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PDG prepares pilot for global expansion of membership

The Pharmacopoeial Discussion Group (PDG), which brings together the European Pharmacopoeia (Ph. Eur.), the Japanese Pharmacopoeia (JP) and the United States Pharmacopoeia (USP), with the World Health Organization (WHO) as an observer, is preparing a pilot to integrate additional world pharmacopoeias. This is a critical step in the PDG's commitment to expanding recognition of harmonised pharmacopoeial standards with a view to achieving global convergence.

Since it was founded in 1989, the PDG has successfully harmonised and maintained 29 general chapters, including such important analytical procedures as Dissolution Testing, Sterility and Microbiological Examination. In addition, the PDG has harmonised 46 excipient monographs and has approximately 20 new texts in its pipeline. The aim of the three founding pharmacopoeias is to extend this significant success story to further jurisdictions/regions and to create an inclusive global platform from which to elaborate harmonised pharmacopoeial standards.

To this end, the PDG has been working on 3 areas considered as key to ensuring the future of the Group: (1) membership expansion as a means of enhancing its global outreach, (2) stakeholder engagement and (3) regulatory engagement. The first outcome of these efforts has been a detailed plan for extending PDG membership beyond the original 3 pharmacopoeias, together with entry criteria for new members. This plan will help ensure that the successes of the past 32 years are not compromised and that the current pharmacopoeial harmonisation model can continue to work effectively with new members. The PDG will further adjust its working methods based on the lessons learned after the expansion procedure is rolled out.

The PDG put the finishing touches to its plan for extending PDG membership during its annual meeting in October 2021. The plan is intended to be announced by the end of October 2021, inviting other world pharmacopoeias to join forces in providing strong, science-based harmonised pharmacopoeial standards.

Contact: Caroline Larsen Le Tarnec, Public Relations Division, EDQM, Council of Europe
Tel.: +33 (0) 3 88 41 28 15 – E-mail: caroline.letarnec@edqm.eu

Note for the Editor: Further information is available on the internet site <https://www.edqm.eu/>.

The EDQM is a leading organisation that protects public health by enabling the development, supporting the implementation and monitoring the application of quality standards for safe medicines and their safe use. Its standards are recognised as a scientific benchmark worldwide. The European Pharmacopoeia is legally binding in member states.¹ The EDQM also develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

1. There are 40 members of the [European Pharmacopoeia Commission](#): *Austria, Albania, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Republic of Moldova, Montenegro, Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom and the European Union.*

A political organisation set up in 1949, the Council of Europe works to promote democracy and human rights continent-wide. It also develops common responses to social, cultural and legal challenges in its 47 member states.