VIGICARIB NEWS

18TH AUGUST, 2022

OVERVIEW

This issue includes:

- Case Safety Reports to VigiCarib Network
- CARICOM COVID-19 Vaccine Safety Reports in VigiBase
- Summary of Case Safety Reports from CARICOM to WHO Programme for International Drug Monitoring (PIDM)
- Global Alerts of Substandard / Falsified Medical Products
- COVID-19 Vaccines and Therapeutics: Regulatory Updates
- COVID-19 Resources for Regulation and Vigilance

Image by: Polina Tankilevitch, Source: pexels.com

Note to Reader:

The following summary presents data on case reports of adverse events following immunization (AEFIs) with COVID-19 vaccines, and suspected adverse drug reactions, based on Individual Case Safety Reports (ICRSs) in regional (CRS) and global (WHO) databases. The ICSRs in the global database have been submitted by national pharmacovigilance centres in CARPHA Member States with membership in the WHO Programme for International Drug Monitoring (PIDM). The information provided is ***for descriptive purposes*** *only, e.g. reporting trends. Some of the ICSRs may not have been clinically reviewed or may be pending investigation.*

Any assessment of an association between COVID-19 vaccines and an increased risk of a given outcome requires additional investigation to get full information*.*

CASE SAFETY REPORTS TO VIGICARIB NETWORK

Between 16th July and 15th August 2022, the Caribbean Regulatory System received no safety case report of Adverse Events Following Immunization (AEFI), Adverse drug reactions (ADR), or Substandard / Falsified / Unregistered Medical Products (SF).

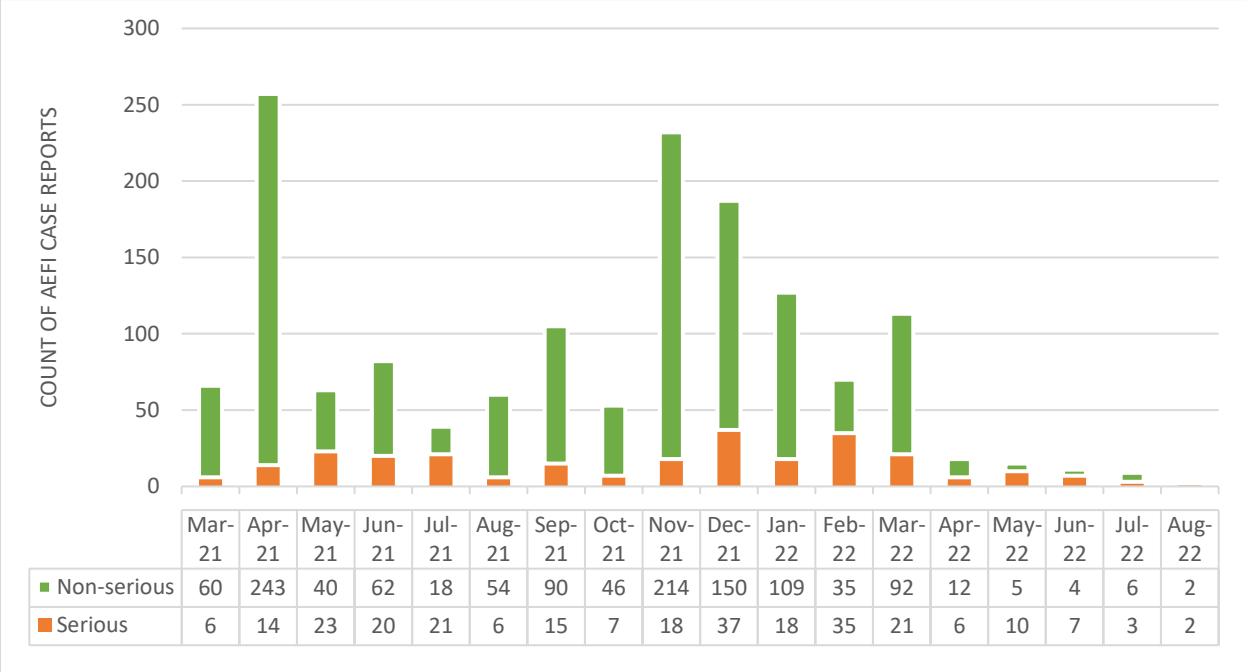
In all, 510 case reports have been shared with the CRS and the VigiCarib network since its inception in November 2017: suspected ADRs (326 – 63.9%), SFs (102 – 20.0%), and AEFIs (82 – 16.1%) – Table A1 (See Appendix I).

CARICOM COVID-19 VACCINE SAFETY REPORTS IN GLOBAL DATABASE

As of 15th August, 2022, there have been 1,496 case reports of AEFIs involving COVID-19 vaccines submitted to the global database, VigiBase from Barbados, Haiti, Jamaica and St Vincent and the Grenadines, mostly non-serious events, involving persons under 65 years (85.0%), and females (74.5%). The month with the greatest reporting activity is April 2021: Figure 1. Two hundred and sixty-four reports (17.6%) were classified as Serious, including 59 where deaths were reported outcomes – Figure 2, Table 3.

Four (4) additional COVID-19 AEFI case reports were submitted between 16th July and 15th August, 2022, with the most commonly reported reactions overall as: headache, fever, dizziness, fatigue, chills and myalgia – Table 3. The downward trend of reporting of AEFIs may be due to multiple factors including reduction in vaccinations, lack of awareness of reporting systems, and reduced risk perception. However, further study at the national level would be needed to confirm causality and factors affecting reporting.

Figure 1: Case reports of adverse events following immunization (AEFIs) with COVID-19 vaccines from 1st March 2021 to 15th August 2022*



	Mar-21	Apr-21	May-21	Jun-21	Jul-21	Aug-21	Sep-21	Oct-21	Nov-21	Dec-21	Jan-22	Feb-22	Mar-22	Apr-22	May-22	Jun-22	Jul-22	Aug-22
Non-serious	60	243	40	62	18	54	90	46	214	150	109	35	92	12	5	4	6	2
Serious	6	14	23	20	21	6	15	7	18	37	18	35	21	6	10	7	3	2

* - *Monthly mid-points are cut-off points for the AEFI count*

The reported ICSRs involved the following vaccines:

- COVID-19 vaccine NRVV Ad (ChAdOx1-S recombinant) by AstraZeneca or Serum Institute of India (COVISHIELD)
- COVID-19 vaccine NRVV Ad26 (Gam-Covid-Vac – Sputnik V)
- Tozinameran (Pfizer-BioNTech COVID-19 vaccine)
- COVID-19 vaccine NRVV Ad26 (JNJ 78436735) Johnson & Johnson
- COVID-19 vaccine inactivated (Vero cell) HB02 – BIBP-Sinopharm
- COVID-19 vaccine inactivated (Vero cell) WIV04- Sinopharm-Wuhan
- Elasomeran, COVID-19 Vaccine Moderna
- Covid-19 Vaccine (unspecified).

Note: *The case reports describe events that occurred after vaccination, which may include coincidental events that are not attributed to the vaccine(s).*

Reporting Rates by Doses Administered

Data from the Pan American Health Organization's (PAHO) dashboard on COVID-19 vaccines administered in various Caribbean countries was used in the estimation of the reporting rate of AEFIs per 100,000 doses for countries reporting to the global database. Among the countries with reports in the global database, there were approximately 65.6 AEFI reports per 100,000 doses of COVID-19 vaccines administered, with 11 serious adverse events reported per 100,000 doses. These estimates include coincidental and/or unconfirmed reports. The reporting rates provide an overview of reporting in the given country, which may be influenced by various factors external to the national system.

Table 1: Consolidated number of reported AEFI and reporting rate, by country as of 12th August, 2022

Country	Total Doses	Total AEFIs	AEFIs per 100,000 doses	Total Serious AEFIs	Serious AEFIs per 100,000 doses
Barbados	373,390	595	159.4	84	22.5
Haiti	360,163	1	0.3	0	0
Jamaica	1,474,979	878	59.5	174	11.8
St Vincent and the Grenadines	72,280	22	30.4	6	8.3
Total	**2,280,812**	**1,496**	**65.6**	**264**	**11.6**

*Key: *- Includes 5 reports where the vaccine was reported using multiple names: brand and the generic name or platform.*
¥ - Calculated using counts of reports and doses administered.

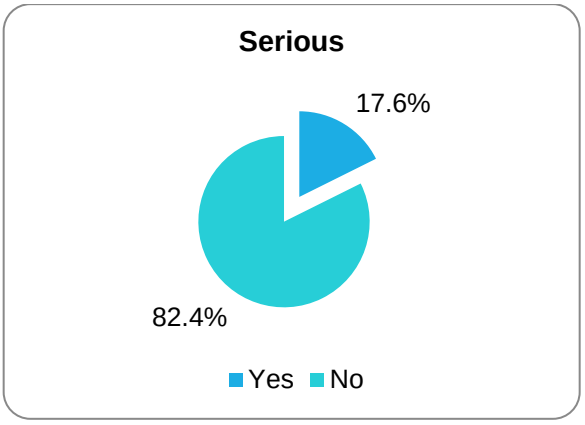
Table 2: Patient Age Groups Reported for AEFIs in VigiBase to 15th August, 2022 (N=1,496)

Patient age	Count	Percent
12 - 17 years	95	6.4%
18 - 44 years	688	46.0%
45 - 64 years	488	32.6%
65 - 74 years	104	7.0%
≥ 75 years	76	5.1%
Unknown	45	2.9%

Table 3: Top Reported Reactions for AEFIs in VigiBase to 15th August, 2022 (N=1,496)

Top Reported Reactions	Count	Percent
PT: Headache	446	29.8%
PT: Pyrexia	295	19.7%
PT: Dizziness	294	19.7%
PT: Fatigue	246	16.4%
PT: Chills	243	16.2%
PT: Myalgia	217	14.5%
PT: Arthralgia	207	13.8%
PT: Nausea	169	11.3%
PT: Vaccination site pain	159	10.6%
PT: Malaise	148	9.9%

Figure 2: Total AEFI Case Reports by Seriousness (N = 1,496)



Seriousness criteria	Count	Percent
Death	59	3.9%
Life threatening	19	1.3%
Caused/prolonged hospitalization	93	6.2%
Disabling/incapacitating	49	3.3%
Other medically important condition	94	6.3%

Note: Total exceeds 264 due to selection of multiple seriousness criteria in individual case reports

Table 4: Seriousness of Cases (n = 264)

SUMMARY OF CASE SAFETY REPORTS FROM CARICOM TO WHO PIDM

A review of the Uppsala Monitoring Centre's VigiBase identified 4,120 case reports from CARICOM countries with membership in the WHO Programme for International Drug Monitoring (PIDM) – 1,496 COVID-19 AEFI case reports, 142 non-COVID AEFI case reports, and 2,421 reports of suspected adverse drug reactions (ADRs). Table 5 identifies the number of case reports of suspected ADRs and AEFIs submitted by Member States between April 2007 and 15th August, 2022, inclusive of reports submitted by the CRS on behalf of Member States. Most of the case reports involved adults – Table 6.

Between 16th July and 15th August, 2022, ten (10) additional case reports were submitted to VigiBase from CARICOM: 4 AEFI reports, 6 ADR reports.

Table 5: All VigiBase Reports from CARICOM: suspected ADRs/AEFIs

Countries	Count	Percent
Barbados	1,372	33.3%
Dominica	14	0.3%
Guyana	12	0.3%
Haiti	19	0.5%
Jamaica	1,973	47.9%
Saint Vincent and the Grenadines	502	12.2%
Suriname	221	5.4%
Virgin Islands (British)	7	0.2%

Table 6: ICSR Patient Ages Reported

Patient age	Count	Percent
0 - 27 days	10	0.2%
28 days - 23 months	111	2.7%
2 - 11 years	91	2.2%
12 - 17 years	139	3.4%
18 - 44 years	1,307	31.7%
45 - 64 years	1,176	28.5%
65 - 74 years	423	10.3%
≥ 75 years	298	7.2%
Unknown	565	13.7%

GLOBAL ALERTS OF SUBSTANDARD / FALSIFIED VACCINES AND MEDICINES

There have been no medical product alerts issued by the WHO in the past month. Given that medical products for the diagnosis, treatment and prevention of COVID-19 are in demand globally, this along with supply chain vulnerabilities and limited capacities in some countries creates opportunities for illicit goods (e.g. falsified test kits, vaccines and medicines), and diversion of legitimate products. We remind regulators in our Member States to remain vigilant and to work closely with national security agencies to assist to prevent, detect and respond to threats of falsified COVID-19 medical products.

For ease of reference and to assist with the identification of substandard / falsified medical products, we include the following reminders:

 Ensure that the supplier or donor is duly authorized by the emergency authorization holder of the vaccine or medicine to distribute the product in your country.

 Request quality documentation, such as: authorization letters, product dossiers, and lot release certificates for the proposed batches. The CRS team will assist focal points of CARPHA Member States in verification, including review of eligible products and pre-submission meetings.

Identifying a Substandard or Falsified Medical Product (WHO SF products)

Some falsified medical products are almost visually identical to the genuine product and very difficult to detect. However, many can be identified by:

- Examining the packaging for condition, spelling mistakes or grammatical errors;
- Checking the manufacture and expiry dates and ensuring any details on the outer packaging match the dates shown on the inner packaging; and
- Ensuring the medicine looks correct, is not discoloured, degraded, or has an unusual smell.

Patients or consumers should be advised to:

- Discuss anomalies with a doctor or pharmacist as soon as possible if he or she suspects the product is not working properly or he or she has suffered an adverse reaction;
- Refrain from buying, receiving or using medicines or vaccines from unauthorized or unregulated sources; and
- Report suspicious medical products to the National Medicines Regulatory Authority.

COVID-19 VACCINES AND THERAPEUTICS: REGULATORY UPDATES

Overview of COVID-19 Vaccine Development and Approvals

- 170 candidate vaccines are in clinical development: 44 in Phase 3 trials, and 11 in Phase 4 trials; Figure in COVID-19 Vaccines and Therapeutics Regulatory Tracker (Phases tab).
- 40 vaccines are approved in various countries, and 39 are at various stages of engagement with WHO for emergency use listing (EUL).
- CARPHA-CRS has recommended 11 COVID-19 vaccines approved for emergency use listing by the WHO to Member States to date (12 have been reviewed by the team due to different WHO

approval dates for two AstraZeneca vaccines) – Table 7 (See List of CRS Recommended products). The most recently recommended vaccine is by CanSino Biological Inc.: COVID-19 Vaccine, (Ad5.CoV2-S [Recombinant]) - CONVIDECIA.

- On 15th August, the Medicines and Healthcare products Regulatory Agency (MHRA) of the U.K. issued a Conditional Marketing Authorisation for Spikevax bivalent Original/Omicron booster vaccine. This decision is based on data from a clinical trial which showed that a booster with the bivalent Moderna vaccine triggers a strong immune response against both Omicron (BA.1) and the original 2020 strain. Safety monitoring showed that the side effects observed were the same as those seen for the original Moderna booster dose and were typically mild and self-resolving, and no serious safety concerns were identified.
- COVID-19 primary series and first booster vaccines' performance against Omicron variant of concern (VOC) is provided from WHO's Weekly Epidemiology Update (20th July, 2022): Figure 5 and Table 3. *No table or updated information was published in the supplement dated 10th August.*

Additional Resources

- WHO Open Short Course: Ultra-low temperature vaccine management
- UMC New Course 2022 available to national and regional PV centre staff: Regulatory aspects of pharmacovigilance
- Uppsala Reports Current Issue: Uppsala Reports - Latest issues
- EMA HUMAN MEDICINES HIGHLIGHTS Issue 161 August 2022
- PRAC Strategy on Measuring the Impact of Pharmacovigilance Activities
- WHO Emergency Use Listing for In vitro diagnostics (IVDs) Detecting SARS-CoV-2. 15 August 2022 Update.
- News: Improving regulatory systems for medical products and technologies
- Article: Minimizing COVID-19 disruption: Ensuring the supply of essential health products for health emergencies and routine health services

COVID-19 RESOURCES FOR REGULATION, CAPACITY-BUILDING AND VIGILANCE

Resource	Description and Link
CARPHA COVID-19 Webpage	This page provides media releases on regional responses to COVID-19, CARPHA Situation Reports, and Technical Guidance: https://www.carpha.org/What-We-Do/Public-Health/Novel-Coronavirus.
CARPHA CRS VigiCarib Online Reporting Forms	Adverse Events Following Immunization: VigiCaribVaccine Reporting Form Adverse Drug Reactions, and Substandard / Falsified / Unregistered Medical Products: VigiCarib Reporting Form
PAHO COVID-19 Webpage	URL: https://www.paho.org/en/topics/coronavirus-infections/coronavirus-disease-covid- 19-pandemic

Resource	Description and Link
PAHO Technical Documents	URL: https://www.paho.org/en/technical-documents-coronavirus-disease-covid-19.
PAHO Ongoing Living Update of Potential COVID-19 Therapeutics	A summary of evidence on potential therapeutic options for COVID-19, examines 220 therapeutic options. 28th July, 2022 (38th edition) URL: https://iris.paho.org/handle/10665.2/52719?locale-attribute=pt
PAHO Periodic Updates on AEFIs	Consolidated regional and global information on adverse events following immunization (AEFI) against COVID-19 and other updates. 7th July, 2022 (37th Edition): URL: https://covid-19pharmacovigilance.paho.org/img/recursos/62f695e3330b6899d2b674105.pdf
WHO Strategic Advisory Group of Experts on Immunization (SAGE)	COVID-19 Vaccine Technical Documents URL: https://www.who.int/groups/strategic-advisory-group-of-experts-on-immunization/covid-19-materials
WHO Technical Documents for Vaccines and Biologicals	Relevant WHO documents for SARS-CoV-2 vaccines and other biologicals URL: https://www.who.int/biologicals/Relevant_WHO_documents_for_SARS-CoV-2_vaccines_and_other_biologicals.TZ.IK.7_Apr_2020.pdf
WHO COVID-19 Vaccines Safety Surveillance Manual	The COVID-19 vaccine safety guidance manual of Global Advisory Committee on Vaccine Safety (GACVS). URL: https://www.who.int/publications/i/item/10665338400
WHO Regulatory Updates on COVID-19	URL: https://www.who.int/teams/regulation-prequalification/eul/covid-19
WHO Guidelines for MedicineDonations	URL: https://www.who.int/selection_medicines/emergencies/guidelines_medicine_donations/en/
WHO Lot Release of Vaccines by NRAs	URL: https://www.who.int/biologicals/areas/vaccines/lot_release/en/
WHO Model packaging for COVID-19 vaccines	URL: https://www.who.int/teams/regulation-prequalification/eul/covid-19/covid-19-model-packaging

Table 7: COVID-19 Vaccines with Regulatory Approvals by WHO EUL Consideration

Vaccine/ WHO EUL Holder	Vaccine Platform	Dosing/ Storage ¥/ Approvals	NRA of record	WHO Approved Drug Product site(s)	Recommendation issued
WHO EUL status – Approved					
Recommended by CRS					
Tozinameran; COMIRNATY®; Pfizer-BioNTech COVID-19 Vaccine COVD-19 mRNA Vaccine (nucleoside modified)/ BioNTech Manufacturing GmbH §: Ready-to-Use formulation	mRNA (nucleoside modified)	2 doses I.M. -90°C to -60°C (12 mo.); 2°C to 8°C (31 days / 10 wks§) CARPHA + 147 countries Full Market authorization by US FDA (16yrs+) WHO EUL For: Adults and adolescents ≥12 years old; Children 5-11 years old	European Medicines Agency	**Baxter Oncology GmbH**, Germany **BioNTech Manufacturing GmbH,** Germany **Pfizer Manufacturing Belgium NV,** Belgium **Novartis Pharma Stein AG,** Switzerland **Mibe GmbH Arzneimittel,** Germany **Delpharm Saint-Remy,** France **Sanofi-Aventis Deutschland GmbH,** Germany **Siegfried Hameln GmbH,** Germany. **Patheon Italia S.p.A**, Italy.	31st December 2020
			United States Food and Drug Administration	**Pharmacia & Upjohn Company LLC,** USA **Hospira Inc., a Pfizer company,** USA **Exelead, Inc.**, IN, United States **Exela Pharma Sciences, LLC, NC**, United States.	16th July, 2021
VAXZEVRIA® **COVID-19 Vaccine (ChAdOx1-S [recombinant])/ AstraZeneca AB + SK Bioscience Co. Ltd and AstraZeneca AB**	Recombinant ChAdOx1-S adenoviral vector	2 doses I.M. 2°C to 8°C (6 mo.) CARPHA + 148 countries WHO EUL For: Adults ≥18 years old	Ministry of Food and Drug Safety, Korea	**SK Bioscience**, Republic of Korea **Universal Farma, S.L.** ("Chemo"), Spain **Catalent Anagni S.R.L.**, Italy. **IDT Biologika GmbH**, Germany. **Seqirus Pty Ltd**., Australia. **CP Pharmaceuticals Limited**, UK. **Amylin Ohio LLC (AZ),** USA **Seqirus Pty Ltd**., Australia.	15th February 2021
			European Medicines Agency	**SK Bioscience**, Republic of Korea **Universal Farma, S.L.** ("Chemo"), Spain **Catalent Anagni S.R.L.**, Italy. **IDT Biologika GmbH**, Germany. **Amylin Ohio LLC (AZ),** USA **CP Pharmaceuticals Limited**, UK.	16th April 2021
			Ministry of Health, Labour and Welfare, Japan	**Catalent Anagni S.R.L.**, Italy. **Daiichi Sankyo Biotech Co., LTD**., Japan. **KM Biologics Co. Ltd**., Japan. **Nipro Pharma Corporation Ise**, Japan	9th July 2021
			Therapeutic Goods Administration, Australia	**Catalent Anagni S.R.L.**, Italy. **IDT Biologika GmbH**, Germany. **Seqirus Pty Ltd**., Australia.	9th July 2021

				CP Pharmaceuticals Limited, UK. **Amylin Ohio LLC (AZ),** USA **Siam Bioscience Co., Ltd**, Thailand	
			Health Canada	**Catalent Anagni S.R.L**., Italy. **IDT Biologika GmbH**, Germany. **Seqirus Pty Ltd**., Australia. **CP Pharmaceuticals Limited**, UK. **Amylin Ohio LLC (AZ),** USA	27th August 2021
			COFEPRIS (DP), Mexico ANMAT (DS), Argentina	**Liomont, S.A.,** Mexico	23rd December 2021
COVISHIELD™ COVID-19 Vaccine (ChAdOx1-S [recombinant])/ Serum Institute of India Pvt. Ltd	Recombinant ChAdOx1-S adenoviral vector	2 doses I.M. 2°C to 8°C (6 mo.) CARPHA + 49 countries WHO EUL for: Adults ≥18 years old	Central Drugs Standard Control Organization, India	**Serum Institute of India Pvt. Ltd.,** S. No. 105–110, India **Serum Institute of India Pvt. Ltd.,** 212/2, India	15th February 2021
COVID-19 Vaccine (Ad26.COV2-S [recombinant])/ Janssen–Cilag International NV	Viral vector (non-replicating)	1 dose I.M. -25°C to -15°C (24 mo.) 2-8°C (11 mo. within shelf-life) CARPHA + 111 countries Full market approval by Health Canada (23.Nov) WHO EUL For: Adults ≥18 years old	European Medicines Agency	**Janssen Biologics B.V**, The Netherlands **Janssen Pharmaceutica NV**, Belgium **Aspen SVP**., South Africa **Catalent Indiana LLC**., USA. **Grand River Aseptic Manufacturing Inc**., USA. **Catalent Anagni S.R.L**., Italy. **Merck Sharp & Dohme (MSD) Corp**., USA **Sanofi Pasteur,** France **Biological E Ltd,** India	12th March 2021;
Elasomeran; SPIKEVAX™ COVID-19 mRNA Vaccine (nucleoside modified)/ Moderna Biotech and ModernaTX, Inc	mRNA-based in lipid nanoparticle (LNP)	2 doses I.M. -25°C to -15°C (9 mo.); 2-8°C (30d) or 9-25°C (12h) CARPHA + 87 countries WHO EUL For: Adults and adolescents ≥12 years old; Children 6-11 years old	European Medicines Agency	**Rovi Pharma Industrial Services, S.A.,** Spain	30th April 2021
			United States Food and Drug Administration	**Baxter Pharmaceutical Solutions**, USA. **Catalent Indiana, LLC**, USA	6th August, 2021
			Ministry of Food and Drug Safety (MFDS), Rep. of Korea	**Samsung Biologics**, Republic of Korea	23rd December 2021
Inactivated COVID-19 Vaccine (Vero Cell)/ Beijing Institute of Biological Products Co., Ltd. (BIBP)	Inactivated virus	2 doses I.M. 2°C to 8°C (24 mo.) CARPHA + 92 countries	National Medical Products Administration, China	**Beijing Institute of Biological Products Co., Ltd**., People's Republic of China.	7th May 2021

		WHO EUL For: Adults ≥18 years old			
CoronaVac™ COVID-19 Vaccine (Vero Cell), Inactivated/ Sinovac Life Sciences Co., Ltd	Inactivated virus	2 doses I.M. 2°C to 8°C (12 mo.) CARPHA + 56 countries WHO EUL For: Adults ≥18 years old	National Medical Products Administration, China	**Sinovac Life Sciences Co., Ltd**., People's Republic of China.	1st June 2021
COVAXIN® Covid-19 vaccine (Whole Virion Inactivated Corona Virus vaccine)/ Bharat Biotech International Ltd	Whole virion inactivated	2 Doses I.M. 2°C to 8°C (9 mo.) CARPHA + 14 countries WHO EUL For: Adults ≥18 years old	Central Drugs Standard Control Organization, India	**Bharat Biotech International Limited**, India	3rd November 2021 **Supplies suspended**
COVOVAX™ COVID-19 vaccine (SARS-CoV-2 rS Protein Nanoparticle [Recombinant])/ Serum Institute of India Pvt. Ltd	Protein subunit	2 doses I.M. 2°C to 8°C CARPHA + 5 countries WHO EUL For: Adults ≥18 years old	Central Drugs Standard Control Organization, India	**Serum Institute of India Pvt. Ltd.,** S. No. 105–110, India **Serum Institute of India Pvt. Ltd.,** 212/2, India	17th December 2021
NUVAXOVID™ COVID-19 vaccine (SARS-CoV-2 rS [Recombinant, adjuvanted])/ Novavax CZ a.s.	Protein subunit	2 doses I.M. 2°C to 8°C CARPHA + 39 countries WHO EUL For: Adults ≥18 years old	European Medicines Agency	**Serum Institute of India Pvt. Ltd.,** S. No. 105–110, India	20th December 2021
CONVIDECIA™ COVID-19 Vaccine, (Ad5.CoV2-S [Recombinant])/ CanSino Biological Inc.	Adenovirus; Viral vector (non-replicat)	1 dose I.M. 2°C to 8°C CARPHA + 10 countries WHO EUL for: Adults 18 to 59 years old	National Medical Products Administration, China	**CanSino Biologics Inc.,** People's Republic of China.	19th May 2022
WHO EUL status – Pending/Not under review yet *(Not eligible for CRS review)*					
Gamaleya Research Institute & Russian Health Ministry (Sputnik V)	Adenovirus Viral vector (non-replicat)	2 doses I.M. 2°C to 8°C 74 countries	Russian NRA	Not applicable	Anticipated date pending

Sinopharm + China National Pharma. Group + Wuhan Institute of Biol. Products	Inactivated virus	2 doses I.M. 2°C to 8°C 2 countries	National Medical Products Administration	Not applicable	Decision date- To be confirmed
Vector State Research Ctre of Virology and Biotech. (EpiVacCorona)	Peptide vaccine	2 doses I.M. 2°C to 8°C 2 countries	Russian NRA	Not applicable	Pending expression of interest
Anhui Zhifei Longcom Biopharmaceutical, China + IMBCAMS (ZF2001)	Recombinant (protein subunit)	2 or 3 Doses I.M. 2°C to 8°C 4 countries	National Medical Products Administration	Not applicable	Status of assessment- Ongoing
Sanofi Pasteur CoV2 preS dTM-AS03 vaccine	Recombinant, adjuvanted	2 Doses I.M. 2°C to 8°C	European Medicines Agency	Not applicable	Decision date- To be confirmed
Clover Biopharmaceuticals Inc. + GSK + Dynavax (SCB-2019)	Protein subunit	2 doses I.M. 2°C to 8°C	National Medical Products Administration	Not applicable	Status of assessment- Ongoing
BioCubaFarma – Cuba (Soberana 01, Soberana 02 Soberana Plus, Abdala)	SARS-CoV-2 spike protein	2 doses I.M. 2°C to 8°C	Center for State Control of Medicines, Equipment and Medical Devices	Not applicable	In discussion on submission
Shifa Pharmed Industrial Co. (CovIran-Barkat)	Inactivated virus	2 doses I.M. 2°C to 8°C	Iran Food Drug Administration (IFDA)	Not applicable	Rolling data starting in June
Center for Genetic Engineering and Biotechnology CIBG-66 (Abdala)	Protein subunit	3 doses I.M. 2°C to 8°C 6 countries	Center for State Control of Medicines, Equipment and Medical Devices	Not applicable	Rolling data starting in June
Biological E Limited BECOV2A. (Corbevax)	Protein subunit	2 doses I.M. 2°C to 8°C 1 country	Central Drugs Standard Control Organization, India	Not applicable	EOI under review
SK Bioscience Co., Ltd. and CEPI (GBP510)	Recombinant protein subunit	2 doses I.M. 2°C to 8°C	Ministry of Food and Drug Safety (MFDS), Rep. of Korea	Not applicable	EOI under review
WestVac Biopharma Recombinant COVID-19 vaccine	Recombinant SARS-CoV-2 S-RBD protein	2 doses I.M.	National Medical Products Administration	Not applicable	EOI under review
Nanogen Pharmaceutical Biotechnology (Nanocovax)	Recombinant Spike protein	2 doses I.M.	Drug Administration of Vietnam	Not applicable	EOI under review
Vaxine Pty Ltd./CinnaGen Co. (SpikoGen)	Recombinant Protein	2 doses I.M.	Iran Food Drug Administration (IFDA)	Not applicable	EOI under review
R-PHARM (Vaccine R-COVI)	Recombinant ChAdOx1 adeno. vector	Not stated	Russian NRA	Not applicable	EOI under review

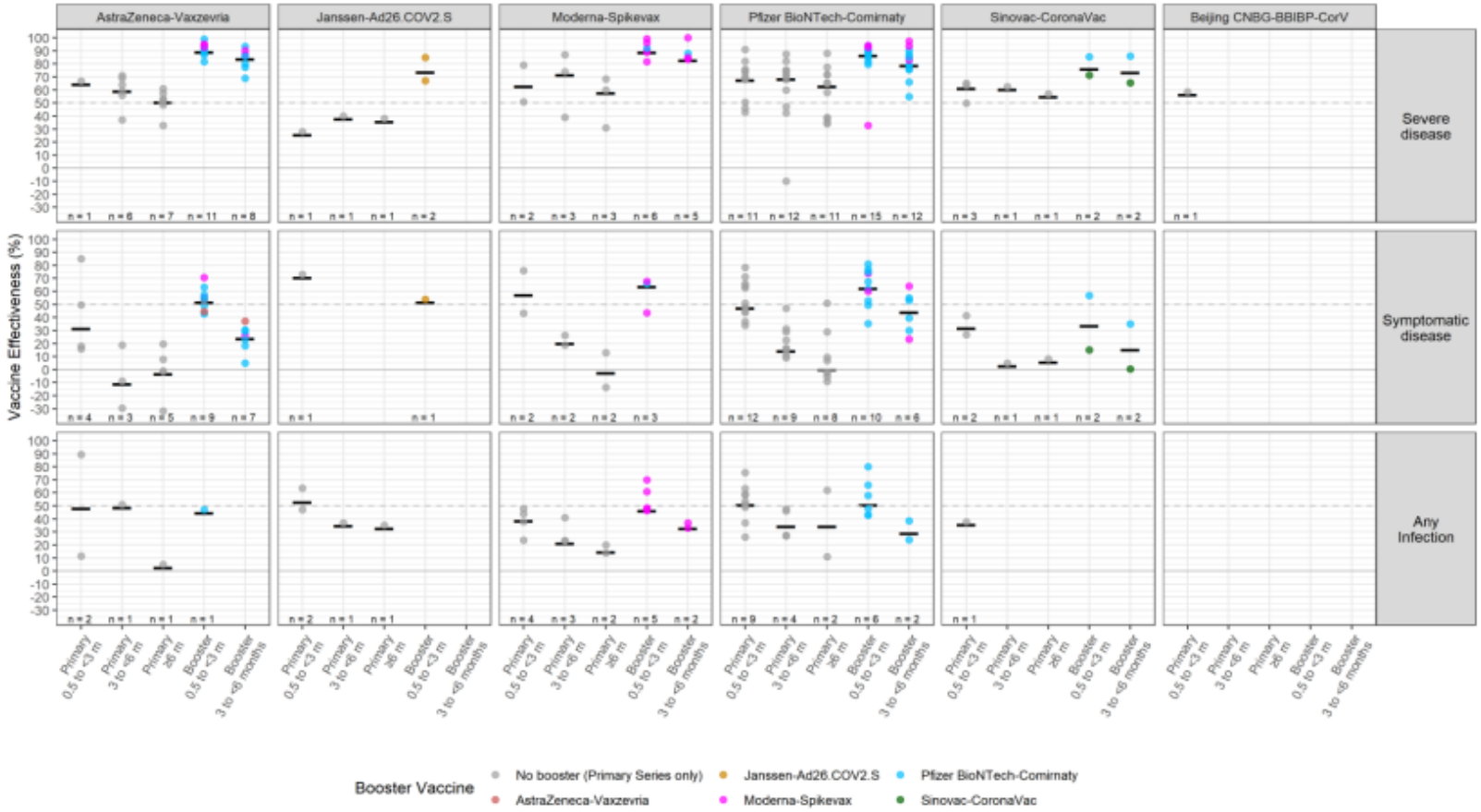
SK Bioscience Co., Ltd. (Nuvaxovid)	Recombinant nanoparticle spike protein	2 doses I.M.	Ministry of Food and Drug Safety (MFDS), Rep. of Korea	Not applicable	Rolling data starting in June
Medicago Inc (COVIFENZ)	Virus-like particles (VLP) of SARS-CoV-2 spike protein	2 doses I.M. 1 country	Health Canada	Not applicable	Application withdrawn by applicant
Arcturus Therapeutics (ARCT-154)	RNA Vaccine	2 doses I.M.	Drug Administration of Vietnam	Not applicable	EOI under review
Bio-Manguinhos/ Fiocruz (AZD1222)	Recombinant ChAdOx1 adeno. vector	Not stated	National Health Surveillance Agency (ANVISA)	Not applicable	EOI under review
Vaxxinity (UB-612)	Protein-peptide vaccine	2 doses I.M.	United States Food and Drug Administration	Not applicable	EOI under review
Sinocelltech, Ltd (SCTV01C)*	Recombinant Protein	1 dose I.M.	National Medical Products Administration	Not applicable	EOI received
Razi Vaccine & Serum Research Institute (Raz Par Cov)*	Recombinant Protein	3 doses I.M. and I.N.	Iran Food Drug Administration (IFDA)	Not applicable	EOI received
Valneva (VLA2001)*	Inactivated Virus	2 doses I.M.	European Medicines Agency	Not applicable	EOI received
Medigen (MVC-COV1901)*	CHO cell derived spike protein	2 doses I.M.	Therapeutic Goods Administration, Australia	Not applicable	EOI received
HIPRA (BIMERVAX)*	Recombinant Protein	2 doses I.M.	European Medicines Agency	Not applicable	EOI received

¥ - Storage information is provided primarily for sealed vials. See product information for additional details on storage and handling.
** - COVID-19 Vaccine recently included in WHO EUL/PQ evaluation process.*

References:

McGill COVID19 Vaccine Tracker. COVID-19 Vaccines. Updated 12th August, 2022. Available at: https://covid19.trackvaccines.org/.
World Health Organization. **Status of COVID-19 Vaccines within WHO EUL/PQ evaluation process**. Updated 7th July, 2022. WHO, Geneva, 2020. Available at: https://www.who.int/teams/regulation-prequalification/eul/covid-19.
World Health Organization. **COVID-19 vaccines WHO EUL issued**. Available at: https://extranet.who.int/pqweb/vaccines/vaccinescovid-19-vaccine-eul-issued
World Health Organization. **Emergency Use Listing Procedure for Vaccines**. WHO, Geneva 2021. Available at: https://www.who.int/teams/regulation-prequalification/eul/eul-vaccines.

Figure 3: WHO Summary of Vaccine effectiveness (VE) of primary series and first booster vaccination against the Omicron variant of concern



Dots represent point estimates of VE from each study; dark black horizontal lines represent median VE across all studies in stratum. All data is from a systematic review of COVID-19 VE studies; methods and summary tables of VE studies can be found on view-hub.org. Vertical panels represent VE for full primary series (grey dots) and VE for homologous or heterologous booster vaccination (other colored dots) following completion of primary series vaccination with vaccine of primary series noted in panel header. All booster VE estimates are for the first booster dose. Severe disease includes hospitalization and pneumonia; symptomatic disease includes disease of any severity level; any infection can include symptomatic and asymptomatic infection. Additional details on the methods for inclusion of the estimates in the plots provided in text. Figure 5 summarizes the impact of the Omicron variant on vaccine effectiveness (VE) over time, grouped by the primary series vaccine; booster doses may have been a different vaccine (i.e., both homologous and heterologous booster vaccination VEs are shown). Additional information on vaccine performance against VOCs can also be found in Annex 3.

Additional information on Methods for Figure 5 and Interpretation of Results are provided at: https://www.who.int/publications/m/item/weekly-epidemiological-update-on-covid-19---20-july-2022

Table 8: WHO Summary of vaccine performance against variants of concern (VOC) relative to ancestral stains

		Omicron Sub-Lineage				
		BA.1	BA.2	BA.2.12.1	BA.3	BA.4/BA.5
Primary Series Vaccination						
WHO Emergency Use Listing (EUL) Qualified Vaccines	AstraZeneca-Vaxzevria/SII-Covishield	HNR_{10}	HNR_{1}			
	Beijing CNBG-BBIBP-CorV	HNR_{7}	HNR_{2}	HNR_{1}	HNR_{1}	HNR_{1}
	Bharat-Covaxin	$\downarrow\downarrow_{1}$				
	Cansino-Covidecia					
	Janssen-Ad26-COV2.S	HNR_{6}				
	Moderna-Spikevax	$\downarrow\downarrow\downarrow_{10}$	HNR_{2}			
	Novavax-Nuvaxovid/SII - Covavax					
	Pfizer BioNTech-Comirnaty	HNR_{47}	$\downarrow\downarrow\downarrow_{2}$		HNR_{1}	HNR_{1}
	Sinovac-CoronaVac	$\downarrow\downarrow\downarrow_{1}$				
Other Vaccines (non-EUL)	Anhui ZL-Recombinant					
	Gamaleya-Sputnik V	HNR_{2}				
Booster Vaccination (Primary Series Vaccine + Booster Vaccine)						
WHO Emergency Use Listing (EUL) Qualified Booster Vaccines	AstraZeneca-Vaxzevria/SII-Covishield + AstraZeneca-Vaxzevria/SII Covishield	HNR_{2}	HNR_{2}		$\downarrow\downarrow_{1}$	$\downarrow\downarrow\downarrow$1
	AstraZeneca-Vaxzevria/SII-Covishield + Moderna-Spikevax	$\downarrow_{1}$				
	AstraZeneca-Vaxzevria/SII-Covishield + Pfizer BioNTech-Comirnaty	$\downarrow\downarrow_{1}$	$\downarrow\downarrow_{1}$		$\downarrow\downarrow_{1}$	
	Beijing CNBG-BBIBP-CorV + Beijing CNBG-BBIBP-CorV	$\downarrow\downarrow$to$\downarrow\downarrow\downarrow_{4}$	HNR_{2}	HNR_{1}	$\downarrow\downarrow_{1}$	HNR_{1}
	Janssen-Ad26-COV2.S + Janssen-Ad26-COV2.S	HNR_{1}				
	Janssen-Ad26-COV2.S + Pfizer BioNTech-Comirnaty	$\downarrow_{1}$				
	Moderna-Spikevax + Moderna-Spikevax	$\downarrow$to$\downarrow\downarrow\downarrow_{9}$	$\downarrow\downarrow_{1}$	$\downarrow\downarrow_{1}$	$\downarrow\downarrow_{1}$	$\downarrow\downarrow\downarrow_{1}$
	Moderna-Spikevax + Pfizer BioNTech-Comirnaty	$\downarrow\downarrow\downarrow_{1}$				
	Pfizer BioNTech-Comirnaty + Pfizer BioNTech-Comirnaty	$\downarrow$to$\downarrow\downarrow\downarrow_{40}$	$\downarrow$to$\downarrow\downarrow_{13}$	$\downarrow$to$\downarrow\downarrow\downarrow_{3}$	$\downarrow$to$\downarrow\downarrow_{4}$	$\downarrow\downarrow$to$\downarrow\downarrow\downarrow_{5}$
	Pfizer BioNTech-Comirnaty + Janssen-Ad26-COV2.S	$\downarrow_{2}$				
	Pfizer BioNTech-Comirnaty + Moderna-Spikevax	$\downarrow$to$\downarrow\downarrow_{2}$				
	Sinovac-CoronaVac + Sinovac-CoronaVac	HNR_{6}	$\downarrow\downarrow_{2}$	$\downarrow\downarrow_{1}$	$\downarrow\downarrow_{1}$	$\downarrow\downarrow_{1}$
	Sinovac-CoronaVac + Pfizer BioNTech-Comirnaty	$\downarrow\downarrow_{2}$	$\downarrow\downarrow_{1}$			
Other Vaccines (non-EUL)	Anhui ZL-Recombinant + Anhui ZL-Recombinant	$\downarrow$to$\downarrow\downarrow_{2}$	$\downarrow\downarrow_{1}$	$\downarrow\downarrow_{1}$	$\downarrow\downarrow\downarrow_{1}$	$\downarrow\downarrow\downarrow_{1}$
	Beijing CNBG-BBIBP-CorV + Anhui ZL - Recombinant	$\downarrow\downarrow$to$\downarrow\downarrow\downarrow$4	HNR_{2}	HNR_{1}	$\downarrow\downarrow\downarrow_{1}$	HNR_{1}
	Gamaleya-Sputnik V + Gamaleya Sputnik Light	$\downarrow\downarrow_{1}$				
	Sinovac-CoronaVac + Anhui ZL - Recombinant	$\downarrow$to$\downarrow\downarrow_{2}$	$\downarrow$to$\downarrow\downarrow_{2}$	$\downarrow$ to $\downarrow\downarrow\downarrow_{2}$	$\downarrow$to$\downarrow\downarrow\downarrow_{2}$	$\downarrow\downarrow_{1}$

Data as of 11 July 2022

Abbreviations: HNR=high non-response. Arrows generalize the magnitude of reduction in neutralization against the Omicron sub-lineage relative to the ancestral strain: "↔" indicates 2 to <5-fold reduction; "↓↓" indicates 5 to <10-fold reduction; "↓↓↓" indicates ≥10-fold reduction. When more than one neutralization study is available, the interquartile range (25th and 75th percentiles) of fold reductions across all studies was used, restricting to studies reporting ≥75% of persons/sera with detectable neutralization titers. HNR indicates a median percent of persons/sera with detectable neutralization titers across all studies of <75%; in these instances, fold-reductions can be biased and, thus are not presented. The number of studies is shown as subscripts. For booster vaccination, only schedules with available results are shown.

Additional notes

• Studies contributing to the table are identified from an ongoing review of the preprint and published literature on neutralization of SARS-CoV-2 variants by COVID-19 vaccines.

• Studies that use samples collected more than seven days and less than six months after complete vaccination and that use an ancestral strain as the reference are included in the table.

• Studies of immunocompromised persons are excluded.

• It is important to note that studies vary in population and other methodological considerations, which may in part explain some differences when comparing products between different studies. In addition, the reductions summarized in the table do not incorporate uncertainty intervals around the degree of reductions, which can vary substantially across studies when reported.

Extracted from WHO Weekly Epidemiological Update: Edition 101, published 20th July, 2022. *No table or updated information was published in the supplement dated 10th August.* Available at: https://www.who.int/publications/m. See updated issue for references and additional information.

INFORMATION

This newsletter is produced by the technical team of the CARPHA Caribbean Regulatory System **for the focal points of CARPHA Member States, drug safety officers, immunization programme managers, public health administrators, public sector procurement agencies, and CARPHA staff** with an interest in the safety and quality of medicines and vaccines. A public version may be posted occasionally, however not all content shared with focal points will be publicized.

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