30 June 2016, Strasbourg, France

155th SESSION OF THE EUROPEAN PHARMACOPOEIA COMMISSION (21-22 June 2016)

Following the election of its Chair, Dr Tobias Gosdschan, in its March session, the European Pharmacopoeia (Ph. Eur.) Commission elected Prof. Torbjörn Arvidsson (Sweden) and Dr Hilda Köszegi Szalai (Hungary) as its first and second Vice-chair, respectively, for a term of three years. The Presidium, which consists of the Chair and the two Vice-chairs, assisted by the Director of the EDQM and the Secretary to the Commission, will support the Ph. Eur. Commission in defining criteria for prioritisation of its work and a set of priorities for the coming three years.

During its 155th session, the Ph. Eur. Commission adopted 9 new monographs, 1 new general chapter, 46 revised monographs and 15 revised general chapters as well as a new version of the glossary. These will be published in the Ph. Eur. Supplement 9.2 and will come into effect in July 2017.

The new general chapter is *Determination of bactericidal, fungicidal or yeasticidal activity of antiseptic medicinal products* (5.1.11). This general chapter fills a gap by providing a method to assess the main quality parameter for this important class of products. It describes a test that can be used for the determination of antimicrobial activity in antiseptic medicinal products, miscible with water and intended for administration by direct contact with the skin or mucous membranes.

The revised monographs include:

- the monograph *Omega-3-acid Ethyl Esters 90* (1250): This represents a significant step forward in the quality control of the substance which is used as an active ingredient in medicinal products approved in Europe for treatment of hypertriglyceridemia, and in adjuvant treatment in secondary prevention after myocardial infarction. In the revised monograph, limits for several persistent organic pollutants have been included under the Production section. These include: polychlorinated dibenzo-p-dioxins and polychlorinated dibenzofurans (PCDD/PCDF), dioxin-like polychlorinated biphenyls (DLPCBs), polybrominated diphenyl ethers (PBDEs) and non-dioxin like-PCBs (NDLPCBS; 7PCB). In addition, tests and limits for unidentified fatty acid ethyl esters and cholesterol have been introduced. The test for peroxide value has also been revised in order to avoid the use of chloroform, and finally the chromatogram of the Assay for content of EPA and DHA ethyl esters has been updated.
- the harmonised monograph *Ethylcellulose* (0822): This has been revised to acknowledge the possibility of including a suitable antioxidant in this excipient. In addition, the Ph. Eur. Commission together with the Pharmacopoeial Discussion Group (PDG) took this opportunity to modernise the assay procedure: the use of a GC capillary column will be implemented, as already prescribed in the harmonised monographs on *Hydroxypropylcellulose* (0337) and *Hydroxypropylcellulose, low substituted* (2083). This modification is based on a collaborative study performed worldwide, and was the subject of lively discussions on the digestion conditions based on the Zeisel reaction.

The revised general chapters include:

- *Volumetric Analyses* (4.2.2): This chapter, which describes the preparation and standardisation of volumetric solutions, has been revised to introduce more direct ways of standardisation. As a corollary, the chapter *Primary standards for volumetric solutions* (4.2.1) has been revised to introduce new substances (e.g. trometamol). During this revision process, experimental data had been produced to introduce potentiometric endpoint determination for many of the most used standardised solutions.
- *Microbial Examination of cell-based Preparations* (2.6.27): Microbiological control for these preparations poses significant challenges, as their shelf-life ranges from days to only a few hours; also, they are usually available in very small volumes. This revised chapter provides guidance on the best approach to use with regard to the constraints associated with cell-based preparations.
- *Methods of preparation of sterile products* (5.1.1) and *Biological Indicators in the Preparation of Sterile Products* (5.1.2): These two chapters have been completely rewritten in order to make them state-of-the-art in terms of approaches to sterilisation.
- *Alternative Methods for Control of Microbiological Quality* (5.1.6): This revision is the result of extensive consultation with stakeholders and takes account of the latest technological developments in the field. It is hoped that the revised chapter will facilitate the develoment and validation of methods known to be more rapid and technologically advanced than conventional methods.
- *Monocyte-activation test* (2.6.30), which is the subject of a separate press release.
- Five general chapters regarding polyolefin materials for pharmaceutical use (plastic containers and closures): *Polyolefins* (3.1.3), *Polyethylene without additives for containers for parenteral preparations and for ophthalmic preparations* (3.1.4), *Polyethylene with additives for containers for parenteral preparations and for ophthalmic preparations* (3.1.5), *Polypropylene for containers and closures for parenteral preparations and ophthalmic preparations* (3.1.6) and *Poly(ethylene - vinyl acetate) for containers and tubing for total parenteral nutrition preparations* (3.1.7).

The Ph. Eur. Commission reviewed the pilot phase for elaborating texts on monoclonal antibodies, using *infliximab* as a case study. In view of the extent of conclusive experimental data generated by Ph. Eur. experts in support of the elaboration of a monograph on *Infliximab concentrated solution* (2928), the Ph. Eur. Commission agreed to publish this draft monograph in *Pharmeuropa* to collect comments from users. At this stage, it has not been decided yet whether a final monograph will indeed be adopted for publication in the Ph. Eur. This decision will be taken based on the outcome of public enquiry, which will therefore help conclude the pilot phase. Publication in *Pharmeuropa* is foreseen for October 2016, and all stakeholders are encouraged to provide their comments on the draft text.

A new general chapter on Process Analytical Technology (PAT) was added to the Ph. Eur. Commission's work programme. The future chapter 5.25 (for information only) will highlight the various modifications that have been made to the Ph. Eur. to support PAT applications. In addition, this general chapter will address the different approaches to interfacing PAT techniques with manufacturing processes and will introduce definitions of terminology used.

List of new monographs adopted:

- *Terlipressin* (2646)
- *Milbemycin oxime for veterinary use* (2536)
- *Remifentanil hydrochloride* (2644)
- *Isopropyl isostearate* (2867)
- *Lutetium (177Lu) solution for radiolabelling* (2798)
- *Selenium for homoeopathic preparations* (2844)
- *Egg phospholipids for injection* (2315)
- *Sodium pyrophosphate for radiopharmaceutical preparations* (2552)
- *Evodia fruit* (2718)

The next session of the Ph. Eur. Commission will take place on 22-23 November 2016.

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NOTES FOR EDITOR:

Further information is available on the website **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 world-wide. The European Pharmacopeia is legally-binding in Member States[1]. Similarly, the EDQM 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 47 member states.

[1] There are thirty-eight 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, 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.