






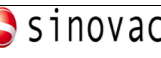







### Status of COVID-19 Vaccines within WHO EUL/PQ evaluation process

|     | Manufacturer   | Name of Vaccine                                     | NRA of Record        | Platform  | EOI accepted  | Pre-submission meeting held | Dossier accepted for review*                               | Status of assessment**  | Anticipated decision date***   |
|-----|--|---|----------------------|---|---|-----------------------------|--|---|--|
| 1.  |   | BNT162b2/COMIRNATY<br>Tozinameran (INN)             | EMA                  | Nucleoside modified mRNA  | ✓   | ✓                           | ✓  | Finalized   | 31/12/20   |
| 2.  | EU Nodes   | AZD1222   | Core – EMA Non-COVAX | Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.                                 | ✓   | ✓                           | Accepted core data of AZ – non-Covax                       | Finalized   | 16 April 2021  |
|     |  |   |                      |   |   |                             | Data for Covax sites expected in April 2021 onwards        | Finalized: SK-Catalent<br>Others expected   | 16 April 2021<br>Other as they come                                  |
| 3.  | SK BIO     | AZD1222   | MFDS KOREA           | Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.                                 | ✓   | ✓                           | ✓  | Finalized   | 15 Feb 2021  |
| 4.  | Serum Institute of India   | Covishield (ChAdOx1_nCoV-19)                        | DCGI                 | Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.                                 | ✓   | ✓                           | ✓  | Finalized   | 15 Feb 2021  |
| 5.  |   | Ad26.COVS.2S  | EMA                  | Recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding the (SARS-CoV-2) Spike (S) protein | ✓   | ✓                           | Core data (US +NL sites)                                   | Finalized   | 12 March 2021  |
|     |  |   |                      |   |   |                             | Additional sites awaited                                   | Awaited   | To be fixed after data submission                                    |
| 6.  |    | SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV) | NMPA                 | Inactivated, produced in Vero cells   | ✓   | ✓                           | ✓  | In progress   | End April 2021   |
| 7.  |   | SARS-CoV-2 Vaccine (Vero Cell), Inactivated         | NMPA                 | Inactivated, produced in Vero cells   | ✓   | ✓                           | ✓  | In progress   | Early May 2021   |
| 8.  |   | mRNA-1273   | EMA                  | mRNA-based vaccine encapsulated in lipid nanoparticle (LNP)   | ✓   | ✓                           | ✓  | In progress using the abridged procedure (EMA).   | End April 2021   |
| 9.  |   | Sputnik V   | Russian NRA          | Human Adenovirus Vector-based Covid-19 vaccine  | Additional information submitted  | Several meetings held.      | “Rolling” submission of clinical and CMC data has started. | Additional data (Non-CLIN, CLIN, CMC) Required. Inspections in April, May and June 2021 | Will be fixed after all data is submitted and inspections completed. |
| 10. |   | Ad5-nCoV  | NMPA                 | Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector)  | ✓   | ✓                           | Rolling data starting April 2021                           |   |  |
| 11. |   |   | EMA                  | No pre-submission meeting yet.  | Submitted EOI on 23 Feb   | Planned on 07 May           |  |   |  |
| 12. | Vector State Research Centre of Virology and Biotechnology   | EpiVacCorona  | Russian NRA          | Peptide antigen   | Letter received not EOI. Reply sent on 15/01/2021                                   |                             |  |   |  |
| 13. | Zhifei Longcom, China  | Recombinant Novel Coronavirus Vaccine (CHO Cell)    | NMPA                 | Recombinant protein subunit   | Response to 2 <sup>nd</sup> EOI sent 29 Jan 2021. Additional information requested. |                             |  |   |  |
| 14. | IMBCAMS, China   | SARS-CoV-2 Vaccine, Inactivated (Vero Cell)         | NMPA                 | Inactivated   | Not accepted, still under initial development                                       |                             |  |   |  |
| 15. |   | Inactivated SARS-CoV-2 Vaccine (Vero Cell)          | NMPA                 | Inactivated, produced in Vero cells   |   |                             |  |   |  |

|     | Manufacturer                 | Name of Vaccine  | NRA of Record | Platform  | EOI accepted   | Pre-submission meeting held | Dossier accepted for review* | Status of assessment** | Anticipated decision date*** |
|-----|------------------------------|--|---------------|---|--|-----------------------------|------------------------------|------------------------|------------------------------|
| 16. | Bharat Biotech, India        | COVAXIN  | DCGI          | SARS-CoV-2 Vaccine, Inactivated (Vero Cell)   | Requested meeting to discuss details of submission/timelines |                             |                              |                        |                              |
| 17. | Clover Biopharmaceuticals    | SCB-2019   | EMA           | Novel recombinant SARS-CoV-2 Spike (S)-Trimer fusion protein                                    | In discussion on submission strategy and timelines           |                             |                              |                        |                              |
| 18. | BioCubaFarma - Cuba          | Soberana 01,<br>Soberana 02<br>Soberana Plus   | CECMED        | SARS-CoV-2 spike protein conjugated chemically to meningococcal B or tetanus toxoid or Aluminum | In discussion on submission strategy and timelines           |                             |                              |                        |                              |
| 19. | Curevac (Bayer AG) – Germany | Zorecimeran (INN) concentrate and solvent for dispersion for injection;<br>Company code: CVnCoV/CV07050101 | EMA           | mNRA-based vaccine encapsulated in lipid nanoparticle (LNP)                                     | In discussion on submission strategy and timelines           |                             |                              |                        |                              |

1. Beijing Bio-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.