30 November 2015, Strasbourg, France

153rd SESSION OF THE EUROPEAN PHARMACOPOEIA COMMISSION

The European Pharmacopoeia Commission held its 153rd Session in Strasbourg on 17-18 November 2015.

During their meeting, the Commission adopted 28 new monographs and 3 new general chapters, including two monographs elaborated under the P4 and P4 Bio Procedure on *Aprepitant (2757)* and *Teriparatide (2829)*, and 10 monographs on herbal drugs used in Traditional Chinese Medicines (see complete list at the end of this press release).

The Commission also adopted 5 revised general chapters and 114 revised monographs, including 42 revised monographs on veterinary vaccines and the general monograph on *Vaccines for veterinary use (0062)*. This is the result of the continued and active involvement of the Commission in the replacement, reduction and refinement of animal testing (3Rs). It is to be noted that the general monograph (0062) and three individual monographs (0447, 1939 & 2674) also include promotion of the move from final product controls to consistency of production*.

In addition, the Commission adopted the deletion of the test for *Heavy Metals (2.4.8)* from approximately 760 individual monographs on substances for pharmaceutical use (except substances for veterinary use only). The list of potentially impacted texts had previously been published in Pharmeuropa 27.2 for public enquiry.

These texts will be published in the 9th Edition of the European Pharmacopoeia and shall become effective on 1st January 2017.

The Commission continued its discussion on the implementation strategy of the ICH Q3D Guideline on Elemental impurities. As a result, it was decided to revise the general monographs *Substances for pharmaceutical use (2034)* and *Pharmaceutical preparations (2619),* which will be published in Pharmeuropa 28.2 for public enquiry.

The next Commission session will take place on 15-16 March 2016. This session will be followed by a special meeting for the observers to the European Pharmacopoeia Commission. Dr Susanne Keitel, Director of the EDQM, also announced the organisation of an international conference to mark the launch of the 9th Edition of the European Pharmacopoeia. This conference will be held in Tallinn, Estonia, on 27 to 28 September under the aegis of the Estonian Chairmanship of the Council of Europe's Committee of Ministers.

- List of new monographs adopted:
  - Two monographs which were elaborated under the Procedure P4 and P4Bio: monographs on *Aprepitant (2757)* and on *Teriparatide (2829),*
  - *Escitalopram (2758), Tacalcitol (2272) Clopidogrel besilate (2790), Clopidogrel hydrochloride (2791), Temozolomide (2780), Irinotecan hydrochloride trihydrate (2675), Hydroxychloroquine sulfate (2849)*
  - Animal epithelia and outgrowths for *Allergen products (2621), Hymenoptera venoms for allergen products (2623)*, *Mites for allergen products (2625), Moulds for allergen products (2626)* and *Pollens for allergen products (2627):* These are the first source materials for allergenic extracts that are described in the European Pharmacopoeia. The monographs will allow producers of allergenic extracts to use well specified source materials in their preparations.

- *Infectious bovine rhinotracheitis vaccine (inactivated) (2674)** including consistency of production and promotion of *in-vitro* testing (3Rs),
- Ten individual monographs on herbal drugs used in TCM *Traditional Chinese Medicines*): *Akebia stem (2472), Codonopsis root (2714), Cape jasmine fruit (2565), Gastrodia rhizome (2721), Peony root, white (2424), Peony root, red (2425), Polygonum cuspidatum rhizome and root (2724), Polygonum orientale fruit) (2726), Uncaria stem with hooks (2729)* and *Zanthoxylum bungeanum pericarp (2656)*,
- *Horse-chestnut* (1830)* and *Horse-chestnut dry extract, standardised* (1829)*,
- *Magnesium fluoratum for homoeopathic preparations (2676).*

- New chapters adopted:
  - the general method on *Qualitative high performance thin-layer chromatography of herbal drugs and herbal drug preparations* (2.8.25)*,
  - the general method on *Immunonephelometry for vaccine component assay (2.7.35)*,
  - the general chapter on *Healthy chicken flocks for the production of inactivated vaccines for veterinary use* (5.2.13)* to set quality requirements that will provide guarantees with regard to extraneous agents contamination, making the test for Specified extraneous agents performed on the final product obsolete in the 8 individual monographs concerned with this change (0249, 0870, 0959, 0960, 0963, 1202, 1392, 2324).

** the texts marked with an "*" will be subject of dedicated press release to be published soon on the EDQM website.*

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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-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. There are twenty-eight observers: Albania, Algeria, Argentina, Armenia, Australia, Azerbaijan, Belarus, Brazil, Canada, China, Georgia, Guinea, Israel, Kazakhstan, Republic of Korea, Madagascar, Malaysia, Republic of Moldova, Morocco, Russian Federation, Senegal, Singapore, South Africa, Syria, Tunisia, United States of America, the Taiwan Food and Drug Administration (TFDA) and the World Health Organization (WHO).*

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