VIGICARIB NEWS

18TH MAY, 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 April and 15th May, 2022, the Caribbean Regulatory System received eight safety case reports of:

- Four suspected adverse drug reactions (ADRs) from St Vincent and the Grenadines,
- Four reports of substandard and/or falsified (SFs) medicines from Bahamas and Belize.
- No adverse event following immunization (AEFIs) reports were received.

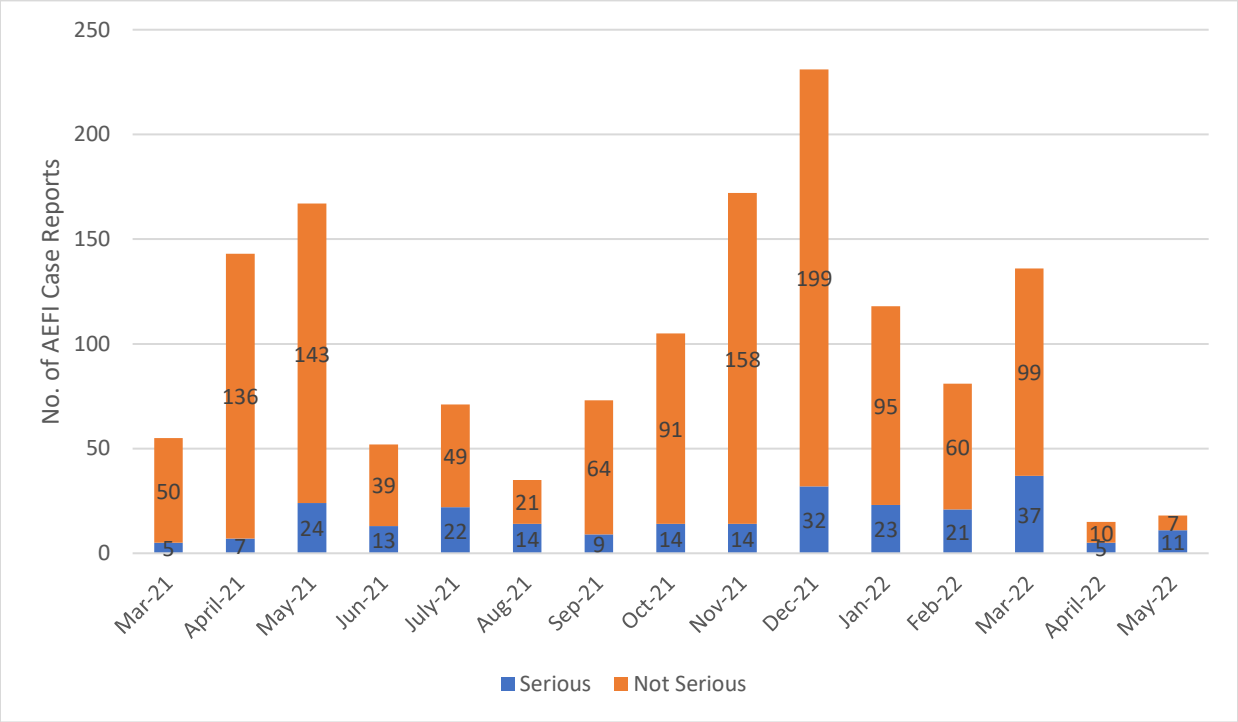
In all, 503 case reports have been shared with the CRS and the VigiCarib network since its inception in November 2017: suspected ADRs (320 – 63.6%), SFs (102– 20.3%), and AEFIs (81 – 16.1%) – Table A1 (See Appendix I – *restricted circulation*). During the reporting period, one report was submitted as an AEFI but did not satisfy the case definition – Table A4 (See Appendix I – *restricted circulation*).

CARICOM COVID-19 VACCINE SAFETY REPORTS IN GLOBAL DATABASE

As of 15th May, 2022, there have been 1,472 case reports of AEFIs involving COVID-19 vaccines submitted to the global database, VigiBase from Barbados, Jamaica, and St Vincent and the Grenadines, mostly non-serious and involving persons under 65 years (84.9%), and females (74.4%). The month with greatest reporting activity is December 2021: Figure 1. Two hundred and fifty-one (251) reports (17.1%) were classified as Serious, including 51 where deaths were reported outcomes – Figure 2, Table 3.

Eighteen (18) AEFI case reports were submitted between 16th April and 15th May, 2022, with the most commonly reported reactions were headache, fever, dizziness, fatigue, chills and myalgia – Table 3.

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

Reports 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 reporting countries, there were approximately 79.3 AEFI reports per 100,000 doses of COVID-19 vaccines administered, with 13.4 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 13th May, 2022

Country	Total Doses	Count of AEFIs*	AEFIs per 100,000 doses	Count of SAEs	SAEs per 100,000 doses
Barbados	362,338	587	162.0	77	21.3
Jamaica	1,424,600	863	60.6	166	11.7
St Vincent and the Grenadines	70,331	22	31.3	6	8.5
Total for Reporting Countries	1,857,269	1,472	79.3¥	249	13.4¥

*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 = 1,472) – up to 15th May, 2022

Patient age	Count	Percent
12 - 17 years	93	6.3%
18 - 44 years	675	45.9%
45 - 64 years	482	32.7%
65 - 74 years	103	7.0%
≥ 75 years	74	5.0%
Unknown	45	3.1%

Table 3: Top Reported Reactions for AEFIs in VigiBase (N = 1,472) – up to 15th May, 2022

Top Reported Reactions	Count	Percent
Headache	442	30.0%
Pyrexia	293	19.9%
Dizziness	291	19.8%
Fatigue	245	16.6%
Chills	242	16.4%
Myalgia	215	14.6%
Arthralgia	204	13.9%
Nausea	166	11.3%
Vaccination site pain	158	10.7%
Malaise	148	10.1%

Figure 2: Total AEFI Case Reports by Seriousness (N =1,472)

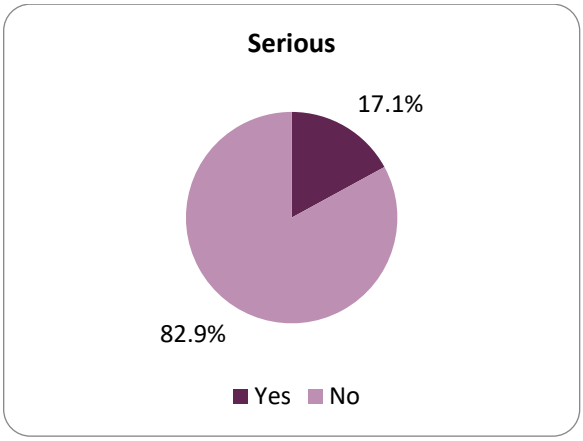


Table 4: Seriousness of Cases (n=251)

Seriousness criteria	Count	Percent
Death	58	3.9%
Life threatening	17	1.2%
Caused/prolonged hospitalization	89	6.0%
Disabling/incapacitating	45	3.1%
Other medically important condition	89	6.0%

Note: Total exceeds 251 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 4,045 case reports from CARICOM countries with membership in the WHO Programme for International Drug Monitoring (PIDM) – 1,472 COVID-19 AEFI case reports, 203 non-COVID AEFI case reports, and 2,370 reports of suspected adverse drug reactions (ADRs). Two case reports were submitted as AEFI (1) and ADR (1) but did not meet the case definitions – Table A4 (See Appendix I – *restricted circulation*).

Table 5 identifies the number of case reports of suspected ADRs and AEFIs submitted by Member States between April 2007 and 15th May, 2022, inclusive of reports submitted by the CRS on behalf of Member States. Most of the case reports involved adults – Table 6.

Between 16th April and 15th May, 2022, 21 additional case reports were submitted to VigiBase from CARICOM: 15 AEFI reports, 6 ADR reports.

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

Countries	Count	Percent
Barbados	1,362	33.7%
Dominica	14	0.3%
Guyana	12	0.3%
Haiti	18	0.4%
Jamaica	1,928	47.7%
Saint Vincent and the Grenadines	486	12.0%
Suriname	221	5.5%
Virgin Islands (British)	4	0.1%

Table 6: ICSR Patient Ages Reported

Patient age	Count	Percent
0 - 27 days	10	0.2%
28 days to 23 months	110	2.7%
2 - 11 years	89	2.2%
12 - 17 years	136	3.4%
18 - 44 years	1,286	31.8%
45 - 64 years	1,163	28.8%
65 - 74 years	414	10.2%
≥ 75 years	293	7.2%
Unknown	544	13.4%

GLOBAL ALERTS OF SUBSTANDARD / FALSIFIED VACCINES AND MEDICINES

Regional Medical Product Alerts

On 25th April, the CRS received a case report from a market authorization holder (Roche) of falsified Actemra™ (tocilizumab 400mg/20mL) discovered in Belize. The market authorization holder confirmed that the batch number was falsified; folding boxes did not have genuine tamper evident labels; the material number was missing; and there were differences in box perforation, artwork and printing quality.

Additionally, on 28th April, the national regulatory authority of The Bahamas submitted three (3) reports of confirmed substandard medicines identified through post-marketing surveillance of selected medicines, to the VigiCarib network. The issues were identified as part of the post-market surveillance programme for quality testing by the CARPHA Medicines Quality Control and Surveillance Department (MQCSD) – Table 7.

Table 7: Medicinal Product Alerts in April 2022

Date reported	Product	Batch Number/ Manufacturing Date/ Expiry Date	Manufacturer	Summary
21st April, 2022	Carbimazole	Not provided	Not provided	Product quality issue
25th April, 2022	Tocilizumab (Actemra or RoActemra - labelled Cipla for the Indian market) - 400mg/ 20mL Injection	B3015B15/ Jan 2023	F. Hoffmann-La Roche Ltd., Switzerland.	Batch number was falsified; the folding boxes did not have genuine tamper evident labels; the material number was missing; and there were differences in box perforation, artwork and printing quality.
28th April, 2022	Amoxicillin and Clavulanate Potassium for Oral Suspension USP	JM8110	Sandoz GmbH, Austria	Assay did not meet the requirements.
28th April, 2022	Aspirin BP 81mg tablet	KE18109/ Jun-21	Kausikh Therapeutics (P) Ltd., India	Dissolution test does not meet requirements and assay does not meet requirements.
28th April, 2022	Paracetamol BP 500mg tablet	H003/ May-24	Health 2000 Canada Inc., Toronto, Canada	Dissolution does not meet requirement and assay does not meet requirement.

Global Medical Product Alerts

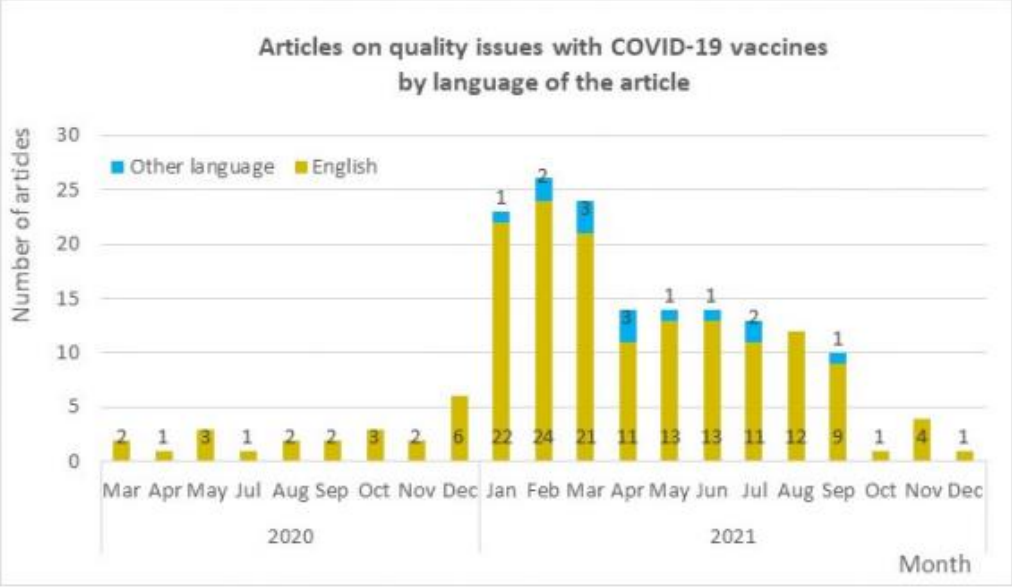
No medical product alerts were issued by the WHO in the past month. Given that medical products for the diagnosis, treatment and prevention of COVID-19 are in demand globally, this along with supply chain vulnerabilities and limited capacities in some countries creates opportunities for illicit goods (e.g. falsified test kits, vaccines and medicines), and diversion of legitimate products.

Global Articles of COVID-19 Medical Product Quality Issues

Equitable access to quality-assured COVID-19 vaccines is threatened by falsified, diverted and substandard (especially degraded) vaccines. The Medicines Quality Research Group published its most recent Medical Product Quality Report on substandard and falsified (SF) COVID-19 vaccines, which summarizes reports in the public domain including data from the lay press, regulatory authorities, scientific literature and public alerts and warnings. The group found 178 individual reports of diverted or substandard / falsified (SF) COVID-19 vaccines from 45 countries in the lay press between 12th March 2020 and 31st December 2021 - Figure 3. Between October and December 2021, six new incidents were reported. For the first time quality issues were reported in Papua New Guinea.

Two incidents involved falsified COVID-19 vaccines wrongly labelled as manufactured by Pfizer/BioNTech and Oxford-AstraZeneca. One incident involved substandard vaccines and one incident involved unregistered vaccines. Inequitable access is highly likely to fuel an increase in such incidents, negating the global good on health and economy of these remarkable vaccines. The most recent edition as of Issue 14 April 2022 is available at: Medical Product Quality Report – COVID-19 vaccine issues.

Figure 3: Number of Articles on MQM Globe Reporting Quality Issues with COVID-19 vaccines



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:

- 156 candidate vaccines are in clinical development: 36 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 31 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 all 11 COVID-19 vaccines under WHO EUL, and two COVID-19 medicines to Member States to date – Table 8. (See List of CRS Recommended products).
- COVID-19 vaccines' performance against variants of concern (VOC) is provided from WHO's Weekly Epidemiology Update (11th May 2022): Table 9.
- On 5th May, 2022, the U.S. Food and Drug Administration concluded that the authorized use of Janssen COVID-19 Vaccine should be limited to individuals 18 years of age and older for

whom other authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and to individuals 18 years of age and older who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine.

- The World Health Organization (WHO) on 2nd April, 2022 has suspended the supply of Covaxin produced by Bharat, through UN procurement agencies and recommending to countries that received the vaccine to take actions as appropriate. Bharat has committed to comply by addressing the GMP deficiencies and is developing a corrective and preventive action plan, for submission to the Drugs Controller General of India (DCGI) and WHO.

- The World Health Organization (WHO), with the support of the Strategic Advisory Group of Experts (SAGE) on Immunization on 17th May, 2022 issued the **Interim statement on the use of additional booster doses of Emergency Use Listed mRNA vaccines against COVID-19.** The group concluded that:
  - Evidence showing the value of an additional booster dose for some population groups and highlights research gaps.
  - Short-term benefit of an additional booster dose of mRNA vaccines in the highest risk group (health workers, those over the age of 60 and immunocompromised persons).
  - Limited data regarding the duration of protection and the benefits of an additional booster dose for healthy younger people.
  - More data is needed to evaluate the benefits of an additional booster dose for other population groups and vaccine platforms.
  - Countries considering introducing a fourth additional booster dose should carefully weigh up the financial and programmatic challenges against the incremental benefits expected.

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 public sector, national and regional pharmacovigilance centres: Drug induced liver injury (DILI)
- UMC New Course 2022 available to national and regional PV centre staff: Regulatory aspects of pharmacovigilance
- Uppsala Reports Current Issue: Uppsala Reports - Latest issues
- MHRA Drug Safety Update. Volume 15 Issue 10 May 2022
- EMA HUMAN MEDICINES HIGHLIGHTS Issue 158 May 2022
- Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 2-5 May 2022
- PRAC Strategy on Measuring the Impact of Pharmacovigilance Activities
- WHO Emergency Use Listing for In vitro diagnostics (IVDs) Detecting SARS-CoV-2. 16 May 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
- Podcast: DIA Maximizing Regulatory Resources Across Latin America with PAHO's Chief of Medicines and Health Technologies Unit.

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 193 therapeutic options. 4th May 2022 (36th 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.31st March 2022 (34th Edition): URL: https://covid-19pharmacovigilance.paho.org/img/recursos/626ff853af5e93cb92c95d155.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 8: 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					
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 (9 mo.); 2°C to 8°C (31 days / 10 wks§) CARPHA + 144 countries Full Market authorization by US FDA (16yrs+)	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.) South Korea via COVAX / PAHO + CARPHA + 138 countries	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 + 47 countries	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 (4.5 mo. within shelf-life) CARPHA + 111 countries Full market approval by Health Canada (23.Nov)	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;
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 + 85 countries	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	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 + 55 countries	National Medical Products Administration, China	**Sinovac Life Sciences Co., Ltd.**, P.R.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	Central Drugs Standard Control Organization, India	**Bharat Biotech International Limited**, India	3rd November 2021
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 + 4 countries (under CRS review)	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	Protein subunit	2 doses I.M. 2°C to 8°C	European Medicines Agency	**Serum Institute of India Pvt. Ltd.,** S. No. 105–110, India	20th December 2021

[Recombinant, adjuvanted])/ Novavax CZ a.s.		CARPHA + 37 countries			
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
CanSino Biological Inc + Beijing Institute of Biological Products (Convidicea (Ad5-nCoV))	Adenovirus; Viral vector (non-replicat)	1 dose I.M. 2°C to 8°C 10 countries	National Medical Products Administration	Not applicable	Decision date- To be confirmed
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	2 Pre-submission meetings held
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	Presubmission meeting held on 26 January 2022
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	EOI under review
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	Not stated
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 adenoviral vector.	Not stated	Russian NRA	Not applicable	EOI under review
SK Bioscience Co., Ltd. (Nuvaxovid)*	Recombinant nanoparticle prefusion spike protein formulated with Matrix-M™ adjuvant	2 doses I.M.	Ministry of Food and Drug Safety (MFDS), Rep. of Korea	Not applicable	EOI under review
Medicago Inc (COVIFENZ)*	Virus-like particles (VLP) of SARS-CoV-2 spike protein	2 doses I.M. 1 country	Health Canada	Not applicable	*Not accepted*

¥ - 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 13th May, 2022. Available at: https://covid19.trackvaccines.org/.

World Health Organization. **Status of COVID-19 Vaccines within WHO EUL/PQ evaluation process**. Updated 2nd April 2022. WHO, Geneva, 2020. Available at: https://www.who.int/teams/regulation-prequalification/eul/covid-19.

World Health Organization. **Draft landscape of COVID-19 candidate vaccines**. WHO, Geneva, 13th May, 2022. Available at: Draft landscape of COVID-19 candidate vaccines (who.int).

World Health Organization. **Emergency Use Listing Procedure for Vaccines**. WHO, Geneva 2021. Available at: https://www.who.int/teams/regulation-prequalification/eul/eul-vaccines.

Table 9: 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↓↓↓ 3	↔to↓↓↓ 4	↓↓↓18	↓↓↓45	↓↓to↓↓↓5	↓↓1		↓↓1	

VE data as of 5 May 2022; Neutralization data as of 2 May 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 91, published 11th May, 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 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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