JUDGMENT OF THE COURT
29 July 2016

(Failure by an EFTA State to fulfil its obligations – Failure to implement – Directive 2011/62/EU amending Directive 2001/83/EC on the Community Code relating to medicinal products for human use)

In Case E-30/15,

EFTA Surveillance Authority, represented by Carsten Zatschler, Clémence Perrin and Marlene Lie Hakkebo, Members of its Department of Legal & Executive Affairs, acting as Agents,

applicant,

v

Iceland, represented by Jóhanna Bryndís Bjarnadóttir, Counsellor, Ministry for Foreign Affairs, acting as Agent,

defendant,

APPLICATION for a declaration that Iceland has failed to fulfil its obligations under the Act referred to at point 15q of Chapter XIII of Annex II to the Agreement on the European Economic Area (Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community Code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products) as adapted to the Agreement by way of Protocol 1 thereto, and under Article 7 of the Agreement, by failing to adopt the measures necessary to implement the Act within the time prescribed, or in any event by failing to inform the EFTA Surveillance Authority thereof,

THE COURT,

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

Registrar: Gunnar Selvik,

having regard to the written pleadings of the parties,

having decided to dispense with the oral procedure,

gives the following

Judgment

I Introduction

1 By an application lodged at the Court Registry on 16 December 2015, the EFTA Surveillance Authority ("ESA") brought an action under the second paragraph of Article 31 of the Agreement between the EFTA States on the Establishment of a Surveillance Authority and a Court of Justice ("SCA") seeking a declaration from the Court that Iceland has failed to fulfil its obligations under the Act referred to at point 15q of Chapter XIII of Annex II to the Agreement on the European Economic Area ("the EEA Agreement" or "EEA"), that is Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community Code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products (OJ 2011 L 174, p. 74, and Icelandic EEA Suppl. 2013 No 56, p. 521) ("the Act" or "the Directive"), as adapted to the EEA Agreement under its Protocol 1, and under Article 7 EEA, by failing to adopt or in any event to inform ESA of the measures necessary to implement the Act within the time prescribed.

II Law

2 Article 3 EEA reads:

> *The Contracting Parties shall take all appropriate measures, whether general or particular, to ensure fulfilment of the obligations arising out of this Agreement.*
>
> *They shall abstain from any measure which could jeopardize the attainment of the objectives of this Agreement.*
>
> *…*

3 Article 7 EEA reads:

> *Acts referred to or contained in the Annexes to this Agreement or in decisions of the EEA Joint Committee shall be binding upon the Contracting Parties and be, or be made, part of their internal legal order as follows:*
>
> *…*
>
> *(b) an act corresponding to an EEC directive shall leave to the authorities of the Contracting Parties the choice of form and method of implementation.*

4 Article 31 SCA reads:

> *If the EFTA Surveillance Authority considers that an EFTA State has failed to fulfil an obligation under the EEA Agreement or of this Agreement, it shall, unless otherwise provided for in this Agreement, deliver a reasoned opinion on the matter after giving the State concerned the opportunity to submit its observations.*
>
> *If the State concerned does not comply with the opinion within the period laid down by the EFTA Surveillance Authority, the latter may bring the matter before the EFTA Court*.

5 EEA Joint Committee Decision No 159/2013 of 8 October 2013 (OJ 2014 L 58, p. 12, and EEA Supplement 2014 No 13, p. 14) ("Decision 159/2013") amended Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement by adding the Directive to point 15q of Chapter XIII of the Annex. Constitutional requirements were indicated by Norway and Liechtenstein for the purposes of Article 103 EEA. By April 2014 both States had notified that the constitutional requirements had been fulfilled. Consequently, Decision 159/2013 entered into force on 1 June 2014. The time limit for the EFTA States to adopt the measures necessary to implement the Directive expired on the same date.

III Facts and pre-litigation procedure

6 On 17 September 2014, ESA issued a letter of formal notice concluding that Iceland had failed to fulfil its obligations under the Act and Article 7 EEA by failing to adopt, or in any event to inform ESA of the measures necessary to implement the Directive. Iceland did not reply to the letter of formal notice.

7 On 14 January 2015, ESA delivered a reasoned opinion maintaining the conclusion set out in its letter of formal notice. Pursuant to the second paragraph of Article 31 SCA, ESA required Iceland to take the measures necessary to comply with the reasoned opinion within two months following the notification, that is, no later than 14 March 2015. Iceland did not reply to the reasoned opinion.

8 Since Iceland did not comply with the reasoned opinion by the set deadline, ESA decided to bring the matter before the Court pursuant to the second paragraph of Article 31 SCA.

IV Procedure and forms of order sought

9 ESA lodged the present application at the Court Registry on 16 December 2015. Iceland's statement of defence was registered at the Court on 23 February 2016. By letter of 3 March 2016, ESA waived its right to submit a reply and consented to dispense with the oral procedure should the Court wish to do so. By letter of 6 May 2016, Iceland also consented to dispense with the oral procedure.

10 The applicant, ESA, requests the Court to:

> 1. *Declare that Iceland has failed to fulfil its obligations under the Act referred to at point 15q of Chapter XIII of Annex II to the Agreement on the European Economic Area (Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community Code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products) as adapted to the Agreement under its Protocol 1 thereto, and under Article 7 of the Agreement, by failing to adopt the measures necessary to implement the Act within the time prescribed, or in any event by failing to inform the EFTA Surveillance Authority thereof; and*
>
> 2. *Order Iceland to bear the costs of these proceedings.*

11 The defendant, Iceland, submits that it does not dispute the facts of the case as they are set out in ESA's application. Furthermore, it does not contest the declaration sought by ESA. Nevertheless, in its defence, Iceland indicated that it was foreseen that the implementation of the Directive would be finalised around 1 June 2016.

12 After having received the express consent of the parties, the Court, acting on a report from the Judge-Rapporteur, decided, pursuant to Article 41(2) of the Rules of Procedure ("RoP"), to dispense with the oral procedure.

V Findings of the Court

13 Article 3 EEA imposes upon the EFTA States the general obligation to take all appropriate measures, whether general or particular, to ensure fulfilment of the obligations arising out of the EEA Agreement (see, *inter alia*, Case E-21/15 *ESA* v *Iceland*, judgment of 1 February 2016, not yet reported, paragraph 14 and case law cited).

14 Under Article 7 EEA, the EFTA States are obliged to implement all acts referred to in the Annexes to the EEA Agreement, as amended by decisions of the EEA Joint Committee. An obligation to implement the Directive also follows from its Article 2. The Court notes that the lack of direct legal effect of acts referred to in decisions by the EEA Joint Committee makes timely implementation crucial for the proper functioning of the EEA Agreement in Iceland also. The EFTA States

find themselves under an obligation of result in that regard (see, *inter alia*, *ESA* v *Iceland*, cited above, paragraph 15 and case law cited).

15 Decision 159/2013 entered into force on 1 June 2014. The time limit for the EFTA States to adopt the measures necessary to implement the Directive expired on the same date.

16 The question whether an EFTA State has failed to fulfil its obligations must be determined by reference to the situation as it stood at the end of the period laid down in the reasoned opinion (see, *inter alia*, *ESA* v *Iceland*, cited above, paragraph 17 and case law cited). It is undisputed that Iceland had not adopted the measures necessary to implement the Directive by the expiry of the time limit set in the reasoned opinion.

17 Since Iceland did not implement the Directive within the time prescribed, there is no need to examine the alternative form of order sought against Iceland for failing to inform ESA of the measures implementing the Directive.

18 It must therefore be held that Iceland has failed to fulfil its obligations under the Act referred to at point 15q of Chapter XIII of Annex II to the Agreement on the European Economic Area (Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community Code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products) as adapted to the Agreement under its Protocol 1, and under Article 7 of the Agreement, by failing to adopt the measures necessary to implement the Act within the time prescribed.

VI Costs

19 Under Article 66(2) RoP, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since ESA has requested that Iceland be ordered to pay the costs, the latter has been unsuccessful and none of the exceptions in Article 66(3) RoP apply, Iceland must be ordered to pay the costs.

On those grounds,

THE COURT

hereby:

1. Declares that Iceland has failed to fulfil its obligations under the Act referred to at point 15q of Chapter XIII of Annex II to the Agreement on the European Economic Area (Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community

Code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products) as adapted to the Agreement under its Protocol 1, and under Article 7 of the Agreement, by failing to adopt the measures necessary to implement the Act within the time prescribed.

2. Orders Iceland to bear the costs of the proceedings.

Carl Baudenbacher Per Christiansen Páll Hreinsson

Delivered in open court in Luxembourg on 29 July 2016.

Birgir Hrafn Búason
Acting Registrar

Páll Hreinsson
Acting President