Health care policy and its tools – drug policy

Introduction to pharmacoeconomic: structures of economic evaluations

Pharmacoeconomic methods and its principles

SYLLABUS of 5th LECTURE
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Drug policy and its tools

A DRUG POLICY is the policy, usually of a government, regarding the control and regulation of drugs consumption by a population, using following tools:

1. Finances allocating (cash flow allocating)

2. „Fellowship" of patient / participating of patient

3. Support of effective drug using

1. Finances allocating (cash flow allocating)

Primary care physicians:

Finantial limits per patient

Secundary care physicians:

Finantial limits per service

Tertiary care (hospitals):

Fixed finantial limits

Finantial limits per diagnosis

Primary, secundary and tertiary care physicians:

Specialization limitations for drugs prescription
- limits (physician`s specialization) are defined in Drug Tariff

Indication limitations for drugs prescription

- limits (patient`s indication) are defined in Drug Tariff

- in some drugs: **Dual reimbursement**

    (according to patient`s defined indications)

2. „Fellowship" / participating of patient

Primary care – pharmacies:

Assesment of drug reimbursement

1.covered drugs

2.non-covered drugs

Switching

Category Rx

- drug is safe

(no risk of abuse

- drug is long period on the market

- suitable dosage form and dosing for self medication by patient

- drug indication suitable for self medication by patient

Category OTC (Over The Counter Drugs)

Fee for prescription – in a physician

Fee for prescription – in a pharmacy

- **fee for prescription**

- **fee for every prescribed drug on prescription**

3. Support of effective using of drugs

Generic prescription
- *INN name* (international non-proprietary name)

Generic substitution

Pharmacoeconomic evaluation

Generic drugs

- copies of brand-name drugs

- the same in:
  1. **dosage form**
  2. **safety**
  3. **strength**
  4. **route of administration**
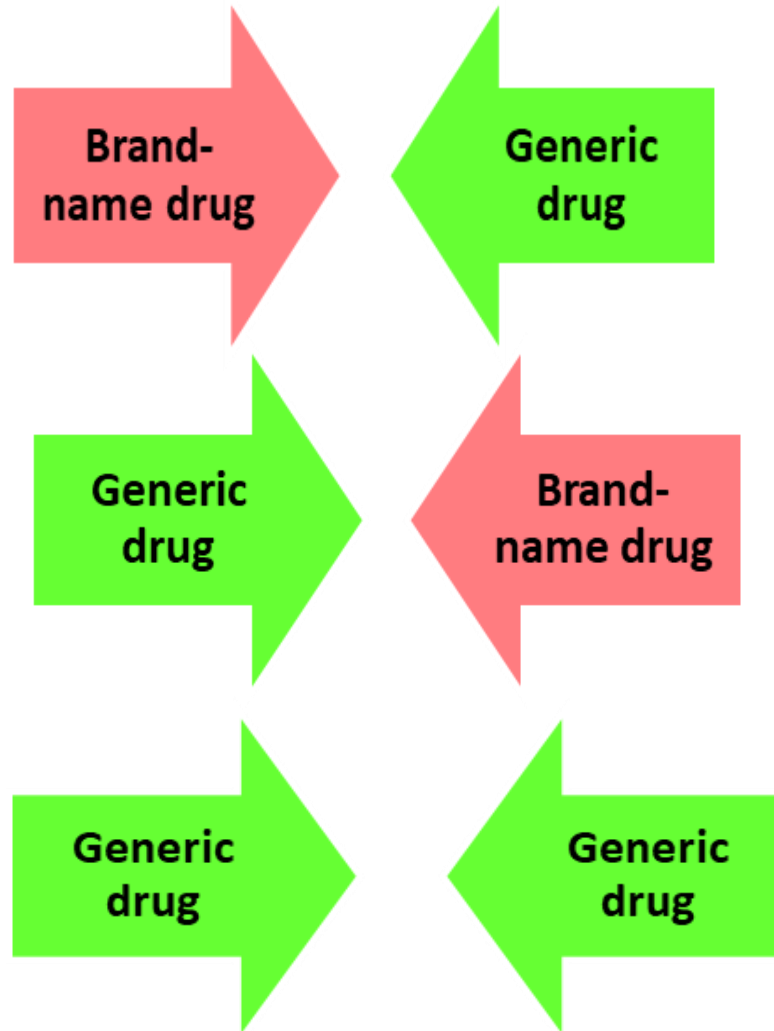 5. **quality**
  6. **intended use**

Perspective of patient:

Therapeutical equivalence

Demonstration of biological ekvivalence of generic drug:

- farmakokinetic parameters
    - **AUC**
    - **c_{max}**
    - **t_{max}**

Reciprocal convertibility of brand-name drug and generic drug

Generic substitution

= substitution of a prescribed branded drug by a different form of the same active substance (generic drug)

Generic substitution is <u>not</u> recommended in

1. **<u>Aspect of active substance</u>**

- Active substances with narrow therapeutic index

- Active substances with non-linear kinetic
- Active substances with poor solubility
- Drugs with more active substances

- Drugs with active substance, that has more indications

2. **Aspect of dosage form**

- Solutions and powders for dosage inhalators

- Topic dosage forms with high effective substances

- Released dosage forms

3. Aspect of patient

- Hypersensitive patient

- Patients with diabetes mellitus

- Asthmatic patients

- Depression or psychosis patients
- Patients after organ transplantation
- Polymorbid and geriatric patients

Pharmacoeconomic evaluation

Pharmacoeconomic research is used to:

- identify, measure and compare

  - costs, risks and benefits of programs, health care services or therapies

- and determine, which alternative produces the **best health outcomes**

Criteria for selecting suitable pharmacoeconomic method

Research Question	Appropriate method	Outcomes measure	Interpreting study results
Similar therapies	**Cost minimization analysis (CMA)**	Equal	Choose program with lowest cost
Different therapies	**Cost-benefit analysis (CBA)**	Finantial	*Benefit-to-cost ratio* of greater than 1.0
Different therapies resulting in clinical comparable patient outcomes	**Cost-effectiveness analysis (CEA)**	Non-finantial	Lowest cost per unit of effectiveness
Similar therapies affecting quality of life	**Cost utility analysis (CUA)**	QALYs	Lowest cost per unit „QALY"

Cost minimization analysis (CMA)

- **Inputs (costs):**   monetary units
- **Outputs:**   no measure (assumed to be equal)

- use when otcomes (benefits) of two or more alteranatives are same (**equal**)

Cost-benefit analysis (CBA)

- **Inputs (costs):**   monetary units
- **Outputs:**   monetary units

- for comparison of costs and benefits of program or treatment alternative (alteranatives are not equal)

- costs and benefits are expressed as a **ratio** (**benefit-to-cost ratio**)

- B:C ratio > 1:   **program or treatment is of value**

- B:C ratio equals 1:   **benefits equal the costs**

- B:C ratio < 1:   **program or treatment is not economically beneficial**

Cost-effectiveness analysis (CEA)

- **Inputs (costs):**   monetary units
- **Outputs:**   natural clinical units

- where outcomes are one-dimensional:
  - **physical units**

  - **natural units**

- **Equivalence principle** - equivalent:

❖ 10 years of life saved for 1 patient = 1 year of life saved for 10 patients
(mesure outcome: number of years of life saved)

❖ 1 year of life saved for patient with hypertension = 1 year of life saved for patient with cancer
(mesure outcome: number of years of life saved)

- results of CEA are expressed as a 2 ratios:

1. **average cost-effectiveness ratio (ACER)**

- <u>total cost</u> of treatment alternative divided by its <u>clinical outcome (effectiveness)</u>

ACER = $\dfrac{\text{health care costs (€)}}{\text{clinical outcome (not in €)}}$

2. incremental cost-effectiveness ratio (ICER)

- <u>additional cost</u> and <u>additional effectiveness</u> gained when one treatment alternative (alterantive A) is compared with the next best treatment alternative (alterantive B)

ICER = $\dfrac{\text{health care cost A (€)} - \text{health care cost B (€)}}{\text{effect A (\%)} - \text{effect B (\%)}}$

Cost utility analysis (CUA)

- **Inputs (costs):** monetary units
- **Outputs:** Quality of life

- if we want to include a measure of **patient preference** or **quality of life** when comparing competing treatment alternatives

Measure outcomes:

1. **QALY (Quality-Adjusted Life Years)**
   quality ratio (scale)

2. **HYE (Health-Year Eqivalent)**

3. **DALE (Disability-Adjusted Life Expectancy)**

4. **Willigness to pay**