


| | Manufacturer / WHO EUL holder | Name of Vaccine | NRA of Record | Platform | EOI accepted | Pre-submission meeting held | Dossier accepted for review* | Status of assessment** | Decision date*** |
|----|--|---|-----------------|---|--------------|-----------------------------|--|---|--|
| 1. |  BioNTech Manufacturing GmbH | BNT162b2/COMIRNATY Tozinameran (INN) | EMA | Nucleoside modified mRNA | ✓ | ✓ | ✓ | Finalized: Additional sites: – Baxter Oncology GmbH Germany (DP) – Novartis Switzerland – Mibe (Dermapharm) Germany (DP) – Delpharm, Saint-Remy FRANCE (DP) – Shelf life extension: 09 months at -70 to -90°C | 31/12/2020 30/06/2021 08/07/2021 16/07/2021 17/09/2021 20/09/2021 |
| | | | USFDA | | | | | Finalized: – Pharmacia & Upjohn, Kalamazoo (DP) PGS McPherson (DP) | 18/06/2021 16/07/2021 16/07/2021 |
| 2. |  AstraZeneca, AB | AZD1222 Vaxzevria | EMA | Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2. | ✓ | ✓ | ✓ | Core data finalized | 16 April 2021 |
| | | | MFDS KOREA | | | | | Finalized: Additional sites: – SK-Catalent – Wuxi (DS) – Chemo Spain – Amylin Ohio US (DP) | 16 April 2021 30 April 2021 04 June 2021 23 July 2021 |
| 3. |  AstraZeneca, AB | AZD1222 Vaxzevria | MFDS KOREA | Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2. | ✓ | ✓ | ✓ | Finalized | 15 Feb 2021 |
| 4. | | AZD1222 Vaxzevria | Japan MHLW/PMDA | Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2. | ✓ | ✓ | ✓ | Finalized Additional site | 09 July 2021 TBC |
| 5. | | AZD1222 Vaxzevria | Australia TGA | Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2. | ✓ | ✓ | ✓ | Finalized Additional site: Thailand | 09 July 2021 TBC |
| 6. |  Serum Institute of India Pvt. Ltd | Covishield (ChAdOx1_nCoV-19) | DCGI | Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2. | ✓ | ✓ | ✓ | Finalized | 15 Feb 2021 |
| 7. |  Janssen-Cilag International NV | Ad26.COVS.2.S | EMA | Recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding the (SARS-CoV-2) Spike (S) protein | ✓ | ✓ | ✓ | Core data finalized (US +NL sites) | 12 March 2021 |
| | | | | | | | Additional sites: - Merck, Durham, UK (DS) - Merck, West Point/PA (DP) | Finalized – Aspen RSA (DP) – Catalent Agnani Italy (DP) - Future submission - Future submission | -25 June 2021 - 02 July 2021 - As submitted - As submitted |

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| 8. |  Moderna Biotech | mRNA-1273 | EMA | mNRA-based vaccine encapsulated in lipid nanoparticle (LNP) | | ✓ | ✓ | Finalized | 30 April 2021 |
| | | | USFDA | mNRA-based vaccine encapsulated in lipid nanoparticle (LNP) | ✓ | ✓ | ✓ | Finalized ModernaTx, Norwood (DS) - Catalent Indiana, LLC (DP) - Lonza Biologics, Inc. Portsmouth, USA (DS) - Baxter, Bloomington, USA (DP) | 06 August 2021 |
| 9. |  Sinopharm / BIBP ¹ Beijing Institute of Biological Products Co., Ltd. (BIBP) | SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV) | NMPA | Inactivated, produced in Vero cells | ✓ | ✓ | ✓ | Finalized 2 and 5 dose presentation (new manufacturing site) | 07 May 2021 TBC |
| 10. |  Sinovac Life Sciences Co., Ltd. Sinovac Life Sciences Co., Ltd. | COVID-19 Vaccine (Vero Cell), Inactivated/ Coronavac™ | NMPA | Inactivated, produced in Vero cells | ✓ | ✓ | ✓ | Finalized 2 dose presentation | 01 June 2021 30 September 2021 |
| 11. |  THE GAMALEYA NATIONAL CENTER OF EPIDEMIOLOGY AND MICROBIOLOGY | Sputnik V | Russian NRA | Human Adenovirus Vector-based Covid-19 vaccine | Additional information submitted | Several meetings have been and continue to be held. | “Rolling” submission incomplete. | On hold, awaiting completion of rolling submission | Anticipated date will be set once all data is submitted and follow-up of inspection observations completed. |
| 12. |  Bharat Biotech, India | SARS-CoV-2 Vaccine, Inactivated (Vero Cell)/ COVAXIN | DCGI | Whole-Virion Inactivated Vero Cell | ✓ | ✓ | Rolling data started 06 July 2021 | Ongoing | October 2021 |
| 13. |  Sinopharm / WIBP ² | Inactivated SARS-CoV-2 Vaccine (Vero Cell) | NMPA | Inactivated, produced in Vero cells | ✓ | ✓ | Rolling data started 23 July 2021 | Ongoing | To be confirmed (TBC) |
| 14. |  CanSinoBIO | Ad5-nCoV | NMPA | Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector) | ✓ | ✓ | Rolling data started 09 August 2021 | Ongoing | TBC |
| 15. |  NOVAVAX | NVX-CoV2373/Covovax | EMA | Recombinant nanoparticle prefusion spike protein formulated with Matrix-M™ adjuvant. | ✓ | ✓ | Rolling data starting in August 2021 | Ongoing | TBC |
| 16. |  SANOFI | CoV2 preS dTM-AS03 vaccine | EMA | Recombinant, adjuvanted | ✓ | | Rolling data started 30 July 2021 | Ongoing | TBC |
| 17. |  SERUM INSTITUTE OF INDIA PVT. LTD. Cyrus Poonawalla Group | NVX-CoV2373/Covovax | DCGI | Recombinant nanoparticle prefusion spike protein formulated with Matrix-M™ adjuvant. | ✓ | 10 August 2021 | Rolling data starting in August 2021 | Ongoing | TBC |
| 18. | Clover Biopharmaceuticals | SCB-2019 | NMPA | Novel recombinant SARS-CoV-2 Spike (S)-Trimer fusion protein | ✓ | ✓ | Rolling data starting 20 September | Ongoing | TBC |

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| 19. |  CUREVAC Live RNA people® | Zorecimeran (INN) concentrate and solvent for dispersion for injection; Company code: CVnCoV/CV07050101 | EMA | mNRA-based vaccine encapsulated in lipid nanoparticle (LNP) | ✓ | Planned for Q4 of 2021, at request of the applicant. | | | |
| 20. | Vector State Research Centre of Virology and Biotechnology | EpiVacCorona | Russian NRA | Peptide antigen | Letter received not EOI. Reply sent on 15/01/2021 | | | | |
| 21. | Zhifei Longcom, China | Recombinant Novel Coronavirus Vaccine (CHO Cell) | NMPA | Recombinant protein subunit | Response to 2 nd EOI sent 29 Jan 2021. Additional information requested. | | | | |
| 22. | IMBCAMS, China | SARS-CoV-2 Vaccine, Inactivated (Vero Cell) | NMPA | Inactivated | Not accepted, still under initial development | | | | |
| 23. | BioCubaFarma - Cuba | Soberana 01, Soberana 02 Soberana Plus Abdala | CECMED | SARS-CoV-2 spike protein conjugated chemically to meningococcal B or tetanus toxoid or Aluminum | Awaiting information on strategy and timelines for submission. | | | | |

1. Beijing Institute of Biological Products Co-Ltd
2. Wuhan Institute of Biological Products Co Ltd

* Dossier Submission dates: more than one date is possible because of the rolling submission approach. Dossier is accepted after screening of received submission.

**Status of assessment: 1. Under screening; 2. Under assessment; 3. Waiting responses from the applicant. 4. Risk-benefit decision 5. Final decision made

*** Anticipated decision date: this is only an estimate because it depends on when all the data is submitted under rolling submission and when all the responses to the assessors' questions are submitted.

Please send any questions you may have to: WHOEU@who.int