Shortages occur when the right products are not available in:
- Right quantities
- Right time
- Right place
- Right conditions

ultimately creating a stockout at the point of appropriate service delivery to people.

WHAT CAN MANUFACTURERS DO?

Manufacturers implement a combination of approaches to pre-empt shortages and ensure reliable supply of medicines and vaccines, including:
- Establish robust quality, business, and communication management processes, e.g., holistic quality management systems, market forecasting methods, and inventory management techniques
- Optimize usage of existing industrial capacity, and if sustainability can be insured, continue to invest in industrial capacity and more robust control processes to increase production
- Manage country specific product and packaging requirements and post-approval complexity
- Engage with health authorities to improve security of supply and on early notification of potential supply disruptions

WHAT CAN OTHERS DO?

To ensure a reliable supply of medicines and vaccines, proposed additional measures include:
- Instigate early dialogue between manufacturers and public health authorities
- More timely and accurate demand forecasting to enable manufacturers to better anticipate and meet public health needs
- Introduce more appropriate and flexible procurement practices, adapted to long production cycles
- When supply is constrained, apply interim allocation and supply strategies to maximize availability to prevent or treat priority conditions or groups
- Implement consistent and harmonized regulatory approaches for the management of global post-approval changes
- Reduce duplicate testing, eliminate animal testing, and faster regulatory adaptation AND 
- Reduce the number of special national and regional product and packaging requirements

IMPACT: patients and health care workers
Disruption in the supply of medicines and vaccines can result in:
- Delays or interruption of ongoing treatments
- Use of alternative, unfamiliar or less suitable medications
- Failure to treat
- Interruption of immunization services leading to missed opportunities to vaccinate children

WHAT ARE THE ROOT CAUSES?

SUPPLY

Complexity of manufacturing processes compounded by:
- Long lead time (up to 2 years), with up to 70% is quality control for vaccines
- Scale up production (up to 5-10 years) with significant investments and long timelines for regulatory approvals
- Divergent regulatory requirements, notably for post-approval changes
- In vivo testing and dual or multiple batch release testing, performed by health authorities
- Diverse country specific product and packaging requirements

Limited number of manufacturers due to high start up investment, technical knowledge, and uncertainty in demand

DEMAND

- Increased, often unpredictable, global demand
- Limited anticipation of evolution of national health programs
- Unexpected demand changes or fluctuations, incl. outbreaks
- Inflexible purchasing mechanisms and delays in payment
- Vaccine hesitancy
- Limited efficiency of supply chain system, including coordination of stock management, delivery issues, cold chain equipment, and wastage

WHAT DO WE KNOW ABOUT IT?

Shortages are global, complex and occur at multiple points in the supply chain from manufacture to procurement and distribution.

55% of vaccine stockout events (for at least one vaccine and for at least one month) occur in middle-income countries.
80%+ countries reporting district level vaccine stockouts experience interruption of vaccination services.
15 OUT OF 25 vaccines in shortage or at risk of shortage
11% of causes of national vaccine stockouts are global in nature – either resulting from a global shortage or a quality issue related to a particular vaccine.


The Complex Journey of a vaccine – Part I (IFPMA). For more information: www.ifpma.org