



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

9 July 2015
EMA/483660/2015
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: diphtheria, tetanus, pertussis (acellular, component), poliomyelitis (inactivated), haemophilus type b conjugate vaccine

Procedure no.: PSUSA/00001124/201411



Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Ditekipol/Act-Hib		32847	Statens Serum Institut	Denmark
Infanrix-Ipv+hib	DE/H/0145/002	2-00370	Glaxosmithkline Pharma Gmbh.	Austria
Infanrix-IPV+hib	DE/H/0145/002	HR-H-255493749	Glaxosmithkline D.O.O.	Croatia
Infanrix-Ipv+hib	DE/H/0145/002	59/101/05-C	Glaxosmithkline Biologicals S.A.	Czech Republic
Infanrix-Ipv+hib		329900	Glaxosmithkline Biologicals S.A.	Estonia
Infanrix-Ipv+hib	DE/H/0145/002	76A/97	Glaxosmithkline Gmbh & Co. Kg	Germany
Infanrix-Ipv+hib	DE/H/0145/002	PA 1077/029/002	Glaxosmithkline (Ireland) Limited	Ireland
Infanrix-Ipv+hib		00- 1011	Glaxosmithkline Biologicals S.A.	Latvia
Infanrix-Ipv+hib		LT/1/2000/2129/001	Glaxosmithkline Lietuva Uab	Lithuania
Infanrix-Ipv+hib		MA172/00901	Smithkline Beecham Plc	Malta
Infanrix-Ipv+hib		RVG34567	Glaxosmithkline B.V.	Netherlands
Infanrix-Ipv+hib		8916	Glaxosmithkline Biologicals S.A.	Poland
Infanrix-Ipv+hib	DE/H/0145/002	2856383	Smith Kline & French Portuguesa-Produtos Farmaceuticos, Lda	Portugal
Infanrix-Ipv+hib	DE/H/0145/002	2856482	Smith Kline & French Portuguesa-Produtos Farmaceuticos, Lda	Portugal
Infanrix-Ipv+hib	DE/H/0145/002	2856581	Smith Kline & French Portuguesa-Produtos Farmaceuticos, Lda	Portugal
Infanrix-Ipv+hib	DE/H/0145/002	2857688	Smith Kline & French Portuguesa-Produtos Farmaceuticos, Lda	Portugal
Infanrix-Ipv+hib	DE/H/0145/002	2857787	Smith Kline & French Portuguesa-Produtos Farmaceuticos, Lda	Portugal
Infanrix-Ipv+hib	DE/H/0145/002	2857886	Smith Kline & French Portuguesa-Produtos Farmaceuticos, Lda	Portugal
Infanrix-Ipv+hib	DE/H/0145/002	2857985	Smith Kline & French Portuguesa-Produtos Farmaceuticos, Lda	Portugal
Infanrix-Ipv+hib	DE/H/0145/002	2858082	Smith Kline & French Portuguesa-Produtos Farmaceuticos, Lda	Portugal
Infanrix-Ipv+hib	DE/H/0145/002	2858181	Smith Kline & French Portuguesa-Produtos Farmaceuticos, Lda	Portugal
Infanrix-Ipv+hib	DE/H/0145/002	4059283	Smith Kline & French Portuguesa-Produtos Farmaceuticos, Lda	Portugal
Infanrix-Ipv+hib	DE/H/0145/002	4059382	Smith Kline & French Portuguesa-Produtos Farmaceuticos, Lda	Portugal
Infanrix-Ipv+hib	DE/H/0145/002	4059481	Smith Kline & French Portuguesa-Produtos Farmaceuticos, Lda	Portugal
Infanrix-Ipv+hib	DE/H/0145/002	4059580	Smith Kline & French Portuguesa-Produtos Farmaceuticos, Lda	Portugal

Infanrix-Ipv+hib	DE/H/0145/002	4059689	Smith Kline & French Portuguesa-Produtos Farmaceuticos, Lda	Portugal
Infanrix-Ipv+hib	DE/H/0145/002	4059788	Smith Kline & French Portuguesa-Produtos Farmaceuticos, Lda	Portugal
Infanrix-Ipv+hib	DE/H/0145/002	4059887	Smith Kline & French Portuguesa-Produtos Farmaceuticos, Lda	Portugal
Infanrix-Ipv+hib	DE/H/0145/002	4059986	Smith Kline & French Portuguesa-Produtos Farmaceuticos, Lda	Portugal
Infanrix-Ipv+hib	DE/H/0145/002	4060083	Smith Kline & French Portuguesa-Produtos Farmaceuticos, Lda	Portugal
Infanrix-Ipv+hib	DE/H/0145/002	4060182	Smith Kline & French Portuguesa-Produtos Farmaceuticos, Lda	Portugal
Infanrix-Ipv+hib	DE/H/0145/002	4068680	Smith Kline & French Portuguesa-Produtos Farmaceuticos, Lda	Portugal
Infanrix-Ipv+hib	DE/H/0145/002	4068789	Smith Kline & French Portuguesa-Produtos Farmaceuticos, Lda	Portugal
Infanrix-Ipv+hib		5880/2013/01	Glaxosmithkline Biologicals S.A.	Romania
Infanrix-Ipv+hib		5880/2013/02	Glaxosmithkline Biologicals S.A.	Romania
Infanrix-Ipv+hib		5880/2013/03	Glaxosmithkline Biologicals S.A.	Romania
Infanrix-Ipv+hib		5880/2013/04	Glaxosmithkline Biologicals S.A.	Romania
Infanrix-Ipv+hib		5880/2013/05	Glaxosmithkline Biologicals S.A.	Romania
Infanrix-Ipv+hib		5880/2013/06	Glaxosmithkline Biologicals S.A.	Romania
Infanrix-Ipv+hib		5880/2013/07	Glaxosmithkline Biologicals S.A.	Romania
Infanrix-Ipv+hib		5880/2013/08	Glaxosmithkline Biologicals S.A.	Romania
Infanrix-Ipv+hib		5880/2013/09	Glaxosmithkline Biologicals S.A.	Romania
Infanrix-Ipv+hib		5880/2013/10	Glaxosmithkline Biologicals S.A.	Romania
Infanrix-Ipv+hib		5880/2013/11	Glaxosmithkline Biologicals S.A.	Romania
Infanrix-Ipv+hib		5880/2013/12	Glaxosmithkline Biologicals S.A.	Romania
Infanrix-Ipv+hib		5880/2013/13	Glaxosmithkline Biologicals S.A.	Romania
Infanrix-Ipv+hib		5880/2013/14	Glaxosmithkline Biologicals S.A.	Romania
Infanrix-Ipv+hib		5880/2013/15	Glaxosmithkline Biologicals S.A.	Romania
Infanrix-Ipv+hib		5880/2013/16	Glaxosmithkline Biologicals S.A.	Romania
Infanrix-Ipv+hib		5880/2013/17	Glaxosmithkline Biologicals S.A.	Romania
Infanrix-Ipv+hib		5880/2013/18	Glaxosmithkline Biologicals S.A.	Romania
Infanrix-Ipv+hib		5880/2013/19	Glaxosmithkline Biologicals S.A.	Romania
Infanrix-Ipv+hib		5880/2013/20	Glaxosmithkline Biologicals S.A.	Romania
Infanrix-Ipv+hib		5880/2013/21	Glaxosmithkline Biologicals S.A.	Romania
Infanrix-Ipv+hib	DE/H/0145/002	59/0416/08-S	Glaxosmithkline Biologicals S.A.	Slovakia
Infanrix-Ipv+hib		5363-I-1250/13	Gsk D.O.O.	Slovenia

Infanrix-Ipv+hib		62.827	Glaxosmithkline S.A.	Spain
Infanrix-Ipv+hib	DE/H/0145/002	PL 10592/0216	Smithkline Beecham Ltd	United Kingdom
Infanrix-Ipv+hib (Dtpa-Ipv+hib)		BE193961	Glaxosmithkline Biologicals S.A.	Belgium
Infanrix-Ipv+hib (Dtpa-Ipv+hib)		2005038707	Glaxosmithkline Biologicals S.A.	Luxembourg
Infanrix-Ipv-Hib		OGYI-T-9521/01	Glaxosmithkline Kft.	Hungary
Infanrix-Ipv-Hib		OGYI-T-9521/02	Glaxosmithkline Kft.	Hungary
Infanrix-Polio+hib	DE/H/0145/002	13043	Glaxosmithkline Biologicals S.A.	Finland
Infanrix-Polio+hib		970540	Glaxosmithkline Ehf.	Iceland
Infanrix-Polio+hib		97-3108N	Glaxosmithkline As	Norway
Infanrix-Polio+hib		13864	Glaxosmithkline Ab	Sweden
Infanrix-polio+hib		19126	Glaxosmithkline Pharma A/S	Denmark
Infanrixquinta		NL22370	Laboratoire Glaxosmithkline S.A.S.	France
Ivfarix Ipv Hib		19619	Glaxosmithkline Biologicals S.A.	Cyprus
Ivfarix Ipv Hib	DE/H/0145/002	74423/22-10-2012	Glaxosmithkline Aebe	Greece
Pediacel		UP/I-530-09/12-01/450	Sanofi Pasteur SA (France)	Croatia
Pediacel		UP/I-530-09/07-01/203	Sanofi Pasteur SA (France)	Croatia
Pediacel		21485	Sanofi Pasteur Sa	Cyprus
Pediacel	UK/H/2388/01/DC	59/128/11-C	Sanofi Pasteur Sa	Czech Republic
Pediacel	UK/H/2388/001	28104	Sanofi Pasteur Msd	Finland
Pediacel	UK/H/2388/01	NL38860	Sanofi Pasteur MSD snc (France)	France
Pediacel	UK/H/2388/01/DC	MA573/01601	Sanofi Pasteur Sa	Malta
Pediacel	UK/H/2388/001	RVG 106334	Sanofi Pasteur Msd	Netherlands
Pediacel	UK/H/775/01	RVG 32118	Sanofi Pasteur Msd	Netherlands
Pediacel	UK/H/2388/001	73.316	Sanofi Pasteur Msd S.A. (Spain)	Spain
Pediacel	UK/H/2388/001	PL06745/0128	Sanofi Pasteur Msd Limited (Uk)	United Kingdom
Pediacel	UK/H/775/01	PL 06745/0120	Sanofi Pasteur Msd Limited (Uk)	United Kingdom
Pentavac	SE/H/0153/001	2-00227	Sanofi Pasteur Msd Snc	Austria
Pentavac	SE/H/0153/001	BE196131	Sanofi Pasteur Msd	Belgium
Pentavac	SE/H/0153/001	30187	Sanofi Pasteur Msd	Denmark
Pentavac	SE/H/0153/001	13677	Sanofi Pasteur Msd	Finland
Pentavac	SE/H/0153/001	NL22417	Sanofi Pasteur MSD S.N.C.France	France
Pentavac	SE/H/0153/001	11A/97	Sanofi Pasteur Msd Gmbh	Germany
Pentavac	SE/H/153/01/E01	65299/10/29-7-2011	Sanofi Pasteur Msd Snc	Greece
Pentavac	SE/H/0153/001	970044	Sanofi Pasteur Msd	Iceland
Pentavac	SE/H/0153/001	PA544/32/1	Sanofi Pasteur Msd Limited	Ireland
Pentavac	SE/H/0153/001	034126019/M	Sanofi Pasteur Msd Snc	Italy

Pentavac	SE/H/0153/001	034126021/M	Sanofi Pasteur Msd Snc	Italy
Pentavac	SE/H/0153/001	034126033/M	Sanofi Pasteur Msd Snc	Italy
Pentavac	SE/H/0153/001	034126045/M	Sanofi Pasteur Msd Snc	Italy
Pentavac	SE/H/0153/001	034126058/M	Sanofi Pasteur Msd Snc	Italy
Pentavac	SE/H/0153/001	034126060/M	Sanofi Pasteur Msd Snc	Italy
Pentavac	SE/H/0153/001	034126072/M	Sanofi Pasteur Msd Snc	Italy
Pentavac	SE/H/0153/001	034126084/M	Sanofi Pasteur Msd Snc	Italy
Pentavac	SE/H/0153/001	034126096/M	Sanofi Pasteur Msd Snc	Italy
Pentavac	SE/H/0153/001	034126108/M	Sanofi Pasteur Msd Snc	Italy
Pentavac	SE/H/0153/001	2009020171	Sanofi Pasteur Msd	Luxembourg
Pentavac	SE/H/0153/001	97-710	Sanofi Pasteur Msd	Norway
Pentavac	SE/H/0153/001	2782282	Sanofi Pasteur Msd, S.A. (Portugal)	Portugal
Pentavac	SE/H/0153/001	2782381	Sanofi Pasteur Msd, S.A. (Portugal)	Portugal
Pentavac	SE/H/0153/001	5458880	Sanofi Pasteur Msd, S.A. (Portugal)	Portugal
Pentavac	SE/H/0153/001	5458989	Sanofi Pasteur Msd, S.A. (Portugal)	Portugal
Pentavac	SE/H/0153/001	5459086	Sanofi Pasteur Msd, S.A. (Portugal)	Portugal
Pentavac	SE/H/0153/001	5459185	Sanofi Pasteur Msd, S.A. (Portugal)	Portugal
Pentavac	SE/H/0153/001	5459284	Sanofi Pasteur Msd, S.A. (Portugal)	Portugal
Pentavac	SE/H/0153/001	5459383	Sanofi Pasteur Msd, S.A. (Portugal)	Portugal
Pentavac	SE/H/0153/001	62.483	Sanofi Pasteur Msd S.A. (Spain)	Spain
Pentavac	SE/H/0153/001	13523	Sanofi Pasteur Msd	Sweden
Pentavac	SE/H/153/01/000	PL 06745/0101	Sanofi Pasteur Msd Limited (Uk)	United Kingdom
Pentaxim		UP/I-530-09/10-02/383	Sanofi Pasteur Sa	Croatia
Pentaxim		19523	Sanofi Pasteur Sa	Cyprus
Pentaxim		430604	Sanofi Pasteur Sa	Estonia
Pentaxim		NL 22 418	Sanofi Pasteur Sa	France
Pentaxim		OGYI-T-9414/01-06-05	Sanofi Pasteur Sa	Hungary
Pentaxim		02-0311	Sanofi Pasteur Sa	Latvia
Pentaxim		LT/1/99/3124/001-006	Sanofi Pasteur Sa	Lithuania
Pentaxim		10130	Sanofi Pasteur Sa	Poland
Pentaxim		4956/2012/01-05	Sanofi Pasteur Sa	Romania
Pentaxim		5363-I-629/11, 5363-I-630/11, 5363-I-631/11, 5363-I-632/11	Sanofi Pasteur Sa	Slovenia
инфанрикс-Ipv+hib	DE/H/0145/002	20090475	Glaxosmithkline Eood	Bulgaria
пентаксим		II-9935/15.06.2010	Sanofi Pasteur Sa	Bulgaria