GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH
MINISTRY OF HEALTH AND FAMILY WELFARE
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
105-106, Motijheel Commercial Area, Dhaka.

CERTIFICATE OF REGISTRATION

We hereby declare that **PNEUMO-23** manufactured by **M/s. sanofi pasteur SA 2, avenue Pont Pasteur 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 (Drug) under Registration No 102-4473-10 The drug as described below is allowed to be imported into Bangladesh under **The Drugs Act. 1940 (XXIII of 1940)** and Drug (control) Ordinance 1982 subject to the provision of import policy published by Government from time to time. MM 1/4/13

Name of the Product	:	**PNEUMO-23** Pneumococcal Polysaccharide Vaccine.
Dosage Form	:	**Solution for Injection in prefilled syringe.**
Pack Size	:	**Solution for Injection in a prefilled syringe - 0.5ml -box of 1.**

Composition: For one 0.5 ml dose.

Ingredient(s)	**Specification**	**Quantity**
A. Active Ingredient(s)		
Purified capsular polysaccharides of ***Streptococcus pneumoniae***: 1,2,3,4,5,6B,7F,8,9N,9V,10A,11A,12F,14,15B,17F,18C,19A,19F,20,22F,23F,33F For each of the 23 serotypes	Ph. Eur	25µg
B. Excipient(s)		
Phenolated buffered solution containing		
Phenol	Ph.Eur	≤1.250mg
Sodium chloride	Ph.Eur	4.150mg
Dihydrate Disodium Phosphate	Ph.Eur	0.065mg
Dihydrate monosodium Phosphate	Ph.Eur	0.023mg
Water for Injection	Ph.Eur	Qs 0.5ml

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

16 FEB 2010

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

Conditions

(1) Labeling should contain name and address of the manufacturer, batch number, manufacturing date, expire date, M.R.P. (Maximum Retail Price) DAR No. (Drug Administration Registration Number) etc. should be displayed on the label or container and also on the outer cover containing the container.

(4) The registration will be valid for 05(five) years from the date of issue unless it is revoked, suspended or cancelled earlier.

(5) The certificate will be treated as cancelled if any violation of conditions and the name or the formula of this product changed or modified qualitatively or quantitatively without approval of the Licensing Authority.

Memo. No.DA/ 15-5/102/97/ 1979 Date 23/02/10

For Director General
Directorate General of Drug Administration

C.C. M/S. Sanofi-~~aventis~~ Bangladesh Limited
6/2/A, Segun Bagicha, Dhaka-1000,
→ Station Road, Tongi, Gazipur
MM 1/4/13

This Registration shall remain valid
up to 15-02-2020 unless it is suspended
Cancelled or revoked earlier.

Md. Salahuddin
16.04.15

Md. Salahuddin
Assistant Director
For Director General
Directorate General of Drug Administration
&
Licensing Authority (Drugs)
Government of the People's Republic of Bangladesh