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12 July 2024

To: Director General of the Jordan Food and Drug Administration (JFDA)
Shafa Badran - Marj AlFaras- Saad Juma Street, Building No. 10
Amman - Jordan P.O Box /Zip Code: 811951/11181 Amman - Jordan

Safety Notification: Risk of myelitis and Hepatitis B surface antigen recombinant vaccine – updated information (update July 2024).

Dear Sir,

GSK would like to share with you a safety notification relating to TGA (Australian HA), SAPHRA (South Africa HA), JFDA (Jordan HA), TMDA (Tanzania HA), The National Drug Authority (Uganda HA) and Saudi FDA communications regarding Risk of myelitis. The announcement relates to the Hepatitis B surface antigen recombinant vaccine.
In Jordan, Hepatitis B surface antigen recombinant vaccine is registered under the trade names of Engerix-B 10 µg dose vaccine (Paediatric) and 20 µg dose vaccine (Adult).

Summary of Communication:

TGA's assessment concluded that there are sufficient grounds to update the PIs for all hepatitis B surface antigen recombinant vaccines to inform health professionals of the potential risk of myelitis including transverse myelitis.

22-Jan-2024: This direct communication received in response of GSK communications relating Engerix-B. Jordan HA (JFDA) requested to submit an application to update Engerix leaflet.

08-Feb-2024: This direct communication from Tanzania HA received in response of GSK communications relating Engerix-B and myelitis. TMDA asked to include information in the next RMP and PBRER

12-Feb-2024: The National Drug Authority (Uganda) advised GSK via direct communication that they would like to make their own assessment of the Engerix-B and Myelitis signal. They have requested additional information from TGA assessment and evidence supporting the company's position.

14-Mar-24: GSK received notification from SAPHRA (South Africa HA) regarding Engerix Professional Information (PI)/Patient Information Leaflet (PIL) update to include the risk of myelitis and transverse myelitis.

06-May-24: GSK received a label update request for Engerix B from the Saudi Arabia HA (SFDA) concerning "transvers

05-Jul-24: SAPHRA request to update the PI/PIL of Engerix-B vaccine, to include the risk of myelitis and transverse myelitis in alignment with the TGA.

New/ongoing/closed signal:
Refuted signal.

Company Position:
21-Dec-23: A signal assessment has been performed with following conclusion: ‘Considering the inconsistency of disproportionality analysis with other sources of data examined, the available evidence does not support an increased risk of Myelitis including Transverse Myelitis after vaccination with ENGERIX-B. Based on the available information, the signal is considered refuted. No labelling changes to GDS are proposed.‘
RTQ was submitted in time on the 18th of December to the Australian TGA.

05-Jan-24: Company position updated to comply with the requested update of the Australian label. A response has been drafted and will be submitted by the due date. As per process, information on this signal assessment will be included in all upcoming periodic reports for the product (PBRERs and DSURs). No labelling changes to GDS are proposed.

22-Jan-2024: Company position updated to comply with this repeated request and update the Australian SmPC, however maintained its position that the update of the GDS is not required as based on the completed signal assessment the available evidence does not support an increased risk of Myelitis including Transverse Myelitis after vaccination with Engerix-B. Therefore, no labelling update is planned in Belgium, which is a reference market of Jordan.

06-May-24: Company’s position remains the same on this matter: the available evidence does not support an increased risk of myelitis.
’Considering the inconsistency of disproportionality analysis with other sources of data examined, the available evidence does not support an increased risk of Myelitis including Transverse Myelitis after vaccination with ENGERIX-B. Based on the available information, the signal is considered refuted. No labelling changes to GDS are proposed’

18-Jun-24: Saudi Arabian PI will be updated to comply with HA request. No labelling changes to GDS are proposed: ’Considering the inconsistency of disproportionality analysis with other sources of data examined, the available evidence does not support an increased risk of Myelitis including Transverse

Myelitis after vaccination with ENGERIX-B. Based on the available information, the signal is considered refuted.

08-Jul-24: No changes in the company position. A country labeling difference will be created to comply with the Regulator's request.

For further information or any Human Safety Information reporting (HSI), please contact the pm.Safety@gsk.com

Yours sincerely,

Nawal Alila
Partner Markets Medical Director

Electronically signed by: Nawal Alila
Reason: I am signing for the reasons as stated in the document.
Date: Jul 12, 2024 15:45 GMT+1