

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	Nucleoside modified mRNA	✓	✓	✓	Finalized: Additional sites: – Baxter Oncology GmbH Germany (DP) – Novartis Switzerland – Mibe (Dermapharm) Germany (DP) – Delpharm, Saint-Remy FRANCE (DP) – Sanofi-Aventis Deutschland GmbH Germany (DP) – Siegfried Hameln GmbH, Germany (DP) – Patheon Italia S.p.A, Italy (DP) Diluent suppliers: – Pfizer Perth, Australia – Fresenius Kabi, USA – Pfizer Manufacturing Belgium Shelf life extension: 09 months at -70 to -90°C	31/12/2020 30/06/2021 08/07/2021 16/07/2021 17/09/2021 18/06/2021 11/11/21 07/12/21 20/09/2021 30/11/2021 06/10/2021
			USFDA				✓	Finalized: – Pharmacia & Upjohn, Kalamazoo (DP)PGS – McPherson (DP) – Exelead, Inc. Indianapolis USA	16/07/2021 16/07/2021 30/09/2021
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
		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
3.		AZD1222 Vaxzevria	Japan MHLW/PMDA		✓	✓	✓	Finalized Additional sites: Nipro Pharma Corporation Ise, Japan	09 July 2021 11 October
4.		AZD1222 Vaxzevria	Australia TGA	Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.	✓	✓	✓	Finalized Additional site: Siam Bioscience Co., Ltd Thailand	09 July 2021 11 October 2021
5.					✓	✓	✓	Finalized DS and DP Manjari Bk Pune	15 Feb 2021 12 Nov 2021
6.					✓	✓	✓	Core data finalized (US +NL sites)	12 March 2021
7.	 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 DS and DP Manjari Bk Pune	15 Feb 2021 12 Nov 2021
8.	 PHARMACEUTICAL COMPANIES OF Johnson & Johnson	Ad26.COVS.2.S	EMA	Recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding the (SARS-CoV-2) Spike (S) protein	✓	✓	✓ Additional sites:	Finalized – Aspen RSA (DP)	-25 June 2021

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	Janssen–Cilag International NV						- Merck, Durham, UK (DS) -	- Catalent Agnani Italy (DP) - Grand River Aseptic Manufacturing Inc., USA - MSD (Merck), West Point/PA, USA (DP)	- 02 July 2021 - 05 November 2021
9.	 Moderna Biotech	mRNA-1273	EMA	mRNA-based vaccine encapsulated in lipid nanoparticle (LNP)		✓	✓	Finalized	30 April 2021
			USFDA	mRNA-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
10.	 Sinopharm / BIBP ¹ 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 after ongoing inspection
11.	 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
12.	 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.	Process restarted, awaiting completion of rolling submission and CAPAs to last inspection-	Anticipated date will be set once all data is submitted and follow-up of inspection observations completed.
13.	 Bharat Biotech, India	SARS-CoV-2 Vaccine, Inactivated (Vero Cell)/ COVAXIN	DCGI	Whole-Virion Inactivated Vero Cell	✓	✓	✓	Finalized	03 November 2021
14.	 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
15.	 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
16.	 NOVAVAX	NVX-CoV2373/Covovax	EMA	Recombinant nanoparticle prefusion spike protein formulated with Matrix-M™ adjuvant.	✓	✓	Rolling data started 19 August 2021	Ongoing	TBC
17.	 SANOFI	CoV2 preS dTM-AS03 vaccine	EMA	Recombinant, adjuvanted	✓	✓	Rolling data started 30 July 2021	Ongoing	TBC
18.	 SERUM INSTITUTE OF INDIA PVT. LTD. Cyrus Poonawalla Group	NVX-CoV2373/Covovax	DCGI	Recombinant nanoparticle prefusion spike protein formulated with Matrix-M™ adjuvant.	✓	✓	Rolling data started 21 September 2021	Ongoing	TBC
19.	Clover Biopharmaceuticals	SCB-2019	NMPA	Novel recombinant SARS-CoV-2 Spike (S)-Trimer fusion protein	✓	✓	Rolling data started 20 September	Ongoing	
20.	 LUREVAC The Resta people®	Zorecimeran (INN) concentrate and solvent for dispersion for injection; Company code: CVnCoV/CV07050101	EMA	mRNA-based vaccine encapsulated in lipid nanoparticle (LNP)	✓	Application withdrawn by manufacturer			

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21.	Zhifei Longcom, China	Recombinant Novel Coronavirus Vaccine (CHO Cell)	NMPA	Recombinant protein subunit	✓	Presubmission planned			
22.	Vector State Research Centre of Virology and Biotechnology	EpiVacCorona	Russian NRA	Peptide antigen	Letter received not EOI. Reply sent on 15/01/2021				
23.	IMBCAMS, China	SARS-CoV-2 Vaccine, Inactivated (Vero Cell)	NMPA	Inactivated	Not accepted, still under initial development				
24.	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