



GAVI Vaccination Efforts Ramp Up Worldwide

(Source: GAVI and WHO Press Releases)

GAVI's COVAX facility is ramping up efforts as COVID vaccines receive emergency use listings (EUL) from the World Health Organization (WHO). More than a half million doses were received in Cote d'Ivoire from Mumbai on February 26th and additional doses were shipped to Ghana, some of which will be delivered by drone in partnership with Zipline, a drone delivery company operating on the African continent. Shipments of AstraZeneca/Oxford's vaccine are being prepared for other countries as well and South Korea (a self-financing participant in the COVAX facility) also received 117,000 doses of the Pfizer/BioNTech vaccine

The Ghana and Cote d'Ivoire vaccines will be used to protect healthcare and frontline workers and signify an important milestone for the COVAX program which is committed to protecting the most vulnerable and at-risk individuals in developing countries.

Doses delivered via the first allocation round must meet several criteria put in place for each participant, including:

All facility participants must have given national regulatory authorization for the vaccines in question. This process may be expedited by issuing special authorizations for use based on granting of WHO EULs.

All facility participants must have signed indemnity agreements with the manufacturers in order to receive the doses through COVAX, a process that is being facilitated by COVAX.

A National Deployment and Vaccination Plan must be submitted through the COVID-19 Partners Platform to be reviewed and validated by COVAX.

In preparation for this unprecedented global rollout, COVAX partners have been working closely with all Facility participants for many months, providing support for regulatory and indemnity and liability issues as well as the submission of completed NDVPs. Throughout this process, Facility participants have been ensuring all preparations are in place for the first deliveries.

As participants fulfill the necessary criteria and finalize readiness preparations, COVAX will issue purchase orders to the manufacturer and ship and deliver doses via an iterative process. This means deliveries for this first round of allocation will take place on a rolling basis. Due to the high number of doses available as well as the high number of countries getting ready for delivery in Q1 2021, the capacity of supplier and freight forwarders will be under considerable pressure. Shipment timelines will be impacted by logistical preparedness and delivery lead times, which may vary depending on the location of the receiving participant.

COVAX anticipates the bulk of the first round of deliveries taking place in March, with some early shipments to those that have already fulfilled the above criteria, occurring in late February. The partners have signed an advance purchase agreement with Pfizer/BioNTech a little more than a month after this first COVID-19 vaccine received WHO's EUL.

There will be two versions of the AstraZeneca/Oxford vaccine – one produced by AstraZeneca and SKBio. The second will be produced by the Serum Institute of India. All vaccines distributed under

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Around the Globe...

◆ **Janssen Pharmaceuticals, Johnson & Johnson's** research business unit, received Emergency Use Authorization (EUA) from the **U.S. Food and Drug Administration** and has submitted its phase III data to the **World Health Organization (WHO)** for its "one and done" COVID-19 vaccine, asking the WHO for an Emergency Use Listing (EUL). The vaccine has shown to cut out hospitalizations and deaths and poses fewer logistical challenges which will make it easier to distribute and administer, particularly in developing countries.

◆ Vaccine maker **Novavax** has signed a memorandum of understanding with **GAVI, the Vaccine Alliance** to provide 1.1 billion doses of its coronavirus vaccine candidate to the **COVAX program** pending appropriate authorizations. The vaccine will be produced in part by the **Serum Institute of India**. Phase III trials in the UK showed an 89.3% efficacy, although there it shows lower efficacy with COVID variants.

◆ The **World Health Organization (WHO)** has prepared a ten-step strategy for the COVID-19 vaccine rollout in Africa. It involves a strong groundwork for what will be the continent's largest-ever immunization campaign. WHO is setting recommendations that all countries set up a National Immunization Technical Advisory Group to provide scientific guidance for vaccine introduction to their respective health ministries. WHO also recommends the establishment of coordination structures to develop and monitor vaccine delivery timelines, identification of priority groups and an implementation plans along with the basis upon

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The Launch of the New Fight the Fakes Alliance

(Source: Press Release)



The Fight the Fakes Alliance (FTF Alliance), a new multi-stakeholder non-profit association headquartered in Geneva, Switzerland, is stepping up the fight against falsified medicines. Seven years since its first activities as a grass root advocacy campaign, the new formal governance structure will allow the FTF Alliance to take the fight against substandard and falsified medicines to the next level.

With over 15 members representing health care professionals, manufacturers, wholesalers, researchers and patients, the Alliance is uniquely positioned to scale up action to prevent falsified medicines from endangering people's health and well-being. The FTF Alliance aims to do so by expanding its advocacy and awareness raising efforts through dedicated social media campaigns and events, strengthening capacity of organizations working in the area of medicines quality, as well as promoting initiatives to combat substandard and falsified medicines.

The goal is to create a global movement of like-minded organizations to ensure this issue receives the attention it deserves on the global health policy agenda. Falsified medicines not only put patients' lives at risk

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GAVI (cont.)...

the COVAX program are expected to cover approximately 3.3% in 145 countries currently enrolled, and final allocations of the AstraZeneca/Oxford vaccines will be communicated to all participants the week of February 22nd.

The Coalition for Epidemic Preparedness Innovations (CEPI), Gavi, the Vaccine Alliance and the World Health Organization, as co-leads of the COVAX initiative for equitable global access to COVID-19 vaccines (and alongside key delivery partner UNICEF), have published COVAX's first interim distribution forecast for COVID vaccines through the COVAX program.

Building on the publication of the 2021 COVAX global and regional supply forecast, the interim distribution forecast provides information on early projected availability of doses of the Pfizer/BioNTech vaccine in Q1 2021 and the AstraZeneca/Oxford vaccine candidate in first half 2021 to COVAX Facility participants.

The purpose of sharing the interim distribution with countries, even in today's highly dynamic global supply environment, is to provide governments and health systems with the information needed to plan for their national vaccination programs. The interim distribution forecast outlines projected delivery of vaccine doses to all Facility participants, except those participants who have either exercised their rights to opt-out, have not submitted vaccine requests, or have not yet been allocated doses.

For more information on the COVAX interim distribution forecast, please visit [COVAX-Interim-Distribution-Forecast.pdf](https://www.gavi.org/covax-interim-distribution-forecast) (gavi.org)

FTF Alliance (cont.)...

but undermine trust in healthcare systems and modern medicine, and hamper crucial progress made so far by countries towards universal health coverage. Although this is a global issue, the burden is still disproportionately higher in low- and middle-income countries where 1 in 10 medicines are thought to be either substandard or falsified.

Recently the FTF Alliance issued a statement on behalf of its members at the 148th session of the WHO's Executive Board regarding falsified and substandard medicines. A complete transcript of the FTF Alliance's statement is available at <http://fightthefakes.org/world-health-organization148th-executive-board-statement/>.

Nearly 170,000 children die annually of falsified pneumonia medicines, and substandard and falsified antimalarials may cause as many as 116,000 deaths from malaria annually in sub-Saharan Africa. The limited data available on this issue means the known figures almost certainly represent just a fraction of the true burden of falsified medicines around the globe. Fake medicines have been an under-addressed global health issue for years, but the COVID-19 pandemic has not only concentrated attention on the burden and dangers of falsified medicines but underscored the devastating impact they have on higher-, middle-, and lower-income countries alike. Since the start of the pandemic, an unprecedented rise in falsified COVID-19 related medical products has been reported by both Interpol and the United Nations Office on Drugs and Crime (UNODC).

"During a public health crisis such as the current COVID-19 pandemic, tackling this global scourge becomes even more acute and urgent," the OECD has warned earlier this year. COVID-19-related fake products reported so far this year include personal protective equipment, such as surgical masks, hand sanitizers and gloves, as well as diagnostic tests, potential treatments and even "cures". With COVID-19 vaccines likely to win regulatory approval and even enter the market in the coming

weeks and months, the risk of falsified versions of such vaccines being advertised is imminent, stressing the urgent nature of the work FTF Alliance is set out to undertake.

Adam Aspinall, Senior Director, Access and Product Management at Medicines for Malaria Venture (MMV), and the newly elected chair of the FTF Alliance, highlights: "After months of hard work, I'm excited to start the new chapter of the Fight the Fakes Alliance. With the ongoing COVID-19 pandemic and the rise in falsified medicines now and in future, our combined efforts to mitigate, control and ultimately eradicate the damage they cause to patient health and lives are more crucial than ever."

Private sector companies will now be able to join the Alliance as corporate partners via a separate membership classification, something that was previously not possible.

If you are interested in joining the FTF Alliance, please contact info@fightthefakes.org for further information.

Around the Globe (cont.)...

which vaccines are allocated and administered.

- ◆ A global emergency stockpile of 500,000 doses of Ebola vaccine, funded by **GAVI, the Vaccine Alliance**, will be available to all countries for outbreak response following a procurement process concluded by **UNICEF** with a vaccine manufacturer. GAVI-eligible low- and lower middle-income countries will be able to access the stockpiles free of charge. They will also receive support for operational costs to conduct outbreak response immunization activities.

- ◆ The Kaduna state of Nigeria has signed a deal with medical delivery company **Zipline**. The agreement will allow drone shipment of COVID-19 vaccines without significant state investment in cold-chain storage. Kaduna has maintained a partnership with Zipline to deliver more than 1 million doses of other vaccines in Africa over the past year, along with blood products and other medications.

- ◆ **Nigeria Food and Drug Administration and Control (NFDAC)** made a statement that it is aware of fake COVID-19 vaccines circulating in the country. The agency's director-general, **Mojisola Adeyeye**, told a press conference "NFDAC is pleading with the public to be aware. No COVID vaccines have been approved by NFDAC." Statistics show that the African continent is extremely vulnerable to vaccine crime, according to the World Health Organization. Between 2013 and 2017, almost half of all substandard and falsified medicines found on the continent were discovered in sub-Saharan Africa where regulations are weak and borders are easily crossed without detection.

- ◆ The **Journal of American Medicine Association (JAMA)** reported that there has been a 556% surge in the number of reported measles cases, and a 50% increase in measles-related deaths since 2016, according to a report published by the **World Health Organization**. Although measles vaccination efforts have saved an estimated 25.5 million lives since 2000, measles incidence increased to 120 per million in 2019, a significant rise from 18 per million in 2016. The trend is particularly concerning given the ongoing disruptions in vaccinations caused by COVID-19.

- ◆ Drug store chains **Walgreens** and **CVS**, and retailer **Walmart** will be administering COVID-19 vaccines in the U.S. to those who are eligible to receive the doses. The companies are working with state and local health department agencies to register online those who meet eligibility requirements.

Sources: FierceBiotech, FiercePharma, Journal of American Medicine Association, Pharma Technology, and Press Releases)

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- ◆ Support expanded collaborations with GAVI, the Vaccine Alliance (including the STEP leadership course) to strengthen health systems, improve supply chain effectiveness and increase availability of vaccines, with particular focus on COVID vaccinations.
- ◆ Continue the important work of the Fight the Fakes Alliance against falsified medicines and substandard medical products.
- ◆ Expand awareness of and familiarity with global health agendas, priorities and entities; creating opportunities for the private sector to directly participate in meaningful initiatives.
- ◆ Represent the pharmaceutical distribution sector within the global health community, as well as raise awareness around the industry's capabilities and current contributions to healthcare delivery.

Proceeds will directly support the continuation of global efforts by the IFPW Foundation to improve access to safe and effective medicines and vaccines through our existing and new partners.

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