Transparency of the National Health System drug reimbursement decisions

1 Basic Information
1.1 CRIS Number: 2005/017-488.02.01

Twinning No: PL2005/IB/SO/02
1.2 Title: Transparency of the National Health System drug reimbursement decisions
1.3 Sector: Internal Market
1.4 Location: Poland

2 Objectives
2.1 Overall objective
• to build capacity for transparency in National Health System reimbursement decisions according to Council Directive 89/105/EEC;

2.2 Project purpose
• to verify the outcome of law harmonization in regard to the transposition of EU Directive 89/105/EEC to the Polish legal system, in order to propose improvements for the procedures and structure of the Agency for Health Technology Assessment, in regard to the following:
  - assessment and aggregation of evidence according to Evidence-Based Medicine (EBM),
  - performing a critical appraisal of health economic analyses with inclusion of social, ethical and other implications, according to Health Technology Assessment (HTA).

2.3 Justification
The Comprehensive Monitoring Report on Poland’s preparation for membership of 5 November 2003
Chapter 13, Social and employment policy: In the field of public health […] it is necessary to continue the policy aiming at improvement of human health as well as to allocate adequate funds on health.
Chapter 23, Consumer and health protection: It is necessary to continue development and strengthening of administrative structures in regard to financial and human resources.
European Community Treaty
Chapter 13, article 152, Public Health: When determining and realizing all policies of the Community the high level of protection of human health is being ensured.
Aarhus Convention 1998 on public information
3 Description

3.1 Background and justification
The deficit of knowledgeable and skilled professionals in the field of Evidence Based Medicine and Health Technology Assessment constitutes a real problem in Poland, especially in the public administration service responsible for national health policy (and especially reimbursement of health technologies within the National Health System). It makes transparent reimbursement decisions even more difficult to be realized.

Recently, the Constitutional Court made a decision that the law on health benefits is insufficient and does not make clear what benefits a Polish citizen is entitled to through public health insurance scheme.

The European Commission points out the weaknesses of the process of reimbursement decision-making in Poland, especially lack of transparency, incompatibility with EU 89/105/ECC directive, and large delays in making decisions.

Poland commits itself to improve its procedures for processing pricing and reimbursement applications with a view to reaching decisions timely and in line with the criteria of Directive 89/105/EEC.

The correct transposition of the Directive 89/105/EEC to Polish legal system is anticipated to be completed before the start of the project (the relevant law changing procedures have been initiated, as of February 2005). Therefore the issue is not within the scope of the project, which instead focuses on actual practical aspects of enactment of the law required by the Directive.

The problems briefly described above are mostly the consequence of administrative incapacity and scarcity of competent human resources.

On the basis of article 250 of the law on health care services financed from public sources Minister of Health is obliged to establish the Agency for Health Technology Assessment, to efficiently tackle the above problems.

The Task Force to develop a detailed concept of Polish Agency for Health Technology Assessment has been established by the Minister of Health on February 3, 2005. The deadline to establish the Agency is set at the beginning of second quarter of 2005. Its task will be to deal with evidence concerning new health technologies (pharmaceutical and other, e.g. interventional) to be reimbursed in Polish National Health System and to essentially help to create a standard health care benefits package.

As time frame to establish the Agency is very short, the Ministry does not expect the project to provide input for the concept associated with the creation stage. It is however expected the RTA will be able to critically review and propose improvements for the Agency procedures and structure, as well as the outcome of Transparency Directive transposition process.

Organizing comprehensive trainings in the field of EBM and HTA for the national health administration employees will improve the situation.

3.2 Linked activities
ECHTA/ECAHI project: European Collaboration for Health Technology Assessment - Assessment of Health Interventions; 2002.

No known Phare projects on this issue.

3.3 Results
By the end of the project, the following results will be achieved:
1) the national system of preparing and/or assessing medical and health economic evidence as a component of Polish National Health System reimbursement decision making, set up and operating transparently and within time limits, and verified by the RTA in regard to compliance to Transparency Directive;

2) the group of EBM and HTA specialists and people acquainted with the subject within the national and regional health administration (medicals and non-medicals) trained, prepared to work, assess, aggregate and use evidence according to Evidence-Based Medicine (EBM), and in performing, critical appraising and use health economic analyses with inclusion of social, ethical and other implications, according to Health Technology Assessment (HTA);

3) the group of tutors equipped with educational materials, who already started cascading knowledge and skills in the field of reimbursement-oriented EBM and HTA by organizing courses and seminars;

3.4 Activities
Contract: Twinning

Task 1
• assistance in reviewing the law and the organisational and procedural excellence of the Agency for Health Technology Assessment
• to review and propose improvements for the tasks, structure and procedures of the Agency for Health Technology Assessment
• verification of law harmonization outcome in regard to transposition of Transparency Directive

Task 2
Trainings in the field of EBM and HTA
• for up to 300 people from national and regional health administration
  o set of training courses in assessment and aggregation of evidence according to Evidence-Based Medicine (EBM), and in performing and critical appraising of health economic analyses with inclusion of social, ethical and other implications, according to Health Technology Assessment (HTA)
• for 10–30 tutors
  o “training the trainers” courses in essentially the same field as described above, but with special focus on educational materials and methods to be used by tutors when cascading knowledge and skills
  o administrative support for sustainable cascades

Internships in HTA agencies in EU countries
• for future tutors (trainers) within the administrative system
• provided under condition to start cascading knowledge and skills
• for up to nine (9) people
• each stay associated with certain medical technology assessment performed in a given agency, to enable maximum insight into practicalities of the process
• one person will stay in a given institution for up to six (6) months
• the results of HTA performed/completed during stay may be shared between the two institutions: the one that sends a person (hereinafter, the sender) and the other (hereinafter, the host)
• the host will appoint its employee to be the sent person’s personal tutor throughout his/her stay within the host

The project will be implemented according to the rules and procedures of Twinning.

Resident Twinning Adviser (RTA)

RTA’s profile:
• practical working experience in the field of assessing and aggregating medical evidence, and producing and critical appraising of health economic analyses with inclusion of social, ethical and other implications
• knowledge of issues or experience associated with successful implementation of the Directive 89/105/EEC in other EU member states
• university degree in the field relevant to health or health economic issues
• good management skills
• fluency in English

RTA’s function and tasks:

Task 1
• to review and propose improvements for the tasks, structure and procedures of the Agency for Health Technology Assessment
• to verify law harmonization outcome in regard to transposition of Transparency Directive

Task 2
• to analyze the specific training needs of the Polish health administration in regard to the scope of the project
• assistance to define and prepare plans and programs of the training courses
• assistance to recruit participants
• assistance to establish cooperation with the relevant units of European Commission, EU agencies, health technology assessment agencies in the Member States

More specific tasks of the RTA will be described in the Terms of Reference after the fiche is accepted.

Task 2

Experts

Experts’ profile:
• theoretical and practical knowledge of the issues related to assessing and aggregating medical evidence, and producing and critical appraising health economic analyses with inclusion of social, ethical and other implications
• practical working experience in the field of assessing and aggregating medical evidence, and producing and critical appraising health economic analyses with inclusion of social, ethical and other implications
• good training skills
• fluency in English.
• university degree in the field relevant to health or health economic issues

Experts’ tasks:
• cooperation with RTA on preparing of training programs and tasks associated with review of the Agency
• preparation of lectures, presentations, practical exercises, etc.
preparation of educational materials to be published and distributed among participants

training of participants

3.5 Lessons learned

As there are no known Phare projects related to this project issues, the lessons are learned from the general experience of other EU countries. Health Technology Assessment Agencies are operating and supporting reimbursement decisions in various EU countries, e.g. National Institute for Clinical Excellence (NICE) in England and Wales, Catalan Agency for Health Technology Assessment and Research (CAHTA) in Spain, Statens beredning för medicinsk utvärdering (SBU) in Sweden, Nederlandse Vereniging voor Technology Assessment in de Gezondheidszorg (NVTAG) in Holland, Agence Nationale d’Accréditation et d’Évaluation en Santé (ANAES) in France, Institut für Technikfolgen-Abschätzung (ITA) in Austria, Deutsche Agentur für HTA (DAHTA) in Germany, Finnish Office for Health Care Technology Assessment (FinOHTA) in Finland, Kwaliteits Centrum Examining (KCE) in Belgium, Danish Center for Evaluation and Health Technology Assessment (DACEHTA) in Denmark.

Healthcare Technology Assessment (HTA) first came to prominence in 1972 when the United States Congressional Office of Technology Assessment was established. From that time many Western countries have formal HTA programs. They promote production and use of scientific knowledge to prevent disease and promote better health, needs assessment and equity analysis in health service delivery and financing. Web site offers health technology assessment reports, newsletters, technical notes, articles, information for patients, ongoing projects, educational and training activities.

Basing on foreign experience Polish Agency for Health Technology Assessment will revue existing evidence and prove an evaluation of the effectiveness, cost-effectiveness and impact on patient health and on the health care system of medical technology and its use. Group of people will be trained in the scope of EBM and HTA.

4 Institutional Framework

- Pharmaceutical Policy Department of the Polish Ministry of Health
- Department of Health Insurance of the Polish Ministry of Health
- Department of Health Policy of the Polish Ministry of Health
- the Office of Accreditation of the Polish Ministry of Health
- to-be-created Agency for Health Technology Assessment
  - basis for creation: article 250 of the law on health care services financed from public sources Minister of Health is obliged to establish the Agency for Health Technology Assessment
  - according to the ordinance by the Minister of Health on establishing the Task Force to develop a detailed concept of Polish Agency for Health Technology Assessment, the Agency will have been created in Poland until beginning of second quarter of 2005
  - expected tasks: assessment and aggregation of evidence according to Evidence-Based Medicine (EBM), performing and critical appraisal of health economic analyses with inclusion of social, ethical and other implications, according to Health Technology Assessment (HTA)
the Agency will report to the Minister of Health, it will feed the recommendation decision bodies with outcomes of analyses of relevant evidence.

5 Detailed Budget

<table>
<thead>
<tr>
<th>€M</th>
<th>Transition Facility Support</th>
<th>Co-financing</th>
<th>Total cost (TF plus co-financing)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Investment Support</td>
<td>Institution Building</td>
<td>Total Transition Facility (=I+IB)</td>
</tr>
<tr>
<td>Contract: Twinning</td>
<td>1 905 000</td>
<td>1 905 000</td>
<td>95 000</td>
</tr>
<tr>
<td>Total</td>
<td>1 905 000</td>
<td>1 905 000</td>
<td>95 000</td>
</tr>
</tbody>
</table>

(*) contributions form National, Regional, Local, Municipal authorities, FIs loans to public entities, funds from public enterprises

(**) private funds, FIs loans to private entities

The amount for co-financing is entirely parallel co-financing. All costs for study visits outside Poland as part of the Twinning will be borne by the beneficiary country, except for internships in HTA agencies in other Member States.

It is to be noted that no part of the project budget will finance neither the actual creation of the Agency for Health Technology Assessment, nor its operational functioning. The same is true in regard to the departments of the Polish Ministry of Health to be involved in this project.

In the case of Joint Co-financing, where the final overall cost is lower than foreseen in the project fiche, the National Public and Transition Facility Co-financing are reduced proportionally so as to maintain the agreed rate of co-financing. In the case of Parallel Co-financing, where the final cost is lower than foreseen in the project fiche, it must be shown that the overall objectives of the project have been fully achieved.

6 Implementation Arrangements

6.1 Implementing Agency

CFCU: Cooperation Fund, ul. Górnośląska 4A, 00-444 Warsaw, tel. +48 22 622 00 31, fax +48 22 622 95 69.

PAO: Mr Tadeusz Kozek, Under-secretary of State, Office of the Committee for European Integration, Al. Ujazdowskie 9, 00-918 Warsaw, tel. +48 22 455 52 41, fax +48 22 455 52 43.

6.2 Twinning

The project will be implemented according to the procedures of twinning.

Transition Facility support will cover the costs of RTA stay in Poland that should last 16 months.

National co-financing will cover the expenses regarding training rooms renting, equipment and other services necessary to organize trainings.
Twinning budget national co-financing 95 000 EUR.
The beneficiary institution is Pharmaceutical Policy Department of the Polish Ministry of Health, Warsaw, Poland.
The contact person is Norbert Wilk, Director of the Office of Accreditation, former Deputy Director of Pharmaceutical Policy Department, Ministry of Health, 15 Miodowa Street, 00-952 Warsaw, Poland, tel. +48 22 6356648, fax +48 22 6355847, mobile +48 608 085363, email n.wilk@mz.gov.pl.

6.3 Non-standard aspects
N/A

6.4 Contracts
Contract: Twinning = TF 1 905 000 EUR + National parallel co-financing 95 000 EUR

7 Implementation Schedule
Tender commencement: 4th quarter of 2005
Project commencement: 1st quarter of 2006
Project completion: 3rd quarter of 2007

8 Sustainability
The beneficiary institution will nominate responsible persons (National Project Manager, Senior Project Officer) to ensure effectiveness and compatibility with the work plans of running projects.
The Minister of Health has already foreseen co-financing of the project in the budget, and financing the Agency for Health Technology Assessment is already planned in 2005 budget.

9 Conditionality and sequencing
• the transposition of the Directive 89/105/EEC to Polish legal system before the beginning of the project, or shortly after, at the latest
• the Agency for Health Technology Assessment created in the beginning of second quarter of 2005 – the relevant decision’s legal form is published in the Official Journal of Laws of the Minister of Health
• finding partners who are both willing and able to work as RTA and experts
• finding HTA agencies in EU countries who are both willing and able to host people
• no contracts will be signed under this project unless the discussion on the correct transposition of the Directive 89/105/EEC is held with the Commission
### Annex 1: Logframe matrix

**LOGFRAME PLANNING MATRIX FOR THE PROJECT**

<table>
<thead>
<tr>
<th>Programme name and number</th>
<th>Contracting period expires</th>
<th>Disbursement period expires</th>
<th>Total budget</th>
<th>Transition Facility Budget</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project: Transparency of the National Health System drug reimbursement decisions</td>
<td>IV quarter 2007</td>
<td>IV quarter 2008</td>
<td>2 000 000 EUR</td>
<td>1 905 000 EUR</td>
</tr>
</tbody>
</table>

#### Overall objective
- to build capacity for transparency in National Health System reimbursement decisions according to Council Directive 89/105/EEC;

#### Project purpose

**Objective Verifiable Indicators**

- By the end of the project the decisions concerning reimbursement of pharmaceuticals in National Health System will have been compliant with Directive 89/105/EEC

**Sources of Verification**

- Reports, publications, regulations

**Assumptions**

- willingness of the participating Departments and other health administration institutions to cooperate with the Twinning Partner and with one another
- suitable tools to achieve objectives (adequate financial and human support and management)

**Results**

- By the end of the project, the following results will be achieved:
  1) the national system of preparing and/or assessing medical and health economic evidence as a component...
Transparency of the National Health System drug reimbursement decisions

of Polish National Health System reimbursement decision making, set up and operating transparently and within time limits;

2) the group of EBM and HTA specialists and people acquainted with the subject within the national and regional health administration (medicals and non-medicals) trained, prepared to work, assess, aggregate and use evidence according to Evidence-Based Medicine (EBM), and in performing, critical appraising and use health economic analyses with inclusion of social, ethical and other implications, according to Health Technology Assessment (HTA);

3) the group of tutors equipped with educational materials, who already started cascading knowledge and skills in the field of reimbursement-oriented EBM and HTA by organizing courses and seminars;

<table>
<thead>
<tr>
<th>Activities</th>
<th>Objectively Verifiable Indicators</th>
<th>Sources of Verification</th>
<th>Assumptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contract: Twinning</td>
<td>Twinning – RTA and short term experts</td>
<td>as above</td>
<td>as above</td>
</tr>
<tr>
<td>Task 1</td>
<td>assistance in reviewing the law and the organisational and procedural excellence of the Agency for Health Technology Assessment</td>
<td>as above</td>
<td>as above</td>
</tr>
<tr>
<td></td>
<td>to review and propose improvements for the tasks, structure and procedures of the Agency for Health Technology Assessment</td>
<td>as above</td>
<td>as above</td>
</tr>
<tr>
<td></td>
<td>verification of law harmonization outcome in regard to transposition of Transparency Directive</td>
<td>as above</td>
<td>as above</td>
</tr>
<tr>
<td>Task 2</td>
<td>Trainings in the field of EBM and HTA</td>
<td>as above</td>
<td>as above</td>
</tr>
<tr>
<td></td>
<td>for up to 300 people from national and regional health administration</td>
<td>as above</td>
<td>as above</td>
</tr>
<tr>
<td></td>
<td>o set of training courses in assessment and aggregation of evidence according to Evidence-Based Medicine (EBM), and in performing and critical appraising of health economic analyses with inclusion of social, ethical and other implications, according to Health Technology Assessment (HTA)</td>
<td>as above</td>
<td>as above</td>
</tr>
<tr>
<td></td>
<td>for 10–30 tutors</td>
<td>as above</td>
<td>as above</td>
</tr>
<tr>
<td></td>
<td>o “training the trainers” courses in essentially the same field as described above, but with special</td>
<td>as above</td>
<td>as above</td>
</tr>
</tbody>
</table>

reimbursement decision-making.

evaluation sheets presented by the trainees

• up to 300 people from national and regional health administration who have attended the courses on EBM and HTA

• 10-30 people who act as trainers of personnel equipped with educational materials

• 5-20 people who have practically worked in health technology assessment agencies in Europe.
**Transparency of the National Health System drug reimbursement decisions**

- Focus on educational materials and methods to be used by tutors when cascading knowledge and skills
  - Administrative support for sustainable cascades

Internships in HTA agencies in EU countries

- For future tutors (trainers) within the administrative system
- Provided under condition to start cascading knowledge and skills
- For up to nine (9) people
- Each stay associated with certain medical technology assessment performed in a given agency, to enable maximum insight into practicalities of the process
- One person to stay in a given institution for up to six (6) months
- The results of HTA performed/completed during stay may be shared between the two institutions: the one that sends a person (hereinafter, the sender) and the other (hereinafter, the host)
- The host will appoint its employee to be the sent person’s personal tutor throughout his/her stay within the host agency.

**Preconditions**

- The transposition of the Directive 89/105/EEC to Polish legal system before the beginning of the project, or shortly after, at the latest
- The Agency for Health Technology Assessment created in the beginning of second quarter of 2005 – the relevant decision’s legal form is published in the Official Journal of Laws of the Minister of Health
- Finding partners who are both willing and able to work as RTA and experts
10 Annex 2-3: Implementation, contracting and disbursement schedule

| Building Capacity for Transparency in National Health System Reimbursement Decisions | Date of Drafting | 10.12.2004 |
| Planning period | 2005-2007 |

<table>
<thead>
<tr>
<th>PLANNED</th>
<th>Budget Allocation</th>
<th>Cost Estimate (in MEUR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I’05</td>
<td>I’06</td>
<td>I’07</td>
</tr>
<tr>
<td>II’05</td>
<td>II’06</td>
<td>II’07</td>
</tr>
<tr>
<td>III’05</td>
<td>III’06</td>
<td>III’07</td>
</tr>
<tr>
<td>IV’05</td>
<td>IV’06</td>
<td>IV’07</td>
</tr>
<tr>
<td>V’05</td>
<td>V’06</td>
<td>V’07</td>
</tr>
<tr>
<td>VI’05</td>
<td>VI’06</td>
<td>VI’07</td>
</tr>
<tr>
<td>VII’05</td>
<td>VII’06</td>
<td>VII’07</td>
</tr>
<tr>
<td>VIII’05</td>
<td>VIII’06</td>
<td>VIII’07</td>
</tr>
<tr>
<td>IX’05</td>
<td>IX’06</td>
<td>IX’07</td>
</tr>
<tr>
<td>X’05</td>
<td>X’06</td>
<td>X’07</td>
</tr>
<tr>
<td>XI’05</td>
<td>XI’06</td>
<td>XI’07</td>
</tr>
</tbody>
</table>

### Implementation schedule

<table>
<thead>
<tr>
<th>I’05</th>
<th>II’05</th>
<th>III’05</th>
<th>IV’05</th>
<th>I’06</th>
<th>II’06</th>
<th>III’06</th>
<th>IV’06</th>
<th>I’07</th>
<th>II’07</th>
<th>III’07</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>II</td>
<td>III</td>
<td>IV</td>
<td>V</td>
<td>VI</td>
<td>VII</td>
<td>VIII</td>
<td>IX</td>
<td>X</td>
<td>XI</td>
</tr>
</tbody>
</table>

### Contracting schedule

<table>
<thead>
<tr>
<th>I’05</th>
<th>II’05</th>
<th>III’05</th>
<th>IV’05</th>
<th>I’06</th>
<th>II’06</th>
<th>III’06</th>
<th>IV’06</th>
<th>I’07</th>
<th>II’07</th>
<th>III’07</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>I</td>
<td>I</td>
</tr>
</tbody>
</table>

### Disbursement schedule

<table>
<thead>
<tr>
<th>I’05</th>
<th>II’05</th>
<th>III’05</th>
<th>IV’05</th>
<th>I’06</th>
<th>II’06</th>
<th>III’06</th>
<th>IV’06</th>
<th>I’07</th>
<th>II’07</th>
<th>III’07</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,905</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0,805</td>
<td>0,905</td>
<td>1,105</td>
<td>1,305</td>
<td>1,505</td>
<td>1,705</td>
<td>1,905</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Key:

I = contract implementation and payment  
* show amounts in Meuro increasingly  
D = design of sub-project  
C = tendering and contracting

11