

 <p>대한민국 대전환 한국판뉴딜</p>	<h1>Press Release</h1>	Released on	Mar. 28, 2021 (Sun)
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## Pfizer COVID-19 Vaccine Comirnaty Lot Release Approved for 250,000 People

- On March 28, the Ministry of Food and Drug Safety (MFDS, Minister Kim Ganglip) approved the lot release of Comirnaty Inj. for 250,000 people (or 500,000 doses), which was filed by Pfizer Korea.
- The lot release for Comirnaty was swiftly carried out to ensure timely and sufficient supply of vaccines amid the ongoing COVID-19 pandemic.
- National Lot Release is a system designed to reassure the quality of biological products such as vaccines before their market distribution by conducting quality control testing for each individual lot of a product and by reviewing Summary Protocol (SP) - a summarized document on manufacturing processes and test results of a product.

### << Preparation for National Lot Release >>

- The MFDS has made thorough preparations for national lot release since November 2020 by establishing test methods after reviewing data on manufacturers' test methods and by introducing necessary equipment for testing such as ultra performance liquid chromatography.

- The MFDS has also established an RNA laboratory for testing and a cryogenic freezer for the storage of lot release samples.

#### << Outcome of National Lot Release >>

- The MFDS approved the release of 500,000 doses of Comirnaty after concluding that the vaccine complied with the national lot release standards according to the examination of its efficacy, safety and quality by reviewing the test results and SP on manufacturing and testing.
- Comirnaty, which is a messenger RNA vaccine, was tested for ▲ (efficacy) where testing items included potency, identity and content to measure the amount of RNA that shows efficacy and of lipid nanosphere that protects the RNA, ▲ (safety) where the testing for purity and endotoxin verified that the product was not contaminated, and ▲ (quality) where quality consistency was confirmed by the review of quality test data issued by the manufacturer's Quality Assurance manager.

#### << Future Plan >>

- The MFDS will continue to do its utmost to make sure that safe vaccines are delivered to the people by tapping into relevant workforce and infrastructure for national lot release and thereby ensuring thorough evaluation of COVID-19 vaccines that are supplied to Korea.