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.	Pfizer BioNTech 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 Diluent suppliers: – Pfizer Perth, Australia – Fresenius Kabi, USA – Pfizer Manufacturing Belgium – Kwang Myung Pharm Co., Ltd. Shelf life extension: 09 months at -70 to -90°C Booster dose approved for adults 18 years of age and older Age extension to children 5 – 11 years of age	31/12/2020 30/06/2021 08/07/2021 16/07/2021 17/09/2021 18/062021 11/11/2021 07/12/2021 21/01/2022 20/09/2021 20/09/2021 30/11/2021 12/01/2022 06/10/2021 17/12/21 14/12/22 12/02/2022
			USFDA				✓	Finalized: – Pharmacia & Upjohn, Kalamazoo (DP)PGS McPherson (DP) – Exelead, Inc. Indianapolis USA	16/07/2021 16/07/2021 30/09/2021
2.	AstraZeneca 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
							✓	Finalized: Additional sites: – SK-Catalent – Wuxi (DS) – Chemo Spain – Amylin Ohio US (DP)	 16/04/2021 30/04/2021 04/06/2021 23/07/2021
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
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

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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)	12 March 2021
							Additional sites: - Merck, Durham, UK (DS)	Finalized – Aspen RSA (DP) – Catalent Agnani Italy (DP) – Grand River Aseptic Manufacturing Inc., USA - MSD (Merck(, West Point/PA, USA (DP) - Sanofi Pasteur France (DP)	25 June 2021 02 July 2021 05 Nov 2021 27 Jan 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 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.	Bharat Biotech, India	SARS-CoV-2 Vaccine, Inactivated (Vero Cell)/ COVAXIN	DCGI	Whole-Virion Inactivated Vero Cell	✓	✓	✓	Finalized	03 November 2021
13.		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	20 December 2021
15.		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.

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16.	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
17.	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
18.	SANOFI	CoV2 preS dTM-AS03 vaccine	EMA	Recombinant, adjuvanted	✓	✓	Rolling data started 30 July 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.	Zhifei Longcom, China	Recombinant Novel Coronavirus Vaccine （CHO Cell)	NMPA	Recombinant protein subunit	✓	2 Pre-submission meeting held on 1 and 21 Dec 2021			
21.	Shifa Pharmed - Barkat, Iran	CovIran® vaccine	Iran Food Drug Administration (IFDA)	Inactivated, produced in Vero cells	✓	Presubmission meeting held on 26 January 2022			
22.	CIGB	Abdala	CECMED	Protein subunit	EOI under review				
23.	Biological E	Corbevax	DCGI India	RBD antigen of SARS CoV-2 (Covid-19)					
24.	SK Bioscience	GBP510	MFDS (RoKorea)	Recombinant protein subunit	EOI under review				
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				
29.	SK Bioscience	Nuvaxovid prefilled syringe	MFDS (RoKorea)	Recombinant nanoparticle prefusion spike protein formulated with Matrix-M™ adjuvant	EOI under review				
30.	Medicago	COVIFENZ®	Health Canada	Plant-based virus-like particle [VLP], recombinant, adjuvanted	Not accepted				
31.	CUREVAC the 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			
32.	Vector State Research Centre of Viralogy and Biotechnology	EpiVacCorona	Russian NRA	Peptide antigen	Letter received not EOI. Reply sent on 15/01/2021				
33.	IMBCAMS, China	SARS-CoV-2 Vaccine, Inactivated (Vero Cell)	NMPA	Inactivated	Not accepted, still under initial development				
34.	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.				

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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: WHOEUL@who.int