IPC Updates

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Pharmacopoeial Discussion Group welcomes Indian Pharmacopoeia Commission as a member, facilitating reach and enhancing impact of pharmacopoeial standards harmonisation

Hyderabad, India, October 5, 2023 – The Pharmacopoeial Discussion Group (PDG) today announced the Indian Pharmacopoeia Commission (IPC) as a PDG member. IPC officially joined as a member in the PDG, which was established by the European Pharmacopoeia (Ph. Eur.), Japanese Pharmacopoeia (JP), and the U.S. Pharmacopeia (USP), at the PDG's Annual Meeting on Oct. 3-4 in Hyderabad. The World Health Organization (WHO) also continues to serve as observer of the group.

"IPC is honoured to be considered for membership of the PDG," said Rajeev Singh Raghuvanshi, Ph.D., Secretary-cum-Scientific Director, IPC. "Since becoming PDG's pilot for expansion to its membership in October 2022, IPC has participated in PDG meetings and technical discussions, and submitted implementation timelines for various PDG standards. As a PDG member, we look forward to continuing to work to advance standards convergence around the world."

"We warmly welcome IPC to PDG," said Cathie Vielle, Secretary to the European Pharmacopoeia Commission. "This is a milestone in PDG's commitment to expanding recognition of harmonized

pharmacopoeial standards. Working together will further advance convergence around robust science-based quality standards across pharmacopoeias for the benefit of public health."

"For over three decades, the original PDG members – including JP, Ph. Eur., and USP – have worked to increase the reach and impact of global standards harmonisation efforts," said Yoshiro Saito, Ph.D., Deputy Director General of the National Institute of Health Sciences and Chair of the JP Expert Committee. "Adding IPC marks the culmination of several years of discussions on new member participation to help increase global access to quality medicines and ensure PDG's continued success."

"USP is delighted to welcome IPC as a PDG member following its successful participation in a year-long pilot for global expansion of PDG membership," said Jaap Venema, Ph.D., Executive Vice President and Chief Science Officer for USP. "It's the latest step in the USP's and PDG's commitment to expand access to PDG quality standards by approximately 1.3 billion people, as well as to the Indian pharmaceutical industry as a major manufacturer of the world's medicines."

PDG's progress in recent years has included addressing emerging quality issues such as the potential for impurities and reaching consensus on harmonisation of select pharmacopoeial standards. Recent examples include standards for chromatography and dynamic light scattering to help ensure the quality of medical products. Looking ahead, PDG priorities include working toward harmonisation of standards for elemental impurities and excipients including polysorbate 20, purified water and water for injection, and modernising a significant number of already harmonised general methods and excipient monographs.

About the PDG

Pharmacopoeial standards play a critical role in ensuring public health by setting quality expectations for each stage in the drug manufacturing process. Many manufacturers and regulatory agencies around the globe use the same standards to test for characteristics like identity, purity, potency and performance. The purpose of the PDG is to facilitate harmonisation of select pharmacopoeial standards (including excipient monographs and select general chapters) on a global level. Harmonisation reduces manufacturers' burden of having to perform analytical procedures in different ways, using different acceptance criteria, in order to satisfy pharmacopoeial requirements that vary across geographies. PDG strives to maintain a consistent level of science across the pharmacopoeias, with the shared goal of protecting public health.