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PSEHB/MDED Notification No. 1007-1

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October 7, 2020

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

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

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

Information Documents for Patients with Gel-filled Breast Implants, Tissue Expanders, etc.

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 “Ensuring the Provision of Information



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for Patients etc. with Gel-filled Breast Implants and Tissue Expanders (Request for Cooperation)” (PSEHB/PSD Notification No1001-2 issued by the Director of Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare dated October 1, 2019).

In response to the new approval of the “Sientra breast implant” which is smooth type implants or textured type implants (the MAH: Medical U&A, Inc.), the safety information on the products was included in the information provision documents and published by the 4 academic societies as shown in the Annex*.

Since it is extremely important to provide accurate information widely to those who have intention of undergoing breast reconstruction with gel-filled breast implant, those who are waiting for breast reconstruction surgery after undergoing tissue expander implantation for breast reconstruction, and those who had undergone breast reconstruction with gel-filled breast implant, we would like to ask for your further cooperation in widely disseminating the information.

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 Annexes
<https://www.pmda.go.jp/files/000237414.pdf>
<https://www.pmda.go.jp/files/000237415.pdf>
<https://www.pmda.go.jp/files/000237416.pdf>
<https://www.pmda.go.jp/files/000237413.pdf>