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PSEHB/SD Notification No. 0531-1
May 31, 2022

To: Directors of Prefectural Health Department (Bureau)

Director of Pharmaceutical Safety Division,
Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare
(Official seal omitted)

Implementation Method, etc. of Early Post-marketing Phase Vigilance for Prescription Drugs

Although the implementation method of early post-marketing phase vigilance should be determined for each drug, the standard method, etc. of early post-marketing phase vigilance has been instructed in the “Implementation Method, etc. of Early Post-marketing Phase Vigilance for Prescription Drugs” (PFSB/SD Notification No. 0324001 by the Director of Safety Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare (hereinafter referred to as “MHLW”) dated March 24, 2006; hereinafter referred to as “previous notification”).

In light of the fact that meetings have been conducted online according to the needs of medical institutions, etc. in recent years, the contents of the previous notification have been reviewed and the standard method, etc. of early post-marketing phase vigilance has been updated as described below. Please understand the new standard method and give guidance to relevant organizations, etc. under your jurisdiction.

The previous notification will be abolished upon issuance of this notification.

Notice

1 The marketing authorization holder (hereinafter referred to as “MAH”) shall prepare an early post-marketing phase vigilance implementation plan in accordance with the provision of Article 10, Paragraph 1 of the Ministerial Ordinance on Good Vigilance Practice for Drugs, Quasi-drugs, Cosmetics, Medical Devices, and Regenerative

Medicine Products (MHLW Ministerial Ordinance No. 135 of 2004). A sample form is shown in Attachment 1.

2 The MAH shall provide the following explanation and request for cooperation to medical institutions which use a drug manufactured and marketed by the MAH, in principle, before delivery of the drug, through a face-to-face or online meeting by medical representatives, etc.

If the explanation and request for cooperation by medical representatives, etc. cannot be provided before delivery, the contents of the explanation and request for cooperation shall be notified in writing before delivery, and the explanation and request for cooperation shall be provided by medical representatives, etc. within approximately 2 weeks after the start of delivery.

- The drug is subject to early post-marketing phase vigilance and the survey is ongoing.
- Medical institutions should make an effort to use the drug properly. If any serious adverse reaction or infection suspected to be related to the drug occurs, medical institutions should promptly report it to the MAH

3 The MAH shall make requests for cooperation to medical institutions which use the drug, in principle, approximately once within 2 weeks for the 2 months after the start of delivery and at an appropriate frequency (approximately once within 1 month) thereafter.

4 The MAH shall prepare an early post-marketing phase vigilance report after the end of the early post-marketing phase vigilance period. A sample form is shown in Attachment 2.

5 The MAH shall submit the early post-marketing phase vigilance report, along with the early post-marketing phase vigilance implementation plan, within 2 months after the end of the early post-marketing phase vigilance period to the Office of Pharmacovigilance I or Office of Pharmacovigilance II of the Pharmaceuticals and Medical Devices Agency.

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Attachment 1

Early Post-marketing Phase Vigilance Implementation Plan

Target drug	Brand name		
	Nonproprietary name		
	Approval (license) number Approval (license) date		
	Therapeutic category		
Purpose of early post-marketing phase vigilance			
Planned number of medical institutions subject to early post-marketing phase vigilance (by type)		Type	Number of medical institutions
Method of early post-marketing phase vigilance (Methods and frequencies of providing proper use information, making requests for cooperation, and calling for attention to medical institutions)			
Early post-marketing phase vigilance period		DD/MM/YYYY to DD/MM/YYYY	
Name and address of the outsourcee and scope of the outsourced activities when part of the early post-marketing phase vigilance activities is outsourced			
Other necessary matters			
Remarks			

Prepared on: DD/MM/YYYY
(Date of revision if revised)

Marketing Supervisor-General or Safety Management Supervisor

Note) In the column for the planned number of medical institutions subject to early post-marketing phase vigilance (by type), the type of medical institutions should be described according to the definitions of “hospital” and “clinic” in Article 1-5 of the Medical Care Act (Act No. 205 of 1948).

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Attachment 2

Early Post-marketing Phase Vigilance Report

Target drug	Brand name		
	Nonproprietary name		
	Approval (license) number Approval (license) date		
	Therapeutic category		
Date of initial marketing		DD/MM/YYYY	
Early post-marketing phase vigilance period		DD/MM/YYYY to DD/MM/YYYY	
Number of medical institutions subject to early post-marketing phase vigilance (by type)		Type	Number of medical institutions
Estimated number of patients		(Describe the method for calculating the estimated number of patients)	
Occurrence of serious adverse reactions, etc.		Type of adverse reactions, etc.	Number of events
		(Describe them by preferred term (PT) for each system organ class using the ICH Medical Dictionary for Regulatory Activities/Japanese version (MedDRA/J).)	
Safety assurance measures taken during the implementation period		(Describe them in detail in an attachment.)	
Remarks		(Enter the name and contact telephone number of the person in charge of this report.)	

I hereby submit the early post-marketing phase vigilance report.

DD/MM/YYYY

Address: (Address of the main office in the case of a corporation)

Name: (Name of the corporation and its representative in the case of a corporation)

To: Director of Office of Pharmacovigilance I or Office of Pharmacovigilance II
Pharmaceuticals and Medical Devices Agency

Note) In the column for the number of medical institutions subject to early post-marketing phase vigilance (by type), the type of medical institutions should be described according to the definitions of “hospital” and “clinic” in Article 1-5 of the Medical Care Act (Act No. 205 of 1948).