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The Complexities of Bringing an Approved COVID-19 Vaccine to Market

(Sources: An article by Elizabeth Weise of USA Today)

It is still unknown when an approved COVID-19 vaccine will be available worldwide, but how it will be distributed is a paramount concern. Logistics experts, immunization professionals, pharmaceutical distribution specialists, and global government agencies are working tirelessly to give a clearer picture of how coronavirus vaccines will get from manufacturers to the general population.

In the U.S., the process will be run by the U.S. Centers for Disease Control (CDC), which has overseen vaccine distribution in the U.S. for decades including oversight of the vaccination effort during the 2009 H1N1 influenza pandemic. All the vaccines supplied in the initial phases will be purchased by the U.S. government, and no one will be charged for the actual dose. As of early September, it is still undetermined whether clinics would be allowed to charge an administration fee to those getting their shots, and if charged, whether insurance could be reimbursed for it if the vaccine is issued under an Emergency Use Authorization. Initially, the vaccine is expected to be in short supply, though CDC planning documents say significantly more will be available by January 2021. The CDC is still finalizing who will be eligible to be vaccinated first, but from meetings of its Advisory Committee on Immunization Practices, it appears front-line medical workers, first responders and people at high risk will be first in line.

Dozens of experimental COVID-19 vaccines are being developed around the world, seven of which have been funded at least in part by the U.S. government. All but one will require two doses, given 21 or 28 days apart. People getting vaccinated will get a COVID-19 vaccination record card stating which vaccine they received, when it was administered and when they should get their next shot. Two of the seven vaccine candidates, manufactured by Pfizer and Moderna, are considered front-runners since they are in Phase III clinical trials involving large-scale tests in humans. The two vaccines must be stored at different temperatures which will require slightly different storage methods. A third, from AstraZeneca in the United Kingdom, was in Phase III trials but was put on hold to allow for an adverse incident investigation.

In an initial vaccine plan formed by the CDC, medical offices, clinics, hospitals, pharmacies and other groups that want to vaccinate people for COVID-19 must first enroll in the U.S. COVID-19 vaccination program. They will sign an agreement with the CDC and prove they have the space, the necessary equipment and properly trained staff to administer the shots. Because the requirements for storing, handling and administering the shots are so challenging, the government will prioritize getting the vaccine to sites that can reach large numbers of priority populations and vaccinate many people quickly. When a vaccine becomes available, a vaccination site will request doses through a state agency, usually its department of public health, the same procedure followed during the 2009 H1N1 influenza pandemic. Once the

(continued on page 2)

In Brief...

- **Walgreens Boots Alliance** named industry veteran *John Standley* to the position of president of Walgreens, effective immediately. He replaces *Richard Ashworth*, who departed the organization earlier this year. Standley previously held the position of CEO and chairman of Rite Aid. He also served as CEO of Pathmark Stores prior to joining Rite Aid.
- The **American Pharmacists Association** and 12 other pharmacy organizations today told a special committee of the **National Academies of Science, Engineering and Medicine** (NASEM) that pharmacists should be given tier 1 priority status in the allocation and distribution of COVID-19 vaccine(s). The organizations said that pharmacies in all practice settings should be included in this designation. This includes community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities.
- **AstraZeneca** and the **University of Oxford** have put a voluntary clinical trial hold on their COVID-19 vaccine candidate due to an adverse event with one of the study

(continued on page 2)

More Countries Pledge Financial Commitment to the Global COVAX Facility

(Sources: An article by Pharma Japan and a press release by GAVI, the vaccine alliance)

More than 170 countries are in talks regarding participation in the COVID-19 Vaccines Global Access (COVAX) facility. Coordinated by GAVI the vaccine alliance, the World Health Organization, and the Coalition for Epidemic Preparedness Innovation, COVAX hopes to speed vaccine development, secure doses for all countries and distribute them to the most high-risk segment of each population. It will support the participation of lower- and middle-income economies in the COVAX Facility, ensuring that the world's poorest populations do not miss out on safe and effective COVID-19 vaccines. Countries including Japan, Germany, the European Commission, Australia, and others have pledged financial commitment to the effort. However, so far the United States will not join the global initiative.

To date, the Gavi COVAX Advanced Market Commitment (AMC) has raised more than US$600 million against an initial target of US$2 billion in seed funding that is needed from sovereign donors, philanthropy sources and the private sector by the end of 2020. Funding will be critical to ensure that the ability to pay for vaccine participation does not become a barrier to underserved and poorer countries. That potential scenario would likely leave much of the world unprotected and allow the pandemic to continue unabated. There are 92 AMC-eligible countries plus other World Bank International Development Association (IDA)-eligible economies.

The Australian government will contribute AU$80 million

(continued on page 2)

Complexities (cont.)...

site is approved to distribute the vaccine, if vaccine supplies are limited, the state could determine how much vaccine to allocate to that specific site. The CDC could also decide how many doses to allocate to a site. Once a determination on the number of doses is made, the CDC will transmit the order to its contracted partner McKesson Corporation, the largest pharmaceutical distribution and technology company in the U.S. with distribution centers across the country. Vaccine orders will be shipped within 24 hours of approval depending on the available supply. National pharmacy chains such as Walgreens and CVS could partner directly with the CDC. Military allocations would go through the Department of Defense. Along with the vaccine, a separate supply kit will be sent that includes needles, syringes, alcohol prep pads and a small supply of personal protective equipment, including surgical masks and face shields for the staff administering the vaccine.

The point where details diverge is in the necessary cold chain supply requirements. Moderna's candidate vaccine must be stored at minus 4 degrees Fahrenheit, but Pfizer's requires it be stored at -94F. That 90-degree difference necessitates different methods of distribution. The Moderna vaccine will be stored either at the manufacturing plant or at a McKesson distribution center. McKesson will ship it directly to the medical facility upon receiving the order. The Moderna vaccine comes as a frozen liquid in a 10-dose vial and contains no preservatives. It can be stored in a freezer or in its shipping container if the containter is replenished with dry ice. It can be stored for up to two weeks at normal refrigerator temperatures (36F to 46F degrees) according to data provided by the Immunization Action Coalition. Once at room temperature, it must be used within six hours. Once the vial is punctured to take out the first dose, it is good for up to six hours.

Since vaccines will be in short supply initially, clinical sites will need to schedule patients so none is wasted. To be effective, the Moderna vaccine requires two doses of the same vaccine given 28 days apart. The Pfizer vaccine is more sensitive because of its ultra-low temperature storage requirements, though that may change as more tests are done. Because of requirements, the CDC will send orders straight to Pfizer, which will ship to the vaccination sites in a special transportation container filled with dry ice. The box can be topped off with dry ice every five days to keep it at the appropriate temperature. The vaccine comes in five-dose vials without preservatives, according to a presentation the company gave to the CDC last week. The individual vaccine vials can be refrigerated for up to 48 hours but kept at room temperature for only six hours. The Pfizer vaccine will be shipped in large volumes and is likely to be distributed at larger medical centers or public health departments that have proper storage facilities and the capacity to vaccinate large numbers on site. Before use, Pfizer's vaccine will have to be mixed with a special liquid to dilute it, likely sterile water which would be shipped separately. It requires two doses given 21 days apart.

Adding to storage challenges is a critical shortage of dry ice, which is magnified by the its need as part of the cold chain storage supply chain for vaccines. Pharmaceutical companies, as well as food deliveries (which are up due to the COVID-19 pandemic) have raised demand to levels not seen before. At the same time, dry ice production has slowed because the supply of carbon dioxide, from which dry ice is made, is down. Carbon dioxide is captured during the production of ethanol, which has dropped off, in part, because fewer Americans are driving and buying gas.

Among the other vaccines closest to applying for authorization with the U.S. FDA, some require refrigeration and at least one can be stored at room temperature. If more than one vaccine is authorized, distribution will depend on how well each works for different populations, said Prashant Yadav, a medical supply chain expert and senior fellow at the Center for Global Development, a think tank in Washington, D.C. The complexity of storage, delivery and tracking multiple vaccines with different requirements means planning for these cold chain storage systems needs to begin today.

COVAX (cont.)...

(US$58.2 million) to the COVAX AMC, and the Japanese government expects to put up an initial payment of over ¥10 billion (US$80.03 million) in October. Japan expressed its intent to join the scheme, which is non-binding, and is now working on the details of a potential arrangement towards the September 18th deadline for turning it into a binding commitment to participate – in part because it has become clear that taking part in the COVAX scheme will have no impact on a bilateral vaccine deal with individual drug makers. Australia emphasized the importance of participation in the COVAX effort. Australia's Minister of Foreign Affairs and Minister for Women, Senator Marise Payne, said "We also know that early access to vaccines will play a critical role in the economic recovery of all countries – including our Pacific family and regional partners."

In Brief (cont.)...

participants. The hold on the Phase III study highlights the high stakes for the industry and the public if a vaccine were approved before safety and efficacy were thoroughly understood. Earlier a statement was issued by nine pharma CEOs, including AstraZeneca CEO, *Pascal Soriot*, pledging to uphold the safety and efficacy of a new vaccine, and refusing to bow to political pressure to approve one quickly.

- China has put its coronavirus vaccines on display for the first time, as the country looks to shape the narrative surrounding the pandemic. The small vials displayed at a Beijing trade fair this week were produced by **Sinovac Biotech** and **Sinopharm**. The companies hope that they will be approved as early as year-end after phase III trials end.
- Russia has announced that it is prepared to roll out immunization for its COVID-19 vaccine in October prior to the completion of Phase III trials, and has published peer reviewed Phase I/II trial data in *The Lancet*. Named *Sputnik V*, the adenovirus-based product was granted provisional approval in Russia on August 11th, making it the world's first COVID-19 immunization to gain regulatory clearance.
- **Johnson & Johnson (J&J)** has announced that it will buy **Momenta Pharmaceuticals Inc.** for approximately US$6.5 billion. The deal provides J&J with entry into a potentially profitable new class of drugs to treat certain autoimmune diseases as well as access to an experimental autoimmune drug, *nipocalimab*. Momenta is a biotechnology company focused on developing treatments for rare immune-mediated diseases. J&J already has built a strong business with drugs including *Remicade* and *Stelara*.

(Sources: Company Press Releases, Drug Store News, Economic Times, Financial Times, and Scrip)