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MFDS Begins Review of Moderna COVID-19 Vaccine

- ☐ The Ministry of Food and Drug Safety (MFDS, Minister Kim Ganglip) announced that Green Cross Corporation, or GC Pharma, filed an application for the Moderna COVID-19 vaccine's marketing authorization.
 - The Moderna COVID-19 vaccine, administered as a two-dose schedule given 28 days apart, is among the vaccines to be distributed in Korea according to the government's national inoculation plan.
 - The Moderna vaccine is an mRNA vaccine manufactured by injecting antigen genes in the form of mRNA for antigen production against SARS-CoV-2, using the same platform as the Pfizer vaccine Comirnaty.
 - The MFDS will thoroughly examine the vaccine's safety and efficacy to determine whether to grant a marketing authorization through a rigorous review of quality, non-clinical, clinical and GMP data while carrying out a three-tiered advisory review by the COVID-19 Treatment and Vaccine Safety and Efficacy Assessment Advisory Committee, Central Pharmaceutical Advisory Committee and Final Evaluation Committee.
 - The Moderna COVID-19 vaccine has thus far received Emergency Use Authorizations (EUA) in countries including the United Kingdom and United States; and has been granted a conditional approval from the European Union, Canada and Switzerland among others on condition that additional documents be submitted following the approval.





