World Health Organization

UPDATE on COVID-19 Vaccines Rollout

WHO Member States information Session

18 FEBRUARY 2021

Recent developments

1. WHO EUL for AstraZeneca vaccine

2. Interim SAGE recommendations for Oxford/AstraZeneca vaccine

3. Next steps for accelerated roll-out of COVAX Facility vaccines

State of Vaccines: key numbers (data at 18 February 2021)

- **74 days** since first countries started vaccinating[1] and **52 days** since all EU countries received vaccines

- **187 million vaccine doses** have been administered:
  - ~83% of these doses have been administered in 10 countries
  - At least 8 different vaccines (3 platforms) have been administered[2]

- Campaigns **have started in 84 economies:**
  - incl. 55 HICs, 17 UMICs, 11 LMIC and 1 LIC
  - Pfizer-BioNTech vaccine is by far the most used vaccine (59 economies using it), followed by Oxford/AZ (40 economies), Moderna (27 economies), Sinopharm (10 economies) and Gamaleya (10 economies)

1. Dec. 8, 2020 in the UK (Pfizer)
2. Pfizer, Moderna, Gamaleya, Sinovac, Sinopharm, SII, Bharat Biotech, AZ

2

Source: Our World in data; Bloomberg

WHO Emergency Use Listing (EUL) – indicative review timelines

31st December: Pfizer/BioNTech

15th February: AZ/Serum Institute of India

AZ/SK Bio, Korea

End Feb: Moderna

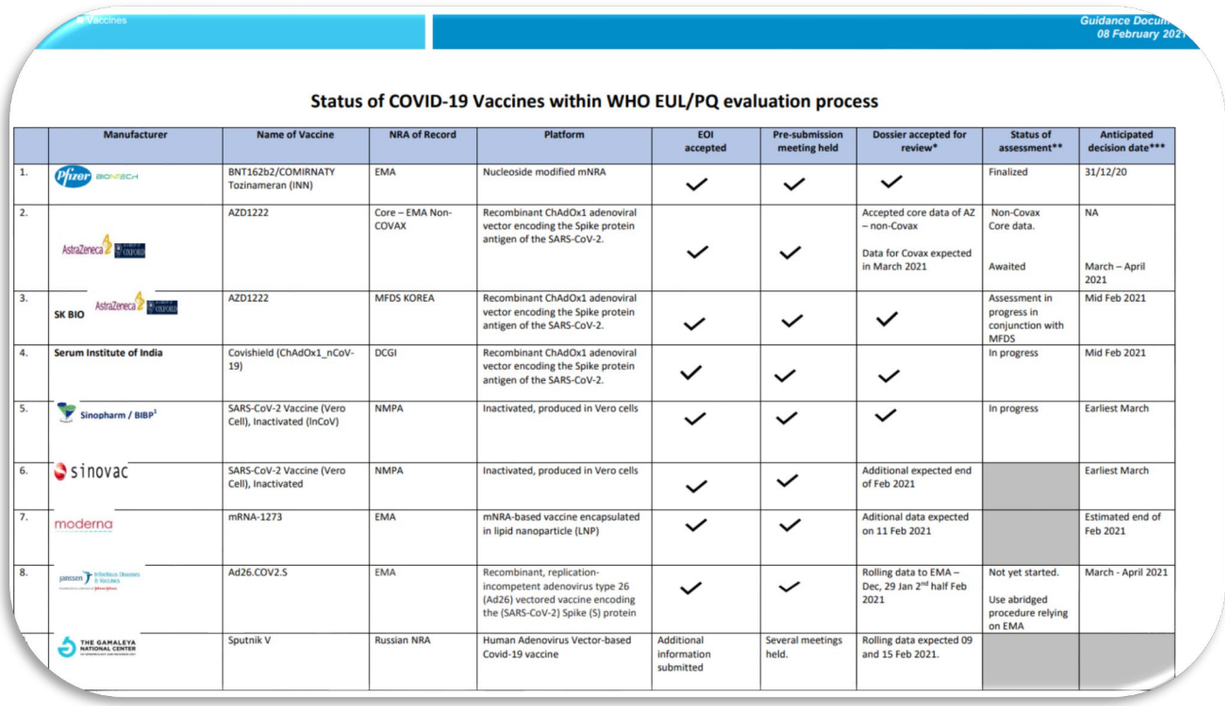
March: Sinopharm BIBP

Sinovac

March/April: J&J*

In discussion: Gamaleya

Novavax



Status of COVID-19 Vaccines within WHO EUL/PQ evaluation process

	Manufacturer	Name of Vaccine	NRA of Record	Platform	EOI accepted	Pre-submission meeting held	Dossier accepted for review*	Status of assessment**	Anticipated decision date***
1.	Pfizer BioNTech	BNT162b2/COMIRNATY Tozinameran (INN)	EMA	Nucleoside modified mNRA	✓	✓	✓	Finalized	31/12/20
2.	AstraZeneca / Serum Institute of India	AZD1222	Core – EMA Non-COVAX	Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.	✓	✓	Accepted core data of AZ – non-Covax Data for Covax expected in March 2021	Non-Covax Core data. Awaited	NA March – April 2021
3.	SK BIO / AstraZeneca / Serum Institute of India	AZD1222	MFDS KOREA	Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.	✓	✓	✓	Assessment in progress in conjunction with MFDS	Mid Feb 2021
4.	Serum Institute of India	Covishield (ChAdOx1_nCoV-19)	DCGI	Recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2.	✓	✓	✓	In progress	Mid Feb 2021
5.	Sinopharm / BIBP[1]	SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV)	NMPA	Inactivated, produced in Vero cells	✓	✓	✓	In progress	Earliest March
6.	sinovac	SARS-CoV-2 Vaccine (Vero Cell), Inactivated	NMPA	Inactivated, produced in Vero cells	✓	✓	Additional expected end of Feb 2021		Earliest March
7.	moderna	mRNA-1273	EMA	mNRA-based vaccine encapsulated in lipid nanoparticle (LNP)	✓	✓	Aditional data expected on 11 Feb 2021		Estimated end of Feb 2021
8.	Janssen	Ad26.COV2.S	EMA	Recombinant, replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding the (SARS-CoV-2) Spike (S) protein	✓	✓	Rolling data to EMA – Dec, 29 Jan 2nd half Feb 2021	Not yet started. Use abridged procedure relying on EMA	March - April 2021
	The Gamaleya National Center	Sputnik V	Russian NRA	Human Adenovirus Vector-based Covid-19 vaccine	Additional information submitted	Several meetings held.	Rolling data expected 09 and 15 Feb 2021.		

https://extranet.who.int/pqweb/key-resources/documents/status-covid-19-vaccines-within-who-eulpq-evaluation-process

https://extranet.who.int/pqweb/sites/default/files/documents/Product-Eligibility_COVAX-Facility_Dec2020_0.pdf

* Abridged procedure - EMA

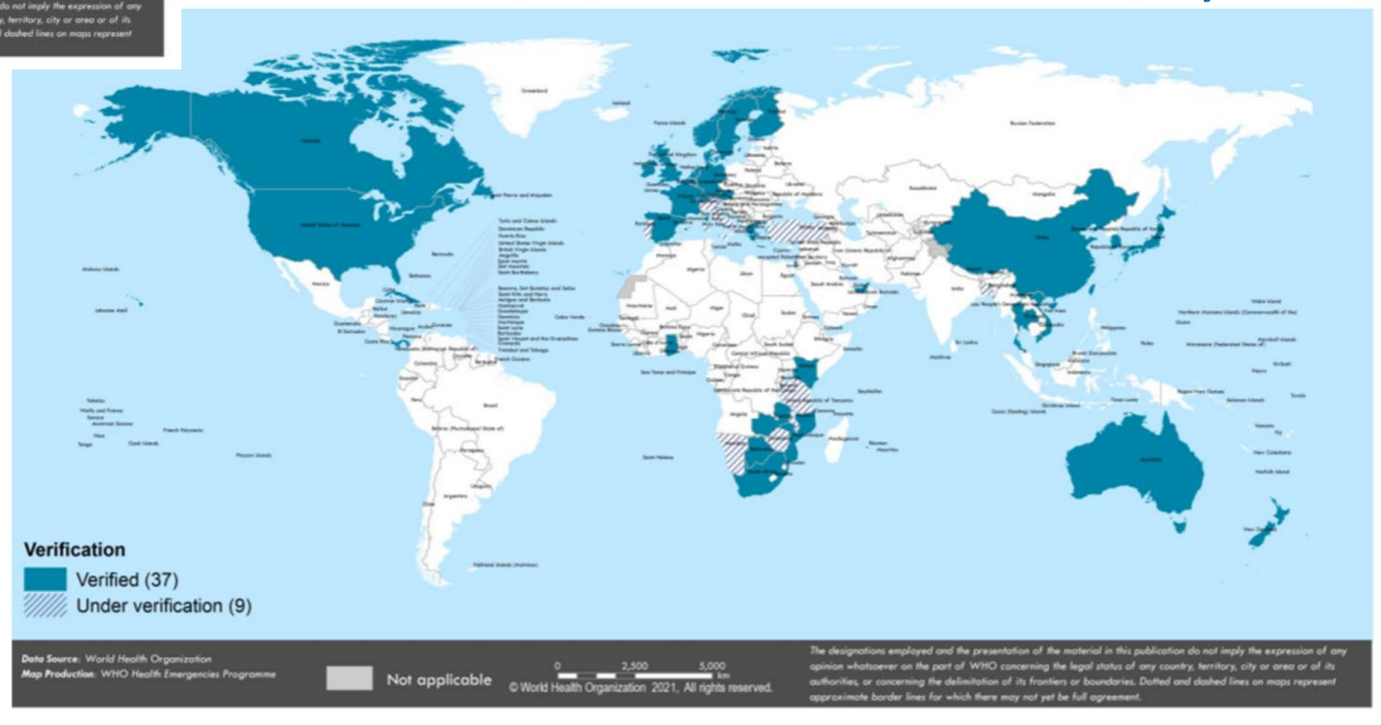
WHO SAGE interim recommendation for the use of AZD1222

- AZD1222 has been shown to have an **efficacy of 63.1%** [1] against symptomatic SARS-CoV-2 infection (3-23 wk dosing interval).
- Vaccination is recommended for persons aged **18 years and above**.
- The **recommended schedule** is two doses given intramuscularly with an interval of **8 – 12 weeks** between the doses.
- No data are available related to impact on **transmission** or viral shedding.
- The same product should be used for both doses. There are no studies on **interchangeability** with other vaccines against COVID-19.
- Countries are recommended to use the WHO **Prioritization Roadmap** and the WHO **Values Framework** as guidance for their prioritization of target groups.

1. (95% CI 51.8; 71.7)

Countries, territories and areas reporting SARS-CoV-2 variant VOC 202012/01 as of 16 February 2021

Countries, territories and areas reporting SARS-CoV-2 variant 501Y.V2 as of 16 February 2021



COVID-19 Vaccine and SARS-CoV2 variants

Data are limited, early, and incomplete

Availability of Evidence (10 Feb 2021)

	B 1.1.7 (original report SSA)		B 1.351 (original report AZ)		P 1 (original report Brazil)	
	Clinical	Lab	Clinical	Lab	Clinical	Lab
AstraZeneca	✓	pending	limited	✓	pending	pending
J & J			prelim	pending		
Moderna		✓		✓		
Novavax	prelim		prelim	pending		
Pfizer		✓		✓		
Sinopharm				prelim		

Evidence on protection against severe disease, hospitalization and deaths are especially limited

COVID Vaccines and the B.1.351 virus variant

(first identified in South Africa)

World Health Organization

PRELIMINARY

	Reduction of neutralizing activity in laboratory assays	Clinical efficacy in South Africa	Clinical efficacy in global studies	Clinical efficacy criteria
Pfizer	**3x**	-	95%	-
moderna	**6x**	-	94.1%	-
AstraZeneca	**2.5-31x / eliminated**[3]	22% (NS)[2]	62-90%	Mild & moderate
THE GAMALEYA NATIONAL CENTER OF EPIDEMIOLOGY AND MICROBIOLOGY	-	-	91.6%	-
Johnson & Johnson	**pending**	57%	72%	Moderate to severe
NOVAVAX	**pending**	49%[1] 60%[2]	89%	Mild, moderate & severe
Sinopharm	**1.6x**	-	79 - 86%	-
sinovac	-	-	50.4%	-

1. Including HIV positive subjects (6% of the study population); 2. Excluding HIV positive subjects; 3. previously infected placebo participants showed similar results

Sources South Africa: J&J; Novavax; Moderna; Pfizer 1 & Pfizer 2; AstraZeneca/Oxford; Sinopharm Sources global: 1. The Lancet on AZ/Oxford, The Lancet on Sputnik V, Bloomberg on Sinovac, Bloomberg on Sinopharm, Novavax website, J&J website

Considerations of AstraZeneca Vaccine and SARS-CoV2 variants

- **Slightly reduced vaccine effectiveness of AZD1222 against B1.1.1.7** in the United Kingdom and limited reduction in neutralizing antibody (Preliminary analyses)

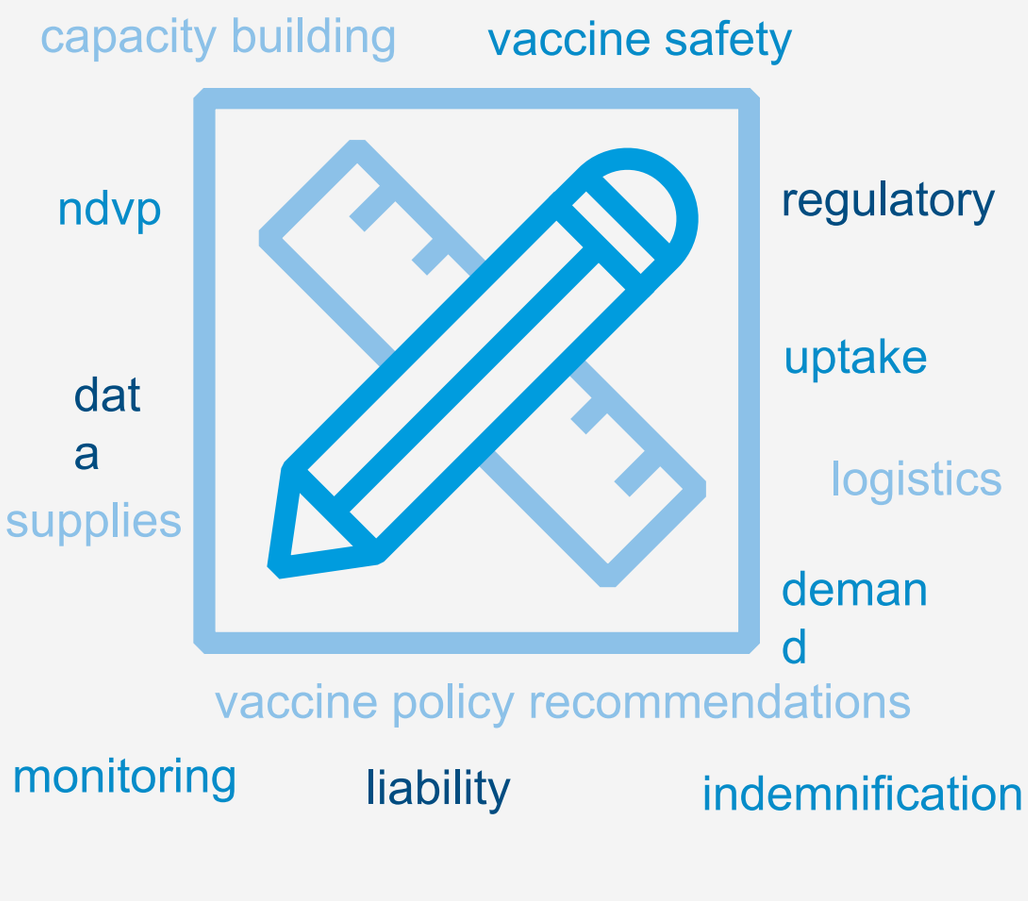
- **B.1.351 virus variant:**
  - **Phase 1/2a trial in South Africa indicate marked reduction in vaccine effectiveness** against mild and moderate disease based on a small sample size and substantial loss of neutralizing antibody activity (Preliminary analyses)
  - **Indirect evidence is compatible with protection against severe COVID-19**, however this remains to be demonstrated in ongoing clinical trials and post-implementation evaluations. (Preliminary analyses)

- **WHO currently recommends the use of AZD1222 vaccine** according to the Prioritization Roadmap even if variants are present in a country.

- **Countries should conduct benefit-risk assessment** according to the local epidemiological situation.

- **These preliminary findings highlight the urgent need for a coordinated approach** for surveillance and evaluation of variants and their potential impact on vaccine effectiveness.

Vaccine Introduction toolbox: purpose



COVID-19 Vaccine Introduction Toolbox

- repository for resources and training documents
- help countries in their preparation to rollout COVID-19 vaccines
- updated frequently to ensure the webpage is complete

The Toolbox slide deck will be sent to countries, including all the links to guidance, tools, training, …

For comments, questions, queries, and / or feedback, please contact COVID19vaccineresources@who.int

NEXT STEPS: 5 key action for COVAX AstraZeneca & Pfizer Rollout

Red = urgent action from countries needed

Regulatory & PQ[1]

Country regulatory authorization for Pfizer, AZ/SK Bio & AZ/SII (asap)

Issue import licenses for vaccine shipments (as applicable)

Policy & Guidance

Country plan for priority populations to match supply (SAGE Pfizer & AZ recs)

Preparedness & Readiness

Execute indemnity & liability agreements (asap)

Trainings and Simulations

Vaccine Volumes

COVAX confirmation of volumes & allocation of Q1 doses (week 15 Feb)

Full allocation mechanism for March-May doses by week of 22 Feb

Product deliveries

COVAX Facility, Unicef & PAHO initiating Purchase Orders (from 18 Feb onwards!)

[1] https://extranet.who.int/pqweb/sites/default/files/documents/Status_COVID_VAX_01Feb2021.pdf

[2] 94 NDPs (National Deployment & Vaccination Plans) completed with 83 of 87 from AMC countries (5 AMC countries opted out)

BACK-UP

Immediate next steps to ensure first roll-out

UPDATED: 17 Feb 2021 12pm

PRELIMINARY – TO BE CONFIRMED

		Formal allocation	I&L submitted	I&L signed	Regulatory approval	Import licence	Devices
February doses (early POs for SII)		Jan 30	7/7	0/7	7/7	TBD	5/7
First allocation (March doses and later)	**Pfizer (1st wave)**	Jan 30	0/18	0/18	7/18	TBD	TBC
	SII	Feb 23	18/53	0/53	3/53	TBD	1/53 (TBC)
	AZ	Feb 23	14/85	1/85	1/85	TBD	TBC

Next steps for countries:

1) **Execute I&L agreements** (incl. legislative requirements as applicable)
2) **Provide proof of regulatory approval** to COVAX Facility
3) **Approve import license** (as applicable)

NDVP submission and review data

Data as of 16 Feb

NDVP Submission & Review

Process

101 Total NDVPs submitted for review through PP
(Access country list)

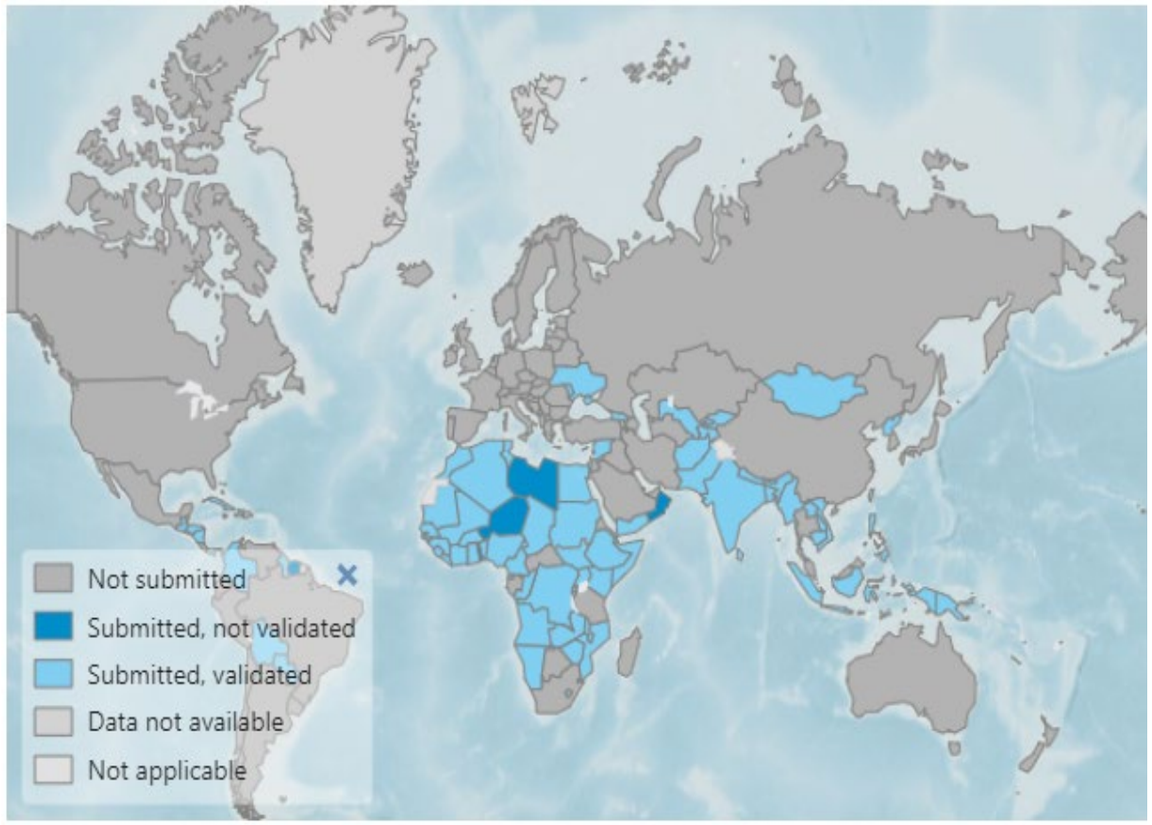
86 AMC92 submitted
(List)

6 AMC92 not submitted
(List)

93 NDVPs validated by MoH of those submitted
(Access country list)

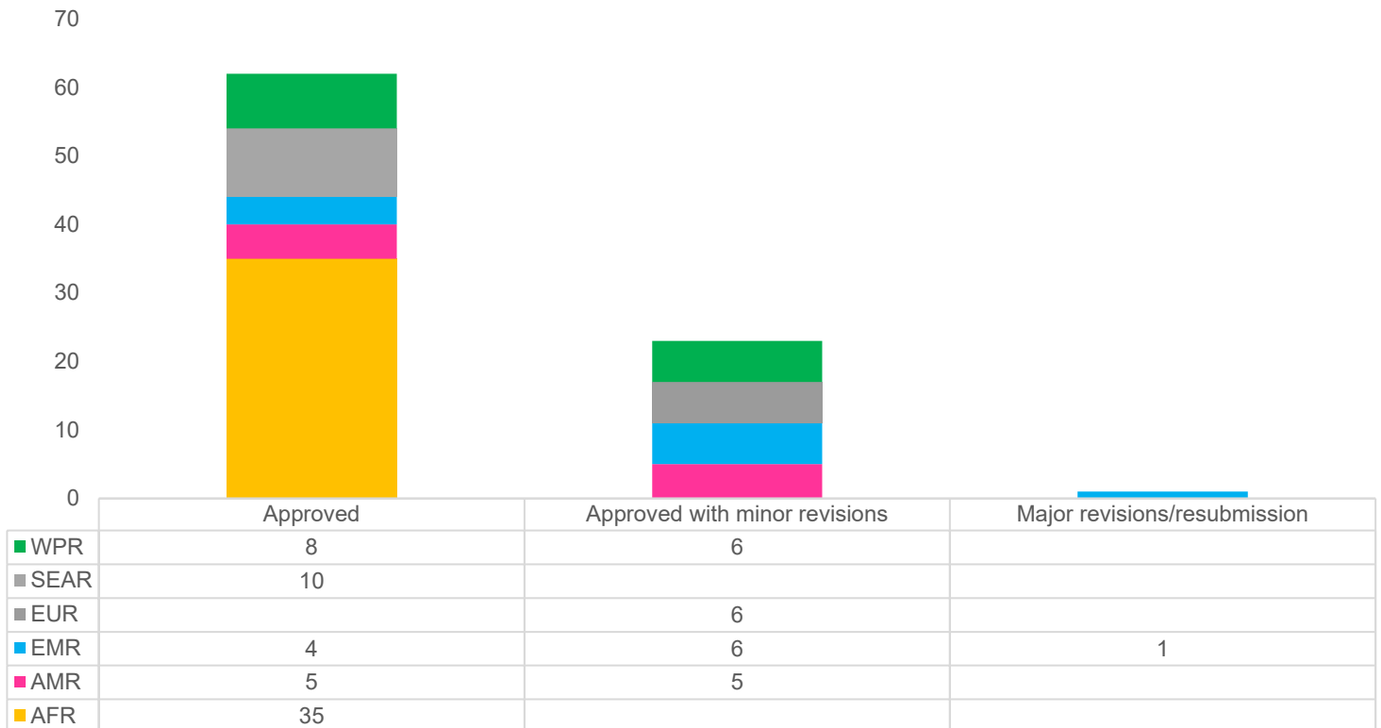
92% of NDVPs submitted have been validated by MoH

AMC 92 countries not submitted	
Country	**Updates**
Burundi	Not decided on vaccine introduction
Central African Republic	Expected to submit NDVP later
Eritrea	No information available
Madagascar	Not decided on vaccine introduction
Marshall Islands	Not decided on vaccine introduction
Tanzania	Not decided on vaccine introduction



NDVP Standard Review Form (SRF) Minimal Requirements Outcome (data at 16 Feb 2021)

NDVP Standard Review Form (SRF) Minimal Requirements Outcome							
RRC outcome	**AFR**	**AMR**	**EMR**	**EUR**	**SEAR**	**WPR**	**Total**
Approved	35	5	4		10	8	**62**
Approved with minor revisions		5	6	6		6	**23**
Major revisions/ resubmission			1				**1**
Total	**35**	**10**	**11**	**6**	**10**	**14**	**86**



Additional priorities to assure rollout

Area	Activity
Emerging hot topics	**Costing for vaccine delivery**, e.g. budgets need to be fine-tuned or developed
	Securing resources to deliver vaccine, including govt resources, reprogramming of WB funds, other
	Microplanning for vaccine delivery
	Risk communications and vaccine acceptance and demand
	HR planning, e.g. explore task shifting and mobilize all needed HR resources

Indemnity agreements

AMC92

- **Model Indemnity Agreement** agreed with manufacturers and shared with AMC92
- A **compensation program** for AMC92 participants to cover serious adverse events arising from vaccines received through COVAX is being established

SFPs

- SFPs without bilateral deals will be provided with manufacturer-specific indemnity

Country Readiness and Delivery webpage: https://www.who.int/initiatives/act-accelerator/covax/covid-19-vaccine-country-readiness-and-delivery
OpenWHO COVID-19 Course Series: https://openwho.org/covid-19

I&L support to AMC92 countries

O'Neill Institute for National and Global Health Law (at Georgetown Law)

- Agreement with Gavi on 14 Jan 2021
- Support elements:
  - ***a list of concrete legislation or executive actions of other countries***
  - ***concise checklist of principles*** *to have the necessary legislation*
  - ***preliminary (and non-exclusive) list of consultants*** *that countries can choose to work with in drafting the required legislation*

Additional Support in Development

No-Fault Compensation Program

Details

The program is for **AMC eligible economies to provide no-fault lump-sum compensation** in full and final settlement of any claims to persons who suffer a **SAE resulting in permanent impairment or death** associated with the use or administration of a COVID-19 vaccine made available through the Facility.

Individuals will be able to apply for compensation under the Program even if the SAEs arise from vaccines administered before the Program is fully operational.

Next Steps

- **Identify if any legislative action is needed** to enable I&L agreements
- **Implement such legislative action**

Once the Compensation Program has been established, AMC92 countries will need to:

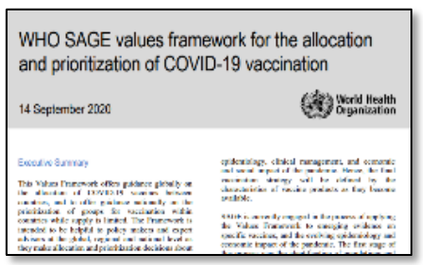
- **Make "How to Submit an Application" instructions** (as provided by the Program's independent claims administrator in due course) available to vaccine recipients, inform healthcare professionals and raise awareness in the country.
- **Work with independent claims administrator** to facilitate the submission and investigation of claims, as well as the exchange of safety information.

Further information will be made available once the Compensation Program is closer to launch.

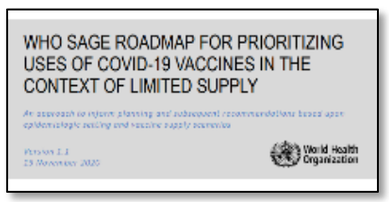
Country Readiness and Delivery webpage: https://www.who.int/initiatives/act-accelerator/covax/covid-19-vaccine-country-readiness-and-delivery
OpenWHO COVID-19 Course Series: https://openwho.org/covid-19

SAGE policy recommendations (to date, 18 Feb 2021) - Products with WHO/EUL or SRA

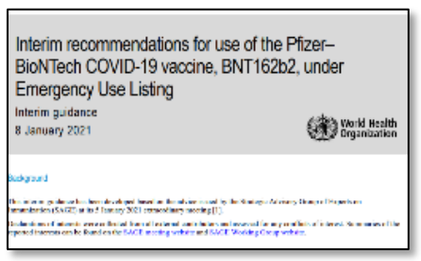
WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccines
14 Sep 2020



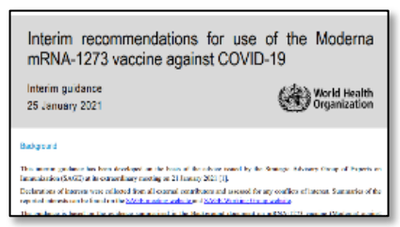
WHO SAGE Roadmap for Prioritizing Uses Of COVID-19 Vaccines In The Context Of Limited Supply
13 Nov 2020



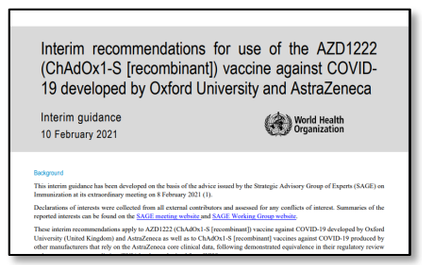
Interim recommendations for use of the Pfizer–BioNTech COVID-19 vaccine, BNT162b2, under Emergency Use Listing
5 Jan 2021



Interim recommendations for use of the Moderna mRNA-1273 vaccine against COVID-19
25 Jan 2021



Interim recommendations for use of the AZD1222 (ChAdOx1-S (recombinant)) vaccine against COVID-19 developed by Oxford University and AstraZeneca
8 Feb 2021



https://www.who.int/publications/i/item/who-sage-values-framework-for-the-allocation-and-prioritization-of-covid-19-vaccination ; https://www.who.int/publications/m/item/who-sage-roadmap-for-prioritizing-uses-of-covid-19-vaccines-in-the-context-of-limited-supply ; https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-BNT162b2-2021.1 ; https://www.who.int/publications/i/item/interim-recommendations-for-use-of-the-moderna-mrna-1273-vaccine-against-covid-19 ; https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-AZD1222-2021.1