REPORT FOR THE HEARING

in Case E-7/11

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 Héraðsdómur Reykjavíkur (Reykjavík District Court), in the case of

Grund, elli- og hjúkrunarheimili

and

the Icelandic Medicines Agency (Lyfjastofnun)

concerning the interpretation of Directive 2001/83/EC and Articles 11 and 13 of the EEA Agreement.

I Introduction

1. By a letter of 25 March 2011, registered at the EFTA Court on 31 March 2011, Reykjavik District Court made a request for an Advisory Opinion in a case pending before it between Grund, elli- og hjúkrunarheimili ("the Plaintiff") and the Icelandic Medicines Agency, Lyfjastofnun ("the Defendant").

2. The case before Reykjavík District Court concerns the decision by the Defendant not to grant the Plaintiff permission to import into Iceland medicinal products from Norway.

II Legal background

EEA law

3. Article 11 of the EEA Agreement provides as follows:

> *Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between the Contracting Parties.*

4. Article 13 of the EEA Agreement reads as follows:

> *The provisions of Articles 11 and 12 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between the Contracting Parties.*

5. 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[1] ("the Directive") was incorporated into the EEA Agreement by Decision of the EEA Joint Committee No 82/2002 of 25 June 2002, amending Annex II to the EEA Agreement.

6. Article 1(17) of the Directive establishes the following definition:

> *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 authorised or entitled to supply medicinal products to the public in the Member State concerned.*

7. Article 6(1) of the Directive reads as follows:

> *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 unless 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.*

8. Article 40 of the Directive provides as follows:

> *1. Member States shall take all appropriate measures to ensure that the manufacture of the medicinal products within their territory is subject to the holding of an authorisation. This manufacturing authorisation shall be*

[1] OJ 2001 L 311, p. 67.

required notwithstanding that the medicinal products manufactured are intended for export.

...

3. Authorisation referred to in paragraph 1 shall also be required for imports coming from third countries into a Member State; this Title and Article 118 shall have corresponding application to such imports as they have to manufacture.

9. Article 48 of the Directive reads as follows:

Member States shall take all appropriate measures to ensure that the holder of the manufacturing authorisation has permanently and continuously at his disposal the services of at least one qualified person, in accordance with the conditions laid down in Article 49, responsible in particular for carrying out the duties specified in Article 51.

10. Article 51 of the Directive provides as follows

1. Member States shall take all appropriate measures to ensure that the qualified person referred to in Article 48, without prejudice to his relationship with the holder of the manufacturing authorisation, is responsible, in the context of the procedures referred to in Article 52, for securing:

(a) in the case of medicinal products manufactured within the Member States concerned, that each batch of medicinal products has been manufactured and checked in compliance with the laws in force in that Member State and in accordance with the requirements of the marketing authorisation;

(b) in the case of medicinal products coming from third countries, irrespective of whether the product has been manufactured in the Community, that each production batch has undergone in a Member State a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or checks necessary to ensure the quality of medicinal products in accordance with the requirements of the marketing authorisation.

The batches of medicinal products which have undergone such controls in a Member State shall be exempt from the controls if they are marketed in another Member State, accompanied by the control reports signed by the qualified person.

11. Article 59 of the Directive sets out the information that a package leaflet must include, for example, the necessary and usual instructions for proper use,

and a description of the adverse reactions which may occur under normal use of the medicinal product and, if necessary, the action to be taken in such a case.

12. Article 63 of the Directive reads as follows:

> *1. The particulars for labelling listed in Articles 54, 59 and 62 shall appear in the official language or languages of the Member State where the product is placed on the market.*
>
> *…*
>
> *3. When the product is not intended to be delivered directly to the patient, the competent authorities may grant an exemption to the obligation that certain particulars should appear on the labelling and in the package leaflet and that the leaflet must be in the official language or languages of the Member State in which the product is placed on the market.*

13. Article 76 of the Directive reads as follows:

> *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 authorisation 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.*
>
> *3. Any distributor, not being the marketing authorisation holder, who imports a product from another Member State shall notify the marketing authorisation holder and the competent authority in the Member State to which the product will be imported of his intention to import it. In the case of products which have not been granted an authorisation pursuant to Regulation (EC) No 726/2004, the notification to the competent authority shall be without prejudice to additional procedures provided for in the legislation of that Member State.*

14. Article 80 of the Directive reads as follows:

> *Holders of the distribution authorisation must fulfil the following minimum requirements:*
>
> *...*
>
> *(c) they must supply medicinal products only to persons who are themselves in possession of the distribution authorisation or who are authorised or entitled to supply medicinal products to the public in the Member State concerned;...*

National law[2]

15. Directive 2001/83 has been implemented in Icelandic law by the Medicinal Products Act No 93/1994 and subsequently by Regulation No 699/1996 on the importation and wholesale distribution of medicinal products ("the Icelandic Medicinal Products Regulation").

16. According to Article 7 of the Icelandic Medicinal Products Act, only medicinal products that have a valid Icelandic marketing authorisation may be imported and placed on the market in Iceland. That article implements Article 6 of the Directive.

17. Articles 13 and 14 of the Icelandic Medicinal Products Regulation, which implement Article 51 of the Directive, provide as follows:

> *Article 13*
>
> *Whoever imports a medicinal product, which has a marketing authorisation in Iceland, from other EEA States, shall have at his disposal a Qualified Person. The Qualified Person shall ensure that each batch of a medicinal product is produced in accordance with Good Manufacturing Practice for Medicinal Products and that its quality is in line with the provisions which form the basis for granting the marketing authorisation. The Qualified Person shall approve each batch in writing, thereby attesting that the quality of the medicinal product is in accordance with the criteria as set out in the second paragraph above. A register of all approved batches shall be maintained.*
>
> *Article 14*
>
> *The controls required in paragraph 2 of Article 13 can be waived if they have been conducted in another EEA State and if a Control Report is presented for confirmation to that effect.*

III Facts and procedure

18. The Plaintiff is a nursing home which purchases medicinal products for the people in its care. The case concerns the importation of four medicinal products[3] which the Plaintiff purchased from the medicinal product wholesaler Norsk Medisinaldepot AS in Norway in 2008.

---

[2] Translations of national provisions are based on those contained in the documents of the case.

[3] FUCIDIN KREM 2 %, PEVARYL KREM 1%, MILDISON LIPID KREM 1% and SERETIDE INH.PULV. 207250 DISKUS.

19. By a decision of 20 October 2008, the Defendant, the Icelandic Medicines Agency, refused to allow these imports. Medicinal products with the same names are on the Icelandic market with valid Icelandic national marketing authorisations. However, in the Defendant's view, the invoice and the Norwegian summary of product characteristics, which were provided by the Plaintiff, did not confirm that the products fulfilled the requirements of the Icelandic marketing authorisations. According to the Defendant, the Plaintiff should have provided a "control report", as referred to in Article 14 of the Icelandic Medicinal Products Regulation and Article 51 of Directive 2001/83, confirming that the medicinal products fulfilled the requirements of the Icelandic marketing authorisations.[4]

20. By a letter of 1 December 2008, the Plaintiff requested the Defendant to review its refusal. The Defendant rejected that request by a letter of 15 December 2008 in which it stated that the importation was not permitted, as a summary of the properties of the medicinal products was not regarded as equivalent to the control report it had requested by letter of 20 October 2008.

21. The Plaintiff appealed against the rejection. By a ruling of 18 January 2010, the Ministry of Health upheld the Defendant's decision. In the case now pending before Reykjavík District Court, the Plaintiff seeks to have the ruling of the Ministry of Health set aside. Moreover, the Plaintiff also seeks, *inter alia*, a declaration by the court that the requirements under Icelandic law concerning exemptions from labelling in Icelandic were satisfied in connection with the importation of the medicinal products.[5] In contrast, the Defendant rejects the Plaintiff's claims and submits that the Ministry's ruling is in conformity with legislation and other rules.

22. In the proceedings before the national court, the Plaintiff contends that the provisions of Articles 13 and 14 of the Icelandic Medicinal Products Regulation and Article 51 of Directive 2001/83, referred to by the Defendant, apply only to parties that import medicinal products for further distribution and not to parties such as the Plaintiff, which imports these products for private use by the persons in its care. The Plaintiff submits further that it bases its case partly on the final subparagraph of Article 51(1) of the Directive and argues that on the basis of that provision it cannot be required to submit the control report required by the Defendant.

23. By a ruling of 23 February 2011, the District Court decided to seek an Advisory Opinion from the EFTA Court on the interpretation of the Directive and, as appropriate, of other EEA legislation.

24. The following questions were submitted to the Court:

---

[4] Article 14 and the second paragraph of Article 11 of the Icelandic Medicinal Products Regulation issued under Article 49 of the Medicinal Products Act No 93/1994.

[5] See Articles 26 and 38 of Regulation No 462/2000.

1. **Is Directive 2001/83/EC and, as appropriate, other relevant EEA legislation, including Articles 11-13 of the EEA Agreement on the free movement of goods, to be interpreted as meaning that a health-care institution such as the Plaintiff, which provides people with health care and medical services, may not import, for use by the people in the care of the institution, medicinal products from Norway which have been granted Norwegian national marketing authorisation, by reference to an Icelandic national marketing authorisation for medicinal products under the same name, if the authorisations were granted before Directive 2001/83/EC entered into force?**

2. **If this is the situation, then how is a health-care institution like the Plaintiff, which maintains that medicinal products imported from another EEA Contracting Party have Icelandic marketing authorisation, to demonstrate that this is the case? Is Article 51(1) i.f. of Directive 2001/83/EC of the European Parliament and of the Council to be interpreted as meaning that the health-care institution is required to present a control report to the Defendant as the competent surveillance authority? Is it possible that less stringent requirements regarding the burden of proof could be made regarding the import of medicinal products from Norway, if the products are not intended for further sale or other distribution or marketing in Iceland, but only for the use of persons in the care of the health-care institution?**

3. **Do the competent authorities have completely unrestricted discretion as to whether, and then to whom, they grant exemptions under Article 63(3) of Directive 2001/83/EC of the European Parliament and of the Council in the case of medicinal products that are imported by a health-care institution such as the Plaintiff when the products are not intended for self-administration but are prepared by a pharmacist employed by the health-care institution and delivered to the users in specially-designed medicinal-product boxes?**

IV Written observations

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

- the Plaintiff, represented by Stefán Geir Þórisson, Supreme Court Attorney;
- the Defendant, represented by Einar Karl Hallvarðsson, Supreme Court Attorney;

- the Icelandic Government, represented by Bergþór Magnússon, Director, Ministry for Foreign Affairs, acting as Agent;
- the Norwegian Government, represented by Ida Thue, Advocate, Office of the Attorney General for Civil Affairs, and Kaja Moe Winther, Advisor, Ministry of Foreign Affairs, acting as Agents;
- the Czech Government, represented by Martin Smolek and David Hadroušek, acting as Agents;
- the Spanish Government, represented by Sonsoles Centeno Huerta, State Advocate of the Spanish State Legal Service before the Court of Justice of the European Union ("ECJ") , acting as Agent;
- the EFTA Surveillance Authority ("ESA"), represented by Gjermund Mathisen and Fiona M. Cloarec, Officers, Department of Legal & Executive Affairs, acting as Agents;
- the European Commission ("the Commission"), represented by Marketa Simerdova, Luis Banciella, and Ken Mifsud-Bonnici, members of its Legal Service, acting as Agents.

V Summary of the pleas and arguments submitted

The first question

The Plaintiff

26. The Plaintiff submits that, pursuant to the regime established by the Directive, for the purposes of importing the medicinal products concerned from Norway, it cannot be required to submit control reports.

27. The Plaintiff observes that the Defendant bases its refusal to allow the importation in the absence of a proper "control report" on Articles 13 and 14 of the Icelandic Medicinal Products Regulation. As those articles were adopted to implement the rules established in Article 51 of the Directive, it contends that the Regulation must be interpreted in light of that provision.

28. Having regard to Article 51(1) of the Directive, the Plaintiff argues that the rules in question only govern the situation where the imported medicinal products are meant for further distribution on the market. The said article of the Directive states that batches of medicinal products are to be exempted from controls "*if they are marketed in another Member State, accompanied by the control reports signed by the qualified person"*. The wording of the provision thus clearly refers only to marketing and not importation by a health institution for the direct use of its patients.

29. According to the Plaintiff, this view is supported by the letter to the Ministry of Health from the Commission's Dr Martin Terberger in reply to the

Ministry's questions to the Commission regarding the Directive.[6] In his letter, Dr Terberger takes the view that a nursing home which supplies medicinal products to its residents, i.e. to the public, is not a wholesale distributor as defined in Article 1(17) of the Directive. Therefore, the requirements set out in Title VII of the Directive do not apply. Moreover, Dr Terberger does not view the Plaintiff's purchase of medicinal products from Norway as constituting importation for the purposes of Title IV of the Directive, including Article 51, since both Norway and Iceland are part of the EEA.

30. The Plaintiff contends further that the Defendant's response of 25 February 2009 to the Plaintiff's administrative complaint to the Ministry of Health indirectly confirms the Plaintiff's view that Article 51 of the Directive, and thus Article 14 of the Icelandic Medicinal Products Regulation, is only applicable where the intention is to market medicinal products in another EEA State.

31. Finally, the Plaintiff notes that it is common ground between the parties that the medicinal products in question have both Norwegian and Icelandic national marketing authorisations. According to the Plaintiff, it is of no importance whether these authorisations were granted before or after the entry into force of the Directive.

32. In light of the above, the Plaintiff proposes that the Court should answer the first question as follows:

> *Directive 2001/38 of the European Parliament and the Council and other EEA legislation, including Articles 11-13 of the main text of the EEA Agreement on the free movement of goods, are to be interpreted as meaning that a healthcare institution such as the Plaintiff which provides people with health care and medicinal services, may import, for use by the people in the care of the institution, medicinal products from Norway which have been granted Norwegian national marketing authorization, by reference to an Icelandic national marketing authorization for medicinal products under the same name, irrespective of whether the authorizations were granted before or after Directive 2001/38/EC entered into force.*

The Defendant

33. The Defendant, supported by the Icelandic Government, submits that the first question must be answered in the affirmative.

34. At the outset, the Defendant argues that traceability of medicinal products is of major importance for safeguarding public health. It is paramount that the distribution of medicinal products is under the supervision of the competent national authority in the EEA State where the product is consumed. The Defendant notes that the national authorities issue a marketing authorisation for a

---

6 Annex 8 to the Plaintiff's written observations.

medicinal product to be placed on the market and inspect all relevant parties, including wholesalers. A national marketing authorisation constitutes an independent standalone marketing authorisation, only valid in the State of issue. The holder of the marketing authorisation is responsible for informing the competent national authority of defects or safety issues. However, the holder of the marketing authorisation will not be aware of a wholesaler selling the product to another EEA State, in this case Iceland. In turn, the wholesaler in one EEA State, in this case Norway, is not responsible for ensuring that a medicinal product fulfils the requirements of a marketing authorisation in another EEA State, for example, Iceland. In such a situation, the Defendant argues, the traceability of a defective batch of a medicinal product is compromised.

35. The Defendant notes further that the four medicinal products concerned have a Norwegian marketing authorisation, valid only in Norway. Medicinal products with the same names are on the Icelandic market with Icelandic marketing authorisations. However, neither the labelling of the products concerned nor the patient information leaflet was fully or even partly in Icelandic. According to the Defendant, this confirms that the products have not been released for the Icelandic market.

36. The Defendant contends that, according to Article 7 of the Medicinal Products Act and Article 6 of the Directive, only medicinal products having a valid Icelandic marketing authorisation may be imported and placed on the market in Iceland. When purchasing medicinal products from wholesalers in other EEA States, those products have to fulfil the requirements of the Icelandic marketing authorisations.

37. According to the Defendant, the invoice and the Norwegian summary of product characteristics, provided by the Plaintiff, do not confirm that the products purchased fulfil the requirements of the Icelandic marketing authorisations. The proper way to confirm that the products have been released for the Icelandic market is to provide control reports, as referred to in Article 51 of the Directive. The control report confirms that each batch of product meets the requirements on which the marketing authorisation was based.

38. The Defendant asserts that medicinal products with a national marketing authorisation cannot be moved freely within the EEA in this case except (i) as a parallel import or (ii) on the basis of a control report from the wholesaler in the exporting State, as required in Articles 13 and 14 of the Icelandic Medicinal Products Regulation and Article 51 of the Directive.

39. The Plaintiff did not apply for a parallel import licence, although advised to do so by the Defendant. Hence, provision of control reports was a necessary requirement for importation.

40. The Defendant rejects the view that the obligation imposed by Article 51 of the Directive to provide control reports does not apply to parties such as the

Plaintiff. Although Article 51 of the Directive is included in a chapter dealing with manufacture and importation, it establishes the basic rules which apply to all trade in medicinal products within the EEA. The security requirements with regard to the purchase of medicinal products are applicable not only to wholesalers, but also to parties permitted to purchase medicinal products from wholesalers, such as healthcare institutions. Moreover, even if the Plaintiff's purchase is not regarded as importation for further distribution, the Defendant submits that the same security requirements apply irrespective of whether the products are used in private homes or healthcare institutions. Thus, a medicinal product used in a nursing home must have an Icelandic marketing authorisation.

The Czech Government

41. The Czech Government argues that trade in medicinal products between Norway and Iceland should not be regarded as importation within the meaning of the Directive, since it does not concern products coming from outside the internal market, but as intra-EEA trade. Therefore, the Plaintiff has not imported the medicinal products and cannot be said to have purchased the products with the intention to place them on the market in Iceland. It thus appears as if, in principle, the purchase in the main proceedings falls outside the scope of the Directive. In essence, for the purposes of the Directive, there is no difference between the Plaintiff and a mere customer who buys medicinal products while travelling abroad.

42. However, according to the Czech Government, this does not necessarily mean that the medicinal products have been lawfully marketed for the purposes of the Directive. It stresses that the purchase at issue in the present case is a transaction involving two parties, one of which is the Norwegian wholesaler. The Government questions whether the Norwegian wholesaler fulfilled the requirements of Article 80 of the Directive, according to which a holder of a distribution authorisation may only supply medicinal products to persons who are themselves holders of a distribution authorisation, or who are authorised or entitled to supply medicinal products to the public in the Member State concerned.

43. Thus, if the Plaintiff is neither a holder of a distribution authorisation nor otherwise entitled in Iceland to supply medicinal products to the public (typically as a pharmacy), the medicinal products at issue must be considered to have been supplied unlawfully. In that case, the Icelandic authorities cannot be considered to have acted in contravention of EEA law in rejecting the "importation".

44. Consequently, the Czech Government contends that, only if the Plaintiff is authorised to supply medicinal products to the public in Iceland, will it be relevant to consider whether the requirements imposed on the Plaintiff regarding the marketing authorisation are contrary to EEA law. In that regard, it stresses that, subject to compliance with EEA law, in particular the provisions on free

movement of goods, EEA States are empowered to lay down rules regarding the provision of medicinal products to hospitals.[7]

45. In the Government's view, the requirements imposed on the Plaintiff in the main proceedings may not be considered a restriction on the free movement of goods, that is, they are not liable to hinder, directly or indirectly, actually or potentially, trade between EEA States, if they apply to all relevant traders operating within the national territory and if they affect in the same manner, in law and in fact, the marketing of domestic production and those of other EEA States.[8] If, however, they are considered to constitute a restriction, it may be justified under Article 13 EEA on grounds relating to the protection of human health.[9] In that connection, the Government agrees with the view taken by the Defendant, namely, that, in a situation such as the present case, the control report requirement is justified having regard to the necessity for the medicine surveillance authorities to have the relevant information on the medicinal products which enter the market in Iceland.

46. The Czech Government proposes that the Court should answer the first question as follows:

> *A transaction such as the one at issue in the main proceedings can only be considered lawful for the purposes 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, as later amended, provided that the requirement laid down in Article 80(c) of that Directive is fulfilled. In this regard, it is for the referring court to verify whether the holder of the distribution authorization supplied the medicinal products at issue to a person who is also in possession of the distribution authorization or who is authorized or entitled to supply medicinal products to the public in the Member State concerned.*
>
> *If so, it shall be for the referring court to verify whether the restrictions imposed by the legislation of the Member States concerned on the recipient of the medicinal products at issue can be justified in terms of Article 13 of the EEA Agreement.*

The Norwegian Government

47. The Norwegian Government refers to Article 2(1) of the Directive which provides that the Directive applies to medicinal products "intended to be placed on the market" in an EEA State. Consequently, it questions whether the Directive is applicable to a health care institution such as the Plaintiff. As the imported medicinal products are not intended for further sale, but for the use of persons in

---

[7] Reference is made to Case C-141/07 *Commission* v *Germany* [2008] ECR I-6935, paragraph 25.

[8] Ibid., paragraph 29.

[9] Ibid., paragraphs 46-51.

the institution's care only, it is not evident that medicinal products are "intended to be placed on the market".

48. The Government submits that, if the Directive is not applicable, it is for the national court to assess whether the Icelandic authorities have adopted measures which correspond to the Directive. Should such measures constitute a restriction on trade prohibited by Article 11 EEA, they may nevertheless be justified on grounds of public health under Article 13 EEA.

49. If the Court concludes that the Directive is applicable, the importer must obtain a marketing authorisation in accordance with the Directive, prior to marketing the medicinal product in the State of importation.[10] According to the Norwegian Government, the obligation on the importer to obtain such a marketing authorisation cannot, in any event, be regarded as a restriction on trade between the EEA States prohibited by Article 11 EEA.[11]

50. The Government notes, however, that these principles are subject to exceptions as regards parallel imports. According to case-law of the ECJ, the provisions governing the issue of marketing authorisations cannot apply to a medicinal product covered by a marketing authorisation in one EEA State which is being imported as a parallel import into another EEA State.[12] If the normal procedure for the issue of a market authorisation were to apply when a medicinal product is imported by way of parallel import, this would constitute a measure having equivalent effect to a quantitative restriction on the free movement of goods under Article 11 EEA.[13] Such a requirement cannot be imposed on importers unless justified on grounds of public health under Article 13 EEA. In this regard, rules or practices which make it possible for a manufacturer to enjoy a monopoly of importation cannot be justified under Article 13 EEA unless it is clearly proved that the alternatives would obviously be beyond the means which can be reasonably expected of an administration operating in a normal manner.[14]

51. Against this background, the Government contends that the national authorities must not obstruct parallel imports by requiring parallel importers to satisfy the same requirements as those which are applicable to importers which seek to place a medicinal product on the market for the first time, unless such requirements are justified on grounds of public health under Article 13 EEA.

52. The Government adds that the principles governing parallel imports apply equally where the marketing authorisations in the States of export/import were

---

[10] Reference is made to Article 6(1) of the Directive.

[11] Reference is made to Case C-319/05 *Commission* v *Germany* [2007] ECR I-9811, paragraph 35.

[12] Reference is made to Case 104/75 *De Peijper* [1976] ECR 613, paragraph 21.

[13] Reference is made to Case C-201/94 *Smith & Nephew and Primecrown* [1996] ECR I-5819, paragraph 21.

[14] Reference is made to *De Peijper*, cited above, paragraph 32.

granted before the entry into force of the Directive. The Directive constitutes a codification of previous directives, and there is nothing to indicate that the adoption of that directive was intended to have the effect of invalidating marketing authorisations issued under previous directives.

The EFTA Surveillance Authority

53. ESA understands the first question to concern whether a marketing authorisation may be relied upon to import medicinal products from another EEA State. If, in principle, a marketing authorisation may be relied upon for importation, the national court asks whether it is of relevance that the marketing authorisations were granted before the entry into force of the Directive.

54. ESA notes that under the Directive, marketing and importation are separate issues, in the sense that a marketing authorisation does not, as such, allow for importation. Whilst no medicinal product may be placed on the market of an EEA State unless a marketing authorisation has been issued, as required under Article 6(1) of the Directive, the marketing authorisation relates to the product in general, and not the individual batches manufactured.[15]

55. Therefore, a marketing authorisation, whether pre-dating the Directive or not, cannot be relied upon by the Plaintiff as a basis for importation of the medicinal products at issue. Should the EFTA Court consider it necessary to address the date of the national marketing authorisations, ESA adds that, for the authorisation to be valid, it must have been brought into compliance with the requirements of the Directive as updated.[16]

56. ESA proposes that the first question should be answered as follows:

> *A marketing authorisation for a medicinal product does not entitle a health care institution, whether or not the institution is the holder of the marketing authorisation, to import such medicinal products for use in the institution.*

The European Commission

57. The Commission notes that Article 51 forms part of Title IV of the Directive, which contains provisions on the manufacture of medicinal products, and their importation from third countries. The Title includes provisions requiring manufacturers of medicinal products and persons importing such products from third countries to be in possession of a manufacturing authorisation and establishes requirements for the grant of manufacturing

---

[15] This is demonstrated by Article 8(3) of the Directive on the particulars and documents to accompany an application for a marketing authorisation.

[16] Reference is made to Case C-350/08 *Commission* v *Lithuania*, judgment of 28 October 2010, not yet reported, paragraphs 51 to 81.

authorisations. Article 51 sets out that a qualified person must be permanently and continuously at the disposal of the holder of a manufacturing authorisation.

58. The Commission argues that since the case concerns the trade of medicinal products between two EEA States (intra-EEA trade), Article 51 of the Directive is not applicable, and a manufacturing authorisation is not required for the activities carried out by the Plaintiff.

59. Pursuant to Article 1(17) of the Directive, wholesaling means all activities consisting of procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public. Having regard to the facts set out in the request for an Advisory Opinion, the Commission concludes that the Plaintiff is not a wholesaler. Apart from supplying medicinal products to persons in its care, it does not procure, hold, supply or export medicinal products.

60. On the other hand, according to the Commission, Norsk Medisinaldepot AS would appear to be a medicinal product wholesaler. Pursuant to Article 80(c) of the Directive, a wholesaler may supply medicinal products 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.

61. Accordingly, Norsk Medisinaldepot was only entitled to supply medicinal products to the Plaintiff if the latter was a manufacturer, wholesaler, importer (which requires either a manufacturing or wholesale authorisation), pharmacy, or other person authorised under Icelandic law to supply medicinal products to the public. If the Plaintiff does not fall into any of those categories, any importation contravenes Article 80(c) of the Directive. Provisions of national law preventing importation on that basis are thus consistent with the Directive.

62. However, in the Commission's view, even if the Plaintiff were to fall into any of these categories, the products are required to have a marketing authorisation in Iceland before being supplied to the public.[17] In other words, the products in question must be subject to a national authorisation under Icelandic law issued in accordance with Article 6 of the Directive, a centralised authorisation in accordance with Regulation (EC) No 726/2004,[18] or a parallel import licence. This applies even if the products are not intended for further distribution, but for use of persons in the Plaintiff's care.

63. In this regard, the Commission observes further that a marketing authorisation granted under national law not in conformity with the relevant EEA legislation cannot be considered an authorisation for the purposes of Article 6 of

---

[17] Reference is made to Articles 6(1) and 76(1) of the Directive and Case C-322/01 *Deutscher Apothekerverband eV* [2003] ECR I-14887, paragraph 52 et seq.

[18] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ 2004 L 136, p. 1.

the Directive, unless that authorisation was subsequently revised and put into compliance with EEA law.

64. Against that background, the Commission submits that the first question should be answered in the negative, provided that the health care institution in question, such as the Plaintiff, was in possession of a wholesale authorisation, or was otherwise entitled under Icelandic law to supply medicinal products to the public, and provided further that a marketing authorisation or a parallel import licence has been granted to the products concerned.

The second question

The Plaintiff

65. In the Plaintiff's view, by its second question the national court essentially asks whether the Plaintiff, in the event that it does not have to provide a control report in order to import the medicinal products from Norway, is responsible for demonstrating or proving that the products have an Icelandic marketing authorisation and, if so, how the Plaintiff is to prove the existence of such marketing authorisation.

66. First, according to the Plaintiff, the Defendant has repeatedly admitted that the medicinal products at issue had national marketing authorisation in Iceland. In any event, the burden of proof must be on the Defendant to demonstrate that the medicinal products do not have national marketing authorisations in Iceland.

67. The Plaintiff asserts that it has done everything in its power to demonstrate that the medicinal products have national marketing authorisations, with the submission of evidence to that effect. The Plaintiff presented certificates on the origin and nature of each product, as well as a statement from Norsk Medisinaldepot, where there is information on the origin of the purchase of the medicinal product. There is also detailed information on the products from the Norwegian Medicines Control Agency. In the Plaintiff's view, these data describe the characteristics of the medicinal products and demonstrate that they should have national marketing authorisation in Iceland.

68. Finally, the Plaintiff notes that the rules on the provision of medicinal products to hospitals have not been harmonised in the EEA.[19] By analogy, in its view, Article 51 of the Directive and, thus, also Articles 13 and 14 of the Icelandic Medicinal Products Regulation governing the obligation to supply control reports do not apply to the Plaintiff's purchasing of the disputed medicinal products from the Norwegian wholesaler. All discriminatory barriers to the Plaintiff's importation of medicine amount to quantitative restrictions and are, as such, contrary to Article 11 EEA and, in the present case, cannot be justified by Article 13 EEA.

---

[19] Reference is made to Case C-141/07 *Commission* v *Germany*, cited above, paragraph 25.

69. The Plaintiff proposes that the Court should answer the second question as follows:

> *Article 51(1) i.f. of Directive 2001/38/EC of the European Parliament and of the Council is to be interpreted as meaning that a health-care institution such as the Plaintiff is not required to present a control report to the Defendant as the competent surveillance authority. A health-care institution like the Plaintiff which maintains that medicinal products imported from another EEA Contracting Party have Icelandic marketing authorization does not have to prove that the products have Icelandic marketing authorizations if the products are not intended for further sale or other distribution or marketing in Iceland, but only for the persons in the care of the health-care institution. The burden of proof to the contrary is on the relevant surveillance authority; the Defendant.*

The Defendant, supported by the Icelandic Government

70. According to the Defendant, the Plaintiff has to follow the same rules as apply to all actors on the market for medicinal products, namely, to provide the medicine surveillance authorities with control reports, or make them available upon request. It notes that the products concerned have Norwegian marketing authorisations. The proper way to import these products, for which no control reports can be provided, would be to apply for a parallel import licence in Iceland, thereby fulfilling legal requirements, including those necessary for traceability.

71. Were it otherwise, there would be discrimination between wholesalers and nursing homes regarding the importation of medicinal products within the EEA. This would distort competition between different actors involved in distribution, depending on the characteristics of the purchaser and seller.

The Spanish Government

72. In the view of the Spanish Government, the second question relates to the interpretation of Article 51 of the Directive. In particular, the national court asks whether less stringent requirements concerning the burden of proof may apply when importing medicinal products from Norway, if the products are not intended for further sale or other distribution or marketing in Iceland, but only for the use of persons in the care of the Plaintiff.

73. The Government stresses that medicinal products need a marketing authorisation. This fact distinguishes medicinal products from other types of goods for the purposes of the rules on free movement of goods. It contends that the Directive establishes requirements to be fulfilled regardless of the final destination of medicinal products. Therefore, contrary to the view advanced by the Plaintiff, no distinction is possible between products to be distributed and products to be self-administered. The interest protected in that regard is public

health and such interest would not be ensured if the measures adopted in the EU as a whole could be circumvented simply by reason of the fact that the final destination is private use. The Plaintiff has submitted to the Defendant a summary of properties regarding the medicinal products at issue. However, this appears insufficient to fulfil the requirements of the Directive. The aim of such a summary is not the control of quality and quantity of the medicinal product, but rather to inform the patient about the properties of the medicinal product in an objective manner.

74. In the Government's view, whether or not the Plaintiff demonstrated that the medicinal products imported have been granted a marketing authorisation in Iceland is a question for the national court, as it necessitates an analysis of facts.

The EFTA Surveillance Authority

75. In light of its proposed answer to the first question, ESA does not find it necessary to consider in detail the first part of the second question, on how a health care institution such as the Plaintiff should demonstrate that medicinal products it wishes to import from another EEA State are covered by an Icelandic marketing authorisation. In its view, this appears to be a question of national law.

76. According to ESA, what the referring court is essentially asking must be whether, in order to import medicinal products from Norway for use in its institution, the Plaintiff is required to submit a control report pursuant to Article 51 of the Directive.

77. In ESA's view, a batch of medicinal products cannot be imported from one EEA State to another without being followed by the necessary control report. Where control reports are not presented by the importer, Article 51(1) of the Directive appears to imply that the competent authorities may require that the controls to which the control reports refer are carried out anew.

78. ESA can see no grounds for any exemptions applicable to imports made by a health care institution such as the Plaintiff for use within that institution. The controls to which the control reports refer, and which concern, *inter alia*, the quality of the individual batches of the medicinal product, are of no less importance in this context than in the context of importation for wholesale or retail use.

79. ESA proposes that the Court should reply to the second question as follows:

> *It follows from Article 51(1) of Directive 2001/83/EC that the competent national authorities may require a health care institution to present the relevant control report in order to import from another EEA State medicinal products for use in the institution, failing which the authorities may require the control to which the control report refers to be carried out anew.*

The European Commission

80. The Commission submits that the second question should be answered to the effect that it is for national law to determine how a health care institution such as the Plaintiff is to demonstrate that the medicinal products it intends to import from another EEA State have been granted the requisite marketing authorisations, provided that the provisions of the Directive and other requirements of EEA law, including the principles of proportionality and equal treatment, are respected. Article 51 of the Directive is not relevant in this regard.

The third question

The Plaintiff

81. The Plaintiff argues that an exemption to the language requirements set out in Article 63(3) of the Directive should be given where importation is carried out by health institutions, since the medicinal products which are imported will not be given directly to the patients, but kept with the pharmacologist at the institution and passed out in special medicine boxes. It stresses that it imports the medicinal products with the sole objective of distributing these to its patients, based on a prescription from doctors of the institution and under the guidance of an internal pharmacologist. Thus, the patients never obtain the packaging or the patient information leaflets which follow the medicine. Furthermore, the medicine is not for any further distribution or other usage. In light of the above, it is clear that the aforementioned exemption applies in its case.

82. The Plaintiff proposes that the third question should be answered as follows:

> *The competent authorities do not have completely unrestricted discretion as to whether and to whom they grant exemptions under Article 63(3) of Directive 2001/38/EC of the European Parliament and of the Council in the case of medicinal products that are imported by a health-care institution such as the Plaintiff when the products are not intended for self-administration but are prepared by a pharmacist employed by the health-care institution and delivered to the users in specially-designed medicinal-product boxes. The exemption is tailor made for such cases and should be granted*

The Defendant, supported by the Icelandic Government

83. The Defendant notes that a marketing authorisation holder may apply for an exemption from the requirement regarding labelling in Icelandic for a product for which the authorisation holder is responsible. As the Plaintiff is not the marketing authorisation holder, it is, according to the Defendant, for this reason alone, not possible to grant the Plaintiff an exemption.

84. Moreover, once a parallel import licence has been granted, such products will be available in the distribution chain and must fulfil the relevant conditions, that is, labelling and patient information leaflet in Icelandic. The products in question, which following a parallel import are available to all who may purchase medicinal products from a wholesaler, will not be used in institutions only, but also by patients at home. Consequently, these products cannot be exempted from the language requirements pursuant to Article 63(3) of the Directive.

The Spanish Government

85. The Spanish Government notes that Member States have a discretion to grant exemptions regarding labelling and packaging of medicines, provided that public health is safeguarded and the criteria used do not introduce unnecessary restrictions to the free movement of goods. However, exemptions may only be granted when the product is not intended to be delivered to the patient for self-administration. In the present case, this is a factual question for the national court and does not fall within the competence of the EFTA Court. However, for the purposes of the Directive, it appears clear that if the Plaintiff does not have a marketing authorisation, no exemption can be granted and, consequently, no further analysis is required.

86. The Spanish Government proposes that the Court should answer the third question as follows:

> *Member States have discretional powers in order to establish exemptions under Article 63(3) of Directive 2001/83/EC of the European Parliament and of the Council, as far as the competent authorities ensure that the medicinal products shall be for the use of the institution and not for private administration.*

The EFTA Surveillance Authority

87. In ESA's view, by its third question the national court asks whether the competent authorities may refuse to grant an exemption from the requirement for labelling in Icelandic where medicinal products imported by healthcare institutions such as the Plaintiff are intended for delivery to the persons in its care without packaging or package leaflets, following prescription from the institution's physician and under the supervision of a pharmacist employed by the institution.

88. ESA notes that the Directive does not require the grant of such exemption. Pursuant to Article 63(3) of the Directive, the competent authorities may grant exemptions, but are not obliged to do so. This discretion must be exercised in accordance with general principles of EEA law, such as the principle of equal treatment, but there is nothing in the request from the national court to indicate that this is an issue in the present case.

89. ESA submits that the answer to the third question should be as follows:

> *Under Article 63(3) of Directive 2001/83/EC, the competent national authorities may refuse to grant an exemption from the requirement for labelling in Icelandic, in the case of medicinal products imported by a health care institution such as Grund and intended for delivery to the persons in the care of the institution in specially designed boxes, without packaging or package leaflets, following a prescription from the institution's physician and under the supervision of a pharmacist employed by the institution.*

The European Commission

90. The Commission notes that Article 63(3) of the Directive establishes the possibility for a competent authority to grant an exemption from the standard labelling requirements of Title V of the Directive where a product is not intended to be delivered directly to the patient.

91. According to the Commission, the requirements on labelling and package leaflets are integral parts of the marketing authorisation or parallel import licence for a medicinal product. Thus, only holders or applicants for such authorisations or licences may apply for an exemption.

92. Against that background, the Commission submits that the answer to the third question should be that a Member State has a discretion to determine, having due regard to public health requirements, whether holders of a marketing authorisation or parallel import licence may be granted exemptions under Article 63(3) of Directive 2001/83, provided that the provisions of Directive 2001/83 and other requirements of EEA law, including the principles of proportionality and equal treatment, are respected.

Per Christiansen
Judge-Rapporteur