Press release

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JP and Ph. Eur. launch a bilateral prospective harmonisation project for active substance and medicinal product monographs

The Japanese Pharmacopoeia (JP) and the European Pharmacopoeia (Ph. Eur.) are pleased to announce the launch of a bilateral prospective harmonisation project targeting pharmacopoeial standards for active substances and medicinal products. Pharmacopeial harmonisation serves to further reduce the burden on manufacturers to perform different compendial tests by aligning the pharmacopoeial standards in different regulatory jurisdictions.

Since the launch of the Pharmacopeial Discussion Group (PDG) in 1989, the JP and Ph. Eur., together with the United States Pharmacopeia and more recently the Indian Pharmacopoeia, have been working on the retrospective harmonisation of general chapters and excipient monographs. This new bilateral prospective harmonisation project will take place outside of the PDG processes and will build upon the experience gathered over the many years of collaboration between JP and Ph. Eur. to apply it to the elaboration of active substance and medicinal product monographs. The project will be conducted within the framework of the memorandum of co-operation (MOC) and confidentiality arrangement between the European Directorate for the Quality of Medicines & HealthCare (EDQM) and the Ministry of Health, Labour and Welfare (MHLW)/Pharmaceuticals and Medical Devices Agency (PMDA) of Japan, that was established in September 2016 with the aim of further strengthening relations and promoting co-operation between the organisations.

Macitentan and macitentan tablets have been selected as the first candidates for this co-operation. As a first step, the JP and Ph. Eur. will work jointly on bilateral harmonisation of these two monographs while taking the specificities of their respective regulatory frameworks into account. Discussions will include an overview of current and future possibilities and the challenges met when expanding the harmonisation of pharmacopoeial standards to both active substances and medicinal products. The lessons learned during this project may pave the way towards further strengthened co-operation between the two organisations and contribute to expanding the work of convergence of pharmacopoeial standards.

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Note for the Editor: Further information is available on the internet site **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.

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 46 member states.

1. The European Pharmacopoeia Commission comprises 40 members: Albania, Austria, 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, Türkiye, Ukraine, United Kingdom and the European Union.