



## SAFETY ALERT

DRAP ALERT NO. 09

### HIGHER THAN NORMAL INCIDENCE OF AGGREGATION IN LIQUID PENTAVALENT VACCINE (LPV), ALTHOUGH, VACCINE POTENCY AND SAFETY UNAFFECTED: **WHO RECOMMENDS CONTINUED VACCINATION**

**Date:** February 11, 2020

#### **Target Audience:**

- Extended Program on Immunization (EPI) Staff
- Healthcare Professionals- Physicians, Pharmacists, Nurses and Vaccinators

#### **Problem or Issue:**

World Health Organization has informed that higher than normal incidence of white sticky aggregates found in some batches of the pentavalent vaccine manufactured by Biological E. Limited India. Only lots of the single dose presentation have been impacted that fail to resuspend upon shaking.

Liquid pentavalent Diphtheria-Tetanus-Pertussis (whole cell)-Hepatitis B-Haemophilus influenzae type b vaccine (LPV) is presented as a suspension which needs to be shaken before use to ensure a homogenous turbid white suspension. The instructions for use state that the vaccine should be visually inspected for any foreign particulate matter and/or variation for physical aspect prior to administration. Failing that, the vials should be discarded.

No adverse events following immunization with the use of LPV have been reported to WHO. Recent clinical studies using this vaccine as a comparator did not raise safety or efficacy concerns. Following thorough investigation and independent testing, WHO confirms that the safety and efficacy profiles of the vaccine remain unchanged. Accordingly, revaccination is not recommended. WHO recommends continued vaccination with unaffected vials of the vaccine.

#### **Product affected:**

Name: **DTwP-rHepB-Hib Vaccine**

Manufacturer: **Biological E.India**

#### **Action to be taken/ Advice for Healthcare Professionals:-**

EPI and Healthcare Professionals who are administering vaccines are requested to check stock for this problem and should follow the instructions for use stated as:

- I. the vaccine requires to be shaken before use to ensure a homogenous turbid white suspension;
- I. the vaccine should be visually inspected for any foreign particulate matter and/or variation for physical aspect prior to administration;
- II. the vials should be discarded if any foreign particulate matter and/or variation appeared.





### Advice to Healthcare Professionals:-

All vaccine must be carefully administered following the instructions of use and their physical aspects should be checked.

If the patient was administered the vaccine with higher than normal incidence of aggregation and has suffered an adverse event or an unexpected event, he/she should immediately seek the advice from a qualified healthcare professional, and ensure that events shall be reported to **Pakistan National Pharmacovigilance Centre**, Drug Regulatory Authority of Pakistan through **DRAP Med Vigilance e-reporting system** [http://: https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PK](http://https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PK) or at [npc@dra.gov.pk](mailto:npc@dra.gov.pk).

