This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

PSB/PSD Notification No. 1204-1
December 4, 2024

To: Commissioners of Prefectural Health Departments (Bureaus)

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

Self-Inspection of Package Inserts for In Vitro Diagnostics for Detection of Influenza Viruses

The intranasal live attenuated influenza vaccine is a vaccine that is sprayed into the nasal cavity and live attenuated influenza viruses multiply in the nasopharynx, which are expected to induce immunity similar to that induced after natural infection. Given this mechanism of action of the vaccine, there is a possibility that the measurement results of in vitro diagnostic products that detect influenza viruses may be affected. The package insert of an intranasal live attenuated influenza vaccine includes a precautionary statement that rapid tests may yield positive results for vaccine-derived influenza virus for a certain period after the vaccination, based on the results of clinical studies.

Please understand the contents of this notification and inform the relevant marketing authorization holders (hereinafter referred to as “MAHs”) of the in vitro diagnostics for detection of influenza viruses under your jurisdiction so that they perform self-inspection of the package inserts of their products as described below, revise them if necessary, and provide related information to medical institutions, etc.

1. The MAHs of in vitro diagnostics for detection of influenza viruses (including the Nucleic Acid Amplification test) should check their products to determine whether the measurement results may be affected by influenza viruses in the samples when the samples of subjects vaccinated with intranasal live attenuated influenza vaccine are used. Confirmation based on the verification test results is not necessarily required.

2. For the products for which the measurement results were determined to be potentially affected as a result of the confirmation described in 1 above, it should be assured that the following actions have been taken:
   (1) Products with the nonproprietary name of “OTC SARS-CoV-2 & Flu virus antigen kit” include the statement that “this kit may show a positive result due to vaccine-derived influenza virus for a certain period after vaccination with intranasal live attenuated influenza vaccine” in the “Precautions for assessment” section under “Please pay attention to the following when using” in their package inserts. In addition, the explanation materials by the MAHs to distributors, the user guides, and the explanation materials which distributors use to explain to users have applicable descriptions in appropriate sections.
   (2) Products other than those listed in (1) include a statement that “this product may show a positive result due to vaccine-derived influenza virus for a certain period after vaccination with intranasal live attenuated influenza vaccine” in the “Precautions for assessment” section of Method for Determining Measurement Results in their package inserts.

3. If the descriptions in the package inserts, etc. are determined to be insufficient as a result of 2 above, the package inserts, etc. should be promptly revised, and necessary information should be provided to medical institutions, etc. Regardless of the section in which the contents are described, if the equivalent contents have already been described in the package insert, revision is not necessary. If only a revision of the package insert in response to this notification is to be made, consultations to the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as “PMDA”) are generally not required. If necessary, a request should be made for consultation in connection with revisions to the package inserts, etc.

4. The results of confirmation of 1 to 3 described above and the resulting revision of the package insert, etc. should be reported to the Office of Vigilance and Standards

for Medical Devices, PMDA by December 27, 2024. Reports should be submitted by an e-mail (md-chousakekka@pmda.go.jp) using the attached form. If the revision of the package insert has not been completed as of December 27, 2024, the status of the progress at that point should be reported.