



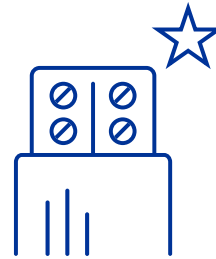
Examples of measures taken by EMA and national authorities to tackle shortages

Monica Dias

Examples of shortages tackled at the EU level



Critical shortages
managed at **EU level** in
addition to national level



Critical medicines,
for serious diseases,
often without alternatives



In close **collaboration**
with all partners



Visudyne



What it is used for

Macular degeneration due to age and a severe type of myopia called choroidal neovascularisation



Cause of shortage

Technical issue with the machine used to fill vials



Reduced manufacturing capacity

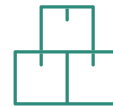


worldwide shortages



Context

- One manufacturer makes the active ingredient worldwide
- Making the final medicine is complicated and requires several ingredients



What EMA/EU did

- Provided support to company to establish new supply chain
- Worked with company to distribute stocks fairly between EU countries, based on past demand



What national authorities did

Expert committees or national guidance to allocate available supply to patients who need it most

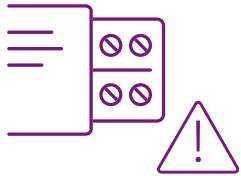


NovoSeven



What it is used for

Treat bleeding and prevent bleeding after surgery



Cause of shortage

Capacity constraints and issues with the packaging process



What EMA/EU did

- Temporarily allowed distribution with a package leaflet in English
- Communicated with healthcare professionals and patients

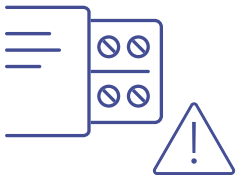


Metalyse



What it is used for

Dissolve blood clots during a heart attack or stroke



Causes of shortage

- Rising number of patients
- Manufacturing capacity constraints



Context

Complex manufacturing process



What EMA/EU did

- Goal: increase supply and prevent disposal of usable stocks
- Action:
 - allowed use beyond the expiration date, based on new data confirming this approach was safe
 - communicated with healthcare professionals and the public
 - approved a new manufacturing site in Austria with an accelerated process



Antibiotics



What it is used for

To treat bacterial infections
(ex: amoxicillin)



Context

- Seasonal need (fall and winter)
- Overuse for diseases for which antibiotics are not effective (e.g. viral infections such as cold and flu)



Causes of shortage

- Increase in respiratory infection in autumn and winter 2022
- Reduced production due to COVID-19 pandemic



Consequence of the shortage

Many patients could not receive the antibiotic prescribed, and alternatives had to be found



Antibiotics





Antibiotics



What EMA/EU did

- Continuous monitoring since 2022
- Close cooperation with companies
- Supply and demand matching
- Shared best practices
- Expert group set up
- Clear communication to public
- Worked with EU institutions and international partners



What it achieved

- Extra supplies for EU countries
- Flexibility in packaging (foreign languages allowed)
- Faster assessment of new manufacturing sites by EMA

Fall–winter 2023/2024 & 2024/2025: only a few critical shortages

2025/2026: activities continue

Conclusion

- EMA and National Authorities continue to monitor supplies, work with companies and collaborate with stakeholders to prevent or mitigate the impact of shortages
- Communication to healthcare professionals and patients is key
- To prevent future shortages, companies are asked to prepare shortage prevention plans
- Tailored recommendations to address weaknesses in the production of critical medicines and strengthen supply chain
- Further measures to reinforce supply chains are also included in the new legislation