Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2017-101

29 MAR 2017

TO: **ALL HEALTH FACILITIES, DRUG ESTABLISHMENTS AND HEALTHCARE PROFESSIONALS (PARTICULARLY GENERAL PRACTITIONERS & PEDIATRICIANS)**

SUBJECT: **Reiteration of FDA Advisory No. 2016-087 entitled "Switch from trivalent Oral Polio Vaccines (tOPV) to bivalent OPV (bOPV) as part of the Polio Endgame Strategy"**

On 16 August 2016, the Food and Drug Administration (FDA) released FDA Advisory No. 2016-087 in line with the Department of Health (DOH) issued Department Memorandum (DM) No. 2016-0146 which required the removal, cessation of use and disposal of all tOPV to avoid re-emergence of circulating vaccine-derived polioviruses type 2 which may threaten or postpone the global eradication of polio from the continued utilization of these tOPV in the Philippines.

This advisory is to reiterate to all concerned that the Certificates of Product Registration (CPRs) of the following tOPV have been cancelled. The following products are no longer authorized to be marketed or administered to the consuming public:

REG. NO.	GENERIC NAME	BRAND NAME	MANU-FACTURER	IMPOR-TER
BR-101	Live Attenuated Trivalent Oral Polio Vaccine (Sabin Strains)	Polioral Trivalent Vaccine	Novartis Vaccines and Diagnostics S.r.l.	Novartis Healthcare Phils., Inc.
BR-832	Live Attenuated Trivalent Oral Polio Vaccine	Opvero	Sanofi Pasteur, S.A.	Sanofi Pasteur, Inc.
BR-505	Oral Poliomyelitis Vaccine Type 1, 2 ,3	Opvero	Sanofi Pasteur, S.A.	Sanofi Pasteur, Inc.
BR-847	Live Attenuated Trivalent Oral Polio Vaccine	–	PT Biofarma (Indonesia)	Euro Pharma, Inc.

Violators of the said directive shall be given appropriate sanctions by this Office and by partner agencies. The public is advised to inform us at **www.fda.gov.ph/ereport**, or e-mail us at **report@fda.gov.ph** or call us at telephone number **(02) 809-5596** regarding violations of this advisory.

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