V

(Announcements)

COURT PROCEEDINGS

EFTA COURT

Request for an Advisory Opinion from the EFTA Court by Héraðsdómur Reykjavíkur dated 25 March 2011 in the case of Grund, elli- og hjúkrunarheimili v Lyfjastofnun (Icelandic Medicines Control Agency)

(Case E-7/11)

(2011/C 215/13)

A request has been made to the EFTA Court by a letter of 25 March 2011 from Héraðsdómur Reykjavíkur (Reykjavik District Court), which was received at the Court Registry on 31 March 2011, for an Advisory Opinion in the case of Grund, elli- og hjúkrunarheimili (an old peoples' and nursing home) v Lyfjastofnun (Icelandic Medicines Control Agency), on the following questions:

1. Is Directive 2001/83/EC of the European Parliament and of the Council and, as appropriate, other EEA legislation, including Articles 11-13 of the main text 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 the first paragraph of Article 51 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 the third paragraph of Article 63 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?