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TITLE: THE EUROPEAN PHARMACOPOEIA LOOKS INTO ITS BIOLOGICAL FUTURE

In the spirit of continuous improvement, the Ph. Eur. Commission is eager to ensure its sustainability by verifying that it not only fully embraces the current technological and regulatory trends, but also appropriately paves the way for the future. In response to this, the European Directorate for the Quality of Medicines & HealthCare (EDQM) has undertaken an extensive consultation among regulatory authorities and Expert Groups. The feedback gathered from this consultation has led the Ph. Eur. Commission to undertake the following actions in the field of biologicals:

- Creation of a Working Party that will elaborate a text on Raw materials for the production of cellular and gene transfer products. The raw materials to be included within the scope of the text are: antibodies, basal media (for cell culture), serum/serum replacements and growth factors. Specialists in the production and development of cellular and gene transfer products and their raw materials, and experts in the assessment of applications for clinical trials and marketing authorisations will be part of the Group.
- Creation of a Working Party that will elaborate a text on Host cell-derived proteins. The resulting text will provide recommendations for the development, validation and use of in-house or commercial kits or test methods for the detection and quantification of host-cell proteins.
  The two Working Parties were created at the 141st Session (November 2011) of the Ph. Eur. Commission and specialists will be nominated at its 142nd Session (April 2012).
- Initiation of a pilot phase to evaluate the need for finished product monographs for biologicals. It has been proposed that, following elaboration and introduction of a monograph for bulk drug substances, the need for further monographs regulating the dosage form should be assessed on a case-by-case basis. Filgrastim was proposed to be used as a case study for the pilot phase.
- Expansion of the "P4Bio" pilot phase to two further case studies: one pegylated protein monograph and one monoclonal antibody monograph The P4 Procedure, a unique way of establishing quality standards before patents expire and involving close collaboration with innovators, is a procedure that has already proved successful in the chemical field and is currently undergoing a pilot phase for biologicals. In expectation of a high rate of submissions for biosimilars of currently approved monoclonal antibodies and pegylated proteins, the Ph. Eur. Commission has decided to explore a way of establishing standards for these important biologicals.

The need for greater awareness of the role of the Ph. Eur. in the field of biologicals has also been identified. It has been pointed out that users of the Ph. Eur. in the biological field are not always aware of its role, its flexibility and the need for it to remain up-to-date. In response to this, the EDQM has planned a training session on the Ph. Eur., with a special emphasis on biologicals, which will take place on 9-10 May 2012.

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Note for the Editor: 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 world-wide. The European Pharmacopeia [1]is legally-binding in European Member States. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

The purpose of the European Pharmacopoeia (Ph. Eur.) is to promote public health through the provision of recognised common standards for use by healthcare professionals and others concerned with the quality of medicines. Such standards should be applied as a basis for the safe use of medicines by patients. The Ph. Eur. has a long history for setting up high quality standards in the field of biologicals. The related monographs and general chapters of the Ph. Eur. have proved to be essential tools for manufacturers, developers, assessors and control laboratories.

[1]There are currently thirty-seven members of the European Pharmacopoeia Commission: *Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, the former Yugoslav Republic of Macedonia, Turkey, United Kingdom and the European Union* and twenty-three observers: *The World Health Organisation (WHO); 6 member states of the Council of Europe: Albania, Armenia, Georgia, Moldova, Russian Federation and Ukraine; 16 other countries in the world: Algeria, Argentina, Australia, Brazil, Canada, China, Israel, Madagascar, Malaysia, Morocco, Republic of Belarus, Republic of Kazakhstan, Senegal, Syria, Tunisia, United States of America*.