

Annexure-I(b)
Details of Import Permissions of Human Vaccines

| Year-2023 | | | | |
|------------------|--|--|--|-------------------------------------|
| S. No | Name of Firm | Name of Formulation | Indication(s) | Permission No. & Date |
| 1 | M/s TechInvention Lifecare Pvt. Ltd, Mumbai, India | Choler Vaccine (Inactivated, Oral), I.P | For Prevention of Cholera in individuals from age 1 years and above caused by Vibrio cholerae. | IMP/BIO/23/000044 dated 17-Apr-2023 |
| 2 | M/s Prosper Channel Life Science India Pvt., Ltd, New Delhi, India | Hepatitis A vaccine (Human Diploid Cell) Inactivated | for active immunization against Hepatitis A virus in 18-40 years of age group". | IMP-30/2023, dated 21-April-2023 |

| Year 2022 | | | | |
|------------------|---|--|--|-------------------------------------|
| S. No | Name of Firm | Name of Formulation | Indication(s) | Permission No. & Date |
| 1. | M/s Dr Reddy's Laboratories Limited, Hyderabad, India | Recombinant adenoviral vector vaccine containing particles of serotype 26 containing the protein S gene of the SARS-CoV-2virus | For the prevention of the Novel Coronavirus infection (COVID-19) in adults aged over 18 year, when administered in single dose of (0.5ml) for restricted use in emergency situation. | IMP/BIO/20/000067 dated 04-Feb-2022 |
| 2. | M/s GlaxoSmithKline Pharmaceuticals Limited, 252, Dr. Annie Besant Road Worli Mumbai, Maharashtra | Herpes Zoster Vaccine (Recombinant, Adjuvanted) | For prevention of Herpes Zoster (HZ) and Post-Herpetic Neuralgia (PHN), in adults 50 years of age or older when administered in two doses of 0.5 ml each two months apart | IMP/BIO/22/000014 dated 21-Feb-2022 |
| 3. | M/s Sanofi Healthcare India Private Limited, Mumbai, India | Inactivated Quadrivalent Influenza Vaccine (Split Virion) I.P. for 0.5ml dose | Inactivated Quadrivalent Influenza Vaccine (Split Virion) I.P. for 0.5ml dose in the age group of 6 to 35months. | 22.04.2022 |

Annexure-I(b)

Details of Import Permissions of Human Vaccines

| | | | | |
|------------------|--|---|---|---|
| 4. | M/s GlaxoSmithKline Pharmaceuticals Limited Dr. Annie Besant Road, Worli, Mumbai 400030, India. | Inactivated Quadrivalent Influenza Vaccine (Split Virion) I.P., 0.5ml, single dose, prefilled syringe (PFS). | For active immunization of adults and children from 6 months of age for the prevention of influenza disease caused by the two influenza A virus subtypes and the two influenza B virus types contained in the vaccine | Dated 06.05.2022 BIO/IMP/21/000021 |
| 5. | M/s G. C. Chemie Pharmie Ltd., 5/C, Shree Laxmi Industrial Estate, New Link Road, Andheri (West), Mumbai, India | Pneumococcal Polysaccharide Vaccine I.P.(23 valent) | For active immunization for the prevention of pneumococcal disease caused by the 23 serotype contained in the vaccine (1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F and 33F) for use in adults aged 18 to 65 years when administered in single dose of 0.5 ml | IMP/BIO/22/000065 dated 03.10.2022 |
| Year-2021 | | | | |

| S. No | Name of Firm | Name of Formulation | Indication(s) | Permission No. & Date |
|-------|--|--|---|--|
| 1 | M/s Dr Reddy's Laboratories Limited, 8-2-337, Road No. 3 Banjara Hills Hyderabad (India) – 500034. | Gam-COVID -Vac combined vector vaccine (Component I & Component II) | For Restricted use in emergency situation: For the prevention of the novel Coronavirus infection (COVID-19) in adults aged over 18, when given in two separate doses three weeks apart. Day 0: Component I (0.5 ml) & Day 21: Component II (0.5ml) | IMP/BIO/21/000011 dated 12-Apr-2021 |
| 2 | M/s Pfizer Ltd., The Capital 1802/1901 Plot No. C-70, G Block Bandra-Kurla Complex, Bandra (E) Mumbai City (India) – 400051 | Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent | For active immunization for the prevention of Pneumonia and invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in adults of 18 years to 49 years of age | Additional indication dated 17-May-2021 |

Annexure-I(b)

Details of Import Permissions of Human Vaccines

| | | | | |
|----|--|--|---|-------------------------------------|
| 3 | M/s Cipla Limited, Cipla House, Peninsula Business Park Ganpatrao Kadam Marg, Lower Parel, Mumbai Lower Parel (India) – 400013 | mRNA-1273 COVID-19 vaccine (Moderna) | For Restricted use in emergency situation: For active immunization to prevent COVID-19 caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older when given in two doses. (0.5 mL each) 28 days apart. | IMP/BIO/21/000035 dated 29-Jun-2021 |
| 4 | M/s. Johnson & Johnson Pvt. Ltd., L.B.S. Marg, Mulund (West) Mumbai, Maharashtra India Pincode : 400080 | COVID-19 vaccine (Ad26.COVS-S [recombinant]) | For Restricted use in emergency situation: For active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 18 years of age and older when given in single dose (0.5 mL). | IMP/BIO/21/000048 dated 06-Aug-2021 |
| 5. | M/s Dr. Reddy's Laboratories Limited,8-2-337, Road No. 3, Banjara Hills, Hyderabad, 500 034, Telangana, India. | Live Attenuated Hepatitis A Vaccine (Freeze-dried) | Active immunization against Hepatitis A in adults and children Above one year age. | IMP/BIO/21/000090 dated 25-OCT-2021 |
| 6. | M/s. Glaxosmithkline Pharmaceuticals Limited, 252, Dr. Annie Besant Road, Worli, Mumbai, Maharashtra – 400030, India | Rotavirus Vaccine (Live Attenuated, Oral) I.P. | For active immunization of infants from the age of 6 weeks for prevention of gastro-enteritis due to rotavirus infection (Dose schedule 0,1 month) | IMP/BIO/21/000099 dated 08-Dec-2021 |

| Year-2020 | | | | |
|------------------|--|--|--|------------------------------------|
| S. No | Name of Firm | Name of Formulation | Indication(s) | Permission No. & Date |
| 1 | M/s Sinopharm India Private Limited, Unit 403-404, 4th floor Southern Park, Saket District Centre, Tal Greater Kailash(50) Delhi-110017,India. | Hepatitis A (Live) vaccine, Freeze dried | For immunization against Hepatitis A virus to prevent Hepatitis A in age group of 1 to 12 years. | IMP/BIO/20/000067 dated 03.09.2020 |

Annexure-I(b)

Details of Import Permissions of Human Vaccines

| | | | | |
|----------|---|---|---|---------------------------------------|
| 2 | M/s Zuventus HealthcareLtd., Office No. 5119, 5th Floor, "D" Wing, Oberoi Garden states, Chandivali, Andheri (E), Mumbai-400072, India. | Rabies Vaccine, Human, IP (Vero Cell), (Freeze Dried) | For Pre-exposure prophylaxis and post exposure prophylaxis of Rabies. As per following schedule Pre-exposure prophylaxis : Day0, Day7 & Day28 Post exposure prophylaxis : Day 0, Day 3, Day 7, Day 14 & Day 28 | IMP/BIO/20/000002 dated 14.02.2020 |
|----------|---|---|---|---------------------------------------|

Year-2019

| S. No | Name of Firm | Name of Formulation | Indication(s) | Permission No. & Date |
|-------|--|--|---|---------------------------------------|
| 1 | M/s GlaxoSmithKline Pharmaceuticals Limited, 252, Dr. Annie Besant Road, Worli, Mumbai, | Inactivated Influenza Vaccine (Surface Antigen) I.P. (Quadrivalent) | For active immunisation of children from 6 to 35 months of age for the prevention of influenza disease caused by the two influenza A virus | IMP/BIO/19/000003 dated 04.04.2019 |

| | | | | |
|---|---|--|--|---------------------------------------|
| | Maharashtra – 400030, India. | | subtypes and the two influenza B virus types contained in the vaccine . | |
| 2 | M/s. Abbott India Limited, 2nd floor, unit no 3, Corporate Park Sion Trombay road, Chembur, Mumbai400071, Maharashtra, India | Inactivated Influenza Vaccine (Surface Antigen) I.P. (Quadrivalent) | Prophylaxis of influenza, especially those who run an increased risk of associated complications. Inactivated Influenza Vaccine (Surface Antigen) I.P. (Quadrivalent) is indicated in adults (18 years of age and older) and children from 6 months of age | IMP/BIO/19/000021 dated 16.07.2019 |

Year-2017

| S. No | Name of Firm | Name of Formulation | Indication(s) | Permission No. & Date |
|-------|--------------|---------------------|---------------|-----------------------|
|-------|--------------|---------------------|---------------|-----------------------|

Annexure-I(b)

Details of Import Permissions of Human Vaccines

| | | | | |
|---|--|---|---|---------------------------------|
| 1 | M/s Zuventus Healthcare Ltd., Mumbai, India | Varicella Vaccine, Live, I.P. (Oka Strain) | For Active immunization against Varicella Zoster in adults & infants of the age group of 12 months & above. | IMP-46/2017, dated: 01.03.2017 |
| 2 | M/s Sanofi Healthcare India Pvt. Ltd., Mumbai, India | Quadrivalent Inactivated Influenza Vaccine (Split Virion) I.P. | Inactivated Quadrivalent Influenza vaccine indicated for the prevention of influenza disease caused by Influenza types A and B viruses contained in the vaccine and use in persons 18 years of age and older. | IMP-119/2017, dated: 30.05.2017 |
| 3 | M/s MSD Pharmaceuticals Pvt. Ltd., Gurgaon, India | Human Papillomavirus 9-valent Vaccine, Recombinant [Serotypes: [Type 6 L1, 11 L1, 16 L1, 18 L1, 31 | 1. Human Papillomavirus 9-valent Vaccine, Recombinant is a vaccine indicated in girls and women from 9 years to 26 years age at 03 dose regimen (schedule: 0, 2 & 6 months) for | IMP-121/2017, dated: 01.06.2017 |

Annexure-I(b)

Details of Import Permissions of Human Vaccines

| | | | | |
|---|---|---|--|---------------------------------|
| | | L1, 33 L1, 45 L1, 52 L1 & 58 L1] | <p>the prevention of cervical, vulvar, vaginal and anal cancer; precancerous or dysplastic lesions; genital warts and persistent infections caused by Human Papillomavirus (HPV).</p> <p>2. Human Papillomavirus 9-valent Vaccine, Recombinant is a vaccine indicated in boys from 9 years to 15 years at 03 dose regimen (schedule: 0, 2& 6 months) for the prevention of external genital lesions and persistent infections and the following diseases caused by HPV types included in the vaccine.</p> <ul style="list-style-type: none"> • Anal Cancer caused by HPV Types caused by HPV types 16, 18, 31, 33, 45, 52 and 58. • Genital warts (Condyloma acuminata) caused by HPV types 6, 11. • And the following Precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58. • Anal intraepithelial neoplasia (AIN) grades 1,2 and 3 grades 1,2 and 3 | |
| 4 | M/s GlaxoSmithKline Asia Private limited, Mumbai, India | Diphtheria, Tetanus, Pertussis (acellular component), Hepatitis B (rDNA), Inactivated | Diphtheria, Tetanus, Pertussis (acellular component), Hepatitis B (rDNA), Inactivated Poliomyelitis and Haemophilus influenza type b | IMP-122/2017, dated: 01.06.2017 |

Annexure-I(b)

Details of Import Permissions of Human Vaccines

| | | | | |
|--|--|--|---|--|
| | | Poliomyelitis and Haemophilus influenza type b conjugate vaccine (adsorbed) [(DTaP-HBV-IPV) + Hib] Vaccine | conjugate (adsorbed) [(DTaP-HBV-IPV) + Hib] vaccine is indicated for primary and booster vaccination of infants against <i>diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis</i> and disease caused by <i>Haemophilus influenza type b</i> . | |
|--|--|--|---|--|

| Year-2016 | | | | |
|------------------|---|---|---|----------------------------------|
| S. No | Name of Firm | Name of Formulation | Indication | Permission No. & Date |
| 1 | M/s Sanofi Healthcare India Pvt., Ltd. ,Mumbai, India | DTaP-IPV-HepB-Hib-PRP-T vaccine | For primary and booster vaccination of infants and toddlers from 6 weeks to 24 months of age against Diphtheria, Tetanus, Pertussis, Hepatitis B, Poliomyelitis and invasive diseases caused by Haemophilus influenza type b (Hib). | IMP-53/2016,dated: 15.03.2016 |
| 2 | M/s Man mill Chemicals Pvt. Ltd., Mumbai, India | Inactivated Influenza vaccine (Spilt Virion) I.P. | For active Immunization against Susceptible Influenza. | IMP-103/2016, dated: 30.06.2016 |
| 3 | M/s MSD Pvt. Limited, 6th & 7th floor Tower B, Vartika tower, Sect-54, Gurgaon 122002, India. | Human Papillomavirus Quadrivalent (Type 6, 11, 16 & 18) Vaccine Recombinant (0.5 ml single dose vial and Pre-Filled Syringes) | Indicated in girls and women 9-26 years of age for prevention of Cervical cancer and Genital warts (condyloma acuminata) caused by HPV type 6, 11, 16 and 18 vide permission dated 04.07.2008. | 08.08.2016 |

Annexure-I(b)

Details of Import Permissions of Human Vaccines

| | | | | |
|---|---|---|---|---------------------------------|
| | | | Further Post Approval Change for update in package insert for an alternative 2-dose regime for 9-13 years of age group to the existing approved 3 dose regimen for HPV vaccine | |
| 4 | M/s GlaxoSmithKline Pharmaceuticals Ltd., Mumbai, India | Meningococcal A, C, W-135 & Y Conjugate vaccine | For active immunization of children (from 2 years of age), adolescents and adults to prevent invasive meningococcal disease caused by Neisseria Meningitidis A, C, W-135 and Y. | IMP-221/2016, dated: 22.12.2016 |

Year-2015

| S. No | Name of Firm | Name of Formulation | Indication | Permission No. & Date |
|-------|--|---------------------|---|---------------------------------|
| 1 | M/s Prosper Channel Life Sciences, India | Rabies Vaccine | For active immunization against rabies virus for Human use only. | IMP-133/2015, dated: 27.05.2015 |
| 2 | M/s Sinopharm India Private Limited, Unit 403-404, 4th floor Southern Park, Saket District Centre, Tal Greater Kailash(50) Delhi-110017, India | Varicella Vaccine | For active immunization against Varicella Zoster in adults & infants in the age group of 12 months & above. | IMP-145/2015, dated: 18.06.2015 |

Annexure-I(b)

Details of Import Permissions of Human Vaccines

| | | | | |
|---|---|---------------------------|--|---------------------------------|
| 3 | M/s VHB Life Sciences Ltd. ,India | Varicella vaccine | For active immunization against Varicella zoster in adults & infants in the age group of 12 months and above | IMP-170/2015,dated: 04.08.2015 |
| 4 | M/s Novo-Medi Sciences Pvt. Ltd. ,India | Live Varicella vaccine | The vaccine is indicated for the active immunization against varicella vaccine of healthy, varicella susceptible subjects from age of 12 months. | IMP-183/2015, dated: 14.08.2015 |
| 5 | M/s Serum Institute of India Pvt. Ltd. ,India | Inactivated Polio Vaccine | Active Immunization against Poliomyelitis. | IMP-231/2015, dated: 27.11.2015 |

Annexure-I(b)
Details of Import Permissions of Human Vaccines

| Year-2014 | | | | |
|------------------|---|--|---|----------------------------------|
| S. No | Name of Firm | Name of Formulation | Indication | Permission No. & Date |
| 1 | M/s MSD Pvt. Limited, 6th & 7th floor Tower B, Vartika tower, Sect-54, Gurgaon 122002, India. | Varicella vaccine | For active immunization for the prevention of varicella in individuals from 12 months to 12 years of age. | IMP-148/14 , dated: 03.07.2014 |
| 2 | M/s GlaxoSmithKline Pharmaceuticals Ltd., Mumbai, India | MMRV vaccine | For active immunization are subjects from the age of 1 year to 12 years of age inclusive against Measles, Mumps, Rubella and varicella. | IMP-163/2014, dated: 18.07.2014 |
| 3 | M/s Pfizer India Limited, Pfizer Centre, Patel Estate, Jogeshwari (W), Mumbai-400102, India. | Pneumococcal Saccharine conjugate vaccine adsorbed 13-valent | For active immunization for the prevention of disease caused by Streptococcus Pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F (including species, Meningitis, Bacteraemia, pneumonia and acute Otitis media) in infants and children from 2 months to 5 years of age). | IMP-278, dated: 18.12.2014 |

Annexure-I(b)
Details of Import Permissions of Human Vaccines

| Year-2013 | | | | |
|-----------|--------------|---------------------|------------|-----------------------|
| S. No. | Name of Firm | Name of Formulation | Indication | Permission No. & Date |
| NIL | | | | |

| Year-2012 | | | | |
|-----------|---------------------------------------|--|---|--------------------------------|
| S. No. | Name of Firm | Name of Molecule Approved | Indication | Permission No. & Date |
| 1 | M/s Sanofi Healthcare India Pvt. Ltd. | Meningococcal A C Y and W-135 Polysaccharide Diphtheria Toxoid Conjugate | For active immunization of healthy 2 years to 55 years age group for prevention of invasive meningococcal disease caused by N.meningitides serogroups A, C, Y, and W-135. | IMP-134/2012 dated: 12.06.2012 |

| Year-2011 | | | | |
|-----------|--|---|---|---------------------------------|
| S. No. | Name of Firm | Name of Molecule Approved | Indication | Permission No. & Date |
| 1 | M/s HLL Life Care Ltd.(formerly Hindustan Latex Limited), HILL Bhavan, Poojappura, Thiruvananthapuram ,Kerala, India | Purified Rabies vaccine (Vero cell) for Human Use Freeze dried | For active immunization against Rabies for Human use only. | IMP-94/2011, dated: 22.03.2011 |
| 2 | M/s GlaxoSmithKline Pharmaceuticals Ltd., Mumbai, India | Synflorix [Pneumococcal polysaccharide and Non-Typeable Haemophilus | Active immunization of all infants and children from 6 weeks up to 5 years of age against diseases caused by Streptococcus pneumonia serotypes 1, 4, 5, | IMP-102/2011, dated: 20.04.2011 |

Annexure-I(b)

Details of Import Permissions of Human Vaccines

| | | | | |
|--|--|---|---|--|
| | | influenzae(NTHi) protein D conjugate vaccine, adsorbed (10 Pn-PD-DiT)] | 6B, 7F, 9V, 14, 18C, 19F and 23f (including sepsis, meningitis, pneumonia, bacteremia and acute otitis media) and against acute otitis media caused by Non Typeable Haemophilus influenzae. | |
|--|--|---|---|--|

| Year- 2010 | | | | |
|-------------------|--|---|---|----------------------------------|
| S. No. | Name of Firm | Name of Molecule Approved | Indication | Permission No. & Date |
| 1 | M/s. Kiran Agencies, A/40, Kalayanji Morarji, Warehousing Co. Ltd. Prem Industrial estate, Santa Savta Marg, Mazgoan, Mumbai,India | Purified Rabies vaccine (Vero cell Freeze dried) | For active immunization against Rabies for Human use only. | IMP-205/10, dated: 09.03.2010 |
| 2 | M/s Sanofi Healthcare India Pvt. Ltd., D-2, Fourth Floor, Southern Park, DDA Commercial Centre, Saket- Delhi, India. | Influenza Inactivated, Split Virion, Non-Adjuvanted H1N1 vaccine. | For active immunization for H1N1 Pandemic Influenza | IMP-222/10, dated: 12.03.2010 |
| 3 | M/s Pfizer Ltd., Mumbai Level 6 & 7, Platina, Plot No. C- 59, G-block, Bandra- Kurla Complex, Bandra (East), Mumbai-400098,India | Pneumococcal Saccharide conjugate vaccine (Adsorbed), 13 valent Suspension | For active immunization for the prevention of Pneumonia and invasive disease caused by streptococcus pneumonia serotypes 1,3,4,5,6A,6B,7F,9V,14,18C,19A,19F and 23F (including species, meningitis, bacteremia, pneumonia and acute otitis media) in infants and children from 2 months to 5 years of age). | IMP-237-2010 dated: 23.03. 2010 |

Annexure-I(b)

Details of Import Permissions of Human Vaccines

| | | | | |
|---|--|--|--|----------------------------------|
| 4 | M/s. MSD Pvt. Ltd. 7th floor, Tower-B, Vatika Towers, Sector-54, Gurgaon, India | Rotavirus Vaccine Live (Oral) | Rota Teq is indicated for the prevention of rotavirus gastroenteritis in infants and children caused by the serotypes G1, G2, G3 and G4 when administered as a 3 dose series to infants between 6 to 32 weeks. The first dose of Rota Teq should be administered between 6 to 12 weeks of age. | IMP-339/10, dated: 28.04.2010 |
| 5 | M/s Sun pharma Limited., Gurgaon ,India | Purified Rabies vaccine (Vero cell Freeze dried) | For active immunization against Rabies for Human use only. | IMP-647/2010, dated: 22.09. 2010 |

Year-2009

| S. No. | Name of Firm | Name of Molecule Approved | Indication | Permission No. & Date |
|---------------|---|--|--|-----------------------------------|
| 1 | M/s. GC Chemie Pharma Ltd., 5/C, Shri Laxmi Indl. Estate, New Link Road, Andheri (west), Mumbai, India. | Influenza Vaccine Split | For active Immunization against susceptible Influenza. | Import-449/09, dated: 12.05. 2009 |
| 2 | M/s Synergy Diagnostics Pvt. Ltd. 127/128, Laxmi Market, Vartak Nagar, Thane, India | Rabies Vaccine (Freeze Dried) (Vero Based) | For active immunization against Rabies, both as prophylaxis and post bite cases. | Import-810/09, dated: 21.10. 2009 |