March 31, 2016

Notification

PFSB/ELD/OMDE Notification No. 0331-3
PFSB/SD Notification No. 0331-3

To: Representatives (of the Companies listed in Appendix 1)

Counsellor of Minister's Secretariat, Ministry of Health, Labour and Welfare
(Evaluation and Licensing of Medical Device/Cellular and Tissue-based Products)

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

Revision of the Precautions in the Package Insert of Medical Devices that Constitute Metal-on-Metal Artificial Hip Prosthesis

Metal-on-Metal total hip replacement utilizing artificial hip prosthesis with metallic sliding parts (hereinafter referred to as Metal-on-Metal artificial hip prosthesis) may induce pain or mass lesions referred to as pseudotumors thought to be adverse reactions to metal debris. It has been reported that, in such cases, re-operation must be conducted within a relatively short period of time after the first surgery.

Revision of the "Precautions" in the package insert of related medical devices is necessary given that the Japanese Society for Replacement Arthroplasty recently compiled the incidence and treatment algorithms of complications due to Metal-on-Metal total hip replacement in the "Treatment Guide on Complications due to Metal-on-Metal Total Hip Replacement".

This notification is issued to advise the Marketing Authorization Holders dealing with these products to revise the "Precautions" in the respective package insert as explained as follows and asks for your cooperation in making this information widely known to medical institutions, etc.

1. In the “Important Precautions” section in the Precautions in the package insert of medical devices that are components of Metal-on-Metal artificial hip prosthesis, the following text should be added:

   Refer to most recent information such as “Treatment Guide on Complications due to Metal-on-Metal Total Hip Replacement” composed by the Japanese Society for Replacement Arthroplasty when treating complications after Metal-on-Metal total hip replacement.

2. The revised package inserts of relevant products as advised in the abovementioned item 1 should be uploaded on Information Services on the website of the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as “PMDA”) as information on package inserts for medical devices.

3. The respective Marketing Authorization Holders should report to the Medical Device Safety Division, Office of Safety 1, PMDA by May 2, 2016, regarding the actions taken for the abovementioned item 1 in addition to the information provided in the revised package insert to the medical institutions, etc.

4. For any related products under application for approval, the applicant should report to the PMDA that the revision will be made in the respective package insert (draft).

(Appendix 1)

Zimmer Biomet G.K.
Johnson & Johnson K.K.
MicroPort Orthopedics Japan K.K.
Senko Medical Instrument Mfg. Co., Ltd.
MMT Co., Ltd.
Corin Japan K.K.
Smith & Nephew Orthopaedics K.K.