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Equitable and appropriate access to quality medicines and vaccines in the Commonwealth
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Collaborative Working with the Private Sector to Overcome Access Issues, During COVID-19 and Beyond – a Global Perspective

Mr Greg Perry, Assistant Director General, IFPMA
Introduction

IFPMA – International Federation of Pharmaceutical Manufacturers and Associations

We represent research-based biopharmaceutical companies, and regional and national associations across the world. Currently 10 of our national associations are from Commonwealth countries:

We facilitate collaboration, dialogue, and understanding within our industry and with other international stakeholders in the health community.
“Supply chain” encompasses a complex set of interlinked processes (R&D, regulatory, production, storage, design of distribution channels, transportation, trade, tax, procurement and delivery) by a variety of different actors in the life of a medicine or vaccine.

**Seamless interaction** between these actors and processes is necessary to provide patients, healthcare professionals and health systems with the right product they need, when and where they need it.
Key Supply Chain Enablers

**Data Management**
- Data aggregation and information sharing among manufacturing, wholesaler, distribution and end-user facilities via producer, warehouse and healthcare provider information systems
- Health Management Information Systems (HMIS)
- Logistics Management Information Systems (LMIS)

**Quality Assurance**
- Maintenance of Quality Management Systems for Good Distribution Practices (GDP) including shortage prevention plans, “track and trace” and authentication serialization solutions (barcoding, RFID/GTIN identification, etc.).

**Capacity building including human resources**
- Training (including virtual and e-learning programs), SOPs-standard operating procedures, and the local sharing of information and best practices.

**Collaboration and Coordination**
- Joint undertakings between biopharmaceutical companies and across other industrial sectors and stakeholders (health authorities, GDP inspectors, NGOs/humanitarian organisations, multilateral agencies, providers, etc.) to optimize supply chain performance and share innovative ideas and practices.
Challenges in managing complex supply chains for medicinal products

- Global Complexity:
  - Multi-sites: Manufacturing, Distribution, Testing

- Integrity:
  - Counterfeit: Theft

- Requirements Guidelines:
  - Divergent: Guidelines, Data Requirement

- Resources:
  - Capacity Issues: Backlog, Reviews, Inspections, Training to Strengthen Expertise

- Fragmentation:
  - Mandatory: Minimum Inventory, Product Specific Monograph (PSM) Adherence, Release Testing

- Implementation of Changes:
  - Divergent: Submission Categories, Review Times
COVID-19: Systems under pressure

— Increased pressure on supply chain and health systems globally
— Industry, NRAs, health care professionals having to adapt to challenging circumstances: Agile regulations
— Importance of regulatory reliance tools and guidance on best practices

Efficient supply chains are key in deploying & delivering supplies, aid and donations

$750M in monetary donations

25M donated units of medicines and personal protective equipment
Vaccine Supply Chain Complexities

Unprecedented challenges:

- Vaccine manufacturing is complex
- The vaccine manufacturing process is dependent on a complex global network of suppliers of raw materials and equipment
- Skilled human resources are another significant constraint

Scale-up:

- 0-14 billion doses by end of 2021
- Pre-COVID global demand for vaccines was between 3.5-5.5 billion doses

The use of new technologies such as mRNA in response to COVID-19 poses additional challenges

- On-time input supply (100+ components)
- Equipment and personnel
- Quality control and safety
- Capacity ramp-up/ Transfer of Technology
- Global Manufacturing network
- Lengthy manufacturing times
Supply Chain Challenges for Vaccine Scale Up

Tech transfer happening at unprecedented levels

Vaccine companies are leaving no stone unturned.

IP has enabled technology transfer

Restrictions on the movement of good and people have created bottlenecks

Number of collaborations confirmed in vaccine manufacturing deals

- 275 Vx Manufacturing Deals
- 215 Vx Manufacturing deals with some form of collaboration
Regulatory Reliance | Multiple advantages

*All stakeholders impacted by regulatory systems have the potential of benefiting from Regulatory Reliance*

**Patients & Healthcare Providers**
Timely access to safe, effective and quality medical products.

**Regulatory Agencies**
Efficient utilization of resources by avoiding duplication of work and providing opportunities to strengthen the regulatory system, while maintaining sovereignty over decision-making.

**Manufacturers**
Streamlined management of regulatory submissions and global supply systems as well as predictable, timely approvals.
Critical Role of Data & Information management and sharing

Private sector working on innovative approaches but needs support from regulatory agencies

Ensures effective access:

- Influences pricing
- Quality Control
- Substandard and Falsified medicines

Neglected Disease Supply Chain Forum

- Statistical modelling tools
- PCT-NTD Supply Chain Management tool
- DHL Control Tower
  - forecasting and planning for logistics management
  - coordination of NTD shipments
Multiple challenges
Key Recommendations

Leverage the convening power of the Commonwealth:

- Maintain dialogue with all key stakeholders including patient groups, industry and regulators
- For a Commonwealth led forum specifically discussing supply chain challenges and solutions
- Consider feasibility of Commonwealth regulatory cooperation and reliance
Thank you

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