

**Annexure-I(b)**  
**Details of Manufacturing Permissions of Human Vaccines**

| Year 2026 |                                                                                                                                                       |                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                |                                        |
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| S. no     | Name of Firm                                                                                                                                          | Name of Vaccine                                                                                                                                                      | Indication                                                                                                                                                                                                                                                                                     | Permission No. & Date                  |
| 1         | M/s. Serum Institute of India Pvt. Ltd S. Nos. 203-205, 212, 223, 268-270 (H) & 104-110, 113-114,168-170 (M), Hadapsar, Pune -411028                  | Inactivated Salk Polio vaccine (Adsorbed) (Reduced Antigen Content) POLIOVAC-RD                                                                                      | For active immunization of infants (6 - 8 weeks of age)                                                                                                                                                                                                                                        | MF/BIO/26/000019,<br>Dated: 24-02-2026 |
| 2         | M/s Biological E. Limited, Plot No. 1, Phase II, Biotech Park, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana, India-500078      | Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14 Valent)                                                                                                 | <b>Additional Indication:</b><br>For active immunization against invasive disease caused by Streptococcus pneumonia serotypes 1, 3, 4, 5, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F in infants from 6 weeks of age group for 2 + 1 dose schedule (6 weeks, 14 weeks and 9 months of age) | BIO/MA/25/000121<br>Date: 01/04/2026   |
| 3         | M/s. Serum Institute of India Pvt. Ltd., S. Nos. 203-205, 212, 223, 268-270 (H) & 104-110, 13-114, 168- 170 (M), Hadapsar, Pune, 411028, Maharashtra. | COVID-19 Vaccine, Adjuvanted (SARS-CoV-2 rS Protein (COVID-19) Nanoparticle Vaccine, (Omicron JN.1 Variant) with Matrix M1 adjuvant (also denoted as Matrix-M)       | For active immunization to prevent COVID – 19 disease In individuals of 12 years of age and older as a single dose.                                                                                                                                                                            | BIO/MA/25/000098<br>Date:07/04/2026    |
| 4         | M/s Biological E. Limited, Sy No. 549, 550, 552 to 556, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana, INDIA -500 078           | Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA), Inactivated Poliomyelitis and Haemophilus Influenzae Type b conjugate vaccine (Adsorbed) -(DTwP-Hep | Indicated for active immunization against Diphtheria, Tetanus, Pertussis, Hepatitis B, Poliomyelitis and invasive diseases caused by Haemophilus influenzae type b in 6 to 8 weeks old healthy infants, following a 6-10-14 weeks dosing schedule.                                             | MF/BIO/26/000057<br>dated: 07-May-2026 |

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|                  |                                                                                                                                                                                                | B-IPV-Hib) Vaccine                                                                      |                                                                                                                                                                                                                          |                                    |
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| <b>Year 2025</b> |                                                                                                                                                                                                |                                                                                         |                                                                                                                                                                                                                          |                                    |
| <b>S. no</b>     | <b>Name of Firm</b>                                                                                                                                                                            | <b>Name of Vaccine</b>                                                                  | <b>Indication</b>                                                                                                                                                                                                        | <b>Permission No. &amp; Date</b>   |
| 1                | M/s Biological E Limited, Plot No.1, Biotech Park, Phase-II, Kolthur Village, Shameerpet, Medchal — Malkajgiri District, Telangana—500078                                                      | COVID-19VaccineSARS-CoV-2-RBD203 N1_XBB.1.5                                             | Active immunization against COVID-19 disease in individuals of 5 years of age and above who have received primary vaccinations series & to be administered in two dose schedule (0.5mL each)28days apart (Day 0& Day 28) | MF/BIO/21/000136, Date: 13-01-2025 |
| 2                | M/s Zydus Lifesciences Limited, PlotSurveyNo.23,25/P,37, 40/P,42to47,49&50,Sarkhej-BavlaN.H.No.8A,Opp.Ramdev Masala, Village—Changodar, Taluka: Sanand, Dist.: Ahmedabad,Gujarat-382213, India | Measles and Rubella Vaccine (Live) I.P. (Freeze Dried)- Multidose vial (5.0 ml-10 dose) | For active immunization in children of 9 months of age and older against Measles and Rubella infections simultaneously                                                                                                   | MF/BIO/25/000001, dated14-01-2025  |
| 3                | M/s. Serum Institute of India Pvt. Ltd. S. No. 105-110, Manjari Bk. Manjari Bk. Pune Maharashtra (India) — 412307                                                                              | Diphtheria and Tetanus Vaccine (Adsorbed)                                               | For primary vaccination and revaccination of adults and adolescents, who are having contraindications of DTP                                                                                                             | BIO/MA/24/000087, Date: 20-01-2025 |
| 4                | M/s GCBC Vaccines Pvt Ltd, Survey. No 274, Athvelly Village, Medchal Mandal, Medchal-Malkajgiri District, Hyderabad Telangana, India501401                                                     | Cholera Vaccine, Inactivated, Oral I.P                                                  | For active immunization against Vibrio Cholera                                                                                                                                                                           | BIO/MA/24/000132, Date: 23-01-2025 |

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| 5 | M/s. Biological E. Limited,<br>SEZ Unit, Sy. No. 549, 550, 552<br>To 556, Kolthur Village,<br>Shameerpet, Medchal<br>Malkajgiri, District: Telangana—<br>500078 (India). | Diphtheria, Tetanus,<br>Pertussis (Whole<br>Cell), Hepatitis B (rDNA)<br>and Haemophilus<br>influenzae Type b<br>Conjugate Vaccine<br>(Adsorbed) liquid<br>pentavalent vaccine | Active immunization against<br>Diphtheria, pertussis, tetanus,<br>Hepatitis b, Hib type b infection.                                                                                                                                                                                                                   | BIO/MA/24/000118<br>Date:13-02-2025  |
| 6 | M/s. Serum Institute of India Pvt.,<br>Ltd.,212/2,Off.SoliPoonawalla<br>Road, Hadapsar Pune (India)—<br>411028                                                           | BCG for Immunotherapy<br>(80 mg/vial)                                                                                                                                          | For intravesical use in the treatment<br>and prophylaxis of primary or<br>recurrent carcinoma in situ (CIS) of<br>the urinary bladder and for<br>prophylaxis following trans urethral<br>reaction (TUR) of primary recurrent<br>stage Ta and/or T1 papillary tumors.<br>(It is not for prevention of<br>Tuberculosis). | BIO/MA/23/000062<br>Date:24-02-2025  |
| 7 | M/s. Serum Institute of India Pvt.,<br>Ltd.,212/2,Off.SoliPoonawalla<br>Road, Hadapsar Pune (India)—<br>411028                                                           | Rotavirus Vaccine (Live<br>Attenuated, Oral)<br>(Liquid)                                                                                                                       | For active immunization of healthy<br>infants from the age of 6 weeks for<br>the prevention of gastroenteritis due<br>to rotavirus infection when<br>administered as a 3-dose series.<br>The three dose regimen should be<br>Completed by one year of age.                                                             | MF/810/19/000031<br>Date: 18-03-2025 |
| 8 | M/s Indian Immunological<br>Limited, Rakshapuram<br>Gachibowli Post, Hyderabad<br>Ranga reddy Hyderabad<br>(India)— 500032                                               | Diphtheria & Tetanus<br>vaccine for Adults &<br>Adolescents I.P.                                                                                                               | For active immunization against<br>Diphtheria and Tetanus in<br>Adolescents (10 years to below<br>18years) & Adults (age 18 years to<br>60years).                                                                                                                                                                      | MF/BIO/25/000037<br>Date: 21-03-2025 |

**Annexure-I(b)****Details of Manufacturing Permissions of Human Vaccines**

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| 9  | M/s Zydus Lifesciences Limited, PlotSurveyNo.23,25/P,37, 40/P, 42 to 47,49 & 50, Sarkhej-Bavla N. H. No. 8A, Opp. Ramdev Masala, Village: Changodar, Taluka: Sanand, Dist.:Ahmedabad-382213, Gujarat, India | Inactivated Influenza Vaccine (Split Virion) I.P (Trivalent)-Single dose (0.5 ml)       | The vaccine indicated in adults (≥18 years of age) for active immunization for the prevention of disease caused by influenza A subtype viruses and type B viruses contained in the vaccine.                                  | BIO/MA/24/000099<br>Date:24-04-2025 |
| 10 | M/s Serum Institute of India Pvt. Ltd.,212/2,Hadapsar,Pune,Off. Soli Poonawalla Road., Maharashtra (India) —411028                                                                                          | Influenza Vaccine (Human, Live Attenuated), Seasonal, Trivalent (Liquid) (NASOVAC S3)   | For active Immunization against influenza disease caused by two influenza A subtype viruses and one influenza Type B virus in the age group of 2 years and above,                                                            | MF/BIO/25/000080<br>30-05-2025      |
| 11 | M/s Human Biologicals Institute (A division of Indian Immunologicals Limited), Rakshapuram, Gachibowli, Hyderabad, Telangana (India)—500032                                                                 | Inactivated Hepatitis A vaccine (Adsorbed), I.P.” (0.5 ml) in pre-filled syringes (PFS) | For prevention of Hepatitis A infection for 0.5mL dose of children (above1 year) & adolescents and 1mLin adults (age19 years to 49 years).                                                                                   | BIO/MA/24/000161<br>Date12-06-2025  |
| 12 | M/s. Biological E. Limited, SEZ Unit, Sy. No. 549, 550, 552 To 556, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana - 500078, India                                                     | Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P. (14 Valent)               | For active immunization against invasive disease caused by Streptococcus pneumonia serotypes 1,3,4,5,6B,7F,9V,14,18C,19A, 19F, 22F, 23F and 33F in infants from 6 weeks of age group for 3 dose schedule (6, 10 & 14 weeks). | BIO/MA/24/000109<br>Date:12-08-2025 |

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| Year2024 |                                                                                                                                                                                                              |                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                   |                                      |
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| S. no    | Name of Firm                                                                                                                                                                                                 | Name of Vaccine                                                                                                                        | Indication                                                                                                                                                                                                                                                                                                                                                        | Permission No. &Date                 |
| 1        | M/s Zydus Lifesciences Limited, Plot Survey No. 23, 25/P,37,40/P,42to 47,49& 50,Sarkhej-BavlaN.H.No.8A, Opp.Ramdev Masala, Village—Changodar,Taluka:Sanand, Dist.: Ahmedabad, Gujarat (India)—382213.        | Measles, Mumps and Rubella Vaccine(Live) I.P. (Freeze Dried) - Multi dose Vial (5.0 ml - 10 dose).                                     | It is indicated for prevention of Measles, Mumps and Rubella virus infections.                                                                                                                                                                                                                                                                                    | MF/BIO/24/000069, Date:25-June-2024  |
| 2        | M/s Serum Institute of India Pvt. Ltd., S. No. 105 110, Manjari BK, Tal Haveli, Pune 412307, Maharashtra (India)                                                                                             | Covid-19 Vaccine, Adjuvanted 2023-24 Formula [SARSCoV-2 rS Protein (COVID-19) Nanoparticle Vaccine, Omicron XBB 1.5 variant] (COVOVAX) | Vaccine is indicated for active immunization to prevent COVID —19 disease (a) in individuals of $\geq 12$ to $< 18$ years of age as primary series of two doses (0.5mL each) 3 weeks apart (b) as single precautionary dose in individuals of $\geq 18$ years of age, who have received primary series of vaccinations for restricted use in emergency situation. | BIO/MA/23/000137, dated;06-June-2024 |
| 3        | M/s Serum Institute of India Pvt. Ltd., 212/2, Off. Soli Poonawalla Road, Hadapsar, Pune, Maharashtra - 411028                                                                                               | Measles and Rubella Vaccine(Live Attenuated) (Freeze-Dried),(10Dose) (0.5ml/Vial)                                                      | For active immunization against Measles and Rubella in infants, children, adolescents of age upto 10 years.                                                                                                                                                                                                                                                       | MF/BIO/24/000055 dated20-May-2024    |
| 4        | M/s Zydus Lifesciences Limited, Plot , Survey No. 23, 25/P,37,40/P,42to47,49& 50,Sarkhej-BavlaN.H.No.8A, Opp. Ramdev Masala, Village —Changodar, Taluka: Sanand, Dist.: Ahmedabad, Gujarat (India) - 382213, | Measles and Rubella Vaccine (Live) I.P. (Freeze Dried) - Multi Dose vial (2.5ml -5 dose).                                              | For active immunization in children of 9 months of age and older against Measles and Rubella infections simultaneously                                                                                                                                                                                                                                            | MF/BIO/24/000052, Date:16-May-2024   |

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| 5 | M/s Serum Institute of India Pvt. Ltd., 212/2, Off. Soli Poonawalla Road, Hadapsar, Pune, Maharashtra - 411028 | Measles Vaccine, Live Attenuated(Freeze-Dried)                                                                                                                    | For active immunization of all susceptible children against measles at 9 months of age.                                                                                          | MF/BIO/24/000045 dated25-April-2024 |
| 6 | M/s Bharat Biotech International Ltd, Genome Valley, Shameerpet, Hyderabad, India -500078.                     | Cholera Vaccine (Inactivated, Oral), V. cholerae (O1 El Tor Hikojima Serotype recombinant strain) formaldehyde inactivated whole Cell, Phosphate Buffered Saline. | For active immunization against Diarrhoeal infection caused by Vibrio cholerae to the children, adolescents and adults aged 1 year and above with two doses on Day 0 and Day 14. | MF/BIO/24/000043 dated16-April-2024 |
| 7 | M/s Bharat Biotech International Ltd, Genome Valley, Shameerpet, Hyderabad, India -500078.                     | Rotavirus Vaccine (Live Attenuated, Oral) I.P (ROTAVAC5D)"vaccine without antibiotics.                                                                            | Active Immunization of infants from the age of 6-8 weeks for prevention of gastroenteritis due to rotavirus infection.                                                           | MF/BIO/24/000028 dated07-March-2024 |

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| Year 2023 |                                                                                      |                                                                        |                                                                                                                                                                                                                                       |                                      |
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| S. No.    | Name of Firm                                                                         | Name of Vaccine                                                        | Indication                                                                                                                                                                                                                            | Permission No.& Date                 |
| 1.        | M/s Cadila Pharmaceuticals Limited, 1389, Dholka, Ahmadabad, Gujarat- 382225, India. | Quadrivalent Seasonal Influenza Virus-Like Particle (VLP) Vaccine, I.P | For active immunization in adults and children from 6 months of age for the prophylaxis against influenza disease caused by influenza virus subtype A and B contained in the vaccine.                                                 | MF/BIO/23/000003 dated 18-Jan-2023   |
| 2.        | M/s Gennova Biopharmaceuticals Limited                                               | Lyophilized mRNA Vaccine for Injection (COVID-19) [GEMCOVAC®-OM]       | The vaccine is indicated as a single booster dose in individuals aged ≥18 years administered at least 4 months after completion of primary vaccination with either COVISHIELD™ or COVAXIN® for restricted use in emergency Situation. | MF/BIO/23/000055, dated 19-June-2023 |

| Additional Indications |                                                                                                                                                                          |                                                                                 |                                                                                                                                                                                                                                                                                                     |               |
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| 1.                     | M/s. Zydus Lifesciences Limited, Plot Survey No.23, 25/P,37,40/P,42to47, Opposite Ramdev Masala, Sarkhej-Bavla N.H. No. 8A, Changodar, Ahmedabad (Dist.) India -382 213. | Novel Corona Virus 2019-nCoV Vaccine (Recombinant) (3mg, Single dose)           | for administration of heterologous booster (third) dose of Novel Corona Virus 2019- nCoV Vaccine (Recombinant) (3mg, Single dose) to individuals aged ≥18 years after 6 months of primary vaccination (two doses) of either COVAXIN or COVISHIELD vaccine for restricted use in emergency situation | 20-April-2023 |
| 2.                     | M/s Serum Institute of India Pvt.Ltd., 212/2, Off. Soli Poonawalla Road, Hadapsar, Pune,                                                                                 | SARS-CoV-2 rS Protein (COVID-19) recombinant spike protein Nanoparticle Vaccine | For administration of heterologous booster (third) dose to individuals Aged ≥18 years after 6 months of primary vaccination (two doses) of                                                                                                                                                          | 16-Jan-2023   |

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|    | Maharashtra-411028                                                                                                                                                                     |                                                                 | either COVAXIN or COVISHIELD vaccines for restricted use in emergency situation                                                                                                                                                                                                                                                                                                 |                                       |
| 3. | M/s. Zydus Lifesciences Ltd, Plot Survey No. 23, 25/P,37,40/P,42To47 Sarkhej-Bavla N.H. No-8A, Opposite Ramdev Masala, Village Changodar, Tal. Sanand Ahmedabad Gujarat (India)—382213 | Inactivated Influenza Vaccine (Split Virion) IP (Tetravalent) - | For active immunization of pediatrics & Children from 6 months to 35 months age with two dose schedule 0.5 ml each to 17 years of age as an additional indication(a dose of 0.5 ml for 3 years to 17 years age group and a dose of 0.25ml for 6 months to group) for active immunization for the prevention of disease caused by influenza A subtype viruses and type B viruses | 24-May-2023<br><br>(BIO/MA/22/000146) |

| Year 2022 |                                                                                                                |                                                           |                                                  |                                      |
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| S. No.    | Name of Firm                                                                                                   | Name of Vaccine                                           | Indication                                       | Permission No. & Date                |
| 1.        | M/s Bharat Biotech International Ltd., Genome Valley, Shameerpet, Hyderabad, India - 500078.                   | Whole-Virion Inactivated Corona virus (SARS-CoV-2)vaccine | For sale or for distribution in Adult population | BIO/MA/22/000002<br>Date:27-01-2022  |
| 2.        | M/s Serum Institute of India Pvt. Ltd., 212/2, Off. Soli Poonawalla Road, Hadapsar, Pune, Maharashtra - 411028 | ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant)        | For sale or for distribution in Adult population | BIO/MA/22/000102<br>Date: 27-01-2022 |

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| 3. | M/s Biological E. Limited,<br>18/1 & 3, Azamabad,<br>Hyderabad, Telangana -<br>500020.                                                                                                                            | SARS-CoV-2(Covid-19)<br>Vaccine containing Receptor<br>Binding Domain of SARS-<br>CoV-2                                                      | For active immunization against<br>COVID- 19 disease in adults aged18<br>years and above when given in two<br>doses at day 0 & day 28 for<br>restricted use in emergency situation                                                                                                           | MF/BIO/22/000011<br>Dated11-FEB-2022  |
| 4. | M/s Hetero Biopharma<br>Limited, H. No. 8-3-166/1<br>&2,105To108,1 <sup>st</sup><br>Floor, G Block, EastWing,<br>Challa Estates,<br>Erragadda, Hyderabad-<br>500018                                               | Recombinant adenoviral<br>vector vaccine containing<br>particles of serotype 26<br>containing the protein S gene<br>of the SARS-CoV- 2 virus | For the prevention of the COVID-19)<br>in adults aged over 18 year, when<br>administered in single dose of(0.5ml)<br>for restricted use in emergency<br>situation                                                                                                                            | MF/BIO/22/000024<br>dated16-MAR-2022  |
| 5. | M/s Zydus Lifesciences<br>Limited., Plot Survey No.<br>23,25/P,37, 40/P, 42 to<br>47, Opp. Ramdev<br>Masala, Sarkhej- Bavla,<br>N.H. No. 8A, Village-<br>Changodar, Taluka-<br>Sanand, Dist.<br>Ahmedabad-382213, | Novel Corona virus-2019-<br>nCoV Vaccine<br>(Recombinant)                                                                                    | For active immunization to prevent<br>COVID-19 caused by SARS- CoV- 2<br>in individuals 12 years of age and<br>older when given in two separate<br>doses of 3mg (0.3ml) each to be<br>given at an interval of 28 days each<br>(day 0, day 28).                                               | MF/BIO/22/000034<br>Dated25-Apr-2022  |
| 6. | M/s Panacea Biotec Ltd.,<br>Ambala-Chandigarh<br>Highway, Post office<br>Lalru, District Sahibzada<br>Ajit Singh Nagar Punjab-<br>140 501, India                                                                  | Adsorbed Diphtheria,<br>Tetanus, Pertussis,<br>Poliomyelitis (Inactivated)<br>and Haemophilus influenzae<br>Type b Conjugate Vaccine<br>I.P. | For active immunization for<br>prevention against Diphtheria,<br>Tetanus, Pertussis (Whooping<br>Cough), infections caused by<br>Haemophilus influenzae Type b<br>&Poliomyelitis.<br>Posology: One paediatric dose is of<br>0.5 ml to be administered<br>Intramuscularly with an interval of | MF/BIO/22/000043<br>dated:20-May-2022 |

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|     |                                                                                                                                                |                                                                                           | four weeks between doses, starting at 6 weeks of age (6, 10 and 14 weeks of birth)                                                                                                                                                                                                              |                                      |
| 7.  | M/s Human Biologicals Institute (A division of Indian Immunologicals Limited), Rakshapuram Gachibowli Post Rangareddi Hyderabad (India)-500032 | Measles and Rubella Vaccine (Live) I.P.                                                   | For active immunization in children of 9 months of age and older against Measles and Rubella. (0.5ml single dose).                                                                                                                                                                              | MF/BIO/22/000058 dated 27-JUNE-2022. |
| 8.  | M/s Gennova Biopharmaceuticals Limited                                                                                                         | Lyophilized mRNA Vaccine for Injection (COVID-19) [HGCO-19]                               | For active immunization against COVID-19 disease in adults aged 18 years and above when given in two doses at day 0 & day 28.                                                                                                                                                                   | MF/BIO/22/000064 Dated 28-JUN-2022   |
| 9.  | M/s Seasons Biologicals Private Limited,                                                                                                       | Tetanus Vaccine (Absorbed) I.P                                                            | For active immunization against tetanus infection when administered as single dose of 0.5 ml in the age group of 10 to 45 years.                                                                                                                                                                | MF/BIO/22/000068 dated 04-JULY-2022  |
| 10. | M/s Serum Institute of India Pvt., Ltd., 212/2, Off. Soli Poonawalla Road, Hadapsar Pune (India) — 411028                                      | Quadrivalent Human Papilloma Virus (Serotypes 6,11, 16 & 18) Vaccine (Recombinant) (qHPV) | For active immunization in the age group of 9-14 years (male and female), two- doses schedule (0 and 6 months) and for age group of 15-26 years (male and female), three-dose schedule (0,2 and 6 months) for prevention of the disease caused by Human Papilloma Virus types 6, 11, 16 and 18. | MF/BIO/22/000072 Dated 12-JULY-2022  |

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| 11. | M/s Human Biologicals Institute (A division of Indian Immunologicals Limited), Rakshapuram Gachibowli Post Rangareddi Hyderabad (India) - 500032 | Diphtheria & Tetanus vaccine for Adults & Adolescents I.P.                                                                                                       | For active immunization against Diphtheria and Tetanus in Adolescents (10 years to below 18 years) & Adults (age 18 years to 60 years).                                                                                                                                                                                 | MF/BIO/22/000078<br>Dated 25-Aug-2022 |
| 12. | M/s Bharat Biotech International Ltd., Genome Valley Shamirpet, Hyderabad, Telangana, India—500 078                                              | ChAd36-SARS-CoV-S COVID-19 (Chimpanzee Adenovirus Vectored) recombinant COVID-19 Vaccine (Nasal)                                                                 | For active immunization against COVID-19 in the age group of 18 years and above when given in two doses [0.5ml each administered intranasally as 4 drops (0.25 mL) in each nostril] at day 0 & day 28 interval.                                                                                                         | MF/BIO/22/000083<br>Dated 05-Sep-2022 |
| 13. | M/s Serum Institute of India Pvt., Ltd., 212/2, Off. Soli Poonawalla Road, Hadapsar Pune (India) — 411028                                        | Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis-B (rDNA), Poliomyelitis (Inactivated) and Haemophilus influenzae type b Conjugate Vaccine (Adsorbed) I.P. | For active immunization of infants, at or above the age of 6 weeks against Diphtheria, Tetanus, Pertussis, Hepatitis B, Poliomyelitis and invasive disease caused by <i>Haemophilus influenzae</i> type b for 3 dose regimen (6, 10 & 14 weeks) for primary vaccine action and Booster dose at The age of 12-24 months. | MF/BIO/22/000086 Dated 14-SEPT-2022   |
| 14. | M/s Serum Institute of India Pvt., Ltd., 212/2, Off. Soli Poonawalla Road, Hadapsar Pune (India) — 411028                                        | Diphtheria, Tetanus and Pertussis (Acellular, component) Vaccine [adsorbed, reduced antigen(s) content]                                                          | For active booster immunization against Tetanus, Diphtheria, and Pertussis in individuals aged 4 years to 65 years.                                                                                                                                                                                                     | MF/BIO/22/000088<br>Dated 21-SEP-2022 |

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| <b>15</b>  | M/s Serum Institute of India Pvt Ltd, 212/2, Off. Soli Poonawalla Road, Hadapsar Pune(India)–411028                                              | [Meningococcal (A,C,Y,W,X) Polysaccharide Conjugate Vaccine (Freeze-Dried)] | For active immunization of individuals aged 18-85 years against invasive meningococcal disease caused by Neisseria Meningitidis serogroups A, C, Y,W, and X.                                                             | MF/BIO/22/000089 Dated 26-SEPT-2022 |
| <b>16.</b> | M/s Human Biologicals Institute (A division of Indian Immunologicals Limited) Rakshapuram, Gachibowli Hyderabad, Telangana-500032                | Inactivated Hepatitis A Vaccine, IP (Adsorbed) IP                           | For prevention of Hepatitis A infection for 0.5mL dose of children (above 1 years) & adolescents and 1 mL in adults (aged 10 years to 49 years).                                                                         | MF/BIO/22/000095 Dated:17-OCT-2022  |
| <b>17.</b> | M/s Biological E. Limited, Plot No. 1, Phase II, Biotech Park, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana INDIA 500078. | Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P. (14 Valent)   | For active Immunization against invasive disease caused by Streptococcus Pneumonia serotype 1,3,4,5,6B,7F,9V,14,18C,19A,19F,22F ,23F and 33F in infants from 6 weeks of age group for 3 dose schedule (6,10 & 14 weeks). | MF/BIO/22/000112 Dated:10-DEC-2022  |

**Approval of New indications of Approved Vaccines**

| <b>S. No.</b> | <b>Name of Firm</b> | <b>Name of Vaccine</b> | <b>Indication</b> | <b>Date of approval</b> |
|---------------|---------------------|------------------------|-------------------|-------------------------|
|---------------|---------------------|------------------------|-------------------|-------------------------|

**Annexure-I(b)**

**Details of Manufacturing Permissions of Human Vaccines**

|    |                                                                                                                                                                 |                                                                                                               |                                                                                                                                                                                                                                                             |             |
|----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|
| 1. | M/s Biological E. Limited,<br>Plot No. 1, Phase II,<br>Biotech Park, Kolthur<br>Village, Shameerpet,<br>Medchal-Malkajgiri District,<br>Telangana INDIA 500078. | Covid-19 vaccine containing<br>Receptor Binding Domain of<br>SARS-CoV-2(RBD antigen of<br>SARSCoV-2(Covid-19) | For Covid-19 vaccine containing<br>Receptor Binding Domain of SARS-<br>CoV-2 (RBD antigen of SARS CoV-<br>2(Covid-19) for use in age group of<br>≥12 to <18 years with the dose<br>schedule of 0 & 28 days for<br>restricted use in emergency<br>Situation. | 21-FEB-2022 |
|----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|

**Annexure-I(b)**  
**Details of Manufacturing Permissions of Human Vaccines**

|    |                                                                                                                                                  |                                                                                                         |                                                                                                                                                                                                                                                         |              |
|----|--------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| 2. | M/s Serum Institute of India Pvt. Ltd. 212/2, Off Soli Poonawalla Road, Hadapsar, Pune, Maharashtra (India) - 411028.                            | SARS-CoV-2 rS Protein (COVID- 19) recombinant spike protein Nanoparticle Vaccine                        | For SARS-CoV-2 rS Protein (COVID-19) recombinant spike protein Nanoparticle Vaccine for use in age group of $\geq 12$ to $< 18$ years with the dose schedule of 0 & 21 days for restricted use in emergency situation.                                  | 09-MAR-2022  |
| 3. | M/s Bharat Biotech International Ltd., Genome Valley, Shameerpet, Hyderabad, India -500 078.                                                     | Whole Virion inactivated corona virus vaccine                                                           | Whole Virion inactivated corona virus vaccine for use in age group of $> 6$ to $< 12$ years with the dose schedule of 0 & 28 days for restricted use in emergency situation.                                                                            | 25-APR-2022  |
| 4. | M/s Biological E. Limited, Plot No. 1, Phase II, Biotech Park, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana INDIA 500078. | Covid-19 vaccine containing Receptor Binding Domain of SARS-CoV-2 (RBD antigen of SARS CoV-2 (Covid-19) | for Covid-19 vaccine containing Receptor Binding Domain of SARS-CoV-2 (RBD antigen of SARS CoV-2 (Covid-19) for use in age group of $\geq 5$ to $< 12$ years with the dose schedule of 0 & 28days for restricted use in emergency situation.            | 25-APR-2022  |
| 5. | M/s Biological E. Limited, Plot No. 1, Phase II, Biotech Park, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana INDIA 500078. | SARS-CoV-2 (RBD antigen of SARS CoV-2 (Covid-19)                                                        | For administration as heterologous booster (third) dose to individuals aged $\geq 18$ years to 80 years after 6 months of administration of primary vaccination (two doses) of COVAXIN or COVISHIELD vaccine for Restricted use in emergency situation. | 03-JUNE-2022 |

**Annexure-I(b)**  
**Details of Manufacturing Permissions of Human Vaccines**

|    |                                                                                                                                                                                      |                                                                                  |                                                                                                                                                                                                                                                                |                                 |
|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| 6. | M/s Serum Institute of India Pvt. Ltd., 212/2, Off Soli Poonawalla Road, Hadapsar, Pune, Maharashtra (India)-411028                                                                  | SARS-CoV-2 rS Protein (COVID- 19) recombinant spike protein Nanoparticle Vaccine | SARS-CoV-2 rS Protein (COVID-19) recombinant spike protein Nanoparticle Vaccine for use in the age group of $\geq 7$ to $<12$ years for restricted use in Emergency situation.                                                                                 | 28-JUNE-2022                    |
| 7. | M/s Zydus Lifesciences Limited, Plot Survey No. 23, 25/P,37,40/P,42to47, Opp. Ramdev Masala, Sarkhej- Bavla, N.H. No. 8A, Village - Changodar, Taluk- Sanand, Dist. Ahmedabad-382213 | Typhoid Vi Conjugate Vaccine I.P.                                                | For active immunization against <i>Salmonella typhi</i> infection in 6 months to 65 years age group.                                                                                                                                                           | 08-SEPT-2022                    |
| 8. | M/s Serum Institute of India Pvt. Ltd., 212/2, Off Soli Poonawalla Road, Hadapsar, Pune, Maharashtra (India)-411028                                                                  | Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (IO-Valent)             | For additional indication to permission no. MF/BIO/20/000059 dated 14-Jul-2020 as to be administered as 2+1 schedule (6 weeks, 14 weeks & 9 months of age)                                                                                                     | 01-NOV-2022<br>BIO/MA/22/000063 |
| 9  | M/s Bharat Biotech International Ltd., Genome Valley Shamirpet, Hyderabad, Telangana, India — 500 078                                                                                | ChAd36-SARS-CoV-S (Chimpanzee Adenovirus vectored) recombinant COVID-19 vaccine  | For new (additional) indication to permission no. MF/BIO/22/000083 dated 06.09.2022 administer booster dose (third dose) after 6 months to individuals of age $>18$ years who have already administered primary (two doses) of COVAXIN or COVISHIELD vaccines. | 25-NOV-2022<br>BIO/MA/22/000095 |

**Annexure-I(b)**  
**Details of Manufacturing Permissions of Human Vaccines**

| Year 2021 |                                                                                                                                                           |                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                    |
|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| S. No.    | Name of Firm                                                                                                                                              | Name of Vaccine                                           | Indication                                                                                                                                                                                                                                                                                                                                                                                                                            | Permission No. & Date              |
| 1.        | M/s Serum Institute of India Pvt. Ltd. 212/2, Off. Soli Poonawalla Road, Hadapsar Pune, Maharashtra, India.                                               | ChAdOx1nCoV-19Corona Virus Vaccine (Recombinant)          | <b>For Restricted use in emergency situation:</b> For active immunization of individuals of $\geq 18$ years old for the prevention of corona virus disease (COVID-19) when administered in two doses schedule. The second dose should be administered between 4 to 6 weeks after the first dose. However, there is data available for administration of the second dose upto 12 weeks after the first dose from the overseas studies. | MF/BIO/21/000001 dated 03-Jan-2021 |
| 2.        | M/s Bharat Biotech International Limited, Sy. No. 230, 231 & 235, Genome Valley, Shameerpet Mandal, Medchal-Malkajgiri District, Telangana-500078, India. | Whole Virion Inactivated Corona Virus Vaccine, [BBV152]   | For Restricted use in emergency Situation in clinical trial mode: For active immunization against Corona Virus Disease (COVID-19) for age $\geq 18$ years when administered in two doses interval of day 0 & day 28.                                                                                                                                                                                                                  | MF/BIO/21/000002 dated 03-Jan-2021 |
| 3.        | M/s Serum Institute of India Pvt. Ltd. 212/2, Off. Soli Poonawalla Road, Hadapsar Pune, Maharashtra, India.                                               | Diphtheria, Tetanus and Pertussis Vaccine (Adsorbed) I.P. | For the primary immunization of infants, at or above the age of 6 weeks, and of children through six years of age against diphtheria, tetanus and whooping cough.                                                                                                                                                                                                                                                                     | MF/BIO/21/000003 dated 04-JAN-2021 |

**Annexure-I(b)**  
**Details of Manufacturing Permissions of Human Vaccines**

|    |                                                                                                                                                   |                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                |                                       |
|----|---------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|
| 4. | M/s Serum Institute of India Pvt., Ltd., S.No. 105-110, Manjari, Budruk, Pune, Maharashtra - 412307, India.                                       | ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) | For Restricted use in emergency situation: For active immunization of individuals of $\geq 18$ years old for the prevention of corona virus disease (COVID-19) when administered in two doses schedule. The second dose should be administered between 4 to 6 weeks after the first dose. However, there is data available for administration of the second dose upto 12 weeks after the first dose from the overseas studies. | MF/BIO/21/000019<br>Dated 11-Feb-2021 |
| 5. | M/s Biological E. Limited, Plot No. 1, Phase II, Biotech Park, Kolthur Village, Shameerpet Mandal, Medchal-Malkajgiri District, Telangana -500078 | Inactivated Hepatitis A Vaccine (Adsorbed), IP     | For active immunization against Hepatitis A virus (HAV) in 1 to 15 years of age group                                                                                                                                                                                                                                                                                                                                          | MF/BIO/21/000033<br>dated 13-Apr-2021 |
| 6. | M/s Serum Institute of India Pvt. Ltd., 212/2, Off. Soli Poonawalla Road, Hadapsar Pune (India)—411 028.                                          | BCG for immunotherapy I.P.                         | For treatment of flat Urothelial cell carcinoma in situ of urinary bladder and as adjunctive therapy following transurethral resection of primary or relapsing superficial non-invasive papillary tumors that are limited to the bladder mucosa (stage Ta or T1). Intravesical BCG Immunotherapy has been shown to reduce tumor recurrence and prevent progression                                                             | 21-June-2021<br>BIO/MA/21/000044      |

**Annexure-I(b)**  
**Details of Manufacturing Permissions of Human Vaccines**

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| 7.  | M/s Ra (biologicals) Panacea Biotech Ltd., A-27,B-1ExtensionMohan Cooperative Industrial Estate, Mathura Road New Delhi—110044, India.                                                      | Gam-COVID-Vac combined vector vaccine (Component I & Component II) Sputnik V vaccine | For Restricted use in emergency situation: For the prevention of the novel Corona virus infection (COVID-19) in adults aged over 18, when given in two separate doses three weeks apart. Day 0: Component I (0.5ml) & Day 21: Component II (0.5ml) | MF/BIO/21/000057<br>Dated02-Jul-2021  |
| 8.  | M/s Zydus Lifesciences Limited, Zydus Corporate Park Scheme No. 63, Survey No. 536, Near Nirma University, Vaishnov Devi Circle Khoraj (Gandhinagar)S. G.Highway, Ahmedabad –382481,Gujarat | Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents I.P.            | For active immunization of children 10 years of age or older, adolescents and adults, against tetanus and diphtheria.                                                                                                                              | MF/BIO/21/000059<br>dated15-Jul-2021  |
| 9.  | M/s Bharat Biotech International Limited at M/s Chiron Behring Vaccines Private Limited, PlotNo.3502,G.I.D.C., EstateP.BNo.136, Dist. Bharuch, Ankleshwar, Gujarat (India)-393002.          | Whole Virion Inactivated Corona Virus Vaccine, [BBV152]                              | For Restricted use in emergency situation: For active immunization against Corona Virus Disease (COVID-19) for age ≥18 years when administered in two doses interval of day 0 & day 28.                                                            | MF/BIO/21/000069<br>dated09-Aug-2021  |
| 10. | M/s. Biological E. Limited, SEZ- Unit Sy.No:549, 550,552to556,Kolthur Village, Shameerpet, Medchal- Malkajgiri District, Telangana, India                                                   | COVID-19 vaccine (Ad26.COV2-S [recombinant]) (Janssen Vaccine)                       | For active immunisation to prevent COVID-19 caused by SARS-CoV-2in individuals 18 years of age and older when given in single dose (0.5 mL).                                                                                                       | MF/BIO/21/000080<br>Dated 18-Aug-2021 |

**Annexure-I(b)**  
**Details of Manufacturing Permissions of Human Vaccines**

|     |                                                                                                                                                                                     |                                                                                                                       |                                                                                                                                                                                                                                                                                    |                                        |
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|     | –500 078.                                                                                                                                                                           |                                                                                                                       |                                                                                                                                                                                                                                                                                    |                                        |
| 11. | M/s Zydus Lifesciences Limited, Plot Survey No. 23,25/P,37,40/P,42to 47,Opp.RamdevMasala, Sarkhej- Bavla, N.H. No. 8A, Village - Changodar, Taluka—Sanand Dist. Ahmedabad - 382 213 | Novel Corona virus-2019-nCoV Vaccine (Recombinant)                                                                    | For Restricted use in emergency situation: For active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older when given in three separate doses of 2mg (0.2ml) each to be given at an interval of 28 days each (day 0, day 28 and day 56). | MF/BIO/21/000081<br>Dated 20-Aug-2021  |
| 12. | M/s Bharat Biotech International Ltd., Genome Valley, Shameerpet, Hyderabad, India-500078.                                                                                          | Typhoid Vi conjugate vaccine IP [Typhoid (Vi Capsular Polysaccharide)—Tetanus Toxoid conjugate vaccine]               | For active immunization against <i>Salmonella Typhi</i> infection in ≥6 months to ≤65 year age group                                                                                                                                                                               | 23-Aug-2021<br>(Additional indication) |
| 13. | M/s Bharat Biotech International Ltd., Genome Valley, Shameerpet, Hyderabad, India-500078.                                                                                          | Diphtheria, Tetanus, Pertussis (Whole Cell) and <i>Haemophilus influenzae</i> Type b Conjugate Vaccine (Adsorbed) IP. | For the primary immunization of infants aged 6 weeks and above as three dose schedule at 6, 10 & 14 weeks against disease like diphtheria, tetanus and whooping cough and those caused by <i>Haemophilus Influenzae</i> Type b.                                                    | MF/BIO/21/000107<br>dated 20-SEP-2021  |

**Annexure-I(b)**  
**Details of Manufacturing Permissions of Human Vaccines**

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| 14. | M/s<br>CENTRALRESEARCH<br>INSTITUTE KASAULI<br>DIST-SOLANKASAULI<br>IndiaPincode:173204                                                                                    | Diphtheria and Tetanus<br>Vaccine (Adsorbed) for<br>Adults and Adolescents<br>I.P.            | For active immunization as booster<br>dose at the age of 10 years and 16<br>years against tetanus and<br>diphtheria                                                                                                                                                                                                                                                                           | MF/BIO/21/000112<br>dated08-Oct-2021 |
| 15. | M/s. Hetero Biopharma<br>Limited H.No. 8-3-166/1 &<br>2, 105 To 108, 1st Floor,G<br>Block, East Wing, Challa<br>Estates, Erragadda,<br>Hyderabad India Pincode :<br>500018 | Gam-COVID-Vac combined<br>Vector vaccine (Component<br>I & Component II) Sputnik V<br>vaccine | For the prevention of the novel<br>Corona virus infection (COVID-19)<br>in adults aged over 18, when given<br>in two separate doses three weeks<br>apart. Day 0: Component I (0.5<br>ml)& Day 21: Component II (0.5ml)                                                                                                                                                                        | MF/BIO/21/000110<br>Dated05-Oct-2021 |
| 16. | M/s Human Biologicals<br>Institute (A division of<br>Indian Immunologicals<br>Limited), Rakshapuram<br>Gachibowli Post<br>Rangareddy Hyderabad<br>(India)-500032           | Tetanus Vaccine<br>(Adsorbed) I.P.                                                            | For active immunization at more than<br>equals to 6 weeks against Tetanus.<br>Also For Prevention of tetanus in all<br>age groups following injury or animal<br>bite and to persons who are at<br>increased risk of<br>attaining injuries through their<br>occupation or recreational activities.                                                                                             | MF/BIO/21/000117<br>dated09-NOV-2021 |
| 17. | M/s Serum Institute of<br>India Pvt., Ltd., S.No.<br>105-110, Manjari, Budruk,<br>Pune, Maharashtra 412307                                                                 | BCG for immunotherapy<br>I.P., 40mg/ml                                                        | For treatment of flat Urothelial cell<br>carcinoma in situ of urinary bladder<br>and as adjunctive therapy following<br>transurethral resection of primary or<br>relapsing superficial non-invasive<br>papillary tumors that are limited to<br>the bladder mucosa (stage Ta orT1).<br>Intravesical BCG Immunotherapy<br>has been shown to reduce tumor<br>recurrence and prevent progression. | MF/BIO/21/000128<br>dated16.12.2021  |

**Annexure-I(b)**  
**Details of Manufacturing Permissions of Human Vaccines**

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|-----|------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|
| 18. | M/s Bharat Biotech International Ltd., Genome Valley, Shameerpet, Hyderabad, India-500078.                                                     | Whole Virion inactivated coronavirus vaccine                                     | Additional indication of whole virion inactivated corona virus vaccine for use in age group of >12 to 18 years with the dose schedule of 0 and 28 days for restricted use in Emergency situation. | 24.12.2021                            |
| 19. | M/s Serum Institute of India Pvt. Ltd. S. No. 105-110, Manjari BK, Tal -Haveli, Pune- 412307, Maharashtra (India)                              | SARS-CoV-2 rS Protein (COVID- 19) recombinant spike protein Nanoparticle Vaccine | For active immunization to prevent COVID-19 caused by SARS CoV-2 in individuals 18 years of age and older when administered in two Dose schedule of day 0 & day 21.                               | MF/BIO/21/000138<br>Dated 28-Dec-2021 |
| 20. | M/s Serum Institute of India Pvt. Ltd. 212/2, Off Soli Poonawalla Road, Hadapsar, Pune, Maharashtra (India)- 411028                            | SARS-CoV-2 rS Protein (COVID- 19) recombinant spike protein Nanoparticle Vaccine | For active immunization to prevent COVID-19 caused by SARSCoV-2 in individuals 18 years of age and older when administered in two dose schedule of day 0 & day 21.                                | MF/BIO/21/000137<br>Dated 28-Dec-2021 |
| 21. | M/s Biological E. Limited Plot No. 1, Phase II, Biotech Park, Kolthur Village, Shameerpet, Medchal-Malkajgiri District, Telangana INDIA 500078 | SARS-CoV-2 (Covid-19) Vaccine containing Receptor Binding Domain of SARS-CoV-2   | For active immunization against COVID-19 disease in adults aged 18 years and above when given in two doses at day 0 & day 28.                                                                     | MF/BIO/21/000136<br>Dated 28-Dec-2021 |
| 22. | M/s Serum Institute of India Pvt. Ltd. 212/2, Off Soli Poonawalla Road, Hadapsar, Pune, Maharashtra (India)- 411028                            | Influenza Vaccine (Human, Live Attenuated) I.P., Quadrivalent                    | For active Immunization against influenza disease caused by two influenza A subtype viruses and two influenza Type B viruses in the age group of 2 years and above.                               | MF/BIO/21/000139<br>Dated 30-Dec-2021 |

**Annexure-I(b)**  
**Details of Manufacturing Permissions of Human Vaccines**

| Year 2020 |                                                                                                                                                                            |                                                        |                                                                                                                                                                                                                                                                  |                                      |
|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| S. No.    | Name of Firm                                                                                                                                                               | Name of Vaccine                                        | Indication                                                                                                                                                                                                                                                       | Permission No. & Date                |
| 1         | M/s Biological E. Limited,<br>Plot No. 1, Phase II,<br>Biotech Park, Kolthur<br>Village, Shameerpet<br>Mandal, Medchal-<br>Malkajgiri District,<br>Telangana- 500078,India | Typhoid Vi Conjugate<br>Vaccine, IP                    | For active immunization against<br>infection caused by Salmonella<br>typhi in infants, children,<br>adolescents and adults aged $\geq 6$<br>months to $\leq 45$ years.                                                                                           | MF/BIO/20/000001<br>dated 28.01.2020 |
| 2         | M/s Serum Institute of<br>India Pvt., Ltd., S. No.105-<br>110, Manjari, Budruk,<br>Pune, Maharashtra-<br>412307, India                                                     | Bacillus Calmette-Guerin<br>Vaccine I.P.(Freeze-Dried) | For prevention of tuberculosis.<br>(Dose of 0.05 ml for children under<br>one month of age and 0.1ml for<br>children over one month of age and<br>adults)                                                                                                        | MF/BIO/20/000037<br>Dated 29.04.2020 |
| 3         | M/s. Cadila<br>Pharmaceuticals Limited<br>1389-Trasad Road Dholka<br>Ahmedabad - 382225<br>Gujarat (India)                                                                 | Recombinant Rabies G<br>Protein Vaccine                | Active immunization against rabies<br>for Post-exposure treatment (after<br>exposure) in 18 to 65 years of age:<br>Treatment after contact with<br>animals which are rabid or<br>suspected to be rabid, or after<br>contact with an inoculated rabies<br>carcass | MF/BIO/20/000040<br>dated 08.05.2020 |

**Annexure-I(b)**  
**Details of Manufacturing Permissions of Human Vaccines**

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|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| 4 | M/s Zydus Lifesciences Limited, plot survey no.23, 25/P, 37, 40/P, 42 To 47 Sarkhej-Bavla N.H.No-8A, Opposite Ramdev Masala, Village Changodar, Tal. Sanand, Ahmedabad-382213, Gujarat, India | Hepatitis B Vaccine (r-DNA) I.P.                                                                                                   | For active immunization against Hepatitis B vaccine infection in adults up to 50 years of age.                                                                                                                                                  | MF/BIO/20/000052 dated 09.06.2020  |
| 5 | M/s Zydus Lifesciences Limited, plot survey no.23, 25/P, 37, 40/P, 42 To 47 Sarkhej-Bavla N.H.No-8A, Opposite Ramdev Masala, Village Changodar, Tal. Sanand, Ahmedabad-382213, Gujarat, India | Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (r-DNA) and Haemophilus Influenzae Type b Conjugate Vaccine(Adsorbed)I.P. | For active immunization of infants, at or above the age of 6 weeks against Diphtheria, Tetanus, Whooping cough, Hepatitis B and Haemophilus influenza type b infections for 3 dose regimen.                                                     | MF/BIO/20/000053 dated 19.06. 2020 |
| 6 | M/s Serum Institute of India Pvt. Ltd. 212/2, Off. Soli Poonawalla Road, Hadapsar Pune, Maharashtra, India.                                                                                   | Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P. (10- Valent)                                                         | For active immunization against invasive disease & pneumonia caused by <i>Streptococcus pneumonia</i> serotypes 1,5, 9V, 14, 19A,19F,23F,7F,6A &6B in Infants from 6 weeks of age group for 3 dose regimen (dosing schedule : 6, 10 & 14 weeks) | MF/BIO/20/000059 dated 14.07.2020  |

**Annexure-I(b)**

**Details of Manufacturing Permissions of Human Vaccines**

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|---|-------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| 7 | M/s Serum Institute of India Pvt., Ltd., 212/2, Off. Soli Poonawalla Road, Hadapsar, Pune<br>Maharashtra (India)-411028 | Diphtheria and Tetanus Vaccine (Adsorbed) I.P. | For the primary immunization of infants, at or above the age of two months and of pre-school children (<6 years of age) against diphtheria and tetanus in whom simultaneous immunization against pertussis is not indicated. | MF/BIO/20/000095<br>date: 17.12.2020 |
|---|-------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|

**Annexure-I(b)**  
**Details of Manufacturing Permissions of Human Vaccines**

| <b>Year 2019</b> |                                                                                                                       |                                                                                                                                                      |                                                                                                                                                                                                                                                            |                                   |
|------------------|-----------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
| <b>S. No.</b>    | <b>Name of Firm</b>                                                                                                   | <b>Name of Vaccine</b>                                                                                                                               | <b>Indication</b>                                                                                                                                                                                                                                          | <b>Permission No. &amp; Date</b>  |
| 1                | M/s Venky Parenterals, Unit of Sriguru Capital Services Limited Advipolam Yanam Puducherry (India) - 533464           | Tetanus Vaccine (Adsorbed), I.P.                                                                                                                     | For active immunization against all children's from age of 6 weeks onwards and those who are exposed to occupational /risks such as road workers, Athletes, agricultural workers, industrial workers, defense personnel, home guards and police personnel. | MF/BIO/19/000001 dated28-Jan-2019 |
| 2                | M/s Serum Institute of India Pvt., Ltd., 212/2, Off. Soli Poonawalla Road, Hadapsar, Pune Maharashtra (India)- 411028 | Poliomyelitis Vaccine (Inactivated) I.P. (Manufactured using Poliomyelitis bulks imported from M/s Bilthoven Biologicals B.V.(BBIO),The Netherlands) | For active immunization of infants (as young as 6 weeks of age), children and adults for the prevention of poliomyelitis caused by poliovirus Types 1, 2, and 3.                                                                                           | MF/BIO/19/000002 dated31-Jan-2019 |
| 3                | M/s Bio Vaccines (India) Private Limited 46-A, Sector A Sanwer Road, Industrial Area, Madhya Pradesh 452015           | Tetanus Vaccine(Adsorbed) I.P.                                                                                                                       | For active immunization against tetanus between 10 to 60 years age group.                                                                                                                                                                                  | MF/BIO/19/000015 dated18.03.2019  |
| 4                | M/s Serum Institute of India Pvt., Ltd., 212/2, Off. Soli Poonawalla Road, Hadapsar, Pune Maharashtra (India)- 411028 | Rotavirus Vaccine (Live Attenuated, Oral) IP(Liquid)                                                                                                 | For active immunization of healthy infants from the age of 6 weeks for the prevention of gastroenteritis due to rotavirus infection when administered as a 3-doseseries.The Three dose regimen should be Completed by one year of age.                     | MF/BIO/19/000031 dated10.06.2019  |

**Annexure-I(b)**  
**Details of Manufacturing Permissions of Human Vaccines**

|   |                                                                                                                      |                                                    |                                                                                                                                                               |                                    |
|---|----------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| 5 | M/s BCG Vaccine Laboratory, 110, 33 Feet Wide Road, Mount Road, Guindy, Chennai Guindy, Tamil Nadu (India)—600 032   | Bacillus Calmette-Guerin vaccine (Freeze Dried) IP | For immunization of infants from birth untill age of 1 year against childhood tuberculosis.                                                                   | MF/BIO/19/000036 dated 26-Jul-2019 |
| 6 | M/s Cadila Pharmaceuticals Limited, 1389-Trasad Road, Dholka (India)—38781, India                                    | Mycobacterium w (Heat Killed)                      | Indicated as an adjuvant in sepsis (due to gram negative infections) treatment when given as 0.1ml for three consecutive days in age group Of 18 to 65 years. | MF/BIO/19/000057 dated 28.11.2019  |
| 7 | M/s Serum Institute of India Pvt., Ltd., 212/2, Off. Soli Poonawalla Road, Hadapsar, Pune Maharashtra (India)-411028 | Bacillus Calmette-Guerin Vaccine I.P.              | For prevention of tuberculosis. (dose of 0.05 ml for children under one month of age and 0.1 ml for children over one month of age and adults)                | MF/BIO/19/000012 dated 13.03.2019  |

**Annexure-I(b)**  
**Details of Manufacturing Permissions of Human Vaccines**

| Year 2018 |                                                                                                                                                                                            |                                                           |                                                                                                                         |                                    |
|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| S. No.    | Name of Firm                                                                                                                                                                               | Name of Vaccine                                           | Indication                                                                                                              | Permission No. & Date              |
| 1         | M/s Bharat Biotech International Limited, Genome Valley, Shameerpet, Hyderabad-500078, A.P., India                                                                                         | Rotavirus Vaccine (Live Attenuated, Oral) I.P. [ROTVAC5D] | Active immunization of infants from the age of 6-8 weeks for preventions of gastroenteritis due to rotavirus infection. | MF/BIO/18/000022, dated:31.08.2018 |
| 2         | M/s. Zydus Lifesciences Limited, Plot Survey No.23,25/P,37, 40/P,42To 47 Sarkhej-Bavla N.H. No-8A, Opposite Ramdev Masala, Village Changodar, Tal. Sanand Ahmedabad Gujarat (India)–382213 | Measles and Rubella Vaccine (Live), I.P. (Freeze Dried)   | For active immunization in children of 9 months of age and older against Measles and Rubella infections simultaneously  | MF/BIO/18/000036 dated:26.12.2018  |

**Approval of New indications of Approved Vaccines**

| S. No. | Name of Firm                                                                                                                                                                               | Name of Vaccine                                                 | Indication                                                                                                                                                                                                                                                                                                                                 | Date of approval                 |
|--------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|
| 1      | M/s. Zydus Lifesciences Limited, Plot Survey No.23,25/P,37, 40/P,42To 47 Sarkhej-Bavla N.H. No-8A, Opposite Ramdev Masala, Village Changodar, Tal. Sanand Ahmedabad Gujarat (India)–382213 | Inactivated Influenza Vaccine (Split Virion) IP (Tetravalent) - | For active immunization of pediatrics & Children from 6 months to 17 years of age as an additional indication (a dose of 0.5 ml for 3 years to 17 years age group and a dose of 0.25ml for 6 months to 35 months age group) for active immunization for the prevention of disease caused by influenza A subtype viruses and type B viruses | 10.12.2018<br>(BIO/MA/18/000030) |

**Annexure-I(b)**  
**Details of Manufacturing Permissions of Human Vaccines**

| Year2017 |                                                                                                                                                  |                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                      |                                 |
|----------|--------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| S. No.   | Name of Firm                                                                                                                                     | Name of Vaccine                                                                                                                      | Indication                                                                                                                                                                                                                                                                                                                           | Permission No. & Date           |
| 1        | M/s Human Biologicals Institute (A division of Indian Immunologicals Limited), Rakshapuram Gachibowli Post Rangareddi Hyderabad (India) - 500032 | Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA) and <i>Haemophilus influenza</i> Type b Conjugate Vaccine (Adsorbed) | Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA) and <i>Haemophilus influenza</i> Type b Conjugate Vaccine (Adsorbed) is indicated for the active immunization of infants, at or above the age of 6 weeks against Diphtheria, Tetanus, whooping cough, Hepatitis-B and <i>Haemophilus influenza</i> type b infections | MF-131/2017, dated:09.06.2017   |
| 2        | M/s Bio-Med Ghaziabad (P) Ltd.,                                                                                                                  | Varicella Vaccine Freeze dried (Live)I.P.                                                                                            | Varicella Vaccine, Live, I.P. is indicated for active immunization against Varicella virus (Chicken Pox) for use in children of 1 to 12 Years of age.                                                                                                                                                                                | MF-183/2017, dated:31.07.2017   |
| 3        | M/s Biological Telangana E. Limited,                                                                                                             | Measles and Rubella Vaccine (Live), I.P. (Attenuated, Freeze Dried)                                                                  | For active immunization against Measles and Rubella in 9 to 12 Months healthy infants at risk.                                                                                                                                                                                                                                       | MF- 190/2017, dated:16.08.2017  |
| 4        | M/s. ZydusLife sciences Limited, Ahmedabad Gujarat                                                                                               | Typhoid Vi Conjugate Vaccine I.P.                                                                                                    | For active immunization against <i>Salmonella typhi</i> infection in adults, children and infants.                                                                                                                                                                                                                                   | MF-274/2017, Dated:15.12.2017   |
| 5        | M/s. Zydus Lifesciences Limit Ahmedabad Gujarat                                                                                                  | Varicella Vaccine (Live) I.P. (Freeze Dried)                                                                                         | For active immunization for the prevention of varicella in age group between 1-12 years                                                                                                                                                                                                                                              | MF-18/2017,dated: 18.01.2017    |
| 6        | M/s Human Biologicals Institute (A Division of Indian Immunologicals                                                                             | Rabies Vaccine (Human) I.P. (Lyophilized, Purified, Vero cell Rabies)                                                                | For prophylaxis against human rabies and post bite therapy against rabies infection                                                                                                                                                                                                                                                  | MF- 288/2017, dated: 22.12.2017 |

**Annexure-I(b)**

**Details of Manufacturing Permissions of Human Vaccines**

|  |                                                                                                                                                |  |  |  |
|--|------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|
|  | Limited) Survey No. 281-284 and 321, Biotech Park, Phase-III, Karkapatla Village, Markook, Mandal, Siddipet, District-502281, Telangana, India |  |  |  |
|--|------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|

**Annexure-I(b)**  
**Details of Manufacturing Permissions of Human Vaccines**

| Year-2016 |                                                     |                                                          |                                                                                                                                                                                       |                               |
|-----------|-----------------------------------------------------|----------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| S. No.    | Name of Firm                                        | Name of Vaccine                                          | Indication                                                                                                                                                                            | Permission No. & Date         |
| 1         | M/s Serum Institute of India Pvt. Ltd., Pune        | Rabies Vaccine Human I.P. (Freeze Dried)                 | Rabies Vaccine Human I.P. is indicated for the prevention of rabies in children and adults. It can be used before and after exposure, as a Primary immunization or as a booster dose. | MF-77/2016, dated: 20.05.2016 |
| 2         | M/s Panacea Biotec Ltd., New Delhi                  | Easy Four-TT (DTwP-Hib) Vaccine                          | For active immunization against Diphtheria, Tetanus, Pertussis (Whooping cough) and infection caused by Haemophilus Type-b.                                                           | MF-99/2016, dated: 13.06.2016 |
| 3         | M/s. Zydus Lifesciences Limited, Ahmedabad, Gujarat | Measles, Rubella Mumps Vaccine (Live) I.P. (Freeze Dried | For prevention of Measles , Rubella & Mumps Virus Infection                                                                                                                           | MF-104/2016, Dated30.06.2016  |
| 4         | M/s. Zydus Lifesciences Limited, Ahmedabad, Gujarat | Tetanus Vaccine (Adsorbed) I.P.                          | For prevention of Clostridium Tetani.                                                                                                                                                 | MF-117/2016, Dated:13.07.2016 |

**Annexure-I(b)**

**Details of Manufacturing Permissions of Human Vaccines**

|   |                                                     |                                            |                                                                                                                                                                                  |                               |
|---|-----------------------------------------------------|--------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| 5 | M/s. Zydus Lifesciences Limited, Ahmedabad, Gujarat | Measles Vaccine (Live) I.P. (Freeze Dried) | Measles vaccines (Live) I.P. (Freeze Dried) is for immunization of all susceptible children against measles. It is recommended to be given to children at 9 months of age or, as | MF-123/2016,Dated :14.07.2016 |
|---|-----------------------------------------------------|--------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|

**Annexure-I(b)**  
**Details of Manufacturing Permissions of Human Vaccines**

|   |                                                        |                                                                  |                                                                                                                                                                                             |                               |
|---|--------------------------------------------------------|------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
|   |                                                        |                                                                  | soon as thereafter, to protect against measles in early life.                                                                                                                               |                               |
| 6 | M/s Bharat Biotech International Ltd.,<br>Hyderabad    | Inactivated JE vaccine                                           | For active immunization of disease caused by Japanese Encephalitis Virus(JEV)                                                                                                               | MF-149/2016,dated: 29.08.2016 |
| 7 | M/s. Zydus Lifesciences Ltd.,<br>Ahmedabad,<br>Gujarat | Inactivated Influenza Vaccine (Split Virion) I. P. (Tetravalent) | The vaccine indicated in adults (≥18 years of age) for active immunization for the prevention of disease caused by influenza A subtype viruses and type B viruses contained in the vaccine. | MF-176/2016, dated:01.11.2016 |

**Annexure-I(b)**  
**Details of Manufacturing Permissions of Human Vaccines**

|    |                                                                                                                                       |                                                                     |                                                                                                                                                                                                    |                                               |
|----|---------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| 8  | M/s Panacea Biotec Ltd., New Delhi                                                                                                    | DTwP-HepB-Hib-IPV Vaccine                                           | For active immunization for prevention against Diphtheria, Tetanus, Pertussis (Whooping Cough), Hepatitis B infection, Infections caused by Haemophilus influenza type b and poliomyelitis         | MF-186/2016, dated:16.11.2016                 |
| 9  | M/s. Zydus Lifesciences Limited Ahmedabad Gujarat                                                                                     | Diphtheria, Tetanus, Pertussis (whole cell) Vaccine (Adsorbed) I.P. | For prevention of Clostridium tetani and Corynebacterium diphtheriae and Bordetella Pertussis                                                                                                      | MF-192/2016, dated:28.11.2016                 |
| 10 | M/s. Zydus Lifesciences Limit Ahmedabad Gujarat                                                                                       | Inactivated Influenza Vaccine (Split Virion) I. P. (Trivalent)      | The vaccine indicated in adults ( $\geq 18$ years of age) for active immunization for the prevention of disease caused by influenza A subtype viruses and type B viruses Contained in the vaccine. | MF-204/2016,dated: 07.12.2016                 |
| 11 | M/s Serum Institute of India Pvt. Ltd., Pune                                                                                          | Rotavirus Vaccine (Attenuated, Oral) I.P. (Freeze Dried)            | It is indicated for active immunization of healthy infants from the age of 6 weeks for the prevention of gastroenteritis due to rotavirus infection when administered as a 3 dose series.          | MF-222/2016,dated: 23.12.2016                 |
| 12 | M/s Chiron Behring Vaccines Pvt. Ltd., Plot Nos. 3501/A, 3502 & 3503/A, Post Box No. 94 GIDC Estate, Ankleshwar, Dist. Bharuch-393102 | Rabies Vaccine I.P. (Purified Chick Embryo Cell Rabies Vaccine)     | Pre exposure prophylaxis and post exposure treatment of Rabies                                                                                                                                     | Permission No. MF- 10/2016, dated: 11.03.2016 |

**Annexure-I(b)**  
**Details of Manufacturing Permissions of Human Vaccines**

| Year 2015 |                                                                                                                                                |                                    |                                                                                                                                                                    |                                   |
|-----------|------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
| S. No.    | Name of Firm                                                                                                                                   | Name of Vaccine                    | Indication                                                                                                                                                         | Permission No. & Date             |
| 1         | M/s Cadila Pharmaceuticals,<br>Survey No. 1389,<br>Trasad Road, Dholka,<br>Ahmedabad- 387810                                                   | Monovalent H1N1-VLP09 Vaccine      | For active immunization for the prevention of disease caused by H1N1 2009 influenza virus in the age group of 18 years and above.                                  | MF-70/2015,<br>dated:12.03.2015   |
| 2         | M/s Sanofi Healthcare India Pvt Ltd<br>Hyderabad                                                                                               | Inactivated Polio vaccine          | For active immunization against Poliomyelitis caused by Poliovirus types1, 2 and 3 in infants, children and adults both for primary immunization and for boosters. | MF-147/2015,<br>dated:19.06.2015  |
| 3         | M/s Bharat Biotech Limited., Hyderabad                                                                                                         | Rabies Vaccine,<br>Thiomersal Free | Active Immunizing Agent against Rabies caused by Rabies Virus Infection                                                                                            | MF-.200/2015,<br>dated:11.09.2015 |
| 4         | M/s Human Biologicals Institute (A division of Indian Immunologicals Limited),Rakshapuram Gachibowli Post Rangareddi Hyderabad (India) -500032 | Rabies Vaccine, Human I.P. (1ml)   | Pre-exposure & Post-exposure prophylaxis against Rabies Infection.                                                                                                 | MF-244/2015,<br>dated:08.12.2015  |
| 5         | M/s Human Biologicals Institute (A division of Indian                                                                                          | Rabies Vaccine, Human I.P. (0.5ml) | Pre-exposure & Post-exposure prophylaxis against Rabies Infection.                                                                                                 | MF-245/2015,<br>dated:08.12.2015  |

**Annexure-I(b)**  
**Details of Manufacturing Permissions of Human Vaccines**

|   |                                                                                                        |                             |                                                                                                                                                              |                                  |
|---|--------------------------------------------------------------------------------------------------------|-----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|
|   | Immunologicals<br>Limited),Rakshapuram<br>Gachibowli Post<br>Rangareddi<br>Hyderabad(India)<br>-500032 |                             |                                                                                                                                                              |                                  |
| 6 | M/s Cadila<br>Pharmaceuticals Ltd.                                                                     | Trivalent Influenza Vaccine | Active immunization of adults,<br>18years of age and above against<br>disease caused by Influenza virus Sub<br>types A& Types B contained in the<br>vaccine. | MF-252/2015,<br>dated:16.12.2015 |

**Annexure-I(b)**  
**Details of Manufacturing Permissions of Human Vaccines**

| <b>Year 2014</b> |                                                                                                                                            |                                                                |                                                                                           |                                  |
|------------------|--------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|-------------------------------------------------------------------------------------------|----------------------------------|
| <b>S. No.</b>    | <b>Name of Firm</b>                                                                                                                        | <b>Name of Vaccine</b>                                         | <b>Indication</b>                                                                         | <b>Permission No. &amp; Date</b> |
| 1                | M/s Human Biologicals Institute, {A division of Indian Immunologicals Ltd.}, Kozhipannai, Pudumund Post, Udhagamandalam-643007, Tamil Nadu | Rabies Vaccine, Human I.P. (Purified Vero Cell Rabies Vaccine) | For immunization of Human against Rabies Infection for prophylaxis and post bite therapy. | MF No. 69/2014, 20.03.2014       |
| 2                | M/s Human Biologicals Institute, {A division of Indian Immunologicals Ltd.}, Kozhipannai, Pudumund Post, Udhagamandalam-643007, Tamil Nadu | Rabies Vaccine, Human I.P. (Purified Vero Cell Rabies Vaccine) | For immunization of Human against Rabies Infection for prophylaxis and post bite therapy. | MF No. 76/2014, 21.03.2014       |
| 3                | M/s Human Biologicals Institute, {A division of Indian Immunologicals Ltd.}, Kozhipannai, Pudumund Post, Udhagamandalam-643007, Tamil Nadu | Rabies Vaccine, Human I.P. (Purified Vero Cell Rabies Vaccine) | For immunization of Human against Rabies Infection for prophylaxis and post bite therapy. | MF No. 77/2014, 21.03.2014       |

**Annexure-I(b)**

**Details of Manufacturing Permissions of Human Vaccines**

|   |                                                                                                                                             |                                         |                                                                                                                                  |                               |
|---|---------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| 4 | M/s Biomed Pvt Limited, C-96, Site—1,BulandshahrRoad Industrial Area, Ghaziabad—201 009(U.P.)INDIA                                          | Typhoid Polysaccharide vaccine (IP)     | For prevention of Typhoid fever                                                                                                  | MF-123/2014, dated:02.06.2014 |
| 5 | M/s HLL Biotech Limited, PlotNo.1,S. P. Biotech Park, Phase-II,Kolthur Village, Shameerpet Mandal, R. R. District, Andhra Pradesh- 500078.  | Hepatitis B vaccine (r-DNA)             | Indicated for the prevention of Hepatitis B infection                                                                            | MF-243/2014, dated:14.11.2014 |
| 6 | M/s HLL Biotech Limited, PlotNo.1,S. P. Biotech Park, Phase-II, Kolthur Village, Shameerpet Mandal, R. R. District, Andhra Pradesh- 500078. | DTP-Hib –Hep                            | Active immunization against Diphtheria, Tetanus, Pertussis, Hepatitis–Band Haemophilus Type b infection                          | MF-245/2014, dated:17.11.2014 |
| 7 | M/s Biomed Pvt Limited, C-96, Site—1,BulandshahrRoad Industrial Area, Ghaziabad – 201 009 (U.P.) INDIA                                      | Rabies vaccine human (cell culture IP ) | Pre exposure immunization- The vaccine is recommended for the prevention of Rabies in subject sat a continuous risk of exposure. | MF253/2014 ,dated:20.11.2014  |

**Annexure-I(b)**

**Details of Manufacturing Permissions of Human Vaccines**

|   |                                                                                                       |                                      |                                                      |                               |
|---|-------------------------------------------------------------------------------------------------------|--------------------------------------|------------------------------------------------------|-------------------------------|
| 8 | M/s Biomed Pvt Limited, C-96, Site—1, Bulandshahr Road Industrial Area, Ghaziabad—201009 (U.P.) INDIA | Oral Poliomyelitis vaccine, Live IP. | For active Immunization against Poliomyelitis virus. | MF-269/2014, dated:10.12.2014 |
|---|-------------------------------------------------------------------------------------------------------|--------------------------------------|------------------------------------------------------|-------------------------------|

**Annexure-I(b)**  
**Details of Manufacturing Permissions of Human Vaccines**

| Year 2013 |                                                                                                                |                                                                                                                  |                                                                                         |                                |
|-----------|----------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|--------------------------------|
| S. No.    | Name of Firm                                                                                                   | Name of Vaccine                                                                                                  | Indication                                                                              | Permission No. & Date          |
| 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 Poliovirus type I and type III.                         | MF-78/2013, dated: 23.04.2013  |
| 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.               | MF-79/2013, dated:22.05.2013.  |
| 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 Type3)                              | Active immunization against Poliomyelitis caused by type 1, type2 and type 3 infection. | MF-154/2013, dated:24.07.2013. |

**Annexure-I(b)**  
**Details of Manufacturing Permissions of Human Vaccines**

|   |                                                                                                |                                                        |                                                                                                                                                                                                                                                                                                                     |                                   |
|---|------------------------------------------------------------------------------------------------|--------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
| 4 | M/s Bio-Med (P) Ltd.,<br>C- 96, B.S. Road,<br>Indl. Area,<br>Ghaziabad-201009,<br>U.P., India. | Poliomyelitis Vaccine, Live<br>(Oral), I.P., Trivalent | Poliomyelitis vaccine, Live(Oral)<br>I.P. (trivalent) is indicated for<br>active immunization of<br>Poliomyelitis virus. Infants should<br>receive at least three doses of<br>OPV at minimum interval of 4<br>weeks. WHO recommends the<br>following schedule in endemic<br>countries at birth, 6, 10, 14<br>weeks. | MF-188/2013,<br>dated:16.08.2013. |
|---|------------------------------------------------------------------------------------------------|--------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|

**Annexure-I(b)**  
**Details of Manufacturing Permissions of Human Vaccines**

| Year 2013 |                                                                                                                              |                                                                                                                    |                                                                                                                                          |                               |
|-----------|------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| S. No.    | Name of Firm                                                                                                                 | Name of Vaccine                                                                                                    | Indication                                                                                                                               | Permission No. & Date         |
| 5         | M/s Serum Institute of India Ltd., 212/2, Hadapsar, Pune-411-028                                                             | Influenza Vaccine, Live attenuated (Human) Seasonal Trivalent freeze dried2013Southern Hemisphere influenza season | For active Immunization against influenza disease caused by influenza subtype A and type B viruses in the age group of 2 years and above | MF 193/2013, date:03.09.2013  |
| 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.                 | MF-192/2013, dated 03.09.2013 |
| 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                                                                                   | MF- 197/2013 dated 05.09.2013 |
| 8         | M/s GlaxoSmithKline AsiaPvtLtd.,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     | MF-70/2013 dated: 09.09.2013  |

**Annexure-I(b)**  
**Details of Manufacturing Permissions of Human Vaccines**

| Year 2013 |                                                                                                                             |                                                                          |                                                                                                  |                                  |
|-----------|-----------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|----------------------------------|
| S. No.    | Name of Firm                                                                                                                | Name of Vaccine                                                          | Indication                                                                                       | Permission No. & Date            |
| 9         | M/s Dano Vaccines & Biologicals Private Ltd.<br>575,Sivareddyguda,<br>Ghatkesar, R.R. Distt.,<br>Andhra Pradesh-<br>501301. | Tetanus Toxoid (Adsorbed) I.P                                            | For active immunization against Tetanus.                                                         | MF-145/2013,<br>dated:08.07.2013 |
| 10        | M/s Biologicals E. Ltd.,<br>18/1 & 3, Azamabad,<br>Hyderabad- 500 020 A.<br>P. India.                                       | Diphtheria and Tetanus<br>Vaccine (Adsorbed) IP                          | Indication for prevention of Disease caused by Diphtheria and Tetanus in Adults and adolescents. | MF-142/2013,<br>dated:12.07.2013 |
| 11        | M/s Biologicals E. Ltd.,<br>18/1 & 3, Azamabad,<br>Hyderabad-500 020<br>A.P. India.                                         | Tetanus Vaccine(Adsorbed) IP                                             | Indicated for prevention of Tetanus Infections.                                                  | MF-196/2013,<br>dated:04.09.2013 |
| 12        | M/s Biologicals E. Ltd.,<br>18/1 & 3, Azamabad,<br>Hyderabad- 500 020 A.<br>P. India.                                       | Diphtheria, Tetanus and whole<br>cell Pertussis Vaccine<br>(Adsorbed) IP | Indicated as Prophylaxis for<br>Diphtheria, Tetanus and Pertussis                                | MF-201/2013,<br>dated:13.09.2013 |

**Annexure-I(b)**  
**Details of Manufacturing Permissions of Human Vaccines**

| Year 2012 |                                                                                                                              |                                                                             |                                                                                                                                                                                       |                                  |
|-----------|------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|
| S. No.    | Name of Firm                                                                                                                 | Name of Vaccine                                                             | Indication                                                                                                                                                                            | Permission No. & Date            |
| 1         | M/s Bharat Biotech<br>Internal limited,<br>Genome Valley,<br>Shameerpet Mandal,<br>Hyderabad, Andhra<br>Pradesh India-500078 | Inactivated Japanese<br>Encephalitis Vaccine                                | For the Immunization of disease<br>Caused by Japanese Encephalitis<br>virus (JEV). Dosage schedule<br>Adult/Children (1 to 50 years)-Two<br>doses of 0.5 ml on day 0 and day<br>28±2. | MF-181/2012,<br>dated;07.06.2012 |
| 2         | M/s Bharat Biotech<br>International Ltd.,<br>Genome Valley,<br>Shameerpet,<br>Hyderabad-500078                               | Typhoid (Vi Capsular<br>Polysaccharide)-Tetanus<br>Toxoid Conjugate vaccine | For active immunization against<br>Salmonella Typhi infection in ≥ 6<br>months to 45 year age group.                                                                                  | MF-244/2012<br>Dated:20.12.2012  |

**Annexure-I(b)**  
**Details of Manufacturing Permissions of Human Vaccines**

| Year 2011 |                                                                                                   |                                                                                                                                            |                                                                                                                                                                                                                               |                                 |
|-----------|---------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| S. No.    | Name of Firm                                                                                      | Name of Vaccine                                                                                                                            | Indication                                                                                                                                                                                                                    | Permission No. & Date           |
| 1         | M/s Panacea Biotech Ltd.,B-1Extn./A-27, MCIE, Mathura Road, New Delhi-110044,India.               | Bivalent Oral Poliomyelitis Vaccine Type 1 and Type3, Live (Oral) (bOPV) [Bulk Source: Sanofi Pasteur, France]                             | For Prophylactic for prevention caused by Type 1 and Type 3 strains of poliovirus                                                                                                                                             | MF-195/11, dated:29.04.2011     |
| 2         | M/s Serum Institute of India Ltd.,212/2, Hadapsar, Pune-411 028, India.                           | Influenza Vaccine (Whole Virion, Inactivated) (Pandemic H1N1 Vaccine), (Embryonated hen eggs derived and inactivated By beta propiolactone | Inactivated H1N1 split virion vaccine is an inactivated influenza virus vaccine indicated for active immunization of children above 3 years of age and adults against influenza disease caused by Pandemic (H1N1) 2009 virus. | MF- 242/2011, dated: 02.06.2011 |
| 3         | M/s. Zydus Lifesciences Limited, Sarkhej-Bavla, N.H. 8A, Moraiya, Tal. Sanand, Ahmedabad-380 015. | Rabies Vaccine, Human IP (Purified Chick embryo cell culture rabies vaccine) PCECVPM                                                       | For active Immunization against rabies;- For Intramuscular administration, use 1 full dose(1ml) for pre & Post exposure prophylaxis For Intradermal administration, use 0.1ml per ID site for Post exposure prophylaxis       | MF-320/2011, dated:16.08.2011   |

**Annexure-I(b)**

**Details of Manufacturing Permissions of Human Vaccines**

|   |                                                                                                                              |                                           |                                                                                                                                                                                                                            |                               |
|---|------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| 4 | M/s Biological E Ltd, Plot No. 1, SP Biotech Park, Phase II, Kolthur (V), Shameerpet (M), Ranga Reddy (Dist.) Andhra Pradesh | Japanese Encephalitis Inactivated Vaccine | For the immunization of disease caused by Japanese Encephalitis virus (JEV) for adult (18-49 years) and Children (1-3 years) Dosage Schedule: Adult-Single dose of 0.5ml and Children –Two dose of 0.25ml at 4 week apart. | MF-456/2011, dated:29.09.2011 |
|---|------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|

**Annexure-I(b)**  
**Details of Manufacturing Permissions of Human Vaccines**

|   |                                                                   |                                                                                                       |                                                                                                                                                                                   |                               |
|---|-------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| 5 | M/s Serum Institute of India Ltd.,212/2, Hadapsar, Pune-411 - 028 | Meningococcal A Conjugate vaccine, Lyophilized (Clear glass vial with white Aluminium flip-off seals) | For active immunization against invasive meningococcal disease caused by Meningococcus group A only, in the children of age 2 years, adolescent and adults up to 29 years of age. | MF 458/2011, dated:18.10.2011 |
|---|-------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|

**Annexure-I(b)**  
**Details of Manufacturing Permissions of Human Vaccines**

| Year 2010 |                                                                                                                                   |                                                                                                         |                                                                                                                                                          |                                 |
|-----------|-----------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| S. No.    | Name of Firm                                                                                                                      | Name of Vaccine                                                                                         | Indication                                                                                                                                               | Permission No. & Date           |
| 1         | M/s. Bharat Biotech International Ltd.,<br>Genome Valley,<br>Shameerpet(Mandal),<br>Reddy<br>(Dist.),<br>Hyderabad-500078<br>(AP) | Bivalent Polio Type 1 & Type 3 vaccine , Live Oral                                                      | For active Immunization against Type 1 & Type 3 Poliomyelitis infection in Children from 0 to 5 years of age.                                            | MF-224/10, dated:<br>12.03.2010 |
| 2         | M/s. Zydus Lifesciences Limited.,<br>Sarkhej-Bavla, N.H.<br>No.8A,Moraiya,Tal,<br>Sanand, Dist.<br>Ahmedabad– 382 210             | Inactivated Influenza vaccine (Whole virion) IP<br>Pandemic Influenza (H1N1) 2009, Monovalent vaccine). | For active immunization against influenza disease caused by pandemic (H1N1) 2009 virus in the age group of 18 years and above.                           | MF-466/10,<br>dated:11.05.2010  |
| 3         | M/s Serum Institute of India Ltd.,212/2,<br>Hadapsar,Pune-411 028,                                                                | Influenza Vaccine (Live Attenuated freeze dried) for Intranasal.                                        | For active immunization against influenza disease caused by pandemic (H1N1) 2009 virus in the age group of 03 years and above.                           | MF-558/10, dated:<br>18.06.2010 |
| 4         | M/s Panacea Biotech Ltd.,B-1Ext/A-27,<br>Mohan Co-op Indl. Estate , Mathura Road, New-Delhi- 110 044                              | DTwP-vaccine(adsorbed)                                                                                  | For the primary immunization of infants at or above the age of 6 weeks & of children through 6 years of age against Diphtheria, Tetanus & Whooping cough | MF 822/10, dated:<br>21.09.2010 |

**Annexure-I(b)**

**Details of Manufacturing Permissions of Human Vaccines**

|   |                                                                           |                                                                                                                                                                                                |                                                                                                        |                                 |
|---|---------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|---------------------------------|
| 5 | M/s Biological E. Ltd.,<br>18/1 and 3,<br>Azamabad,<br>Hyderabad- 500 020 | Diphtheria, Tetanus,<br>Pertussis (Whole Cell),<br>Hepatitis B (rDNA) and<br>Haemophilus influenza<br>Type B Conjugate Vaccine<br>(Adsorbed) (DTwP-rHepB-<br>Hib)Liquid pentavalent<br>vaccine | Active immunization of Against<br>Diphtheria, pertussis, tetanus,<br>Hepatitis b, Hib type b infection | MF 843/10, dated:<br>29.09.2010 |
|---|---------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|---------------------------------|

**Annexure-I(b)**  
**Details of Manufacturing Permissions of Human Vaccines**

|   |                                                                                                       |                                                                 |                                                                                                                                           |                              |
|---|-------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| 6 | M/s Bharat Biotech International Ltd., Genome Valley, Shameerpet, Hyderabad-500078 (A.P.)             | Pandemic Influenza Vaccine A( H1N1) Virus vaccine (Inactivated) | For active immunization of persons of age 18 years to 65 years against influenza disease caused by pandemic influenza A (H1N1) 2009 virus | MF-847/10, dated: 30.09.2010 |
| 7 | M/s Panacea Biotec Ltd., B-1 Extn. A-27, Mohan Co-op. indl. Estate, Mathura Road, new Delhi- 110 044. | Inactivated H1N1 split virion Influenza vaccine (adjuvanted)    | For active immunization of children above 3 years of age and adults against disease caused by Pandemic (H1N1) 2009 virus.                 | MF-898/10, dated:08.11.2010  |

**Annexure-I(b)**  
**Details of Manufacturing Permissions of Human Vaccines**

| Year 2009 |                                                                                                                 |                                                                                                                   |                                                                                                                                                                  |                              |
|-----------|-----------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| S. No.    | Name of Firm                                                                                                    | Name of Vaccine                                                                                                   | Indication                                                                                                                                                       | Permission No. & Date        |
| 1         | M/s Biomed (P) Ltd.,C-96, Site No1, Bulandsahar Road, Industrial Area, Ghaziabad, U.P.                          | Meningococcal polysaccharide vaccine (Group A &C)                                                                 | For active immunization against Neisseria meningitidis Group A & C                                                                                               | MF-7/09, dated:12.01.2009    |
| 2         | M/s Serum Institute of India Ltd., 212/2, Hadapsar, Pune-411 028, India.                                        | Diphtheria, Tetanus, Pertussis, Hepatitis-B and Haemophilus Influenzae Type b Conjugate Vaccine Adsorbed, liquid. | For active immunization against Diphtheria, Tetanus, Pertussis, Hepatitis- B and Haemophilus Influenzae Type b in infants.                                       | MF-167/09, dated: 12.02.2009 |
| 3         | M/s Panacea Biotec Ltd.,B-1 Extn. A/27., MCIE, Mathura Road, New Delhi                                          | Oral Poliomyelitis Vaccine (Type 1, 2, &3)                                                                        | Active Immunization against infection caused by type 1, 2 & 3 Polioviruses.                                                                                      | MF-175/09, dated: 24.02.2009 |
| 4         | M/s Panacea Biotec Ltd., ,B-1 Extn .A-27,MCIE,MathuraRoad, New-Delhi-110 044                                    | Diphtheria ,Tetanus and whole cell pertussis (DTwP) vaccine                                                       | For the primary immunization of Infants ,at or above the age of 6 weeks ,and of children through six years of age against Diphtheria ,Tetanus and whooping cough | MF-282/09, dated: 19.03.2009 |
| 5         | M/s Human Biologicals Ltd., (A Division of Indian Immunological Ltd.), Rakhshapuram, Gachibowli, Hyderabad (AP) | Rabies Vaccine (Vero Cell cultured , Freeze Dried)                                                                | For active immunization against Rabies, both as prophylaxis and post bite cases.                                                                                 | MF-295/09, dated: 23.03.2009 |

**Details of Human Vaccines approve by CDSCO (for manufacture)**  
**(Year 1998 to 2008)**

| S. No       | Name of Firm                                                                                               | Name of Vaccine                                          | Indication                                                                                              | Permission No. & Date          |
|-------------|------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|---------------------------------------------------------------------------------------------------------|--------------------------------|
| <b>1998</b> |                                                                                                            |                                                          |                                                                                                         |                                |
| 1           | M/s Bharat Biotech International 726, Road-3, Banjara Hills, Hyderabad-500034                              | Hepatitis B Vaccine (recombinant DNA)                    | For active immunization against infection caused by Hepatitis-B Viruses.                                | 12-30/86-DC, Date:- 14-10-1998 |
| <b>2003</b> |                                                                                                            |                                                          |                                                                                                         |                                |
| 1           | M/s Aventis Pasteur India Pvt. Ltd. Chaitanya 1, Chaman Farm Village, Bundh Road, Chattarpur, New Delhi-30 | Inactivated adsorbed Hepatitis A Vaccine 80 antigen unit | For prevention of Infection caused of Hep. A virus in children in the age group of 12 months —15 years. | MF-675/2003, Dated: 07-06-2003 |
| 2           | M/s Cadila Healthcare Ltd., Zyklus Towers, Satellite cross Roads, Ahmedabad-15                             | Vi-Capsular Polysaccharide typhoid vaccine               | For active immunization against typhoid fever in adults and children over 2 years of age.               | MF-821/2003, Date: 09-09-2003  |
| 3           | M/s Bharat Biotech International Ltd., Genome Valley Turkapally, Shameerpet (Mandal), Hyderabad —500078    | Vi capsular Polysaccharide Typhoid Vaccine               | For immunization against typhoid fever.                                                                 | 12-3/2002-DC, Date: 23-01-2003 |
| <b>2004</b> |                                                                                                            |                                                          |                                                                                                         |                                |
| 1           | M/s Bio-Med Pvt. Ltd., Bulandsahar Road Indi. Area, Ghaziabad-201001                                       | Haemophilus Influenza type-b Conjugated Vaccine.         | For prevention of invasive disease caused By Haemophilus Influenza type-b in children.                  | MF-1350/2004, Date: 14-06-2004 |

| 2           | M/s Bio-Med Pvt. Ltd., KB-27, Kavi Nagar, Ghaziabad-201002 (UP) India                                    | Meningococcal Polysaccharide Vaccine (Group A, C, W135 & Y) | For prevention of cerebrospinal meningitis caused by Neisseria meningitides group A, C, Y, W135 & Y. Vaccination is recommended for travelers moving in the endemic regions. | MF-1752/2004,<br>Date: 23-09-2004 |
|-------------|----------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
| <b>2005</b> |                                                                                                          |                                                             |                                                                                                                                                                              |                                   |
| 1           | M/s Serum Institute of India Ltd., 212/2, Hadapsar, Pune-411028                                          | Combined DP (Whole Cell) T+ Hepatitis B Vaccine.            | For active immunization against Diphtheria, Tetanus, Pertussis and Hepatitis B in infants And children.                                                                      | MF-2090/2005,<br>Date: 28-02-2005 |
| <b>2006</b> |                                                                                                          |                                                             |                                                                                                                                                                              |                                   |
| S. No       | Name of Firm                                                                                             | Name of Vaccine                                             | Indication                                                                                                                                                                   | Permission No.& Date              |
| 1           | M/s Human Biologicals Road No.44, Jubilee Hills Hyderabad-500033                                         | Recombinant Hepatitis B vaccine                             | For active immunisation against Hepatitis-B virus infection                                                                                                                  | MF-6491/06,<br>Date— 23-03-2006   |
| 2           | M/s. Biological E. Ltd., 1811 & 3, Azamabad, Hyderabad-500020, A.P                                       | Combined DTwP (whole cell) + r-Hepatitis-B Vaccine.         | For active immunisation against Diphtheria, Tetanus, Pertussis & Hep.-B in children.                                                                                         | MF-6567/06,<br>Date— 24-04-2006   |
| 3           | M/s Bharat Biotech International Ltd., Genome Valley Turkapally, Shameerpet (Mandal), Hyderabad — 500078 | Anti-Rabies Vaccine(Vero cell)                              | For active immunization against Rabies                                                                                                                                       | MF-7076/2006,<br>Date: 14-12-2006 |
| 4           | M/s Bharat Biotech International Ltd., Genome Valley Turkapally, Shameerpet (Mandal), Hyderabad — 500078 | Diphtheria, Tetanus & Pertussis Vaccine (adsorbed)          | For the active immunization against Diphtheria, Tetanus & Pertussis                                                                                                          | MF-6857/2006,<br>Date: 28-08-2006 |

|   |                                                                                 |                        |                                                                                              |                                   |
|---|---------------------------------------------------------------------------------|------------------------|----------------------------------------------------------------------------------------------|-----------------------------------|
| 6 | M/s. Indian Immunologicals Ltd., Rakshapuram, Gachibowli Post, Hyderabad-500032 | Tetanus Toxoid Vaccine | For active immunisation in human beings $\geq$ 6 weeks against tetanus (clostridium Tetanus) | MF-7065/2006,<br>Date: 13-12-2006 |
|---|---------------------------------------------------------------------------------|------------------------|----------------------------------------------------------------------------------------------|-----------------------------------|

| 2007 |                                                                                                                |                                                                                                 |                                                                                                                                                                 |                                |
|------|----------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| 1    | M/s Panacea Biotech Ltd., B-1 Extn. / A-27 Mohan Co-operative Industrial Estate, Mathura Road New Delhi-110044 | Diphtheria+Pertussis+Tetanus Vaccine with Hepatitis B and Haemophilus influenza type B Vaccine. | For active immunization against Diphtheria, Pertussis, Tetanus, Hepatitis B and Haemophilus influenza type B infection.                                         | MF-7912/2007, Date: 12-09-2007 |
| 2    | M/s Panacea Biotech Ltd., B-1 Extn. / A-27 Mohan Co-operative Industrial Estate, Mathura Road New Delhi-110044 | Haemophilus type b (Hib) conjugate vaccine.                                                     | For active immunization against Haemophilus influenza type b infection in children of the age group of 6 weeks to 5 years.                                      | MF-7517/2007, Date: 06-06-2007 |
| 3    | M/s Bharat Biotech International Ltd., Genome Valley Turkapally, Shameerpet (Mandal), Hyderabad —500078        | Haemophilus Influenza type b (Hib) conjugate vaccine                                            | For active immunization against Haemophilus influenza type b infection in children of the age group of 6 weeks to 5 years.                                      | MF-7581/2007, Date; 03-07-2007 |
| 4    | M/s Serum Institute of India Ltd., 212/2, Hadapsar, Pune-411028                                                | Diphtheria, Tetanus, Pertussis (Whole Cell) + Haemophilus Influenza-b vaccine.                  | For the active immunization of infants, at or above the age of 6 weeks against Diphtheria, Tetanus, Whooping cough and Haemophilus influenza type-b infections. | MF-7929/2007, Date: 04-10-2007 |
| 5    | M/s Serum Institute of India Ltd., 212/2, Hadapsar, Pune-411028                                                | DTwP+HepatitisB+Hib Vaccine                                                                     | For active immunization against Diphtheria, Tetanus, Pertussis, Hepatitis B and Haemophilus influenza type b                                                    | MF-7390/2007, Date: 03-05-2007 |
| 6    | M/s Serum Institute of India Ltd., 212/2, Hadapsar, Pune-411028                                                | Haemophilus Influenza type b (Hib) conjugate vaccine                                            | For active immunization against Haemophilus influenza type b infection in children of the age Group of 6 weeks to 5 years.                                      | MF-7100/2007, Date: 12-01-2007 |

| S. No       | Name of Firm                                                                                                                 | Name of Vaccine                                                                                                                      | Indication                                                                                                                 | Permission No. & Date          |
|-------------|------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|--------------------------------|
| 7           | M/s Biological E Ltd.,18/1&3, Azamabad, Hyderabad-500020                                                                     | Haemophilus Influenza type b (Hib) conjugate vaccine (Lyophilized)                                                                   | For active immunization against Haemophilus influenza type b infection in children of the age Group of 6 weeks to 5 years. | MF-7496/2007, Date: 08-06-2007 |
| 8           | M/s Bharat Biotech International Ltd., Genome Valley Turkapally, Shameerpet (Mandal), Hyderabad — 500078                     | Monovalent Poliomyelitis Vaccine Type 1 Live (Oral).                                                                                 | For active immunization against Polio in children.                                                                         | MF-7633/2007, Date: 20-07-2007 |
| <b>2008</b> |                                                                                                                              |                                                                                                                                      |                                                                                                                            |                                |
| 1           | M/s Bharat Biotech International Ltd., Genome Valley Turkapally, Shameerpet (Mandal), Hyderabad —500078                      | Diphtheria, Tetanus, Pertussis (W), r-Hepatitis B & Haemophilus Influenza Type-B Vaccine                                             | For active immunization against Diphtheria, Tetanus, Pertussis (W),r-Hepatitis B & Haemophilus Influenza Type-B infection  | MF-227/2008, Date: 31-01-2008  |
| 2           | M/s Aventis Pasteur India Pvt. Ltd. Chaitanya 1,Chaman Farm Village, Bundh Road, Chattarpur,New Delhi-30                     | Diphtheria, Tetanus, Acellular Pertussis and Inactivated Poliomyelitis (DtaP-IPV) combined vaccine.(From M/s Sanofi Pasteur, France) | For the immunization of Diphtheria, Tetanus, Pertussis and poliomyelitis in infants from 2 months of age.                  | MF-370/2008, Date: 31-03-2008  |
| 3           | M/s Human Biologicals Institute Rakshapuram, Gachibowli Post, Hyderabad-500032                                               | Diphtheria+Tetanus+B. Pertussis (whole cell) vaccine.                                                                                | For active immunisation against Diphtheria, Tetanus, Pertussis and B. Pertussis infections.                                | MF-228/ 2008, Date: 31-01-2008 |
| 4           | M/s Green Signal Bio Pharma Pvt. Ltd., Old No. 86, New No. 114,Dr.RadhakrishnaSalai,Mylapore, Chennai,Tamilnadu-600004,India | BCG Vaccine (Live, Freeze Dried, attenuated)                                                                                         | For active immunization against tuberculosis                                                                               | MF-1395/2008, Date: 22-12-2008 |

|   |                                                                                        |                                                  |                                            |                                      |
|---|----------------------------------------------------------------------------------------|--------------------------------------------------|--------------------------------------------|--------------------------------------|
| 5 | M/s Bio-Med Pvt. Ltd., C-96<br>Site1,B.S.Road,Industrial,<br>Area,Ghaziabad-201009(UP) | Typhoid Vaccine (Vi Polysaccharide<br>Conjugate) | For active immunization against<br>Typhoid | MF-528/2008,<br>Date: 09-05-<br>2008 |
|---|----------------------------------------------------------------------------------------|--------------------------------------------------|--------------------------------------------|--------------------------------------|

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|---|--------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|----------------------------------|
| 6 | M/s Bharat Biotech International Ltd., Genome Valley Turkapally, Shameerpet (Mandal), Hyderabad-500078 | Monovalent Oral Poliomyelitis Type-3 vaccine                                     | For the active immunization against Poliomyelitis.                                                          | MF-262/2008,<br>Date: 29-02-2008 |
| 7 | M/s Bharat Biotech International Ltd., Genome Valley Turkapally, Shameerpet (Mandal), Hyderabad-500078 | Diphtheria+ Tetanus +Pertussis + Hepatitis+ Haemophilus influenza Type B-Vaccine | For active immunizations against diphtheria, Tetanus, Pertussis, Hepatitis B & Haemophilus influenza Type B | MF-515/2008,<br>Date: 12-05-2008 |