COMMISSION IMPLEMENTING DECISION

of 20.7.2015


(Text with EEA relevance)

(ONLY THE ENGLISH TEXT IS AUTHENTIC)
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THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency¹, and in particular Article 10(2) and Article 82(1) thereof,

Having regard to the application submitted by Bristol-Myers Squibb Pharma EEIG, on 24 September 2014, under Article 4(1) of Regulation (EC) No 726/2004,

Having regard to the opinion of the European Medicines Agency, formulated on 21 May 2015 by the Committee for Medicinal Products for Human Use,

Whereas:


(2) It also complies with the second subparagraph of Article 82(1) of Regulation (EC) 726/2004 in accordance of which more than one application may be submitted when there are objective verifiable reasons relating to public health regarding the availability of medicinal products for health-care professionals and/or patients, or for co-marketing reasons.

(3) It is therefore appropriate to authorise its placing on the market.

(4) The Committee for Medicinal Products for Human Use considered that "nivolumab" was a new active substance at the time of submission of the marketing authorisation application.

(5) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use, HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation provided for in Article 3 of Regulation (EC) No 726/2004 is granted for the medicinal product "Nivolumab BMS - nivolumab", the characteristics of which are summarised in Annex I to this Decision. "Nivolumab BMS - nivolumab" shall be registered in the Community register of medicinal products under number EU/1/15/1026.

Article 2

The marketing authorisation concerning the medicinal product referred to in Article 1 shall be subject to compliance with the conditions set out in Annex II and, in particular, with those relating to manufacture and importation, control and issue.

Article 3

The labelling and package leaflet concerning the medicinal product referred to in Article 1 shall comply with the conditions set out in Annex III.

Article 4

The period of validity of the authorisation shall be five years from the date of notification of this Decision.
Article 5

This Decision is addressed to Bristol-Myers Squibb Pharma EEIG, Uxbridge Business Park, Sanderson Road, Uxbridge UB8 1DH, United Kingdom.

Done at Brussels, 20.7.2015

For the Commission

Ladislav MIKO
Acting Director-General

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION