Provisional Translation
From Japanese Original

November 21, 2014
Notification PFSB No. 1121-7

To: Prefectural Governors

Director-General of Pharmaceutical and Food Safety
Bureau, Ministry of Health, Labour and Welfare
(Official seal omitted)

Application for Approval of Quasi-drugs, etc.

The scope, etc. of data to be attached to the application for marketing approval of quasi-drugs and cosmetics (hereinafter referred to as "quasi-drugs, etc.") have been handled in accordance with the "Data to be Attached to Application for Manufacturing or Import Approval of Quasi-drugs, etc." (PAB Notification No. 700 by the Director-General of Pharmaceutical Affairs Bureau, dated May 30, 1980). However, based on the provisions of Article 2 of the "Cabinet Order for Development, etc. of Related Cabinet Orders and Transitional Measures in Association with the Enforcement of the Act for Partial Revision of the Pharmaceutical Affairs Act, etc." (Cabinet Order No. 269, 2014), a part of the Cabinet Order for Fees Related to the Pharmaceutical Affairs Act (Cabinet Order No. 91, 2005) has been revised; and regarding the fees for application for marketing approval of quasi-drugs, the categories for quasi-drugs with different active ingredients, indications, etc. from those of already-approved quasi-drugs have been newly established. Based on the above, the handling of application for marketing approval of quasi-drugs, etc. has been specified as shown below. Therefore, we request that you inform related businesses under your administration of this handling.

This notification applies to approval applications for quasi-drugs, etc. that will be made on or after November 25, 2014.

With the application of this notification, the following notifications will be abolished: PAB Notification No. 700 by the Director-General of Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, dated May 30, 1980; PMSB Notification No. 286 by the Director-General of Pharmaceutical and Medical Safety Bureau, Ministry of Health and Welfare, dated March 12, 1999; and PFSB Notification No. 0716010 by the Director-General of Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, dated July 16, 2004.

Notice

Chapter I General Provisions

Terms and application categories used for approval applications for quasi-drugs are as follows:

(1) Quasi-drugs with new active ingredients refer to quasi drugs whose active ingredients are different from those of already-approved quasi drugs or whose application methods are obviously different (Category (1)).

(2) Quasi-drugs with new indications refer to quasi-drugs whose active ingredients are the same as those of already-approved quasi-drugs, but whose indications are different (Category (2)-1).

(3) Quasi-drugs in new dosage forms refer to quasi-drugs whose active ingredients are the same as those of already-approved quasi-drugs, but whose dosage forms are different (Category (2)-2).

(4) Quasi-drugs with new strengths refer to quasi-drugs whose active ingredients are the same as those of already-approved quasi-drugs, but the strength of active ingredients are different (Category (2)-3).

(5) New combination quasi-drugs refer to quasi-drugs whose active ingredients and their contents are the same as those of already-approved quasi-drugs, but the combinations of active ingredients are different from those of already-approved quasi-drugs (Category (2)-4).

(6) Quasi-drugs with new administration methods refer to quasi-drugs whose active ingredients are the same as those of already-approved quasi-drugs, but whose administration methods are different (Category (2)-5).

(7) Quasi-drugs containing new excipients refer to quasi-drugs that contain excipients that have not been used in the past or excipients that have been used in the past but are contained in amounts exceeding those in the past, etc (Category (3)).

(8) Similar quasi-drugs refer to quasi-drugs that are not identical to already-approved products but can be regarded as equivalent to already-approved products even if no studies on efficacy and safety are newly conducted (Category (4)).

(9) Identical quasi-drugs refer to quasi-drugs whose active ingredients, contents and combinations of active ingredients, indications, dosage and administration, and dosage forms are the same as those of already-approved quasi-drugs, or quasi-drugs that meet the standards for marketing approval of quasi-drugs (Category (5)-1).

(10) Newly designated (Shin-Shitei) quasi-drugs refer to quasi-drugs that are listed in (1), (13), (15), (19), (20), and (24) of the quasi-drugs designated by the Minister of Health, Labour and Welfare (Ministry of Health, Labour and Welfare Public Notice No. 25, dated February 6, 2009, hereinafter referred to as the "Designation Notice") based on the provisions of Article 2, Paragraph 2, Item 3 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960, hereinafter referred to as the "Act") (Category (5)-2).

(11) New scope (Shin-Han'i) quasi-drugs refer to quasi-drugs that are listed in (2), (4) to (12), (14), (16), (22), (23), and (27) of the Designation Notice (Category (5)-3).

Chapter II Data to Be Attached to the Application for Approval of Quasi-drugs, etc.

1 Data to be attached to the approval application shall be handled as follows:

(1) Studies to prepare data to be attached to the approval application must be conducted properly by experienced researchers at well-equipped facilities based on the academic standards in medicine, pharmacology, etc. at that time.

(2) Data to be attached to the approval application must be described in Japanese. If the data are translated, the full text must be translated. In this case, the original text before translation shall also be submitted, and the name and affiliation of the translator and the expert technician who finally examined the

contents shall be listed. However, if the original text is written in English, it is acceptable to submit the original text and a summary in Japanese, but if it is considered necessary in the review process, the translation of the full text shall be submitted.

(3) When an application for quasi-drugs, etc. that are considered to have the same ingredients/strength, dosage and administration, and indications as those of quasi-drugs, etc., which are required to conduct a survey on the safety in use based on the provisions of Article 79 of the Act, is made during the said survey period, data equivalent or superior to those of quasi-drugs, etc. that are required to conduct the said survey must be attached.

(4) Even if the above (3) is applicable, some of the data to be attached do not need to be attached depending on the reason when making an application for partial change in approved product information based on Article 14, Paragraph 9 of the Act.

2 The data shown in the right column of Attached Table 1 summarize the contents of the data listed in Article 40, Paragraph 1, Item 2 of the Regulation for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Ministry of Health and Welfare Ordinance No. 1 of 1961, hereinafter referred to as "Regulation") after revision by the Ministerial Ordinance on the Development of Related Cabinet Orders in Accordance with the Act on Partial Revision of the Pharmaceutical Affairs Act and the Enforcement of the Act on Partial Revision of the Pharmaceutical Affairs Act and the Development of Related Ministerial Ordinances in Accordance with the Enforcement of the Cabinet Orders Related to Interim Measures (Ministry of Health, Labour and Welfare Ordinance No. 87 of 2014). The data shown in the right column of Attached Table 1 shall primarily be referred to for the contents of the data listed in Article 40, Paragraph 1, Item 3 of the Regulation.

Chapter III Data to Be Attached to the Application for Approval of Quasi-drugs

1 The scope of data to be attached to the approval application shall be the data shown in the right column of Attached Table 2, according to the application categories in the left column of the table in principle.

2 For the approval application for quasi-drugs that fall into Categories 1 to 3 of Attached Table 2, the contents of the attached data shall be properly and concisely summarized. The summary of the product application including information on dosage and administration, indications, draft precautions, and the rationale for setting them shall be submitted.

The summary of the product application must be written in Japanese.

3 Regardless of the above, the application categories and data to be attached to the approval application for insecticides that are not used directly on the human body are presented separately.

(Attached Table 1) Scope of Data to Be Attached to the Application for Approval of Quasi-drugs

Data specified in Article 40, Paragraph 1, Item 2 of the Regulation	Scope of data in the left column
(a) Origin or history of discovery, Use in foreign countries, and other information.	1 Origin or history of discovery 2 Use in foreign countries 3 Properties and comparison with other quasi-drugs
(b) Physicochemical properties and specifications and testing methods	1 Structure determination 2 Physicochemical properties 3 Specifications and testing methods
(c) Stability	1 Long-term testing 2 Stress testing 3 Accelerated testing
(d) Safety	1 Single-dose toxicity 2 Repeated-dose toxicity 3 Genotoxicity 4 Carcinogenicity 5 Reproductive and developmental toxicity 6 Local tolerance 7 Skin sensitization 8 Photosafety 9 Absorption, distribution, metabolism, and excretion 10 Human patch test 11 Long-term administration (safety) study in humans
(e) Indications	1 Basic studies supporting indications 2 Clinical Trial

(Attached Table 2)

	(a)			(b)			(c)			(d)											(e)	
	1	2	3	1	2	3	1	2	3	1	2	3	4	5	6	7	8	9	10	11	1	2
(1) Quasi-drugs with new active ingredients	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○
(2)-1 Quasi-drugs with new indications	○	○	○	×	×	○	△	×	△	×	×	×	×	×	×	×	×	×	×	△	○	○
(2)-2 Quasi-drugs in new dosage forms	○	○	○	×	×	○	○	△	○	×	×	×	×	×	×	×	×	○	△	△	△	○
(2)-3 Quasi-drugs with new strengths	○	○	○	×	×	○	△	×	△	×	×	×	×	×	△	△	△	△	△	△	△	○
(2)-4 New combination quasi-drugs	○	○	○	×	×	○	△	×	△	×	×	×	×	×	△	×	×	△	△	△	△	○
(2)-5 Quasi-drugs with new administration methods	○	○	○	×	×	○	△	×	△	×	×	×	×	×	△	×	×	△	△	△	△	○
(3) Quasi-drugs containing new excipients	Attached data for the product shall be in accordance with the corresponding application category (1), (2), (4), or (5). Attached data for new excipients shall be as shown below.																					
	○	○	○	○	○	○	△	△	○	○	△	○	△	△	○	○	○	△	○	×	×	×
(4) Similar quasi-drugs	×	×	×	×	×	○	△	×	△	×	×	×	×	×	×	×	×	×	×	×	×	×
(5)-1 Identical quasi-drugs	×	×	×	×	×	○	△	×	△	×	×	×	×	×	×	×	×	×	×	×	×	×
(5)-2 Newly designated quasi-drugs	×	×	×	×	×	○	△	×	△	×	×	×	×	×	×	×	×	×	×	×	×	×
(5)-3 Newly categorized quasi-drugs	×	×	×	×	×	○	△	×	△	×	×	×	×	×	×	×	×	×	×	×	×	×

Note) The symbols and numbers in the right column indicate the symbols and numbers of data specified in Attached Table 1. In principle, ○ means that attachment is required, × means that attachment is not required, and △ means that whether or not data should be attached shall be determined for individual quasi-drugs. Even if the data are indicated as ×, it may be required to attach the data depending on the application for individual products.