VIGICARIB NEWS

22ND MARCH, 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 February 2022 and 15th March 2022, the Caribbean Regulatory System received six (6) case reports of suspected adverse drug reactions (ADRs) from its focal point in St Vincent and the Grenadines. No additional reports of adverse events following immunization (AEFI), or of suspected substandard and/or falsified medicines were received.

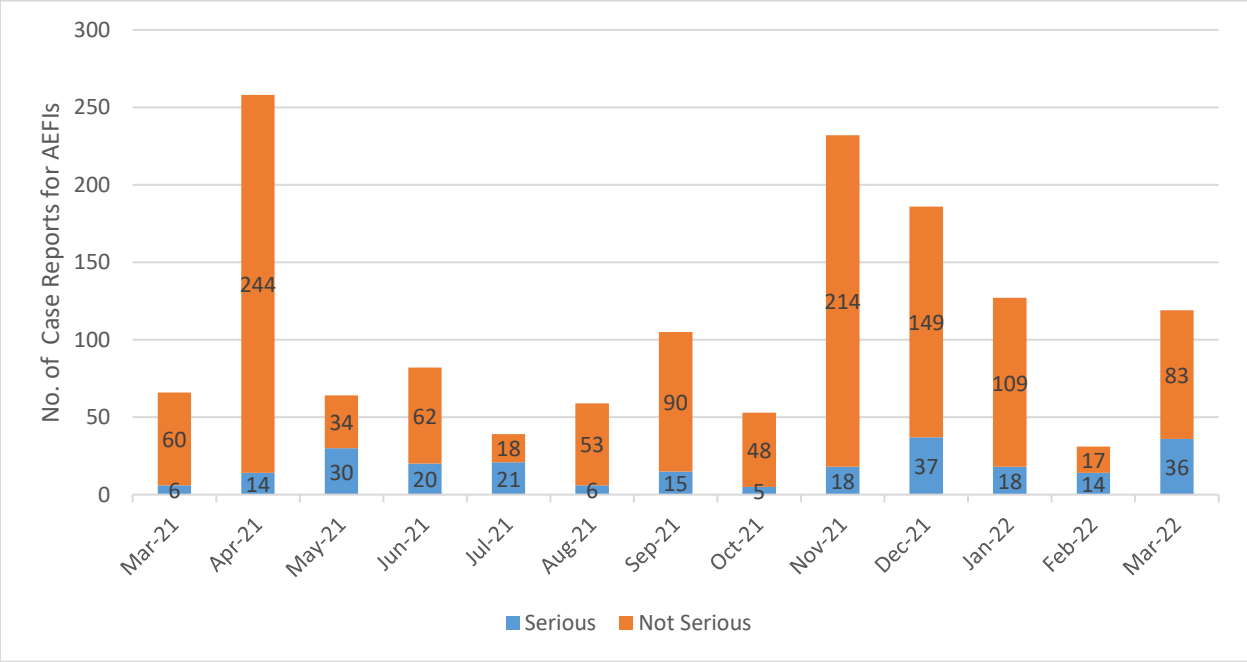
In all, 486 case reports have been shared with the CRS and the VigiCarib network since its inception in November 2017: suspected adverse drug reactions (310 – 63.8%), substandard / falsified medical products (98 – 20.2%), and adverse events following immunization (78 – 16.0%) – Table A1 (See Appendix I – *restricted circulation*).

CARICOM COVID-19 VACCINE SAFETY REPORTS IN GLOBAL DATABASE

As of 15th March 2022, there were 1,422 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 (85.1%), and females (1,062 reports, 74.7%). The months with greatest reporting activity were April 2021 and November 2021 – Figure 1.

One hundred and nineteen (119) additional AEFI case reports were submitted between 16th February and 15th March, 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 March 2022.



Two hundred and forty (240) reports (16.9%) were classified as Serious, including 50 where deaths were reported outcomes – Figure 2, Table 3. 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 AEFI reports per 100,000 doses of COVID-19 vaccines administered, with 13 serious adverse events reported per 100,000 doses. For COVID-19 AEFI case reports, reporting rates were highest in Barbados. 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 11th March, 2022

Country	Doses Administered	Count of AEFIs*	AEFIs per 100,000 doses	Count of SAEs	SAEs per 100,000 doses
Barbados	357,585	575	160.8	75	21
Jamaica	1,372,538	830	60.5	153	11.1
St Vincent and the Grenadines	69,096	22	31.8	6	8.7
Total for Reporting Countries	**1,799,219**	**1,427**	**79.3¥**	**234**	**13¥**

*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 = 1,422) – up to 15th March, 2022

Patient age	Count	Percentage
12 - 17 years	91	6.4%
18 - 44 years	648	45.6%
45 - 64 years	471	33.1%
65 - 74 years	99	7.0%
≥ 75 years	69	4.9%
Unknown	44	3.0%

Table 3: Top Reported Reactions for AEFIs in VigiBase (N = 1,422) - 15th March, 2022

Top Reported Reactions	Count	Percent
Headache	437	30.7%
Pyrexia	287	20.2%
Dizziness	285	20.0%
Fatigue	244	17.2%
Chills	241	16.9%
Myalgia	211	14.8%
Arthralgia	200	14.1%
Nausea	161	11.3%
Vaccination site pain	157	11.0%
Malaise	146	10.3%

Figure 2: Total AEFI Case Reports by Seriousness (N =1,422)

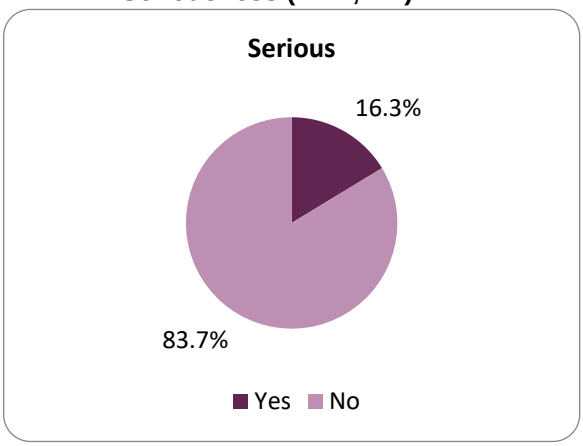


Table 4: Seriousness of Cases (n=232)

Seriousness criteria	Count	Percent
Death	50	3.5%
Life threatening	17	1.2%
Caused/ prolonged hospitalization	76	5.3%
Disabling/incapacitating	39	2.7%
Other medically important condition	88	6.2%

Note: Total exceeds 232 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 3,996 case reports from CARICOM countries with membership in the WHO Programme for International Drug Monitoring (PIDM) – 1,422 COVID-19 AEFI case reports, 177 non-COVID AEFI case reports, and 2,397 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 March 2022, inclusive of reports submitted by the CRS on behalf of Member States. Most of the case reports involved adults – Table 6.

Between 16th February and 15th March 2022, 169 additional case reports were submitted to VigiBase from CARICOM: 119 AEFI reports, 50 ADR reports.

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

Countries	Count	Percent
Barbados	1,345	33.7%
Dominica	14	0.4%
Guyana	12	0.3%
Haiti	18	0.5%
Jamaica	1,896	47.4%
Saint Vincent and the Grenadines	486	12.2%
Suriname	221	5.5%
Virgin Islands (British)	4	0.1%

Table 6: ICSR Patient Ages Reported

Patient age	Count	Percent
0 - 27 days	10	0.3%
28 days to 23 months	109	2.7%
2 - 11 years	89	2.3%
12 - 17 years	134	3.4%
18 - 44 years	1,184	31.7%
45 - 64 years	1,112	29.3%
65 - 74 years	396	9.9%
≥ 75 years	276	7.2%
Unknown	530	13.3%

GLOBAL ALERTS OF SUBSTANDARD / FALSIFIED VACCINES AND MEDICINES

WHO MEDICAL PRODUCT ALERTS

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 centres, 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.

Table 7: Medical Product Alert 2022

Alert number and date	Product	Manufacturer	Alert summary
N° 2/2022 9th March 2022	DESREM (Remdesivir for Injection 100mg/vial)	Mylan Laboratories Ltd	• Deliberately/fraudulently misrepresent their identity, composition or source. • Laboratory analysis established that it did not contain any of the stated active pharmaceutical ingredient (remdesivir). • The vials may be smaller than genuine DESREM and the labels have multiple spelling errors and use the wrong font styles and colours. • The expiry dates listed are falsified.

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.

Rapid Alert Notification

Table 8: Notification of a Quality Defect / Recall

RAN notification type/ Date	Product	Market Authorization Holder/ Manufacturer	Notification summary
Class I/ 7th March 2022	Panto–Denk 40 mg Gastro-resistant tablet (INN: Pantoprazole sodium sesquihydrate) Batch numbers: 3755, 3940, 4051 Manufacture dates: 15.02.2019, 12.09.2019, 12.09.2019 Expiry dates: 31.01.2022, 31.08.2022, 12.09.2022	Denk Pharma GmbH & Co. KG, in Germany/ Advance Pharma GmbH, Germany	• Out of specification (OOS) result in ongoing stability study – change in appearance of several tablets (dark discoloration) leading to considerable impurities. • Discoloration is suspected to be caused by oxidation of Iron-oxides, which are part of the tablet-coating.

COVID-19 VACCINES AND THERAPEUTICS: REGULATORY UPDATES

Overview of COVID-19 Vaccine Development and Approvals:

- 148 candidate vaccines are in clinical development: 34 in Phase 3 trials, and 10 in Phase 4 trials; Figure in COVID-19 Vaccines and Therapeutics Regulatory Tracker (Phases tab).
- 35 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 9. (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 March, 2022): Table 10.

Additional Resources:

- FRPath ® Project enlists CARPHA/CRS on the curated repository of key information about Facilitated Regulatory Pathways (FRPs): https://erudee.xyz/FRP/60cdfb1a0a1e6ea1d74c57ac
- UMC New Course 2022: Collecting high quality ADR reports
- Webinar: Medication Error Reporting and Learning, and Pharmacovigilance Systems 12 April 2022, 7:00 am (EST). Simultaneous interpretation will be available in English, French, and Spanish.
- Draft for public consultation: EMA Guideline on good pharmacovigilance practices (GVP) Module XVI Addendum III – Pregnancy prevention programme and other pregnancy-specific risk minimisation measures
- Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 7-10 March 2022 including:
    - COVID-19 Vaccine Janssen: small vessel vasculitis added as a side effect
    - Spikevax: new warning for flare-ups of capillary leak syndrome
- MHRA Drug Safety Update. Volume 15 Issue 8 March 2022
- EMA HUMAN MEDICINES HIGHLIGHTS Issue 156 March 2022
- HealthCanada Health Product Info Watch February 2022
- WHO Emergency Use Listing for In vitro diagnostics (IVDs) Detecting SARS-CoV-2. 23 February 2022 Update.
- WHO. SARS-CoV-2 IVDs: Products not accepted for EUL: Last update: 15 March 2022.

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 178 therapeutic options. 22nd Feb. 2022 (33rd 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 January 2022 (32nd Edition): URL: https://covid-19pharmacovigilance.paho.org/img/recursos/6218d0c6d665fd2b9bfa61373.**pdf**

Resource	Description and Link
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 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					
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 + 138 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 + 107 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 + 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 + 54 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	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

		CARPHA + 3 countries (under CRS review)			
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 + 36 countries	European Medicines Agency	**Serum Institute of India Pvt. Ltd.,** S. No. 105–110, India	20th December 2021
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-replicating)	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 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 encoding the Spike protein antigen of the SARS-CoV-2.	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 11th March, 2022. Available at: https://covid19.trackvaccines.org/.
World Health Organization. **Status of COVID-19 Vaccines within WHO EUL/PQ evaluation process**. Updated 2nd March 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, 11th March, 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 10: WHO Summary of vaccine performance against variants of concern (VOC) relative to ancestral stains *(VE data as of 3 Mar. 2022; Neutralization data as of 28 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, 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 ↓6					
Neutralization	↓14	↔ to ↓2	↔ to ↓↓10	↓14	↔ to ↓40	↓to↓↓9	↔ 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				↓/ ↓↓1	↓↓/↓↓↓3					
Symptomatic disease	↓↓↓1			↓↓/ ↓↓↓2	↓↓↓2					
Infection	↓↓↓1			↓↓↓3	↓↓↓3					
Neutralization	↓↓↓7	↔to ↓↓↓3	↔ to ↓↓↓3	↓↓↓16	↓↓↓35	↓↓to↓↓↓4	↓↓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 BioNTechComirnaty" indicates that both vaccines were evaluated together in the 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.

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.

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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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