VIGICARIB NEWS

21ST JUNE, 2022

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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

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 May and 15th June, 2022, the Caribbean Regulatory System received six safety case reports of suspected adverse drug reactions (ADR) from St Vincent and the Grenadines. No reports of Adverse Events Following Immunization (AEFI) and Substandard / Falsified / Unregistered Medical Products (SF) were received.

In all, 509 case reports have been shared with the CRS and the VigiCarib network since its inception in November 2017: suspected ADRs (326 – 64%), SFs (102– 20%), and AEFIs (81 – 15.9%) – Table A1 (See Appendix I). During the reporting period, one report was submitted as an AEFI but did not satisfy the case definition – Table A4 (See Appendix I).

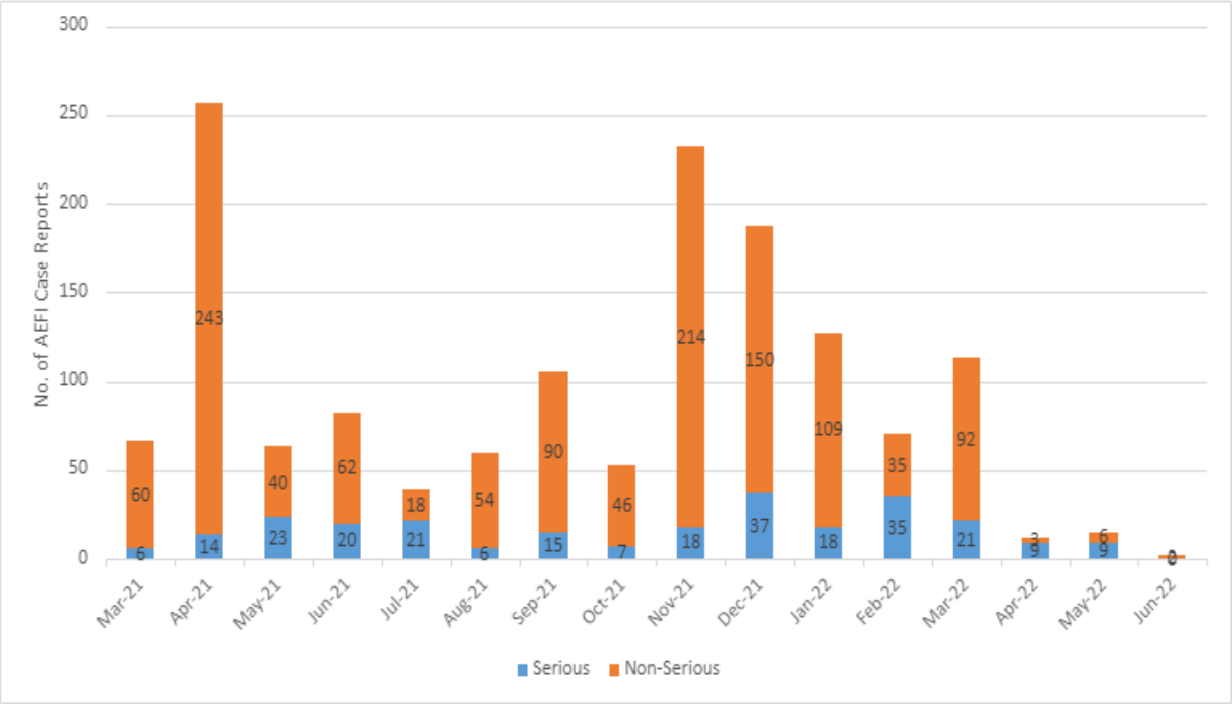
CARICOM COVID-19 VACCINE SAFETY REPORTS IN GLOBAL DATABASE

As of 15th June, 2022, there have been 1,483 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, and involving persons under 65 years (85.2%), and females (74.4%). The month with

greatest reporting activity is December 2021: Figure 1. Two hundred and fifty-nine (259) reports (17.5%) were classified as Serious, including 59 where deaths were reported outcomes – Figure 2, Table 3.

Eleven (11) AEFI case reports were submitted between 16th May and 15th June, 2022, with the most commonly reported reactions 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, reduced risk perception, and less adverse events. 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 June 2022



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 inact (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 68.3 AEFI reports per 100,000 doses of COVID-19 vaccines administered, with 11.9 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 adverse events and reporting rate, by country as of 15th June, 2022

Country	Total Doses	Total Adv. Events*	Total AEFIs per 100,000 doses	Total Serious AEFIs	Total Serious AEFIs per 100,000 doses
Barbados	363,560	591	162.6	82	22.6
Haiti	289,890	1	0.3	0	0
Jamaica	1,446,546	868	60.0	171	11.8
St Vincent and the Grenadines	71,280	22	30.9	6	8.4
Total	2,171,276	1,482	68.3¥	259	11.9¥

*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. SAE – serious adverse event.

Table 2: Patient Age Groups Reported for AEFIs in VigiBase (N = 1,483) – up to 15th June, 2022

Patient age	Count	Percent
12 - 17 years	93	6.3%
18 - 44 years	682	46.0%
45 - 64 years	485	32.7%
65 - 74 years	104	7.0%
≥ 75 years	74	5.0%
Unknown	41	3.0%

Table 3: Top Reported Reactions for AEFIs in VigiBase (N = 1,483) – up to 15th June, 2022

Top Reported Reactions	Count	Percent
PT: Headache	445	30.0%
PT: Pyrexia	294	19.8%
PT: Dizziness	291	19.6%
PT: Fatigue	246	16.6%
PT: Chills	243	16.4%
PT: Myalgia	216	14.6%
PT: Arthralgia	207	14.0%
PT: Nausea	168	11.3%
PT: Vaccination site pain	158	10.7%
PT: Malaise	148	10.0%

Figure 2: Total AEFI Case Reports by Seriousness (N =1,483)

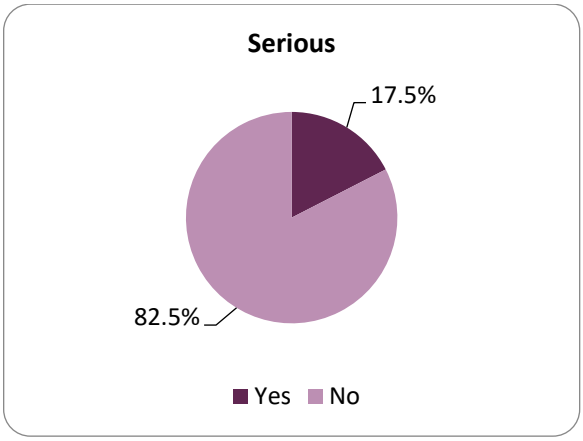


Table 4: Seriousness of Cases (n=259)

Seriousness criteria	Count	Percent
Death	59	4.0%
Life threatening	19	1.3%
Caused/prolonged hospitalization	92	6.2%
Disabling/incapacitating	48	3.2%
Other medically important condition	91	6.1%

Note: Total exceeds 259 due to selection of multiple seriousness criteria in individual case reports

SUMMARY OF CASE SAFETY REPORTS FROM CARICOM TO WHO PIDM

A review of the Uppsala Monitoring Centre's VigiBase identified 4,077 case reports from CARICOM countries with membership in the WHO Programme for International Drug Monitoring (PIDM) – 1,483 COVID-19 AEFI case reports, 203 non-COVID AEFI case reports, and 2,391 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 June, 2022, inclusive of reports submitted by the CRS on behalf of Member States. Most of the case reports involved adults – Table 6.

Between 16th May and 15th June, 2022, 32 additional case reports were submitted to VigiBase from CARICOM: 11 AEFI reports, 21 ADR reports.

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

Countries	Count	Percent
Barbados	1,368	33.6%
Dominica	14	0.3%
Guyana	12	0.3%
Haiti	19	0.5%
Jamaica	1,940	47.6%
Saint Vincent and the Grenadines	496	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 to 23 months	111	2.7%
2 - 11 years	91	2.2%
12 - 17 years	137	3.4%
18 - 44 years	1,296	31.8%
45 - 64 years	1,171	28.7%
65 - 74 years	421	10.3%
≥ 75 years	295	7.2%
Unknown	545	13.4%

GLOBAL ALERTS OF SUBSTANDARD / FALSIFIED VACCINES AND MEDICINES

Regional Medical Product Alerts

On 13th June, 2022, the Federal Commission for the Protection against Sanitary Risk (COFEPRIS) issued two (2) alerts of Substandard / Falsified / Unregistered Medical Products (SF) to the PAHO network for Omnitrope (Somatropin) and Caltrate 600+D, which were detected in Mexico. The authority confirmed that both products were falsified.

Table 7: Medical Product Alert 2022

Date	Product	Manufacturer	Alert summary
10th June 2022	Caltrate 600+D, batch number R64248 and expiration dates DEC 24, DEC 2024 and JUL 23.	Wyeth Pharmaceuticals Company	• The manufacturer acknowledged the batch number R64248 was manufactured in May 2016 and original expiration date was July 2018. • Differences exist in the format of expiration dates on the bottle and on the box.
10th June 2022	Omnitrope solution 10 mg/1.5 mL (30IU), Lot number GV8327 and expiration date 11 2022	Sandoz SA de CV	• The batches LM4521 and KG5787 of the product Omnitrope with presentation of 5 mg/1.5 mL, were detected in other countries as falsified. • Analysis revealed the absence of active ingredient somatropin and it had a thick consistency, which confirms the falsification of the product. • Batch GV8327 does not correspond to the manufacture of the Omnitrope product or to any drug marketed by Sandoz SA de CV. This batch corresponds to another drug marketed by Sandoz in Spain. • Counterfeit product was also detected in Germany, Spain and Hungary.

WHO MEDICAL PRODUCT ALERTS

On 27th May, 2022, the WHO issued its third medical product alert for four lots of falsified immunoglobulin product discovered in various countries: Brazil (September 2021), India (February 2022), Bolivia (Plurinational State of) (April 2022), and Egypt (April 2022). “Genuine Intratect contains human normal

immunoglobulin which is used to treat patients who do not have sufficient antibodies (replacement therapy) or to treat patients with certain inflammatory disorders (immunomodulation). The genuine manufacturer of Intratect is Biotest GmbH, who has confirmed that all the products referenced in this alert are falsified, including those labeled “Immunoglobulina G Endovenosa Biotest”. Biotest GmbH does not manufacture any products with this name. The stated lot numbers are also confirmed as falsified.” (WHO, May 2022) – Table 8.

Table 8: Medical Product Alert 2022

Alert number and date	Product	Manufacturer	Alert summary
N° 3/2022 27th May 2022	Intratect (Human normal immunoglobulin)	Biotest GmbH	• Deliberately/fraudulently misrepresent product identity and source. • Incorrect product name “Immunoglobulina G Endovenosa Biotest” • Lot numbers confirmed as falsified.

WHO advises regulatory authorities and the public to increase vigilance within the supply chains of countries and regions likely to be affected by these falsified products. Increased vigilance should include hospitals, clinics, health centers, wholesalers, distributors, pharmacies, and any other suppliers of medical products.

All medical products must be obtained from authorized/licensed suppliers. The products’ authenticity and physical condition should be carefully checked. Seek advice from a healthcare professional in case of doubt.

The detection and response to substandard, falsified and/or unregistered medical products is a challenge to regulatory authorities and national systems with limited capacity. The presence of substandard and/or falsified and/or unregistered medicines, vaccines or test kits for COVID-19 poses a threat to the prevention of deaths and hospitalization and undermines the needed efficacy in the treatment of the disease. Poorly treated infections also create opportunities for antimicrobial resistance, and more severe disease and death.

The following is a brief list that technical officers in regulatory divisions may keep on hand for their own use or for patient education.

Reminders:

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:

- 166 candidate vaccines are in clinical development: 37 in Phase 3 trials, and 11 in Phase 4 trials; Figure in COVID-19 Vaccines and Therapeutics Regulatory Tracker (Phases tab).
- 38 vaccines are approved in various countries, and 34 are at various stages of engagement with WHO for emergency use listing (EUL) – 11 have been approved for EUL by 10 developers.
- CARPHA-CRS has recommended 10 of 11 COVID-19 vaccines under WHO EUL, and two COVID-19 medicines to Member States to date – Table 9. (See List of CRS Recommended products).
- On 17th June, 2022 the U.S. Food and Drug Administration authorized emergency use of the Moderna COVID-19 Vaccine and the Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 to include use in children down to 6 months of age. FDA concluded that:
  - The evaluation and analysis of the safety, effectiveness and manufacturing data of these vaccines was rigorous and comprehensive, supporting the EUAs.
  - The known and potential benefits of the Moderna and Pfizer-BioNTech COVID-19 vaccines outweigh the known and potential risks in the pediatric populations.
  - The FDA's independent Vaccines and Related Biological Products Advisory Committee was consulted and voted in support of the authorizations.
- COVID-19 vaccines' performance against variants of concern (VOC) is provided from WHO's Weekly Epidemiology Update (8th June, 2022): Table 10.

Additional Resources

- WHO Open Short Course: Ultra-low temperature vaccine management
- UMC New Course 2022: Collecting high quality ADR reports
- 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 159 June 2022
- PRAC Strategy on Measuring the Impact of Pharmacovigilance Activities
- WHO Emergency Use Listing for In vitro diagnostics (IVDs) Detecting SARS-CoV-2. 7 June 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
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 204 therapeutic options. 8th June, 2022 (37th 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. 30th April 2022 (35th Edition): URL: https://covid-19pharmacovigilance.paho.org/img/recursos/62a4b80a8553f43fd25fee90e.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

Resource	Description and Link
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

EVALUATION OF VIGICARIB NEWS

In early June, the CRS issued a questionnaire to allow focal points and other stakeholders for regional pharmacovigilance to evaluate the VigiCarib newsletter, in the areas of its utility, recipients and design. However, only five responses have been received to date. The questionnaire will be re-issued to allow for additional feedback, and will remain open until **Monday 11th July, 2022.** The questionnaire is available at: https://form.jotform.com/221375197527058.

Table 9: 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 + 146 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	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 + 141 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. CP Pharmaceuticals Limited, UK. Amylin Ohio LLC (AZ), USA Siam Bioscience Co., Ltd, Thailand	9th July 2021
			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	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 + 86 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 + 91 countries WHO EUL For: Adults ≥18 years old	National Medical Products Administration, China	Beijing Institute of Biological Products Co., Ltd., People's Republic of China.	7th May 2021
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 + 37 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 10 countries WHO EUL Adults 18 to 59 years old	National Medical Products Administration	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)	Recomb. (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	Recomb., 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)	Recomb. 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	Recomb. 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)	Recomb. ChAdOx1 adenoviral vector	Not stated	Russian NRA	Not applicable	EOI under review
SK Bioscience Co., Ltd. (Nuvaxovid)	Recomb. nanoparticle with Matrix-M™ adjuvant	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 adenoviral 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

¥ - 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 10th June, 2022. Available at: https://covid19.trackvaccines.org/.
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World Health Organization. **COVID-19 vaccine tracker and landscape**. WHO, Geneva, 10th June, 2022. Available at: Draft landscape of COVID-19 candidate vaccines (who.int).
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Table 10: WHO Summary of vaccine performance against variants of concern (VOC) relative to ancestral stains

	AstraZeneca SII – Covishield	Beijing CNPG - BBIBP-CorV	Janssen-Ad26.COV 2.5	Moderna - mRNA-1273	Pfizer BioNTech-Comirnaty	Sinovac - CoronaVac	Bharat - Covaxin	Novavax, Nuvaxovid-SII, Covovax	Gamaleya-Sputnik V	Anhui ZL-Recomb.
Alpha (B.1.1.7)										
Summary of VE*	Protection retained against all outcomes									
Severe disease	↔2			↔2	↔6					
Symptomatic disease	↔ to ↓5			↔1	↔4			↓1		
Infection	↔ to ↓4			↔3	↔3					
Neutralization	↔ to ↓9	↔1	↔5	↔ to ↓15	↔ to ↓48	↔ to ↓↓8	↔2	↓2	↔ to ↓4	↔2
Beta (B.1.351)										
Summary of VE*	Protection retained against severe disease; reduced protection against symptomatic disease; limited evidence									
Severe disease			↔1	↔1	↔3					
Symptomatic disease	↔ to ↓↓↓2		↔1	↔1	↔2			↓↓↓1		
Infection				↔1	↓1					
Neutralization	↓ to ↓↓11	↓3	↓ to ↓↓9	↓ to ↓↓26	↓to↓↓57	↓to↓↓↓7	↓2	↓↓to↓↓ ↓2	↓↓to↓↓↓5	↔ to ↓3
Gamma (P.1)										
Summary of VE*	Unclear impact; very limited evidence									
Severe disease	↔1			↔1	↔2					
Symptomatic disease	↔1			↔1	↔1					
Infection	↔1			↔1	↔1	↔1				
Neutralization	↔ to ↓4		↔ to ↓5	↓10	↔ to ↓28	↓5		↓1	↓ to ↓↓3	↔1
Delta (B.1.617.2)										
Summary of VE*	Protection retained against severe disease; possible reduced protection against symptomatic disease and infection; limited evidence									
Severe disease	↔3		↓1	↔4	↔7					
Symptomatic disease	↔ to ↓↓6			↔2	↔ to ↓5		↓1			
Infection	↔ to ↓5		↓↓↓1	↔6	↔ to ↓7					
Neutralization	↓15	↔ to ↓3	↔ to ↓↓11	↓15	↔ to ↓41	↓to↓↓10	↔ to ↓4		↓ to ↓↓ ↓3	↔ to ↓2
Omicron										
Summary of VE*	Reduced protection against infection and symptomatic disease; possible reduced protection against severe disease; limited evidence									
Severe disease				↓to↓↓ / ↓↓↓ 2	↓↓to↓↓↓5					

Symptomatic disease	↓↓↓1			↓↓/ ↓↓↓2	↓↓↓3			
Infection	↓↓↓1			↓↓↓3	↓↓↓3			
Neutralization	↓↓↓7	↔to↓↓4	↓ to↓↓↓4	↓↓↓18	↓↓↓46	↓↓to↓↓↓ 5	↓↓1	↓↓1

VE data as of 28 May 2022; Neutralization data as of 2 June 2022.

VE refers to vaccine effectiveness and vaccine efficacy. *Summary of VE: indicates the general conclusions but only for the vaccines evaluated against the specific variant. Arrows generalize the magnitude of reduction in VE or neutralization: "↔" <10 percentage point (pp) reduction in VE, or VE >90% with no comparator, or that there was a <2-fold reduction in neutralization; "↓" 10 to <20 pp reduction in VE, or 2 to <5-fold reduction in neutralization; "↓↓" 20 to <30 pp reduction in VE, or 5 to <10-fold reduction in neutralization; "↓↓↓" ≥30 pp reduction in VE, or ≥10-fold reduction in neutralization. When more than one neutralization study is available, the interquartile range (25th and 75th percentiles) of fold-reductions across all studies for specific vaccine/variant was used. "Moderna-mRNA-1273/Pfizer BioNTech-Comirnaty" indicates that both vaccines were evaluated together in study. References indicated by superscripts next to VOC name in column 1 are vaccine efficacy results from randomized controlled trials informing this table.

Additional notes on VOC impacts on vaccines are included in the WHO Weekly Epidemiological Update.

• Reductions in VE do not necessarily mean a loss of protection, as indicated by the absolute VE estimate. For example, a 10-percentage point reduction in VE against symptomatic disease for mRNA vaccines would still mean high vaccine effectiveness of ~85%. Likewise, vaccines have shown higher VE against severe disease; thus, small reductions in VE against severe disease due to VOCs may still mean substantial protection.

• The summary presented describes the impact of VOCs on COVID-19 vaccine performance in the absence of waning, and, therefore, does not include studies that only assess VE greater than 4 months post final dose.

Extracted from WHO Weekly Epidemiological Update: Edition 95, published 8th June, 2022. 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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