Press release

17 August 2022, Strasbourg, France

11th edition of the European Pharmacopoeia now available in print

The European Directorate for the Quality of Medicines & HealthCare (EDQM)[1] is pleased to announce the release of the print version of the 11th Edition of the European Pharmacopoeia (Ph. Eur.). This latest edition contains numerous revised and new texts, reflecting the latest scientific and technological progress and regulatory developments in the quality control and safety of medicinal products and their constituents. The launch of this new edition will be marked by a three-day international conference from 19-21 September.

With a total of 2 469 monographs, 386 general texts and more than 2 800 descriptions of reagents, the 11th Edition offers new additions such as general chapter *2.7.26. Cell-based assay for potency determination of TNF-alpha antagonists,* the landmark first 'horizontal' or 'performance-based' standard for monocolonal antibodies that was elaborated in response to stakeholder demand, and *5.26. Implementation of pharmacopoeial procedures,* a general text providing more detailed practical information on one of the key processes underpinning the correct use and application of Ph. Eur. texts.

This Edition also includes the long-awaited final revised version of the harmonised general chapter *2.2.46. Chromatographic separation techniques*. Chromatography being one of the most widely used techniques in analytical quality control, this is a significant accomplishment and signifies the successful outcome of global quality standard convergence efforts involving the United States Pharmacopeia, the Japanese Pharmacopoeia and the Ph. Eur.

Whether revised or new, all these texts have been through the robust procedure (prepared by a group with specific expertise in the subject matter, public consultation in Pharmeuropa and adoption by the Ph. Eur. Commission) established by the EDQM to ensure that the Ph. Eur. remains fit for purpose and relevant in an increasingly global environment, one that has been placed under particular strain over the past two and a half years.

"We can be extremely proud that, despite the pandemic, work on the 11th Edition was able to continue to the same standards of excellence that the Ph. Eur. is known for" says Torbjörn Arvidsson, outgoing Chair of the European Pharmacopoeia Commission (2019-2022). He adds, *"The Ph. Eur. will continue to ensure the quality of medicines for the benefit of public health for many years to come."*

The 11th Edition will be applied in more than 130 countries worldwide, a continuing testament to the global footprint of Ph. Eur. quality standards for medicinal products and their

1. The EDQM is a directorate of the Council of Europe. The Council of Europe has 46 member states, including all EU member states. The origins of EDQM date back to 1964, when the Convention on the Elaboration of a European Pharmacopoeia was adopted by the Committee of Ministers of the Council of Europe. To date, this convention has been signed and ratified by 39 member states of the Council of Europe, including the 27 member states of the European Union, and by the EU.
The EDQM is responsible for the development of technical rules for safety and quality of SoHO through dedicated experts group, then adopted by the CD-P-TS or the CD-P-TO. These committees are intergovernmental structures answerable to the Committee of Ministers of the Council of Europe. Members eligible to these committees are the members that have signed the Convention on the Elaboration of a European Pharmacopoeia.

constituents. All new and revised texts adopted over the next three years of the 11th Edition publication cycle will be added to the online version and printed as individual supplements.

More information on the 11th Edition and the advantages of subscribing can be found here.

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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. 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.