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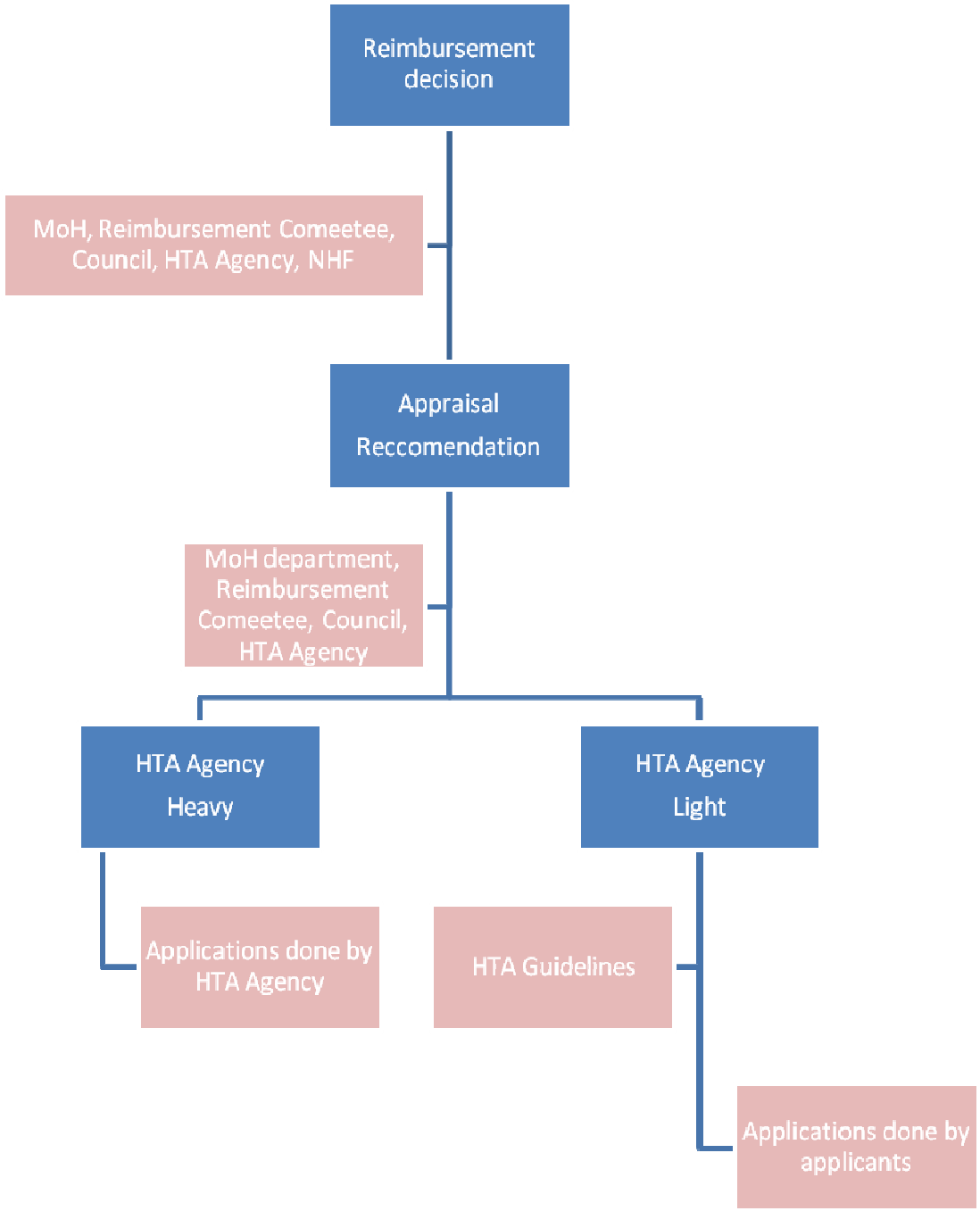
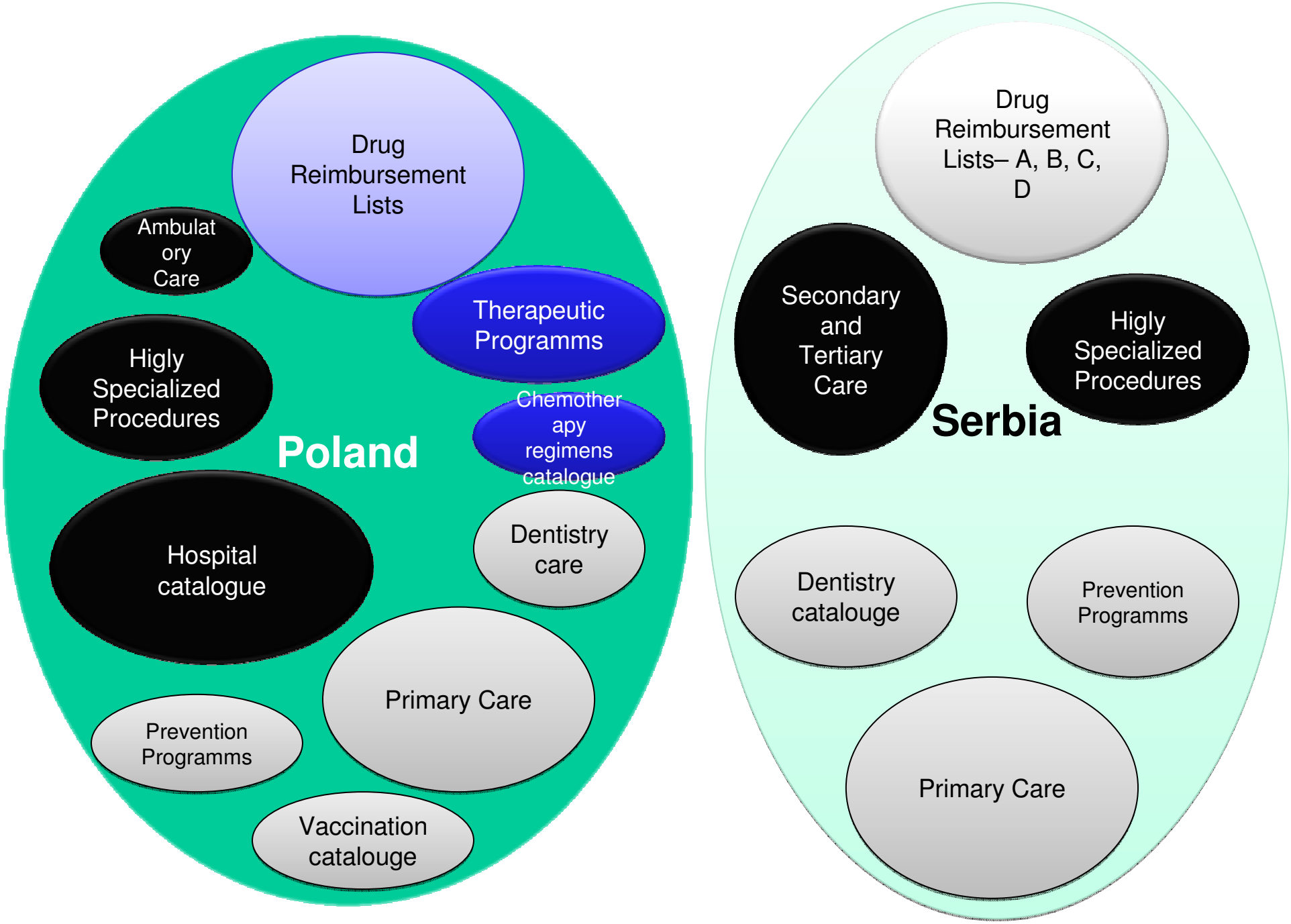
"The latest developments in P&R policy in Poland – focus on systemic efficiency"

Krzysztof Łanda, M.D.



Evidence based coverage decision-making – general proces


Drug Reimbursement Lists
Ambulat ory Care
Therapeutic Programms
Higly Specialized Procedures
Poland
Chemother apy regimens catalogue
Hospital catalogue
Dentistry care
Primary Care
Prevention Programms
Vaccination catalouge
Drug Reimbursement Lists– A, B, C, D
Secondary and Tertiary Care
Higly Specialized Procedures
Serbia
Dentistry catalouge
Prevention Programms
Primary Care

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CU/CE thresholds

3x GDP / **person** per 1 LYG or 1 QUALY (**WHO** per 1 DALY)

Poland – about 18 000 £ (23 500 €)

Serbia – about 11 000 £ (14 500 €)

NICE: ***UK cannot effort 3xGDP per 1 QUALY***

UK – 30 000 £ (39 000 €)

but now even less 20 000 £ (26 000 €)

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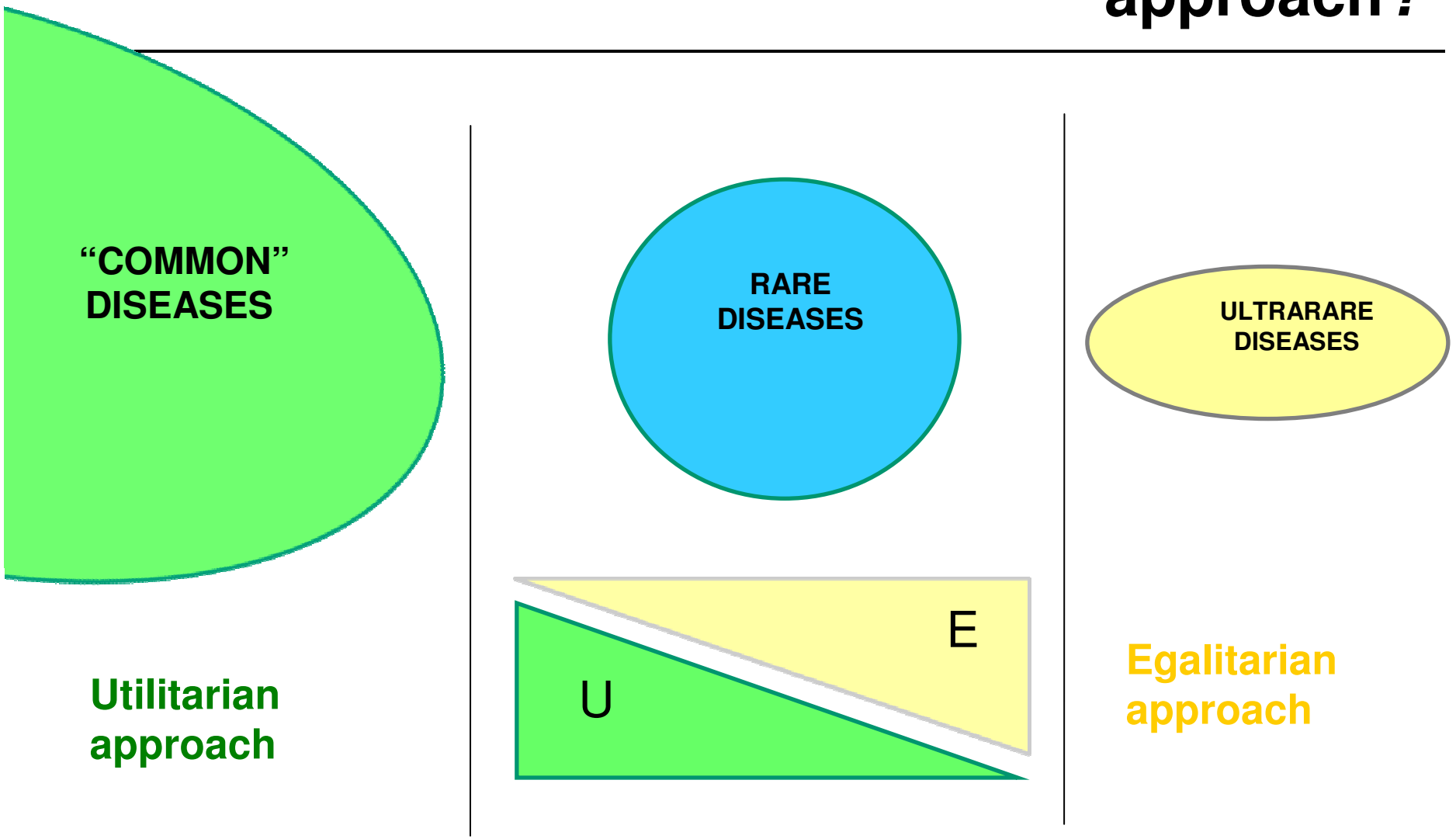
Reimbursement criteria – utilitarian, egalitarian or mixed approach?



Utilitarian approach

Egalitarian approach

2 extreme models of HTA Agency – a HEAVY model (PROACTIVE)

OVERALL GOAL:

To answer demand for HTA reports to decision-makers and to society for informed decision-taking

The heavy Agency develops HTA reports by itself spending public resources

2 extreme models of HTA Agency – *a LIGHT one (REACTIVE)*

Development of HTA reports is the task of those who apply for reimbursement (hence a privileged market position for their product) – they incure costs of analyses requested to apply for coverage decision-making

Industry pays for HTA reports (if there is a company „behind" a technology)

In the LIGHT MODEL, an HTA Agency plays a role of gate keeper (or quality check – validity and completeness of comparisons) for all analyses being directed to decision-makers for coverage

Reimbursement/coverage criteria

1. **Proven efficacy & fair safety profile**
2. **Cost-effectiveness or cost-utility ratio**

(that embraces importance of health problem and strength of intervention – therefore no prioritization or other weights with that respect needed)

„**Project risk**" – risk of taking a wrong coverage decision (uncertainty around estimates) -> RANKING

BIA only for calculation of the cumulative budget spending and drawing a general threshold of affordability

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New pricing and reimbursement criteria in Poland

1. Recommendation of the Economic Commission
2. Recommendation of the President of Agency for Health Technology Assessment in Poland
3. Signifficance of clinical state
4. Effectiveness and efficacy of a drug technology
5. Safety profile
6. Clinical benefit/risk ratio
7. Cost-effectiveness or cost-utility ratio

Bylaw on Reimbursement of Medicines, 13.10.2010

New pricing and reimbursement criteria in Poland

8. Explanation of price competitiveness
9. Budget impact
10. Optional health technologies and their effectiveness and safety profile
10. Reliability and precision of estimates items 3-10
11. Health care priorities in the country
12. Referal to CU/CE threshold (3xGDP / person per 1 QALY)

Bylaw on Reimbursement of Medicines, 13.10.2010

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Rigorousness differs

Due to a unit price or/and budget impact health technologies (includidng drugs) can be classified as:

1. CHEAP
2. EXPENSIVE
3. VERY EXPENSIVE

Therefore requirements for set of analyses, acceptable „project risk” and rigorousness in appraisal vary in different parts of BBP

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Role of Risk-Sharing Schemes in Middle Income Countries

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Types of risk on the manufacturer's side

- the risk of not obtaining reimbursement;
- obtaining reimbursement on unfavorable conditions or less favorable conditions than expected;
- failure of the reimbursement and pricing strategy and inefficient activity for the company;
- ect.

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Types of risk on the regulator's side

- taking a wrong reimbursement decision;
- taking a wrong pricing decision;
- failure to keep financial discipline;
- limited access to highly cost-effective technologies resulting from the reimbursement a new expensive technologies;
- political risk associated with unpredicted, high social expectations;
- the risk of charges of unequal treatment of products or manufacturers, or unjust preference or discrimination of somegroups of patients

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Risk associated with uncertainty of estimates lies on both sides

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Classification of risk sharing schemes

Financial utilization scheme	• Price - Volume Agreement • Payback
Risk based pricing scheme Managed Entry Scheme	• Conditional coverage with evidence development
Outcome based pricing scheme	• Pay by results

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Formal agreements versus "unilateral" declarations

Risk sharing may be based on **formal agreements**, regulated by legal acts and/or internal procedures of both parties, but a RSS may also be introduced **without formal agreements** or higher regulations in this respect;

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RSS in Poland

Untill now

- without formal agreements
- “unilateral” declarations

By law on Reimbursement and Pricing in Poland (13.10.2010)

- a legal basis for risk sharing agreements between the regulator and pharmaceutical companies
- publicly available information of settlements, without disclosure of specific provisions

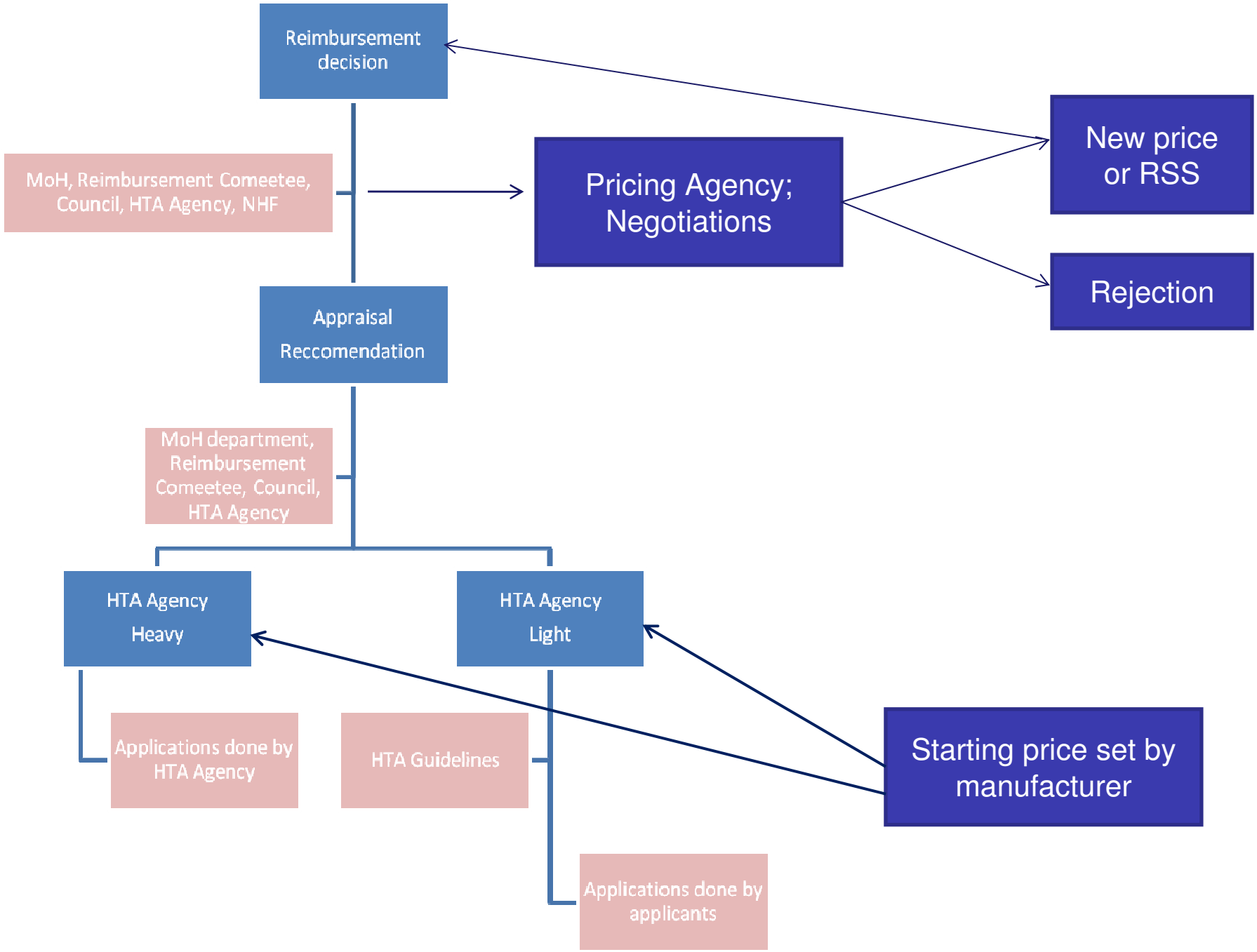
Economic Comission in Poland

1. Negotiations and setting official prices for medicinal products
2. Negotiations and setting level of reimbursement
3. Negotiations and setting reimbursement indications
4. Negotiations and setting the term of reimbursement decision staying in force
5. Analysis of proposals and entering into RSS

Additional tasks:

- Monitoring of total budget on reimbursement
- Activity aimed at rationalizing expenditure on reimbursement

Project of new Reimbursement Act, 13.10.2010


Reimbursement decision
MoH, Reimbursement Comeetee, Council, HTA Agency, NHF
Pricing Agency; Negotiations
New price or RSS
Rejection
Appraisal Reccomendation
MoH department, Reimbursement Comeetee, Council, HTA Agency
HTA Agency Heavy
HTA Agency Light
Applications done by HTA Agency
HTA Guidelines
Starting price set by manufacturer
Applications done by applicants

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Thank you for the attention