




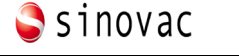







Status of COVID-19 Vaccines within WHO EUL/PQ evaluation process (20 January 2021)

	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 (INN tozinameran)	EMA	Nucleoside modified mRNA	✓	✓	✓	Finalized	31/12/20
2.	Zhifei Longcom, China	Recombinant Novel Coronavirus Vaccine (CHO Cell)	NMPA	Recombinant protein subunit	Not accepted Product in Phase I/II				
3.	IMBCAMS, China	SARS-CoV-2 Vaccine, Inactivated (Vero Cell)	NMPA	Inactivated	Not accepted, still under development				
4.		AZD1222	Core – EMA Non-COVAX	recombinant replication defective chimpanzee adenovirus expressing the SARS-CoV-2 S surface glycoprotein	✓	✓	✓	In progress Core data Non-Covax. Covax data to be reviewed as EMA post approval change	Earliest by EMA End of Jan-Feb 2021 (non- Covax) Additional nodes in March/ April for Covax
5.		AZD1222	MFDS KOREA	=	✓	✓	Tentative 18 and 29 Jan 2021 (CMC for SK Bio)	Core data (non-Covax) in progress	Earliest 2 nd half Feb 2021
6.		Ad26.COVS.2.S	EMA	recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding the (SARS-CoV-2) Spike (S) protein	✓	✓	Rolling data to EMA: Dec, Feb, Apr (critical data), May ✓	Not yet started. Use abridged procedure relying on EMA	Earliest May – June 2021
7.		SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV)	NMPA	Inactivated, produced in Vero cells	✓	✓	End of Dec 2020	In progress	Earliest March
8.		SARS-CoV-2 Vaccine (Vero Cell), Inactivated	NMPA	Inactivated, produced in Vero cells	✓	✓	13Jan2021 (under screening)		Earliest March
9.		Sputnik V	Russian NRA	Human Adenovirus Vector-based Covid-19 vaccine	Additional information submitted – under assessment	✓	22Jan2021 discussion on content and format		
10.	Vector State Research Centre of Virology and Biotechnology	EpiVacCorona	Russian NRA	Peptide antigen	Letter received not EOI				
11.		Ad5-nCoV		Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector)	Additional information requested	26Jan 2021			
12.		mRNA-1273	EMA	mRNA-based vaccine encapsulated in lipid nanoparticle (LNP)	Expected in Feb 2021				Estimated end of Feb 2021
13.	Serum Institute of India	Covishield (ChAdOx1_nCoV-19)	DCGI	recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2	✓	08Jan 2021	13 Jan (Under screening)		Mid Feb 2021
14.			NMPA	No pre-submission meeting yet					
15.			EMA	No pre-submission meeting yet					

* Dossier Submission dates: more than one date is possible because of the rolling submission. Dossier is accepted for submission 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.

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