STANDARD SUMMARY PROJECT FICHE

1. Basic Information

1.1 Désirée Number: 2004/016-710.03.03

1.2 Title: Improving the quality of inspections regarding pharmaceutical, clinical trials and medical devices

1.3 Location: The Republic of Slovenia, Ministry of Health, Agency for Medicinal Products and Medical Devices

2. Objectives

2.1 Overall Objective(s): One of the critical areas of the Agency's mission is effective implementation of EU standards in the pharmaceutical and medical devices market control. This includes the control of clinical trials, production and distribution facilities under the procedures carried out by the pharmaceutical and medical devices inspectors. Appropriately functioning inspection services are a precondition for Agency's mission to protect public health. This cannot be achieved without concurrent development of IT support by regulatory databases upgrade and networking. Recent changes of EU legislation even more imply the growing importance of pharmaceutical inspection services. At the same time, regulatory networking among the national competent authorities and EMEA is becoming a means of priority. Furthermore, the specific structure and size of the Agency implies an advanced and effective use of IT facilities in order to compensate for the lack of manpower. Investment in the field is therefore directly connected with the fulfilment of this Agency's mission in the enlarged EU.

2.2 Project purpose:
- Technical Assistance Support to the Competent Authority for effective implementation of EU standards of pharmaceutical and medical devices market control and control of clinical trials including investment in the IT support of the Competent Authority.

2.3 Comprehensive Monitoring Report

Reference to the AP / Action plan: Chapter 4.1.1. Free movement of goods;
The Agency aims at reinforcing its administrative infrastructure, which will enable it to readily assume the obligations of membership in terms of ensuring the implementation of the EC standards and procedures in the area of public health protection.

2.4 Acquis Communautaire:

3. Description

3.1 Background and justification:

3.1.1. The Republic of Slovenia must ensure implementation of EU standards of pharmaceutical and medical devices market control and control of clinical trials. This implies sufficient number of highly skilled pharmaceutical, clinical trials and medical devices inspectors.

- Pharmaceutical inspection on Good Manufacturing Practice (GMP) and on Good Distribution Practice (GDP) needs the follow up training as it was stated at the end of previous Phare Program (see 3.2.).

- GCP inspection is a relatively new activity and is linked to the directive on Clinical trials (Directive 2001/20/EC of the European Parliament and the Council of 4. April 2001 on the approximation of the laws, regulations and administrative provisions of the member states relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use) which should be implemented in the EU by 1.5.2004, and its guidelines. GCP inspection would ensure control on implementation of EU GCP standards and co-operation with other GCP inspections in the EU.

- The establishment of the Agency for medicinal products and medical devices of the Republic of Slovenia has turned the competence for medical devices inspection to the Agency. We are therefore aware of the great significance of achieving the adequate professional support that would enable our staff to acquire the indispensable knowledge in this field. This area was not covered by any of previously approved Phare or linked programs or activities.

3.1.2. Implementation of EU standards of pharmaceutical and medical devices market control and control of clinical trials implies also the IT support that enables planning of inspection, monitoring of performed inspections, availability of inspection reports and decisions/enforcements and other linked documents necessary for data exchange and recognition of inspections between Slovenia and other EU Member States, other designated countries and enable data exchange with EMEA inspection database. It would reduce the number of inspections, save time and resources up to 20% and support work of local pharmaceutical industry. Participation of the Agency in the European authorization procedures will require its increased performance in a real-time situation along with other countries’ competent authorities. Its ability to communicate and interchange regulatory data with other competent authorities will greatly determine the success of the original application and thus the entry of medicines to the market. Functional databases, e-archives, document management and communication software will be the main kinds of software to be needed. The distributed model of work of this Agency will require that its current software platforms and data be extended under controlled access terms to the external experts. This Agency namely remains one of the smallest in the enlarged Europe and will need to rely on institutional experts form faculties and institutes to bring along the qualified decision. For those, ability to work form remote locations through a safe access to the Agency's data sources, is of utmost importance. For those, existing number of client licenses for document management software will need to be increased. With regard to database management and data mining, gradual transfer to paperless environment is needed. Fast-scanning facilities (50-100 pp/min) will enable the transfer of the data to electronic form and its effective usage, sharing and retrieving. To enable the 24hours-a-day/7days-a-week/365days-per-year alertness in pharmacovigilance, specialized computer faxes will need to be linked to mobile phones of designated management and pharmacovigilance staff which in turn, will
receive forwarded "info-faxes" on any location, and be able to get full access via the internet. Another important means of international communication is via teleconferencing, which again can be video, audio and textual, diminishing greatly the need to travel and its cost. Currently no such facility is available at this Agency. Substantial resources will be saved also through e-archiving using optical and solid-state data carriers.

The IT part of the Project's purpose is to extend the Agency's existing suboptimal information and communication system, which is currently represented principally by the Medicinal Products Database, by upgrading it and by establishing links with the following additional local databases which are equally suboptimal: database with central register of legal / natural persons / customers, database of urgently imported medicinal products and parallel imported medicinal products with all related documents, medical devices database to allow possibility for further supplementing of the network in order to meet due to new legal and scientific requirements. All these IT products critically need upgrading. Further, linking with international databases, which are being developed by the EU competent authorities, is becoming a priority task. EMEA has expressed the need to be able to exchange data (preferably in an automatic manner) with the databases of the national competent authorities. This task could not be successfully realized without the proposed IT upgrade. The purpose of the project is also to create the possibility of presenting certain publicly exportable parts of databases on relevant web-sides, to ensure transfer of specific data to the secondary information sources which are institutionally linked, to train staff to use new IT software and to train the ARSZMP staff, in the EMEA where all relevant regulatory databases on pharmaceuticals are installed and are being developed and constantly improved. For this purpose, the following IT products and tools are needed: database management system (DBMS) for relational databases and relevant (bespoke and standard) applications, based on SQL or equivalent; application products (bespoke and standard) and development tools for internal and external tracking of activities, networking and safe exchange of information with EMEA and other National Competent Authorities; Web application development software to support Agency's intranet, extranet and internet needs; electronic forms development software; XML support software; Project management software.

Agency's work is dependent on IT network and equipment, which would enable the fulfilling of its mission, both before and after the accession. IT represents the essential component of modern regulatory bodies. Regulatory decision to a large extent depends on the IT input and output, so many areas covered by the Agency's competence are initially dependent on its capability to function not only within internal system but also within the EU Drug Regulatory Authorities information exchange. Product and procedure linked IT support is inevitable in the pre-authorisation, authorisation and post-authorisation drug procedure, containing the large amount of technical information, which is either kept archived or appears in the form of publicly available database. Application tracking, assessment reporting, securing information for public (patient information leaflets) or for medical professionals, pharmacists, medical doctors (summary of product characteristics) are communication models in all EU Drug Regulatory Authorities. It also of course includes also internal communications in order to avoid unnecessary multiplications of workload and potential errors occurring due to repetition of data input.

In order to follow recent and future development of IT development successfully, the Agency urgently needs to update its IT infrastructure. Although the Agency started to invest at a very early stage in its IT support; due to an increased level of demands and current level of amortisation, the Agency needs the support for its successful operation. One should bear in mind the fact that pharmaceuticals are one of the most regulated areas in the acquis, including intensive and extensive information share as a prerequisite for the fulfilment of its mission. The EMEA is the European Evaluation Agency, central EU Agency for pharmaceuticals, where all relevant regulatory databases are installed.
and constantly improved and updated. Its work is in many areas connected and relies on efficient participation of national agencies e.g. in linguistic checking, in pharmacovigilance activities, in scientific text drafting etc, where good IT support is essential.

The Agency is facing problems concerning the fulfilment of its obligation regarding informing of professional and general public of all non-confidential data in the area of tested, authorised and imported medicinal products and registered medical devices, and IT communication with the stakeholders. Not least, the management and dissemination of information linked to pharmacovigilance may prove of huge benefit to public health in cases of increased risk management such as quality defects and adverse event cases. It is of utmost importance in such cases for the competent authority to have efficient communication channels with stakeholders.

Feasibility and sustainability of the IT requirements is in the case of this Agency determined by the fact that the infrastructure is developed in accordance to the standards of equipment, software and data security which are set by the central government service. It is the contracting that will provide necessary transparency to the choice of the person(s) to perform the task of building up the system. This Agency has, over a number of years, invested relatively large, albeit still insufficient resources in the development of IT, especially in the LAN hardware and systemic software\(^1\). Currently it finds itself in critical need for applications in the area of database management and web-based products such as application forms and procedure maps. Safe information exchange remains one of the higher priorities. Project that would include certification of the clients along with the lines of marketing authorization holders, wholesalers, manufacturers and detailists would enable them and the Agency safe exchange of data. The fact that EU is developing important regulatory projects such as EuroPharm Database, EudraVigilance, EudraCT\(^2\) which are databases of products, drug adverse effects and clinical trials, will bring about the need that national authorities provide for them appropriate means of contributing, exchanging or comparing the local data with the central network. The costs of the Project are comparable with costs of the previous Phare Project on Pharmaceutical Products and Project on Medicinal Products with the same number of man-days, level of experts and the amount of the IT input.

### 3.2 Linked activities:
- Phare Project Pharmaceuticals SL 9906.01/IB.01.4 helped implementing the acquis, improving the structure of GMP (Good Manufacturing Practice) and GDP (Good Distribution Practice) inspection in terms of setting standard operating procedures, performing basic training and 7d. study visits. The Project was very successful, but needed the follow up. In addition, Directive 2001/20/EC of the European Parliament and the Council of 4. April 2001 on the approximation of the laws, regulations and administrative provisions of the member states relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use will be implemented and inspection of investigational medicinal products should be separately covered.
- GMP (Good manufacturing Practice): Projects included training programme on Validation, GDP, Cleanroom Design and Building, Sterile products manufacturer, three GMP Training Inspection in Slovenia
- GDP (Good Distribution Practice): Project SL 9906.01/IB.01.4 included Training Course and Demonstrated Competence and one GDP Training Inspection.

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\(^1\) Ref.: The URL of the Internet publicly accessible medicinal products database BPZ http://www.zdravila.net
\(^2\) Ref: EMEA home page URL http://www.emea.eu.int
Phare Project Medical Devices SL 9906.01/IB.01.3 helped implementing the acquis, setting up the administrative structure for performing activities of the competent authority, but the Project was not linked to medical devices inspection, which came under the Agency’s competence from February 18, 2004. Transfer of competences for inspection of medical devices has occurred in February 2004 from the Health Inspectorate of the Republic of Slovenia (ZIRS) to ARSZMP.

The main purpose of this project was to compare Slovenian regulations for medical devices with the relevant EU Directives. This comparison has led to amendments to the Slovenian Regulation on medical devices and to the issue of the Regulation on in vitro diagnostic medical devices. The professional support provided by the experts involved in the project enabled the Agency’s staff not only to harmonize the relevant regulations with the EC Directives but also to get an insight into the other duties of a competent authority and to better plan the future activities they will be involved in. However this project provided no support within the framework of inspections in the field of medical devices. The establishment of the Agency for medicinal products and medical devices of the Republic of Slovenia has turned this competence to our Agency. We are therefore aware of the great significance of achieving the adequate professional support that would enable our staff to acquire the indispensable knowledge in this field.

Phare FM’00 Pharmaceutical Products - SI0003.01 in the procedure - electronic file submission and archiving and pharmacovigilance and clinical trials database facilitating safe data exchange with the EU Competent Authorities. The software, which we received through the project, enabled electronic file submission for different areas of work. This is quite important as the Agency is receiving huge amount of paper documentation. The software offers useful tool for reviewing the documentation. Another important thing is system for archiving and looking for documents. This enables quick searching for all documents regarding particular item.

It’s important to encourage the customers to send electronic files instead of paper ones. But for electronic files the structure must be well defined: industry is increasingly announcing their readiness to supply electronic dossiers, and the Agency now has above-mentioned tools to evaluate them in internal procedures. However, the transfer of particular data relating to the products into the local database, which is turn reflected to other agencies in EU and to the professional and general public, remains to be a problem due to the fact that the internal medicinal product database is outdated.

3.3 Results:
- strengthening of GMP/GDP inspection
- setting up the GCP inspection
- strengthening of medical devices inspection
- IT support: Functional Agency’s IT network

Verifiable criteria:

- saving time and resources ca 20% in the area of GMP/GDP inspection
- established GCP inspection in order to inspect approx. 10 clinical trials per year
- well trained GMP, GDP, GCP and medical devices inspectors
- IT support should save time and human resources up to an estimated 20% on the basis of:
• upgraded existing software
• installed new software
• installed network between databases
• trained staff

Anticipated means:
• Medicinal Products database upgrading:
• Tools to exchange data with EMEA and other national competent authorities
• Urgent import and parallel import of Medicinal Products
• Legal/natural persons database
• Medical devices database
• Increased presence of the Agency and its user services through the Web
• installing the network among all databases
• training the staff
• first 3 years of maintenance and additional upgrading.

3.4 Activities:

The project should be carried out in the framework of Technical Assistance Arrangement, which should help strengthening of pharmaceutical and medical devices inspection and IT support. The funds would be used for staff training performed in the Agency for medicinal Products and in Member States Inspection Authorities and for the creating of specified software needs as IT support. In the framework of the Project, the following activities will be carried out:

1. advising the Agency for medicinal Products on setting the GCP inspection and strengthening GMP/GDP and medical devices inspection
2. creating of specified software needs as IT support
3. Train professional staff of the Agency
4. study visits to Member States Inspection Authorities, preferably in the UK, Germany or Denmark: -GMP/GDP inspection: 1 x 6day visit for 4 person
5. GMP/GDP: Cooperation in GMP/GDP Inspections in EU as observers for general GMP Inspection, Product Specific Inspection - Biotechnology, Blood Products, Vaccines, Radiopharmaceuticals, API’s and sterile production, discussion on implementation of newly issued EU legislation and practical problems.
6. -GCP inspection: 1 x 6day visit for 1 person
7. -medical devices inspection: 1x 6days visit for 2 person

2. IT: Investment in the development of software: upgrading of the existing medicinal products database, creating additional databases on urgently imported medicinal products and parallel imported medicinal products with all related documents, medical devices database and establishing the network of all databases, enabling possibility in order to meet for further supplementing of the network due to new legal and scientific requirements, allowing enabling the possibility for presenting certain publicly exportable parts of databases on relevant web-sites, to ensure transfer of specific data to the secondary information sources which are institutionally linked, in order to create central register of legal / natural persons / customers. The software solutions should encompass web-based applications for local intranet and safe internet access, database management tools to enable compilation and maintenance of relational databases, submission of information via electronic forms and transfer of non-confidential product information to secondary databases. Document management system currently in place at the Agency needs to be expanded and linked with the governmental document classification system, which is based on Lotus Notes.
Training activities for developed systems and training in the EMEA, where all EU relevant databases on pharmaceuticals are installed and are permanently improved and updated. IT activities at the EMEA will require training of users and of project managers in order to achieve their purpose. EMEA is undergoing an intensive phase of preparations for the EU enlargement including the accommodation means for the delegates from new Member States both at the London facilities and also from the remote locations where they work throughout Europe. The increasing number of medicinal products that will be processed in the centralized EU procedure will require efficient communication with national Agencies. One of the permanent modes of communication will become the checks of linguistic consistency and correctness within so-called QRD (Quality Review of Documents) service. Better exchange in the regulatory field can be supplemented by the exchange of information in the pharmaceutical inspection area, where local agencies are charged with the mission to control the accordance to the acquis of all the corporate entities established and operating on their territory: manufacturers, wholesalers and sometimes detailists. Exchange of assessment reports, inspection reports and other confidential documents will strengthen the efficiency of European regulatory network and will add to its global leadership role. I will also add to the expected transparency of their decisions and to the improved levels of their information service for the professional and general public. Investing in the infrastructure of local Agencies can contribute substantially to the achievement of that goal.

Precise list of needed software.
1.) Database management system (DBMS) for relational databases and relevant (bespoke and standard) applications, based on SQL or equivalent
2.) Application products (bespoke and standard) and development tools for internal and external tracking of activities, networking, and safe exchange of information with EMEA and other National Competent Authorities
2.) Web application development software to support Agency’s intranet, extranet and internet needs
3.) Electronic forms development software
4.) XML support software
5.) Project management software

3.5 Lessons learned:

Experience in Member States shows the increasing importance of the possibilities to exchange inspection services deliverables such as GMP, GDP, GCP inspection reports and other document in order to save time and resources and to enable the pharmaceutical industry faster access to the markets. The IT component plays a crucial role in fulfilling of the mission of EU competent authorities for medicinal products and medical devices. Strengthening of GMP, GDP, GCP and medical devices inspection in Member States reduces number of inspection because of mutual recognition of inspections.

4. Institutional Framework

- The Project would be implemented in the Agency for medicinal Products, as the beneficiary institution.
- The Agency aims at reinforcing its administrative infrastructure, which will improve its capacity to readily assume the obligations of membership in terms of ensuring the implementation of the EC standards and procedures in the area of public health protection.
5. Detailed Budget (in MIO EUR)

<table>
<thead>
<tr>
<th>TF Support</th>
<th>Support</th>
<th>Total TF (I+IB)</th>
<th>National Cofinancing*</th>
<th>IFI*</th>
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* All the amounts in the table above are indicated net of VAT. National co-financing of 25% will cover the cost of providing adequately equipped office for short term experts by the amount requested by TF rules. The ratio between the Transition Facility and national amount is binding and has to be applied to the final contract price.

6. Implementation Arrangements

6.1 Implementing Agency:

Implementing Agency:
CFCU, Ministry of Finance
Beethovnova 11
SI – 1000 Ljubljana, Slovenia

Responsible person:
Mr. Peter Škofič, PAO
Tel: +386 1 478 69 94
Fax: +386 1 478 62 04
E-mail: peter.skofic@mf-rs.si

Implementing Authority

Ministry of Health, Agency for Medicinal Products
Director: prof Stanislav Primožič
Address: Kersnikova 2, 1000 Ljubljana
Tel: +386 1 478 62 41,
Fax: +386 1 478 62 60,
E-mail: stanislav.primozic@gov.si

Beneficiary Institution:
6.2 Technical assistance + investment

6.3 Non-standard aspects

6.4 Contracts

Technical assistance is required as follows:
- duration of the project: 12 month
- PAA GMP/GDP inspection (60 man days): short-term expert responsible for providing the follow up of the Phare project Pharmaceuticals SL 9906.01/IB.01.4.
- PAA medical devices inspection: (60 man days) short term expert responsible for providing advising and training in the area of medical devices inspection
- PAA clinical trials inspection: (60 man days) short term expert responsible for providing advising and training in the area of GCP inspection
- study visit (6 x 7 days) of EU Member States Inspection Authorities

investments: IT -software: upgrading of the existing medicinal products database, creating additional databases on urgently imported medicinal products and parallel imported medicinal products with all related documents, medical devices database and establishing the network of all databases, enabling possibility in order to meet for further supplementing of the network due to new legal and scientific requirements, allowing enabling the possibility for presenting certain publicly exportable parts of databases on relevant web-sites, to ensure transfer of specific data to the secondary information sources which are institutionally linked, in order to create central register of legal / natural persons / customers. The software solutions should encompass web-based applications for local intranet and safe internet access, database management tools to enable compilation and maintenance of relational databases, submission of information via electronic forms and transfer of non-confidential product information to secondary databases. Document management system currently in place at the Agency needs to be expanded and linked with the governmental document classification system, which is based on Lotus Notes.

7. Implementation Schedule

7.1 Start of tendering/call for proposals
- call for proposals 3rd quarter 2004

7.2 Start of project activity
- start of project activity 4th quarter of 2004

7.3 Project Completion
- project completion 4th quarter of 2005

Equal opportunities policy will be fully respected in the selection of experts

9. Environment
No environmental effects

10. Rates of return

11. Investment criteria

11.1 Cofinancing:
National co-financing will cover the cost of providing adequately equipped office for PAA short-term experts

11.2 Additionality:
Project readiness and Size: acquis adopted, reinforcing of Agency's administrative infrastructure, which will improve its capacity to readily assume the obligations of membership in terms of ensuring the implementation of the EC standards and procedures in the area of public health protection.

12. Conditionality and sequencing
ANNEXES TO PROJECT FICHE : TO BE SUBMITTED LATER

1. Logical framework matrix in standard format (compulsory)
2. Detailed implementation chart (compulsory)
3. Contracting and disbursement schedule by quarter for full duration of programme (including disbursement period) (compulsory)
## Annex 1: TF log frame

<table>
<thead>
<tr>
<th>LOGFRAME PLANNING MATRIX FOR Project</th>
<th>Programme name and number</th>
<th>Date of drafting March 2004</th>
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<td>Improving the quality of inspections regarding the pharmaceutical, clinical trials and medical devices</td>
<td>Contracting period expires 31/12/2006</td>
<td>Disbursement period expires 31/12/2007</td>
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<td>Total budget: 0.39 MIO €</td>
<td>TF budget: 0.34 MIO €</td>
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<table>
<thead>
<tr>
<th>Overall objective</th>
<th>Objectively verifiable indicators</th>
<th>Sources of Verification</th>
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<tbody>
<tr>
<td>Support to the Competent Authority for effective implementation of EU standards of pharmaceutical and medical devices market control and control of clinical trials</td>
<td>- By the end of the project: sufficient number of highly skilled pharmaceutical, clinical trials and medical devices inspectors that enable data exchange and recognition of inspections between Slovenia and other EU Member States and other designated countries; - Consequent reduction of the number of inspections and support work of local pharmaceutical industry.</td>
<td>Comprehensive Monitoring Report Reference to the AP / Action plan: Chapter 4.1.1. Free movement of goods; Evaluation and monitoring reports for the Joint Monitoring committee</td>
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<tr>
<td>Project purpose</td>
<td>Objectively verifiable indicators</td>
<td>Sources of Verification</td>
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<tr>
<td>• Support to the Competent Authority for effective implementation of EU standards of pharmaceutical and medical devices market control and control of clinical trials and Implementation of the 2001/83/EC, 2000/20/EC and 93/42/EEC directives</td>
<td>As above</td>
<td>Commission regular reports and reports for the Joint Monitoring reports Number of inspection Number of recognized inspection Enforced Clinical trials Inspection Information exchange with the CAs</td>
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<table>
<thead>
<tr>
<th>Results</th>
<th>Objectively verifiable indicators</th>
<th>Sources of Verification</th>
<th>Assumptions</th>
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<td>-Strengthening of GMP/GDP inspection</td>
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<td>-Strengthening of medical devices inspection</td>
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<td>-Increased number of recognized inspections</td>
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<td>-Reduced number of inspections</td>
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<td>-Setting up the GCP inspection</td>
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<td>-IT upgrade and networking for implementing the EU standards</td>
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<td>Activities</td>
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| - advising the Agency for medicinal Products on setting the GCP inspection and strengthening GMP/GDP and medical devices inspection  
- Train professional staff of the Agency  
- study visits to Member States Inspection Authorities, preferably in the UK, Germany or Denmark.  
- IT Upgraging and Networking for implementing the EU standards | Technical Assistance | - The Project would be implemented in the Agency for medicinal Products, as the beneficiary institution.  
- The Agency aims at reinforcing its administrative infrastructure, which will improve its capacity to readily assume the obligations of membership in terms of ensuring the implementation of the EC standards and procedures in the area of public health protection. |

**Preconditions**

Availability of needed individual short term experts, supplies and services and/or of important Slovene participants-members of the Slovene working group
Annex 2: Implementation time chart

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Annex 3: Contracting schedule (sheet 1)

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</tbody>
</table>

NB: all contracting should normally be completed within 6-12 months and must be completed within 24 months of signature of FM
Annex 3: Disbursement schedule (sheet 2)

### CUMULATIVE DISBURSEMENT SCHEDULE (EUR million)

<table>
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<tr>
<th>Date</th>
<th>3/31/04</th>
<th>6/30/04</th>
<th>9/30/04</th>
<th>12/31/04</th>
<th>3/31/05</th>
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<th>3/31/06</th>
<th>6/30/06</th>
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<th>12/31/06</th>
<th>3/31/07</th>
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</table>

NB all disbursements must be completed within 36 months of signature of the FM
Annex 3: Contracting and disbursement schedule (sheet 3)

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<th>12/31/04</th>
<th>3/31/05</th>
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</tr>
</tbody>
</table>

NB: 1. all contracting should normally be completed within 6-12 months and must be completed within 24 months of signature of FM
2. all disbursements must be completed within 36 months of signature of the FM