

DECISIONS

COMMISSION IMPLEMENTING DECISION

of 22 November 2012

establishing a list of third countries with a regulatory framework applicable to active substances for medicinal products for human use and the respective control and enforcement activities ensuring a level of protection of public health equivalent to that in the Union, in accordance with Directive 2001/83/EC of the European Parliament and of the Council

(Text with EEA relevance)

(2012/715/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use ⁽¹⁾, and in particular Article 111b(1) thereof,

Whereas:

(1) In accordance with Article 111b(1) of Directive 2001/83/EC a third country may request the Commission to assess whether its regulatory framework applicable to active substances exported to the Union and the respective control and enforcement activities ensure a level of protection of public health equivalent to that of the Union in order to be included in a list of third countries ensuring an equivalent level of protection of public health.

(2) Switzerland requested, by letter dated 4 April 2012, to be listed in accordance with Article 111b(1) of Directive 2001/83/EC. The equivalence assessment by the

Commission confirmed that the requirements of that Article were fulfilled. In exercising this equivalence assessment, account was taken of the agreement on mutual recognition ⁽²⁾ as referred to in Article 51(2) of that Directive between Switzerland and the Union,

HAS ADOPTED THIS DECISION:

Article 1

The list of third countries referred to in Article 111b(1) of Directive 2001/83/EC is set out in the Annex to this Decision.

Article 2

This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 22 November 2012.

For the Commission
The President

José Manuel BARROSO

⁽¹⁾ OJ L 311, 28.11.2001, p. 67.

⁽²⁾ OJ L 114, 30.4.2002, p. 369.

ANNEX

| Third country | Remarks |
|---------------|---------|
| Switzerland | |