



Reykjavík, 18 December 2024

To the President and Members of the EFTA Court

Statement of Defence

submitted pursuant to Article 107 of the Rules of Procedure of the EFTA Court by

the Government of Iceland

represented by

Mr. Hendrik Daði Jónsson, Legal Adviser, Ministry for Foreign Affairs, and
Mr. Gunnar Ingi Ágústsson, Senior Adviser, Ministry of Higher Education, Science and
Innovation, acting as Agents in

Case E-29/24

EFTA Surveillance Authority

v

Iceland

in which the EFTA Surveillance Authority seeks a declaration that Iceland has failed to adopt the measures necessary to make the Act referred to at point 6 of Annex XVII to the Agreement on the European Economic Area, as adapted by Protocol 1 thereto, part of its internal legal order.

The Government of Iceland has the honour of lodging the following Statement of Defence.

I. Introduction

1. By a letter dated 18 October 2024, the Registrar of the EFTA Court served the Government of Iceland the Application of the EFTA Surveillance Authority (“the Authority”), dated 16 October 2024, which was received by the Court, electronically, on that day.
2. The Authority seeks a declaration from the EFTA Court that Iceland has failed to fulfil its obligations under Article 7 of the Agreement on the European Economic Area (“the EEA Agreement”) by failing to make the Act referred to at point 6 of Annex XVII to the Agreement (*Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products*), as adapted by Protocol 1 thereto, (“the Act”) part of its internal legal order.
3. In the Court’s letter of 18 October 2024, the Government of Iceland was invited, with reference to Article 107 of the Rules of Procedure of the EFTA Court, to lodge a defence within two months from the date of the notification, that is by Wednesday 18 December 2024.

II. Submissions

4. The Government of Iceland submits that the facts of the case, as presented in the Application, are correct and undisputed by the Government. The Government will therefore not dispute the declaration sought by the Authority under Section 5 of the Application.
5. The Government wishes to inform the Court, however, of the state of the implementation of the Act into the Icelandic legal order, which are not reflected in the Authority’s Application.
6. The Act was incorporated into the EEA Agreement by Decision of the EEA Joint Committee No 197/2022 of 10 June 2022 (“the Decision”), which entered into force on 1 February 2023. Pursuant to Paragraph 11 of Protocol 1 to the EEA Agreement, the Act entered into force as a provision of the EEA Agreement from 1 February 2023, which as is stated in paragraph 14 of the Application, was the time limit for the EFTA States to adopt the measures necessary to make the Act part of their internal legal orders.
7. As is stated in the Authority’s reasoned opinion¹, on 20 March 2023, the Government of Iceland notified the Authority that the Act had been made part of Iceland’s legal order, by way of a Form 1 Notification of national measures implementing an act referred to in an Annex or a Protocol to the EEA Agreement.
8. The implementation into the Icelandic legal order was effected by Act No. 57/2021 on the amendment of Act No. 17/1991 on Patents, which was published in Section A of

¹ Document No. 1435876; Annex A.3 to the Application.

the Government Gazette of Iceland on 28 May 2021, and entered into force on 1 July that year. The Act was thereby implemented into the Icelandic legal order prior to the adoption and entry into force of the Decision.

9. As is stated in the Authority's reasoned opinion, while the substantive provisions of the Act had been implemented into the Icelandic legal order, this did not meet the formalistic requirement of Article 7(a) of the EEA Agreement which foresees that regulations "shall as such be made part of the internal legal order of the Contracting Parties". The shortcoming of the Icelandic implementation was therefore that the Act itself was not explicitly referenced in the Icelandic Act No. 17/1991 on Patents.
10. The Government of Iceland has, in communication with the Authority, undertaken to rectify the technical shortcomings of its implementation of the Act so as to fully comply with its obligation under Article 7(a) of the Agreement.
11. A parliamentary bill to complete the transposition of the Act into the Icelandic legal order was included in the Government's Programme of Bills for the 155TH legislative session of Althing, which commenced in September 2024. The bill was to be disseminated in the Althing as Bill No. 255 on 17 October 2024.
12. On 17 October 2024, the day on which the dissemination of the parliamentary bill transposing the Act was scheduled, the President of Iceland announced the dissolution of the Althing and a parliamentary election was held on 30 November 2024. As a result, the submission of the bill completing the implementation of the Act has necessarily been delayed pending the formation of a new Government of Iceland.
13. In light of the foregoing, the Government of Iceland wishes to underscore that, while the formal completion of the implementation of the Act into the Icelandic legal order has not been completed, individuals and undertakings are nevertheless able to enforce the rights and obligations set out therein as a matter of Icelandic law.

III. Conclusion

14. The Government of Iceland does not dispute the declaration sought by the Authority under Section 5 of the Application.
15. The Government, however, wishes to inform the EFTA Court that the Act has been substantively implemented into the Icelandic legal order and, consequently, individuals and undertakings are able to enforce the rights foreseen thereunder throughout the EEA.

For the Government of Iceland,

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Agent

Gunnar Ingi Ágústsson

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