

Annex 1

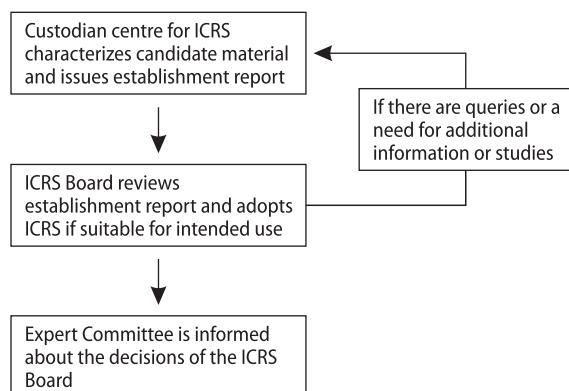
Release procedure for International Chemical Reference Substances

Background

During its forty-fifth meeting in 2010 the Expert Committee on Specifications for Pharmaceutical Preparations agreed on a release procedure for International Chemical Reference Substances (ICRS) (1). Based on this procedure case-reports issued by the custodian centre for ICRS after analytical testing of candidate material were reviewed by the Secretariat with assistance from collaborating laboratories. If the testing was performed according to the *General guidelines for the establishment, maintenance and distribution of chemical reference substances* (2) and the candidate material was found suitable, the Secretariat, in cooperation with the collaborating laboratories, released the ICRS provisionally. In accordance with the rules, the case-reports were subsequently submitted to the Expert Committee on Specifications for Pharmaceutical Preparations during its subsequent meeting, for final adoption. After provisional release the custodian centre for ICRS started the distribution of the ICRS.

This process expedited the release of ICRS and enabled WHO to react more quickly to urgent demands for ICRS. However, the procedure did not clearly allocate the accountability for the release of ICRS to a single time, person or body. Therefore, the Expert Committee members adopted the following new procedure (Figure 1).

Figure 1
New procedure for the adoption of ICRS



New release procedure

After testing of candidate material, the custodian centre for ICRS will submit analytical case-reports to a newly established ICRS Board, which consists of three experts and a representative of the Secretariat. The Board will decide on the suitability of the reference substance on behalf of the Expert Committee and adopt the ICRS, if found to be suitable for the intended use. In case the Board has queries or considers during its in-depth review that there is a need for additional information and/or studies, the Secretariat will contact the custodian centre accordingly. The feedback will in turn be submitted to the Board for its consideration and final decision.

During the subsequent meeting of the Expert Committee its members will be informed about newly adopted ICRS.

References

1. Release procedure of International Chemical Reference Substances. In: *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth report*. Geneva, World Health Organization, 2011, Annex 1 (WHO Technical Report Series, No. 961).
2. General guidelines for the establishment, maintenance and distribution of chemical reference substances. In: *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-first report*. Geneva, World Health Organization, 2001, Annex 3 (WHO Technical Report Series, No. 943).