

**Status of Marketing Authorization (Form 46- Manufacturing Permission) of Vaccine**

<b>S.No</b>	<b>Firm</b>	<b>Name of Formulation</b>	<b>Indication</b>	<b>Permission No.</b>
1	M/s Bharat Immunologicals & Biologicals Corporation Limited, Village Chola, Bulandshahr-203203 (U.P.)	Bivalent Oral Polio Vaccine- Sabin strain (Type I and Type III) (Bulk source from M/s P.T. Bio Farma, Indonesia)	For the immunization of against Polio virus type I and type III.	Permission no. MF-78/2013, dated: 23rd April 2013
2	M/s Bharat Immunologicals & Biologicals Corporation Limited, Village Chola, Bulandshahr-203203 (U.P.)	Trivalent Oral Polio Vaccine-Sabin (Type 1, Type 2 and Type 3) (Bulk source from M/s P.T. Bio Farma, Indonesia)	For the immunization of against Polio virus type I, type II and type III.	Permission no. MF-79/2013, dated: 22nd May 2013.
3	M/s Bharat Biotech Internal limited, Genome Valley, Shameerpet Mandal, Hyderabad, Andhra Pradesh India-500078	Poliomyelitis Vaccine, Live (Oral), I.P., Trivalent-Sabin (Type1, Type 2 and Type 3)	Active immunization against Poliomyelitis caused by type 1, type 2 and type 3 infection.	Permission no. MF-154/2013, dated 24 July 2013.
4	M/s Bio-Med (P) Ltd., C-96, B.S. Road, Indl. Area, Ghaziabad-201009, U.P., India.	Poliomyelitis Vaccine, Live (Oral), I.P., Trivalent	Poliomyelitis vaccine, Live (Oral) I.P. (trivalent) is indicated for active immunization of Poliomyelitis virus. Infants should receive at least three doses of OPV at minimum interval of 4 weeks. WHO recommends the following schedule in endemic countries at birth, 6, 10, 14 weeks.	Permission no. MF-188/2013, dated 16 Aug 2013.
5	M/s Serum Institute of India Ltd., 212/2, Hadapsar, Pune-411 -028	Influenza Vaccine, Live attenuated (Human) Seasonal Trivalent freeze dried 2013 Southern	For active Immunization against influenza disease caused by influenza subtype A and type B viruses in the age group of 2 years	Permission no. MF-193/2013, dated 03 Sep 2013

		Hemisphere influenza season	and above.	
6	M/s Bharat Biotech Internal limited, Genome Valley, Shameerpet Mandal, Hyderabad, Andhra Pradesh India-500078	Oral Rotavirus Vaccine (ORV) 116E	Active Immunization of infants from the age of 6 weeks for the prevention of gastroenteritis due to rotavirus infection.	Permission no. MF-192/2013, dated 03 Sep 2013
7	M/s Biological E Ltd, Plot No. 1, SP Biotech Park, Phase II, Kolthur(V), Shameerpet(M), Ranga reddy (Dist.) Andhra Pradesh	Hepatitis B vaccine (rDNA) I.P.	Indicated for the prevention of Hepatitis B infections	Permission no. MF-197/2013 dated 05 Sep 2013
8	M/s GlaxoSmithKline Asia Pvt Ltd., A-10/1, M.I.D.C. Ambad-Pathardi Phara, Ambad, Nashik-422010	Hepatitis B vaccine (rDNA) IP (Engerix B)	Active immunization against HBV infection caused by all known subtypes in subjects of all ages considered at risk of exposure to HBV	Permission no. MF-70/2013 dated 09 Sep 2013
9.	M/s Dano Vaccines & Biologicals Private Ltd. 575, Sivareddyguda, Ghatkesar,R.R. Distt., Andhra Pradesh, 501301.	Tetanus Toxoid (Adsorbed) I.P	For active immunization against Tetanus.	MF-146/2013, Dated: 08 <sup>th</sup> July 2013
10.	M/s Biologicals E. Ltd.,18/1 & 3, Azamabad, Hyderabad-500 020 A. P. India.	Diphtheria and Tetanus Vaccine (Adsorbed) IP	Indication for prevention of Disease caused by Diphtheria and Tetanus in Adults and adolescents.	MF-142/2013, Dated: 12 <sup>th</sup> July 2013
11.	M/s Biologicals E. Ltd., 18/1 & 3, Azamabad, Hyderabad-500 020 A. P. India.	Tetanus Vaccine (Adsorbed) IP	Indicated for prevention of Tetanus Infections.	MF-196/2013, Dated: 04 <sup>th</sup> Sep 2013

12.	M/s Biologicals E. Ltd.,18/1 & 3, Azamabad, Hyderabad-500 020 A. P. India.	Diphtheria, Tetanus and whole cell Pertussis Vaccine (Adsorbed) IP	Indicated as Prophylaxis for Diphtheria, Tetanus and Pertussis	MF-201/2013, Dated: 13 <sup>th</sup> Sep 2013
13.	M/s Shantha Biotechnics Ltd., Hyderabad, A.P.	Fully liquid Pentavalent vaccine (DTwP-HepB-Hib vaccine)	Active immunization against Diphtheria, Tetanus, Pertussis, Hepatitis-B, and Haemophilus influenza type b infections in 6-8, 10-12 and 14-16 weeks of age	Permission no. MF/55/2014 dated 07/03/2014

### Status of Import Permission (Form 45) of Vaccine

S.No	Firm	Name of Formulation	Indication	Permission No.
1	M/s. Wockhardt Limited Wockhardt Towers, Bandra Kurla Complex, Bandra (East), Mumbai 400051	Freeze Dried Live Attenuated Hepatitis – A Vaccine	Active immunization against Hepatitis A in adults & Children above one year age.	Permission no. IMP - 101/2013, dated; 25 Jun 2013
2	M/s Novartis Healthcare Pvt. Ltd, Vaccine Division division, 501, Shree Amba Shanti Chambers, Andheri Kurla Road, Andheri-East, Mumbai-400059	Influenza vaccine, surface antigen, inactivated	For Active immunization against influenza (flu), especially in those who run an increased risk of associated complications.	Permission no. IMP- 139/2013, dated 26 Jun 2013.
3.	M/s Novartis Healthcare Pvt. Ltd, Vaccines and Diagnostics, Sandoz House, Shivsagar Estate, Dr. Annie Besant Road, Worli, Mumbai – 400 018, India	Quinvaxem (DTwP- Hib-HepB vaccine)	Paediatric combination vaccine against diphtheria, Tetanus, pertussis, Hepatitis B and disease caused by Haemophilus influenzae type b.	Permission No. IMP- 189/2013 dated:30 <sup>th</sup> Aug 2013