Press release

5 July 2022, Strasbourg, France

Outcome of the 173rd session of the European Pharmacopoeia Commission, June 2022

The European Pharmacopoeia (Ph. Eur.) Commission held its 173rd session on 21 and 22 June 2022. 48 texts were adopted and will be published in Ph. Eur. Supplement 11.2, effective as of 1 July 2023.

Of these 48 texts, four were new monographs: *Pumpkin seed (2941), Propylene glycol monocaprylate (2799), Mirabegron (3132)* and *Saxagliptin monohydrate (3136)*.

The remaining 44 were revisions and included:

- 6 monographs on excipients revised to include a functionality-related characteristics (FRC) section and 2 others whose FRC section had been updated. As of Supplement 11.2 and with these 6 additions, the Ph. Eur. will contain more than 100 excipient monographs with an FRC section supporting the definition of critical material attributes for specific applications;
- a revised version of the general monograph on *Monoclonal antibodies for human use (2031)*, to ensure alignment with the dosage form monograph *Parenteral preparations (0520)* with regard to visible particles. The revised monograph now refers directly to new general chapter *5.17.2. Recommendations on testing of particulate contamination: visible particles*, and includes the requirement 'practically free from visible particles' for liquid parenteral preparations, together with recommendations on testing for visible particles;
- four monographs on somatropin revised to harmonise their content. In particular, the analytical procedure capable of detecting additional oxidised forms already included in *Somatropin injection (2370)* was also introduced in *Somatropin concentrated solution (0950)*, *Somatropin (0951)* and *Somatropin powder for injection (0952)*. In combination with the CZE detection of deamidation forms, this approach offers a superior control of the related proteins in somatropin.

A list of all the texts adopted will be made available on the Ph. Eur. Work Programme web page in the coming weeks.

The Commission also:

- decided to refine the strategy for excipient monographs in the Ph. Eur., taking into account quality, functionality and interaction aspects, by tasking a new working party to consider the specificities of and need for excipients;
- raised the need to create a new working party that would assess the feasibility and impact of incorporating analytical procedures developed using the concepts of analytical quality by design (aQbD) in Ph. Eur. monographs and give advice on appropriate elaboration/revision strategies when such analytical procedures are proposed;
- put the finishing touches to its strategy aimed at removing the rabbit pyrogen test from 60 texts of the Ph. Eur. within a 4-year time frame (the texts will be published for consultation in January 2023 in Pharmeuropa 35.1).

It was agreed to add 7 new items to the work programme and in particular the following items:

- 4 new monographs:
  - the first monograph on a fixed combination medicinal product *Metformin hydrochloride and Dapagliflozin propanediol tablets (3207)*;
  - monographs on *Methacholine chloride (3209), Methocarbamol (3210) and Tenofovir disoproxil fumarate (3211)*.
- and a new general chapter on recombinant viral-vectored vaccines for human use (5.37) together with the decision to become active in the field of mRNA vaccines.

Lastly, the Commission also approved a number of texts that might be of broad interest:

- a new edition of the *Technical Guide for the Elaboration of monographs* (i.e. 8th Edition) that has been updated to reflect approaches followed by Ph. Eur. groups of experts (specific News item to be issued in the following weeks);
- a document containing examples of approaches for the implementation of pharmacopoeial procedures to better illustrate the concepts laid out in the recently adopted general chapter *5.26 Implementation of pharmacopoeial procedures* (available in the 11th Edition);
- a revised version of the Guide for the Work of the European Pharmacopoeia and of the Code of Practice for the work of the European Pharmacopoeia.

More detailed information on several of the items mentioned in this press release will follow.

The 174th session of the Ph. Eur. Commission will take place in hybrid mode on 22 and 23 November 2022.

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 the development, supporting the implementation, and the monitoring the application of quality standards for safe medicines and their safe use. Its 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.

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1. There are 40 members of the European Pharmacopoeia Commission: *Albania, 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, North Macedonia, Norway, Poland, Portugal, Romania, Serbia, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Türkiye, Ukraine, United Kingdom and the European Union.*