SOCIETA' ITALIANA DI FARMACIA
OSPEDALIERA E DEI SERVIZI FARMACEUTICI
DELLE AZIENDE SANITARIE

XXXV CONGRESSO NAZIONALE SIFO

IL FARMACISTA: UNA RISORSA PER LA SALUTE.

RESPONSABILITA', APPROPRIATEZZA, SOSTENIBILITA'

Top 5 current EU policy issues for Italian hospital pharmacy

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making the difference in medication

Top 5 current EU policy issues

1 – The common training framework

2 – Medicines shortages

3 – The Falsified Medicines Directive

4 – Proposed Medical Devices Regulation

5 – New Clinical Trial Regulation

1 – The Common Training Framework for Hospital Pharmacy specialisation

The common training framework: background

- Long term policy of EAHP members to promote hospital pharmacy specialisation
- Revision of Professional Qualification Directive 2011-13 gave opportunity
- Amendment achieved – pharmacy specialisations can use ‘common training framework’

What is a Common Training Framework?

- A version of ‘automatic recognition’ across countries
- Operates on a voluntary basis
- Minimum of 1/3 EU states (10)
- Professional associations can take the lead
- Based on agreed knowledge, skills and competencies
- Linked to the European Qualifications Framework

Why would a CTF for HP be a good thing?

- Highly skilled professionals can take their skills to contribute to patient care **across Europe**
- **A benchmark standard** for HP education
- **Legal recognition** for the distinctiveness of the HP skillset, *(in line with EAHP Policy Statement 2011)*

Beginning CTF formation

- Initial phases will **be led** by 6 countries with specialisation already (e.g. harmonising existing programmes) incl. Italy
- Structures and governance should also be created **to ensure all members have involvement**
- Kick off meeting on 10 November 2014

The common training framework: Italy

- Italy's well established hospital pharmacy specialisation programme is respected across Europe

- EAHP hopes **Italy**, alongside Spain, France, Netherlands, Belgium and Portugal, will give leadership to Europe on a hospital pharmacy CTF

The common training framework: More information

- **EAHP website:**

http://www.eahp.eu/practice-and-policy/hospital-pharmacy-specialisation

- **European Commission:**

http://ec.europa.eu/internal_market/qualifications/index_en.htm

- **EAHP video:**

https://www.youtube.com/watch?v=o7HN2ZS2dUo

2 – Medicines shortages

Medicines shortages: background

- EAHP members passed policy in 2012
- Research conducted in 2012-13
- Key results:
  - 99% of HPs experiencing problems with medicines shortages
  - 67% said its a daily or weekly problem
  - 73% said the problem is getting worse

Towards solutions…

- Brussels-based pan-European **coalitions formed**
- EIPG, PGEU & EAHP working together
- 40 organisations signed up to **Common Position Paper**
- Co-authored by EAHP, patients & healthcare professionals

Common position between patients', consumers, and healthcare professionals' organisations involved in the activities of the European Medicines Agency on:

Supply Shortages of Medicines

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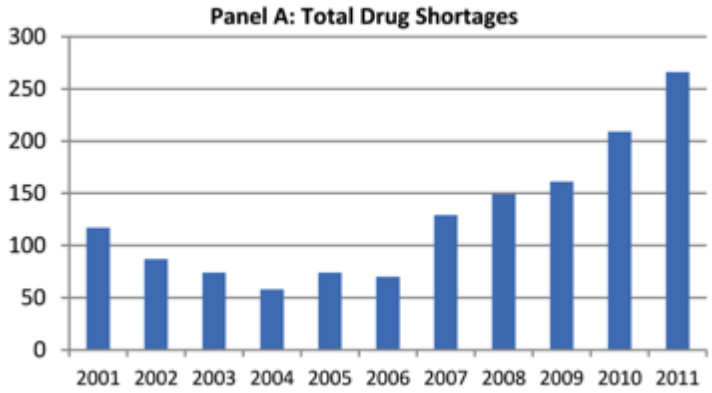
Jurate Svarcaite	Pharmaceutical Group of the European Union (PGEU)

http://www.eurordis.org/content/common-position-adopted-preventing-managing-and-solving-medicine-shortages

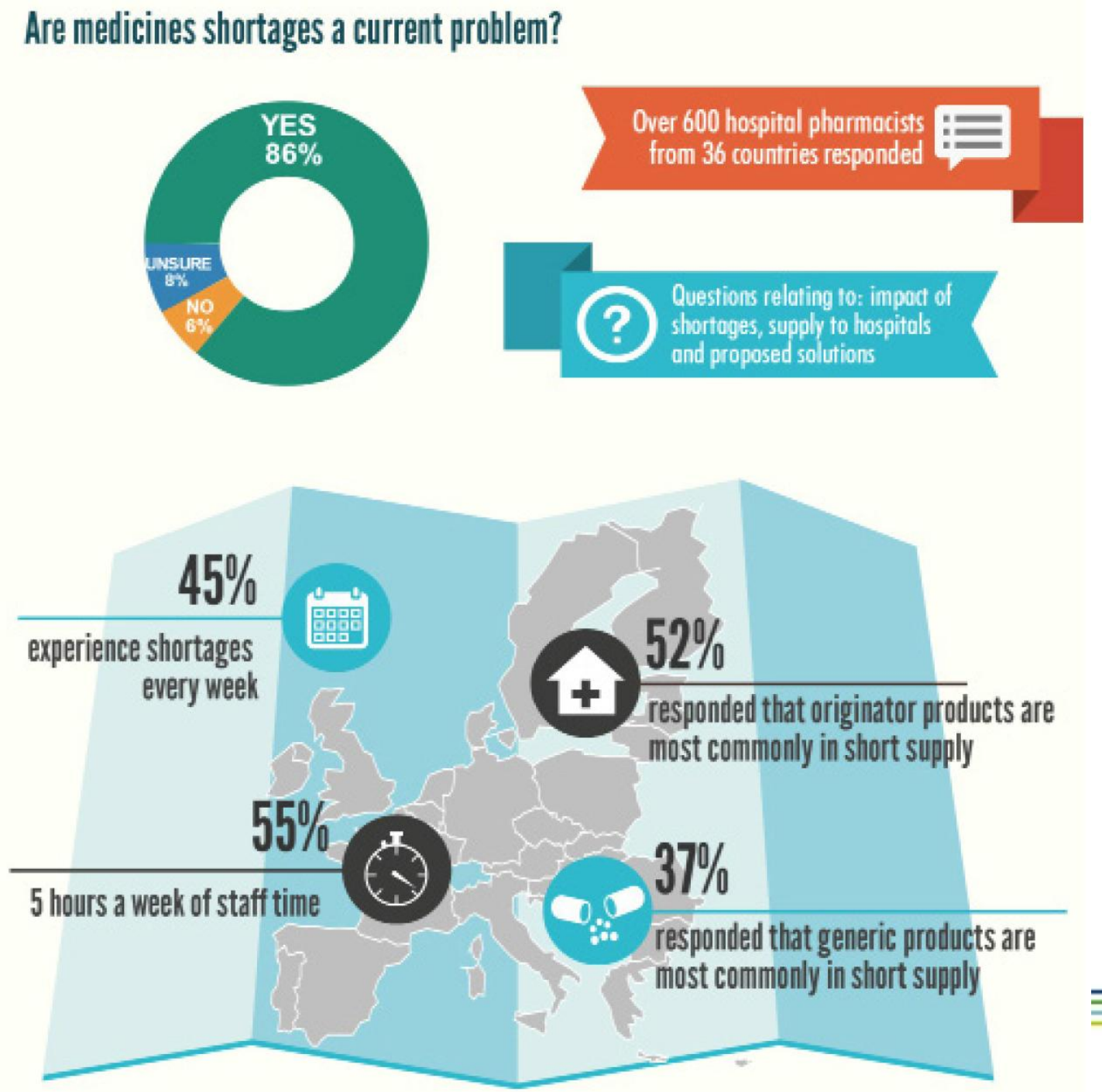
EAHP calls for…

- **EMA database** of medicines in shortage across Europe
- **EMA annual report** with suggested remedial actions *(similar to 2012 FDA legislation)*
- Clear **legal requirements** on industry to report disruptions at an early stage
- Commission to **take a lead** in investigating causes & advising Governments
- International Government dialogue



- However, repeated meetings with the European Commission remain disappointing
- **<u>Commission believe they have no mandate</u>** from EU Member State Governments to act on the topic
- EAHP strategic refocus to **<u>national level advocacy</u>**

Results of EAHP's 2014 survey



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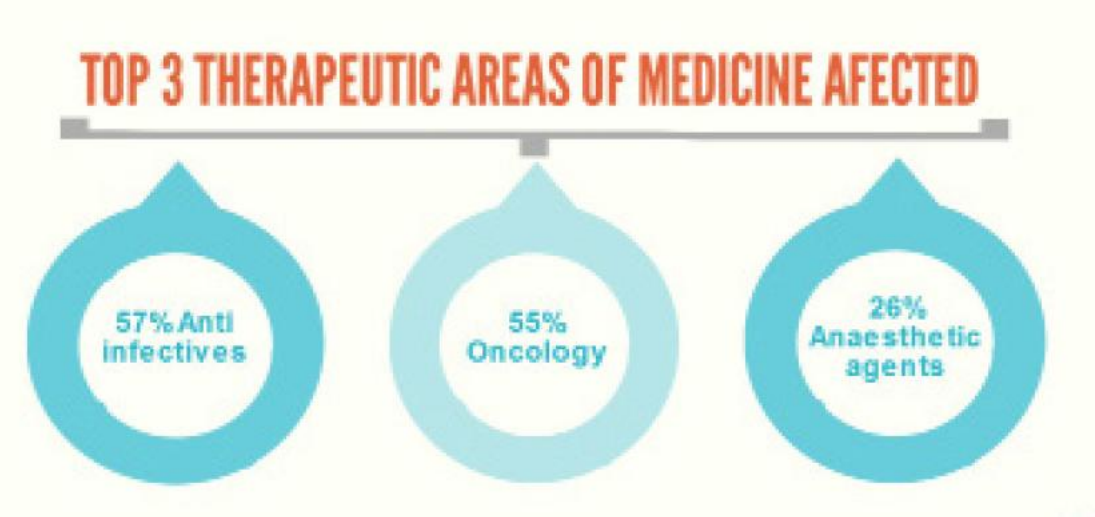
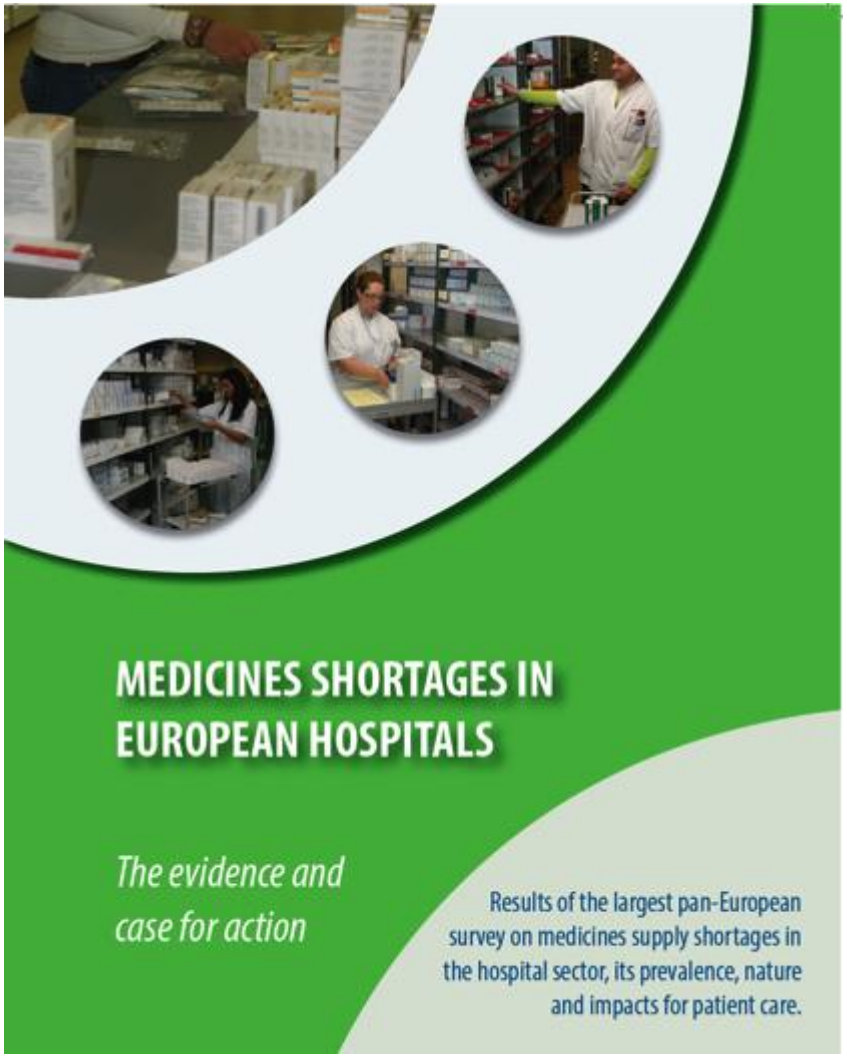


"Greater legal clarity on the responsibility of manufacturers to openly report forthcoming disruption in supply at an early stage, underpinned in European level legislation" was the most popular suggested remedial action

Access to medicines: Next steps

- Report launch in Brussels in November 2014
- Work on European agreed definitions
- Discussions with industry on improvements to information sharing
- New Commission, New Opportunities?



Access to Medicines: More information

- **EAHP website:**

http://www.eahp.eu/practice-and-policy/medicines-shortages

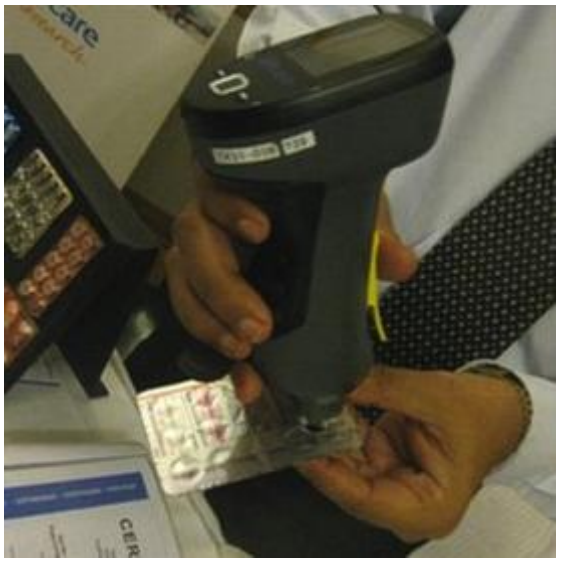
- **Common Position Paper:**

http://www.eurordis.org/content/common-position-adopted-preventing-managing-and-solving-medicine-shortages

- **Sign up to EAHP EU Monitor for updates….**

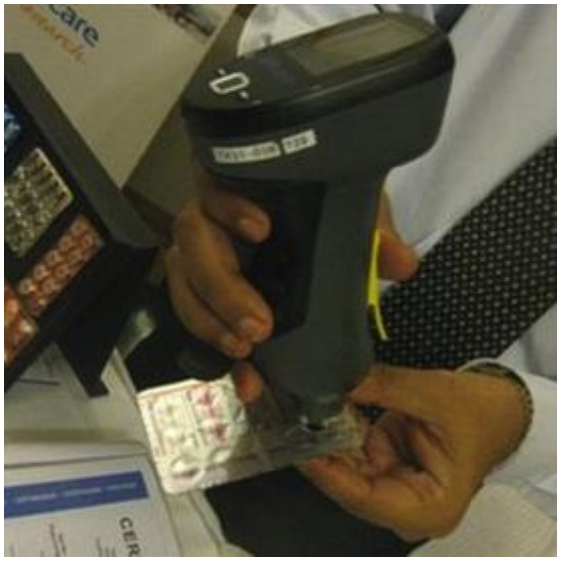
http://www.eahp.eu/newsletter/subscribe

3 – Falsified Medicines Directive 2011



The story the Falsified Medicines Directive

- 2011 Directive requires outer packaging of medicines to include safety features to verify authenticity
- Applies to all prescription-only medications at risk of counterfeiting
- Details of how the system will operate in practice remain uncertain with the European Commission still to publish the text of the ‘Delegated Act’



Falsified Medicines Directive: Making it work for hospital pharmacy

We **DO** know:

- It WILL apply to hospital pharmacy
- Should be implemented by all MS in 2017/18
- Member States can interpret (not an EU ‘one size fits all)

We **DON’T** know:

- Does EVERY medicines package need to be scanned in the hospital pharmacy?
- WHEN? (e.g. arrival or departure from pharmacy?)
- EAHP seeking to input and scrutinise
- Help members **be aware and prepare**

Falsified Medicines Directive: More information

- **European Commission:**

http://ec.europa.eu/health/human-use/falsified_medicines/index_en.htm

- **European Stakeholder Model:**

http://www.esm-system.eu/home.html

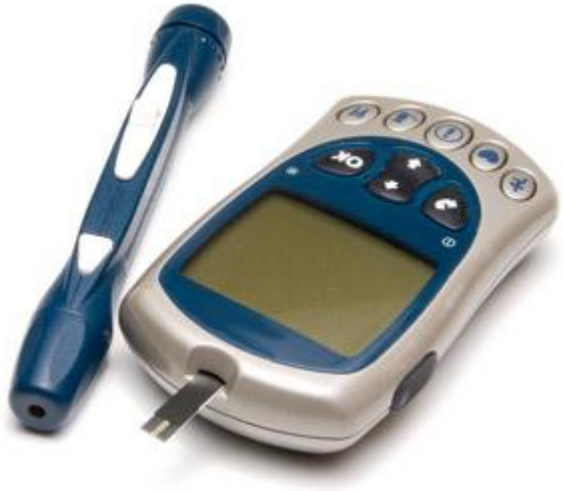
- **EDQM E-Tact system**

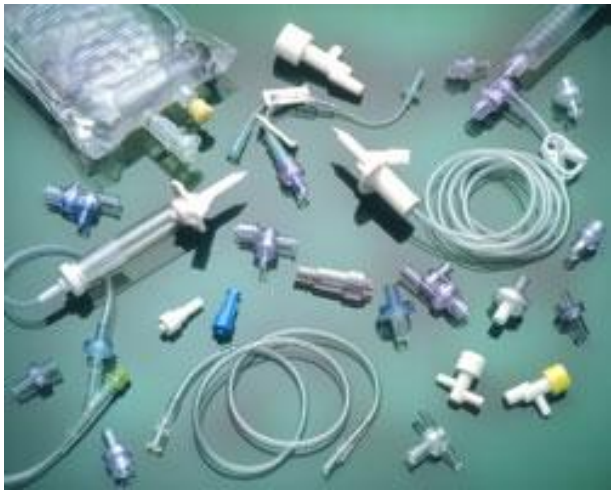
https://www.edqm.eu/en/eTACT-1466.html

4 – Proposed Medical Devices Regulation

Proposed Medical Devices Regulation: key points

- New **UDI system** for medical devices to improve traceability
- Overhaul of the system for **approval and authorisation** of devices (subject of robust debate)
- Improvements to the accessibility of the **Eudamed** vigilance database
- Debate over issue of **reprocessing single use devices**





Proposed Medical Devices Regulation: Next steps

- New European Parliament returns to the issue
- European Governments still not settled on a common position
- Will Juncker's change of responsibility for device regulation make a difference?
- Meanwhile, EAHP discussing with industry and Commission implementation issues e.g. UDI & Eudamed

Medical Devices Regulation: more information

- EAHP website:

http://www.eahp.eu/practice-and-policy/medical-device-regulation

- European Commission website:

http://ec.europa.eu/health/medical-devices/documents/revision/index_en.htm

- European Parliament position:

http://www.europarl.europa.eu/news/en/news-room/content/20130923IPR20607/html/Health-MEPs-call-for-stricter-controls-on-medical-devices

- Medical device industry position:

http://www.eucomed.org/key-themes/medical-devices-directives

5 –Clinical Trial Regulation

Clinical trial regulation

New EU clinical trial regulation:

- From 2016 at the earliest
- **Single submission portal** for multi country trial application and assessment (run by the EMA)
- 1 MS competent authority will be lead reporter to streamline bureaucracy ("**coordinated authorisation**")
- **Clinical Study Reports not commercially confidential** & published no more than 1 year after marketing authorisation

Clinical trial regulation

EMA trials publication policy: key points

- Over 12 months of stakeholder consultation
- Industry & other stakeholders not agreed on transparency
- EU Ombudsman, consumer organisations & others critical of on-screen only access & redaction principles
- EMA retreated – new accessibility arrangements from 1 Jan 2015

Grazie a tutti!

Further information

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