PHARMACOPOEIAL DISCUSSION GROUP ACHIEVEMENTS

The Pharmacopoeial Discussion Group (PDG), which brings together the European Pharmacopoeia, the Japanese Pharmacopoeia and the United States Pharmacopeia, held its annual autumn meeting via videoconference on 22-23 September 2020, with WHO attending as Observer. Due to the COVID-19 pandemic, the face-to-face meeting originally scheduled was reorganised as a videoconference devoted entirely to discuss strategy and policy topics.

The discussions focused on a number of strategic aspects of the challenges related to pharmacopoeial harmonisation including discussing opportunities to enhance the global reach and impact of international harmonization of quality standards. Also on the agenda was the maintenance of the Q4B Annexes, a role attributed to the PDG by decision of the ICH Assembly in November 2018. Subsequent to this decision, the PDG had drafted and submitted a detailed proposal on how the respective annexes would be maintained. It was suggested that proof-of-concept studies could be performed on selected Annexes to demonstrate how the PDG would carry out the task. After the ICH Management Committee and Assembly Meetings in May 2020 (see SUMMARY of MC SESSION ACTIONS AND DECISIONS: ICH Management Committee Virtual Meeting, 13, 25 and 26 May 2020, B. Q4B Maintenance), the PDG agreed to provide a mapping document highlighting the various engagement points where stakeholders, including ICH Members and Observers, would be able to contribute to the harmonised standards development process. This mapping document was discussed at the PDG's latest meeting and was sent to the ICH Secretariat for reflection in preparation for the next ICH Management Committee and Assembly meeting in November 2020.

A subsequent PDG videoconference to discuss individual technical items on the PDG workplan will be scheduled for later this autumn. This is intended to ensure that, even without the usual multiple exchanges that take place in face-to-face meetings, all items on the PDG workplan will continue to progress during the current global pandemic. As ever committed to transparency, the PDG will inform its stakeholders about the outcome of these discussions and any newly finalised and signed-off texts following this meeting.

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