GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH
MINISTRY OF HEALTH & FAMILY WELFARE
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
105-106, MOTIJHEEL COMMERCIAL AREA, DHAKA-1000

CERTIFICATE OF REGISTRATION

We hereby declare that **Vaxigrip Enfants Suspension for Injection in Pre-filled Syring** manufactured by M/S. **Sanofi Pasteur SA, Siege Mondial, 2, avenue pont Pasteur, F-69007 Lyon, France** and represented by M/s. **Sanofi ~~-aventis~~ Bangladesh Limited, ~~6/2/A, Segun Bagicha, Dhaka-1000~~** Station Road, Tongi, Gazipur **Bangladesh** is registered with Directorate General of Drug Administration and Licensing Authority (Drugs) under Reg. No. 102-4732-012 The drug as described below is allowed to be imported into Bangladesh under **The Drugs Act 1940 (XXIII of 1940), The Drugs (Control) Ordinance, 1982** and The Drug (Control) (Amendment) Act, 2006 subjected to the provision of import policy published by the Government from time to time.

Name of the Product	:	**Vaxigrip Enfants**
Dosage Form	:	**Suspension for Injection in Pre-filled Syring**
Pack Size	:	1 Syringe 1 dose

Composition : Each 0.25ml contains:

	Name of ingredients	Specification	Quantity
A.)	**Active ingredient**		
	A/California/7/2009(H1N1)-derived Strain Used ~~NYMC X-179A~~ A/Hong Kong/4801/2014(H3N2)-like virus	Ph.Eur	7.5 Micrograms HA**
	~~A/Perth/16/2009 (H3N2)-Like strain used NYMC X-187 Derived from A/Victoria/210/2009~~	Ph.Eur	7.5 Micrograms HA**
	B/Brisbane/60/2008 - like virus	Ph.Eur	7.5 Micrograms HA** Per 0.25ml dose
B)	**Excipients:**		
	Saline buffer Solution	In-house	qs 0.25ml
	Formula of the saline solution buffered pH 7.2 (PBS)	In-house	
	Sodium Chloride	In-house	8.00gm
	Potassium Chloride	In-house	0.20gm
	Disodium phosphate dihydrate	In-house	1.15gm
	Potassium dihydrogen phosphate	In-house	0.20gm
	Water for Injection	In-house	q.s 1000ml

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

Major General Md Abul Kalam Azad
Director General
Directorate General of Drug Administration
&
Licensing authority (Drugs)
Government of the People's Republic of Bangladesh

23 JAN 2012

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, expiry date, M.R.P. (Maximum Retail Price), DAR No. (Drug Administration Reg. Number) etc. should be displayed on the label of the 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 the conditions and the name or the formula of this product is changed or modified qualitatively or quantitatively without due approval of the Licensing Authority.

Memo No. DA 15-5/102/97/ 1649 Date: 02/02/2012

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

Mustafa 31/1/12
For Director General ,
Directorate General of Drug Administration