

DECISION OF THE EEA JOINT COMMITTEE
No 88/2018

of 27 April 2018

**amending Annex II (Technical regulations, standards, testing and certification) to the
EEA Agreement**

THE EEA JOINT COMMITTEE,

Having regard to the Agreement on the European Economic Area (“the EEA Agreement”),
and in particular Article 98 thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) 2017/1569 of 23 May 2017 supplementing Regulation (EU) No 536/2014 of the European Parliament and of the Council by specifying principles of and guidelines for good manufacturing practice for investigational medicinal products for human use and arrangements for inspections¹ is to be incorporated into the EEA Agreement.
- (2) Annex II to the EEA Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

The following point is inserted after point 18 (Regulation (EU) No 536/2014 of the European Parliament and of the Council) of Chapter XIII of Annex II to the EEA Agreement:

- ‘18a. **32017 R 1569:** Commission Delegated Regulation (EU) 2017/1569 of 23 May 2017 supplementing Regulation (EU) No 536/2014 of the European Parliament and of the Council by specifying principles of and guidelines for good manufacturing practice for investigational medicinal products for human use and arrangements for inspections (OJ L 238, 16.9.2017, p. 12).

The provisions of the Delegated Regulation shall, for the purposes of this Agreement, be read with the following adaptation:

‘The inspections in Liechtenstein shall be carried out, on behalf of Liechtenstein, by the Swiss inspectorate.’

Article 2

The text of Delegated Regulation (EU) 2017/1569 in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Union*, shall be authentic.

¹ OJ L 238, 16.9.2017, p. 12.

Article 3

This Decision shall enter into force on 28 April 2018, provided that all the notifications under Article 103(1) of the EEA Agreement have been made*.

Article 4

This Decision shall be published in the EEA Section of, and in the EEA Supplement to, the *Official Journal of the European Union*.

Done at Brussels, 27 April 2018.

*For the EEA Joint Committee
The President*

Claude Maerten

*The Secretaries
to the EEA Joint Committee*

Dag Wernø Holter Vaclav Navratil

* [No constitutional requirements indicated.] [Constitutional requirements indicated.]