HTA in Poland: the process of adoption and current application

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Warsaw, September 25th, 2014
Step-wise process of implementing HTA in Polish health care system

- 2005: Launching AOTM by ordinance of MoH
- June 2009: Health Care Benefits Act
- 01 Jan 2012: Reimbursement Act

in line with „transparency” Dir 89/105/EEC
rules of coverage/disinvestment (health benefits basket)
ICER=3xGDP per capita
in the process

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

- **2005** – launching AOTM 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 disinvestment

- **01 Jan 2012** – Reimbursement Act:
  1) more restrictive rules for financing drug technologies set with ICER threshold of 3xGDP per capita (2014: ~111 400 PLN= ~26 500 euro),
  2) rules for NHF budget for drug reimbursement growing up,
  3) the limit for NHF budget for drugs set: no more then 17%; when overfilled – MAH obliged to pay-back;
Place of AHTAPol in Polish system 2014

- **MAH submission**
  - AOTM
  - MoH Decision-maker
  - NHF Payer

- Reimbursement decisions
  - Inflow to NHF

- Contracts with providers

- Healthcare providers (eg. hospitals, GP practices)

- Patients
Tasks of AOTM

• 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 chemotherapy – procedure triggered by submission of drug dossier by Market Authorisation Holder (MAH) to MoH; if active substance has not been reimbursed yet – AOTM recommendation needed; AOTM 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 AOTM advice; AOTM opinion is to be consider, but adoption is not mandatory; 3 months statutory time limit for AOTM advice
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; to cover new, expensive therapies, but as well the old ones under new circumstances)

3. On the catalogue of chemiotherapeutics (delivered in hospitals)

4. On the reimbursement list of drugs funded in specific off-label indications (positive list)

5. A few specific MoH therapeutic programs (eg. clotting factors for haemophilia; drugs for HIV/AIDS)

6. On demand dedicated for individual patients (specific indications in chemotherapy; drugs not approved for Polish market)
Who applyes for coverage?

- In case of drugs delivered by pharmacies or in hospitals: under drug program/in the catalogue of chemotherapy – MAH should initiate the process
- In case of the list of off-label indications – MoH initiates process by asking National Consultants in specific medical domains to indicate drugs and their off-label indications
- Drugs for individual demand – MoH may ask AOTM to assess specific technology if the number of demands exceeds the limit; negative recommendation causes refusal of financing

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Proceedings with MAH submission in Ministry of Health

- Checking formal completeness of the submission
- If reimbursement under „drug program” – program inclusion/exclusion criteria to be agreed (between MoH & drug/drugs producers)
- If active substance not currently on reimbursement lists, HTA analysis compulsory; they should be provided to AOTM (together with the fee for the assessment)
- After AOTM recommendation is 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

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Process of assessment of HTA analysis of reimbursement dossier (AOTM)

- Minimal requirements checking
- MAH updates HTA analysis (optional)
- Critical assessment of technology on the base of MAH analysis
- Public consultations
- TC position/President recommendation

14 days 7 days
60 days (+14 days)
Process of assessment of HTA analysis of reimbursement dossier (AOTM)

- Checking of formal requirements: regulation of MoH (http://www.aotm.gov.pl/index.php?id=766) plays a role as the transposition of HTA Guidelines into act of law; if gaps found, process is stopped for updating analysis by MAH (14 days)
- Analytic team: assessment according to HTA Guidelines and good HTA practice rules
- Report placed on AOTM website for 7-days public consultations; declaration of CoI needed for comments to be considered
- Transparency Council statement (TC: body of 20 experts, including 2 from NHF, Drug Registration Office & Patients Rights Attorney; proceeds on meetings of randomized members)
- President final recommendation (both recommend. & statement sent to MoH)
- Whole process should take no longer then 60 (optionally +14) days

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Consultative/Transparency Council performance

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Conditions of drug reimbursement under Reimbursement Act

• 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 ICUR/QALY (ICER/LYG) not higher then 3xGDP per capita; negotiation on risk sharing schemes otherwise

• 3xGDP per capita ~PLN 111 400 ~EUR 26 500 (2014)

• Charge: PLN 101 600 (~EUR 24 200)
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.
- MAH may reduce ICER proposing risk sharing agreement (RSA).
- AOTM assess credibility of ICER & threshold price estimates.
- MAH negotiates with Economic Commission in MoH final price & RSA, as well as details of drug program (to keep program population under control).
Current effects of reimbursement Act

• Increased control on NHF budget
• Lower prices of the drugs („the lowest in Europe”? High rates of parallel export noted)
• „Cleaning” reimbursement basket of old & noneffective drugs
• Restrictions on coverage of drugs in off-label indications (positive list)
• Savings by NHF due to risk sharing agreements nominally high but not exceeding 0.01% of the budget for reimbursement
Current problems of reimbursement system

• Growing patients copayment, which may cause problems for low-income households
• In some cases severe restrictions on drug reimbursement, gradually withdrawn (eg. therapy for SM – initially financed for no more than 60 months; now – w/o time limits, if effective)
• Still some innovative therapies are not financed and new financing is implemented cautiously
• More explanations and education for patients needed, eg. on the role of generic drugs

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Planned update to Reimbursement Act

- New rules of reassessment – in 5-year periods
- MAH due to provide reimbursement dossier on demand of Ministry of Health (and not only on its own decision)
- Regulation of the process of individual agreements for oncological chemotherapy
- In general – further regulations to keep the NHF budget under the control
Thank you for your attention

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References
2. Regulation of the Minister of Health of 2 April 2012 on the minimum requirements to be satisfied by the analyses accounted for in the applications for reimbursement and setting the official sales price and for increasing the official sales price of a drug, a special purpose dietary supplement, a medical device, which do not have a reimbursed counterpart in a given indication

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