# 6th India-Japan
# Medical Products Regulatory Symposium
**(Through Zoom, 01st Feb 2023)**

# International Cooperation
# and
# Reliance from India's viewpoint


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**CDSCO, DGHS, MoHFW, Govt. of India**

# International Cooperation

**Broad Areas of Cooperation of MOU/MOC/MOI/SOI/JDI**

- Promoting an understanding between the Parties of each other's regulatory framework, requirements and processes
- Exchange of information and cooperation on Good Laboratory Practices (GLP), Good Clinical Practices (GCP), Good Manufacturing Practices (GMP) and Good Pharmacovigilance Practices (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

**MOU/MOC/MOI/SOI/JDI signed with**

- ✓ **MHLW, Japan**
- ✓ **USFDA, USA**
- ✓ **UK-MHRA, UK**
- ✓ **MPA, Sweden**
- ✓ **ANVISA, Brazil**
- ✓ **NADFC, Indonesia**
- ✓ **BfArM, Germany**
- ✓ **ANMAT, Argentina**
- ✓ **FDA, Saudi Arabia**
- ✓ **Roszdravnadzor, Russia**
- ✓ **FDA, Myanmar**

# Presence at International Platforms

ICH harmonisation for better health

- Currently Observer
- Experts participating in 05 Working Groups
  - ✓ **Q1/Q5C EWG** Targeted Revisions of the ICH Stability Guideline Series
  - ✓ **S12 EWG** Non-clinical Biodistribution Considerations for Gene Therapy Products
  - ✓ **E6(R3) EWG** Good Clinical Practice (GCP)
  - ✓ **M4Q(R2) EWG** Revision of M4Q(R1)
  - ✓ **M14 EWG** General principles on plan, design, and analysis of pharmacoepidemiological studies that utilize real-world data for safety assessment of medicines
- Also participated in the informal WG of ICH MIDD in developing concept note and business plan

World Health Organization

- Board Member UMC
- Past Immediate Chairman WHO MSM on Substandard and Falsified Medical Products
- Currently representing as Vice Chair WHO MSM on Substandard and Falsified Medicine (since Dec 2021)
- Member of SEARN
- Member of COVAX
- Active member of WHO guidelines preparations groups, ECPPS, etc
- R&D blue print Blue print
- Access to COVID 19 tools (ACT) Accelerator

**Pharmacopoeial Discussion Group**

- Formed by the EDQM, MHLW and USP.
- Indian Pharmacopoeia Commission (IPC) joined as a pilot participant in the PDG pilot for global expansion

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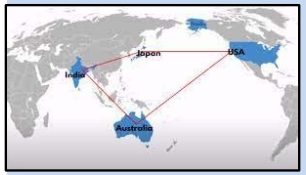
# Presence at International Platforms

ICMRA
International Coalition of Medicines Regulatory Authorities

- Participates in Monthly and Biweekly meetings

- Vaccine Pharmacovigilance Network Group Meetings
- Workshops conducted by ICMRA




**QUAD Partnership**
Australia, India, Japan, USA

- Clinical Trial Cooperation Group
- Vaccine Expert Group (Now Quad Health Security Partnership)

Asia Development Bank – Regional Vaccine Advisory Group (ADB-RVAG)

- Chair: TGA
- Vice Chair: India

ADB

COVAX-Regulatory Advisory Group (COVAX-RAG-WHO-CEPI)

- Co-led by WHO & CEPI

World Health Organization

CEPI

For Medical Devices

IMDRF International Medical Device Regulators Forum

Asian Harmonization Working Party

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

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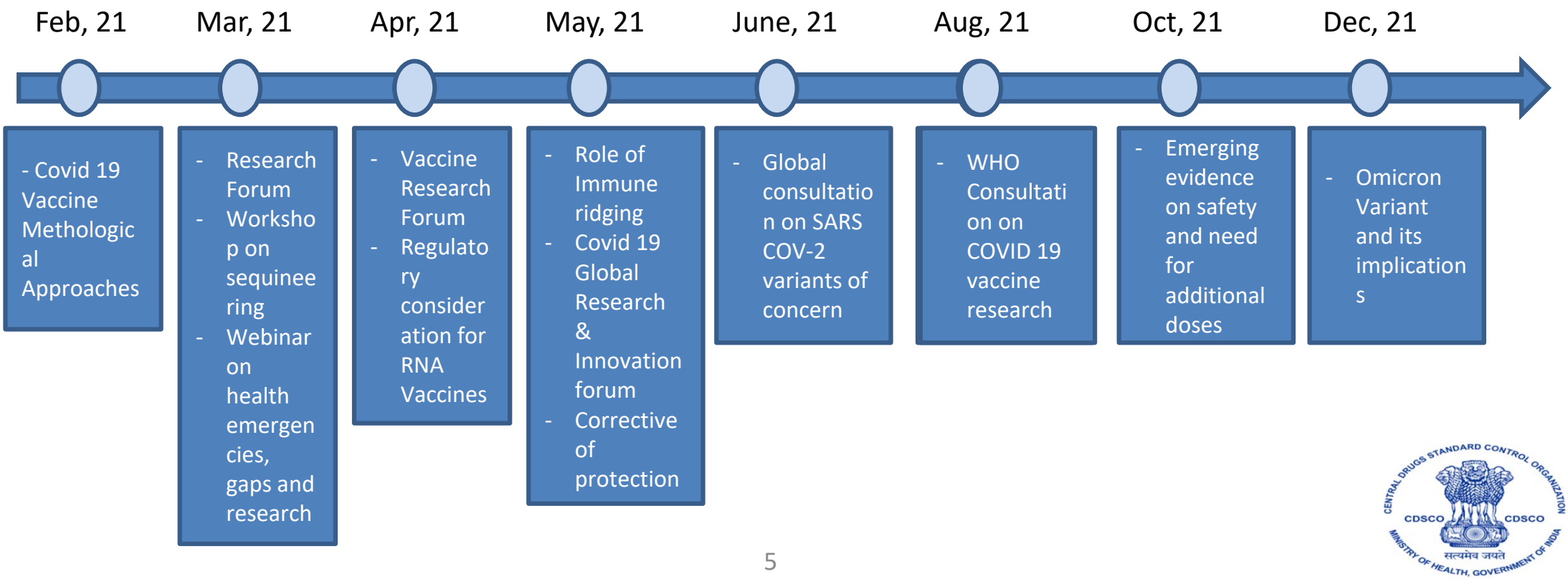
# WHO R&D Blue Print

- India represented in around 28 meetings as participant and/or panelist



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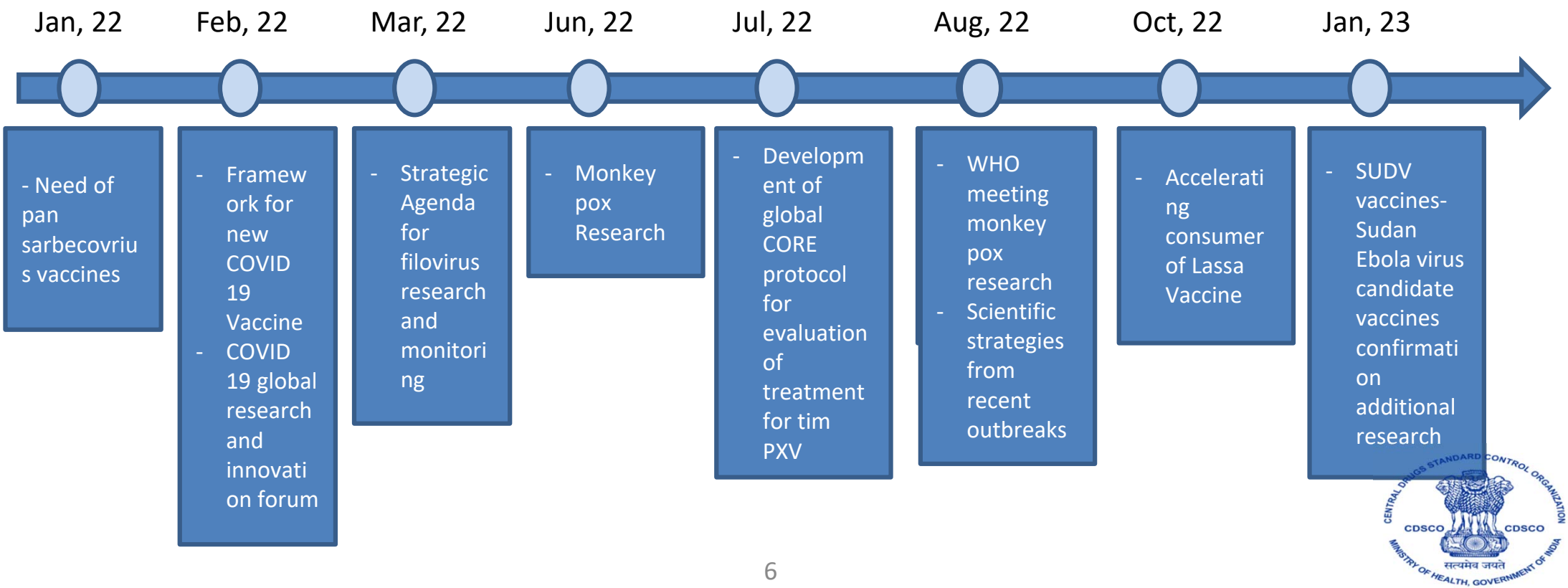


# Regulatory Reliance

## MHLW/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)

## USFDA

- Quarterly meetings
- Observed Inspections
- Regulatory Forum Workshops
- Capacity Building activities/Trainings

## WHO-SEARN

- 11 member countries
- To enhance information sharing, collaboration and convergence of medical product regulatory practices across the Region to guarantee access to high-quality medical products
- Member of 5 Working Groups
  - **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**

# Regulatory Reliance

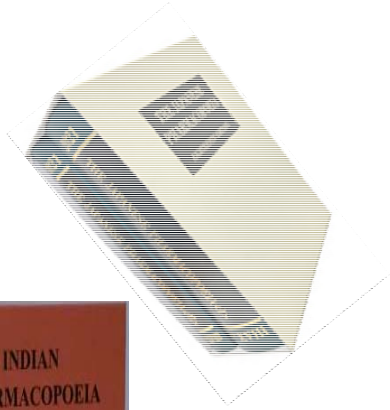
- ✓ In order **to facilitate the early development** of safe, effective and quality vaccine especially COVID-19 vaccines in the country, **guidance has been prepared and draft regulatory guidelines** were published in consideration of WHO, USFDA , EMA and applicable CDSCO guidelines.

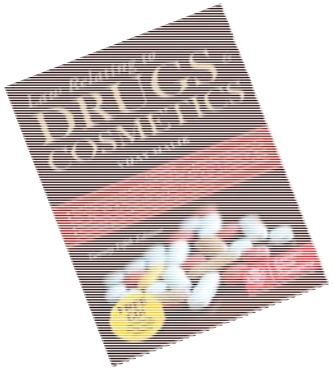
- ✓ **Guidance was issued on 01.06.2021 for approval COVID-19 Vaccines** in India for restricted use in emergency situation **which are already approved for restricted use** by US FDA, EMA, UK MHRA, PMDA Japan or which are listed in WHO Emergency Use Listing (EUL) and has been established by immunizing millions of people were **exempted from pre & post approval bridging trial** and also **exempted from compulsion of every batch being tested by CDL, Kasauli**, if it has been released/certified by National Control Laboratory (NCL) of country of origin

# Regulatory Reliance

- ✓ Marketing Authorisation of Astrazeneca Vaccine (COVISHIELD), Sputnik V and Moderna vaccine for restricted use in emergency situation was issued on the basis of evaluation through regular interaction with concerned regulatory authorities.
- ✓ Regular participation in various international regulatory platform like ICMRA, WHO, R&D Blue Print, RVAG with the regulatory agencies to ensure regulatory agility and decision making to cope with the pandemic outbreak.

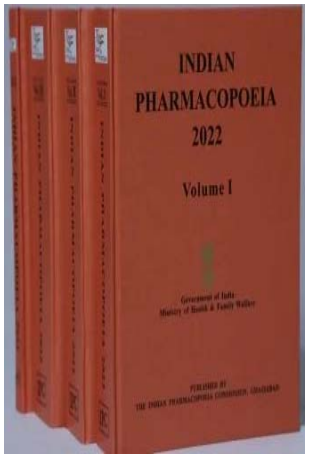
# Regulatory Reliance in approval process



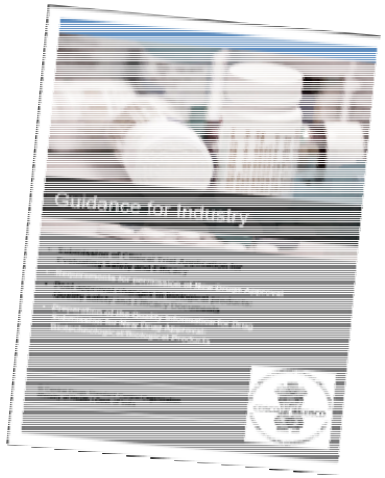




**Good Clinical Practice Guidelines**











**CDSCO GUIDANCE DOCUMENT FOR ZONAL/SUB-ZONAL OFFICES**

# Interactions with Overseas Regulatory Authorities

Mexico
Meeting Dt.: 14.11.2022

Netherlands
Meeting Dt.: 23.11.2022

Cuba
Meeting Dt.: 27.09.2022

# Interactions with Overseas Regulatory Authorities


USFDA
Meeting Dt.: 22.12.2022


Sweden
Meeting Dt.: 02.12.2022

# Thank You