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European Pharmacopoeia Commission adopts a new monograph for *Infliximab concentrated solution* – the first monograph on a monoclonal antibody

The European Pharmacopoeia (Ph. Eur.) Commission has achieved an important milestone in the field of biotherapeutic products at its 159th Session, held in Strasbourg on 21-22 November 2017, with the adoption of the monograph for *Infliximab concentrated solution* (2928).

The Ph. Eur. Commission embarked upon the setting of public standards for therapeutic monoclonal antibodies (mAbs) in 2014 with a pilot phase and following extensive consultation with its stakeholders. A 'bottom-up' approach has been undertaken, that started with an investigation of the feasibility of establishing individual monographs (using Infliximab as a case study), building on knowledge and exploring areas for the development of general Ph. Eur. texts applicable to mAbs.

The Infliximab monograph is the successful outcome of a collaborative effort by Ph. Eur. experts, and another fruitful example of the close cooperation between the Ph. Eur. and its key partners. Elaboration of the monograph involved extensive and rigorous analytical testing by Ph. Eur. experts from Official Medicines Control Laboratories. This, together with feedback received from stakeholders during the Pharmedica public enquiry, demonstrated that it is feasible to set meaningful quality requirements for a complex mAb (150 kDa). The approach used to set the monograph specifications is oriented towards promoting flexibility, notably in addressing process-dependent product heterogeneity (e.g. glycosylation, charge profile). Significantly, criteria for verifying the performance of analytical methods are included, which will support robust methodologies, while the provision of examples of suitable procedures for complex assays enables the use of alternative methods.

The monograph for *Infliximab concentrated solution* (2928) will be published in Ph. Eur. Supplement 9.6 and will become effective in January 2019.

In the meantime, the Ph. Eur. Commission will continue its activities in the field of setting public standards for therapeutic mAbs by pursuing the development of horizontal approaches: these will aim to establish a suitable set of general requirements and methodologies applicable to various quality attributes common to (classes/sub-classes of) mAbs (e.g. TNF-alpha product-based standards).

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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 states¹. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

¹There 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.*



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