

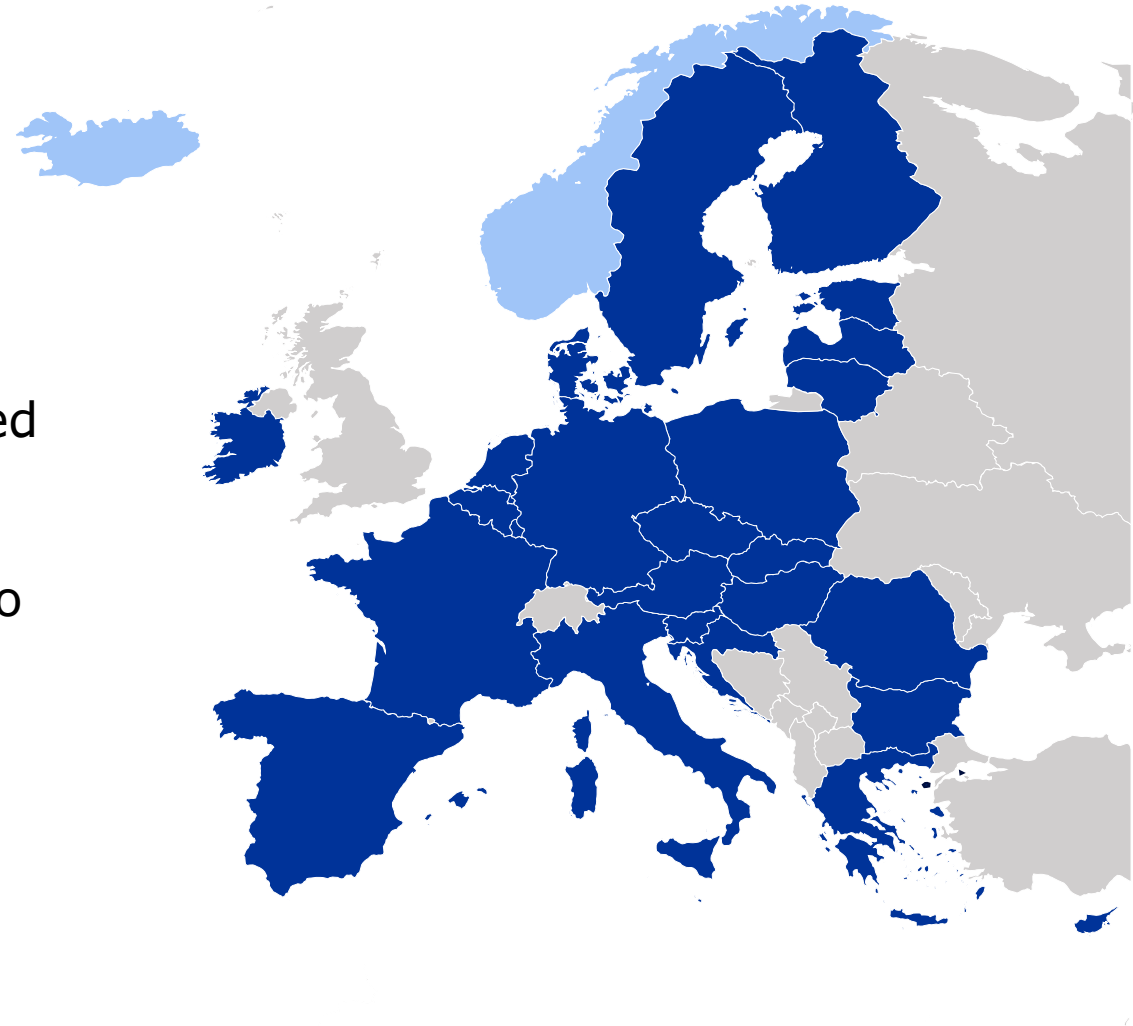


What measures do EMA and national authorities take to address shortages?

Emmanuel Cormier

Solving shortages is complex

- Solving shortages involves **many players** and **tools**
- There is **no one-size-fits-all solution** to shortages
- **EMA** is only involved when shortages cannot be solved at **national level**
- Coordinated EU response through dedicated groups to monitor (SPOC WP) and provide response (MSSG)
- Before, the focus was on **limiting the impact** of shortages. Today, it is also on **preventing** them.



Managing shortages in the EU: a collective effort



How EMA and national authorities manage shortages

1 Engage with and support companies



Gather data on supply



Support to increase supply and distribute fairly

However, regulators cannot force manufacturers to produce more medicine



Allow flexibility with certain rules

For example, approve longer shelf-life or labelling exemptions

How EMA and national authorities manage shortages

2 Engage with patients and healthcare professionals



Gather feedback to shape measures

Shortages of antibiotics and GLP-1 medicines



Provide recommendations

Such as prioritising existing patients, if needed



Communicate to inform and guide

Shortage catalogue on EMA website

Letters to healthcare professionals

Social media campaigns

Public statements

How EMA and national authorities manage shortages

3 Engage with European and international partners



Gather data on demand

Inform of early signs of shortages within the EU and internationally (antibiotic use in Australia – summer)



Share good practices



Coordinate response

- joint assessments & harmonised communication
- collaborate and align across the EU on actions to take at national level
- avoid duplication

How EMA and national authorities prevent shortages

Take measures to prevent shortages and limit their impact



Improved reporting and monitoring
'You can't fix what you don't see'



From reaction to prevention
The Union list of critical medicines
Shortage prevention plans



Recommendations to strengthen supply chains
for critical medicines



New/change in legislation (Critical Medicines Act
and EU Pharmaceutical Legislation Reform)



Measures take time to take effect

Spotlight on the voluntary solidarity mechanism



Allows a Member State to request assistance from other Member States to obtain stocks of a medicine during critical shortages



To be used as a last resort to temporarily alleviate critical shortages in Member States

i.e. when no other alternatives are available, other measures have been exhausted, and short-term measures (e.g. imports) are not possible



In the last 2 years, 12 requests have been received, and medicines were sourced in most cases (at least 1 member state was able help)

Conclusion

- Shortages are a shared responsibility.
- Regulators have a toolkit—ready to deploy the right measures at the right time.
- There is a shift from reacting to shortages to preventing them before they happen.
- New EU pharmaceutical legislation aims to strengthen supply chains and improve availability to critical medicines.
- By working together, we can achieve a more resilient, reliable, and sustainable medicine supply.