DRUG NATIONAL AUTHORITY

Safe Drugs Save Lives

376/NDA/DPS/04/2018

27th April 2018

CIRCULAR NO. 13

To Health Care Workers

Hepatitis B Vaccination for Adults

The NDA, through its vigilance discovered falsified Hepatitis B Vaccine manufactured by the Serum Institute of India. While the regulatory investigations and actions proceed, the NDA wishes to issue this circular to health workers in all vaccination centers to remind them about their role in vaccine safety.

Healthcare providers have an important role in vaccine safety by ensuring that vaccines are stored, handled and administered properly. They are also to manage, document and report any adverse events following immunization to the National Drug Authority. It is the responsibility of the health worker to share information about the vaccines including the side effects to the patient.

Hepatitis B Vaccine is contraindicated in people who have had an allergic reaction in the past to this vaccine. There is a chance of side effects with any medicine, including vaccines. In some cases, Hepatitis B Vaccine causes mild reactions that last up to a few days, these include fever and soreness at the site of injection. Severe reactions are extremely rare for example allergic reactions which are characterized by hives, difficulty in breathing, a fast heartbeat, dizziness, and weakness.

NDA recommends that health workers;

1. Advise patients who receive the hepatitis B vaccine to report to a health worker if they experience any signs of allergic reactions or any other side effects.
2. Manage any adverse reactions that patients experience following vaccination appropriately.
3. Report any side effects that patients experience after receiving Hepatitis B vaccination and (or) any other vaccines/medicines, to National Drug Authority by email to druginfo@nda.or.ug or Tel 0414-255665 or Whatsapp 0791415555 or by completing the Adverse Drug Reaction form or AEFI form and returning it to any NDA office.

Private health facilities which wish to be accredited to provide the Hepatitis B vaccination should apply for accreditation in writing to the nearest National Drug Authority offices.

Thank you for your continued cooperation.

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OUR MISSION
Promoting and protecting public health through the effective regulation of human and animal medicines and healthcare products

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