REPORT FOR THE HEARING

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.

I Introduction

1. By a letter of 2 June 2020, registered at the Court on 10 June 2020, the Princely Court of Appeal (*Fürstliches Obergericht*) made a request for an Advisory Opinion ("Request") in a case pending before it concerning an appeal in criminal proceedings against M and X AG.

2. The case before the Princely Court of Appeal concerns the manufacture of "burnout infusions" in accordance with the formula of M by a pharmacy in Germany, their subsequent sale and distribution to M's practice in Austria or directly to patients in Germany, Austria and Switzerland under the name of and invoiced to X AG. M and X AG were found guilty and sentenced at first instance 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.

II Legal background

EEA law

3. 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.

4. Article 32 EEA reads:

The provisions of this Chapter shall not apply, so far as any given Contracting Party is concerned, to activities which in that Contracting Party are connected, even occasionally, with the exercise of official authority.

5. Article 33 EEA reads:

The provisions of this Chapter and measures taken in pursuance thereof shall not prejudice the applicability of provisions laid down by law, regulation or administrative action providing for special treatment for foreign nationals on grounds of public policy, public security or public health.

6. Article 34 EEA reads:

Companies or firms formed in accordance with the law of an EC Member State or an EFTA State and having their registered office, central administration or principal place of business within the territory of the Contracting Parties shall, for the purposes of this Chapter, be treated in the same way as natural persons who are nationals of EC Member States or EFTA States.

'Companies or firms' means companies or firms constituted under civil or commercial law, including cooperative societies, and other legal persons governed by public or private law, save for those which are non-profit-making.

7. Article 35 EEA reads:

The provisions of Article 30 shall apply to the matters covered by this Chapter.

8. 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; "Directive 2001/83") was incorporated in 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.

9. Directive 2001/83 has been amended on numerous occasions, as well as corrected. At the material time, Directive 2001/83 had been amended by the following measures:

10. Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ 2003 L 33, p. 30) was incorporated in the EEA Agreement by Decision of the EEA Joint Committee No 99/2004 of 9 July 2004 (OJ 2004 L 376, p. 23), inserting it after point 15t of Chapter XIII of Annex II to the EEA Agreement. Constitutional requirements were indicated and fulfilled by Liechtenstein and Iceland by May 2005 and the decision entered into force on 1 July 2005.

11. Commission Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use (OJ 2003 L 159, p. 46) was incorporated in the EEA Agreement by Decision of the EEA Joint Committee No 3/2004 of 6 February 2004 (OJ 2004 L 116, p. 44), inserting it in point 15q of Chapter XIII of Annex II to the EEA Agreement. No constitutional requirements were indicated, and the decision entered into force on 7 February 2004.

12. Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ 2004 L 136, p. 85) was incorporated in the EEA Agreement by Decision of the EEA Joint Committee No 61/2009 of 29 May 2009 (OJ 2009 L 232, p. 13), inserting it in point 15q of Chapter XIII of Annex II to the EEA Agreement. Constitutional requirements were indicated and fulfilled by Liechtenstein and Norway by December 2009, and the decision entered into force on 23 December 2009.

13. Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ 2004 L 136, p. 34) was incorporated in the EEA Agreement by Decision of the EEA Joint Committee No 61/2009 of 29 May 2009 (OJ 2009 L 232, p. 13), inserting it in point 15q of Chapter XIII of Annex II to the EEA Agreement. Constitutional requirements were indicated and fulfilled by Liechtenstein and Norway by December 2009, and the decision entered into force on 23 December 2009.

14. Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ 2007 L 324, p. 121) was incorporated in the EEA Agreement by Decision of the EEA Joint Committee No 47/2012 of 30 March 2012 (OJ 2012 L 207, p. 27), inserting it after point 15zl of Chapter XIII of Annex II to the EEA Agreement. No constitutional requirements were indicated, and the decision entered into force on 31 March 2012.

15. Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009 amending Directive 2001/82/EC and Directive 2001/83/EC, as regards variations to the terms of marketing authorisations for medicinal products (OJ 2009 L 168, p. 33) was incorporated in the EEA Agreement by Decision of the EEA Joint Committee No 72/2011 of 1 July 2011 (OJ 2011 L 262, p. 28), inserting it in point 15p of Chapter XIII of Annex II to the EEA Agreement. No constitutional requirements were indicated, and the decision entered into force on 2 July 2011.

16. Commission Directive 2009/120/EC of 14 September 2009 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use as regards advanced therapy medicinal products (OJ 2009 L 242, p. 3) was incorporated in the EEA Agreement by Decision of the EEA Joint Committee No 72/2011 of 1 July 2011 (OJ 2011 L 262, p. 28), inserting it in point 15q of Chapter XIII of Annex II to the EEA Agreement. No constitutional requirements were indicated, and the decision entered into force on 2 July 2011.

17. Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ 2010 L 348, p. 74) was incorporated in the EEA Agreement by Decision of the EEA Joint Committee No 158/2013 of 8 October 2013 (OJ 2014 L 58, p. 10), inserting it in point 15q of Chapter XIII of Annex II to the EEA Agreement. Constitutional requirements were indicated and fulfilled by Iceland and Liechtenstein by May 2014, and the decision entered into force on 28 May 2014.

18. 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 in 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.

19. Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance (OJ 2012 L 299, p. 1) was incorporated in the EEA Agreement by Decision of the EEA Joint Committee No 160/2013 of 8 October 2013 (OJ 2014 L 58, p. 13), inserting it in point

15q of Chapter XIII of Annex II to the EEA Agreement. Constitutional requirements were indicated and fulfilled by Liechtenstein by April 2014, and the decision entered into force on 1 June 2014.

20. Directive 2001/83 as amended will be referred to as "the Directive".

21. 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.*

22. 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.*

23. 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.*

24. Recital 30 of the Directive reads:

> *In this connection persons moving around within the Community have the right to carry a reasonable quantity of medicinal products lawfully obtained for their personal use. It must also be possible for a person established in one Member State to receive from another Member State a reasonable quantity of medicinal products intended for his personal use.*

25. 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.*

26. 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.

27. Article 1(2) of the Directive reads:

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.

28. Article 1(17) of the Directive reads:

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.

29. Article 1(17a) of the Directive reads:

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.

30. 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.
…

31. 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).*
> *…*
> *7. ...*
> *Manufacturing of these products shall be authorised by the competent authority of the Member State. Member States shall ensure that national traceability and pharmacovigilance requirements as well as the specific quality standards referred to in this paragraph are equivalent to those provided for at Community level in respect of advanced therapy medicinal products for which authorisation is required pursuant 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.*

32. 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.*
> *…*

33. Articles 76, 77 and 79, 80, 81, 84 and 85b of the Directive form part of Title VII, headed "Wholesale Distribution and Brokering of Medicinal Products".

34. 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.

…

35. 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.
…

36. 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.

37. Article 80 of the Directive reads, in extract:

Holders of the distribution authorization must fulfil the following minimum requirements:
…
(g) they must comply with the principles and guidelines of good distribution practice for medicinal products as laid down in Article 84;
…

38. 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.

…

39. Article 84 of the Directive reads:

The Commission shall publish guidelines on good distribution practice. To this end, it shall consult the Committee for Medicinal Products for Human Use and the Pharmaceutical Committee established by Council Decision 75/320/EEC.

40. 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.

…

41. Article 118 of the Directive reads:

1. The competent authority shall suspend or revoke the marketing authorization for a category of preparations or all preparations where any one of the requirements laid down in Article 41 is no longer met.
2. In addition to the measures specified in Article 117, the competent authority may suspend manufacture or imports of medicinal products coming from third countries, or suspend or revoke the manufacturing authorization for a category of preparations or all preparations where Articles 42, 46, 51 and 112 are not complied with.

National law[1]

42. The Act of 18 December 1997 on the marketing of medicinal products and the handling of human tissues and cells in the EEA[2] ("Liechtenstein EEA Medicinal Products Act") regulates the marketing of medicinal products and the handling of human tissues and cells in the European Economic Area.

43. 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. ...*

44. 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.*

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

> *(2) The manufacture of medicinal products requires an authorisation from the Office for Public Health (manufacturing authorisation).*

46. 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.*

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[1] The translations are unofficial.

[2] *Gesetz vom 18. Dezember 1997 über den Verkehr mit Arzneimitteln sowie den Umgang mit menschlichen Geweben und Zellen im Europäischen Wirtschaftsraum* (*EWR-Arzneimittelgesetz*; EWR-AMG; LR 812.103).

(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.

47. Section 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.

48. 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.

49. 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

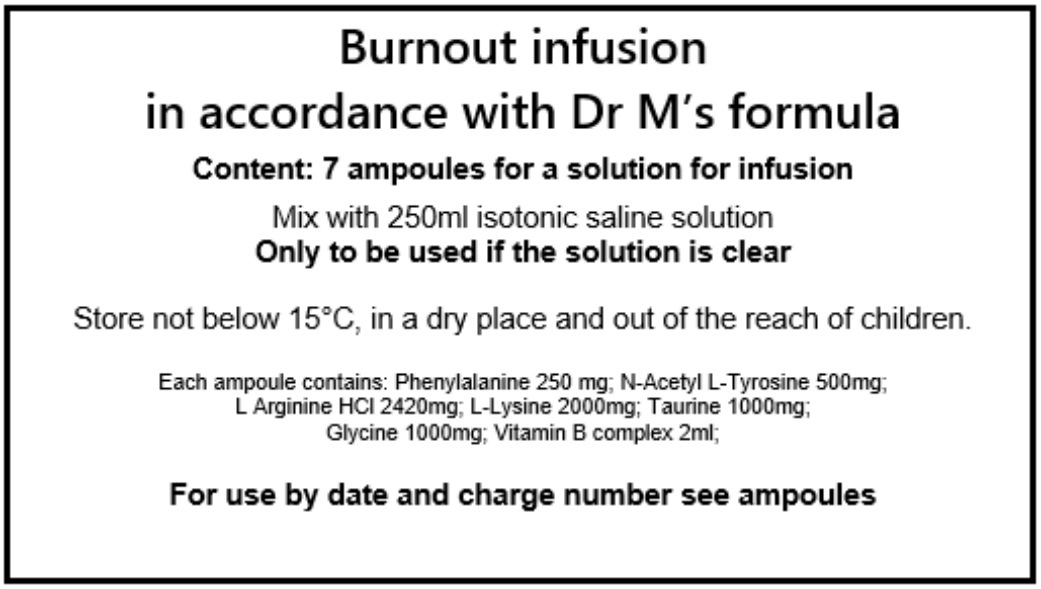
custodial sentence for a period not exceeding six months or a fine not exceeding 360 daily units on whosoever:
(a) contrary to the provisions of this Act, without licence or authorisation, manufactures, procures, tests, dispenses, imports, exports, stores, brokers, advertises, offers or dispenses in distance selling, medicinal products or human tissues or cells, or trades in them abroad;
…

III Facts and pre-litigation procedure

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

51. X AG is a legal person with its seat in Liechtenstein and whose corporate purpose is the conduct of seminars, lectures and congresses, trade in food supplements and goods of all kind, the drafting of texts, referral of laboratory services, purchase, administration and commercial exploitation of patents, licences and other intellectual property rights. M is the only board member and managing director of X AG and no other persons are employed by X AG.

52. X AG began trading in the burnout infusions in 2015/16. The infusion boxes each bore a label, which in translation reads as follows:



53. The ampoules of the "burnout infusions" (see the label above) are administered intravenously together with a saline solution. The infusions were manufactured by Arnika Pharmacy in Germany, in accordance with M's formula. Arnika 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.

54. Between 23 January 2015 to 23 December 2016, X AG sent the "burnout infusions" manufactured by Arnika 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 paid in each case to an account X AG held with a Liechtenstein bank. The infusions were described as "burnout infusions" because these strengthen the natural immune system and make people more resistant to stress. The infusions combat the causes of depression.

55. Before X AG took up business, M enquired with Price Waterhouse Coopers ("PwC") whether the "triangular transaction" (manufacture of the ampoules in Arnika Pharmacy in Germany, invoicing of X AG, supply to Austria or directly to patients) would be legal. M wanted PwC to clarify the issue of invoicing even if the goods did not physically come in contact with Liechtenstein and Switzerland. M did not raise the question with PwC whether the infusions had possibly to be qualified as medicinal products.

56. M went twice to the Office for Economic Affairs (*Amt für Volkswirtschaft*). On one occasion he had an infusions box with him. M enquired there whether the triangular transaction he was considering is 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.

57. 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 burnout infusions require an authorisation. By an email of 4 November 2015, M informed the Office for Public Health that the burnout infusions are not subject to the Liechtenstein EEA Medicinal Products Act as they are not medicines but simply essential nutrients in the sense of a food supplement which are applied intravenously.

58. 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.

59. 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.

60. M and X AG appealed against the Princely Court's judgment to the Princely Court of Appeal, which decided to make a reference to the Court. Against this background, 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?**

IV Written observations

61. Pursuant to Article 20 of the Statute of the Court and Article 97 of the Rules of Procedure, written observations have been received from:

- M and X AG, represented by Mag. iur. Sabine Mohr-Egger, Rechtsanwältin;

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

- Ireland, represented by Maria Browne, acting as Agent, and assisted by David Fennelly;

- the EFTA Surveillance Authority ("ESA"), represented by Ewa Gromnicka, Stewart Watson, Catherine Howdle and Carsten Zatschler, Department of Legal & Executive Affairs, acting as Agents; and

- the European Commission ("the Commission"), represented by Ken Mifsud-Bonnici and Attila Sipos, Members of its Legal Service, acting as Agents.

V Proposed answers submitted to the Court

M and X AG

62. M and X AG propose the following answers to the questions referred:

1. In order to qualify as a medicinal product under Article 1(2) of Directive 2001/83/EC a product must be either a medicinal product by presentation within the meaning of Article 1(2)(a) of the Directive or a medicinal product by function within the meaning of Article 1(2)(b) of the Directive. A medicinal product by presentation exists where a product is expressly indicated as such, for example, by means of labels, or is presented in a form which is usual exclusively for medicinal products. In order to qualify as a medicinal product by function, the pharmacological properties of the product must, on the other hand, be scientifically observed. As the burnout infusion does not bear the designation "medicinal product" nor does it have an external form that is used exclusively for medicinal products and, in addition, its pharmacological properties have not been scientifically observed it is not a medicinal product within the meaning of Article 1(2) of the Directive.

(a) Both by reason of the recitals to Directive 2001/83/EC according to which

- *although health should be safeguarded, the development of the pharmaceutical industry or trade in medicinal products within the Community should, at the same time, not be hindered (recitals 2 and 3),*
- *persons moving within the Community should be permitted to carry a reasonable quantity of medicinal products or to receive such for their personal use (recital 30),*
- *pharmacists and persons authorised to supply medicinal products to the public, and who confine themselves to this activity, should be exempt from an authorisation obligation (recital 36),*

and from the fact that Article 2(1) of the Directive establishes the scope of the Directive as only for the placing on the market of medicinal products prepared industrially or using an industrial process, in other words in large quantities, Article 2(1) of the Directive must be interpreted as meaning that placing on the market includes the manufacture, supply and administration of medicinal products in large quantities but not, however, the trade in burnout infusions which are manufactured by a German pharmacy in a quantity not exceeding 100 units per day on the basis of the prescription from doctor M, authorised and practising in Austria, and which are sent to M to be administered to his patients and, in this connection, only the invoicing is carried out via X AG.

(b) According to the case law of the ECJ, Article 2(1) of Directive 2001/83/EC must be interpreted as meaning that a medicinal product, which, under national legislation, does not require a marketing authorisation by reason of the proven frequency with which it is the subject of medical prescriptions, the essential manufacturing steps for such products are carried out in a pharmacy as part of the normal pharmacy business producing in the course of one day up to 100 packages ready for dispensation and intended for supply under the existing pharmacy operating licence, cannot be regarded as having been prepared industrially or manufactured by a method involving an industrial process, within the meaning of that provision, and consequently does not come within the scope of the Directive (judgment of 26 October 2016, C-276/15, Hecht-Pharma v Hohenzollern Apotheke, EU:C:2016:801). As the burnout infusions are manufactured and dispensed in precisely this way, they are not medicinal products which within the meaning of Article 2(1) of the Directive are industrially prepared or manufactured by a method involving an industrial process.

(c) The burnout infusion is manufactured by a German pharmacy under the provisions applicable in Germany laid down in point 1 of Paragraph 21(2) of the German Act on the Marketing of Medicinal Products, read in conjunction with Paragraph 6(1) of the German Regulation on the Operation of Pharmacies, on the basis of a prescription from M and supplied to the doctor's practice under its pharmacy operating licence. Since the ECJ ruled in Case C-276/15 Hecht-Pharma v Hohenzollern Apotheke that Article 3(2) of the Directive does not preclude the German provisions mentioned, in so far as those provisions, in essence, require pharmacists to comply with the pharmacopoeia when manufacturing officinal formulae (judgment of 26 October 2016, C-276/15, Hecht-Pharma v Hohenzollern Apotheke, EU:C:2016:801, paragraph 42), the burnout infusion falls within the exception provided for in Article 3(2) of Directive 2001/83/EC.

2. The answer to this question must be derived from the requirements on holders of a distribution authorisation, as provided for in Articles 79 and 80 of Directive 2001/83/EC. The requirement

- for suitable and adequate premises, installations and equipment, so as to ensure proper conservation and distribution of the medicinal products;

- for qualified staff;

- to obtain medicinal products only from other wholesalers or manufacturers; and

- for an emergency plan for recall actions

clearly presupposes trade in medicinal products in large quantities and not the "trade" at issue here of on average 1.04 burnout infusions per day, in which, in addition, not the supply but only the invoicing was carried out via X AG.

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?

Article 38 of the EEA Medicinal Products Act infringes the freedom of establishment already on account of the fact that an authorisation obligation, as applies to wholesalers, is provided for therein for the trade (in medicinal products) abroad regardless of the kind and extent thereof, which is at any rate disproportionate.

According to settled case law, Article 43 EC and thus also Article 31 EEA precludes any national measure which, even though it is applicable without discrimination on grounds of nationality, is liable to hinder or render less attractive the exercise by Community nationals of the freedom of establishment that is guaranteed by the Treaty (judgment of 21 April 2005, Commission v Greece, C-140/03, EU:C:2005:242, paragraph 27).

The authorisation obligation pursuant to Article 38 of the EEA Medicinal Products Act and the punishment of non-compliance therewith pursuant to Article 47(1)(a) of the EEA Medicinal Products Act with a six-month custodial sentence is a measure which is liable to hinder or render less attractive the exercise of the freedom of establishment that is guaranteed by the EEA Agreement. Even if it was adopted for the protection of health, the interference with the freedom of establishment is not justified. The measure goes far beyond what is necessary and is completely disproportionate.

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?

It contradicts the spirit and purpose of Directive 2001/83/EC and the principle of the uniform application of EEA law and would, in particular, deprive the exception provided for in Article 3(2) of Directive 2001/83/EC of its practical effectiveness if the burnout infusions manufactured according to the German provisions, held by the ECJ not to be precluded by Article 3(2) of the Directive, and thus not within the scope of the Directive were to be qualified in Liechtenstein as medicinal products within the meaning of the Directive.

The Government of Liechtenstein

63. The Government of Liechtenstein respectfully proposes that the questions referred are answered as follows:

1. Burnout infusions with the combination of substances determined in the present case must be qualified as "medicinal products" within the meaning of Article 1(2) of Directive 2001/83/EC.

a. The manufacture, supply and administration of the Burnout Infusions constitute a placing on the market within the meaning of Article 2(1) of Directive 2001/83/EC.

b. 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. The Burnout Infusions due to the method of their manufacture are not covered by the exception provided for in Article 3(2) of the Directive.

2. For an understanding of the term "wholesale distribution", reference is made to the definition of the term in Article 1(17) of the Directive, to Title VII of the Directive and to the comments in paragraphs 74 to 85 [of the Liechtenstein Government's observations].

3. It is compatible with the freedom of establishment pursuant to Article 31 et seq. EEA and, moreover, it must 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 into 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. It does not 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 a marketing authorisation.

Ireland

64. Ireland suggests that the Court answer the questions as follows:

> *1. With respect to the first part of the first question, on the basis of the evidence before the Court, burnout infusions of the kind at issue in the national proceedings must be classified as "medicinal products" within the meaning of Article 1(2) of Directive 2001/83/EC.*
>
> *2. With respect to the second and third parts of the first question, the burnout infusions at issue in the national proceedings appear to have been "intended to be placed on the market in Member States" and, subject to the findings of fact of the national court, may be regarded as having been "either prepared industrially or manufactured by a method involving an industrial process" within the meaning of Article 2(1) such that they come within the scope of Directive 2001/83/EC.*
>
> *3. With respect to the fourth part of the first question, the burnout infusions are not covered by the exception in Article 3(2) of Directive 2001/83/EC and, accordingly, must be regarded as falling within the scope of the Directive.*
>
> *4. With respect to the second question, the concept of "wholesale distribution" in Article 1(17) of Directive 2001/83/EC (as amended by Directive 2011/62/EU) includes all activities consisting of procuring, holding, supplying or exporting medicinal products (apart from supplying medicinal products to the public). This therefore includes the activities of M and/or X AG in procuring and supplying the burnout infusions at issue in this case.*
>
> *5. With respect to the third question, the facts of the present case disclose no factor which would affect the compatibility of Directive 2001/83/EC with Article 31 or any other provision of the EEA Agreement.*
>
> *6. With respect to the fourth question, the fact that the medicinal products in question might not require authorisation in another EEA Member State for a particular purpose has no influence on the answer to the preceding questions as it does not of itself affect the applicability of Directive 2001/83/EC in the national proceedings.*

ESA

65. ESA submits that the questions referred should be answered as follows:

> *1. A product such as the burnout infusion in issue in the case pending before the national court does appear, subject to verification by that court, to satisfy the definition of "medicinal product" the Directive. It is for the national court to determine, on the basis of the information available to it, whether this product has been prepared industrially or manufactured by a method involving an industrial process. This is the case if the process is characterised by a succession of operations, which may, in particular, be mechanical or chemical, in order to obtain a significant quantity of a standardised product. If the national court were*

to arrive at the conclusion that the conditions of Article 2(1) of the Directive are fulfilled, the product would appear not to qualify for an exception under Article 3(2) of the Directive, which, again, must be ascertained by the national court.

2. The notion of "wholesale distribution", defined in point 17 of Article 1 of the Directive, must be interpreted as not encompassing activities such as those of the defendant in the proceedings pending before the national court.

3. A provision such as Article 38 of the Liechtenstein EEA Medicinal Products Act, which subjects the commercial trade in medicinal products, effected from Liechtenstein, within the EEA or between an EEA Member State and a third country, without these medicinal products coming in contact the territory of Liechtenstein, to an authorisation requirement granted when 'the applicant meets the requirements for wholesalers', infringement of which is a criminal offence, constitutes a restriction of the freedom of establishment guaranteed by Article 31 EEA.

4. In order to be able to justify a restriction, enforced through criminal sanctions, on the trade in products taking place entirely in another EEA State where their production and marketing are lawful, an EEA State will need to adduce particularly cogent evidence that such a restriction is appropriate and necessary to achieve an overriding objective in the common interest or a derogation afforded by the EEA Agreement.

The Commission

66. The Commission considers that the questions referred should be answered as follows:

1. The referring national court should assess whether the concrete product at issue, the burnout infusions called "Neurostress" should, first, be qualified as a medicinal product under Article 1(2) 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, second whether it was prepared industrially or manufactured by a method involving an industrial process in accordance with Article 2(1), and third, whether the exception provided in Article 3(2) applies. In this assessment, the criteria set out by the union courts should be taken into account.

2. The referring national court should assess whether the activities of the accused can be characterised as "wholesale distribution" or "brokering medicinal products" in the meaning of the Directive and in this assessment, the criteria set out by the union courts should be taken into account.

3. and 4. The referring national court should assess whether the provisions of national law, which subject the commercial trade in medicinal products, effected from Liechtenstein, within the EEA or between an EEA Member State and a third country, without these medicinal products coming in contact the territory of Liechtenstein, to an authorisation requirement, infringement of which is a criminal offence, even if the trade in products taking place entirely in another EEA State where their production and marketing are lawful, are

precluded by the directive or if they constitute a restriction of the free movement of goods or the freedom to provide services guaranteed by Article 36 EEA, and whether it can be demonstrated that the restriction is appropriate, and does not go beyond that which is necessary to achieve an overriding objective in the common interest or a derogation afforded by the EEA Agreement.

Bernd Hammermann
Judge-Rapporteur