Ph. Eur., JP and USP announce the launch of a trilateral prospective harmonisation project on pharmacopoeial standards for osimertinib mesilate and osimertinib tablets

The European Pharmacopoeia (Ph. Eur.), the Japanese Pharmacopoeia (JP) and the United States Pharmacopeia (USP) are pleased to announce the launch of the first trilateral prospective harmonisation project targeting the pharmacopoeial documentary standards for osimertinib mesilate and osimertinib tablets.

Building on more than three decades of collaboration through the Pharmacopoeial Discussion Group (PDG), during which the three pharmacopoeias have focused on the retrospective harmonisation of general chapters and excipient monographs, this new project marks the first coordinated trilateral effort to pursue prospective harmonisation. Conducted outside the traditional PDG pathway, the initiative leverages the experience gained through longstanding PDG and bilateral collaborations among the Ph. Eur., JP, and USP, and expands harmonisation efforts to include small molecule drug substances and finished dosage forms, with the goal of developing unified monographs for active ingredients and drug products.

Through this project, the three pharmacopoeias aim to support consistent quality expectations for medicines across regulatory regions, reduce multiple testing burdens for manufacturers, and ultimately contribute to improved global public health outcomes.

The Ph. Eur., JP and USP thank their stakeholders for their support and engagement and look forward to productive discussions. The three pharmacopoeias anticipate that the insights gained from this project will help further strengthen collaboration and contribute to expanding the work of convergence of pharmacopoeial documentary standards in the future.

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