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 **Avaxim 80U Pediatric,** manufactured by **Sanofi Pasteur, 1541 Avenue Marcel Merieux, 69280 Marcy l'Etoile, 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. **102-3931-2004**. 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 : **Avaxim 80U Pediatric**
Dosage Form : **Suspension for injection**
Packing : **0.5ml of suspension, in pre-filled syringe (glass), 1 dose**

Composition (Amount(s) per unit dose)

Name of ingredients	Specification	Quantity
Active Ingredient:		
Inactivated Hepatitis A virus	**Ph. Eur.**	**80 antigen units**
Excipients:		
Aluminum Hydroxide	**Ph. Eur.**	**0.3 mg**
2 phenoxyethanol	**Ph. Eur.**	**2.5 µl**
Formaldehyde	**Ph. Eur.**	**12.5ml**
Hanks Medium 199	**Ph. Eur.**	**Upto 0.5 ml**
Hydrochloride acid or sodium hydroxide for pH adjustment		

Registration Date: 22-06-2004
Validity: 19-06-2019

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/ 4979 Date 22/06/2004

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

MINISTRY OF HEALTH & FAMILY WELFARE ★ DIRECTORATE GENERAL OF DRUG ADMINISTRATION ★ PEOPLE'S REPUBLIC OF BANGLADESH DHAKA

For Director General,
Directorate General of Drug Administration

This Registration shall remain valid up to 19-06-2024 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