EUROPEAN
COMMISSION

Brussels, 10.5.2021
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COMMISSION IMPLEMENTING DECISION

of 10.5.2021

transferring and amending the marketing authorisation granted by Decision C(2001)11 for "Aerius - desloratadine", a medicinal product for human use

(Text with EEA relevance)

(ONLY THE DUTCH 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) No 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 Agency[1],

Having regard to Commission Regulation (EC) No 2141/96 of 7 November 1996 concerning the examination of an application for the transfer of a marketing authorisation for a medicinal product falling within the scope of Council Regulation (EEC) No 2309/93[2], and in particular Article 6 thereof,

Having regard to the application submitted by Merck Sharp & Dohme B.V. on 16 February 2021 under Article 3 of Regulation (EC) No 2141/96,

Having regard to Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products[3], and in particular Article 20(7)(a) thereof,

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[4], and in particular Article 61(3) thereof,

Having regard to the changes to the terms of the decision granting the marketing authorisation requested by Merck Sharp & Dohme B.V. in accordance with Regulation (EC) No 1234/2008 and in accordance with Article 61(3) of Directive 2001/83/EC,

Having regard to the opinion of the European Medicines Agency, formulated on 28 January 2021 by the Committee for Medicinal Products for Human Use,

Having regard to the opinion of the European Medicines Agency, formulated on 17 March 2021 on the transfer of a marketing authorisation,

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1 OJ L 136, 30.4.2004, p. 1.
2 OJ L 286, 8.11.1996, p. 6.
3 OJ L 334, 12.12.2008, p. 7.
4 OJ L 311, 28.11.2001, p. 67.

Whereas:

(1) The medicinal product "Aerius - desloratadine", entered in the Union Register of Medicinal Products under the number EU/1/00/160 and authorised by Commission Decision C(2001)11 of 15 January 2001, remains in compliance with the requirements set out in 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[5] .

(2) A change of holder of the marketing authorisation for which the transfer application is made is a change of an administrative nature, which does not affect the scientific characteristics of the medicinal product already authorised.

(3) It is appropriate to set the date by which all the operations resulting from the transfer of the marketing authorisation must be completed.

(4) The European Medicines Agency's opinion is favourable to the transfer and the variation of the terms of the decision granting the marketing authorisation as submitted by the marketing authorisation holder.

(5) Decision C(2001)11 should therefore be amended accordingly. The Union Register of Medicinal Products should also be updated.

(6) For the sake of clarity and transparency, it is appropriate, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C(2001)11 should therefore be replaced.

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation granted by Decision C(2001)11 of 15 January 2001 to Merck Sharp & Dohme B.V. for the medicinal product "Aerius - desloratadine", entered in the Union Register of Medicinal Products under No EU/1/00/160, is transferred to N.V. Organon.

Article 2

Decision C(2001)11 is amended as follows:

1) Annex I is replaced by the text set out in Annex I to this Decision;

2) Annex II is replaced by the text set out in Annex II to this Decision;

3) Annex III is replaced by the text set out in Annex III to this Decision.

Article 3

1) The transfer referred to in Article 1 shall be authorised from the date of notification of this Decision.

2) All the operations resulting from this transfer must be completed by 8 November 2021 at the latest.

[5] OJ L 311, 28.11.2001, p. 67.

Article 4

This Decision is addressed to:
1. N.V. Organon, Kloosterstraat 6, 5349 AB Oss, Nederland
and
2. Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem, Nederland.

Done at Brussels, 10.5.2021

For the Commission

Sandra GALLINA
Director-General