PMDA Updates

April, 2020

News

1. Message from Head of International Programs

Mr. UZU
Senior Executive Director
and
Head of International Programs

The world is now facing difficulties to fight against the novel coronavirus disease (COVID-19) which we have never experienced. Although this reminds me of the influenza pandemic in 2009, the situation is more serious this time considering the availability of treatments and diagnostic tests. In the ever-changing circumstances, PMDA has been making every effort to respond by cooperating with MHLW and other organizations (Please refer to the announcement by the Chief Executive: 1, 2, 3, 4 and 5).

There still remains numerous unmet medical needs, not just for the treatments of novel coronavirus disease but for other various diseases such as intractable disease and malignant tumor, even though many innovative drugs have been developed recent years. Timely delivery of treatments to healthcare settings quickly is expected by those who are suffering. At the same time, it is necessary to take measures to minimize adverse health events caused by medical products. Development, manufacturing, delivery and providing safety information of medical products cannot be completely managed in a single country, instead, they are borderless. How we can work together to overcome this crisis surely depends on the close collaboration between regulators. PMDA has been collaborating and cooperating with other regulatory authorities of the US and Europe as well as WHO, and we will keep contributing to activities at ICMRA and other initiatives proactively.

As for the Asian region where Japan is located, PMDA established "Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC)" in 2016 and we have been contributing to human resource development of Asian regulatory authorities. In current circumstance, the business programs of this year may not progress as scheduled. Still, PMDA continues to prepare cooperative activities to meet the needs of each Asian country and will advance cooperation in human resource development proactively when the conditions allow.

UZU Shinobu
Senior Executive Director, Head of International Programs
Pharmaceuticals and Medical Devices Agency

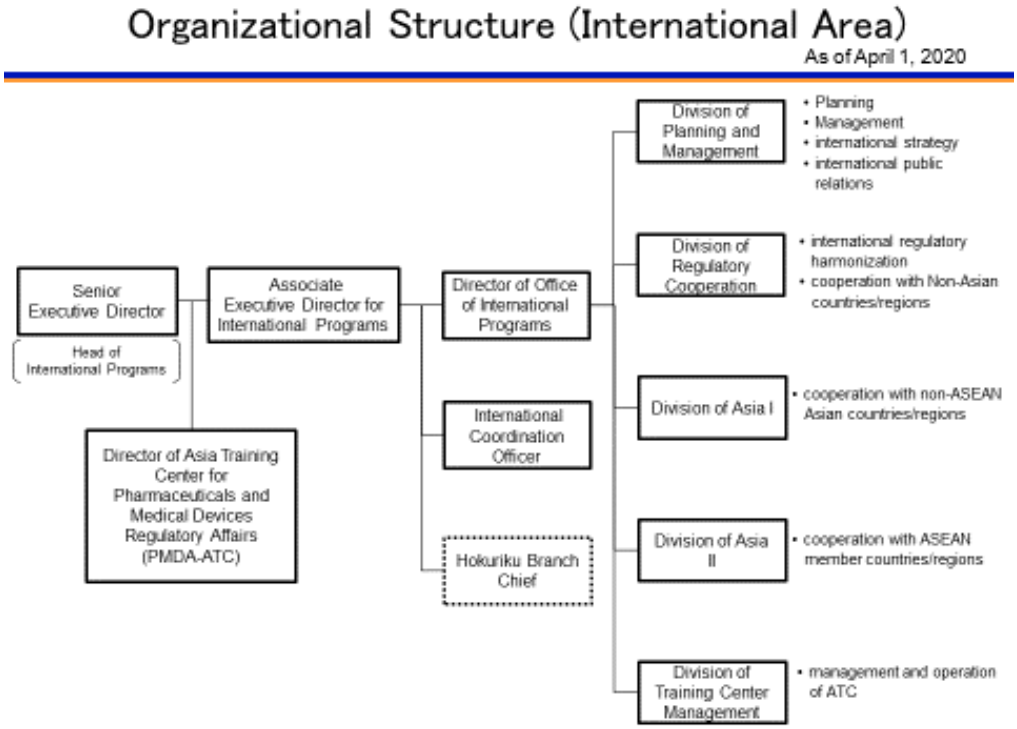
2. PMDA to Announce Organizational Restructuring of Office of International Programs: For Further Strengthening of Cooperative Relationships with Asian Countries/Regions

PMDA implemented an organizational restructuring of Office of International Programs on April 1, 2020[1]. This effort was made to respond to "Grand Design for Asian Pharmaceutical and Medical Device Regulatory Harmonization," published by Japanese government last year, as well as to transform "Asia First"— one of 4Fs[2] pursued by Dr. FUJIWARA (Chief Executive of PMDA)— into concrete actions. As part of this restructuring, Division of Asia I and Division of Asia II were newly established in the Office of International Programs with the appointment of International Coordination Officers and other dedicated staff members for priority countries/regions in Asia. This allows us to further promote dialogue and collaboration with the partner counties/regions and to offer individualized cooperative activities based on an understanding of the partner countries/regions' needs. Also, Division of Training Center Management was newly created to operate the projects concerning Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC), the pillar of cooperative activities with Asian countries/regions. The division plans to bolster its domestic and overseas ATC seminars[3), 4)].

Further, the governance systems and public relations in Office of International Programs were also strengthened. Mr. UZU (Senior Executive Director) was appointed as Head of International Programs, and the former Office of International Cooperation was integrated into Office of International Programs in order to enhance the governance and to improve the efficiency of international operations. We have also allocated Chief, International Public Relations Section in Division of Planning and Management (renamed from Division of Planning and Coordination) to organize the services of international public relations.

With regard to bilateral cooperation activities with non-Asian countries and multilateral activities with ICH, IMDRF and ICMRA, which we have traditionally focused on, Division of Regulatory Cooperation (division name stays the same in English) continues to engage in and to further strengthen these activities.

1) Organizational Structure of International Area (as of April 1, 2020)



2) 4Fs: Four service areas that Dr. FUJIWARA (Chief Executive of PMDA) especially prioritizes in PMDA's activities, i.e. Patient First, Access First, Safety First, and Asia First.
https://www.pmda.go.jp/english/about-pmda/outline/0009.html
3) List of Seminars in FY 2019 (10 seminars provided)
4) List of Seminars in FY 2020 (planned)

3. Activities of PMDA's Patient Centricity Working Group - Workshop for the COML Registered Committee Bank Members -

On March 7, PMDA's Patient Centricity Working Group members participated in a Workshop for the registered committee bank members of the COML, Medical Human Rights Center, a certified NPO, and exchanged opinions. In this study session, PMDA's Patient Centricity Working Group members introduced the main services of PMDA such as product reviews, safety measures and relief services and also pharmaceutical regulations. Registered committee bank members of the COML asked questions on these topics and exchanged opinions with PMDA members on PMDA's activities from the patients' point of view. Experiences from these interactions are to be considered when PMDA discusses how patient involvement should be in near future.

PMDA staff giving a speech at the workshop

English translations of review reports

The followings are current information about English version of review reports on PMDA website.

Pharmaceuticals

http://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html

Brand Name	Non-proprietary Name	Posting date
Tremfya [Initial Approval]	guselkumab (genetical recombination)	April 9

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 371 (March 24, 2020)

1. For the Promotion of Pediatric Clinical Development (development and safety measures) through Active Use of Medical Information Database
   (Part 2) Assessment of Adverse Events with Use of the Pediatric Medical Data Collecting System and Efforts Focused on Future Utilization of the System
2. Handling of Relative Contraindications associated with Revision of Instructions for Package Inserts of Prescription Drugs
3. Important Safety Information
   1. Rotigotine
   2. Aminolevulinic acid hydrochloride]
4. Revision of Precautions (No. 311)
   Rotigotine (and 8 others)
5. List of Products Subject to Early Post-marketing Phase Vigilance

http://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0017.html

Pharmaceuticals Revisions of PRECAUTIONS (March 31, 2020)

- Spiperone
- Timiperone
- Pipamperone hydrochloride
- Sultopride hydrochloride
- Fluphenazine decanoate
- Sulpiride
- Nemonapride
- Haloperidol
- Haloperidol decanoate
- Bromperidol
- Mosapramine hydrochloride
- Pimozide
- Blonanserin
- Perospirone hydrochloride hydrate
- Aclatonium napadisilate
- Pegfilgrastim (genetical recombination)
- Pembrolizumab (genetical recombination)
- Aciclovir (oral and injectable dosage forms)
- Valaciclovir hydrochloride
- Amenamevir
- Baloxavir marboxil

http://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0007.html

PMDA Medical Safety Information Extra 1 (April)

Reminder Series No. 1 (Precautions in Ventilator Use, etc.)

https://www.pmda.go.jp/english/safety/info-services/safety-information/0001.html

PMDA Medical Safety Information Extra 2 (April)

Reminder Series No. 2 (Precautions in Handling Tracheal Tubes)
https://www.pmda.go.jp/english/safety/info-services/safety-information/0001.html

PMDA Medical Safety Information No.29 Revised version (April)

Precautions in ECG Monitoring
https://www.pmda.go.jp/english/safety/info-services/safety-information/0001.html

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
June 14-18	56th DIA 2020 Global Annual Meeting	Virtual
June 30-July 3	32th DIA Europe Meeting	Virtual

Reports from overseas

Our officers deliver lively reports of their activities at their stationed overseas authorities.

EMA Regulatory Science Strategy to 2025 and its Publication Process

This month I would like to introduce EMA's Regulatory Science Strategy 2025 [1)] which was published on 31th March 2020.

The aim of the strategy is to provide a plan for advancing regulatory science over the next five years for both human and veterinary medicines. It comes in response to the dramatic acceleration of the pace of innovation in recent years and the need for regulators to be ready to support the development of increasingly complex human and veterinary medicines that combine different technologies [2)]. The document is composed of vision, strategies and goals to fulfill EMA's motto. For further details, see EMA's Regulatory Science Strategy 2025.

In this report I would also like to focus on the process of its publication. EMA organized workshops for human and veterinary medicines before starting a six-month public consultation in December 2018. After the public consultation, EMA organized separate human and veterinary medicines workshops to share the outcome of the analysis of the public consultation and identify concrete actions in order to implement the key goals and recommendations. A wide range of stakeholders joined these workshops, including healthcare professionals, patient representatives, pharmaceutical industry, academia and other regulatory bodies. The inputs from stakeholders during public consultation and workshops have been reflected in the final document. The materials used in the workshops and the final analysis and summaries of public consultation results have also been published on EMA website [3)]. These documents will help further understanding EMA's Regulatory Science Strategy 2025.

Although PMDA also takes a similar approach to the development of key guidelines/documents in some areas, I think this approach may give stakeholders the opportunity to have a clear understanding of the guidelines/documents to be developed and lead to a better use of the guideline/document after its publication.

1) https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/ema-regulatory-science-2025-strategic-reflection_en.pdf
2) https://www.ema.europa.eu/en/news/advancing-regulatory-science-eu-new-strategy-adopted
3) https://www.ema.europa.eu/en/about-us/how-we-work/regulatory-science-strategy#consultation-process-section

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