衞生署藥物辦公室
藥物資訊及警戒科
香港九龍觀塘巧明街 100 號
Landmark East 友邦九龍大樓
20 樓 2002-05 室

電話號碼 Tel. No.: 3974 4175
詢問處 Enquiries: (852) 3974 4175
傳真號碼 Faxline No.: (852) 2803 4962
本署檔號 OUR REF.:

DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG INFORMATION AND PHARMACOVIGILANCE DIVISION
Suites 2002-05, 20/F, AIA Kowloon Tower,
Landmark East, 100 How Ming Street,
Kwun Tong, Kowloon, Hong Kong

(來函請敍明此檔案號碼) DH DO PRIE/7-30/15
(IN REPLY PLEASE QUOTE THIS FILE REF.)

25 Mar 2021

Dear Healthcare Professionals,

FDA requires a warning about Guillain-Barré Syndrome (GBS) be included in the Prescribing Information for Shingrix

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 Shingrix (Zoster Vaccine Recombinant, Adjuvanted) to include a new warning about the risk for Guillain-Barré Syndrome (GBS) following administration of Shingrix. FDA required GlaxoSmithKline (GSK), the manufacturer of Shingrix, to revise the Prescribing Information to include the following language in the Warnings and Precautions section:

- In a postmarketing observational study, an increased risk of GBS was observed during the 42 days following vaccination with Shingrix.

FDA evaluated data from a postmarketing observational study that assessed the risk of GBS following vaccination with Shingrix. Based on this evaluation, FDA has determined that the results of this observational study show an association of GBS with Shingrix, but that available evidence is insufficient to establish a causal relationship.

The Centers for Disease Control and Prevention (CDC) conducted postmarketing safety surveillance of Shingrix in the Vaccine Safety Datalink (VSD) by monitoring prespecified adverse events, including GBS, among individuals 50 years of age and older who received Shingrix. The VSD analyses identified a preliminary statistical signal suggesting an increased risk of GBS among individuals who received Shingrix compared to a historical control group of individuals who had received Zostavax (Zoster Vaccine Live), another FDA-approved vaccine for the prevention of shingles. To evaluate this statistical signal, FDA, the Centers for Medicare & Medicaid Services (CMS), and CDC investigated GBS risk following administration of Shingrix in the Medicare claims database. This is the largest postmarket study evaluating GBS risk following vaccination with Shingrix.

The association between vaccination with Shingrix and GBS was evaluated among Medicare beneficiaries aged 65 years or older. Using Medicare claims data, from Oct 2017 through Feb 2020, 3,729,863 vaccinations with Shingrix (administered to 2,113,758 Medicare beneficiaries) were identified through National Drug Codes, and potential cases of hospitalized GBS among recipients of Shingrix were identified through International Classification of Diseases codes.

The risk of GBS following vaccination with Shingrix was assessed in self-controlled case series analyses using a risk window of 1 to 42 days post-vaccination and a control window of 43 to 183 days post-vaccination. The primary analysis (claims-based, all doses) found an increased risk of GBS during the 42 days following vaccination with Shingrix, with an estimated 3 excess cases of GBS per million doses administered to adults aged 65 years or older. In secondary analyses, an increased risk of GBS was observed during the 42 days following the first dose of Shingrix, with an estimated 6 excess cases of GBS per million doses administered to adults aged 65 years or older, and no increased risk of GBS was observed following the second dose of Shingrix. These analyses of GBS diagnoses in claims data were supported by analyses of GBS cases confirmed by medical record review.

FDA evaluated data from the above study, and based on this evaluation, FDA has determined that the results of this observational study show an association of GBS with Shingrix, but that available evidence is insufficient to establish a causal relationship. FDA has concluded that revision to the Warnings and Precautions section of the Prescribing Information for Shingrix to include a warning about GBS is warranted. FDA has determined that the benefits of vaccination with Shingrix continue to outweigh its risks.

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

In Hong Kong, Shingrix Vaccine Powder And Suspension For Suspension For Injection (HK-66840) is a pharmaceutical product registered by GlaxoSmithKline Limited, and is a prescription-only medicine. So far, the Department of Health (DH) has not received any case of adverse drug reaction related to Shingrix. In light of the above FDA's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board. 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 Undesirable Medical Advertisements and Adverse Drug Reaction 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,

(Joseph LEE)
for Assistant Director (Drug)