

FDA/HPT/SMC/SMD/VGU/22/0106

21st February 2022

Dear Healthcare Professional,

Important Safety Information

**VERY RARE CASES OF TRANSVERSE MYELITIS WITH OXFORD/ASTRAZENECA
COVID-19 VACCINE AND COVID-19 VACCINE JANSSEN**

The Food and Drugs Authority (FDA) wishes to bring to your notice that it has followed closely and reviewed information on few reports from Europe, of very rare cases of transverse myelitis (TM) reported following vaccination with Oxford/AstraZeneca COVID-19 Vaccine (Vaxzevria) or COVID-19 Vaccine Janssen. Here in Ghana, no cases of TM following vaccination with either of the two vaccines have been received by the FDA.

TM is a rare neurological condition characterized by an inflammation of one or both sides of the spinal cord. It can cause weakness in the arms or legs, sensory symptoms (such as tingling, numbness, pain or loss of pain sensation) or problems with bladder or bowel function.

After extensive in-depth review and assessment of available information the FDA's Joint COVID-19 Vaccine Safety Review Committee (JCVSRC) concluded that a causal relationship between these two vaccines and TM is at least a reasonable possibility but the benefits of using the Vaxzevria and COVID-19 Vaccine Janssen far outweigh the potential risk of TM.

Although, no reports of TM were received in Ghana, the FDA would like to advise health care professionals to closely monitor persons vaccinated with Vaxzevria or COVID-19 Vaccine Janssen and ask them to seek immediate medical attention if they develop any of the underlisted symptoms after vaccination:

- weakness in the arms or legs, sensory symptoms (such as tingling, numbness, pain or loss of pain sensation).
- problems with bladder or bowel.

Page 1 of 2



The FDA would also like to advice patients and healthcare professionals to report adverse reactions to all products including COVID-19 vaccines through the following:

- Download and complete the Med Safety App (Google Play Store or App Store)
- Complete and submit the report online at <http://adr.fdaghana.gov.gh/patient.php>;
- Call Mobile No. 024 4310 297
- Call Hot line No. 0308250070
- Download and complete the ADR and AEFI Form, then submit it at the nearest health facility

Yours faithfully,



SETH K. SEANEKE (MR.)
DCEO, HEALTH PRODUCTS AND TECHNOLOGIES DIVISION
FOR: CHIEF EXECUTIVE OFFICER