Global Regulators Conclave

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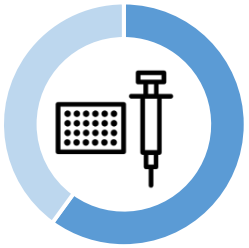
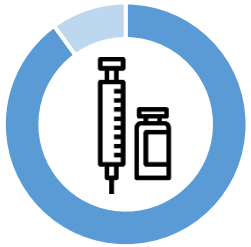
Indian pharmaceutical industry – Contribution to global health outcomes

India is third–largest medicine manufacturer in the world and is rightly described as the **"Pharmacy of the World"**

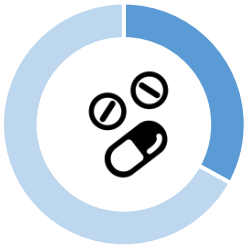


60% Global Vaccine Production

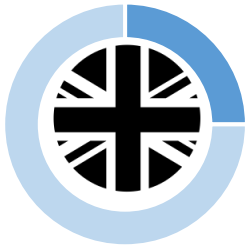
37% AIDS patients receiving treatments in 2009, vs 2% in 2003 in Africa



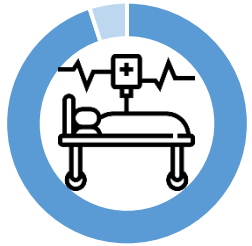
90% WHO demand for measles vaccine



33% Pills consumed in USA is produced by Indian generic manufacturer



25% Medicines consumed in UK are made in India



95% Lower treatment costs of life threatening diseases

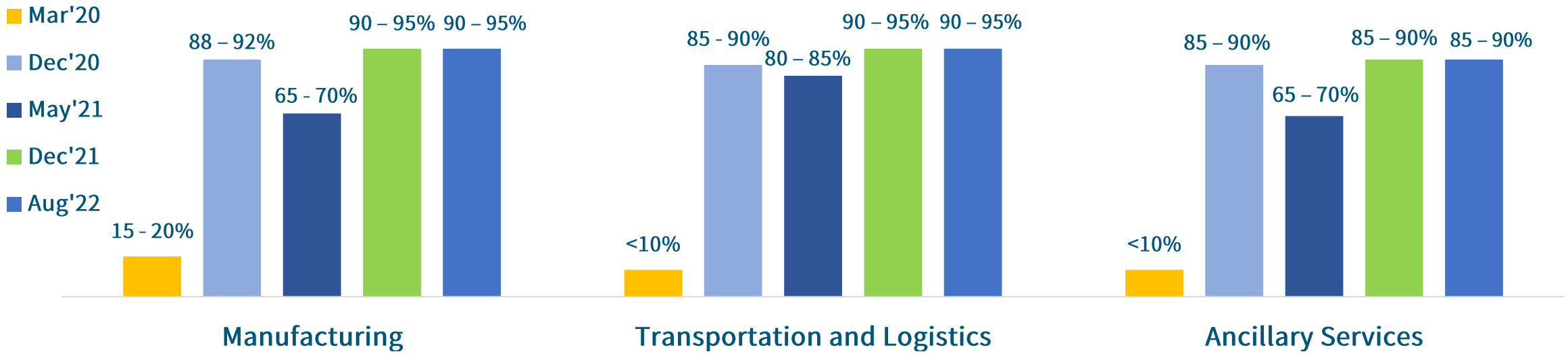
Indian Pharmaceutical Alliance (IPA) Profile

- 80% of the country's export of pharmaceuticals
- 57% of domestic market sales
- 85% of private sector investment in pharmaceutical R&D
- Established in 1999 and now with membership of 24 leading companies

- Abbott Healthcare Pvt Ltd
- Ajanta Pharma Ltd
- Alembic Ltd
- Alkem Laboratories
- Aurobindo Pharma Ltd
- Cadila Healthcare Ltd
- Cadila Pharmaceuticals Ltd
- Cipla Ltd
- Dr Reddy's Laboratories Ltd
- Emcure Pharmaceuticals Ltd
- Glenmark Pharmaceuticals Ltd
- Intas Pharmaceuticals Ltd
- IPCA Laboratories Ltd
- Lupin Ltd
- Mankind Pharma
- Micro Labs Ltd
- Natco Pharma Ltd
- Piramal Pharma Ltf
- Panacea Biotec Ltd
- Sun Pharmaceutical Industries Ltd
- Torrent Pharmaceuticals Ltd
- Unichem Laboratories Ltd
- USV Ltd
- Wockhardt Ltd

Manufacturing and Supply Chain

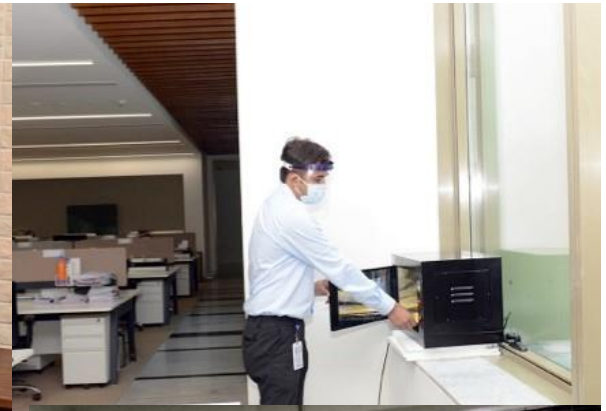
- Industry stepped up to the plate to meet the challenges posed by COVID-19
  - **Focus on ensuring global supply of medicines (including those used for the treatment of COVID-19)**
- High-level of engagement with the Government of India :
  - **Pharmaceuticals recognized as Essential Goods and Services; Permissions granted for movement of people and materials**
  - **Resolution of challenges faced by manufacturing facilities; Ensuring continuity of Transport and Logistics;**
- Coordination with industry associations in India and with WHO, IGBA, AAM, Medicines of Europe and others



Ensuring employee safety and wellbeing at facilities

Successful implementation of safety protocols across the industry has limited the spread of COVID-19





Key learnings from COVID-19 pandemic

- **Collaboration is key** - integrated efforts and consistent dialogue between industry and government worked well during COVID-19 pandemic
- **Fast track approval of Vaccines, Drugs and Diagnostic kits**
  - **Emergency Use Authorization** such as Remdesivir, Favipiravir, Tocilizumab and Molnupiravir
- **Regulatory pathways** to be developed for accelerated development
- WHO has set up intergovernmental negotiating body (INB) on pandemic prevention, preparation and response effect
  - COVID-19 vaccines, diagnostics, and treatments (VDTs) were developed at record speed, e**nsuring inclusive and equitable access to VDTs is fundamental**
- In the book "The Age of Pandemics" Prof Chinmay Tumbe highlights that **learnings** from pandemics **should be recorded** and leveraged to **strengthen pandemic prevention, preparedness and response** for future

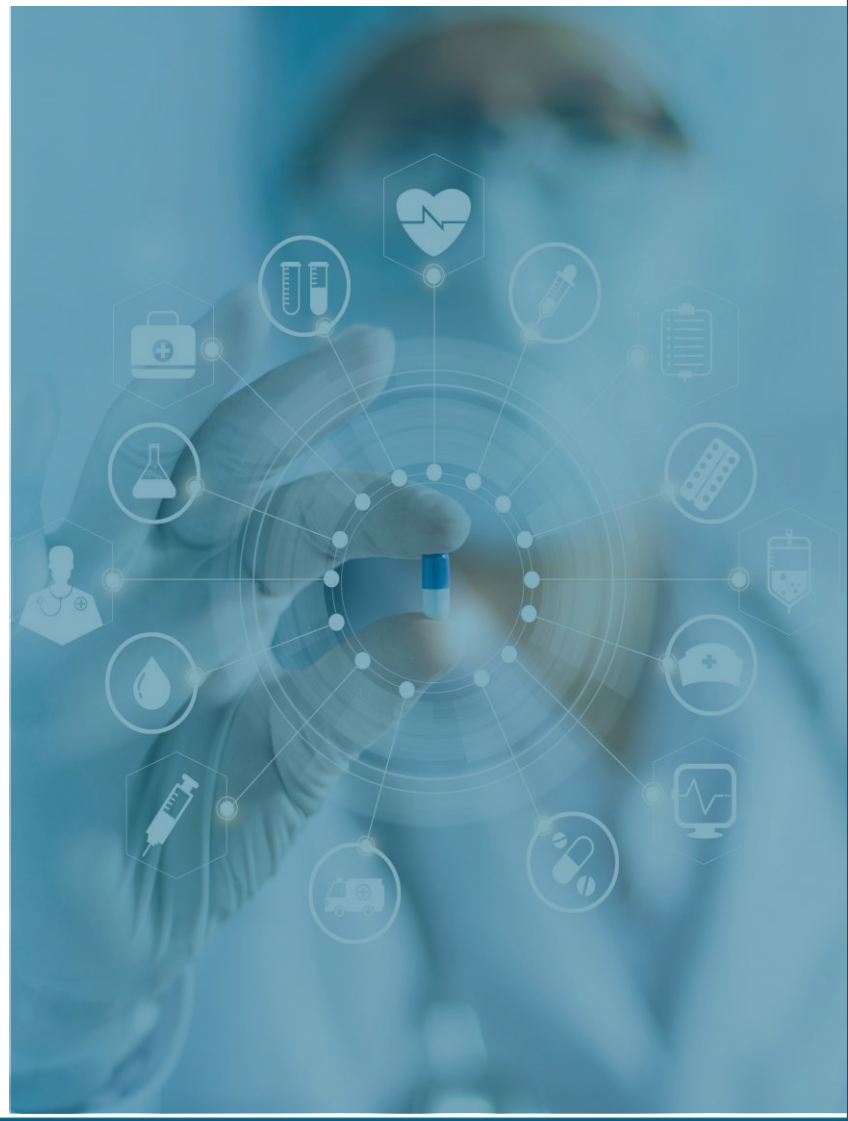
Major challenges: An Industry Perspective

1. **Divergences between national/regional regulatory frameworks** for assessments of generic products - multiple/varied pharmacopeias for a product/standard, different processes and guidelines, amongst regulatory agencies

2. **Multiple Reference Product:** Regulators in several markets approve a new product based on a global multi- country clinical trial or insist on 'local' product as reference product

3. **Product Approval Timing:** Time taken for approval of generics varies from 4 months to 36 months in various jurisdictions, delays entry of generics

4. **Inspections:**
   - Multiple inspections conducted for the same facility by different regulatory agencies
   - Time taken for inspection of new manufacturing facilities and re-inspection of old facilities under warning letters/ import alerts, the waiting period is a major cost

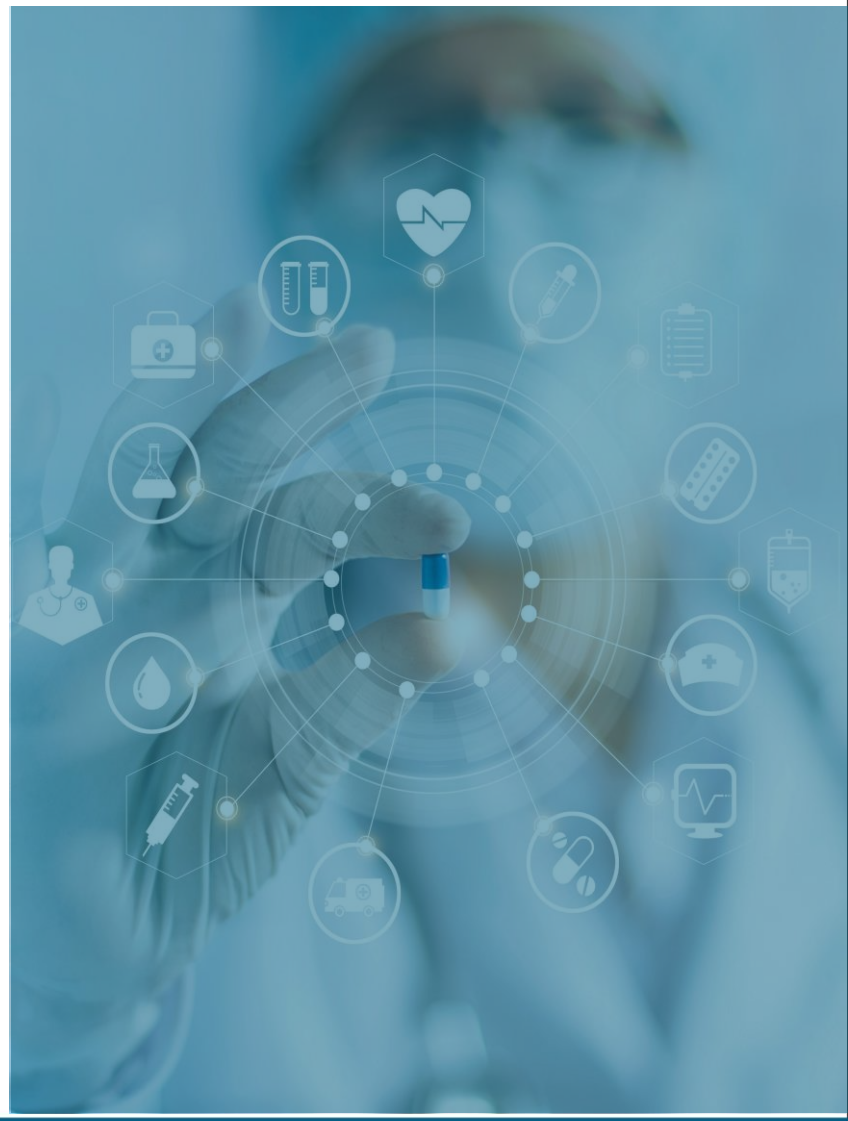


Suggestions

1. **Regulatory Convergence:** Establishing regulatory frameworks that allow convergence of requirements for the assessment of generic medicines and enable the industry to increase patient access to quality assured generic medicines.

2. **Global Comparator:** safety and efficacy of the product is estd by the innovator, irrespective of geography, for generic manufacturer it should suffice to provide bioequivalence with a product from the country of origin or use of foreign comparator products

3. **Timely Product Approval:** Compress the period of approval/ waiting period to max 12 months; not only the manufacturers could commence production earlier, but will also benefit patients by early on- set of competition



Suggestions

Mutual recognition:

- Joint / Mutually recognised inspections to reduce the number of inspections of a facility

4

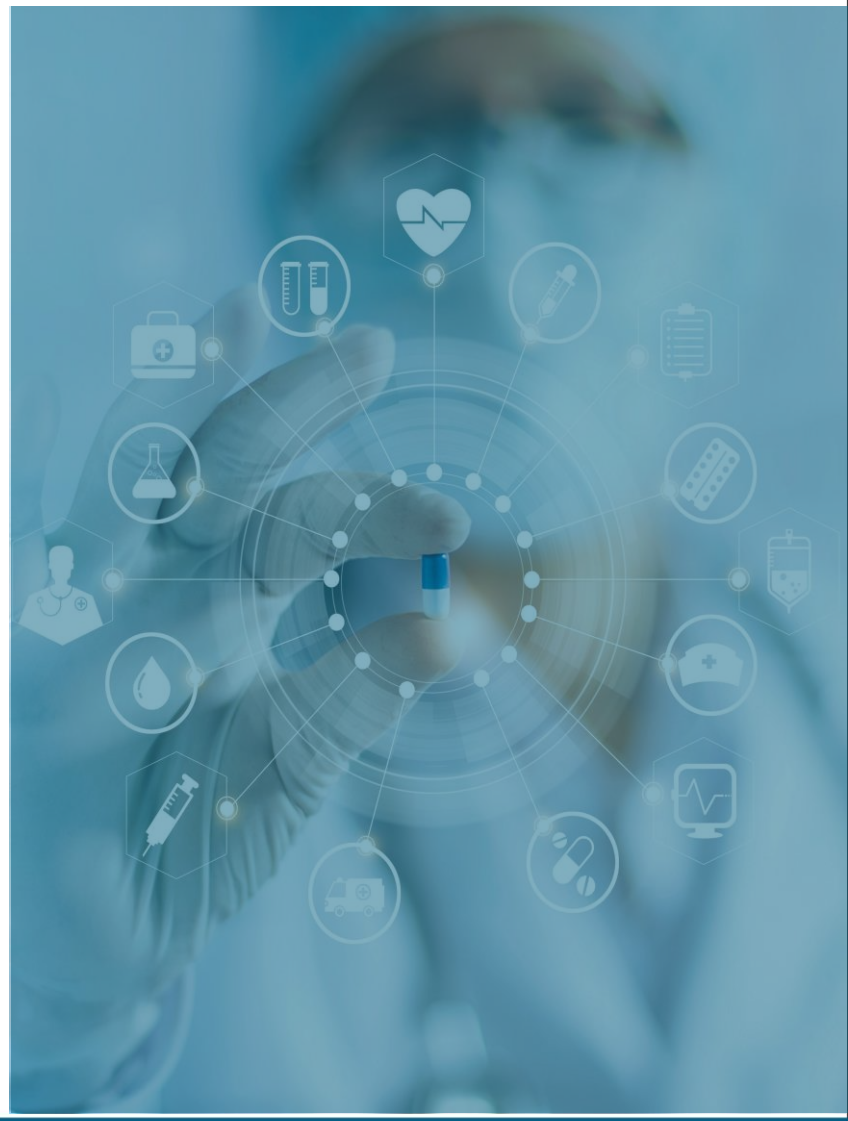
- Remote inspections in today's digital

- Specify clear next steps to achieve compliance within defined timelines in case of non-conformities

5 **Common Technical Document:** Standardized dossier filing format to reduce load per inspection

6 Employ interchangeability concept in biosimilars to allow accessibility to patients

Overall a coordinated approach to regulatory convergence will improve patient access



Thank You