

 대한민국 대전환	<h1 style="text-align: center;">News release</h1>	Date 22 NOV 2020 (SUN)
 Ministry of Food and Drug Safety		Division Director for International Cooperation/ Biopharmaceutical Quality Management Division/ Expedited Review Division of Medicine and Medical Devices

## MFDS decides to cooperate with WHO in COVID-19 Vaccines PQ Evaluation Activities

- The Ministry of Food and Drug Safety (MFDS, Minister Kim Ganglip) announced the participation of its staff as reviewers in the World Health Organization's (WHO's) Prequalification (PQ) of COVID-19 vaccines that will be supplied through the COVAX Facility, a multinational alliance created to support an equitable distribution of vaccines, and other international vaccine suppliers.
- WHO conducts PQ evaluation to assess the quality, safety, and efficacy of vaccines and other medical products for international procurement. All medical products need to be prequalified to be invited to the bidding for international procurement.
- COVID-19 vaccines intended to be supplied through the COVAX facility will also be prequalified by the WHO.

### WHO PQ Process

- √ PQ is a program provided by WHO to assess the safety and efficacy of medical products intended for international procurement to developing countries. The assessment also takes the safety management capacity of the manufacturing country's regulatory authority into consideration.
- √ Process (5 components): Invitation (Submission of Application) → Dossier submission (data on ingredients used in manufacture, the finished pharmaceutical product, clinical trials, etc.) → Assessment (evaluation of all the data presented) → Inspection (verify that the manufacturing sites and competent authorities comply with WHO's good manufacturing practice, good clinical practice and good laboratory practice, etc.) → Decision

- ☐ MFDS has participated in WHO PQ since 2012 as WHO has acknowledged the competency of MFDS in the regulation of vaccines. Ever since MFDS signed an arrangement on “collaboration in the prequalification process” in 2016 and a mutual confidentiality arrangement with WHO in 2017, it has provided technical supports to the Korean vaccine manufacturers for WHO PQ.
- ☐ Through the participation of MFDS in WHO’s PQ of COVID-19 vaccines, Korea will be able to make substantial contribution to the global efforts to fight against COVID-19 pandemic.