Press Release

Wednesday, 13 June 2012

The Pharmaceuticals and Medical Devices Agency (PMDA) convenes the inaugural Science Board meeting

~ Enhancing the review system responding to the Medical Innovations ~

While PMDA has advanced various efforts to make its review process faster and more efficient by increasing the number of reviewers and revamping its review system, it is increasingly required to evaluate products using advanced science and technology precisely and to provide sound advice and guidance.

Hence, PMDA has decided to create the system, in close collaboration with academia that is active in the front line of the research, which ensures constant upskilling of its reviewers to allow them to assess such products with proper scientific mindset.

PMDA came to the decision to establish the Science Board on 14 May 2012. The Board is set up as a high-level consultative body which consists of external experts from medical, dental, pharmaceutical, and engineering fields. Those experts are all leading researchers in their fields. The 1st Science Board meeting will be held according to the following schedule (See Annex 1 for the list of Board members, and Annex 2 and 3 for the latest organization of PMDA and the Office of Review Innovation).

The Science Board is positioned as one of the initiatives on “Increasing the number of reviewers and safety staff (including those who are responsible for regenerative medicinal products)” provided in the “Five-year Strategy for Medical Innovations” which was developed by the “Council for Medical Innovations” chaired by the Minister on National Strategies.

In the 1st Board meeting, the Board members will discuss PMDA’s current situation and challenges for the future as well as the future plan of the Board itself. Since several subcommittees on the fields of pharmaceuticals, medical devices, biologics, cellular and tissue-based products (regenerative medicinal products) are to be set up under the Science Board, the Board is also expected to address issues of these subcommittees.

The Board meeting is a closed session since it is planed to make some presentations with marketing authorised specific products' dossiers. However, as press companies are allowed to film at the beginning of the meeting, please contact the secretariat in advance if you are interested in. The press briefing by the Office of Review Innovation, with the chair of the Board, is scheduled after the meeting (14:00 -) at the meeting room No 26, 14th Floor of the PMDA building.

1st Science Board meeting
Place: Meeting room No.1 - 5, 6th floor of the PMDA building
Time and Date: 11:00~12:30 (JST), Monday, 18 June 2012
Note: Filming is allowed only at the beginning of the meeting.

Annex 1

List of the Science Board Members

Akinori Akaike
Professor, Graduate School of Pharmaceutical Sciences, Nagoya University

Yukihide Iwamoto
Professor, Orthopaedic Surgery, Department of Clinical Medicine, Kyushu University

Tatsuro Irimura
Professor, Graduate School of Pharmaceutical Sciences, the University of Tokyo

Hideyuki Okano
Professor, Department of Physiology, Graduate School of Medicine, Keio University

Chieko Kai
Professor, Institute of Medical Science, the University of Tokyo

Hideo Kusuoka
Director General, Osaka National Hospital, National Hospital Organization

Hideo Saji
Professor, Graduate School of Pharmaceutical Sciences, Kyoto University

Toshiya Sato
Professor, Biostatistics, Public Health, Graduate School of Medicine, Kyoto University

Yuichi Sugiyama
Invited Senior Scientist, Sugiyama Laboratory, RIKEN Innovation Center, RIKEN

Tatsutoshi Nakahata
Deputy Director, Center for iPS Cell Research and Application, Kyoto University

Masahiro Hayashi
Director, Department of Pharmacy, Toranomon Hospital

Akira Matsuda
Professor, Faculty of Pharmaceutical Sciences, Hokkaido University

Yoichiro Matsumoto
Professor, Graduate School of Engineering, the University of Tokyo

Masaki Mori
Professor, Department of Gastroenterological Surgery, Graduate School of Medicine, Osaka University

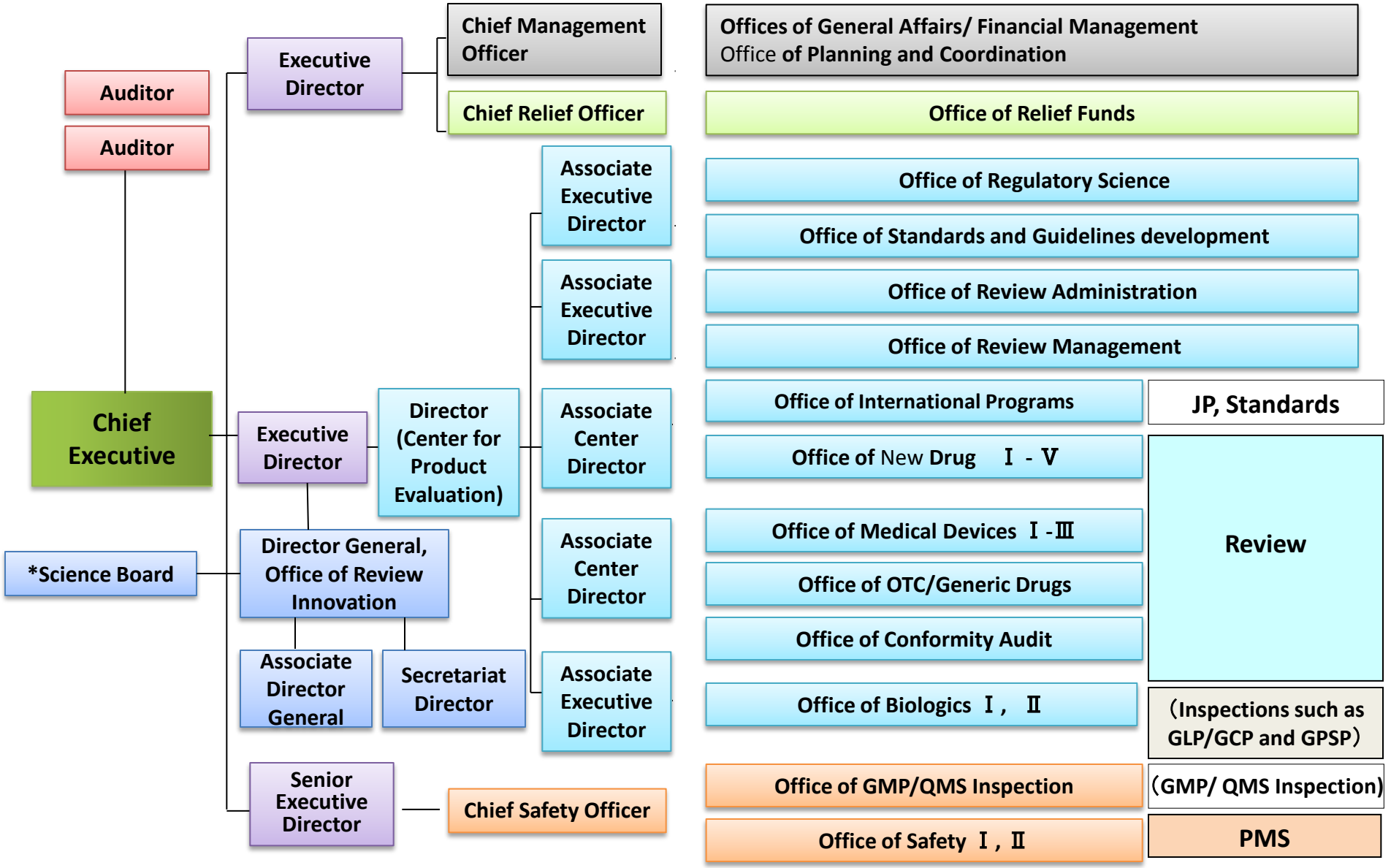
Nobuhiro Yamada
President, University of Tsukuba

Kazuhiko Yamamoto
Professor, Graduate School of Medicine, the University of Tokyo

Teruko Yamamoto
Professor, Graduate School of Dentistry, Tohoku University

Annex 2

Organization Chart of PMDA as of April 2012



Annex 3

List of the Office of Review Innovation Members

Office of Review Innovation

Director General

Dr. Hideo Utsumi, Executive Director, PMDA

Associate Director General

Dr. Takao Yamori, Director of Center for Product Evaluation, PMDA

Deputy Associate Director General

Dr. Akihiro Umezawa, Deputy Center Director (for Cellular and Tissue-based Products), PMDA

Deputy Associate Director General

Dr. Ichiro Sakuma, Deputy Center Director (for Medical Devices), PMDA

Secretariat Director

Dr. Soichiro Isobe, Office Director, Office of Review Management, PMDA

Deputy Secretariat Director

Mr. Masakatsu Imoto, Review Director, Office of Medical Devices III, PMDA

Annex 4.

Five-Year Strategy of Medical Innovation (Excerpt)

III–1–5 Acceleration of the review, improvement of the review quality, strengthening of safety measures

1. Increasing the number/improving the quality of reviewers and safety staff (including those who are responsible for regenerative medicinal products)

(2) PMDA makes active use of the Science Board which is newly established internally and is composed of external experts from medical, dental, pharmaceutical, and engineering fields. PMDA strengthens cooperation and communication with academia and healthcare professionals in line with the principle of regulatory science, and promotes adequate response to products using advanced science and technology as represented by the Pharmaceutical Affairs Consultation on R&D Strategy. PMDA also enhances its review system by inviting external experts with superior insights through the framework of the Joint Graduate School Program and the Centre for the Alliance between Medicine and Engineering（This should be implemented annually by MHLW）.

III–2–1–3 Enhancement of the system and its operation to accelerate the practical use of regenerative medicines

1. Increasing the number/improving the quality of reviewers and safety staff

(2) PMDA makes active use of the Science Board which is newly established internally and is composed of external experts from medical, dental, pharmaceutical, and engineering fields. PMDA strengthens cooperation and communication with academia and healthcare professionals in line with the principle of regulatory science, and promotes adequate response to products using advanced science and technology as represented by the Pharmaceutical Affairs Consultation on R&D Strategy. PMDA also enhances its review system by inviting external experts with superior insights（This should be implemented annually by MHLW）.