



How can we better prevent and
manage medicines shortages? How
can we better inform the public?

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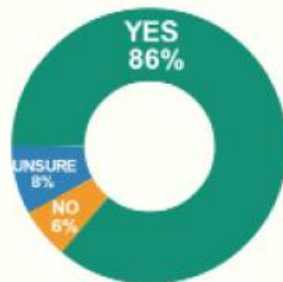
Director of Treatment Information & Access

EMM 2015, workshop 2, Madrid 30 May 2015



European Association Hospital Pharmacists Survey 2014 (www.eahp.eu)

Are medicines shortages a current problem?



Over 600 hospital pharmacists from 36 countries responded



Questions relating to: impact of shortages, supply to hospitals and proposed solutions

45%
experience shortages
every week



52%
responded that originator products are
most commonly in short supply

55%

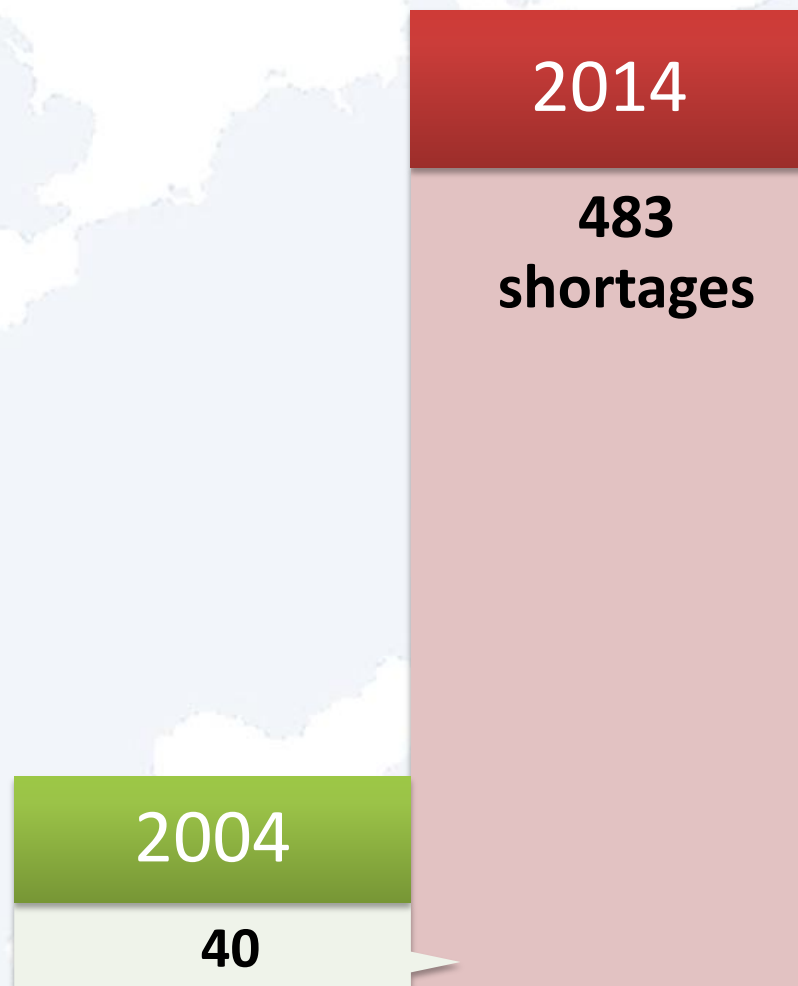
5 hours a week of staff time



37%
responded that generic products are
most commonly in short supply

2500 to 2800
FTE / year

For medicines with no alternatives, reports to National Agency, France



Main concerns for the patients

Information

- ✓ Often only at pharmacy to renew prescription
- ✓ “out of stock” and no other information
- ✓ Reporting
- ✓ When prejudice, do they tell you?

Consequences

- ✓ Disease evolution can start again
- ✓ Clinical impact rarely measured
 - ✓ Anxiety
- ✓ Going from one pharmacy to the next
- ✓ Medication errors (substitution with unfamiliar products)
- ✓ What is the cost to public health?

Management

- ✓ Transparency on causes
- ✓ Transparency on available supplies
- ✓ Transparency on duration and on measures taken
- ✓ Participation in decision-making
- ✓ Legal Liability (Obligations of MAH and Distributors, Article 81 of Directive 2001/83)

Why does it matter to us, patients?

Important decisions are made that affect our health

- CHMP recommendations. Shouldn't we be consulted?
- Inadequate care: are we always informed when we don't receive the appropriate treatment due to shortages? Think of hospital care

Marketing authorisation holder and regulators decide on criteria to select patients who will continue/stop treatment

- And decide how to allocate remaining supply
- Shouldn't we be consulted?

Communication materials

- Shouldn't we be involved?

A Common Position signed by 45 organisations

- AGE Platform Europe (AGE)
- Alzheimer Europe
- Asociación de Addison y Otras Enfermedades Endocrinas-Adisen (Spain)
- Association Surrénales (France)
- Behcet Syndrome Society UK
- DEBRA International
- European Association of Hospital Pharmacists (EAHP)
- European Aids Treatment Group (EATG)
- European Association of Urology (EAU)
- European Federation of Allergy and Airways Diseases Patients associations (EFA)
- European Federation of Neurological Associations (EFNA)
- European Federation of Internal Medicine (EFIM)
- European Institute of Women Health (EIWH)
- European Multiple Sclerosis Platform (EMSP)
- European Organisation for Rare Diseases (EURORDIS)
- European Public Health Alliance (EPHA)
- European Specialist Nurses Organisations (ESNO)
- European Union of Geriatric Medicine Society (EUGMS)
- International Patient Organisation for Primary Immuno-deficiencies (IPOPI)
- Patients Network for Medical Research and Health (EGAN)
- The European Consumers' Organisation (BEUC)
- The European Society of Oncology Pharmacy (ESOP)
- European Patients Forum (EPF)
- Spinal Muscular Atrophy Europe (SMAE)
- European Heart Network (EHN)
- European Haematology Association (EHA)
- European Working Group on Gaucher Disease (EWGGD)
- European Gaucher Alliance (EGA)
- European AIDS Clinical Society (EACS)
- European Liver Patient Association (ELPA)
- Pulmonary Hypertension Association Europe (PHA Europe)
- Standing Committee of European Doctors (CPME)
- European Academy of Paediatrics (EAP)
- Rett Syndrome Europe (RSE)
- European Foundation for the Care of Newborn Infants (EFCNI)
- European Federation of Neurological Societies (EFNS)
- European Society for Medical Oncology (ESMO)
- International Diabetes Federation European Region (IDF Europe)
- European Cancer Patient Coalition (ECPC)
- Thalassaemia International Federation (TIF)
- European Haemophilia Consortium (EHC)
- Myeloma UK
- European Association for Clinical Pharmacology and Therapeutics (EACPT)
- Myeloma Patients Europe (MPE)
- Rare Voices Australia Ltd.

(some proposals) EMA with NCAs should:

Create an unit to facilitate prevention, coordination of resolution and of communication on shortages

Create a public catalogue on supply shortages ([catalogue](#))

Work more closely with industry to prevent shortages and to better organise the end of a shortage

Involve patients and HCPs in decision making and communication

Public authorities should

Explore the establishment of buffer stocks to be held by wholesalers for more flexibility to supply chain

Ensure fair distribution of the remaining supply

When a MS stockpiles some supply, this should not pre-empt stocks to the detriment of others

Establish a mechanism for stakeholders to report evidence of a product shortage to the authorities

Industry: preventing shortages

Supply Shortage Risk Assessment Plan with MA submission (SSRAP)

Inform EMA, NCAs, HCP and patients' organisations when a shortage is possible (even if false alerts)

Involve POS and HCPs in the crisis management: guidelines, programmes, communication

Treat all countries equally, and within countries, each hospital / wholesaler equally

Initiatives

- November 2012: [EMA reflection paper](#) on shortages
- October 2013: Common position on medicines supply shortages by patients and healthcare professionals
- EMA workshop 14/10/2013
- Meeting at EC DG Sanco/ DG Enterprise 30/06/14
- Press Conference EAHP 17/11/2014
- HMA Stakeholders' Forum 26/11/2014
- Meeting with PermRep Latvia April 2015
- EMA 2nd Workshop 9 October 2015
- To come: HMA conference, ICRMA meeting
- Research: COST project with EAHP

Roberto Frontini. EAHP [survey](#) 2014

Are medicines shortages a current problem in the hospital you work in, in terms of delivering the best care to patients and/or operating the hospital pharmacy?

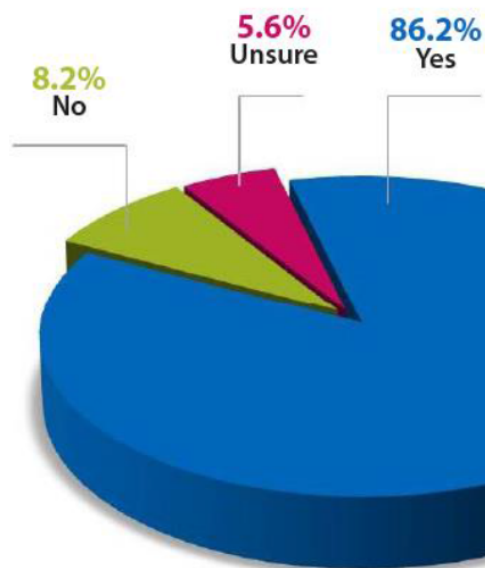


Chart 2: proportion of hospital pharmacists (%) stating that medicines shortages were a current problem in their country. (N=537)

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EAHP survey 2014. Roberto Frontini

Specific examples of medicines in shortage provided by respondents in 3 or more countries

- **Antibiotics:** amoxicillin, co-amoxiclav, gentamicin, linezolid & meropenem.
- **Anti-cancer drugs:** 5-Fluorouracil, carboplatin, cisplatin, doxorubicin (liposomal), methotrexate & vincristine.
- **Analgesics (pain relief):** ibuprofen, morphine & tramadol
- **Cardiology drugs:** digoxin, labetalol & furosemide

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EAHP survey 2014. Roberto Frontini

In your experience, how long would you estimate the average or typical medicines shortage normally lasts for?

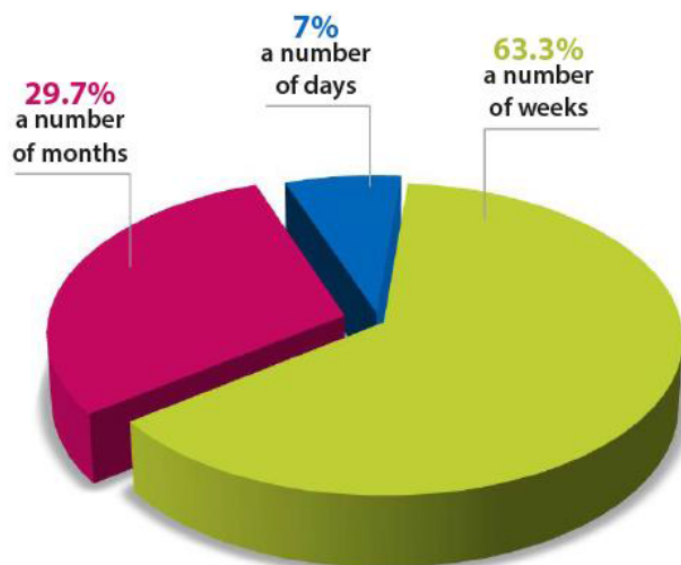


Chart 14: Typical duration of a typical medicine shortage according to European Hospital Pharmacists (n=387)

- High % of respondents in **Ireland, Italy, Slovakia** and **Spain** report that a typical medicine shortage takes a number of months to resolve

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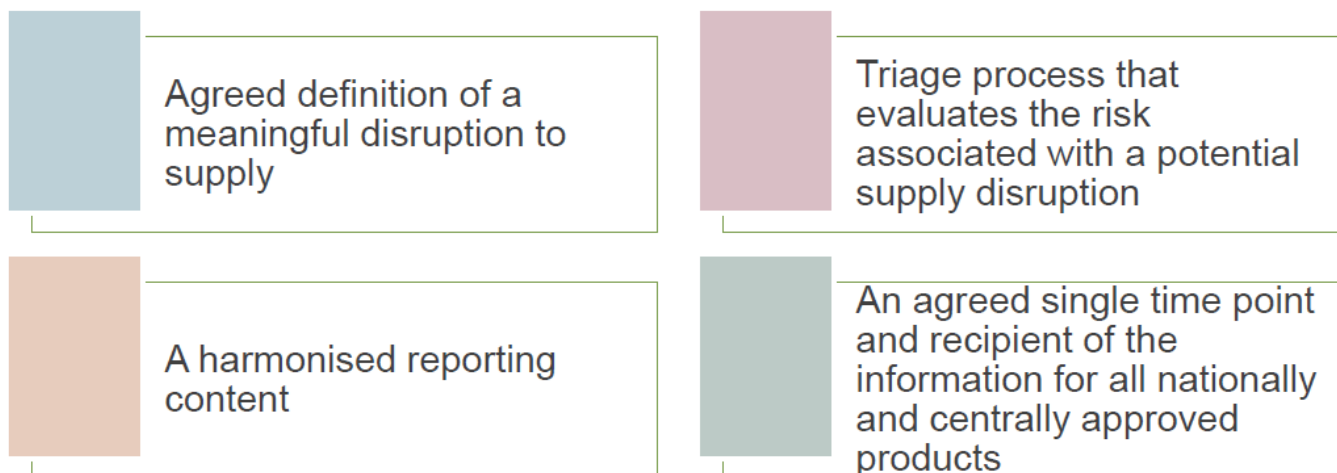
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Julie Maréchal-Jamil (EGA)

An Inter-Association Task Force perspective

Proposed Communication Framework

- An identical trigger point for notification based on:



Julie Maréchal-Jamil (EGA)

An Inter-Association Task Force perspective

Triaging Process: Evaluating the risk associated with a potential supply disruption

Define risk to patient		Access to Therapies		
		No alternatives	Alternative products available Similar therapy	Exact products available but in other presentations
Product Indications	Life supporting or life sustaining	Risk Level A	Risk Level A	Risk Level B
	Acute short term or chronic long term	Risk Level A	Risk Level B	Risk Level C
	Other Indications	Risk Level B	Risk Level C	Risk Level C

Categorisation of Notification

- High risk - Risk Level A
- Medium risk - Risk Level B
- Low risk - Risk Level C

Level of effort and formality is commensurate with the level of risk to the patient when:

- Assessing impact on public health, and
- Agreeing on and performing corrective actions, where needed.

Could be different in the 28 markets

- Depends on what's
 - available
 - the products used for

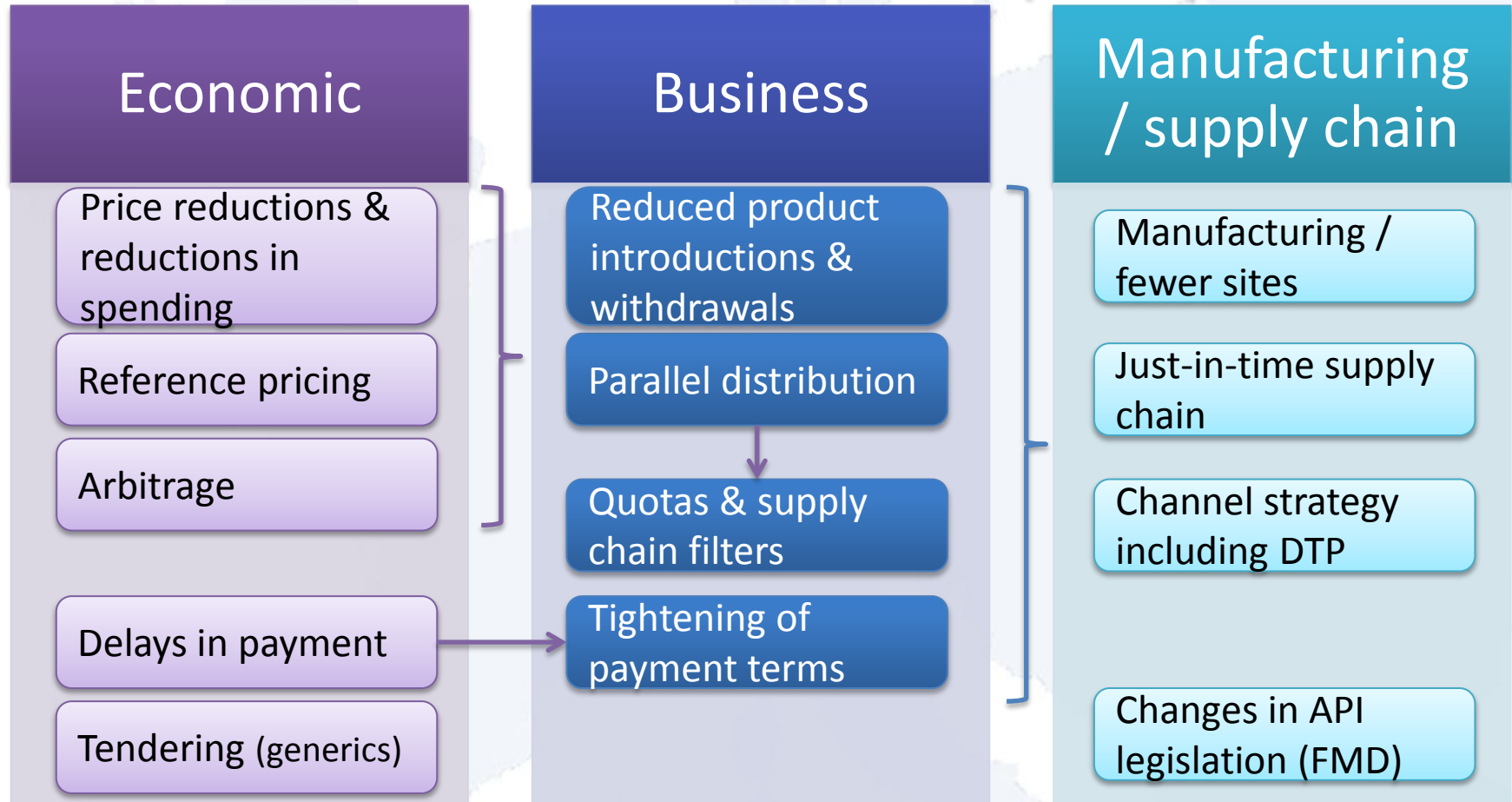
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Source | An Evaluation of Medicines Shortages in Europe with a more in-depth review of these in France, Greece, Poland, Spain, and the United Kingdom -By birgli® ag. <http://www.eaepc.org/medien/an-evaluation-of-medicines-shortages-in-europe-with-a-more-in-depth-review-of-these-in-france-greece-poland-spain-and-the-united-kingdom.pdf>

Outstanding issues for us (1)

- **Prevention**

- Parallel trade: how can we restrict arbitrageurs' practices? Lists (Spain), Dual pricing (LEEM)?
- Box tracking /unique identifier/ Falsified medicine legislation
- Stress test: simulate a problem at a manufacturing site
- Medicines of major Public Health Interest: definition and lists

- **Information**

- Which info do POs expect from MAH?
- Which role can patients have in reporting shortages? Web-RADR?
- Real time shortage catalogues?
- How to make sure shortage is over?
- How to prevent aggressive market practices?

Outstanding issues (2)

- **Shortage management**

- Which scientific/political body to decide on the allocation of remaining supply among MS? EMA? EC?
- In extreme situations, Ethics committees recommend a lottery. Any other solution? Who will run it?
- When a community pharmacy is facing a shortage, how can they inform patients where to find a pharmacy that has the product in stock?
- When should the MAH first inform on a potential problem? Who? False alerts ok.