Article 76 of the Directive reads, in extract:

> *1. Without prejudice to Article 6, Member States shall take all appropriate action to ensure that only medicinal products in respect of which a marketing authorization has been granted in accordance with Community law are distributed on their territory.*
>
> *2. In the case of wholesale distribution and storage, medicinal products shall be covered by a marketing authorisation granted pursuant to Regulation (EC) No 726/2004 or by the competent authorities of a Member State in accordance with this Directive.*
>
> *…*

15 Article 77 of the Directive reads, in extract:

> *1. Member States shall take all appropriate measures to ensure that the wholesale distribution of medicinal products is subject to the possession of an authorisation to engage in activity as a wholesaler in medicinal products, stating the premises located on their territory for which it is valid.*
>
> *2. Where persons authorized or entitled to supply medicinal products to the public may also, under national law, engage in wholesale business, such persons shall be subject to the authorization provided for in paragraph 1.*
>
> *3. Possession of a manufacturing authorization shall include authorization to distribute by wholesale the medicinal products covered by that authorization. Possession of an authorization to engage in activity as a wholesaler in medicinal products shall not give dispensation from the obligation to possess a manufacturing authorization and to comply with the conditions set out in that respect, even where the manufacturing or import business is secondary.*
>
> *…*

16 Article 79 of the Directive reads:

> *In order to obtain the distribution authorization, applicants must fulfil the following minimum requirements:*
>
> *(a) they must have suitable and adequate premises, installations and equipment, so as to ensure proper conservation and distribution of the medicinal products;*
>
> *(b) they must have staff, and in particular, a qualified person designated as responsible, meeting the conditions provided for by the legislation of the Member State concerned;*

(c) they must undertake to fulfil the obligations incumbent on them under the terms of Article 80.

17 Article 80 of the Directive reads, in extract:

Holders of the distribution authorization must fulfil the following minimum requirements:

...

(b) they must obtain their supplies of medicinal products only from persons who are themselves in possession of the distribution authorization or who are exempt from obtaining such authorization under the terms of Article 77(3);

(c) they must supply medicinal products only to persons who are themselves in possession of the distribution authorization or who are authorized or entitled to supply medicinal products to the public in the Member State concerned;

...

(g) they must comply with the principles and guidelines of good distribution practice for medicinal products as laid down in Article 84;

...

18 Article 81 of the Directive reads, in extract:

With regard to the supply of medicinal products to pharmacists and persons authorised or entitled to supply medicinal products to the public, Member States shall not impose upon the holder of a distribution authorisation which has been granted by another Member State any obligation, in particular public service obligations, more stringent than those they impose on persons whom they have themselves authorised to engage in equivalent activities.

...

19 Article 83 of the Directive reads:

The provisions of this Title shall not prevent the application of more stringent requirements laid down by Member States in respect of the wholesale distribution of:

— narcotic or psychotropic substances within their territory,

— medicinal products derived from blood,

— *immunological medicinal products,*

— *radiopharmaceuticals.*

20 Article 85a of the Directive reads:

In the case of wholesale distribution of medicinal products to third countries, Article 76 and point (c) of the first paragraph of Article 80 shall not apply. Moreover, points (b) and (ca) of the first paragraph of Article 80 shall not apply where a product is directly received from a third country but not imported. However, in that case wholesale distributors shall ensure that the medicinal products are obtained only from persons who are authorised or entitled to supply medicinal products in accordance with the applicable legal and administrative provisions of the third country concerned. Where wholesale distributors supply medicinal products to persons in third countries, they shall ensure that such supplies are only made to persons who are authorised or entitled to receive medicinal products for wholesale distribution or supply to the public in accordance with the applicable legal and administrative provisions of the third country concerned. The requirements set out in Article 82 shall apply to the supply of medicinal products to persons in third countries authorised or entitled to supply medicinal products to the public.

21 Article 85b of the Directive reads, in extract:

1. Persons brokering medicinal products shall ensure that the brokered medicinal products are covered by a marketing authorisation granted pursuant to Regulation (EC) No 726/2004 or by the competent authorities of a Member State in accordance with this Directive.

Persons brokering medicinal products shall have a permanent address and contact details in the Union, so as to ensure accurate identification, location, communication and supervision of their activities by competent authorities.

The requirements set out in points (d) to (i) of Article 80 shall apply mutatis mutandis *to the brokering of medicinal products.*

2. Persons may only broker medicinal products if they are registered with the competent authority of the Member State of their permanent address referred to in paragraph 1. Those persons shall submit, at least, their name, corporate name and permanent address in order to register. They shall notify the competent authority of any changes thereof without unnecessary delay.

Persons brokering medicinal products who had commenced their activity before 2 January 2013 shall register with the competent authority by 2 March 2013.

The competent authority shall enter the information referred to in the first subparagraph in a register that shall be publicly accessible.

…

22 Article 85c of the Directive reads, in extract:

> *1. Without prejudice to national legislation prohibiting the offer for sale at a distance of prescription medicinal products to the public by means of information society services, Member States shall ensure that medicinal products are offered for sale at a distance to the public by means of information society services as defined in Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services under the following conditions:*
>
> > *(a) the natural or legal person offering the medicinal products is authorised or entitled to supply medicinal products to the public, also at a distance, in accordance with national legislation of the Member State in which that person is established;*
>
> …

23 Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products (OJ 2011 L 174, p. 74) ("Directive 2011/62") was incorporated into the EEA Agreement by Decision of the EEA Joint Committee No 159/2013 of 8 October 2013 (OJ 2014 L 58, p. 12), adding it to point 15q of Chapter XIII of Annex II to the EEA Agreement. Constitutional requirements were indicated and fulfilled by Liechtenstein and Norway in April 2014 and the decision entered into force on 1 June 2014.

24 Recital 6 of Directive 2011/62 reads:

> *Persons procuring, holding, storing, supplying or exporting medicinal products are only entitled to pursue their activities if they meet the requirements for obtaining a wholesale distribution authorisation in accordance with Directive 2001/83/EC. However, today's distribution network for medicinal products is increasingly complex and involves many players who are not necessarily wholesale distributors as referred to in that Directive. In order to ensure the reliability of the supply chain, legislation in relation to medicinal products should address all actors in the supply chain. This includes not only wholesale distributors, whether or not they physically handle the medicinal products, but also brokers who are involved in the sale or purchase of medicinal products without selling or purchasing those products themselves, and without owning and physically handling the medicinal products.*

25 Recital 15 of Directive 2011/62 reads:

The provisions applicable to the export of medicinal products from the Union and those applicable to the introduction of medicinal products into the Union with the sole purpose of exporting them need to be clarified. Under Directive 2001/83/EC a person exporting medicinal products is a wholesale distributor. The provisions applicable to wholesale distributors as well as good distribution practices should apply to all those activities whenever they are performed on Union territory, including in areas such as free trade zones or free warehouses.

National law

26 The Act of 18 December 1997 on the marketing of medicinal products and the handling of human tissues and cells in the EEA (*Gesetz vom 18. Dezember 1997 über den Verkehr mit Arzneimitteln sowie den Umgang mit menschlichen Geweben und Zellen im Europäischen Wirtschaftsraum*; LR 812.103) ("Liechtenstein EEA Medicinal Products Act") regulates the marketing of medicinal products and the handling of human tissues and cells in the European Economic Area.

27 Article 4 of the Liechtenstein EEA Medicinal Products Act reads, in extract:

(1) For the purposes of this Act, the following definitions apply:

(a) 'medicinal product' means medicinal products for human and veterinary use in accordance with the provisions of Directives 2001/83/EC and 2001/82/EC. ...

...

28 Article 8 of the Liechtenstein EEA Medicinal Products Act reads:

Medicinal products may be placed on the market provided that this complies with the provisions of this Act. Medicinal products may be placed on the market only by persons or undertakings holding an authorisation to do so.

29 Article 30(2) of the Liechtenstein EEA Medicinal Products Act reads:

The manufacture of medicinal products requires an authorisation from the Office for Public Health (manufacturing authorisation).

30 Article 35 of the Liechtenstein EEA Medicinal Products Act reads:

(1) The wholesale trade in medicinal products includes any activity that involves the procurement, storage, delivery, advertisement, or transfer, whether for a fee or free of charge, or the export of ready-to-use medicinal products and active substances, with the exception of the distribution of medicinal products to the public.

(2) The wholesale trade in medicinal products requires an authorisation from the Office for Public Health (wholesale authorisation). The Office for Public Health shall record the information on the wholesale authorisation in the database of the European Medicines Agency.

(3) Any wholesaler who is not the holder of the marketing authorisation and imports a medicinal product from another EEA State shall notify the holder of the marketing authorisation and the Office for Public Health of this intention. In the case of medicinal products for which an authorisation has been granted in accordance with Regulation (EC) No 726/2004, notification to the holder of the marketing authorisation and the European Medicines Agency shall be made by the distributor.

(4) Chapter III of the Act on the Provision of Services does not apply to the wholesale trade in medicinal products.

(5) The details shall be governed by the provisions of Directives 2001/83/EC and 2001/82/EC.

31 Article 38 of the Liechtenstein EEA Medicinal Products Act reads:

(1) The commercial trade in medicinal products carried out from Liechtenstein within the EEA or between an EEA State and a third country, without these medicinal products coming into contact with the territory of Liechtenstein, requires an authorisation from the Office for Public Health.

(2) The authorisation shall be issued where:

(a) the applicant fulfils the requirements for wholesalers; and

(b) the trading transactions are, subject to the mutatis mutandis application of the provisions on storage, carried out in conformity with the provisions of Directives 2001/83/EC and 2001/82/EC as well as in conformity with the principles and guidelines for good distribution practice.

(3) This is without prejudice to special provisions for blood and blood components.

32 Article 38a of the Liechtenstein EEA Medicinal Products Act, headed “Brokering”, reads:

(1) Persons brokering medicinal products must be registered with the Office for Public Health. In order to be registered the person must provide at least their name, company name and permanent address. The person must notify the Office for Public Health immediately of any change to this information.

(2) The Office for Public Health shall record persons brokering medicinal products with the information specified in paragraph 1 in a publicly accessible register and monitor their activities.

(3) Persons brokering medicinal products shall ensure that the medicinal products brokered are covered by a marketing authorisation granted in accordance with Regulation (EC) No 726/2004 or by the competent authorities of an EEA State in accordance with Directive 2001/83/EC.

(4) Persons brokering medicinal products must comply mutatis mutandis with the requirements of Article 37(1)(e) to (i).

(5) If a person brokering medicinal products does not fulfil the requirements of this Article, the Office for Public Health shall remove that person from the register referred to in paragraph 2. The Office for Public Health shall inform the person accordingly.

(6) The details shall be governed by the provisions of Directive 2001/83/EC.

33 Article 47 of the Liechtenstein EEA Medicinal Products Act reads, in extract:

(1) Unless a misdemeanour or criminal offence punishable with a greater penalty is present, the Princely Court shall impose for a misdemeanour a custodial sentence for a period not exceeding six months or a fine not exceeding 360 daily units on whosoever:

(a) contrary to the provisions of this Act, without licence or authorisation, manufactures, procures, tests, dispenses, imports, exports, stores, brokers, advertises, offers or dispenses in distance selling, medicinal products or human tissues or cells, or trades in them abroad;

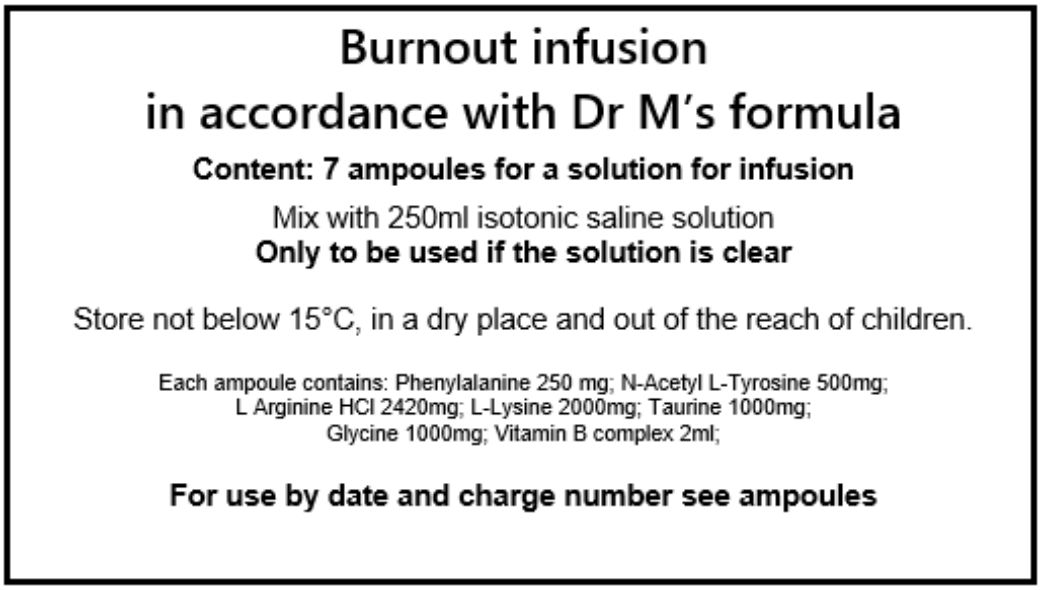
…

II Facts and procedure

34 M, a graduate in medicine, has been practising as a doctor for 30 years. M operates a medical practice in Austria.

35 X AG is a legal person with its seat in Liechtenstein whose corporate purpose is, inter alia, trade in food supplements and goods of all kinds. M is the only board member and managing director of X AG and no other persons are employed by X AG.

36 Between 2015 and 2016, X AG began trading in a product referred to as a “burnout infusion”. The boxes containing the product “burnout infusion” each bore a label, which read as follows:



37 The ampoules of the "burnout infusion" (see the label above) are administered intravenously together with a saline solution. The infusions were manufactured by a pharmacy in Germany, in accordance with M's formula. The pharmacy invoiced X AG for the ampoules and supplied these to M's practice in Austria, where M administered these to his patients intravenously, or supplied them directly to patients in Germany, Austria and Switzerland under the name of X AG.

38 Between 23 January 2015 to 23 December 2016, X AG sent the "burnout infusion" manufactured by the pharmacy under the name "Neurostress" to customers in Germany, Austria and Switzerland and, in particular, more than 465 products to 66 customers and 250 products to M's practice in Austria. The payments from customers/patients were made in each case to an account X AG held with a Liechtenstein bank. The products were described as a "burnout infusion" because they are intended to strengthen the natural immune system and make people more resistant to stress, and to combat the causes of depression.

39 M went twice to the Office for Economic Affairs (*Amt für Volkswirtschaft*). On one occasion he had a box of burnout infusions with him. M enquired there whether the triangular transaction he was considering, where the ampoules would be manufactured by a pharmacy in Germany, invoiced to X AG and supplied to M in Austria or directly to patients elsewhere would be legal. M was informed by the director of the Office for Economic Affairs that provided that the trade concerns only Austria and Germany, Liechtenstein is not affected. According to the official, only the national legislative provisions in Austria or the country in which the products are delivered have to be observed. The invoicing of the ampoules produced in Germany to the address of X AG in Liechtenstein was done for tax reasons.

40 On 27 October 2015, the Office for Public Health (*Amt für Gesundheit*) requested X AG to provide a statement, as the Office for Public Health presumed that the manufacture of the "burnout infusion" required an authorisation. By an email of 4

November 2015, M informed the Office for Public Health that the product referred to as a "burnout infusion" is not subject to the Liechtenstein EEA Medicinal Products Act as it is not a medicine but simply essential nutrients in the sense of a food supplement which are applied intravenously.

41 In 2015, criminal proceedings were brought before the Princely Court (*Fürstliches Landgericht*) against M and X AG on account of a suspicion pursuant to point (b) of Article 86(1) and point (f) of Article 87(1) of the Swiss Therapeutic Products Act (*Schweizer Heilmittelgesetz*) and points (a) and (f) of Article 47(1) of the Liechtenstein EEA Medicinal Products Act. The proceedings were discontinued by the Public Prosecutor's Office.

42 In 2019, in further criminal proceedings, M and X AG were found guilty and sentenced at first instance by the Princely Court for the misdemeanour of trading in medicinal products abroad without the requisite authorisation pursuant to point (a) of Article 47(1) in conjunction with Article 38 of the Liechtenstein EEA Medicinal Products Act.

43 M and X AG appealed against that judgment to the Princely Court of Appeal, which decided to make a reference to the Court. The request, dated 2 June 2020, was registered at the Court on 10 June 2020. The Princely Court of Appeal has referred the following questions to the Court:

> *1. Must burnout infusions with the combination of substances determined here be qualified as "medicinal products" within the meaning of Article 1(2) of Directive 2001/83/EC?*
>
> *a. If the answer to this question is in the affirmative: Does in the present case the manufacture, supply and administration of the burnout infusion constitute a placing on the market within the meaning of Article 2(1) of the Directive?*
>
> *b. If the preceding questions are answered in the affirmative: Do the burnout infusions constitute medicinal products which, within the meaning of Article 2(1) of the Directive, are prepared industrially or manufactured by a method involving an industrial process?*
>
> *c. Are the burnout infusions due to the method of their manufacture covered by the exception provided for in Article 3(2) of the Directive?*
>
> *2. What must be understood under "wholesale distribution" within the meaning of Directive 2001/83/EC as amended by Directive 2011/62/EU and what criteria must be fulfilled for this?*
>
> *3. In the event that the above Directives are, in principle, applicable to the present case:*
>
> *Is it compatible with the freedom of establishment pursuant to Article 31 et seq. EEA and, moreover, must it be regarded as*

proportionate, if commercial trading in medicinal products of the kind in question carried out from the State of residence of a natural or legal person within the EEA or between an EEA State and a third country, without these medicinal products coming in contact with the territory of the State of residence, is subjected to a statutory authorisation obligation, whose infringement may be penalised as a misdemeanour by a custodial sentence of up to six months?

4. *Does it have an influence on the answer to the above questions if in another EEA State (here: EU Member Germany) the medicinal products in question do not require authorisation?*

44 On 25 November 2020, measures of organization of procedure were issued pursuant to Article 49(1) of the Rules of Procedure ("RoP"), and in accordance with Article 49(3)(b) and (c) RoP. Those participating in the proceedings were requested to answer the Court's questions in writing by 4 December 2020. The Court received responses from ESA on 3 December 2020 and from M and X AG, the Liechtenstein Government and Ireland on 4 December 2020.

45 Reference is made to the Report for the Hearing for a fuller account of the legal framework, the facts, the procedure and the proposed answers submitted to the Court. Arguments of the parties are mentioned or discussed hereinafter only insofar as is necessary for the reasoning of the Court.

III Answer of the Court

Question 1

46 By its first question, the referring court asks in essence whether a product, such as that at issue in the main proceedings, may be qualified as a "medicinal product" within the meaning of point 2 of Article 1 of the Directive.

47 Point 2 of Article 1 of the Directive gives two different definitions of the term "medicinal product". First, point 2(a) of Article 1 provides that "any substance or combination of substances presented as having properties for treating or preventing disease in human beings" is a medicinal product. Second, according to point 2(b) of Article 1 "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" constitutes a medicinal product. It is settled case law that a product is a medicinal product if it falls within either of those two definitions (compare the judgment in *D and G*, C-358/13 and C-181/14, EU:C:2014:2060, paragraphs 27 and 28). Accordingly, medicinal products may be classified into two categories: medicinal products by presentation, or medicinal products by function.

48 While those two provisions of the Directive are separated by the word "or", they cannot be regarded as unconnected with each other and must, therefore, be read conjunctively. That presupposes that the various elements of those provisions cannot be read in such a way as to render one element in conflict with another (compare the judgment in *D and G*, cited above, paragraph 29).

49 A product is "presented for treating or preventing disease" when it is expressly "indicated" or "recommended" as such, by means of labels, leaflets or oral representation. The criterion of the "presentation" of the product must be interpreted broadly. It is intended to cover not only medicinal products having a genuine therapeutic or medical effect, but also those which are not sufficiently effective or do not have the effect which consumers would be entitled to expect from the way in which they are presented. The Directive thereby intends to protect the consumers not only from harmful or toxic medicinal products, but also from a variety of products used instead of the proper remedies (compare the judgment in *Commission* v *Germany*, C-319/05, EU:C:2007:678, paragraphs 43 and 44 and case law cited).

50 Furthermore, a product is also "presented for treating or preventing disease" whenever any averagely well-informed consumer gains the impression that the product in question should, having regard to its presentation, have the properties in question. This impression may even result from implication, provided it is definite (compare the judgment in *Commission* v *Germany*, cited above, paragraph 46).

51 In that regard, account must be taken of the attitude of an averagely well-informed consumer, in whom the form given to a product may inspire particular confidence similar to that normally inspired in him by proprietary medicinal products, having regard to the safeguards normally associated with their manufacture and marketing. Although the external form given to the product may serve as strong evidence of its classification as a medicinal product by presentation, the "form" must be taken to mean not only the form of the product itself but also that of its packaging, which may, for reasons of marketing policy, tend to make it resemble a medicinal product (compare the judgment in *Commission* v *Germany*, cited above, paragraph 47). However, the external form given to a product, although it may serve as strong evidence of the seller's or manufacturer's intention to market that product as a medicinal product, cannot be the sole or conclusive evidence, since otherwise certain food products which are traditionally presented in a similar form to medicinal products would also be covered (compare the judgment in *Commission* v *Germany*, cited above, paragraph 52 and case law cited).

52 The definition of medicinal product by function is intended to cover products whose pharmacological properties have been scientifically observed and which are genuinely designed to make a medical diagnosis or to restore, correct or modify physiological functions (compare the judgment in *Commission* v *Germany*, cited above, paragraph 61).

53 In accordance with established case law, whether a product falls within the definition of medicinal product by virtue of its function for the purposes of the Directive must be

determined by the national authorities on a case-by-case basis, acting under the supervision of the courts, taking account of all the characteristics of the product, in particular its composition, its pharmacological, immunological 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 (compare the judgment in *Laboratoires Lyocentre*, C-109/12, EU:C:2013:626, paragraph 42).

54 Products containing a substance having a physiological effect cannot automatically be classified as medicinal products by function unless the competent administration has made an assessment, with due diligence, of each product individually, taking account, in particular, of that product's specific pharmacological, immunological or metabolic properties, to the extent to which they can be established in the present state of scientific knowledge (compare the judgment in *Hecht-Pharma I*, C-140/07, EU:C:2009:5, paragraph 40).

55 Furthermore, according to Article 2(2) of the Directive, in cases of doubt where, taking into account all its characteristics, a product may fall within the definition of a "medicinal product" and also within the definition of a product covered by other EEA legislation, then the provisions of the Directive shall apply to that product.

56 It appears that the product at issue in the main proceedings is intended to alleviate the causes of depression, a well-established medical condition. According to the request, it is intended to be mixed with an isotonic saline solution and contains essential amino acids, taurine and a vitamin B complex. This solution is then administered intravenously, and is presented as being in accordance with a medical practitioner's formula. A product may be regarded as a medicinal product by virtue of its presentation if its form and the manner in which it is packaged render it sufficiently similar to a medicinal product and, in particular, if on its packing and the information provided with it reference is made to substances developed by medical practitioners (compare the judgment in *Delattre*, C-369/88, EU:C:1991:137, paragraph 41). Accordingly, the Court finds that a product, such as that at issue in the main proceedings, which is intended to be administered intravenously, presented as being in accordance with the formula of a medical practitioner and as alleviating the symptoms of diseases in human beings, constitutes a medicinal product within the meaning of point 2 of Article 1 of the Directive.

57 In the light of the foregoing, the answer to Question 1 must be that the determination of whether a product falls within the definition of a medicinal product in point 2 of Article 1 of the Directive must be made on a case-by-case basis taking into account the factors set out in that provision, such as the product's presentation or pharmacological, immunological or metabolic properties. A product, such as that at issue in the main proceedings, which is intended to be administered intravenously, presented as being in accordance with the formula of a medical practitioner and as alleviating the symptoms of diseases in human beings, constitutes a medicinal product within the meaning of point 2 of Article 1.

Question 1(a)

58 By Question 1(a), the referring court asks in essence whether the manufacture, supply and administration of a medicinal product, in circumstances such as those of the main proceedings, constitutes a placing on the market within the meaning of Article 2(1) of the Directive.

59 Article 2(1) of the Directive makes a positive determination of the scope of that directive, by providing that it is to apply to medicinal products for human use intended to be placed on the market in EEA States and either prepared industrially or manufactured by a method involving an industrial process, while Article 3 provides for certain exceptions to its scope. It follows that, in order to come within the scope of the Directive, the product in question, first, must satisfy the conditions laid down in Article 2(1), and, second, must not come within one of the exceptions expressly provided for in Article 3 (compare the judgment in *Hecht-Pharma II*, C-276/15, EU:C:2016:801, paragraph 29).

60 According to Article 2(1) of the Directive, the Directive shall apply to medicinal products for human use "intended to be placed on the market" in EEA States. While the Directive does not further define what constitutes a "placing on the market", this condition is a fundamental prerequisite for the Directive's application pursuant to Article 2(1). Accordingly, only a broad interpretation is capable of being consistent with the fundamental objective of the Directive, which is to safeguard public health, as is also noted in recital 2.

61 According to the request, the product at issue in the main proceedings was manufactured by a pharmacy in Germany prior to being supplied to M's practice in Austria, where M, as a medical practitioner, administered it to certain patients. The product at issue was also directly supplied by the pharmacy on behalf of X AG to patients and customers in Austria, Germany and Switzerland. In circumstances where a product has been sold wholesale and retail to customers in EEA States, such as in the main proceedings, it must be held that it was "intended to be placed on the market" for the purposes of the Directive.

62 Accordingly, the answer to Question 1(a) must be that in circumstances, such as those of the main proceedings, where a medicinal product has been sold at the wholesale and/or retail level in EEA States, it must be considered as having been intended to be placed on the market in EEA States for the purposes of the Directive.

Question 1(b)

63 By Question 1(b), the referring court asks in essence if a product, such as that at issue in the main proceedings, may be considered as being prepared industrially or manufactured by a method involving an industrial process within the meaning of Article 2(1) of the Directive.

64 Pursuant to Article 2(1), the Directive is applicable only if the medicinal products are "prepared industrially" or "manufactured by a method involving an industrial process". Having regard to the Directive's objective to safeguard public health as set out in recital 2, those terms cannot be interpreted narrowly and must be understood as to include any preparation or manufacture involving an industrial process. Such a process is characterised, in general, by a succession of operations, which may be mechanical or chemical, in order to obtain a significant quantity of a standardised product (compare the judgment in *Abcur*, C-544/13 and C-545/13, EU:C:2015:481, paragraph 50). The standardised production of significant quantities of a medicinal product to be stocked and sold wholesale and the large-scale or serial production of magistral formulae in batches are characteristic of industrial preparation or manufacture by a method involving an industrial process. In this regard, an industrial process differs from an artisanal process in the means of production used and, consequently, in the quantities produced (compare the judgment in *Hecht-Pharma II*, cited above, paragraphs 32 and 33).

65 The Court of Justice of the European Union found in *Hecht-Pharma II* that, in light of the regulatory conditions of the EEA State concerned in that case, which limited the maximum authorised production of officinal formulae to 100 packages per day, that limit precluded the view being taken that the production of officinal formulae reached a sufficient scale to be considered significant and to come within the concept of an "industrial process" within the meaning of Article 2(1) of the Directive (compare the judgment in *Hecht-Pharma II*, cited above, paragraph 34). The Court notes that while the quantity of the product may be a relevant factor in this regard, the possibility that a relatively small quantity of a medicinal product is produced does not necessarily exclude that product from the scope of Article 2(1).

66 As argued by the Commission, a low level of daily production may result in the manufacture of a substantial quantity of medicinal products over the course of a year. To place such quantities on the market in EEA States without applying the provisions of the Directive would result in the circulation of significant amounts of medicinal products without a marketing authorisation under the Directive, and hence undermine the Directive's purpose.

67 Having regard to the foregoing, the Court finds that the answer to Question 1(b) must be that a medicinal product is prepared industrially or manufactured by a method involving an industrial process if its preparation or manufacture involves an industrial process characterised, in general, by a succession of operations, which may be mechanical or chemical, in order to obtain a significant quantity of a standardised product.

Question 1(c)

68 By Question 1(c), the referring court enquires whether, due to its method of manufacture, the product at issue in the main proceedings is covered by the exception contained in Article 3(2) of the Directive.

69 Pursuant to Article 3(2), the Directive does not apply to any medicinal product which is prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and is intended to be supplied directly to the patients served by the pharmacy in question (commonly known as the officinal formula). Accordingly, in order to benefit from that exception a medicinal product must be prepared "in a pharmacy", "in accordance with the prescriptions of a pharmacopoeia" and "intended to be supplied directly to the patients served by the pharmacy in question". These conditions are cumulative so that the exception provided for in Article 3(2) cannot be applied if one of them is not satisfied (compare the judgment in *Abcur*, cited above, paragraph 66).

70 According to the request, the product at issue in the main proceedings was manufactured in Germany by a pharmacy, in accordance with M's formula, and directly supplied to M's practice, where it was administered to patients by M, and to customers or patients in Germany, Austria and Switzerland.

71 While it is for the referring court to ascertain, in the light of the facts of the main proceedings, whether the conditions of Article 3(2) of the Directive are fulfilled, it appears that two of the conditions are not satisfied as the product at issue in the main proceedings does not appear to have been prepared in accordance with the prescriptions of a pharmacopoeia and was not intended to be supplied directly to patients served by the pharmacy in question (compare the judgment in *Abcur*, cited above, paragraph 70).

72 In light of the foregoing, the Court finds that the answer to Question 1(c) must be that a medicinal product that has not been prepared in accordance with the prescriptions of a pharmacopoeia or is not intended to be supplied directly to the patients served by the pharmacy in question cannot benefit from the exception contained in Article 3(2) of the Directive.

Question 2

73 By its second question, the referring court asks in essence what criteria must be fulfilled in order for an activity to constitute "wholesale distribution" within the meaning of the Directive.

74 Point 17 of Article 1 of the Directive defines "wholesale distribution of medicinal products" as all activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public. It is further provided by that definition that such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorised or entitled to supply medicinal products to the public in the EEA State concerned.

75 It follows from the request that the product at issue in the main proceedings was manufactured by a pharmacy in accordance with M's formula while X AG was invoiced for the manufacture of the product. It is further stated in the request that X AG had the product at issue sent to a number of customers or patients in Germany, Austria and Switzerland and to M's practice. As pointed out by Ireland, in such circumstances, a

medicinal product must be considered to have been procured, supplied and exported for the purposes of the definition in point 17 of Article 1 of the Directive, to the extent that it did not constitute supply of medicinal products to the public, which is specifically excluded from the scope of that definition.

76 The fact that a wholesale distributor does not physically handle a medicinal product, does not prevent the qualification of an activity as wholesale distribution, as is noted in recital 6 of Directive 2011/62.

77 M and X AG have argued that the activity of X AG did not constitute wholesale distribution but rather retail supply. However, even if the activity at issue in the main proceedings may also comprise the retail supply of medicinal products, that cannot be decisive. While the definition of wholesale distribution does not cover supplying medicinal products to the public, a wholesale distributor may engage in both wholesale distribution as well as supplying medicinal products to the public, as envisaged by Article 77(2) of the Directive. In such circumstances, the activities constituting wholesale distribution will still come within the scope of point 17 of Article 1 and the obligation to possess a special authorisation pursuant to Article 77(1) will apply (compare the judgment in *Caronna*, C-7/11, EU:C:2012:396, paragraphs 28 and 29).

78 The issue of the retail supply of a medicinal product itself falls outside the scope of the questions referred. Nevertheless, it should be noted that the conditions applicable to the supply of medicinal products to the public are not harmonised under EEA law. Consequently, the regime applicable to persons entrusted with the retail supply of medicinal products varies from one EEA State to another (compare the judgment in *Caronna*, cited above, paragraph 43). However, the Court notes that point (a) of Article 85c of the Directive provides that EEA States shall ensure that medicinal products are offered for sale at a distance to the public by means of information society services under the condition that the natural or legal person offering the medicinal products is authorised or entitled to supply medicinal products to the public, also at a distance, in accordance with national legislation of the EEA State in which that person is established.

79 Finally, it follows from the wording of point 17 of Article 1 of the Directive that exporting medicinal products is an activity that constitutes wholesale distribution of medicinal products, as is also stated in recital 15 of Directive 2011/62. As is made further evident by that recital, export in the definition of "wholesale distribution of medicinal products" refers, in particular, to the export of medicinal products from the EEA. In that regard, it must be noted that Article 85a of the Directive specifically provides that where wholesale distributors supply medicinal products to persons in third countries, they shall ensure that such supplies are only made to persons who are authorised or entitled to receive medicinal products for wholesale distribution or supply to the public in accordance with the applicable legal and administrative provisions of the third country concerned.

80 In their written observations and during the hearing, ESA and the Commission raised the issue of whether the activities at issue in the main proceedings may be characterised

instead as the "brokering of medicinal products" within the meaning of point 17a of Article 1 of the Directive.

81 That provision defines "brokering of medicinal products" as all activities in relation to the sale or purchase of medicinal products, except for wholesale distribution, that do not include physical handling and that consist of negotiating independently and on behalf of another legal or natural person. Recital 6 of Directive 2011/62, which introduced that definition into the Directive, refers to brokers who are involved in the sale or purchase of medicinal products without selling or purchasing those products themselves and without owning and physically handling the medicinal products.

82 The definition in point 17a of Article 1 of the Directive explicitly excludes "wholesale distribution" from its scope. Accordingly, procuring, supplying and exporting that comes within the scope of the definition of point 17 of Article 1 cannot, by definition, come within the scope of "brokering of medicinal products". This is further made clear by the fact that pursuant to Article 85b(1) only the requirements set out in points (d) to (i) of Article 80 apply *mutatis mutandis* to the brokering of medicinal products. Thus, brokers are exempt from the requirements of points (b) and (c) of Article 80 which prescribe that supplies of medicinal products must be obtained only from persons who are themselves in possession of a distribution authorisation or who are exempt from obtaining such authorisation under the terms of Article 77(3) and that the medicinal products must be supplied only to persons who are themselves in possession of a distribution authorisation or who are authorised or entitled to supply medicinal products to the public in the EEA State concerned.

83 Recital 35 of the Directive refers to the necessity of exercising control over the entire chain of distribution of medicinal products, from their manufacture or import into the EEA through to supply to the public, so as to guarantee that such products are stored, transported and handled in suitable conditions (compare the judgment in *Abcur*, cited above, paragraph 49). This objective would be defeated if brokers were able to obtain and supply medicinal products without being subject to the requirements of points (b) and (c) of Article 80.

84 In the light of the foregoing, the answer to the second question must be that the activity of procuring, supplying, and exporting medicinal products, apart from supplying medicinal products to the public, constitutes wholesale distribution of medicinal products within the meaning of point 17 of Article 1 of the Directive even if a wholesale distributor has not physically handled those products.

Question 3

85 By its third question, the referring court asks in essence, in the event that the Directive is applicable, whether it is compatible with Article 31 EEA if commercial trading in medicinal products, such as that at issue in the main proceedings, carried out from the State where the trader is established within the EEA or between an EEA State and a third country, without these medicinal products coming in contact with the territory of the State of establishment, is subjected to a statutory authorisation obligation, whose

infringement may be penalised as a misdemeanour by a custodial sentence of up to six months.

86 Although the referring court has limited its question to the interpretation of Article 31 EEA, it is incumbent on the Court to give as complete and as useful a reply as possible and it does not preclude the Court from providing the national court with all the elements of the interpretation of EEA law which may be of assistance in adjudicating the case before it, whether or not reference is made thereto in the question referred (see Case E-4/19 *Campbell*, judgment of 13 May 2020, paragraph 45).

87 Persons procuring, holding, storing, supplying or exporting medicinal products are only entitled to pursue their activities if they meet the requirements for obtaining a wholesale distribution authorisation in accordance with the Directive, as is also stated in recital 6 of Directive 2011/62. As noted in recital 15 of that directive, the provisions of the Directive applicable to wholesale distributors apply to all those activities whenever they are performed on the territory of the EEA.

88 The minimum requirements to be satisfied by applicants for and holders of authorisation for the wholesale distribution of medicinal products are harmonised by the Directive, in particular in Articles 79 to 82 (compare the judgment in *Caronna*, cited above, paragraph 44). Thus, except for the situations identified in Article 83 of the Directive, which allows EEA States to apply more stringent requirements in respect of the wholesale distribution of certain categories of medicinal products, the requirements for wholesale distribution of medicinal products are exhaustively harmonised under the Directive. In accordance with well-established case law, where a situation has been the subject of exhaustive harmonisation at EEA level, any national measure relating thereto must be assessed in the light of the provisions of the harmonising measure and not those of the main provisions of the EEA Agreement, such as Article 31 EEA (see Case E-9/11 *ESA* v *Norway* [2012] EFTA Ct. Rep. 442, paragraph 72).

89 Title VII of the Directive on wholesale distribution and brokering of medicinal products places certain obligations on wholesale distributors and brokers of medicinal products. These obligations differ in their extent based on whether the activity at issue constitutes wholesale distribution or brokering. Thus, the compatibility of a measure such as that at issue in the main proceedings with the Directive may differ depending on whether the activity being regulated by the measure constitutes wholesale distribution or brokering of medicinal products.

90 Article 77(1) of the Directive provides that EEA States shall take all appropriate measures to ensure that the wholesale distribution of medicinal products is subject to the possession of an authorisation to engage in activity as a wholesaler in medicinal products. Recital 36 emphasises that any person involved in the wholesale distribution of medicinal products should be in possession of a special authorisation. As explained in recital 35, the need for such authorisation follows from the necessity to exercise control over the entire chain of distribution of medicinal products, from their manufacture or import into the EEA through to supply to the public, so as to guarantee that such products are stored, transported and handled in suitable conditions. The

requirements which must be adopted for this purpose are intended to considerably facilitate the withdrawal of defective products from the market and allow more effective efforts against counterfeit products. Recital 37 further states that authorisation must be subject to certain essential conditions and it is the responsibility of the EEA State concerned to ensure that such conditions are met, whereas each EEA State must recognise authorisations granted by other EEA States.

91 In order to ensure that the Directive's objectives are achieved, in particular those relating to the protection of public health, the removal of barriers to trade in medicinal products within the EEA and the need to exercise control over the entire chain of distribution of medicinal products, the minimum requirements for wholesale distribution of medicinal products must be fulfilled in a uniform and effective manner by all persons who engage in that activity in all EEA States (compare the judgment in *Caronna*, cited above, paragraph 48).

92 Accordingly, a national measure such as that described in the third question which requires authorisation, to the extent that the activity in question constitutes "wholesale distribution of medicinal products" within the meaning of point 17 of Article 1 of the Directive, is compatible with the Directive. In addition, Article 118a of the Directive provides that EEA States shall lay down rules on penalties applicable to infringements of national provisions adopted pursuant to the Directive and shall take all necessary measures to ensure that those penalties are implemented. The penalties must be effective, proportionate and dissuasive.

93 As noted in the Court's answer to the second question, the provisions of the Directive regulating wholesale distribution are aimed at wholesale distributors whether or not they physically handle the medicinal products, as set out in recital 6 of Directive 2011/62. Thus, the fact that a wholesale distributor does not physically handle medicinal products in its EEA State of establishment does not preclude the qualification of an activity as wholesale distribution subject to authorisation under Article 77(1) of the Directive. As noted in recital 15 of Directive 2011/62, the provisions applicable to wholesale distributors should apply to all those activities whenever they are performed on the territory of the EEA States.

94 In the light of the foregoing, the answer to the third question must be that a national measure subjecting an activity constituting "wholesale distribution of medicinal products" within the meaning of point 17 of Article 1 of the Directive to an authorisation requirement in conformity with Article 77(1) is compatible with EEA law.

Question 4

95 By its fourth question, the referring court enquires whether it has an influence on the answer to the previous questions if another EEA State, and the referring court refers to Germany in this regard, does not require authorisation for the medicinal product in question.

96 It has been disputed by the various parties submitting observations to the Court whether the product at issue in the main proceedings, which is intended to be administered intravenously and, according to the request, was sold to customers or patients in Germany, Austria and Switzerland, is considered to be a medicinal product in the EEA States Austria or Germany requiring a marketing authorisation pursuant to Article 6(1) of the Directive.

97 As EEA law currently stands, it is still possible that differences will continue to exist between EEA States in the classification of a product as a medicinal product or another product. Thus, the fact that a product is not classified as a medicinal product in one EEA State cannot prevent it from being classified as a medicinal product in another EEA State, if it displays the characteristics of such a product (compare the judgment in *HLH Warenvertrieb*, joined cases C-211/03, C-299/03 and C-316/03 to C-318/03, EU:C:2005:370, paragraph 56). Asymmetries in scientific information, new scientific developments and differing assessments of risk to human health and the desired level of protection can explain why different decisions are taken by the competent authorities of two EEA States as regards the classification of a product (compare the judgment in *Laboratoires Lyocentre*, cited above, paragraph 46).

98 Accordingly, the fact that a product, such as the product at issue in the main proceedings, is not categorised as a medicinal product in one EEA State does not have an influence on whether another EEA State may classify it as a medicinal product in accordance with the Directive.

99 In the light of the foregoing, the answer to the fourth question must be that the fact that a product is not classified in one EEA State as a medicinal product does not have an influence on whether the competent authorities of another EEA State may classify it as a medicinal product in accordance with the Directive.

IV Costs

100 The costs incurred by Ireland, ESA, and the Commission, which have submitted observations to the Court, are not recoverable. Since these proceedings are a step in the proceedings pending before the national court, any decision on costs for the parties to those proceedings is a matter for that court.

On those grounds,

THE COURT

in answer to the questions referred to it by the Princely Court of Appeal hereby gives the following Advisory Opinion:

1. **The determination of whether a product falls within the definition of a medicinal product in point 2 of 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 must be decided on a case-by-case basis taking into account the factors set out in that provision, such as the product's presentation or pharmacological, immunological or metabolic properties.**

   A product, such as that at issue in the main proceedings, which is intended to be administered intravenously, presented as being in accordance with the formula of a medical practitioner and as alleviating the symptoms of diseases in human beings, constitutes a medicinal product within the meaning of point 2 of Article 1.

2. **In circumstances, such as those of the main proceedings, where a medicinal product has been sold at the wholesale and/or retail level in EEA States, it must be considered as having been intended to be placed on the market in EEA States for the purposes of Directive 2001/83/EC.**

3. **A medicinal product is prepared industrially or manufactured by a method involving an industrial process if its preparation or manufacture involves an industrial process characterised, in general, by a succession of operations, which may be mechanical or chemical, in order to obtain a significant quantity of a standardised product.**

4. **A medicinal product that has not been prepared in accordance with the prescriptions of a pharmacopoeia or is not intended to be supplied directly to the patients served by the pharmacy in question cannot benefit from the exception contained in Article 3(2) of Directive 2001/83/EC.**

5. **The activity of procuring, supplying and exporting medicinal products, apart from supplying medicinal products to the public, constitutes wholesale distribution of medicinal products within the meaning of point 17 of Article 1 of Directive 2001/83/EC even if a wholesale distributor has not physically handled those products.**

6. **A national measure subjecting an activity constituting "wholesale distribution of medicinal products" within the meaning of point 17 of Article 1 of Directive 2001/83/EC to an authorisation requirement in conformity with Article 77(1) of that directive is compatible with EEA law.**

7. **The fact that a product is not classified in one EEA State as a medicinal product does not have an influence on whether the competent authorities of another EEA State may classify it as a medicinal product in accordance with Directive 2001/83/EC.**

Páll Hreinsson Per Christiansen Bernd Hammermann

Delivered in open court in Luxembourg on 15 July 2021.

Ólafur Jóhannes Einarsson
Registrar

Páll Hreinsson
President