PDG's efforts to engage other ICH pharmacopoeias in the Q4B Annexes maintenance process

At its November 2020 meeting, the ICH Assembly approved the proposal made by the PDG (Pharmacopoeial Discussion Group) on how to include the pharmacopoeias of the non-Founding ICH Regulatory Members in the maintenance of the ICH Q4B Annexes. The expansion of ICH membership provides an excellent opportunity to further promote the global convergence of pharmacopoeial quality standards, through the extended recognition – potentially by all ICH Regulatory Members – of the harmonised pharmacopoeial texts referenced in the Q4B Annexes. The PDG has now reached the first crucial milestone in its efforts to involve the pharmacopoeias of non-Founding ICH Regulatory Members in this work.

The "Q4B process", the process for the "evaluation and recommendation" of selected pharmacopoeial texts to facilitate their recognition by regulatory authorities for use as interchangeable by the ICH Regulatory Members, is separate from the process for pharmacopoeial harmonisation in PDG. Following evaluation in the "Q4B process", topic-specific annexes with information about these texts and their implementation are issued. The process was initially the responsibility of the ICH Q4B Expert Working Group (EWG) until it was disbanded at the end of 2010. The PDG took over this responsibility and the maintenance of the existing Q4B annexes in November 2018.

The current Q4B annexes cover texts from the three PDG pharmacopoeias and include declarations of interchangeability by ICH Founding and Standing ICH Regulatory Members only [i.e. EC (Europe); FDA (United States); MHLW/PMDA (Japan); Health Canada (Canada); Swissmedic (Switzerland]. However, since the Q4B Annexes were last updated by ICH Q4B EWG, the ICH has expanded its membership to include additional Regulatory Members whose pharmacopoeias may include texts impacted by the Q4B Annexes.

In April 2020, the PDG submitted a detailed proposal on how to extend the scope of the Q4B process to pharmacopoeial texts of the non-Founding ICH Regulatory Members to the ICH Management Committee and ICH Assembly. The PDG also recommended launching a "proof of concept" pilot study on three selected Q4B annexes – Annex 6: Uniformity of Content/Mass, Annex 7: Dissolution and Annex 8: Sterility – before considering extending the proposal to all others.

This proposal was approved by the ICH Assembly in November 2020.

The PDG has since contacted the pharmacopoeias of the non-Founding ICH Regulatory Members and asked them to evaluate their own text versus the PDG sign-off text and to inform the PDG if they have implemented the PDG sign-off texts or if they consider their own text as already harmonised with them. They were also asked to provide the PDG with a detailed review of potential residual differences as well as an English version of their pharmacopoeial text. This process is liable to take several months. The PDG will review the feedback from these pharmacopoeias and, where appropriate, update the Q4B Annexes with additional information on the acceptance by additional ICH Regulatory Members. The revised Q4B Annexes will be submitted to the ICH secretariat which will then launch a consultation among the ICH Regulatory Members. This consultation will focus on the regulatory considerations in the Q4B Annexes.

The PDG will provide a status update to the ICH Assembly after the PDG Annual Meeting, which will be hosted by the EDQM in October 2021.

(*) the PDG brings together the European Pharmacopoeia (Ph. Eur.), the Japanese Pharmacopoeia (JP) and the United States Pharmacopeia (USP), with WHO as an observer.