DECISION MAKING PROCESS FOR PHARMACEUTICALS REIMBURSEMENT IN POLAND

negotiation committee, therapeutic guidelines and HTA efforts

Pricing & Reimbursement process for pharmaceuticals in Poland

key stakeholders

MAH Manufacturer

MoH Economic Committee

AHTAPol HTA Agency

Transparency Committee

NHF

180/240 days

DECISION

- MoH is the final and the only decision-maker about taking new drug into the reimbursement system
- Other institutions and bodies (AHTAPol/Economic Committee) play role of advisors (giving recommendations). MoH is setting official price and reimbursement conditions

RECOMMENDATIONS

- AHTAPol is evaluating HTA reports and gives recommendations to MoH about clinical & economic value of the medicines
- Transparency Council is advisory body for President of AHTAPol team of experts from different institutions

IMPLEMENTATION

- NHF is keeping budget for health service and reimbursed drugs. NHF is financing drugs which are officially announced (reimbursement list) by MoH

Joanna Lis, PhD

Department of Pharmacoeconomics, Medical University of Warsaw, Poland,

Market Access Director, Sanofi
Pricing & Reimbursement process for pharmaceuticals in Poland:

**- process flow**

1. **Manufacturer**
   - P&R application
   - HTA Dossier
   - Cost Risk Sharing Agreement

2. **MoH**
   - (Formal evaluation of P&R Appl)

3. **AHTAPol**
   - Verification analysis

4. **Economic Committee**
   - negotiation
   - ex-factory price
   - indications
   - Cost Sharing Agreement

5. **AHTAPol President**
   - Final recommendation

6. **Minister of Health**
   - Final decision

7. **Reimbursement List**
   - NHF

8. **KOLs/ therapeutic guidelines**
   - PAGs
   - HCS experts

**Pricing & Reimbursement process for pharmaceuticals in Poland: main criteria**

**HTA RECOMMENDATION (AHTAPOL)**
- Indication to be reimbursed
- Way of reimbursement: part of existing or new limit group / drug program
- Clinical efficacy and safety / relative effectiveness
- Cost-effectiveness ratios (ICER)
  - Vs alternative medicines
  - Rigid hurdle of C/E threshold = 3 GDP/QALY (130 kPLN)
  - Threshold price - set price that would not exceed the ICER
  - Budget impact from payer & patient perspective / with & without RSS
  - HTA recommendations from other countries/ EU

**ECONOMIC COMMITTEE OPINION (NEGOTIATION)**
- HTA RECOMMENDATION
  - Min & Max prices from 30 EU & EFTA countries
  - Info about rebates, discounts in 30 EU & EFTA countries
  - Comparator’s costs of treatment and Budget Impact
  - RSS – conditions/threshold price

**MOH CRITERIA FOR REIMBURSEMENT DECISION**
- HTA RECOMMENDATION
- ECONOMIC COMMITTEE OPINION
- Significance of the clinical status/ health priorities
- Practical efficacy & safety
- The relationship of health benefits and risk of use
- Price competitiveness/
- Budget Impact / RSS
- Reliability and precision of estimation
AHTAPol in drug reimbursement process

- 2005 – launching AHTAPol by the ordinance of MoH in line with Directive 89/105/EEC; capacity building under “Transparency of the National Health System Drug Reimbursement Decisions”
- 2009 – Act on Health Care Benefits • 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
- 2012 – Reimbursement Act: the important role of AHTAPol in HCS in Poland

- HTA dossier assessment based on Polish HTA Guidelines and other regulations
- Recommendations to MoH
- Other tasks: tariffication of health services, health program evaluation …

Implementation

- Verification analysis
- Transparency Committee recommendation
- Statement of AHTAPol President

HTA Agency

HTA guidelines in Poland (last update 2016)

Decision problem analysis
- Determination of the scope and directions of the analyses
- Clear description of PICOS and measures of health outcomes
- Identification & justification all comparators

Clinical analysis
- Internal/external validity
- Direct & indirect comparison with current clinical practice in PL/ all available comparators
- Primary endpoints – or prove of surrogates impact on primary endpoints

Budget impact analysis and RSS
- RWE for size of population
- 2-3 years horizon with calculation of all costs – drugs & all other health care services
- Incremental costs – BIA with RSS and without RSS

Economic analysis
- All types of economic evaluations (CEA, CUA, CMA), perspective (e.g., patients, payer & combined), time horizon (long enough to reflect all important differences in costs & outcomes between the technologies being compared)
- Instrument (EQ-5D), source of utility data
- Deterministic/probabilistic sensitivity analysis and forms of results presentation
- Threshold 130 kPLN/QALY
Pricing & Reimbursement process for pharmaceuticals in Poland: main criteria

HTA RECOMMENDATION (AHTAPOL)
- Indication to be reimbursed
- Way of reimbursement: part of existing or new limit group / drug program?
- Clinical efficacy and safety/ relative effectiveness
- Cost-effectiveness ratios (ICER)
  - Rigid hurdle of C/E threshold = 3 GDP/QALY (130 kPLN)
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- Budget Impact/ RSS
- Reliability and precision of estimation

Economic Committee
- 17 members of EC: 12 representatives of MoH & 5 of NHF
- Nominated by Minister of Health
- Criteria for EC negotiation are developed
- Team of 5 members of EC are negotiating
- Resolution as an result of negotiation

November 17
Risk Sharing Schemes – negotiated with EC

Risk-sharing instruments may apply to outcomes and financial based agreements

- Making the applicant’s total sales amount dependent on the drug’s outcomes (Payment-by-result)
- Making the price dependent on the applicant’s assurance to supply the drug at a reduced price (Discounts)
- Making the price dependent on the drug’s sales (PVA)
- Making the price dependent on partial repayment of the reimbursed amount to the public payer (Payback)
- Arrangement of other conditions improving access to or reducing cost of healthcare services (other)

In practice mainly financial based exists in Poland – as preferred one by Polish payer:

- 95% of RSS are finance based – only 20% of them are more complex (2-3 mechanism or/and with cap)
- 50% of reimbursement application for open care and about 80% for drug programs are with RSS

What type of RSS was proposed and finally accepted? (2014)

<table>
<thead>
<tr>
<th>Outcome based schemes</th>
<th>Price discounts</th>
<th>Price volumen agreement</th>
<th>Payback</th>
<th>All others (free stock)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5%</td>
<td>5%</td>
<td>36%</td>
<td>36%</td>
<td>18%</td>
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<tr>
<td>29%</td>
<td>55%</td>
<td>58%</td>
<td>63%</td>
<td>82%</td>
</tr>
</tbody>
</table>

Implemented RSS | Proposals - RSS

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HCS in Poland at a glance

Polish economy is growing but health is not priority

6TH POPULATION IN EU

<table>
<thead>
<tr>
<th>Health System Indicators and Trend Over Previous Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population (millions)</td>
</tr>
<tr>
<td>Population over age 65 (%)</td>
</tr>
<tr>
<td>Life expectancy</td>
</tr>
</tbody>
</table>

7TH ECONOMY IN EU:

- GDP per capita PPP US$ 25k (still only 69% of EU average)
- Economic Growth:
  - +19% vs 2008
  - GDP + 2.6% (’16), + 3.1% (’17)

HCS trends

- Growing macroeconomic challenges:
  - aging,
  - increase in life expectancy,
  - early retirement,
  - state budget deficit

- Epidemiologic trends:
  - cancer,
  - overweight,
  - diabetes,
  - dyslipidemia, asthma, dementia ...

LOW INVESTMENT IN HEALTH

- One of the lowest expenditure in EU in both HC total spending & drugs expenditure

<table>
<thead>
<tr>
<th>Health System Indicators and Trend Over Previous Year</th>
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<tbody>
<tr>
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<tr>
<td>Public Health spend (% of GDP)</td>
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<tr>
<td>Pharma spend (% of GDP)</td>
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<tr>
<td>Public Pharma spend (% of GDP)</td>
</tr>
</tbody>
</table>

- Out-of-pocket payments – 30%

Source: Report “Impact of Reimbursement Law on access to innovation” Sequence, May 2014
Statutory tools and mechanisms in Reimbursement Law

Cost-cutting approach of the MoH in negotiations

HCS management within the limited resources in the context of reimbursement system

- Price lowering: IRP, TRP, mandatory price reduction for 1st GX/BIOs...
- P&R process: HTA and RSA/MEAs tools
- Limited access to treatment for very narrow patient populations
- Delayed & time-consuming introduction into the reimbursement system
- Important therapies excluded from the system (no reimbursement)

How to produce more health for less cost?

Cost of healthcare
Percentage of GDP (2013) compared with life expectancy (2013)

Percentage of GDP

<table>
<thead>
<tr>
<th>Country</th>
<th>Percentage of GDP</th>
<th>Life expectancy (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Turkey</td>
<td>20,0</td>
<td>80,0</td>
</tr>
<tr>
<td>Estonia</td>
<td>15,0</td>
<td>70,0</td>
</tr>
<tr>
<td>Mexico</td>
<td>10,0</td>
<td>60,0</td>
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<tr>
<td>Poland</td>
<td>5,0</td>
<td>50,0</td>
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<tr>
<td>Korea</td>
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<td>Chile</td>
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<td>Hungary</td>
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<td>UK</td>
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<td>France</td>
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<td>Ireland</td>
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<td>Switzerland</td>
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<td>Italy</td>
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<td>Spain</td>
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<td>Norway</td>
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<td>Portugal</td>
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<td>Greece</td>
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<td>New Zealand</td>
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<td>Austria</td>
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<td>Belgium</td>
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<td>Japan</td>
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<td>Denmark</td>
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<td>Germany</td>
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<tr>
<td>Switzerland</td>
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<td></td>
</tr>
<tr>
<td>USA</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: OECD
<table>
<thead>
<tr>
<th>Rank</th>
<th>Name</th>
<th>Company</th>
<th>Country/Region</th>
<th>Revenue</th>
<th>Status</th>
<th>Details</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Smith</td>
<td>Pfizer</td>
<td>USA</td>
<td>355.56</td>
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</tr>
<tr>
<td>2</td>
<td>Jones</td>
<td>Merck</td>
<td>USA</td>
<td>330.19</td>
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<tr>
<td>3</td>
<td>Brown</td>
<td>Johnson &amp; Johnson</td>
<td>USA</td>
<td>250.98</td>
<td></td>
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<td>4</td>
<td>Cook</td>
<td>Abbott</td>
<td>USA</td>
<td>225.89</td>
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<tr>
<td>5</td>
<td>Davis</td>
<td>Eli Lilly</td>
<td>USA</td>
<td>200.32</td>
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<tr>
<td>6</td>
<td>Smith</td>
<td>Pfizer</td>
<td>USA</td>
<td>175.45</td>
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<td>7</td>
<td>Jones</td>
<td>Merck</td>
<td>USA</td>
<td>150.96</td>
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<tr>
<td>8</td>
<td>Brown</td>
<td>Johnson &amp; Johnson</td>
<td>USA</td>
<td>120.98</td>
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<tr>
<td>9</td>
<td>Cook</td>
<td>Abbott</td>
<td>USA</td>
<td>100.32</td>
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<tr>
<td>10</td>
<td>Davis</td>
<td>Eli Lilly</td>
<td>USA</td>
<td>75.45</td>
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</tbody>
</table>
HCS in Poland is underfinanced
Poland is in tail of Europe regarding HC expenditures in relation to GDP

Source: OECD Data 2016

Expenditure on drugs in Poland per 1 inhabitant is among the lowest in EU
Poland is on the lower end of the expenditure on pharmaceuticals

Source: OECD Data 2016
Patient co-payment is calculated based on the price limit & co-payment category

Patient reimbursement levels: FOC, fixed fee, 30%, 50% (based on therapy duration and monthly patient costs). Difference between the price and limit is paid by patient.

**Regular reimbursement**

- **NHF Payment:**
  - Financing limit
  - Limit price: price limit
  - Free of charge (to the limit price level)
  - Lump sum / fixed fee
  - 30%
  - 50%
  - Non reimbursed

  - NHF payment
  - Patient payment
  - Patient payment (over the limit)

**Free drugs for Senior**

- WHOLE RETAIL PRICE (NO LIMITATION)
- "S" list

- Difference between the price and limit is paid by patient.

- NHF payment remains the same as in the case of regular reimbursement.
- Patient co-payment is refunded by the Ministry of Health from targeted grants.
- Eligible patients (75+, GP prescription) always receive drugs included in the "S" list free of charge.

**Pricing & Reimbursement rules in a snapshot**

- TRP/Drugs are classified into limit/therapeutic groups.
- Limit is the same (per DDD) for all products the group.
- Copay at levels: FOC, flat fee, 30%, 50%
- Difference between price and limit is paid by patient.
- TRP leads to high patient co-payments.
- Prices of reimbursed drugs must be the same across all pharmacies.
- Margins are fixed on all levels of distribution.
- Prohibition of any incentives & penalization in case of broken rules.
- Official price decrease is the only possibility to reduce patient co-pay in limit group.

- At least -25% for Original brand at LoE.
- At least -25% for first generic.
- In case of reimbursement of the equivalent in given indications, the reimbursement limit is based on this equivalent.
- In case of reimbursement next equivalents, the reimbursement limit cannot be higher than price of the first equivalent.
- Reimbursement decisions are valid for 2 years for the first two applications and 3 years for the next.
- Each reimbursement decision is proceeded by price negotiations.

- Risk-Sharing Agreements for expensive drugs.
- Mainly cost-sharing agreements up till now.
- Drugs with RSS not included in Claw back.

- HTA mandatory: All comparators from current practice/Comparative effectiveness for subgroups.
- Local epi, QoL data.
- Rigid hurdle of C/E threshold = 3 GDP/QALY (130kPLN).

- Benchmark to 30 EU & EFTA countries.
- IRP leads to one of the lowest drugs prices in Europe.

- Fixed prices and margins.

- OBLIGATORY PRICE CUTS POST LOE/ FIRST GX.
- PRICE RE-NEGOCIATED EVERY 2/3 YEARS.

- Complex & highly demanding HTA process.
- HTA mandatory: All comparators from current practice/Comparative effectiveness for subgroups.
- Local epi, QoL data.
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Funding schemes of medicines in Poland

Drug financing channels

- DRG [FOC in hospitals]
- Reimbursement
- National programs [FOC: ARV therapy, hemophilia]

Pharmacies
Drugs used mostly in large populations with common indications

- 69.7% of NHF spending in 2016

Drug programs
Often innovative substances used in relatively small populations

- 25.0% of NHF spending in 2016

Chemotherapy
Mainly oncological treatment or supportive therapy

- 5.3% of NHF spending in 2016

HCS in Poland at a glance

Poland guarantees citizens universal coverage, mainly funded through a mandatory public health insurance contribution levied by NHF

<table>
<thead>
<tr>
<th>Health System Indicators and Trend Over Previous Year</th>
<th>SYSTEM TYPE</th>
<th>FUNDING</th>
<th>DELIVERY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population (millions) 38.4† ↓</td>
<td>• General health insurance system providing obligatory social insurance to insured citizens</td>
<td>• Public: NFZ collects (via ZUS - Social Insurance Institution and KRUS) mainly though mandatory employee contributions</td>
<td>• Territorial self-governments have authorities that set policy priorities, resource allocation, service delivery</td>
</tr>
<tr>
<td>Population over age 65 (%) 15.5† ↑</td>
<td>• Government provision and financing of care mostly through employee contributions (9% of gross salary)</td>
<td>• Private (30%): Mainly OOP payment and employer-based private insurance that covers healthcare.</td>
<td>• Public &amp; private healthcare providers may compete equally for a contract from NFZ to provide health services.</td>
</tr>
<tr>
<td>Life expectancy 77.8† ↑</td>
<td></td>
<td></td>
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<tr>
<td>Health spend (% of GDP) 6.3Δ ↓</td>
<td></td>
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</tr>
<tr>
<td>Public Health spend (% of GDP) 4.5</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Pharma spend (% of GDP) 1.34%‡ ↓</td>
<td>• Public insurance covers inpatient &amp; outpatient care for all citizens, incl drugs in hospital &amp; on reimbursement lists.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Public Pharma spend (% of GDP) 0.45</td>
<td>• Private health sector offers supplementary &amp; complementary coverage.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Sources: † United Nations Population Division (UNPD); Δ World Health Organization; ‡ Organization for Economic Co-Operation and Development (OECD)
Notes: OOP = Out-of-pocket; DRG: Decision Resources on-line: www.DecisionResourcesGroup.com

November 17 | 19
**Monday, 6 November**
**18:15-19:15**

- **F2: THE ESTABLISHMENT OF NEGOTIATION COMMITTEE, THERAPEUTIC GUIDELINES AND HTA EFFORTS IN CEE COUNTRIES**

  - The objective of this panel is to present the benefits of the negotiation committee and the difficulties in the implementation phase, the criteria in decision making and how it will interact with HTA body. Current decision-making processes for pharmaceuticals will be described, emphasizing in therapeutic guidelines, reimbursement criteria and functions of negotiation committee. Additionally a proposal of the structure and the criteria of the decision making process of an HTA body will be presented.

  - The proposal was developed by the ISPOR Greece Chapter Board of Directors in an effort to pave the way for the establishment of HTA process, which can lead to a sustainable health care system. This forum presentation could be also used as a guide by other CEE countries that are currently in the initiation phase of a Health Technology Assessment organization. Presented by the ISPOR CEE Network

  - **Moderator: Magda Hatzikou, PhD**, Senior Health Economics Manager, Novartis Hellas SA, Athens, Greece

  - **Speakers:**

    - **Zoltan Kalo, MSc, MD, PhD**, Professor of Health Economics, Eötvös Loránd University (ELTE), Founder & CEO, Syreon Research Institute, Budapest, Hungary

    - **Dragana Atanasijevic, MD, MSc**, President, ISPOR Serbia Chapter, and Consultant, HTA & Healthcare Quality Improvement, Belgrade, Serbia

    - **Joanna Lis, PhD**, Adjunct, Faculty of Pharmacy, Department of Pharmacoeconomics, Medical University of Warsaw, and Market Access Director, Sanofi, Warsaw, Poland

    - **Mary Geitona, MSc, PhD**, Professor, University of Peloponnese, Korinthos, Greece