PMDA Updates

June, 2020

News

1. ICH Vancouver virtual meeting

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) held a virtual meeting on May 13 and from May 25 to 27, 2020. This virtual meeting was an alternative meeting of the face to face meeting scheduled on May 23 to 28 in Vancouver, Canada 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 approval of TITCK, Turkey as a new Regulatory Member and MOPH, Lebanon as a new Regulatory Observer, bringing the ICH Association to a total of 17 Members and 32 Observers.

Revision of M4Q(R1), Common Technical Document (CTD), and "Structured Product Quality Submissions" were adopted as a new topics and agreed to initiate its work. The ICH Assembly additionally supported the establishment of a Discussion Group to further consider the scope and approach of potential new harmonisation activities relating to the following topic proposals, "General Considerations for Model-Informed Drug Development to support Drug Registration" and E4, Dose Response Information to Support Drug Registration. ICH Assembly also agreed to initiate work for revision of ICH Q9 guideline, Quality Risk Management, which had been adopted in last ICH meeting in Singapore with a delayed start time.

The next ICH meeting will be held on November 15-20, 2020, in Athens, Greece, and ICH 30th Anniversary is planning to be held a day before the ICH meeting, November 14, 2020.

2. IPRP Activities

International Pharmaceutical Regulators Programme (IPRP) is established by only regulators for the purpose of creating an environment for them to exchange information on issues of mutual interest, enable cooperation and promote convergence of regulatory approaches for pharmaceutical medicinal products for human use. IPRP was created as a result of the consolidation of the International Pharmaceutical Regulators Forum (IPRF) and the International Generic Drug Regulators Programme (IGDRP) and was officially launched on January 1st, 2018. IPRP is consist of Management Committee (MC) and 8 Working Groups (WGs). Through this MC and WGs, IPRP facilitates discussions on global regulatory issues and on emerging technologies. IPRP also supports the implementation of ICH guidelines and other standards. Furthermore, IPRP is committed to engage with its external stakeholders such as ICH, Industry Associations, and ICMRA etc. to actively take the opportunities to share and cooperate with the IPRP's activities and deliverables.

As of today, IPRP MC consists of 29 regulatory members and 2 observers. There are 8 WGs, The Bioequivalence WG for Generics, The Biosimilars WG, The Cell Therapy WG, The Gene Therapy WG, The Identification of Medicinal Products WG, The Information Sharing WG for Generics, The Nanomedicines WG, and The Quality WG for Generics, which proceed activities based on their Mandate describing WG's scope and objectives. As a member of MC, PMDA attend 7 WGs and have active discussions. In addition to present WGs, MC decided in November 2019 to proceed with the establishment of Pharmacovigilance WG. This WG will initiate activities within 2020 and PMDA is planning to participate.

Once a year, the MC shall elect a MC Chair and MC Vice-Chair for a term of 1 year. The MC elected Dr. SATO Junko as Chair of the IPRP MC to serve for a one-year term at the MC meeting in June 2019.This year during the MC meeting (virtual setting) which was held in end of May, the election of new Chair and Vice-Chair was conducted. Dr. SATO was re-elected as Chair of the IPRP MC to serve until June 2021. As such, PMDA, as Chair of the IPRP MC, will continue to lead IPRP.

As described above, PMDA make a substantial contribution on entire IPRP and take a leadership in all IPRP

activities. PMDA will continue to take the leadership in IPRP activities to make the best use of the information from regulators and asserting Japan's opinions to have active and beneficial discussions.

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
Vizimpro [Initial Approval]	dacomitinib hydrate	June 2
Tecentriq [Partial Change Approval]	atezolizumab (genetical recombination)	June 12
Tecentriq [Partial Change Approval]	atezolizumab (genetical recombination)	June 12
Actemra [Partial Change Approval]	tocilizumab (genetical recombination)	June 12

In Vitro Diagnostics (Review Summary)

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

Brand Name	Non-proprietary Name	Posting date
Espline SARS-CoV-2	SARS-CoV-2 antigen kit	May 21

Safety Information

Pharmaceuticals Revisions of PRECAUTIONS (June 1, 2020)

- Selexipag
- Clopidogrel sulfate
- Clopidogrel sulfate/aspirin

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

Pharmaceuticals and Medical Devices Safety Information No. 373 (June 16, 2020)

1. Recent Trends in Cybersecurity Assurance of Medical Devices
2. Important Safety Information
   (1) Apalutamide
3. Revision of Precautions (No. 313)
   (1) Insulin human (genetical recombination) (vial preparations)
   (2) Insulin aspart (genetical recombination) (vial preparations without description for continuous subcutaneous insulin infusion (CSII) therapy in the Dosage and Administration section)
   (3) Insulin glargine (genetical recombination) (vial preparations) (and 7 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/0018.html

Pharmaceuticals Revisions of PRECAUTIONS (June 16, 2020)

- Memantine hydrochloride
- Bevacizumab (genetical recombination)

- Bevacizumab (genetical recombination) [Bevacizumab biosimilar 1]
- Bevacizumab (genetical recombination) [Bevacizumab biosimilar 2]

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

Reports from Overseas

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

ICH E6 (R3) GCP workshop with PCWP and HCPWP

On 3rd June 2020, EMA organized a virtual workshop on ICH E6 (R3) Good Clinical Practice (GCP) with Patients' and Consumers' Working Party (PCWP) and Healthcare Professionals' Working Party (HCPWP) [1]. The workshop was held in line with the ICH E6 (R3) Stakeholder Engagement Approach [2]. It was designed to cover some key aspects of ICH (e.g. history, organization and guideline development process), the work plan and current progress of ICH E6 (R3) development, and to collect inputs on the revision of GCP from patient and researcher representatives [1].

People have been increasingly aware of stakeholder engagement in pharmaceutical development and regulation. In my view, EMA is the pioneer in this field and has PCWP and HCPWP as well-established platforms for exchange of information and discussion of issues of common interest between EMA and patients, consumers or healthcare professionals. The PCWP and the HCPWP were established in 2006 and 2013, respectively, and both WPs have provided their inputs and feedback on various EMA activities, ultimately contributing to promote a safer and more rational use of medicines [3], [4]. This would be a great reference to establish a sustainable interaction with stakeholders. The past meeting materials of the WPs are published on EMA website [5],[6], which is an information repository to know EMA's activities at different times.

1) https://www.ema.europa.eu/en/events/ich-e6r3-good-clinical-practice-workshop-patients-consumers-pcwp-healthcare-professionals-hcpwp
2) https://www.ich.org/page/reflection-papers#4-1
3) https://www.ema.europa.eu/en/documents/other/mandate-objectives-composition-healthcare-professionals-working-party-hcpwp_en.pdf
4) https://www.ema.europa.eu/en/documents/other/mandate-objectives-composition-patients-consumers-working-party-pcwp_en.pdf
5) https://www.ema.europa.eu/en/committees/working-parties-other-groups/chmp/patients-consumers-working-party/patients-consumers-working-party-meetings
6) https://www.ema.europa.eu/en/committees/working-parties-other-groups/chmp/healthcare-professionals-working-party/healthcare-professionals-working-party-meetings

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