

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



**CERTIFICATE OF REGISTRATION**

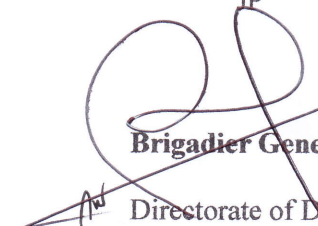
We hereby declare that OKAVAX manufactured by The Research Foundation for Microbial Diseases of Osaka University (BIKEN), 3-1 Yamada-oka, Suita, Osaka, Japan and represented by M/s. Sanofi-aventis Bangladesh Limited, 6/2/A Segun Bagicha, Dhaka-1000, Bangladesh is registered with Directorate of Drug Administration and Licensing Authority (Drug) under Registration No. 102-4474-09. 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** : OKAVAX.  
**Dosage Form** : Solution for Injection.  
**Pack Size** : 1 vial contains one dose. Solvent (water for injection J.P):  
0.7ml per vial is provided.

**Composition: 0.7ml contains the following:**

<u>Ingredient(s)</u>	<u>Specification</u>	<u>Quantity</u>
<b><u>A. The Vaccine ( 1 vial) contains:</u></b>		
An attenuated live Varicella-zoster Virus (OKA Strain )	JP	≥ 1400 PFU
Sodium Chloride	JP	1.6 mg
Potassium Chloride	JP	0.04 mg
Monobasic Potassium Phosphate	JIS	0.4 mg
Dibasic sodium phosphate hydrate	JP	4.395 mg
Sucrose	JP	35.0 mg
Monosodium L-glutamate monohydrate	JPC	0.5 mg
Kanamycin Sulfate	JP	≤ 10μg ( potency)
Erythromycin Lactobionate	JP	≤ 3μg ( potency)
<b><u>B. The diluent ( 1 vial) contains</u></b>		
Water for Injection	JP	0.7 ml

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

  
21 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)97/ 5469  
C.C. M/S. Sanofi-aventis Bangladesh Limited  
6/2/A, Segun Bagicha, Dhaka-1000,  
Bangladesh.

Date: 22.06.09  
For Director  
Directorate of Drug Administration