



# **THE CHALLENGES FOR ADAPTING HTA FOR USE IN POLAND**

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**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

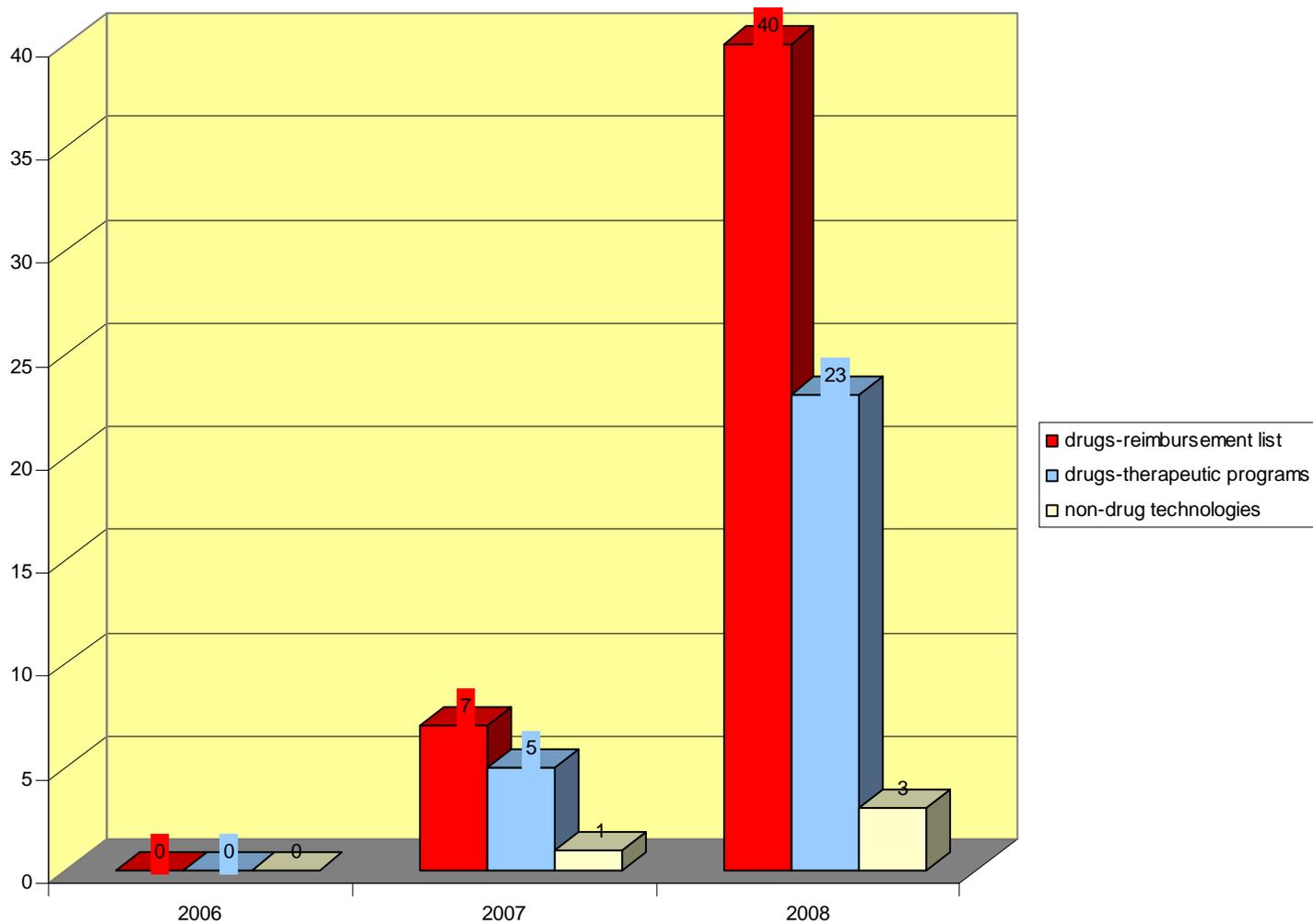
- Created in Sept 2005 (Ordinance of MoH)
  - ✓ The possible lowest legal act
- So far updated every year:
  - ✓ June 2006
  - ✓ Sept 2007
  - ✓ Sept 2008
- Steps undertaken to prepare the Law on AHTAPoL establishment
  - ✓ Called „BBP Law”
- The Bill prepared and submitted for Parliament work
  - ✓ 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



# AHTAPol – tasks and activities

- Still discussions
  - ✓ BBP was the first task of AHTAPol
- 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

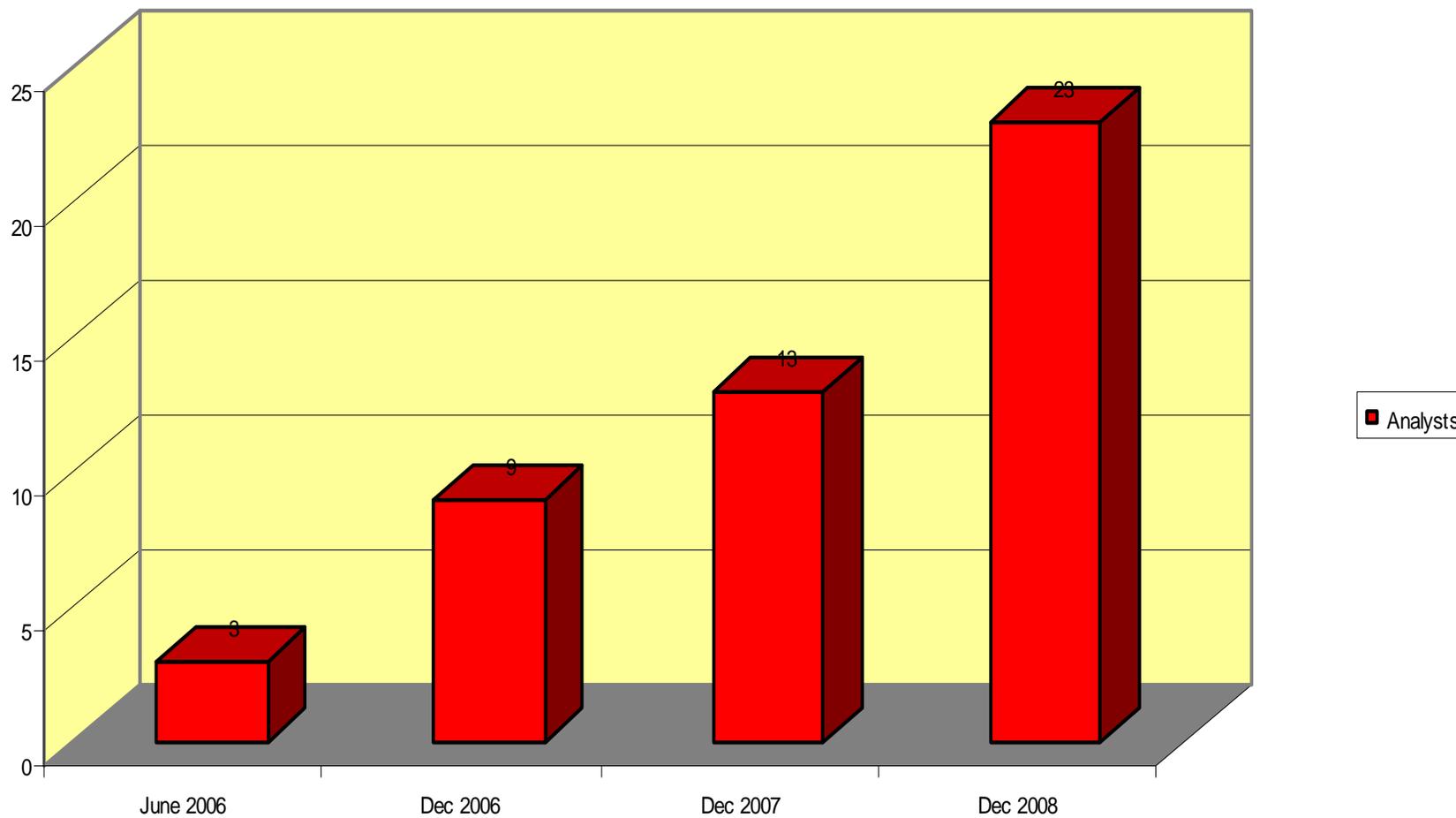
# AHTAPol - Analytic team POSSIBILITIES



- 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 AHTAPol
- 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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