Regulator’s actions to combat COVID-19

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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 ongoing, 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

Discussion on Product Development

- 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.

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

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

Trainings provided in FY2020

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(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
1. INTRODUCTION

Infectious disease prevention using vaccines is the ultimate goal of vaccine development. For general consideration of the importance of preventive vaccines for infectious disease prevention, the Principles for the Evaluation of Vaccines Against the Novel Coronavirus SARS-CoV-2 (Appendix 1) evaluation of vaccines against variants were developed.

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