Key Messages

On 1st March 2021, the first COVID-19 vaccination campaigns in Africa using COVAX doses began in Ghana and Côte d’Ivoire as the first to use doses provided by the COVAX Facility. On 24th February, Ghana became the first country outside India to receive doses of COVID-19 vaccine allocated to Advance Market Commitment (AMC) countries from the COVAX Facility, followed by Côte d’Ivoire on 26th February. More doses will be shipped to more countries in the coming days and weeks, as we move towards our target of starting vaccination in all countries within the first 100 days of the year.

Highlights and main issues

- As of 2 March 2021, 101 countries had issued regulatory authorizations of COVISHIELD or AZ/SKBio - COVID-19 vaccines, meeting a 15-day target recommended in the National Deployment and Vaccination Plan. This is major progress with in-country authorizations of COVID-19 vaccines following WHO EUL of the two vaccines on 15 February 2021.

- On behalf of COVAX Facility, WHO signed an agreement for the administration of no-fault compensation programme for the 92 AMC countries and economies without need to resort to law courts. This is the first and only vaccine injury compensation mechanism operating on an international scale.

- WHO has provided working definitions for variants of interest and variants of concern, which will help focus efforts on SARS CoV-2 variants of public health significance.

- Regulators have rapidly developed guidance on evaluation of changes, if needed, to SARS CoV-2 vaccines to address emerging variants. There is a high level of alignment between regulators on how vaccines will be evaluated to address emerging SARS CoV-2 variants.

- To date, WHO has not received any complaints for misdiagnosis using WHO EUL listed IVDs that could be linked to emerging SARS CoV-2 variants.

- Updated WHO treatment guidelines recommend against using hydroxychloroquine to prevent COVID-19. This recommendation applies to individuals with any baseline risk of developing COVID-19 and any hydroxychloroquine dosing regimen.

- WHO published updated interim guidance on maintaining a safe and adequate blood supply and collecting convalescent plasma in the context of the COVID-19 pandemic.

- Improper disposal of used Covid-19 vaccine vials may create an increased risk of circulation of falsified vaccines.

- Recognizing the importance of sustainable oxygen supply for the treatment of COVID-19, a COVID-19 Oxygen Emergency Taskforce was established to bring together key organizations working on oxygen access.
# 30th WHO Regulatory Update on COVID-19

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New virus variants

WHO’s working definitions of variants of interest and variants of concern

On 25th February, WHO has published working definitions for variants of interest and variants of concern, which will help focus efforts on variants of public health significance. A variant can be considered a “SARS-CoV-2 Variant of Interest (VOI)” if it (1) has mutations that are suspected or known to cause significant phenotypic changes and (2) is circulating widely (e.g. known to cause many clusters, or found in many countries) or assessed by WHO in consultation with the WHO SARS-CoV-2 Virus Evolution Working Group.

A VOI becomes a “SARS-CoV-2 Variant of Concern (VOC)” if it increases transmissibility or causes detrimental change in epidemiology, changes clinical presentation, or decrease effectiveness of known tools – public health and social measures or available diagnostics, treatments and vaccines.

The bar is set low for VOI so that there is sensitive surveillance, whereas the bar for VOC is high so that attention and resources are focused on those variants that are of public health importance. These are working definitions will be revised as necessary.

Special edition of Weekly epidemiological update (25 Feb 2021)

WHO’s Science in 5: Evolution of the SARS-CoV-2 virus with Dr Maria Van Kerkhove (05 Mar 2021)

Report of the WHO Consultation to identify approaches to assess variants

WHO held a global consultation on 11 February 2021 to identify methodological approaches to assess variants effect on vaccine efficacy, effectiveness and impact. The report of this consultation is now published with the following highlights.

This consultation outlined current WHO efforts to set up a mechanism to:

- provide guidance to vaccine manufacturers and countries, and to coordinate changes that may be needed for vaccines;
- discuss the most robust methodological approaches to assess, during vaccine roll-out, if a circulating new COVID variant has an impact on vaccine effect; and
- deliberate the research approaches that could be considered when assessing vaccines that have been adjusted to address vaccine efficacy issues with new variants.

The consultation affirmed that WHO must play a role in coordinating activities to identify the need for vaccines against new SARS-CoV-2 variants and the sequences that are most appropriate for global
use. The consultation concluded that as vaccines are deployed, it will be essential to gather data on their performance against evolving variants.

Regulatory alignment at a global level is critical as harmonized approaches across regulatory agencies will help to expedite the development of vaccines targeting important new variants, as well as to ensure timely access to safe, effective and quality assured vaccines.

In addition, alongside open communication among multiple global professional communities, it is essential that public communication is also prioritized to raise awareness of key challenges and ongoing activities, and to build and maintain public confidence in COVID-19 vaccination.

Report: Methodological approaches to assess variants effect on vaccine efficacy, effectiveness and impact (01 Mar 2021)

Regulatory guidance on changes to vaccines made to address variants

Regulators have rapidly developed guidance to evaluate changes made on already authorized COVID-19 vaccines that address emerging SARS CoV-2 variants and living guidances have already been published by the US FDA, the EMA and regulators from the ACCESS Consortium (Australia, Canada, Singapore, Switzerland and the UK). As these regulators had opportunities to share key features of the guidance during the development process, the published guidances indicate a high level of alignment on requirements to evaluate changes made on already-approved vaccines that are addressing SARS-CoV-2 variant(s).

The guidances assume that neutralizing antibody to SARS-CoV-2 is a major component of the vaccine protective response and it is not feasible to conduct clinical disease endpoint efficacy studies rapidly enough to respond to the emergence of SARS-CoV-2 variants that may escape immunity conferred by prototype vaccines. Instead, clinical immunogenicity studies are recommended to compare immune responses induced by the modified vaccine against the SARS-CoV-2 variant(s) of concern with those induced by the prototype vaccine against the virus upon which the prototype vaccine was based. The immunogenicity studies should assess the effectiveness of a primary series and a booster dose of the modified COVID-19 vaccine.

All guidance’s will be “living guidance” to be modified, if needed, as further knowledge and data on variants become available.


EMA: Reflection paper on the regulatory requirements for vaccines intended to provide protection against variant strain(s) of SARS-CoV-2 (25 Feb 2021)

ACCESS Consortium: Guidance on strain changes in authorized COVID-19 vaccines (04 Mar 2021)

The effects of virus variants on COVID-19 vaccines

As part of a series of explainers on vaccine development and distribution, WHO published a webpage on the effects of virus variants on COVID-19 vaccines.

It features the following topics:

- What causes a virus to change to a new variant?
- What impact do the new variants of the COVID-19 virus have on vaccines?
- What is WHO doing to monitor and understand the impact of virus variants on the efficacy of COVID-19 vaccines?
- How can we prevent future new variants of the COVID-19 virus?
- Why is it important to get vaccinated even if there are new variants of the virus?

The effects of virus variants on COVID-19 vaccines (01 Mar 2021)

WHO’s Science in 5: Vaccines, variants & herd immunity with Dr Soumya Swaminathan (26
US FDA Policy guidances to address the variants of SARS-CoV-2

In addition to the above-mentioned vaccines specific guidance, the US FDA issued guidances for diagnostics and therapeutics products, to address the emergence and potential future emergence of variants of SARS-CoV-2, the virus that causes COVID-19.


Policy guidance for evaluating impact of variants on COVID-19 tests

FDA issued a new guidance for COVID-19 test developers, providing information on evaluating the potential impact of emerging and future viral mutations of SARS-CoV-2 on COVID-19 tests for the duration of the COVID-19 public health emergency. The guidance includes design considerations and ongoing monitoring as mutations in the SARS-CoV-2 virus can influence molecular test performance. Changes in the viral genome can result in changes to viral proteins and, therefore, can also impact the performance of an antigen or serology test.

The FDA has already issued a safety alert to caution that the presence of viral genetic mutations in a patient sample can potentially change the performance of a diagnostic test. The FDA identified a few tests that are known to be impacted by emerging viral mutations, though at this time the impact does not appear to be significant.

Policy for Evaluating Impact of Viral Mutations on COVID-19 Tests (Feb 2021)

Development of monoclonal antibody products and the impact of variants

To address the impact of emerging variants of SARS-CoV-2 on the development of monoclonal antibody products targeting the virus, the FDA has issued a new guidance. Emerging variants may, in some cases, result in reduced susceptibility to currently authorized or approved therapeutic products, compounding an urgent unmet medical need. Monoclonal antibody products are designed to bind to the viral envelope protein that mediates attachment of the virus to the host cell receptor and thereby sterically inhibit viral entry, and/or elicit fragment crystallizable-mediated (Fc-mediated) effector function by binding to the viral envelope protein in the host cell membrane of infected cells.

The FDA strongly recommends that individual monoclonal antibody products be developed with the expectation that they will be combined with one or more monoclonal antibody products that bind to different epitopes to minimize the risk of losing activity against emergent variants. The guidance includes recommendations on chemistry, manufacturing, and controls; pharmacology toxicology; virology; and clinical evaluations.

Development of Monoclonal Antibody Products Targeting SARS-CoV-2, Including Addressing the Impact of Emerging Variants, During the COVID 19 Public Health Emergency (22 Feb 2021)

Revised guidance covering drugs and biological products

FDA has also revised a second guidance covering drugs and biological products more broadly for COVID-19, regarding phase 2 and phase 3 clinical trials for drugs and biological products under development to treat or prevent COVID-19, including the patient population, trial design, efficacy endpoints, safety considerations and the statistical considerations for such trials and more.

COVID-19: Developing Drugs and Biological Products for Treatment or Prevention Guidance for Industry (Feb 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.

**Ghana and Côte d’Ivoire began COVID-19 vaccination campaigns**

On 1st March, the governments of Côte d’Ivoire and Ghana began COVID-19 vaccination campaigns aimed at protecting healthcare workers. This first vaccination campaigns happen as a further 11 million COVAX doses are expected to be delivered over the next seven days.

The campaigns in Ghana and Côte d’Ivoire follow deliveries to both countries with Ghana taking delivery of 600’000 doses on 24th February, shipped from Mumbai via Dubai, where the flight also collected a shipment of syringes from a Gavi-funded stockpile at UNICEF’s regional Supply Hub and Côte d’Ivoire 504’000 doses on 26th February.

Both countries received the COVISHIELD, AstraZeneca vaccine licensed and manufactured by the Serum Institute of India. The deliveries mark the start of what will be the largest, most rapid and complex global rollout of vaccines in history. In total, COVAX aims to deliver at least 2 billion doses of COVID-19 vaccines by the end of 2021, including at least 1.3 billion to the 92 economies eligible for support through the COVAX AMC.

Confirmation of first-round allocations, covering the majority of the COVAX Facility participants, was published 2nd March 2021. COVAX COVISHIELD to date have been delivered to India, Ghana, Cote d’Ivoire, while Pfizer-BioNTech vaccines were delivered to the Republic of Korea. More deliveries by these two manufacturers are planned in the coming days and AstraZeneca SKBio doses are set to commence shipments shortly.

- First COVID-19 COVAX vaccine doses administered in Africa (01 Mar 2021)
- COVID-19 vaccine doses shipped by the COVAX Facility head to Ghana, marking beginning of global rollout (24 Feb 2021)

**Country preparedness prior to receiving COVID-19 vaccines**

COVAX Facility participates must clear a number of critical pieces in order to receive COVID-19 vaccines from the COVAX Facility. Critical pieces include confirmation of national regulatory authorisation criteria related to the vaccines delivered, indemnification agreements, national vaccination plans, as well as other logistical factors such as export and import licenses.

Over the past several months, COVAX partners, Gavi, WHO and CEPI, working in partnership with UNICEF as well as the World Bank, civil society organisations, manufacturers, and others, have been supporting governments, particularly for AMC-eligible participants, in readiness efforts, in preparation for this moment. This includes assisting with the development of national vaccination plans, support for cold chain infrastructure, as well as stockpiling of half a billion syringes and safety boxes for their disposal, masks, gloves and other equipment to ensure that there is enough equipment for health workers to start vaccinating priority groups as soon as possible.

- Country readiness for COVID-19 vaccines (19 Feb 2021)
WHO COVID-19 vaccine introduction toolbox

WHO has launched a the COVID-19 vaccine introduction toolbox, which provides guidance, tools, and training to equip all countries to prepare for and implement COVID-19 vaccination. This toolbox – intended to support Ministries of Health, health workers, partner organizations, and other stakeholders – is organized in line with the Guidance on Developing a National Deployment and Vaccination Plan for COVID-19 vaccines and will be updated as new resources become available.

WHO support for regulatory authorizations of COVID-19 vaccines

Since the start of the pandemic, WHO has been working with National Regulatory Authorities (NRAs) and WHO Regional offices to share information on regulatory preparedness and key updates to ensure streamlined regulatory processes for emergency use authorization of COVID-19 vaccines. WHO has been engaging with NRAs on two major regulatory approaches for expedited in-country regulatory authorizations based on reliance to (a) WHO PQ EUL or Stringent Regulatory Authority EUA or conditional marketing authorization or (b) other authorization for use under exceptional circumstances.

WHO has also been supporting NRAs with signed confidentiality disclosure agreements to facilitate accessing to documentation (manufacturer’s dossier and PQ/EUL assessment report). Based on these approaches, as of 2 March 2021, 101 countries, out of 145 COVAX participating countries and economies, had issued regulatory authorizations of COVISHIELD or AZ SKBio COVID-19 vaccines, successfully meeting a 15-days target recommended in the NDVP. In addition, Pfizer vaccine was granted regulatory authorization in 15 of 18 COVAX AMC countries to receive the first wave of vaccine. WHO will continue to follow up countries where authorization is in progress or not yet complete and the use of reliance on WHO PQ EUL in issuing a regulatory authorization is strongly encouraged.

WHO PQ Confidentiality form for NRAs

COVAX publishes first round of allocations

Following from the publication of an interim distribution forecast, and based on current knowledge of supply availability, the first round of allocations outlines delivery of doses of the AZ/Oxford vaccine – manufactured by AstraZeneca (AZ) SK BIO and COVISHIELD, licensed to and manufactured by Serum Institute of India – to Facility participants through May 2021 has been published. Indicative timelines for the supply of these doses, split into Feb-March and April-May will also be published. These timelines are dependent on a variety of factors including national regulatory requirements, availability of supply, and fulfilment of other criteria such as validated national deployment and vaccination plans from Facility participants, indemnification & liability agreements, and export and
import authorizations.

WHO News: **COVAX publishes first round of allocations** (02 Mar 2021)

GAVI: **1st Round of Allocation: AZ vaccines, Feb-May 2021** (02 Mar 2021)


**Report of the Joint Allocation Taskforce (JAT) on the distribution of COVAX Facility secured vaccines** (19 Feb 2021)

Allocations results (excel)

**Allocation logic and algorithm to support allocation of vaccines secured through the COVAX Facility: Explainer based on commonly asked questions** (15 Feb 2021)

**List of COVAX AMC Countries** (15 Dec 2020)

### No-fault compensation programme for COVAX AMC Countries

On behalf of COVAX Facility, WHO signed an agreement for the administration of no-fault compensation programme for the 92 AMC countries and economies without need to resort to law courts. As the first and only vaccine injury compensation mechanism operating on an international scale, the programme will offer eligible individuals in AMC-eligible countries and economies a fast, fair, robust and transparent process to receive compensation for rare but serious adverse events associated with COVAX-distributed vaccines until 30 June 2022. EISI Inc., a Chubb company, is the independent administrator of the programme, and was selected in accordance with WHO’s procurement rules and procedures, and charges no fees to applicants.

The COVAX no-fault compensation programme will be operationalized through its web portal, [www.covaxclaims.com](http://www.covaxclaims.com), by 31 March 2021, which will include resources such as the programme’s protocol, Frequently Asked Questions and information on how to submit an application.

Eligible individuals may apply for compensation under the programme once the portal becomes operational, even if a COVAX-distributed vaccine is administered to them before 31 March 2021. The programme is financed initially through Gavi COVAX AMC donor funding, calculated as a levy charged on all doses of COVID-19 vaccines distributed through the COVAX Facility to the AMC eligible economies until 30 June 2022.

**No-fault compensation programme for COVID-19 vaccines is a world first** (22 Feb 2021)

### Alignment of approaches by regulators

**ICMRA pregnancy and lactation workshop**

In the current context of the COVID-19 pandemic pregnant and lactating/breastfeeding women become infected and require treatment for COVID-19, but there are no data from this population for most of emerging treatments and vaccines. For example, pregnant and breastfeeding women have not been included in clinical trials for COVID-19 vaccines. This reality is reason to reflect and act not only for COVID-19 medicines and vaccines but also use the experience to agree a new global strategy to obtain systematic data in these populations. To have a real impact, international collaboration and a global convergent regulatory approach are key.

To address these needs ICMRA held a workshop on 9 February 2021 with the objective to take stock of available information and development strategies for COVID-19 vaccines and therapies in pregnant and breastfeeding women; to understand knowledge gaps and how these can be overcome; to work towards regulatory convergence to address the gaps; and to explore how to leverage the experience from COVID-19 vaccines in pregnant and breastfeeding women to move forward on a global strategy aiming at getting systematic information on these population groups.

**ICMRA Pregnancy and Lactation Workshop** (09 Feb 2021)
Draft WHO Guidance for comments

Draft proposals for inclusion in The International Pharmacopeia
- Gelatin (Comments by 31 Mar 2021)
- Ethanol, Anhydrous (Comments by 31 Mar 2021)
- Ethanol 96% (V/V) (Comments by 31 Mar 2021)

Draft guidance for comments:
- Good manufacturing practices 6 for medical gases (Comments by 30 Mar 2021)
- Guidance on setting remaining shelf life for the supply and procurement of Emergency Health Kits (Comments by 15 Apr 2021)

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 128 expressions of interest (59 for NAT assays, 40 for antibody detection assays and 29 for antigen detection RDTs) have been received.
- EUL listed IVDs (17 Feb 2021)
- Status of each EUL application (02 Mar 2021)

Impact of variants on safety of SARS-CoV-2 IVDs
WHO is in contact with each manufacturer of WHO emergency use listed products to specifically remind them to update their post-market surveillance plan with a procedure for proactive surveillance of mutations that might impact their product. To date, WHO has not received any complaints for misdiagnosis using IVDs that are WHO emergency use listed that could be linked to emerging variants.

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.
**Webinar on SARS CoV-2 diagnostic tests**

Understanding the significance and clinical impact of the latest diagnostic innovation is essential for healthcare providers. For this purpose, a webinar with international experts was held on 1st March 2021 to discuss the ways diagnostic developments impact public health and the challenges associated with regulation and implementation during the pandemic.

Speakers included:
- Hanan Balkhy, Assistant Director General for Antimicrobial Resistance, also leading ACT-A Diagnostics Pillar, WHO
- Emma Hannay, ACT-A Diagnostics Secretariat, Foundation for Innovative New Diagnostics
- Frank Konings, Senior Laboratory Advisor, WHO
- Irena Prat, Team lead, Prequalification Diagnostics, WHO

Videos: [English](#) / [French](#) / [Spanish](#)  

**Call for experts: SAGE IVDs, by 31 March 2021**

The World Health Organization (WHO) invites highly qualified experts to submit their application to become members of the WHO Strategic Advisory Group of Experts on In Vitro Diagnostics (SAGE IVD), an advisory body to WHO on matters of global policies and strategies related to IVDs including the ones pertaining to WHO Model List of Essential In Vitro Diagnostics.

SAGE IVD members are appointed for 2 years and can be re-appointed once.

**Therapeutics**

**WHO guidelines advise against use of hydroxychloroquine to prevent COVID-19**

Updated WHO guidelines recommend against using hydroxychloroquine to prevent COVID-19. This recommendation applies to individuals with any baseline risk of developing COVID-19 and any hydroxychloroquine dosing regimen. This follows previous guidance issued in December 2020 against the use of the drug to treat COVID-19. The guideline development group also concluded that the drug is no longer a research priority; resources should focus on other more promising drugs to prevent COVID-19. Note: the use of hydroxychloroquine and chloroquine are accepted by WHO as generally safe for use in patients with autoimmune diseases or malaria.

[ BMJ 2021, 372 (02 Mar 2021) ]

**WHO Global consultation on COVID-19 therapeutics**

WHO hosted a Global consultation on COVID-19 therapeutics on 3 March 2021 to discuss knowledge gaps and research priorities, with the following objectives to outline:

- the main priority research questions of importance to public health and a targeted research agenda for 2021 that identifies knowledge gaps and prioritization pathways for therapeutics in clinical development phase and those being repurposed, including combinations, and research priorities for new COVID therapeutics; and
- additional steps to ensure further international collaboration supports the coordinated implementation of key research.
A report of the meeting will be published in the near future.

**Clinical trials**

**International Clinical Trials Registry Platform (ICTRP)**

Information on clinical trials and trial registration. Clinical trials registered with the ICTRP platform can be searched and details of COVID-19 clinical trials can be downloaded in csv and xml formats.


A real-time monitoring and mapping of new evidence for treating and preventing COVID-19, with living mapping of trials and living synthesis of published trials.

**Global Coronavirus COVID-19 Clinical Trial Tracker (Cytel)**

An interactive dashboard of clinical trials on COVID-19 that can be explored by type of product, trial status and country.

**Convalescent plasma and blood**

**Updated WHO interim guidance** on maintaining a safe and adequate blood supply and collecting convalescent plasma in the context of the COVID-19 pandemic

Updated interim guidance from WHO include considerations for a precautionary deferral period of up to seven days for recipients of SARS-CoV-2 vaccines to minimize the impact of call-backs from donors who develop symptoms subsequent to donating soon after vaccination. Recommendations include the use of reference reagents for determining the binding and neutralizing activity of SARS-CoV-2 antibodies that have been calibrated against the First WHO International Standard for anti-SARS-CoV-2 immunoglobulin (NIBSC code 20/136), to express the assay results in International Units. The document also provides scientific updates on reported experience with experimental use of convalescent plasma, including randomized controlled trials and several uncontrolled case series.

[LINK TO DOCUMENT]

**Vaccines**

**Online access to clinical data used to support vaccine authorizations**

To support vaccine confidence, trust in regulators and transparency the EMA and Health Canada have published the full clinical data package reviewed as part of their authorisations of the Moderna COVID-19 vaccine. The data sets are available through these public portals:

- Health Canada Public Release of Clinical Information Portal
- EMA Clinical Data Portal

**Draft landscape of observational study designs on the effectiveness of COVID-19 vaccination**

WHO has published a new landscape document that provides an overview of the different observational studies that are being conducted to assess the effectiveness of COVID-19 vaccination, including key features in terms of study design, sample size, study population, key outcomes measured and location of study.

[LINK TO DOCUMENT]
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.

Please visit the site regularly for the latest updated version.

Below is version 01 Mar 2021

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<th>Manufacturer</th>
<th>Name of Vaccine</th>
<th>NRA of record</th>
<th>Platform</th>
<th>EUL accepted</th>
<th>Pre-submission meeting held</th>
<th>Dossier accepted for review</th>
<th>Status of assessment**</th>
<th>Anticipated decision date***</th>
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</table>

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 although unless WHO has specific access to data, the Organization cannot speak to the details of the product. Nevertheless, to help stakeholders, WHO is providing the following links to emergency listings by selected other countries.

**USA**

On February 27, 2021, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) to allow the Janssen COVID-19 Vaccine to be distributed in the U.S. for use in
individuals 18 years of age and older. Vaccine efficacy (VE) against central laboratory-confirmed moderate to severe/critical COVID-19 across all geographic areas in which the trial was conducted was 66.9% (95% CI 59.0, 73.4) when considering cases occurring at least 14 days after the single-dose vaccination and 66.1% (55.0, 74.8) when considering cases occurring at least 28 days after vaccination. For the vaccine and placebo groups, respectively, there were 116 and 348 COVID-19 cases that occurred at least 14 days after vaccination, and 66 and 193 cases that occurred at least 28 days after vaccination.

There was country-to-country variation in VE estimates for the prevention of moderate to severe or critical COVID-19 and severe/critical COVID-19, but the confidence intervals were overlapping. Predominant strains among those sequenced were Wuhan-H1 variant D614G in the U.S. (96.4% of sequenced cases), 20H/501Y.V2 variant (B.1.351) in South Africa (94.5% of sequenced cases), and variant of the P.2 lineage in Brazil (69.4% of sequenced cases, with the remaining 30.6% Wuhan-H1 variant D614G). There were no cases identified as B.1.1.7 or P1 lineages as of February 12, 2021.

Safety analysis through the January 22, 2021 data cut-off included 43,783 randomized (1:1) participants ≥18 years of age with 2-month median follow-up.

The analysis supported a favourable safety profile with no specific safety concerns identified that would preclude issuance of an EUA.

Janssen COVID-19 Vaccine (27 Feb 2021)

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.

China
On 25th February, NMPA granted conditional approval to CanSino’s (adenovirus type-5 vectored) recombinant COVID-19 vaccines and Sinopharm' inactivated Covid-19 vaccines.

NMPA grants conditional approval to CanSino’s recombinant COVID-19 vaccine (25 Feb 2021)
NMPA conditionally approves COVID-19 vaccine developed by Sinopharm's Wuhan institute (25 Feb 2021)

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.

Workshop on “Emerging challenges to the development of COVID-19 vaccines”

The COVAX Clinical Development and Operations SWAT Team hosted a workshop 'Immune Correlates, SARS-CoV-2 variants and 'mix and match': How vaccine developer approaches might be impacted by emerging data' on 25th February 2021. 60 unique vaccine developers and 10 national regulatory agencies joined the meeting together with many others.

Presentations used at the Workshop (25 Feb 2021)

Workshop on “Best practices for post approval changes”

On 3rd March, the COVAX SWAT Team hosted a workshop on “Best practices for post-approval changes” of vaccines, highlighting the importance of harmonized regulatory requirements for vaccines around the world, critical component for efficient and effective regulatory assessment of vaccines which will allow quality assured safe and effective vaccines to reach the target population.

To access presentations, send a request to COVAX-Reg@who.int

Webinar on “Platform technology”

On 18th February, International Alliance for Biological Standardization (IABS) organized a webinar on
Platform Technology, more specifically on the question ‘Is it possible to reduce the vaccine development time’ on 18th February

Presentations used at the Workshop (18 Feb 2021)
Video recording

Living mapping and living systematic review of COVID-19 studies

Living mapping and living systematic reviews are available based on daily searches of the literature for candidate vaccines against COVID-19. As of 26 February 2021, the Covid-19 - living NMA initiative collected 171 RCTs and 52 non-randomized studies of vaccines from the ICTRP. 104 of these trials are recruiting patients. The tool allows vaccine comparisons where data are available as well as a table with the general characteristics of each trial. For each vaccine comparison, forest plots for all the outcomes of interest are available as well as the Summary of Findings table.

The mapping tool

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. The landscape is updated regularly.

Update (05 Mar 2021)

Substandard and falsified products

Risk of falsified vaccines linked to improper disposals of vials

Improper disposal of used Covid-19 vials vaccine vials may present a risk that the empty vials may be repurposed, and refilled and used for falsified vaccines. In 2019, WHO received reports of the identification of falsified Meningitis vaccines in the WHO Region of Africa where improperly disposed vials were recovered, refilled and presented as genuine products. Due to the risk that empty vials may be recovered from waste systems, it is advisable that secure disposal is assured or failing that the empty vials are crushed if safe to do so.

Need to ensure coordination between national authorities: health and law enforcement

A number of substandard/falsified (SF) medical products relating to COVID19 have been detected and responded to by law enforcement authorities (police and/or customs). At this stage, WHO is not aware of SF vaccines for COVID19 distributed via national programmes. However it is essential that national regulatory / health authorities have open communication channels with their law enforcement counterparts, in order to better assess the scope, scale and harm caused by these products in their oversight territories and wider regions.

Supply Chain

Supply chain of ultracold products

International capacity to deliver cold chain products is currently considered sufficient to manage current demand for transportation; however, advance planning is strongly encouraged due to limited commercial flights and especially to African countries. Tracking of batch numbers in distribution should be prioritized in all countries from release of products from the manufacturer to all points up to the point of care. Some countries are reporting limited capacity of refrigerated vehicles to move vaccines to internal destinations.
Newly added shortages

The following medicines are showing signals of imminent shortage and should be watched carefully. Hording and speculative procurement should be avoided. Care should be used to ensure the best use of available national inventories. These shortages are reported in Western European and South American countries:

- Propofol
- Morphine
- Heparin (porcine based only)

The shortages of propofol, morphine and heparin are presumed to be from spikes in demand related to the increasing number of cases requiring hospitalization. The heparin shortage limited to countries that do not have access to other forms of heparin (bovine-derived) or other new generation anti-coagulants.

Watch list

WHO is still maintaining a watch list on the following products.

- Antibiotics: azithromycin, levofloxacin, metronidazole, amoxiclav, piperacillin, tazobactam
- epinephrine and norepinephrine
- Benzodiazepine sedatives: midazolam and lorazepam
- Nonbenzodiazepine sedatives: propofol
- Antipsychotics: haloperidol
- Neuromuscular relaxants: succinylcholine, atracurium, or vecuronium.
- Opioids: morphine and fentanyl
- Malaria treatments: hydroxychloroquine, chloroquine, artemether-lumafantrine, artemisinin-based combination therapies, sulfadoxine-pyrimethamine + amodiaquine)
- NCD: Metformin and insulin
- Antipyretics: paracetamol (aka acetaminophen)
- PPE
- Oxygen and related equipment
- Ventilators

Medical Devices

COVID-19 Oxygen Emergency Taskforce

A COVID-19 Oxygen Emergency Taskforce has been established and brings together key organizations working on oxygen access under ACT-A Therapeutics pillar, as COVID-19 surges and preventable deaths occur. Oxygen is an essential medicine, and despite being vital for the effective treatment of hospitalised COVID-19 patients, access in LMICs is limited due to cost, infrastructure and logistical barriers. Health facilities often cannot access the oxygen they require, resulting in the unnecessary loss of lives. It is estimated that more than half a million people in LMICs currently need 1.1 million cylinders of oxygen per day, with 25 countries currently reporting surges in demand, the majority in Africa. This supply was constrained prior to COVID-19 and has been exacerbated by the pandemic.

Recognizing the central importance of sustainable oxygen supply – alongside therapeutic products such as dexamethasone – for the treatment of COVID-19, the Access to COVID Tools Accelerator Therapeutics pillar (co-led by Unitaid and Wellcome Trust), is taking a new role to coordinate and advocate for increased supply of oxygen, and, in partnership with a WHO-led consortium, has launched a COVID-19 Oxygen Emergency Taskforce.

COVID-19 oxygen emergency impacting more than half a million people in low- and middle-income countries every day, as demand surges (25 Feb 2021)
Upcoming events

Global COVID-19 Vaccine Supply Chain & Manufacturing Summit (08-09 Mar 2021)
COVAX, BIO, DVCMN and IFPMA are co-sponsoring a Global C19 Vaccine Supply Chain & Manufacturing Summit convened by Chatham House, with the aim to:
- Provide a platform to explore a range of solutions to address bottlenecks;
- Lead to a series of recommendations, ideally commitments, on the priority areas for monitoring and/or action.
- Representatives from government, international non-governmental organizations, critical manufacturers and suppliers, and other vaccine stakeholders will be in attendance.

The meeting will be held under the Chatham House Rule so that the meeting is conducive to frank, open and problem-solving discussions in respect of anti-trust rules. This will be a virtual event, which will run over two consecutive days on Monday 8th and Tuesday 9th March from 14h to 18h CET.

concept note about the summit

WHO-ECHO Webinar: Regulation and Procurement (09 Mar 2021)
As part of series on COVID-19 Vaccination Planning and Implementation, Webinar on Regulation and Procurement will be held on Tuesday 09 March 12h-13h CET.

Please register

COVID-19 vaccine update (10 Mar 2021)
WHO is organizing a webinar on COVID-19 vaccine update to cover the science behind the immune response to viral infections, such as SARS-COV-2; the different vaccine platforms being used for the development of the COVID-19 vaccine; and aspects related to access and allocation of vaccines.

Webinar will be held on Wednesday 10 March from 16h to 17h CET.

Please register