






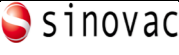







### Status of COVID-19 Vaccines within WHO EUL/PQ evaluation process

	Manufacturer / WHO EUL holder	Name of Vaccine	NRA of Record	Platform	EOI accepted	Pre-submission meeting held	Dossier accepted for review*	Status of assessment**	Anticipated decision date***
1.		BNT162b2/COMIRNATY Tozinameran (INN)	EMA	Nucleoside modified mRNA	✓	✓	✓	Finalized	31/12/20
2.		AZD1222	EMA	Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.	✓	✓	Accepted core data	Finalized	16 April 2021
							Data for Covax sites expected in April 2021 onwards	Finalized: SK-Catalent Wuxi (DS)	16 April 2021 30 April 2021
3.		AZD1222	MFDS KOREA	Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.	✓	✓	✓	Finalized	15 Feb 2021
4.		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.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: - Aspen South Africa - Other sites	- Ongoing* - Awaiting	- June 2021 - As submitted
6.		mRNA-1273	EMA	mRNA-based vaccine encapsulated in lipid nanoparticle (LNP)	✓	✓	✓	Finalized	30 April 2021
7.		SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV)	NMPA	Inactivated, produced in Vero cells	✓	✓	✓	Finalized	07 May 2021
8.		SARS-CoV-2 Vaccine (Vero Cell), Inactivated	NMPA	Inactivated, produced in Vero cells	✓	✓	✓	In progress	Early June 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 set after all data is submitted and inspections completed.
10.		Ad5-nCoV	NMPA	Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector)	✓	✓	Rolling data starting June 2021		
11.		NVX-CoV2373/Covovax	EMA	Recombinant nanoparticle prefusion spike protein formulated with Matrix-M™ adjuvant.	✓	✓			
12.		Inactivated SARS-CoV-2 Vaccine (Vero Cell)	NMPA	Inactivated, produced in Vero cells	EOI submitted on 30 April and more on 26 May 2021.	Requested information just received			
13.		Zorecimeran (INN) concentrate and solvent for dispersion for injection; Company code: CVnCoV/CV07050101	EMA	mRNA-based vaccine encapsulated in lipid nanoparticle (LNP)	Submitted EOI on 12 April	Planned for 15 July 2021, based on company request			

	Manufacturer / WHO EUL holder	Name of Vaccine	NRA of Record	Platform	EOI accepted	Pre-submission meeting held	Dossier accepted for review*	Status of assessment**	Anticipated decision date***
14.	Vector State Research Centre of Virology and Biotechnology	EpiVacCorona	Russian NRA	Peptide antigen	Letter received not EOI. Reply sent on 15/01/2021				
15.	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.				
16.	IMBCAMS, China	SARS-CoV-2 Vaccine, Inactivated (Vero Cell)	NMPA	Inactivated	Not accepted, still under initial development				
17.	Bharat Biotech, India	COVAXIN	DCGI	SARS-CoV-2 Vaccine, Inactivated (Vero Cell)	Submitted EOI on 19/04/2021. More information required.	To be planned in June 2021			
18.	Clover Biopharmaceuticals	SCB-2019	EMA	Novel recombinant SARS-CoV-2 Spike (S)-Trimer fusion protein	In discussion on submission strategy and timelines				
19.	BioCubaFarma - Cuba	Soberana 01, Soberana 02, Soberana Plus	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 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.