STANDARD SUMMARY PROJECT FICHE

1. **BASIC INFORMATION**

   6.4 Désirée Number: SI0003.01
   1.2 Title: Free Movement of Goods
   1.3 Sector: *Internal Market* (Twinning no. SI 2000/IB/FI-01)
   1.4 Location: Slovenia

2. **OBJECTIVES**

   2.1 **WIDER OBJECTIVE(S):**
   The wider objective is to enforce the horizontal and sector specific legislation as well as to strengthen the institutions for the implementation of the acquis and to fulfil the requirements for participation in the EU Internal Market.

   2.2 **IMMEDIATE OBJECTIVE:**

   **A. Horizontal Activities**
   
   A.1 Market Surveillance
   The objective is to improve the functioning of the Market Surveillance authorities in Slovenia.

   A.2 Standardisation
   The objective is to strengthen the information and terminology management on European standards supporting technical regulation.

   **B. Sector Specific Activities**
   
   B.1 Conformity Assessment Bodies
   The objective is to provide the Ministry of Economic Relations and Development (MoERD) with the relevant information on the competence of potential notified bodies and other conformity assessment bodies in particular fields that are intended to be included in PECA.

   B.2 Pharmaceutical products
   The objective is to strengthen the functioning of the Agency for Medicinal Products and shorten the period needed for a new drug submission.

   **C. Alignment and Implementation of Technical Legislation for Industrial Products on Company Level**
   The objective is to proceed with the implementation of technical legislation on industrial products, related to “new approach” directives, at company level in SMEs.

   2.3 **Accession Partnership and NPAA priority**
   *Short term priorities:* Internal market - Free movement of goods - enforce framework legislation; start transposition of New Approach directives and proceed with alignment of technical legislation;
   *Medium term priorities:* Internal market - Free movement of goods - complete adoption of sectoral legislation and alignment of EN standards; ensure proper implementing structures for all sectors, establish a market surveillance system.
3. DESCRIPTION

3.1. BACKGROUND AND JUSTIFICATION:

A. Horizontal activities

A.1 Market surveillance
The relevant authorities in Slovenia have been carrying out market surveillance in accordance with the existing legislation and related to particular technical regulation, which, mostly, has not been harmonised with the relevant Community acts yet. In a new legislation, which transposes a relevant Community act, the relevant market surveillance authority shall be defined.

Some studies on the capabilities of the market surveillance authorities in Slovenia have been carried out in the past: "Evaluation of Market Surveillance Systems" (PRAQ III - Regional Programme on Quality Assurance; WP: TR07; July 1998) and "Short term advice on the organisation of Market Surveillance in Slovenia" (PRAQ III - Regional Programme on Quality Assurance; FAST; December 1999).

These two studies indicate the needs for improvements in the field of market surveillance. Better co-operation between market surveillance authorities and other parties involved in the implementation of a particular directive (legislators, enterprises, conformity assessment bodies) has to be established. Slovenia estimates that with such an improved co-ordination the possible overlapping between actions carried out by different market surveillance authorities could be avoided.

The effective co-operation with customs is necessary (imports from third countries) in order to avoid placing those products on the market which have been recognised as not conform to the requirements.

The system for gathering the information concerning products which have not fulfilled the technical regulations’ requirements should be established. This should include a study on the possible software supporting the exchange of the relevant information on the national and European level.

A.2. Standardisation
All standardisation activities necessary to implement the European standards on the national level are already being carried out. However, terminology management should be improved in this field. Therefore the appropriate software shall be developed, enabling the user to extract, collect, store and publish terminology. The needed terminological database (a glossary) will be adapted to Slovenian users and will be available on the internet application.

Interlinkage between Slovenian Standards Body and governmental bodies (in particular with Governmental Office of the European Affairs) shall be made possible as well as better communication links with the European Standards bodies CEN, CENELEC and ETSI.
Moreover, in order to improve information for Slovenian enterprises on standards which have to be taken into account in the international trade, software interlinking different standard databases (CEN, CENELEC, ETSI, DIN) shall be developed.

B. Sector Specific Activities

B.1 Conformity Assessment Bodies
In Slovenia a number of conformity assessment bodies exist, mostly dealing with the tasks related to the national technical regulation which is not yet harmonised with the Community one. Some of them have already expressed their intention to take part in the conformity assessment procedures related to some “new” and “old” approach directives. There is a need for an “external” assessment since the Slovenian authorities have no experience in assessing the competence of such a body. According to the Slovenian legislation a national accreditation body is a body which has to be involved in the relevant assessment procedures. Therefore the involvement of the representatives of that body as well as the representatives of the authority responsible for metrology is envisaged in the assessments where relevant.

The bodies assessed shall be those which expressed their interest to take part in the sectors envisaged to be covered by the particular “PECA” directives.

B.2 Pharmaceutical Products
The Agency for Medicinal Products carries out a new drug submission in a traditional (paper) way. This takes a lot of time and needs a lot of space for archiving the documentation. The exchange of the relevant information with other Drug Regulatory Agencies in the EU Member States is not efficient enough.

To improve the work and to be able to follow the practices and needs in this particular area in the Internal Market some investments and investment related training for the Agency is needed.

DAMOS (Drug Application Methodology and Optical Storage) is a widely used successful international standard for an electronic new drug submission and specifies the format and the structure of the electronic dossier. It is accepted word-wide in many drug regulatory agencies which are using compliant software. It serves as an electronic submission-reviewing tool for the regulatory agencies (i.e. Pharmbridge) with a number of reviewer specific functionality's which allows faster and higher quality work. It enables an electronic archiving system which allows long term data security (100 years and more) and easy conversion to a new future media. Archived documents can be viewed, copied, deleted, updated, scanned and secured. The same basis is also used for clinical trial documentation. It serves as an electronic basis for pharmacovigilance data exchange with the EU database which is extremely important for the protection of public health.

C. Alignment and Implementation of Technical Legislation for Industrial Products on Company Level
An important part of the integration of the Slovene companies in the Internal Market is upgrading the Slovene industry to meet the EU requirements. SMEs are not aware of the requirements and their responsibilities related to the acquis.

With the proposed project, at least 200 companies will be included in the awareness raising activities and 40 will be assisted in making progress towards preparedness for the
implementation of the relevant Community technical legislation. The project is designed for small and medium sized industrial companies that are financially stable. It shall assist the selected companies with the implementation of technical legislation in the following areas: electro-technology: EMC (89/336/EEC), LVD (73/23/EEC), ATEX (94/9/EC), machinery (98/37/EC), CPD (89/106/EEC), simple pressure vessels (87/404/EEC) and pressure equipment (97/23/EC), lifts (95/16/EC, 84/528/EEC, 84/529/EEC), gas appliances (90/396/EEC), gas cylinders (84/525/EEC, 84/526/EEC, 84/527/EEC) and personal protective equipment (89/686/EEC).

The selection of the companies within the proposed project will be mainly based upon the criteria such as the level of the alignment of the sector specific legislation and the possible inclusion of the sector in a future PECA agreement. On a secondary level the enterprises in the three target regions for social and economic cohesion Zasavje, Savinjska and Pomurje should be given priority.

Special attention shall be paid to the explanation of the harmonised standards related to the particular directive and/or product. A participation of the representative from the relevant technical committee of the national standard body is envisaged. This shall help to get a relevant knowledge for the correct interpretation of the “essential requirements” translated by standards.

3.2 LINKED ACTIVITIES:

In Slovenia PHARE support in the area of the Free Movement of Goods has so far focused on helping with the establishment of the necessary hardware, testing equipment etc. Significant investments have been made in such equipment over the past years (COP96/COP97). FM 99 started focusing on setting up the necessary institutional framework for the implementation of the "new" approach directives on the Free Movement of Goods and the implementation of the necessary horizontal as well as sector specific legislation. The PHARE project “Horizontal Framework Legislation and Institutional Infrastructure” (SI99/03.01) is scheduled to start in May 2000. The aim is to assist the Republic of Slovenia to adequately regulate the elements relevant to ensuring the Free Movement of Goods. Since this legislation is complex and essential for the enforcement of the internal market rules and effective participation of Slovenia in the single EU market it is necessary to continue with the assistance in the field of the Internal Market. There will be no overlapping with the proposed project since either focus will be on other fields of the Internal Market, or the proposed project will constitute a logical continuation.

One of the beneficiary sectors under FM 99 is the pharmaceutical sector (SI99/03.02.04) with the main objective to develop and implement integrated and harmonised legislation in this particular field and to harmonise all the procedures in order to strengthen the Agency for Medicinal Products to meet EU standards. The project is scheduled to start in autumn 2000. There is no overlapping with the proposed project since the focus of the proposed project is to shorten the period needed for a new drug submission and improve the data exchange with the EU databases.

In the field of Implementation of Technical Legislation Slovenia has been participating in a PHARE project Legislation, Regulation and Enforcement Programme-SI9602, run by Deutsche Stiftung (Office for Legislation). This project aimed to prepare the legal framework
for the implementation of Technical Legislation. Assistance has been also provided through PHARE PRAQ III Programme and TAIEX training.
The project “Alignment and Implementation of Technical Legislation for Industrial Products at Company Level” is a continuation of the technical assistance provided by the Phare 1997 project “Implementation of technical legislation on company level” which will be concluded by the end of October 2000. The Phare 1997 project results will serve as a basis for further elaboration of the proposed project on the ‘Alignment and Implementation of Technical Legislation for Industrial Products’ at company level. Under Phare COP 96 two more projects have been financed: “Organisation and methodology of harmonisation of technical regulation in Slovenia” and “Translation of EU legislation on industrial policy and internal market”.

In 2000, a project "EU Internal Market Conferences" financed from the Small Projects Programme will be implemented within the Chamber of Commerce and Industry. This project will focus on the organisation of seminars in the fields of "the organisation and working of the Internal Market", "environmental protection policy" and "finding a business partner in the EU". The final beneficiaries will be large companies from the agriculture, trade, electro, chemicals, textile and metal industry. The currently proposed project will focus on the needs and the problems of the SMEs and has thus a different target group.

3.3 RESULTS:

A. Horizontal Activities

A.1 Market Surveillance
A transparent well functioning and co-ordinated market surveillance system will be established. An assessment report on the functioning of the responsible authorities in different fields will be prepared which will reflect the possibility of Slovenia to enforce the technical regulations and will serve as the basis for a functional co-ordination system for market surveillance authorities. The potential needs for improving the market surveillance system will be defined. The basis for further monitoring and functioning of the market surveillance authorities and the basis for an operational information system will be prepared. The training needs analysis shall be prepared, the training programme shall be finalised and the staff shall be trained.

A.2 Standardisation
Software equipment shall be developed and installed. The staff shall be trained accordingly. This will enable more active participation of the Slovenian Standards Institute in the European standardisation work and will improve trade facilities for Slovenian enterprises.

B. Sector Specific Activities

B.1 Conformity Assessment Bodies
A report on the competence of the potential conformity assessment bodies for the particular work in a specific regulated area (notified and/or competent bodies) will be prepared. The training needs analysis and the analysis on the equipment needed will be prepared. The training programme will be prepared and the staff will be trained.
B. 2 Pharmaceutical products
The international standards for a new drug submission will be implemented. The period needed for a new drug submission will be shortened. Long-term data security and the protection of public health will be improved. Staff shall be trained.

C. Alignment and Implementation of Technical Legislation for Industrial Products on Company Level

The project will result in the implemented harmonised national legislation on company level (in approx. 40 companies/SMEs). Technical awareness in Slovene industry on the requirements posed by the newly harmonised legislation and related standards will be raised. The relevant know-how in Slovene SMEs will be improved. A programme for each SME on the implementation of technical legislation, with an investment plan, shall be prepared.

3.4 ACTIVITIES:

A. Horizontal Activities
A.1 Market Surveillance
- to assist in the preparation of the organisational scheme on the co-ordination of market surveillance authorities including the co-operation with customs
- to organise training (workshops, on-the job training in Slovenia and in Member States, study tours) related to the provisions of, in particular NAWI and ATEX directives, directives on toys, lifts, recreational crafts and pre-packed products
- to prepare a proposal for an information system on products which are not in conformity with the regulations’ requirements

A.2. Standardisation
- development and installation of the software for the standardised terminology and for the terminology database which will include a genuine glossary (explanatory dictionary) based on the existing terminology used by CEN, CENELEC, ETSI and ISO
- development and installation of the software for database which will enable searching and extracting the information concerning available national, European and international standards
- training of staff and training of trainers in the use of the above mentioned software

B. Sector Specific Activities
B.1. Conformity Assessment Bodies
- to prepare an assessment on the competence of the potential notified and/or competent bodies which will deal with the particular part of the conformity assessment procedure related to the specific directive and the report on the result of the assessment
- to prepare the training needs analysis and the training programme
- to train staff
- to estimate the measurement capabilities and measurement traceability (including the needs for the national standards in the particular sectors)

B.2. Pharmaceutical products
- installation of DAMOS software
- to train staff
C. Alignment and Implementation of Technical Legislation for Industrial Products on Company Level

- organisation of 8 (eight) awareness raising seminars for at least 200 industrial companies - four for the management and four for the technical staff (at the beginning and at the end of the project)
- in-company advise on the implementation of technical regulations for 40 SMEs (this will include the analysis of present status concerning applicability and implementation of relevant technical regulations, preparation of a programme on the implementation of technical regulations, assistance in the implementation of technical regulations and in the preparation of a technical file with workshops, training of employees, advise on other aspects related to the implementation of technical regulations and subsequent norms and advise on investments needed for further implementation)

4. Institutional Framework

The Ministry of Economic Relations and Development (MoERD) has the overall responsibility for the internal market and Free Movement of Goods and will take the overall co-ordination of the project.

A Management Committee Meeting for the project will be held every two months, where the representatives from the MoERD, the Ministry of Economic Affairs, the Ministry for Small Business and Tourism, the Ministry for Environment and Spatial Planning, the Ministry for Transport and Telecommunications, the Ministry for Labour, Family and Social Affairs, the Ministry of Science and Technology - Standards and Metrology Institute, the Government Office for Legislation and the Delegation (as observer) will be present.

5. Detailed Budget in MEUR

<table>
<thead>
<tr>
<th>Phare</th>
<th>Support</th>
<th>Total Phare (=I+IB)</th>
<th>National Cofinancing</th>
<th>IFI*</th>
<th>TOTAL</th>
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<tbody>
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<td>A. Horizontal Framework Legislation</td>
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<td>B. Sector Specific Legislation</td>
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<td>Pharmaceutical Products</td>
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<td>C. Implementation of Technical Legislation</td>
<td>0.50</td>
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<td>Total</td>
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<td>1.80</td>
<td>0.55</td>
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</table>

*In cases of co-financing only

6. Implementation Arrangements

6.1 Implementing Agency

The overall co-ordination is under the Ministry of Economic Relations and Development (MoERD). The contact person is Mr Anton Grabeljšek, State Secretary for Internal Market, tel. ++ 386 1 478 3600, fax. ++ 386 1 478 3588, e-mail: anton.grabeljsek@gov.si.

Tendering and contracting shall be carried out by the CFCU in the Ministry of Finance. The
contact person is Mr. Peter Skofic, Head of CFCU, tel. ++386-1-1786305, fax. ++386-1-1786204, e-mail: peter.skofic@mfi.sigov.mail.si. The tendering and contracting of the projects components shall follow standard DIS procedures where applicable, including the twinning manual.

A. Horizontal Activities

A.1 Market Surveillance
The implementing agency is the Ministry of Economic Relations and Development, Kotnikova 5, Ljubljana, Slovenia. The contact person is Ms Vinka Soljacic, Counsellor to the Government, Tel. ++ 386 1 478 35 04, Fax. ++ 386 1 478 3588, e-mail: vinka.soljacic@gov.si.

All relevant market surveillance authorities responsible for the particular kind of product will be included in the project.

A.2 Standardisation
The implementing agency is the Standards and Metrology Institute within the Ministry of Science and Technology, Kotnikova 6, Ljubljana, Slovenia. (In the near future the Slovenian Standards Body will be an independent agency. This body is expected to be fully operation by the end of 2000.) The contact person is Ms Marjetka Strle-Vidali, Assistant to the Director, Tel. ++386 1 478 3114, Fax. ++ 386 1 478 3196, e-mail: marjetka@usm.mzt.si.

B. Sector Specific Legislation

B.1 Conformity Assessment Bodies
The implementing agency is the Ministry of Economic Relations and Development, Kotnikova 5, Ljubljana, Slovenia. The contact person is Ms Vinka Soljacic, Counsellor to the Government, Tel. ++ 386 1 478 3504, Fax. ++ 386 1 478 3588, e-mail: vinka.soljacic@gov.si.

The national accreditation body, the authority responsible for metrology and the ministries responsible for the relevant particular technical regulation will be included in the project.

B.2 Pharmaceutical products
The implementing agency is the Agency for Medicinal Products within the Ministry of Health, Kersnikova 2, Ljubljana, Slovenia. The contact person is Ms Vesna Koblar, Counsellor to the Government, Tel. ++ 386 1 473 6559, Fax. ++ 386 1 473 6607, e-mail: vesna.koblar@gov.si.

Although the Agency for Medicinal Products is operating within the Ministry of Health of the Republic of Slovenia, it acts as an independent institution. The scope of activities performed by the Agency is determined by the Medicinal Products Act, the Act on the Ministries' Organisation and Activities, and by other regulations adopted by the National Assembly, the Government of Slovenia and the Minister of Health. In performing its duties the Agency cooperates with other administrative bodies, university institutions, institutes and public institutes.
C. Alignment and Implementation of Technical Legislation for Industrial Products at Company Level

The implementing agency is the Ministry of Economic Affairs, Kotnikova 5, Ljubljana, Ljubljana. The contact person is Ms Staša Baloh-Plahutnik, State under-secretary, Tel. ++386 1 478 3260, Fax. ++ 386 1 478 3238, e-mail: stasa.baloh-plahutnik@gov.si.

The project will be carried out within the Chamber for Commerce and Industry, an independent, non-governmental institution which will act as a host organisation. There will be approx. 40 SMEs involved in the in-company part of project implementation.

6.2 TWinning

There will be one twinning covenant in the total amount of MEUR 1,2. The contracting authority will be the Ministry of Economic Relations and Development.

Three experts are needed for the projects "Market Surveillance" and "Conformity Assessment Bodies". One LT PAA (24 months) and 2 (two) short term experts (each 9 months). Additional 20 man-months of ST expertise is needed. All experts will have extensive experience in the market surveillance and conformity assessment fields. The experts must have experience inside their national administration or inside the EU.

LT PAA must have an advanced university degree in Engineering, Law, Economy, Business or Public Administration, senior experience in the national or European administration dealing with all aspects of market surveillance and conformity assessment, good communication skills and good written skills in English.

Two short term experts (each 9 months) will have the same profile as the LT PAA, emphasis will be put on training skills, know how in information technology, one will have special expertise in the field of market surveillance, and the other will have special expertise in the field of conformity assessment.

6.3 NON-STANDARD ASPECTS

There will be one supply contract in the amount of MEUR 0,2 for the sub-component of the project - "Pharmaceutical Products". The equipment is of EU origin. It will be procured through a direct agreement without informal consultation in a view of the fact that one single supplier exists for this software. The contracting authority for the sub-component of the project - "Pharmaceutical Products" will be the Agency for Medicinal Products within the Ministry of Health. The owner of the software will become the Agency for Medicinal Products.

6.4 CONTRACTS

In addition to the twinning covenant (€ 1.2 million) and the above mentioned supply contract (€ 0.2 million) there will be two service contracts for the projects "Standardisation" (in the amount of MEUR 0,1) and "Alignment and Implementation of Technical Legislation for Industrial Products on Company Level" (in the amount of MEUR 0,5). The contracting authority for the project "Standardisation" will be the Standards and Metrology Institute. The contracting authority for the project "Alignment and Implementation of Technical Legislation for Industrial Products on Company Level" will be the Ministry of Economic Affairs.
7. IMPLEMENTATION SCHEDULE

ToRs and project specifications with technical specifications will be ready by the end of 2000.

7.2 Start of project activity: June 2001

7.3 Project Completion: June 2003.

8. EQUAL OPPORTUNITY
Participation in this programme, both by Government Employees or other types of personnel, contracted by the Government, will be open to both males and females involved in the sector. Records of staff participating in training and other project related activities will reflect this.

9. ENVIRONMENT: Not relevant.

10. RATES OF RETURN: Not relevant.

11. INVESTMENT CRITERIA
11.1 Catalytic effect: The objective of the project is the alignment and implementation of, above all, New Approach Directives which is a short and medium accession priority stressed both in NPAA and Accession Partnership.

11.2 Cofinancing: The project will be cofinanced by national sources.

11.3 Additionality: Not applicable.

11.4 Project readiness and Size: All necessary technical studies will be completed by the end 2000/beginning 2001.

11.5 Sustainability: The project supports the implementation of the Community acquis and will result in an established implementation structure which will help beneficiaries with future maintenance of the implementation process.

11.5 Compliance with state aids provisions: Not relevant.

11.7 Contribution to National Development Plan: Not relevant.

12. CONDITIONALITY AND SEQUENCING
• A pre-condition for the start of the project ‘Alignment and Implementation of Technical Legislation for Industrial Products’ is the successful conclusion of the Phare 1997 project (Implementation of technical regulations on company level) in 2000. The above mentioned project will be completed in October 2000 and its results will be used for the preparation of a detailed Terms of Reference for this project which should be positively assessed by the Commission.

• With regard to the same project, it is expected that the necessary appropriate national legislative acts transposing Community technical legislation will be in place. The most important project milestones are situation analysis and work plan, execution of seminars, training and informing.
Annexes to project Fiche

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)
4. Reference to feasibility /pre-feasibility studies. For all investment projects, the executive summary of the economic and financial appraisals, and the environmental impact assessment should be attached (compulsory)
5. List of relevant Laws and Regulations (optional)
6. Reference to relevant Government Strategic plans and studies (may include Institution Development Plan, Business plans, Sector studies etc.) (optional)
7. Project "Alignment and Implementation of Technical Legislation for Industrial Products on Company Level"
**Annex 1 to Project Fiche**

**LOGFRAME PLANNING MATRIX FOR INTEGRATION IN THE INTERNAL MARKET**

<table>
<thead>
<tr>
<th>Wider Objective</th>
<th>Indicators of Achievement*</th>
<th>How, When and By Whom Indicators Will Be Measured</th>
<th>Assumptions and Risks</th>
</tr>
</thead>
</table>
| To enforce the horizontal and sector specific legislation as well as strengthening the institutions for the implementation of the acquis and to fulfil the requirements to participate in the EU Internal Market. | • signed PECA agreement for the particular kind of products | - EU Progress Reports on accession process  
- NPAA | - Adoption of relevant legislation  
- Continuity in negotiations |

**Immediate Objectives**

1 **Market Surveillance**
- to improve the functioning of the market surveillance authorities  
- to establish a co-ordination system between market surveillance authorities, including the co-operation with customs  
- to set up an effective information system on the national level for gathering the relevant information on dangerous products on the EU level

2 **Standardisation**
- to improve functioning of Slovenian Standardisation as the potential full member of CEN and CENELEC  
- To improve standards and terminological databases

<table>
<thead>
<tr>
<th>Indicators of Achievement*</th>
<th>How, When and By Whom Indicators Will Be Measured</th>
<th>Assumptions and Risks</th>
</tr>
</thead>
</table>
| • functional co-ordination system for market surveillance authorities  
• operational information system  
• reports on market surveillance authorities' activities | - Official Journal of Slovenia.  
- EU Progress Reports on accession process  
- Governmental reports  
- NPAA | - timely adoption of the pertinent legislation by Slovene Parliament.  
- availability of the resources as planned in the national budget and the NPAA  
- co-operation of market surveillance authorities |
### Outputs

<table>
<thead>
<tr>
<th>1 Market Surveillance</th>
<th>Indicators of Achievement*</th>
<th>How, When and By Whom Indicators Will Be Measured</th>
<th>Assumptions and Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>- assessment report on the proper functioning of the responsible authorities</td>
<td>- a number of trained staff (estimation: 20 staff)</td>
<td>- assessment report</td>
<td></td>
</tr>
<tr>
<td>- training needs analysis and the training programme</td>
<td>- functioning information system</td>
<td>- quarterly reports and final project report</td>
<td></td>
</tr>
<tr>
<td>- trained staff</td>
<td>- co-ordination scheme</td>
<td>- training needs analysis</td>
<td></td>
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<tr>
<td>- improved co-operation and working methods</td>
<td>- prepared working methods</td>
<td>- training reports</td>
<td></td>
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<tr>
<td>- improved information system on non conform products</td>
<td>2 Standardisation</td>
<td></td>
<td></td>
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<tr>
<td>2 Standardisation</td>
<td>- installed software providing for terminology management and the standards information</td>
<td>- project report</td>
<td></td>
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<tr>
<td>- trained staff</td>
<td>- active participation in the EU standardisation work</td>
<td>- training report</td>
<td></td>
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<tr>
<td></td>
<td>- installed software</td>
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<tr>
<td></td>
<td>- terminological database (a glossary)</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>- operational information system</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>- a number of trained staff and other users (members of Technical Committee, Chamber of Commerce and Industry etc.) - estimation: 30 people</td>
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</tbody>
</table>

### Inputs

- LT PAA, short term expertise, training, procurement of the equipment (investment)
LOGFRAME PLANNING MATRIX FOR  INTEGRATION IN THE INTERNAL MARKET

Project Number: SI0003.01  SUB-COMPONENT: "SECTOR SPECIFIC ACTIVITIES"

<table>
<thead>
<tr>
<th>Wider Objective</th>
<th>Indicators of Achievement*</th>
<th>How, When and By Whom Indicators Will Be Measured</th>
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</thead>
</table>
| To enforce the horizontal and sector specific legislation as well as strengthening the institutions for the implementation of the acquis and to fulfil the requirements to participate in the EU Internal Market. | • signed PECA agreement for the particular kind of products | - Slovene legislation and institutional reform  
- EU Progress Reports on accession process  
- NPAA | - Adoption of relevant legislation  
- Continuity in negotiations |

<table>
<thead>
<tr>
<th>Immediate Objectives</th>
<th>Indicators of Achievement*</th>
<th>How, When and By Whom Indicators Will Be Measured</th>
<th>Assumptions and Risks</th>
</tr>
</thead>
</table>
| 1. Conformity Assessment Bodies  
- to assess the competence of the potential notified or competent bodies  
- to estimate the measurement capabilities and measurement traceability  
2. Pharmaceutical products  
- to improve marketing authorisation procedure, clinical trials approval procedure, quality and capacity of archiving and pharmacovigilance data exchange with the EU database  
- to shorten the period needed for a new drug submission | • a number of notified/competent bodies  
- data exchange with the EU databases  
- shortened period for a new drug submission for at least 50% per reviewed dossier | - Official Journal of Slovenia.  
- EU Progress Reports on accession process  
- Governmental reports  
- NPAA | - availability of the resources as planned in the national budget and the NPAA |
### Outputs

<table>
<thead>
<tr>
<th>Indicators of Achievement*</th>
<th>How, When and By Whom Indicators Will Be Measured</th>
<th>Assumptions and Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Conformity Assessment Bodies</td>
<td>• a number of trained staff (according to the number of the potential notified bodies) - estimation: 50 experts • notification of the relevant conformity assessment bodies</td>
<td>- Quarterly reports and final project report - Assessments - Training needs analysis - Training reports</td>
</tr>
<tr>
<td></td>
<td>2 Pharmaceutical products</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Implemented international standards for New Drug submissions, improved long term data security and protection of public health, trained staff.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• shorter new drug submission • 20 trained staff (internal and external experts)</td>
<td></td>
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</tbody>
</table>

### Inputs

- LT PAA, short term expertise, training, procurement of the equipment (investment)
## LOGFRAME PLANNING MATRIX FOR INTEGRATION IN THE INTERNAL MARKET
### SUB-COMPONENT “ALIGNMENT AND IMPLEMENTATION OF TECHNICAL LEGISLATION FOR INDUSTRIAL PRODUCTS ON COMPANY LEVEL”

### Contracting period expires: December 2002
### Disbursement period expires: December 2003

### Project Number SI0003.01
### Total Budget: MEUR 1.0
### Phare contribution: MEUR 0.5

### Wider Objective

<table>
<thead>
<tr>
<th>Indicators of Achievement*</th>
<th>How, When and By Whom Indicators Will Be Measured</th>
<th>Assumptions and Risks</th>
</tr>
</thead>
</table>
| To enforce the horizontal and sector specific legislation as well as strengthening the institutions for the implementation of the acquis and to fulfil the requirements to participate in the EU Internal Market. | - Slovene legislation and institutional reform  
- Progress Report on accession process  
- NPAA | - Adoption of relevant legislation  
- Continuity in negotiations |

### Immediate Objectives

<table>
<thead>
<tr>
<th>Indicators of Achievement*</th>
<th>How, When and By Whom Indicators Will Be Measured</th>
<th>Assumptions and Risks</th>
</tr>
</thead>
</table>
| - to proceed with the implementation of technical legislation on industrial products related to the “new” approach directives on company level in SMEs. | - adaptation of a certain amount of industrial companies to the requirements set by the EU “new” approach directives on industrial products | - timely adoption of the relevant national legislation on technical regulations  
- availability of financial and human resources in enterprises |
|  | - Commission Progress Report on Slovenia’s accession  
- NPAA |  |

### Outputs

<table>
<thead>
<tr>
<th>Indicators of Achievement*</th>
<th>How, When and By Whom Indicators Will Be Measured</th>
<th>Assumptions and Risks</th>
</tr>
</thead>
</table>
| • implemented harmonized national legislation on company level (in approx. 40 companies)  
• raised technical awareness in Slovene industry on the requirements posed by the newly harmonised legislation and related standards  
• a programme for each SME on the implementation of technical legislation, with an investment plan | - a number of awareness seminars  
- monitoring of the project with respect to the set milestones  
- conformity assessment procedures implemented / in place  
- a number of completed technical files | - willingness of SMEs to actively participate in the sub-project  
- co-ordinated activities of the institutions and bodies involved in the implementation of technical regulation  
- availability of appropriate resources, esp. financial and human, in SMEs |

### Inputs

Technical assistance and training.
Annex 2 of Financing Proposal

Integration in the Internal Market  
SI0003.01

CUMULATIVE CONTRACTING SCHEDULE
(EUR million)

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<tr>
<th>Date</th>
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NB: all contracting should normally be completed within 6-12 months and must be completed within 24 months of signature of FM
# CUMULATIVE DISBURSEMENT SCHEDULE

(�UR million)

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NB all disbursements must be completed within 36 months of signature of the FM
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</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
### Annex 3

#### Implementation time chart - SI0003.01

<table>
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<tr>
<td>Standardisation</td>
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<tr>
<td><strong>Sector Specific Activities</strong></td>
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<tr>
<td>Conformity Assessment Bodies</td>
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<tr>
<td>Pharmaceutical Products</td>
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</tr>
<tr>
<td><strong>Alignment and Impl. of Techn. Regul.</strong></td>
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<tr>
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</tbody>
</table>
Annex 4: Reference to feasibility/pre-feasibility studies  Not relevant

Annex 5: List of relevant Laws and Regulations:
• Act on technical requirements for products and conformity assessment (O. J. RS, no. 59/99)
• Standardisation Act (O.J. RS, no. 59/99)
• Accreditation Act (O. J. RS, no. 59/99)
• Metrology Act (O.J. RS, no. 22/00)
• General Safety of Products Act (O.J. RS, no 23/99)
• Draft regulations, implementing EU legal metrology directives (all together 26 EU directives)

Annex 6: Relevant Government Strategic Plans and Studies
• Strategy to Increase the Competitiveness of Slovenian Industry (Further development of the strategy is under preparation at the Ministry of Economic Affairs)

Annex 7: Project "Alignment and Implementation of Technical Legislation for Industrial Products on Company Level"

Description:
The proposed project is the continuation of the technical assistance provided by the Phare 1997 project “Implementation of technical legislation on company level”. The total value of the project is MEUR 1.2. Phare contribution is EUR 500.000.

The project outputs by March 2000 are as follows:
• situation analysis (see below)
• 2 (two) awareness raising seminars delivered and attended by 255 participants from 150 companies
• 19 Slovene experts have been selected to assist in the implementation of the project
• selection of companies for the in-company advise

Expected results by the end of the project activities are:
• approx. 40 companies will receive advise on the implementation of technical regulations
• production lines, laboratory facilities and documentation analysed
• staff trained on the procedures of the transposition of technical regulations
• the time table and the plan for further implementation of technical regulations
• templates for technical files developed and in-company workshops organised

In company advice will be performed by mixed teams composed of the EU and Slovene consultants.

The project is hosted by the Chamber of Commerce and Industry. It is monitored by a Steering Committee (it has meetings on a monthly basis) composed of the representatives the Ministry of Economic Affairs, the Ministry of Economic Relations and Development, the Ministry of Small Business and Tourism and the Chamber and Commerce and Industry.

An extensive analysis of the situation in Slovene industry regarding the transposition of the acquis in the field of technical regulations performed under Phare COP97 project represents an important input to the proposed sub-project. It reveals that out of 417 companies included in the analysis approximately 75% are either in an initial stage or have not started the adaptation activities regarding the requirements laid down in the Community technical legislation yet. Almost the same percentage of companies has either not yet started or only
partly completed the necessary technical documentation. Only 70% of companies have at least nominated the responsible person for the internal implementation of the Community technical regulations.

The Phare COP97 project has encompassed approximately 150 companies in its awareness raising activities and is to assist 40-50 industrial companies to overcome the above situation by providing in-company technical assistance. With the proposed sub-project, at least further 200 companies will be included in awareness raising activities and 40 will be assisted in making progress towards preparedness for the implementation of the Community technical legislation for industrial products. The project is designed for small and medium sized industrial companies that are financially stable. It will aim at assisting the selected companies with the implementation of technical legislation in the following areas: electro-technology: EMC (89/336/EEC), LVD (73/23/EEC), ATEX (94/9/EC), CPD (89/106/EEC), machinery (98/37/EC), simple pressure vessels (87/404/EEC) and pressure equipment (97/23/EC), lifts (95/16/EC, 84/528/EEC, 84/529/EEC), gas appliances (90/396/EEC), gas cylinders (84/525/EEC, 84/526/EEC, 84/527/EEC) and personal protective equipment (89/686/EEC).

**Detailed content of the project:**

1. **Organisation of 8 (eight) awareness raising seminars for at least 200 industrial companies:**
   - four for the management and four for the technical staff (at the beginning and at the end of the project).

2. **In-company advise on the implementation of technical regulations for 40 SMEs:**
   - analysis of the present status concerning applicability and implementation of relevant technical regulations and preparation of activity program for implementing technical regulations
     At the beginning, a situation analysis regarding adaptation of the company to the requirements of technical regulations will have to be performed and a programme for necessary measures for the implementation will be prepared for each individual enterprise. Out of that a set of activities to be performed under the project will be determined. These are expected to differ from enterprise to enterprise, depending on the type and number of directives relevant for the company, complexity of the directives, status of implementation (assessed through the situation analysis) and availability of quality management system, availability and status of equipment and testing devices, technical competence of staff, etc.
   - the situation analysis and the implementation programme will be followed by the assistance in the initiation and implementation of technical regulations:
     Practical assistance on how to prepare a technical file:
     - workshops for individual company,
     - company-related advise and monitoring for companies that have not yet started implementation;
     - product-related advise on the preparation of technical files for companies which have already started implementation but require specific assistance;
     - problem-related advise, coaching and monitoring for companies which are at an advanced stage in the implementation but have specific problems to be solved;
     Progress monitoring and coaching during the implementation:
     - organisation of training for employees;
     - clarification of other aspects related to the implementation of technical regulations and subsequent norms;
     - consulting on investments needed for further implementation