



6th India Pharmaceutical Forum (IPF) 2021

Global View on Regulatory Affairs

**Partnership
for
Progress
in
Patient Care**

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Breakthroughs that change patients' lives

Disclaimer

This presentation does not necessarily represent the views or official position of the organization, Pfizer, or any of their subsidiaries, or leaders or employees or partners, but is solely based on my personal thoughts, ideas, and opinions.

- Babu KS

Today's World

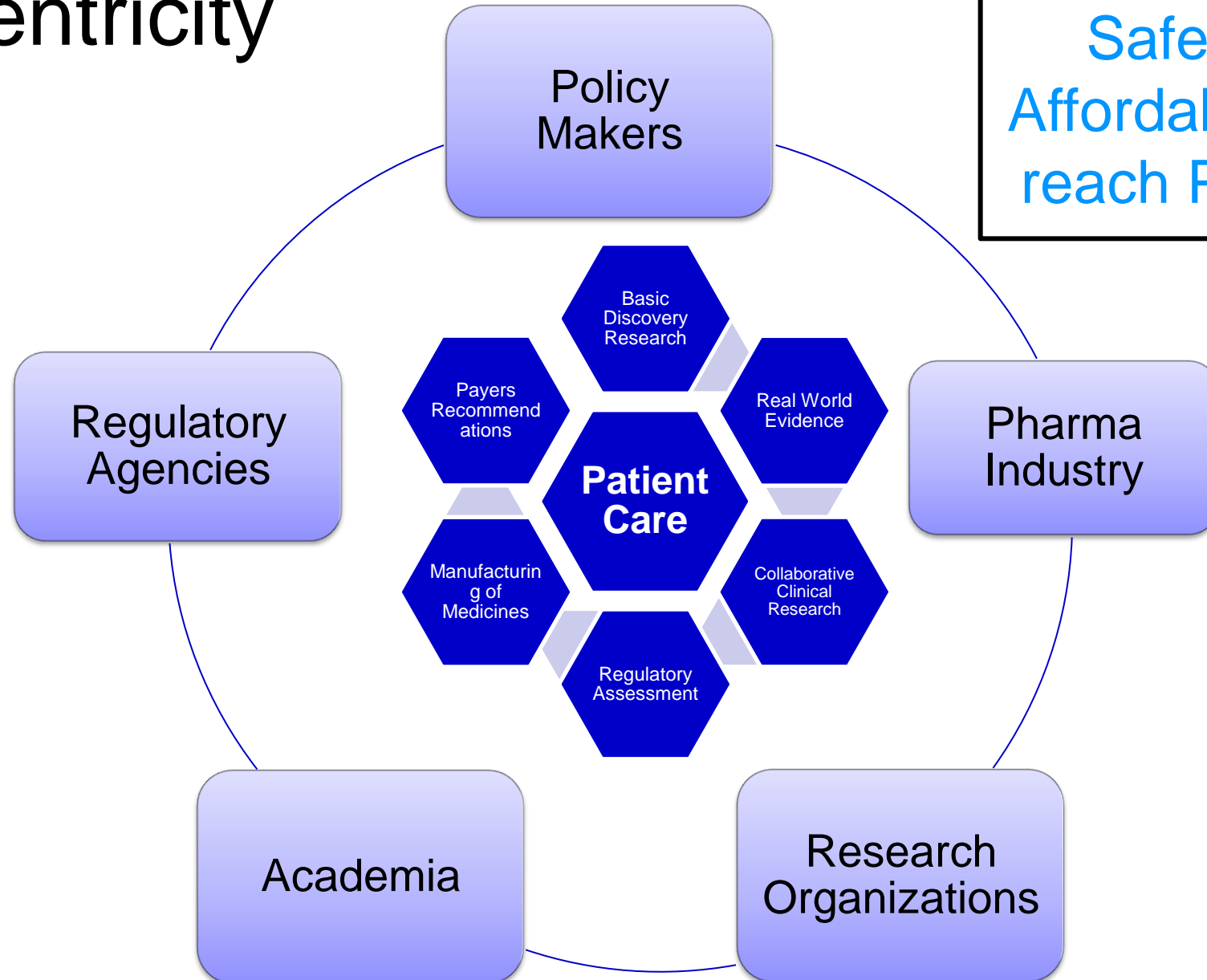
- **VUCA** - *Volatile, Uncertain, Complex & Ambiguous*
- High potential for disruption
- **Are we prepared to manage another pandemic?**
- Can we predict or prevent another pandemic?

Need of Today and Tomorrow:

Unprecedented Collaborations & Partnerships

Patient Centricity

Shared Objective:
Safe, Effective,
Affordable Medicines
reach Patients Fast!





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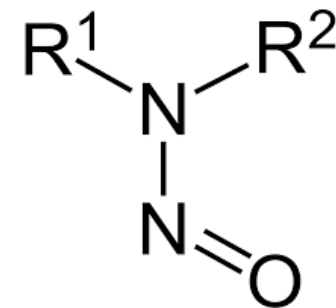
**Regulatory Agencies &
Policy Makers**

Increasing Convergence: EMA & US FDA

- Remarkable alignment
- 90% of MA Decisions for New Drugs 😊
- Great focus on investment, intent, effort for the common goal (Patient Centricity)
- Mutual Recognition Act
- Joint inspections
- Exchange of Reports
- Batch Testing Waiver



Successful Convergence of Regulatory Agencies: Nitrosamines



- International Strategic Group' led by Health Canada
- Members: HC, EMA, US FDA, MHLW, TGA, S-HSA, SwissMedic
- Well-coordinated efforts: Exchange of info, methods, datasets
- Outcome: Internationally-recognized “Acceptable Daily-Intake Limits”
- **Collaboration to Conquer Common Challenges**

Recommendations: EMA Lessons Learnt Group

- Nitrosamines International Working Group Experience
- Create a Strategic Working Group for all future incidents, crises, challenges
- **Exchange of commercially confidential information:** Public Health Interests outweigh Confidentiality
- Increased International **cooperation on GMPs;** Information Exchange, **Workload** Sharing etc.
- International partnerships on the review of Toxicological Data Review, Risk Assessment; PV Data Review
- Common Procedures, Guidelines, Norms for Global Crisis Management
- ICMRA – International Coalition of Medicines Regulatory Authorities

Additional Areas of Convergence: HAs

- Real-time Regulatory Data Exchange
- Minimize duplicate testing (animal & human) across the world
- Regulatory Harmonization: Can this become a REALITY?
- One Global Dossier
- **Drug Development data standards for complex / novel dosage forms**
- Risk-based Approach (continue the Good Work!)
- **Greater Efforts towards Pharmacopeial Convergence**

Dossier Requirements: Regulated Markets vs Rest of World

- Regulatory Harmonization: Can this become a REALITY?
- One Global **D**ossier: **D**ream – **D**esire – **D**emand – **D**estination (???)
- **Leveraging Existing MA approvals, with minimal administrative data**
- **QbD vs Traditional Dev Approach**
- Post-approval Change Mgmt through Harmonized Regulatory Tools/ Enablers
- Differences in License Maintenance / Renewal requirements (across HAs)
- **Acceptable Customization: Zone-relevant Stability, Translations etc.**

Opportunities for Greater Convergence of HAs

- Dream: “Medicines for All across Globe” – **Challenges?**
- International Data Stds by Global Reg Agencies: Set up & Adopt
- Developed vs ROW Markets: Lack of alignment in regulatory framework / systems / preparedness
- Differences in License Maintenance / Renewal Reqts. (across HAs)
- Greater Mutual Recognition Efforts; keeping ROW Markets in mind
- Harmonization of Clinical Trial Stds. / Reqts. where possible
- Balanced approach in recognizing Global Clinical Trial Data for Critical Care products & products for Emergency Use
- Global Data Standards for Novel Emerging Technologies; can we help adoption by all HAs?



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Industry

Collaboration with Competitors

10 Pharma Giants,
1 Pledge,
1 Purpose



We Stand With Science

"Today, Pfizer and several other leading biopharmaceutical companies are sending a clear and united message that we will not compromise the integrity of science nor the scientific process as we each move forward with urgency to deliver safe and effective vaccines that we hope will change the course of this pandemic."

Albert Bourla, Chairman and CEO



Industry Collaborations

- IPA leading the Collaborations in Indian Pharma Industry
- Asset-based Collaborations (**business-focused**) to Service-based (**cause-focused**)
- Pfizer & BioNTech - Co-development of Covid-19 vaccine
- Novartis & Sanofi - Leveraging the manufacturing capabilities for Pfizer Vaccine
- ICON plc. - Clinical Trial services for Pfizer Vaccine
- Global Logistics Partners for Supply Chain / Distribution
- AZ & University of Oxford
- Moderna & National Institute of Allergy & Infectious Diseases
- Bharath Biotech & Indian Council of Medical Research (ICMR)
- Pfizer's support to Gilead in Remdesivir manufacturing
- HCQ Supplies from India to the World



Additional Industry-Agency Partnership Opportunities

- Tech Revolutions are faster than Regulatory Revisions
- Novel Methods, Novel Technologies, Novel theories
- AI-based evaluations, Robotic Process Automation, Digital Pills
- Rule Book becomes Obsolete and Irrelevant in no time
- Help HAs catch up with “Speed of Science”
- Industry-HA Partnerships : Most Crucial
- Connect with Regulators Proactively
- FDA’s Innovation Challenge: Alternatives to Ethylene Oxide Sterilization
- Are academic institutes catching up with the speed? – Edu. Reforms (Industry Responsibility; another partnership opportunity)

- Transparency
- Trust
- Timeliness
- Together in it

Lessons from COVID-19 Vaccine EUA

- EUA within a year
- Rolling Review (MHRA, EU, HC) – Expediting Approval Process
- Risk-based approach
- Crisis brings out the Best: Can this be the new normal?
- COVID-19 Vaccine Success Story must continue:

Why not: Cancer, Alzheimer's, Muscular Dystrophy etc.

- Key to Success:

Partnerships across Health Agencies-Industry-Academia-Research Organizations

Last Words... The India Advantage!

- Strong Chemistry foundation (Powerhouse for API Technology)
- Research & Dev Competence (Novel / Complex Formulations)
- Manufacturing Infrastructure & Capabilities
- Deep Regulatory understanding & Compliance Mindset
- Strong & Conducive Ecosystem (Associations, Regulators etc.)
- Scientific & Technical Educational System
- Information Technology as a backbone
- Collaborative Spirit & Global Mindset
- Entrepreneurial Capabilities

THANK YOU

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