

Provisional Translation (as of March 2011)*

PMDA Notification No. 0206007

February 6, 2009

To: As specified in the Appendix separately

From: Tatsuya Kondo,
Chief Executive of Pharmaceuticals and
Medical Devices Agency

Re: Procedures for Public Release of Information on Review of Applications for New Medical Devices

The Pharmaceuticals and Medical Devices Agency (hereinafter referred to as the “PMDA”) has made information on the review of applications for new medical devices publicly available at the request of the Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare (MHLW). Following the issuance of PFSB/ELD/OMDE Notification No. 0130001 from the Director of the Office of Medical Devices Evaluation, Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, MHLW, dated January 30, 2009 (“Public Release of Information on Review of Applications for New Medical Devices”) (hereinafter referred to as the “Director Notification”), we have set forth the specific procedures for submission and public release of documents pertaining to the review of product applications, as shown below, to make such information publicly available more promptly. Please inform your members of this Notification.

1. A person or entity who has filed an application for marketing approval of a medical device (hereinafter referred to as the “applicant”) must submit draft versions of the masked review report and masked summary technical document (hereinafter referred to as “STED”) to PMDA, as specified in Attachment 1 or Attachment 2 hereto, within two weeks after the applicant is requested to do so through a notification from the Director of the Office of Medical Devices Evaluation, Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, MHLW. The notification is issued around the same time when the Medical Devices and In Vitro Diagnostics Committee of the Pharmaceutical Affairs and Food Sanitation Council deliberates on the medical device.

* This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

If the applicant cannot submit draft versions of the masked review report and masked STED simultaneously, the applicant should submit a draft version of the masked review report first. When the review report for public release is finalized, submit a draft version of the masked STED prepared based on the review report.

2. Each draft version of the masked documents will be checked by PMDA and the adjustment between the applicant and PMDA will be made as follows:

(1) After the applicant submits a draft version of the masked document, the comment of PMDA on the draft version of the masked document will be conveyed to the applicant by the staff in charge of the product approval information in the Review Planning Division, Office of Review Administration at PMDA.

(2) If the applicant has any objections to PMDA's comment, the applicant may express the objection(s) and the specific reasons thereof, and meet the relevant PMDA staff to discuss this issue as necessary, thereby making adjustments to finalize the document for public release.

(3) After all adjustments to the masked document have been made, the applicant will be requested to submit the test file¹.

(4) The Director Notification urges the applicant to help ensure that the review report is made publicly available immediately after approval and the STED no later than three months after approval. Therefore, if the adjustments to those masked documents are not completed by the approval date and three months after approval, respectively, PMDA will tentatively publish the extent to which the documents can be made public at that time. In this case, please enter "Under Adjustment" in the top margin of the first page of the review report or STED. The adjustments will continue to be made, and when they are completed, the review report published tentatively will be replaced with the final one without the "Under Adjustment" mark.

¹ An electronic data file that contains the masked document agreed finally between the applicant and PMDA after the adjustment process.

Instructions on Preparing the Masked Review Report as a Draft

1. Basic concept of preparing the masked review report as a draft

The Appendix to PFSB Notification No. 0330022 from the Director General of the Pharmaceutical and Food Safety Bureau, MHLW, dated March 30, 2007 (“Procedural Guidance for Administrative Processing Related to Access to Information Held by the Pharmaceutical and Food Safety Bureau”) defines the basic concept of deciding whether or not to disclose information: “Administrative documents concerning evaluation and licensing shall, in principle, be disclosed because it is necessary to explain to, and foster the proper understanding of, the people on the overall regulatory review process, such as approving drug products etc. after properly evaluating the efficacy, safety, and quality of such drug products etc., based on the intent of the law.” As a general rule, therefore, review reports are subject to disclosure.

For this reason, in preparing the masked review report as a draft, it is necessary to minimize masked areas, while taking into account that the review report may contain the following information:

- Personal information that may be used to identify a certain individual or that may damage the right or interests of an individual, if made public
- Information that may damage a company's rights, competitive position, and other rightful interests, if made public

2. Masking of review reports

The following instructions focus primarily on information that, in principle, cannot be masked.

It should be noted, however, that this is not a complete list of information that cannot be masked. It is necessary to determine whether each piece of information can be masked in light of the basic concept described in Section 1 above.

(1) General information

- a. Do not mask the Chinese characters for the Japanese era, “month” or “day”² so it is recognizable as a date.
- b. If the date is in Christian year, then do not mask the thousands place or hundreds place so that it can be seen whether the date is in the 1900’s or 2000’s.
- c. Do not mask the application date or approval date of the approved medical device.

² Arabic numerals that represent the corresponding month and day may be masked.

- d. If dates are provided on the outcome of a subject and when the applicant wishes to mask the dates, then the applicant should replace the dates with the number of days from the reference date. In this case, add a footnote to the bottom margin of the relevant page, such as “*Replaced upon public release.”
 - e. Do not mask the units of values.
 - f. Do not mask the titles of published guidelines used as reference.
 - g. Do not mask the name(s) of the country(ies) where non-clinical tests were conducted, where measurements were made, or where clinical studies were conducted.
 - h. Do not mask the number of sites where studies were conducted.
 - i. When masking the brand name of the comparator device, replace with a generic name. In this case, add a footnote to the bottom margin of the relevant page, such as “*Replaced upon public release.”
 - j. Do not mask information that has already been published through newspapers, academic journals, websites, magazines, etc.
 - k. Do not mask punctuations, parentheses, particles (in Japanese, “*te*,” “*ni*,” “*wo*”, or “*ha*”), etc.
- (2) Information related to Sub-item 1 (Origin or history of discovery and usage conditions in foreign countries, etc.) that is one of the sub-items of Article 40, Paragraph 1, Item 5 of the Ordinance for Enforcement of the Pharmaceutical Affairs Act (hereinafter referred to as the “Regulations”)
- a. Do not mask the fact (if applicable) that an application was withdrawn in the past due to noncompliance based on the document-based reliability assessment or GCP inspection.
 - b. If the public release of both the incidence and number of malfunctions would reveal the sales quantity that the applicant plans to mask, then the applicant may mask either the incidence or number of malfunctions.
 - c. Do not mask the date of approval or the date of market launch of the device in foreign countries.
 - d. Do not mask the fact on whether or not the device has been developed overseas, unless such information is not made public.
- (3) Information related to Sub-item 2 of the Regulations (Setting of specifications)
- a. Do not mask the titles of standards or the names of tests that are specified in relevant guidelines, etc., and must, in principle, be set.
 - b. Do not mask the fact (if applicable) that specifications were changed during development.
- (4) Information related to Sub-item 3 of the Regulations (Stability and durability)

- a. Do not mask the names of tests, etc., that are specified in relevant guidelines, etc., and must, in principle, be set.
 - b. Do not mask measurement methods or analytical methods, unless they have originality.
- (5) Information related to Sub-item 4 of the Regulations (Conformity to the standards specified in Paragraph 3 of Article 41 of the Pharmaceutical Affairs Act)
- a. Do not mask the information. The applicant may, however, mask words or phrases that are permitted to be masked elsewhere in the document.
- (6) Information related to Sub-item 5 of the Regulations (Performance)
- a. Do not mask information on safety. The applicant may, however, mask words or phrases that are permitted to be masked elsewhere in the document.
 - b. Do not mask the names of tests, etc., that are specified in relevant guidelines, etc., and must, in principle, be set.
 - c. Do not mask measurement methods or analytical methods, unless they have originality.
- (7) Information related to Sub-item 6 of the Regulations (Risk analysis)
- a. Do not mask the information. The applicant may, however, mask words or phrases that are related to the company's risk management system or original methods, or that are permitted to be masked elsewhere in the document.
- (8) Information related to Sub-item 7 of the Regulations (Manufacturing method)
- a. Do not mask the fact (if applicable) that manufacturing process was changed during development.
 - b. Do not mask the fact (if applicable) that self management has been set for the manufacturing process.
 - c. Do not mask names of general tests (e.g., appearance test, dimensional test, residual ethylene oxide test, endotoxin test).
- (9) Information related to Sub-item 8 of the Regulations (Clinical data)
- a. Do not mask figures or tables that show the complete clinical data package, figures or tables that show the positioning and relevance of clinical studies, or contents thereof.
 - b. Do not mask the basis for determining the target number of subjects.
 - c. Do not mask the statistical analysis methods.
 - d. Do not mask the fact (if applicable) that the applicant had consultations with PMDA, or the advice given by PMDA to the applicant for the safety of trial subjects.
 - e. If there is a risk that the trial subject's identity may be revealed, replace the subject number with another symbol. In this case, add a footnote to the bottom margin of the relevant page, such as “*Replaced upon public release.”

- f. Do not mask the age of the trial subject etc. In the case of an orphan medical device etc., however, if there is a risk that the identity of the trial subject etc. may be revealed, mask the one decimal place of the age.
 - g. Do not mask any information that has already been published by an academic society, etc. even if an individual or company can be identified by the information.
 - h. Do not mask numerals that represent study numbers.
 - i. Do not mask the fact (if applicable) that the specifications were changed during development.
- (10) Information on inquiries and responses thereto during the review process
- a. Do not mask areas describing the concerns expressed by PMDA during the review process.
- (11) Information on the results of compliance assessment concerning the submitted data (the results of document-based GCP/GLP inspection and reliability assessment and the results of GCP on-site inspection) and PMDA's conclusion thereon.
- a. Do not mask the results of compliance assessment concerning the submitted data and PMDA's conclusion thereon, even if the descriptions include information contrary to the interests of the applicant, such as noncompliance or protocol deviation.
- (12) Information on the Overall Evaluation
- a. Do not mask information on the Overall Evaluation, even if it is contrary to the interests of the applicant, unless such information is as stipulated in (13)-b-ii) below.
- (13) Miscellaneous (handling of special circumstances)
- a. Do not mask the conditions for approval (if any).
 - b. Information excluded from the approved application:
 - i) Information withdrawn during the review process (when part of the application is withdrawn)
Do not mask any intended use, etc., proposed in the application that was later withdrawn by the applicant during the review process, unless the development is continued.
 - ii) Information on the refusal by MHLW to grant approval due to administrative reasons, etc.
The "application for which a regulatory decision to refuse approval has been made" as specified in Section 2-A-2 of Appendix to PFSB Notification No. 0330022 from Director General of the Pharmaceutical and Food Safety Bureau, MHLW, dated March 30, 2007 (Procedural Guidance for Administrative Processing Related to

Access to Information Held by the Pharmaceutical and Food Safety Bureau) is applicable.

- c. Claims that the consent from the information provider or device provider cannot be obtained

In light of the purpose of the public release, no applicant is permitted to mask information merely on the grounds that the consent from the information provider or device provider cannot be obtained or that the contract was not concluded on the premise that the information will be made public.

The applicant must fully explain to the information provider or device provider on the purpose of the public release before filing the application, considering the future public release of the information pertaining to the review of application for the new medical device.

It is the applicant's responsibility to ensure that the applicant have obtained the consent of the information provider or device provider prior to the arrival of relevant notifications from the Director of Office of Medical Devices Evaluation, Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, MHLW.

- d. Unpublished documents or data

If the regulatory review has been conducted using any documents or data from papers that are unpublished at the time of approval (including the cases where papers submitted to an academic journal are under peer review), information based on such papers should not be masked. The titles of such papers may, however, be masked.

Instructions on Preparing the Masked STED as a Draft

General information on STED

1. The provision of “Documentation which is prepared based on the prescribed elements of the content” as stipulated in Section 2-A-3-(2) of Appendix to PFSB Notification No. 0330022 from the Director General of the Pharmaceutical and Food Safety Bureau, MHLW, dated March 30, 2007 (“Procedural Guidance for Administrative Processing Related to Access to Information Held by the Pharmaceutical and Food Safety Bureau”) shall apply mutatis mutandis to the procedures for preparing the masked STED.
2. The provisions of Sections 1, 2-(1), and 2-(13) of Attachment 1 shall apply mutatis mutandis to the procedures for preparing the masked STED.
3. In principle, do not mask the table of contents or the list of abbreviations. The applicant may mask, however, the table of contents and the list of abbreviations if they contain words or phrases that are permitted to be masked in elsewhere in the document.
4. Ensure consistency between the masked review report and the masked STED. The information made public in the review report should not be masked in the STED.
5. Do not mask titles and table headings or axis labels for tables or figures.
6. Do not mask the instructions for use (draft) and the basis for setting the content of the instructions for use, or the label (draft).

(Appendix)

The Chairman of the Japan Federation of Medical Devices Associations

The Chairman of the Medical Devices and Diagnostics Subcommittee, American Chamber of Commerce in Japan

The Chairman of the Medical Equipment Committee of the European Business Council in Japan

The Chairman of the Association of Registered Certification Bodies under PAL