November 2, 2017

Notification

PFSB/SD Notification No. 1102-1

To: Commissioners of the Prefectural Health Department (Bureau)

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

Revision of Precautions in the Package Inserts of Medical Devices Containing Chlorhexidine Gluconate or Chlorhexidine Hydrochloride

Recently, revision of package inserts to add precautions with regard to shock (anaphylaxis) has been requested for prescription drugs, over-the-counter drugs, and quasi-drugs containing chlorhexidine gluconate or chlorhexidine hydrochloride (hereinafter referred to as “chlorhexidine”) as active ingredients through notifications of Revision of Precautions in the Package Inserts (PFSB/SD Notification No. 1017-1, by the Director of Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, dated October 17, 2017) and Revision of Precautions in the Package Inserts for Quasi-Drugs Containing Chlorhexidine Gluconate or Chlorhexidine Hydrochloride (PFSB/SD Notification No. 1017-2, by the Director of Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, dated October 17, 2017).

In line with the drugs, it is considered appropriate to take similar measures for medical devices that contain chlorhexidine as ingredients or involve chlorhexidine as a component (hereinafter referred to as “medical devices containing CHG”). Commissioners of the prefectural health department are requested to circulate this notification among Marketing Authorization Holders of these products or other related business entities under commissioners’ supervision to ensure the earliest possible revision of precautions as below and appropriate information provision to medical institutions by them.

1. In the Important Precautions section under the Precautions in the package inserts for medical devices containing CHG, the following text should be added:

In order to predict reactions such as shock or anaphylaxis, a sufficient medical interview should be performed regarding the history of hypersensitivity to chlorhexidine preparations and for predisposition to drug hypersensitivity in advance.

2. In the Important Adverse Events section under the Precautions in the package inserts for medical devices containing CHG, the following text should be added:

Shock, anaphylaxis:
Shock or anaphylaxis may occur. Patients should be carefully monitored, and if decreased blood pressure, urticaria, dyspnoea, etc. are observed, the use of this drug should be discontinued immediately and appropriate measures should be taken.

3. The package inserts for medical devices containing CHG as revised according to 1 and 2 above should be uploaded on the website of the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as “PMDA”) as information on package inserts for medical devices.

4. Progress should be reported to the Medical Device Safety Division, Office of Safety 1, PMDA by February 2, 2018, in the measures taken regarding 1 through 3 above as well as in the information provision to the medical institutions, etc. on revised package inserts.