



Press release

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EDQM provides COVID-19 vaccine developers with free access to quality standards applicable in Europe

The EDQM is committed to supporting vaccine developers during the coronavirus disease (COVID-19) pandemic – as well as contributing to the wider global effort to combat the virus – by openly sharing knowledge and offering temporary free access to relevant guidance and standards.

It is important to take into account relevant quality requirements, such as those available in the European Pharmacopoeia (Ph. Eur.), from the early stages of development and during definition of analytical strategies for candidate vaccines.

Therefore, the EDQM and the Ph. Eur. have decided to share Ph. Eur. quality standards for vaccines in order to support vaccine developers (many of which are universities and small and medium-sized enterprises) in designing appropriate analytical strategies for their candidate vaccines and to help ensure the quality and safety of the final product. Application of such quality requirements may ultimately help to facilitate regulatory acceptance of a subsequent marketing authorisation application.

The selection of quality standards for vaccines is temporarily available to the public in a freely accessible database on the EDQM website and will be regularly reviewed and updated as deemed appropriate.

Learn more about the European Pharmacopoeia (Ph. Eur. fact sheet).

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.edgm.eu/.

The EDQM is a leading organisation that protects public health by enabling the development, supporting the implementation, and the monitoring the application of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark worldwide. The European Pharmacopoeia is legally binding in member states. Similarly, the EDQM 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.