[C. Method of economic evaluation/HTA]

C-1. Recommended methodology or guidelines for economic evaluation

・Does your organization have a recommended methodology or guidelines for economic evaluation?

2009年版が公開されている(別添参照)。(例) 割引率は費用5%、アウトカム3.5%など
http://www.aotm.gov.pl/assets/files/wytyczne_hta/2009/Guidelines_HTA_eng_MS_29062009.pdf
また2012年には、最低限満たすべき要件について保健省から文書が出されている。
http://www.aotm.gov.pl/assets/files/wytyczne_hta/2012/Regulation_MOH_minimum_requirements_03042012_eng.pdf

C-2. Methods of economic evaluation or HTA

C-2.1. Time of evaluation

❑ Before the new drug approval (NDA)
■ Between the NDA and reimbursement
❑ After it is marketed

C-2.2. Healthcare technology targeted by the economic evaluation

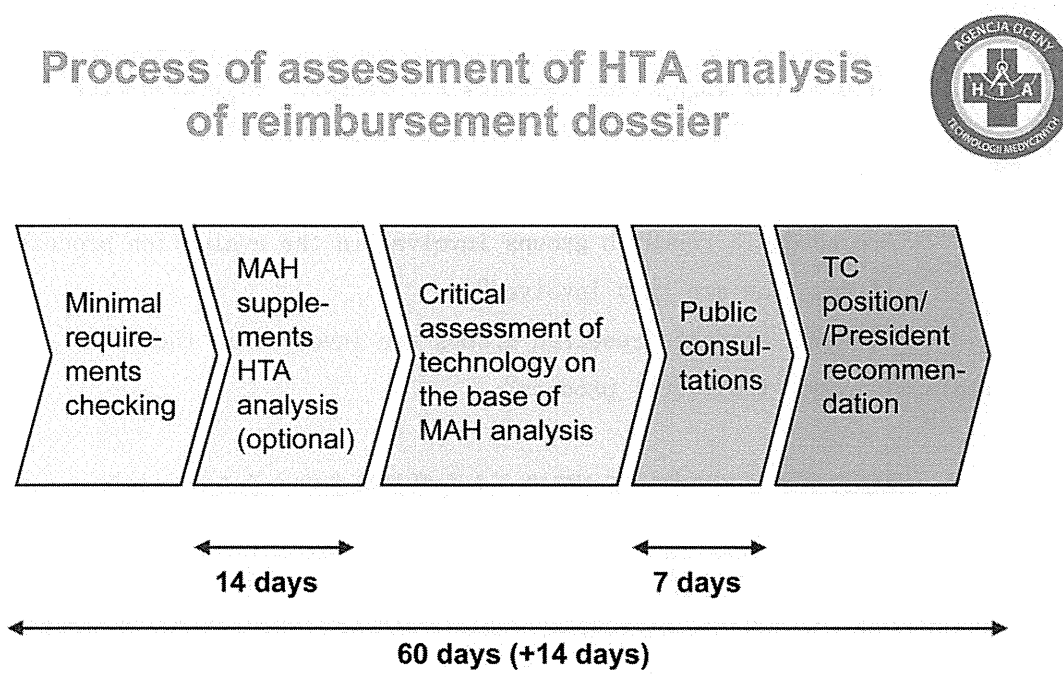
・Are all technologies assessed by the economic evaluation?
・If not all technologies are targeted, who determines the targeted technologies, and how?
・Which technologies are targeted?

医薬品の場合、現在償還されていない新規有効成分については、HTAのプロセスが必須である。ただし、rapid reportのものは経済評価が含まれていない。

C-2.3. Evaluation process

C-2.3.1. Process

・Please explain the process of evaluation.



・MAH(Market Approval Holder)の提出データがガイドライン等に一致しているか最低限のチェックを行う。
・上記に課題があれば、MAH に再分析を要求する。
・分析の批判的評価を行い、その結果を報告にまとめ TC(Transparency Council)に送付する。
・一般からの意見募集を経て、TC が開催され、最終的な推奨(president recommendation)が出される。
・これらのプロセスは 60 日以内に完了しなければならない。

C-2.3.2. Economic evaluation analysts

・Who performs the economic evaluations? *(e.g., manufacturers, third-parties, academic groups, etc.)*

企業が提出する。

C-2.3.3. Reviewers of the economic evaluation

・Who reviews the submitted economic evaluations? *(e.g., members of the organization, academic groups, etc.)*

AHTAPol でレビューを行う。企業はモデルも電子ファイルによって提出し、必要であ

ればモデルの仮定等をチェックし、修正をおこなう。

C-2.3.4. Involvement by external researchers (from universities and research institutes)

・Are academic research groups involved in the evaluation process?
・If yes, how are they involved?
・How much academic research groups are involved in the organization, not individual process?

評価のプロセスにおいてAHTAPolから意見等を求めることもある。

C-2.3.5. Involvement of citizens or patient groups

・Are citizens or patient groups involved in the evaluation process?
・If yes, how are they involved?

・一般の人々もpublic consultationの期間中にコメントを出すことはできる(ただし実際にはまれ)
・患者団体の代理人がTC(Transparency Council)にも含まれている。

C-2.4. Evaluation period

・On average, how long does it take to perform one economic evaluation or HTA?

全体のプロセスで60日

C-3. Threshold

・Do you have referable thresholds used in your economic evaluations?
・If yes, what are the approximate values of these?
・If no, how does your evaluation determine whether a healthcare technology is cost-effective or not?

・Reimbursement Act(2012年)により、3xGDP per capita (2013: ~105 000 PLN= ~25 000 euro)であることが定められている。
・“Threshold price”は経済委員会と企業が交渉する際にも用いられる。

C-4. Completed evaluation

C-4.1. Number of completed evaluations

・What are the total and annual counts for completed evaluations?
・If possible, please list the URL or the results of the evaluation.

・ 2013 年は 65 件のメーカー提出データを評価した。90 件のその他の勧告、適応外使用における償還等医薬品に関する意見 30 件、地方政府プログラムへの意見 280 件。
・ 推奨するかどうかは公開するが、経済評価の部分は非公開となっている。

[D. The role of the evaluation in decision-making]

D-1. Application of evaluation to decision-making

・How are the economic evaluations or HTA utilized? *(e.g., reimbursement, pricing, etc.)*
・How do those making decisions utilize the evaluation results? *(e.g., mandatory, optional, etc.)*

AHTAPol は保健省に償還の可否を勧告する。また、経済委員会が価格交渉を行う際に”threshold price”を用いる。

D-2. Decision-making based on evaluation results

・Please describe the decision-making process as it employs the evaluation results.

D-3. Positive/negative results of the evaluation

・How are positive and negative evaluations handled? How do these results influence which processes, and in what way?

D-4. Feedback (in particular, negative feedback) about your organization from citizens/patient groups

・How do citizens or patient groups respond to decisions made based on economic evaluations or HTAs (in particular, negative assessments)?

D-5. Example of an evaluation and decision-making

・Please elaborate on the evaluation and decision-making process, using the example of sunitinib (®Sutent) for renal cell cancer.

・Please do the same for long-acting insulin (insulin glargin (®Lantus) and/or insulin detemir (®Levemir)).

(Please note: We commonly inquire about sunitinib and long-acting insulin and compare the answers from many organizations. If neither sunitinib nor long-acting insulin is utilized, please skip this question.)

HTA in Poland:
Current status and future development

Anna Zawada a.zawada@aotm.gov.pl
Agency for Health Technology Assessment in Poland (AHTAPol)
Warsaw, November 26th, 2013

Step-wise process of implementing HTA in Polish health care system

Launching AHTAPol by ordinance of MoH	June 2009 Act on Health Care Benefits	01 Jan 2012 Reimburse-ment Act	2014 Reimbursement Act update
2005 (in line with Dir 89/105/EEC)	coverage/ desinvestment rules	ICER=3xGDP per capita	in the process

Step-wise process of implementing HTA in Polish health care system

- **2005** – launching AHTAPol by the ordinance of Ministry of Health in line with Directive 89/105/EEC; capacity building under "Transparency of the National Health System Drug Reimbursement Decisions" TF 2005 EC project: proposals of structural and procedural improvements and HTA involvement in Polish health care system
- **June 2009 – Act on Health Care Benefits** financed of public funds – confirmation of the place of HTA in the system by setting the rules of making decisions on coverage new health technologies under benefit basket and desinvestment
- **01 Jan 2012 – Reimbursement Act**:
  1) set up more restrictive rules for financing drug technologies with ICER threshold of 3xGDP per capita (2013: ~105 000 PLN= ~25 000 euro),
  2) rules for NHF budget for drug reimbursement growing up,
  3) setting the limit for NHF budget for drugs: no more then 17%; when overfilled – MAH obliged to pay-back;
- **Jan (?) 2014 – update of Reimbursement Act planned**

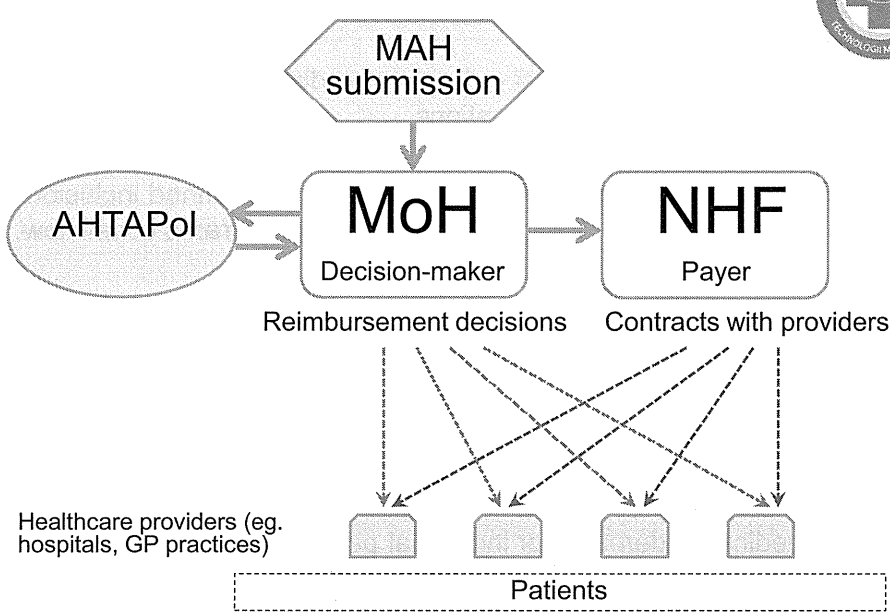
Current means of funding drugs in Polish healthcare system

1. On the reimbursement list – drugs to be distributed by pharmacy on the basis of registered indications
2. On the list of drugs to be funded under „regimen (drug) programs" (designed for defined group of patients, tightly defined inclusion/ /exclusion criteria, careful monitoring; drug programs cover new, expensive therapies)
3. On the catalogue of chemiotherapeutics delivered in hospital care in oncology
4. On the reimbursement list of drugs funded in specific off-label indictions
5. A few specific MoH therapeutic programs (eg. clotting factors for haemophilia; in-vitro insemination for infertility)
6. On dedicated demand for individual patients (special cases of chemiotherapy or even drugs not approved for Polish market)

Who applyes for coverage?

- In case of reimbursement on list, under drug program or in the catalogue of chemiotherapy – MAH should initiate the process
- In case of the list of off-label use – MoH initiates process by asking National Consultants in specific medical domains to indicate drugs and their off-label indications
- As for individual approval – MoH may ask AHTAPol to assess specific technology in case the number of demands exceeds the limit; negative recommendation causes refusal

Place of AHTAPol in Polish system 2013



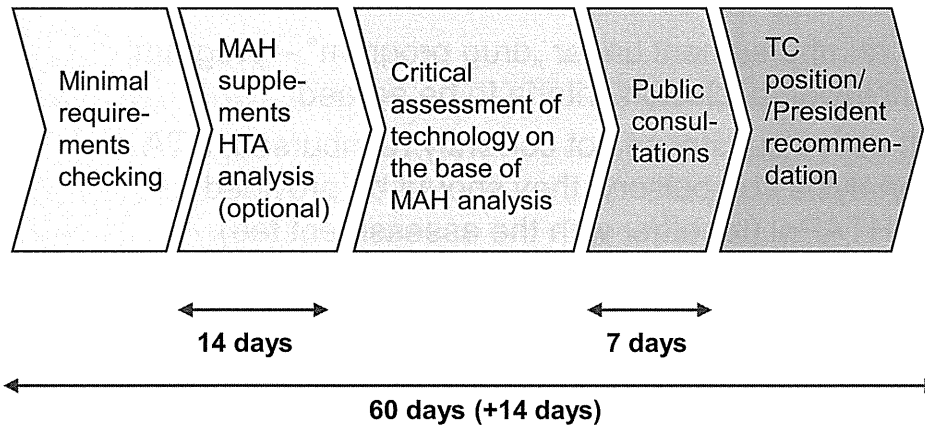
Proceedings with MAH submission in Ministry of Health

- Checking formal completness of the submission
- If reimbursement under „drug program" – program inclusion/exclusion criteria to be agreed
- If active substance not currently reimbursed, HTA analysis compulsory; they should be provided to AHTAPol (together with the assessment fee)
- After AHTAPol recommendation delivered – price and risk sharing agreement to be negotiated with Economic Commission in MoH
- Reimbursement decision made by MoH; only an appeal to the court possible

Tasks of AHTAPol

- Primary task: assessment of health technologies and health care procedures on the demand of Ministry of Health (MoH) to inform decision making on financing medical procedures
- In case of drugs (medical devices, food supplements) financed on reimbursement lists/drug programs/catalogue of chemiotherapy – procedure triggered by submission of drug dossier by Market Authorisation Holder (MAH) to MoH; if active substance has not been reimbursed yet – AHTAPol recommendation needed; AHTAPol assessment is charged
- Additional task (not covered in this presentation): assessment of health programmes of local governments (LG) to advice on effective spending of public funds – LGs are obliged to seek AHTAPol advice; AHTAPol opinion is to be consider, but adoption is not mandatory; 3 months statutory time limit for AHTAPol advice

Process of assessment of HTA analysis of reimbursement dossier



Process of assessment of HTA analysis of reimbursement dossier

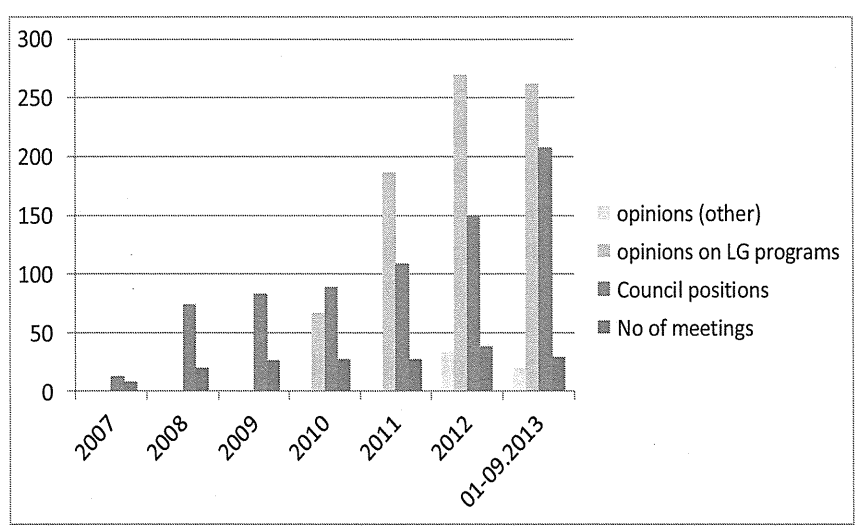
Steps of submission assessment:

- Checking if HTA analysis fulfill minimal requirements; regulation of MoH (http://www.aotm.gov.pl/index.php?id=766) plays a role as the transposition of HTA Guideliness into act of law
- If gaps found, process is stopped for updating analysis by MAH (14 days)
- Analysis assessment according to HTA Guideliness and good HTA practice rules; the report is provided to Transparency Council and placed on AHTAPol website
- 7-days public consultations; declaration of conflict of interest needed for comments to be considered
- Transparency Council position; President final recommendation
- Whole process should take no longer then 60 (optionally +14) days

Process of assessment of HTA analysis of reimbursement dossier

- Assessment by analytic team
- Apprisal by Transparency Council (the body of 20 experts, representatives of NHF, Drug Registration Office, Patients Rights Attorney included; proceeds on meetings; for every meeting 10 person are randomized) –TC positions provided
- Apprisal by AHTAPol President – provides AHTAPol recommendations
- Both TC position and President recommendation passed to Minister of Health

Consultative/Transparency Council performance



How to achieve cost-effectiveness?

- During the process of HTA assessment „threshold price" is counted – the price at which ICER does not exceeds threshold of 3 x GDP per capita (in 2013 about 25 000 euro)
- MAH may reduce ICER by proposal of risk sharing sheme (RSS)
- AHTAPol assess credibility of ICER & threshold price estimates
- MAH negotiates with Economic Commission in MoH final price & RSS, as well as details of drug program (to keep program population under control)

Stakeholders involvement in HTA assessment process

- Ministry of Health – originator of the process, recipient of recommendations, by law independent decision maker
- National Health Fund – payer, involved in the process as consultee and data provider; has the representative in TC
- Professionals – their opinion are asked by AHTAPol in the assessment/appraisal process
- Patients – if organized in association, may be involved in assessment/appraisal process as professionals; Patients Rights Attorney representative in TC
- MAH – when applying for reimbursement is obliged to provide HTA analysis and is entitled to comment on the assessment; no appeal procedure to AHTAPol recommendations is forseen
- Public – may provide comments to analysis in the public consultations – however rarely used

Planned update to Reimbursement Act

- New rules of reassessment – after 5-year period
- MAH due to provide reimbursement dossier on demand of Ministry of Health
- Regulation of the process of individual agreement for oncological chemiotherapeutics
- In general – further regulations to keep the budget under the control

Thank you for your attention

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Conditions of drug reimbursement under Reimbursement Act – extention to path 3rd

- Budget of National Health Fund – no more than 17% for drug reimbursement: when overfilled – pay-back; restricted growth year-to-year
- „Limit groups" – aggregate drugs of similar therapeutic indication or pharmacodynamics and set limit for their reimbursement according to the price of the cheapest drug fulfilling 15% turnover
- Reimbursement decision on the base of ICER/QALY not higher then 3xGDP per capita; negotiation on risk sharing schemes otherwise
- 3xGDP per capita = 105 800 PLN = 25 000 euro
- Charge: 88 500 PLN = ok. 21 000 euro

Agency for Health Technology Assessment

Guidelines for conducting Health Technology Assessment (HTA)

Version 2.1

Warsaw, April 2009

The study was commissioned by the Agency for Health Technology Assessment and prepared in cooperation with the Agency.
The document "Guidelines for conducting Health Technology Assessment (HTA)" form march 2007 served as a starting point for the guidelines elaboration.
All members of the Team participated actively in discussions and contributed to the improvement of the document by submitting their remarks orally and in writing.
Zbigniew J. Król was in charge of the Teams activities and he is responsible for the final redaction of the dokument.
Guidelines (Version 2.0) where revised by Consultative Council of AHTAPol. The revision was an editorial only. Consultative Council of AHTAPol gave positive opinion on revised document (Version 2.1).
In the last voting, Jacek Spławiński gave dissenting opinion.

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