**ACT-A, COVAX and COVID-19 Vaccine Talking Points**

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**Key messages/toplines (proactive messaging)**

**COVAX and equitable access:**

* **This pandemic still has a long a way to run**: Intense transmission is ongoing and is putting enormous pressure on hospitals, intensive care units and health workers. Decisions made by leaders and citizens in the coming weeks will determine when the acute phase of the pandemic will end.
* **Vaccines will be a critical new tool in the battle against COVID-19**: It is encouraging to see so many vaccines in development. Working as quickly as they can, scientists from across the world are collaborating and innovating to bring us tests, treatments and vaccines that will collectively save lives and end this pandemic.
* **Safe and effective vaccines will be a gamechanger:** but for the foreseeable future we must continue wearing masks, physically distance and avoid crowds. Being vaccinated doesn't mean that we can throw caution to the wind and put ourselves and others at risk, particularly because it is still not clear the degree to which the vaccines can protect not only against disease but also against infection and transmission.
* **COVID-19 cannot be beaten one country at a time:** The epidemiology shows that no country will be safe from the fallout of the pandemic until all countries are protected. The fact that numerous countries have had measles outbreaks and even lost their measles elimination status in the recent past, despite having extremely high vaccination rates shows that national coverage is not enough – it has to be achieved in every community and every family.
* **The global economy cannot recover if there are disparities in global coverage**: Not only will vaccines help save lives and stabilize health systems, but they can help to drive a global economic recovery. That recovery cannot take place if half of the world is hamstrung from the economic fallout of COVID-19.
* **It is a false economy for countries to go it alone:** G20 alone has spent over $10 tn to deal with the fallout so far.Stopping the acute phase of the pandemic will cost only a tiny fraction of the costs our societies are incurring to deal with its impact.
* **Producing sufficient doses of the vaccines depends on international cooperation:** If the world comes together through investments in research, manufacturing capacity, procurement, and investment in delivery; unprecedented speed can be achieved.
* **Safe and effective vaccines alone cannot solve the pandemic:** Rapiddiagnostics and life-saving therapeutics are also vital to end the pandemic and accelerate global recovery. These life-saving tools will only be effective if they are available for the most vulnerable equitably and simultaneously in all countries, and if strong health systems and services are in place to deliver them.
* **Significant political and financial commitments are needed urgently from governments:** Without them, COVAX cannot deliver the vaccines to everyone, everywhere, needed to end this pandemic.
* **Variants are concerning and demonstrate the importance of collective action:** Suppressing the virus through existing public health measures, as well as scaling up vaccine manufacturing and rolling out the vaccine as quickly as possible will be critical. Coordinated action on strain surveillance, collaboration among vaccine development, research and vaccine manufactures along with access to vaccines by all countries are essential for getting ahead of the virus.

**Vaccine Quality and Safety:**

* **Ensuring the quality, safety and efficacy of vaccines is one of WHO’s highest priorities:**  WHO works closely with national authorities to ensure that global [norms and standards](https://www.who.int/immunization_standards/en/) are developed and implemented to assess the quality, safety and efficacy of vaccines.
* **The process to develop COVID vaccines is fast-tracked while maintaining the highest standards:** The same steps are used for COVID vaccine development as are used for other vaccines. Given the urgent need to stop the pandemic, pauses between steps, often needed to secure funding, have been shortened, or eliminated, and in some cases, steps are being carried out in parallel to accelerate the process, wherever that is safe to do.

**Vaccine distribution**

* **Fairer is wiser:** WHO guidance on vaccine allocation across countries will ensure all countries can immunize their highest priority, most at-risk groups AND in so doing maximize the impact of the limited initial supply.
* **The priority is to protect the health system and those at highest risk of serious disease:** This is the best approach to maximize the impact of the limited supply of vaccines that will be available in the initial phase and to start addressing the societal and economic impacts of COVID-19.
* **WHO is engaging with partners at all levels to ensure countries are ready for rapid deployment of vaccines:** Countries are being asked to rapidly carry out a country readiness assessment that will form the basis of national deployment and vaccination plans (NDVPs). This will help to identify bottlenecks that need be addressed in the country plan and secure the resources, technical assistance and training.
* **Rapid scale-up of manufacturing capacity and cooperation is needed**: the mechanisms to share knowledge and data to expedite the end of the pandemic exist. The investment in the development of vaccines needs to be matched by increased manufacturing - vaccine manufacturers can share know-how with C-TAP to scale up vaccine manufacturing and substantially increase the global supply of vaccines.
* As of 4th February 2021, more people have been vaccinated against COVID-19 globally than those that have been confirmed to have been infected since the beginning of the epidemic.

## **Facts and figures at a glance:**

**AN IMPORTANT NOTE: any questions regarding vaccine specific deals for the COVAX Facility (or potential deals) should be directed to Gavi (primary point of contact: Meg Sharafudeen, msharafudeen@gavi.org).**

**The COVAX Pillar funding needs**:

* **The COVAX Pillar funding needs**: To achieve its ambitious goal, COVAX is seeking to raise at least US$ 7.7 billion in 2021[[1]](#footnote-1).
* **The COVAX Facility**: as of 15 December[[2]](#footnote-2), **190 countries and territories** are engaged in the COVAX Facility. These countries and territories account for over 90% of the world’s population. This includes 98 self-financing participants (60 higher-income economies, 29 Team Europe and 8 non-UN Member States) and 92 low and middle-income countries which are eligible for support through the COVAX Advance Market Commitment (AMC). This is a tremendous vote of confidence in this mechanism, and a sign that countries are seeing that equitable access isn’t just the right thing to do, it’s in all our interests.
* **Priority Populations:** Given that manufacturing capacity will be insufficient in 2021 to supply all global needs, countries must determine a policy to specify the priority populations for initial vaccination. WHO’s Strategic Advisory Group of Experts on Immunization (SAGE) has issued [policy recommendations](https://www.who.int/docs/default-source/immunization/sage/covid/sage-prioritization-roadmap-covid19-vaccines.pdf?Status=Temp&sfvrsn=bf227443_2) on population prioritization (November 2020) and issued a [values framework](https://apps.who.int/iris/handle/10665/334299) (September 2020) to underpin the development of specific policies. Country governments can use these two global policy positions as the basis for developing their national COVID-19 vaccine and immunization policies. SAGE is also providing vaccine specific recommendations as vaccines become authorized for use (this will be updated after each SAGE update; as of 21st January SAGE has reviewed & issued recommendations for Pfizer (8th January 2021, link [here](https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-BNT162b2-2021.1)), Moderna (25th January 2021, link [here](https://www.who.int/publications/i/item/interim-recommendations-for-use-of-the-moderna-mrna-1273-vaccine-against-covid-19)) & Oxford/AstraZeneca (10th February 2021, link [here](https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-AZD1222-2021.1)) See section 1.8, page 9.

# **WHO’s work on vaccines**

## **Development of target product profiles and clinical trial advice**

* WHO has published the [target product profiles for COVID-19 vaccines](https://www.who.int/publications/m/item/who-working-group-target-product-profiles-for-covid-19-vaccines), which describe the preferred and minimally acceptable profiles for human vaccines for long term protection of persons at high ongoing risk of COVID-19, and for reactive use in outbreak settings with rapid onset of immunity. WHO has also published the [criteria for prioritization of vaccines for clinical trials](https://www.who.int/publications/m/item/criteria-for-covid-19-vaccine-prioritization).
* The updated WHO [Guidelines on clinical evaluation of vaccines: regulatory expectations](https://www.who.int/biologicals/expert_committee/WHO_TRS_1004_web_Annex_9.pdf?ua=1) (2017) provide scientific advice for use by national regulatory authorities, companies developing and holding licences for vaccines, clinical researchers and investigators. The document offers guidance on immunogenicity, efficacy and effectiveness, and safety, among other issues.
* Considerations for the assessment of Covid 19 vaccine can be found [**here**](https://www.who.int/publications/m/item/considerations-for-the-assessment-of-covid-19-vaccines-for-listing-by-who).
* **Selected documents available from the WHO R&D blueprint** [**website**](https://www.who.int/teams/blueprint/covid-19) **include:** 
  + [Coordination of scientific discussion on Animal Models relevant for prioritizing vaccines and for evaluating potential for vaccine-enhanced disease needed to be developed.](https://www.who.int/publications/m/item/who-working-group-animal-models)
  + [Coordination of scientific discussion on Assays relevant for evaluating immune response to new vaccines and their standardization.](https://www.who.int/publications/m/item/who-working-group-viruses-reagents-and-immune-assays)
  + [COVID-19 antibody standard urgently for serological assay development](https://www.who.int/docs/default-source/biologicals/ecbs/reference-materials/2020/bs-2383-one-pagers.pdf?sfvrsn=3affb9bd_4)
  + [WHO Target Product Profiles for COVID-19 Vaccines](https://www.who.int/publications/m/item/who-target-product-profiles-for-covid-19-vaccines)

## **Regulatory and policy**

* Once a vaccine has gone through established development, manufacturing and clinical testing procedures and is demonstrated to be safe, efficacious, and meets manufacturing standards, the data must be assessed by regulators to authorize its use.
* Once manufacturers believe they have the requisite data to secure emergency use authorization, conditional marketing authorization or equivalent, they can submit their product for evaluation to WHO prequalification (PQ) or for WHO emergency listing (EUL). WHO EUL or PQ is usually a prerequisite for a vaccine that will be supplied through procurement partners such as UNICEF and PAHO, and for funding through Gavi for countries who are eligible.[[3]](#footnote-3)
* Policies on use of specific products are developed once there is sufficient information about a specific vaccine against COVID-19 that will inform authorization and use beyond the clinical trial setting. These policies will consider product specific attributes related to the safety and efficacy of the products, as well as aspects relates to delivery, handling and storage of the products.[[4]](#footnote-4)
* Once vaccines are authorized through the regulatory process, including the assessment of safety and efficacy from phase III clinical trials, WHO’s Strategic Advisory Group of Experts on Immunization (SAGE) will issue **vaccine-specific policy recommendations**; these recommendations may be updated as additional evidence of vaccine effectiveness and safety, and additional vaccines and other interventions become available.

## **Global mapping of vaccines in development**

* The [draft landscape of COVID-19 vaccine candidates](https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines) – updated twice a week - contains information on vaccine candidates collected through public information (e.g. clinical trial registries) and information that vaccine developers directly provide to WHO.
* There **is reason to be optimistic**: there are **263** vaccine candidates in development, of which **81** are in clinical development[[5]](#footnote-5).
* This many vaccine candidates, combined with a variety of vaccine platforms and technologies (both traditional, such as inactivated whole virus or viral vectors and new ones, which are being used for the first time, such as mRNA and DNA vaccines), increase our chances to find multiple safe and effective vaccines.[[6]](#footnote-6)
* Clinical trials to develop additional COVID-19 vaccines must continue. The world needs multiple vaccines that work in different populations, are made by multiple manufacturers, and are optimized for delivery in a range of settings to meet the global demand.

## **Fair allocation framework**

* As between countries, in consultation with Member States and ACT-A partners, WHO has developed a [**Fair allocation mechanism**](https://www.who.int/docs/default-source/coronaviruse/who-covid19-vaccine-allocation-final-working-version-9sept.pdf) **for COVID-19 vaccines through the** [**COVAX Facility**](https://www.gavi.org/sites/default/files/covid/covax/COVAX_Facility_Explainer.pdf). It is a strategy to rapidly contain the pandemic, save lives, protect health care systems, and restore global economies, based on the human rights principle of equity and epidemiological evidence from the pandemic.
* Once vaccines are shown to be safe and effective and are authorized for use with either WHO EUL/PQ or by an SRA, **all countries should receive doses in proportion to their population size to immunize the highest priority groups** – especially those most likely to die or who have severe disease.
* Important to note that all of this is pending the readiness of participating economies, including regulatory approval, legal agreements with manufacturers on indemnification and liability and availability of supplies from COVAX.
* **Phase 1 (proportional allocation for all countries)**:
  + A transparent [method](https://www.who.int/publications/m/item/allocation-logic-and-algorithm-to-support-allocation-of-vaccines-secured-through-the-covax-facility) for allocating vaccines has been put in place tosupport the allocation of vaccines secured through the COVAX Facility
  + This involves consolidating supply information to create a forecast for allocation and then determining which participants can receive which products.
  + Based on this, a range of maximum and minimum allocation is fixed per facility participant.
  + Supply is then matched to demand and factors considered at this stage include:
    - participation model
    - optional purchase opt-outs
    - committed purchase price opt-outs (ie non-eligible for any vaccine costing more than the opt-out threshold)
    - cost-sharing commitment status,
    - participant readiness,
    - completion of the vaccine request form
  + The formula then optimizes allocation by weighing the three key objectives set out below:
    - Equality of doses received proportionally to population
    - Participants should receive a single product throughout where possible
    - Participants receive products in line with their vaccine characteristic preferences where possible
  + All countries will receive tranches of doses gradually building up to 20% coverage of the population (to allow for vaccination of most of the at-risk groups in countries) by the end of 2021.
* **Phase 2 - weighted allocation based on risk assessment**: a follow-up phase to expand coverage beyond 20% coverage in each country will follow from Phase 1, if resources allow. If there is no severe supply constraint, the rate at which participants receive vaccines is such that all countries will achieve the same coverage at the same time (up to their requested coverage) where possible (as in phase 1)
  + If severe supply constraints persist during this phase, a weighted allocation approach would be adopted, taking account of a country’s COVID-19 threat and vulnerability.
* **A humanitarian buffer:** Gavi is the administrator of the COVAX Facility and AMC. Gavi is the administrator of the COVAX Facility and AMC, and the GAVI Board is to approve the establishment of a humanitarian buffer. The COVAX Facility will maintain a buffer of doses for humanitarian and contingency use, including to address severe outbreaks before they spiral out of control.[[7]](#footnote-7)
  + This is a real time allocation of vaccine doses procured through the COVAX facility (5% of the 2b doses goal: 100m) and should be considered a measure of last resort, as governments are in principle accountable for the health needs of at-risk populations and should include them in their national allocation plans. The details for how the humanitarian buffer will work are under development for review and approval by the GAVI Board at the 22 March Board meeting.
  + High-risk groups in humanitarian contexts include not only refugees but also internally displaced persons, asylum seekers, populations in conflict settings or those affected by humanitarian emergencies [and] vulnerable migrants in irregular situations”
* **A Vaccine allocation explainer is available** [**here**](https://www.who.int/publications/m/item/allocation-mechanism-for-covax-facility-vaccines-explainer)
* **COVAX vaccine allocation explainer is** [**here**](https://www.who.int/publications/m/item/allocation-logic-and-algorithm-to-support-allocation-of-vaccines-secured-through-the-covax-facility)**.** This document aims to explain the logic of how COVAX Facility secured vaccines will be allocated among participants during Phase 1 using the Allocation Algorithm.
* The first vaccines procured through COVAX outside of India, began arriving in recipient countries on the 24 February (Ghana), to supply vaccine to each participating economy’s for the highest priority populations – in the first half of the year, building towards our goal of protecting at least 20% of the population by the end of 2021. Within COVAX, UNICEF is leading shipping and delivery of vaccines to countries, in partnership with PAHO for shipments to that region.
* On 2nd March COVAX announced the first round of allocations for the AstraZeneca vaccine. The breakdown of allocations can be found [here](https://www.who.int/news/item/02-03-2021-covax-publishes-first-round-of-allocations).
* Important to note that all of this is pending the readiness of participating economies, including legal agreements with manufacturers on indemnification and liability.[[8]](#footnote-8)
* More information on the allocation mechanism [here](https://www.who.int/publications/m/item/allocation-mechanism-for-covax-facility-vaccines-explainer).

# **FAQs: Vaccine allocation**

**Q: Why did some countries receive COVAX delivery earlier than others?**

* A number of countries, including Ghana, received initial deliveries of COVAX vaccines, and the criteria as to who was appropriately prepared to receive the vaccines included the following:
  + the vaccine has been allocated to a country by JAT/IAVG;
  + the country has signed an indemnification and liability agreement with the manufacturer; and
  + the country has regulatory approval and import license
* Countries were not chosen in a particular order, COVAX is delivering doses according to country readiness, and operational issues (e.g. flights to ship vaccines).

**Q: When will the next allocation round begin?**

* There is no date for the next allocation round, it is “triggered” by 3 elements:
* A product is EUL-ed by WHO (or – exceptionally -  authorized by an SRA), and
* SAGE-IVB has a recommendation for that product, and
* There is favourable supply forecast for the COVAX Facility (a contract is signed or being signed with that manufacturer).

**Q: Billions of COVID-19 vaccines doses will be needed in the coming months and vaccines are likely to appear with different efficacy levels. How will decisions be made as to which countries receive which vaccines?**

* A: The initial phase of vaccine allocation will be proportional to countries’ populations in accordance with the Fair Allocation Framework which has been developed earlier in the year. Only after vaccines have received either a EUL, PQ or approval from a recognized Stringent Regulatory Authority, can they be allocated to countries. This is to ensure that the products distributed have been assessed and are efficacious, safe and meet quality standards. Each country willing and able to receive vaccines will receive the same share of vaccine in each allocation round. Exceptions are envisaged for small countries and to ensure compliance with COVAX Facility terms and conditions that countries have opted for. The vaccines will be allocated to countries on the bases of their expressed product preferences whenever possible. WHO and partners have put in place governance arrangements to ensure allocation in line with the principles highlighted in the Fair Allocation Framework.

**Q: What does an effective vaccine rollout strategy look like? How important is it to have a good reporting system?[[9]](#footnote-9)**

* A: An effective vaccine roll-out strategy requires careful advance planning and adequate financing to cover the key programme components as outlined in WHO-UNICEF National Deployment and Vaccination Plan (see link).  All dimensions expressed in the guidance are important, but the unique characteristics of the initial COVID-19 vaccines require particular attention on a strong cold chain system and a robust strategy for public communications, community engagement and vaccine demand promotion to encourage uptake.
* A good reporting system is essential in any vaccination programme to monitor progress of vaccine roll-out in target populations, to enable corrective action on delivery strategies if required.  As the highest priority target populations being immunized by COVID-19 are not those widely and traditionally immunized in national programmes (health workers, adults and seniors as opposed to infants/children), the data monitoring collection systems are even more important to inform success of implementation.

**Q: Is COVAX concerned about changes to supply timelines due to demand from countries bilateral agreements with manufacturers?**

* A: It is inevitable that there will be supply challenges for COVID-19 vaccines while we wait for global manufacturing to reach capacity, which is why it makes sense for countries to participate in COVAX, which has the largest, most actively managed portfolio of vaccines candidates in the world. At this time, we have not been made aware of any changes to supply timetables and or impact on the AstraZeneca sites supplying COVAX; in addition, our agreement with the Serum Institute of India to provide COVAX with Oxford/AstraZeneca doses under a technology transfer agreement offers us greater flexibility to source vaccines from across the globe.

**Response to questions about the threat of Covax being sued**

* **OVERARCHING MESSAGE:** A [method](https://www.who.int/publications/m/item/allocation-logic-and-algorithm-to-support-allocation-of-vaccines-secured-through-the-covax-facility) for allocating vaccines has been put in place tosupport the allocation of vaccines secured through the COVAX Facility. Accordingly, the order in which COVAX doses are allocated is not an arbitrary one. It is determined by this method and has been communicated as such to all COVAX participating economies.
* In order for doses to be delivered to Facility participants via this first allocation round, several critical pieces must be in place, including:
* confirmation of national regulatory authorisation criteria related to the vaccines delivered
* indemnification agreements (for all participants with the respective manufacturers)
* national vaccination plans from AMC participants
* as well as other logistical factors such as export and import licenses
* We are in close touch with each of the COVAX participating economies in relation to the roll-out of COVID-19 vaccines. Only once each participant completes the necessary steps COVAX issues purchase orders to the manufacturers who ship and deliver doses.
* [The first round of allocations](https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.gavi.org%2Fnews%2Fmedia-room%2Fcovax-publishes-first-round-allocations&data=04%7C01%7Clshevlin%40gavi.org%7Cecfaab3e221b4962f96b08d8dd9b1958%7C1de6d9f30daf4df6b9d65959f16f6118%7C0%7C0%7C637503005501496269%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=RlZB%2FhT%2B6tIOr1N1m%2FlyIgsCdh99kAcOtB4eMgLzSy0%3D&reserved=0) has been communicated to the relevant governments who are working closely with COVAX partners and vaccine manufacturers on the specific dates for deliveries.

**WHO position on teachers being vaccinated**

* WHO recommends vaccinating teachers, and those in community-facing roles as a priority.
* In an epidemiological setting where a disease is spread through community transmission and vaccines are limited, SAGE recommends teachers in two stages
  + Stage II: vaccination for high priority teachers and teaching staff as part of the second priority group depending on country context, examples of this group may include: preschool and primary school teachers because of the critical developmental stage of the children they teach, teachers of children where distance learning is very difficult or impossible
  + Stage III: All teaching staff included as part of priority group
* For countries without community transmission but instead sporadic outbreaks of a disease, SAGE recommends vaccinating all teachers in Stage III
* See [SAGE prioritization roadmap](https://www.who.int/publications/m/item/who-sage-roadmap-for-prioritizing-uses-of-covid-19-vaccines-in-the-context-of-limited-supply) from November 2020.
* Countries may prioritise differently according to the national data available.

**Q: What will happen if there is more than one vaccine to allocate?**

* Participants under the Optional Purchase Arrangement will receive options to purchase their pro rata share of each vaccine.
  + These participants will be able to opt-out of certain vaccines.
  + The Pro Rata Share is calculated by dividing the estimated number of doses required (the Total Participant Doses) by the total number of doses that the Facility intends to procure based on demand from all Participants (the Total Facility Doses).
* For other participants, the allocation will strive to allocate products as soon as possible while accounting for:
  + Country preferences based on product characteristics.
  + Country readiness.

## **EUL and PQ process**

* WHO prequalifies vaccines for diseases of priority to low and middle-income countries through its vaccine prequalification programme. WHO is not a regulatory agency; instead prequalification is a WHO recommendation that ensures that candidate vaccines:
  + (a) meet the WHO recommendations on quality, safety and efficacy, including compliance with WHO recommended Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP) standards; and
  + (b) meet the operational specifications for packaging and presentation of the relevant UN agency. This is to ensure that vaccines provided through the UN for use in national immunization services in different countries are safe and effective, and are suitable for the target populations, at the recommended immunization schedules, and with appropriate concomitant products.
* The WHO Emergency Use Listing Procedure (EUL) is a risk-based procedure for assessing and listing unlicensed vaccines, therapeutics and in vitro diagnostics with the ultimate aim of expediting the availability of these products to people affected by a public health emergency.
* The Emergency Use Listing process usually takes two to three months to complete, depending on the quality and availability of the data submitted by the vaccine developers, among other factors; the prequalification process is more complex and thus takes longer.
* EUL or Prequalification verifies to those countries that would want to procure a particular vaccine that there has been an assurance by WHO that the regulatory review process in the country of manufacture has held up to the highest standards.
* WHO’s assessment of candidate COVID-19 vaccines by the Prequalification Team has started, with independent experts from different regions included in a global assessment team. WHO will ensure that its assessment of these vaccines is robust, representative and facilitates timely access at the country level.
* For vaccines that achieve emergency use listing or prequalification by WHO, support to facilitate national level approval processes will be offered to countries in product specific roadmaps and regulatory preparedness plans outlined in WHO Interim Guidance on National Deployment and Vaccination Planning.
* On 25 November, following consultation WHO published a [document](https://www.who.int/publications/m/item/considerations-for-the-assessment-of-covid-19-vaccines-for-listing-by-who) on considerations for assessment of Covid 19 vaccines for listing by WHO. **WHO’s emergency use listing (EUL) procedure is based on a benefit/risk assessment in the context of a public health emergency.** If an EUL is provided, the manufacturer is expected to complete the development of the products and submit for national licensure and for WHO prequalification. Link to document [here](https://www.who.int/publications/m/item/considerations-for-the-assessment-of-covid-19-vaccines-for-listing-by-who)
* The first [Invitation to manufacturers of vaccines against Covid-19](https://www.who.int/medicines/regulation/prequalification/prequal-vaccines/resources/1_EOI-Covid-19_Vaccines.pdf?ua=1) undergoing Phase III clinical trials to submit an **Expression of Interest (EOI)** for evaluation by the WHO (EUL or Prequalification) was posted online on 1 October. Link to document [here](https://www.who.int/medicines/regulation/prequalification/prequal-vaccines/resources/1_EOI-Covid-19_Vaccines.pdf?ua=1)
* WHO encourages vaccine developers and manufacturers to be aware of the WHO prequalification process, even at the early stages of development, and to discuss the product and the regulatory requirements with the WHO prequalification team early in the process.[[10]](#footnote-10)
* In line with their national regulations and legislation, countries have the autonomy to issue emergency use authorizations for any health product. Domestic emergency use authorizations are issued at the discretion of countries and not subject to WHO approval.
* In emergency situations, such as the current COVID pandemic, and for countries whose regulatory authorities are under-resourced, WHO supports the regulatory process by running independent parallel reviews, usually involving independent experts and experts from regulatory authorities at global level [[11]](#footnote-11)
* To maximise production, vaccines will be manufactured in multiple countries, and therefore under the responsibility of different national regulatory authorities (NRAs). WHO is required to issue a separate EUL for each manufacturing site under an NRA not previously approved for that vaccine.

**FAQs**

**Response to criticism that the WHO is slow to regulate vaccines from China & Russia**

* **WHO evaluates all data from applicants as it comes in** (in rolling submission), without preference, and provides feedback on completeness or gaps. The decision on listing is based on availability of complete information to confirm safety, quality and efficacy
* **WHO works with regulators from all regions** in the assessment of vaccines under EUL. We are currently in late stage assessment of the Chinese and other vaccines
* As with all vaccine candidates, COVAX is open to procuring vaccines that complement its portfolio from any producer in the world, once they have received approval from a stringent regulatory authority and / or WHO.
* **Even if the process for EUL has been initiated, it does not mean that WHO has all of the data that it requires:** WHO can only speak about the attributes of specific products for which it has comprehensive data. It is those processes that provide assurance of quality, safety and efficacy.
* **The EUL/prequalification process is necessarily onerous but the system works:** Where assessments and inspections have not been conducted according to international requirements and standards, WHO carries out the full spectrum of assessment activities. Hundreds of products have received prequalification in this way, including from Chinese, Russian and Indian companies.

**Questions on Countries allowing vaccines before EUL & SRA**

* There are and will likely continue to be manufacturers of some vaccine candidates who may be delayed in seeking or choose not to seek emergency use listing by WHO or authorisation by an SRA. The use of some of these products has proceeded in a number of countries with the agreement of national authorities. It is possible that the data required for a WHO EUL assessment may not have been available at the time of national decisions to use such vaccines.
* In usual circumstances, it is common for UNICEF and WHO to provide countries with technical assistance for vaccines which are not WHO prequalified but are approved by national regulatory authorities in the country of use. WHO, and partners in COVAX, would not be involved in the procurement of these vaccines.
* WHO’s support is provided to the immunization programme of the country, not to a specific vaccine. This support includes capacity assessments, planning, advising on delivery strategies, ensuring adequate cold chain, data monitoring, communication including raising public awareness and promoting demand for vaccination, and risk communication.[[12]](#footnote-12)

**Why did it take so long for WHO to assess AZ vaccine?**

* WHO took under four weeks to assess both the AZ vaccine manufactured by SII and the AZ vaccine manufactured by SK Bio in South Korea. WHO relies on manufacturers and developers to provide the required information about their vaccines and to prioritize submission to WHO to facilitate global access. WHO is working with the highest urgency to complete the assessments.

**What is the difference between the EUL process and SAGE?**

* The EUL process is centered on determining if a product can be used – it assesses vaccines to make sure they meet acceptable standards of quality, safety and efficacy. It bases its decision on evaluation of clinical trial data, manufacturing and quality control processes.
  + National regulators and other UN bodies can then use this review to supplement and expedite national regulatory approval for the products.
  + COVAX allocation cannot happen without EUL or national regulatory approval
  + SAGE is policy-oriented – it looks at data to formulate recommendations on how a vaccine should be used – which population and age groups, how many doses and intervals between jabs.
  + SAGE Interim recommendations provide guidance for national vaccination policy makers.

## **Vaccine rollout and distribution**

* 1st mass vaccination programme started **in early December 2020[[13]](#footnote-13)** and as of 16th March 2021, **325 million vaccine doses** have been administered.[[14]](#footnote-14) For latest number of doses administered please see the [WHO dashboard](https://covid19.who.int/).
* At least 10 different vaccines (4 platforms) have been administered[[15]](#footnote-15)
* Campaigns **have started in 143 economies**[[16]](#footnote-16)
* The Pfizer-BioNTech vaccine is by far the most widely used vaccine: 83 economies [[17]](#footnote-17) are using the by AstraZeneca (UK) /Covishield vaccine, followed by Pfizer BioNTech (82 Countries[[18]](#footnote-18)) Moderna (32 countries[[19]](#footnote-19)), Sinopharm (20 countries[[20]](#footnote-20)), Gamaleya (19 countries[[21]](#footnote-21)), Sinovac (12 countries[[22]](#footnote-22)), J&J (2 country[[23]](#footnote-23), Covaxin (1 country[[24]](#footnote-24)) and EpiVac (1 country[[25]](#footnote-25)). Information correct as of 12th March.
* The first vaccines procured through the COVAX Facility, outside of India, were shipped on the 23rd February (to Ghana, landing on 24th February).
* For number of doses delivered please see the [UNICEF dashboard](https://www.unicef.org/supply/covid-19-vaccine-market-dashboard).
* **We strongly encourage COVID vaccine manufacturers to proceed at haste with WHO EUL or PQ review once the data are sufficient for submission. The link to the status of evaluation can be found** [**here**](https://extranet.who.int/pqweb/sites/default/files/documents/Status_COVID_VAX_Dec2020.pdf)**.**

**Current Covax agreements with manufacturers**

* **Pfizer** and BioNTech
  + On 22nd January 2021 COVAX announced the signing of the advanced purchase agreement for up to 40 million doses of the Pfizer-BioNTech vaccines. [[26]](#footnote-26) COVAX press release [here](https://www.gavi.org/news/media-room/covax-announces-new-agreement-plans-first-deliveries)
  + On 11th February, UNICEF announced the signing of an agreement with Pfizer on behalf of the COVAX Facility for the supply of the Pfizer-BioNTech COVID-19 Vaccine through 2021. Press release [here](https://www.unicef.org/press-releases/unicef-signs-supply-agreement-pfizerbiontech-covid-19-vaccine)
* **Oxford**/AstraZeneca
  + **As** of 22nd January 2021, WHO announced that pending regulatory approvals, nearly 150 million doses of the AstraZeneca/Oxford candidate are anticipated to be available in Q1 of 2021. This is through two separate agreements with 240 million doses being produced by the Serum Institute of India & another 96 million produced by AstraZeneca.[[27]](#footnote-27)
  + **Serum Institute of India agreement:** COVAX will be exercising the option to receive the first 100 million doses from the State Serum Institute of India. The majority of these are expected to be delivered in the first quarter of the year, pending WHO Emergency Use Listing.[[28]](#footnote-28)
* **AZ Agreement:** COVAX also anticipates that a further 50 million doses of the AstraZeneca/Oxford vaccines will be available for delivery to COVAX participants in Q1 of 2021, pending EUL authorization by the WHO. Press release (22/01) for further information available [here](https://www.who.int/news/item/22-01-2021-covax-announces-new-agreement-plans-for-first-deliveries).
* Following the announcement that AstraZeneca has been granted EUL by WHO (15 February 2021), COVAX will now complete the process of final Q1/Q2 allocations of the AstraZeneca vaccine to Facility participants. Exact timings of delivery will depend on country readiness.[[29]](#footnote-29)
* J&J Vaccine was granted WHO EUL on 12th March 2021. Once final advance purchase agreement is signed, this vaccine will be available for global rollout to COVAX Facility participants in the second half of 2021.

**FAQs**

**Q: Why are there two AstraZeneca/Oxford vaccine needing EUL & separate agreements with COVAX?**

* AstraZeneca/Oxford has a number of manufacturing ‘nodes’ around the world. This is positive because it will speed up production of the vaccine and make more doses available for countries.
* The AZ-SKBio node in the Republic of Korea is part of AstraZeneca, while the Serum Institute of India is a separate company and has been able to access the AZ/Ox technology to manufacture the vaccine through what is called a technology transfer.
* Both versions of the vaccine are part of COVAX.

## **SAGE policy recommendations for priority population groups**

* Countries will have discretion on how to use their allocated doses based upon their own epidemiologic situation and guidance from national policy making bodies.
* Policies determining the population prioritization of vaccine rollout within economies may be guided by recommendations from the **WHO Strategic Advisory Group of Experts on Immunization (SAGE)**.
* See [**here**](https://www.who.int/groups/strategic-advisory-group-of-experts-on-immunization/covid-19-materials)for a link to the COVID vaccine materials on the SAGE website.
* SAGE has released a [Roadmap for Prioritizing Population Groups for Vaccines against COVID-19](https://www.who.int/publications/m/item/who-sage-roadmap-for-prioritizing-uses-of-covid-19-vaccines-in-the-context-of-limited-supply), (v 1.1 issued 13 November 2020, replacing version 1.0 issued on 20 October 2020) which lays out the priorities according to vaccine supply and epidemiologic scenario. SAGE also released a [Values Framework](https://apps.who.int/iris/bitstream/handle/10665/334299/WHO-2019-nCoV-SAGE_Framework-Allocation_and_prioritization-2020.1-eng.pdf?sequence=1&isAllowed=y) (14 September 2020) which underpins and laid the groundwork and ethical principles for the aforementioned guidance on target populations and policies on vaccine use.
* The Values Framework is specific for Covid vaccines and represents a high-level foundation for future global, regional and national vaccination policies. It is complementary to the Fair Allocation Framework that describes the product allocation framework, inclusive of but not only for vaccines, under the ACT-Accelerator, that responds to pragmatic needs to make the process work with all interested Member States.
* SAGE will be providing product specific recommendations as products are evaluated for quality, safety and efficacy by the WHO Prequalification department and/or by stringent regulatory authorities.

**Relating specifically to Pfizer/BioNTech vaccine, the WHO interim recommendations (based on SAGE[[30]](#footnote-30)). Assessed 5th January 2021:**

* + Explainer available [here](https://www.who.int/news-room/feature-stories/detail/who-can-take-the-pfizer-biontech-covid-19--vaccine)
  + **On 29th January 2021 the EMA published its first safety update on this vaccine. Available** [**here.**](https://www.ema.europa.eu/en/news/first-covid-19-vaccine-safety-update-published)

**Relating specifically to Oxford/AstraZeneca vaccine, the WHO interim recommendations (based on SAGE). Assessed 8th February 2021**

* WHO SAGE AZ explainer available [here](https://www.who.int/news-room/feature-stories/detail/the-oxford-astrazeneca-covid-19-vaccine-what-you-need-to-know).

**Relating specifically to Moderna vaccine, the WHO interim recommendations (Based on SAGE). Assessed 21st January 2021.**

* Explainer available [here.](https://www.who.int/news-room/feature-stories/detail/the-moderna-covid-19-mrna-1273-vaccine-what-you-need-to-know)
* SAGE recommendations can be found [here](https://www.who.int/news-room/feature-stories/detail/the-moderna-covid-19-mrna-1273-vaccine-what-you-need-to-know)

**What is WHO response to French authorities recommending only one shot for people who have had the COVID-19 infection?**

* SAGE make interim recommendations – called this as they can be updated -which are intended to form the basis of countries policy recommendations. WHO maintains their recommendation to use 2 doses, for the vaccines WHO have evaluated so far.
* There are preliminary studies to suggest that single doses are enough if you have had Covid-19 infection before, however more studies are needed. “When countries are faced with scarcity of vaccines, countries are using policies to make those vaccine doses go further.” [[31]](#footnote-31)

## **Supporting national authorization after WHO EUL**

TALKING POINTS FOR THIS ARE IN DEVELOPMENT.

## **Supporting post-authorization safety monitoring, impact and implementation**

* Substantial measures are being taken to monitor vaccine safety during its use following authorization, to be transparent and to take action immediately should any safety issues emerge.
* A Global Advisory Committee on Vaccine Safety subcommittee on COVID vaccine has been established, to:
  + Review, evaluate, interpret post-introduction COVID-19 vaccine safety data
  + Advise WHO on the safety of the different COVID-19 vaccines
  + Provide recommendations on safety studies, investigations, validations
  + Guide development of COVID-19 vaccines-safety advisories and communication materials[[32]](#footnote-32)
* Vaccine efficacy as determined by clinical trials may differ from vaccine effectiveness when the vaccine is introduced and used into real-world settings. With COVID-19 vaccines moving from clinical trials to authorization and use in countries, ongoing post-authorization monitoring of how well the COVID-19 vaccines work is important.
* Post-authorization monitoring and evaluations of how well the vaccines work will help provide evidence to questions about how well the vaccines work in various populations, in different locations, in different dosing schedules, for different strains, and how long vaccines will protect. The evidence will be important to make programme and policy decisions and for updating recommendations on vaccine use. WHO is preparing global guidance on the conduct of vaccine effectiveness studies and other evaluations of vaccines in use. In addition, WHO is monitoring where and what types of vaccine effectiveness and impact evaluations are being undertaken around the world, and summarizing the findings from those studies so the evidence can be used by policy makers and vaccine developers worldwide.
* Assessment and ongoing monitoring of how well countries are delivering COVID-19 vaccines is another key area of work. WHO is establishing a reporting system to monitor vaccine coverage and uptake on a real-time basis to complement the annual electronic Joint Reporting Form (eJRF) on vaccine implementation.
* Programmatic implementation has many components, including service delivery, logistics, data, and communication. Reaching the target populations for vaccination with locally tailored strategies is critical to help achieve the high acceptance and uptake which is necessary for COVID-19 vaccines to effectively interrupt the pandemic. Thus, understanding local community perspectives and addressing operational bottlenecks for high-quality vaccine delivery is needed.
* WHO is providing guidance and supporting countries to conduct assessments and programmatic evaluations to actively glean lessons learned and apply them to improve vaccination activities.
* WHO and partners have made available a globally standardized package of tools and guidance to enable programmes to gather and use behavioural and social data for planning and evaluation of demand for Covid-19 vaccines. These tools can be found [here](https://www.who.int/initiatives/act-accelerator/covax/covid-19-vaccine-country-readiness-and-delivery/acceptance-and-demand).

## **Country readiness and delivery**

* WHO, UNICEF, Gavi and many other partners are working together to help countries prepare to be ready to introduce COVID-19 vaccines.
* The [Vaccine Readiness Assessment Tool](https://www.who.int/publications/i/item/WHO-2019-nCoV-Vaccine-introduction-RA-Tool-2020.1) (VIRAT) is a tool for use by Ministries of Health, with support from WHO and UNICEF Country Offices. It provides countries with an integrated roadmap of milestones and a framework for self-monitoring progress in preparing for vaccine introduction. Countries can use the VIRAT/VRAF 2.0 to identify areas where support may be needed.
* Countries are advised to develop and complete their National Deployment and Vaccination Plan (NDVP) with urgency. The Country Readiness and Delivery (CRD) workstream of COVAX has developed [Guidance on Developing a National Deployment and Vaccination plan for COVID-19 vaccines and a template](http://cdcp.gd.gov.cn/attachment/0/405/405481/3130772.pdf) for NDVP development which will help countries develop an operational plan for COVID-19 vaccine introduction.
* WHO is setting up the monitoring of vaccination introduction status, target population and administered vaccination doses as a special module to our routine immunization monitoring system. The development of the reporting questions and frequency is ongoing, with a view to start data collection in the first quarter of 2021. More information can be found [here](https://www.unicef.org/supply/covid-19-vaccine-market-dashboard).
* Meanwhile – and through WHO regional offices and websites of Ministries of Health - we will track the information from countries that will roll-out the vaccine before this data collection system will be functional.[[33]](#footnote-33)
* Strategies for COVID-19 vaccine storage and deployment will likely vary among countries and depend on a number of factors such as the kinds of vaccines that have been approved, country size, available vaccine supply, the number of vaccine doses required, priority populations needing vaccination, and existing cold chain infrastructure.
* Information on the cold chain assessment tool can be found [here](https://www.who.int/teams/immunization-vaccines-and-biologicals/essential-programme-on-immunization/supply-chain/vaccine-management-and-logistics-support/logistics-tools). The COVID-19 Vaccine Supply and Logistics[**guidance**](https://www.technet-21.org/en/library/main/6717-covid-19-vaccination,-country-readiness-and-delivery:-supply-and-logistics-guidance) includes helpful information for countries to plan for the many aspects of storage and deployment.
* There are currently a number of vaccines, including the Pfizer vaccine, that require ultra-cold storage (-60°c to -90°C) posing challenges for many countries for use of these vaccines. Other vaccines require usual freezer temperatures (ie. -20°C) or refrigeration (ie. 2°C to 8°C).
* WHO, UNICEF, and partners are supporting countries in preparing for COVID-19 vaccine introduction. The Country Readiness and Delivery workstream – which is part of the ACT Accelerator – has developed a [toolbox](https://www.who.int/initiatives/act-accelerator/covax/covid-19-vaccine-country-readiness-and-delivery/country-readiness-and-delivery-faqs) with guidance, tools, and trainings. More information is available [here.](https://www.who.int/initiatives/act-accelerator/covax/covid-19-vaccine-country-readiness-and-delivery/country-readiness-and-delivery-faqs)
* The trainings for [national/subnational focal points](https://openwho.org/courses/covid-19-ndvp-en) and [health workers](https://openwho.org/courses/covid-19-vaccination-healthworkers-en) to prepare for COVID-19 vaccination have been taken by more than 35,000 learners globally and are being translated into 12 languages. Additional trainings and resources, including for acceptance and uptake of COVID-19 vaccines and preparing for COVID-19 supply and logistics, will be added to the toolbox shortly.
* To be allocated COVID-19 vaccine doses, the COVAX Facility’s AMC92 countries must submit their COVID-19 National Deployment and Vaccination Plan (NDVP) to the [Partners Platform](https://covid19partnersplatform.who.int/en/). The submission deadline for the next allocation round of COVID-19 vaccines was 9 February 2021. AMC92 countries are encouraged to submit their NDVP as soon as possible.[[34]](#footnote-34)

**Vaccine Wastage**

* Vaccine wastage is the sum of all vaccines discarded, lost, damaged or destroyed that may occur during storage, transport or vaccination service delivery.
* WHO is providing support to countries to ensure that NVDPs include data driven planning to prevent and minimise wastage. WHO encourages countries to closely monitor, record and report vaccine utilization and wastage to determine the country-specific wastage rates. This information is crucial in planning and in improving efficiency and equity in the succeeding COVID-19 vaccine supply allocation.
* There are two types of vaccine wastage:

1. Unopened vial wastage: This occurs during storage and transportation due to inefficiencies of the supply chain system, including cold chain failures, poor stock management leading to vaccine expiration, brakages and other factors.  This is avoidable and careful planning helps to minimise this.
2. Opened vial wastage: this occurs during service delivery when multi dose vaccine vials are opened but the doses are not fully used prior to expiration. This is inevitable but can be minimised through data driven planning and forecasting.

* It is recommended to keep vaccine wastage to less than 1%. The WHO developed a Wastage Rate Calculator that will allow tracking and monitoring of vaccine wastage rates.
* WHO has developed guidance and tools to support countries in planning, managing and monitoring their vaccine stocks and supply chain system. These tools can be found [here](https://www.who.int/teams/immunization-vaccines-and-biologicals/essential-programme-on-immunization/supply-chain/vaccine-management-and-logistics-support/logistics-tools).
* The WHO, in collaboration with other partners like UNICEF, is also providing technical support on the use of these tools or when developing supply chain continuous improvement plan. Further details of the Effective Vaccine Management initiative can be found [here](https://extranet.who.int/evm2/web/Public).

**FAQs**

Reactive – regarding delivery of short shelf-life vaccines to countries through COVAX

* All vaccines have an expiry date and expired vaccines, including vaccines for COVID-19 should not be administered.
* COVAX only deploys vaccines to countries immediately ready to start immunization campaigns.
* In order to reach as many people as possible, pending EUL, AZ pre-produced and stockpiled as many doses of its vaccine as it could.
* The expiry date for the AZ vaccine (and all COVID vaccines to date) is six months. This is largely because manufacturers have only had six months’ data to work with. It is expected that expiry dates will be extended once more data is available.
* UNICEF and PAHO are working alongside airlines, and freight and logistics providers to ensure that COVID vaccines are delivered safely and efficiently but the distribution of vaccines is a logistical challenge at the best of times and during a pandemic, those challenges have been exacerbated.
* WHO will continue to work with COVAX partners and manufacturers to ensure that any vaccine wastage is kept to an absolute minimum.

## **Manufacturing and vaccine distribution**

* Countries’ upfront payments to manufacturers will help secure manufacturing capacity, promote R&D and make advanced market commitment to companies.
* Each of the manufacturers has a supply plan with multiple sites of manufacture.
* Serum Institute of India has contractual arrangements with Astrazeneca (AZ) and with Novavax to produce both of these products under license, with 200 million doses (and options for up to 900 million more) committed to the Facility.
* CEPI is the partner who holds primary responsibility for the expansion of manufacturing capacity, and this is one of the criteria that is considered for investments in upstream R&D of the products.
* Gavi also considers manufacturing capacity as a criteria for investment when procuring doses on behalf of the Facility.
* Procurers of vaccines should stick to the regulated supply chain and conduct due diligence on any offers / suppliers
* **On the risk of falsified vaccine reaching patients:** At this stage, there is no reason for the general public to be alarmed about falsified versions of vaccines as long as they procure products in the regulated / controlled supply chain. Regulators and national agencies are aware of the threat and implementing mitigation measures to ensure supply chain integrity. It is important to procure from safe and reliable sources that have undergone due diligence checks.
* **On the harm caused:** Assessing the harm caused by substandard and falsified (SF) medical products is complex and difficult. In the case of falsified vaccines, the socio-economic and public health harm includes loss of trust in public organizations. It is important to stress that any harm caused by a falsified vaccine does not reflect any safety failure of an authentic / genuine version. Genuine vaccines which have been subject to regulatory approval are considered to be safe, efficacious, and quality assured.
* **On WHO work to mitigate the risk of SF vaccines:** WHO works with Member States to prevent-detect-respond to SF medical products. This covers technical and operational approaches (including a case reporting system) and a policy approach (the Member State mechanism on SF medical products). Please refer to[**this**](https://www.who.int/health-topics/substandard-and-falsified-medical-products#tab=tab_1 .).
* As of 07 January, WHO is aware of some versions of falsified Covid19 vaccines, however the incidents reported to date do not provide cause for alarm and appropriate regulatory action has been taken. A number of these have already been the subject of media articles and reported to WHO and most are small-scale operations.

FAQs

**Q: Has WHO heard of any black market usage of the COVID vaccine (such as refilling vials and selling them 'privately') or whether this is something that WHO have deemed a risk.**

* Procedures should be in place for the secure disposal of original packaging of any medical product (good storage and handling practices exist at international and national levels). Improper disposal of used vaccine vials may create an opportunity for these to be repurposed and refilled with falsified versions. In the past, WHO received reports whereby vials had been refilled and redistributed (falsified vaccines).
* WHO is aware of some versions of falsified Covid19 vaccines, however the incidents reported to date do not provide any cause for alarm and appropriate regulatory action has been taken (at the national level). People should not be excessively alarmed of the risk of falsified COVID-19 vaccines as long as vaccines are supplied through regulated (legal) supply chains, there is very low risk of falsified vaccines and people can be confident they are receiving quality products.

**Q: How does the WHO and the global community prepare for such issues surrounding the medical black market with regards to Covid-19?**

* The [Global Surveillance & Monitoring System for Substandard & Falsified (SF) medical products](https://www.who.int/health-topics/substandard-and-falsified-medical-products#tab=tab_1) was launched in July 2013. Its objective is to work with WHO Member States in improving the quantity, quality and analysis of accurate data concerning SF medical products, and to use that data in the better prevention, detection and response to those products, in order to protect public health.
* Member States submit reports of SF medical products to the WHO global database: immediate short term support is provide to help the member states deal with the incident, and in the long term the data pooling allows deep analysis of the driving forces, vulnerabilities and needs at national, regional and global levels. The GSMS is principally made up of a database of SF medical product records and incidents, network of focal points, online portal, thematic analysis, various services (global alerts, target market surveillance lists, etc.), training and workshops, etc. We deliver GSMS-related services in English, French, and Spanish.
* In addition to this technical work, WHO hosts the Member State mechanism on substandard/falsified medical products. This Member State mechanism aims to: (a) protect public health and promote access to affordable, safe, efficacious, and quality medical products; and (b) promote prevention and control of substandard and falsified medical products and associated activities.

## **1.13 Scale up of manufacturing capacity**

* Rapid scale-up of manufacturing capacity and cooperation is possible: For example, companies can turn over their facilities to produce other companies’ vaccines and enter into partnerships with other producers – Oxford/Astra Zeneca, for instance, has multiple production nodes around the world; in some countries, this is allowing for rapid and simultaneous scale-up of their vaccine.
* Companies can also issue non-exclusive licenses, so that as many producers as needed can manufacture their vaccine. There is a precedent for this: voluntary licenses have played a key role in expanding access to HIV and hepatitis C treatments. C-TAP, a WHO initiative, facilitates the voluntary license of technologies in a non-exclusive and transparent manner by providing a one-stop shop where developers can share knowledge, IP and data.
* The sharing of this knowledge and data could help enable immediate use of untapped production capacity: Open-sourcing will enable immediate use of untapped production capacity, through such initiatives as the Developing Countries Vaccine Manufacturers Network, and help build additional manufacturing bases—especially in Africa, Asia, and Latin America—which will be essential to meeting ongoing demand for COVID-19 booster shots and future vaccines. Expanding production globally would make poor countries less dependent on donations from rich ones

**Q: Does the WHO believe that the 20% target for 2021 is still realistic given current issues with scaling up manufacturing?**

* COVAX now has agreements in place to access nearly two billion doses of several promising vaccine candidates, and laid the groundwork for further doses to be secured through contributions from donors. These agreements mean that all COVAX’s 190 participating and eligible economies will be able to access doses to protect vulnerable groups in the first half of 2021. At least 1.3 billion donor-funded doses will be made available to 92 economies eligible for the Gavi COVAX AMC, targeting up to 20% population coverage by the end of the year.

Q:**Why is there a vaccine “shortage”?**

* Dr Bruce Aylward on [29 Jan 2021](https://www.who.int/multi-media/details/who-daily-press-conference-on-novel-coronavirus---29-january-2021): the projections on the supply of vaccines made by manufacturers were very ambitious, and have had to be revised downwards. The process of producing vaccines, a biological product, is hard to immediately scale up. He added: “There's been a contraction in global producers of vaccines for years. It's a difficult business to be in and as we go forward, part of what we're going to have to look at is, to take a hard look at how we solve that and make sure that we move more quickly.”
* Dr Soumya Swaminathan on [2 Feb 2021](https://www.youtube.com/watch?v=E1hoAI3v4cM): “One thing we would like to encourage, for developers who now have vaccines that have passed the clinical efficacy trials, is to explore how they would expand manufacturing capacity by partnering with other manufacturers which have spare capacity in different parts of the world,” stating that the utility of this capacity building would extend beyond the pandemic.

# **COVAX**

## **2.1 What is COVAX?**

* [COVAX](https://www.who.int/initiatives/act-accelerator/covax/covid-19-vaccine-country-readiness-and-delivery/acceptance-and-demand) is part of the Act accelerator which WHO launched with partners in 2020. COVAX**,** the vaccines pillar of ACT-A, convened by CEPI, Gavi and WHO, with UNICEF aims to end the acute phase of the COVID-19 pandemic by:
  + speeding up the **search and development** of a safe and effective vaccine against COVID-19;
  + supporting the building of **manufacturing capabilities** and buying supply ahead of time so that at least 2 billion doses of vaccine, including 1.3 billion doses for the 92 countries being supported by the COVAX Advance Market Commitment, can be fairly distributed by the end of 2021;
  + COVAX will continue beyond 2021 as the need for coordinated action on vaccine development, supply, allocation, and deployment will certainly be needed. As we respond to the variants and the need to scale coverage, manufacturers will continue to scale up their capacity to ensure that vaccines are available to all and prioritised to those that need them most. Dose-sharing from countries with substantial doses through bilateral mechanisms may begin as early as Q1 2021 but the majority is expected to take place in the second half of 2021 and 2022
  + COVAX is working with governments and manufacturers to ensure fair and equitable allocation of thevaccines for all countries and is the only global initiative to do so.
* COVAX is co-led by Gavi, the Vaccine Alliance, the World Health Organization (WHO) and the Coalition for Epidemic Preparedness Innovations (CEPI), working in partnership with UNICEF as well as the World Bank, civil society organisations, manufacturers, and others

## **2.2 COVAX R&D work**

* CEPI is leading COVAX vaccine research and development work, which aims to develop safe and effective vaccines which can be made available to countries participating in the COVAX Facility. To date, $1.3bn has been raised in support of COVID-19 vaccine research and development, but CEPI urgently needs $800m in additional funds to continue to support the development of safe and effective vaccines which will be made globally available through COVAX.[[35]](#footnote-35)
* CEPI has invested in 11 vaccine candidates. 9 of these candidates are still in development, and 7 are in clinical trials. CEPI is also evaluating additional candidates for support, including ‘next generation’ vaccine candidates to provide additional options for the future.[[36]](#footnote-36) More information available [here](https://cepi.net/research_dev/our-portfolio/).

# **COVAX Facility**

## **3.1 The COVAX vaccine portfolio**

* Gavi, on behalf of the COVAX Facility, is negotiating deals for doses of promising vaccine candidates. Agreements for **nearly 2 billion doses** of the AstraZeneca, Pfizer, Novavax, Johnson&Johnson and Sanofi/GSK candidates are already in place (see [Gavi press release](https://www.gavi.org/news/media-room/covax-announces-additional-deals-access-promising-covid-19-vaccine-candidates-plans) 18 Dec 2020, [GAVI/Pfizer press release](https://www.gavi.org/news/media-room/covax-announces-new-agreement-plans-first-deliveries) 22nd Jan 2021 & [GAVI/Novavax](https://www.gavi.org/news/media-room/gavi-signs-memorandum-understanding-novavax-behalf-covax-facility) 18th February 2021 for more details).
* Additionally, COVAX has the **largest and most diverse R&D portfolio** of COVID-19 candidate vaccines in the world supported by CEPI. It contains a range of technology platforms and is constantly reviewed and optimized to ensure access to the best possible range of products. In addition to the doses already secured, the COVAX Facility has secured first right of refusal in 2021 to potentially over one billion doses in 2021 of promising candidates in the COVAX R&D portfolio through R&D partnership agreements with CEPI.[[37]](#footnote-37)
* Given that the supply arrangements are for 2 billion doses of vaccine candidates, some of which are still under development, COVAX will continue developing its portfolio: this will be critical to achieve its goal of securing access to 2 billion doses of safe and effective, authorized vaccines that are suitable for all participants’ contexts, and available by the end of 2021.
* COVAX has an agreement with Serum Institute of India (SII) for 200 million doses – with options for up to 900 million doses more – of either or both the AZ or Novavax COVID-19 vaccine candidates. These are exclusively for lower income countries supported by the Gavi COVAX Advanced Market Commitment (AMC). Our goal, supported by the Government of India, remains to begin supplying doses in February and early March so that all countries can have timely and equitable access to vaccines.
* The full list of deals that have so far been secured by Gavi on behalf of the Facility as announced on 22nd January can be located [here](https://www.gavi.org/news/media-room/covax-announces-new-agreement-plans-first-deliveries).
* These agreements mean that all COVAX’s 190 participating and eligible economies will be able to access doses to protect vulnerable groups in the first half of 2021. At least 1.3 billion donor-funded doses will be made available to 92 economies eligible for the Gavi COVAX AMC, targeting up to 20% population coverage by the end of the year.
* The COVAX Facility has developed [Principles for Dose-Sharing](https://www.gavi.org/news/document-library/principles-sharing-covid-19-vaccine-doses-covax) - see s4.2.
* COVAX is engaging with these countries to ensure COVAX becomes the primary recipient of shared-doses.
* We will be providing to the countries a clearer picture of the pace of doses that can be expected in Q1 and Q2, which will be limited, and then much larger volumes in Q3 and Q4.

## **3.2 When will we have the vaccine and return to “normal life”?**

* **Lines agreed between CEPI, Gavi and WHO:** In a supply limited environment, which it will be for 2021, a global approach, which can distribute vaccines fairly, and equitably is the best approach. The Covax Facility is the only such global mechanism and WHO is fully supporting the Facility. It was less than three months ago that COVAX declared itself open for business. Today, thanks to unprecedented international collaboration, COVAX has secured access to nearly 2 billion doses of vaccines and is on track to start delivering to all 190 participating economies in the first half of the year, possibly starting as early as February.
* The list of vaccine related SRAs (i.e. those from which approval will be acceptable), under exceptional circumstances, for product eligibility under the COVAX Facility can be found [**here**](https://extranet.who.int/pqweb/sites/default/files/documents/Product-Eligibility_COVAX-Facility_Dec2020_0.pdf).
* COVAX’s stated goal is to end the acute phase of the pandemic globally by delivering doses of safe and effective vaccines, on a global, fair and equitable basis by the end of 2021. According to forecasting and assuming funding availability, as many as ~1.8 billion doses are expected to be available to the 92 economies of the Gavi COVAX Advance Market Commitment (AMC) in 2021, corresponding to ~27% coverage of AMC populations. The COVAX Global Supply Forecast is available [here](https://www.gavi.org/sites/default/files/covid/covax/COVAX%20Supply%20Forecast.pdf) and provides a global and regional overview. It should be noted that the supply forecasts reflect a preliminary distribution of doses based on each participant’s share of the available supply pro rata by demand and are to be treated as indicative.
* This process is subject to a number of caveats, as there are a number of uncertainties affecting the supply of covid-19 vaccines in 2021, not least around manufacturing capacity regulation and, funding availability, final contract terms and the readiness of countries themselves to begin their vaccination programmes.
* For COVID-19, a new disease causing a global pandemic, many vaccines are in development and some are in the early phase of rollout, having demonstrated safety and efficacy against disease.  The fraction of the population that must be vaccinated against COVID-19 to begin inducing herd immunity is not known. This is an important area of research and will likely vary according to the community, the vaccine, the populations prioritized for vaccination, and other factors.
* It is important to maintain the interventions that we know are effective against infection such as washing hands and mask-wearing, until the vaccine is rolled out to levels that can begin to induce herd immunity. Because there is limited evidence about the performance of the vaccines to prevent infection or transmission the proportion of population needed to be vaccinated, to begin herd immunity, is not yet known.
* Vaccines alone will not return the world to pre-COVID life. And we are looking at 2022 before enough people have immunity through vaccination to see community protection from COVID-19. This means that, for many months to come, we have to maintain the measures that we know are having an effect like physical distancing, masking and respiratory hygiene.[[38]](#footnote-38)
* The scientific community has set a new standard for vaccine development, with no vaccine in history being developed as rapidly. It is now up to governments around the world to set a new standard for access.
* The urgency and speed with which COVID-19 vaccines are being developed must be matched by the same urgency to ensure everyone can benefit from them.

**Q:** **How much immunization will be needed to reach herd/population immunity?**

In short: we do not know. We need information on the impact of vaccines on infection and transmission, which is still being worked on. It also depends on the virus itself---the more transmissible the higher the vaccine coverage needed for herd immunity. Also, the mixing patterns of people make a difference. Modelling studies provide some insights but we should tread with caution as these provide information about what attributes of the vaccine and the epidemiology are most influential on getting to herd immunity rather than a specific prediction of the coverage level.

Also, we should not rely on a single number. An overall high rate of vaccine coverage does not imply that we are all safe. We have seen examples of clusters of measles in subpopulations, even when the overall population had high rates of vaccine coverage. Instead of focussing on an overall statistic, we should take advantage of our knowledge of COVID-19 transmission to have a smart and targeted approach. Herd immunity is relevant from a local perspective. It is about the coverage in the community in which you live, and the social mixing patters, and the degree of transmission of the virus in that community.

# **WHO positions on:**

## **4.1 Access and distribution**

* WHO sees COVID-19 technologies that save lives and prevent infections as **global public goods.** In the [COVID-19 resolution](https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_R1-en.pdf) adopted at the World Health Assembly in May 2020, WHO Member States have prioritized equitable and fair access and distribution of COVID-19 health technologies and products.
* It will require a fundamental change in funding and approach to realize the full promise of the ACT Accelerator. The development of COVID vaccines would not have been possible without public funding and should be available to all as a public good.
* Intellectual property should maximize health-related innovation and promote access to health products.
* The [COVID-19 Technology Access Pool](https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool#:~:text=The%20COVID%2D19%20Technology%20Access,knowledge%2C%20intellectual%20property%20and%20data.) (C-TAP) will compile, in one place, pledges of commitment made under the Solidarity Call to Action to voluntarily share COVID-19 health technology related knowledge, intellectual property and data. The Pool will draw on relevant data from existing mechanisms, such as the Medicines Patent Pool and the UN Technology Bank-hosted Technology Access Partnership. Shared knowledge, intellectual property and data will leverage our collective efforts to advance science, technology development and broad sharing of the benefits of scientific advancement and its applications based on the right to health.[[39]](#footnote-39)
* C-TAP, a WHO initiative, facilitates the voluntary license of technologies in a non-exclusive and transparent manner by providing a one-stop shop where developers can share knowledge, IP and data.
* **Reactive:** C-TAP is an innovative initiative and has potential for the middle to longer term, but we were aware from the outset that it would take greater efforts and a longer timeframe to bring the different interest groups together. For that reason the global health community is relying on the ACT-Accelerator, of which COVAX is a part, as a crucial mechanism to deliver results more rapidly.
* **People’s Vaccine initiative:** The People’s Vaccine is a growing movement of health and humanitarian organisations, past and present world leaders, health experts, faith leaders and economists urging that when safe and effective vaccines are developed, they are produced rapidly at scale and made available for all people, in all countries, free of charge.
* WHO agrees with the human rights and access principles behind the People’s Vaccine initiative. As WHO has stated since the beginning of the pandemic, equitable access to safe and effective vaccines, treatments and other tools is the only way the virus can be beaten and to get societies and economies up and running again. This is why we have created the ACT-Accelerator with health partners and COVAX in particular. 190 countries and economies have signed up and in so doing, they commit to an allocation framework for fair and equitable access to COVID-19 vaccines. The guidance on vaccine distribution will ensure that countries can prioritize at-risk groups AND maximize limited initial vaccine supplies.
* We believe that for the next year we will be facing a scarcity of manufacturing capacity and production. Along with the President of Costa Rica, WHO has launched the COVID-19 Technology Access Pool (C-TAP), which is aimed at increased sharing of knowledge and scientific information but also the voluntary pooling of patents and licenses. This will help expand local production and technology transfer to address supply chain bottlenecks. We need to increase our efforts in this area.
* Technology transfers often take place over years, rather than the weeks and months that are currently being suggested a timeline. WHO recognises that this ‘business as unusual’ will take time to adjust to, and call upon governments and companies to actively engage in conversations to enable rapid scale-up and equitable distribution.
* Sharing Intellectual Property is one of a number of barriers to achieving equitable and affordable access to COVID-19 tools and technologies. The affordability and availability of vaccine ingredients/components may become an issue, manufacturing capacity must be substantially increased as well the requirements for cold-chain which need to be carefully planned in order to be mitigated. [[40]](#footnote-40)
* **Iran’s access to COVAX:** An OFAC license has been secured so there is no legal barrier to Iran procuring vaccines through the COVAX Facility. Please cite, according to WHO
* When it comes to doses that countries will be receiving, it is important to note that to meet the large demand that we foresee, COVAX will need as many vaccine candidates as possible for use across a range of populations and settings. COVAX has deals with Pfizer, AstraZeneca, the Serum Institute of India (for AZ and Novavax vaccines), Johnson & Johnson and Sanofi-GSK. This varied portfolio is augmented by manufacturers supported by CEPI, which has secured a potential additional 1 billion doses in 2021 through R&D partnership agreements.
* There are ongoing negotiations with other manufacturers. We will be announcing future deals and doses secured in due course.
* The COVAX Facility is open for discussions with all manufacturers meeting the priority criteria of the Facility for the managed portfolio

## **4.2 Vaccine nationalism**

* Joining the COVAX Facility does not preclude countries from entering **bilateral deals**: many of those that have joined the COVAX Facility have bilateral deals as well. By joining the Facility at the same time as having bilateral deals, countries will be betting on a larger number of vaccine candidates.
* Regarding bilateral deals, we recognize that countries are responsible to their populations and are working in their interest, however, in a supply limited environment, which it will be for 2021, a global approach, which can distribute vaccines fairly, and equitably is the best approach.
* The ambition of COVAX is to be a global scheme for equitable access: it was set up as a mechanism to provide equity in vaccine distribution across countries of all types; high-income, middle-income, low-income. Over the last few months, many have done bilateral deals and have their own supplies but the COVAX Facility will maintain the commitment to dose allocation for all countries. The WHO strongly encourages countries with access to substantial numbers of doses to share them with the COVAX facility and discourage vaccine nationalism.
* “There was a lot of negotiation as COVAX was taking shape as to whether or not we should count bilateral deals and the agreement in the end was no we wouldn't count bilateral deals because too many countries would not be able to participate, it was much more important than they participate in COVAX”[[41]](#footnote-41)
* A [study](https://www.gavi.org/vaccineswork/equitable-covid-19-vaccine-distribution-will-lead-biggest-reduction-deaths) by [Northeastern’s MOBS lab in partnership with the Bill and Melinda Gates Foundation](https://www.mobs-lab.org/uploads/6/7/8/7/6787877/global_vax.pdf), recently estimated that if the first 2 billion doses of an 80% effective vaccine are distributed equitably worldwide, 6 out of 10 of deaths could be prevented. But if 50 countries were to monopolize COVID-19 vaccine supplies, only about half as many deaths would be averted.[[42]](#footnote-42)
* The Covax Facility is the only such global mechanism and WHO is fully supporting the Facility.
* We applaud all COVAX participants for their commitment to global solidarity through their contributions to the Facility. We are especially grateful to those who are generously supporting the Advance Market Commitment to assure that countries of all means have access to COVID-19 vaccines.
* The Facility encourages countries that have bilateral arrangements with manufacturers to consider sharing their doses with the Facility so that the doses can support the AMC92 countries. The COVAX Facility has developed [Principles for Dose-Sharing](https://www.gavi.org/news/document-library/principles-sharing-covid-19-vaccine-doses-covax) which provides a framework for higher-income economies to make additional volumes secured via bilateral deals available through the Facility primarily to AMC participants, on an equitable basis.
* The Principles for Dose-Sharing provide a way for high-income economies to make additional volumes from bilateral deals available primarily to AMC participants, for this purpose on an equitable basis. Shared doses are ideally paid for by the dose-sharing country, including ancillary costs. Document [here](https://www.gavi.org/sites/default/files/covid/covax/COVAX_Principles-COVID-19-Vaccine-Doses-COVAX.pdf)
* The Facility ensures these doses are distributed equitably, effectively & transparently while supporting readiness in AMC economies.[[43]](#footnote-43)
* The Gavi COVAX AMC is the mechanism within the COVAX Facility that will [support the participation of 92 lower-income economies](https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.gavi.org%2Fnews%2Fmedia-room%2F92-low-middle-income-economies-eligible-access-covid-19-vaccines-gavi-covax-amc&data=02%7C01%7Cmsharafudeen%40gavi.org%7C6e78613ee49e4a37761f08d83df439fd%7C1de6d9f30daf4df6b9d65959f16f6118%7C0%7C0%7C637327466449089736&sdata=nRHVDqAc%2FpOXaRfxmH3UL6UvqIIeSsVEE%2BkqygT7JoA%3D&reserved=0), ensuring equitable access to the most at-risk everywhere in the world – regardless of their ability to pay. The Gavi COVAX AMC will be funded primarily by official development assistance. If the AMC does not receive adequate funding, it is highly likely that poorer countries will miss out on COVID-19 vaccines in the first few years after they become available – meaning the pandemic will continue, as will its unprecedented impact.

**Vaccine nationalism FAQs**

**Q: Dr Tedros referred to countries bilateral deals which are undermining COVAX in a recent speech. Which countries are these?**

* Apart from the original ‘richest’ countries that made bilateral deals months ago, even before vaccines came off the pipeline, some other high-income countries have recently made bilateral deals with a number of companies that have signed up to the COVAX Facility. We’ve observed that companies will give priority to bilateral deals, which in this initial period of supply constraints inevitably affects the availability of batches that could have gone to COVAX AMC countries. This is why WHO has been advocating for a coordinated global plan. The current piecemeal approach favours those who can pay most and leads to some populations already vaccinating younger people while (many) others haven’t even started vaccinating health workers and high-risk groups.

**Q: What seems to be happening currently, is that rich countries are buying what little vaccine doses are available with vague assurances that they will share doses in the future with poorer countries. How does WHO think this can be addressed?**

* Regarding bilateral deals, we recognize that countries are responsible to their populations and are working in their interest, however, in a supply limited environment, which it will be for 2021 a global approach, which can distribute vaccines fairly, and equitably is the best approach.
* The Covax Facility is the only such global mechanism and WHO is fully supporting the Facility. COVAX is engaging with these countries to ensure COVAX becomes the primary recipient of shared-doses.
* When the mechanism was designed, it was not known that there would be so many bilateral deals. The COVAX Facility will maintain the commitment to dose allocation for all countries. The WHO strongly encourages countries with access to substantial numbers of doses to share them with the COVAX facility and discourage vaccine nationalism.
* There's also the option for countries to opt out, so countries that have vaccines through other sources can choose to have their doses reallocated to other countries which may not have access already.
* The [Principles for Dose-Sharing](https://www.gavi.org/news/document-library/principles-sharing-covid-19-vaccine-doses-covax) provide a framework for higher-income economies to make additional volumes secured via bilateral deals available through the Facility primarily to AMC participants, on an equitable basis. Link to the Principles [here](https://www.gavi.org/sites/default/files/covid/covax/COVAX_Principles-COVID-19-Vaccine-Doses-COVAX.pdf).

**Q: Is Vaccine nationalism undermining COVAX/Making it a failure?**

* COVAX now has agreements in place to access nearly two billion doses of several promising vaccine candidates, and laid the groundwork for further doses to be secured through contributions from donors.
* These agreements mean that all COVAX’s 190 participating and eligible economies will be able to access doses to protect vulnerable groups in the first half of 2021. At least 1.3 billion donor-funded doses will be made available to 92 economies eligible for the Gavi COVAX AMC, targeting up to 20% population coverage by the end of the year.[[44]](#footnote-44)
* With the correct funding in place, we believe COVAX may be able to deliver 2.27 billion doses of COVID-19 vaccines worldwide by the end of this year. Of these, 1.8 billion doses [[45]](#footnote-45)could be available to lower-income countries at no cost to their governments, including over 700 million doses for African nations.

**Q: Why were Canada and other rich countries included in the COVAX interim allocation of countries?**

* Countries joined COVAX under specific rules, which cannot be changed. However we can adapt and create space for participating countries to engaged with the principles of the COVAX facility. This means giving them options to opt out or options to move to a different point in the queue [[46]](#footnote-46)
* Some countries may have taken the indicative allocation but may yet take a decision to opt out.
* Those doses can then be reallocated to other countries which may not have access to any vaccine doses
* However, bilateral agreements by wealthier nations are in some cases making fair and equitable allocation of vaccines a challenge. We know that protecting high-income countries alone will not end the pandemic. We must ensure that COVID-19 vaccines are affordable and accessible to all countries. Only by allowing all countries equal access to vaccines, tests and treatments, can we end the pandemic and its devastating impacts for everyone, including children.[[47]](#footnote-47)
* WHO calls upon countries with bilateral deals to consider donating their doses to other COVAX participants with less means through the [Principles of Dose Sharing.](https://www.gavi.org/sites/default/files/covid/covax/COVAX_Principles-COVID-19-Vaccine-Doses-COVAX.pdf)

**On why rich countries don’t have to complete an NVDP (reactive)**

* It is a means to support countries with weaker health systems to get ready – it is a service not a filter

## **Vaccine safety – how can we trust the rushed process?**

* See **key messages above** also.
* We have efficacy results now from 7 products in the public domain, but only 3 have peer reviewed efficacy results (Astrazeneca-Lancet, Pfizer-NEJM, and Moderna-NEJM), 1 has been successfully reviewed by the WHO & SRAs (Pfizer), 3 are under review by SRA and WHO (AZ, Sinopharm and Moderna) and three (Gamaleya, Sinovac and Serum Institute of India) are in discussions with WHO PQ team for data submission to WHO. Link to document [here](https://extranet.who.int/pqweb/sites/default/files/documents/Status_COVID_VAX_20Jan2021.pdf)
* WHO itself is not a regulator. Regulators are national authorities with enforcement responsibilities. There are also some regional mechanisms, where national authorities have come together for reliance and collaboration such as the European Medicines Agency (EMA).

**FAQs on vaccine safety:**

**Is the Pfizer/BioNTech vaccine safe?**

* The clinical trials for the Pfizer-BioNTech Covid-19 vaccine enrolled more than 40,000 volunteers, half of whom received the vaccine. This amounts to a substantive data set on the safety of the vaccine. Most safety issues are usually observed in the hours immediately following the administration of the vaccine (although full recovery could take a few days).
* [Shanthi Pal to provide update on an analysis that shows that the vast majority of any ‘longer term’ safety issues are within 30 -45 days after immunization and as a result the trials were required to have at least 50% of their subjects followed for at least 60 days. I don’t know the citation but perhaps someone on the Safety Team can point to this. This is what WHO and the stringent regulatory authorities have required.]
* Any rare or possible longer-term safety assessment will be conducted through continued follow up of the clinical trial participants, as well as through specific studies and general continued surveillance of secondary effects or adverse events of those being vaccinated in the roll out. This represents standard practise for all newly authorized vaccines.

**Q: Are we seeing worse side effects from the Pfizer/BioNTech vaccine compared with vaccines for other diseases? Is this something to be concerned about?**

* The vaccine has shown relatively higher reactogenicity, including local reactions, compared to other vaccines such as influenza. These normally abate within a few days. However, anaphylactic reactions, as have been reported, can be serious and this has been taken into account in the current recommendations both by the governments currently implementing COVID-19 vaccination and by WHO, as we continue to monitor incoming data.

**Q: In response to the concerns about AstraZeneca’s vaccine efficacy - will COVAX continue to distribute the AZ vaccine?**

* WHO has recommended the AZ product for use during the pandemic following the advice of SAGE.
* COVAX has signed an Advance Purchase Agreement with AstraZeneca and has published plans to distribute nearly 350 million doses in the first half of the year. WHO has listed the Oxford-AZ vaccine for Emergency Use Listing and has provided recommendations for its use following the recommendations of SAGE.

**In response to concerns about Sinovac vaccine after reports of illness after inoculation**[[48]](#footnote-48). 

* This is in response to a [news report from the South China Morning Post on the 7th March](https://www.scmp.com/news/hong-kong/health-environment/article/3124410/hong-kongs-no-2-official-stresses-vaccines-are)
* WHO is aware of reports from Hong Kong & Chinese authorities regarding concerns about a batch of the Sinovac vaccine.
* WHO is carefully monitoring the rollout of all COVID-19 vaccines. We are working closely with countries to manage potential risks, and will continue to use science and data to drive our response and recommendations.
* Sinovac is under review for EUL; an announcement is expected at the end of March or early April.
* Sinovac has been authorized for use by 10 national regulators.
* When vaccines are authorized, evidence comes mainly from controlled, randomized clinical trials in tens of thousands of participants, whereas after authorization, vaccines will be used in real conditions by a far larger population.
* Following the introduction of a vaccine, close monitoring continues to take place to detect any unexpected adverse side effects and further assess effectiveness among even larger numbers of people, to continue assessing how best to use the vaccine for the greatest protective impact.
* **Q: Are you concerned that COVAX is shipping vaccines that are already out-dated?**
* A: The Oxford-AstraZeneca vaccine has been shown to be effective and has already received regulatory approval from a number of stringent regulatory authorities. The EUL has been granted by WHO, and the vaccine will have a key role to play in our effort to end the acute phase of this pandemic.
* The latest data underline the importance of adapting vaccines to new and emerging variants of the virus, continuing research on efficacy and safety in different countries, as well as the importance of maintaining a diverse portfolio of vaccines capable of use in a range of settings and circumstances.
* A diverse portfolio of vaccines capable of use in a range of settings and circumstances.

## **Safety and efficacy for different population groups**

* More information is still needed to determine the safety and efficacy of different COVID-19 vaccines in some population groups. For example, children under 16 years of age have not been enrolled in COVID-19 vaccine trials, so it is not yet clear if these vaccines are safe and effective for children.
* As COVID-19 vaccines are introduced, WHO will support work with vaccine manufacturers, health officials in each country, and other partners to monitor for any safety concerns on an ongoing basis.
* Well-designed vaccine trials are critical for determining if a vaccine has worthwhile efficacy. Even in the context of high vaccination coverage, if a vaccine with weak efficacy is deployed, only a small proportion of the people vaccinated will be protected/immune, and changes in other public health measures may be relaxed under the impression that vaccine has provided greater protection than it has.
* Initial use of a vaccine with limited efficacy also complicates the development pathway and testing of subsequent vaccine candidates that may have greater efficacy.  This may delay and even imped the opportunity to have the most impactful vaccines possible (thus losing precious time and increasing danger of worsening the outbreak).
* It has not been possible to establish the duration of efficacy of the vaccines. In addition, there are no established correlates of protection which would allow inferring protection from immunogenicity data. However, immunogenicity data from early studies show that immunity persists for several months but the full duration is not yet known. It is premature to conclude that this results in long-term protection, so continued monitoring will be needed.

**Pregnancy**

* While pregnancy puts women at higher risk of severe COVID-19, very little data are available to assess vaccine safety in pregnancy.
* Pregnant women may receive the vaccine if the benefit of vaccinating a pregnant woman outweighs the potential vaccine risks.
* For this reason, pregnant women at high risk of exposure to SARS-CoV-2 (e.g. health workers) or who have comorbidities which add to their risk of severe disease, may be vaccinated in consultation with their health care provider.

**Claims about the vaccine leading to female infertility**

* + When any vaccines are authorized, evidence comes mainly from controlled, randomized clinical trials in tens of thousands of participants. Following the introduction of a vaccine, close monitoring continues to take place to detect any unexpected adverse side effects and further assess effectiveness among even larger numbers of people. There is no evidence to suggest that COVID-19 vaccines cause infertility. There are no licensed vaccines of any type that cause infertility.

*Note: the below answers are used by Facebook internally to help provide guidance as to where users should be directed for this information internally. These are not provided as answers in the public domain. The ‘questions’ are as provided by Facebook*

**Inclusion of in people with mental illness in high-priority category for vaccination**

* The rationale for vaccinating persons with mental illness is the fact that they cannot use nonpharmaceutical interventions, be it masks, or even just simple physical distancing. So they are at higher risk of exposure, rather than higher risk of more severe disease. They fall under Stage II of SAGE’s prioritization roadmap.
* *“Groups with comorbidities or health states determined to be at significantly higher risk of severe disease or death in areas with high transmission or anticipated high transmission. Efforts should be made to ensure that disadvantaged groups where there is underdiagnosis of comorbidities are equitably included in this category”[[49]](#footnote-49)*

**Claims people died after taking the Pfizer vaccine--how can we verify?**

* + Refer to safety and efficacy points above.
  + WHO is aware of data from Pfizer-BioNTech vaccine trials regarding deaths among the trial participants. These are part of the clinical trial published reports. All trials monitor for health events occurring among trial participants and then assess whether those events have anything to do with the vaccine. It is important to recognize that among any group of people observed over time, especially among older adults, deaths will occur. Reuters [reported](https://www.reuters.com/article/uk-factcheck-pfizer-health-concerns/fact-check-clarifying-claims-around-pfizer-vaccine-deaths-and-side-effects-idUSKBN28K2R6) that only two of these people were given the vaccine and that the other four were given a placebo solution of salt and water. No causal relationship was established between the vaccine and the two deaths, which occurred in line with the normal death rate for the general population.

Claims **that COVID-19 vaccines are not Halal**

* + No vaccine being developed for COVID-19 contains animal products/components of animal origin
  + In the UK, the Pfizer-BioNTech vaccine, which is being given to the public, was approved by the British Islamic Medical Association (BIMA) and other Islamic scholars, stating the vaccine was halal "based on the information available."
  + **From UKgov website:** The [Medicines and Healthcare products Agency](https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency) can confirm that the Pfizer/BioNTech COVID-19 vaccine does not contain any components of animal origin.
* From UKGov [website](https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca): The MHRA can confirm that the COVID-19 Vaccine AstraZeneca does not contain any components of animal origin.
  + For other COVID vaccines, there is no product summary upon which scholars and health professionals could make a decision.

**Norway:**

* In January there was data from Norway regarding deaths of a number of very frail elderly individuals who had been vaccinated. This was picked up by the press.
* On 19th January 2021, the WHO Global Advisory Committee on Vaccine Safety reviewed all available data including data regarding from Norway, and announced that it would continue to recommend Pfizer/BioNTech as a safe vaccine for elderly people. More details can be found [here.](https://www.who.int/news/item/22-01-2021-gacvs-review-deaths-pfizer-biontech-covid-19-vaccine-bnt162b2)
* COVID-19 vaccines are being given as a priority to older people as they are at higher risk of developing a severe form of COVID-19 and dying from it.
* Vaccination against COVID-19 will not reduce deaths from other causes. Deaths from other causes will continue to occur, including after vaccination but causally unrelated.
* Over 30 million people in the world have received a COVID-19 vaccine. No cases of death have been found to have been caused by COVID-19 vaccines to date.
* As soon as WHO and partners have gained a full understanding of these events, the findings and any changes to current recommendations will be immediately communicated to the public.

WHO is carefully monitoring the rollout of all COVID-19 vaccines. We are working closely with countries to manage potential risks, and will continue to use science and data to drive our response and recommendations.

**Effect of Alcohol on efficacy**

* Current WHO guidance regarding alcohol consumption and immune response: Current evidence indicate that alcohol use has a clear impact on immune responses in high doses of consumption and in people with alcohol dependence and in the presence of comorbid conditions.
* The WHO has no specific guidance on alcohol use and effectiveness of COVID- 19 vaccines, it is at discretion of national authorities to provide advice reflecting their national circumstances.

## **Variant strains**

* WHO is working with scientists and health officials in the countries where variants are known to be circulating to understand how these changes affect the virus’ behaviour. WHO will continue to inform countries and the public as we learn more.
* Transmission is multifactorial, depends on virus characteristics but also a population’s ways of living and measures put in place. It is also important to note that whilst we still don’t know why the variants are more transmissible in some countries, we haven’t yet seen any changes in modes of transmission so far. This means there is no change to the recommended methods of prevention.
* To determine whether variants may alter how well vaccines work, viruses need to be isolated from clinical specimens for further study in the laboratory, especially studies to assess how well serum (blood) from people who have been vaccinated neutralize the virus (stop it from replicating). Some of these studies have been done and more are underway.
* Many of the vaccines currently being used have been tested in the laboratory to assess whether the response to these vaccines results in neutralizing (inactivating) the virus. For some of the variants and some of the vaccines there is no reduction in neutralization while for other combinations of vaccine and variant there is more substantial reduction in the neutralization. What is most important is not neutralization but the clinical findings.
* Please refer to the latest Disease Outbreak News ([DON](https://www.who.int/csr/don/en/)): “As of 30 December, VOC-202012/01 variant have been reported in 31 countries in five of the six WHO regions.”
* Countries need to continue increasing sequencing of SARS-CoV-2 viral isolates, upload to GISAID (a global science initiative providing open-access to genomic data of influenza and COVID-19 viruses) and report any new mutations to WHO through their International Health Regulations National Focal Points.
* The new variants highlight the need for better genomic surveillance and sequencing across the world; the need for sharing data and strengthening national data platforms to document clinical and epidemiological data and sequencing capacities across the world and for reinforcing collaboration among public health partners.[[50]](#footnote-50)
* Viruses change as they circulate, and these changes may alter the virus characteristics. It’s key to stop the spread of the virus at its source: maintain hand hygiene, physical distancing, masking and all other measures to reduce transmission. The more people get vaccinated, the more virus circulation will be reduced and lower the chance there is for new mutations and variants.
* Whilst at present, WHO is not recommending the application of widespread travel restrictions, we understand that some countries introduce such restrictions as a time limited, precautionary measure, and with consideration of their domestic situation. WHO recommends taking a risk based approach to reduce travel-associated exportation, importation and onward transmission of SARS-CoV-2 while avoiding unnecessary interference with international traffic. Essential travel should always be prioritized and facilitated.[[51]](#footnote-51)
* **B.1.1.7:** This variant was first identified in the UK in December 2020. We are still learning about the possible impact of B.1.1.7 on public health and clinical aspects. Current evidence alludes to the fact that this variant spreads more rapidly. We will update as soon as more information comes in. However, COVID-19 is already a deadly disease, and all needed measures should be taken to control its spread.
  + Impact on vaccines: Studies are ongoing but preliminary in vitro studies (available as pre-prints) show that the Pfizer and Moderna vaccines have limited to no significant loss in efficacy against VOC202012/01. These are preliminary findings which require further investigation involving larger sample sizes. On 28 Jan 2021, Novavax announced that its vaccine was slightly less effective but still sufficiently effective against VOC 202012/01.
* **B1.351:** This variant was first identified in South Africa in December 2020**.**
  + **Oxford AstraZeneca vaccine and the new viral variant (B.1.351) first identified in South Africa**
    - The Oxford AstraZeneca vaccine has been shown in randomized clinical trials in UK and Brazil to be safe and efficacious and has received approval from a number of stringent regulatory authorities. The trial sites did not include sites with B1.351 circulation but did include B1.1.7.
    - A small clinical trial in South Africa concluded that the vaccine is minimally effective at preventing mild to moderate COVID-19 disease caused by a new viral variant (B.1.351) first identified in South Africa.
    - Given the small sample size of the trial and the low-risk nature of the participants (whose median age was 31), the trial was unable to assess efficacy against severe disease or hospitalization, or death, which are the main strategic targets for vaccination. It is now important to determine the vaccine’s efficacy when it comes to preventing more severe illness.
    - SAGE reviewed the available evidence on 8 Feb and recommended to proceed with vaccine rollout recognizing also for country tailoring and the importance of additional studies to fill critical evidence gaps to drive vaccine policy and vaccine development.
    - What these results tell us is that we need to do everything we can to reduce circulation of the virus and delay mutations that may reduce the efficacy of existing vaccines. It also seems increasingly clear that manufacturers will have to adjust to the COVID-19 viral evolution, taking into account the latest variants for future booster shots.
* **P.1** : This variant was first identified in Brazil & has now been found in multiple countries. More detail will be included in the next version.
  + **Impact on vaccines**: There is limited data from the laboratory on the effect of the this variant on several vaccines in use. There are no reports on the clinical impact in the scientific literature at this time but these data will be coming.

**FAQ**

**Q: What is WHO’s response to the UK variant strain?**

* **A:** The Virus Evolution Working Group have observed a number of changes in this variant strain in the UK. Viruses evolve and this behaviour is not unexpected – in fact there are other viruses that do it much quicker eg. flu.
* WHO will continue to study the impact of these mutations.
* Importantly, the interventions needed, regardless of variant, are the same.
* There is no evidence that monoclonal antibodies or vaccines will not work on this strain.
* There are still questions to be answered as to whether it enhances transmissibility.

## **Adverse effects following immunization**

* WHO is aware that there have been reports of allergic reactions to the Pfizer-BioNTech COVID-19 and to the Moderna vaccine.
* This kind of reaction is a known but rare side effect with any vaccine.
* When vaccines are authorized, evidence comes mainly from controlled, randomized clinical trials in tens of thousands of participants, whereas after authorization, vaccines will be used in real conditions by a far larger population.
* Following the introduction of a vaccine, close monitoring continues to take place to detect any unexpected adverse side effects and further assess effectiveness among even larger numbers of people, to continue assessing how best to use the vaccine for the greatest protective impact.
* WHO considers a history of severe allergic reaction (e.g., anaphylaxis) as a precaution but not a contraindication to vaccination. In persons who report a history of anaphylaxis, a risk assessment should be conducted.

**FAQs: Adverse Events Following Immunisation and different population groups**

**Q: Are reports of allergic reactions Pfizer-BioNTech’s Covid-19 vaccine cause for concern?**

* A: WHO is aware that there have been reports of allergic reactions to the Pfizer-BioNTech COVID-19 vaccine.
* This kind of reaction is a known but rare side effect with any vaccine.
* When vaccines are authorized, evidence comes mainly from controlled, randomized clinical trials in tens of thousands of participants, whereas after authorization, vaccines will be used in real conditions by a far larger population.
* Following the introduction of a vaccine, close monitoring continues to take place to detect any unexpected adverse side effects and further assess effectiveness among even larger numbers of people, to continue assessing how best to use the vaccine for the greatest protective impact.

**Q: What is WHO’s advice for people who may have a history of allergic reactions; should they get the vaccine?**

* **A:** A history of allergic reaction (e.g., anaphylaxis) to any component of the vaccine is a contraindication. In particular, the Pfizer vaccine, should not be administered to individuals with a known history of a severe allergic reaction to polyethylene glycol as this polymer can cause anaphylaxis and it is a component of this vaccine.
* In persons who report a history of anaphylaxis, a risk assessment should be conducted to determine type and severity of reaction and reliability of information. These persons may still receive vaccination, but should be counselled about the unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination. Such persons should be observed for 30 minutes after vaccination.
* As a small number of anaphylactic reactions have also been reported in vaccinees without a history of severe allergic reactions, vaccination should only be administered in a health care setting where anaphylaxis can be treated. Until more data and insights are available with regard to severe allergic reactions to the Pfizer vaccine,  all vaccinees should be observed for 30 minutes after vaccination.

**Q: How will the public know if they are having side-effects caused by the vaccine?**

* A: Persons being vaccinated are encouraged to follow local guidance with respect to observation periods immediately following vaccination and to alert their respective health providers of any potential side-effects or unexpected health events experienced following vaccination.

**Q: Does WHO support setting up an apparatus within countries to respond to people who are experiencing an adverse reaction?**

* A: Yes, this kind of monitoring is a standard practice in all national immunization programmes, irrespective of the vaccine being administered.
* WHO has also produced a [dedicated set of training materials](https://www.who.int/initiatives/act-accelerator/covax/covid-19-vaccine-country-readiness-and-delivery) and tools to ensure health care workers carrying out this vaccination are fully informed and up to date on recommended practices.

**Q: Are there concerns that different population groups (eg different sexes, ethnicities and morbidities) could be afforded different levels of protection by COVID vaccines?**

* **A:** The vaccine has been tested in a large randomized controlled trial that included a broad age range, both sexes, people of different ethnicities and morbidities. Within the limits of the statistical power of the study, all populations showed the same high level of efficacy.

## **Vaccine effectiveness**

* While several COVID-19 vaccines appear to have high levels of efficacy, no vaccine is 100% protective. As a result, there will always be some people who do not develop protection as expected after COVID-19 vaccination.
* In addition to a vaccine's specific characteristics, several factors such as a person's age, their underlying health conditions, or previous exposure to COVID-19 may have an impact on a vaccine's effectiveness.
* Evaluations of vaccines’ effectiveness in the routine use setting will be critical for continuing to optimize the use of these vaccines and to further the development of ever more effective vaccines. This is a normal part of the lifecycle of vaccine development and assures that we continue to improve the vaccines and their use.
* This is why, even as COVID-19 vaccines start to be rolled out, we must continue using all public health measures that work, such as physical distancing, masks and handwashing.

FAQs

Q: Is it true that natural immunity is stronger or more effective than COVID-19 vaccine acquired immunity?

* There is not enough data to make a conclusive statement one way or another but what can be said is that Covid-19 vaccines have predictably prevented illness, and they are a far safer bet, than contracting the virus itself.
* A vast majority of people infected produce at least some antibodies and immune cells that can fight off the infection. But there is a huge range in the extent of that immune response and in people who are only mildly ill, the immune protection that can prevent a second infection may wane within a few months.

## **Herd** **immunity**

* ‘Herd immunity', also known as 'population immunity', is the indirect protection from an infectious disease that happens when immunity develops in a population either through vaccination or through previous infection.
* WHO supports achieving 'herd immunity' through vaccination, not by allowing a disease to spread through population, as this would result in unnecessary cases and deaths. The latter is especially concerning in the context of the COVID-19 pandemic, as some people are advocating for a dangerous form of population immunity despite the existence of evidence-based measures people can and should take to protect themselves.
* This is why our updated Q&A piece emphasizes vaccination but because this has generated questions we’ll be updating our content to sharpen the distinction between the benefits of vaccination, and our concerns about letting a disease spread through.

## **Direct protection vs transmission reduction**

* Substantive evidence on the extent to which COVID-19 vaccines can prevent infection and onward transmission to contacts of people who are infected is not yet available.
* Evidence is expected to accrue during the course of the vaccine rollout and WHO will continue to monitor the data, in conjunction with national policy makers and regulatory authorities.
* It is however reasonable to assume there will be some level of protection against transmission.
* [This](https://twitter.com/doctorsoumya/status/1344335042894413824?lang=en-gb) Twitter thread from Soumya Swaminathan is helpful

## **National authorisations on vaccine use without SRA or WHO EUL/PQ**

* WHO invites all manufacturers who have the quality, safety and efficacy data to support WHO PQ/EUL, to fully engage with WHO and submit data for review and consideration.
* That data then has to be comprehensively reviewed for regulatory authorization. The requirements for regulatory review have been established, including the [WHO Target Product Profile](https://www.who.int/publications/m/item/who-working-group-target-product-profiles-for-covid-19-vaccines) for COVID vaccines.
* WHO expects vaccines that are widely used to meet all internationally agreed standards and criteria.
* Several vaccines are being deployed outside vaccine clinical trials, under national authorization, but have not undergone assessment by WHO EUL/PQ or by a SRA. These include the Russian Gamaleya (Sputnik) vaccine, and the Chinese Sinovac and Sinopharm products.
* Sinopharm and Sinovac are in active review for EUL
* There are and will likely continue to be manufacturers of some vaccine candidates who may be delayed in seeking or choose not to seek emergency use listing by WHO or authorisation by an SRA. The use of some of these products has proceeded in a number of countries with the agreement of national authorities. It is possible that the data required for a WHO EUL assessment may not have been available at the time of national decisions to use such vaccines.
* Vaccines will only be procured by the COVAX Facility if they have WHO EUL/PQ or and SRA authorization. Both UNICEF and PAHO Revolving Fund will require such authorizations.
* SAGE develops policy positions on the use of COVID-19 vaccines with WHO EUL/PQ or exceptionally authorised by an SRA.
* 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. We also acknowledge the review by recognized SRAs, although unless we have specific access to data we cannot speak to the details of the product. It is those processes that provides assurance of quality, safety and efficacy.
* **EUL procedures without review by an SRA:** WHO generally relies on already conducted assessments and inspections when they are made available to WHO and have been conducted according to international requirements and standards.
  + When that is the case, WHO will focus only on aspects not already covered – for example, programmatic suitability for low- and middle-income countries, such as safe handling and use under prevailing storage conditions, interactions with other vaccines in use in the countries, mass campaign plans for roll-out and appropriate risk management.
  + In cases where a vaccine has not been evaluated by a stringent regulatory authority, WHO carries out the full spectrum of assessment activities: namely, it evaluates non-clinical and clinical trial data on safety and efficacy, quality of the vaccine, including its manufacture (by physically inspecting the production site), as well as programmatic suitability. [JC to confirm whether it is also a requirement that the product has been assessed by a Functional Regulatory Authority (as determined by WHO?) or can it be any regulatory authority]

## **COVID Vaccines and WHO/EUL:**

* + Vaccines with EULs;
    - Pfizer: Listed 31st December 2020. Press release [here](https://www.who.int/news/item/31-12-2020-who-issues-its-first-emergency-use-validation-for-a-covid-19-vaccine-and-emphasizes-need-for-equitable-global-access)
    - AstraZeneca/State Institute of India: Press release [here](https://www.who.int/news/item/16-02-2021-covax-statement-on-who-emergency-use-listing-for-astrazeneca-oxford-covid-19-vaccine)
    - AstraZeneca/SK Bio: Press release [here](https://www.who.int/news/item/16-02-2021-covax-statement-on-who-emergency-use-listing-for-astrazeneca-oxford-covid-19-vaccine)
    - J&J: Press release [here](https://www.who.int/news/item/12-03-2021-who-adds-janssen-vaccine-to-list-of-safe-and-effective-emergency-tools-against-covid-19)
  + This guidance [document](https://extranet.who.int/pqweb/sites/default/files/documents/Status_COVID_VAX_08Feb2021.pdf) on the status of COVID-19 vaccines outlines the vaccine candidates which are in the process of receiving EUL and Gavi has also published this [supply forecast](https://www.gavi.org/sites/default/files/covid/covax/COVAX%20Supply%20Forecast.pdf)
  + WHO is on track to EUL other vaccine products in February and through June. The EUL process is performed on a rolling data submission in parallel to the review done by regulatory authorities overseeing the vaccines, so these have very similar timelines.
  + The products and progress in regulatory review by WHO is provided by WHO and updated regularly. The document called ‘Status of Covid-19 Vaccines with WHO EUL/PQ evaluation process’ provides an overview and is found [here](https://www.who.int/teams/regulation-prequalification/eul/covid-19).

## **Country and vaccine-specific information**

* **Russian vaccine (Gamaleya, Sputnik Vaccine):** 
  + **Sputnik by Gamaleya Research Institute** is included in the WHO [draft landscape of COVID-19 vaccine candidate](https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines)s as being in phase III of clinical development.
  + In Russia, the Gamaleya Institute (Sputnik V) was registered for medical use on 11 August 2020.[[52]](#footnote-52)
  + The process for WHO EUL is on-going. Clinical review is currently in progress and an indication of decision date is yet to be confirmed. Updates can be found [here.](https://extranet.who.int/pqweb/sites/default/files/documents/Status_COVID_VAX_10March2021.pdf)[[53]](#footnote-53)
  + The Clinical data for Sputnik was published in the Lancet on 02/02/21 and can be found [here](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00234-8/fulltext).
* **Chinese vaccines (Sinopharm (BBIBP and Wuhan Institute), Sinovac, Cansino, and West China Hospital+Sichuan University):** 
  + **Sinopharm by Beijing Institute of Biological Products** is included in WHO’s [draft landscape of COVID-19 vaccine candidate](https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines)s as being in active review for EUL, with an outcome expected in March
    - WHO is aware that regulators in China have issued an emergency use authorization for a vaccine from the China National Pharmaceutical Group (Sinopharm). The United Arab Emirates and Bahrain have now also approved the vaccine based upon the release of the efficacy data.
  + Sinovac is under active review for EUL, with more information expected in March.
  + Cansino is included is included in WHO’s draft landscape as being in Stage III of clinical trials. The initial stages of EUL review have been begun, but there is no date for the expected outcome.
  + West China Hospital+Sichuan University is included in WHO’s draft landscape as being in pre-clinical development in phase 2 of clinical development.
* **Cuban Vaccine (Soberana 1 and Soberana 2):**

Soberana 01 by Instituto Finlay de Vacunas of Cuba (registered in the Cuban Registry of Clinical Trials, RPCEC), is included in WHO’s [draft landscape of COVID-19 vaccine candidate](https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines)s lists in phase I of clinical development.

* J&J
  + SAGE Interim recommendations regarding Janssen and Janssen were developed on 15 March 2021 and will be available shortly afterwards.

## **Vaccine uptake/hesitancy**

* The ACT Accelerator’s Country Readiness and Delivery workstream has developed tools to support local strategies to generate acceptance and uptake of COVID-19 vaccines. The tools can be found [here](https://www.who.int/initiatives/act-accelerator/covax/covid-19-vaccine-country-readiness-and-delivery/acceptance-and-demand).
* The success of any COVID-19 vaccine will depend on public trust. We hear many references to the importance of accelerating vaccine development for COVID-19 and bringing it to the markets as soon as possible in order to put an end to the pandemic.
* WHO has been working to address vaccine hesitancy for many years. Reasons for hesitancy are often very context specific, so we work with countries and partners to thoroughly understand why people might not be motivated or willing to accept or seek vaccination.
* Misinformation about COVID-19 vaccines has been circulating even before any such vaccines had results or have been available:
* The impact on uptake of COVID-19 vaccines is unknown and will change over time as new information becomes available about the vaccines.
* Even if misinformation may influence confidence or attitudes, this isn’t predictive of behaviour
* Practical factors (ease of access, convenience, etc) affect the path from intentions to vaccination and therefore have the greatest potential to drive acceptance and uptake.[[54]](#footnote-54)
* We support the design, implementation, and evaluation of a mix of tailored strategies to respond, which includes, among other actions:
* Promoting investments in quality immunization systems and primary care
* Providing credible information on the safety and benefits of vaccines, and the severity of the diseases they prevent
* Supporting countries to ensure that health workers are well trained, and ready and able to recommend vaccination and respond to any questions or concerns from the community
* Engaging and supporting local community influencers to build trust in vaccines
* At the same time, for those who already reject vaccines in general, acceptance or rejection of a COVID-19 vaccine may depend on the nature of the vaccine itself and its perceived safety. It is unlikely that those already strongly opposed to vaccination would change their views, but it may also depend on how the pandemic evolves.

Q: How **might the WHO perceive vaccine hesitancy/resistance will be impacted by reported errors in the AstraZeneca vaccine’s clinical trials? Are there particular messages that will be more impactful as a result to help mitigate harm?**

A: AstraZeneca advised regulators that during the clinical trial, a product manufacturing error resulted in some participants receiving half the intended dose for the first dose of the vaccine series. No safety concerns occurred to the participants as a result of the error. AstraZeneca has published their data in peer-reviewed journals including for the participants who received the half-dose product. Because this was not a planned part of the study the results are still being looked in to.

There are usually three phases to clinical trials, with the last one designed to assess the ability of the product to protect against disease, which is called efficacy. All phases assess safety. The last phase, phase III, are usually conducted in a large number of people, often 10’s of thousands. After that, the vaccine needs to go through a review by the national regulatory authority, who will decide if the vaccine is safe and effective enough to be put on the market, and a policy committee, who will decide how the vaccine should be used.

The success of any COVID-19 vaccine will depend on public trust. WHO has been working to address vaccine hesitancy for many years. Reasons for hesitancy are often very context specific, so we work with countries and partners to thoroughly understand why people might not be motivated or willing to accept or seek vaccination.

## **Fighting misinformation**

* WHO has set up direct lines of communication with social media platforms to review possible misinformation. When WHO wants to contest false content online, it shares WHO guidance or published WHO information to debunk the claim to empower the platforms to act with authority and efficiency.
* WHO also works with social media policy teams to ensure their policies are fit for purpose.
* WHO’s work with YouTube, Google, Facebook and several other tech partners also provides industry-leading insights that help identify burgeoning misinformation and subsequently allow us to target science-based health information where it’s needed most, as well as inform our communications products.

## **Promoting public health messages to fill the vacuum**

* With Google Search, WHO is able to ensure that people who search for COVID-19 related content are met with science-based information from WHO, as well as accurate news from accredited news agencies, as opposed to the most popular myth circulating that day.
* WHO also has pro-bono Ad space with Google, Facebook and YouTube to promote public health messages and WHO Guidance. To date, Ads on these platforms have reached hundreds of millions of people around the world.
* In another effort to democratize health information, WHO is partnering with Facebook Free Basics to make science-based health information on COVID-19 available free of data charges on multiple carriers.

## **Creating tools to amplify public health messages**

* The WHO Health Alert chatbot provides the latest news and information on how to protect yourself and others from COVID-19. First launched in March 2020, the chatbot is now accessible across several platforms, including WhatsApp, Facebook Messenger and Viber. These initiatives allow WHO to deliver life-saving health messages into the hands of hundreds of million of people, the WhatsApp chatbot alone has reached over 13 million people.
* WHO has found that chatbot services like this are especially critical in fragile states where the health system may be too fractured or strained to keep communities informed and safe. For example, 50% of all Arabic users of the WhatsApp chatbot are from Yemen, a country whose health system has collapsed.

## **Human vaccine and challenge trials**

* Human challenge studies are controlled human infection studies involving the deliberate infection of healthy volunteers. They are done for pathogens where there is a treatment.
* Such studies can be particularly valuable for testing vaccines. They can be substantially faster to conduct than vaccine field trials, because trial participants have a known exposure to the pathogen of interest rather than waiting for participants to potentially be exposed in the community. This also means far fewer participants need to be exposed to experimental vaccines in order to provide (preliminary) estimates of efficacy and safety.
* WHO Working Group for Guidance on Human Challenge Studies in COVID-19 has developed [key criteria for the ethical acceptability of COVID-19 human challenge studies](https://www.who.int/ethics/publications/key-criteria-ethical-acceptability-of-covid-19-human-challenge/en/). These criteria aim to provide guidance to scientists, research ethics committees, funders, policy-makers, and regulators.
* This is not a WHO recommendation, but guidance on what countries need to consider before embarking on a challenge trial.
* WHO is not aware of any such studies having taken place but there have been media reports that such studies will take place.  WHO is not involved in such studies.
* It is not true that human vaccine trials involve altering human DNA. This is misinformation. Reuters wrote a detailed article on this: <https://www.reuters.com/article/uk-factcheck-covid-19-vaccine-modify/false-claim-a-covid-19-vaccine-will-genetically-modify-humans-idUSKBN22U2BZ>[[55]](#footnote-55)

## **Mandatory vaccinations and vaccination passports**

* WHO does not envision that countries will implement mandates for vaccination against COVID-19 at this time, but there are certainly situations where a strong recommendation to be vaccinated might be issued. One example would be health care professionals, to ensure the safety of both staff and the patients.
* However, in situations where voluntary vaccine uptake is inadequate and COVID-19 transmission rates remain unacceptably high, it is possible that some countries may consider introducing mandatory programmes in the interest of saving lives. Extreme care should be taken with the implementation of such mandates or requirements, including the use of any penalties or fines, as they can reinforce social and health inequalities.
* At present, WHO does not support the introduction of requirements for proof of vaccination against COVID-19 for international travellers, whether by national authorities, or by conveyance operators, neither as a condition for exiting or entering a country, nor as a condition for traveling internationally. There is currently no legal basis under IHR for conveyance operators to request a proof of vaccination as a condition for travelling.
* There are still scientific unknowns with regards to duration of protection for vaccinated people, protection from asymptomatic infection, timing of the booster doses in relation to travel, contraindications, possible exemptions of people who have antibodies against SARS-CoV-2.
* In addition, WHO is considering the policy, legal and ethical aspects that need to be taken into account before such recommendation can be made.
* Any use of the vaccine against COVID-19 in international travelers, and the subsequent potential introduction of any requirement for proof of vaccination against COVID-19 in international travelers needs to consider the limited global production capacity and reduced access to vaccines.
* WHO does not recommend the use of [immunity passports](https://www.who.int/news-room/commentaries/detail/immunity-passports-in-the-context-of-covid-19), for either international travel or movement within countries, in the context of COVID-19.
* In the absence of universal access to vaccines, there are serious human rights and ethical issues regarding the application of restrictions on travel based on vaccination status.
* The limited global supply of vaccines is another factor. Preferential vaccination of travellers could lead to fewer vaccines for those who are considered at-risk. It also has other ethical implications, including “if access to vaccine is (unequal), then inequity and unfairness can be further branded into the system” as per Dr Mike Ryan’s remarks at the press conference on 8 March 2021.
* WHO published guidance on a risk-based approach for international travel in Dec 2020:
  + Interim guidance considerations for implementing a risk-based approach to international travel in the context of COVID-19: [https://www.who.int/publications/i/item/WHO-2019-nCoV-Risk-based-international-travel-2020.1](https://eur02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.who.int%2Fpublications%2Fi%2Fitem%2FWHO-2019-nCoV-Risk-based-international-travel-2020.1&data=04%7C01%7Cawimmer%40iom.int%7Ca6b7b0c2223142fdd14b08d8a26163c5%7C1588262d23fb43b4bd6ebce49c8e6186%7C1%7C0%7C637437886463648470%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=u%2Br2YhZT8WzxtJrR3JaaTT2YkUDf8%2B9iiimOz9YfPBA%3D&reserved=0) - These links will be updated.
  + Annex Risk assessment tool to inform mitigation measures for international travel in the context of COVID-19: [https://www.who.int/publications/i/item/WHO-2019-nCoV-Risk-based\_international\_travel-Assessment\_tool-2020.1](https://eur02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.who.int%2Fpublications%2Fi%2Fitem%2FWHO-2019-nCoV-Risk-based_international_travel-Assessment_tool-2020.1&data=04%7C01%7Cawimmer%40iom.int%7Ca6b7b0c2223142fdd14b08d8a26163c5%7C1588262d23fb43b4bd6ebce49c8e6186%7C1%7C0%7C637437886463658466%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=tkuXq%2BW%2FsItk%2FANpnTAzn9TaL%2BTdBbbPggYkrnJKfp4%3D&reserved=0)
  + Scientific brief COVID-19 diagnostic testing in the context of international travel: <https://apps.who.int/iris/handle/10665/337832>
  + On 5 February 2021, WHO published a [position paper](https://www.who.int/news-room/articles-detail/interim-position-paper-considerations-regarding-proof-of-covid-19-vaccination-for-international-travellers) on the scientific, ethical, legal and technological considerations on the introduction of requirements for proof of COVID-19 vaccination for outgoing or incoming international travellers.
  + Our recommendations will evolve as supply expands and as evidence about existing and new COVID-19 vaccines is compiled.
  + These recommendations are in accordance with the advice of the International Health Regulations Emergency Committee, which met for the sixth time on 14 January 2021 and made the following [recommendation](https://www.who.int/news/item/15-01-2021-statement-on-the-sixth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic) to Member States: “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.”

Note: It is important to distinguish between a proof of vaccination for travel and a certificate of vaccination, which is the personally held card (electronic or paper) which shows what vaccines a person has received. WHO is currently exploring how the common vaccination record could be done electronically (see [here](https://www.who.int/news-room/articles-detail/world-health-organization-open-call-for-nomination-of-experts-to-contribute-to-the-smart-vaccination-certificate-technical-specifications-and-standards-application-deadline-14-december-2020) for more).

Questions regarding vaccine passports within countries

Does the WHO support vaccine passports?

* At the present time the use of certification of vaccination as a requirement for travel is not advised.
* In the absence of universal access to vaccination there are serious human rights and ethical issues regarding the use of vaccine passports. Restrictions on travel in the absence of universal access to vaccination there are serious human rights and ethical issues regarding the application of restrictions on travel on that basis and again going back to this idea of getting as many people vaccinated as possible.
* We also have a group working with the project on the electronic or the e-certification of vaccination.
* We will be working with our member states and providing them with advice. Each and every member state has a sovereign duty to its own population and makes its own national health policies. We will try in as much as we can to provide advice, recommendations for governments to make proper decisions based on science and evidence and in the context of ethics and human rights being preserved.

Q: How are WHO supporting the development of smart vaccine certificates?

* We have a process underway with a group of independent experts to establish the common specifications for any digital or augmented paper vaccination certificate, under an initiative called the Smart Vaccination Certificate.
* This specification is intended for all WHO member states to use to ensure that all modalities of issuing a vaccination certificate are consistent, interoperable, and aligned with expected national and international scenarios of use, regardless of which technology member states choose to use.
* To strengthen the potential for trust between member states and holders of certificates, and to mitigate the potential for fake certificates, WHO recognizes the need for, and aims to serve a role as a global trust anchor/broker, to ensure the trust network is within the realm of Global Public Health.
* WHO has deliberately taken a software neutral approach in the development of the specifications for the Smart Vaccination Certificate.

## **Vaccine pricing**

* GAVI the gatekeepers on this info and more to be added here but review COVAX hot issues. Urgent issues should be directed to Gavi (primary point of contact: Meg Sharafudeen, [msharafudeen@gavi.org](mailto:msharafudeen@gavi.org)).
* Pfizer has not consented to publishing its prices.[[56]](#footnote-56)
* Further information regarding pricing for AstraZeneca will be forthcoming

**Reactive Q&A about pricing**

**Q: Are the prices COVAX have agreed with manufacturers been fixed for 2021 and beyond? Once COVAX’s goal of securing access to vaccines to cover 20% of a country’s population is achieved, will poorer countries be subject to higher prices?**

* The agreements UNICEF is entering into will be valid for 2021 with a possibility of extension for an additional year subject to agreement between both parties. As manufacturers gain experience with production at a large scale and as clinical development provide more clarity on the dosage to use, we will know more about the future price level. Different production technologies also have different cost structures, while some technologies may be faster to shift to produce new vaccines, if such are needed due to variants. In the current pandemic phase, a number of manufacturers have offered not-for-profit pricing. The price of vaccines in the future will depend on many factors.

# **Reactive Holding statements / Questions**

Questions **regarding Tokyo Olympics**

* **Q: What is the WHO’s advice regarding vaccinating athletes so that they can attend the Olympics Games which may take place in later in 2021?**
* A: WHO have developed a priority population roadmap. The first priority for vaccination is health workers, older adults, and those with underlying conditions. Vaccinations are a limited resource, and vulnerable populations in all countries are the highest priority. Young elite athletes who otherwise are not in a priority group, would not constitute a priority group as they are not at specific risk of severe disease and death. Regardless of vaccination, all the same mitigation steps are required because vaccines are not known to fully interrupt infection or transmission.
* The WHO fully support the IOC and host countries with the planning and organization of Olympics in the last 20 years. For Tokyo 2020, WHO provided risk assessment tools to help the IOC & Government of Japan make their assessment. The WHO regularly attends the meetings of the IOC/Tokyo 2020 task force on COVID-19, and is an observer in the IOC Independent Expert Panel.
* WHO is currently supporting all national governments in developing national vaccination plans. These will inform national plans to vaccinate athletes. The WHO develops and regularly updates guidance on best practices, based on current best evidence, and makes it available to relevant authorities and institutions, for them to make an informed decision.

**Q: What are WHO thoughts on US joining COVAX?**

* WHO is delighted that the Biden-Harris Administration has confirmed the United States will join the COVAX Facility. The U.S. has a long history of leadership in global public health, and the Administration’s leadership in ensuring equitable COVID-19 vaccine access will move us closer to our goal of ending the acute phase of the pandemic in 2021
* The Biden-Harris stated commitment to supporting local, multilateral and international actions to address the pandemic is a crucial aspect in ensuring that global equity is foremost in the rollout of Covid-19 vaccinations.

Q: WHO statement on vaccine issues in occupied Palestinian Territories

For full statement please see the TPs on vaccination issues in the oPt/Israel: WHO position

* WHO has repeatedly called for international solidarity and vaccine equity. The COVID-19 challenges can only be addressed collectively and in solidarity: no country or territory will be safe until everyone is safe and all countries are protected.
* In the context of the oPt/Israel, WHO addresses vaccine distribution issues within its health mandate, emphasizing global health security and right to health perspectives, with commitment to the realization of the right to the highest attainable standard of health. WHO’s view is that any contribution of vaccines by Israel to the Palestinian Authority should be in a spirit of solidarity and based on public health rationale.
* The oPT through the COVAX mechanism are expected to receive 37K Pfizer vaccines from the first wave allocation and up to 405K doses of AstraZeneca by end of March given global supply constraints and pending supplier’s specific arrangements that needs to be in place before delivery of vaccines.

Q: What is the WHO comment on the EU blocking vaccine exports?

* The WHO is aware that the Italian government has blocked the export of an Oxford/AstraZeneca vaccine shipment to Australia, pursuant to EU regulations that allow exports to be stopped if the company providing the vaccines has failed to meet its obligations to the EU.
* The regulation is known as the transparency and authorisation mechanism and a detailed Q&A can be found here.
* COVAX vaccines are exempt from the export restrictions so exports to COVAX participants are not affected by this.
* It is to be hoped that as manufacturers continue to gain experience with production at a large scale of COVID-19 vaccine doses that the need for this regulation will largely become obsolete.
* Rapid scale-up of manufacturing capacity and cooperation is possible: for example, companies can turn over their facilities to produce other companies’ vaccines and enter into partnerships with other producers. Oxford/Astra Zeneca, for instance, has multiple production nodes around the world; in some countries and this is allowing for rapid and simultaneous scale-up of their vaccine.

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2. https://www.gavi.org/sites/default/files/covid/pr/COVAX\_CA\_COIP\_List\_COVAX\_PR\_15-12.pdf [↑](#footnote-ref-2)
3. Daniela, 20/08 [↑](#footnote-ref-3)
4. SAGE Values Framework QA [↑](#footnote-ref-4)
5. WHO Draft landscape of COVID vaccines 12th March 2021 [↑](#footnote-ref-5)
6. Soumya, DW 18/08 [↑](#footnote-ref-6)
7. Update from Renee Van de Weerdt, 16 Dec 20 [↑](#footnote-ref-7)
8. Covax Hot Issues, 26/01 [↑](#footnote-ref-8)
9. SAGE TPs, 26/01/21 [↑](#footnote-ref-9)
10. Cleared by Daniela and Diane, 27/08 [↑](#footnote-ref-10)
11. Media team answers, 06/12 [↑](#footnote-ref-11)
12. UNICEF WHO GAVI joint position on supporting delivery and uptake of COVID-19 vaccines not yet EUL/pre-qualified by WHO or authorised by stringent regulatory authorities [↑](#footnote-ref-12)
13. Dec. 8 in the UK (Pfizer-BioNTech); Dec. 5 in Russia (Gamaleya) [↑](#footnote-ref-13)
14. WHO Coronavirus (COVID-19) Vaccine Tracker, 14thMarch 2021 [↑](#footnote-ref-14)
15. Pfizer, Moderna, Gamaleya, Sinovac, Sinopharm, SII, Bharat Biotech, AZ, Johnson & Johnson, EpiVacCorona. Platforms: Inactivated virus, mRNA, adenoviral vector, peptide.​ [↑](#footnote-ref-15)
16. Our World in Data via State of Vaccines ppt, 16thMarch 2021 [↑](#footnote-ref-16)
17. For non-exhaustive list please contact Kate Thompson [↑](#footnote-ref-17)
18. For non-exhaustive list please contact Kate Thompson [↑](#footnote-ref-18)
19. Bulgaria, Canada, Denmark, Germany, Spain, USA (Non-exhaustive list) [↑](#footnote-ref-19)
20. Bahrain, Cambodia, China, Egypt, Macao, Morocco, Pakistan, Peru, Serbia, Seychelles, UAE (Beijing); China, UAE (Wuhan) (Non-exhaustive list) [↑](#footnote-ref-20)
21. Algeria, Argentina, Azerbaijan, Bolivia, Guinea, Iran, Pakistan, Russia, Serbia, UAE (non-exhaustive list) [↑](#footnote-ref-21)
22. Brazil, Chile, China, Colombia, Hong Kong SAR, Indonesia, Malaysia, Philippines, Thailand, Turkey and Uruguay. [↑](#footnote-ref-22)
23. United States and South Africa [↑](#footnote-ref-23)
24. India [↑](#footnote-ref-24)
25. Russian Federation [↑](#footnote-ref-25)
26. COVAX press release, 22/01 [↑](#footnote-ref-26)
27. WHO COVID-19 Weekly Epidemiological Update, 7th February 2021 [↑](#footnote-ref-27)
28. COVAX press release, 22/01 [↑](#footnote-ref-28)
29. COVAX Statement on WHO Emergency Use Listing for AstraZeneca/Oxford COVID-19 vaccine, 16th February 2021 [↑](#footnote-ref-29)
30. SAGE interim recommendations for Pfizer/BioNTech, 8th January 2021 available [here](https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-BNT162b2-2021.1) [↑](#footnote-ref-30)
31. Dr Soumya Swaminathan. WHO press conference, 12th February 2021 [↑](#footnote-ref-31)
32. Shanthi Pal, 13 January 2021 [↑](#footnote-ref-32)
33. Language from Marta Gacic-Dobo, 8 Dec 2020 [↑](#footnote-ref-33)
34. Email from Shoshanna Goldin on 27 Jan 2021 [↑](#footnote-ref-34)
35. Covax Hot Issues Brief, 26/01/2021 [↑](#footnote-ref-35)
36. Update from Tom Mooney, CEPI on 16 Dec 20, no update as of 15th February 2021 [↑](#footnote-ref-36)
37. Tom Mooney, CEPI, 16 Dec 20 [↑](#footnote-ref-37)
38. Soumya [↑](#footnote-ref-38)
39. Taken from [here](https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool) [↑](#footnote-ref-39)
40. Mariangela Simoa, Off the record interview, 16th February 2021 [↑](#footnote-ref-40)
41. Bruce Aylward, CBC Canada interview. 10th February 2021 [↑](#footnote-ref-41)
42. Mbooth vaccine messages [↑](#footnote-ref-42)
43. UNCG special session on ACT-A and COVAX, 11 Dec 2020 [↑](#footnote-ref-43)
44. [COVAX press release,](https://www.who.int/news/item/22-01-2021-covax-announces-new-agreement-plans-for-first-deliveries) 22nd January 2021 [↑](#footnote-ref-44)
45. Seth Berkley ACANU TPs, 26/01 [↑](#footnote-ref-45)
46. Bruce Aylward. Interview with CBC Canada. February 10th 2021 [↑](#footnote-ref-46)
47. Pfizer LTA Reactive Q&A. Email on 12/02 [↑](#footnote-ref-47)
48. [South China Morning Post report,](https://www.scmp.com/news/hong-kong/health-environment/article/3124410/hong-kongs-no-2-official-stresses-vaccines-are) 7th March 2021 [↑](#footnote-ref-48)
49. Email Joachim Homback. 11/02 [↑](#footnote-ref-49)
50. Global Science Discussion on transmission of variants, 28/01 [↑](#footnote-ref-50)
51. From WHO Regional Office for Europe Media Q&A [↑](#footnote-ref-51)
52. https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(20)30402-1/fulltext [↑](#footnote-ref-52)
53. Status of Covid-19 Vaccines within WHO EUL/PQ Evaluation process, 10th March [↑](#footnote-ref-53)
54. Points from Lisa Menning 16 Dec 20 [↑](#footnote-ref-54)
55. By Margaret, 18/09 [↑](#footnote-ref-55)
56. Pfizer LTA and supply agreements in general [↑](#footnote-ref-56)