EDA Assessment Report for Biological Medicinal Product

(Scientific Discussion)

Abrysvo

Date: November 2024

Unit: Technical Assessment Unit

Assessment report

Abrysvo

Administrative information:

Trade name of the medicinal product:	Abrysvo
INN (or common name) of the active substance(s):	RSV subgroup A stabilised prefusion F antigen 60 ug/ml; RSV subgroup B stabilised prefusion F antigen 60 ug/ml;
Manufacturer of the finished product	Pfizer Manufacturing Belgium NV Rijksweg 12 2870 Puurs-Sint-Amands - BELGIUM
Marketing Authorization holder	Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 Bruxelles, - BELGIUM
Applied Indication(s):	1.Passive protection against lower respiratory tract disease caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age following maternal immunization during pregnancy. 2.Active immunization of individuals 60 years of age and older for the prevention of lower respiratory tract disease caused by RSV
Pharmaceutical form(s) and strength(s):	-Powder and Solvent for Solution for injection -Strength: 60 ug/ml
Route of administration	I.M injection
Approved pack	**Powder** :Powder for 1 dose in a vial (type 1 glass or equivalent) with a stopper (synthetic

	chlorobutyl rubber) and a flip off cap **Solvent** :Solvent for 1 dose in a pre-filled syringe (type 1 glass) with a stopper (synthetic chlorobutyl rubber) and a tip cap (synthetic isoprene/bromobutyl blend rubber)Vial adaptor Sterile vial adaptor. **Pack size** :Pack containing 1 vial of powder, 1 pre-filled syringe of solvent, 1 vial adaptor with 1 needle

List of abbreviations:

RSV	respiratory syncytial virus
FP	finished product
Al[OH]3	aluminum hydroxide
RSVpreF	respiratory syncytial virus prefusion F vaccine

Dossier initial submission and evaluation process:

- The product was submitted for registration via reliance level 1
- The dossier was initially received by the registration administration units on 11.8.2024 after providing all the required documents according to Preliminary checklist (EMA Assessment with Full CTD for the product)

1. **'General introduction about the product including brief description of the AI, its mode of action and indications**:

-The active substance of Abrysvo has been developed by Wyeth BioPharma Division of Wyeth Pharmaceuticals LLC 1 Burtt Road Andover, MA 01810 - UNITED STATES OF AMERICA
-The finished product (FP) is a a sterile lyophilized powder for injection that consists of equal amounts of two stabilized drug substance antigens, 847A and 847B.
- The product is available in The lyophilized drug product is presented in a 2 mL clear glass vial sealed with a stopper and an aluminum over seal with flip-off plastic cap.
-Abrysvo is intended for the treatment of Passive protection against lower respiratory tract disease caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age following maternal immunization during pregnancy.

And Active immunization of individuals 60 years of age and older for the prevention of lower respiratory tract disease caused by RSV

2. **Quality aspects:**

- **Manufacturer(s):**

-The active substance is performed at Wyeth BioPharma Division of Wyeth Pharmaceuticals LLC 1 Burtt Road Andover, MA 01810 - UNITED STATES OF AMERICA.
- drug product manufacture is performed at Pfizer Manufacturing Belgium NV Rijksweg 12 2870 Puurs-Sint-Amands – BELGIUM.

- **Stability**

Drug substance:

Approved Shelf Life: Diluent: 36 months **847A DS:**24 months **847B DS:** 24 months
Approved Storage Conditions:
847A DS:
Store at -40°C ± 10°C
847B DS:
Store at -40°C ± 10°C
Drug product:
Approved Shelf Life: 30 months
Approved Storage Conditions:
-Store in a refrigerator (2ºC - 8ºC).
-Do not freeze. Discard if the carton has been frozen.
-The unopened vial is stable for 5 days when stored at temperatures from (8-30°C). At the end of this period Abrysvo should be used or discarded.

3. **Non-clinical aspect and clinical aspect**

-the final clinical formulation selected for pivotal efficacy studies was RSVpreF 120 µg without $Al(OH)_3$, based on clinical safety and immunogenicity data and this is acceptable.Overall, Abrysvo is acceptable from the non-clinical point of view.

-In conclusion the overall benefit/risk of abrysvo is favorable in the treatment of of Passive protection against lower respiratory tract disease caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age following maternal immunization during pregnancy.
And Active immunization of individuals 60 years of age and older for the prevention of lower respiratory tract disease caused by RSV

- **General Conclusion and Recommendations if any:**
  Based on the review of CTD modules and other supplementary documents, the product is approved.

  For more information, please visit EMA published assessment report link:
  https://www.ema.europa.eu/en/medicines/human/EPAR/abrysvo