27 June 2017, Strasbourg, France

Outcome of the 158th Session of the European Pharmacopeia Commission

The European Pharmacopoeia (Ph. Eur.) Commission adopted nine new monographs at its 158th Session, which took place in Strasbourg on 20 June 2017:

- four monographs elaborated under the P4 procedure (single-source products), of which two for finished products: *Raltegravir tablets (2938)* and *Raltegravir chewable tablets (2939)*, and the other two for *Lacosamide* (2292) and *Deferiprone* (2236),
- a monograph on *Zolmitriptan* (2737),
- a monograph on *Mometasone furoate* (2858),
- a monograph on *Fipronil for veterinary use* (2869),
- two monographs on: *Acidum succinicum for homeopathic preparations (2824)*, and *Calcium fluoride for homeopathic preparations (2996).*

In particular, the two monographs on finished products follow on from the decision of the Ph. Eur. Commission in 2014, after the positive results of a pilot phase, to make finished product monographs part of its regular work programme. The decision was based on various considerations, including the fact that finished product monographs help Official Medicines Control Laboratories (OMCLs) in their market surveillance tasks and that they can support the development of generic drugs, which are vital for the sustainability of healthcare systems. Finished product monographs also facilitate the assessment of marketing authorisation applications by regulatory authorities.

Other adopted texts included 49 revisions, of which 44 on monographs and 5 on general chapters; all were aimed at keeping the Ph. Eur. content updated and in line with regulatory developments and scientific state of the art. The revised texts include:

- The general monograph on *Vaccines for human use (0153)* and the one on *Vaccines for veterinary use (0062).* At its 156th Session, the Ph. Eur. Commission adopted the new general chapter *5.2.14* on *Substitution of in vivo method(s) by in vitro methods for the quality control of vaccines*. This chapter is a guidance document (non-mandatory text) intended to facilitate the transition from *in vivo* to *in vitro* methods. It forms an additional tool in the efforts of the Ph. Eur. Commission to reduce animal testing and encourage the use of alternatives. Both general monographs *0153* and *0062* contain a section titled "Animal tests" providing recommendations on how to meet the animal welfare requirements of the *European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes*, in the context of vaccine control. The sentence, "*Guidance on how to substitute in vivo methods by in vitro methods where a direct head-to-head comparison is not possible may be found in general chapter 5.2.14*." which will not leave any ambiguity as regards the non-mandatory character of the chapter but still direct the user to the new chapter 5.2.14, will be added in the section "Animal tests" of these two general monographs.

- The general monograph *Pharmaceutical preparations (2619)* which has been updated to include reference to the general monographs *Homoeopathic pillules, impregnated (2079)*, and *Homoeopathic pillules, coated (2786)* in its "Definition" section.

- The general chapter *Rubber closures for containers for aqueous parenteral preparations, for powders and for freeze-dried powders (3.2.9)* which has been revised mainly to have a wider scope and define quality requirements of a larger range of rubber closure currently marketed. It now also encompasses coated closures, bi-layer seals and lubricated closures.

- Four monographs on sutures for human or veterinary use *(Sutures, sterile non-absorbable (0324), Polyamide 6/6 suture, sterile, in distributor for veterinary use (0610), Polyamide 6 suture, sterile, in distributor for veterinary use (0609), Poly(ethylene terephthalate) suture, sterile, in distributor for veterinary use (0607))* which have been updated to replace the use of hazardous chemicals by infrared spectroscopy using attenuated total reflection for their identification and to include sutures composed of blends of materials cited in the monographs.

To date, the Ph. Eur. has been updated with 240 new or revised monographs and 26 chapters since the release of the Edition 9.0 in 2016.

All the texts will become effective on 1 July 2018 and will be published in Supplement 9.5 of the Ph. Eur.; the list of all adopted texts will be made available on the EDQM website.

The next Ph. Eur. Commission Session will take place on 21-22 November 2017.

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Note for the Editor: Further information is available on the internet site **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.

[1]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.