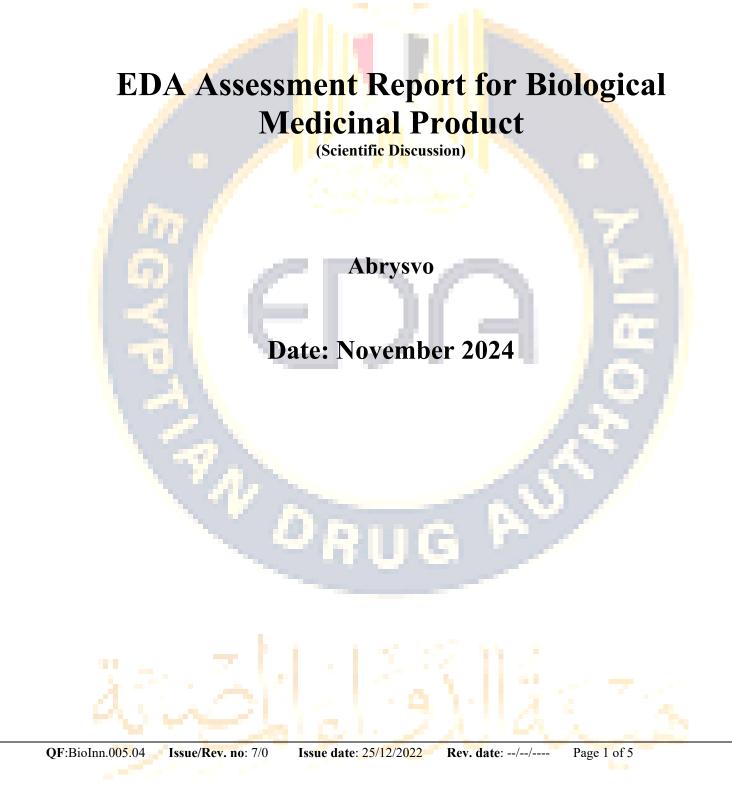
> GA of Biological Products Administration of Registration



جمهورية مصر العربية هيئة الدواء المصرية الإدارة المركزية للمستحضرات الحيوية والمبتكرة والدراسات الإكلينيكية الإدارة العامة للمستحضرات الحيوية إدارة التسجيل



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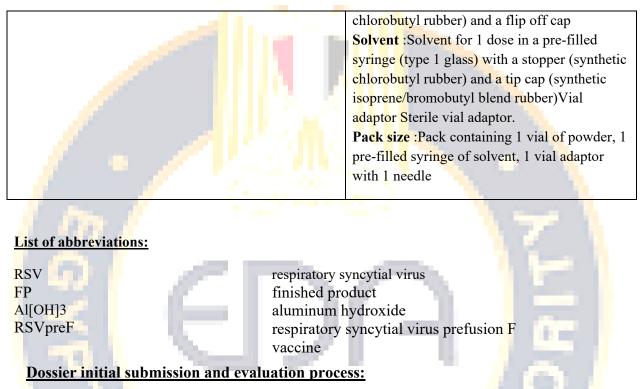
	Unit: Technical Assessment U
Assessment report	
Abrysvo	
Administrative information:	
Trad <mark>e n</mark> ame of the medicinal product:	Abrysvo
INN (or common name) of the active	RSV subgroup A stabilised prefusion F
substance(s):	antigen 60 ug/ml;
61	RSV subgroup B stabilised prefusion F
	antigen 60 ug/ml;
	and the second sec
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):	<ul> <li>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.</li> <li>2.Active immunization of individuals 60 years of age and older for the prevention of lower respiratory tract disease caused by RSV</li> </ul>
Pharmaceutical form(s) and strength(s):	-Powder and Solvent for Solution for injection -Strength: 60 ug/ml
Route of administration	I.M injection
	- 1
Approved pack	<b>Powder</b> : Powder for 1 dose in a vial (type 1
	glass or equivalent) with a stopper (synthetic

**QF**:BioInn.005.04 **Issue/Rev. no**: 7/0 **Issue date**: 25/12/2022 **Rev. date**: --/--/---- Page 2 of 5

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- 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. <u>'General introduction about the product including brief description of the AI, its mode</u> 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.

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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

### <u>Drug substance:</u>

Approved Shelf Life: <u>Diluent:</u> 36 months <u>847A DS</u>:24 months <u>847B DS</u>: 24 months Approved Storage Conditions:

847A DS:

# Store at -40°C ± 10°C

<u>847B DS:</u>

Store at -40°C ± 10°C

#### Drug product:

Approved Shelf Life: 30 months

## Approved Storage Conditions:

-Store in a refrigerator (2°C - 8°C).

-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)<sub>3</sub>, 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

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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: <u>https://www.ema.europa.eu/en/medicines/human/EPAR/abrysvo</u>

