



Drug shortage reporting systems in Europe

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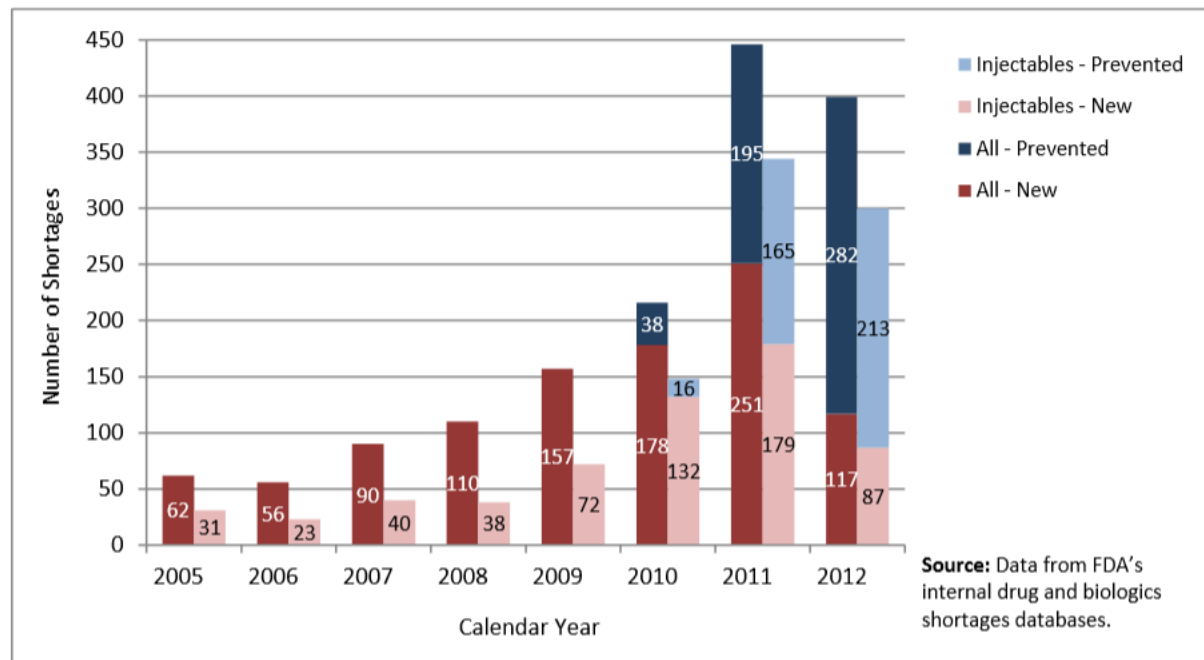


Drug shortages: a complex global challenge



U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

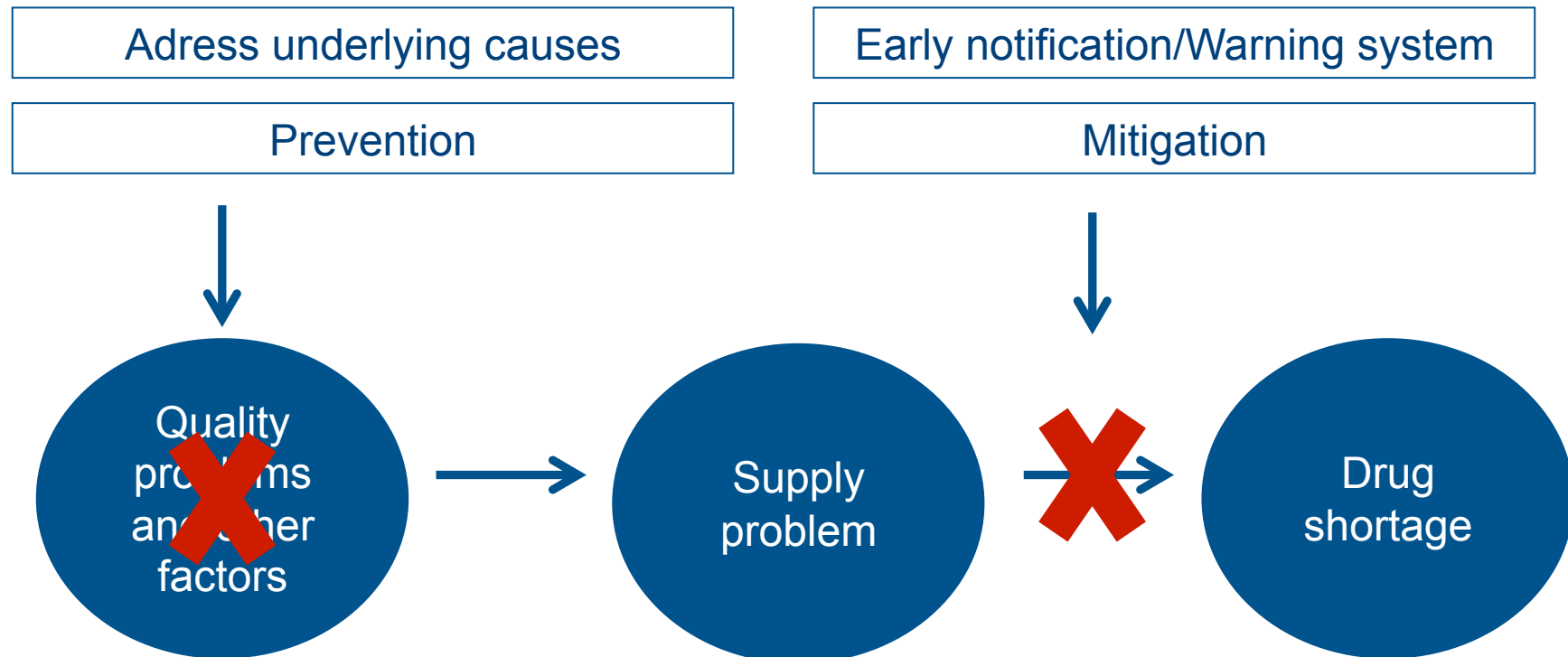
Figure 1. Number of New and Prevented Shortages by Dosage Form, 2005-2012



Drug shortages: a complex global problem



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Drug shortages: a complex global challenge

- EAHP Survey “Medicine shortages in European hospitals” (2012) (2014)
- Common position between patients, consumers, health care professionals organisations involved in the activities of the EMA on supply shortages of medicines (2013)
- Reflection paper by EMA on medicinal product supply shortages (2012)
- Case reports in literature
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Aim of the study

Explore national and European reporting systems to collect and present data about drug shortages in European countries

Methods

Drug shortage reporting systems at websites of regulatory authorities in EU



Reporting template

Analysis on prescription drugs

Scope and definition of a drug shortage

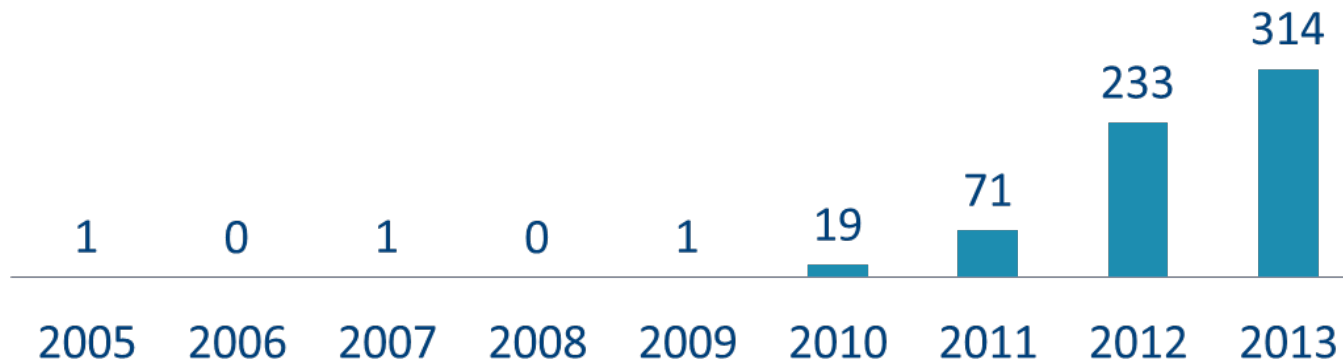
The definition of drug shortages and scope of reporting systems is not uniform

	Reporting system	Drugs included in reporting system
Belgium	Federal Agency for Medicines and Health Products Farmaco-contingentering.be	Drugs for which unavailability cause a risk for public health and have no therapeutic alternative Products subjected to supply quotas
The Netherlands	Farmanco.nl	Any type of drugs
England	Pharmaceutical Services Negotiation Committee (PSNC)	Products for community pharmacy only
Italy	Italian Medicines Agency (AIFA)	Any type of drugs
Germany	Federal Institute for Drugs and Medical Devices (BfArM)	Products for treatment of threatening or serious disease for which no alternatives are available
Spain	Spanish Agency for Medicines and Health Products (AEMPS)	Any type of drugs
France	National Agency for Safety of Drugs and Health Products (ANSM)	Drugs for which unavailability cause a risk for public health and have no therapeutic alternative

Timing of a drug shortage

Information on the timing and likely duration of the shortages is incomplete

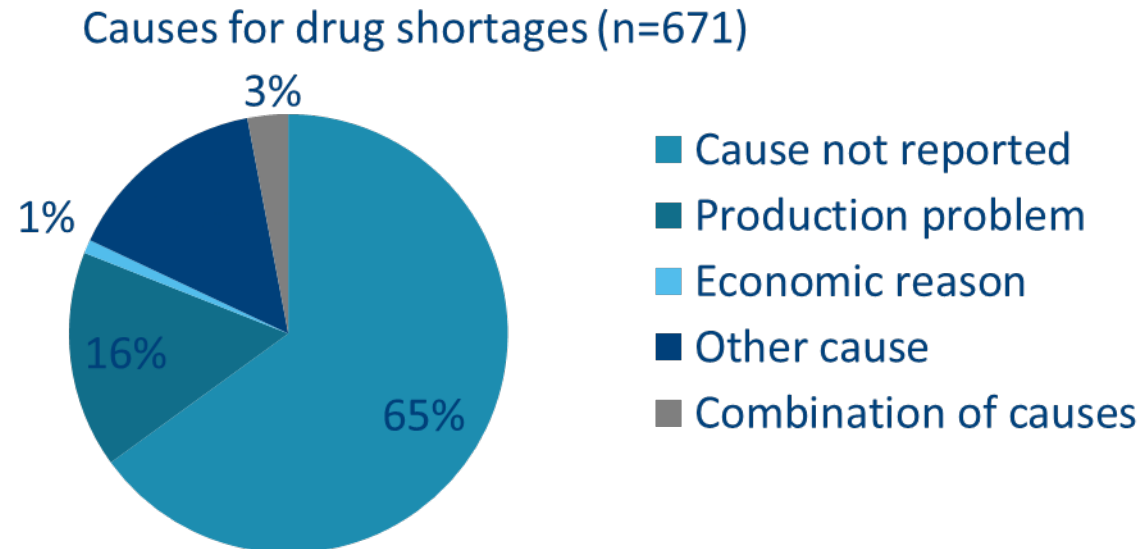
Number of shortages reported per year (2005-2013)



- 31 cases (5%): no information about start date
- 459 cases (68%): information about the predicted end-date was not present
- 38 drug shortages: early notified (start date after date of data collection)
- Median duration 139 days (n=54)

Causes of drug shortages

Causes for drug shortages are underreported

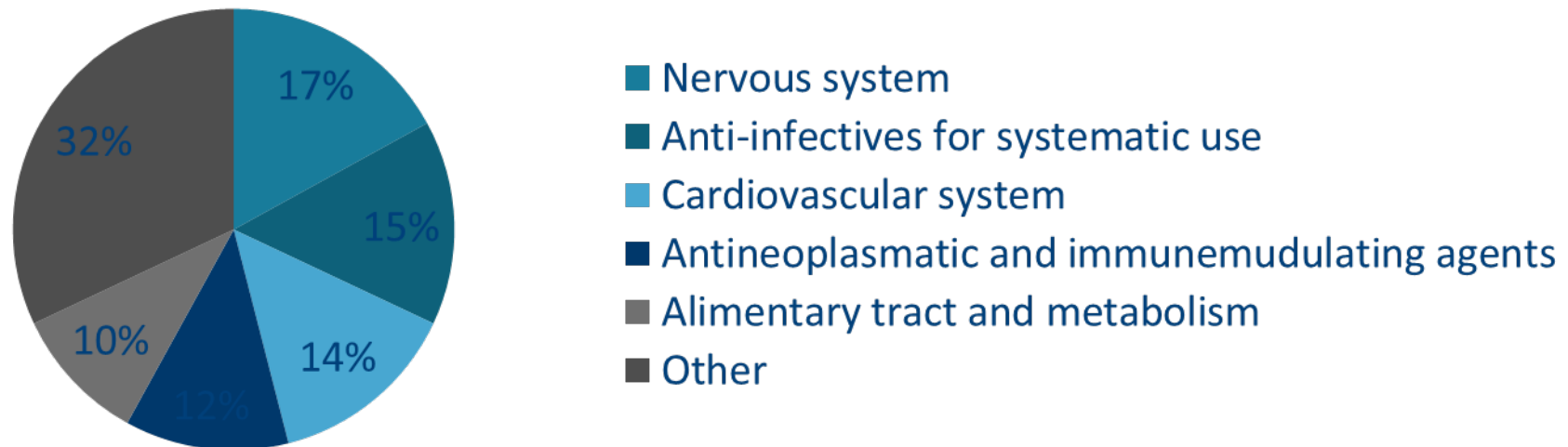


- **Production problems:** Impurities, lack of API, technical defect in production process, problem with manufacturing the solvent, problems with quality, delay start-up new production line,...
- **Economic reasons:** commercial reason, commercial problem, economic reasons
- **Other causes:** limited stock because unavailability alternative product, logistic problem, delayed supply, natural disaster,...

Drugs affected by shortages

Shortages affect essential medicines and drugs used in life threatening and urgent situations

Anatomic therapeutic classes affected by shortages (n=671)



Other = antiparasitic products, insecticides and repellents, products for the respiratory system, products for the sensory organs, drugs affecting blood and blood forming organs and dermatologicals.






30% of the shortages affected drugs defined as essential medicines by the WHO

European reporting system

Information in EMA drug shortage catalogue is limited

- 9% of drug shortages concerned drugs that obtained marketing authorization through the centralized procedure, involving 32 different products (n=671)
- Only for 7 of these products shortage was reported on the website of EMA (at the time point of data analysis)

Current shortages

Document(s)	Status
 Buccolam (midazolam) supply shortage	Ongoing
 Cerezyme (imiglucerase) supply shortage	Ongoing
 Fabrazyme (agalsidase beta) supply shortage	Ongoing
 Maci (matrix applied characterised autologous cultured chondrocytes) implant supply shortage	Ongoing
 Xofigo (radium-223 dichloride) supply shortage	Ongoing

Resolved shortages

Document(s)	Status
 Enbrel (etanercept) supply shortage	Resolved
 Increlex (macasermin) shortage resolution	Resolved

Conclusion: points for improvement in Europe



Shortages affect essential medicines and drugs used in life threatening and urgent situations

Early and systematic reporting

Only a limited number of European countries has a publicly available reporting system for drug shortages

Information in EMA drug shortage catalogue is limited

Standardized reporting

The definition of drug shortages and scope of national reporting systems is not uniform

Transparent reporting

Causes for drug shortages are underreported

Information on timing and likely duration of the shortages is incomplete

Conclusion: points for improvement in Europe



Conclusion: points for improvement in Europe

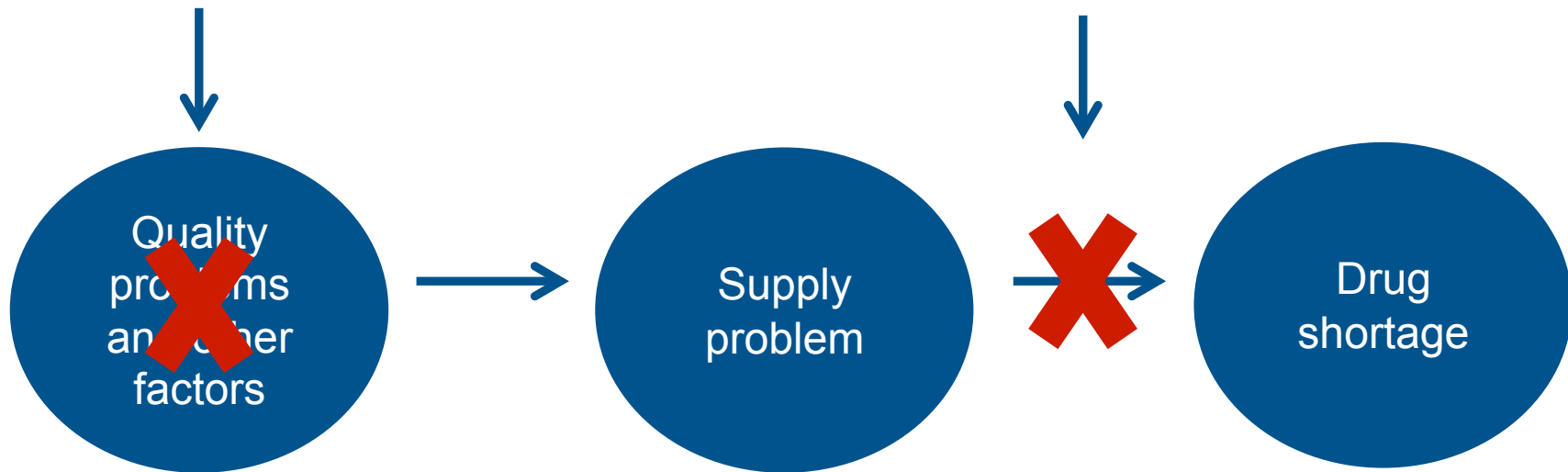


Address underlying causes

Early notification/Warning system

Prevention

Mitigation



Questions?