JUDGMENT OF THE COURT
30 March 2012*

(Directive 2001/83/EC – Free movement of goods – Pharmaceuticals – Parallel import – Control reports – Protection of public health – Justification – Language requirements for labelling and package leaflets)

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,

THE COURT,

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

Registrar: Skúli Magnússon,

having considered the written observations submitted on behalf of:

- Grund, elli- og hjúkrunarheimili ("the Plaintiff" or "Grund"), represented by Stefán Geir Þórisson, Supreme Court Attorney;
- the Icelandic Medicines Agency (Lyfjastofnun) ("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;

* Language of the request: Icelandic.

- 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, acting as Agent;
- the EFTA Surveillance Authority ("ESA"), represented by Xavier Lewis, Director, 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,

having regard to the Report for the Hearing,

having heard oral argument of the Plaintiff, represented by Stefán Geir Þórisson; the Defendant, represented by Einar Karl Hallvarðsson; the Czech Government, represented by David Hadroušek; ESA, represented by Xavier Lewis and Maria Moustakali; and the Commission, represented by Marketa Simerdova, Luis Banciella, and Ken Mifsud-Bonnici, at the hearing on 16 November 2011,

gives the following

Judgment

I Legal background

EEA law

1 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.*

2 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.*

3 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 ("the Directive") (OJ 2001 L 311, p. 67) 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.

4 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.*

5 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.*

6 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.

7 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.

8 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.

…

2. The package leaflet must be written in clear and understandable terms for the users and be clearly legible in the official language or languages of the Member State where the medicinal 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.

9 Article 82 of the Directive reads as follows:

…

Member States shall take all appropriate measures to ensure that persons authorized or entitled to supply medicinal products to the public are able to provide information that makes it possible to trace the distribution path of every medicinal product.

National law

10 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 Regulation").

11 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.

12 Articles 13 and 14 of the Icelandic 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 [sic] 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.*

II Facts and procedure

13 By letter of 25 March 2011, registered at the Court on 31 March 2011, Reykjavík District Court made a request for an Advisory Opinion in a case pending before it between Grund and the Icelandic Medicines Agency.

14 The Plaintiff is a nursing home which purchases medicinal products for the people in its care. The case concerns the importation of the four medicinal products FUCIDIN KREM 2 %, PEVARYL KREM 1%, MILDISON LIPID KREM 1% and SERETIDE INH.PULV. 207250 DISKUS which the Plaintiff purchased from the wholesaler Norsk Medisinaldepot AS in Norway in 2008.

15 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 Regulation and Article 51 of the Directive, confirming that the medicinal products fulfilled the requirements of the Icelandic marketing authorisations.

16 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.

17 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 Ministry's ruling set aside. Moreover, the Plaintiff also seeks, *inter alia*, a declaration by the national court that the requirements under Icelandic law concerning exemptions from labelling in Icelandic were satisfied in connection with the importation of the medicinal products. The Defendant rejects the Plaintiff's claims and submits that the Ministry's ruling is in conformity with legislation and other rules.

18 In the proceedings before the national court, the Plaintiff contends that the provisions of Articles 13 and 14 of the Icelandic Regulation and Article 51 of the Directive, 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 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.

19 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.

20 The following questions were submitted:

> *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?

21 Reference is made to the Report for the Hearing for a fuller account of the legal framework, the facts, the procedure and the written observations submitted to the Court, which are mentioned or discussed hereinafter only insofar as is necessary for the reasoning of the Court.

III The first and second questions

22 By its first question, the referring court essentially asks whether the Plaintiff's importation of the four said medicinal products from Norway to Iceland may be rejected on the basis that the products in question, which have marketing authorisations in Norway, do not satisfy the requirements of the Icelandic marketing authorisations for products having the same name as those imported. In this regard, the national court also asks whether it is of any significance if the authorisations were granted before the Directive entered into force.

23 By its second question, the referring court asks, in essence, in the event that the first question is answered in the affirmative, how the Plaintiff is to demonstrate that the conditions of the Icelandic marketing authorisations are fulfilled, in particular whether the Plaintiff, whose intention is to use the products solely within its institution, must present control reports referred to in Article 51 of the Directive. The Court considers it appropriate to address these questions together.

Observations submitted to the Court

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

25 The Plaintiff observes that the Defendant bases its refusal to allow the importation on Articles 13 and 14 of the Icelandic Regulation. As those articles were adopted to implement the rules established in Article 51 of the Directive, the Plaintiff contends that the Icelandic Regulation must be interpreted in light of that provision.

26 In this regard, the Plaintiff argues that Article 51(1) of the Directive only governs the situation where the imported medicinal products are meant for further

distribution on the market. The wording of the provision clearly refers only to marketing and not importation by a health care institution for the direct use of its patients. In any event, the Plaintiff's purchase of medicinal products from Norway does not constitute importation for the purposes of Title IV on manufacturing and importation of the Directive, including Article 51, since both Norway and Iceland are Contracting Parties to the EEA.

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

28 The Plaintiff asserts that it has done everything in its power to describe the characteristics of the medicinal products and to demonstrate that the requirements of the Icelandic marketing authorisations are fulfilled. The Plaintiff presented certificates on the origin and nature of each product, as well as a statement from Norsk Medisinaldepot containing 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.

29 The Defendant, supported by the Icelandic Government, submits that the first question must be answered in the affirmative. It argues that according to Article 7 of the Medicinal Products Act and Article 6 of the Directive, only medicinal products fulfilling the requirements of a valid Icelandic marketing authorisation may be imported and placed on the market in Iceland. This applies even if the Plaintiff's purchase is not regarded as importation for further distribution. The same security requirements apply irrespective of where the products are used, whether in private homes or health care institutions. Thus, a medicinal product used in a nursing home must have an Icelandic marketing authorisation.

30 The Defendant notes that the four medicinal products concerned have Norwegian marketing authorisations, 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 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.

31 In the Defendant's view, traceability of medicinal products is of major importance for safeguarding public health. The holder of the national 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 traceability of a defective batch of a medicinal product is compromised.

32 The Defendant submits further that since the Plaintiff did not apply for a parallel import licence, 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 is based. According to the Defendant, 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 them, such as health care institutions.

33 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 intra-EEA trade. In addition, the Plaintiff cannot be said to have imported the medicinal products with the intention to place them on the market in Iceland. 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.

34 In any event, the Czech Government argues 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. In this regard, the requirements imposed on the Plaintiff in the main proceedings may not be considered a restriction on the free movement of goods, 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 products and those of other EEA States. 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. In that connection, the Government submits that the control report requirement is justified having regard to the need for the medicines surveillance authorities to have the relevant information on the products which enter the market in Iceland.

35 The Norwegian Government questions whether the Directive applies to a health care institution such as the Plaintiff, as the imported medicinal products are not intended for further sale, but only for the use of persons in the institution’s care.

36 Should the Directive apply, the Norwegian Government submits that an importer must obtain a marketing authorisation in accordance with the Directive, prior to marketing the medicinal product in the State of importation. However, according to the case-law of the ECJ, the provisions governing the issuance of marketing authorisations cannot apply to a medicinal product covered by a marketing authorisation in one EEA State which is being imported by way of parallel import into another EEA State, as this would constitute a measure having equivalent effect to a quantitative restriction on the free movement of goods

under Article 11 EEA. Such a requirement cannot be imposed on importers unless justified on grounds of public health under Article 13 EEA.

37 The Spanish Government contends that the Directive establishes requirements to be fulfilled regardless of the final destination of medicinal products. Therefore, no distinction can be made between products to be distributed and products to be self-administered. The Government notes that the Plaintiff 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 to enable the control of quality and quantity of the medicinal product, but to inform the patient about the properties of the medicinal product in an objective manner. The question whether the Plaintiff demonstrated that the medicinal products imported were granted a marketing authorisation in Iceland is for the national court to answer, as it requires an analysis of facts.

38 ESA contends that 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. Whilst no medicinal product may be placed on the market of an EEA State unless a marketing authorisation has been issued, as specified by Article 6(1) of the Directive, the marketing authorisation relates to the product in general, and not the individual batches manufactured.

39 In ESA's view, a batch of a medicinal product 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.

40 ESA cannot see any grounds for exemptions to be granted in favour of 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.

41 The Commission submits that the Directive is applicable to the purchase of medicinal products intended for the use by the patients of a nursing home such as the Plaintiff. Since the products are not for personal use, it follows from the scheme of the Directive that they must be regarded as intended to be placed on the market. According to the Commission, such imported medicinal products are required to have a marketing authorisation in the State of importation before being supplied to the public.

42 Article 51 of the Directive forms part of Title IV, which contains provisions on the manufacture of medicinal products and their importation from third countries. Since the case concerns the trade in medicinal products between two EEA States (intra-EEA trade), and a manufacturing authorisation is not required for the activities carried out by the Plaintiff, Article 51 of the Directive is not applicable

to the purchase in question. Since Article 13 of the Icelandic Regulation requires control reports to be submitted also in the case of intra-EEA trade, the Directive has been incorrectly transposed in Iceland.

43 Moreover, the Commission asserts that the Directive does not contain special provisions on intra-EEA trade. Instead, trade in medicinal products within the EEA is governed by the primary law rules on the free movement of goods.

44 According to the Commission, the four medicinal products in question appear essentially similar to products having marketing authorisation in Iceland, and the Plaintiff's purchase must be regarded as a parallel import.

45 Although the authorities in the State of importation are obliged to require traceability information from parallel importers, it follows from Case 104/75 *De Peijper* [1976] ECR 613 that the authorities cannot require a parallel importer to provide control reports. Since the parallel importer does not have access to these manufacturing control reports, the national authorities have to adopt a more active policy when they wish to verify the controls carried out by the manufacturer on a given batch. The requirement for control reports is thus evidently too onerous and cannot be objectively justified.

46 According to the Commission, the authorities in the State of import may require a parallel importer to have a parallel import licence or other authorisation issued under a simplified procedure, before it undertakes parallel imports. However, assessment of an application for such an authorisation must be limited to verification of the medicinal product imported being compliant with the marketing authorisation in the State of import.

Findings of the Court

47 Directive 2001/83 repealed earlier directives on medicinal products for human use, in particular Directive 65/65/EEC. According to recital 1 of the preamble, the purpose of the Directive is to codify, in the interests of clarity and rationality, the earlier directives by assembling them in a single text. The case law concerning the repealed directives may therefore be relevant for the interpretation of Directive 2001/83.

48 Recital 2 of the preamble to the Directive states that the essential aim of any rules governing the production, distribution and use of medicinal products must be to safeguard public health. However, as recital 3 sets out, this objective must be attained by means which will not hinder trade in medicinal products within the Community.

49 As stated in recital 14 of the preamble, the Directive represents an important step towards achievement of the objective of the free movement of medicinal products, in removing disparities between national provisions – as follows from recitals 4 to 6 – through laying down common rules on the control of medicinal products and the duties incumbent upon the Member States' competent

authorities. Nonetheless, the Directive constitutes merely a first stage in the harmonisation of national legislation on the manufacture and distribution of medicinal products (compare Case C-319/05 *Commission* v *Germany* [2007] ECR I-9811, paragraph 36).

50 Accordingly, in areas where full harmonisation of national rules has not been achieved, the rules of primary law concerning the free movement of goods, in particular Article 11 EEA, continue to apply in relation to the manufacture and marketing of specialised pharmaceutical products.

51 It follows from Articles 2 and 6(1) of the Directive that no industrially manufactured medicinal product may be placed on the market of an EEA State unless a marketing authorisation has been issued by the competent authority of that EEA State. Alternatively, although not relevant to the case, an authorisation can be issued in accordance with the centralised Community authorisation procedure established by Regulation No 2309/93. The purpose of the marketing authorisation requirement is to demonstrate that the potential risks of the product are outweighed by its therapeutic efficacy.

52 To that extent, it is irrelevant whether a marketing authorisation was granted before the Directive entered into force, as long as the authorisation is valid and satisfies the Directive's rules in this regard.

53 As the Commission correctly asserts, the Directive's requirement for a marketing authorisation applies to the purchase of medicinal products by a nursing home such as the Plaintiff. As the products are not for personal use, but intended to be made available for the use of the Plaintiff's patients, they must be regarded as intended to be placed on the market, within the meaning of Article 6(1) of the Directive. Thus, in order to make the products available for such use, the Plaintiff must either demonstrate that the products in question are covered by an existing valid marketing authorisation in accordance with Article 6(1) or procure a new marketing authorisation.

54 As a precondition to the granting of a marketing authorisation, Article 8 of the Directive requires that a series of documents as well as precise, detailed information be submitted. This requirement applies even where the medicinal product concerned is covered by an authorisation issued by the competent authority of another EEA State (compare, in a similar vein, Case C-201/94 *Smith & Nephew and Primecrown* [1996] ECR I-5819, paragraph 19). Consequently, if a product manufactured industrially comes within the definition of medicinal product in Article 1(2) of the Directive, the obligation on the importer to obtain a marketing authorisation in accordance with the Directive prior to marketing it in the EEA State of importation cannot, in any event, constitute a restriction on trade between EEA States prohibited by Article 11 EEA (see, for comparison, Case C-88/07 *Commission* v *Spain* [2009] ECR I-1353, paragraph 68; and *Commission* v *Germany*, cited above, paragraph 35).

55 However, the objective of safeguarding public health pursued by the Directive justifies such stringent measures only in regard to medicinal products which are being put on the market for the first time (see, to that effect, *Smith & Nephew and Primecrown*, cited above, paragraph 20).

56 It follows from the request for an Advisory Opinion that the medicinal products the Plaintiff purchased have marketing authorisations in Norway, and that products with the same names have marketing authorisations in Iceland. The Court notes further that the purchase must be regarded as a parallel import, that is, import taking place outside the manufacturer's or its licensed distributor's formal channel of distribution (see Case E-1/98 *Astra Norge* [1998] EFTA Ct. Rep. 140, paragraph 20).

57 The provisions of the Directive concerning the procedure for issuance of marketing authorisations cannot apply to a medicinal product covered by a valid marketing authorisation in one EEA State which is being imported into another EEA State as a parallel import of a product essentially similar or identical to a product already covered by a marketing authorisation in the EEA State of importation. In this case, the imported medicinal product cannot be regarded as being placed on the market for the first time in the EEA State of importation (see, for comparison, *Smith & Nephew and Primecrown*, cited above, paragraph 21).

58 The public health authorities of the EEA State of importation may already have in their possession, as a result of an existing marketing authorisation, all the pharmaceutical particulars necessary for checking that the product is effective and safe. In that case, it is clearly unnecessary, in order to protect the health and life of humans, for those authorities to require a second trader who has imported a medicinal product which is in every respect the same or whose differences have no therapeutic effect to produce these particulars again (see, for comparison, *De Peijper*, cited above, paragraph 2; *Smith & Nephew and Primecrown*, cited above, paragraph 22; and Case C-94/98 *Rhône-Poulenc Rorer and May & Baker* [1999] ECR I-8789, paragraph 26).

59 According to the case-file, in Iceland, a parallel import licence is needed. The Court recalls, however, that the procedure for the issue of such a licence must be limited to controlling that the medicinal product in question has a valid marketing authorisation in the EEA State of export, and that the product is identical or essentially similar to a product having marketing authorisation in the EEA State of importation. A product is essentially similar if it is manufactured according to the same formulation, uses the same active ingredient, and has the same therapeutic effects and does not pose a problem of quality, efficacy or safety in normal conditions of use as a medicinal product which has a marketing authorisation in the EEA State of importation (see, for comparison, *Smith & Nephew and Primecrown*, cited above, paragraph 26; and *Rhône-Poulenc*, cited above, paragraphs 45 and 48).

60 Moreover, it follows from Article 82(2) of the Directive that the competent authorities are under an obligation to ensure that persons authorised or entitled to

supply medicinal products to the public are able to provide information that makes it possible to trace the distribution path of every medicinal product. Accordingly, in the case of a parallel import, the national authorities must require traceability information from the parallel importer.

61 In this regard, the Court notes that, pursuant to Article 51(1)(a) and (3) of the Directive, each batch of medicinal products manufactured in an EEA State must be checked by the manufacturer's qualified person who registers the operations carried out in control reports, which remain at the disposal of the agents of the competent authority for at least five years. This provision is only applicable in the context of manufacture and imports from third countries, that is, countries outside the EEA.

62 However, to request a parallel importer to provide to the national authorities traceability information in the form of the manufacturing control reports constitutes a measure having equivalent effect to a quantitative restriction on imports, and if thus contrary to Article 11 EEA unless it can be justified under Article 13 EEA (see, for comparison, *De Peijper*, cited above, paragraphs 12 to 13).

63 The health and life of humans rank foremost among the assets or interests protected by Article 13 EEA. However, national rules or practices likely to have a restrictive effect, or having such an effect, on the importation of pharmaceutical products are compatible with the EEA Agreement only to the extent that they are necessary for the effective protection of health and life of humans. A national rule or practice cannot benefit from the derogation provided for in Article 13 EEA if the health and life of humans may be protected as effectively by measures which are less restrictive of intra-EEA trade (see, in a similar vein, Case C-322/01 *Deutscher Apothekerverband* [2003] ECR I-14887, paragraph 103, and case-law cited).

64 In this regard, the Court recalls that parallel importers in the pharmaceutical sector are often in a position to offer the goods at a price lower than the one asked by the official distributor and thereby provide less expensive drugs for the benefit of both patients and national health care systems (see Case E-3/02 *Paranova* [2003] EFTA Ct. Rep. 101, paragraph 37).

65 Furthermore, the existence of parallel imports prevents an unnecessary partitioning of the EEA States' markets and ensures that the system of marketing authorisation does not lead to certain traders in medicinal products having a monopoly. Parallel imports guarantee price competition between economic operators (see, for comparison, Opinion of Advocate General Geelhoed in Case C-172/00 *Ferring Arzneimittel* [2002] ECR I-6891, point 44).

66 A parallel importer does not normally have access to control reports. Thus, national rules or practices which make it possible for a manufacturer of the pharmaceutical product in question and its duly appointed representative to restrict competition simply by refusing to supply the documents relating to a

specific batch, cannot be justified, unless it is clearly proved that any other rules or practices would obviously be beyond the means which can be reasonably expected of an administration operating in a normal manner (see *De Peijper*, cited above, paragraph 32).

67 What the national authorities may do is either (i) obtain the control reports by taking legislative or administrative measures compelling the manufacturer itself, or its duly appointed representative, to supply them; (ii) use all the necessary information already in its possession and the information it can obtain through cooperation with the health authorities in other EEA States (see, for comparison, Case C-112/02 *Kohlpharma* [2004] ECR I-3369, paragraphs 18 to 20); (iii) lay down, wherever possible, a presumption of conformity, with the result that it would be for the authorities, in appropriate cases, to rebut this presumption; or (iv) allow the parallel importer to provide proof of conformity by means other than by documents to which it has no access (see *De Peijper*, cited above, paragraphs 26 to 29).

68 The reply to the first and second questions must therefore be that the national authorities may make importation by a health care institution, such as the Plaintiff, for use by the people in the care of the institution, of medicinal products from Norway which have been granted national marketing authorisations in Norway, and which are identical or essentially similar to products which have national marketing authorisations in Iceland, subject to a parallel import licence. Such a licence must be issued under a procedure limited to controlling that the medicinal products in question have a valid marketing authorisation in the EEA State of export, and that the product is identical or essentially similar to products having marketing authorisation in the EEA State of importation. In this context, the national authorities may not require parallel importers, such as the Plaintiff, to submit manufacturing control reports. Such a practice cannot be justified under Article 13 EEA.

IV The third question

69 By its third question, the national court essentially asks whether the competent authorities have unfettered discretion whether and also to whom they grant exemptions under Article 63(3) of the Directive. Such an exemption derogates from requirements set out in Article 63(1) and (2). The national court also seeks to establish whether it is of any importance that the products are intended for delivery by a health care institution 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, and delivered to the users in special medicine boxes.

Observations submitted to the Court

70 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 care institutions. In that case, the medicinal products will not be given

directly to the patients, but kept with the pharmacist at the institution and distributed in special medicine boxes. In such a situation, the patients never obtain the packaging or the package leaflets which accompany the medicine.

71 The Defendant, supported by the Icelandic Government, 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.

72 Moreover, according to the Defendant, 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, be labelled and have a patient information leaflet in Icelandic. The products in question, which after a parallel import will be available to all who may purchase medicinal products from a wholesaler, will not be used only in institutions, but also by patients at home. Consequently, these products cannot be exempted from the language requirements in Article 63(1) of the Directive.

73 ESA contends that pursuant to Article 63(3) of the Directive, the competent authorities may grant exemptions, but are not obliged to do so. That discretion must be exercised in accordance with general principles of EEA law, such as the principle of equal treatment. There is nothing in the request from the national court to indicate that equality of treatment is an issue in the present case.

74 The Commission asserts that, pursuant to Article 63(1) and (2) of the Directive, the labelling and package leaflet must appear in the official language or languages of the EEA State where the product is placed on the market, unless an exemption is granted according to Article 63(3). The labelling and package leaflet forms an integral part 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.

75 According to the Commission, the national authorities have discretion to determine, having due regard to public health requirements, whether holders or applicants for a marketing authorisation or a parallel import licence may be granted exemptions under Article 63(3) of the Directive, provided that the provisions of the Directive and other requirements of EEA law, including the general principles of proportionality and equal treatment, are respected.

76 The Commission submits further that if an exemption is not granted, and, as a consequence, the importer has to change the labelling and package leaflet, the importer will require a manufacturing authorisation in accordance with Article 40(2) of the Directive.

Findings of the Court

77 According to Article 1(25) of the Directive, "labelling", for the purposes of the Directive, means providing information on the immediate or outer packaging. Similarly, pursuant to Article 1(26), "package leaflet" means a sheet of paper containing information for the user which accompanies the medicinal product.

78 Title V of the Directive sets out specific rules as regards labelling and package leaflets. In particular, Article 63(1) and (2) requires the labelling and package leaflet, respectively, to appear in the official language or languages of the EEA State where the product is placed on the market.

79 However, pursuant to Article 63(3) of the Directive, the competent authorities may exempt package leaflets for specific medicinal products from this obligation, when the product is not intended to be delivered directly to the patient. Notwithstanding the specific wording of that provision, the Court finds that this derogation must apply also to the labelling.

80 The situation described in the request would appear to satisfy the requirements of Article 63(3). When exercising their discretion, the national authorities must respect the general principles of EEA law. The discretion must not be exercised in a disproportionate, arbitrary or abusive, in particular protectionist, manner. A refusal to consider any applications for an exemption or exclusion of an applicant simply on account of the fact that it is a parallel importer would not be compatible with these principles.

81 For the sake of completeness, the Court notes from the request for an Advisory Opinion and the observations submitted by the parties to the main proceedings that the competent Icelandic authorities denied the Plaintiff an exemption from the requirement for labelling in Icelandic. From the same documents, it appears that the basis for the rejection was the fact that the Plaintiff is not the "responsible" holder of the Icelandic marketing authorisation of the products in question, as required pursuant to Articles 26 and 38 of the Icelandic Regulation.

82 It is for the national court to assess whether it follows from Icelandic law that only the holder of a marketing authorisation may apply for an exemption from the language requirements of Article 63(1) and (2). If that is the case, such a condition is contrary to the Directive, interpreted in the light of primary EEA law. Although Article 63(3) does not specify who may apply for an exemption, that provision must be interpreted in a manner which does not restrict parallel imports, which, according to case-law, are governed by Articles 11 and 13 EEA. If parallel importers of medicinal products were not eligible to apply for an exemption from the language requirements laid down in Article 63(1) and (2), this would render it impossible or excessively difficult for them to exercise the freedom conferred on them under the EEA Agreement. As the Commission correctly asserts, the labelling and package leaflet forms an integral part not only of the marketing authorisation for a medicinal product, but also of a parallel import licence for such a product. Consequently, Article 63(3) of the Directive

must be interpreted as precluding national rules under which parallel importers may not apply for the exemption.

83 Since the national authorities are prevented from exercising their discretion under Article 63(3) of the Directive in a disproportionate manner, in cases where the medicinal product is not self-administered and the importation is carried out by a medical institution which administers the medicinal products to the patients in its care under appropriate professional supervision, the requirement that an applicant for an exemption holds a marketing authorisation clearly imposes an excessive burden. The primary objective of the Directive is the protection of public health. The fact that a medicinal product has already been authorised in the EEA State of exportation and that it is identical or essentially similar to a medicinal product which is authorised in the EEA State of importation must lead to the conclusion that an exemption from the language requirement for holders or applicants for a parallel import licence does not entail a higher risk for public health than an exemption for holders or applicants for a marketing authorisation. The Court notes for the sake of completeness that national courts must apply the interpretative methods recognised by national law as far as possible in order to achieve the result sought by the relevant EEA law rule (see Case E-1/07 *Criminal proceedings against A* [2007] EFTA Ct. Rep. 245, paragraph 39).

84 The answer to the third question must therefore be that when a medicinal product is not intended to be delivered directly to the patient, the competent authorities have a discretion under Article 63(3) of the Directive to grant exemptions from the requirement established in Article 63(1) and (2) that the labelling and package leaflet, respectively, must appear in the official language or languages of the EEA State where the product is placed on the market. The exercise of this discretion is, however, limited by the general principles of EEA law. The discretion must not be exercised in a disproportionate, arbitrary or abusive, in particular protectionist, manner.

V Costs

85 The costs incurred by the Icelandic Government, the Norwegian Government, the Czech Government, the Spanish Government, ESA and the European Commission, which have submitted observations to the Court, are not recoverable. Since these proceedings are a step in the proceedings pending before the Héraðsdómur Reykjavíkur, any decision on costs for the parties to those proceedings is a matter for that court.

On those grounds,

THE COURT

in answer to the question referred to it by the Héraðsdómur Reykjavíkur hereby gives the following Advisory Opinion:

1. **The national authorities may make importation by a health care institution, such as the Plaintiff, for use by the people in the care of the institution, of medicinal products from Norway which have been granted national marketing authorisation in Norway, and which are identical or essentially similar to products which have national marketing authorisation in Iceland, subject to a parallel import licence.**

   Such a licence must be issued under a procedure limited to controlling that the medicinal products in question have a valid marketing authorisation in the EEA State of export, and that the product is identical or essentially similar to products having marketing authorisation in the EEA State of importation.

   In this context, the national authorities may not require parallel importers, such as the Plaintiff, to submit manufacturing control reports. Such a practice cannot be justified under Article 13 EEA.

2. **When a medicinal product is not intended to be delivered directly to the patient, the competent authorities' right to grant exemptions under Article 63(3) of Directive 2001/83/EC is limited by the general principles of EEA law. The discretion must not be exercised in a disproportionate, arbitrary or abusive, in particular protectionist, manner**.

Carl Baudenbacher Per Christiansen Páll Hreinsson

Delivered in open court in Luxembourg on 30 March 2012.

Skúli Magnússon
Registrar

Carl Baudenbacher
President