Administrative Notice
August 10, 2023

To: Prefectural Public Health Bureau (Department)

Pharmaceutical Safety Division,
Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare

Questions and Answers (Qs & As) on the Guidance for Provision of Dear Healthcare Professional Letters of Emergent/Rapid Safety Communications

The Questions and Answers (Qs & As) on the Guidance for Provision of Dear Healthcare Professional Letters of Emergent/Rapid Safety Communications were presented in the Administrative Notice from the Safety Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare (hereinafter referred to as “MHLW”) on July 15, 2011, followed by the "Questions and Answers (Qs & As) on the Guidance for Provision of Dear Healthcare Professional Letters of Emergent/Rapid Safety Communications" (Administrative Notice issued by the Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau, MHLW on May 15, 2020 [hereinafter referred to as the "old Administrative Notice"]).

In line with the revision of "Partial Revision of the ‘Guidelines for Provision of Dear Healthcare Professional Letters of Emergent/Rapid Safety Communications’" (PSEHB/PSD Notification No. 0810-2 issued by the Director of Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau, MHLW on August 10, 2023), the Qs & As on the Guidance presented in the old Administrative Notice have also been reviewed and compiled as shown in the appendix. Please understand the content, and make it thoroughly known to the relevant organizations under your jurisdiction so that the Qs & As can be used as a reference for their operations.

With the issuance of this Administrative Notice, the old Administrative Notice is abolished.

(Appendix)

Questions and Answers (Qs & As) on the Guidance for Provision of Dear Healthcare Professional Letters of Emergent/Rapid Safety Communications

Q1 It is stated that "When giving an order or instruction to a marketing authorization holder (hereinafter referred to as “MAH”), etc. to prepare a Dear Healthcare Professional Letter of Emergent Safety Communications and to provide information, the Pharmaceutical Safety Division of the Pharmaceutical Safety and Environmental Health Bureau shall notify the marketing authorization holder of the reason, etc. in writing." Should such a notification be issued for a Dear Healthcare Professional Letter of Emergent Safety Communications based on a voluntary decision by the MAH, etc.?

A1 The Pharmaceutical Safety Division may issue a notification to the MAH as necessary in cases where a Dear Healthcare Professional Letter of Emergent Safety Communications is issued based on a voluntary decision of the MAH, etc.

Q2 It is stated that "...shall consider posting the information in the media such as a company announcement in newspapers." What specifically should the contents of the post be?

A2 When posting a company announcement, the company needs to consider contents that ensure appropriate communication to patients, etc. depending on the information to be provided. This should be discussed on a case-by-case basis. Cases of recalls of medical devices, etc. may also be useful as references. The size of the article and the number of newspapers in which the announcement is posted should be determined by the company based on the contents to be posted.

Q3 It is stated that "It shall be confirmed that the information has been received within 1 month by an appropriate department of the medical institution or pharmacy, etc. where it was confirmed that the relevant product had been delivered (the department to which the medical safety manager, the safety management supervisor for drugs and medical devices, or the person in charge of product information, etc. at the medical institution belongs)." How should the receipt of information be confirmed?

A3 Confirm the receipt of information based on the visit records, the interview records, and/or the history of incoming and outgoing direct mail, e-mail, fax messages, etc.

Q4 Regarding information provision to the relevant medical and pharmaceutical associations, etc. or the groups of patients using the product, how should the selection of the target associations/groups and the request for information provision be made?

A4 The selection of target associations/groups (including the determination of the necessity of providing information in the case of a Dear Healthcare Professional Letter of Rapid Safety Communications) should be made during a prior consultation with the PMDA on the plan for provision. Who will provide the information to the associations/groups should be discussed during a prior consultation with the Pharmaceutical Safety Division and the PMDA.

When more than one MAH of the product is involved in information provision to the relevant associations/groups, it is desirable to determine a representative MAH in charge of this task through a consultation with the authorities.

Q5 What does the "document clarifying the contents of revision" mean specifically?

A5 A "document clarifying the contents of revision" refers to a notification document of the contents of revision or "Drug Safety Update (DSU)" issued by the Federation of Pharmaceutical Manufacturers' Associations of Japan.

Q6 The example of "Dear Healthcare Professional Letter of Emergent Safety Communications" includes the number of reported deaths and the estimated number of patients treated. When a generic drug is available, should the number of reported deaths and the estimated number of patients treated with the generic drug also be included?

A6 When a generic drug is available, it is desirable to share the information among the relevant MAHs, etc. and integrate the information into the Dear Healthcare Professional Letter of Emergent Safety Communications at the time of preparation.

Q7 Regarding the deadline for the submission of a plan for provision of Dear Healthcare Professional Letter of Emergent/Rapid Safety Communications, is it acceptable to submit it by the start of the provision of a Dear Healthcare Professional Letter of Emergent/Rapid Safety Communications?

A7 As a general rule, yes.

Q8 Regarding the deadline for the submission of a report on provision of Dear Healthcare Professional Letter of Emergent/Rapid Safety Communications, is it acceptable to submit it promptly after the completion of provision according to the plan for provision?

A8 Yes.

Q9 What specifically is the "date of distribution through the PMDA medi-navi" described in Attachment Form 3 and 4 "Report of Provision of Dear Healthcare Professional Letter of Emergent Safety Communications" and Attachment Form 7 and 8 "Report of Provision of Dear Healthcare Professional Letter of Rapid Safety Communications"?

A9 It is the date when the information was provided in the text of the e-mail through the PMDA Pharmaceuticals and Medical Devices Information E-mail Alert Service ("PMDA medi-navi").

Q10 Among the matters to be implemented by the MAH in relation to the provision of the Dear Healthcare Professional Letter of Emergent Safety Communications, how should the press release be handled when the drug is manufactured by more than one MAH?

A10 As a general rule, the representative MAH determined through consultation with the Pharmaceutical Safety Division and the PMDA is responsible for coordinating the press release contents with the Pharmaceutical Safety Division and the PMDA.

While the representative MAH should communicate the coordinated contents to all other MAHs involved in the matter, the Pharmaceutical Safety Division or the PMDA is responsible for the communication of the administrative instruction, etc. for the details of the decided contents.