

Health Economics: a decision making tool

Monika Szkultecka-Dębek, MD, PhD

Health Economics Support Manager for CEMAI Region, Roche



Health Economics

common issues in CEE

- Only some countries have official guidelines for HTA analysis (e.g.: Hungary, Croatia, Poland, Turkey),
- Law regulations not in every country (e.g. Hungary, Poland, Turkey, Romania, Czech Republic),
- No officially published cost guidelines,
- No local utilities data,
- Limited information about the QoL of the population,
- Quality and validity of morbidity and mortality data is questionable,
- Disease registries are rare and data availability is low,
- Limited access to innovative drugs.

Key elements in the decision making process

- Budget impact
- How can an intervention reduce the burden of disease?
- Health care priorities
- Cost-effectiveness: cost/QALY, cost/LYG

Role of HTA in reimbursement

- Reference basis for policy makers (informed decision making process)
- To show savings or additional spending
- To show budget impact options
- To identify subgroups which can be efficiently treated

Examples of HTA in CEE region

- Croatia
- Hungary
- Romania
- Poland
- Slovakia
- Slovenia
- Czech Rep.
- ...and others

HTA in Croatia

01.01.2010 Ordinance for Establishing Criteria for Inclusion of Medicinal Products in the Basic and the Supplementary Reimbursement List of the Croatian Institute for Health Insurance (CIHI).

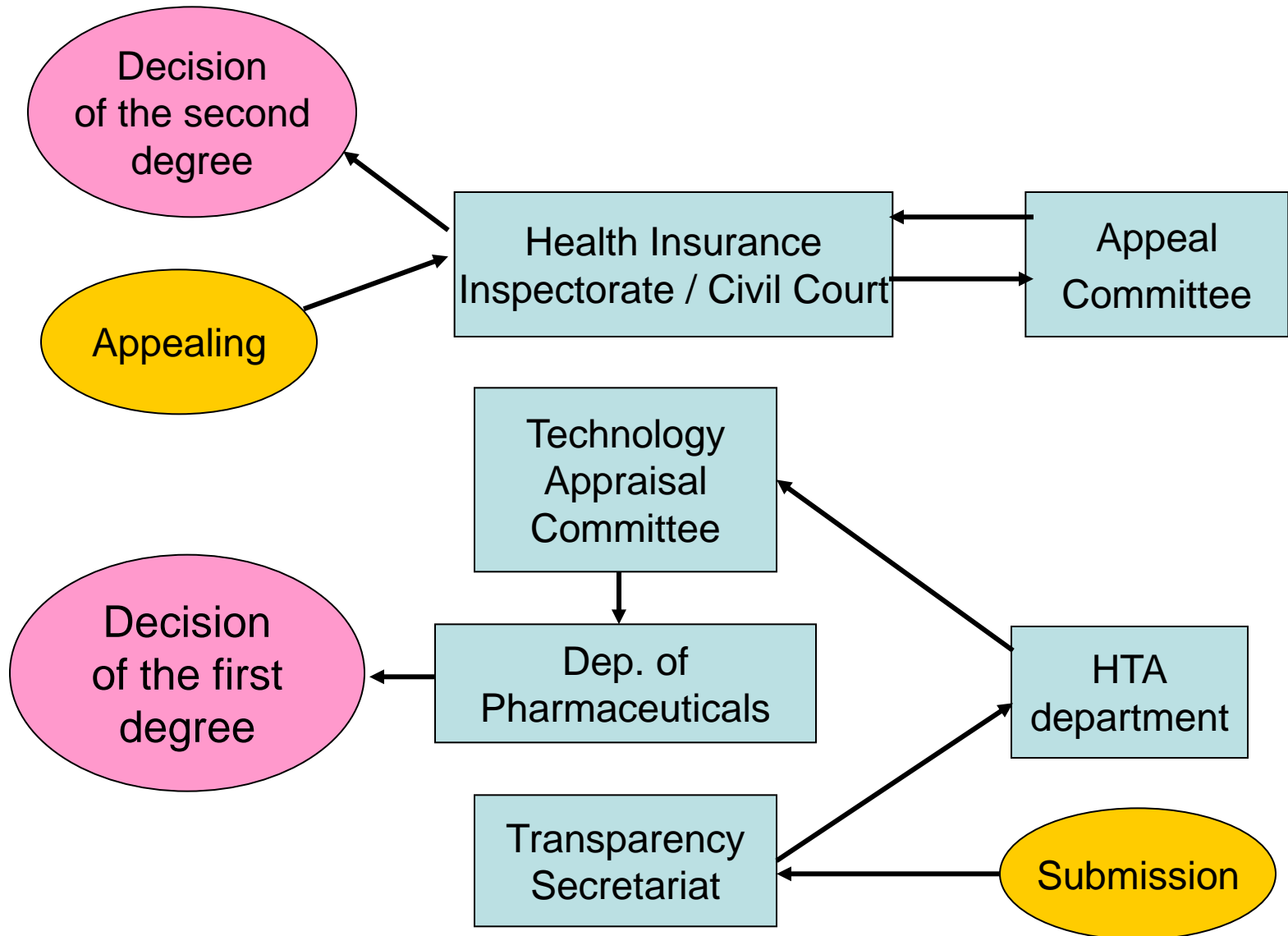
Budget Impact Study (BIS):

- mandatory
- based on ISPOR guidelines

HTA in Romania

- 2008 new legislation: formal process of PE value assessment introduced (guideline based on Swedish model, imposing both clinical effectiveness and cost-effectiveness evaluations),
- Compulsory information in the dossiers submitted to NHIH for reimbursement: international and *local evidence* of PE value,
- Regulatory bodies: National Commission for Transparency and Specialty commissions at NHIH level are approving patient' dossier for reimbursement,
- No reference to other HTA agencies approvals is made for reimbursement decisions; however, evidence on cost-effectiveness from other countries is required.

HTA in Hungary



HTA Agency in Hungary

Health Strategic Research Center:

- established in 2004
- direct subordinate to the Ministry of Health
- Health Technology Assessment Department:
 - evaluates submissions from medical and economical point of views
 - recommends decision to NHIF
 - deadline is 43 days
 - involves external experts
 - points can be discussed at Technology Appraisal Committee meeting

HTA in Hungary

Guidelines for HE studies (2002):

- ministerial decree
- created using 60 references:
 - education books,
 - handbooks,
 - guidelines from other countries,
 - NICE guidance,
 - articles,
 - newspapers,
 - publications of HE conferences (ISPOR, IHEA).

HTA in Hungary

Assessment is focused on:

- Clinical efficacy:
 - complete medical evaluation
 - list and review of publications from the last 5 years
- Cost effectiveness:
 - mandatory element of reimbursement submission
 - model can be adapted, implemented with Hungarian data
- Budget impact model:
 - not mandatory

HTA in Poland (AHTAPol)

- Advisory board supporting the Minister of Health in the decision-making process
- Provides guidance in offering the highest quality of evidence based healthcare
- Core activities:
 - develops Polish guidelines for HTA reports (March 2007, April 2009)
 - produces and assesses HTA reports
 - collects, makes available and disseminates information on HTA results, methodologies and recommendations
 - recommends medical procedures to Minister of Health
 - coordinates work on Basic Benefit Package

AHTAPol in practice

- Internal experts audit the HTA dossier submitted by manufacturer
- A „Verification analysis” is prepared by AHTAPol and presented to Council Board
- Council Board:
 - composed of 8-15 members
 - meets every 2 weeks
 - at each meeting assesses 3-5 technologies
 - consults clinical experts on their opinion about new technology
 - patients can be invited to participate in the Council’s meeting
 - issues positions that are supportive to AHTAPol President
- AHTAPol President issues Recommendations for the Ministry of Health

Impact of AHTAPol recommendations

Positive, conditional or temporary recommendation:

- necessary incentive to start the reimbursement process implementation
- starting point for any systematized financing from public resources
- open way to negotiations with public payer
- can be outcomes related (e.g. safety monitoring required)
- can be cost related (allows for price negotiations and agreements: risk sharing, price volume, etc)

Negative recommendation:

- closed way for given technology financing from public funds
- no possibility to negotiate with public payer
- technology can be once again assessed by AHTAPol only if and when new evidence for its efficacy and safety is available

Some examples of HTA based decisions

Romania:

- Mircera,
- RoActemra

Croatia:

- Xeloda (CRC),
- RoAcremra,
- Mabthera (RA)

Poland:

- Herceptin (BC),
- Valcyte,
- Xeloda (GC),
- Mircera,
- Pegasys

**How is it done in Western
Europe?**

National Institute for Health and Clinical Excellence (NICE)

- NHS organization set up in 1999, London, UK
- to ensure everyone has equal access to medical treatments and high quality care from the NHS
- recommendations, standards and services are developed in consultation with independent committees and experts (including industry and health experts, academics, patients and other members of the public)

NICE activities are underpinned by the need for:

- transparency
- collaboration
- involvement of relevant stakeholders

National Institute for Health and Clinical Excellence (NICE)

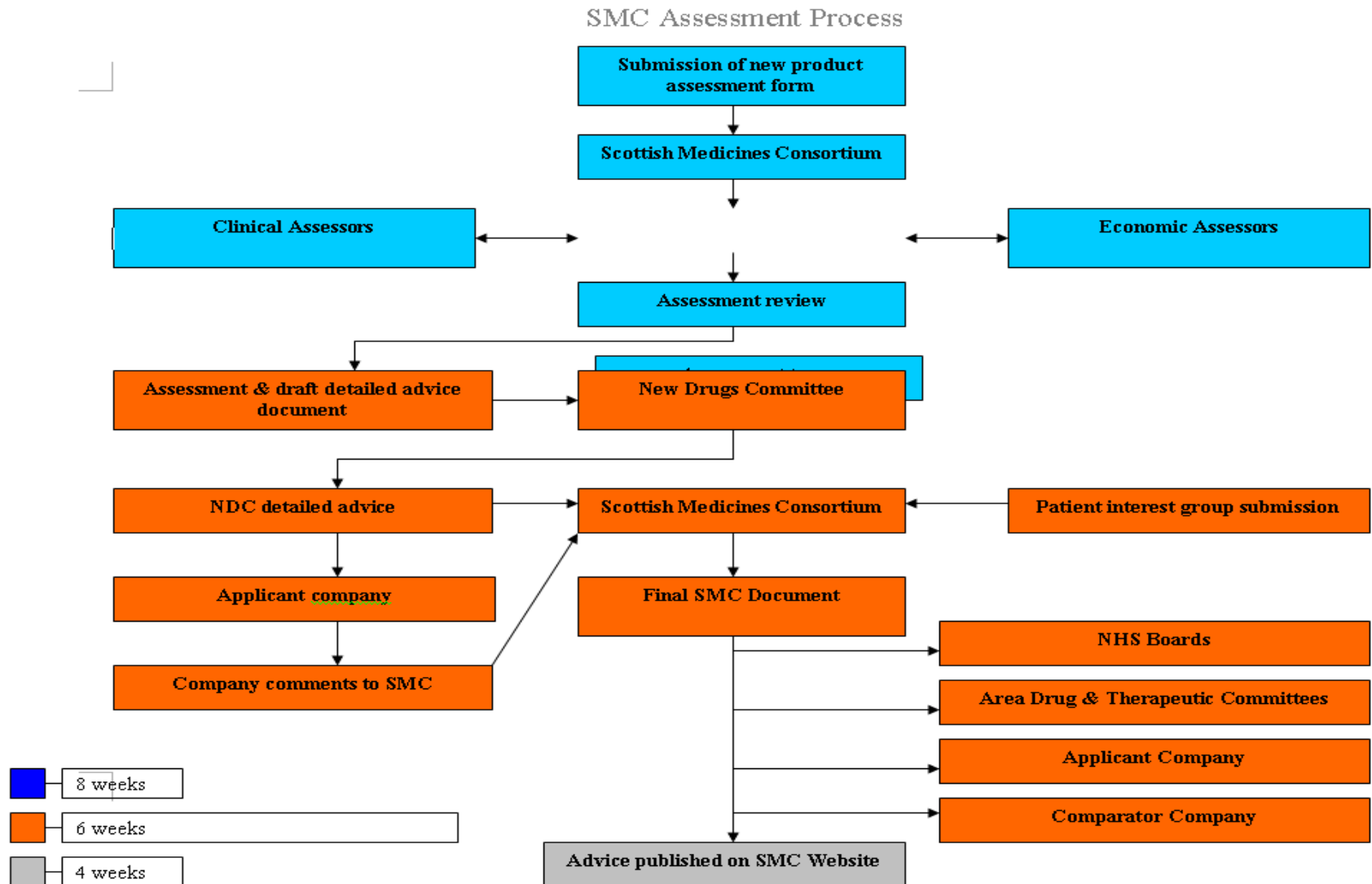
Technology assessment process:

- **Choice of appraisal topic**
- **Scope defined** (scope defines the disease, the patients and the technology and the questions it aims to answer).
- **Evidence submitted** (the manufacturer or sponsor of the technology is invited to provide an evidence. Non-manufacturer consultees are also invited to submit a statement on the potential clinical and cost effectiveness of a treatment.)
- **Evidence Review Group (ERG) report prepared** (independent academics review of the evidence submission)
- **Evaluation report prepared** (evidence includes: the ERG report, written submissions, patient expert personal statements, clinical specialist personal statements, comments received on the ERG report).
- **Appraisal Committee** considers the evaluation report and hears evidence from nominated clinical experts, patients and caregivers. Discussions are held in public.
- **Appraisal consultation document (ACD) produced** (provisional recommendations, four weeks to comment on the ACD, ACD is available on website)
- **Final appraisal determination (FAD) produced** (Appraisal Committee considers the comments on the ACD and makes its final recommendations in the FAD on how the technology should be used. Consultees can appeal against the FAD.
- **Guidance issued** (Technology appraisal- TA or Single technology appraisal- STA)

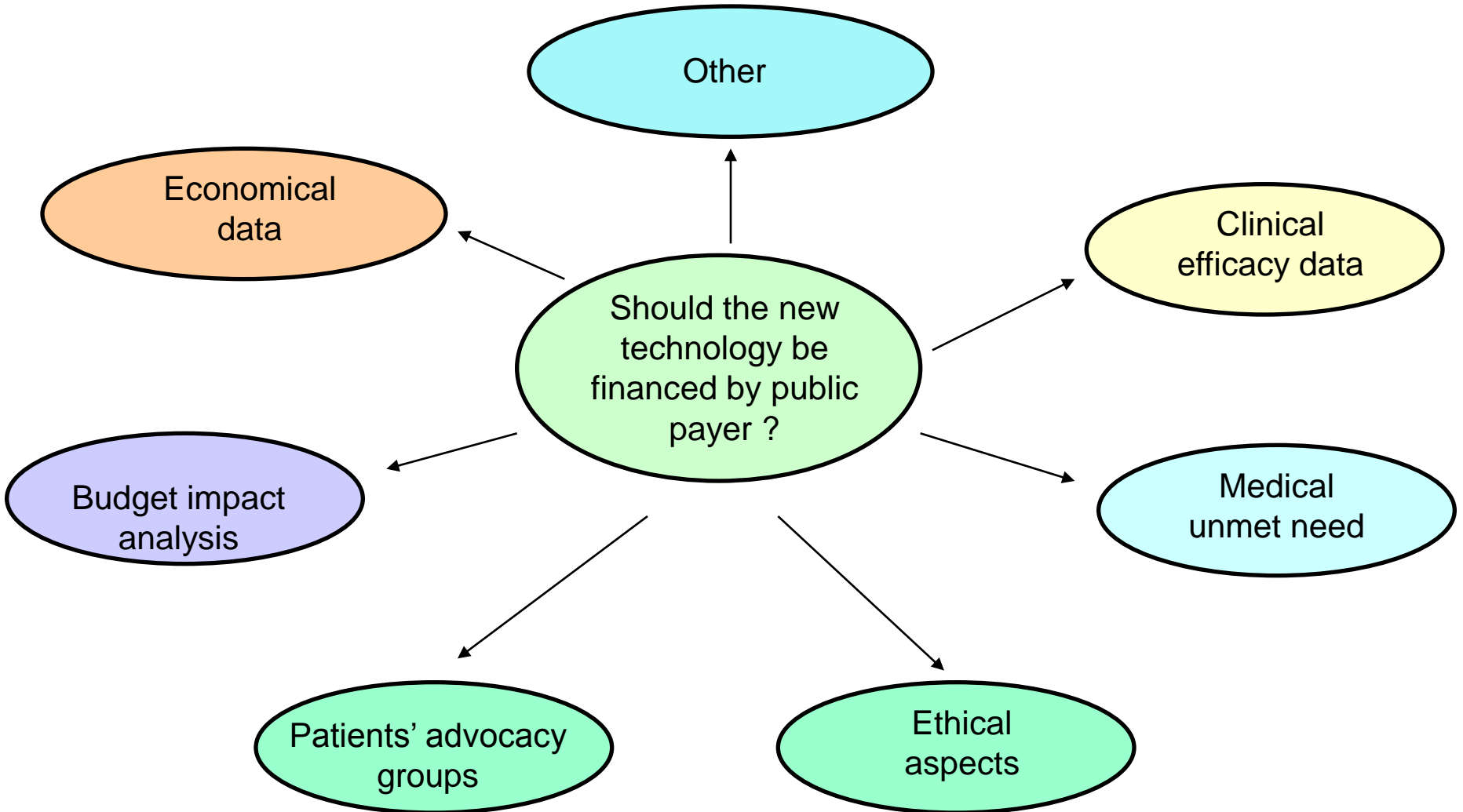
Scottish Medicines Consortium (SMC)

- to accept for use newly licensed drugs that represent good value for money to NHS Scotland.
- analyses information supplied by the drug manufacturer on the health benefits of the drug and justification of its price.
- works to make sure that drugs which represent good value for money are accepted for routine use as quickly as possible for patients' benefit.
- made up of lead clinicians, pharmacists and health economists together with representatives of health boards, the pharmaceutical industry and the public.

Scottish Medicines Consortium (SMC)



What can influence payer's decisions?



**Thank you for your
attention!**

monika.szkultecka-debek@roche.com