PMDA Updates

July 2021

News

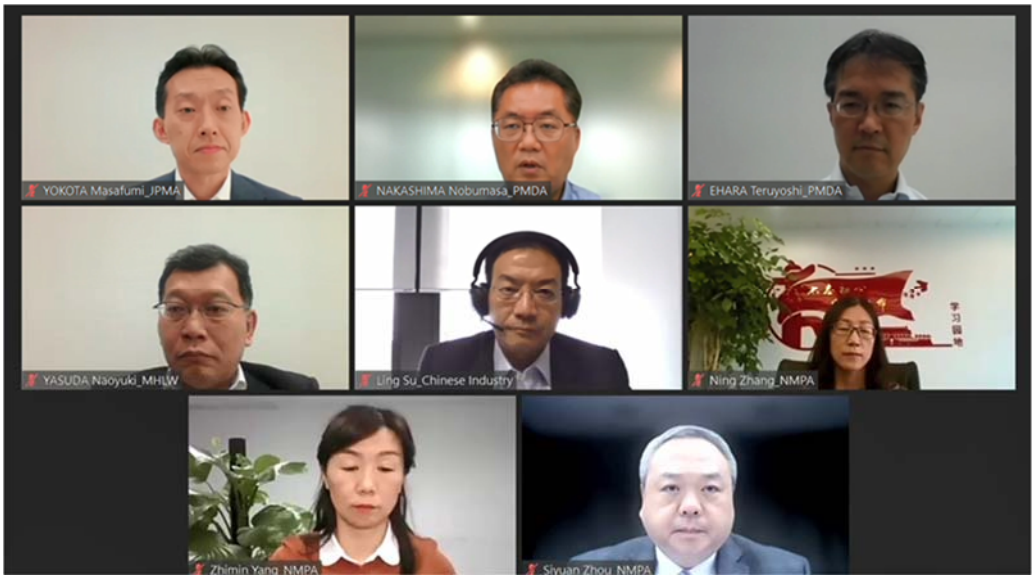
1. China and Japan Regional Joint Public Meeting on ICH

Four years have passed since China became a member of ICH (The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) in 2017. In the beginning of June, ICH held the Incheon virtual meeting, and to discuss that, the China and Japan Regional Joint Public Meeting was held on June 18, 2021.

There were six sessions in all: the first was "Report on ICH Incheon Meeting", the second "Panel Discussion on China-Japan Cooperation in ICH", and the others were the topics focusing on each area of the ICH guidelines—"Clinical Trials", "Real World Data", "Quality" and "Cell Therapy, Gene Therapy, and Regenerative Medicines". In the sessions, our progress, future challenges, and the cooperation between China and Japan were focused on and discussed.

There were lively discussions and Q&A rounds in all the sessions. Many viewers participated from China and Japan. This meeting helped better understand the legislations in each country and implementation of the ICH guidelines—this led us to promote such implementation, a better relationship, and future cooperation between China and Japan through ICH. Please click on the link given below for details of the meeting agenda.

https://www.pmda.go.jp/english/symposia/0206.html



Panel discussion on "China-Japan Cooperation in ICH"

2. PMDA-ATC Regenerative Medicinal Products Review Webinar 2021 for CDSCO, India

On June 3, the PMDA held the "PMDA-ATC Regenerative Medicinal Products Review Webinar 2021 for CDSCO, India." A total of 39 Central Drugs Standard Control Organization (CDSCO) regulators, who are engaged in the review of pharmaceutical products, including regenerative medicinal products, participated in it.

The webinar was opened with remarks by Dr. SATO Daisaku (Chief Management Officer, PMDA) and Mr. Sanjeev Kumar (Deputy Drugs Controller (India), CDSCO). Subsequently, speakers from the PMDA and CDSCO shared information on the regulatory framework for regenerative medicinal products, and the former shared the experience of reviewing cell therapy and gene therapy products.

At the end of the webinar, Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA) and Dr. V. G. Somani (Drugs Controller General, CDSCO) gave the closing remarks.

Top row, from left: Mr. Sanjeev Kumar (Deputy Drugs Controller, CDSCO) and others, Dr. V.G. Somani (Drugs Controller General, CDSCO), Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA), PMDA speakers, and Dr. SATO Daisaku (Chief Management Officer, PMDA)

3. Joint MHLW/PMDA-USP Workshop "Role of Quality in Pharmaceuticals"

The PMDA; Ministry of Health, Labour and Welfare (MHLW); and the United States Pharmacopeia (USP) organized a joint virtual workshop titled "Role of Quality in Pharmaceuticals" on June 16 and 17, 2021. The scientific and strategic priorities of the USP and Japanese Pharmacopoeia (JP), international harmonization, and collaborative projects between the MHLW/PMDA/JP and USP were discussed with more than 1,000 participants mainly from the United States (US) and Asian countries such as Japan.

In the Opening Session, Dr. Ronald T. Piervincenzi (CEO, USP), introduced the role of pharmacopoeia in the COVID-19 era and USP's subsequent response (e.g., quality assessment and handling toolkits for vaccine, supply chain enhancements). In the Keynote Session, Dr. Jaap Venema, USP, and Dr. OKUDA Haruhiro, Pharmaceutical and Medical Device Regulatory Science Society of Japan, shared their views on the critical importance of promoting medicine quality, and each pharmacopoeia's approach to address this issue. In addition, future perspectives on collaboration between the MHLW/PMDA/JP and USP were discussed. Furthermore, experts from Japan and the US made presentations on the key technical topics facing pharmacopoeial stakeholders, including continuous manufacturing, standards for biologics, and the control of nitrosamines. Technical speakers also participated in a panel discussion to answer questions. Based on this workshop, further progress on strong collaboration between the MHLW/PMDA/JP and USP is expected.

The slides presented in the workshop can be accessed through the following link: https://www.pmda.go.jp/english/symposia/0196.html.

4. PMDA-ATC Quality Control (Herbal Medicine) Webinar 2021

From June 22 to 24, the PMDA held the "PMDA-ATC Quality Control (Herbal Medicine) Webinar 2021". It was designed for officials of overseas regulatory agencies engaged in drug reviews, attended by 31 regulators from Azerbaijan, Brazil, India, Indonesia, Malaysia, Myanmar, Philippines, Singapore, Taiwan, Thailand, Uganda, Vietnam, and Zimbabwe.

Before attending the webinar, participants took the PMDA-ATC E-learning course, "Quality Control (Herbal Medicine)" covering the following: Regulation and Review Process of OTC Drugs; Japanese Pharmacopoeia (JP), Japanese Standards for Non-Pharmacopoeial Crude Drugs (Non-JP Crude Drug Standards); Approval Standards for Over-the-Counter Kampo Medicines and Crude Drug Preparations; and Evaluation process and GMP inspection by prefectural authorities.

The webinar comprised lectures on Overview of Regulations on Herbal Medicines in Japan, Quality Evaluation of Crude Drugs (Herbal Medicine), Quality Management and Manufacturing Management of Crude Drugs and Herbal Medicines, and Overview of JP and Approval Standards for Over-the-Counter Kampo Medicines and Crude Preparations, in addition to two virtual site tours via video recordings: 1) Efforts of the Center for Medicinal Plant Resources (Toyama Prefectural Institute for Pharmaceutical Research) on cultivation and processing of medicinal plants and 2) Overview of the manufacturer on storage of crude drugs' raw materials.

On Days 2 and 3, case study sessions, including group discussions on the topics "GMP Inspection for Herbal Medicines" and "Approval of Herbal Medicines based on the Approval Standards", were held. These case studies were conducted as the first trial this year.

This seminar is also one of the activities of the PMDA Hokuriku Branch. The lectures and case studies were carried out by representatives of the Toyama prefectural government, Institute of Natural Medicine of Toyama University, National Institute of Health Sciences, the Federation of Pharmaceutical Manufacturers' Associations of Japan and PMDA staff.

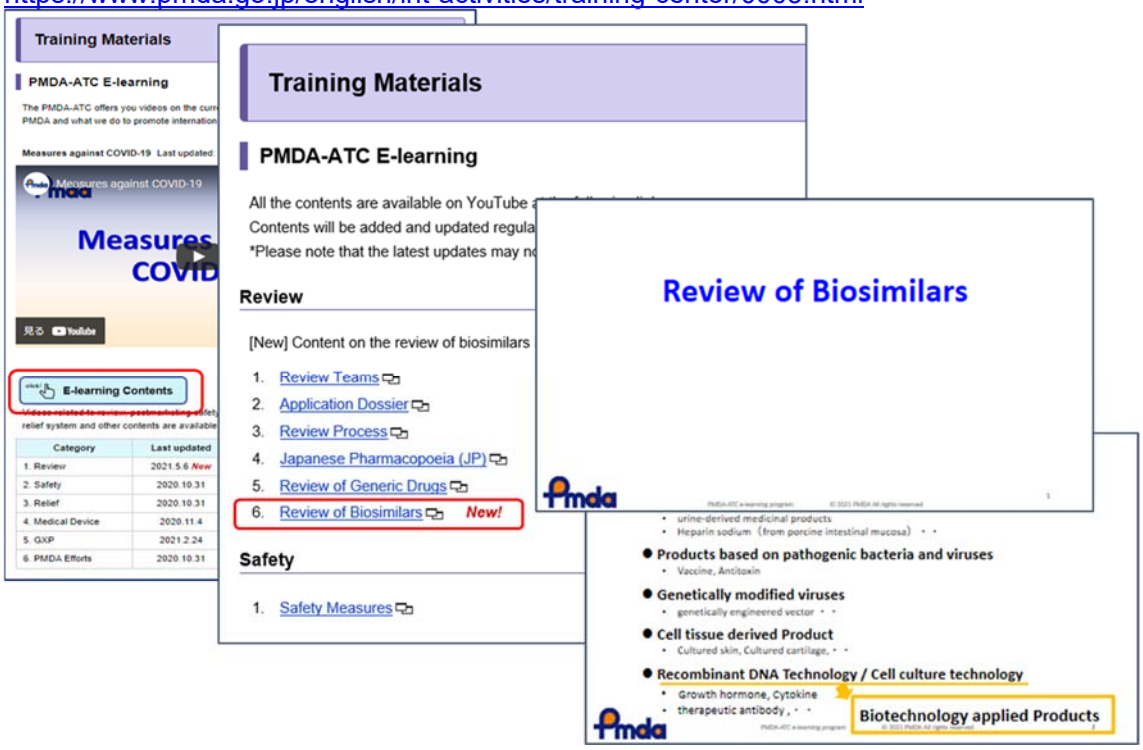
Picture on top: Webinar participants
Picture above, from left: Mr. UZU Shinobu (Director of the Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs, PMDA), Ms. AOYAGI Yumiko (Toyama Prefectural Government), Dr. FUJIWARA Yasuhiro (Chief Executive, PMDA), and Dr. SATO Junko (Office Director, Office of International Programs, PMDA)

Please click on the following link for details of the PMDA-ATC Quality Control (Herbal Medicine) Webinar 2021:
https://www.pmda.go.jp/english/symposia/0204.html

5. PMDA-ATC E-learning Updated Content Information

The PMDA has been providing the PMDA-ATC E-learning system since January 2020. In it, we are pleased to announce the release of new content entitled "Review of Biosimilars." This content introduces the types and characteristics of biological products, the guideline for biosimilars in Japan. The E-learning website can be accessed through the following link:

https://www.pmda.go.jp/english/int-activities/training-center/0003.html



English Translations of Review Reports

The following is the latest information on the English version of review reports on the PMDA website.

Pharmaceuticals

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

Brand Name	Non-proprietary Name	Posting Date
Orkedia [Partial Change Approval]	evocalcet	June 17
Opdivo [Partial Change Approval]	nivolumab (genetical recombination)	June 17
Velexbru [Partial Change Approval]	tirabrutinib hydrochloride	June 17
Comirnaty [Special Approval for Emergency]	Coronavirus Modified Uridine RNA Vaccine (SARS-CoV-2) (active ingredient: tozinameran)	June 17
Mayzent [Initial Approval]	siponimod fumaric acid	July 1

Safety Information

Pharmaceuticals Revisions of PRECAUTIONS (June 21, 2021)

- Nivolumab (genetical recombination)

https://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0009.html

Pharmaceuticals Revisions of PRECAUTIONS (July 7, 2021)

- Coronavirus modified uridine RNA vaccine (SARS-CoV-2)

https://www.pmda.go.jp/english/safety/info-services/drugs/revision-of-precautions/0009.html

Pharmaceuticals and Medical Devices Safety Information No. 384 (July 13, 2021)

1. Blood Monitoring and Rechallenge with Clozapine
2. Important Safety Information
   1. Pembrolizumab (genetical recombination)
   2. Ixekizumab (genetical recombination)
3. Revision of Precautions (No. 324)
   Diclofenac etalhyaluronate sodium (and 3 others)
4. List of Products Subject to Early Post-marketing Phase Vigilance

https://www.pmda.go.jp/english/safety/info-services/drugs/medical-safety-information/0019.html

Events

Conferences/Meetings the PMDA will host or participate in:

Date	Title	Location
August 25–26	PMDA-ATC/AMDC Medical Devices Webinar	Virtual
September 9–15	RAPS Convergence 2021(*)	Virtual
September 9, 13, 14, 16	IMDRF Management Committee Meeting	Virtual
September 20–24	WHO/ICDRA Meeting	Virtual
September 21–24	PMDA-ATC & US FDA Pediatric Review Webinar	Virtual

* The MHLW/PMDA will lead a one-day pre-conference workshop and two sessions.

Reports from Overseas

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

EMA regular press briefing on COVID-19

EMA has been implementing exceptional measures to maximize the transparency of its COVID-19 related activities and strengthening the communication and information transmission during the current pandemic [1)]. In addition to the efforts already introduced in previous reports, EMA has also used social media to reach wider audiences and promote transparency [2)], especially through updates on Twitter, stories and "live chats" with the Executive Director on LinkedIn, contributing to increase awareness of EMA's role. On top of that, EMA has started a new effort since May 2021.

On 12th May 2021, EMA held the first regular briefing for the media on COVID-19 [3)]. The briefing is aimed to provide an update on the most recent activities in the context of the COVID-19 pandemic and has been held every two weeks. Five briefings have been held so far and the most recent one was held on 15th July 2021. After an EMA representative gives an overview of the state-of-play in the first part of the briefing, they subsequently

respond to the questions from the media. The briefing is broadcast live and the recordings are available on EMA website [4]. The regular press briefing is announced on "What's new" [5] in EMA website and the next briefing will be held early September. It's a good opportunity for not only the media but also others to listen to the explanation from EMA directly.

1) https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/transparency-exceptional-measures-covid-19-medicines
2) https://www.ema.europa.eu/en/news-events/press-social-media
3) https://www.ema.europa.eu/en/events/first-ema-regular-press-briefing-covid-19
4) https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines-covid-19
5) https://www.ema.europa.eu/en/news-events/whats-new

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