### Status of COVID-19 Vaccines within WHO EUL/PQ evaluation process

<table>
<thead>
<tr>
<th>Manufacturer / WHO EUL holder</th>
<th>Name of Vaccine</th>
<th>NRA of Record</th>
<th>Platform</th>
<th>EOI accepted</th>
<th>Pre-submission meeting held</th>
<th>Dossier accepted for review*</th>
<th>Status of assessment**</th>
<th>Decision date***</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.</strong> BioNTech Manufacturing GmbH</td>
<td>BNT162b2/COMIRNATY (INN)</td>
<td>EMA</td>
<td>Nucleoside modified mRNA</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>Finalized:</td>
<td>31/12/2020</td>
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<tr>
<td>Additional sites:</td>
<td>Baxter Oncology GmbH Germany (DP)</td>
<td>30/06/2021</td>
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<td>Novartis Switzerland</td>
<td>08/07/2021</td>
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<tr>
<td>Mibe (Dermapharma) Germany (DP)</td>
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<tr>
<td>Delpharm, Saint-Remy FRANCE (DP)</td>
<td>17/09/2021</td>
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<td>Sanofi-Aventis Deutschland GmbH Germany (DP)</td>
<td>18/06/2021</td>
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<tr>
<td>Siegfried Hameln GmbH, Germany (DP)</td>
<td>11/11/2021</td>
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<tr>
<td>Patheon Italia S.p.A, Italy (DP)</td>
<td>07/12/2021</td>
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<td>Catalent Agnani</td>
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<td>Exela Pharma Sciences, LLC, NC</td>
<td>16/03/2022</td>
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<td>Diluent suppliers:</td>
<td>Pfizer Perth, Australia</td>
<td>20/09/2021</td>
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<td>Fresenius Kabi, USA</td>
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<td>Pfizer Manufacturing Belgium</td>
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<td>Age extension to adolescents 12-15</td>
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<td>Age extension to children 5 – 11 years of age</td>
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<td>Pharmacia &amp; Upjohn, Kalamazoo (DP)</td>
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<td>Exelead, Inc. Indianapolis USA</td>
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<td><strong>2.</strong> AstraZeneca, AB</td>
<td>AZD1222 Vaxzevria</td>
<td>EMA</td>
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<td>✓</td>
<td>✓</td>
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<td>Chemo Spain</td>
<td>04/06/2021</td>
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<td>Platform</td>
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<td>Dossier accepted for review*</td>
<td>Status of assessment**</td>
<td>Decision date***</td>
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<td>3.</td>
<td>MFDS KOREA</td>
<td>Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Finalized</td>
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<td>15/02/21</td>
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<td>4.</td>
<td>Japan MHLW/PMDA</td>
<td>Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Finalized</td>
<td>Additional sites: Nipro Pharma Corporation Ise, Japan</td>
<td>09/07/21</td>
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<td>5.</td>
<td>Australia TGA</td>
<td>Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Finalized</td>
<td>Additional site: Siam Bioscience Co., Ltd Thailand</td>
<td>09/07/21</td>
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<td>6.</td>
<td>COFEPRIS (Mexico) / ANMAT (Argentina)</td>
<td>Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Finalized</td>
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<td>23/12/21</td>
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<td>7.</td>
<td>Serum Institute of India Pvt. Ltd</td>
<td>Covishield (ChAdOx1_nCoV-19)</td>
<td>DCGI</td>
<td>Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.</td>
<td>Yes</td>
<td>Yes</td>
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<td>8.</td>
<td>Janssen–Cilag International NV</td>
<td>Ad26.COV2.S</td>
<td>EMA</td>
<td>Recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding the (SARS-CoV-2) Spike (S) protein</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Core data finalized (US +NL sites)</td>
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<td>- Grand River Aseptic Manufacturing Inc., USA</td>
<td>02 July 2021</td>
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<td>- MSD (Merck), West Point/PA, USA (DP)</td>
<td>17 sept 2021</td>
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<td>- Sanofi Pasteur France (DP)</td>
<td>05 Nov 2021</td>
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<td>- Biological E Ltd India (DP)</td>
<td>27 Jan 2022</td>
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<td>Storage conditions extension at 2-8 °C from 4,5 months to 11 months within the 24 months of shelf-life at -25°C to -15°C</td>
<td>07 July 2022</td>
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<td>Booster dose approved for adults 18 years of age and older</td>
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<td>Ongoing</td>
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</tbody>
</table>

9. **moderna**

Moderna Biotech

| | mRNA-1273/Spikevax | EMA | mRNA-based vaccine encapsulated in lipid nanoparticle (LNP) | Yes | Yes | Yes | Finalized | | 30 April 2021 |
| | | | | | | | | Shelf life extension to 09 months -20±5°C | 14 Feb 2022 |
| | | | | | | | | - ModernaTx. Norwood (DS) | 06 August 2021 |
| | | | | | | | | - Catalent Indiana, LLC (DP) | |
| | | | | | | | | - Lonza Biologics, Inc. Portsmouth, USA (DS) | |
| | | | | | | | | - Baxter, Bloomington, USA (DP) | |

10. **Sinopharm / BIBP**

Beijing Institute of Biological Products Co., Ltd. (BIBP)

<p>| | SARS-CoV-2 Vaccine (Vero Cell), Inactivated (mCoV) | NMPA | Inactivated, produced in Vero cells | Yes | Yes | Yes | Finalized | | 07 May 2021 |
| | | | | | | | | 2 and 5 dose presentation (new manufacturing site) | 28 December 2021 |</p>
<table>
<thead>
<tr>
<th>Manufacturer / WHO EUL holder</th>
<th>Name of Vaccine</th>
<th>NRA of Record</th>
<th>Platform</th>
<th>EOI accepted</th>
<th>Pre-submission meeting held</th>
<th>Dossier accepted for review*</th>
<th>Status of assessment**</th>
<th>Decision date***</th>
</tr>
</thead>
<tbody>
<tr>
<td>12. Bharat Biotech, India</td>
<td>SARS-CoV-2 Vaccine, Inactivated (Vero Cell)/COVAXIN</td>
<td>DCGI</td>
<td>Whole-Virion Inactivated Vero Cell</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>Finalized</td>
<td>03 November 2021 SUPPLY OF VACCINE SUSPENDED</td>
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<td>13. Sera Institute of Blood Transfusion (India)</td>
<td>NVX-CoV2373/Covovax</td>
<td>DCGI</td>
<td>Recombinant nanoparticle prefusion spike protein formulated with Matrix-M™ adjuvant</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>Finalized</td>
<td>17 December 2021</td>
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<td>14. NOVAVAX</td>
<td>NVX-CoV2373/Nuvaxovid</td>
<td>EMA</td>
<td>Recombinant nanoparticle prefusion spike protein formulated with Matrix-M™ adjuvant</td>
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<td>✔</td>
<td>✔</td>
<td>Finalized</td>
<td>20 December 2021 1/09/2022</td>
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<td>15. WestVac Biopharma</td>
<td>Ad5-nCoV/Convidecia</td>
<td>NMPA</td>
<td>Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector)</td>
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<td>✔</td>
<td>✔</td>
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<td>19 May 2022</td>
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<td>16. Russian Direct Investment Fund</td>
<td>Sputnik V</td>
<td>Russian NRA</td>
<td>Human Adenovirus Vector-based Covid-19 vaccine</td>
<td>Additional information submitted</td>
<td>Several meetings have been and continue to be held. “Rolling” submission incomplete.</td>
<td></td>
<td>Process restarted, awaiting completion of rolling submission and CAPAs to last inspection</td>
<td>Anticipated date will be set once all data is submitted and follow-up of inspection observations completed.</td>
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<td>17. Sanofi</td>
<td>CoV2 preS dTM-A503 vaccine</td>
<td>EMA</td>
<td>Recombinant, adjuvanted</td>
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<td>✔</td>
<td>Rolling data started 30 July 2021</td>
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<td>18. Clover Biopharmaceuticals</td>
<td>SCB-2019</td>
<td>NMPA</td>
<td>Novel recombinant SARS-CoV-2 Spike (S)-Trimer fusion protein</td>
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<td>Rolling data started 20 September 2021</td>
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<td>19. Zhifei Longcom, China</td>
<td>Recombinant Novel Coronavirus Vaccine (CHO Cell)</td>
<td>NMPA</td>
<td>Recombinant protein subunit</td>
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<td>✔</td>
<td>Rolling data started 28 March 2022</td>
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<td>20. Shifa Pharmed - Barkat</td>
<td>Coviran® vaccine</td>
<td>IFDA</td>
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<td>✔</td>
<td>Rolling data started 3 August 2022</td>
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<td>21. CIGB</td>
<td>Abdala</td>
<td>CECMED</td>
<td>Protein subunit</td>
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<td>✔</td>
<td>Rolling data started 7 June 2022</td>
<td>Ongoing</td>
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<td>22. SK Bioscience</td>
<td>Nuvaxovid prefilled syringe</td>
<td>MFDS (RoKorea)</td>
<td>Recombinant nanoparticle prefusion spike protein formulated with Matrix-M™ adjuvant</td>
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<td>✔</td>
<td>Rolling data pending</td>
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<td>23. Biological E</td>
<td>Corbevax</td>
<td>DCGI India</td>
<td>RBD antigen of SARS-CoV-2 (Covid-19)</td>
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<td>24. SK Bioscience</td>
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<td>Recombinant protein subunit</td>
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<td>Rolling data pending</td>
<td>Ongoing</td>
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<td>25. WestVac Biopharma</td>
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<td>NMPA China</td>
<td>Recombinant SARS-CoV-2 5-RBD protein</td>
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<td>Nanocovax</td>
<td>Drug Administration of Vietnam</td>
<td>Recombinant Spike protein</td>
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<td>27. Cinnagen</td>
<td>SpikaGen</td>
<td>Iran Food Drug Administration (IFDA)</td>
<td>Recombinant Protein</td>
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<td>28. R-PHARM</td>
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<td>30. Bio-Manguinhos/Fiocruz</td>
<td>AZD1222</td>
<td>ANVISA</td>
<td>Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.</td>
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<td>31. Vaxxinity</td>
<td>UB-612</td>
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<td>Protein-peptide vaccine</td>
<td>EOI under review</td>
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<td>32. Sinocelltech, Ltd</td>
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<td>NMPA</td>
<td>Recombinant Protein</td>
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<td>33. Razi Vaccine &amp; Serum Research Institute</td>
<td>Razi Cov Pars Vaccine</td>
<td>Iran Food Drug Administration (IFDA)</td>
<td>Recombinant Protein</td>
<td>EOI received</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>34. Vaineva</td>
<td>VLA2001</td>
<td>EMA</td>
<td>Inactivated</td>
<td>EOI received</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>35. Medigen</td>
<td>MVC-COV1901</td>
<td>TGA</td>
<td>CHO cell derived spike protein (Subunit)</td>
<td>EOI received</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>36. HIPRA</td>
<td>BIMERVAX</td>
<td>EMA</td>
<td>Recombinant Protein</td>
<td>EOI received</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>37. Stelis Biopharma Limited</td>
<td>AKS-452 Vaccine</td>
<td>DCGI India</td>
<td>Protein subunit</td>
<td>EOI received</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>38. PT Biofarma</td>
<td>SARS CoV-2 RBD</td>
<td>Badan Pom Indonesia</td>
<td>Recombinant Protein Vaccine</td>
<td>EOI received</td>
<td></td>
<td></td>
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<tr>
<td>39. Medicago</td>
<td>COVIFENZ®</td>
<td>Health Canada</td>
<td>Plant-based virus-like particle [VLP], recombinant, adjuvanted</td>
<td>Application withdrawn by applicant</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>40. Zorecerriceran (INN)</td>
<td>Concentrate and solvent for dispersion for injection; Company code: CVnCov/CV07050101</td>
<td>EMA</td>
<td>mRNA-based vaccine encapsulated in lipid nanoparticle (LNP)</td>
<td>Application withdrawn by manufacturer</td>
<td></td>
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<tr>
<td>41. Sinopharm / WIBP</td>
<td>Inactivated SARS-CoV-2 Vaccine (Vero Cell)</td>
<td>NMPA</td>
<td>Inactivated, produced in Vero cells</td>
<td></td>
<td></td>
<td></td>
<td>Rolling data started 23 July 2021</td>
<td>Dossier withdrawn on 7 September 2022</td>
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<tr>
<td>42. Vector State Research Centre of Viralogy and Biotechnology</td>
<td>EpiVacCorona</td>
<td>Russian NRA</td>
<td>Peptide antigen</td>
<td>Letter received not EOI. Reply sent on 15/01/2021</td>
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<td></td>
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</table>
### Vaccines

**Guidance Document**

08 November 2022

<table>
<thead>
<tr>
<th>No.</th>
<th>Company/Location</th>
<th>Vaccine Name</th>
<th>Regulatory Authority</th>
<th>Status</th>
<th>Notes</th>
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<tbody>
<tr>
<td><strong>43.</strong></td>
<td>IMBCAMS, China</td>
<td>SARS-CoV-2 Vaccine, Inactivated (Vero Cell)</td>
<td>NMPA</td>
<td>Not accepted, still under initial development</td>
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<td><strong>44.</strong></td>
<td>BioCubaFarma - Cuba</td>
<td>Soberana 01, Soberana 02, Soberana Plus</td>
<td>CECMED</td>
<td>Awaiting information on strategy and timelines for submission</td>
<td></td>
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</tbody>
</table>

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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.


*** 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: WHOEUL@who.int