28 November 2017, Strasbourg, France

Outcome of the 159th Session of the European Pharmacopeia Commission

The European Pharmacopoeia (Ph. Eur.) Commission adopted 11 new monographs at its 159th Session, which took place in Strasbourg on 21-22 November 2017:

- a monograph elaborated under the P4 procedure, Rotigotine (3014). This procedure applies to substances still under patent protection.
- the first monograph on a multisource monoclonal antibody, Infliximab concentrated solution (2928); a dedicated press release will be published soon.
- Monographs on Phenoxymethylpenicillin, benzathine (2636), Zoledronic acid monohydrate (2743), Imidacloprid for veterinary use (2924), Podophyllotoxin (2750), Sulfobutylbetadex sodium (2804), Concentrated solutions for haemofiltration and haemodiafiltration (2770), Digitalis purpurea for homoeopathic preparations (2705), Lightyellow sophora root (2440), Gastrodia rhizome (2721) and Phytomenadione, racemic (3011).

The Ph. Eur. Commission also decided to suppress the following text as of the Ph. Eur. Supplement 9.6.:

- General chapter on Abnormal toxicity (2.6.9). Along with the suppression of this chapter, the Commission also adopted the revision of 49 monographs where this test was also deleted. A dedicated press release will be published soon.
- Monographs on Desoxycortone acetate (0322) and on Emetine hydrochloride pentahydrate (0081)

At this 159th session, 108 revised monographs (including the 49 monographs mentioned above) and 18 revised chapters were also adopted by the Ph. Eur. Commission. All were aimed at keeping the Ph. Eur. content updated and in line with regulatory developments and scientific state of the art.
The adopted revised texts included a revision of the general chapter on glass containers for pharmaceutical use to add specific instructions for the testing of hydrolytic resistance, seven chapters on Materials and Containers in order to provide manufacturers with alternatives to di(2-ethylhexyl)phthalate (DEHP), a substance of very high concern (SvHC) according to the criteria of Article 57 of regulation (EC) 1907/2006 (REACH). A dedicated press release will be published soon.

All the texts will become effective on 1 January 2019 and will be published in Supplement 9.6 of the Ph. Eur.; the list of all adopted texts will be made available on the EDQM website (link to the Ph. Eur. publication schedules: https://www.edqm.eu/sites/default/files/publication_calendar_for_the_9th_edition_pheur_july_2016.pdf).

The next Ph. Eur. Commission Session will take place on 20-21 March 2018.

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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[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.*

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