

### CARPHA UPDATE FOR Incident Manager / SITUATION REPORT

# **COVID-19 Vaccines Update Supplement**

Week of: 29th March, 2021

## I. Overview of Development and Regulatory Approvals:

- 83 candidate vaccines are in clinical development: 15 in Phase 3 trials, and 5 in Phase 4 trials see Figure in <u>CARPHA COVID-19 Vaccine Regulatory Tracker</u> (Phases tab).
- 13 vaccines have received regulatory approvals in various countries, and 15 vaccines are at various stages of engagement with WHO for emergency use listing (EUL).
- 4 vaccines have been approved by WHO for Emergency Use Listing: Pfizer-BioNTech's vaccine: <u>COMINARTY</u>®, <u>AstraZeneca-SK Bio</u>, <u>AstraZeneca-SII</u> (<u>Covishield</u>), and <u>Janssen-Cilag</u>.
- 4 additional vaccines are expected to be approved by WHO in April Tables 1 and 3.
- The WHO Strategic Advisory Group of Experts on Immunization (SAGE) interim recommendations and background documents are available for vaccines by: Moderna, Pfizer-BioNTech, AstraZeneca-Oxford and Janssen-Cilag at <u>SAGE Interim Guidance</u>. The recommendations provide guidance on the use the vaccines, including use in various groups.
- CARPHA has shared its <u>COVID-19 vaccine regulatory tracker</u> with Member States for viewing as updates are made.
- The CARPHA Caribbean Regulatory System (CRS) has reviewed and recommended the COVID-19 vaccine by Pfizer-BioNTech. The CRS' recommendation and report have been shared with Member States.

Table 1: Predicted WHO EUL Approvals in April

WHO Predicted Approval	Vaccines				
April	- Moderna + NIAID				
	<ul> <li>AstraZeneca-Oxford vaccine (European or UK node)</li> </ul>				
	<ul> <li>Sinopharm + Beijing Institute of Biological Products</li> </ul>				
	<ul> <li>Sinovac Research and Development (Coronavac)</li> </ul>				

# **II. COVAX Updates Participating States on Deliveries**

The COVAX Facility has notified participating economies that deliveries of doses from the Serum Institute of India (SII) will be delayed in March and April. The delays in supplies from SII are due to the increased demand for COVID-19 vaccines in India. Participating economies in the COVAX Facility that have been allocated doses from the AstraZeneca manufacturing network have been notified that some first deliveries anticipated in March will now take place in April. See full statement here: <a href="https://www.who.int/news/item/25-03-2021-covax-updates-participants-on-delivery-delays-for-vaccines-from-serum-institute-of-india-(sii)-and-astrazeneca">https://www.who.int/news/item/25-03-2021-covax-updates-participants-on-delivery-delays-for-vaccines-from-serum-institute-of-india-(sii)-and-astrazeneca</a>. (26<sup>th</sup> March, 2021)

Caribbean countries that have received COVAX deliveries: Jamaica, Suriname.



Caribbean countries due to receive COVAX deliveries this week: Guyana, Bahamas, Belize, Trinidad and Tobago.

# **Vaccine Deployment Surveillance**

Several Caribbean countries have approved / received COVID-19 vaccines purchases and/or donations. A search of the PAHO Dashboard of COVID-19 Vaccination in the Americas revealed information on COVID-19 vaccinations by 20 countries of the Caribbean / CARPHA Member States, as of 26<sup>th</sup> March, 2021 - Figure 1.

FIGURE 1: Number of Doses of COVID-19 Vaccines Administered per 100 population in Member States as of 26<sup>th</sup> March, 2021



Source of base graphic: Metric Pioneer | CARICOM



Table 2: COVID-19 Vaccines Deployed Among CARPHA Member States as of 26th March, 2021

Country	Vaccine(s)	Total Doses
Anguilla	AstraZeneca - AZD1222	5,510
Antigua & Barbuda	SII - Covishield	26,000
Bahamas	SII - Covishield	110
Barbados	SII - Covishield	62, 765
Virgin Islands (British)	AstraZeneca - AZD1222	7, 162
Belize	SII - Covishield	18, 241
Bermuda	Pfizer BioNTech - Comirnaty	33, 498
Cayman Islands	Pfizer BioNTech - Comirnaty	45, 051
Dominica	SII - Covishield	15, 737
	Beijing CNBG - Inactivated	
Grenada	SII - Covishield	11, 506
Guadeloupe	Information not available	19, 378
Guyana	SII - Covishield	25, 341
	Beijing CNBG - Inactivated	25, 541
Jamaica	SII - Covishield	33, 642
Martinique	Information not available	13, 963
Montserrat	AstraZeneca - AZD1222	1,396
St. Kitts & Nevis	SII - Covishield	8, 134
St. Lucia	SII - Covishield	20, 963
St. Vincent & Grenadines	SII - Covishield	0.200
	Gamaleya - Sputnik V	9, 380
Suriname	SII - Covishield	18, 600
Trinidad & Tobago	SII - Covishield	1, 137

Source: PAHO COVID-19 Vaccination in the Americas Dashboard

### III. Falsified COVID-19 Vaccines in the Americas

WHO issued a Medical Product Alert No.2/2021 for falsified COVID-19 vaccine identified as "BNT162b2" (stated manufacturer Pfizer-BioNTech) found to be distributed in Mexico in February. The falsified product was supplied and administered to patients outside authorized vaccination programs, and may still be in circulation in the region. The product identified in the alert was confirmed falsified on the basis that it deliberately/fraudulently misrepresents identity, composition, or source:

- The genuine manufacturer of COVID-19 Vaccine BNT162b2 confirmed they did not manufacture the product.
- The batch number and expiry dates are falsified.
- The glass vials and label are different from genuine COVID-19 Vaccine BNT162b2 vials.

The medical product alert including photographs of the falsified product may be found at: <a href="https://www.who.int/news/item/26-03-2021-medical-product-alert-n-2-2021-falsified-covid-19-vaccine-bnt162b2">https://www.who.int/news/item/26-03-2021-medical-product-alert-n-2-2021-falsified-covid-19-vaccine-bnt162b2</a>.



#### IV. Caribbean Vaccine Introduction Readiness

Although some countries have received vaccines, we are monitoring vaccine readiness in the Caribbean to identify areas for strengthening. The PAHO Vaccine Introduction Readiness Tool (VIRAT) as of 29<sup>th</sup> March, 2021 for the Caribbean is shown below – Figure 2. The countries include Latin and non-Latin Caribbean countries.

Indicators of areas that are pending readiness in the Caribbean are: Safe injection and waste management, Demand generation, community engagement and communication, Human resources and security, and Vaccination data and information management.

Number of Countries/Recognized Territories Reported preparedness status by area Region Caribbean Region В Country (AII) C Monitoring framework for COVID-19 vaccine deployment and vaccination in the American Region: areas E G Н ılı. 50 Percentage by status Status Not Started In progress- early ... Completed Not Reported In progress- matur...

FIGURE 2: COVID-19 Vaccine Introduction Readiness Tool Dashboard – Caribbean Region



Table 3: COVID-19 Vaccines with Regulatory Approvals by WHO EUL Consideration

<b>Developers</b> Vaccine name	Vaccine Platform	Dosing	Storage ¥	Authorized by	WHO EUL status and anticipated decision date:	Eligible for CRS review?
Pzifer & BioNTech (Tozinameran (INN); BNT162b2 / COMIRNATY)	mRNA	2 doses I.M.	Ship: -80°C to -60°C; Store: -25°C to -15°C (2wk) 2°C to 8°C (12h)	WHO EUL + 79 countries including United Kingdom, Canada, Mexico, USA, Chile, Argentina, Switzerland, EU, Colombia, Israel, Australia, Brazil, Guyana	December 2020 (completed)	Yes – Recommended
AstraZeneca-Oxford University (AZD1222)	Recombinant ChAdOx1-S adenoviral vector	2 doses I.M.	2°C to 8°C (6 mo.)	81 countries including UK, Argentina, Mexico, Brazil (local production by Fiocruz), EU, Canada (AZ Canada), Colombia, Chile	In progress: April	Yes
AstraZeneca-Oxford + SK Bioscience (supplier) (AZD1222)	Recombinant ChAdOx1-S adenoviral vector	2 doses I.M.	2°C to 8°C (6 mo.)	WHO EUL + South Korea For COVAX (Americas)	Approved: 15 <sup>th</sup> February	Yes - Recommended
Serum Institute of India + AstraZeneca-Oxford University (AZD1222; Covishield)	Recombinant ChAdOx1-S adenoviral vector	2 doses I.M.	2°C to 8°C (6 mo.)	WHO EUL + CRS + 31 countries including India, Argentina, Bangladesh, South Africa, Guyana, Canada (+VerityPharma)	Approved: 15 <sup>th</sup> February	Yes - Recommended
Janssen-Cilag (Johnson & Johnson) (JNJ-78436735)	Viral vector (non-replicating)	1 dose I.M.	Sealed: 2-8°C or 9- 25°C (12h) Open: 2-8°C (6h) or 25°C (2h).	WHO EUL + 35 countries including: USA, Canada, South Africa, Bahrain	Approved: 12 <sup>th</sup> March	Yes
Moderna & NIAID (mRNA-1273)	mNRA-based in lipid nanoparticle (LNP)	2 doses I.M.	To ship: -25°C to -15°C Sealed: 2-8°C (30d) or 9-25°C (12h) Open: 2-25°C (6h)	41 countries including Canada, Switzerland, United Kingdom, United States, EU, Guyana	In progress – April	Yes
Sinopharm + China National Pharmaceutical Group + Beijing Institute of Biological Products (BBIBP-CorV)	Inactivated virus	2 doses I.M.	2°C to 8°C	27 countries including China, Argentina, Bahrain, United Arab Emirates, Egypt, Jordan, Iraq, Pakistan, Peru, Guyana	In progress – April	No
Sinovac Research and Development Co. Ltd (CoronaVac)	Inactivated virus	2 doses I.M.	2°C to 8°C	19 countries including China, Colombia, Turkey, Indonesia, Brazil, Chile, México, Guyana	In progress – April	No
Gamaleya Research Institute & Russian Health Ministry (Sputnik V)	Adenovirus Viral vector (non-replicating)	2 doses I.M.	2°C to 8°C	55 countries including Russia, Argentina, Guinea, Bolivia, Venezuela, Paraguay, México, Belize, Guyana, StVincent&Gren	Under Clinical review – undetermined	No
CanSino Biological Inc + Beijing Institute of Biological Products (Convidicea (Ad5-nCoV))	Adenovirus; Viral vector (non-replicating)	1 dose I.M.	2°C to 8°C	4countries: China, Mexico, Pakistan, Hungary	Rolling data starting in April	No
NOVAVAX (NVX-CoV2373)	Protein subunit	2 doses I.M.	2°C to 8°C	None to date	Pending presubmission meeting	No



<b>Developers</b> Vaccine name	Vaccine Platform	Dosing	Storage ¥	Authorized by	WHO EUL status and anticipated decision date:	Eligible for CRS review?
Sinopharm + China National Pharma. Group + Wuhan Institute of Biol. Products	Inactivated virus	2 doses I.M.	2°C to 8°C	2 countries: China, United Arab Emirates	Pending presubmission meeting	No
Vector State Research Ctre of Virology and Biotech. (EpiVacCorona)	Peptide vaccine	2 doses I.M.	2°C to 8°C	Russia, Turkmenistan	Pending expression of interest	No
Bharat Biotech + Indian Council of Medical Research (ICMR) (Covaxin)	Whole virion inactivated	2 Doses I.M.	2°C to 8°C	5 countries: India, Iran, Zimbabwe, Nepal, Mauritius	Requested meeting to discuss details of submission/timelines	No
Clover Biopharmaceuticals Inc. + GSK + Dynavax (SCB-2019)	Protein subunit	2 doses I.M.	2°C to 8°C	None to date	In discussion on submission strategy and timelines	No

<sup>¥ -</sup> 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 26th March 2021. Available at: https://covid19.trackvaccines.org/.

World Health Organization. **Status of COVID-19 Vaccines within WHO EUL/PQ evaluation process**. Updated 23<sup>rd</sup> March 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, 26<sup>th</sup> March 2021. Available at: <u>Draft landscape of COVID-19</u> candidate vaccines (who.int).

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