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FDA Authorizes Second Coronavirus (SARS-CoV2) Vaccine for Use

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On December 18, 2020, one week after authorizing the first SARS-CoV2 vaccine (Pfizer) for emergency use, the U.S. Food and Drug Administration (FDA) has granted a second emergency use authorization (EUA) for a messenger RNA (mRNA) vaccine developed by Moderna. The EUA authorizes use of the Moderna vaccine for the prevention of COVID-19 disease caused by SARS-CoV2 in individuals 18 years of age and older. The Moderna COVID-19 vaccine is administered as two recommended doses, one month apart.

Early deployment of the Pfizer vaccine across the US began the week of December 14, 2020, targeted largely to frontline healthcare workers, and is proceeding through their closely managed internal distribution channels to assure that extreme cold chain requirements for that vaccine are maintained. Moderna vaccine doses will be distributed through McKesson's national wholesaler network, as the vaccine can be more easily stored in conventional refrigeration. Moderna is projecting distribution of 20 million doses nationwide by the end of 2020 in addition to the 25 million from Pfizer as the US vaccination push builds.

In early 2021, vaccine production, distribution and availability is projected to accelerate rapidly, with Pfizer and Moderna estimating that they'll each deliver 100 million doses in the first quarter. Moderna has contracted for an additional 100 million doses to deliver in Quarter 2, negotiations with Pfizer are continuing and additional vaccines from Johnson and Johnson, Novavax, Oxford-AstraZeneca and others are expected to come forward in early 2021. First shipments of vaccine targeted for use in long-term care residents and facility staff are now underway, in keeping with the recommendations of an independent expert panel advising the Centers for Disease Control and Prevention (CDC).

FDA Commissioner Stephen Hahn, M.D. remarked that “Through the FDA's open and transparent scientific review process, two COVID-19 vaccines have been authorized in an expedited timeframe while adhering to the rigorous standards for safety, effectiveness, and manufacturing quality needed to support emergency use authorization that the American people have come to expect from the FDA. These standards and our review process, which are the same we have used in reviewing the first COVID-19 vaccine and intend to use for any other COVID-19 vaccines, included input from independent scientific and public health experts as well as a thorough analysis of the data by the agency's career staff.”

According to the CDC, “An Emergency Use Authorization (EUA) is a mechanism available to FDA that facilitates the availability and use of medical countermeasures, including vaccines, during public health

emergencies, such as the current COVID-19 pandemic." Under an EUA, the FDA may allow the use of unapproved medical products to diagnose, treat or prevent serious or life-threatening diseases or conditions when certain statutory criteria have been met, including that there were no adequate, approved and available alternatives. The FDA must determine that the known and potential benefits outweigh the known and potential risks of the vaccine. The FDA expects manufacturers whose COVID-19 vaccines are authorized under an EUA to continue their ongoing clinical trials to obtain additional safety and effectiveness information in pursuit of full approval.

Mitchell Pharmacy Solutions will continue to monitor this situation and provide any relevant updates. If you have any questions about this update, please contact your client services manager.



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