




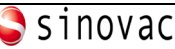







Status of COVID-19 Vaccines within WHO EUL/PQ evaluation process

	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 (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, April (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	✓	✓	13 January 2021 (under screening)		Earliest March
9.		Sputnik V	Russian NRA	Human Adenovirus Vector-based Covid-19 vaccine	Additional information submitted – under assessment	✓	22 nd January 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	26 January 2021			
12.		mRNA-1273	EMA	mNRA-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	✓	08 Jan 2021	13 Jan (Under screening)		Mid Feb 2021
14.	 Sinopharm / WIBP ¹		NMPA	No pre-submission meeting yet					
15.			EMA	No pre-submission meeting yet					
	1. Wuhan Institute of Biological Products Co Ltd 2. Beijing Bio-Institute of Biological Products Co-Ltd								

* 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

