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: – Single dose vial	31/12/2020 11/07/2023
								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)	30/06/2021 08/07/2021 16/07/2021 17/09/2021 18/062021 11/11/2021 07/12/2021 21/01/2022 16/03/2022 12/09/2022
								Diluent suppliers: – Pfizer Perth, Australia – Fresenius Kabi, USA – Pfizer Manufacturing Belgium – Kwang Myung Pharm Co., Ltd.	20/09/2021 20/09/2021 30/11/2021 14/01/2022
								Shelf life extension: 12 months at -70 to -90°C PBS/Tris Shelf life extension: 15 months at -70 to -90°C (PBS/Sucrose) Shelf life extension: 18 months at -70 to -90°C (Tris/Sucrose) for monovalent vaccines and bivalent booster dose Shelf life extension: 18 months at -70 to -90°C (PBS/Tris)	18/05/2022 29/08/2022 06/01/2023 01/02/2023
								Age extension to adolescents 12-15 Age extension to children 5 – 11 years of age	08/09/2021 12/02/2022
								Booster dose approved for adults 18 years of age and older Bivalent booster Original/Omicron BA.1 for individuals 12 years of age and older Bivalent booster Original/Omicron BA.4-5 for individuals 12 years of age and older Age extension to children 5 – 11 years of age	17/12/2021 19/10/2022 11/11/2022 17/04/23
			USFDA				✓	Finalized Additional sites: – 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 University of Oxford AstraZeneca, AB	AZD1222 Vaxzevria	EMA	Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.	✓	✓	✓	Core data finalized Shelf life extension: 9 months at 2 °C to 8 °C	16/04/ 2021 01/06/2023

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								Booster dose approved for adults 18 years of age and older	19/07/ 2022
								Additional sites: – SK-Catalent – Wuxi (DS) – Chemo Spain – Amylin Ohio US (DP) – WuXi Biologics, Germany (DP) – Shelf life extension to 09 months at 2°C to 8°C	 30/04/2021 30/04/2021 04/06/2021 23/07/2021 08/03/2022 20/04/2023
3.			MFDS KOREA	Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.	✓	✓	✓	Manufacturing site SK Bioscience, Republic of Korea withdrawn	28/10/2022
4.			Japan MHLW/PMDA	Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.	✓	✓	✓	Nipro Pharma Corporation manufacturing site in Japan withdrawn	05/31/2023
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	09/07/21 11/10/21
6.			COFEPRIS (Mexico) ANMAT (Argentina)	Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.	✓	✓	✓	Manufacturing sites in Mexico and Argentina withdrawn	05/31/2023
7.	SERUM INSTITUTE OF INDIA PVT. LTD. Cyrus Poonawalla Group 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 Additional site: - DS and DP Manjari Bk Pune Shelf life extension to 09 months at 2°C to 8°C Booster dose approved for adults 18 years of age and older	15/02/2021 12/11/2021 25 June 2021 22 July 2022
8.	Janssen Infectious Diseases & Vaccines 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)	12/03/2021
								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 (DS)	 25/06/2021 02/07/2021 17/09/2021 05/11/2021 27/01/2022 07/07/2022
								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	16/03/2022
								Booster dose approved for adults 18 years of age and older	25/03/2022
9.	moderna Moderna Biotech	mRNA-1273/Spikevax	EMA	mRNA-based vaccine encapsulated in lipid nanoparticle (LNP)	✓		✓	Finalized Shelf life extension to 09 months -20±5°C	30/04/2021 14/02/2022
								Booster dose approved for adults 18 years of age and older Age extension to individuals as of 6 years of age	11/11/2022 11/11/2022

	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***
			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)	06/06/2021
			MFDS	mRNA-based vaccine encapsulated in lipid nanoparticle (LNP)	✓	✓	✓	Finalized	23/12/ 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) Age extension to 60 years and older Age extension 3 to 17 years of age	07/05/2021 2/12/2021 30/11/2022 17/04/2023
11.	sinovac 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 Age extension to 3-17 years of age Shelf life extension to 24 months at 2 °C to 8 °C	01/06/2021 30/09/2021 02/11/2022 03/01/2023
12.	BHARAT BIOTECH Bharat Biotech, India	SARS-CoV-2 Vaccine, Inactivated (Vero Cell)/ COVAXIN	DCGI	Whole-Virion Inactivated Vero Cell	✓	✓	✓	Finalized	03/11/2021 SUPPLY OF VACCINE SUSPENDED
13.	SERUM INSTITUTE OF INDIA PVT. LTD. Cyrus Poonawalla Group	NVX-CoV2373/Covovax	DCGI	Recombinant nanoparticle prefusion spike protein formulated with Matrix-M™ adjuvant	✓	✓	✓	Finalized Age extension to 12 – 17 Booster dose for adults 18 years of age and older	17/12/2021 17/11/2022 17/11/2022
14.	NOVAVAX	NVX-CoV2373/Nuvaxovid	EMA	Recombinant nanoparticle prefusion spike protein formulated with Matrix-M™ adjuvant	✓	✓	✓	Finalized Additional sites: SK Bioscience Co., Ltd., (DS) Age extension to 12 – 17 Booster dose for adults 18 years of age and older	20/12/2021 1/09/2022 17/11/2022 17/11/2022
15.	康希诺生物 CanSinoBIO	Ad5-nCoV/Convidecia	NMPA	Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector)	✓	✓	✓	Finalized Booster dose for adults 18 years of age and older	19/05/2022 17/03/2023
16.	SK Bioscience	GBP510	MFDS (RoKorea)	Recombinant protein subunit	✓	✓	✓	*Finalized*	16/06/2023
17.	RUSSIAN DIRECT INVESTMENT FUND	Sputnik V	Russian NRA	Human Adenovirus Vector-based Covid-19 vaccine	Additional information submitted	Several meetings have been and continue to be held.	✓	Process restarted *Assessment process following termination of the PHEIC under discussion with manufacturers*	To be confirmed
18.	SANOFI	CoV2 preS dTM-AS03 vaccine	EMA	Recombinant, adjuvanted	✓	✓	Rolling data started 30 July 2021	*Assessment process following termination of the PHEIC under discussion with manufacturers*	To be confirmed
19.	Clover Biopharmaceuticals	SCB-2019	NMPA	Novel recombinant SARS-CoV-2 Spike (S)-Trimer fusion protein	✓	✓	Rolling data started 20 September	*Assessment process following termination of the PHEIC under discussion with manufacturers*	To be confirmed
20.	Zhifei Longcom, China	Recombinant Novel Coronavirus Vaccine （CHO Cell)	NMPA	Recombinant protein subunit	✓	✓	Rolling data started 28 March 2022	*Assessment process following termination of the PHEIC under discussion with manufacturers*	To be confirmed

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21.	Shifa Pharmed - Barkat	CovIran® vaccine	Iran Food Drug Administration (IFDA)	Inactivated, produced in Vero cells	✓	✓	Rolling data started 3 August 2022	*Assessment process following termination of the PHEIC under discussion with manufacturers*	To be confirmed
22.	CIGB	Abdala	CECMED	Protein subunit	✓	✓	Rolling data started 7 June 2022	*Assessment process following termination of the PHEIC under discussion with manufacturers*	To be confirmed
23.	SK Bioscience	Nuvaxovid prefilled syringe	MFDS (RoKorea)	Recombinant nanoparticle prefusion spike protein formulated with Matrix-M™ adjuvant	✓	✓		*Assessment process following termination of the PHEIC under discussion with manufacturers*	To be confirmed
24.	Biological E	Corbevax	DCGI India	RBD antigen of SARS CoV-2 (Covid-19)	✓	✓	Rolling data started 10th of June	*Assessment process following termination of the PHEIC under discussion with manufacturers*	To be confirmed
25.	WestVac Biopharma	Recombinant COVID-19 Vaccine	NMPA China	Recombinant SARS-CoV-2 S-RBD protein	*PQ assessment process following termination of the PHEIC will be communicated to manufacturers*				
26.	Nanogen	Nanocovax	Drug Administration of Vietnam	Recombinant Spike protein	*PQ assessment process following termination of the PHEIC will be communicated to manufacturers*				
27.	Cinnagen	SpikoGen	Iran Food Drug Administration (IFDA)	Recombinant Protein	*PQ assessment process following termination of the PHEIC will be communicated to manufacturers*				
28.	R-PHARM	Vaccine R-COVI	Russian NRA	Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.	*PQ assessment process following termination of the PHEIC will be communicated to manufacturers*				
29.	Arcturus Therapeutics	ARCT-154	Drug Administration of Vietnam	RNA Vaccine	*PQ assessment process following termination of the PHEIC will be communicated to manufacturers*				
30.	Bio-Manguinhos/Fiocruz	AZD1222	ANVISA	Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.	*PQ assessment process following termination of the PHEIC will be communicated to manufacturers*				
31.	Vaxxinity	UB-612	FDA	Protein-peptide vaccine	*PQ assessment process following termination of the PHEIC will be communicated to manufacturers*				
32.	Sinocelltech, Ltd	SCTV01C	NMPA	Recombinant Protein	*PQ assessment process following termination of the PHEIC will be communicated to manufacturers*				

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33.	Razi Vaccine & Serum Research Institute	Razi Cov Pars Vaccine	Iran Food Drug Administration (IFDA)	Recombinant Protein	*PQ assessment process following termination of the PHEIC will be communicated to manufacturers*				
34.	Valneva	VLA2001	EMA	Inactivated	*PQ assessment process following termination of the PHEIC will be communicated to manufacturers*				
35.	Medigen	MVC-COV1901	TGA	CHO cell derived spike protein (Subunit)	*PQ assessment process following termination of the PHEIC will be communicated to manufacturers*				
36.	HIPRA	BIMERVAX	EMA	Recombinant Protein	*PQ assessment process following termination of the PHEIC will be communicated to manufacturers*				
37.	Stelis Biopharma Limited	AKS-452 Vaccine (AmbiVax -CTM)	DCGI India	Protein subunit	*PQ assessment process following termination of the PHEIC will be communicated to manufacturers*				
38.	PT Biofarma	SARS CoV-2 RBD	Badan Pom Indonesia	Recombinant Protein Vaccine	*PQ assessment process following termination of the PHEIC will be communicated to manufacturers*				
39.	Shionogi & Co.,Ltd	S-268019	Japan MHLW/PMDA	Modified recombinant spike protein	*PQ assessment process following termination of the PHEIC will be communicated to manufacturers*				
40.	Liaoning Yisheng Biopharma Co	PIKA recombinant protein	NMPA	Recombinant Protein Vaccine	*PQ assessment process following termination of the PHEIC will be communicated to manufacturers*				
41.	CanSino Biologics	Convidecia Air™	NMPA	Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector)	*PQ assessment process following termination of the PHEIC will be communicated to manufacturers*				
42.	Medicago	COVIFENZ®	Health Canada	Plant-based virus-like particle [VLP], recombinant, adjuvanted	Application withdrawn by applicant				
43.	CureVac	Zorecimeran (INN)	EMA	mRNA-based vaccine encapsulated in lipid nanoparticle (LNP)	✓	Application withdrawn by manufacturer			

44.	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	

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