



Dr Agnes Saint-Raymond,
Head of International Affairs Division
European Medicines Agency (EMA)
Domenico Scarlattilaan 6, 1083 HS Amsterdam, The Netherlands

24 June 2020

Dear Dr Agnes Saint-Raymond,

Subject: Ad hoc confidentiality arrangement between the Ministry of Food and Drug Safety of Republic of Korea (MFDS) and the European Medicines Agency (EMA)

I hereby confirm that the MFDS undertakes to keep under conditions of strict confidentiality all confidential information and confidential documents that it receives from the EMA in relation to SARS-CoV2, COVID-19, and medicinal products that may be intended for the diagnosis, prevention or treatment of those two conditions (which may include drugs, biologics, and vaccines). Information and documents may include, inter alia, information in relation to the development, clinical trials, review, assessment, safety issues and new safety signals of medicinal products developed or used to diagnose, prevent or treat COVID-19.

The MFDS undertakes not to disclose to any third party, including the pharmaceutical industry, apart from officers and personnel of its own organisation, any such confidential information or confidential documents. The EMA will advise the MFDS of the non-public status of the information at the time that the information is shared.

The unauthorised disclosure of information exchanged under the present ad hoc confidentiality arrangement could seriously jeopardise any further confidential scientific and regulatory interactions between the MFDS and the EMA.

Kind regards,



Dr Young-Ok Kim
Director General of the Pharmaceutical Safety Bureau
Ministry of Food and Drug Safety
Republic of Korea