27th WHO Regulatory Update on COVID-19

24 January 2021

World Health Organization

Key Messages

As the first vaccines begin to be deployed, the promise of equitable access is at serious risk. WHO calls on countries and manufacturers to prioritize supplying COVAX rather than bilateral deals. WHO also calls on all countries introducing vaccines to only use vaccines that meet rigorous international standards for safety, efficacy and quality, and to accelerate readiness for deployment.

Highlights and main issues

- COVAX announced the signing of an advance purchase agreement for up to 40 million doses of the Pfizer-BioNTech vaccine and, pending WHO emergency use listings, nearly 150 million doses of the AstraZeneca/Oxford candidate are anticipated to be available in Q1 2021.
- Given that the impact of vaccines in reducing transmission is yet unknown, and the current availability of vaccines is too limited, the 6th meeting of the International Health Regulations (2005) Emergency Committee regarding the COVID-19 pandemic recommended that countries do not require proof of vaccination from incoming travellers.
- The WHO Virus Evolution Working Group is working to assess the significance of SARS CoV-2 variants in terms of transmissibility, clinical presentation or severity, or if they impact on countermeasures, including diagnostics, therapeutics and vaccines.
- There is consensus on the importance of integrating the new SARS-CoV-2 variants research into the global research and innovation agenda while enhancing coordination across disciplines.
- A WHO Information Note for IVD users concerning SARS CoV-2 variants has been issued.
- The Emergency Committee on COVID-19 strongly encouraged vaccine manufacturers to rapidly provide safety and efficacy data to WHO for emergency use listing.
- On 19 January, the GACVS COVID-19 Vaccine Safety subcommittee virtually met, reviewed available information and data on deaths reported in frail, elderly individuals who had received the Pfizer BioNTech COVID-19 mRNA vaccine and concluded that the benefit-risk balance of BNT162b2 remains favourable in the elderly at this moment.
- WHO Operational tool for efficient lot release of COVID-19 vaccines has been published. WHO's recommended lot release strategy is to rely on the lot release certificates issued by the responsible NCL that are provided with each batch of EUL vaccines.
- A global meeting on a 2021 research agenda for COVID vaccines concluded with agreement to establish a WHO-hosted platform for global sharing and coordination of emerging vaccine research information on efficacy and safety. The forum would enable scientists to share and discuss unpublished and published data and research protocols to further our collective understanding of SARS-CoV-2 vaccines.

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Contents

New virus variants

Variants notified to WHO

WHO was notified on 9 January 2021 by the Japanese authorities of a new variant of SARS-CoV-2, the virus that causes COVID-19. The variant was identified when whole-genome sequencing was conducted on samples from 4 travelers from Brazil who were tested at the airport. The variant belongs to the B.1.1.248 lineage and has mutations including the N501Y (which was also found in the variants first reported by UK and South Africa) and E484K.

Technical brief from National Institute of Infectious Diseases, Japan

Recently, a variant that includes mutations N501Y, E484K, K417T, and deletion in ORF1b (del11288-

11296) in the spike protein has been reported from Brazil, but the strain detected in Japan is distinct.

> WHO COVID-19 Weekly Epidemiological Update (19 Jan 2021)

The WHO Virus Evolution Working Group is working to assess the significance of these variants as well as others identified in recent months in terms of transmissibility, clinical presentation or severity, or if they impact on countermeasures, including diagnostics, therapeutics and vaccines. As countries increase sequencing, more variants are expected to be identified.

WHO R&D agenda for the SARS-CoV-2 new variants

On 12th January, WHO convened a virtual meeting of scientists from around the globe, bringing together more than 1'750 experts from 124 countries, to discuss critical knowledge gaps and research priorities for emerging variants of the virus. The consultation was structured in six thematic areas covering epidemiology and mathematical modelling, evolutionary biology, animal models, assays and diagnostics, clinical management and therapeutics and vaccines.

Scientists noted the importance of research to urgently detect and understand the potential impact of emerging variants on diagnostics, treatments and vaccines. There was a consensus on the importance of integrating the new SARS-CoV-2 variants research into the global research and innovation agenda while enhancing coordination across disciplines.

A report of the meeting will be published shortly.

> WHO News: Global scientists double down on SARS-CoV-2 variants research at WHO-hosted forum (12 Jan 2021)

The WHO Working Groups on Animal Models and on Assays and Reference Preparations, each of which meet weekly (see reports below), are fora for academic groups to rapidly share emerging data to characterize biological properties of variants, and the impact of variants on diagnostics, therapeutics and vaccines.

International Health Regulations (2005) Emergency Committee

On 14th January, the Emergency Committee on COVID-19 met and issued recommendations to the WHO Secretariat and to State Parties on SARS-CoV-2 variants, COVID-19 vaccines, health measures in relation to international traffic, evidence-based response strategies, surveillance, and strengthening health systems.

Given that the impact of vaccines in reducing transmission is yet unknown, and the current availability of vaccines is too limited, the committee recommended that countries do not require proof of vaccination from incoming travelers. WHO will continue to consider the scientific, regulatory, legal, and ethical aspects of introducing such a requirement

> **(extract) Recommendations to State Parties on Health Measures in Relation to International Traffic**
>
> - At the present time, do not introduce requirements of proof of vaccination or immunity for international travel as a condition of entry as there are still critical unknowns regarding the efficacy of vaccination in reducing transmission and limited availability of vaccines. Proof of vaccination should not exempt international travellers from complying with other travel risk reduction measures.
> - Implement coordinated, time-limited, risk-based, and evidence-based approaches for health measures in relation to international traffic in line with WHO guidance and IHR provisions. Careful consideration should be given to when and if travel bans should or should not be used as tools to reduce spread. Such decisions should be based on the best available evidence.
> - Share information with WHO on the effects of health measures in minimizing transmission of SARS-CoV-2 during international travel to inform WHO's development of evidence-based guidance.

Committee will be reconvened within three months at the discretion of the Director-General.

> IHR Emergency Committee recommendations: Statement on the sixth meeting of the International Health Regulations (2005) Emergency Committee regarding the coronavirus disease (COVID-19) pandemic (15 Jan 2021)

COVID-19 IHR Emergency Committee (list of members and advisors - Jan 2021)

Update on the ACT-Accelerator

COVAX

COVAX, the vaccines pillar of the ACT-Accelerator, is convened by CEPI, GAVI and WHO, with the ambition of contracting enough volumes to equitably deliver 2 billion doses of safe, effective and quality vaccines by the end of 2021. Candidates to be included in the COVAX Facility portfolio are being selected from the COVAX R&D portfolio and other clinical candidates.

At the opening of the 148th session of the Executive Board, Dr Tedros called for global solidarity and action, saying that WHO wants to "see vaccination underway in every country in the next 100 days" (by World Health Day on 7 April). This year's theme for World Health Day is health inequality

From Dr Tedros' opening remarks:

- countries with bilateral contracts – and control of supply – to be transparent on these contracts with COVAX, including on volumes, pricing and delivery dates
- vaccine producers to provide WHO with full data for regulatory review in real time, to accelerate approvals
- all countries introducing vaccines to only use vaccines that meet rigorous international standards for safety, efficacy and quality, and to accelerate readiness for deployment.

Dr Tedros' Opening Remarks at the Executive Board (18 Jan 2021)

Links to the 148th Executive Board

On 22 January 2021, COVAX Facility announced **the signing of an advance purchase agreement** for up to 40 million doses of the Pfizer-BioNTech vaccine and rollout would commence with the successful negotiation and execution of supply agreements.

COVAX Facility also confirmed that, pending WHO Emergency Use validation, it will exercise an option to receive its first 100 million doses of the AstraZeneca/Oxford University-developed vaccine manufactured by Serum Institute of India (SII) through an existing agreement with SII. COVAX also anticipates additional 50 million doses will be made available for delivery in Q1 2021.

Building on the work to support country readiness, a **"Country Readiness Portal"** will be launched by WHO this month, which will allow AMC participants to submit final national deployment and vaccination plans (NDVPs).

Joint press release: COVAX Announces new agreement, plans for first deliveries (22 Jan 2021)

COVAX Supply Forecast (20 Jan 2021)

Draft landscape and tracker of COVID-19 candidate vaccines (22 Jan 2021)

Alignment of approaches by regulators

Draft WHO Guidance for comments

Guidelines on monoclonal antibodies for infectious diseases: (inputs by 15 Feb 2021)

WHO is drafting a guideline on the quality and manufacture of monoclonal antibodies (mAbs), as well as a separate regulatory guidance document on the safety and efficacy evaluation of mAbs and antibody mimetics (AMs) for use in the pre-exposure prophylaxis and treatment of infectious diseases. Supplements that provide additional guidance for the development and evaluation of products to specific diseases, including Covid-19, are proposed.

WHO would like to identify any regulatory considerations that may be unique to the clinical evaluation

of mAbs, AMs, or DNA/RNA-encoded mAbs directed to Covid-19.

> Guidelines on monoclonal antibodies for infectious diseases: call for public comment
>
> Please use the WHO Comment Form to provide your comments to Dr Richard Isbrucker, at isbruckerr@who.int, by 15 Feb 2021

Evaluation of the quality, safety and efficacy of RNA-based prophylactic vaccines for infectious diseases: regulatory considerations (comments by 31 Jan 2021)

Given the potential of mRNA vaccines as a platform technology to quickly respond to public health emergencies, such as the current COVID-19 pandemic, the need for international regulatory convergence for evaluation of mRNA vaccines is clear. The WHO Expert Committee on Biological Standardization discussed these issues at its meetings in August and December 2020 and supported the development of a document on regulatory considerations for the evaluation of mRNA vaccines, which could be updated as more scientific and clinical data became available. WHO therefore initiated activities to review scientific and regulatory issues of mRNA vaccines, set up drafting group and working group to develop regulatory considerations for the evaluation of mRNA vaccines.

A draft document has been published for inviting public comments. This document provides scientific information and regulatory considerations on key aspects of the manufacture and quality control, nonclinical and clinical evaluation of prophylactic mRNA-based vaccines.

> Draft Guidance - Evaluation of the quality, safety and efficacy of RNA-based 6 prophylactic vaccines for infectious diseases: regulatory considerations (22 Dec 2020)
>
> Please use the WHO Comment Form to provide your comments to Dr Tiequn ZHOU, at zhout@who.int, by 31 Jan 2021.

WHO is also seeking comments on draft proposals for inclusion in *The International Pharmacopeia* on **remdesivir, remdesevir intravenous infusion and oxygen**.

Comments are requested by **28 Feb 2021**.

> REMDESIVIR (REMDESIVIRUM
>
> REMDESIVIR INTRAVENOUS INFUSION (REMDESIVIRI INFUSIO INTRAVENO)
>
> OXYGEN (OXYGENIUM)

ICMRA statement for healthcare professionals on COVID-19 vaccines

The global impact of the COVID-19 pandemic has resulted in an unprecedented level of public interest in vaccines and their development and regulatory review. This has taken place mainly through mass and social media some of which have also led to a significant amount of misinformation and disinformation, raising concerns on vaccine hesitancy or opposing to vaccination.

To assist healthcare professionals and public health authorities who have a central role in discussing about COVID-19 vaccines and vaccination with their patients, the ICMRA developed a statement which describes the regulatory processes associated with the review of COVID-19 vaccines for safety, efficacy and quality. It also explains the arrangements put in place both nationally and globally for ongoing safety monitoring of different COVID-19 vaccines once they are on the market.

> ICMRA statement for healthcare professionals: How COVID-19 vaccines will be regulated for safety and effectiveness (including Q&As)

In vitro diagnostics

WHO EUL and listing update

The WHO Prequalification Unit is assessing products for Emergency Use Listing (EUL) for candidate

in vitro diagnostics (IVDs) to detect SARS-CoV-2. The following IVDs are eligible for EUL submission:

- Assays for the detection of SARS-CoV-2 nucleic acid;
- Rapid diagnostic tests and enzyme immunoassays for the detection of IgM/IgG to SARS-CoV-2; and
- Rapid diagnostic tests for the detection of SARS-CoV-2 antigens.

WHO EUL submissions

Applicants are asked to submit their applications for assessment based on WHO instructions and requirements for NAT and Ag detection RDTs and IVDs detecting antibodies to SARS-CoV-2 virus.

Manufacturers who are interested in an EUL submission for assays to detect SARS-CoV-2 are invited to contact diagnostics@who.int, to arrange a pre-submission meeting/videoconference/phone conversation.

So far, 27 products have been listed as eligible for WHO procurement among a total of 113 expressions of interest (59 for NAT assays, 35 for antibody detection assays and 19 for antigen detection RDTs) have been received.

> The status of each EUL application (19 Jan 2021)

WHO Information Note for IVD users concerning SARS CoV-2 variants

A new product agnostic WHO Information Notice for IVD Users (2021/01) was issued for all IVDs for detection of SARS-CoV-2. Following the detection of SARS-CoV-2 variants containing mutations, including SARS-CoV-2 VOC 202012/01, and SARS-CoV-2 501Y.V2, WHO reminds users of IVDs to monitor detection rates for SARS-CoV-2 at their site. IVD users should routinely review test results to detect unexpected increases or decreases in test results, including positivity rate, target detection rate, invalid or unreturnable result rate, etc. These variations may be early indicators of impact on the safety, quality or performance of the IVD products. Certain mutations may increase the risk of delayed diagnosis (due to inconclusive or invalid results) and misdiagnosis.

> WHO Information Notice for IVD Users 2021/01: all IVDs for detection of SARS-CoV-2 (19 Jan 2021)

Updated WHO Information Note on nucleic acid testing technologies

In a product agnostic Information Note, WHO Information Notice for IVD Users (2020/05) WHO **re-affirms that PCR tests, properly used, are a highly reliable tool for COVID-19 diagnosis** and requests users to follow the instructions for use (IFU) when interpreting results for specimens tested using PCR methodology. Users of IVDs must read and follow the IFU carefully to determine if manual adjustment of the PCR positivity threshold is recommended by the manufacturer.

WHO guidance on Diagnostic testing for SARS-CoV-2 states that careful interpretation of weak positive results is needed. The cycle threshold (Ct) needed to detect virus is inversely proportional to the patient's viral load. Where test results do not correspond with the clinical presentation, a new specimen should be taken and retested using the same or different NAT technology.

> WHO Information Notice for IVD Users (2020/05): NAT technologies that use PCR for detection of SARS-CoV-2 (20 Jan 2021)

IVDs listed by National Regulatory Authorities in IMDRF jurisdictions

To help countries, WHO publishes links to emergency lists, together with contact details, on IVDs authorized for use in the International Medical Device Regulators Forum (IMDRF) jurisdictions along with other useful information on policies and guidance.

The most recent update (18 Jan 2021)

Note: **WHO does not endorse any of the lists provided by NRAs. The information is provided exclusively to assist stakeholders with identifying the links to the various lists.**

Therapeutics

Research mapping of candidate therapeutics

A living research mapping of candidate COVID-19 therapeutics, displaying studies per country, showing study design, disease severity in study participants, and type of treatment being studied, as well as network maps of these studies, has been made available at: https://www.covid-nma.com/dataviz/

Living synthesis of Covid-19 study results

A list of treatment comparisons, a summary of the evidence for that comparison, and a detailed description of primary studies, including a risk of bias assessment is at: https://covid-nma.com/living_data/index.php

Convalescent plasma and blood

Advisory Group on Blood Regulation, Availability and Safety: Call for Experts:

WHO has announced a call for experts for an Advisory Group on Blood Regulation, Availability and Safety. One of the functions of the Advisory Group being formed is to provide scientific assessment of current and emerging threats to the safety and availability of blood and blood products. The Advisory Group will advise on the recommended measures and actions to be taken by the Member States in preparedness for and in response to the emerging public health threats.

Nomination requested by **28 February 2021**.

Call for Experts - Advisory Group on Blood Regulation, Availability and Safety

Vaccines

Pfizer/BioNTech Comirnaty COVID-19 mRNA vaccine

WHO COVID-19 Vaccine Explainer: COMIRNATY®

This document has been developed to help explain the newly COVID-19 vaccine manufactured by Pfizer that has received Emergency Use Listing by WHO: COMIRNATY®.

COMIRNATY® is a messenger RNA (mRNA) based vaccine against coronavirus disease 2019 (COVID-19). The mRNA instructs the cell to produce proteins of the S antigen (a piece of the spike protein unique to SARS-CoV-2) to stimulate an immune response. Efficacy shown in clinical trials in participants with or without evidence of prior infection with SARS-CoV-2 and who received the full series of vaccine (2 doses) was approximately 95% based on a median follow-up of two months.

Vaccine Explainer: COMIRNATY® COVID-19 mRNA vaccine

EMA authorizes extra dose from vials of Comirnaty COVID-19 vaccine

The EMA's human medicines committee (CHMP) has recommended updating the product information for Comirnaty to clarify that each vial contains 6 doses of the vaccine.

In order to extract six doses from a single vial, low dead-volume syringes and/or needles should be used. The low dead-volume syringe and needle combination should have a dead volume of no more

than 35 microliters. If standard syringes and needles are used, there may not be enough of the vaccine to extract a sixth dose from a vial.

If the amount of vaccine remaining in the vial after the fifth dose cannot provide a full dose (0.3 ml), the healthcare professional must discard the vial and its contents. There should be no pooling from multiple vials to make up a full dose, and any unused vaccine should be discarded 6 hours after dilution.

Comirnaty Product Information as approved by the CHMP (08 Jan 2021)

EMA Product information on Comirnaty

Updates from the Global Advisory Committee on Vaccine Safety

On 19th January, the GACVS COVID-19 Vaccine Safety subcommittee met virtually to review available information and data on deaths reported in frail, elderly individuals who had received the Pfizer BioNTech COVID-19 mRNA vaccine, BNT162b2 (hereafter, BNT162b2). Experts invited from the European Medicines Agency (EMA) and the Uppsala Monitoring Center (UMC) provided an overview of deaths reported in Europe and in the WHO global database (VigiBase) following vaccination with BNT162b2.

The subcommittee concluded the current reports do not suggest any unexpected or untoward increase in fatalities in frail, elderly individuals or any unusual characteristics of adverse events following administration of BNT162b2. Reports are in line with the expected, all-cause mortality rates and causes of death in the sub-population of frail, elderly individuals, and the available information does not confirm a contributory role for the vaccine in the reported fatal events.

In view of this, the committee considers that the benefit-risk balance of BNT162b2 remains favorable in the elderly, and does not suggest any revision, at present, to the recommendations around the safety of this vaccine. The GACVS subcommittee will continue to monitor the safety data from these vaccines and update any advice as necessary.

GACVS COVID-19 Vaccine Safety subcommittee meeting to review reports of deaths of very frail elderly individuals vaccinated with Pfizer BioNTech COVID-19 vaccine, BNT162b2 (22 Jan 2021)

WHO COVID-19 vaccination training course for health workers

WHO is working in collaboration with scientists, businesses and global health organizations to speed up the pandemic response and facilitate the equitable access and distribution of COVID-19 vaccines. This Open course, primarily for frontline health workers provides general information on COVID-19 and specific information on storage, handling and administration of the vaccine, recording and monitoring including for adverse events following immunization (AEFI), and communication (acceptance and demand) through a series of short video lectures and quizzes to test your knowledge.

COVID-19 vaccination training for health workers

WHO Operational Tool for efficient lot release of COVID-19 vaccines

WHO issued an operational tool to assist NRAs in all countries to apply principles described in WHO Technical Guidelines to implement efficient and effective lot release of COVID-19 vaccines. The scope of the document includes those granted WHO EUL and is intended to mitigate potential bottlenecks and unnecessary wastage of these urgently needed products under the public health emergency of international concern.

WHO's recommended lot release strategy is to rely on the lot release certificates issued by the responsible NCL that are provided with each batch of EUL vaccines. If countries are required by law to review the summary lot protocols, vaccine release should be done quickly and through the review

of the minimum documents. The overall release time should not be more than 2 working days.

Several countries have indicated to WHO that, rather than retest, they will implement reliance on the release performed by the responsible NRA/NCL. WHO considers this to be a good model and countries considering repeat in-country laboratory testing for COVID-19 vaccines are strongly encouraged to consult with WHO on the challenges of doing so and on other strategies available prior to making any decision on lot release procedures.

WHO Operational Tool for efficient and effective lot release of SARS-CoV-2 (Covid-19) vaccines (20 Jan 2021)

WHO Model NRA/NCL Lot Release Certificate for SARS-CoV-2 (Covid-19) vaccines (20 Jan 2021)

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

WHO has placed into the public domain the status of COVID-19 vaccines for which an expression of interest has been received by WHO/PQ. The information shared includes the National Regulatory Authority (NRA) of record for each vaccine; whether the expression of interest has been accepted; if a pre-submission meeting has been held; if the dossier has been accepted for review; the status of the assessment; and the anticipated decision date.

Version 20 Jan 2021

Status of COVID-19 Vaccines within WHO EUL/PQ evaluation process (20 January 2021)

	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 (INN tozinameran)	EMA	Nucleoside modified mNRA	✓	✓	✓	Finalized	31/12/20
2.	Zhifei Longcom, China	Recombinant Novel Coronavirus Vaccine (CHO Cell)	NMPA	Recombinant protein subunit	Not accepted Product in Phase I/II				
3.	IMBCAMS, China	SARS-CoV-2 Vaccine, Inactivated (Vero Cell)	NMPA	Inactivated	Not accepted, still under development				
4.	AstraZeneca / Oxford	AZD1222	Core – EMA Non-COVAX	recombinant replication defective chimpanzee adenovirus expressing the SARS-CoV-2 S surface glycoprotein	✓	✓	✓	In progress Core data Non-Covax. Covax data to be reviewed as EMA post approval change	Earliest by EMA End of Jan-Feb 2021 (non- Covax) Additional nodes in March/ April for Covax
5.	SK BIO AstraZeneca / Oxford	AZD1222	MFDS KOREA	=	✓	✓	Tentative 18 and 29 Jan 2021 (CMC for SK Bio)	Core data (non-Covax) in progress	Earliest 2nd half Feb 2021
6.	Janssen Infectious Diseases & Vaccines	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, Feb, Apr (critical data), May ✓	Not yet started. Use abridged procedure relying on EMA	Earliest May – June 2021
7.	Sinopharm / BIBP[2]	SARS-CoV-2 Vaccine (Vero Cell), Inactivated (InCoV)	NMPA	Inactivated, produced in Vero cells	✓	✓	End of Dec 2020	In progress	Earliest March
8.	sinovac	SARS-CoV-2 Vaccine (Vero Cell), Inactivated	NMPA	Inactivated, produced in Vero cells	✓	✓	13Jan2021 (under screening)		Earliest March
9.	The Gamaleya National Center	Sputnik V	Russian NRA	Human Adenovirus Vector-based Covid-19 vaccine	Additional information submitted – under assessment	✓	22Jan2021 discussion on content and format		
10.	Vector State Research Centre of Virology and Biotechnology	EpiVacCorona	Russian NRA	Peptide antigen	Letter received not EOI				
11.	康希诺生物 CanSinoBIO	Ad5-nCoV		Recombinant Novel Coronavirus Vaccine (Adenovirus Type 5 Vector)	Additional information requested	26Jan 2021			
12.	moderna	mRNA-1273	EMA	mNRA-based vaccine encapsulated in lipid nanoparticle (LNP)	Expected in Feb 2021				Estimated end of Feb 2021
13.	Serum Institute of India	Covishield (ChAdOx1_nCoV-19)	DCGI	recombinant ChAdOx1 adenoviral vector encoding the Spike protein antigen of the SARS-CoV-2	✓	08Jan 2021	13 Jan (Under screening)		Mid Feb 2021
14.	Sinopharm / WIBP[1]		NMPA	No pre-submission meeting yet					
15.	NOVAVAX		EMA	No pre-submission meeting yet					

* Dossier Submission dates: more than one date is possible because of the rolling submission. Dossier is accepted for submission after screening of received submission
** Status of assessment: 1. Under screening; 2. Under assessment; 3. Waiting responses from the applicant. 4. Risk-benefit decision 5. Final decision made
*** Anticipated decision date: this is only an estimate because it depends on when all the data is submitted under rolling submission and when all the responses to the assessors' questions are submitted.
1. Wuhan Institute of Biological Products Co Ltd
2. Beijing Bio-Institute of Biological Products Co-Ltd

Please visit the site regularly for the updated version.

https://extranet.who.int/pqweb/vaccines/covid-19-vaccines

The WHO EUL/PQ assessment of the Sinovac inactivated Vero cell grown vaccine is in progress with an anticipated decision March 2021 at the earliest.

The Oxford/AstraZeneca recombinant chimpanzee adenovirus vector vaccine encoding the SARS-CoV-2 Spike (S) glycoprotein is being manufactured in several nodes worldwide.

The WHO EUL/PQ assessments of the vaccine being produced in these nodes, which are under the responsibility of different NRAs, are in progress with anticipated decisions from February 2021 onwards.

Status of COVID-19 vaccines: country- or region-specific information *(selected)*

WHO is aware that regulators in several countries have issued various types of authorizations to enable emergency use of specific COVID-19 vaccines. WHO can only speak about the attributes of specific products for which we have access to data which would require the product being assessed through EUL/PQ. WHO also acknowledges the regulatory reviews by specified stringent regulatory authorities (see "Product eligibility for the COVAX Facility", above), although unless WHO has specific access to data, the Organization cannot speak to the details of the product. Nevertheless, to help regulators and stakeholders, WHO is providing the following links to emergency listings by selected other countries.

Brazil

The Board of Directors of Anvisa approved the temporary authorization for emergency use of the CoronaVac vaccine, developed by the pharmaceutical company Sinovac in partnership with the Butantan Institute, and of the Covishield vaccine, produced by the pharmaceutical company Serum Institute of India, in partnership with AstraZeneca / Oxford University / Fiocruz.

Anvisa unanimously approves emergency use of vaccines (in Portuguese)

***Note:* WHO does not endorse any of the country-, or region-, specific information provided here. The information is provided exclusively to assist regulators and stakeholders with identifying the links to the various products.**

Research priorities for vaccines against SARS-CoV-2

On 15th January, WHO hosted a virtual forum with more than 2'800 scientists from 130 countries to identify knowledge gaps and set research priorities for vaccines against SARS-CoV-2, the virus that causes COVID-19. They discussed the safety and efficacy of existing vaccines and new candidates, ways to optimize limited supply, and the need for additional safety studies.

Experts agreed the need for critical research on administering vaccines in different target populations, as well as on vaccination delivery strategies and schedules. This includes trials, modelling and observational studies, all of which would help to inform policy. They discussed the impact of emerging SARS-CoV-2 variants on the efficacy of vaccines, the impact of vaccines on transmission of infection, and the need to develop the next generation of vaccine platforms.

The meeting concluded with agreement to establish a WHO-hosted platform for global sharing and coordination of emerging vaccine research information on efficacy and safety. The forum would enable scientists to share and discuss unpublished and published data and research protocols to further our collective understanding of SARS-CoV-2 vaccines.

A report of the meeting will be published shortly.

Scientists tackle vaccine safety, efficacy and access at global R&D forum (16 Jan 2021)

COVAX workshop on pre-and post-licensure assessments

On 17th December 2020, the COVAX Clinical Development & Operations SWAT Team and Post-introduction Evaluations Workstream hosted a workshop on "Pre-and Post-Licensure Assessments of COVID-19 Vaccine Efficacy Against Infection & Transmission." The main aim was to discuss available evidence concerning infection and transmission from ongoing Phase 3 efficacy trials, highlight remaining gaps in the understanding of COVID-19 infection and transmission following vaccination, and identify optimal study designs to collect effectiveness data once an emergency use

authorisation (EUA)/licensure is achieved.

The first part of the workshop provided an update on correlates of protection following a workshop held on November 19th. The second part of the workshop focused on lessons learnt related to prevention of asymptomatic virus infection and transmission from pre-licensure trials. The third part of the workshop focused on additional approaches to evaluating vaccine effectiveness against infection/transmission, including post-licensure studies.

COVAX Workshop Report (17 Dec 2020)

Landscape and tracker of COVID-19 candidate vaccines

The COVID-19 candidate vaccine landscape database compiles detailed information on COVID-19 vaccine candidates in development. (updated on Tuesdays and Fridays)

The landscape:

- provides summary tables of COVID-19 vaccine candidates in both clinical and pre-clinical development;
- provides analysis and visualization for several COVID-19 vaccine candidate categories;
- tracks the progress of each vaccine from pre-clinical, Phase 1, Phase 2 through to Phase 3 efficacy studies,
- provides links to published reports on safety, immunogenicity and efficacy data of the vaccine candidates;
- includes information on key attributes of each vaccine candidate; and
- allows users to search for COVID-19 vaccines through various criteria such as vaccine platform, dosage, schedule of vaccination, route of administration, developer, trial phase and clinical endpoints being measured in Phase 3.

Draft landscape and tracker of COVID-19 candidate vaccines (22 Jan 2021)

Research protocols, assays and reference standards

WHO Working Group: Animal Models

The Working Group, which meets weekly, has invited researchers to share emerging data on the characterization of SARS CoV2 variants, and also on the impact of the variants on diagnostics, therapeutics or vaccine-induced immunity or protection.

WHO Working Group: Assays and Reference Preparations

The WHO working group meeting on COVID-19 assays held on 20 Jan 2021 was open to vaccine developers and attended by >200 participants. The meeting focused on promoting the use of WHO international standards for SARS-CoV-2.

The WHO Expert Committee on Biological Standardization established the First WHO International Standard of anti-SARS-CoV-2 immunoglobulin with an assigned unitage of 250 International Unit (IU)/ampoule (neutralizing antibody activity) and the First WHO International Reference Panel of anti-SARS-CoV-2 immunoglobulin on 10th December 2020. These standards are primary calibrants with limited stock, but are intended to last for years. Secondary standards such as regional or national reference preparations should be established and calibrated against the WHO standards. Calibration of national references against a single global standard will facilitate comparison of results across assays (e.g., of the antibody response to COVID-19 vaccines) conducted in different settings/countries.

WHO called on participants to make use of international standards in such a way that assay results can be traced to IU to enable comparison of data. The meeting heard that a number of national or network initiatives to establish secondary standards are underway with intent to calibrate to these

materials against WHO standards.

Standardization of vaccines for coronavirus disease (COVID-19) (12 Jan 2021)

Substandard and falsified products

Risk mitigation measures for the threat of falsified COVID-19 vaccines

The global surveillance and monitoring system of WHO continues to receive notifications of SF medical products relating to Covid19. It is crucial that national regulatory focal points report any suspicious products to rapidalert@who.int.

The WHO team is also available to help NRAs respond to media queries relating to SF medical products with ready-made talking points (that can then be tailored). The general public should be reminded to only source products from the regulated / legitimate supply chain and, in particular, should not seek to directly procure COVID-19 vaccines.

Medical Devices

Two topics are on the agenda of the 148th WHO Executive Board:

EB148/12: Substandard and falsified medical products.

EB148/13: Standardization of medical devices nomenclature

More information on medical device nomenclatures

Join the launch: 3rd WHO Model List of Essential in vitro diagnostics

On 29th January from 14:30 to 16:00 CET, WHO will host the launch of the 3rd WHO Model List of Essential in vitro Diagnostics.

Please register at https://who.zoom.us/webinar/register/WN_WXNKujhjQKGqLbTqa8RxEA

For additional information, please contact EDL Secretariat at EDLsecretariat@who.int