

PMI Breakfast Briefing

Fionnuala Kennedy BSc(Pharm), MPSI, MA, MSc
Chief Pharmacist Mater Private Dublin, President HPAI

Current Issues

- Shortages
- Brexit
- Falsified Medicines Directive
- Novel treatments
- Biosimilars
- Private hospital / insurance perspective
- HPAI

Shortages 2018

Antimicrobial drugs

- piperacillin / tazobactam inj
- aciclovir injection
- co-amoxiclav injection
- co-trimoxazole injection
- clindamycin injection
- amikacin injection

Others

- dexamethasone intravitreal injection (Ozurdex®)
- Dibotermin alpha (Inductos®)
- methylprednisolone injection
- Clomipramine capsules
- ondansetron injection
- co-careldopa (Sinemet®) tabs
- calcium chloride mini-jects
- vaccines

Anaesthetic drugs

- bupivacaine for injection
- lidocaine and adrenaline for injection
- bupivacaine / adrenaline for injection
- Intralipid® bags
- preservative-free (spinal) morphine HCl
- lorazepam injection
- fentanyl injection

Chemotherapy and adjunctive therapy

- calcium leucovorin injection
- 5-fluorouracil injection
- methotrexate injection
- vinblastine injection

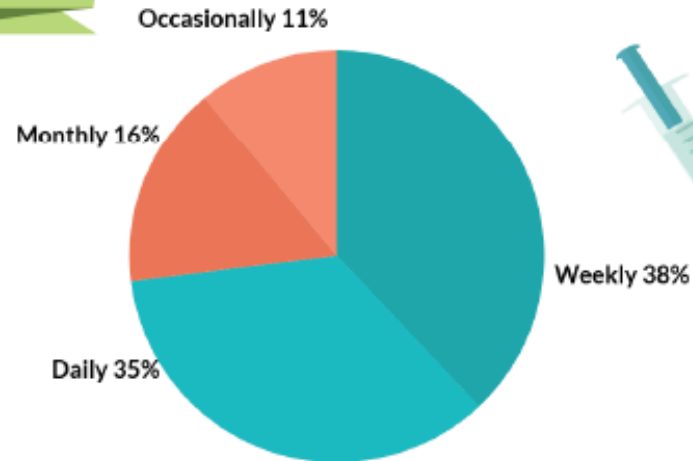
EAHP survey 2018

Medicines Shortages Survey results

Are medicines shortages a current problem?
91.8% (2018) vs 86.2% (2014)

1,666 responses from 38 countries

How often does your hospital pharmacy experience medicines shortages?



5 Hours per week spent dealing with medicines shortages



2.2 months is the duration of a typical medication shortages

Types of medicines most frequently reported



77%
Antimicrobial
agents

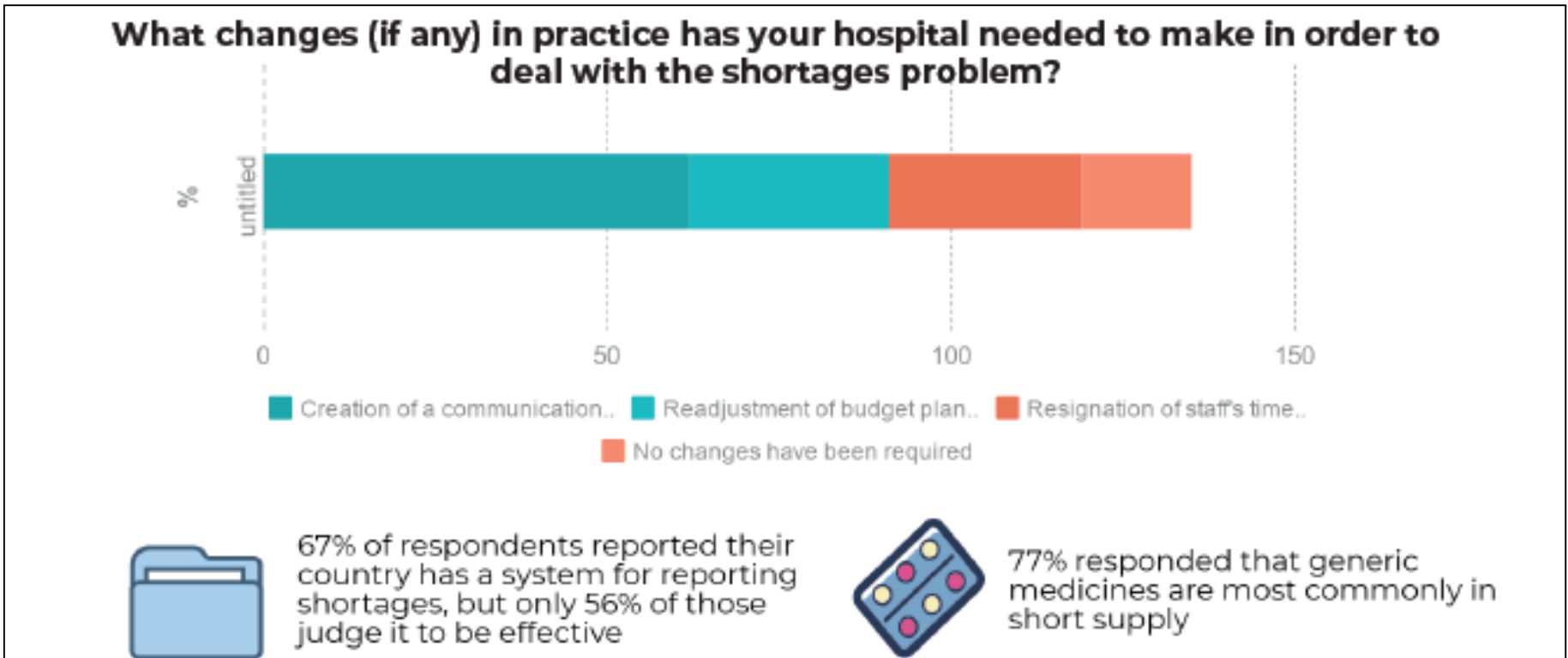


43%
Vaccinations



39%
Oncology
medicines

EAHP shortages survey 2018



Clinical dilemmas

- Source a replacement – from whom? Effect of legislation.
- Similar to existing licensed short product?
- Where is the product licensed (EU, USA, Japan . . .)?
- Is the replacement product safe to use?
 - complex calculations
 - expression of constituents
 - concentration
 - English language information
 - risk of sound-alike-look-alike drug (SALAD)
- Is there resilience of supply?
- What is the lead time?
- What are the storage conditions?
- How much does it cost?
- Is it available in primary care under community drug payment schemes?
- If no replacement possible – switch to an alternative drug – temporarily or long-term – onerous clinical change management

- Expect shortages to worsen
- Dual UK / Ireland (and Malta) packs
- Marginal products often used in hospitals
 - Increase in Exempt Medicinal Products (EMPs)
- UK will become a 3rd country
- Hospitals currently importing directly from UK
 - Move to an authorised operator

- DoH-led Brexit working group with multiple stakeholders
- National strategy document
- Changes to legislation published
- Recent information disseminated



Falsified Medicines Directive

- IMVO started work in 2016
 - Multi-stakeholder group set up
- Issues identified early on for hospitals
- Expected shortages did not materialise
- Culminated in start date on 9th Feb 2019
- Use and learn period agreed and now extended
 - Technical issues
 - On-boarding delays
 - Out-standing issues for some hospitals

Novel pharmaceutical treatments

- Licensing
- Health technology assessment
- Approval for use
- Reimbursement
- Budgetary implications
 - Budget silos in healthcare system
 - Big picture

Biosimilars

- Slow to gain market share
- Hospital-only or hospital-initiated high tech medicinal products
- Develop clinical experience with biosimilars
- Secondary vs primary care budget

Private insurance providers

- Contract with private hospitals to provide services at fixed rates
- Will pay for a small number of named drug products in their contracts with hospitals
 - Predominantly oncology and haematology hospital-only treatments
 - Eye injections
 - Infusion clinics (immunotherapy)
- 80:20 rule
- Management of patients on clinical trials
- Approval for novel treatments
 - Clinical approval by insurer
 - Budgetary implications of new treatments
- Approval for biosimilars
- Approval for generics
- Use of EMPs if licensed products are short
- Evidence-based medicine - formulary management in private setting

Hospital Pharmacists' Association of Ireland (HPAI)



- Good working relationship with pharma industry and distribution
- Partners in healthcare
- Changing face of delivery of healthcare in Ireland
- Hospital pharmacist are the experts in medicines management
 - recognition of this medicines experts role
 - hospital pharmacists as partners in managing medicines