STANDARD SUMMARY PROJECT FICHE

1. Basic Information
   1.1 Désirée Number: CZ01-04-03
   Twinning Number: CZ01/IB/OT/03
   1.2 Title: Strengthening of market surveillance of medicinal products for human use including alignment of authorisation conditions with EU practice
   1.3 Sector: Internal Market
   1.4 Location: State Institute for Drug Control (SUKL) Czech Republic, Prague,

2. Objectives
   2.1 Overall Objective(s):
   Existence of a functioning market economy and capacity to withstand competitive pressures and market forces within the EU reflecting protection of public health.

   2.2 Project purpose:
   Practical implementation of Acquis Communautaire in the area of regulation of quality, safety and efficacy of human medicinal products in the CR by the date of project completion, readiness of the CR for the involvement in the EU regulatory network system and capability of the SUKL to act fully in the line with EU standards (in particular concerning efficiency of operations, scientific standard of expertise and transparency).

   2.3 Accession Partnership and NPAA priority
   The Accession Partnership - Internal Market - Free Movement of Goods and National Programme July 2000 (3.2.2):
   Short-term: Improve market surveillance structures as regards equipment and training of staff, reinforce implementing structures in sectors covered by product specific legislation, improve utilisation of information technology, introduce links to EU rapid alert system; improve involvement in the relevant EU working groups and committees and intensify collaboration with EU regulatory authorities.
   Medium-term: Complete alignment of sector legislation including marketing authorisation for medicinal products. Ensure implementing structures for pharmaceutical sector and their co-operation with European Agency for the Evaluation of Medicinal Products and drug regulatory authorities of EU Member States, ensure connection to EU information network of regulatory authorities (EUDRANET). Apart of NPAA the importance of strengthening and increase of capacity of drug regulatory authorities has been identified in the EC regular report.

3. Description
   3.1 Background and justification:
   Medicinal products, as products bearing relatively high risk for public safety and being also of significant commercial importance, are subject of specific regulation. Such a regulation represents in EU part of Acquis Communautaire dealing with regulation of these products on the national level, co-operation among the MS and with regulation practised by specific EU structures. Transposition and implementation of relevant parts of Acquis together with harmonised regulatory practice and mutual confidence of authorities of EU Member States are prerequisites of function of Community regulatory network ensuring satisfactory level of public health protection and free movement of medicinal products.
   As EU regulatory system in this respect has been developed during past 35 years, it is an enormous task for the associating countries to apply the same regulatory criteria, the same standard of scientific expertise and develop confidence of existing EU Member States in short period of time. The existence of pool of well trained experts is a basic prerequisite. Moreover, the adoption of EU regulatory principles has direct impact on the operators and availability of medicinal products on national market. Modification of regulatory environment therefore has to be done sensibly.
   State Institute for Drug Control (SUKL) is the authority directed by the Ministry of Health, which is responsible for the regulation of human medicinal products from the point of view of quality, safety and efficacy, including market surveillance and issuing relevant authorisations/certificates. Its effective operations are crucial for successful alignment of regulatory conditions with EU and smooth inclusion into the EU regulatory network. In this respect, the increased standard of expertise and harmonisation of regulatory conditions of authorised medicinal products with the EU, improved market surveillance and
pharmacovigilance, improved management and implementation of quality system in SUKL are considered as key elements.

The effective implementation of Acquis can be supported in the Czech Republic by already existing legislation concerning medicinal products, which is mostly harmonised with the Acquis. In principle, only procedural aspects of EU MA system and newly arising EU legal acts have to be implemented yet. Even if all the relevant Acquis (see relevant EU legislation in the Annex 4) is transposed to the national legislation there still remains a huge amount of guidelines and practical interpretations which have to be introduced into practice in order to act fully in line with EU standards in a way compatible with EU Member States. This project is planned to be completed in the beginning of 2004 as the last project before the accession and therefore it covers all aspects of effective regulation of medicinal products from the quality, safety and efficacy point of view.

3.2 Linked activities:
Phare sponsored “National GMP* Project” was organised in 1995-1996. In the scope of this project, “pharmaceutical” inspectors of SUKL were trained together with Qualified Persons of Czech manufacturers and Czech manufacturing facilities were audited.

In 1999-2000 “Pan-European Regulatory Forum” (PERF I.) was established from the initiative of European Commission and funded by PHARE/PRAQIII. This activity provided training opportunities for selected staff of drug regulatory authorities from EU associating countries. PERF I. project should continue as of 2001 as PERF II. covering general needs of all accessing countries, e.g. interagency training. Final content of PERF II. will be determined by Steering Committee chaired by EC representative. Submitted project is considered to be complementary to PERF II. activities, tailored more on specific need of the Czech Republic.

SUKL inspectorate participates actively in co-operation and training activities of PIC/S and OECD. In 2000 short term training by visiting expert was organised for GMP inspectors using funds of Phare/PRAQIII/FAST programme.

The improvement of standards of inspection, laboratory work, confidentiality, evidence of clinical trials, implementation of European Commission/European Agency for the Evaluation of Medicinal Products guidelines and information of the public on EU legislation was supported in 2000 by special fund of the Ministry of Health.

3.3 Results:
1. Functional regulatory system in the area of marketing authorisations
   1a Readiness for entering of the human medicinal products related EC decisions into the force in the CR as of the day of accession and impact thereof identified.
   1b Outcomes of scientific assessment and administrative procedures in respect of granting and maintenance of marketing authorisations in line with EU requirements.

   By the end of the project there will be achieved not only reproducible performance of authorisation process respecting conditions of Acquis, which can be controlled by defined performance parameters, but also in written the analysis of consequences of Acquis implementation on availability of medicinal products and guidance for MA holders helping them to overcome accession period. Such measures will aim at harmonisation of the conditions of marketing authorisations, which are prerequisite of free movement of medicinal products inside EU.

2. Functional system of market supervision in place
   Quality system implemented by the inspectorate (PIC/S standard / ISO 9001) and the control laboratories (ISO 17025/ ISO 9001).

   Achievement of quality system will be verified by accreditation. Quality system implemented by supervisory authority is the key element in implementation of Acquis, standard performance and reliability.

3. Functional system of pharmacovigilance in place
   3a Safety actions concerning products available on EU market coordinated with the EU authorities
   3b Database of ADRs in format enabling information and data exchange with EU authorities and MA holders available.

* For abbreviations see Logframe Matrix in the Annex 1.
Achievement of functional pharmacovigilance system, being in compliance with Acquis and guaranteeing protection of the public in respect of ADRs of medicinal products will be subject to audit.

4. Strengthening of SUKL management system and implementation of quality system
   4a Operational management of the SUKL improved
   4b System on adoption of EU requirements/ regulatory standards (guidelines, positions, recommendations, points to consider etc.) functional
   4c Readiness of information technology for connection to EUDRA systems (telematic network between European authorities responsible for medicinal products).

   Introduction of quality system of SUKL, which includes also mechanisms on continuous implementation of new elements of Acquis, will be audited. In addition to the outcomes of benchmarking with EU drug regulatory authorities the audit can indicate the improvement of management.

   Staff of SUKL and collaborating experts adequately trained in all four above mentioned areas - Permanent education and training system developed including monitoring and verification of the individual knowledge and skills.

   This achievement will be verified by criteria developed during the project.

3.4 Activities:

   The project will provide for 1 PAA who will have a supervisory and co-ordinating role for the entire project, steering the work of the numerous short and medium-term experts involved in the different parts and will be located in SUKL. He/she should have experience from a similar institution in an EU Member State, should be fluent in English (written and oral) and experienced in inspections and enforcement of good practices and capable to build quality systems and train inspectors and laboratory personnel within the institution. Such a person should be aware of functioning of EU drug regulatory system also in areas of granting and maintenance of marketing authorisations and pharmacovigilance.

   part (1)
   1a Review of harmonisation status of medicinal products (taking into account the latest development of Acquis, esp. EC decisions on MA, referrals and other decisions, if relevant to the products authorised in the CR) and identification of impact of complete harmonisation of MA conditions
   1b Elaboration of procedures for phasing-in EU MA procedures and decisions
   1b Assessment of needs of outsourcing in case of scientific expertise and development of pool of collaborating experts
   1b Development of application tracking system
   1b Development of system of re-evaluation of MA conditions of authorised products to be in line with EU requirements

   Twinning covenant for part (1) of the project will consist of
   - 2 medium term experts specialised in assessment of pharmaceutical and preclinical and clinical part of the dossier knowledgeable of EU authorisation procedures and capable of resolving logistic issues, should be fluent in English
   - 3 short term experts specialised in those areas of assessment, that are not covered by medium term experts (e.g. biological, biotechnology, gene therapy), should be fluent in English
   - Educational activities (training, incl. EU legislation, attendance of seminars and workshops, visits and study stays) covering 35 SUKL employees and training in clinical assessment of 35 collaborating experts.

   part (2)
   - Introduction and maintenance of quality system of inspectorate (PIC/S standard/ISO 9001) and the control laboratories (ISO 17025/ISO 9001)
   - Analysis of needs in respect of laboratory equipment
   - Improvement of Rapid Alert System for defects of medicinal products
   - Improvement of databases of operators including inspection planning system
Twinning covenant for part (2) of the project will consist of:
- 1 PAA specified above
- 1 medium term expert experienced in laboratory control of medicinal products and official batch release, should be fluent in English
- 2 short term experts experienced in inspection techniques for specific areas, eg. GCP, blood centres or pharmacovigilance, should be fluent in English
- Educational activities (training, incl. EU legislation, joint inspections, attendance of seminars and workshops) covering 35 SUKL employees specialised in inspection and laboratory activities.

part (3)
3a Creation of system of regular monitoring of ADRs, documented scientific evaluation of reports, and signal generation enabling cooperation with EU authorities
3a Improvement of Rapid Alert System in pharmacovigilance
3b Modification of databases ensuring EU comparable sets of data on ADRs enabling information and data exchange with EU structures and MA holders

Twinning covenant for the part (3) of the project will consist of
- 1 medium term expert experienced in daily operations of national pharmacovigilance centre, esp. signal generation and evaluation, databases of ADRs and transmission of ADR reports, should be fluent in English
- 1 short term expert experienced in pharmacoepidemiology, should be fluent in English
- Educational activities (training, incl. EU legislation, attendance of seminars and workshops, study visits and stays) covering 5 SUKL employees and 5 collaborating experts.

part (4)
4a Mobilisation of internal and external human resources, including improvement of conditions for development and evaluation of professional growth
4a Establishment of electronic communication with applicants
4a Elaboration of analysis of optimum financing system and dealing with resources
4a Optimisation of internal processes and organisational structure
4a Benchmarking study indicating strengths and weaknesses of SUKL and of Czech regulatory system
4b Monitoring of existing and drafted EU requirements/regulatory standards and transposition into local guidelines and practice
4c Analysis of the needs in respect of upgrade of HW and SW for information systems enabling connection to EUDRA systems

Twinning covenant for the part (4) of the project will consist of
- 2 medium term experts experienced in institutional management, incl. strategic planning, project management, financial and resource planning and telematics and information management, should be fluent in English
- 2 short term experts experienced in quality systems, benchmarking and personnel management, should be fluent in English
- Educational activities (training, attendance of seminars and workshops, study visits and stays) covering 25 SUKL managers.

Development of system of permanent monitoring and verification of the individual knowledge and skills and training of internal staff (100 persons) and external collaborating experts (40) concentrating on (1) assessment of dossiers, (2) compliance with good practices and laboratory control, (3) pharmacovigilance and (4) management, project management and managerial skills.
- 1 medium term expert experienced in educational and training activities, should be fluent in English

Means – One twinning covenant as specified above, incl. support to carry out the audits (3, 4), information campaigns (1, 3) and elaboration of analyses (1, 4), action plans and progress evaluation reports and activities of project co-ordinator are included.
If the needs of modification of SW or investment into the purchase of HW or other equipment are identified within initial phases of twinning activities in any part of the project, these expenses will be covered from SUKL budget.

4. Institutional Framework

Beneficiary of the project is State Institute for Drug Control (SUKL) i.e. regulatory authority for medicinal products in the Czech Republic. SUKL is appropriately empowered by existing legislation for that function. The institutional framework will not change during the project and there is no intention that the project will lead to a change in the institutional framework. No constraints are identified in this respect.

There is indirect benefit of the project to the collaborating regulatory authority for veterinary medicinal products, as the procedures developed for phasing-in EU MA procedures and decisions may also be valid for veterinary medicinal products.

The project will be assisted by project co-ordinator and supervised by steering committee, both appointed at SUKL specifically for the project. Steering committee will supervise the detailed project plan, project progress.

Results achieved by the project will bring direct benefits to the Czech regulatory system of human medicinal products, i.e. to the public, both domestic and international pharmaceutical industry and other operators on the Czech territory and to the state administration, in particular to the SUKL.

5. Detailed Budget in M €

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<tr>
<th>Phare Support</th>
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There is no investment part planned.

If the needs of modification of SW, investment into the purchase of HW or other equipment are identified within initial phases of twinning activities within the project, there are 0.34 M€ assigned in total for investment and non-investment expenditures of SUKL/MoH in the National Programme for the year 2002 (medicinal products - 3.2.2.5).

6. Implementation Arrangements

6.1 Implementing Agency

The CFCU is the Implementing Agency responsible for tendering, contracting and accounting. The beneficiary is responsible for technical preparation and control. Steering Committee mentioned above is involved in control activities.

6.2 Twinning

The Contact person is Mrs. Jitka Šabartová, quality manager and head of harmonisation unit of SUKL, Šrobárova 48, 100 41 Praha 10, Czech Republic, tel. +420 2 67311153, fax +420 2 7273 9995, e-mail sabartova@sukl.cz.

6.3 Non-standard aspects

The "Practical Guide to Phare, Ispa & Sapard contract procedures" shall be followed.

6.4 Contracts

1 contract is foreseen - Twinning Covenant = 1.4 M €

7. Implementation Schedule

Start of twinning selection 4Q/2001
Start of project activity 1Q/2002
Project completion 4Q/2003

8. Equal Opportunity
Equal opportunity principles and practices on ensuring equitable gender participation in the Project will be guaranteed.

9. Environment  N/A

10. Rates of return  N/A

11. Investment criteria  N/A

12. Conditionality and sequencing
    Different parts of the project can run in parallel. There is the conditionality of the purchase of SW, HW or laboratory equipment sponsored by SUKL/MoH arising from initial expertise of twinning part.

ANNEXES TO PROJECT FICHE

1. Logical framework matrix
2. Detailed implementation chart
3. Contracting and disbursement schedule by quarter for full duration of programme
4. List of EU legislation related to quality, safety and efficacy of human medicinal products
**LOGFRAME PLANNING MATRIX FOR**

**Project**: Strengthening of market surveillance of medicinal products for human use including alignment of authorisation conditions with EU practice  

**Programme name and number**: CZ01-04-03  

**Contracting period expires**: 31/10/2003  

**Disbursement period expires**: 31/10/2004  

**Total Budget**: 1,5 M €  

**Phare contribution**: 1.4 M €

### Overall objective

- Existence of a functioning market economy and capacity to withstand competitive pressures and market forces within the EU reflecting protection of public health
- Implementation of Acquis (see relevant EU legislation in the Annex) in the area of human medicinal products

### Sources of verification

- Public information released by SUKL: Bulletin, Annual report, homepage
- SUKL database of medicinal products
- SUKL database of personnel

### Results

#### 1. Functional regulatory system in the area of marketing authorisations

1a Readiness for entering of the human medicinal products related EC decisions into the force in the CR as of the day of accession and impact thereof identified

1b Outcomes of scientific assessment and administrative procedures in respect of granting and maintenance of marketing authorisations in line with EU requirements

1. Index of “centralised and post-referral products” with identified differences in the terms of marketing authorisation

1a Impact analysis of implementation of EC decisions

1a Guidance for MA holders clarifying how to proceed on the day of accession published

1b Assessment reports, Public assessment reports on

- PAA reports and interim reports
- Public information released by SUKL: Bulletin, Annual report, homepage, Pharmacotherapeutical Information

### Assumptions

- Adoption of the Amendment to the Act No. 79/1997 Coll. on Pharmaceuticals, covering procedural aspects of EU regulatory system and any new relevant Community legislation
- Appropriate system of financing of SUKL in place
- Sufficient availability of human medicinal products conforming with EU requirements
- Health care system and practice ready to absorb EU standards on medicinal products

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2. **Functional system of market supervision in place**  
Quality system implemented by the inspectorate and the control laboratories

- Functional system of pharmacovigilance in place  
  3a Safety actions concerning products available on EU market co-ordinated with the EU authorities  
  3b Database of ADRs in format enabling information and data exchange with EU authorities and MA holders available

3. **Functional system of pharmacovigilance in place**  
3a Safety actions concerning products available on EU market co-ordinated with the EU authorities  
3b Database of ADRs in format enabling information and data exchange with EU authorities and MA holders available

4. **Strengthening of institute management system and implementation of quality system**  
4a Operational management of the SUKL improved  
4b System on adoption of EU requirements/ regulatory standards (guidelines, positions, recommendations, points to consider etc.) functional  
4c Readiness of information technology for connection to EUDRA systems (telematic network between European authorities responsible for medicinal products)

**Staff and collaborating experts adequately trained in all four above mentioned areas**  
Permanent education and training system developed including monitoring and verification of the individual knowledge and skills

- Written procedure on system of permanent education and training  
- Following numbers of staff and collaborating experts trained:  
  1. 35 internal and 35 external - assessment of dossiers;

**Audit report on quality system**  
4a Plan on optimisation of organisation structure, financial and human resources and resource adjustment  
4b Report from benchmarking study  
4c Guidelines of SUKL covering all EU regulatory documents available with maximum 6 month lag time  
4d Connection to EUDRA systems prepared to be functional

<table>
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<th><strong>Training</strong></th>
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<tr>
<td>- Written procedure on system of permanent education and training</td>
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<tr>
<td>- Following numbers of staff and collaborating experts trained:</td>
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<td>1. 35 internal and 35 external - assessment of dossiers;</td>
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- Educational curricula of trainees ??certificates??  
- Evaluation reports of trainers  
- Audit reports  
- SUKL databases and internal documents  
- Documentation of the quality system of SUKL  
- Reports transmitted to other regulatory authorities
<table>
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<tr>
<th>Activities</th>
<th>Means</th>
<th>Assumptions</th>
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<tbody>
<tr>
<td>1. Identification of harmonisation status of medicinal products and impact of complete harmonisation of MA conditions</td>
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<td>• Co-operation of relevant EU authorities and pharmaceutical industry</td>
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<td>1a Elaboration of procedures for phasing-in EU MA procedures and decisions</td>
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<td>• Staff consolidation, especially in IT area</td>
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<td>1b Assessment of needs of outsourcing in case of scientific expertise and development of pool of collaborating experts</td>
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<td>• Support of medical professional bodies</td>
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<td>1b Development of application tracking system</td>
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<td>• Adequate provision from state budget</td>
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<td>1b Development of system of re-evaluation of MA conditions of authorised products to be in line with EU requirements</td>
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<td>• Availability if trainers</td>
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<td>2. Introduction and maintenance of quality system of inspectorate (PIC/S standard/ISO 9001) and the control laboratories (ISO 17025/ISO 9001)</td>
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<td>- Improvement of databases of operators including inspection planning system</td>
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<td>3. Creation of system of regular monitoring of ADRs, documented scientific evaluation of reports, and signal generation enabling cooperation with EU authorities</td>
<td>Twinning covenant</td>
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<tr>
<td>3a Improvement of Rapid Alert System in pharmacovigilance</td>
<td>• 1 PAA for 12 months covering the area of market supervision (inspection and enforcement activities, building quality system of inspectorate and training of inspectors and laboratory staff)</td>
<td>• Co-operation of relevant EU authorities and pharmaceutical industry</td>
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<td>3b Modification of databases ensuring EU comparable sets of data on ADRs enabling information and data exchange with EU structures and MA holders</td>
<td>– apx 0.200 M €</td>
<td>• Staff consolidation, especially in IT area</td>
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<td>4. Mobilisation of internal and external human resources, including improvement of conditions for development and evaluation of professional growth</td>
<td>• 7 medium-term experts each for 3 months covering areas of assessment and logistics of management of marketing authorisations, laboratory control, pharmacovigilance, institutional management, incl. strategic planning, project management and financial and resource planning and telematics.</td>
<td>• Support of medical professional bodies</td>
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<td>4a Establishment of electronic communication with applicants</td>
<td>– apx 0.600 M €</td>
<td>• Adequate provision from state budget</td>
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<td>4a Elaboration of analysis of optimum financing system and dealing with resources</td>
<td>• 8 short term experts, each for 5 days covering assessment of dossiers, specific inspection activities, pharmacovigilance, quality systems and management.</td>
<td>• Availability if trainers</td>
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<td>4a Optimisation of internal processes and organisational structure</td>
<td>– apx 0.05 M €</td>
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<td>4a Benchmarking study indicating strengths and weaknesses of Twinning covenant</td>
<td>• Educational activities consisting of training, attendance of seminars and workshops, organisation of joint inspections, study visits and stays in EU authorities esp. concentrating on areas of inspection activities, pharmacovigilance, MA assessment, laboratory control, information management, institution management and detailed understanding to EU legislation (approx. 70 events and 18 months of study stays) 0,500 M €</td>
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<td>4a Co-operation of relevant EU authorities and pharmaceutical industry</td>
<td>• As a part of twinning covenant support to carry out the audits of institution at final stage of project, information campaigns and elaboration of analyses, action plans and progress evaluation reports and activities of project co-ordinator are included</td>
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<td>4b Establishing electronic communication with applicants</td>
<td>• If the needs of modification of SW or investment into the purchase of HW are specified within initial phases of twinning activities, these expenses will be covered from SUKL budget.</td>
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<td>SUKL and of Czech regulatory system</td>
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<tr>
<td>Monitoring of existing and drafted EU requirements/ regulatory standards and transposition into local guidelines and practice</td>
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<td>Upgrade of HW and SW for information systems enabling connection to EUDRA systems</td>
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<td>Development of system of permanent monitoring and verification of the individual knowledge and skills and training of internal staff (100 persons) and external collaborating experts (40) concentrating on (1) assessment of dossiers, (2) compliance with good practices and laboratory control, (3) pharmacovigilance and (4) management, project management and managerial skills.</td>
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**Preconditions**

Not identified

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**Abbreviations:**

- ADR - adverse drug reaction
- MA – marketing authorisation
- PIC – Pharmaceutical Inspection Convention/Scheme
- SUKL – State Institute for Drug Control
- GMP – good manufacturing practice
- PECA- Protocol on European Conformity Assessment
- GLP- good laboratory practice
- SUKL – State Institute for Drug Control
- PAR – public assessment report
## Detailed Implementation Chart for the Project

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**CZ 2001 – xx - xx**
Cumulative Contracting and Disbursement Schedule for the Project (M€)

Cumulative Quarterly Contracting Schedule (MEUR)

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Cumulative Quarterly Disbursement Schedule (M €)

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