EUROPEAN
COMMISSION

Brussels, 19.2.2021
C(2021) 1309 final

COMMISSION IMPLEMENTING DECISION

of 19.2.2021

amending Commission Decision C(2019) 2698 of 2 April 2019 concerning, in the framework of Article 31 of Directive 2001/83/EC of the European Parliament and of the Council, the marketing authorisations of medicinal products for human use which contain the active substances “candesartan”, “irbesartan”, “losartan”, “olmesartan”, “valsartan”

(Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION

of 19.2.2021

amending Commission Decision C(2019) 2698 of 2 April 2019 concerning, in the framework of Article 31 of Directive 2001/83/EC of the European Parliament and of the Council, the marketing authorisations of medicinal products for human use which contain the active substances "candesartan", "irbesartan", "losartan", "olmesartan", "valsartan"

(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 the opinion of the European Medicines Agency, formulated on 12 November 2020 by the Committee for Medicinal Products for Human Use,

Whereas:

(1) Medicinal products for human use authorised by the Member States must meet the requirements of Directive 2001/83/EC.

(2) A question has been referred to the European Medicines Agency under Article 31(1) of Directive 2001/83/EC, in a specific case where the interests of the Union are involved, as to whether the marketing authorisation concerned should be maintained, varied, suspended or withdrawn.

(3) On 25 June 2020 the Committee for Medicinal Products for Human Use adopted an assessment report on Nitrosamine impurities in human medicinal products under Article 5(3) of Regulation EC (No) 726/2004. At the request of the European Commission, the impact of this assessment report on the scientific conclusions of Decision (2019)2698 was assessed.

(4) The assessment showed that the scientific conclusions and the conditions for the marketing authorisations concerned should be modified.

(5) The scientific assessment on angiotensin-II-receptor antagonist (sartans) containing a tetrazole group ("candesartan", "irbesartan", "losartan", "olmesartan", "valsartan") performed by the Committee for Medicinal Products for Human Use, the conclusions of which are set out in Annex I to this Decision, shows that, in the interests of the Union, a decision should be taken amending the marketing authorisation for the medicinal product concerned.

(6) This Decision amends Decision C(2019)2698 by amending Annex II accordingly.

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

(7) 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

Decision C(2019)2698 is amended as follows:

Annex II shall be replaced by the text set out in Annex II to this Decision.

Article 2

The Member States concerned shall subject the national marketing authorisations for the medicinal products which contain the active substances "candesartan", "irbesartan", "losartan", "olmesartan", "valsartan" to the conditions identified in Annex II on the basis of the scientific conclusions set out in Annex I.

Article 3

The Member States shall take account of the scientific conclusions set out in Annex I for the assessment of the efficacy and safety of medicinal products containing other "sartans".

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 19.2.2021

For the Commission

Sandra GALLINA
Director-General

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION