

**Status of Import License (Form 10) of Recombinant Products, Human and Veterinary Vaccines issued
from 01/01/2017 to 31/12/2017**

S. No.	Firm	Name of Formulation	Import License No. & Validity														
HUMAN VACCINE																	
1.	M/s Zuventus Healthcare Limited Office No. 5119,5 th Floor, Oberoi Garden Estate, Chandivali, Andheri (East) Mumbai, Tal: Sakinaka (Mumbai -Zone 4) Pin: 400072	<table><tr><td colspan="2">Varicella Vaccine, Live I.P. (Oka Strain)</td></tr><tr><td colspan="2">Lyophilized milky white powder for injection in a single dose vial for Subcutaneous administration.</td></tr><tr><td colspan="2">Each single dose (0.5ml) after reconstituted with diluent contains:</td></tr><tr><td>Name of Ingredients</td><td>Quantity</td></tr><tr><td>Active Ingredients</td><td></td></tr><tr><td>Varicella-Zoster Virus Live attenuated (Oka Strain)</td><td>≥ 2000 plaque forming units (PFU)</td></tr><tr><td colspan="2">Sterile Water for Injection as Diluent- 0.6ml</td></tr></table>	Varicella Vaccine, Live I.P. (Oka Strain)		Lyophilized milky white powder for injection in a single dose vial for Subcutaneous administration.		Each single dose (0.5ml) after reconstituted with diluent contains:		Name of Ingredients	Quantity	Active Ingredients		Varicella-Zoster Virus Live attenuated (Oka Strain)	≥ 2000 plaque forming units (PFU)	Sterile Water for Injection as Diluent- 0.6ml		SV-11-144 Valid upto 02-08-2018
Varicella Vaccine, Live I.P. (Oka Strain)																	
Lyophilized milky white powder for injection in a single dose vial for Subcutaneous administration.																	
Each single dose (0.5ml) after reconstituted with diluent contains:																	
Name of Ingredients	Quantity																
Active Ingredients																	
Varicella-Zoster Virus Live attenuated (Oka Strain)	≥ 2000 plaque forming units (PFU)																
Sterile Water for Injection as Diluent- 0.6ml																	
2.	M/s. Shantha Biotechnics Limited, Survey No.274, Athveli Village, Medchal Mandal- 501401, Hyderabad, Andhra Pradesh, India	Inactivated Vero Trivalent Poliovaccine Bulk (Concentrated Trivalent)	SVH-1-126 Valid upto 31/07/2020														
3.	M/s. GlaxoSmithKline Pharmaceuticals Ltd., Dr. Annie Besant Road,Worli, Mumbai-400030, Maharashtra, India.	Diphtheria, Tetanus, Pertussis (acellular component), Hepatitis B (rDNA), Inactivated Poliomyelitis and Haemophilus influenza type b conjugate vaccine (adsorbed) [(DTaP-HBV-IPV) + Hib]Vaccine Dosage Form- Component I: A turbid suspension for Injection in a pre-filled syringe containing Diphtheria, Tetanus, Acellular Pertusis, Hepatitis B (rDNA) and Inactivated Poliomyelitis (DTaP-HBV-IPV). Component II: Lyophilized white powder of Haemophilus influenza type b (Hib) in a glass vial. <i>(Reconstitution is done by adding the entire contents of the supplied container of the DTPa-HBV-IPV liquid component-I to the vial containing the lyophilized adsorbed Hib component-II).</i>	SV-15-3 Valid upto 31/12/2017														

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4.	M/s Sanofi Pasteur India Private Ltd. Sanofi House, CT Survey No. 117-B, L& T Business Park, Saki Vihar Road Powai, Mumbai 400072	Quadrivalent Inactivated Influenza Vaccine (Split Virion) I.P.	SV-49-6828 Valid upto 31/12/2017
5.	M/s Wockhardt Limited Wockhardt Towers, Bandra Kurla Complex, Bandra (East), Mumbai-400051, Maharashtra, India	Varicella Vaccine(Live)I.P., Freeze Dried along with sterile water for injection (as diluent)	SV-9-131 Valid upto 27/07/2020
6.	M/s G. C. Chemie Pharmie Ltd.,5/C, Shree Laxmi Industrial Estate,New Link Road, Andheri (West), Mumbai- 400 053, India.	- Each 0.5 ml Inactivated Influenza Vaccine (Split Virion) I.P., Suspension for injection in prefilled syringes contains: - an A/Michigan/45/2015 (H1N1) pdm 09----- 15 µg - an A/Hong Kong/4801/2014 (H3N2) ----- 15 µg - a B/Brisbane/60/2008----- 15 µg - Each 0.25 ml Inactivated Influenza Vaccine (Split Virion) I.P., Suspension for injection in prefilled syringes contains: - an A/Michigan/45/2015 (H1N1) pdm 09----- 7.5 µg - an A/Hong Kong/4801/2014 (H3N2) ----- 7.5 µg - a B/Brisbane/60/2008----- 7.5 µg	SV-101-112 Valid upto 09/08/2020
7.	M/s GlaxoSmithKline Pharmaceuticals Ltd., Dr. Annie Besant Road, Worli, Mumbai-400030, Maharashtra India	Meningococcal Group A, C, W-135 and Y Conjugate Vaccine	SVH-18-145 Valid upto 24/08/2020
8.	M/s GlaxomithKline Pharmaceuticals Ltd.,S.No. 14/4, Godown No 1 & 2,	Quinvaxem (DTwP-Hip-HepB) vaccine	SVH-17-143 Valid upto 16/01/2020

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S. No.	Firm	Name of Formulation	Import License No. & Validity
	Village Yavai, Near Water Filtration Plant, Bhiwandi, Dist. Thane – 421302, India		
9.	M/s GlaxoSmithKline Pharmaceuticals Limited, Southern Portion of Ground and First Floor, No.144, Poonamallee High Road, Vellappanchavadi, Chennai-77	• Rotavirus Vaccine (live attenuated, Oral) I.P • Human Papillomavirus Vaccine r-DNA Ph.Eur	SV-64-11 Valid upto 11/12/2019
RECOMBINANT PRODUCTS			
1.	M/s Organon India Pvt. Ltd.,Gala No. 1-C, Bldg No. B-3, City Link, Ware housing Com. Mumbai Nashik Highway, Vadapa, Tal Bhiwandi, Dist - Thane – 421302 India	• Follitropin Beta (FSH) solution for injection 50IU & 100 IU in Ampoules/Vials • Follitropin Beta (FSH) solution for injection 300IU & 600 IU in Cartridges	FF-113-214 valid up to 31/10/2020
2.	M/s Sanofi Synthelabo (India) Private Limited, City Link Warehousing Complex, Bldg. No. 3,Gala No. 6A, S. No. 120-121, Village Vadpe,Tal: Bhiwandi-421302, Taluka: Bhiwandi-13 (Bhiwandi Corporation)(Thane Z5), Maharashtra	• Imiglucerase for injection Powder for concentrate for solution for infusion-single use vial	FF-495-19 Valid upto 24/09/2020 *Transfer of Import License from M/s Sandor Medicaids Pvt. Ltd., to M/s Sanofi Synthelabo (India) Private Limited,

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S. No.	Firm	Name of Formulation	Import License No. & Validity
3	M/s Bristol-Myers Squibb India Pvt. Ltd., Bldg. B-4, Gala No. 3, 4, 5A & 6A, Citylink Ware Houses Complex, Mumbai Nashik Highway, Vadpe Village Tal: Bhiwandi-16, District Thane-Z5 Pin 421302	- Belatacept 250mg/vial Lyophilized Powder for Intravenous infusion in 20 ml vial, co- packaged with a silicon free disposable polypropylene Syringe. - Nivolumab 10 mg/ml concentrate for solution for infusion for infusion, (r-DNA origin).	FF-481—12990 Valid upto 30/9/2020
4	M/s Dr. Reddy's Laboratories Ltd., Global Distribution Centre, Survey No. 41, Bachupally (V), Qutubullapur (M), Ranga Reddy District, Hyderabad - 500090, Telangana, India	Evolocumab solution for Injection 140mg/mL	FFR-48-51 Valid upto 26/07/2020
5	M/s Vita Pharma Agencies, 305, Arenja Corner, Plot No. 71, Sector-17, Vashi, Navi Mumbai-400703	Recombinant Human Erythropoietin solution for injection Each Prefilled syringe of 1ml injection contains: Recombinant Human Erythropoietin 2000IU/ml, 3000 IU/ml, 4000 IU/ml	FFR-24-24 Valid upto 25/11/2019
6	M/s Sanofi Synthelabo (India) Private Limited, Citylink Warehousing Complex, Bldg. No. 3, Gala No. 6A, S.No. 120, 121, Village Vadpe, Tal: Bhiwandi-421302, Taluka: Bhiwandi-13 (Bhiwandi Corporation), District: Thane Z5, India	Agalsidase beta Powder for concentrate for solution for infusion	FF-399-9177 Valid upto 08/01/2020
7	M/s Eli Lilly and Company (India) Private Limited, Plot no. 92, Sector-32, Gurgaon 122001	Dulaglutide (r-DNA origin) Solution for injection Each pre-filled pen contains Dulaglutide.....0.75mg/1.5mg Fill Volume:0.5ml (for both presentations)	FFR-20-1 Valid upto 31/01/2018

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S. No.	Firm	Name of Formulation	Import License No. & Validity
	Haryana, India	Presentation: In single use prefilled pen.	
8	M/s Sanofi Synthelabo (India) Private Limited, Citylink Warehousing Complex, Bldg. No. 3, Gala No. 6A, S.No. 120, 121, Village Vadpe, Tal: Bhiwandi-421302, Taluka: Bhiwandi-13 (Bhiwandi Corporation), District: Thane Z5, Maharashtra India	Laronidase for solution for Injection	FFR-26-30 Valid upto 08/01/2020
9	M/s Sanofi India Limited, Gala No. 3,4,5,6B& 6C, 7F, City Link Warehousing Complex Building No. B3, S.No.120-121,Vill. VadpeBhiwandi-Thane 421302, Maharashtra, India	Insulin Glargine 300U/ml (as Solostar Penfilled Pen 1.5ml cartridges)(Monocomponent Insulin Glargine)	FF-141-333 Valid upto 31/12/2017
10	M/s Sanofi Synthelabo (India) Private Limited, Citylink Warehousing Complex, Bldg. No. 3, Gala No. 6A, S.No. 120, 121, Village Vadpe, Tal: Bhiwandi-421302, Taluka: Bhiwandi-13 (Bhiwandi Corporation), District: Thane Z5, India	Aglucosidase alfa for Injection (r-DNA Origin) Lyophilized Powder for Concentrate for solution for Intravenous Infusion	FF-31-26 Valid upto 27/12/2019
11	M/s Sanofi Synthelabo (India) Private Limited, Citylink Warehousing Complex, Bldg. No. 3, Gala No. 6A, S.No. 120,	Thyrotropin Alfa Lyophilized Powder for Solution for Injection (for intramuscular use only)	FF-399-9177 Valid upto 27/12/2019

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S. No.	Firm	Name of Formulation	Import License No. & Validity
	121, Village Vadpe, Tal: Bhiwandi-421302, Taluka: Bhiwandi-13 (Bhiwandi Corporation), District: Thane Z5, India		
12	M/s. Boehringer Ingelheim India Pvt. Ltd., Bld No.D-5, Gala no:1 to 3, Shree Arihant Compound, Ground Floor, Reti Bunder Road, Kalher, Bhiwandi, Tal: Bhiwandi – 15 (Thane Zone 5) Pin: 421302, Maharashtra, India.	Idarucizumab 2.5mg/50ml solution for injection/ infusion	FF-88-6 Valid upto 28/02/2018
13	M/s Pfizer Products India Private Limited., The Capital-B Wing, 1802, 18 th Floor, Plot No. C-70, G-Block, Bandra Kurla Complex, Bandra (East), Mumbai 400051, India.	Recombinant Somatropin (Sterile, Lyophilized Powder) for solution for sub-cutaneous Injection; 5.3 mg (16 IU) and 12 mg (36 IU) with sterile diluents (m-Cresol-Mannitol-Water) for Injection	FF-362-115 Valid upto 31/03/2020
14	M/s Johnson & Johnson Private Limited, Gala No. 3, Bldg. No. B-2, Citylink Warehousing Complex, S.No. 120-121, Mumbai, Nashik Highway, Village – Vadpe, Tal— Bhiwandi-16 (Zone Z5) – 421302, India	- Siltuximab powder for concentrate for solution for infusion 100 mg & 400 mg (r-DNA origin) - Daratumumab concentrate for solution for Infusion 100mg and 400 mg	FF-101-28 Valid upto 01/07/2018
15	M/s Sun Pharmaceutical Industries Ltd., Tandalja, Vadodara - 390020, India.	Recombinant Human Growth Hormone for injection Ch.P.	FFR-7-10 Valid upto 27/03/2020

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S. No.	Firm	Name of Formulation	Import License No. & Validity
16	M/s Biocon Limited, Biocon Special Economic Zone, Plot No. 2-4, Phase IV, Bommasandra- Jigani Link Road, Bommasandra Post, Bangalore- 560 099, India.	Recombinant Human Insulin IP(rDNA origin)- Bulk is permitted for conversion into insulin formulation meant for export purpose only.	FFR-46-49 Valid upto 20/12/2019
17	M/S Novartis India Limitd, Sandoz House, Shivsagar Estate Dr. Annie Besant Road,Worli Mumbai-400018	Basiliximab Injection/I.V Infusion: Basiliximab-20 mg along with ampule of 5ml water for injection	FF-52-7 Valid upto 31/12/2020
18	M/S Alcon Laboratories (India) Pvt. Ltd. 3 rd Floor , Cresent 4,Prestige Shantiniketan, Whitefiled Banglore,Pin:560048,India	Ranibizumab Solution for injection(r-DNA origin) 10mg/ml	FFR-49-52 Valid up to 16/11/2020

VETERINARY VACCINES			
1.	M/s Intervet India Pvt. Ltd., Sagar Complex, Bldg B-1, Gala No. 12 to 14 Ovali Village, Bhiwandi, tal: Bhiwandi-16(Thane-Z5), Maharastra-421302 India	Combined Avian Infectious Bronchitis Vaccine and Ranikhet Disease Vaccine Live , I.P	SV-6-597 valid up to 31/12/2017
2.	M/s Panav Bio-Tech, Shop No. 131, 1 st Floor, Vardhman Big V Plaza,Plot No. 12, C-Centre, Road No. 44, Rani Bagh, Pitampura, Delhi-110034, India.	- Combined Canine Distemper, Canine Contagious Hepatitis infectious laryngotracheitis, Canine Parvovirus & Canine Parainfluenza immunoglobulin - Inactivated vaccine against Rabies - Hyper Immune Heterogenous Immonoglobulins parvovirusis - Polyvalent vaccine against distemper, infectious hepatitis, infectious Laryngotracheitidis, Parvoviroosis, parainfluenza	SV-65-114 Valid upto 28/05/2020

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		- and Leptospirosis for dogs, canids and stoats except ferrets • Hyper Immune heterogeneous immunoglobulin against Distemper • Bivalent Canine Distemper, Live (Lyophilized) and Canine parvovirus (Liquid) vaccine, Inactivated	
3.	M/s. Zoetis India Limited, Godown No. 1&2, Bldg. No. 12B, Prithvi Complex, Reti Bunder Road, Kalher, Tah. Bhiwandi, Dist. Thane 421302, India	• Canine Distemper-Adenovirus Type-2- Coronavirus-Parainfluenza-Parovirus Vaccine, Modified Live & Killed Virus, Leptospira Canicola-Grppotyphosa-Icterhaemorrhagiae-Pomona Bacterin • Canine coronavirus Vaccine, Inactivated, I.P	SVV- 4 -15 Valid upto 18/02/2019
4.	M/s. Stallen South Asia Pvt Ltd., 6 th Floor, Matharu Arcade, Subhash Road, Vile Parle East, Mumbai 400 057, India	• Newcastle Disease vaccine, Inactivated • Combined Ranikhet, Infectious Bronchitis, Infectious Bursal and Avian Reovirus Vaccine, Inactivated • Inactivated Avian Salmonellosis Vaccine I.P. • Inactivated Mycoplasma synoviae vaccine	SV-33-2 Valid upto 31/05/2018
5.	M/s Hester Biosciences Limited., Village: Merda Adraj, Taluka: Kadi, District: Mehsana, Gujarat - 382721, India.	• Quadrivalent Live Attenuated Coccidiosis vaccine	SVV-15 -20 Valid upto 29/12/2019

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6.	M/s Virbac Animal Health India Pvt. Ltd., Chamber No. 6-C, 2nd Floor, Bhanu Ice & Cold Storage Pvt. Ltd., Plot No. D-202, TTC Industrial Area, Turbhe (Thane Zone 7), MIDC, Navi Mumbai- 400 702, Maharashtra, India.	- Freeze Dried Attenuated Canine Distemper, Adenovirus-2, Parvovirus, Parainfluenzae attenuated virus vaccine & Leptospira Vaccine Inactivated, I.P - Rabies Veterinary Vaccine, Inactivated (Cell Culture), I.P. single dose - Rabies Veterinary Vaccine, Inactivated (Cell Culture), I.P. Ten dose - Combined Canine Distemper Canine Adenovirus-Type-2 and Canine Parvovirus Vaccine with Diluent - Freeze dried attenuated vaccine for parenteral use in Cats with diluent	SV-43-10 Valid upto 14/03/2020
7.	M/s. Zoetis India Limited, Godown No. 1&2, Bldg. No. 12B, Prithvi Complex, Reti Bunder Road, Kalher, Tah. Bhiwandi, Dist. Thane 421302, India	- Marek's Disease Vaccine, Live, I.P - Mycoplasma Gallisepticum Bacterin, Vaccine, Inactivated - Marek's Disease Vaccine, Live, I.P. (Serotypes 3) - Equine Rhinopneumonitis Vaccine, Killed Virus (Pneumabort-K +1b) - Reo virus Vaccine, Inactivated, I.P - Bursal Disease Vaccine, Live Virus	SVV-9-13 Valid upto 17/01/2020.
8.	M/s Sanofi –Synthelabo (India) Pvt. Ltd., City Link Warehousing Complex, Bldg No. A-4, Gala No. . 6&7, S.No. 120,121, Mumbai Nasik –Highway vadpae Village, Tal:Bhiwandi-16, Dist: Thane Zone 5, India	Newcastle Disease vaccine, Live, IP	SVV-11-16 Valid upto 26/02/2018
9.	M/s Panav Bio-Tech 70, Ground Floor,Pvt No.-B-6, Najafgarh Road Industrial Area, New Delhi- 110015 India	Himmvac Hog Cholera (T/C) Vaccine	SVV-16-21 valid upto 07/09/2020

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10.	M/s Hipra India Pvt. Ltd. M No. 1/0361, First Floor, C/O Reality Ware Housing Pvt. Ltd. Gut No. 1337/1,old gut no. 2323/1 Wagholi-412207, Tal. Haveli. Dist Pune, India	Infectious Brusal Disease Vaccine,Live I.P.(CH/80 Live Cloned Vaccine)	SVV-13-19
11.	M/s. Zoetis India Limited, Godown No. 1&2, Bldg. No. 12B, Prithvi Complex, Reti Bunder Road, Kalher, Tah. Bhiwandi, Dist. Thane 421302, India.	Feline Rhinotracheitis-Calici- Panleukopenia- Vaccine, Modified Live Virus	SVV-4-15 valid up to 18/02/2019