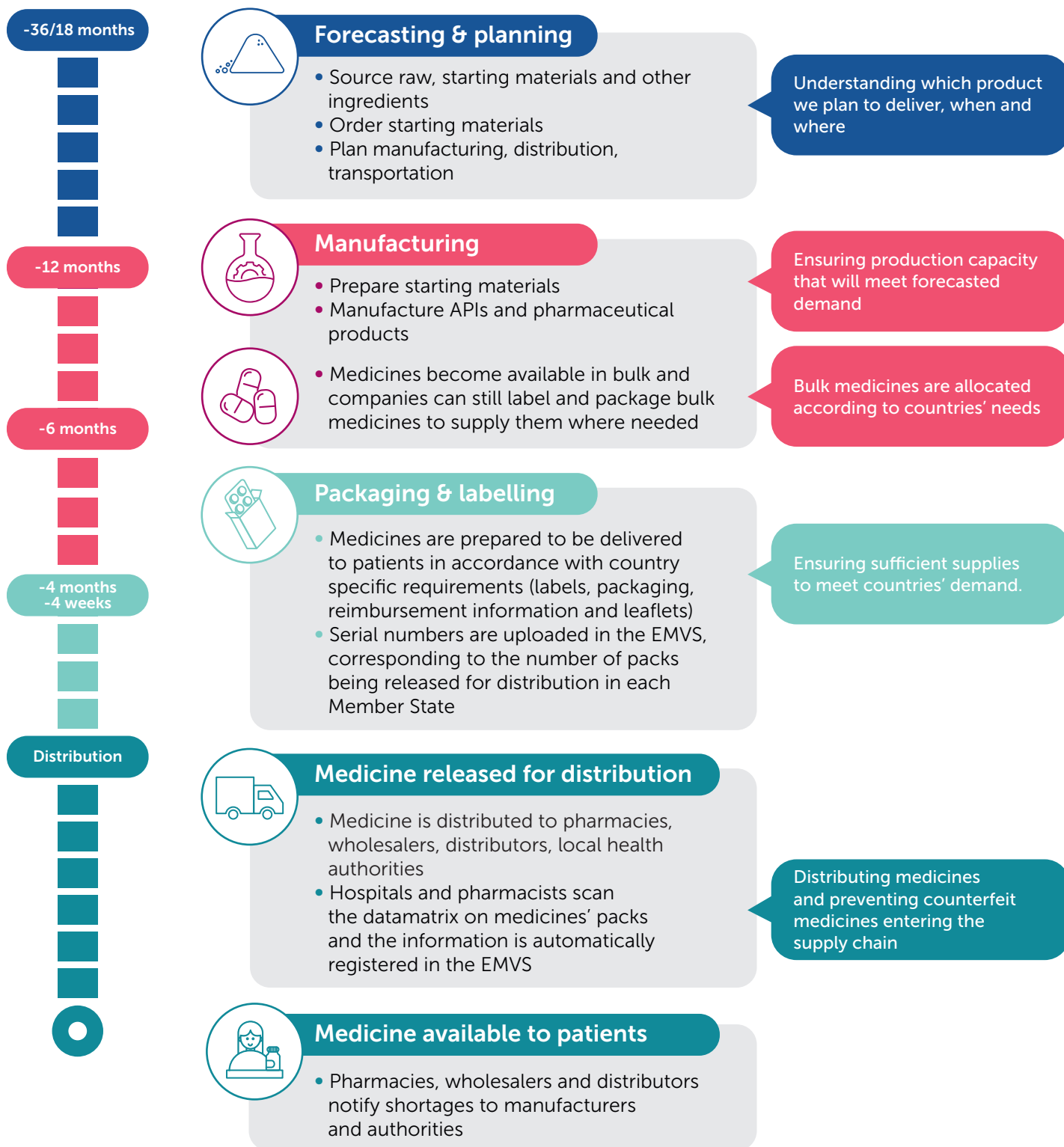


Ensuring patients receive the medicines they need, when they need them

Medicines available in hospitals and pharmacies today began their journey up to 36 months before, when manufacturers start planning production based on demand forecasts.



Medicines supply chains are built to provide the right products, at the right location, at the right time, at the right quantity, at the right amount, with the right documents. However, supply chains are complex and involve many actors. Delays and shortages can occur despite planning and forecasting, creating frustration and worry for patients, their families and clinicians.

What's behind medicine shortages?

The right diagnoses lead to the right solutions

Shortages can occur because of multiple causes:



Shortages predominately affect off-patent medicines:



Shortages of in-patent medicines account for **4% of all reported shortages**

What makes supply chains resilient?



Transparency
on demand allows to plan timely



Flexibility
allows to adjust capacity and allocate medicines to the countries that need them with agility



Global supply chain
allows to mitigate risks through diversified sourcing and cross regional back up



Digitalisation
allows to better FORECAST needs and demand; detect risks and shorten response

Shortages are often not so much a problem of whether a medicine is available but one of where it is available. Policy solutions need to be fit for purpose, carefully tailored to the underlying causes of shortages.

What are manufacturers doing?



- **Investing in advanced technology** and capabilities to forecast demand and manage the stocks
- **Increasing quality management** maturity of individual manufacturing facilities
- **Leveraging science & digital** to improve internal quality, safety and manufacturing processes to increase and optimise capacity
- Strengthening internal operating procedures to **reduce risks** inherent to any step of the manufacturing process
- Transforming supply chains towards **carbon negative emissions**
- Engaging in an **active dialogue** with Health Authorities to improve the security of supply

What can the EU do?



- Develop a **standardised definition** of medicine shortages and a **common IT monitoring and notification portal** to ensure a streamlined alert system
- Increase **transparency** and understanding of demand and supply by harnessing data from the European Centre for Disease Control and the European Medicines Verification System (EMVS)
- **Harmonize and coordinate** actions, avoiding uncoordinated measures at national level and fostering greater regulatory cooperation
- Adopt a **risk-based approach** focusing on critical medicines/critical shortages for **shortage prevention plans** and management of **safety stocks**
- Leverage the **ePIL and other regulatory flexibilities** to move stocks with agility to respond to unpredicted demand flows