



THE REPUBLIC OF UGANDA

MINISTRY OF HEALTH

**PRESS STATEMENT ON SUSPECTED FALSIFIED HEPATITIS B VACCINE
ON THE MARKET**

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STATE MINISTER OF HEALTH – GENERAL DUTIES

18th March 2018

PRESS STATEMENT ON FALSIFIED HEPATITIS B VACCINE ON THE MARKET

The Ministry of Health wishes to inform the public that the National Drug Authority (NDA) during its routine post-marketing surveillance encountered falsified Hepatitis B vaccines from eight health facilities in Mbarara, Mbale, Wakiso and Kampala districts.

These facilities are; Mbarara Community Hospital, Divine mercy, Mayanja Memorial, Family Doctors clinic Ntungamo, Mbarara City clinic, UMC Hospital Bukoto, Malcolm Health care Kisaasi, and Kampala Medical Chambers Buganda Road.

Hepatitis B Vaccine is administered to healthy people to immunize them against Hepatitis B disease.

There are a number of registered brands for Hepatitis B Vaccine for supply to Uganda from various manufacturers worldwide represented by local pharmaceutical companies

- Biological E represented by Gittoes
- Glaxo SmithKline represented by Eris Ltd
- Human Biologicals Institute represented by TATA (U)
- LG Life sciences, Sanofi Pasteur & Pasteur Merieux represented by Laborex
- Serum Institute of India represented by Norvik Enterprises
- Shantha Biotec represented by Laborex

The brand that has been falsified is from Serum Institute of India.

The vaccines from the Company are available in two registered pack sizes i.e. 1 ml vial and 10 ml multi-dose vials.

The 1 ml vial is supplied to the private market and is identified by a white label with two green bands at the top and bottom part of the label, respectively.

The 10 ml multi-dose vial is supplied to the public (Government) sector and is identified by a white label with two purple bands at the top and bottom part of the label, respectively. The vial supplied to Public Health Facilities also bears the words, “**Government of Uganda, Not for sale**”.

The genuine 10ml vial of Hepatitis B vaccine imported from Serum Institute of India has the following features:

- Batch number
- Manufacturing and expiry dates with a shelf life of 3 yearsm
- Two purple bands (top and bottom) on the label
- Only available in Government health facilities and bears the mark “**Government of Uganda, Not for Sale.**”

The available information, however, shows that all eight facilities named above, found with the suspected falsified Hepatitis B vaccines bought them from unlicensed dealers with fake addresses on the invoices and receipts. For instance, Kumate Diagnostics Ltd -Kampala, Forever Green Enterprises Old - Kampala

Some suspects have been arrested and are currently under police custody to assist with investigations while others have recorded statements at the respective police stations.

Ministry of Health is carrying out the following measures to curb the supply of falsified Hepatitis B vaccines;

1. NDA has been instructed to:
 - a. Recall the 10ml vial of Hepatitis B vaccine from Serum Institute of India from all private facilities (hospitals, clinics, pharmacies)
 - b. Test the falsified products to establish the contents of the vaccine

2. The general public is encouraged to receive Hepatitis B vaccination from only the accredited private facilities and Government Health Facilities as investigations into the matter take course.
3. The private health facilities that have been cleared to provide the Hep B Vaccine are: Nsambya Hospital, Kibuli Hospital, Mengo Hospital, Rubaga Hospital, International Hospital Kampala (IHK), Norvik Hospital, Case Hospital and Nakasero Hospital
4. We shall advise the public on other facilities that have been cleared for Hepatitis B vaccination in two weeks.
5. The Ministry of Health has suspended vaccination camps for Hepatitis B by private providers until cleared by the Ministry of Health. DHOs and RDCs are instructed to ensure that this directive is complied with.
6. Immunization of children as part of the routine ***Pentavalent*** vaccine will continue

The Ministry of Health appeals to the general public to:

1. Be vigilant and provide any information about suspicious Hepatitis B Vaccine
2. Report any camps for Hepatitis B Vaccine being organized in your community
3. Please refrain from purchasing drugs from unlicensed suppliers

UPDATE ON HEPATITIS B SITUATION IN UGANDA

According to the Uganda Population-based HIV Impact Assessment Survey (UPHIA), the prevalence of Hepatitis B infection among adults in Uganda stands at 4.3% (5.6% among men and 3.1% among women). Hepatitis B prevalence was highest in Northern region with 4.6% in mid North, 4.4% in North East and 3.8% in West Nile. Hepatitis B infection

was lower in the rest of the country with a range of 0.8% in South West region to 2.7% in East Central region.

The Ministry of Health started the vaccination of adolescents and adults against Hepatitis B virus disease in 2015. This vaccination program was officially launched by H.E the President on the 25th July 2015 in Ngora District.

The Testing and vaccination plan was divided into four phases, in order of prevalence, to be implemented over a period of four years.

We have so far covered 39 districts in West Nile, Acholi, Lango, Karamoja and Teso Sub Regions. The vaccination exercise is now ongoing in Busoga region and will cover Bukedi and Bugisu sub regions.

The Ministry of Health remains committed to ensuring that Ugandan people receive safe, efficacious and good quality medicines.

In case of any inquiries or additional information, please contact us on our Toll free number **0800-100-066**.

I thank you

FOR GOD AND MY COUNTRY

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