Decisions of the Technical Committee for Drug Control at its session on 18/01/2024

***- The Technical Committee decided at its session on 18/01/2024:**

• To approve the submitted recommendation (where the General Administration of Human Pharmaceutical Registration recommended adding the MFDS and HSA that follows South Korea and Singapore as reference regulatory authorities for biological preparations and human preparations, based on their being:

- ICH members
- WLA members
- Operating at ML4 as benchmarked by the WHO
- While taking into account updating the list of reference regulatory authorities according to global developments and after presenting to the Technical Committee for Drug Control.

• In case of human pharmaceutical preparations; active substances and new pharmaceutical preparations submitted by the newly added countries shall be presented to the Scientific Committee before approval to proceed with registration procedures to determine the need.

• The updated list shall be effective as of 01/07/2024.)

• Adopting the criteria for selecting reference countries is in line with the World Health Organization's criteria, with the addition of MFDS and HSA of South Korea and Singapore as reference regulatory authorities for biological preparations and human preparations only.