LAUNCH & SCALE SPEEDOMETER

WEEKLY COVID VACCINE RESEARCH UPDATE

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Attribution: Duke Global Health Innovation Center

For Media Inquiries (Dec 19-Jan 3): Please email info@launchandscalefaster.org. We will do our best to respond quickly to media requests during the holiday period.

Website and Data: https://launchandscalefaster.org/covid-19

Data Notes and FAQ

Data Updates:

- Total worldwide confirmed purchases of Covid-19 vaccines: 7.7 billion doses
  - High-income country confirmed dose total: 4 billion
  - Upper-middle-income country confirmed doses total: 1.1 billion
  - Lower-middle-income country confirmed doses total: 1.8 billion
  - Low-income country total: 0
  - COVAX total: 870 million

INTERESTING TRENDS

Significant updates, changes, and trends we are seeing this week:

- **COVAX partners** Gavi, CEPI, and WHO announced today that they have secured access to nearly 2 billion doses of Covid-19 vaccines. (Most of these doses fall under options on existing deals and are thus shown as potential in our data. We are seeking clarification on the purchase details and will update our data accordingly.) Pending regulatory approval of the vaccines, they expect to begin shipment of doses to all participating countries by the first quarter of 2021, a very positive development for global equity.
- **China** made its first bilateral purchase of a Covid-19 vaccine, buying 100 million doses of the Pfizer-BioNTech vaccine through Shanghai Fosun Pharmaceutical Group.
- **The Inter-American Development Bank** (IDB) announced it will mobilize $1 billion to support the purchase and deployment of Covid-19 vaccines for Latin America and the Caribbean. The IDB will work closely with COVAX and the Pan-American Health Organization (PAHO) in this effort. This funding commitment follows the $9 billion announced by the Asian Development Bank last

week and the $12 billion announced by the World Bank in October to support procurement and distribution of vaccines in low- and middle-income countries.

- Mild to serious **allergic reactions** were reported for individuals who took the Pfizer vaccines in the UK and US. This has led to discussions of whether any populations (e.g. people with known allergies) should be excluded from receiving this vaccine.
- **GSK-Sanofi's clinical trial results** were not promising in achieving the expected immune response in the elderly population, warranting the launch of another study in February 2021. Results from the new trial are expected by the end of 2021, a major setback for global supply of the vaccine.

INSIGHTS

Tracking regulatory approvals around the world

We have seen a lot of movement in regulatory approval of Covid-19 vaccines over the past two weeks, as vaccination campaigns begin to roll out. When tracking the Covid-19 vaccine landscape, it is important to keep in mind the difference between *emergency use* authorization and *full* authorization. Most Covid-19 vaccine approvals received thus far have been limited to emergency use. This may be granted to address a health emergency, on the basis of early clinical trial data (generally results from Phase III trials), is temporary, and may place restrictions on the eligible population (e.g. age) and method of distribution. Vaccines receiving emergency use authorization are expected to apply for full regulatory approval (or licensure) after additional safety data is collected.

Regulatory approval for vaccines is complex in the best of times; there are at least 51 paths to various levels of authorization across 24 countries. While many countries do share information and coordinate in the process of regulatory approval, there is no global vaccine regulatory body, which means that vaccine developers need to seek authorization for every market in which they intend to sell.

Two mechanisms coordinated by the World Health Organization (WHO) help to streamline this process. The Emergency Use Listing process, recently launched by the WHO for public health crises, essentially provides a stamp of approval for unlicensed vaccines, therapeutics, and diagnostics in low- and middle-income countries. The WHO has not yet granted EUL status to any Covid-19 vaccine candidates, though several including Russia's **Sputnik V** and **Moderna** have reportedly applied and are under review.

The WHO also maintains a list of Stringent Regulatory Authorities (SRAs), trusted national regulatory bodies whose decisions can be used to guide other countries. SRAs use rigorous and transparent processes for the review and approval of vaccines and therapeutics. Other governments can use approval by an SRA as the basis for expedited approval in their own country.

China was the first country to grant emergency to any Covid-19 vaccine candidates, approving **CanSino** for use in the Chinese military, and then **Sinovac's Coronavac** for use in high-risk populations, before results from Phase III trials were known. Russia followed with emergency authorization for **Sputnik V**, again without any data from Phase III trials.

The (Beijing-based) **Sinopharm** vaccine is the first to receive full authorization in any country, after the UAE and Bahrain registered it this week, even before Sinopharm has reported Phase III results. China has

granted emergency authorization to both (Beijing- and Wuhan-based) **Sinopharm** vaccines and is currently seeking full approval for domestic use.

However, China, Russia, Bahrain, and the UAE are not recognized as SRAs. We do not yet know whether the vaccines developed in China and Russia will be reviewed and approved by an SRA. Approval by a non-SRA regulator body may not provide enough safety and efficacy evidence for other countries to follow suit without a full review.

There are significant differences in the review process even among SRAs. For example, the UK review process relies on analysis provided by the vaccine developer while in the US, regulators conduct their own analysis with the raw data.

The **Pfizer-BioNTech** vaccine has been first out of the gate to receive emergency use authorizations from SRAs, which was followed by multiple other countries this week. The Pfizer-BioNTech vaccine now has emergency approval in the UK, the US, Canada, Chile, Ecuador, Mexico, Panama, Costa Rica, and Singapore.

Moderna has applied for emergency authorization in the US (the advisory committee has recommended authorization, which is expected next week), the EU, Canada, Switzerland, UK, Israel, and Singapore. As noted above, Moderna has also reported plans to apply for EUL with the WHO.

Other leading contenders are rounding the regulatory bend as well, with the finish line in sight. The **Oxford-AstraZeneca** vaccine is under review in the UK, with a decision expected in December or early January. **Johnson and Johnson's** single-dose vaccine is under rolling review in multiple markets, including the EU, Canada and South Africa, and expects to apply for emergency use authorization with the US in February.

For more information on this research and our findings, please go to https://launchandscalefaster.org/COVID-19.