May 19, 2025

PHARMACOPOEIAL DISCUSSION GROUP ACHIEVEMENTS

The Pharmacopoeial Discussion Group (PDG)[1] held its interim videoconference on 6 March 2025.

The discussions focused on the next phase of PDG's global membership expansion initiative. As previously announced (link), the PDG launched this initiative in summer 2024 and invited pharmacopoeias interested in becoming members to submit their applications by the end of the year 2024. In accordance with the framework (link) and the entry criteria (link), the current members reviewed each application submitted and had an initial exchange on their individual evaluations. The final decision will be made in summer 2025.

The PDG held productive discussions on aligning innovative approaches to the test for Bacterial Endotoxins using recombinant reagents. Through continuous and open dialogue, PDG reached a major achievement by approving a unified position among the four member pharmacopoeias regarding the goal to include methods using recombinant reagents in the harmonzsed chapter. Details on this important topic are shown in the Appendix.

The PDG also discussed the maintenance work on the ICH Q4B annexes on pharmacopoeial harmonisation (link). The progress and challenges of the work on the revision of the three annexes for Uniformity of Dosage Units, Dissolution and Sterility, as well as the next steps toward finalizing the work, were discussed based on the responses received from ICH regulatory members and/or their pharmacopoeias. The timeline for the maintenance of all remaining annexes was also considered. The PDG will pursue the work and continue to update the ICH and related pharmacopoeias on progress at the May 2025 meeting in Madrid. Expanding the interchangeability statements by including additional pharmacopoeias and adding the statements from additional regulatory authorities will be a big step towards wider recognition of harmonised pharmacopoeial standards. However, in view of the responses, a phased approach will be taken to the inclusion of further pharmacopoeias, ensuring a smoother and more timely integration.

Individual work programme sign-offs included a correction of the general chapter Amino Acid Determination (B-01). The current work programme, including all ongoing items, is available on the website (General chapters, Excipients). The PDG signed-off on the revised PDG Working Procedure to add the changes to the operational aspects, including interactions with the IMWP, reference to ICH Q4B and revised sign-off cover sheets.

The next face-to-face meeting will be hosted by the JP on 30 September – 1 October 2025 in Tokyo (Japan).

[1] Comprising the European Pharmacopoeia (Ph. Eur.), the Indian Pharmacopoeia Commission (IPC), the Japanese Pharmacopoeia (JP) and the United States Pharmacopeia (USP) and the World Health Organization (WHO) as observer

Appendix

PDG position

PDG is committed to making efforts to develop and revise existing test methods, for example, the test for Bacterial Endotoxins (BET), to decrease the use of animals or animal derived reagents.

In PDG's general chapter Bacterial Endotoxins (Q-06), six methods are described that use Limulus or Tachypleus Amoebocyte Lysate (LAL/TAL) as a reagent. This reagent consists of cells (amoebocytes) derived from the horseshoe crab.

PDG recognizes the availability of non-animal derived recombinant reagents as alternatives to replace LAL/TAL in the BET. These alternatives include recombinant factor C (rFC) and synthetic mixtures that mimic the coagulation cascade, referred to as “recombinant cascade reagents” (rCR).

The pharmacopoeias of PDG and the regulatory framework they are embedded into are at different stages of acceptance regarding the performance of recombinant reagents compared to LAL/TAL.

PDG's goal is to include new methods using recombinant reagents in the harmonised chapter.