

SOCIAL AND ETHICAL ASPECTS

Seminar 1: Medicines Shortages – Causation
and Approaches to Improvements

European Association of Hospital Pharmacists Academy

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CONFLICT OF INTEREST

- Within recent months - speakers' honorarium from Amgen (research topic not relevant to this seminar's subject)



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POSTGRADUATE STUDIES:

MANAGEMENT OF HEALTH CARE UNITS

EBM AND HTA IN HEALTH CARE MANAGEMENT



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**Zarządzanie Jednostkami
Opieki Zdrowotnej**

PRO-QUO HEALTH

**DRUG SHORTAGES:
A LOCAL PHENOMENON
OR
A GLOBAL THREAT TO PUBLIC HEALTH
AND HEALTH CARE SYSTEMS?**

DRUG SHORTAGES: A COMPLEX AND GLOBAL PROBLEM

- Drug shortages – usually attributed in the past to the low income countries and rather outside of the European continent.
- Numerous cases in recent years, also in the developed countries.
- Drug shortages in the USA: „No more denying. You are in denial too if you believe that this country’s pharmaceutical industry can reliably supply medications for patients.” (Wenzel 2015)

DRUG SHORTAGES: A COMPLEX AND GLOBAL PROBLEM

- ... then Europe (not only the EU)...
- Increasing amount of the evidence - over a decade of problem's existence in public and scientific discourse.
- Indisputable impact of shortages on public health, especially if they cause delay of treatment, difficulties in continuation, lowering or omitting doses, increasing costs of treatment, selection of patients or increased burden of staff.

DRUG SHORTAGES FROM PERSPECTIVE OF PUBLIC HEALTH

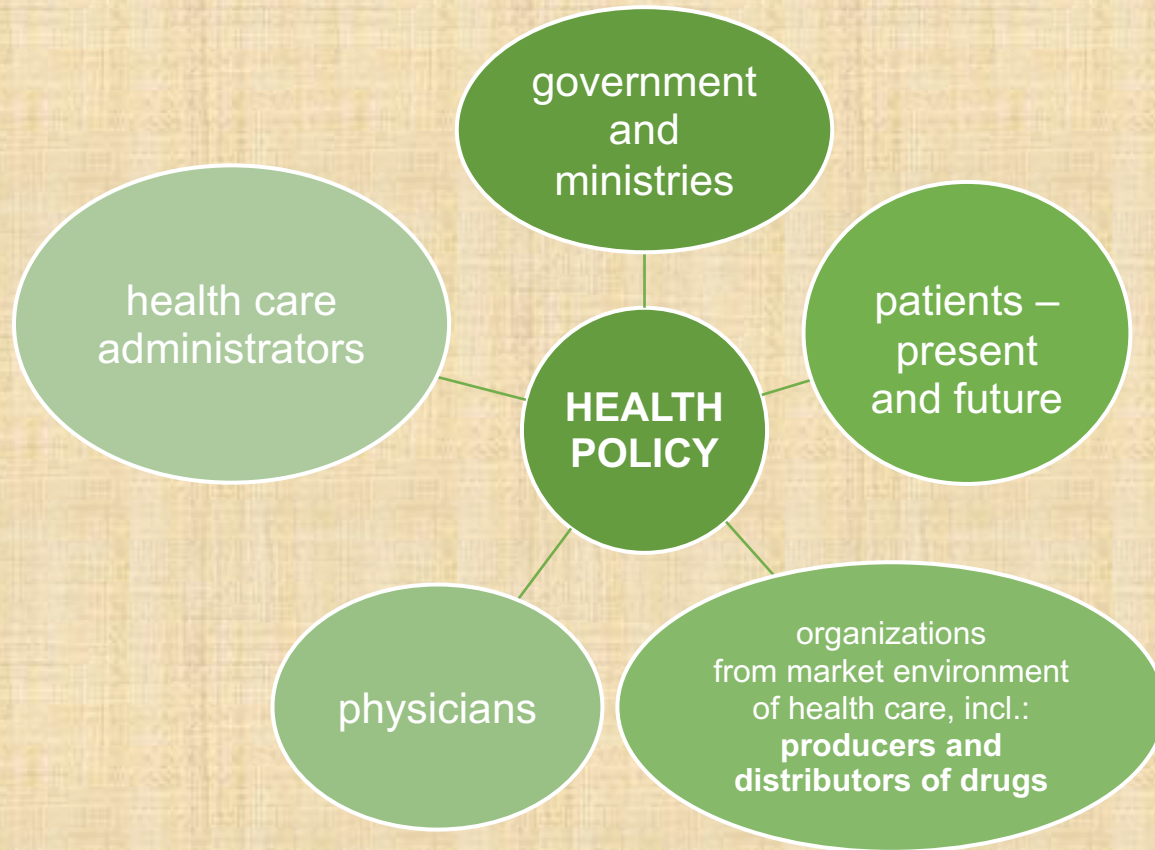
- Public health - the science and art of preventing disease, prolonging life and promoting health through the organized efforts and informed choices of society, organizations, public and private, communities and individuals (Winslow 1920)
- It refers to all organized measures (whether public or private) to prevent disease, promote health, and prolong life among the population as a whole.

DRUG SHORTAGES FROM PERSPECTIVE OF PUBLIC HEALTH

- Three main functions of public health (WHO 2014):
 - the assessment and monitoring of the health of communities and populations at risk to identify health problems and priorities
 - the formulation of public policies designed to solve identified local and national health problems and priorities
 - to assure that all populations have access to appropriate and cost-effective care, including health promotion and disease prevention services
- Focus on entire populations, not individual patients or diseases.

PHARMACEUTICAL POLICY

- Pharmaceutical (medicines; drug) policy as the element of a health policy (i.e. the element of a distinguishable process of intentional actions related to health, in a non-individual scale, in which there are present decisions and solutions of a commanding character)
- Active and causative role of the state as a brachylogy or an intellectual shortcut – there is always somebody acting on behalf of the state



STAKEHOLDERS OF HEALTH POLICY AND PHARMACEUTICAL POLICY

LEVELS OF HEALTH POLICY AND PHARMACEUTICAL POLICY

- STRATEGIC LEVEL

- Shaping organizational units being the executors of a policy (e.g. rules of functioning of health care market, regulations related to medical professions, rules which set a place of a public payer for drugs)
- Defining rules of individual responsibility of citizens for their health (e.g. rules of co-payment for drugs)
- Defining priorities in goals and tasks (e.g. national drug policy declarations and documents, reimbursement lists, reform proposals)
- Setting mechanisms of financing (e.g. setting level of health care insurance premiums)

- OPERATIONAL LEVEL

- Here a real shape is being put on health and pharmaceutical policy (e.g. in: hospitals, ambulatories, pharmacies, local branches of public payer institutions, local branches of pharmaceutical inspection)

UNDERSTANDING DRUG SHORTAGES: AS THEY ARE SEEN FROM PERSPECTIVES OF THE EU AND SELECTED EU COUNTRIES

Bogaert P, Bochenek T, Prokop A, Pilc A (2015) A Qualitative Approach to a Better Understanding of the Problems Underlying Drug Shortages, as Viewed from Belgian, French and the European Union's Perspectives. PLoS ONE 10(5): e0125691.

STUDY GOAL, TASKS AND METHODS

- Main goal: analyse, characterise and assess the problem of drug shortages in Belgium and France, while also adopting a wider perspective of the EU. Multi-dimensional character of the problem was taken into consideration, as well as threats to public health.
- Tasks and methods:
 - Literature review
 - Interviews with selected stakeholders and qualitative analysis of their content
 - Comparative analysis of selected legal acts and regulations
 - Characterisation and classification of problems pertaining to drug shortages, which occurred within recent 10 years
 - Identification, description and critical analysis of organisational arrangements, which have influence on drug shortages

ELEMENTS OF INTERVIEW GUIDES

- Guides in different versions for different stakeholders:
 - Pharmacists
 - Wholesalers
 - Industry
 - Decision-makers/health authorities
- Open questions on:
 - Individual perspective on problems associated with drug shortages and their influence on professional work
 - Legal and organisational aspects – *status quo*, assessment of their significance for inducing and preventing shortages
 - Information and communication channels
 - Solutions, preventive measures, assessment of foreign initiatives

RESULTS

- Defining drug shortages:
 - Formal definitions
 - Level of defining
 - Time-frames
 - Issue of commercialization
 - Measure of severity
- Dynamics and perception:
 - Duration
 - Intensity
- Role of the European and national institutions

RESULTS:

DETERMINANTS OF DRUG SHORTAGES

- Categories and sub-categories of the reported determinants of drug shortages

Manufacturing problems

- Raw material problems
- Production problems
- Globalisation
- Limited capacity
- Non-compliance with regulatory standards

Distribution and supply problems

- Just-in-time inventories
- Levels of stock
- Quotas and rationing
- Parallel distribution
- Transportation issues

Economic aspects

- Reference pricing
- Tendering
- Financial crisis
- Product discontinuation

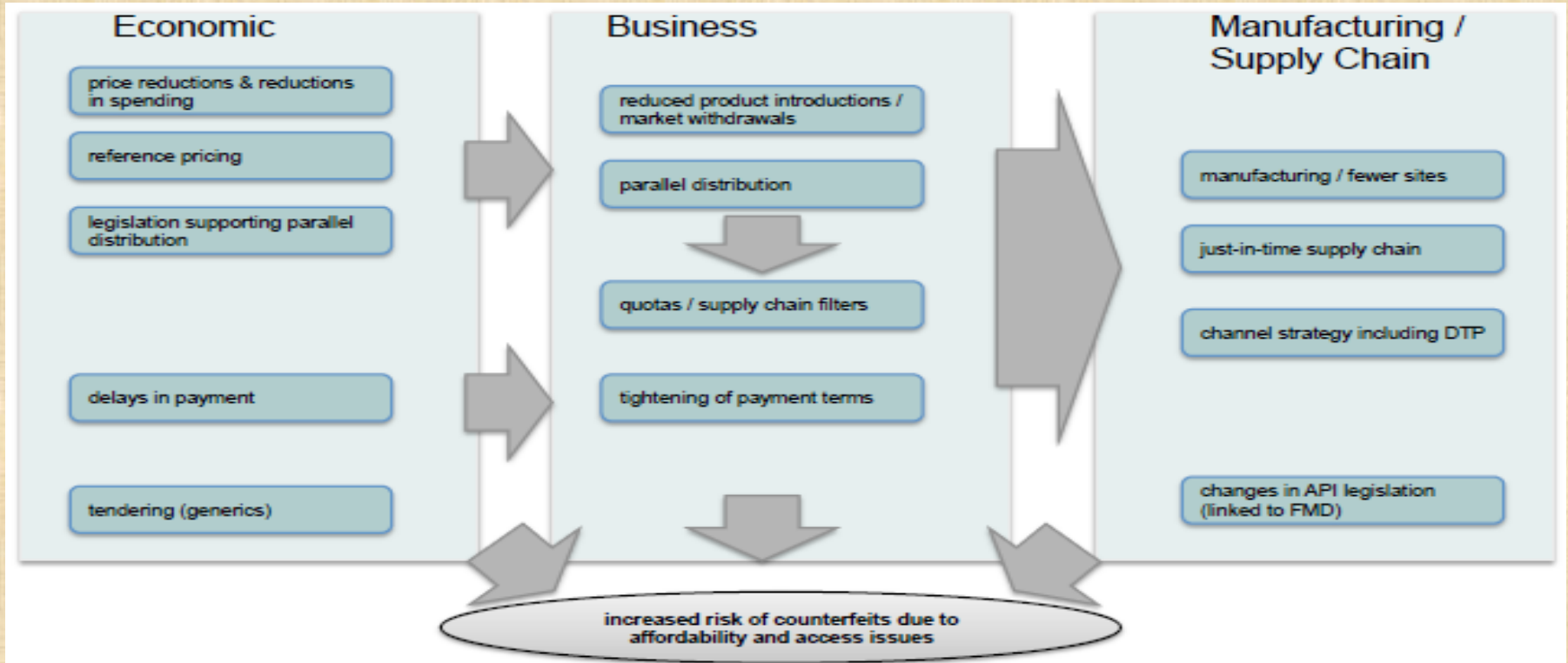
REASONS FOR DRUG SHORTAGES

Birgli's Report (2013)

Nr	Unpredictable	Nr.	Predictable
1.	Natural Disasters	1.	Product discontinuation
2.	Manufacturing problems	2.	Industry consolidation (M&A)
3.	Raw Material Shortages	3.	Limited manufacturing capacity
4.	Non-compliance with regulatory standards	4.	Just-in-time inventories
5.	Packaging shortages	5.	Rationing / quotas
6.	Unexpected demand	6.	Deliberate shortages to manipulate price
7.	Epidemics	7.	Market shifts
8.	Parallel distribution	8.	Launch of a new competitor, new formulation, or patent expiry
9.	Competitive issues		
10.	Foreign exchange effect		
11.	Sovereign issues (financial crisis, debt, default)		

ASSOCIATIONS AMONG CAUSES OF DRUG SHORTAGES

Birgli's Report (2013)



STUDY CONCLUSIONS

- Drug shortages have been increasingly reported and appreciated
- Important but complicated issue of defining the problem
- Four major themes were identified
- Within problem determinants three groups were distinguished
- The EU institutions need to coordinate legal and organizational strategies to address the issue between all Member States

**ETHICAL ASPECTS
OF DRUG SHORTAGES:
ARE MEDICINES IN SHORTAGE
A RATIONED GOOD / COMMODITY ?**

GOODS WHICH CAN BE SUBJECTED TO RATIONING / ALLOCATION / DISTRIBUTION

- Value
- Limited amount / number (availability)
- Possibility to control

Szewczyk K. Bioetyka. Pacjent w systemie opieki zdrowotnej. (*Bioethics. Patient in health care system.*) Wydawnictwo Naukowe PWN. Warszawa. 2009

FORMS OF RATIONING

Rationing - open or confidential mechanisms which allow people for getting by without beneficial services.

- Open rationing:
 - ✓ setting priorities; prioritizing health care services)
- Confidential rationing:
 - ✓ limitation is vigorous; at patient's bed
 - ✓ benefits and drawback

FORMS OF RATIONING (cont.)

- Economic rationing:
 - ✓ market distribution (price distribution)
 - ✓ non-market distribution (cost-effectiveness distribution)
 - ✓ moral considerations; an individual versus a society
- Non-economic:
 - ✓ justified by patient's good and common good

Combinations of rationing forms.

LEVELS OF RATIONING

Health care priority setting levels:

- macro – level:
 - ✓ politico-parliamentary level
 - ✓ main tasks
- meso – level:
 - ✓ intermediary organizations
- micro – level:
 - ✓ at patient's bed side

**HOW WOULD YOU CHARACTERISE
AN APPROACH USED TO RATIONING ASSOCIATED WITH
DRUG SHORTAGES
OCCURRING IN YOUR ORGANIZATION / HOSPITAL /
HEALTH CARE FACILITY ?**



RULES OF RATIONING: CATEGORIZATION - ETHICAL RULES

- Rule of justice
- How to define justice? („A more difficult care for the Second One, taking into account the presence of the Third One (the society)“)
- Measures of justice:
 - ✓ equality of opportunities
 - ✓ equal access to publicly financed health services
 - ✓ universal access; full access to health services
 - ✓ guaranteed, appropriate access, providing a feeling of health security
- Rule of solidarity
- Rule of accountability for health status
- Rule of respecting individual's autonomy

RULES OF RATIONING: CATEGORIZATION – RULES OF CHOICE AMONG INDIVIDUALS

- Beneficence of health services – criteria:
 - ✓ need and diligence (urgency)
 - ✓ separating health needs from personal preferences
- Criterion of age
- Compensatory justice:
 - ✓ negative and positive criteria
- Lottery criterion (based on chance)

RULES OF RATIONING: CATEGORIZATION – RULES OF EFFECT

- Rule of maximizing health gains (benefits):
 - ✓ utilitarian approach
 - ✓ gains to society or patient groups
 - ✓ measuring health gains – QALY-s
- Instrumental-economic norm – calculating treatment effects in relation to their costs:
 - ✓ criteria of efficacy and cost-effectiveness
 - ✓ ranking of health procedures
- Rule of diminishing health inequalities:
 - ✓ increasing availability to health care for societal groups characterized with the worst health indicators
 - ✓ positive form of compensatory justice, mitigating health status differences

RULES OF RATIONING: CATEGORIZATION – PROCEDURAL RULES

- Difficult and necessary requirement for obtaining social acceptance in pluralistic democracies
- Daniels and Sabin criteria:
 - ✓ transparency
 - ✓ meaningfulness
 - ✓ revision (mechanisms of appeal)
 - ✓ realization (mechanisms of implementation the above mentioned rules)

**WHAT IS YOUR OPINION
ON APPLICABILITY OF THESE RULES OF RATIONING
INTO A MANAGEMENT OF DRUG SHORTAGES
AT YOUR ORGANIZATION / HOSPITAL / HEALTH
CARE FACILITY ?**



STAGES OF EVOLUTION OF THE VIEWS ON RATIONING

- Theoretical stage:
 - ✓ just health care (Daniels) – based on theory of justice of Rawls
- Systemic stage:
 - ✓ USA - Oregon state health services plan
 - ✓ The Netherlands – Dunning Report
- Processual / procedural stage

DRUG SHORTAGES IN THE USA

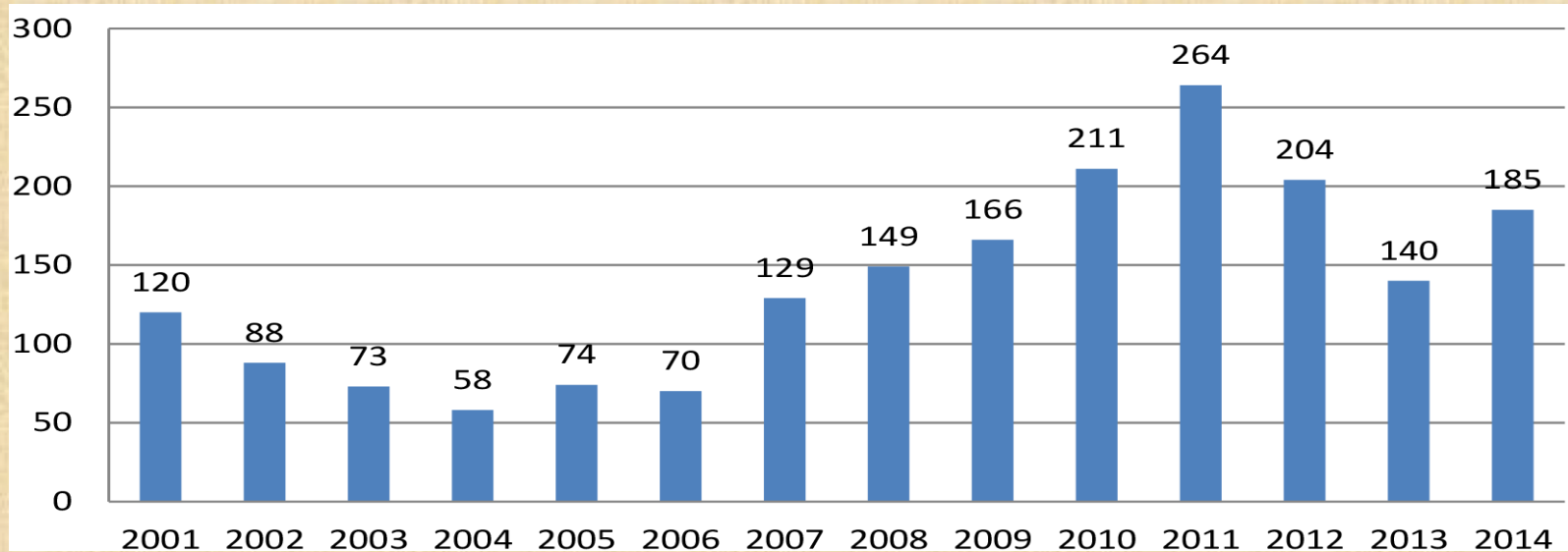
DRUG SHORTAGES IN THE USA

- Over 60% of cases – due to problems with quality of manufacturing
- 80% of quality problems pertain to sterile products (complicated and costly production), non-innovative but not highly profitable
- Often in cases when there exists monopoly or oligopoly in production (similarly in Europe) – effect of globalisation and optimization of production costs
- Anesthesiologic products – in survey among anesthesiologists (USA, 2011) - 90% of them confirmed experiencing this problem now (1 and more drugs), 98% any time, 91% linked it with necessity to replace a drug, 10% with necessity to postpone or cancel a surgical procedure

DRUG SHORTAGES IN THE USA (cont.)

- Questionnaire study (ASHP, 2013) on oncologic drugs: 93% of hospital pharmacists claimed that shortages result in delay, disturbance in continuation or changes in treatment plan; 85% pointed increased treatment costs
- Survey of ASCO (2013) among oncologists: due to drug shortages 79% of physicians were changing therapies of their patients (including: 38% - from cheaper to more expensive, with original product); 43% - had to delay treatment; 37% - had to make a decision on selecting patients to treatment; 29% - omitted doses, 20% - diminished doses
- Threats associated with searching drugs being in shortages through the Internet (falsified medicines - up to 50% of available in the Internet, according to the WHO estimates)

USA – ANNUAL SHORTAGES BY YEAR



Thank you for your attention!

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