




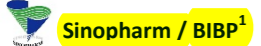
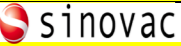










Status of COVID-19 Vaccines within WHO EUL/PQ evaluation process

	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 USFDA	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 Diluent suppliers: – Pfizer Perth, Australia Fresenius Kabi, USA	31/12/2020 30/06/2021 08/07/2021 16/07/2021 17/09/2021 20/09/2021 18/06/2021
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
3.		AZD1222 Vaxzevria	MFDS KOREA	Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.	✓	✓	✓	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
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) Additional sites: – Merck, Durham, UK (DS) – Merck, West Point/PA (DP)	12 March 2021 Finalized – Aspen RSA (DP) – Catalent Agnani Italy (DP) – Future submission – Future submission

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.	 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.	 康希诺生物 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
19.	 CUREVAC أحياءنا شعبنا	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