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 **Vaxigrip suspension for injection in pre-filled syringe** 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. **102-4474-10.** 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 : **Vaxigrip**
Dosage Form : **Suspension for Injection in Pre-filled syringe**
Pack Size : **Pre-filled syringe (0.5ml) with attached needle - box of 1**

Composition:

	Name of ingredients	Specification	Quantity
A	**Active Ingredient**		
	A/Michigan/45/2015 (H1N1)pdm09-like strain	Ph. Eur.	15 µg of HA
	A/Singapore/INFIMH-16-0019/2016 (H3N2)-like strain	Ph. Eur.	15 µg of HA
	B/Phuket/3073/2013-like strain	Ph. Eur.	15 µg of HA
B	**Excipient(s) (composition of PBS solution- for 1000ml)**		
	Buffered saline solution (pH 7.2)		
	Sodium Chloride	In-house	8.00g
	Potassium Chloride	In-house	0.20g
	Disodium Phosphate dihydrate	In-house	1.15g
	Potassium dihydrogen phosphate	In-house	0.20g
	Water for Injections (WFI)	In-house	Upto 1000ml

Registration Date: 16-02-2010
Validity: 15-02-2020

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 /15-5/102/97/1980

Date 16/02/2019

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

09/07/2019

For Director General,
Directorate General of Drug Administration

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

This Registration shall remain valid up to 15-02-2025 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