INTERNATIONAL REGULATORY CONVERGENCE TO PROMOTE ACCESSIBILTY AND AFFODABILITY OF QUALITY MEDICINES

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The Conclave

- Understanding Need for Convergence – Covid 19 Pandemic
- Global drug development and Regulatory Controls
- Regulatory paradigms – Good Regulatory and Reliance Practices
- Collaborative Registration

GLOBAL DRUG DEVELOPMENT CONVERGENCE – THE FUTURE IS NOW

Drug product developed for the world (simultaneous uptake across the globe at a go) as against developing a drug product/medical device on country or regional basis.

- Global clinical trial programme and simultaneous data generation across the globe
- Collaborative Regsitration - Global submission or simultaneous submission of marketing authorization application across the globe
- Global product launch

Need for Convergence Global Drug Development

- Globalization – Covid 19 Pandemic
  - **Emergent health challenges, disease types and spread pattern, epidemiological pattern, demography, multiculturality of country population etc**
- Unmet medical needs
- Timely and equitable access to innovative and essential medicines
- Efficient use of scarce resources (both industry and regulatory)
  - Reliance, collaborative registration and fast track approvals
- New and emerging technologies
- Personalized medicines
- Scientific and regulatory challenges

Challenges to Convergence in Accessibility and Affordability

- Lack of Harmonized regulatory requirements, review standards and timelines
  - Differences in products marketed across regions due to non-global implementation of variations to the approved product.
- Varied regulatory capacity and capability
  - **Weak regulatory capacity and capability of majority world countries particularly the LMICs**
    - **Need to strengthen r*egulatory framework (WHO Global Benchmarking)***
- Legal framework for the acceptance of foreign clinical trial data
  - **New ethnic factors necessitating additional or new studies**
  - **Requirement for bridging studies and justifications**
- Having a truly global drug development programme
  - **intrinsic variability in ethnic and cultural factors that influence drug use and responses**
- Differences in risk management approaches and context among different countries and regions

Regulatory Paradigm Enabling Convergence for Accessibility

- Patient-centric regulatory approaches
  - Informativeness paradigm in clinical trials
- Proactive partnership between regulators and the industry from early phases of drug development
  - Reliance between regulators for information sharing and **equitable access to new and innovative medicines**
  - Regulatory strengthening of the industry for early market launch
- Harmonization of regulatory standards
- Harmonized procedures for regulatory review and decision-making
- Strengthening global regulatory system and enhancing the capacity and capability of NRAs in LMICs
  - Embracing WHO Global Benchmarking Tools (ISO 9004)

Regulatory Paradigm Enabling Convergence for Accessibility

- Legal framework for accepting foreign clinical trials

- **In line with requirements of ICH E5**
- **High quality clinical data**
  - **Studies conducted under Good Clinical Practices (GCP)**
  - **Performed by competent investigators**

- Use of real-world data to support final approval (for medicines addressing unmet medical needs)

- **Review and approval for controlled use at the end of phase IIb e.g EUA**
- **Phase II study design to reach a more robust endpoint and confirmation of efficacy**
- **Rolling submission and review**
- **Risk management programme and including risk communication to prescribers and users**
- **Robust and effective global safety monitoring and information sharing platform**
- **Allows drug exposure to larger patient population in real-word setting and the generation of real-world safety and efficacy data to support final drug approval**

Regulatory Paradigm Enabling Convergence for Accessibility

- Increased use of collaborative and work-sharing models facilitating reliance, mutual recognition and confidence-building among agencies

- **Joint and collaborative reviews**
- **Recognition and designation of lead agency for the review of global regulatory submission and subsequent reliance through mutual recognition by other agencies**
- **Collaborative post-approval change management**
- **Leveraging on well-resourced regulatory agencies**

Criteria for Convergence

- Understanding and recognition of regulatory system strengthening
- Focus on prioritizing global drug development to addressing global unmet medical needs
- *Early consultation and partnership of manufacturers with regulators*
- Fully integrated drug development programme
- Address genetic and cultural heterogeneity in global clinical trial programme
- Robust safety monitoring and transparent communication with all stakeholders

THANK YOU