

# **Building Structured Foundations for HTA in Eastern Europe**

**Krzysztof Landa, MD**

**HTA Audit**

# Background shortly

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- 2003 a founding member of Central & Eastern European Society of Technology Assessment in Health Care (CEESTAHC)
- 2001-2006 the CEO of HTA Consulting – development of more than 80 full HTA reports
- 2004-2007 member of the Board of Directors of Health Technology Assessment International (HTAi)
- 2006-2007 consultations for the Ministry of Health in Serbia within a World Bank project
- 2006-2007 Director of the Drug Policy Department of the National Health Fund in Poland
- 2007-2008 the Team Leader of the World Bank project on systemic implementation of HTA in Serbia and
- Currently: CEESTAHC and quality control of HTAs – company „HTA Audit”

# Short story of HTA in Poland

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- |             |  |
|-------------|--|
| 1996-1999   | basic education & training   |
| 1999        | international workshop in Zakopane (3 CEECs / ISTAHC)  |
| 2000        | international conference in Niedzica (9 CEECs)   |
| 2000        | Bureau for the Standardization of Medical Practice (26 persons / 3 teams – one dealing with HTA) |
| 2000        | the first 3 HTA reports developed by governmental NCQA   |
| 1999/2000   | project with Dutch TNO on HTA and BBP in Poland (team leader: Prof. David Banta)                 |
| 2001        | HTA Consulting General Partnership (15-20 comprehensive HTA reports developed annually)          |
| 2003        | HTA legally bounding for drug reimbursement  |
| 2003        | CEESTAHC   |
| <b>2004</b> | <b>HTAi Annual Meeting in Krakow, Poland</b>   |
| 2005        | AOTM (Agency for HTA in Poland)  |

# Important changes in the reimbursement system in Poland

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1. Governmental HTA Agency
2. HTA guidelines
3. Clear requirements with respect to scope of set of analyses for reimbursement (therapeutic programs, drug reimbursement list) in a regulation and law
4. Transparent criteria for inclusion and exclusion of the drugs into/from the list of reimbursed drugs (out-patient care)
5. Changes in the rules concerning reference price groups
6. EBM taught in Medical Universities
7. Education in HTA / PhE
8. Many other

# The WB project on HTA in Serbia

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A call of Ministry of Health of Republic of Serbia

Serbia Health Project – IDA credit 3768YF

Contract No. SAM-SHP-3768YF-CQ-051B-B5-CS-07

## **Technical Assistance for Health Technology Assessment**

2 phases:

- 1.Led by Prof. Isabelle Durand-Zaleski
- 2.Led by Krzysztof Landa M.D.

# Key question for institutionalisation

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**If HTA Agency in Serbia then what kind of HTA Agency?**

If there should be establishment and implementation plan for HTA Agency in Serbia then for which Agency: light, heavy, mixed and if mixed then at what balance?

Different models between the extremes: **light** and **heavy**

# Key question for institutionalisation

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If HTA Agency is to be established  
in **YOUR COUNTRY**

then what kind of HTA Agency  
it is going to be!

## 2 extreme models of HTA Agency – a HEAVY model

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

The heavy Agency **develops HTA reports by itself spending public resources**

## 2 extreme models of HTA Agency – a LIGHT one

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Development of HTA reports is the task of those who apply for reimbursement (hence a privileged market position for their products) – they incur 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**

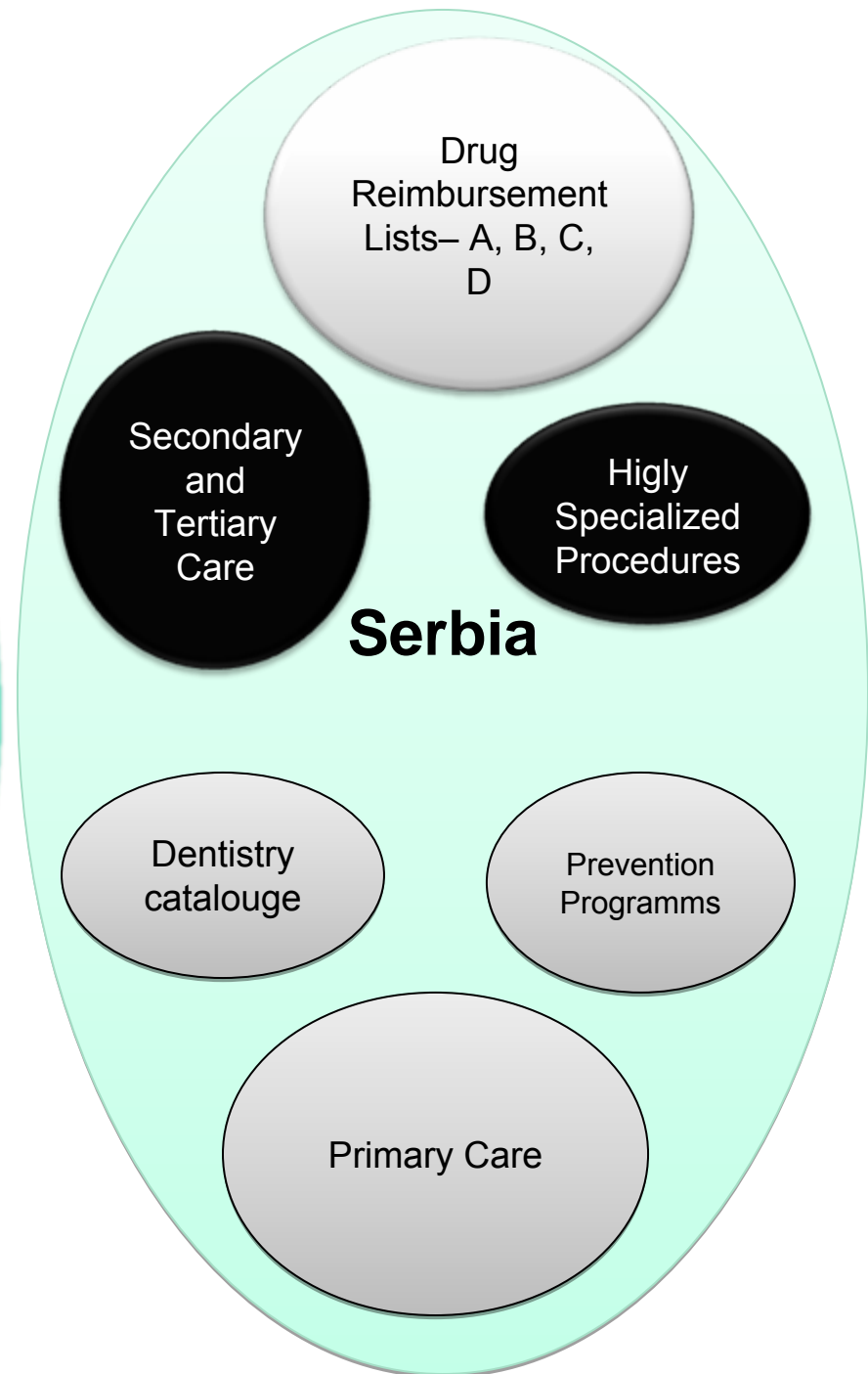
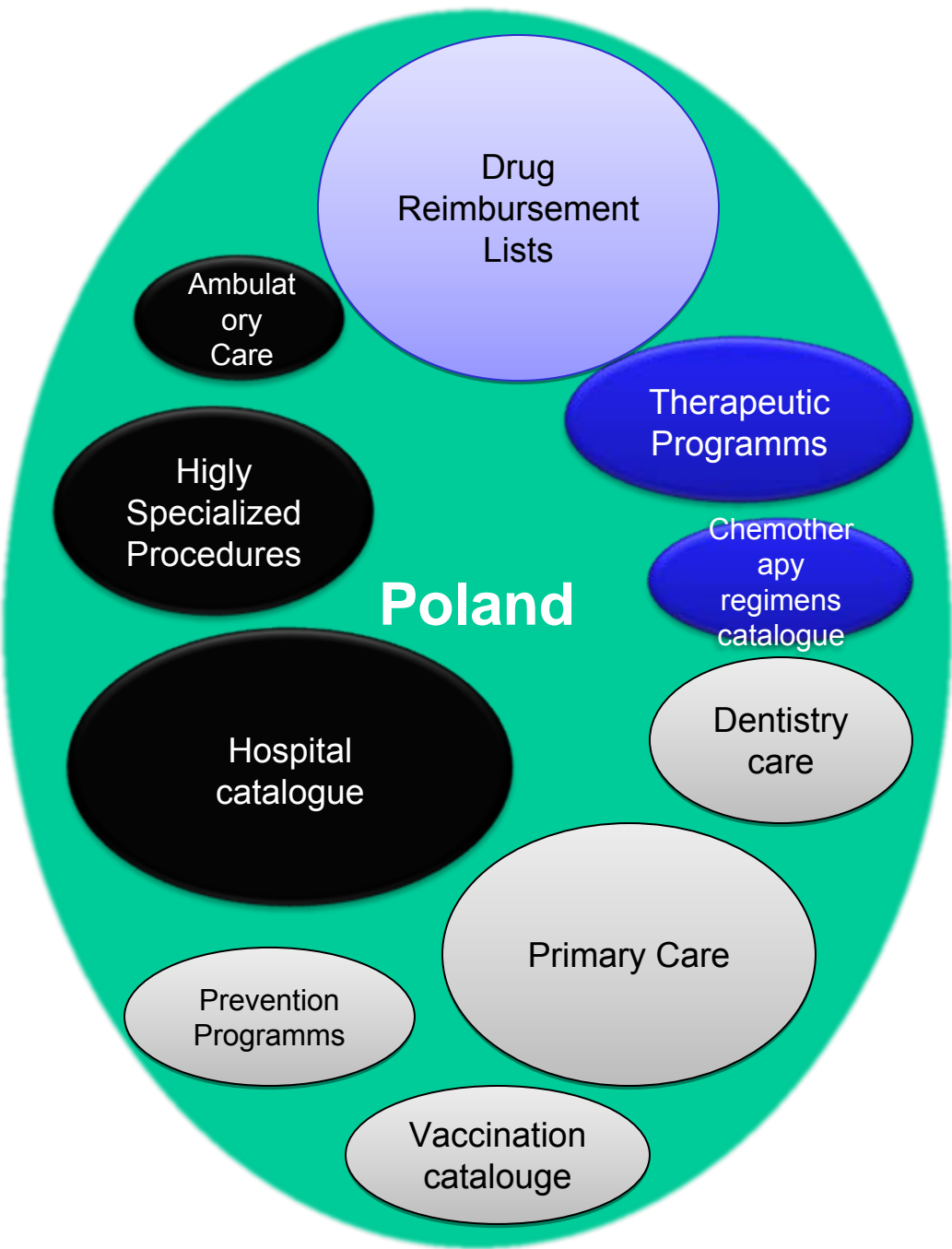
## Comparisons among HTA institutions – e.g.: sources of funding

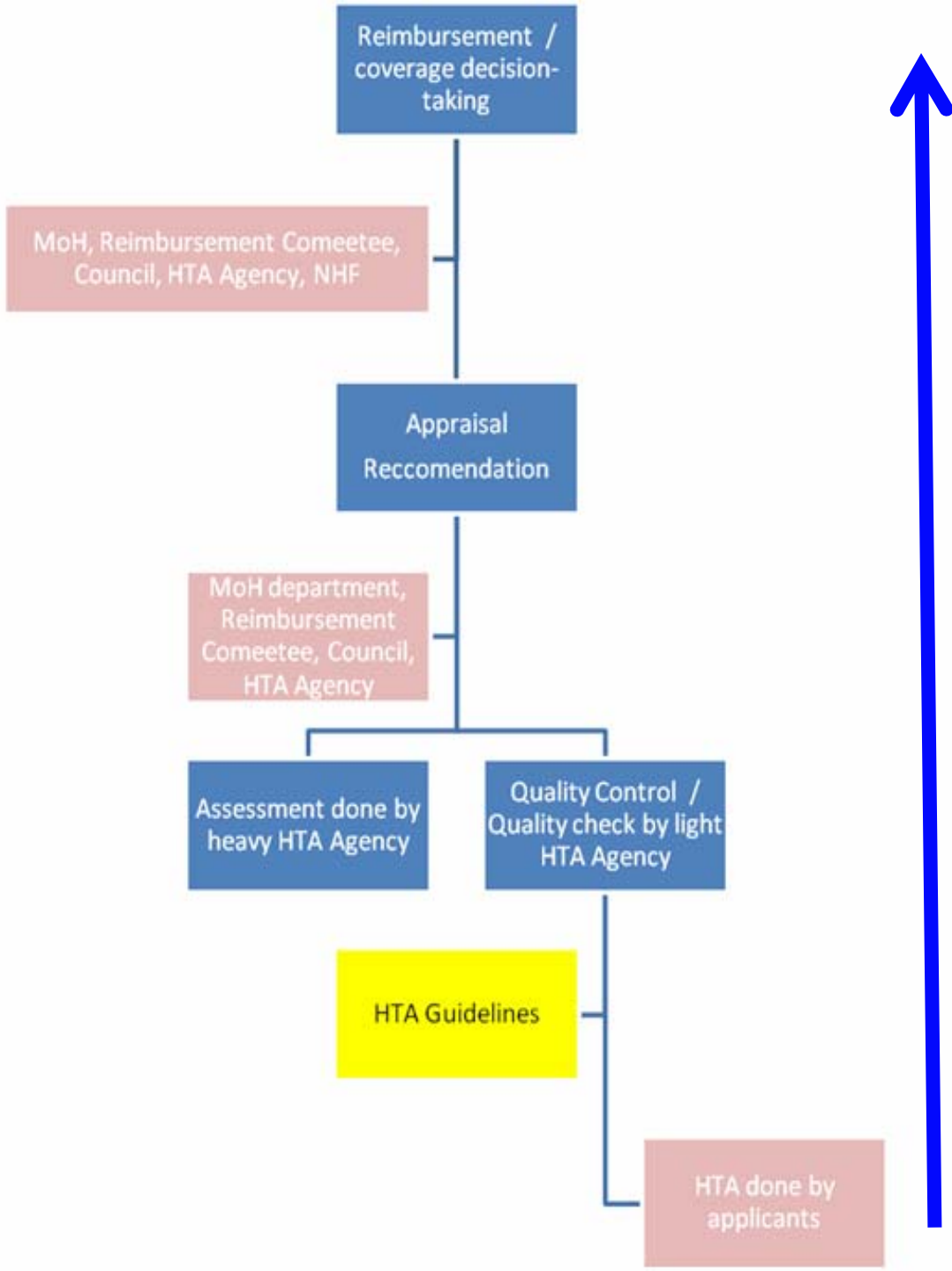
Source of funding	N	%
Government	33	80.5
Research funding bodies	19	46.3
Private industries (e.g. pharmaceutical industry)	10	24.4
Academia/University	10	24.4
Donor agencies ( foundations, patient associations, charity, others)	7	17.1
Public health care providers	7	17.1
Compulsory health care insurance (public)	6	14.6
Intergovernmental organization	3	7.3
Private medical insurance	3	7.3
Private health care providers	3	7.3

# Budget

## (apart from efficiency measures)

Agency	Description
UK NCCHTA	21,6 mil USD
Germany DIMDI (DAHTA)	1,5 mil USD
GERMANY IQWIG	11 mil Euro
AUSTRALIA MSAC	2.3 mil USD
AUSTRALIA AHTA	1.93 mil USD
BELGIUM KCE	3.06 mil USD
LATVIA VSMTVA	0,05 mil USD
NETHERLANDS CVZ	10,3 mil USD
FRANCE HAS	The annual budget is 60 million euros. - taxes on promotional spending by drug companies (33.2%) -National Health Insurance (31%) -state funding (14%),
POLAND / AHTA Pol	Established by the Ministry of Health Financed by public sources Budget: 3,6 mil USD





**Evidence based  
coverage decision-  
making  
– general process**

# Demand - Scotland

	2002	2003	2004	2005	2006	2007
Full submissions	28 (97%)	46 (74%)	52 (70%)	54 (62%)	55 (41%)	61 (55%)
Resubmissions	1 (3%)	8 (13%)	5 (7%)	14 (16%)	15 (11%)	14 (13%)
Abbreviated submissions	0	6 (9%)	16 (22%)	18 (21%)	41 (32%)	20 (18%)
Independent Review Panel (IRP)	0	1 (2%)	1 (1%)	1 (1%)	1 (1%)	0
Non submissions	0	1 (2%)	0 (0%)	0 (0%)	19 (15%)	15 (14%)
<b>TOTAL</b>	<b>29</b>	<b>62</b>	<b>74</b>	<b>87</b>	<b>130</b>	<b>110</b>

# Demand - Serbia

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## 1. HTA Committee (MOH)

2006, 53 requests

2007, 181 requests,

2008 including March 2008, 200 requests

Source: Ministry of Health, Dr Tomislav Stantic State Secretary

## 2. Central Drugs Committee (HIF), No of requests

- Year 2004, No - 273

- Year 2005, No – 140

- Year 2006, No – 138

- Year 2007, including September the same year, No – 127

Source: Health Insurance Fund, Mr. pharm. Nada Pecalj

## 3. Orphan Drug Committee, newly established, working only few months had

- 2 requests, but assessment is around 5 requests yearly

Source: Ministry of Health, Zorica Pavlovic, Assistant Minister

# **Interactive model**

## **A decision support tool for the Minister of Health**

# A decision support tool for the Minister of Health

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## Authors:

1. Robert Plisko,
2. Krzysztof Łanda,
3. Magdalena Władysiuk

## Cooperation in respect to data collection:

- Biljana Parapid,
- Predrag Djukic,
- Ivana Drulovic,
- Dragana Atanasijevic
- Natasa Milic

The interactive tool allows for multivariate calculations, although in the final report the 4 scenarios have been presented:

- Heavy model
- Mixed model
- Light model
- Light model – HTA Agency located inside existing institution

# Demand / supply of HTA reports

## Demand

Demand

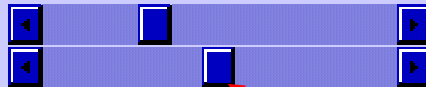


Supply/Demand

300 Number of analysis conducted yearly  
100% Relationship between demand and supply

## Demand

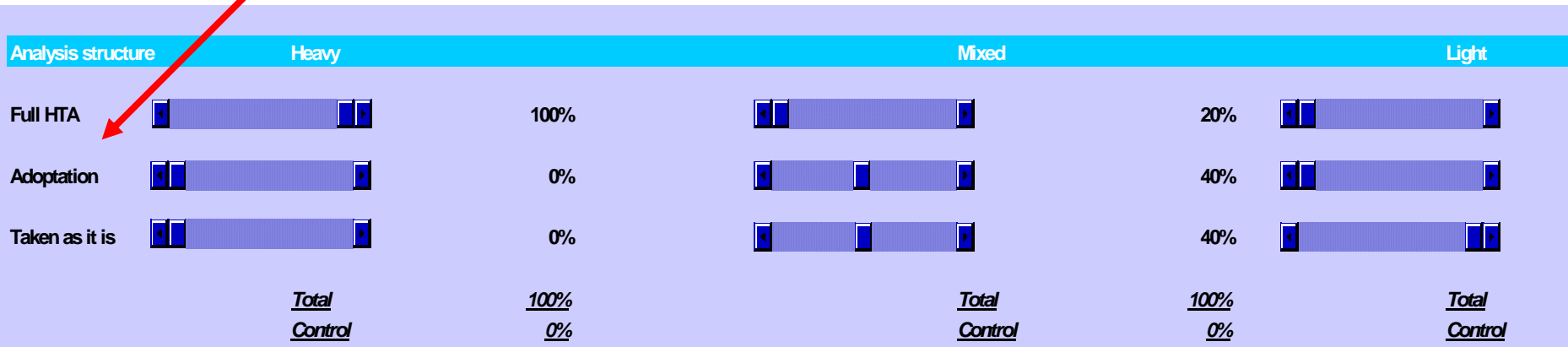
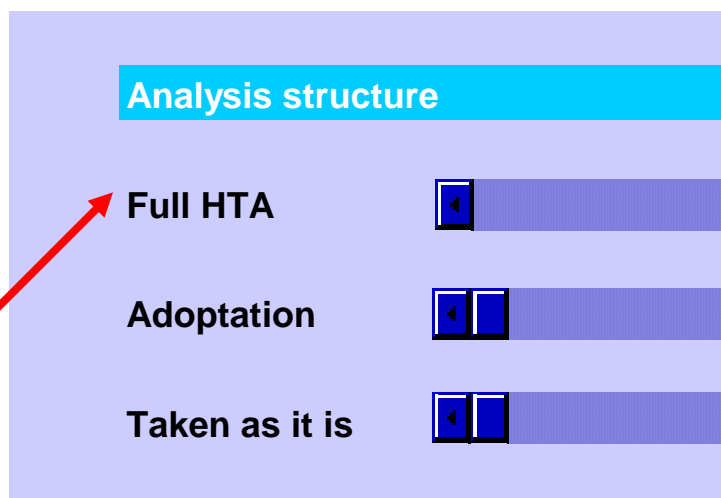
Demand



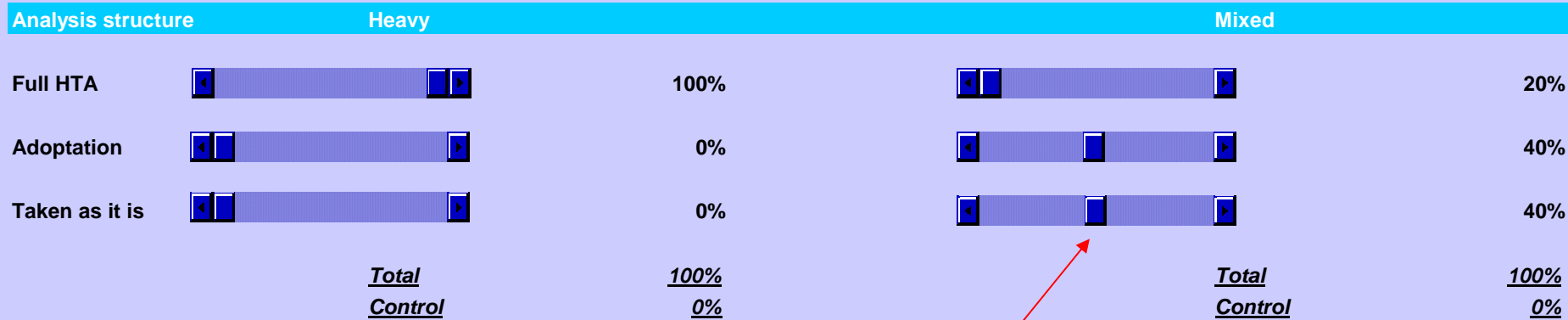
Supply/Demand

300 Number of analysis conducted yearly  
50% Relationship between demand and supply

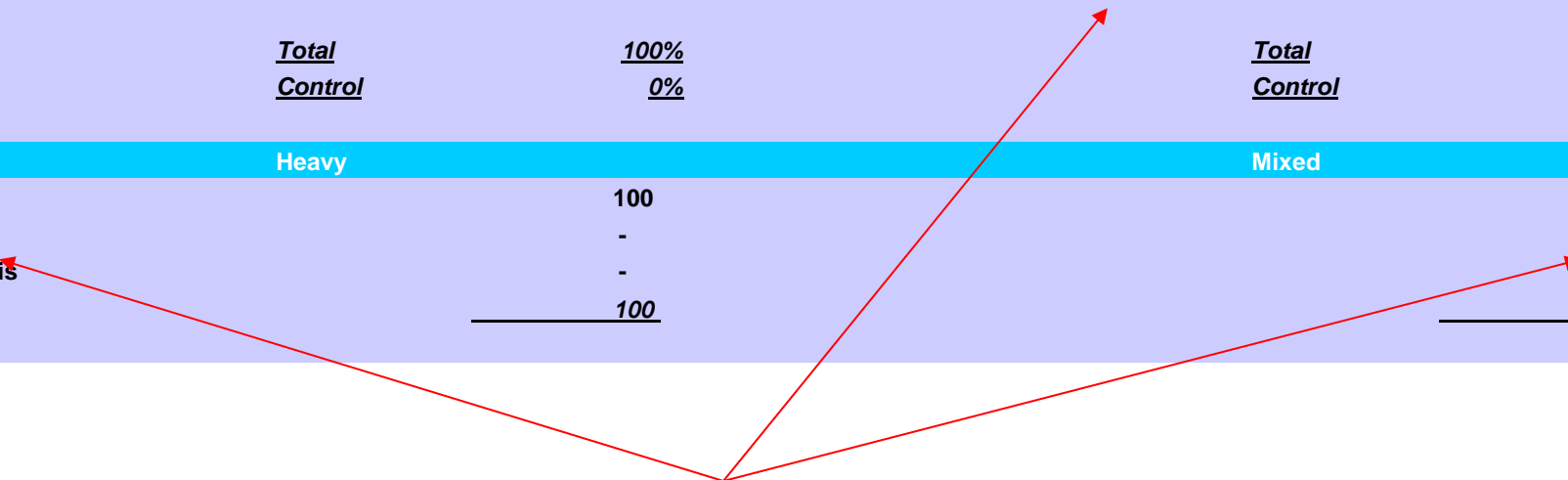
# HTA products of the Agency

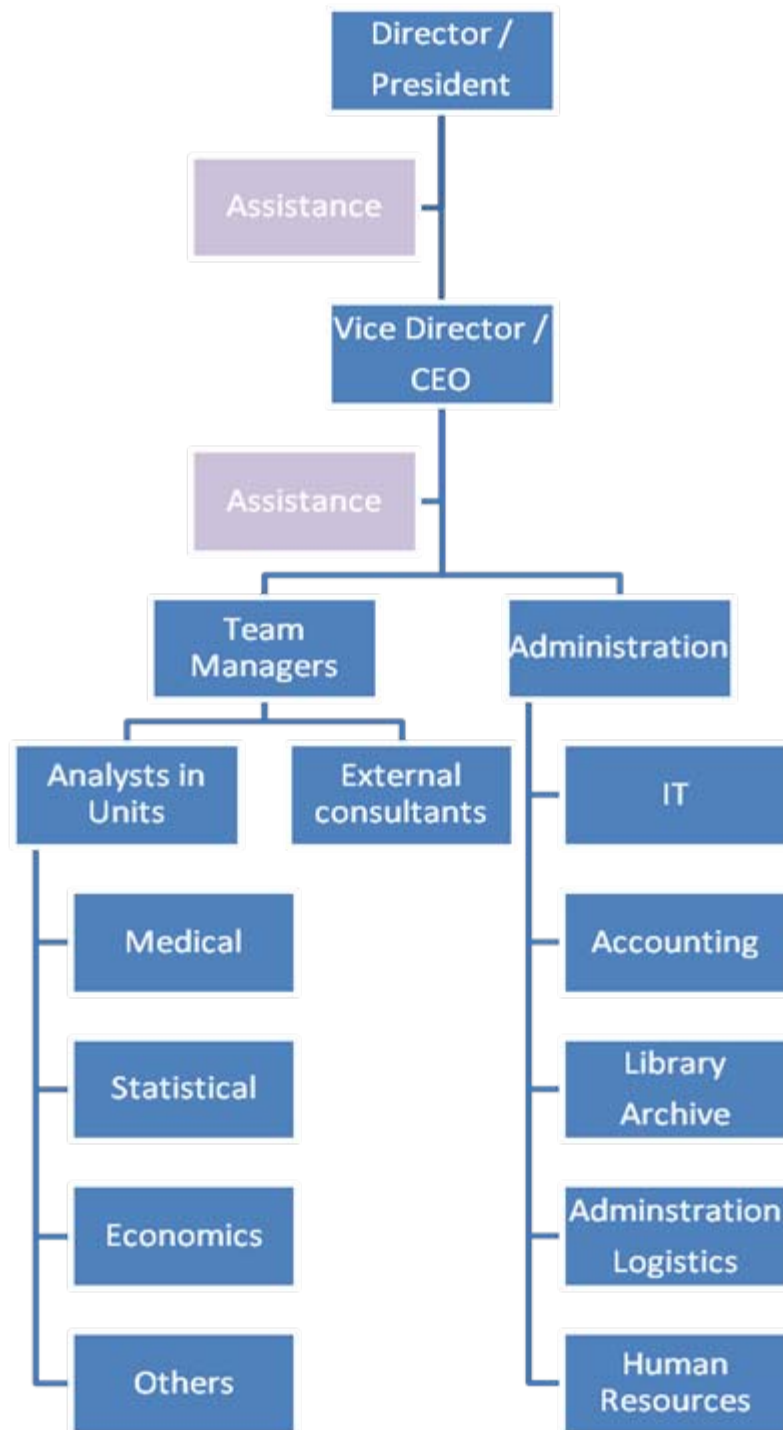


# Default amounts of HTA products: **200** analyses per year



Analysis	Heavy	Mixed
Full HTA	100	20
Adoptation	-	40
Taken as it is	-	40
<b><u>Total</u></b>	<b><u>100</u></b>	<b><u>100</u></b>





# Structure and staff of HTA Agency

# Staff at default input

Staff	Heavy
-specialists	267,0
-top management	6,0
-administration	27,0
<b><u>Total</u></b>	<b><u>300,0</u></b>

Mixed
70,0
2,0
9,0
<b><u>81,0</u></b>

Light
15,0
2,0
4,0
<b><u>21,0</u></b>

# Investment costs presented here in Euro but ... all costs evaluated for Serbia and based on Serbian current prices

Investments	Heavy
-computers	€ 450 000,00
-office furnitures	€ 150 000,00
-car	€ 45 000,00
-LAN network	€ 30 000,00
-office equipment	€ 150 000,00
-initial training	€ 534 000,00
<b><u>Total</u></b>	<b><u>€ 1 359 000,00</u></b>

Light
€ 31 500,00
€ 10 500,00
€ 15 000,00
€ 2 100,00
€ 10 500,00
€ 30 000,00
<b><u>€ 99 600,00</u></b>

Mixed
€ 121 500,00
€ 40 500,00
€ 15 000,00
€ 8 100,00
€ 40 500,00
€ 140 000,00
<b><u>€ 365 600,00</u></b>

Light – inside institution
€ 31 500,00
€ 0,00
€ 0,00
€ 0,00
€ 0,00
€ 0,00
€ 30 000,00
<b><u>€ 61 500,00</u></b>

# Maintenance costs in 4 scenarios – office rented

Maintenance	Heavy	
Investments cost amortization	€	165 000
Internet	€	20 718
Office	€	187 200
Access to databases	€	6 000
Website	€	2 400
Staff	€	4 085 830
External consultants	€	500 000
Training	€	30 000
Translations	€	300 000
<b>Total</b>	<b>€</b>	<b>5 297 149</b>

	Light	
	€	13 920
	€	20 718
	€	13 104
	€	6 000
	€	2 400
	€	293 342
	€	500 000
	€	2 100
	€	300 000
	<b>€</b>	<b>1 151 584</b>

Mixed	
	€ 45 120
	€ 20 718
	€ 50 544
	€ 6 000
	€ 2 400
	€ 1 096 539
	€ 500 000
	€ 8 100
	€ 300 000
	<b>€ 2 029 421</b>

Inside another institution	
yes	€ 6 300
no	€ -
yes	€ 13 104
yes	€ 6 000
yes	€ 2 400
	€ 293 342
	€ 500 000
	€ 2 100
	€ 300 000
	<b>€ 1 123 246</b>

# Public costs per full HTA made available for decision-making on coverage (and pricing)

## Public costs in respect to a single analysis

Heavy € 26 654

Mixed € 10 316

Light € 5 926

This is actually cost of **development** of a single average HTA report in Serbia without profit

This is actually cost of quality control/**audit** of a single average HTA report in Serbia without profit

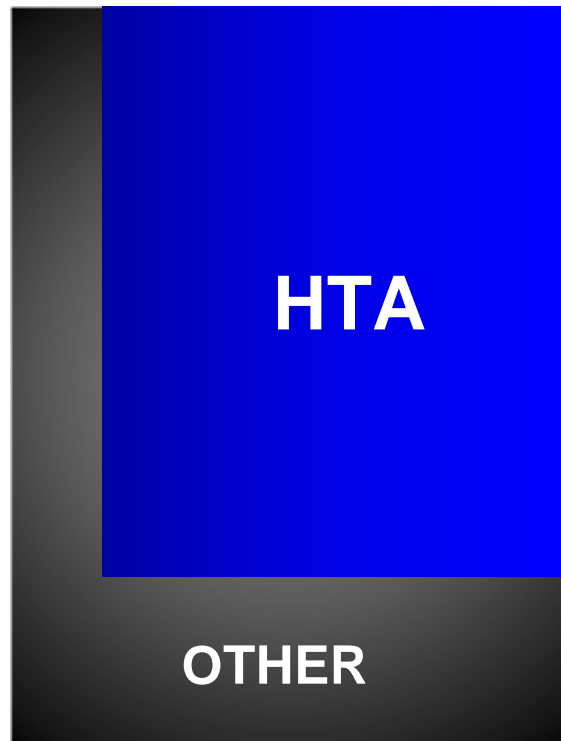
# Example conclusions

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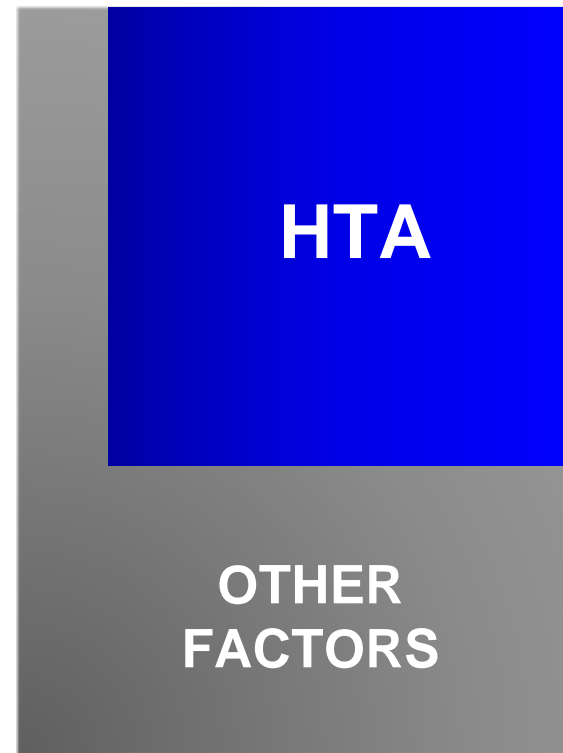
- It should be recognized that different restrictiveness applies to different parts of BBP.
- Shifting mixed model HTA Agency closer to light than to heavy model is especially important for developing countries for two reasons:
  - **their resources for doing HTA from public means are often very limited – poorer countries cannot afford large heavy HTA Agencies.**
  - **the need for economic and financial evaluations in middle and low income countries is the greatest.**

# Role of HTA in reimbursement and in pricing

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**REIMBURSEMENT**

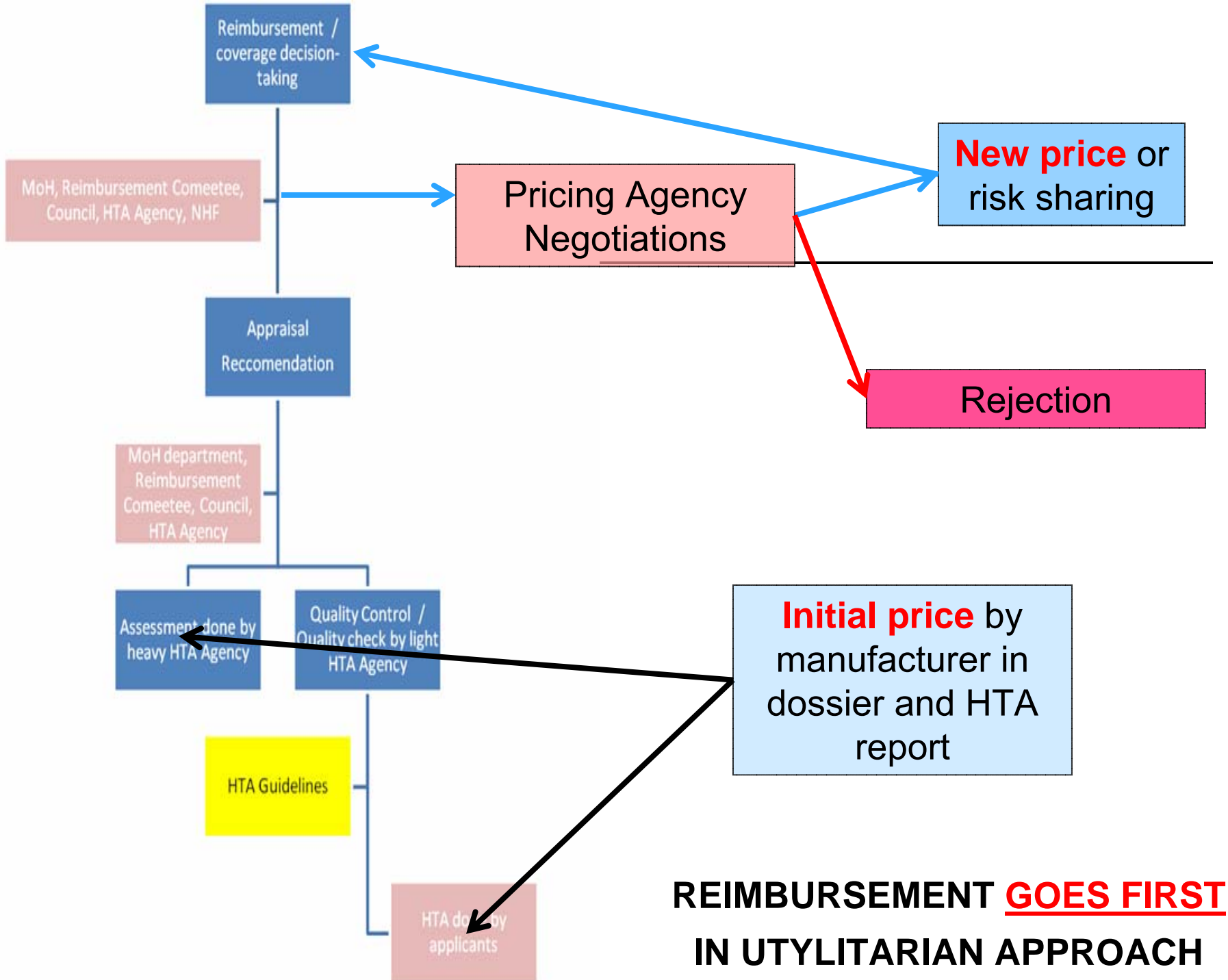


**PRICING**

# Criteria concerned by the PBPA in pricing

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- PBAC advice on **clinical and cost-effectiveness**;
- Prices of alternative brands;
- Comparative prices of drugs in the same therapeutic group;
- **Cost data** information;
- Prescription volumes (**BIA**), economies of scale, expiry dating, storage requirements, product stability, special arrangements;
- Level of activity being undertaken by the company in Australia, including new investment, production, research and development; \*
- Overseas prices;
- Other factors the applicant may wish the Pricing Authority to cover; and
- Other directions as advised by the Minister.



Reimbursement / coverage decision-taking

MoH, Reimbursement Committee, Council, HTA Agency, NHF

Pricing Agency Negotiations

**New price** or risk sharing

Appraisal Recommendation

Rejection

MoH department, Reimbursement Committee, Council, HTA Agency

Assessment done by heavy HTA Agency

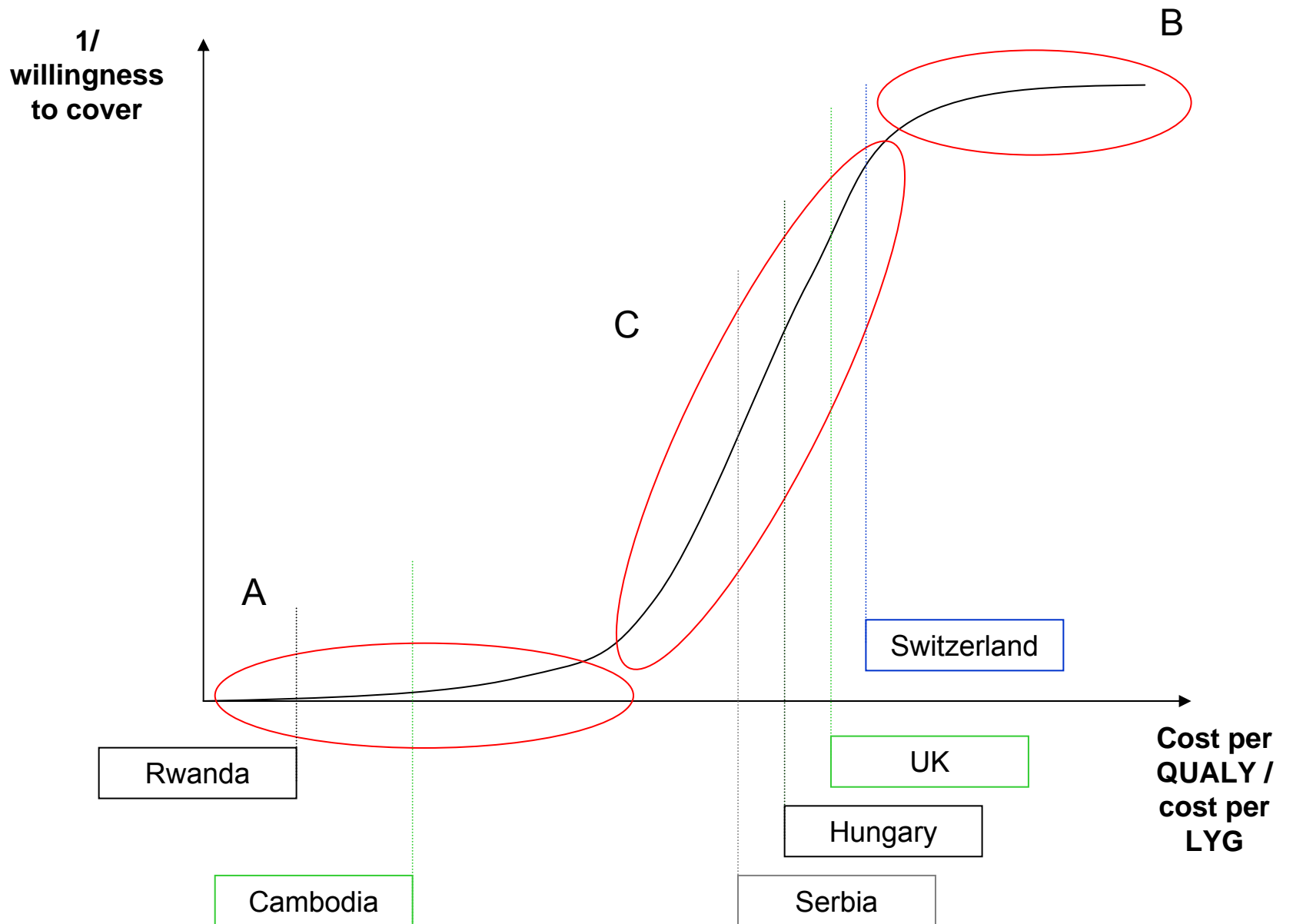
Quality Control / Quality check by light HTA Agency

**Initial price** by manufacturer in dossier and HTA report

HTA Guidelines

HTA done by applicants


**REIMBURSEMENT GOES FIRST IN UTYLITARIAN APPROACH**



**Even greater need for risk  
sharing in middle & low  
income countries!**

# **Feasibility study on Pricing Agency as a functionality of health care system**

**To assure efficient pricing policy**



4<sup>th</sup> International Symposium  
Evidence-Based Health Care  
**„HTA & Pricing”**

December 7<sup>th</sup> - 8<sup>th</sup>, 2009  
Krakow, Poland  
[www.ceestahc.org](http://www.ceestahc.org)



4<sup>th</sup> International  
Symposium EBHC  
„HTA & Pricing”

December 7-8, 2009  
Krakow, Poland  
[www.eestahc.org](http://www.eestahc.org)



## Speakers:

**Prof. Jack Dowie**

London School of Hygiene & Tropical  
Medicine, UK

**Alan Stevens**

FBPA, Australia

**Prof. Gert van der Wilt**

Katholieke Universiteit Nijmegen,  
Netherlands

**Prof. Michael Drummond**

University of York, UK

**Jill M. Sanders**

CADTH, Canada

**Rabia Kahveci**

KDTH, Turkey

**Jamie J. Caro**

USC, USA

**Prof. Jacek Ruszkowski**

Kozminski University, Poland

**Zoltan Kalo**

Eötvös Loránd University, Hungary

**Jorge Wernli**

Vifor Pharma, Switzerland

**Mitchell Sugarman**

Medtronic, USA

**Dragana Atanasijevic**

Ministry of Health, Serbia

**Prof. Paweł Vorobiev**

RSPOR, Russia

**Oleg Borisenko**

RSPOR, Russia

**Jim Furniss**

Bridgehead International, UK

**Anita Burrell**

Sanofi Aventis, France

**Magdalena**

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Thank you for attention!