



MEDICINES CONTROL AGENCY

54 Kairaba Avenue, Pipeline, P.O. BOX 3162, The Gambia. Tel. no. +220 4380632, Website: www.mca.gm.

12th April 2023

Dear Healthcare Professional,

We are writing to inform you of a potential safety issue with the Janssen COVID-19 vaccine (Ad26.COV2.S) which has been granted an Emergency Use Authorization.

The Medicines Control Agency was informed by company Janssen of an increase in the risk for myocarditis and pericarditis following vaccination of the Janssen COVID-19 vaccine. This adverse event was reported to particularly occur in younger males under the age of 40 in the first two weeks following vaccination, with the highest risk at 7 days.

As a precautionary measure, we advise you to exercise caution when administering Ad26.COV2.S vaccine to patients who are at increased risk for pericarditis and particularly younger males under the age of 40 years.

The potential Impact to Public Health of this disease and consistency of data justifies adding it as a safety concern for the vaccine, as an Important Identified Risk in the Risk Management Plan.

We strongly recommend that you closely monitor your patients for signs of pericarditis after administration of the vaccine. If you do observe any concerning symptoms, we encourage you to report them as soon as possible, to MCA office/ Qcell toll free 1233 / telephone number 3363068.

As always, we appreciate your efforts to ensure the safe and effective use of vaccine in your patients.

Approved by:

Markieu Janneh Kaira

Executive Director

Medicines Control Agency, The Gambia.

