Regulation on Re-evaluation of Quasi-Drugs

MFDS Notification No. 2015-91, (December 4, 2015, enacted)

Article 1 (Purpose) In accordance with Article 33 and Article 42, Paragraph 5 of the Pharmaceutical Affairs Act, the purpose of this notification is to raise the right of re-evaluation of quasi-drugs pursuant to provide detailed matters about re-evaluation method and procedure, etc. of quasi-drugs.

Article 2 (Selection Etc. of Enforcement Target) ① The subject of the re-evaluation is the quasi-drug that is selected by the Minister of Food and Drug Safety(hereinafter referred to as the "Minister") that are deemed necessary for re-evaluation of safety or efficacy at the latest scientific level among quasi drugs that received the approval of the item(including the notification) pursuant to Articles 31 and 42 of the Pharmaceutical Affairs Act.

② In spite of Paragraph 1, the items applicable to the following subparagraph shall be excluded from the re-evaluation.

1. Items that are canceled or withdrawn during the re-evaluation period

2. Quasi-drugs approved for export purposes only

③ The Minister of Food and Drug Safety can be consulted by the Central Pharmaceutical Affairs Council(CPAC) to select the items subject to re-assessment in accordance with Paragraph 1 if necessary.

Article 3 (Official Notice of Enforcement) ① The Minister of Food and Drug Safety shall announce on the official website of the Ministry of Food and Drug Safety that re-evaluation shall be carried out by specifying details of the following items selected for the re-evaluation pursuant to Article 2.

1. Quasi-drugs subject to re-evaluation

2. Data to be submitted

3. Method of submission and deadline

② The Minister of Food and Drug Safety can allow the submission of test materials which are tested in Korea among some of the data to be submitted according to paragraph 1.

Article 4 (Scope Etc. of Submitted Data) ① The scope of the data to be submitted for re-evaluation shall be determined in accordance with the safety and efficacy evaluation data specified in Articles 23 to 25 of the Regulation onr Quasi-drugs Approval, Notification and Review notified by the Minister.

② The foreign data among the submitted data in Paragraph 1 shall in principle be submitted as Korean summary(main excerpts) and original text (including accurate source). If necessary, the whole translation (signed by a reviewer who has expert medical/pharmaceutical knowledge) shall be submitted.

③ In submission of re-evaluation data under Paragraph 1, with regard to the effective ingredients, contents and dosage forms approved for item in two or more institutes, part or all persons who have received approval for items in two or more institutes can prepare and submit the

data jointly.

Article 5 (Advance Notice and Formal Objection, Etc.) ① The Minister shall notify the result of the re-evaluation and the follow-up actions (hereinfafter referred to as “the results of re-evaluation, etc.” to persons who has received the approval for items in the re-evaluation of quasi-drugs prior to announcement of re-evaluation results etc. according to Article 6.

② The notification pursuant to paragraph 1 shall include the follow-up measures in the following subparagraphs:

1. Amendment of approval matters according to Article 76, Paragraph 1 of the Pharmaceutical Affairs Act and Article 8, Paragraph 3 of the Enforcement Regulation on the Safety of Pharmaceuticals, etc.

2. Recovery and disposal, etc. according to Article 39, Paragraph 1 of the Pharmaceutical Affairs Act and Article 50, from Articles 88 to 90 of the Enforcement Regulation on the Safety of Pharmaceuticals, etc.

③ The person who receives the approval of the quasi-drug subject to re-evaluation can submit an opinion to the Minister with the relevant materials, etc. within 30 days from the date of notification if he or she has an opinion about the notified re-evaluation results, etc. in accordance with Paragraph 1.

④ The Minister confirms the re-evaluation results, etc. after reviewing in the light of the opinions in accordance with Paragraph 3.

⑤ The Minister can be consulted by the Central Pharmaceutical Affairs Council(CPAC) to confirm the re-evaluation results, etc. in Paragraph 4 if necessary.

Article 6 (Official Notice of Results, Etc.) The Minister shall announce the results of the re-evaluation pursuant to Article 5, Paragraph 4 on the official website of the Ministry of Food and Drug Safety. If necessary, the Minister can notify the person who has received approval for the quasi-drugs subject to the re-evaluation of the re-evaluation results, etc.

Article 7 (Application) Regarding the matters not specified in this regulation about the re-evaluation, the Regulation on Quasi-drugs Approval, Notification and Review notified by the Minister shall be applied.

Article 8 (Period for Re-review) The Minister shall review the feasibility of this notification and take actions such as improvement, etc. every three years as of January 1, 2016 (refers to December 31 of every third year) in accordance with the Regulation on Issue and Management of Instruction and the Established Rule etc.

Addendum <No. 2015-91, 4-Dec-2015>

This notification shall be enforced from the date of notification.