Pharmacopoeial Discussion Group Meeting

Meeting Highlights

1-2 October 2019
PMDA
Tokyo, Japan

1. Harmonisation Topics Signed off

1.1. General Chapters

1.1.1. Revised

1.1.1.1. Q-07 Colour (Rev.1) (EP)

The coordinating pharmacopoeia reported the sign-off of this text by correspondence in June 2019. In this revision, the section on "Compliance with a pharmacopoeial requirement" was deleted.

1.2. Excipients

1.2.1. Revised

1.2.1.1. E-55 Gelatin (Rev. 3) (JP)

PDG signed off this text which integrated gelling grade (E-55a) and non-gelling grade (E-55b). The revised PDG monograph now covers all grades of Gelatin.

1.2.1.2. E-60 Sodium Lauryl Sulfate (Rev. 1) (USP)

PDG signed off this text which included a new Identification (ID) test by Infrared (IR) spectroscopy and optimized the Assay by replacing the indicator and solvent.

2. PDG Work Programme

2.1. Prioritisation of the work programme

As a result of the pilot prioritization for 5 general chapters which were discussed at the PDG 2018 Strasbourg Meeting, PDG decided to expand the scheme to the remaining general chapters. Each pharmacopoeia reported the review results of the remaining general chapters and concluded that the scheme will be helpful for prioritizing future activities.

2.2. Outcome of the technical teleconferences

2.2.1. Q-09 Particulate Contamination (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.

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

2.3.1. General Chapters

2.3.1.1. G-20 Chromatography (EP)

The coordinating pharmacopoeia highlighted additional comments received from stakeholders following the Stage 2 public enquiry. The other two pharmacopoeias shared an initial feedback to the comments. PDG will continue to work to address the remaining issues.

2.3.2. Excipients

2.3.2.1. E-46 Talc (USP)

The coordinating pharmacopoeia provided updates on the proposed methods for evaluating the absence of asbestos in talc. USP had performed a couple of round- robin testings to evaluate different methods for the absence of asbestos in talc. In order to allow an informed official decision by PDG, USP will provide more feedback to PDG after the publication of a USP *Stimuli* article and a USP round table discussion tentatively scheduled for early 2020 to seek stakeholders' feedback.

2.3.2.2. E-51 Glycerin (USP)

The coordinating pharmacopoeia provided a summary of the Stage 1 draft as well as the survey results on colour methods. The other two pharmacopoeias will provide their feedback on the concept.

2.3.2.3. E-62 SWFI in Containers (USP)

The coordinating pharmacopoeia provided updates on specification of organic impurities and conclusions from the round-table discussions with their stakeholders. The coordinating

pharmacopoeia will send a Stage 1 draft to the other two pharmacopoeias.

2.4. Revision Proposals

2.4.1. G-06 Tablet Friability (USP)

The coordinating pharmacopoeia sent a request for revision to clarify requirements in the text by editing formats of the figures and the words. The other two pharmacopoeias will review and provide comments.

3. Maintenance of ICH Q4B annexes

The PDG discussed and agreed a way forward for the future maintenance of ICH Q4B annexes and the revision of the ICH Q4B guideline itself. This proposal will be presented to the ICH Assembly during the November 2019 ICH meeting. In addition, Work has already started to update the ICH Q4B annexes in accordance with the new maintenance process (Standard Operating Procedure of the ICH Working Groups Annex 5), which was approved by the ICH Assembly at the ICH 2018 Meeting in Charlotte, NC. In the meantime, the PDG has performed an initial review of all ICH Q4B annexes, as well as of the related PDG sign-off texts together with each pharmacopoeia's published texts. The three pharmacopoeias discussed a mechanism to share the outcome of the evaluation of Q4B annexes with its sister pharmacopoeias outside PDG. The same mechanism will be applied to share the drafts and final texts of the other PDG harmonisation activities. PDG will share the proposed mechanism with the other pharmacopoeias at the next International Meeting of World Pharmacopoeias (IMWP).

4. Next Meeting

The next face-to-face meeting is tentatively set for 22-23 September 2020 in Rockville, Maryland, USA.