

**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 Syringe** 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, 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 Syringe**  
**Pack Size** : **1 Syringe 1 dose**

**Composition** : Each 0.25ml contains:

<u>Name of ingredients</u>	<u>Specification</u>	<u>Quantity</u>
A.) <b>Active ingredient</b>		
A/California/7/2009(H1N1)-derived Strain Used NYMC X-179A <i>Spn. dm09 like virus</i>	Ph.Eur	7.5 Micrograms HA**
A/Hong Kong/4801/2014(H3N2)- <i>Like virus</i>	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 - <i>Like virus</i>	Ph.Eur	7.5 Micrograms HA**
		Per 0.25ml dose
B) <b>Excipients:</b>		
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

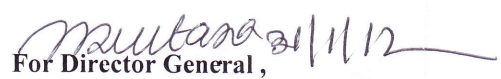
**Conditions:**

- (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.*

  
 For Director General,  
 Directorate General of Drug Administration