Regulator's actions to combat COVID-19

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Session 4: Promoting Transparency and Convergence in the regulatory landscape,
COVID-19 Vaccine Supply Chain and Regulatory Transparency Symposium 29th June, 2021

International Coalition of Medicines Regulatory Authorities (ICMRA)

- **A voluntary, executive-level, strategic coordinating, advocacy and leadership entity of regulatory authorities work together to**
  - **address current and emerging human medicine regulatory and safety challenges globally, strategically and in an on- going, transparent, authoritative and institutional manner**
  - **provide direction for areas and activities common to many regulatory authorities' missions**
  - **identify areas for potential synergies**
  - **wherever possible, leverage existing initiatives/enablers and resources**
- **24 members, 11 associate members, 1 observer (WHO)**

http://www.icmra.info/drupal/

Collective support in countering the global COVID-19 pandemic

28 April 2020

- **It is together, in the face of this unprecedented crisis of global proportion, that we can find solutions. We, ICMRA members have an important role to play in supporting the worldwide effort. We have stepped up our global collaboration to facilitate and expedite the development and evaluation of diagnostics and therapeutics, including possible vaccines, against SARS-CoV2.**
  - **Actions**
  - **Commitments**
  - **Recommendations**

http://www.icmra.info/drupal/news/statement_on_COVID-19

Discussion on Product Development

http://www.icmra.info/drupal/en/covid-19

- **Global regulatory workshop on COVID-19 Real-World Evidence and Observational studies #4 (13 October, 2020)**
- **Global regulatory workshop on COVID-19 Real-World Evidence and Observational studies #3 (22 July 2020)**
- **Global regulatory workshop on COVID-19 therapeutic development #2 (20 July, 2020)**
- **Global regulatory workshop on COVID-19 vaccine development #2 (22 June, 2020)**
- **Global regulatory workshop on COVID-19 Real-World Evidence and Observational studies #2 (19 May, 2020)**
- **Global regulatory workshop on COVID-19 Real-World Evidence and Observational studies #1 (6 April, 2020)**
- **Global regulatory workshop on COVID-19 therapeutic development #1 (2 April, 2020)**
- **Global regulatory workshop on COVID-19 vaccine development #1 (18 March, 2020)**

Information Sharing with Stakeholders

- **Related regulations**
- **Points to Consider for new product development**
- **Approved products**

etc.

https://www.pmda.go.jp/english/index.html

Capacity Building Activities at PMDA

Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs

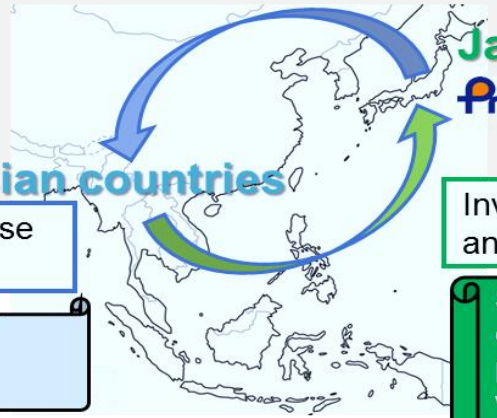
- **Established in April, 2016.**
- **Endorsed as Centers of Excellence (CoE) of APEC-LSIF-RHSC**
- **Promote capacity building and human resource Development through training seminars for Asian regulators**

Action Policy of PMDA-ATC

Contribute to universal health coverage in Asia through developing a foundation for regulatory harmonization in the Asian region.

Visits sites and conducts lectures, case studies and practical trainings.

Provides trainings tailored to local needs for more people.



Invites Asian regulatory representatives and offers training seminars.

Shares Japanese knowledge and experiences in the regulation of pharmaceuticals and medical devices with Asian countries.

Trainings provided in FY2020

Contents	Date	Location
Medical Devices Review	August 26-27, 2020	Online (for Thai FDA)
Quality Control (Herbal Medicine)	September 9-11, 2020	Online
Pediatric Review	September 28-October 1, 2020	Online
Japanese Pharmacopoeia	October 20, 2020	Online (for Thai FDA)
Pharmaceuticals Review	November 6, 2020	Online (for Malaysia NPRA)
Medical Devices Review	November 16-20, 2020	Online
Pharmaceuticals Review	December 2, 2020	Online (for Vietnam DAV)
Pharmaceuticals Review	December 15-17, 2020	Online
Multi-Regional Clinical Trial (MRCT)	January 18-21, 2021	Online
Pharmacovigilance	February 1-4, 2021	Online
Regenerative Medicines Review	March 19, 2021	Online (for Malaysia NPRA)

(As of 15th Feb, 2021)

An Example of Transparency : Chief Executive's Statement

12 statements issued:

- Special Approval for Emergency on First COVID-19 Vaccine in Japan
- PMDA Reveals Principles on Evaluation of COVID-19 Vaccines
- PMDA to Offer Free Scientific Advice for COVID-19 Vaccines Development
- For your Access to Japanese Clinical Trial/Clinical Research Information
- First Approval of Antigen Test for COVID-19
- Special Approval for Emergency on Remdesivir for COVID-19
- Four IVDs Approvals for COVID-19 and Response to the Increased Ventilator Demand
- PMDA Takes Further Steps to Speed up Clinical Development of COVID-19 Products
- PMDA pledge to tackle COVID-19 Pandemic etc.

https://www.pmda.go.jp/english/about-pmda/0002.html

To Accelerate SARS-CoV-2 Vaccine Development

https://www.pmda.go.jp/files/000237021.pdf
https://www.pmda.go.jp/files/000240416.pdf

Principles for the Evaluation of Vaccines Against the Novel Coronavirus SARS-CoV-2

1. INTRODUCTION

- Infectious disease preventi
  antigen. For general cons
  preventive vaccines for in
  for Infectious Diseases (P
  Clinical Studies of Prever
  dated May 27, 2010)[2] can

Principles for the Evaluation of Vaccines Against the Novel Coronavirus SARS-CoV-2 (Appendix 1)

Evaluation of vaccines against variants

April 5th, 2021

Office of Vaccines and Blood Products,

Pharmaceuticals and Medical Devices Agency

1. BACKGROUND

As a result of SARS-CoV-2 virus gene mutation, virus strain(s) which have different infectiveness, transmissibility, and antigenicity are emerged and detected worldwide (https://www.niid.go.jp/niid/ja/diseases/ka/corona-virus/2019-ncov/10220-covid19-36.html (as of March 31, 2021)). In order to prepare for epidemic of variants which can escape from acquired immunity of people recovered from infectious disease caused by SARS-CoV-2(COVID-19) and

Transparency, Convergence, Collaboration

ICMRA
International Coalition of Medicines Regulatory Authorities

CEPI

UNDP

World Health Organization

unicef

Unitaid

World Trade Organization

UNIDO
United Nations Industrial Development Organization