한국판뉴딜 대한민국 대전환 / Ministry of Food and Drug Safety	보 도 자 료	배 포	2020. 12. 18.(금)
		담 당 과	식품의약품안전평가원 신속심사과
		과 장	김희성 (☎043-719-5061)
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MFDS begins rolling review of Pfizer's COVID-19 vaccines

Astrazeneca also applied for additional rolling reviews

☐ The Ministry of Food and Drug Safety (MFDS, Minister Kim Ganglip) announced that Pfizer has begun a rolling submission of non-clinical and clinical (Phase I, II and III) data on its COVID-19 vaccine since Dec. 18. On the same day, Astrazeneca (AZ) also requested an additional rolling review* of quality data on its COVID-19 vaccine, according to the Ministry.

* AZ : applied for a rolling review of non-clinical data on Oct. 6.

☐ MFDS has been operating 2 task force teams* for approvals to expedite the approval process for COVID-19 vaccines.

* (TF team for viral vector vaccines) vaccines from AZ and Johnson & Johnson
(TF team for nucleic acid vaccines) vaccines from Pfizer and Moderna

○ Vaccine developers can submit the quality, non-clinical, and clinical data to MFDS as soon as they become available to request for a rolling review before formally applying for an approval.

- MFDS expects that such processes would help to ensure enough time for the Ministry to conduct thorough reviews on the safety and efficacy of vaccines and reduce the review period starting from the application date to 40 days at shortest.

☐ MFDS said it is committed to doing its utmost to swiftly supply safe and effective vaccines to the people of Korea.