VIGICARIB NEWS

18TH FEBRUARY, 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 January 2022 and 15th February 2022, the Caribbean Regulatory System received seven (7) case reports of suspected adverse drug reactions (ADRs) from focal points, one (1) report of an adverse event following immunization (AEFI) from a market authorization holder's pharmacovigilance office, and one (1) case report of a suspected substandard medicine from a focal point:

- Suspected ADRs (7): St Vincent and the Grenadines
- AEFIs (1): Barbados
- Suspected substandard product (1): St Vincent and the Grenadines.

Case reports that were received from the public or market authorization holders were submitted to the national focal points for local verification and follow-up.

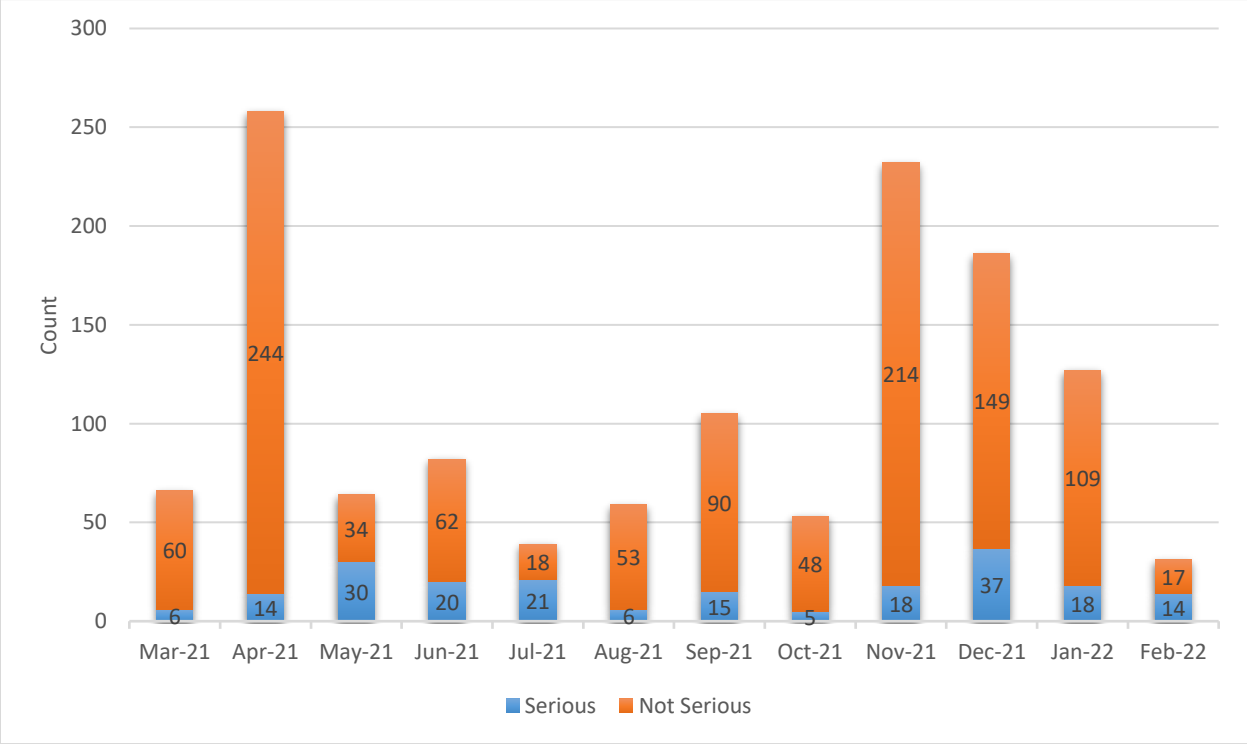
In all, 480 case reports have been shared with the CRS and the VigiCarib network since its inception in November 2017: suspected adverse drug reactions (304 – 63.3%), substandard / falsified medical products (98 – 20.4%), and adverse events following immunization (78 – 16.3%) – Table A1 (See Appendix I – *restricted circulation*).

CARICOM COVID-19 VACCINE SAFETY REPORTS IN GLOBAL DATABASE

As of 15th February 2022, there were 1,300 case reports of AEFIs involving COVID-19 vaccines in the global database, VigiBase from Barbados, Jamaica, and St Vincent and the Grenadines, primarily involving persons under 65 years (85.4%) - Table 2; and females (980 reports, 75.4%). Most reports were submitted in April 2021 – Figure 1.

Eighty (80) additional reports were submitted up to 15th February 2022, and 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 February 2022.



One hundred and ninety-six (196) reports (15.1%) have been classified as Serious, with 42 deaths – Figure 2, Table 3. The reported ICSRs involved the following vaccines:

- COVID-19 vaccine NRVV Ad (ChAdOx1-S recombinant) AstraZeneca
- 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 inact (Vero) HB02
- 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. These estimates include coincidental and/or unconfirmed reports. Among the reporting countries, there were approximately 76 AEFI reports per 100,000 doses of COVID-19 vaccines administered, with 11 serious adverse events reported per 100,000 doses.

Table 1: Consolidated number of reported adverse events and reporting rate, by country as of 11th February, 2022

Country	Doses Administered	Count of AEFIs*	AEFIs per 100,000 doses	Count of SAEs	SAEs per 100,000 doses
Barbados	307,330	572	186.1	73	23.8
Jamaica	132,7491	706	53.2	108	8.0
St Vincent and the Grenadines	64,991	22	33.9	7	10.8
Total for Reporting Countries	**1,699,812**	**1,300**	**76.4¥**	**188**	**11.1¥**

Key: ¥ - Calculated using counts of reports and doses administered. SAE – serious adverse event.

Table 2: Patient Age Groups Reported for AEFIs in VigiBase (N = 1,300) – up to 15th February, 2022

Patient age	Count	Percent
12 – 17 years	85	6.5%
18 - 44 years	584	45.0%
45 - 64 years	438	33.7%
65 - 74 years	91	7.0%
≥ 75 years	60	4.6%
Unknown	4	3.2%

Table 3: Top Reported Reactions for AEFIs in VigiBase (N = 1,300) - 15th February, 2022

Top Reported Reactions	Count	Percent
Headache	413	31.8%
Pyrexia	274	21.1%
Dizziness	247	19.0%
Fatigue	242	18.6%
Chills	238	18.3%
Myalgia	205	15.8%
Arthralgia	190	14.6%
Vaccination site pain	155	11.9%
Nausea	149	11.5%
Malaise	143	11.0%

Figure 2: AEFI Case Reports by Seriousness (N =1,300)

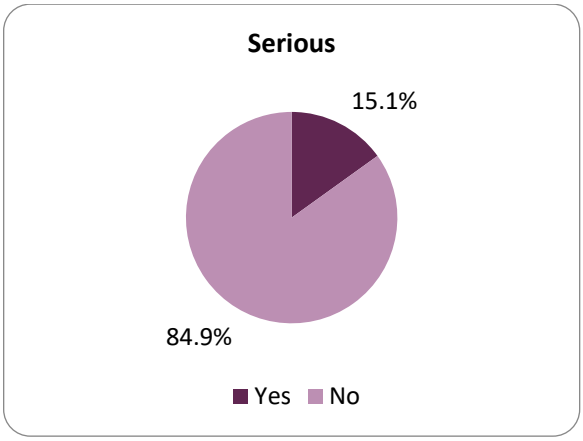


Table 4: Seriousness of Cases (n=196)

Seriousness criteria	Count	Percent
Death	38	2.9%
Life threatening	15	1.2%
Caused/ prolonged hospitalization	56	4.3%
Disabling/incapacitating	32	2.5%
Other medically important condition	81	6.2%

Note: Total exceeds 196 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 3,828 case reports from CARICOM countries with membership in the WHO Programme for International Drug Monitoring (PIDM) – 1,300 AEFI case reports, and 2,528 reports of suspected adverse drug reactions (ADRs). Table 5 identifies the number of case reports of suspected adverse drug reactions submitted by Member States between April 2007 and 15th February 2022, inclusive of reports submitted by the CRS on behalf of Member States. Most of the case reports involved adults – Table 6.

Between 16th January 2021, and 15th February 2022, 93 case reports were submitted to VigiBase from CARICOM: 80 AEFI reports, 13 ADR reports - Appendix I.

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

Countries	Count	Percent
Barbados	1,339	35.0%
Dominica	14	0.4%
Guyana	12	0.3%
Haiti	18	0.5%
Jamaica	1,745	45.6%
Saint Vincent and the Grenadines	475	12.4%
Suriname	221	5.8%
Virgin Islands (British)	4	0.1%

Table 6: ICSR Patient Ages Reported

Patient age	Count	Percent
0 - 27 days	10	0.3%
28 days to 23 months	104	2.7%
2 - 11 years	89	2.3%
12 - 17 years	128	3.3%
18 - 44 years	1,184	30.9%
45 - 64 years	1,112	29.0%
65 - 74 years	396	10.3%
≥ 75 years	276	7.2%
Unknown	529	13.8%

GLOBAL ALERTS OF SUBSTANDARD / FALSIFIED VACCINES AND MEDICINES

Suspected Substandard Medicine: Cisatracurium

In January, 2022, the CRS received a report of therapeutic failure of a muscle relaxant used in surgical procedures from St Vincent and the Grenadines: cisatracurium injection. The report noted that the efficacy was zero, and that health professionals had observed the same reaction with other patients who were given this product. An alternate muscle relaxant was used as a result. Use of the product has since been suspended pending further investigation and testing.

Following consultation with the regulatory focal points for the country where the product was found, the CRS submitted a report to the WHO Global Surveillance and Monitoring System. It is noted here for regional vigilance, in the event the product is also present in other Member States. National focal points may note the information below to increase local vigilance, and to advise health professionals to report any quality issues or therapeutic failures while using the product. We thank the focal points in St Vincent and the Grenadines for sharing their experience with the network.

Table 7: Suspected Substandard Products reported to CRS

Date reported	Product	Manufacturer	Alert summary
21st January, 2022	Cisatracurium besylate injection USP 10mg/5mL single use vial Batch: AL1054 Manufactured: 06.2021 Expiry: 05.2023	Aishwarya Healthcare	Suspected Substandard Product – Therapeutic failure Reported to WHO GSMS for further follow-up with national focal point

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.

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:

- 144 candidate vaccines are in clinical development: 32 in Phase 3 trials, and 10 in Phase 4 trials; Figure in COVID-19 Vaccines and Therapeutics Regulatory Tracker (Phases tab).
- 33 vaccines are approved in various countries, and 22 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 based on the most recently published table of vaccine performance in WHO's Weekly Epidemiology Update (8th February, 2022): Table 9.

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 175 therapeutic options. 26th Jan. 2022 (32nd 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. 20th December 2021 (31st Edition): URL: https://covid-19pharmacovigilance.paho.org/img/recursos/61dd7bb2207db780093bd4a54.pdf
WHO Technical Guidance for evaluation of COVID-19 Vaccines	WHO guidance documents for candidate COVID-19 vaccines. URL: https://www.who.int/teams/health-product-and-policy-standards/standards-and-specifications/vaccine-standardization/
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	mRNA (nucleoside modified)	2 doses I.M. -90°C to -60°C (9 mo.); 2°C to 8°C (31 days / 10 wks*) CARPHA + 137 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 + 137 countries	European Medicines Agency	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.	27th August 2021

Vaccine/ WHO EUL Holder	Vaccine Platform	Dosing/ Storage ¥/ Approvals	NRA of record	WHO Approved Drug Product site(s)	Recommendation issued
				Seqirus Pty Ltd., Australia. CP Pharmaceuticals Limited, UK. Amylin Ohio LLC (AZ), USA	
			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, India SIIPL, 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 + 106 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	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 (7 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 + 89 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 + 53 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 + 13 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 + 3 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	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

Vaccine/ WHO EUL Holder	Vaccine Platform	Dosing/ Storage ¥/ Approvals	NRA of record	WHO Approved Drug Product site(s)	Recommendation issued
[Recombinant, adjuvanted])/ Novavax CZ a.s.		CARPHA + 34 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
CureVac (Zorecimeran: CVnCoV/CV07050101)	mRNA-based in lipid nanoparticle	2 doses I.M. 2°C to 8°C	European Medicines Agency	Not applicable	Application withdrawn by manufacturer
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 3 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

¥ - Storage information is provided primarily for sealed vials. See product information for additional details on storage and handling.

References:

McGill COVID19 Vaccine Tracker. COVID-19 Vaccines. Updated 11th February, 2022. Available at: https://covid19.trackvaccines.org/.
World Health Organization. **Status of COVID-19 Vaccines within WHO EUL/PQ evaluation process**. Updated 23rd December 2021. 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, 11th February, 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: Summary of vaccine performance against variants of concern (VOC) relative to ancestral stains (as of 4 Feb, 2022)

	AstraZeneca SII - Covishield	Beijing CNPG - BBIBP-CorV	Janssen-Ad26.COV 2.5	Moderna - mRNA-1273	Pfizer BioNTech-Comirnaty	Sinovac - CoronaVac	Bharat-Covaxin	Novavax-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 ↓6					
Neutralization	↓13	↓2	↔ to ↓↓10	↓13	↔ to ↓39	↓to↓↓9	↔ to ↓4	↓1	↓ 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					↓↓/↓↓↓2					
Symptomatic disease	↓↓↓1			↓↓1	↓↓↓1					
Infection	↓↓↓1			↓↓↓3	↓↓↓3					
Neutralization	↓↓↓6	↔to ↓↓↓3	↓↓2	↓↓↓15	↓↓↓32	↓↓to↓↓↓4	↓↓1	↓↓1	↓↓1	

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. The number of studies is shown as subscripts: vaccine effectiveness and neutralization studies informing this table can be found on the VIEW-hub Resources Library. References indicated by superscripts next to VOC name in column 1 are vaccine efficacy results from randomized controlled trials informing this table. + Severe disease is defined differently across studies and may include outcomes such as hospitalization, critical disease, and other forms of 'severe' disease.

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 78, published 8th February, 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, however not all content shared with focal points will be publicized.

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