Pharmacoeconomics is formally stated in Polish legislative documents:

- The Reimbursement Act
- The MoH’s minimal requirements for HTA conducting
- The AOTM’s guidelines for conducting HTA [www.aotm.gov.pl](http://www.aotm.gov.pl)
- Law on Publicly Funded Health Care Services
- Pharmaceutical Law

Key Acts regulating PHE and Pricing&Reimbur.

Other legislative docs regulating Pricing&Reimbur.
The Reimbursement Act

new reimbursement environment since Jan 2011

- Objectives:
  - To improve reimbursement process transparency
  - To increase overall access to medicines and to innovative drugs
  - To lower the prices of medicines paid by patients
  - To reduce the part of drugs reimbursement spending in the NHF total spending (from 21% in 2010 down to 17% within the coming 10 years)
    - Immediate savings of approx. 3% of drug reimbursement budget in 2012.
  - Measures
    - 17% cap on reimbursement budget
    - Introduction of payback mechanism (50% - 50%)
    - Introduction of risk sharing mechanism
    - New rules for reimbursement limits and limit groups
    - Introduction of fixed margins and prices
    - Decrease of wholesale and retail margins
    - High penalties for non-compliance with the statute.
    - Ban on any commercial practices (discounts, bonuses, price adjustments for reimbursed products)

The Reimbursement Act

regulates general requirements for reimbursement dossier submission

* HTA Dossier framework:
  - Analysis of the decision problem
  - Clinical analysis
  - Economic analysis
    - based on QALY threshold <3 x GDP per capita [25 190 Euro]
  - BIA
  - Rationalization analysis – when BIA revealed an increase of the costs for the payer
  - Information on research activities and investments of the applicant in health care in Poland and other EU countries

* Pricing data:
  - Selling price of every SKU in EU / EFPIA countries
  - Disclosure of any RSS scheme used in EU countries
  - Providing MoH with translated documents proving reimbursement status in EU / EFPIA countries.
The MoH’s Minimal Requirements for HTA & The Guidelines for Conducting HTA in details regulate requirements for HTA dossier

1. Introductory information
   - Authors and conflict of interest information

2. Decision problem
   - Population
   - Intervention
   - Comparators
   - Health outcomes

3. Clinical analysis
   - Data sources
   - Search strategy
   - Information selection
   - Information quality assessment
   - Meta-analysis (quantitative synthesis)
   - Indirect comparison
   - Safety assessment

4. Economic analysis
   - Analytical technique
   - Cost-consequences analysis
   - Cost-effectiveness analysis
   - Cost-utility analysis
   - Cost-minimization analysis
   - Modelling
   - Health effects assessment
   - Cost assessment
   - Cost categories
   - Identification of used resources
   - Measurement of used resources
   - Determination of unit costs
   - Discounting
   - Sensitivity analysis and result uncertainty assessment

5. Analysis of impact on health care system
   - Budget impact analysis
   - Population
   - Perspective
   - Time horizon
   - Compared scenarios
   - Parameters taken into consideration
   - Budget outlays and receipts
   - Discounting
   - Presentation of results
   - Impact on the organisation providing health care services
   - Ethical and social aspects
   - Final conclusions and summary

6. Rationalisation analysis
   - Presents solutions (e.g. pricing, limiting, switching, jumbo grouping) to ensure public financing without additional reimbursement spending
The Agency’s verification analysis includes the following, in particular:

- Assessment of all HTA analyses
- Reimbursement recommendations from other countries, together with the analysis of their justifications and the detailed conditions for inclusion in the reimbursement;
- Conditions for reimbursement in other countries with the analysis of specific conditions of the reimbursement;
- Specification of the threshold net sales price at which the ratio of the costs of obtaining health effects is not greater than the threshold of the cost of obtaining an additional year of life adjusted for quality;
- And, in the absence of the ability to set this cost - the cost of obtaining an additional year of life.
The recommendation of the President of the Agency contains the following, in particular:

- the establishment of whether the drug should be financed with public funds;
- the specification of the detailed conditions for the inclusion of the drug in the reimbursement with regard to: the suggested level of payment, limit group
- proposals of risk sharing instruments,
- the specification of scientific evidence on the basis of which the recommendation was issued, including: clinical and practical efficacy, safety, the relationship between costs and health effects achieved;
- the indication of the existence of alternative medical technology;
- a discussion on the impact on the spending of the entity obliged to finance benefits with public funds and beneficiaries;
- the indication and discussion on clinical recommendations as well as recommendations on financing provided with public funds in other countries;
- the indication of the threshold net sales price at which the relationship between the costs and the health effects achieved is no higher than the threshold of the cost of achieving an additional year of life, adjusted by the QoL, and, in the event of the inability to specify this cost – the cost of obtaining an additional year of life.

Reimbursement Decision Making process in practice

HTA recommendation impact on reimbursement decisions

Since Jan 2012 until May 2013:

- HTA Agency: 43 opinion
  - 29 positive recommendations
  - 14 negative recommendations

- MoH: 43 reimbursement decisions
  - 24 new reimbursement approvals
  - 19 rejections

<table>
<thead>
<tr>
<th>HTA Agency</th>
<th>Positive</th>
<th>Negative</th>
<th>Approval</th>
<th>Rejections</th>
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<td></td>
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<td>14</td>
<td>24</td>
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<table>
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<tr>
<th>MoH reimbursement decision</th>
<th>Approval</th>
<th>Rejections</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>24</td>
<td>19</td>
</tr>
</tbody>
</table>

21% 7%

Source: INAR Report – HTA workshop; Cracow June 2013
Presentation of some new requirement in reimbursement process

- Payback
- Risk-sharing
- Rationalisation analysis

Payback associated with the excess of planned reimbursement

Payback for a given year is due if:
- The total budget for reimbursement (planned) for this year has been exceeded
- The budget for reimbursement in a given limit group has been exceeded
- The costs of reimbursement of a given product are higher than in the previous year
Payback – decision & calculation formula

\[ KP = W_r' - W_r \]

\[ \frac{S_i}{\sum S_i} \geq 1 \]

\[ K_z = S_{i,\text{unorm}} \times KP \times G \times 0.5 \]

Does the budget of the NHF has been exceeded in range of expenditure on reimbursed drugs at the pharmacy? NO

Does this limit group exceeded expenditures? (Reimbursement amount in this limit group is greater than the planned amount of the reimbursement in the year before?) NO

Are reimbursement dynamics for the product in the limit group greater than or equal to 1? (or a product not subject to refunds in the previous trading period?) NO

Whether a product is covered by the Risk Sharing Agreement? NO

Lack of payback

Lack of payback in the limit group

Lack of payback for the product in the limit group

Lack of payback for the product

Rationalization analysis

- Presented if the analysis of the impact on the budget of the entity obliged to finance benefits with public funds indicates an increase in the cost of reimbursement
- Should provide solutions for the reimbursement of drugs, special purpose dietary supplements and medical devices, the inclusion of which in the reimbursement will result in the release of public funds at an amount which corresponds to at least the increase in the costs arising from the analysis of the impact on the budget
Objective
To find additional financial sources for a new hypertension product

Methods
To assess the economic impact of combining separately existing limit groups of the RAAS inhibitors into one common group, while retaining current reimbursement schemes.

Background
Reimbursement spending in one year horizon was assessed in two scenarios, assuming separate and common limit groups for ACE-Is and ARBs. List of products analyzed in the two groups and their unit prices and reimbursement are based on the Ministry of Health notice on the listing of reimbursed drugs for 1 July 2013. The limit base in the combined group was determined according to the legal rule based on the National Health Fund (NHF) report on the sales volume achieved in March 2013. Yearly volume of reimbursed packs was based on the most recent available yearly data i.e. NHF reports May 2012 through April 2013.

Results
Yearly savings from the public payer perspective are estimated at 155 million PLN, which constitutes a significant fraction (2.3%) of the actual total spending for drug reimbursement. The average unit cost of reimbursement of a monthly therapy using ACE-Is and ARBs is estimated at 2.22 and 3.85 PLN respectively, as compared to 2.35 and 10.85 PLN prior to the change.

<table>
<thead>
<tr>
<th>Limits group identifier</th>
<th>Name of the limit group</th>
<th>Number of standard packages sold within one year [000]</th>
<th>Existing scenario reimbursement spending in one year [000 PLN]</th>
<th>Average unit cost [PLN]</th>
<th>Proposed scenario reimbursement spending in one year [000 PLN]</th>
<th>Average unit cost [PLN]</th>
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<tbody>
<tr>
<td>44.0</td>
<td>Angiotensin-converting enzyme inhibitors (ACE-Is)</td>
<td>75,305</td>
<td>177,276</td>
<td>2.35</td>
<td>166,950</td>
<td>2.22</td>
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<tr>
<td>45.0</td>
<td>Angiotensin receptor blockers (ARBs)</td>
<td>20,642</td>
<td>223,909</td>
<td>10.85</td>
<td>79,372</td>
<td>3.85</td>
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<tr>
<td>TOTAL</td>
<td></td>
<td>95,948</td>
<td>401,185</td>
<td></td>
<td>246,322</td>
<td></td>
</tr>
</tbody>
</table>
Risk-sharing instruments may apply to outcomes and financial based agreements, in particular to:

- making the applicant’s revenue conditional on achieved health effects
- making the amount of the official selling price conditional on the provision by the applicant of supplies of drugs, food products for special dietary purposes or medical devices at reduced prices
- making the official selling price conditional on the sales volume of drugs, food products for special dietary purposes or medical devices
- making the amount of the official selling price conditional on the payback of a part of the obtained reimbursement
- setting other conditions of reimbursement influencing the increase of the access to the guaranteed services or reduction of the cost of these services.

Benefit from risk-sharing agreements – exclusion from the obligation to participate in payback

Thank You For Your Attention