Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems

Article 2

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(1) ‘pharmaceutical product’ means any product of the pharmaceutical sector, including medicinal products as defined in Article 1(2) of 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], active ingredients and diagnostic kits ex vivo;

(2) ‘rights-holder’ means the holder of any patent or supplementary protection certificate in relation to which a compulsory licence has been applied for under this Regulation;

(3) ‘importing country’ means the country to which the pharmaceutical product is to be exported;

(4) ‘competent authority’ for the purposes of Articles 1 to 11, 16 and 17 means any national authority having competence to grant compulsory licences under this Regulation in a given Member State.

(**1**) OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).

Changes to legislation:
There are outstanding changes not yet made to Regulation (EC) No 816/2006 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Signature words omitted by S.I. 2019/801 reg. 50
- Art. 2(4) words substituted by S.I. 2019/801 reg. 39(2)
- Art. 2(5)(6) inserted by S.I. 2019/801 reg. 39(3)
- Art. 5(a) words substituted by S.I. 2019/801 reg. 41(2)
- Art. 5(c) words omitted by S.I. 2019/801 reg. 41(3)