Explanation of Bio Farma with regard to Counterfeit Vaccine

■Bandung, June 30, 2016, 10.00 Local Time

In response to arising news related to suspected counterfeit vaccine, below is Bio Farma's explanation:

- 1. Bio Farma has coordinated with the National Police's Criminal Investigation Agency (Bareskrim), Ministry of Health, the Drug and Food Monitoring Agency (BPOM) and authorized Distributor of Bio Farma Vaccine.
- 2. Based on physical, packaging and result of latoratory test observation, the suspected counterfeit vaccine is **ORIGINAL**, **NOT COUNTERFEITED**.
- 3. Vaccines produced by Bio Farma used by the Government for National Immunization Program are Pentabio (DTP-HB-Hib), DT, Td, TT, Hepatitis B, Measles, Polio and BCG Vaccines. In ensuring safety, efficacy, and quality of vaccines, all vaccines produced by Bio Farma are tested for Release from the Drug and Food Monitoring Agency, Badan POM and in compliance with the standards of the World Health Organization (WHO).
- 4. The community is encouraged not to have doubt to have their children immunized using vaccines as programmed by the Government, either at Hospital, Community Health Center, neighbourhood health center, or clinic.
- 5. Vaccine is distributed in formal distribution channel. Bio Farma Vaccine for national immunization program is distributed via Provincial Health Offices and, for private sector, distributed via authorized distributor by implementing consistent cold chain and Good Distribution Practice (CDOB) thus the quality, safety and effectiveness are maintained.
- 6. Bio Farma fully supports Bareskrim POLRI for further handling and investigation of counterfeit vaccine case.
- 7. As an anticipation and evaluation measure to prevent dissemination of counterfeit vaccine, each healthcare facility and immunization center of the Government and private sector should have management and control facility for vaccine waste/ used vaccine container or expired vaccine.
- 8. For serum and diagnostic products produced by Bio Farma such as BIOSAT (Anti-Tetanus Serum), BIOSAVE (Anti-Snake Venom Serum), and Tuberculin PPD that are counterfeited, are currently handled by Bareskrim POLRI.

Overview of Bio Farma

Bio Farma is a State-Owned Enterprise that is 100% owned by the Government, a Vaccine and Antisera manufacturer. Established on August 6, 1890. During 126 years of its establishment, Bio Farma has contributed to improve the quality of the people's lives, both residing in Indonesia and overseas. More than 130 countries have used Bio Farma products, primarily developing countries, and 50 of them are countries united in the Organization of Islamic Cooperation (OKI). The production of Bio Farma Vaccines has met standard established by The National Agency of Drug and Food Control (BPOM) and the World Health Organization (WHO). This production is in compliance with a series of very strict regulation, from selection of raw material originated from qualified vendor, raw material storing, production process, production facility and competence of Human Resources that must be qualified and well trained and the equipment must be calibrated and validated regularly within specific period. With production capacity more than 3.2 Billion doses

annually, Bio Farma has fulfilled the need for vaccine nationally and internationally via WHO and UNICEF. Under the Dedicated to Improve Quality of Life philosophy, Bio Farma plays active role in improving the availability and production self-sufficiency of Vaccine for developing countries and Islamic countries in maintaining Global Health Security. For further information, go to www.biofarma.co.id

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