EUROPEAN
COMMISSION

Brussels, 4.4.2016
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COMMISSION IMPLEMENTING DECISION

of 4.4.2016

concerning, in the framework of Article 29 of Directive 2001/83/EC of the European Parliament and of the Council, the marketing authorisations for "Tobramycin VVB and associated names", medicinal products for human use which contain the active substance "tobramycin"

(Text with EEA relevance)

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(Text with EEA relevance)

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 34(1) thereof,

Having regard to Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products[2], and in particular Article 8(3) thereof,

Having regard to Commission Regulation (EC) No 847/2000 of 27 April 2000 laying down the provisions for implementation of the criteria for for designation of a medicinal product as an orphan medicinal product and definitions of the concepts "similar medicinal product" and "clinical superiority"[3], and in particular Article 3 thereof,

Having regard to the opinion of the European Medicines Agency, formulated on 28 January 2016 by the Committee for Medicinal Products for Human Use, whose opinion was requested on 22 October 2015,

Whereas:

(1) An application for the medicinal product "Tobramycin VVB and associated names" was submitted under the decentralised procedure in accordance with Directive 2001/83/EC.

(2) The medicinal product "Tobramycin VVB and associated names" is similar, within the meaning of Article 3 of Commission Regulation (EC) No 847/2000, to an authorised orphan medicinal product for the same therapeutic indication.

(3) During the decentralised procedure, the Republic of Poland could not approve the granting of a marketing authorisation, on grounds that the data provided by the applicant on clinical superiority was considered insufficient and therefore not acceptable. The Member States did not reach an agreement within the coordination group in accordance with Article 29 of Directive 2001/83/EC, whether the medicinal product "Tobramycin VVB and associated names" fulfils the criteria provided for in

[1] OJ L 311, 28.11.2001, p. 67.
[2] OJ L 18, 22.1.2000, p.1.
[3] OJ L 103, 28.4.2000, p.1.

Article 8(3) of Regulation (EC) No 141/2000 and the Republic of Lithuania referred the matter to the Committee for Medicinal Products for Human Use.

(4) The scientific assessment by the Committee, the conclusions of which are set out in Annex II to this Decision, shows that the objections raised by the objecting Member State should not prevent granting of a marketing authorisation for the medicinal products concerned.

(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 medicinal products referred to in Annex I fulfil the criteria provided for in Article 8(3) of Regulation (EC) No 141/2000 on the basis of the scientific conclusions set out in Annex II.

Article 2

The national marketing authorisations for "Tobramycin VVB and associated names" shall be based on the summary of the product characteristics, the labelling and the package leaflet as agreed during the decentralised procedure.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 4.4.2016

For the Commission
Xavier PRATS MONNE
Director-General

CERTIFIED COPY
For the Secretary-General,

Jordi AYET PUIGARNAU
Director of the Registry
EUROPEAN COMMISSION