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## EDQM publishes a new section dedicated to biotherapeutics on its website

As public standards for the quality of medicines in Europe, the monographs and reference standards of the European Pharmacopoeia (Ph. Eur.) play a major role in ensuring the quality of biotherapeutics, thereby contributing to overall patient safety. By providing these recognised common standards for the quality of medicines and their components, the Ph. Eur. promotes public health and ensures the safety of medicines for patients. Ph. Eur. standards are designed to meet the needs of all stakeholders, including industry, Official Medicines Control Laboratories (OMCLs) and regulatory authorities.

The new biotherapeutics section on the EDQM website summarises Ph. Eur. Commission activities and achievements in this field. In addition to clarification of the role of Ph. Eur. monographs in the biosimilars regulatory pathway, it describes the recently concluded P4-BIO pilot phase and the ongoing pilot phase on monoclonal antibodies ("MAB pilot phase"), explaining the strategy followed by the Ph. Eur. when setting requirements for the quality of this important class of biotherapeutics. It also describes various levels of flexibility integrated into Ph. Eur. texts, including those introduced recently to address the structural complexity, heterogeneity and compound diversity derived from different manufacturing processes of complex biotherapeutics.

The Ph. Eur. Biotherapeutics monograph portfolio is now available in the new section, showing the active involvement of the Ph. Eur. Commission in this field over the years, which has resulted in a wide range and great variety of monographs for biotherapeutics.

This new section provides links to relevant news and scientific publications, as well as events such as international conferences, training programmes and webinars organised by the EDQM in recent years to share its perspectives and collect feedback from users on their needs and expectations. The section can be accessed here: <https://www.edqm.eu/en/biotherapeutics>.

During its 161<sup>st</sup> session, held in Strasbourg on 19-20 June, the Ph. Eur. Commission also approved a new edition of the *Technical Guide for the elaboration of monographs on recombinant DNA proteins and synthetic peptides* that has undergone a general update to take into account the experience gained in recent years, notably on the elaboration of monographs for complex molecules: a new section entitled "flexibility" provides insight into the approach to be followed when tackling a complex molecule.

The new edition of the Technical Guide for the elaboration of monographs on recombinant DNA proteins and synthetic peptides can be accessed here: <https://edrms.edqm.eu/livelink.exe/overview/2048847>.

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**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 development, supporting implementation, and 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<sup>1</sup>. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

<sup>1</sup>There are thirty-nine members of the [European Pharmacopoeia](#) Commission: 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, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, "the former Yugoslav Republic of Macedonia", 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.***