






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) – Catalent Agnani – Exela Pharma Sciences, LLC, NC – Sanofi-Aventis Deutschland GmbH (DP) Diluent suppliers: – Pfizer Perth, Australia – Fresenius Kabi, USA – Pfizer Manufacturing Belgium – Kwang Myung Pharm Co., Ltd. Shelf life extension: 15 months at -70 to -90°C (PBS/Sucrose) Shelf life extension: 12 months at -70 to -90°C PBS/Tris Booster dose approved for adults 18 years of age and older Age extension to adolescents 12-15 Age extension to children 5 – 11 years of age	31/12/2020 30/06/2021 08/07/2021 16/07/2021 17/09/2021 18/06/2021 11/11/2021 07/12/2021 21/01/2022 16/03/2022 12/09/2022 20/09/2021 20/09/2021 30/11/2021 14/01/2022 29/08/2022 18/05/2022 17/12/2021 08/09/2021 12/02/2022
			USFDA				✓	Finalized – Pharmacia & Upjohn, Kalamazoo (DP) – PGS McPherson (DP) – Exelead, Inc. Indianapolis USA	16/07/2021 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 Booster dose approved for adults 18 years of age and older	16 April 2021 19 July 2022
							✓	Finalized: Additional sites: – SK-Catalent – Wuxi (DS) – Chemo Spain – Amylin Ohio US (DP) – WuXi Biologics, Germany (DP)	16/04/2021 30/04/2021 30/04/2021 04/06/2021 23/07/2021 08/03/2022
3.			MFDS KOREA	Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.	✓	✓	✓	Finalized	15 Feb 2021
4.			Japan MHLW/PMDA	Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.	✓	✓	✓	Finalized Additional sites: Nipro Pharma Corporation Ise, Japan	09 July 2021 11 October 2021

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5.			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
6.			COFEPRIS (Mexico) ANMAT (Argentina)	Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.	✓	✓	✓	Finalized	23 December 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.	 Janssen-Cilag International NV	Ad26.COV2.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) - Additional sites: Aspen RSA (DP) - Catalent Agnani Italy (DP) - Grand River Aseptic Manufacturing Inc., USA - MSD (Merck), West Point/PA, USA (DP) - Sanofi Pasteur France (DP) - Biological E Ltd India (DP) Storage conditions extension at 2-8 °C from 4,5 months to 11 months within the 24 months of shelf-life at -25°C to -15°C Booster dose approved for adults 18 years of age and older	12 March 2021 25 June 2021 02 July 2021 17 sept 2021 05 Nov 2021 27 Jan 2022 07 July 2022 16/03/2022 25/03/2022
			DCGI	Recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding the (SARS-CoV-2) Spike (S) protein	✓	✓	✓	Ongoing	To be confirmed
9.	 Moderna Biotech	mRNA-1273	EMA	mRNA-based vaccine encapsulated in lipid nanoparticle (LNP)	✓	✓	✓	Finalized Shelf life extension to 09 months -20±5°C	30 April 2021 14 Feb 2022
			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
			MFDS	mRNA-based vaccine encapsulated in lipid nanoparticle (LNP)	✓	✓	✓	Finalized	23 December 2021
10.	 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 28 December 2021
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.	 Bharat Biotech, India	SARS-CoV-2 Vaccine, Inactivated (Vero Cell)/ COVAXIN	DCGI	Whole-Virion Inactivated Vero Cell	✓	✓	✓	Finalized	03 November 2021 SUPPLY OF VACCINE SUSPENDED

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13.	 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	Finalized	17 December 2021
14.		NVX-CoV2373/Nuvaxovid	EMA	Recombinant nanoparticle prefusion spike protein formulated with Matrix-M™ adjuvant	✓	✓	Rolling data started 19 August 2021	Finalized Additional sites: SK Bioscience Co., Ltd., (DS)	20 December 2021 1/09/2022
15.	 康希诺生物 CanSinoBIO	Ad5-nCoV	NMPA	Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector)	✓	✓	Rolling data started 09 August 2021	Finalized	19 May 2022
16.		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.
17.		CoV2 preS dTM-AS03 vaccine	EMA	Recombinant, adjuvanted	✓	✓	Rolling data started 30 July 2021	Ongoing	To be confirmed
18.	Clover Biopharmaceuticals	SCB-2019	NMPA	Novel recombinant SARS-CoV-2 Spike (S)-Trimer fusion protein	✓	✓	Rolling data started 20 September	Ongoing	To be confirmed
19.	Zhifei Longcom, China	Recombinant Novel Coronavirus Vaccine (CHO Cell)	NMPA	Recombinant protein subunit	✓	✓	Rolling data started 28 March 2022	Ongoing	To be confirmed
20.	Shifa Pharmed - Barkat	CovIran® vaccine	Iran Food Drug Administration (IFDA)	Inactivated, produced in Vero cells	✓	✓	Rolling data started 3 August 2022	Ongoing	To be confirmed
21.	CIGB	Abdala	CECMED	Protein subunit	✓	✓	Rolling data started 7 June 2022	Ongoing	To be confirmed
22.	SK Bioscience	Nuvaxovid prefilled syringe	MFDS (RoKorea)	Recombinant nanoparticle prefusion spike protein formulated with Matrix-M™ adjuvant	✓	✓	Rolling data pending	Ongoing	To be confirmed
23.	Biological E	Corbevax	DCGI India	RBD antigen of SARS CoV-2 (Covid-19)	✓	✓	Rolling data started 10 th of June	Ongoing	To be confirmed
24.	SK Bioscience	GBP510	MFDS (RoKorea)	Recombinant protein subunit	✓	✓	Rolling data started 7 September 2022	Ongoing	To be confirmed
25.	WestVac Biopharma	Recombinant COVID-19 Vaccine	NMPA China	Recombinant SARS-CoV-2 S-RBD protein	EOI under review				
26.	Nanogen	Nanocovax	Drug Administration of Vietnam	Recombinant Spike protein	EOI under review				
27.	Cinnagen	SpikoGen	Iran Food Drug Administration (IFDA)	Recombinant Protein	EOI under review				
28.	R-PHARM	Vaccine R-COVI	Russian NRA	Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.	EOI under review				

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29.	Arcturus Therapeutics	ARCT-154	Drug Administration of Vietnam	RNA Vaccine	EOI under review				
30.	Bio-Manguinhos/Fiocruz	AZD1222	ANVISA	Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.	EOI under review				
31.	Vaxxinity	UB-612	FDA	Protein-peptide vaccine	EOI under review				
32.	Sinocelltech, Ltd	SCTV01C	NMPA	Recombinant Protein	EOI received				
33.	Razi Vaccine & Serum Research Institute	Razi Cov Pars Vaccine	Iran Food Drug Administration (IFDA)	Recombinant Protein	EOI received				
34.	Valneva	VLA2001	EMA	Inactivated	EOI received				
35.	Medigen	MVC-COV1901	TGA	CHO cell derived spike protein (Subunit)	EOI received				
36.	HIPRA	BIMERVAX	EMA	Recombinant Protein	EOI received				
37.	Stelis Biopharma Limited	AKS-452 Vaccine (AmbiVax -CTM)	DCGI India	Protein subunit	EOI received				
38.	PT Biofarma	SARS CoV-2 RBD	Badan Pom Indonesia	Recombinant Protein Vaccine	EOI received				
39.	Medicago	COVIFENZ®	Health Canada	Plant-based virus-like particle [VLP], recombinant, adjuvanted	Application withdrawn by applicant				
40.	 LUREVAC live RNA 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			
41.	 Sinopharm / WIBP ²	Inactivated SARS-CoV-2 Vaccine (Vero Cell)	NMPA	Inactivated, produced in Vero cells	✓	✓	Rolling data started 23 July 2021	Dossier withdrawn on 7 September 2022	
42.	Vector State Research Centre of Virology and Biotechnology	EpiVacCorona	Russian NRA	Peptide antigen	Letter received not EOI. Reply sent on 15/01/2021				

43.	IMBCAMS, China	SARS-CoV-2 Vaccine, Inactivated (Vero Cell)	NMPA	Inactivated	Not accepted, still under initial development				
44.	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 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