



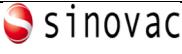








## Status of COVID-19 Vaccines within WHO EUL/PQ evaluation process

	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 Tozinameran (INN)	EMA	Nucleoside modified mRNA	✓	✓	✓	Finalized	31/12/20
2.		AZD1222	Core – EMA Non-COVAX	Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.	✓	✓	✓	In progress Core data Non-Covax.  Covax data to be reviewed as EMA post approval change	Earliest by EMA End of January (non-Covax)  Additional nodes in March/ April for Covax
3.		AZD1222	MFDS KOREA	Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.	✓	✓	18 Jan Additional data expected on 29 Jan 2021 (CMC for SK Bio)	Core data (non-covax) in progress (in parallel with EMA). SK Bio data assessed in conjunction with MFDS	Earliest 2 <sup>nd</sup> half Feb 2021
4.	<b>Serum Institute of India</b>	Covishield (ChAdOx1_nCoV-19)	DCGI	Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.	✓	✓	✓	In progress	Mid Feb 2021
5.		SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV)	NMPA	Inactivated, produced in Vero cells	✓	✓	✓	In progress	Earliest March
6.		SARS-CoV-2 Vaccine (Vero Cell), Inactivated	NMPA	Inactivated, produced in Vero cells	✓	✓	Data submitted on 13 January 2021 for inspection purposes. Dossier expected end January.		Earliest March
7.		mRNA-1273	EMA	mRNA-based vaccine encapsulated in lipid nanoparticle (LNP)	✓	✓	Expected in February		Estimated end of Feb 2021
8.		Ad26.COV2.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
9.		Sputnik V	Russian NRA	Human Adenovirus Vector-based Covid-19 vaccine	Additional information submitted	Several meetings held. Further clarification requested.	Timelines for data availability and submission to be clarified on 28-29 January		

	Manufacturer	Name of Vaccine	NRA of Record	Platform	EOI accepted	Pre-submission meeting held	Dossier accepted for review*	Status of assessment**	Anticipated decision date***
10.	 康希诺生物 CanSinoBIO	Ad5-nCoV	NMPA	Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector)	Additional information requested	26 January 2021			
11.	Vector State Research Centre of Virology and Biotechnology	EpiVacCorona	Russian NRA	Peptide antigen	Letter received not EOI				
12.	Zhifei Longcom, China	Recombinant Novel Coronavirus Vaccine (CHO Cell)	NMPA	Recombinant protein subunit	Not accepted Still under development				
13.	IMBCAMS, China	SARS-CoV-2 Vaccine, Inactivated (Vero Cell)	NMPA	Inactivated	Not accepted, still under initial development				
14.	 Sinopharm / WIBP <sup>2</sup>	Inactivated SARS-CoV-2 Vaccine (Vero Cell)	NMPA	No pre-submission meeting yet					
15.	 NOVAVAX		EMA	No pre-submission meeting yet					

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. 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.