Ministry of Health & Family Welfare
Government of India

厚生労働省
Ministry of Health, Labour and Welfare
Japan Ministry of Health, Labour and Welfare
(JMHLW)

5th India-Japan Medical Products Regulatory Symposium

(Through WEBEX, 21st & 22nd Dec. 2021)

International Collaboration and Reliance

Presented By

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CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
CDSCO CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

Pmda
独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

International Collaboration

CDSCO engages and collaborates with overseas counterparts for ensuring global public health by signing formal MoUs/SoIs etc.

Broad Areas of Collaboration:

- ✓ Promoting an understanding between the Parties of each other's regulatory framework, requirements and processes
- ✓ Exchange of best practices fallowed
- ✓ Exchange of information and cooperation on GMP, GLP, GCP, GPvP
- ✓ Exchange of safety information, including Pharmacovigilance, and adverse events where there is a particular safety concern related to the other party.
- ✓ Participation in scientific and practical conferences, symposiums, seminars and forums organized by the Parties
- ✓ Capacity building in mutually agreed areas
- ✓ Coordination at the international fora

International Cooperation: MoUs/MoC/SoI signed

S.No	Country Name	Drug Regulatory Agency
1	**United States**	US Food and Drugs Administration
2	**United Kingdom**	The United Kingdome Medicines and Healthcare Products Regulatory Agency
3	**Sweden**	The Swedish Medical Products Agency (MPA)
4	**Japan**	The Ministry of Health, Labour and Welfare of Japan
5	**Brazil**	The Brazilian Health Regulatory Agency, Ministry of Health, Government of Federative Republic of Brazil
6	**Russia**	The Federal services on surveillance in Healthcare and Social development (Russian federation)
7	**Argentina**	National Administration of Drugs, food & Medical Device of the Ministry of Health and Social Development of the Argentine Republic
8	**Indonesia**	The National Agency for drugs and food control, the Republic of Indonesia
9	**Saudi Arabia**	Saudi Food and Drug Authority
10	**Afghanistan**	National Medicine and Healthcare Products Regulatory Authority (NMHRA), Afghanistan
11	Myanmar	Food and Drugs Administration, Myanmar

MOUs in Pipeline

- MOUs with regulatory agencies of various countries:
  - Chile
  - Philippines
  - Ukraine
  - France
  - Australia

- **Regular interaction with PMDA**
  - India-Japan Joint Symposium
  - Trainings by Asia Training Centre, Tokyo, Japan
  - Asian Network Meetings
  - APAC meetings (Asia Partnership Conference of Pharmaceutical Associations) &
  - APACRM meetings (Asia Partnership Conference of Regenerative Medicine Associations)

- **Regular Interaction with USFDA**
  - Quarterly meetings
  - Observed Inspections
  - Regulatory Forum Workshops
  - Capacity Building activities/Trainings

- **Regular interaction with UK MHRA**
  - Meetings between CDSCO and MHRA conducted to discuss a variety of mutual topics of interest.
  - CDSCO has granted permission to manufacture ChAdOx1 nCoV-19 vaccine of M/s. Serum Institute on 03 January, 2021, which is technology transfer vaccine from University of Oxford, UK/Astrazeneca.
  - DIA, USFDA, EMA, MHRA, CDSCO collaborative virtual Clinical Trial Workshop organized for regulators on September 15 and 16, 2021.
  - UKMHRA and CDSCO are actively collaborating on various international platform such as ICMRA, WHO training programs , ICDRA, etc.

- **SEARN (South-East Asia Regulatory Network)**

  The WHO South-East Asia Region Member States launched the SEARN to enhance information sharing, collaboration and convergence of medical product regulatory practices across the Region to guarantee access to high-quality medical products.

  The Members of the Steering Group (SG) has established Working Groups (WGs) for:
  - **Quality assurance and standards of medical products,**
  - **Good regulatory practices including GMP, GDP etc.**
  - **Vigilance for medical products by India**
  - **Information sharing platform by India**
  - **Medical devices and diagnostics**

  India is actively contributing and providing support for the South-East Asia Regulatory Network SEARN in a move to guarantee access to high-quality medical products.

Reliance - MA

- ✓ New Drugs already approved and marketed in countries specified by the CLA
- ✓ New Drugs permitted to conduct Multi Regional Clinical Trials
- ✓ No probability or evidence of difference in Indian population
- ✓ No evidence of any factor affecting PK/PD
- ✓ With a condition to conduct phase IV Trials
- ✓ Animal Toxicity data, marketed for more than 2 years in other countries.

Reliance – MA …..Cont

Drugs used in

- ✓ Life threatening conditions
- ✓ Serious Disease Conditions
- ✓ Rare Diseases
- ✓ Disease of special relevance to Indian scenario
- ✓ Unmet medical need

COVID-19 related Collaboration

- ✓ Regular meetings with other country regulators eg MHRA, EMA, USFDA etc
- ✓ Sharing of information
- ✓ Reliance on efficacy data generated out side India (eg. Covishield vaccine, Remdesivir Inj)
- ✓ Approved various IVD kits for COVID-19 based on approval from certain countries.
- ✓ Actively participated in QUAD
- ✓ Exported COVID-19 vaccine to more than 100 countries.

Conclusion

- ✓ Regulatory provisions under New Drugs and Clinical Trials Rules 2019
- ✓ Accelerated Approvals
- ✓ Early access to New drugs/vaccines/IVDs
- ✓ Reduced duplication of work
- ✓ Sharing of best practices fallowed
- ✓ Built trust on each other

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Thank You

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