

Medicines shortages in European Hospitals



***EAHP members
working together to
achieve
improvement***

**A Members' Meeting
on future advocacy**

What we're here to do today

1. Review the picture of **shortages in Europe** (David Preece)
2. Update you on **EAHP's activities** over the past year
3. Look to the year ahead – and where we need **YOUR** Association's help and support



Medicines shortages in European hospitals



What is a pharmacy without medicines?

*A review of the medicine shortages situation in
Europe*

What is a medicine shortage?

Consequences of medicines shortages

What is the scale of medicine shortages across Europe?

Just a European problem?

What are the causes (perceived and in reality)?

What can be done to address these problems?

- Hospital Level
 - National Level
 - European Level

Medicine shortages could be defined as:

“a **supply issue** that **affects** how the pharmacy prepares or dispenses a drug product or **influences patient care** when prescribers must use an alternative agent”

(Fox et al, 2009, AJHP)

“a **period of time** when the total supply of **all versions** of a drug available at the user level will not meet the current demand for the drug at the user level.”

(Thompson, 2011, AJHP)

A medicine in shortage could be defined as:

Medically necessary: “any drug product used to treat or prevent a serious disease or medical condition for which there is no other adequately available drug product that is judged by medical staff to be an appropriate substitute.”

(FDA Catalogue)





(Inconvenience to the patient and cost to the patient, institution, and manufacturer are insufficient reasons for classifying a product as a medical necessity)

European Medicines Agency (EMA):

“medicine shortages that affect or are likely to affect more than one (EU) Member State, where the European Medicines Agency has assessed the shortage and provided recommendations.”

Current shortages

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Document(s)	Language	Status	First published	Last updated	Effective Date
 Enbrel (etanercept) supply shortage	(English only)		19/02/2014		
 Cerezyme (imiglucerase) supply shortage	(English only)		04/11/2013		
 Fabrazyme (agalsidase beta) supply shortage	(English only)		04/11/2013		
 Vistide (cidofovir) supply shortage	(English only)		04/11/2013		

*(It does not give a complete overview of all medicine shortages occurring in the EU, as **most shortages are dealt with at a national level.**)*

What does this mean ? (Hospital Pharmacist)

Uncertain supply of : vaccines, pain medicines, oncology medicines, cardiovascular medicines, emergency medicines, antimicrobials, anaesthetics, fluids, biological products, CNS agents, radiopharmaceuticals, nutrition products and more

Time Up to 9 hours per week (*Kakeeh et al 2011*)

Advising on alternatives (managing potential errors)

Formulation/compounding alternatives

What does this mean ? (Hospital)

Increased medicine expenditure

Antimicrobial resistance

Delays/cancellations in treatments (e.g. surgery)

Impact on conducting clinical trials

Altering protocols/formularies

What does this mean ? (Patient)

Inconvenience

Increased Cost?

Increase in the potential morbidity/mortality of treatments.
Decrease in patient safety?

Delays/cancellations in treatments (e.g. surgery)

Alternatives – allergic patient, complex patient




What is the scale of the problem in Europe?

Not a new problem

Articles in the European Journal of Hospital Pharmacy (EJHP) cited examples in Austria, the Netherlands and France (2004)

European drug shortages: a call to action! (2013)
(Huys, and Simoens, *International Journal of Pharmacy Practice*, 2013)

What is the scale of the problem in Europe?

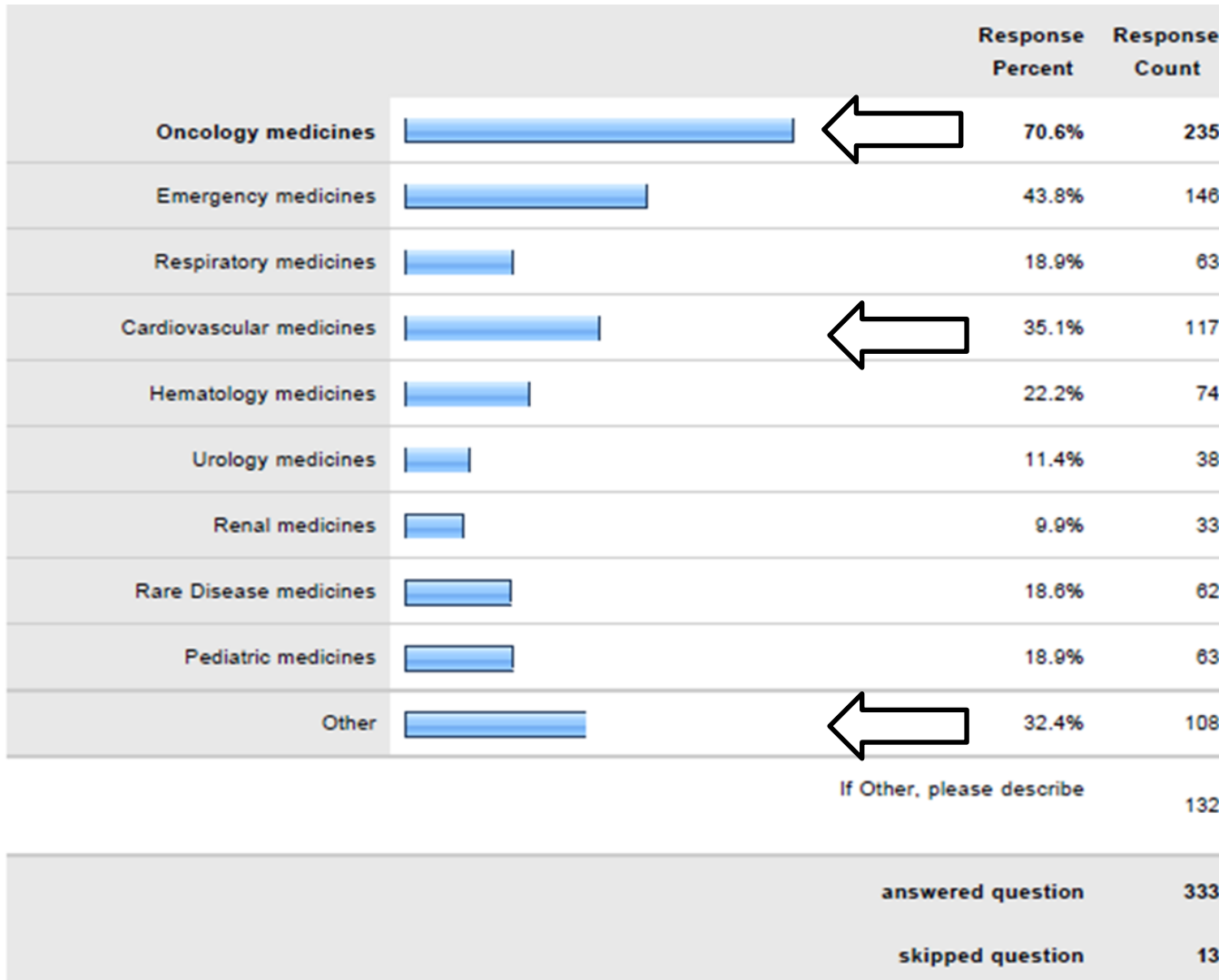
		Response Percent	Response Count
Problems with medicines shortage in our hospital are a weekly, sometimes daily, occurrence		63.1%	214
Our hospital experiences medicines shortage problem at least once a month		27.1%	92
Not very often, maybe a few times a year		9.7%	33

Comment 13

90% at least monthly	answered question	339
	skipped question	7



What is the scale of the problem in Europe?



What is the scale of the problem in Europe?

PGEU (2012)

*“although some countries are more affected than others, medicine shortages have been reported by all respondents to the survey and the problem is increasing” - **Medicine Shortages in European Community Pharmacies***

EMA Reflection Paper (2012)

What is the scale of the problem in Europe?



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 November 2012
EMA/590745/2012
Patient Health Protection

Reflection paper on medicinal product supply shortages caused by manufacturing/Good Manufacturing Practice Compliance problems

1. Introduction

Ensuring the security and Good Manufacturing Practice (GMP) compliance of the manufacturing supply chain is an important responsibility of the Marketing Authorisation Holder (MAH) to ensure appropriate and continued availability of medicinal products for human use to meet the needs of patients in accordance with Article 81 of Directive 2001/83.

What is the scale of the problem in Europe?

“Common position between patients’, consumers, and healthcare professionals’ organisations involved in the activities of the European Medicines Agency on Supply Shortages of Medicines”

Consequences for patients, healthcare professionals

Possible causes

Proposed measures (Short term/Long term)

Changes to the regulatory framework

What are the causes (perceived)

In your experience and estimation, what do you consider to be the MOST common root causes of medicines shortages in the hospital you work in?

	Response Percent	Response Count
Manufacturers experiencing shortage problems with raw materials	43.7%	90
Quality-related production difficulties at manufacturing source (e.g. failed batches, GMP failure etc)	43.7%	90
Supply chain vulnerability from only having a single supplier, or small numbers of suppliers, of a product (e.g. global consolidation of manufacturing)	52.4%	108
Supply chain vulnerability from the		

Without disclosure of **real causes** we cannot properly work towards a solution. Without **information** we cannot plan and hospital pharmacists are left in a helpless situation.

How can these issues be addressed?

Standardised protocols for dealing with shortages

Additional staff? Reallocation of existing staff

Ethical allocation of current stock

Guidelines (Hospital, National, European)

What CAN be done?

EAHP Statements (Still under discussion)

“In collaboration with other local and national health organisations, each hospital pharmacy should have contingency plans for shortages of medicines, and for other health care products which it procures.

Stead, D., **Best practice** standards for managing medicines shortages in hospitals. *European Journal of Hospital Pharmacy: Science and Practice*, 2013. **20(4): p. 251-252.**

Cousins, D., M. Evans, and K. Wind, **Managing risks** arising from medicine shortages in NHS hospitals. *The Pharmaceutical Journal*, 2012. **289: p. 306.**

Examples of successful action

Websites that track shortages:

(FDA/ASHP/UTAH – America)

Canada, France, The Netherlands

(Different definitions – comparable?)

Legislation

Presidential Order (2011) strengthened recently.

EU Directive – expected shortages (2 months)



Thank you for your attention

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Worldwide Literature:

Gray, A. and H.R. Manasse, Shortages of medicines: a complex global challenge. *Bulletin of the World Health Organization*, 2012. 90(3): p. 158.

Kaakeh, R., et al., *Impact of drug shortages on U.S. health systems*. *American Journal of Health-System Pharmacy*, 2011. **68**(19): p. 1811-1819.

Fox, E.R. and L.S. Tyler, Managing drug shortages: seven years' experience at one health system. *American Journal of Health-System Pharmacy*, 2003. 60(3): p. 245-253.

McLaughlin, M., et al., *Effects on Patient Care Caused by Drug Shortages: A Survey*. *Journal of managed care pharmacy: JMCP*, 2013. **19**(9): p. 783-788.

Since we last saw you...



An update on EAHP medicines shortages activity...

Gathering the evidence – EAHP 2013 Survey

- 99% of HPs experiencing problems with medicines shortages
- 67% said its a daily or weekly problem
- 73% said the problem is getting worse



Medicines shortages in European hospitals

Presenting the evidence to the EMA

- October 2013 EMA Workshop with stakeholders
- **Common Position Paper** – over 20 patient & HCP orgs
- Key points include:
 - stronger legislation on shortage notification and comms
 - better investigation of causes by public authorities
 - address the regulatory ‘responsibility gap’
 - enhanced EMA catalogue and info on EU shortages
 - full review of of the pricing system in Europe

Presenting the evidence to the European Parliament

- Part of an EPHA and HAI led coalition
- Presented the problem to MEPs in May 2014
- Further work planned
- Need to energise the Parliament on this ahead of next Commissioners' confirmation hearings



Presenting the evidence to the European Commission

- Alongside PGEU and EIPG, met DG SANCO in September 2013 to present evidence & suggestions
- **Disappointing response:** Commission do not feel they have the mandate from Member States to act
- **Next stage** – improve Commission mandate by activating members to lobby their health ministries on this topic



Where we are on proposed solutions?

Drawing from the EMA patient and HCP position paper...

1. Enhanced and improved EMA database (e.g. FDA)
2. Commission led investigation of pan-European scale, causes and solutions (e.g. production, pricing, parallel trade etc)
3. International Government dialogue
4. Better early reporting requirements & enforcement

Also, drawing from USA's FDASIA legislation:

- Annual reporting by EMA to Commission, Parliament and Government on status of shortages and potential remedial action

So....

**WHERE
NEXT?**

EAHP will...

- Aim to put this issue firmly on the agenda of the **next EU Commission mandate (2014-2019)**
- Continue to build the **evidence-based solutions**
- Continue to **raise public and political awareness**
- Continue to **build the coalitions**



3 kind requests to our members...

1) Take & promote the 2014 EAHP medicines shortages survey!

(... and then promote it again!)

2) Use EP elections to raise this with MEP candidates

3) Write to your health ministries
(June 2014 and September 2014)

