



Medicines shortages Issues and recent actions



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Patient perspective: information in community

- **Community pharmacies**

- Patients are more and more used to receive different presentations (generic substitutions)
- External factors (e.g. national pricing policies) can result in regular product changes
 - e.g. price tendering systems

- **When a shortage occurs**

- The product can also change frequently
- And can come from different countries
- Same information: “This month I have this one”
- Rarely “there is a shortage” and no more

Patient perspective: information in hospital

- Hospital pharmacies or emergency services
 - Differences from community:
 - No copy of prescription, no package leaflet,
 - Only when leaving the hospital, copy of the discharge
 - EAHP survey 2014: 5 most common areas affected by shortages were antimicrobials, oncology, emergency medicines (adrenaline, atropine), cardiovascular medicines and anaesthetic agents
- When a shortage occurs
 - When harm is caused by delays in finding the appropriate alternative, are patients informed?
 - Does the discharge explicitly mention the medicine used was not the one initially prescribed due to a shortage?

Outstanding issues

- **Prevention**

- Unique identifier/
Falsified medicine
legislation / EMVS:
 - if data transmitted to
public authorities in
charge
- Stress test: simulate a
problem at a
manufacturing site?
- Medicines of major Public
Health Interest: definition
and lists?

- **Information**

- Which role can patients
have in reporting
shortages? Web-RADR?
- Real time shortage
catalogues?
- How to make sure a
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?

- **Public Health impact**

- Indicators and tools to measure potential health consequences of shortages?

Initiatives

- Nov. 2012: [EMA reflection paper](#) on shortages
- Oct. 2013: [Common position](#) on medicines supply shortages by patients and healthcare professionals
- 14/10/2013 EMA workshop
- 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
- HMA conference call July 2015
- Contact with PermRep Luxembourg Sept. 2015
- EMA 2nd Workshop 9 October 2015
- Research: COST project (EAHP)