# **DECISION OF THE EEA JOINT COMMITTEE No 238/2018**

## of 5 December 2018

# amending Annex II (Technical regulations, standards, testing and certification) to the EEA Agreement [2021/1505]

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 Regulation (EU) 2018/781 of 29 May 2018 amending Regulation (EC) No 847/2000 as regards the definition of the concept 'similar medicinal product' (1) 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 is added in point 15n (Commission Regulation (EC) No 847/2000) of Chapter XIII of Annex II to the EEA Agreement:

', as amended by:

— **32018 R 0781**: Commission Regulation (EU) 2018/781 of 29 May 2018 (OJ L 132, 30.5.2018, p. 1).'

#### Article 2

The text of Commission Regulation (EU) 2018/781 in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the Official Journal of the European Union, shall be authentic.

### Article 3

This Decision shall enter into force on 6 December 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, 5 December 2018.

For the EEA Joint Committee
The President
Oda Helen SLETNES

The Secretaries To the EEA Joint Committee Hege M. HOFF Mikołaj KARŁOWSKI

<sup>(1)</sup> OJ L 132, 30.5.2018, p. 1.

<sup>\*</sup> No constitutional requirements indicated.