Pharmacopoeial Discussion Group Meeting

Meeting Highlights

2-3 October 2018
EDQM premises
Strasbourg, France

1. Harmonisation Topics Signed off

1.1. Excipients

1.1.1. New

1.1.1.1. E-54 Copovidone (JP)

PDG signed off this new text.

1.1.2. Revised

1.1.2.1. E-10 Microcrystalline Cellulose (rev. 3) (USP)

PDG signed off this text in which the microbial limits had been updated as harmonised attributes.

1.1.2.2. E-43 Wheat starch (rev. 3) (EP)

PDG signed off this text which included an updated test for total protein.

1.1.2.3. E-55 a/b Gelatin, gelling type & Gelatin, non-gelling grade (rev. 2) (EP)

PDG signed off these texts which had been updated to amend the temperature for identification test B.

1.1.3. Other monographs

1.1.3.1. E-58 Mannitol (EP) and E-64 Isomalt (EP)

These two sign-off cover sheets had been amended to reflect the fact that the test for nickel will no longer be stipulated in

these EP monographs.

2. PDG Work Programme

2.1. **Prioritisation of the work programme**

The PDG reviewed the outcome of the pilot phase of a prioritisation scheme for excipient monographs and general chapters. This strategic review was conducted for 10 excipient monographs and 5 general chapters. In view of the outcome, the PDG decided to apply this prioritisation scheme to the remaining general chapters and to further discuss the scheme for excipient monographs.

2.2. **Outcome of the technical teleconferences**

2.2.1. E-08 Carmellose sodium (USP)

The coordinating pharmacopoeia reported back on the success of this technical teleconference for resolving sticking points, with a view to publishing a Stage 2 draft for public enquiry. It was agreed to move forward with an assay method by non-aqueous titration.

2.2.2. G-07 Elemental impurities (USP)

The coordinating pharmacopoeia reported back on the success of this technical teleconference for resolving sticking points, with a view to publishing a Stage 2 draft for public enquiry. PDG discussed comments on precision, intermediate precision and limit of quantitation.

2.3. **Discussion/Decision on way forward for topics requiring specific emphasis**

2.3.1. General Chapters

2.3.1.1. Q-09 Particulate Contamination (USP)

Following the teleconference organised with experts, PDG agreed to cover both biological and chemical medicines in one revised harmonised chapter and to organise another technical teleconference to continue direct discussion with the experts from the three regions.

2.3.2. Excipients

2.3.2.1. E-28 Petrolatum (USP)/E-29 Petrolatum, White (USP)

The coordinating pharmacopoeia had addressed the comments from the other two pharmacopoeias on the previous draft with a

view to publishing the Stage 2 draft for public enquiry. The limit for PAH (Polycyclic aromatic hydrocarbons) was agreed by PDG.

2.3.2.2. E-30 Polyethylene Glycol (USP)

In view of the challenges encountered with the different grades available in the three regions, the coordinating pharmacopoeia proposed a two-phase approach. Phase I would focus on the identification test by IR and the test for aldehydes.

2.3.2.3. E-36 Silicon Dioxide/E-37 Silicon Dioxide, Colloidal (USP, JP)

A PDG pharmacopoeia had reviewed the data package from the round-robin testing provided by the trade associations IPEC Federation. The data had shown some inconsistencies in the differentiation of the two materials; further investigation would be needed.

2.4. **Revision Proposals**

2.4.1. E-09 Croscarmellose Sodium (USP)

The PDG partners supported the request for revision sent by the coordinating pharmacopoeia to include an identification test by IR. The revision would be added to the PDG work programme.

2.4.2. E-45 Sucrose (EP)

The PDG partners in principle supported the request for revision sent by one pharmacopoeia to include a liquid chromatography method for assay and related substances test, subject to confirmation by one PDG partner.

2.5. **Suppression from the work programme**

2.5.1. E-67 Sodium Cetyl Sulfate (JP)

PDG agreed to remove this item from the PDG work programme.

2.5.2. E-63 Lactose for Inhalation (USP)

PDG agreed to the stepwise approach for the introduction of quality tests for inhalation grade in the existing harmonised monographs on E-23 Lactose, anhydrous and E-24 Lactose monohydrate. As a result, E-63 Lactose for inhalation would be removed from the PDG work programme.

3. Next Meeting

The next videoconference meeting would take place in the middle of March 2019 and the next face-to-face meeting on 1-2 October 2019 in Tokyo, Japan.