



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.

PSEHB/PSD Notification No. 0730-4

July 30, 2021

To: Commissioners of Prefectural/Cities with Established Health
Centers/Special District Health Department (Bureau)

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

Occurrence of Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) in Patients Implanted with a Gel-filled Breast Implant or Tissue Expander, and Information Provision to the Patients (Request for Information Dissemination)

We would like to express our sincere appreciation for your continued efforts on implementing safety measures for medical devices.

Regarding the information provision for patients implanted with a gel-filled breast implant or tissue expander and other relevant persons (hereinafter referred to as “patients, etc.”), we have asked for your cooperation in widely disseminating the contents of the information provision materials (hereinafter referred to as “information provision documents”) prepared for patients, etc. and published by the Japan Oncoplastic Breast Surgery Society, the Japan Society of Plastic and Reconstructive Surgery, the Japanese Breast Cancer Society, and the Japan Society of Aesthetic Plastic Surgery (JSAPS) (hereinafter referred to as “4 academic societies”), by issuing the “Information Documents for Patients with Gel-filled Breast Implants, Tissue Expanders, etc.” (PSEHB/MDED Notification No 1007-1 issued by the Director of Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare and PSEHB/PSD Notification No1007-1 issued by the Director of Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare dated



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October 7, 2020).

As shown in the Annex*, the 4 academic societies have recently announced the occurrence of BIA-ALCL, which is counted as the 2nd case in Japan (the first patient who has undergone implantation of an approved gel-filled breast implant in Japan) and raised attention on the importance of regular medical examination and self-examination for disease detection.

Since it is extremely important to provide accurate information widely to those who have undergone breast reconstruction with gel-filled breast implants, we would like to ask for your further cooperation in widely disseminating the contents of the information provision documents again by various means such as publication in public relations magazines of each local government and provision of information using social media.

The latest information provision documents are available on the website of the Japan Oncoplastic Breast Surgery Society.

URL: <http://jopbs.umin.jp/general/> (only in Japanese)

* Please refer to the Japanese version of the Notification for the Annex

<https://www.pmda.go.jp/files/000242188.pdf>