



What is a shortage, why do shortages happen, and what is their impact?

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de Volkskrant

**How the medicine shortage
in the Netherlands
endangered Edwin and
Anne's baby: 'Go to Belgium
or Germany now'**

The Guardian Fri 7

**Man with epilepsy in Leeds died in fall
after pharmacy ran out of drug**

B B C

**Cancer patients 'may starve' without
vital drug
Shortage of key drug 'frightening' for
patients**

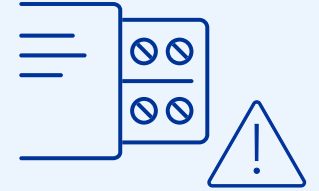
the
PHARMACEUTICAL JOURNAL

**More than half of pharmacy staff struggle
with mental health over medicines
shortages, reveals survey**

What is a medicine shortage?

EMA's definition¹

Supply does not meet demand at national level, whatever the cause



What this means in practice

- Not every missing medicine at the pharmacy is a shortage
- There is a shortage when there is not enough of a medicine to supply patients in a country
- Shortages often affect several countries

¹ Regulation 2022/123

Who is affected by medicines shortages?



Patients

- May take less medicine than prescribed
- Alternatives may be less effective, safe or affordable
- Disease may worsen
- Stress and risk of medication errors



Healthcare professionals

- Increased workload (finding alternatives)
- Unable to provide best care
- Stress and risk of medication errors



Companies

- Regulatory challenges
- Impact on reputation



Regulators¹

- Increased monitoring
- Measures to prevent shortages and reduce their impact
- Strain on regulatory processes



Shortages affect everyone

¹ EMA and national competent authorities

The medicine supply chain is really complicated



From factory to patients: the medicine supply chain

Medicine supply chain

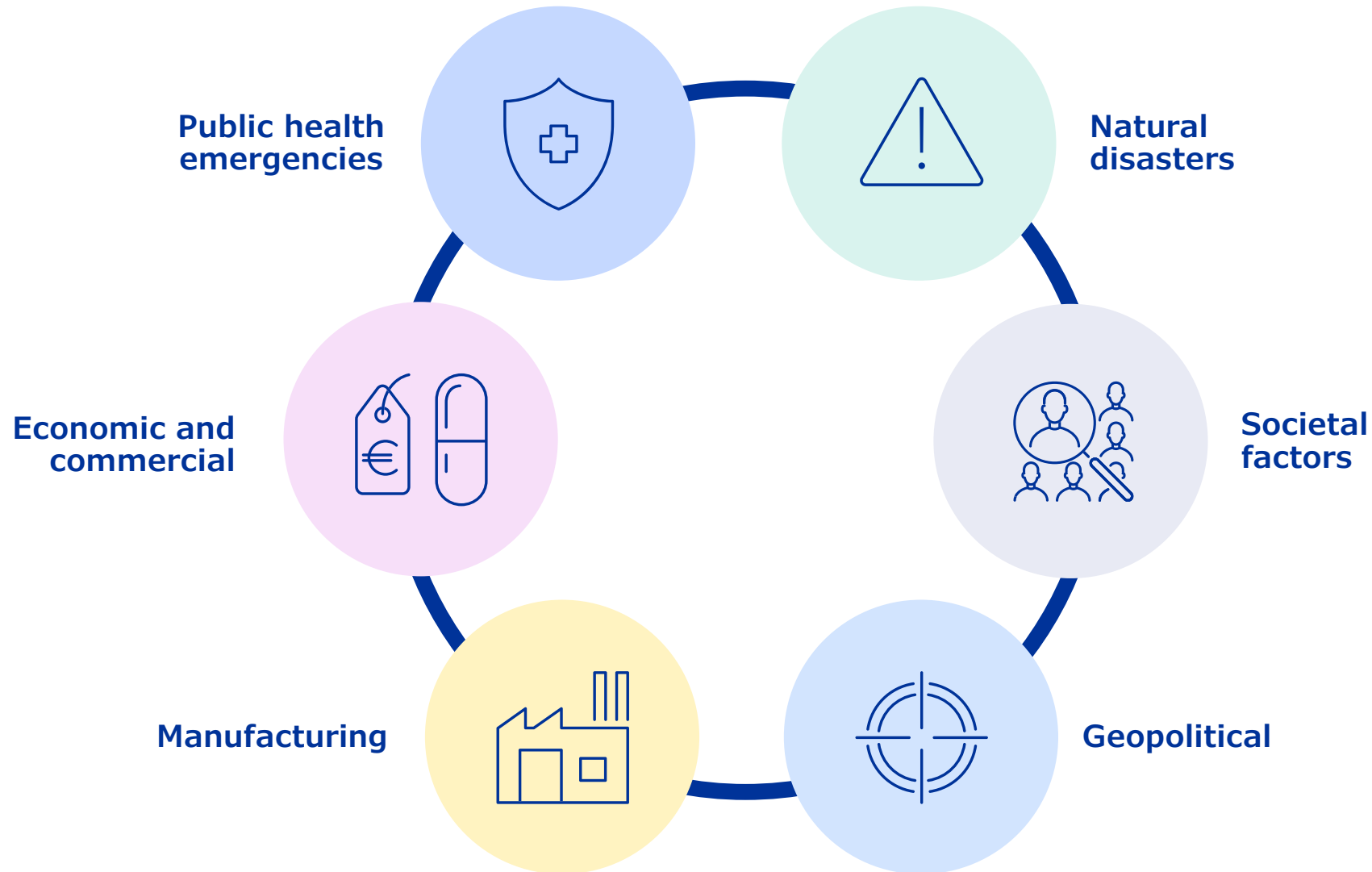
The system that transforms raw materials into a medicine



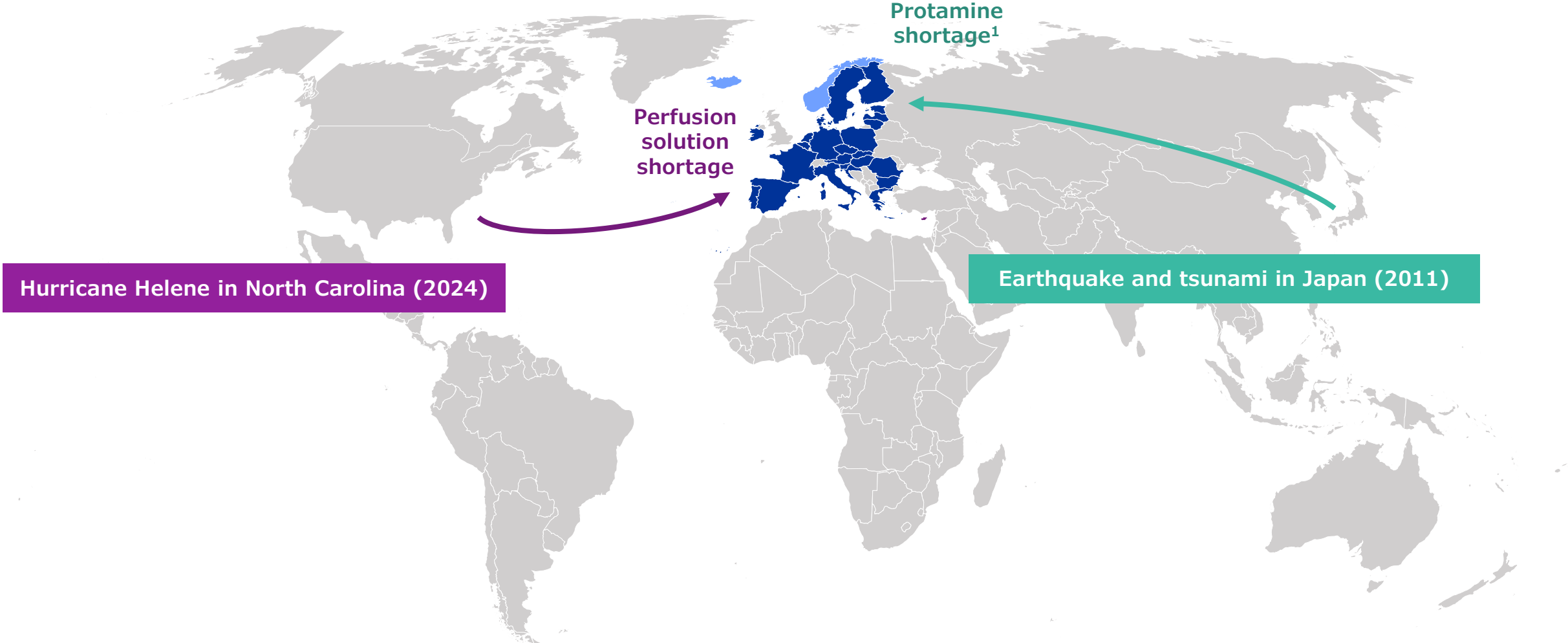
Issues can occur at any step in the chain



What can disrupt a medicine supply chain?



A natural disaster outside the EU can affect medicine supply in the EU



Hurricane Helene in North Carolina (2024)

Earthquake and tsunami in Japan (2011)

Perfusion solution shortage

Protamine shortage¹

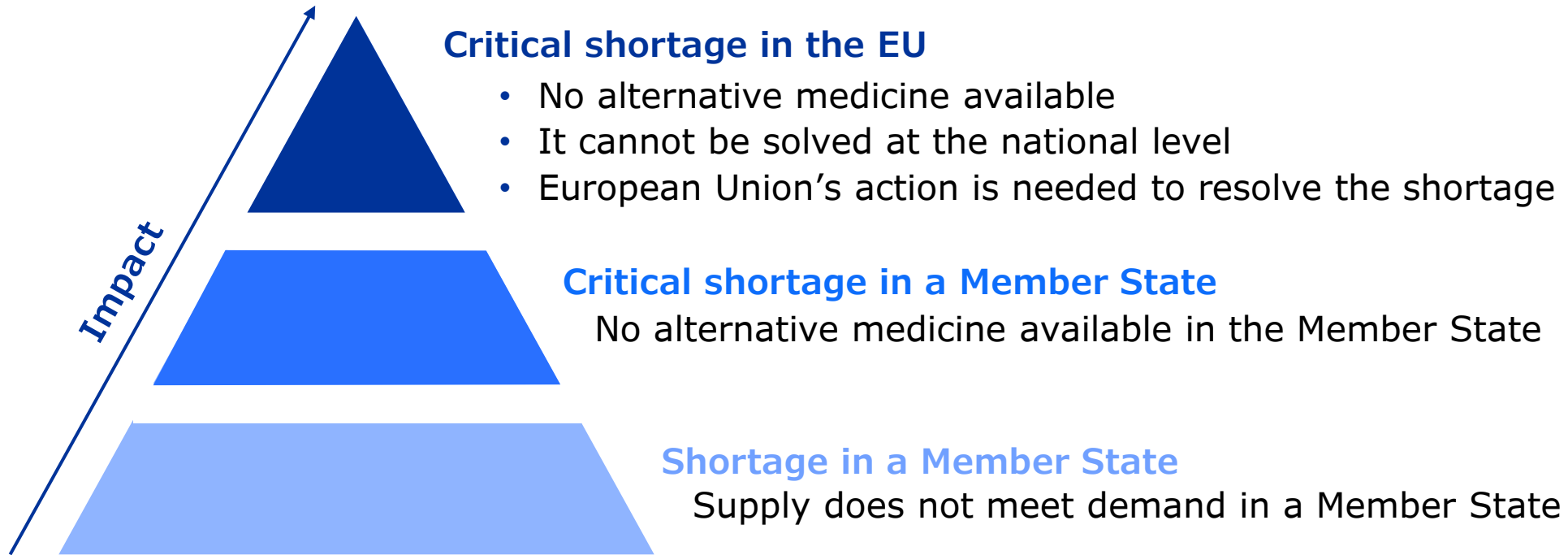
¹ Protamine: medicine used during surgery to counteract the effect of heparin (a medicine to prevent blood from clotting)



Not all shortages have the same impact

- **Many shortages** are **easily solved** with no impact on patients' care
- 4 out of 10 patients who experienced a shortage said the shortage caused a problem
- **Impact** depends on:
 - the seriousness of the disease treated
 - the availability of suitable alternative medicines (**critical** vs **non-critical** medicines)

Not all shortages are the same



Not all shortages require an EU response – only those that cannot be solved at national level

Conclusion

- Medicines supply chains are complicated
- Disruptions can happen anywhere in the supply chain and cause shortages
- Not all shortages have the same impact
- Not all shortages are addressed in the same way
- Shortages that cannot be solved at national level are escalated to EU level



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