PMDA Updates

December, 2020

News

1. ICH Athens virtual meeting

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) held a virtual meeting on November 5 and from 16 to 18, 2020. This virtual meeting was an alternative meeting of the face to face meeting scheduled from November 14 to 19 in Athens, Greece due to the COVID-19 pandemic situation. Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs), Dr. SATO Junko (Director of Office of International Programs) and Mr. YASUDA Naoyuki (Director of Office of International Regulatory Affairs, Ministry of Health, Labour and Welfare (MHLW)) attended with other officers from MHLW and PMDA.

Main outcomes from the meeting included the re-election of Management committee chair and vice-chair, and updated the status of current Working Groups. For the Management committee re-election, Dr. Theresa Mullin (FDA, United States) and Dr. NAKASHIMA Nobumasa (MHLW/PMDA, Japan) were re-elected as Chair and Vice Chair respectively to serve a one-year term. For the status of the Working Groups, currently ICH hold 33 Working Groups and we've noted significant milestones reached recently; such as, E2B(R3), Q3D(R2), E14/S7B , and M7. E2B(R3) reached Step4 (Adoption of an ICH Harmonised Guideline) for v1.1 of the User Guide of EDQM terminologies for Dose Forms and Routes of Administration for Individual Case Safety Reports. Q3D(R2) reached Step2(Adoption of the Draft Guideline) for revision of Appendixes 2 and 3 on Elemental Impurities which is comprised of extracts and addition of a new Appendix 5 on Limits for Elemental Impurities by Cutaneous and Transcutaneous Route. E14/S7B and M7 reached Step2 for Question & Answer document. A new ICH Reflection Paper on Patient-Focused Drug Development (PFDD), which identifies key areas where incorporation of the patient's perspective, presents opportunities for development of new ICH Guidelines, will be made available on the ICH website for public consultation.

The next ICH meeting was planned to be held on May 31- June 2, 2021, in Inchon, South Korea, but due to the COVID-19 pandemic situation it will be held virtually.

2. PMDA-ATC Pharmaceuticals Review Webinar 2020 for NPRA, Malaysia

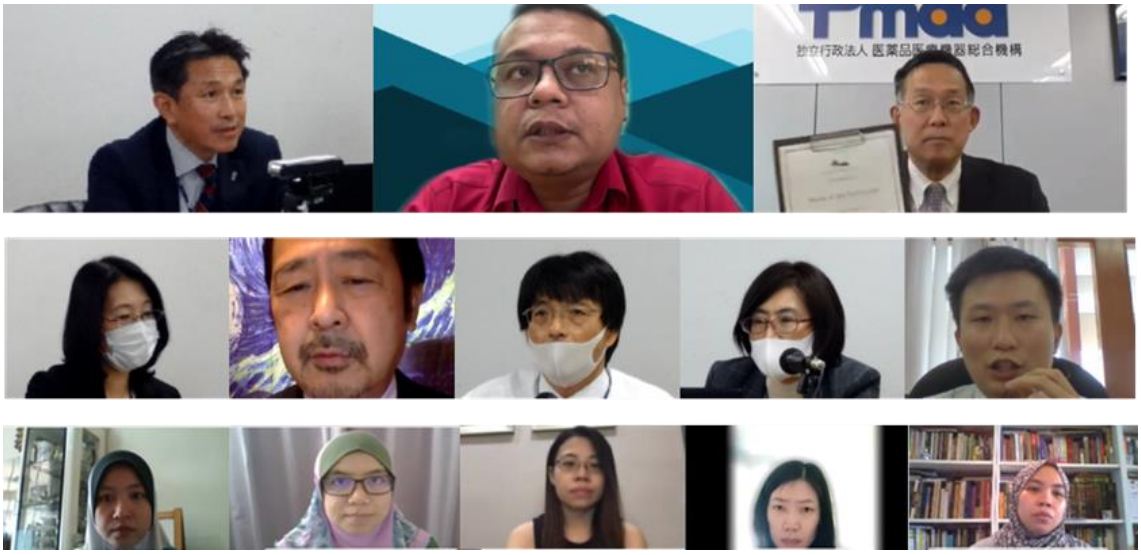
On November 6, PMDA held a seminar entitled "PMDA-ATC Pharmaceuticals Review Webinar 2020 for NPRA, Malaysia". A total of 19 regulators of National Pharmaceutical Regulatory Agency (NPRA), who are engaged in the review of pharmaceuticals, participated in the webinar.

The webinar opened with the remarks by Mr. UZU Shinobu (Director of Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs of PMDA) and by Dr. Zaril Harza Zakaria, Head of Evaluation & Safety of Investigational New Product Section, Centre of Product & Cosmetic Evaluation of NPRA, and the lecturers from PMDA and NPRA shared the information on the regulatory framework for FIH clinical trials and the experiences in GCP inspections, and the lecturers from Japanese academia and PMDA introduced the experience in FIH clinical trials and the review of FIH studies in Japan.

At the end of the webinar, Dr. FUJIWARA Yasuhiro (Chief Executive of PMDA) awarded the course completion certificate to each participant virtually by recorded video, and Dr. Zaril gave the closing remarks.

Please refer to the following web site for the details of PMDA-ATC Pharmaceuticals Review Webinar 2020 for NPRA, Malaysia.

https://www.pmda.go.jp/english/symposia/0181.html



Top row from left: Mr. UZU Shinobu (Director of Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs from PMDA), Dr. Zaril Harza Zakaria (Head of Evaluation & Safety of Investigational New Product Section, Centre of Product & Cosmetic Evaluation from NPRA), FUJIWARA Yasuhiro (Chief Executive from PMDA)
Middle row: Lecturers
Bottom row: some of the NPRA participants.

3. ICH 30th Anniversary Session at 17th DIA Japan Annual Meeting

This year marked the 30th anniversary of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). To celebrate this, commemorating sessions were held at the 17th DIA Japan Annual Meeting on November 8-10. There were five ICH sessions in total, including a session on ICH's organization and management, and four sessions on each of the following 4 areas, Quality, Safety, Efficacy, and Multidisciplinary. In those sessions, the role of Japan in the past 30 years and the future expectations were mainly focused and discussed.

Mr. MORI Kazuhiko (former Councilor of Ministry of Health, Labour, and Welfare, MHLW) and Dr. TOMINAGA Toshiyoshi (former Associate Executive Director for International Programs) chaired the session on ICH's organization and management. In this session, Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs) talked about the ICH's 30 years history and achievements as well as the future from a Japan perspective. Mr. YASUDA Naoyuki (Director of Office of International Regulatory Affairs of MHLW) made a presentation on cooperation with stakeholders and addressing innovative technologies from a Japanese perspective.

Other participants from PMDA in the sessions for each area included Dr. SATO Junko (Director of Office of International Programs), Dr. UYAMA Yoshiaki (Director of Office of Medical Informatics and Epidemiology), and Dr. KISHIOKA Yasuhiro (International Liaison Officer). Dr. SATO and Dr. UYAMA chaired the Multidisciplinary and Efficacy sessions respectively and led the fruitful discussions. Dr. KISHIOKA attended the Quality session and presented overview of Q12 guideline, Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management, as a recent achievement in ICH Quality area.

Lively discussions took place in each session. Moreover, many audiences were participated. We could say all of these commemorative sessions were successful. These commemorative sessions were took place following the DIA Global Annual Meeting and DIA Europe Meeting which were held in June and July respectively, and DIA Japan Annual Meeting was the last one as the ICH 30th Anniversary event. It was a fitting end to a series of events.

The presentation of Dr. NAKASHIMA

4. PMDA-ATC Medical Devices Webinar 2020

From November 16 to 20, 2020, PMDA held a webinar entitled "PMDA-ATC Medical Devices Webinar 2020". PMDA was endorsed as a formal Center of Excellence (CoE) for medical device set by Asia-Pacific Economic Cooperation, Life Sciences Innovation Forum, Regulatory Harmonization Steering Committee (APEC-LSIF-RHSC) in June 2020, and it is the first CoE workshop held after the endorsement.

This webinar was intended for officials of overseas regulatory agencies involved in the review of medical devices or in vitro diagnostics (IVDs). A total of 27 regulators from Azerbaijan, Bahrain, Botswana, Brazil, Chile, India, Indonesia, Malaysia, Myanmar, Oman, Peru, Philippines, Saudi Arabia, South Africa, Sri Lanka, Taiwan, Thailand and Zimbabwe joined the webinar.

Recorded lectures by PMDA staff, representatives from National Cancer Center, and Clinical Research Administration Center of Tohoku University Hospital were provided as preliminary training materials. The lectures covered biological safety, Quality Management System (QMS) and Medical Device Single Audit Program (MDSAP), international standardization, and registered certification bodies, which then were followed during the live webinar by Questions and Answer sessions on the 1st and 2nd day. The participants actively engaged in all discussions.

On the 3rd to 5th days, the group works exploring case studies were provided by PMDA on such topics as Review and Approval of Medical Devices and In Vitro Diagnostics (IVDs), and Post-market Safety Measures for Medical Devices. The participants deepened their understanding throughout the group works.

From the top left: Dr. FUJIWARA Yasuhiro (Chief Executive of PMDA), Mr. UZU Shinobu (Director of the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs from PMDA), Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs of PMDA), Dr. SATO Junko (Director of the Office of Internaltional Programs) and Dr. ISHI Kensuke (Senior coordinator of PMDA)
At the bottom: Some of the participants at the webinar

Please refer to the following web site for the details of PMDA-ATC Medical Devices Webinar 2020.
https://www.pmda.go.jp/english/symposia/0178.html

5. Malaysia-Japan Bilateral Meeting

PMDA held Malaysia-Japan Bilateral Meeting together with National Pharmaceutical Regulatory Agency (NPRA) via the internet on November 17.

Key participants from PMDA included Dr. FUJIWARA Yasuhiro (Chief Executive), Mr. UZU Shinobu (Senior Executive Director), Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs) and Dr. SATO Junko (Director of Office of International Programs). In addition, from Ministry of Health, Labour and Welfare (MHLW), Dr. YASUDA Naoyuki (Director of Office of International Regulatory Affairs) participated. Key participants from Malaysia included Datin Dr. Faridah Aryani Md Yusof (Senior Director of Pharmaceutical Services Programme) and Dr. Hasenah Ali (Director of NPRA).

In the bilateral meeting, Datin Dr. Faridah and Dr. FUJIWARA made opening remarks and then measures against COVID-19 in Malaysia and Japan were shared. After that, any other topics of Malaysia-Japan cooperation concerned with pharmaceutical regulation was discussed by the participants. Although it is difficult to hold face-to-face events due to COVID-19 outbreak, PMDA and NPRA decided to continue the effective cooperation.

The photo of the participants.
Left picture: Dr. FUJIWARA Yasuhiro from PMDA
Right picture: Datin Dr. Faridah from Senior Director of Pharmaceutical Services Programme (center) and Dr. Hasenah from NPRA (the second from the left).

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
Xeljanz [Partial Change Approval]	tofacitinib citrate	November 17

Safety Information

Pharmaceuticals and Medical Devices Safety Information No. 378 (December 1, 2020)

1. Utilization of Risk Management Plan (RMP) of Drugs and Request for Participation in a Survey Investigating Utilization of Safety Information through PMDA Medi-navi
2. Important Safety Information
   (1) Nivolumab (genetical recombination)
3. Revision of Precautions (No. 318)
   Glatiramer acetate (1 other)
4. List of Products Subject to Early Post-marketing Phase Vigilance

https://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0018.html

Pharmaceuticals Revisions of PRECAUTIONS (December 8, 2020)

- Clopidogrel sulfate
- Prasugrel hydrochloride
- Venetoclax
- Posaconazole
- Eculizumab (genetical recombination)

https://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0008.html

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
January 13-14	8th Thailand - Japan Symposium	Virtual
January 18-21	PMDA-ATC with National Cancer Center MRCT Webinar 2021	Virtual
February 1-4	PMDA-ATC Pharmacovigilance Webinar 2021	Virtual

Reports from Overseas

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

EMA public stakeholder meeting on COVID-19 vaccines

On 11th December 2020, EMA held the public stakeholder meeting on COVID-19 vaccines [1)]. This virtual meeting was aimed to inform the public and stakeholders about EU regulatory processes for the development, evaluation, approval and safety monitoring of COVID-19 vaccines, including EMA's role. One of the objectives was also to listen to the voices from the public and stakeholders, so that these can be considered in the relevant regulatory processes [2)]. It was announced during the meeting that approximately 3,500 were watching the live stream.

EMA staff members explained the regulatory processes of COVID-19 vaccines in the EU in plain language, followed by the statements from multi-stakeholders such as patients/carers, consumers/citizens, industry, healthcare professionals and academia. The EMA staff members together with the chair responded to the questions and concerns which were raised and not covered by their presentations. The presentation slides are available [1)] and a similar description of the regulatory processes is provided on EMA website [3)].

In addition, EMA has been implementing exceptional measures to maximize the transparency of its regulatory activities during the COVID-19 pandemic [4)]. It's of interest to me that EMA has been contributing to ensure public trust in COVID-19 vaccines through a holistic approach; not only by conducting robust scientific assessment but also by working on other aspects such as the ones above.

1) https://www.ema.europa.eu/en/events/public-stakeholder-meeting-development-authorisation-safe-effective-covid-19-vaccines-eu
2) https://www.ema.europa.eu/en/documents/agenda/agenda-ema-public-stakeholder-meeting-covid-19_en.pdf
3) https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/covid-19-vaccines-development-evaluation-approval-monitoring
4) https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/transparency-exceptional-measures-covid-19-medicines

Dr. KISHIOKA Yasuhiro
PMDA's International Liaison Officer stationed at EMA in the Netherlands

