Ministry of Food and Drug Safety

Press Release

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From Immediate Release		Date	November 30, 2022 (Wed)
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GBT(Global Benchmarking Tool)

MFDS Achieves Highest Maturity Level in Regulatory System by WHO

– the first country to reach maturity level 4 in both of medicines and vaccines –

□ The Ministry of Food and Drug Safety (MFDS) of the Republic of Korea (Minister Oh Yu-Kyoung) announced on November 30 that it has reached Maturity Level 4, the highest level achievable for regulatory system evaluation against the WHO's Global Benchmarking Tool (GBT), in both medicines and vaccines regulations.

○ WHO utilizes GBT — an evaluation tool that checks 9 regulatory functions* against a total of 268 sub-indicators — to objectively assess the maturity of the regulatory system of a National Regulatory Authority (NRA) on a scale from 1 (the lowest) to 4 (the highest).

* ① National Regulatory System (RS), ② Registration and Marketing Authorization (MA), ③ Vigilance (VL), ④ Market Surveillance and Control (MC), ⑤ Licensing Establishments (LI), ⑥ Regulatory Inspection (RI), ⑦ Laboratory Testing (LT), ⑧ Clinical Trials Oversight (CT) ⑨ NRA Lot Release (LR)

○ The Republic of Korea is the first* country, benchmarked by WHO to reach Maturity Level 4 for both medicines and vaccines among regulatory authorities around the world.

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* Singapore reached Maturity Level 4 in medicines in February 2022.

** Four regulatory systems subject to WHO evaluation: medicines, vaccines, blood products and medical devices. Currently, WLA (WHO-Listed Authority) designation is applied only to medicines and vaccines.

- Achieving the highest Maturity Level means MFDS' regulatory system for medicines and vaccines not only operates at advanced level of performance but also continues to improve. This also acknowledges globally that local manufacturers of medicines and vaccines are producing safe, effective and quality-assured products in compliance with MFDS' standards.

- Dr. Mariângela Simão, Assistant Director-General, WHO, said "This is a great testament for Republic of Korea's commitment for ensuring safe and effective medicines and vaccines, and investing in building a strong regulatory system."

□ MFDS underwent evaluations to be designated as a WHO-Listed Authority (WLA*) to receive global and objective recognition for its excellence in medicines and vaccines regulation. The benchmarking conducted this time is a prerequisite to undergo the procedures of WLA designation.

* WLA (WHO-Listed Authorities) was developed by WHO as a transparent and evidence-based pathway for regulatory authorities operating at an advanced level of performance to be globally recognized, thereby replacing the procurement-oriented concept of stringent regulatory authorities (SRA).

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○ As a WHO TSA* - designated regulatory authority (since 2006), and as a member of PIC/S* (since 2014) and ICH* (since 2016), the advanced regulatory system of the Republic of Korea has been recognized globally. Hence, MFDS was benchmarked against 133 sub-indicators (135 sub indicators exempted) out of 268 sub-indicators.

* Technical Service Agreement / Pharmaceutical Inspection Co-operation Scheme / International Council for Harmonization

○ In January 2022, MFDS submitted the self-benchmarking reports for GBT evaluation. A WHO team of 19 international assessors visited MFDS in May 2022 for the benchmarking with GBT, and the MFDS' regulatory system was finally confirmed at the highest Maturity Level 4 as of November.

- MFDS has received GBT benchmarking as well as Performance Evaluation on Vigilance, GCP (Good Clinical Practice) inspection, and Laboratory and Testing for the WLA process. The Ministry is also planning to take the remote evaluation on Marketing Authorization and Clinical Trials by the first quarter of 2023.

□ Minister Oh Yu-Kyoung highlighted that reaching the highest maturity level is a significant milestone as it is one of the most important steps to becoming a WLA. Minister Oh also said "We will do our best to successfully complete the remaining evaluations, and we will contribute to promoting global public health by sharing this experience to other regulators. The Ministry will enhance access of high-quality Korean medicines and vaccines to the global market through proactive support."

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