গণপ্রজাতন্ত্রী বাংলাদেশ সরকার
ঔষধ প্রশাসন অধিদপ্তর
মহাখালী
ঢাকা-১২১২
www.dgda.gov.bd
একই স্মারক ও তারিখ দ্বারা প্রতিস্থাপিত

নং-ডিজিডিএ/এলার্ট-নোটিশ-০১/২০১৭/৭৫১৭ তারিখঃ ২৭/০৩/২০১৮

বরাবর

1. DG, Directorate General of Health Services.
2. Director, EPI.
3. Director, CMSD.
4. Secretary General, Bangladesh Society of Medicine, Dept. of Medicine, Dhaka Medical College, Dhaka.
5. Secretary General, Bangladesh Medical Associatrion (BMA), BMA Vabon, 15/2 Topkhana Road, Dhaka.
6. Secretary General, Bangladesh Paedriatic Association (BPA), Plot#7/3C, Barabag. sec#2, Mirpur, Dhaka-1216.
7. Secretary General, BAPI.

বিষয়ঃ বিশ্ব স্বাস্থ্য সংস্থা (WHO) মেডিক্যাল প্রোডাক্ট এলার্ট N° 3/2018 প্রসঙ্গে।

বিশ্ব স্বাস্থ্য সংস্থা (WHO) সম্প্রতি মেডিক্যাল প্রোডাক্ট এলার্ট N° 3/2018- এ এই মর্মে সতর্ক করেছে যে, Serum Institute of India কর্তৃক উৎপাদিত Multi dose (10 ml) Hepatitis B Vaccines (rDNA), নামীয় নিম্নোক্ত ১০ (দশ) টি ব্যাচের ভ্যাক্সিন Uganda এর বাজারে নকল (Falsified) হিসেবে পাওয়া গেছে। (সংযুক্ত কপিতে রঙ্গিন ছবি সহ টেবুলেটেড ফর্মে বিস্তারিত উল্লেখ করা আছে)।

Batch No	Manufacturing Date	Expiary Date
035L6010	May, 2016	April, 2019
035L5010	None indicated	Sep, 2019
035L006	Mar, 2016	Feb, 2020
035L3004	May, 2015	Sep, 2018
035L5012	None indicated	Oct, 2018
035L7037	Oct, 2017	Sep, 2020
035L6005	None indicated	Sep, 2019
035L5013	Nov, 2017	Jan, 2020
035L5017	None indicated	Oct, 2019
035L5007	None indicated	July, 2018

এমতাবস্থায়, Serum Institute of India কর্তৃক উৎপাদিত Multi dose (10 ml) Hepatitis B Vaccines (rDNA) নামীয় উল্লিখিত ১০ (দশ) টি ব্যাচের ভ্যাক্সিন ব্যবহার থেকে বিরত থাকার জন্য এবং এতদ্বসংক্রান্ত বিষয়ে প্রয়োজনীয় ব্যবস্থা গ্রহণের জন্য অনুরোধ করা হল।

সংযুক্তিঃ ০২ (দুই) পাতা।

২৭/০৩/২০১৮
নাসরীন সুলতানা
পরিচালক (চঃদাঃ)
ঔষধ প্রশাসন অধিদপ্তর
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Ref. RHT/SAV/Alert_n3.2018

23 March 2018

Medical Product Alert N°3 /2018
Falsified Hepatitis B Vaccines circulating in Uganda

This Medical Product Alert relates to falsified versions of Multi dose (10ml) Hepatitis B Vaccines (rDNA) that have been identified in Uganda and recently reported to WHO.

This vaccine is used to prevent infection by Hepatitis B virus (HBV) and is a WHO prequalified product in its genuine version manufactured by the Serum Institute of India Pvt. Ltd.

HBV is a potentially life-threatening viral infection that attacks the liver and can cause both acute and chronic disease. HBV is a major global health problem. WHO recommends that all infants receive the vaccine as soon as possible after birth.

WHO was recently informed by the Uganda National Drug Authority (NDA) that this falsified vaccine was available at patient level in a number of locations in the Central, South-Western and Eastern regions in Uganda. Investigations are ongoing and samples are currently being collected for full laboratory analysis. The source(s) of the falsified product has not yet been identified.

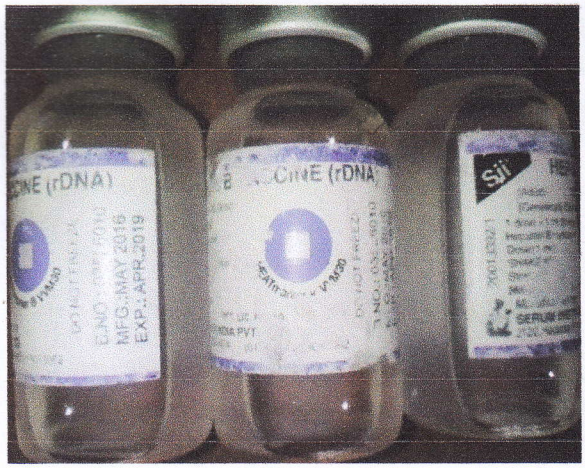
It should be noted that:

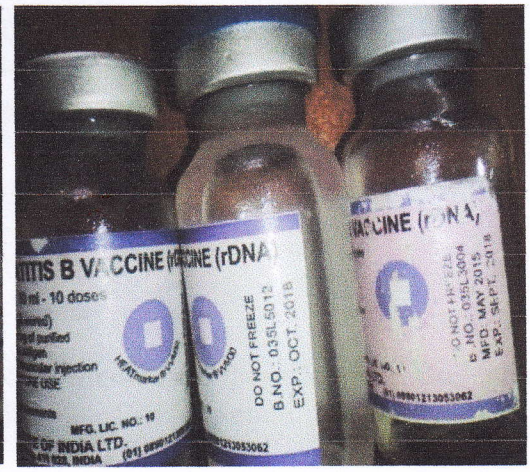
- The stated manufacturer has confirmed the below products are falsified based on label inconsistencies;
- There have been no known adverse reactions reported to WHO at this stage.

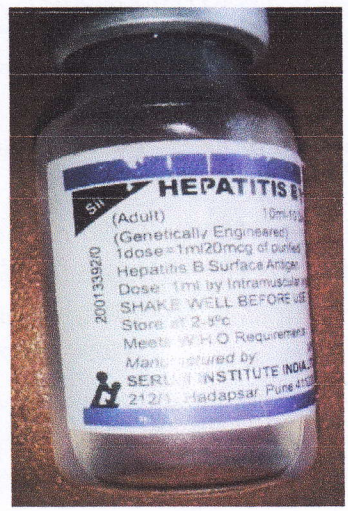
Falsified versions of 10 different batch numbers have so far been discovered and are listed below. Available photographs of the falsified products are shown on the next page.

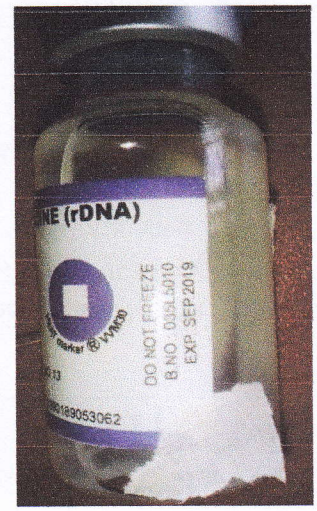
Product Name	**Multi dose (10ml) Hepatitis B Vaccines (rDNA)**	
Stated manufacturer	**Serum Institute of India**	
Batch number	***Manufacturing date***	***Expiry Date***
035L6010	MAY 2016	APR. 2019
035L5010	*None indicated*	SEP . 2019
035L006	MAR. 2016	FEB. 2020
035L3004	MAY 2015	SEPT. 2018
035L5012	*None indicated*	OCT .2018
035L7037	10/2017	09/2020
035L6005	*None indicated*	09/2019
035L5013	11/2017	01/2020
035L5017	*None indicated*	Oct 2019
035L5007	*None indicated*	07/2018

PHOTOGRAPHS OF THE FALSIFIED MULTI DOSE (10ML) HEPATITIS B VACCINES (rDNA)









WHO requests increased vigilance within the supply chains of countries likely to be affected by this falsified product. Increased vigilance should include hospitals, clinics, health centres, wholesalers, distributors, pharmacies and any other suppliers of medical products.

If you are in possession of the above product, please do not use. If you have taken this falsified product, or if you suffer an adverse event having taken this product, please seek immediate advice from a qualified healthcare professional, and report the incident to your local Ministry of Health/National Medicines Regulatory Authorities/National Pharmacovigilance Centre.

All medical products must be obtained from authentic and reliable sources. Their authenticity and condition should be carefully checked. Seek advice from a healthcare professional if case of doubt.

National health authorities are asked to immediately notify WHO if this falsified product is discovered in their country. If you have any information concerning the manufacture, distribution, or supply of these products, please contact rapidalert@who.int

WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products

For further information, please visit our website: http://www.who.int/medicines/regulation/ssffc/en/
To sign up for WHO Medical Product Alerts, please visit: http://www.who.int/about/licensing/rss/en/