JUDGMENT OF THE COURT
1 February 2016

(Failure by an EEA/EFTA State to fulfil its obligations – Failure to implement – Directive 2011/62/EU – Directive 2012/26/EU)

In Case E-22/15,

EFTA Surveillance Authority, represented by Clémence Perrin, Officer, and Íris Ísberg, Temporary Officer, Department of Legal & Executive Affairs, acting as Agents,

applicant,

v

The Principality of Liechtenstein, represented by Dr Andrea Entner-Koch, Director, and Frederique Lambrecht, Senior Legal Officer, EEA Coordination Unit, acting as Agents,

defendant,

APPLICATION for a declaration that by failing to adopt the measures necessary to implement the Acts 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 and Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance), as adapted to the Agreement by way of Protocol 1 thereto, within the time prescribed, the Principality of Liechtenstein has failed to fulfil its obligations under Article 2 of each Act and under Article 7 of the Agreement.

THE COURT,

composed of: Carl Baudenbacher, President, Per Christiansen and Páll Hreinsson (Judge-Rapporteur), 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 17 August 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, by failing, within the time prescribed, to adopt the measures necessary to implement the Acts referred to at point 15q of Chapter XIII of Annex II to the Agreement on the European Economic Area ("EEA"), 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 Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance (OJ 2012 L 299, p. 1) ("the Directives", "the Acts" or "Directive 2011/62/EU" and "Directive 2012/26/EU") as adapted to the Agreement by way of Protocol 1 thereto and by Joint Committee Decisions No 159/2013 of 8 October 2013 (OJ 2014 L 58, p. 12, and EEA Supplement 2014 No 13, p. 14) ("Decision No 159/2013") and No 160/2013 of 8 October 2013 (OJ 2014 L 58, p. 13), (EEA Supplement 2014 No 13, p. 15) ("Decision No 160/2013"), Liechtenstein has failed to fulfil its obligations under Article 2 of the Acts and under Article 7 EEA.

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 Decisions No 159/2013 and No 160/2013 of 8 October 2013 amended Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement by adding the Directives to point 15q of Chapter XIII of the Annex. As regards Directive 2011/62/EU constitutional requirements were indicated by Liechtenstein and Norway for the purposes of Article 103 EEA. As regards Directive 2012/26/EU constitutional requirements were indicated by Liechtenstein. By 29 April 2014 both States had notified that the constitutional requirements had been fulfilled. Consequently, Decision No 159/2013 and Decision No 160/2013 entered into force on 1 June 2014. The time limit for the EEA/EFTA States to adopt the measures necessary to implement the Directives expired on the same date.

III Facts and pre-litigation procedure

6 By a letter of 4 June 2014, ESA reminded Liechtenstein of its obligation to implement the Directives. Liechtenstein did not reply to the letter.

7 On 17 September 2014, having received no further information from Liechtenstein, ESA issued a letter of formal notice, concluding that Liechtenstein had failed to fulfil its obligations under the Acts and Article 7 EEA by failing to take, or in any event, to notify ESA of the necessary measures to ensure implementation of the Acts. Liechtenstein was invited to submit its observations on the content of the letter of formal notice, within two months of receipt of the letter.

8 On 17 November 2014, Liechtenstein replied to the letter of formal notice. In the reply, Liechtenstein informed ESA that the transposition of the Directives was ongoing and that it would be combined with the transposition of Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use. A draft bill would be presented and submitted to comments by interested parties in the autumn of 2014. The first reading in Parliament was foreseen for September 2015, the second reading for December 2015 and the entry into force in March 2016.

9 Furthermore, Liechtenstein argued that implementation of Joint Committee Decision No 158/2013 ("Decision No 158"), by which Directive 2010/84/EU has been incorporated into the EEA Agreement had to be taken into account, and the transposition of the Directives would be combined with the transposition of Directive 2010/84/EU. As for Liechtenstein, Decision No 158 was to enter into force on the same day or on the day of entry into force of the amendments to the Agreement between Liechtenstein and Austria laying down the technical details for Liechtenstein's recognition of Austrian marketing authorisations within the decentralised procedure and the mutual recognition procedure, whichever would be the later.

10 On 11 February 2015, ESA delivered a reasoned opinion arguing that there was no specific adaption which would provide for a later entry into force date for Liechtenstein in Decision No 159/2013 or Decision No 160/2013, which incorporated the Directives into the EEA Agreement. Furthermore, Liechtenstein had not substantiated how the Directives would be inseparably linked to Directive 2010/84/EU.

11 Pursuant to the second paragraph of Article 31 SCA, ESA required Liechtenstein to take the necessary measures to comply with the reasoned opinion within two months following the notification, that is, no later than 11 April 2015.

12 On 10 April 2015, Liechtenstein replied to the reasoned opinion and reiterated that Decision No 158/2013 had to be taken into account. Liechtenstein added that, although no adaptions had been made to Decision No 159/2013 or Decision No 160/2013, it was nevertheless of the opinion that since Directive 2010/84/EU, Directive 2011/62/EU and Directive 2012/26/EU all amended Directive 2001/83/EC, sometimes even the same provisions, it would not be feasible to transpose the Directives before Directive 2010/84/EU. Liechtenstein informed ESA of a revised timetable for implementation of the Acts. The first reading in Parliament was foreseen for autumn 2015, the second reading for March 2016 and entry into force in summer of 2016. Lastly, Liechtenstein stated that it expected that the mentioned timetable for transposition could be adhered to.

13 On 15 July 2015, having received no further information, 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

14 ESA lodged the present application at the Court Registry on 17 August 2015. Liechtenstein's statement of defence was registered at the Court on 19 October 2015. By a letter of 27 November 2015, ESA waived its right to submit a reply and consented to dispense with the oral procedure should the Court wish to do so. By a letter of 3 December 2015, Liechtenstein also consented to dispense with the oral procedure.

15 The applicant, ESA, requests the Court to:

> *1. Declare that, by failing to adopt the measures necessary to implement 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 and Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance) as adapted to the Agreement by way of Protocol 1 thereto, within the time prescribed, Liechtenstein has failed to fulfil its obligations under Article 2 of the Acts and under Article 7 of the EEA Agreement.*
>
> *2. Order Liechtenstein to bear the costs of these proceedings.*

16 The defendant, Liechtenstein, does not dispute the facts of the case as set out in the application. Furthermore, Liechtenstein does not contest the declaration sought by ESA under section 5 paragraph 1 of ESA's application. However, Liechtenstein reiterated its willingness to implement the Directives as swiftly as possible and submitted information for the purposes of providing for an understanding of the delay of the implementing process. As to the costs of the case, Liechtenstein requests the Court to order each party to bear its own costs of the proceedings.

17 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

18 Article 3 EEA imposes upon the EEA/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-18/15 *ESA*

v *Iceland*, judgment of 16 December 2015, not yet reported, paragraph 17 and case law cited).

19 Under Article 7 EEA, the EEA/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 Directives also follows from Article 2 in each of the two Directives. 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 also in Liechtenstein. The EEA/EFTA States find themselves under an obligation of result in that regard (see, *inter alia*, *ESA* v *Iceland*, cited above, paragraph 18 and case law cited).

20 Decision No 159/2013 and Decision No 160/2013 entered into force on 1 June 2014. The time limit for the EEA/EFTA States to adopt the measures necessary to implement the Directives expired on the same date.

21 The question whether an EEA/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 20 and case law cited). It is undisputed that Liechtenstein had not adopted the measures necessary to implement the Directives by the expiry of the time limit set out in the reasoned opinion.

22 It must therefore be held that by failing, within the time prescribed, to adopt the measures necessary to implement the Acts referred to at point 15q, ninth and tenth indent, 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 and Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance) as adapted to the Agreement by way of Protocol 1 thereto, Liechtenstein has failed to fulfil its obligations under Article 2 of each Act and Article 7 EEA.

VI Costs

23 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 Liechtenstein be ordered to pay the costs, and the latter has been unsuccessful, and none of the exceptions in Article 66(3) RoP apply, Liechtenstein must therefore be ordered to pay the costs.

On those grounds,

THE COURT

hereby:

1. **Declares that, by failing, within the time prescribed, to adopt the measures necessary to implement the Acts referred to at point 15q, ninth and tenth indent, 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 and Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance), as adapted to the Agreement by way of Protocol 1 thereto, the Principality of Liechtenstein has failed to fulfil its obligations under Article 2 of each Act and under Article 7 of the EEA Agreement.**

2. **Orders the Principality of Liechtenstein to bear the costs of the proceedings.**

Carl Baudenbacher Per Christiansen Páll Hreinsson

Delivered in open court in Luxembourg on 1 February 2016.

Gunnar Selvik
Registrar

Carl Baudenbacher
President