FROM SHORTAGES TO SUSTAINABLE SUPPLY

WHAT'S BEHIND MEDICINES & VACCINES SHORTAGES

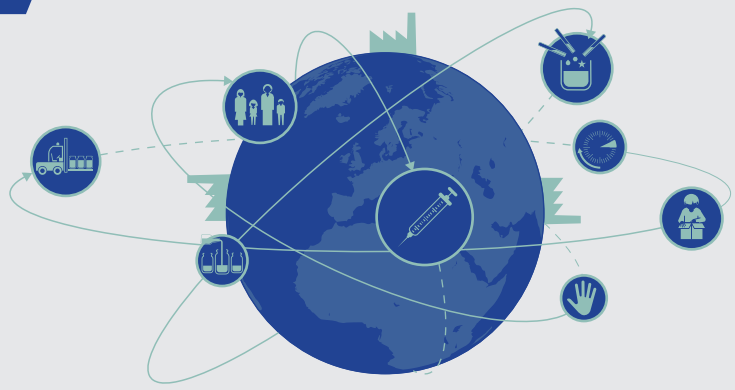
WHAT DO WE KNOW ABOUT IT?

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

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.



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

- Medicines in short supply include many commonly used, generic sterile injectables, antibiotics, cancer and cardiovascular medicines, and pediatric formulations.
- Countries of all income groups and regions are affected, but data is lacking in low- and middle-income countries.
- Reported causes of medicine stockouts in Europe include manufacturing and other supply problems; but nearly half of all medicine stockouts are due to unknown causes.
- Shortages cost US hospitals US$416 million = US$200 million to purchase more expensive alternatives medicines + US$216 million in labor costs.

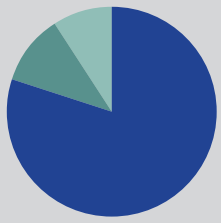
55%
of vaccine stockout events (for at least one vaccine and for at least one month) occur in middle-income countries.

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.

Root cause analysis of national-level vaccine stockouts (UNICEF, 2011-15)



National causes 80%
incl. funding delays, poor forecasting & stock management, procurement delays

Global causes 11%
incl. global shortage, quality issues

Other causes 9%

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

Timeliness of communication between policy makers, health authorities, countries, scientific experts, and vaccine manufacturers

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 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 practices, 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

To address this global public health issue, it is critical that there is open dialogue between all key stakeholders across the health sector. Policy makers, health authorities, countries, scientific experts, and manufacturers need to work together to overcome the many challenges from manufacture to procurement and distribution. It is a global problem that requires global, regional, and national solutions.

Further reading: Medicines shortages, WHO Drug Information Vol. 30, No.2, 2016 | Vaccine stockouts around the world; Lydon et al., Vaccine 35 (2017) 2121-2126
The Complex Journey of a vaccine – Part I (IFPMA). For more information: www.ifpma.org

IFPMA