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

December 26, 2018
Administrative Notice

To Addressees as separately listed

Office of Safety I, Pharmaceuticals and Medical Devices Agency

Office of Safety II, Pharmaceuticals and Medical Devices Agency

Reorganization of the Pharmaceuticals and Medical Devices Agency

As a result of a reorganization (hereinafter, the “Reorganization”), the names and functions of various organizational components of the Pharmaceuticals and Medical Devices Agency (PMDA) overseeing safety measures pertaining to pharmaceuticals, medical devices, *in vitro* diagnostics, and cellular and tissue-based products will be changed as stated in the Appendix.

Notifications issued prior to the Reorganization by the Directors of the Offices of Safety I and II will remain effective as issued by the directors of the corresponding organizational components after the Reorganization unless new notifications are separately issued by such directors.

Names of organizational components and job titles stated in notifications issued prior to the Reorganization will be revised to reflect the Reorganization in future amendments. Until such time, the pre-Reorganization titles and names of organizational components shall be regarded and treated as representing corresponding post-Reorganization titles and names of organizational components.

Pharmaceuticals and Medical Devices Agency

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(Appendix)

1. Amended names of organizational components

Prior to the Reorganization (until December 31, 2018)	**After the Reorganization (as of January 1, 2019)**
Office of Safety I	Office of Informatics and Management for Safety
Planning and Management Division, Office of Safety I	Planning and Management Division, Office of Informatics and Management for Safety
Safety Reports Management Division, Office of Safety I	Safety Reports Management Division, Office of Informatics and Management for Safety
Risk Communication promotion Division, Office of Safety I	Risk Communication promotion Division, Office of Informatics and Management for Safety
International Information Group, Risk Communication promotion Division, Office of Safety I	International Information Group, Risk Communication promotion Division, Office of Informatics and Management for Safety
Consultation Group on Pharmaceuticals and Medical devices, Risk Communication promotion Division, Office of Safety I	Consultation Group on Pharmaceuticals and Medical devices, Risk Communication promotion Division, Office of Informatics and Management for Safety
Medical Safety Information Group, Medical Device Safety Division, Office of Safety I	Medical Safety Information Group, Risk Communication promotion Division, Office of Informatics and Management for Safety
Medical Device Safety Division, Office of Safety I	Division of Safety for Medical Devices, Office of Manufacturing Quality and Vigilance for Medical Devices
Office of Safety II	Office of Pharmacovigilance I Office of Pharmacovigilance II

2. Assignment of functions related to safety measures after the Reorganization

Names of organizational components	Operations assigned
Office of Pharmacovigilance I	· Safety measures related to drugs other than those assigned to the Office of Pharmacovigilance II · Safety measures related to quasi-drugs and cosmetics
Office of Pharmacovigilance	Safety measures related to antibacterial drugs, chemotherapy

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II	drugs, antineoplastic drugs, blood products, biological preparations, respiratory tract drugs, anti-allergy drugs (excluding dermatological drugs), sensory organ drugs (for inflammatory diseases only), radiopharmaceuticals (concerning only those products intended for diagnosing relevant diseases associated with the medicines under the oversight of the Office of Pharmacovigilance II), diagnostic agents (concerning only those products intended for diagnosing relevant diseases associated with the medicines under the oversight of the Office of Pharmacovigilance II), and cellular and tissue-based products
Division of Safety for Medical Devices, Office of Manufacturing Quality and Vigilance for Medical Devices	· Safety measures related to medical devices Note1) · Safety measures related to *in vitro* diagnostics
Medical Safety Information Group, Risk Communication promotion Division, Office of Informatics and Management for Safety	Medical safety of pharmaceuticals and medical devices

Note 1) Including activities related to the receipt of reports from marketing authorization holders (MAHs) regarding medical devices and device parts that constitute the medical device components of combination products.

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