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(來函請敍明此檔案號碼) DH DO DIMC/7-30/1
(IN REPLY PLEASE QUOTE THIS FILE REF.)

8 Jan 2025

Dear Healthcare Professionals,

FDA requires Guillain-Barré Syndrome (GBS) warning in the prescribing information for RSV Vaccines Abrysvo and Arexvy

Your attention is drawn to the United States Food and Drug Administration's (FDA) announcement that it has required and approved safety labeling changes to the Prescribing Information for Abrysvo (Respiratory Syncytial Virus Vaccine) manufactured by Pfizer Inc. and Arexvy (Respiratory Syncytial Virus Vaccine, Adjuvanted) manufactured by GlaxoSmithKline Biologicals. The Prescribing Information for each Respiratory Syncytial Virus (RSV) vaccine has been revised to include the following language in the Warnings and Precautions section:

- Abrysvo: The results of a postmarketing observational study suggest an increased risk of Guillain-Barré syndrome (GBS) during the 42 days following vaccination with Abrysvo.
- Arexvy: The results of a postmarketing observational study suggest an increased risk of Guillain-Barré syndrome during the 42 days following vaccination with Arexvy.

GBS is a rare disorder in which the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis.

Abrysvo was initially approved on May 31, 2023, for the prevention of lower respiratory tract disease (LRTD) caused by RSV in individuals 60 years of age and older. Subsequently, FDA has approved the vaccine for the prevention of LRTD caused by RSV in individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV; immunization of pregnant individuals at 32 through 36 weeks gestational age for the prevention of LRTD and severe LRTD caused by RSV in infants from birth through 6 months of age.

Arexvy was initially approved on May 3, 2023, for the prevention of LRTD caused by RSV in individuals 60 years of age and older. Subsequently, FDA has approved the vaccine for use in

individuals 50 through 59 years of age who are at increased risk for LRTD caused by RSV.

FDA conducted a postmarketing observational study that assessed the risk of GBS following vaccination with Abrysvo and Arexvy. Based on FDA's evaluation of data from clinical trials, reports to the Vaccine Adverse Event Reporting System (VAERS), and the postmarketing study, FDA has determined that the overall body of evidence suggests increased risks of GBS with Abrysvo and Arexvy, but that available evidence is insufficient to establish a causal relationship.

The association between vaccination with Abrysvo and Arexvy and GBS was evaluated among Medicare beneficiaries 65 years of age and older. Using Medicare claims data, between May 2023 through July 2024, vaccinations with Abrysvo and Arexvy were identified through Current Procedural Terminology (CPT)/Healthcare Common Procedure Coding System (HCPCS) codes and National Drug Codes, and potential cases of hospitalized GBS among recipients of Abrysvo and Arexvy were identified through International Classification of Diseases (ICD) codes. GBS diagnoses in claims data were confirmed by medical record review when available.

The risks of GBS following vaccination with Abrysvo and Arexvy were assessed in self-controlled case series analyses using risk windows of 1 to 42 days post vaccination and control windows of 43 to 90 days post vaccination. The analyses of all GBS cases based on claims data suggest an increased risk of GBS during the 42 days following vaccination, with an estimated 9 excess cases of GBS per million doses of Abrysvo, and an estimated 7 excess cases of GBS per million doses of Arexvy administered to individuals 65 years of age and older. Background risks of GBS in study populations influence excess GBS case estimates and may differ between studies and analyses within a study, precluding direct comparisons of excess GBS case estimates from other vaccine studies or populations.

While the results from the self-controlled case series analyses of this observational study suggest increased risks of GBS with Abrysvo and Arexvy, available evidence is insufficient to establish a causal relationship.

FDA has required and approved safety labeling changes to the Prescribing Information for Abrysvo and Arexvy based on the totality of data from clinical trials, reports to VAERS, and the results of self-controlled case series analyses in an observational study conducted by FDA that suggest increased risks of GBS with Abrysvo and Arexvy. FDA has further determined that the benefits of vaccination with Abrysvo and Arexvy continue to outweigh their risks.

Please refer to the following website in FDA for details:
https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-requires-guillain-barre-syndrome-gbs-warning-prescribing-information-rsv-vaccines-abrysvo-and

In Hong Kong, Abrysvo Vaccine Powder And Solvent For Solution For Injection (HK-68213) and Arexvy Vaccine Powder And Suspension For Suspension For Injection (HK-67997) are pharmaceutical

products registered by Pfizer Corporation Hong Kong Limited and GlaxoSmithKline Limited respectively. Both are prescription-only medicines. So far, the Department of Health (DH) has received one case of adverse event following immunisation with Arexvy, but this case was not related to GBS. The DH has not received any case of adverse event following immunisation with Abrysvo. In light of the above FDA's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

Please note that this letter serves as a means for the DH to communicate important new safety information about registered pharmaceutical products with healthcare professionals in Hong Kong and is not intended to serve as guidelines or to replace professional clinical judgement. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Clinical Trials and Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": http://www.drugoffice.gov.hk/adr.html. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,

p.p. (Terence MAN)
for Assistant Director (Drug)