EUROPEAN
COMMISSION

Brussels, 8.8.2022
C(2022) 5859 final

COMMISSION IMPLEMENTING DECISION

of 8.8.2022

amending the conditional marketing authorisation granted by Decision C(2021) 698(final) for "Vaxzevria - COVID-19 Vaccine (ChAdOx1-S [recombinant])", a medicinal product for human use

(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) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[1], and in particular Article 10 and 28 thereof,

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[2],

Having regard to the changes to the terms of the decision granting the marketing authorisation requested by AstraZeneca AB in accordance with Regulation (EC) No 1234/2008,

Having regard to the opinion of the European Medicines Agency, formulated on 21 July 2022 by the Committee for Medicinal Products for Human Use on the periodic safety update report for this medicinal product,

Having regard to the opinions of the European Medicines Agency, formulated on 23 June 2022 and on 21 July 2022 by the Committee for Medicinal Products for Human Use,

Whereas:

(1) The placing on the market of the medicinal product "Vaxzevria - COVID-19 Vaccine (ChAdOx1-S [recombinant])" was authorised by Commission Decision C(2021) 698(final) of 29 January 2021.

(2) The marketing authorisation holder submitted a periodic safety update report for this medicinal product. This report was assessed by the Pharmacovigilance Risk Assessment Committee as to whether the marketing authorisation concerned should be maintained, varied, suspended or withdrawn.

(3) The scientific assessment performed by the Committee for Medicinal Products for Human Use, the conclusions of which are set out in Annex IV to this Decision, shows

[1] OJ L 136, 30.4.2004, p. 1.
[2] OJ L 334, 12.12.2008, p. 7.

that a decision should be taken amending the marketing authorisation for the medicinal product concerned.

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

(5) Decision C(2021) 698(final) 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(2021) 698(final) should therefore be replaced.

(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(2021) 698(final) 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 2

This Decision is addressed to AstraZeneca AB, 151 85 Södertälje, Sverige.

Done at Brussels, 8.8.2022

For the Commission

Sandra GALLINA
Director-General

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION