

## EFTA COURT

### **Action brought on 17 December 2015 by the EFTA Surveillance Authority against Iceland.**

**(Case E-33/15)**

An action against Iceland was brought before the EFTA Court on 17 December 2015 by the EFTA Surveillance Authority, represented by Carsten Zatschler, Clémence Perrin and Íris Ísberg, acting as Agents of the EFTA Surveillance Authority, 35 Rue Belliard, B-1040 Brussels.

The EFTA Surveillance Authority requests the EFTA 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 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, 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.**
- 2. Order Iceland to bear the costs of these proceedings.**

*Legal and factual background and pleas in law adduced in support:*

- The application addresses Iceland's failure to comply, no later than 14 March 2015, with a reasoned opinion delivered by the EFTA Surveillance Authority on 14 January 2015 regarding that State's failure to implement into its national legal order *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 referred to at point 15q of Chapter XIII of Annex II to the Agreement on the European Economic Area, and as adapted to that Agreement by way of Protocol 1 thereto ("the Act").
- The EFTA Surveillance Authority submits that Iceland has failed to fulfil its obligations under the Act and under Article 7 of the EEA Agreement by failing to adopt the measures necessary to implement the Act within the time prescribed.