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

DIRECTORATE OF DRUG ADMINISTRATION ★ MINISTRY OF HEALTH & FAMILY WELFARE ★ DHAKA

CERTIFICATE OF REGISTRATION

We hereby declare that **TETRAct-HIB** 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 MW 1/9/13 **Bangladesh** is registered with Directorate of Drug Administration and Licensing Authority (Drug) under Registration No. 102-4418-09. 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.

Name of the Product	:	**TETRAct-HIB** (Act-HIB – D.T.COQ/D.T.P)
Dosage Form	:	**Suspension for Injection.**
Pack Size	:	**1 vial + 1 syringe.**

Composition: For one 0.5 ml dose after reconstitution.

Ingredient(s)	**Specification**	**Quantity**
A. Active Ingredient(s)		
Act-HIB (Powder Compartment)		
- Haemophilus influenzae type b polysaccharide conjugated to tetanus protein.	Ph.Eur	10µg
D.T.COQ/D.T.P(Suspension Compartment)		
- Purified diphtheria toxoid	Ph.Eur	≥30 I.U.
- Purified tetanus toxoid	Ph.Eur	≥60 I.U.
- Bordetella pertussis	Ph.Eur	≥ 4 I.U.
B. Excipient(s)		
Aluminium hydroxide	Ph.Eur	≤ 1.25 mg
Sodium thiomersal	Ph.Eur	≤ 0.05 mg
Tris	Ph.Eur	0.6 mg
Sucrose	Ph.Eur	42.5 mg
Sodium chloride solution (0.9%)	Ph.Eur	Up to 0.5 ml

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

17 JUN 2009

Brigadier General Ismail Hossain
Director
Directorate 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.

(2) The registration will be valid for 05(five) years from the 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 changed or modified qualitatively or quantitatively without approval of the Licensing Authority.

Memo. No.DA/...15-5(102)971.5470 Date.22/06/09

C.C. M/S. Sanofi-~~aventis~~ MW Bangladesh Limited
6/2/A, Segun Bagicha, Dhaka-1000,
Station Road, Tongi, Gazipur
MW 1/9/13

For Director
Directorate of Drugs Administration