Notice to applicant

Central Administration of Pharmaceutical Products (CAPP)
General Administration For ……
Technical Committee for Drug Control (TCDC)

List of EDA Reference Countries

Year 2024

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Updated List of EDA Reference Countries

The update of EDA List of reference countries is according to Technical Committee for Drug Control (TCDC) decision at its session on 18/01/2024 & is effective from date 01/07/2024 (for Human Pharmaceutical Preparations)

Reference countries: are countries with national regulatory authorities competent for supervisory, executive and regulatory procedures for biological and pharmaceutical preparations and medical supplies of all kinds and in which one of the following reference accreditation standards is met:

1- ICH Founding Regulatory Authority
2- ICH Standing Regulatory Members
3- Regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement
4- Regulatory authority having the following 3 criteria of being (ICH member, WLA and operating as ML4 at benchmarked by WHO)

According to the most updated decision of Technical Committee for Drug Control (TCDC) at its session on 18/01/2024 based on adopting criteria for selecting reference countries in line with the standards of the World Health Organization; the addition of the MFDS & HSA that follows two countries' (South Korea and Singapore) respectively, has been approved as reference regulatory authorities for biological preparations and for human preparations only based on their being:

- ICH member
- WLA
- Operating as ML4 at benchmarked by WHO

The updated list of Reference Countries will be as follows:

No.	Country	No.	Country
1	U.S. A	13	Belgium
2	Australia	14	Austria
3	UK	15	Iceland
4	Canada	16	Denmark
5	Japan	17	Netherlands
6	Ireland	18	New Zealand
7	Norway	19	Luxembourg
8	Germany	20	Spain
9	France	21	Italy
10	Switzerland	22	Portugal
11	Finland	23	South Korea
12	Sweden	24	Singapore

According to Technical Committee for Drug Control (TCDC) decision at its session on 18/01/2024; In case of human pharmaceutical preparations, the active substances and new pharmaceutical preparations submitted by the newly added countries (South Korea & Singapore) respectively, are presented to the Scientific Committee before approval to proceed with the registration procedures to demonstrate the need.