



THE CHALLENGES FOR ADAPTING HTA FOR USE IN POLAND

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in Poland**

AHTAPol



Topics

- About me
- Overview of Poland's health system
- Overview of AHTAPol: legal basis, activities, analytical team
- International collaboration
- Drug and non-drug technology assessment
- Assumptions for HTA adapting
- Adapting – limitations
- HTA in decision making process in Poland



About me

- M.D. by education
- Health care management and bussiness management postdiploma studies
- Over 10 years experience in public administration in Polish health care system
- First mainly involved in health insurance issues
- Involved in HTA activities in Poland since 2002
- And HTA international activities since 2004 (First Annual HTAi meeting in Kraków, Poland)
- International project management experience (EU funded projects)
- Polish representative on the Audit Board EC for 3 years since 2004
- AHTAPol since 1st June 2006 – position Head of HTA Department
- Since 1st June 2009 – Deputy Director for HTA, AHTAPol

Poland in Europe and EU





Polish health care system

- Centralised health insurance system - taxes
- National Health Fund (NHF)
- 16 regional branches
- NHF concludes contracts with health service providers
- NHF budget for 2009 is 56,8 billion PLN (14 billion EURO)
- Drug reimbursement - 7,3 billion PLN (12,9%)
- Therapeutic drug programs - 1,3 billion PLN (2%)



AHTAPol - Legal basis

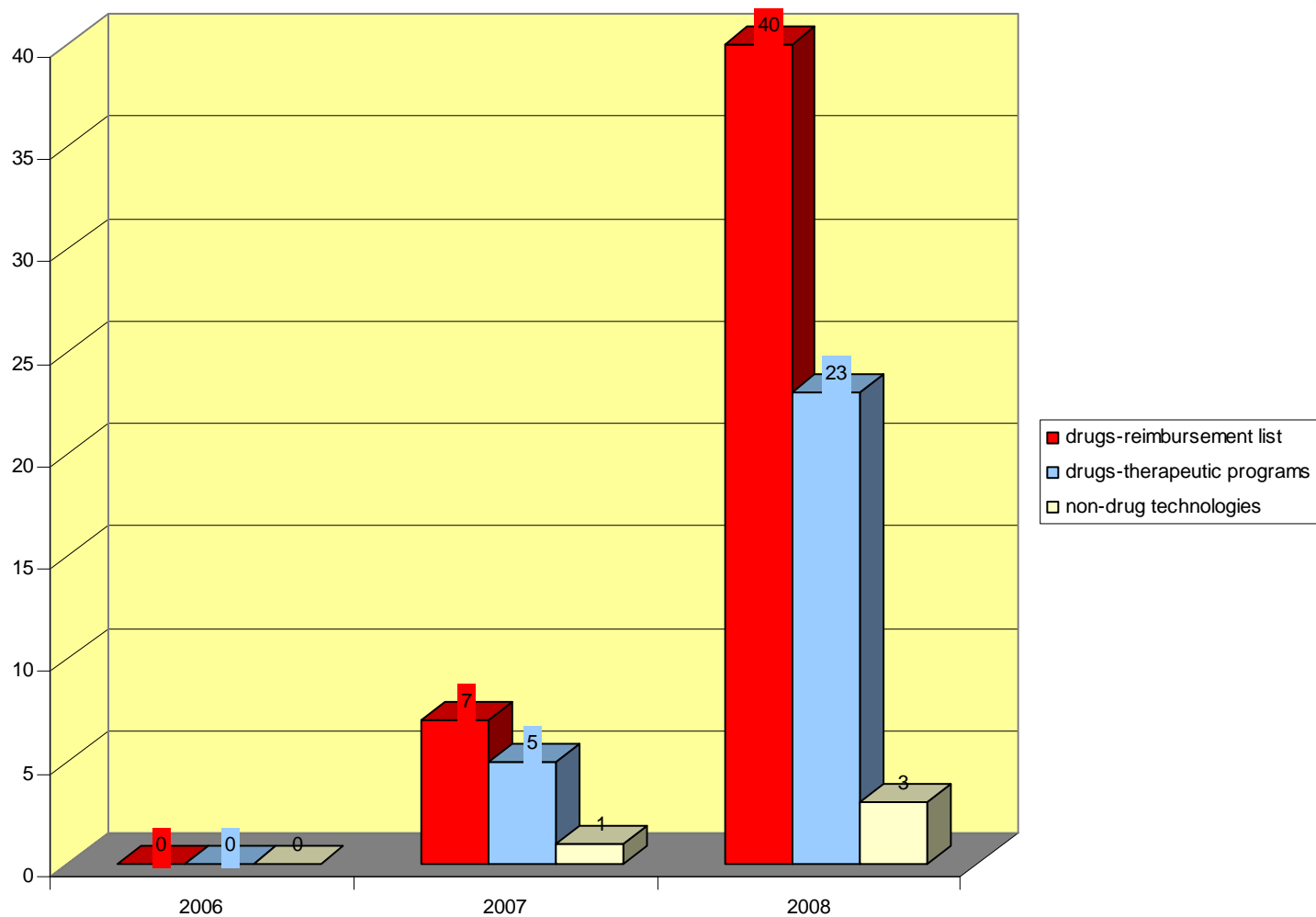
- Created in Sept 2005 (Ordinance of MoH)
 - ✓ The possible lowest legal act
- So far updated every year:
 - ✓ June 2006
 - ✓ Sept 2007
 - ✓ Sept 2008
- Steps undertaken to prepare the Law on AHTAPol establishment
 - ✓ Called „BBP Law”
- The Bill prepared and submitted for Parliament work
 - ✓ Big step forward for sustainability of HTA activities in Poland
- Still planned to come into force in 2009
 - ✓ August? depending on political will, MPs obligatory holiday break



AHTAPoI – tasks and activities

- Still discussions
 - ✓ BBP was the first task of AHTAPoI
- Which model of the Agency should be implemented
 - ✓ Light
 - ✓ Heavy limitations
 - ✓ Mixed
- BUT drug technologies – definitely a priority
 - ✓ Drug reimbursement list (Transparency Directive!)
 - ✓ Therapeutic programmes
- Non – drug technologies – definitely a minority

AHTAPol - tasks and activities





AHTAPoI - Analytic team

- Build a strong team - one of the biggest challenges
- Motivation system created to maintain people working in Agency
 - ✓ Continuous trainings
 - ✓ International collaboration
 - ✓ Professional development
- Money, money, money...
- Financial issues are important
- Salaries - public administration v. private sector

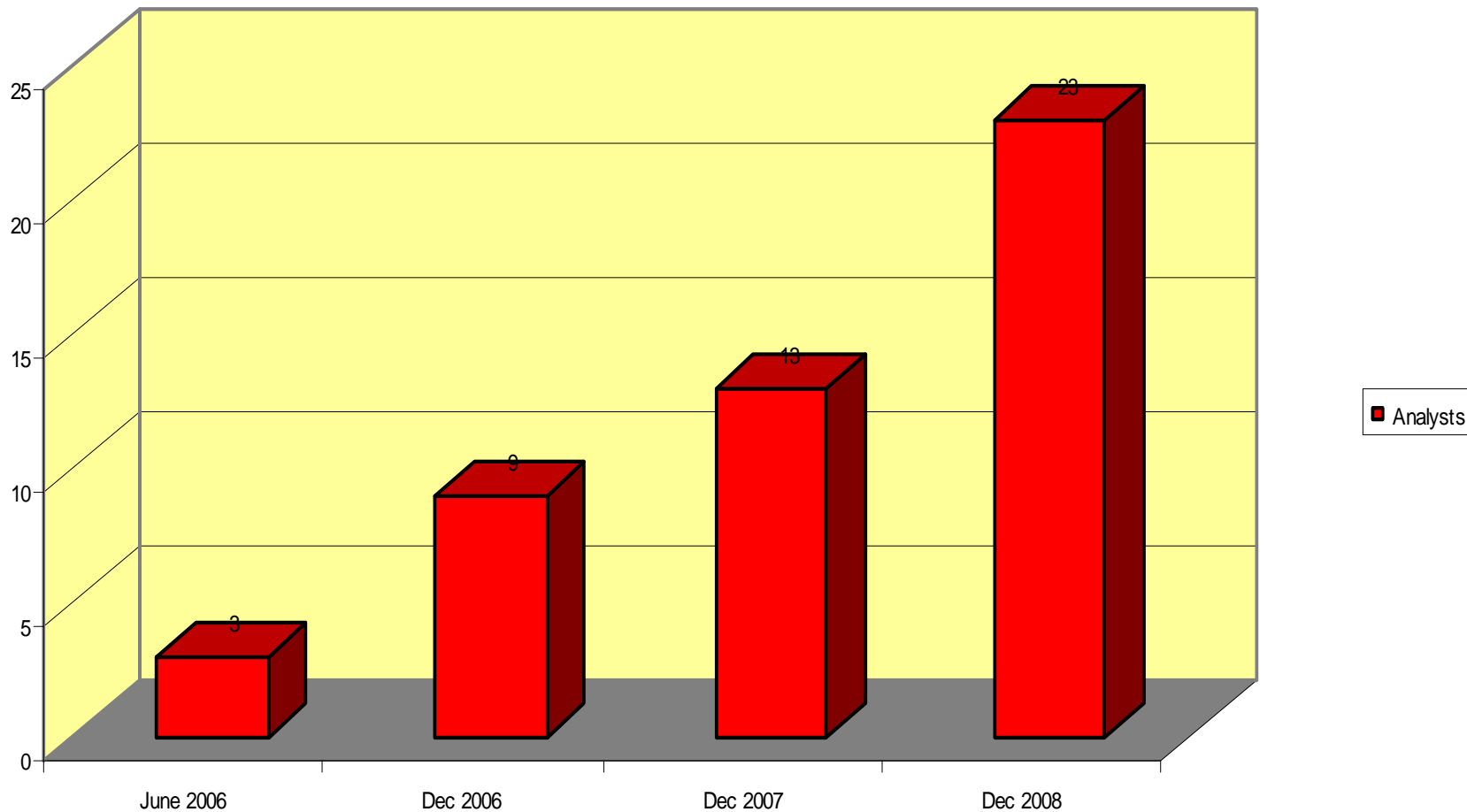


AHTAPol - Analytic team POSSIBILITIES

- EU funded project 2 million EURO
- Twinning project Poland - France (Oct 2006 - Apr 2008)
- 2 Components:
- Institutional - proposals of structural and procedural improvements for AHTAPol and other institutions
- Trainings in EBM and HTA
 - ✓ DOERS – about 30 people
 - ✓ USERS – about 300 people
 - ✓ Training for trainers – about 15 people trained
 - ✓ 7 internships 2 months long
 - ✓ 1 internship 6 months long

CORE of THE TEAM

AHTAPol - Analytic team





International collaboration

- From the beginning very important!
- EUnetHTA
- INAHTA
- HTAi
- MEDEV, ISPOR, GIN, WHO/HEN
- Avoiding the duplication of work
- Exchanging the information/networking



Drug Technology Assessment in AHTAPol - general rule

- Reimbursement list/Therapeutic programmes
- **Full HTA reports submitted by the pharma industry**
 - ✓ Together with reimbursement application
 - ✓ Legal obligation
- **AHTAPol CORE ACTIVITY**
 - ✓ Quality control/audit of reimbursement dossier from the industry
 - ✓ Clinical effectiveness
 - ✓ Cost effectiveness
 - ✓ Budget impact analysis



Drug Technology Assessment in AHTAPol – a few exceptions

- Safety profile for drugs already reimbursed
 - ✓ Systematic review performed internally
 - ✓ Took a lot of time
 - ✓ Decision makers not satisfied with effectiveness of our work
 - ✓ Human Resources dedicated for that task only nothing more
- Multiple Technology Assessment - solutions
 - ✓ Clinical effectiveness analysis performed internally
 - ✓ Cost effectiveness analysis and Budget Impact Analysis subcontracted (there are a few cooperating academic centers)

Non- Drug Technology Assessment in AHTAPoI



- In some cases difficult to identify the industry „behind”
- Then **sollution is ADAPTING HTA** for use in Poland
 - ✓ HTA reports from other countries are found and studied (secondary research)
 - ✓ Data from different countries are compared, decisions made in other countries searched and presented to CC
 - ✓ Examples: Australia/PBAC, Canada/CADTH, UK/NICE, Scotland/SMC, France/HAS, Germany/IQWIG
- Preparation of so called “preliminary report”
- Presented to CC, recommendation prepared OR decision on further research taken



Assumptions for ADAPTING HTA

- there is NOT enough capacity to perform all HTA reports internally by AHTAPoI
- A few reasons
 - ✓ staff shortage
 - ✓ financial limitations
 - ✓ time pressure
- Almost all stakeholders are aware of the above
 - ✓ Even politicians



ADAPTING HTA is a possible solution but with limitations

- Subcontracting HTA reports (externally)
- Cooperation with academic centers
 - ✓ Limitations: staff, financial issues, time pressure
- **Adaptation of HTA reports from other countries**
 - ✓ Limitations: availability of documents (websites, linguistic issues, English as international standard – still an open issue)
 - ✓ Limitations: difficulties with adaptation to local Polish settings, limited Polish health care cost data
 - ✓ Necessary especially in terms of economic analysis
 - ✓ Advantages: time, credibility, quality,

CC recommendation types

- “Finance”
- “Finance temporarily, provided that the data are gathered to a final decision” (CCED)
- “Finance provided that some precisely criteria are met or in particular indications”
- “Finance provided that a cost-effective way of financing was assured” (followed by negotiations)
- “Not to finance”
- “Increase financing”
- “Decrease financing”
- “Not to change financing”



HTA in decision making process in Poland

- Assessment, Appraisal and Decision taking
- Completely separated processes
- Assessment (in most cases quality control/audit of industry's submission)
 - ✓ by Analytic Team
- Appraisal/value judgement
 - ✓ by Consultative Council (CC)
 - ✓ CC recommendations (8 possible types)
- Decision taking/final decision
 - ✓ by Minister of Health



Thank you for your attention

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