20 July 2023
EMA/CHMP/327338/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Abrysvo

Respiratory Syncytial Virus (RSV) vaccine (bivalent, recombinant)

On 20 July 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Abrysvo, intended for the prevention of lower respiratory tract (LRT) disease caused by respiratory syncytial virus (RSV). Abrysvo was reviewed under EMA's accelerated assessment programme. The applicant for this medicinal product is Pfizer Europe MA EEIG.

Abrysvo will be available as a powder and solvent to be made into a solution for injection. The active substances of Abrysvo are two recombinant stabilised RSV prefusion F antigens representing the subgroups RSV-A and RSV-B (ATC code: J07BX05). Abrysvo induces the production of specific antibodies against the prefusion F protein, which inhibits RSV infection and thereby protects against RSV-associated LRT disease.

The benefit of Abrysvo is the prevention of RSV-confirmed lower respiratory tract disease. The most common side effects are injection site pain, myalgia and headache.

The full indication is:

> 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 60 years of age and older for the prevention of lower respiratory tract disease caused by RSV.
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> 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 summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been

[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

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