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Health Technology Assessment utilization for healthcare decision making

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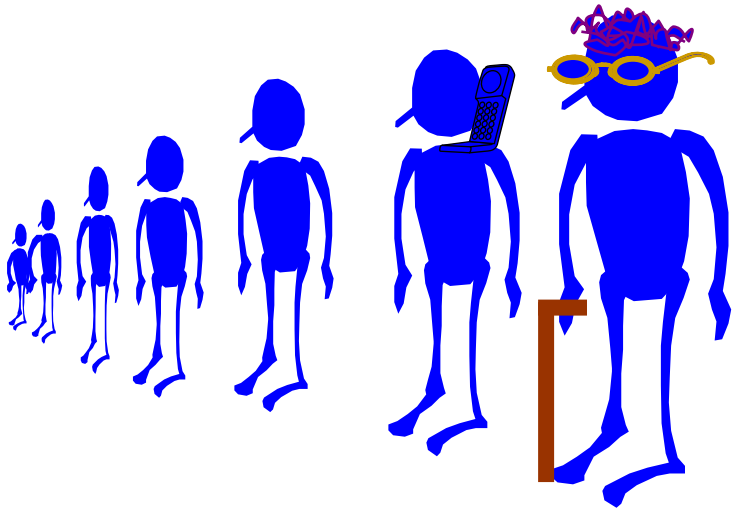
Overall picture in healthcare

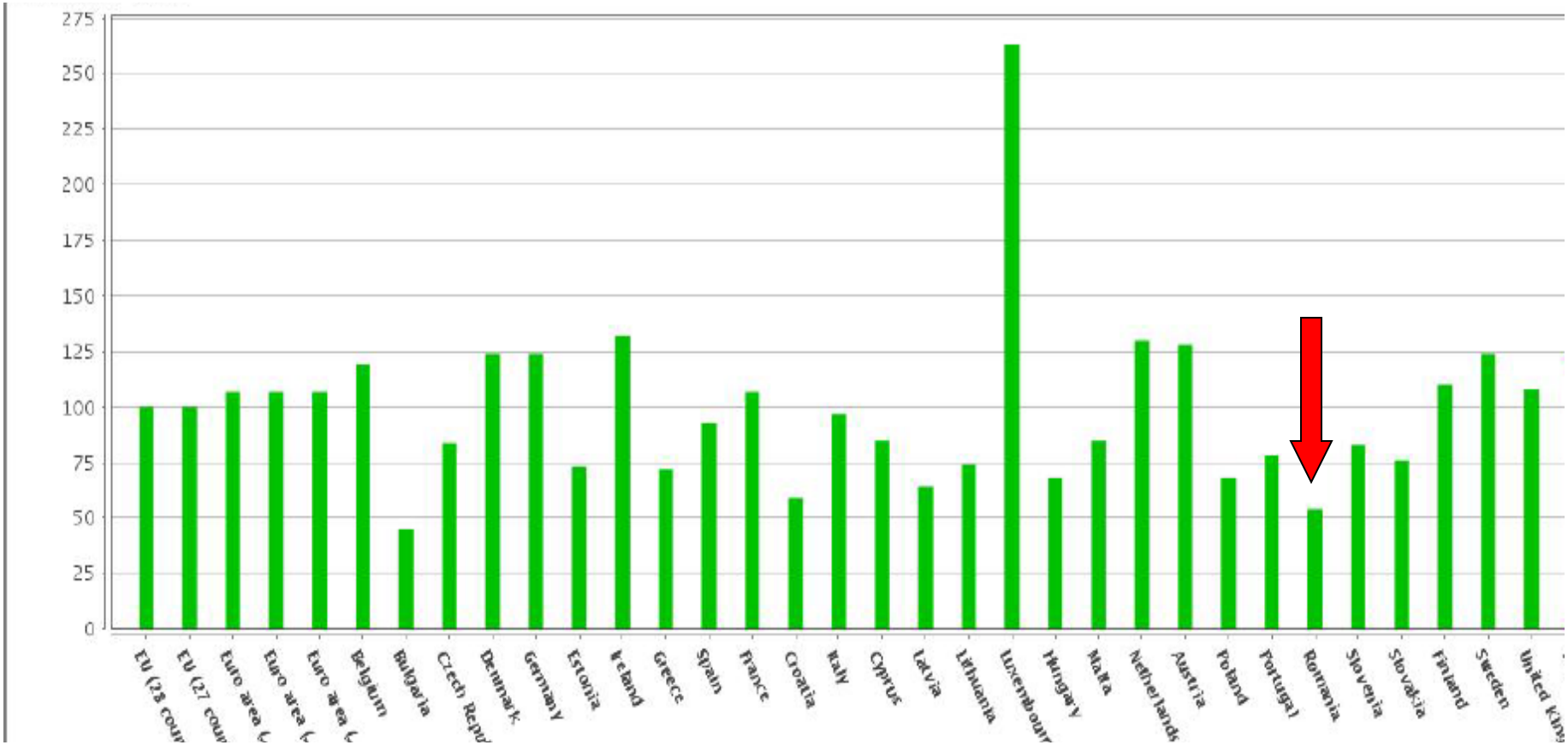
RESOURCES are LIMITED and become SCARCE:
- growing costs of health care – two digits XX%
- rates of economic growth - one digit X%



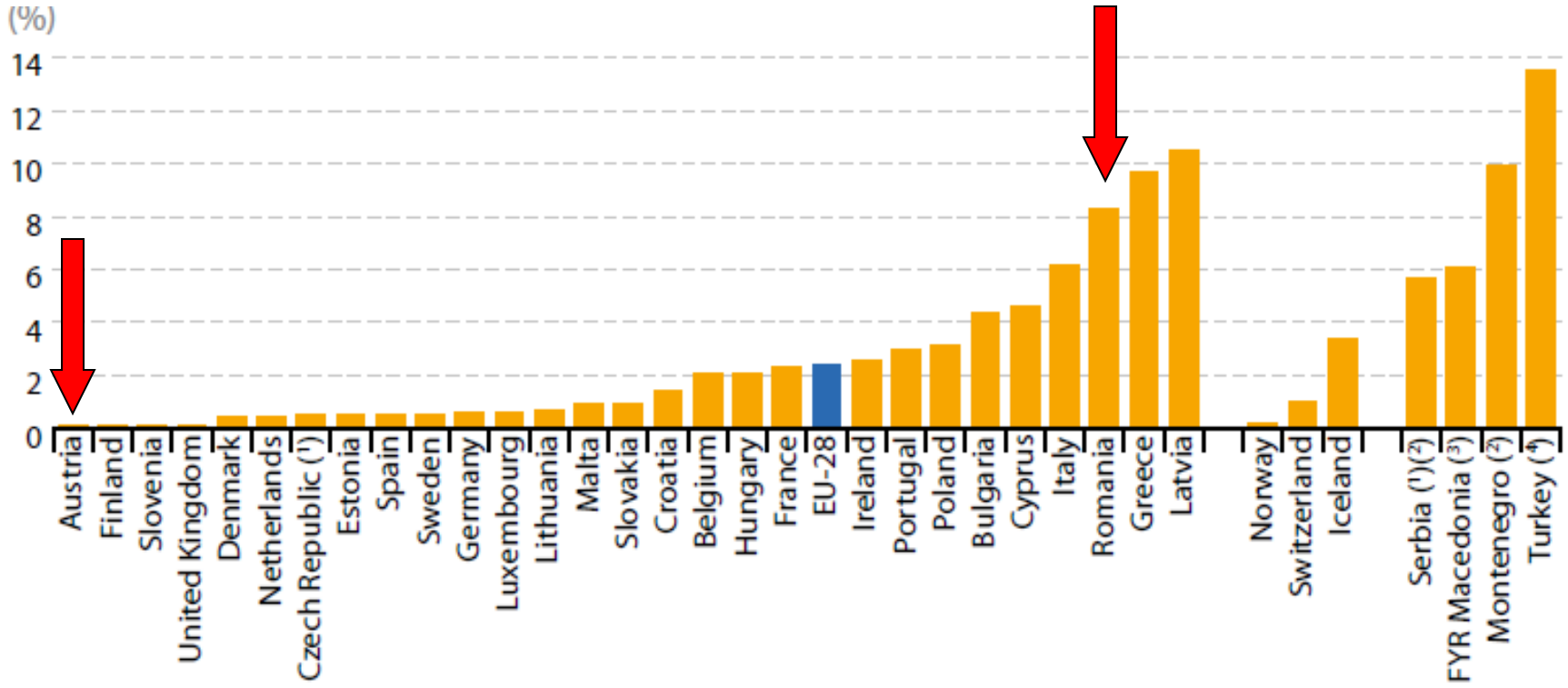
Potential unlimited NEEDS and DEMAND :
- ageing population
- increasing life expectancy
- increasing Prevalence of chronic diseases
- higher expectations of patients
- rapid development of the new technologies
- development of health services supply.

ROMANIA

- World Bank (World Development Indicators 2014): **lower middle-income country** GDP of 199 044 USD (18567, 91 PPP/ capita = **49%** of world average GDP/capita).
- WB - Health Expenditure Romania: **5,6% GDP**, public **4,2%** in 2014 (pos 28 EU)
- EUROSTAT 2014, Romania had a GDP/capita = **6200 EUR (24% EU 28**), with a purchasing parity of **PPS 54% EU 28** (pos 27) - Fig.



Self reported unmet needs for medical care due to financial constraints - 2014



(1) Data have low reliability; (2) 2013 data instead of 2014; (3) 2012 data instead of 2014; (4) 2009 data instead of 2014.

Source: Eurostat (online data code: tsdph270)

- **20 %** of the HC expenditures are coming from private sources – World Bank 2014
- **96%** of private funds are coming from out-of-pocket money – World Bank 2014
- real coverage for drug reimbursement is 60% - EFPIA Report 2013

Decision - always a hard choice

WHAT CAN WE DO?!

EVIDENCE

based decision-making

Clear vision / Added value

HTA

vs.

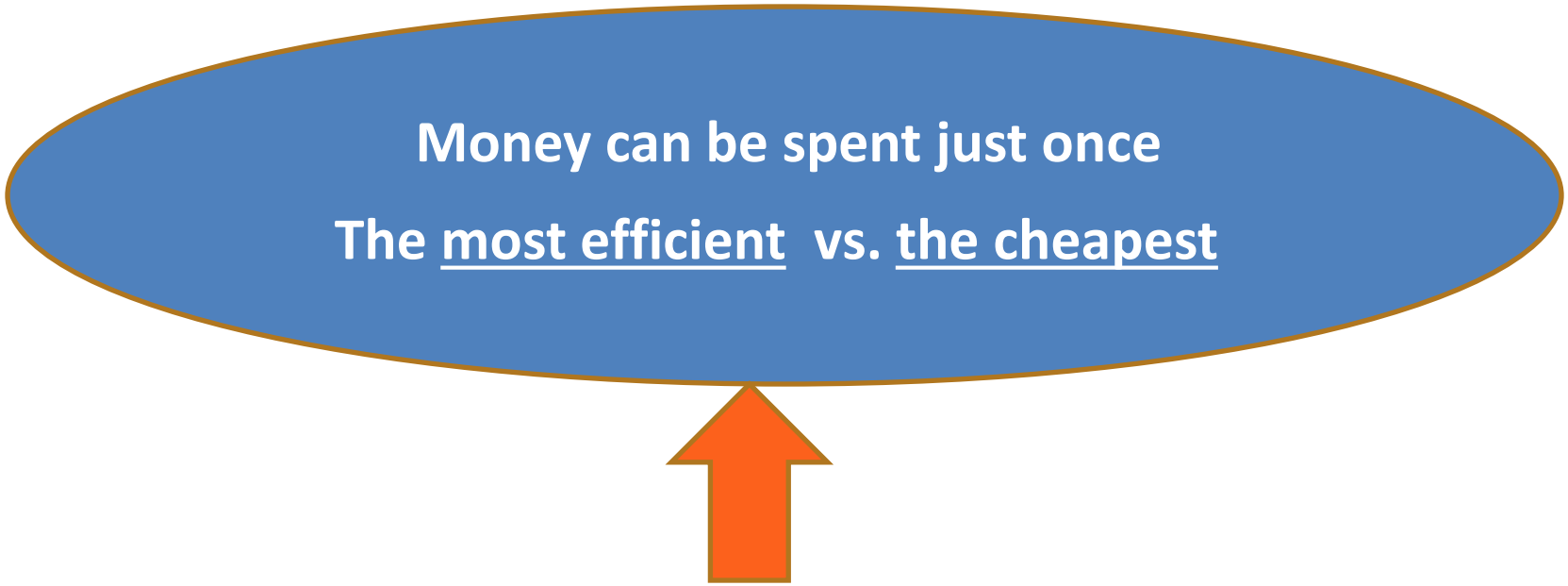
EMINENCE

based decision-making

Small/short time interests & Lobby

“I know better!”

The Key Question: What do we gain if we make a certain choice?



VALUE FOR MONEY
= maximum benefits in terms of health* gained for a monetary unit spent

* All the dimensions of health are taken into consideration

VALUE from different perspectives

Perspective	YoL gained	Patient's (HRQoL)	Efficiency	Budget Impact	Impact on medical practice	Impact on public health	Public perception image/votes
Pacient	+++	+++	-	+++/-	+	-	-
Health care provider	+++	+++	++	+/-	+++	++	-
Payer	+++	++	+++	+++	++	++	+++/-
Government (political)	+	++	+	+++	-	++	+++
Society	+	+++	+	++	+	++	++

+++= very important, ++= important; + = little important; - not important

Solution: A new decision-making model

- Medium and long term vision
- Clear priorities
- Wide stakeholders involvement
- Based on evidences
- Integrated approach – systemic view – wide perspectives
- Unitary implementation – once adopted, the decision should be applied in the same way through the whole healthcare system
- Persistence, continuity, predictability
- Monitoring, assessment, corrections
- Transparence!

HTA = THE TOOL which may integrate all!

HTA – Definitions

"The Health Technology Assessment (HTA) **refers to any process of examination and report of the properties and characteristics of a medical technology utilised in health care, like safety, clinical efficacy, feasibility, indications, costs, cost/effectiveness together with social, economic and ethical consequences of its utilisation, either intentioned or not."**

Goodman, 1998

"HTA is the systematic evaluation of the properties, effects and/or other impacts of healthcare technology."

International Society of Technology Assessment in Healthcare

Classification of health technologies*

- **According to nature:**
  - medicines
  - medical equipments and devices
  - medical and surgical procedures
  - support systems
  - organizational and managerial systems
- **According to purpose:**
  - prevention
  - screening
  - diagnostic
  - treatement
  - reabilitation
- **According to development stage:**
  - experimentale, future
  - in place/in use
  - old, out of fashion, abandoned

** Goodman, 1998*

Potential purposes of HTA*

- Coverage/reimbursement decisions
- Investments - Capital funding decisions
- Formulary decisions (package of health services)
- Referral for treatment
- Programs operation
- Guidelines formulation
- Influence on routine practice
- Indications for further research
- Other – e.g. Critical apraisal of HTA methodologies**

* INAHTA – International Association for Health Technology Assessment

** World Bank- Efficiency of Cost-Effectiveness

EU perspective on HTA *

- ***Health technology assessment (HTA)*** measures **the added value** of a new health technology in comparison to existing technologies/current standard of care.

- **HTA** is **defined** as **a multidisciplinary process** that summarises information in a systematic, unbiased and robust manner about the **medical, economic, organisational, social and ethical issues** related to the use of a health technology.

* European Commission – EUnetHTA Joint Action 2013

EU perspective - The goals of HTA*

- To inform the formulation of **safe, effective, health policies** that are **patient focused** and seek **to achieve the best value**

- **To support decision makers** at national, regional or local level **in their efforts to ensure that patients are treated with the best available treatment while keeping the health budgets under control/in balance.**

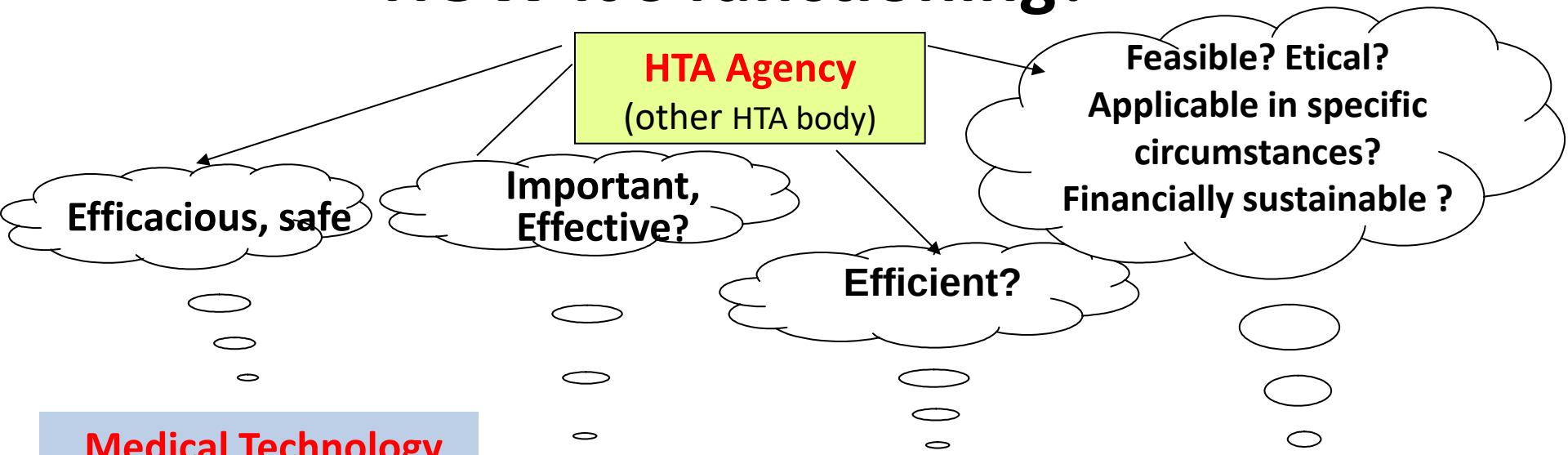
- To encourage the economic stakeholders to **focus their research on areas where they expect significant innovation.**

* European Commission – EUnetHTA Joint Action 2013

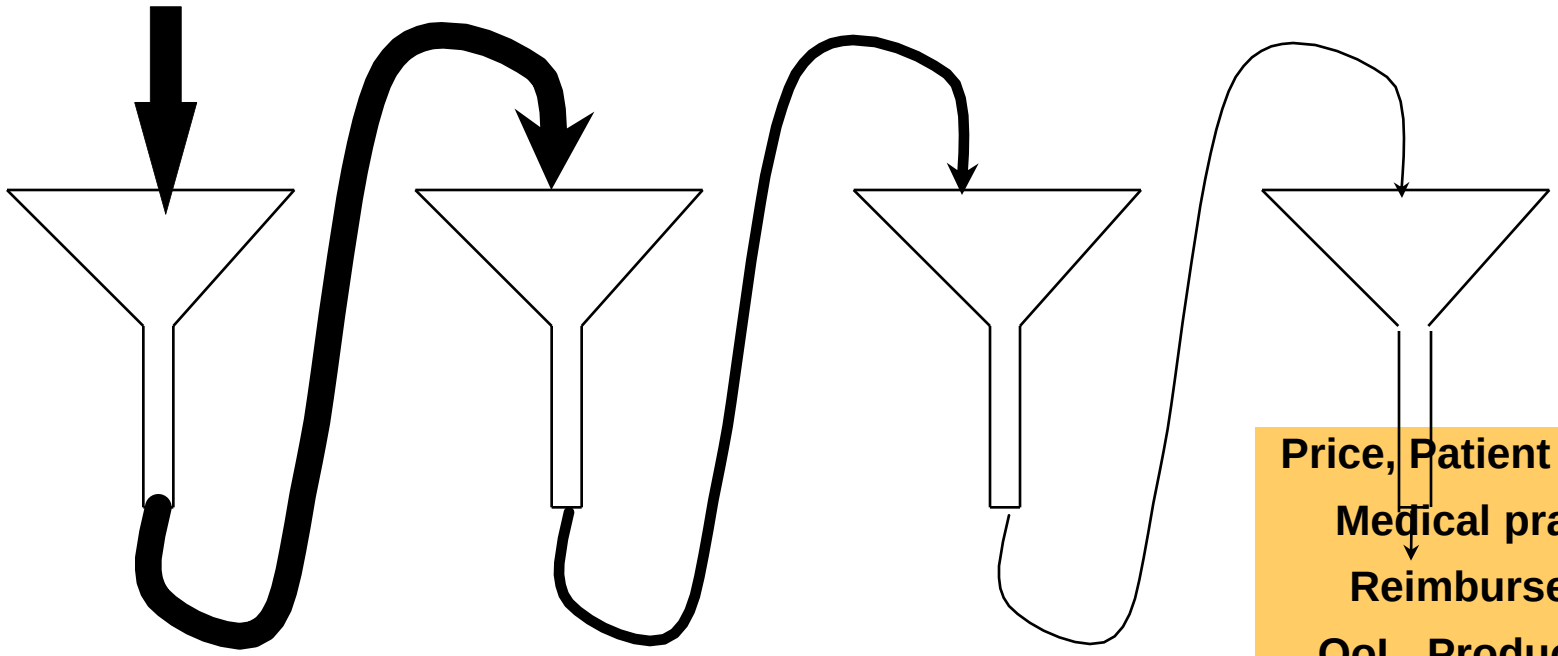
HTA is answering the following questions

1. The new technology was proven to be efficacious and safe for the specific indication?
2. In comparison with other intervention, which one is the most efficacious / effective and which are the differences?
3. Which one is the most efficient and which one brings more added value?
4. What changes are expected if the new technology will be reimbursed/ utilized? (budget impact, impact on HRQoL, medical practice, social security services, society in general, ethical aspects, etc)
5. Is reimbursement / utilization of the new technology possible, justified and sustainable, taking into account the available resources?

HOW it's functioning?



Medical Technology



Price, Patient Access
Medical practice
Reimbursement
QoL, Productivity

HTA Characteristics

- **Continuous:**
  - starts with the RTCs
  - continues during all the product life duration
- **Multidisciplinary:**
  - team work
  - needs a diversity of competencies: medical, (health)economics, ethics, statistics, informatics, legal, etc.
- **Multipurpose:**
  - regulatory, pricing, reimbursement, medical practice, public policies, etc.
- **Multilevel:**
  - national / regional / local level / individual level
  - health service provider level – e.g. hospital – Mini HTA
  - public/private payer
- **Integrative:**
  - integrates all types of evidences, from different domains

The main components of HTA

- ***Clinical evaluation :*** **R&D, Systematic Reviews, Meta-analysis (EBM)**
  - clinical efficacy and safety;
  - medical part of economic evaluation.

  CER- Comparative Effectiveness Research - comparative analysis of clinical effectiveness in real life;

- ***Economic evaluation :*** **Financial & Economic Analysis (Evidence Based)**
  - financial analysis – only costs;
  - economic analysis – both costs and benefits

  Drugs : **Pharmacoeconomics**

- ***Impact Evaluation*** **- Impact analysis (EB)** on:
  - budget
  - health care system
  - medical practice
  - Quality of Life – patients, caregivers
  - diseases profile (morbidity, mortality, etc.)
  - productivity
  - social services
  - ethical issues, legislation, etc.

Clarification of terms

- **EFFICACY** – the capacity of producing the expected/desirable effect –RTCs

- **EFFECTIVENESS** - the capacity of producing the expected/desirable effect in real world

TO DO THE RIGHT THING - WHAT ?

- **EFFICIENCY** – to produce the expected effect with the best resources utilization:
  Report: COSTS/ BENEFITS

TO DO THE THINGS RIGHT - HOW?

ASSESSMENT = EVALUATION BASED ON MEASUREMENT

vs.

APPRAISAL = VALUE JUDGEMENT, BASED ON CRITERIA

Transferability of HTA results*

the degree in which the study results keep their validity in local conditions of another country

Data, methodology and results of a specific study are transferable from a country to another if :

(a) potential users **can evaluate the applicability** in the destination country

and

(b) data, methods and results **are applicable in the destination** country.

- **Clinical efficacy and safety data** are generally more transferable (multicentre, multinational research trials)
- **Cost data** – less transferable - factors influencing transferability :
  - Available resources for health care and budget constraints
  - Epidemiology, diseases profile
  - Structure and functioning of health care System
  - Price / costs level
  - Evaluated benefits
  - Comparators
  - Medical practice patterns.

** Kalo et al, 2012*

Country context - the key issue for HTA*

- Orientation of national policies - priorities
- Decision-making traditions concerning scientific and technological innovation
- Staff numbers and expertise
- Financial situation and priorities
- Health system factors
- Attitudes of policy makers concerning evidence-based working
- Political and societal acceptance of ethical standards in health care
- Education level of general public
- Culture of the country and sub-groups favourable to change.

*INAHTA – International Association for Health Technology Assessment

Trends in HTA – European Commission

- Public consultation on the EU HTA Strategy for **Strengthening of the EU cooperation on Health Technology Assessment** - 21/10/2016 - 20/01/2017 (all types of stakeholders)

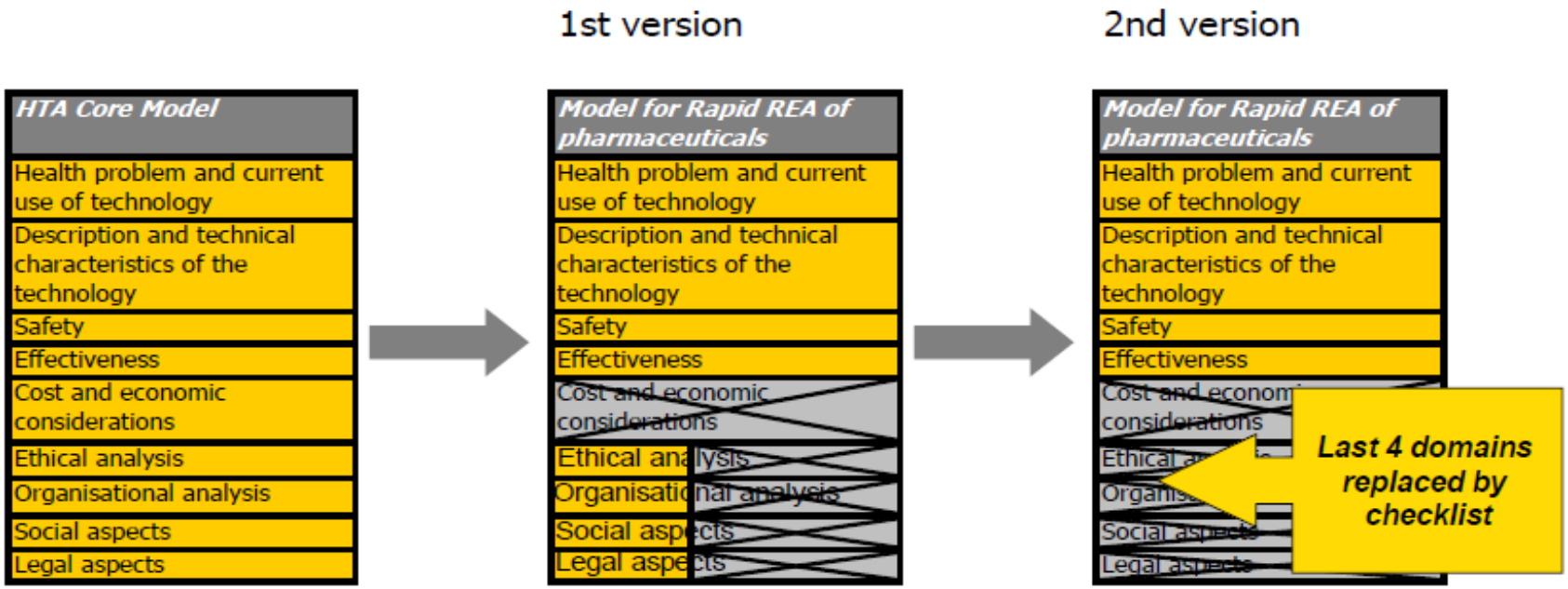
Study Report Conclusions – published in April 2017**:**

- 98% of the respondents: HTA is supporting "rational decision making & control the health care budget“
- EU cooperation on HTA should continue beyond 2020 when EUnetHTA Joint Action 3 will end
- increase joint assessments- clinical/medical assessments of health technologies could be addressed by the EU cooperation on HTA
- avoid duplication – EMA- like system mutual recognition of the HTA reports
- share the costs of HTA between public and private
- share the expertise
- separate the assessment / the appraisal
- separate regulatory institutions / HTA bodies.

Simplification – clear criteria - checklist

- Example-

Relative effectiveness assessment (REA) of pharmaceuticals



eunethta

Trends in HTA – Pragmatic value assessment

Pilot project for medicines based on checklist - Serbia

Value for patients and society	1. Added clinical benefit	Criteria which relate to the performance of a new medicinal product in its indication submitted for reimbursement along main sources of clinical benefit.
	2. International funding and assessment references	Criteria which relate to previous health technology assessments in major international pharmaceutical markets (both economic evaluation and comparative assessment) and international reimbursement / public funding references.
	3. National health policy alignment	Selected criteria which describe how much the a new medicinal product in a new indication helps implement health policy priorities.
	4. Social and ethical considerations	Selected social and ethical considerations the new medicinal product can address in the country.
Affordability	5. Budget impact assessment	Net reimbursement outflow that the new medicinal product is expected to generate in its new indication. Budget impact assessment takes place at net price levels, i.e. budget impact mitigation through managed entry agreements are taken into consideration.

Source: Dankó D, Molnár M. *Balanced Assessment Revisited*. Journal of Market Access and Health Policy, 2017, under peer review

To be expanded in Bulgaria, Croatia, Hungary, **Romania**, Slovakia

Pragmatic approach in Rare Diseases

Multiple Criteria Analysis Decision Project – on going in EU

	Domains	Criteria	Sub- criteria
Value of Inter-vention	Need for intervention	Disease severity	Impact on life-expectancy Impact on Morbidity Impact on Patient QoL Impact on Caregiver QoL
		Size of affected population	
		Unmet needs	
	Comparative outcomes of intervention	Comparative effectiveness	
		Comparative safety/tolerability	
		Comparative patient -perceived health/PROs	
	Type of benefit intervention	Type of preventive benefit	
		Type of therapeutic benefit	
	Economic consequences	Comparative cost-consequences-cost of intervention	Medical costs to healthcare syst. Medical costs to patient
		Comparative cost-consequences- other medical costs	
		Comparative cost-consequences- non-medical cost	Patient/caregiver productivity Costs to wider social-care system Non-medical costs to patient
	Knowledge about intervention	Quality of evidence	
		Expert consensus/Clinical practice guidelines	
	Population priorities	Rare diseases	
		Other priorities	

Wagner et al., Can the EVIDEM Framework Tackle Issues Raised by Evaluating Treatments for Rare Diseases: Analysis of Issues and Policies, and Context-Specific Adaptation

HTA in Romania

- **A long history of discussions and projects**
- HTA is seen as **a tool for cost control** - additional hurdles for patient's access

- **A transitional HTA system for medicines since 2008** (different phases and complexities)
- current system in place since 2014 – **Scorecard = Checklist**

Main issues:

- **No direct evaluation of the value of drug**
- Too much emphasis on the external components
- The **lack of methodology** for Real World Studies
- No clear timelines after the positive opinion
- **Lack of personnel & expertise**
- **Limited availability of local data**
- **Low cooperation** and significant **fragmentation** in the system

- **No systematic evaluation for other health technologies**

Ministry of Health - World Bank Project

Oxford Policy Management, Imperial College London & Management Sciences for Health USA

"TECHNICAL ASSISTANCE FOR INSTITUTIONAL BUILDING OF HEALTH TECHOLOGY ASSESSEMENT STRUCTURE INCLUDING TRAINING FOR NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES"

Objectives:

- to design an institutional framework of the assessment of the health technologies **connecting the structures** carrying out the assessment of the health technologies – the research institutions, NAMMD, MoH, NHIH, and other relevant institutions, in order **to enable smooth information exchange** and to support policy-making
- to design a **HTA methodology**
- to provide a **special training program** to the members of the speciality and national advisory commissions of MoH

"The challenge is that of ensuring the translation towards a decision-making process based on the modern principles of evidence-based-medicine, on cost-effectiveness and on patient centred services"

All the objectives are expressing current issues of the healthcare system!

Phase I WB Report Recommendations

May 2017

- to **expand** both the **infrastructure** and **application of HTA**
- **collection and stewardship of data** necessary for effective HTA
- **expanding and integrating both public sector and academic technical expertise**
- **stimulate greater inter-institutional collaboration**, with MoH leadership
- **coherent and consistent evaluative framework**
- developing a **framework of best practice principles and governance standards for HTA**
- increase **international collaboration** with relevant institutions

All of these - recommended for free by the Romanian Experts -e.g.:

- **National Strategy for HTA** – MoH & AMCHAM working group – **2011-2012** starting from Austrian National Strategy for HTA as inspirational model
- **4 P model** – **Partnership, Pragmatism, Predictability & Prise** (Radu CP, Pană B, **2013**)

Take home messages

- HTA = a valuable tool for Evidence Based Decision making process
- Multiple competencies team work
- Pragmatic approach, simplification
- Joint action – CEE, EU
- Mutual recognition, avoid duplication
- Wide perspective of added value for health.

A very good opportunity for personal & professional development!

Q & A

Thank you for your attention!

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