



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 February 2025
EMA/CHMP/564741/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Abrysvo

respiratory syncytial virus vaccine (bivalent, recombinant)

On 27 February 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending a change to the terms of the marketing authorisation for the medicinal product Abrysvo. The marketing authorisation holder for this medicinal product is Pfizer Europe MA EEIG.

The CHMP adopted an extension to the existing indication to extend the use of Abrysvo to adults from 18 years of age. The full indications for Abrysvo will therefore be as follows:²

Abrysvo is indicated for:

- Passive protection against lower respiratory tract disease caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age following maternal immunisation during pregnancy. See sections 4.2 and 5.1.
- Active immunisation of individuals **18 to** ~~60~~ years of age and older for the prevention of lower respiratory tract disease caused by RSV.

The use of this vaccine should be in accordance with official recommendations.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

² New text in bold, removed text as strikethrough

