Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2016-087

16 AUG 2016

TO : ALL HOSPITALS, HEALTH FACILITIES, DRUG ESTABLISHMENTS AND HEALTHCARE PROFESSIONALS

SUBJECT: Switch from trivalent Oral Polio Vaccines (tOPV) to bivalent OPV (bOPV) as part of the Polio Endgame Strategy

---

In May 2012, the World Health Assembly declared the completion of poliovirus eradication to be a "programmatic emergency for global public health" and called on the Director General of the World Health Organization (WHO) to develop a comprehensive polio endgame strategy. The Global Polio Eradication Initiative's Polio Eradication and Endgame Strategic Plan 2013-2018, approved by the Executive Board of the WHO in January 2013, requires the removal of all oral polio vaccines (OPVs) in a phased manner, from both routine programmes and campaigns, to minimize the risk of new polio cases. This Endgame Strategic Plan aims to complete the interruption of wild poliovirus transmission globally and more rapidly detect and interrupt any new outbreaks due to vaccine-derived polioviruses.

In line with this, the Department of Health (DOH) issued Department Memorandum (DM) No. 2016-0146 entitled "Guidelines on the Disposal of the Remaining trivalent Oral Polio Vaccines (tOPV)", which states that ***"All health facilities nationwide should stop using tOPV and dispose remaining stocks of tOPV after the designated switch day on 27 April 2016 to avoid re-emergence of circulating vaccine-derived polioviruses type 2. Ongoing use of tOPV after the switch day may threaten or postpone the global eradication of polio."*** This answers for the first phase of the OPV removal.

In support of this initiative, the Food and Drug Administration (FDA) hereby informs all concerned personnel that the Certificates of Product Registration (CPRs) of the following tOPVs have been cancelled:

Reg. No.	Generic Name	Brand Name	Manufacturer	Importer	Validity of CPR
BR-101	Live Attenuated Trivalent Oral Polio Vaccine (Sabin Strains)	Polioral Trivalent Vaccine	Novartis Vaccines and Diagnostics S.r.l.	Novartis Healthcare Phils., Inc.	08 November 2016
BR-832	Live Attenuated Trivalent Oral Polio Vaccine	Opvero	Sanofi Pasteur, S.A.	Sanofi Pasteur, Inc.	09 September 2016

BR-505	Oral Poliomyelitis Vaccine Type 1,2,3	Opvero	Sanofi Pasteur, S.A.	Sanofi Pasteur, Inc.	01 August 2017
BR-847	Live Attenuated Trivalent Oral Polio Vaccine	–	PT Biofarma (Indonesia)	Euro Pharma Inc.	20 February 2017

The withdrawal from the market of the abovementioned vaccines have already started. In this regard, the FDA hereby requests all concerned to stop prescribing, dispensing, and using any tOPV.

In the interest of protecting public health and safety, the Officers of the Field Regulatory Operations Office (FROO) are hereby mandated to exercise their regulatory function pursuant to Section 14 of Republic Act No. 9711.

For more information and inquiries, please e-mail us at info@fda.gov.ph or call at telephone number (02) 807-8275.

Dissemination of the information to all concerned is requested.

MARIA LOURDES C. SANTIAGO, MSc, MM
Officer-in-Charge, Director General

DTN: 20160616134020