How to handle drug shortages?

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disclosures

- Member Pharmacotherapy Advisory Board FMS Medical Specialists Association
- ZonMw governmental research grants
- Coordinator Pharmacy Santeon Hospitals
Drug shortage

• Is a situation in which the total supply of all clinically interchangeable versions of a regulated drug is inadequate to meet the current or projected demand at the user level

Dutch consumers organisation’s issue 2016
The patient, it’s about you and me

- Oncology: 5-FU, cisplatin, carboplatin, doxorubicin, folinic acid, BCG, melfalan, bleomycin
- Infectious diseases: penicillin, meropenem, cefazolin, flucloxa
- Cardiovascular diseases: heparin, nitroglycerin
- Hormones: thyroxin, megestrol
- Pain: ibuprofen, indomethacin, piritramide
- Sedation, anxiety: lorazepam, haloperidol
- Anesthesia: remifentanil, atracurium, thiopental, sufentanil, etomidate

Consequences for patients

- Delay in therapy
- Break in protocol, switch regimes, medication safety is at risk
- Different side effects by substitute drug
- Choose among patients
- Omit doses, reduce doses
- New drug package, confusion, error prone
- Extra costs, no coverage insurance
- Refer patients out
EU regulation art 81

"The holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered"

Why it doesn’t work: lack of responsibility? Other excuses?

Dutch shortages update Farmanco

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2013 SURVEY OF US-ONCOLOGISTS & HEMATOLOGISTS

Survey of 250 US oncologists and hematologists finds that more than 80% of cancer doctors encountered cancer drug shortages between March and September of 2012 and many reported that shortages affected the quality of patient care that doctors were able to provide (K. Gogineni et al., University of Pennsylvania, Philadelphia, PA, USA); presented at the 2013 ASCO meeting

2013 SURVEY OF EUROPEAN HOSPITAL PHARMACISTS (n=85) 20 COUNTRIES

Do the drug shortages have impact on your practice?

- Always (36%)
- Frequently (39%)
- Rarely (21%)
- Never (4%)  

⇒ YES (96%)
Adaption?

- Switch regimens (90%)
- Substitute drug (96%)
- Omit doses (40%)
- Reduce doses (44%)
- Delay treatment (79%)
Extra costs

• In The Netherlands 20 fte personel € 2 – 3 mio

• € 70 mio alternative therapy [2012]

• Extra administrative costs, logistic changes, ICT changes, information, education, shipping charges

• Accountability, informing health authorities

What can we do?

• Marketing authorisation = duty to deliver, sanctions?
• GMP-certified hospital pharmacies to full supply gaps
• Dual site production licence, augment redundancy
• Facilitation importation of drugs
• Supply chain management: early warning system
• ISPEN quality assurance reengineering
• Private – public partnership drug production
• Shortage Risk Assessment Plan essential drugs

Responsible Partnership Pharma Pharmacist
Responsible Pharma Partnership

- Supply Chain Management
- Performance Monitoring
- Contracting on deliverance

Balancing risks and costs

Value

Cost

Risk

R&D Partners

Logistic partners

Guarantee deliveries in all circumstances With reference to patient safety

Contract procurement
What can you do?

- Take responsibility to solve a health care problem!
acknowledgements

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