PSB/PED Notification No. 1003-1
October 3, 2025

To: Directors of Prefectural Health Departments (Bureaus)

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

Handling of Application for Confirmation of Change Protocol Related to Change of Strains for Influenza Vaccine or COVID-19 Vaccine

For the system for changes in approved items using a plan for partial changes in approved items of an approved product (hereinafter, it is referred to as “change protocol” and generally called a post approval change management protocol [PACMP]), its handling has been described in the “Handling of Application for Confirmation of Change Protocol for Drugs, etc.” (PSEHB/PED Notification No. 0616-14, dated June 16, 2021, of the Pharmaceutical Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare [MHLW]) (hereinafter referred to as “PACMP Notification”).

Handling of changes in approved items using a change protocol (hereinafter referred to as “Strain Change PACMP”) in cases where production strains or antigen strains used in the manufacture of influenza vaccine or COVID-19 vaccine need to be changed is organized as provided below. Please understand the content and ensure that all the companies under your jurisdiction are informed.

Chapter 1 Purpose of the system for changes in approved items using a change protocol related to change of strains for influenza vaccine or COVID-19 vaccine

For seasonal influenza vaccines (manufactured using strains other than those dispensed by the National Institute of Infectious Diseases, Japan Institute for Health Security) and COVID-19 vaccines, production strains and antigen strains to be used in

the manufacture are recommended and selected by the World Health Organization (WHO) or the MHLW in around the spring of each fiscal year. If the strains need to be changed, regulatory procedure for the change should be completed by around the autumn of the fiscal year. To allow reasonable and highly predictable regulatory procedures for vaccines, which repeatedly require strain changes, handling of the changes utilizing the existing PACMP system is organized.

Chapter 2 Scope of this notification

Strain change PACMPs handled in this notification are change protocols for the changes that are included in the scope of application specified in Chapter 2 of the PACMP Notification and subject to the “Handling of Influenza Vaccines Manufactured Using Strains Other than Those Dispensed by the National Institute of Infectious Diseases (Notification)” (PSB/PED Notification No. 0131-1 and PSB/CND Notification No. 0131-1, dated January 31, 2024, of the Pharmaceutical Evaluation Division and Compliance and Narcotics Division, Pharmaceutical Safety Bureau, MHLW, hereinafter referred to as “Partial Change Notification for Influenza Strain Changes”) or the “Handling of Changes to COVID-19 Vaccine Strains (Notification)” (PSB/PED Notification No. 0523-1 and PSB/CND Notification No. 0523-3, dated May 23, 2024, of the Pharmaceutical Evaluation Division and Compliance and Narcotics Division, Pharmaceutical Safety Bureau, MHLW, hereinafter referred to as “Partial Change Notification for Coronavirus Strain Changes”).

Chapter 3 Matters to be described in the application for confirmation of change protocol for drugs, etc.

Actions should be taken as specified in Chapter 3 of the PACMP Notification. Change plans specified in Chapter 3, 2(2)[2] of the above notification may include the following contents.

- Description of proposed change
- Plan for evaluation necessary for preparation of data listed in (4) of the Partial Change Notification for Influenza Strain Changes or (6) of the Partial Change Notification for Coronavirus Strain Changes
- Other data to explain the change protocol

Chapter 4 Handling of changes in the change protocol

Actions should be taken as specified in Chapter 4 of the PACMP Notification. If partial changes for drugs are approved after completion of confirmation of the change

protocol and thus are intended to be reflected in the change protocol, submission of a minor change notification for confirmation items in the change protocol for drugs may suffice.

Chapter 5　Handling of changes made in accordance with change protocol

Actions should be taken as specified in Chapter 5 of the PACMP Notification.

Chapter 5, 1(1) of the above notification lists data to be attached to the notification for changes made in accordance with the change protocol. However, if submission of the data at the time of notification seems difficult, the applicant should consult with PMDA about the timing of the submission in advance.

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