DUPLICATE

GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH
MINISTRY OF HEALTH & FAMILY WELFARE
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
AUSHAD BHAVAN, MOHAKHALI, DHAKA-1212, BANGLADESH
CERTIFICATE OF REGISTRATION

We hereby declare that **Imovax Polio, Poliomyelitis vaccine (Inactivated)** manufactured by **Sanofi Pasteur, Parc Industriel d'Incarville 27100 Val de Reuil France,** Marketing Authorization Holder (MAH) M/S. **Sanofi Pasteur, 14 Espace Henry Vallee, 69007 Lyon, France** and represented by **M/s. Sanofi Bangladesh Limited, Station Road, Tongi, Gazipur-1710, Bangladesh** is registered with Directorate General of Drug Administration and Licensing Authority (Drugs) under Reg. No. **102-3978-05**. The drug as described below is allowed to be imported into Bangladesh under **The Drugs Act. 1940 (XXIII of 1940), The Drug (control) Ordinance, 1982** and The Drug (Control) (Amendment) Act, 2006 subjected to the provision of import policy published by Government from time to time.

Name of the Product : **Imovax Polio,** Poliomyelitis vaccine (Inactivated)
Dosage Form : Suspension for Injection
Packing : 0.5ml of Suspension, in Pre-filled syringe (glass), 1 dose

Composition: (Amount(s) per unit dose): Each 0.5ml dose of Imovax Polio contains-

Name of ingredients	Specification	Quantity
Active Ingredient:		
Inactivated Poliovirus type 1	Ph. Eur.	40 antigen D units
Inactivated Poliovirus type 2	Ph. Eur.	8 antigen D units
Inactivated Poliovirus type 3	Ph. Eur.	32 antigen D units
Excipients:		
2 phenoxyethanol	Ph. Eur.	2-3 µl
Formaldehyde	Ph. Eur.	2-20 µg
Medium 199, Water for injection		Up to 0.5 ml
Hydrochloride acid or sodium hydroxide for pH adjustment		

Registration Date: 27-01-2005
Validity: 24-01-2020

Instructions
To be dispensed only by or on the prescription of a registered physician.

Major General Md. Mustafizur Rahman
Director General
Directorate General of Drug Administration
&
Licensing Authority (Drugs)
Government of the People's Republic of Bangladesh
06 MAY 2019

Conditions:
(1) Labeling should be done in accordance with the provision of the Drugs Act and Rules which require that the name and address of the manufacturer, batch number, manufacturing date, expire date, M.R.P. (Maximum Retail Price) DAR No. (Drug Administration Reg. Number) etc. should be displayed on the label or container and also on the outer cover containing the container
(2). The registration will be valid for 5 (five) years from its date of issue unless it is revoked, suspended or cancelled earlier.
(3). The certificate will be treated as cancelled if any violation of conditions and the name or the formula of this product is changed or modified qualitatively or quantitatively without approval of the Licensing Authority.

Memo. No. DA /15-5/102/97/684

Date 27/01/2005

c.c. to: M/S. Sanofi Bangladesh Limited
Station Road, Tongi, Gazipur
Contact: 6/2/A, Segun Bagicha, Dhaka-1000, Bangladesh.

For Director General
Directorate General of Drug Administration

MINISTRY OF HEALTH & FAMILY WELFARE ★ GOVT. OF PEOPLES REPUBLIC OF BANGLADESH ★ DIRECTORATE GENERAL OF DRUG ADMINISTRATION ★ DHAKA

This Registration shall remain valid up to 24-01-2025 unless it is suspended Cancelled or revoked earlier.

08.07.2019

Mohammad Mozammel Hossain
Assistant Director
Directorate General of Drug Administration
&
Licensing Authority (Drugs)
Government of the People's Republic of Bangladesh