Briefing on drafts of General Tests and General Information related to Chromatography

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Pharmaceuticals and Medical Devices Agency

Office of Review Management

With the publication of the following four drafts of General Tests and General Information related to Chromatography for public consultation, the information below is provided for your review.

- Draft of new General Test "*<2.00> Chromatography*"
- Draft of new General Information "*<G1-5-181> Control Strategies and Change Control Concepts at Each Stage of Chromatography Lifecycle*"
- Draft of revised General Test "*<2.01> Liquid Chromatography*"
- Draft of revised General Test "*<2.02> Gas Chromatography*"

Harmonization process of G-20 Chromatography by Pharmacopoeia Discussion Group (PDG) has started since 2009. Reviewing the submitted comments on the Stage 2 draft published for the public consultation from July 2017 to October 2017, the Chromatography Working Group (WG) of Japanese Pharmacopoeia (JP) Expert Committee has continuously discussed the draft toward to the harmonization. Since the process reached Stage 3A of the harmonization working procedure, the draft of General Test in the JP *<2.00> Chromatography* based on the Stage 3A draft is published for public consultation. In order to contribute to the proper implementation of the *<2.00>* in the quality control of pharmaceuticals, draft of General Information *<G1-5-181>*, revised draft of General Test *<2.01>* and revised draft of General Test *<2.02>* have also been discussed, and they are published for public consultation simultaneously. Considering the above, when you review these four drafts, we would like to ask you to refer them mutually.

In addition, revised draft of General Information *<G1-2-152> System Suitability* is also under discussion by the Chromatography WG, with the direction that the 3rd chapter "Point to Consider at the Change of Analytical System" in this revised draft is going to be integrated into the *<G1-5-181>*. In the near future, the revised draft of *<G1-2-152>* will be published for public consultation, which will result in listing it in the JP simultaneously along with the above four drafts.

The key points of these four drafts are as follows.

- **Draft of a New General Test: *<2.00> Chromatography***
  - *<2.00>* is not intended to be applied retrospectively to the monographs listed in JP, but to be applicable to the new monographs after *<2.00>* being listed in JP.

- Regarding the 4th chapter "Adjustment of chromatographic conditions" in the <*2.00*>, the following points are going to be provided as JP original contents:
  - The 4th chapter should be applied to liquid chromatography and gas chromatography, but it should not be applied to thin layer chromatography.
  - In cases of some biotechnological/biological products, the 4th chapter is not necessarily applicable.
  - Crude drugs and related drugs are not covered in the 4th chapter.

- **Draft of New General Information: *<G1-5-181> Control Strategies and Change Control Concepts at Each Stage of Chromatography Lifecycle***
  - When applying the 4th chapter "Adjustment of chromatographic conditions" in the <*2.00*> to products, in order to perform the appropriate risk assessment, the points to consider for the change control are provided. The draft *of* <*G1-5-181*> is arranged to promote the effort of the change control, considering the life cycle of analytical procedures which consists of design to development, qualification and continuous verification. This arrangement is made so that the points to consider for the change control can be clearly provided at each stage of chromatography lifecycle.
  - Since the draft of <*G1-5-181*> is positioned as a document that provides technical information from scientific viewpoints, it does not intend to mention any regulatory requirements.
  - It is also taken into consideration that the draft of <*G1-5-181*> will be used as a guide that summarizes the key points for the change control of analytical conditions at the quality tests of pharmaceuticals in public testing institutions.

- **Revised draft of General Test: *<2.01> Liquid Chromatography***
  - In the 6th chapter "System Suitability" in the <*2.01*>, its relationship with the system suitability specified in the <*2.00*> is clarified.
  - Regarding the 7th chapter "Points to Consider on changing the operating conditions" in the <*2.01*>, in terms of international harmonization, it is revised that the change controls based on the appropriate risk assessment will be performed, as shown in the contents of 4th chapter "Adjustment of chromatographic conditions" in the <*2.00*>. In addition, the contents of this chapter duplicate with those of the <*2.00*> are deleted from the <*2.01*>.
  - The 8th chapter "Terminology" in the <*2.01*> is deleted because the terminology related to chromatography in the JP will be provided in the terminology of the <*2.00*>.

- **Revised draft of General Test: *<2.02> Gas Chromatography***
  - Regarding the 7th chapter "Points to Consider on changing the operating conditions" in the

<*2.02*>, in terms of international harmonization, it is revised that the change controls based on the appropriate risk assessment will be performed, as shown in the contents of 4th chapter "Adjustment of chromatographic conditions" in the <*2.00*>. In addition, the contents of this chapter duplicate with those of *the* <*2.00*> are deleted from the <*2.02*>.