1. Basic information
1.1 CRIS number: 2002/000-196.02.01
1.2 Title: Strengthening medicinal products surveillance and registration system
1.3 Sector: Internal market
1.4 Location: Poland

2. Objectives
2.1 Overall objective
Improvement of the surveillance system over medicinal products and of medicinal products’ registration.

2.2 Immediate objectives
Strengthening of the surveillance system over medicinal products and of the registration through reinforcement of such activities as: conducting the proceedings for the authorization to place a medicinal product on the market, registration of medicinal products authorized for marketing, surveillance over the safety of use as well as registration of the notified adverse effects of medicinal products, and surveillance over the application of Good Clinical Practice.
Further improvement of the pre-market measures on quality and safety standards of medicinal products. Cutting-down the time of registration process - from 12 months to 210 days.

2.3 Accession Partnership and NPAA priorities
NPPA PRIORITY 1.10: ADJUSTMENT OF POLISH LEGISLATION IN THE AREA OF PHARMACEUTICALS
1. FINAL OBJECTIVE
Abolishment of barriers on the pharmaceutical market through full harmonization of legislation on pharmaceuticals.
2. INTERMEDIATE OBJECTIVES
Unification of price setting principles (transparent rules on price fixing for medicinal products included into national social security reimbursement schemes); Adjusting the procedure of registration of pharmaceuticals to the acquis communautaire.
AP - Internal Market - Medium term: Free movement of goods: complete alignment including conformity assessment and market surveillance systems; complete adoption of EN standards; complete alignment of sectoral legislation, ensure implementing structures for all sectors.

2.4 Contribution of National Development Plan: n.a.
2.5 Cross Border impact: n.a.

3. Description
3.1 Background and justification
In the framework of PHARE 2001, project PL01.02.03 Medicines and medical devices, an Office for Registration of Medical Devices, Medicinal Products and Biocides will be supported in the first phase of its activity.
Establishment of this Office results from the Act on the President of the Office for Registration of Medical Devices, Medicinal Products and Biocides, which was approved by Sejm (Lower House of Polish Parliament) on 27.07.2001 and by Senat (Upper House of Polish Parliament) on 30.08.2001. Provided that the Office will start its activity in the first quarter of the year 2002, its duties in the scope of medicinal products would be focused on i.a.:
- Conducting the proceedings for the authorization to place a medicinal product on the market, including veterinary medicinal products
- Keeping the register of the Medicinal Products Authorized for Marketing at the territory of the Republic of Poland, with the separate part for veterinary medicinal products
- Carrying out the audits of clinical tests from the standpoint of their compliance with the requirements of Good Clinical Practice and keeping the Central register of the Clinical Tests
- Surveillance over the safety of use of medicinal products and its monitoring as well as keeping the record of the notified adverse effects of the medicinal products authorized for marketing
Aiming at further development of the Office for Registration of Medical Devices, Medicinal Products and Biocides and in order to achieve all EU standards according to expected changes in the field of medicinal products, this project should provide wider know-how transfer and additional equipment purchases.
To this end this project should enable also the upgrading and maintenance of equipment as well as
purchase of additional specialist hardware, software and data base for the Office for Registration of Medical Devices, Medicinal Products and Biocides. Funds granted within this project would also facilitate conducting additional and complementary training of the staff.

The Act “Pharmaceutical law” has been approved by Sejm on 06.09.2001 and has been signed by the President on 01.10.2001. It will create the legal frames for such issues as: manufacturing; authorization to place a medicinal product on the market (the permission of the President of the Office will be the basis of authorization to place on the market); advertising; medicinal products marketing as well as control and surveillance over placing on the market and marketing. Adjustments included in this Act will also, i.a.: improve procedures; unify the requirements for applicants; and become the basis for creation of the Central Evidence of notified adverse effects of medicinal products authorized for marketing. This Act will implement into Polish legislation the certain number of relevant Directives and will adjust the Polish Law to the *acquis communautaire* in the filed of medicinal products form the date of entry into force or from the date of Poland’s accession to the EU. From the date of Poland’s accession to the European Union, the regulations concerning i.a. the following issues will come into force:

- authorization to place on the market of a medicinal product, which holds an authorization awarded according to the central procedure;
- mutual recognition;
- excluding the medicinal products’ series, which passed the EU Member States’ control - from the local control;

The Act “Pharmaceutical law” will introduce regulations concerning increased control and modernization of medicinal products’ registration process. Actual procedure of medicinal products’ registration lasts 12 months. In order to adjust the registration process to standards required by EU, such a process should not take more than 210 days. This Act will come into force on 1st January 2002. For some of the marketing authorization holders, especially Polish, fulfilling all requirements incorporated in the law in such a short time is impossible. Therefore during approximately one year Ministry of Health shall publish detailed regulations related to the “Pharmaceutical law” in order to facilitate fulfilling marketing authorization holders’ obligations.

To ensure the effective registration process and exercising of above-mentioned duties, a certain number of consultations with selected relevant institutions in the field of market surveillance, staff training as well as know-how and experiences’ transmission from the compatible institutions of EU Member States would be constantly necessary. Purchase of additional computer equipment (hardware and specialist software), envisaged in the framework of this project, would improve the level of proficiency of activities performed by the Office for Registration of Medical Devices, Medicinal Products and Biocides and would make its work efficient and compatible with EU standards.

It is of a great importance, that within this project possibility of modifications or amendments in the area of medicinal products - accordingly to the EU expected relevant changes - should be foreseen. It is necessary to underline that one of the aims of this project is the assurance of introducing in Poland the EU pharmaceutical law changes, which would be adopted during the project implementation.

### 3.2 Linked activities

Phare project PL 01.02.03 “Medicines and medical devices”, awarded to the Ministry of Health in the year 2001, aims at the implementation of the quality and safety standards of medicinal products and medical devices.

Phare project PL 9707-01-04-0004 “Harmonization of Polish consumer protection and health and safety legislation to the *acquis communautaire*” was completed in 2000. In the framework of sub-module 9.1 - EU pharmaceutical legislation, the experts analyzed the draft of the Act ‘Pharmaceutical law”, proposed the necessary amendments for the provisions as well as drafted executive decrees related to specific issues linked to the framework law.

### 3.3 Results

Relevant polish law, harmonized with *acquis communautaire*, implemented;

Competent Authority - the Office for Registration of Medical Devices, Medicinal Products and Biocides - performing surveillance i.a. over medicinal products in compliance with EU standards;

Period of time of medicinal products’ registration process cut - down from 12 months to 210 days;

Staff of the Office for Registration of Medical Devices, Medicinal Products and Biocides additionally (according to actual requirements) trained;

Qualifications of the health care institutions staff in the field of new legislation improved;

Additional envisaged information materials - on modified surveillance procedures, control and clinical
tests for medical staff and for healthcare institutions’ management staff actualized and published. Relevant materials - on new rules of functioning on the market for manufacturers - active on the market, on which standards of placing on the market are fully compatible with EU requirements - published. Upgraded relevant hardware, specialist software and data bases as well as maintenance and safety equipment related to all of mentioned hardware and software for Office for Registration of Medical Devices, Medicinal Products and Biocides provided, i.a. for the purposes of registers: in the field of medicinal products - Register of medicinal products authorized for marketing, Central Register of Clinical Tests, Record of the notified adverse effects;

3.4 Activities
Twinning:
In order to achieve the EU standards in the field of surveillance over medicinal products, the additional support from EU experts (PAA and a number of short-term experts) is expected in the frame of twinning – i.a. for necessary coordination and evaluation of work performed by the Office for Registration of Medical Devices, Medicinal Products and Biocides.

Experts ‘areas of activity:
• Assessment and verification of the responsibilities and organizational structure of the Office for Registration – in the light of compliance with EU standards;
• Preparation of expected future necessary adjustment programs – in case of new requirements;
• Evaluation and participation in the complementary training program for Office for Registration of Medical Devices, Medicinal Products and Biocides staff in the field of / for: Procedures of market authorization of medicinal products; Monitoring and surveillance over adverse effects of medicinal products; Auditors of: GCP, GLP and surveillance over medicinal products.
• Evaluation and participation in the necessary additional training programs in the field of: new regulations, adverse effects, clinical tests for healthcare institutions staff;
• Provision of support for Polish experts at the central and regional level in the area of new standards – know-how transmission;
• Co-operation in the field of specific issues, identified by the beneficiary institution in the course of project implementation;
• Support in detailed planning of investments regarding strengthening of electronic system according to the needs.

Requirements:
All experts will be required to specialize and possess depth and practical experience in:
• Practical solutions in relevant institution in one of EU countries (organization, duties and operation);
• Legislative and institutional solutions in the area of medicinal products’ Office for Registration activities and responsibilities;
• Administration of institutions or complex programs, preferably of an international nature, in this area;
• Evaluating programs or projects presenting new solutions in registration and control;
International experience will be seen as an important advantage.

All of experts will be located in the Office for Registration of Medical Devices, Medicinal Products and Biocides.

They will cooperate with all of the Polish counter-part institutions and will provide practical support in the effective and efficient implementation of proposed activities.

In case of any difficulties or problems emerged during performance of activities by the Office for Registration of Medical Devices, Medicinal Products and Biocides, the experts should provide support in development of correction solutions.

The short-term experts will be involved in specific issues, identified by beneficiary institution during project activity.

In the frame of twinning component of this project there are also foreseen relevant information materials: Actualization, publication and distribution of - specified above - additional information materials;

In order to assure required improvement of qualification, i.a. according to expected changes, there would be also a need to provide the following training:
• Study visits if such a need arise and there is no other possibility to solve certain problems by means of training programs (e.g. actual functioning of European Drug Regulatory Authorities: proceedings related to marketing authorization procedures and standard operation procedures related to specific responsibilities performed by EU DRAs); study visits would be limited to certain number of persons.
• Complementary training programs focused on new regulations for healthcare institutions staff.
Training in the framework of EU Directives concerning medicinal products, including consequences resulting from implementation of relevant *aquis communautaire* – in the scope of clinical tests and adverse effects as well;

- Additional, necessary training and, if necessary, study visits for the Office for Registration of Medical Devices, Medicinal Products and Biocides staff - in the field of / for: procedures of market authorization of medicinal products (especially updating of the dossier according to the EU demands and evaluation of pre-clinical, clinical and pharmaceutical documentation) ; monitoring and surveillance over adverse effects of medicinal products; auditors of: GCP, GLP and surveillance over medicinal products.

**Investments**

Taking into account the necessity to strengthen a new established Authority, namely the Office for Registration of Medical Devices, Medicinal Products and Biocides the investment component is devoted to provide this institution with additionally required hardware and some specialist software and safety equipment (especially in relation to future involvement in the European information tracking systems – e.g. Eudra Net, EudraTrack). This could also allow for proper functioning of the Office in order to improve of the surveillance system over medicinal products and of medicinal products’ registration. The other aspect justifying the need to have an investment part within this project is connected with strengthening of the electronic goal information system. The database for this system should fulfil all of the safety standards.

In the framework of this component the following purchases for the purposes of databases (registers) are envisaged: Register of medicinal products authorized for marketing, Central Register of Clinical Tests, Record of the notified adverse effects. What is extremely important in this respect is the fact that all purchases will be made taking into account activities foreseen to be done within the Phare 2001. Under this task the focus will be on hardware upgrade, software and application software. Delivery of database servers in order to upgrade four processor on each server, upgrade RAM Memory, the Internet server and network connections, hardware for the Office equipment (ca. for 70 users), a new server for some new planned solutions and EMAIL SERVERS Cluster Solutions (2 servers) are planned. Additionally, the investment component of the project should include the software for: system, database servers, e-mail Server, database and within Application Software, the system for the Office for Registration operating for established databases and Internet Portal for external users - Ministry of Health, Drug Institute, Ministry of Finance.

**Envisaged purchases (estimated prices)**

**Hardware Upgrade**

**DATABASE SERVERS - upgrade**

| Upgrade to four processor on each server | 20 000 EURO |
| Upgrade RAM Memory on each server | 15 000 EURO |

**Internet Server and network connections**

| New INTERNET Server for cluster solution | 20 000 EURO |
| Internet connection per one location |  | 
| Link speed | 2 Mbps |
| Price for two years Subscription | 40 000 EURO |

**Price for three locations**

\[
3 \times 40 000 \text{ EURO} = 120 000 \text{ EURO}
\]

**Hardware for the Office equipment (ca. 70 users)**

Price - 2 000 Euro for one Desktop PC

**For 70 users = 140 000 Euro**

**New server for new planned solutions**

EMAIL SERVERS Cluster Solutions (2 servers)

**Estimated price of two servers**

80 000 EURO

**Software**

| System | 4 licenses – MS Windows 2000 Advanced Server |
| Database Servers | 8 licenses per each processor MS SQL 2000 Enterprise Server |
| E mail Server | 2 licenses MS Exchange 2000 Enterprise Server |
| Database | Server for 70 users and Internet license |
Software cost - 450 000 EURO
Windows Advanced Svr English Lic/SA MVL - 6 250 EURO x 4
SQL Svr Enterprise Edtn English Lic/SA MVL 1 Processor License - 45 000 EURO x 8
Exchange Svr Ent English Lic/SA MVL - 9 700 EURO x 2
Windows CAL English Lic/SA MVL - 82 EURO x 70
Exchange CAL English Lic/SA MVL - 179 EURO x 70
SharePoint Portal Svr English Lic/SA MVL - 9 200 EURO x 1
SharePoint Portal CAL English Lic/SA MVL - 212 EURO x 70

Application Software
System for the Office for Registration operating for established data bases. Estimated price 380 000 €
Internet Portal for external users - Ministry of Health, Drug Institute, Ministry of Finance
Estimated price - 220 000 €
The Office for Registration of Medical Devices, Medicinal Products and Biocides will become the owner of the newly purchased equipment and all of specified equipment will be located there as well.

4. Institutional framework
Ministry of Health and particularly Office for Registration of Medical Devices, Medicinal Products and Biocides will play the leading role in the project.
Provided that the Office for Registration will start its activity in the first quarter of the year 2002, a Task Force group shall be appointed by the Minister of Health in third/fourth quarter of year 2001 - at the latest. The group consisting i.a. of medicinal products’ specialists will prepare the establishment of the Office for Registration.
Sejm approved the Act on the Office for Registration of Medical Devices, Medicinal Products and Biocides on 27.07.2001 and it has been signed by the President on 28.09.2001. This Act is a legal basis for establishment of this Office. The President of the Office for Registration of Medical Devices, Medicinal Products and Biocides is a Central Authority of Governmental Administration and is responsible for evaluation of quality, effectiveness and safety i.a. of medicinal products.
The aim of this Project is an improvement of the activities performed by the Office for Registration of Medical Devices, Medicinal Products and Biocides.

5. Detailed budget (€)

<table>
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<tr>
<th>Investment INV</th>
<th>Institution Building</th>
<th>Total PHARE</th>
<th>National Co-financing</th>
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The Polish authorities assure that the cofinancing is available either through the reserve budget foreseen specifically by the Ministry of Finance for this purpose or through the budget of the relevant Ministry.

6. Implementation arrangements
6.1 Implementation Agency
PAO: Mr Pawel Samecki, Undersecretary of State at the Office for the Committee for European Integration
Aleje Ujazdowskie 9, 00-918 Warsaw, tel. (48 22) 455-52-41, fax (48 22) 455 52 43
CFCU: Cooperation Fund, Mr. Wojciech Paciorkiewicz, Director, 4A Górnoslaska Str. 00-444 Warsaw, tel. +48 22 622 00 31; fax +48 22 622 95 69
The CFCU is responsible for tendering, contracting and payments in contracts concluded on behalf of the MoH, which is responsible for preparing project and its implementation.
6.2. Twinning
One long-term expert and a certain number of short-term experts will assist in project implementation:
Institutional beneficent – Ministry of Health, Office for Registration of Medical Devices, Medicinal Products and Biocides
Contact
Mr. Piotr Mierzejewski, Director, Department of Drugs' Management, Ministry of Health, 00-952 Warsaw, Miodowa 15 Str.; tel. +48 22 826 27 21, fax +48 22 831 43 54
6.3. Non-standard aspects
No non-standards contracts are envisaged under the project. The DIS manual will be strictly followed.
Twinning covenant is envisaged for the value of 900 000 Euro.

6.4. Contracts
1. twinning covenant – 900 000 Euro
2. investments – 1 100 000 Euro

7. Implementation schedule
1. Start of tendering – III/IV quarter 2002
2. Start of project activity – IV quarter 2002/I quarter 2003
3. Project completion – III/IV quarter 2004

8. Equal opportunity
The project will be open to both women and men, on the equal basis. The guarantee of equal opportunities for women and men is Polish Occupational Act, which excludes discrimination in the employment. Candidate suitability will be judged solely on merits, including professional experience.

11. Investment criteria: n.a.
12. Conditionality and sequencing
Conditionally
Project can be implemented on condition that Office for the Registration of Medical Devices, Medicinal Products and Biocides will start its activity in envisaged time.

- Improvement of activity of the Office for registration of medical devices, medicinal products and biocides – i.a. experts’ assessment;
- Maintenance of the market surveillance system (investments, database, safety equipment);
- Additional Training
- Actualization and publication of information materials
### Overall objective

Improvement of the surveillance system over medicinal products and of medicinal products’ registration.

### Objectively Verifiable Indicators

- Polish law within quality and safety standards of medicinal products fully harmonized with the relevant *acquis communautaire*

### Sources of Verification

- Ministry of Health;
- Competent Authority;
- Law’s situation analysis;
- Analyses of safety of use of medicinal products.

### Project purpose

- Strengthening of the surveillance system over medicinal products and of the registration through reinforcement of such activities as: conducting the proceedings for the authorization to place a medicinal product on the market, registration of medicinal products authorized for marketing, surveillance over the safety of use as well as registration of the notified adverse effects of medicinal products, and surveillance over the application of Good Clinical Practice. Further improvement of the pre-market measures on quality and safety standards of medicinal products.
- Cutting-down the time of registration process - from 12 months to 210 days.

### Objectively Verifiable Indicators

- System of market surveillance fully compliant with EU requirements.
- Relevant registers concerning medicinal products improved.
- Activity of the Office for Registration of Medical Devices, Medicinal Products and Biocides fully compliant with EU standards.
- Know – how transmitted in the frame of training.

### Sources of Verification

- Data of the Office for Registration’ Market Research;
- Reports of inspections from the unit of survey;
- Twinning activities – experts’ reports;
- Analyses of the Ministry of Health.

### Assumptions

- No delays in establishing the Office for Registration of Medical Devices, Medicinal Products and Biocides.

### Results/Outputs

- Relevant polish law, harmonized with *acquis communautaire*, implemented; Competent Authority - the Office for Registration of Medical Devices, Medicinal Products and Biocides - performing surveillance i.a. over medicinal products in compliance with EU standards; Period of time of medicinal products’ registration process cut - down from 12 months to 210 days; Staff of the Office for Registration of Medical Devices, Medical Products and Biocides additionally (according to actual requirements) trained; Qualifications of the health care institutions staff in the field of new legislation improved; Additional envisaged information materials - on modified surveillance procedures, control and clinical tests for medical staff and for healthcare institutions’ management staff actualized and published. Relevant materials - on new rules of functioning on the market for manufacturers - active on the market, on which standards of placing on the market are fully compatible with EU requirements - published. Upgraded

### Objectively Verifiable Indicators

- Office for Registration of Medical Devices, Medical Products and Biocides meets relevant EU standards.
- Effective activity of Office for Registration of Medical Devices, Medical Products and Biocides.
- Know – how transmitted in the frame of training.
- Improved qualifications of staff employed in the Office for Registration of Medical Devices, Medical Products and Biocides – compliant with EU similar institutions’ staff.
- Completion of planned complementary training.
- Period of time of medicinal products’ registration process cut - down from 12

### Sources of Verification

- Ministry of Health;
- Office for Registration;
- Project progress report;
- Twinsing activities – experts’ reports;
- Protocols of executed training;
- Information from addressees.

### Assumptions

- Effective co-operation among institutions and persons involved in the project implementation.
- Selection of suitable twinning partner to provide effective know-how transfer.
- Proper management and utilization of acquired know-how.
- No delays in establishing the Office for Registration of Medical Devices, Medicinal Products and Biocides.
relevant hardware, specialist software and data bases as well as maintenance and safety equipment related to all of mentioned hardware and software for Office for Registration of Medical Devices, Medicinal Products and Biocides provided, i.a. for the purposes of registers: in the field of medicinal products - Register of medicinal products authorized for marketing, Central Register of Clinical Tests, Record of the notified adverse effects; months to 210 days; Distribution of envisaged additional and actualized information materials Additional relevant equipment (hardware and specialist software and their safety equipment) for the Office for Registration of Medical Devices, Medicinal Products and Biocides provided.

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<tr>
<th>Activities</th>
<th>Means</th>
<th>Sources of Verification</th>
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<td>Twinning: Experts areas of activity: Assessment and verification of the responsibilities and organizational structure of the Office for Registration; Preparation of necessary adjustment programs in case of new requirements; Evaluation and participation in complementary training program; Monitoring and surveillance over adverse effects of medicinal products; Auditors of: GCP, GLP and surveillance over medicinal products. Evaluation and participation in training programs in the field of: new regulations, adverse effects, clinical tests for healthcare institutions staff; Provision of support for Polish experts at the central and regional level in the area of new standards; Co-operation in the field of specific issues in case of any difficulties or problems emerged during performance of activities by the Office for Registration of Medical Devices, Medicinal Products and Biocides.</td>
<td>Twinning covenant PAA and a number of short-term experts Relevant complementary training for staff. Publication of relevant information materials.</td>
<td>EU experts’ reports. Project progress report. Ministry of Health. Office for Registration Central and regional institutions involved in project implementation. Monitoring of modernized registration process.</td>
<td>Effective co-operation among institutions involved in the project implementation. No delays in establishing the Office for Registration of Medical Devices, Medicinal Products and Biocides. Providing of required co-financing</td>
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<td>Investments: necessary hardware and specialist software and safety equipment;</td>
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**Preconditions**

Office for Registration of Medical Devices, Medicinal Products and Biocides performing its statutory duties in envisaged time

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**ANNEX 2-3 Implementation, contracting and disbursement schedules**

**Date of drafting**: 08.2001

**Planning period**: 2002 - 2004

**Strengthening of the surveillance over medicinal products and of the registration system**

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<td><strong>Legend</strong>: D= design of sub-project; C= tendering and contracting;</td>
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2002/000-196.02.01 - Strengthening medicinal products surveillance and registration system – p.8