PMDA Updates

January, 2021

News

1. Chief Executive Dr. FUJIWARA's New Year Message for 2021

I would like to wish you all a Happy New Year.

Last year, COVID-19 pandemic devastatingly affected global health. Since the spread of SARS-CoV-2 infection has not subsided yet, we are still forced to live with the virus. The PMDA also continues our operations in light of the current COVID-19 situation.

To address COVID-19, the PMDA has been working to ensure seamless development of COVID-19 related products by providing scientific advice to sponsors from early development stage of those products. Also, we have been reviewing regulatory applications for marketing approval in a timely manner. In addition, we have taken several actions to accelerate research and development to bring COVID-19 vaccines into practice promptly, including the publication of our Principles on Evaluation of COVID-19 Vaccines and the offer of free scientific advice for COVID-19 vaccines development.

Dr. FUJIWARA

In addition to those actions for COVID-19 related products, with a recognition that other operations for non-COVID-19 related products are just as important to protect public health, we will make efforts to even workloads by flexible personnel allocation and improve work environment by promoting its digital transformation to carry out PMDA's operations smoothly even under this COVID-19 situation.

The operations of PMDA consist of those in three key areas - product reviews, post-marketing safety measures and relief services for adverse health effects, cross-sectional operations in the area of regulatory science and international programs, and administrative operations that support them. The PMDA is constantly facing new challenges, but by enhancing the capabilities of our staff members and making the most of their scientific expertise and Information Technology, we continue to make efforts to meet the needs of patients in Japan and the world.

Lastly, bearing in mind that we play an integral part in protecting public health including response to COVID-19 pandemic, we will make every effort to deliver necessary medical products to patients.

Once again, I wish you all health, prosperity, and happiness in the year 2021.

2. MDSAP Forum 2020

MDSAP Forum 2020 was held from November 30 to December 4, 2020. Medical Device Single Audit Program (MDSAP) is an international joint program which utilizes third party auditing organizations, and its purpose is to realize single audit in the field of medical device QMS audit. MDSAP launched its activities in 2012. The forum is annually held and the participants are the stakeholders of MDSAP, which include regulatory authorities, MDSAP auditing organization, etc. Because of the influence by the COVID-19, the forum was remotely conducted this year.

The main topic was the acceptance of the results of remote audits. Remote audit is a type of audit performed by using ICT tools. The participants discussed if remote audits can be utilized for MDSAP audits based on risk based approach, taking into consideration of the experience of MDSAP. The result of the discussion was issued at the end of last year (Please refer to the link below[1]). During the forum, PMDA provided updates on the status of acceptance of MDSAP audit outcome as a feedback from Japan. In fiscal 2019, MDSAP audit outcomes were utilized in approximately 41% of all QMS inspection applications. (The transition of the acceptance rate is open to the public on our website[2].)

The next forum is scheduled in December 2021 in Brazil.

1) https://www.fda.gov/media/144883/download
2) https://www.pmda.go.jp/english/review-services/gmp-qms-gctp/0004.html

3. The 2nd Vietnam-Japan Symposium

The 2nd Vietnam-Japan Symposium was held on December 1, co-hosted by Drug Administration of Vietnam (DAV) and PMDA. Considering the global pandemic of COVID-19, this conference was conducted virtually this year. It was attended by more than 230 people in Vietnam and Japan. The participants from Japan included Dr. SATO Junko (Director of Office of International Programs from PMDA), Dr. YABANA Naoyuki (International Coordination Officer from PMDA) as well as staff from Office of Manufacturing Quality for Drugs and Office of International Programs. From DAV, Mr. Ta Manh Hung (Deputy Director, Drug Quality Management Division from DAV), Mr. Nguyen Ngoc Anh (Deputy Director, Drug Regisration Division, DAV), and other staff participated in the symposium.

In this symposium, the sessions on Review Process, GMP Inspection, E-Labeling were held. Speakers answered the questions collected from attendees before the symposium to each session and facilitated mutual understanding of regulations.

The details of the symposium are available at the following link.
https://www.pmda.go.jp/english/symposia/0185.html

Following the symposium, DAV and PMDA had a bilateral meeting on December 3.to discuss further cooperation in the area of pharmaceutical regulation. In the meeting, it is confirmed that requirement of clinical trial data with Vietnamese population for a vaccine or a biosimilar product application would be waived if those products have already been approved in Japan, because Japan is designated as a reference country in Vietnam.

Group photo of participants in symposium

4. PMDA-ATC Pharmaceutical Review Webinar 2020 for Drug Administration of Vietnam

On December 2, PMDA held an on-line seminar entitled "PMDA-ATC Pharmaceutical Review Webinar 2020 for Drug Administration of Vietnam." This webinar is the course for regulatory agencies, DAV. A total 6 regulators experts from Vietnam (5 DAV staff members and 1 external expert) participated in the webinar.

The program of the webinar included lectures by PMDA staff on the topics of the Review of Vaccines, the Review of Biosimilars and the Review of Chemistry, Manufacturing and Control (CMC), followed by practical case studies.

Please refer to the following web site for the details of Pharmaceutical Review Webinar 2020 for Drug Administration of Vietnam.
https://www.pmda.go.jp/english/symposia/0186.html




From top left: Dr. FUJIWARA Yasuhiro (Chief Executive), Mr. UZU Shinobu (Director of Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs) and Dr. YABANA Naoyuki (International Coordination Officer)
At the bottom: DAV participants in webinar

5. Asia-Pacific Economic Cooperation, Life Sciences Innovation Forum, Regulatory Harmonization Steering Committee (APEC- LSIF-RHSC) Meeting

Asia-Pacific Economic Cooperation, Life Sciences Innovation Forum, Regulatory Harmonization Steering Committee (APEC- LSIF-RHSC) web conference was held on December 11, 2020. Key participants from Japan included Dr. NAKASHIMA Nobumasa (Associate Executive Director for International Programs, PMDA) and staff of MHLW.

The APEC-LSIF-RHSC aims to "promote strategic framework for regulatory convergence of medical products regulation", and is co-chaired by Dr. NAKASHIMA along with Dr. Limoli from the U.S. FDA. Regulatory authorities of APEC economies, representatives from industry coalition (pharmaceuticals, bio-pharmaceuticals, medical devices) and academia participated in the meeting. APEC-LSIF-RHSC has established Centers of Excellence (CoEs) focusing on seven Priority Work Areas (PWAs) to offer workshops. PMDA was endorsed to become formal CoEs for MRCT/GCP inspection PWA, Pharmacovigilance PWA and Medical Device PWA. At the meeting, PMDA reported the result of PMDA-ATC Seminar and Webinar 2020, and announced the PMDA-ATC Seminar/Webinar to be held in 2021. PMDA also announced that PMDA-ATC would co-organize MRCT/GCP webinar with National Cancer Center (NCC) of Japan and enhance the training program from investigator's aspect.

Also, proposal which hold "RHSC Forum" about topics that are not part of any PWA core curriculum was endorsed in principle as mechanism to promote information sharing among APEC economies.

6. PMDA-ATC Pharmaceuticals Review Webinar 2020

From December 15 to 17, 2020, PMDA held a webinar entitled "PMDA-ATC Pharmaceuticals Review Webinar 2020".

This webinar was intended for officials of overseas regulatory agencies involved in the review of pharmaceuticals. A total of 26 regulators from Bangladesh, Ethiopia, Iceland, India, Indonesia, Lao People's Democratic Republic, Moldova, Nepal, Philippines, Saudi Arabia, Sri Lanka, Taiwan, Uganda and Zimbabwe joined the webinar.

Recorded lectures by PMDA staff members were provided as preliminary training materials.

The lectures covered start of clinical trial to New Drug Application/Market Authorization Application, review of new drugs, toxicological studies, Good Laboratory Practice (GLP), First in Human (FIH) studies, clinical trials, Good Clinical Practice (GCP), inspections, review of biosimilars, innovative review pathways, review of CMC and review process and consultation for generic drugs, which then were followed during the live webinar by Questions and Answer sessions on the 1st, 2nd and 3rd day. The participants actively engaged in all the

discussions. On the 2nd day of the live case study session, group discussion on the theme of review of new drugs and on the 3rd day of the live case study session, school-style discussion on the theme of review of generic drugs were held to deepen understanding.




From the top left: Dr. FUJIWARA Yasuhiro (Chief Executive of PMDA), Mr. UZU Shinobu (Director of Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs from PMDA), Dr. KIYOHARA Koshin (Senior coordinator of PMDA)
At the bottom: The participants at the webinar

Please refer to the following web site for the details of PMDA-ATC Pharmaceuticals Review Webinar 2020.
https://www.pmda.go.jp/english/symposia/0183.html

English Translations of Review Reports

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

Pharmaceuticals

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

Brand Name	Non-proprietary Name	Posting date
Steboronine [Initial Approval]	borofalan (^{10}B)	December 15
Refixia [Initial Approval]	nonacog beta pegol (genetical recombination)	December 25
Imfinzi [Initial Approval]	durvalumab (genetical recombination)	January 18

Medical Devices

https://www.pmda.go.jp/english/review-services/reviews/approved-information/devices/0003.html

Brand Name	Term Name	Posting date
NeuCure BNCT System [Initial Approval]	neutron irradiation system for boron neutron capture therapy	December 15
NeuCure BNCT Dose Engine [Initial Approval]	treatment planning program for boron neutron capture therapy	December 15
RETISSA Medical [Initial Approval]	laser retinal scanning type eyewear	December 15

Safety Information

Pharmaceuticals Revisions of PRECAUTIONS (December 21, 2020)

- Lidocaine hydrochloride/adrenaline (excluding preparations for dental use)
- Adrenaline (preparations indicated for prolonged action of local anaesthetics and for prevention and treatment of local haemorrhage during surgery)

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

Pharmaceuticals and Medical Devices Safety Information No. 379 (January 7, 2021)

1. Revision of PMDA Medical Safety Information for Ensuring Use of Insulin Syringes
2. Revision of Precautions (No. 319)
   Clopidogrel sulfate (and 4 others)
3. 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

Events

Conferences/Meetings PMDA hosts or participates in:

Date	Title	Location
February 1-4	PMDA-ATC Pharmacovigilance Webinar 2021	Virtual
March 15-16	ICH Management Committee Interim Meeting	Virtual
March 15-19	33rd DIA Europe Meeting	Virtual

Reports from Overseas

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

Updates on COVID-19 in EU

Continuing from the previous month's report, this report also covers COVID-19 related topics. Since I wrote the last report, there was a significant progress in EU. Two COVID-19 vaccines have been granted for conditional marketing authorizations in EU; the first one was on 21st December 2020 [1)] and the second one was on 6th January 2021 [2)]. According to EMA's exceptional measures to maximize the transparency of its regulatory activities during the COVID-19 pandemic [3)], the public assessment reports and other relevant documents have been published in a timely manner [4),5)]. In addition, following the success of 1st EMA public stakeholder meeting on COVID-19 vaccines on 11th December 2020, EMA held the second public stakeholder meeting on COVID-19 vaccines on 8th January 2021 [6)]. In the meeting, the basis for the approval and use of the new COVID-19 vaccines

and how the safety of the vaccines will be assured were presented by CHMP and PRAC chairs, respectively. Furthermore, EMA commentary on conditional marketing authorizations for COVID-19 vaccines has been published in The Lancet [7]. These communication and information transmission as above are ones of the important activities to be recognized as a trusted regulator of medicinal products.

1) https://www.ema.europa.eu/en/news/ema-recommends-first-covid-19-vaccine-authorisation-eu
2) https://www.ema.europa.eu/en/news/ema-recommends-covid-19-vaccine-moderna-authorisation-eu
3) https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/transparency-exceptional-measures-covid-19-medicines
4) https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty
5) https://www.ema.europa.eu/en/medicines/human/EPAR/covid-19-vaccine-moderna
6) https://www.ema.europa.eu/en/events/public-stakeholder-meeting-approval-roll-out-covid-19-vaccines-eu
7) https://doi.org/10.1016/S0140-6736(21)00085-4

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