Pfizer Limited
Walton Oaks, Dorking Road, Walton on the Hill,
Tadworth, Surrey KT20 7NS, UK
Telephone: +44 (0)1304 616161

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[PRIVATE & CONFIDENTIAL]

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

This information is applicable to Healthcare Professionals based in Northern Ireland only

Abrysvo ®▼ powder and solvent for solution for injection (respiratory syncytial virus vaccine (bivalent, recombinant)): Change of Marketing authority from EMA to MHRA in effect from 1st January 2025 resulting in change to Posology for pregnant individuals

Dear Healthcare Professional,

Summary: From the 1st January 2025, there will be a change in Northern Ireland to the licensed Posology for Abrysvo from administration to pregnant individuals between 24-36 weeks to administration to pregnant individuals between 28-36 weeks gestation to protect infants from birth through to six months of age through maternal immunisation. There are no other significant changes to the licensed use of Abrysvo.

From the 1st January 2025, Medicines and Vaccines supplied in Northern Ireland will be licensed by the MHRA. This is a change from the current, European Medicines Agency (EMA) license as per the Windsor framework.

Currently Abrysvo®▼(respiratory syncytial virus vaccine (bivalent, recombinant)) in supply in Northern Ireland is licensed by the EMA and the indications are as follows:

Up until 31st December 2024 Abrysvo in Northern Ireland will follow the licensing under EMA 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.

With the posology as **Given as a single dose of 0.5 mL which should be administered between weeks 24 and 36 of gestation.**

Active immunisation of individuals 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.

From the 1st January 2025 the indication will be as follows:

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. **Given as a single dose of 0.5 mL which should be administered between weeks 28 and 36 of gestation**
- Active immunisation of individuals 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.

This is in accordance with the UK Summary of Product Characteristics, which can be found here: https://www.medicines.org.uk/emc/product/15309/smpc#gref

Healthcare professionals in Northern Ireland are required to adhere to the updated licensed requirements and adapt their clinical practice accordingly.

In the Great Britain and Northern Ireland, National Immunisation Programmes are led by guidance that has been agreed by UKHSA and the NHS. There will be no changes to this guidance associated with the changes outlined above. The guidance for the National Immunisation Programme for Northern Ireland already stipulates that it should be given from 28 weeks gestation in pregnant individuals: https://www.publichealth.hscni.net/sites/default/files/2024-09/RSV%20Maternal%20Factsheet%20for%20Healthcare%20Professionals%20A4%2009_24.pdf

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

- Abrysvo▼ is subject to additional monitoring. This will allow quick identification of new safety information
- Please report ANY suspected adverse drug reactions (ADRs) to drugs and vaccines identified by the black triangle▼ to the MHRA through the Yellow Card Scheme.

The non-identical nature of biological medicines and vaccines means it is very important that safety surveillance is carried out on a brand/product-specific basis. When reporting a suspected ADR to a biological medicine (such as blood products, antibodies and advanced therapies [such as gene and tissue therapy]) or vaccine, please ensure that you provide the brand name (or product licence number and manufacturer), and the specific batch-number.

Additionally, when providing patients with details of the vaccine or biological medicine administered, it is good practice to give them details of the brand and batch number. This will allow patients and carers to more accurately report suspected ADRs to the Yellow Card scheme.

Company contact point
If you have any questions about this letter or require more information about ABRYSVO, please contact PFIZER UK Medical Information at Medical Information | Pfizer Medical Information - UK or telephone 01304 616161.

Yours faithfully,

DocuSigned by:
Ellsbury, Gillian Frances
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Gillian Ellsbury
Primary Care Medical Director UK
Pfizer Ltd.