Standard Summary Project Fiche

1. Basic Information

1.1 CRIS Number: **2003/004-979-02.02**

1.2 Twinning Number: LV/2003/IB/EC/02

1.3 Title: **Medical devices (Market surveillance and Vigilance system)**

1.4 Sector: Internal Market/Free movement of goods/Consumer Protection

1.5 Location: Republic of Latvia

- Ministry of Health*, Riga, Baznicas street 25, LV 1010
- Health Statistics and Medical Technologies Agency (HSMTA), Riga, Duntes street 12/22, LV 1005
- State Pharmaceutical Inspection (SPI), Riga, Jersikas street 15
- National Custom Board (NCB), Riga, Kr. Valdemara 1A

2. Objectives

2.1 Overall Objective(s):

Ensure safety, quality and performance of medical devices

2.2 Project purpose:

Development of the market surveillance and surveillance system of adverse reactions for medical devices.

2.3 Accession Partnership and NPAA priority

Accession Partnership:

Free movement of goods –

- Complete the process of transposition and implementation of all New Approach and sectoral legislation with the acquis.
- Reinforce national accreditation system; upgrade the national metrology system; complete the reform of the market surveillance system; designate the appropriate bodies regarding notification procedure and ensure their functioning.
- Complete adoption of EN standards.

Consumers and health protection –

- Ensure the effectiveness of the administrative structures involved in market surveillance.

NPAA:

- TA No LA009, "To improve consumers rights protection in Latvia, develop market surveillance system accordance with EU standards, which ensure consumers and health protection".

3. Description

3.1 **Background and justification**:

More than 7000 different Medical devices units are used in health care system in the territory of Latvia. Around 80% of them are manufactured before 1990ies in the former Soviet Union or Eastern Europe. Medical devices are exploited in 3315 health care institutions, including praxes of general practitioners and 140 hospitals. Comparatively small number of manufacturers of Medical devices is in the market (less than 20).

* *Ministry of Health established on Cabinets of Ministers regulations Nr. 20 as of 14 January 2003*

There are 600 distributors of Medical devices and more than 50 representative offices registered in the Republic of Latvia.

EU Regulations, which apply to medical devices are following: 90/385/EEC Council Directive from June 20th 1990 on Active Implantable Medical Devices; 93/42/.EEC Council Directive from June 16th 1993 on Medical Devices; 98/79/EEC Council Directive from October 27th 1998 on *In Vitro* diagnostic Medical Devices and 97/43/EURATOM.

The first step of Latvia to implement *aquis* requirements is the Regulation of Cabinet of Ministers No. 100 adopted 6 March 2001 "Procedures for Registration, Sale and Distribution of Medical Devices and Medical Goods".

Problem description

There is no effective operational Medical devices market surveillance in place yet. At the moment Medical devices Market surveillance is still underdeveloped and requires rapid steps to be taken until 2004, including strengthening of all market surveillance functions:

- monitoring of products placed on the market;
- corrective actions to establish conformity;
- complementary activities (collaboration with manufacturers and suppliers, protection of CE marking, warning of persons, application of sanctions);
- medical devices Vigilance system;
- administrative co-operation.

Above mentioned problem is underlined also in the European Commission Regular Progress Report 2002, stating that "Consumer and producer awareness need to be enhanced in relation to their respective rights and responsibilities. Consumer Health Institutions need to be upgraded in terms of training and equipment, and legal professions need to familiarise themselves better with product liability related cases."

Reasons for the problem

There are several reasons for the problem:

- Incomplete national legislation;
- Respective public structures for market surveillance not in place;
- Lack of appropriate standards (nomenclature of medical devices);
- Procedures of market surveillance not introduced and known;
- Lack or no trained personnel for market surveillance functions;
- Lack of required equipment;
- Lack of required information systems and data bases;
- Weak understating of involved institutions, medical devices users and economic operators on market surveillance.

Negative effects of the problem (backlash)

These problems further cause negative effects (backlash) on the whole society. Health and safety of patients and users is endangered from non-compliant Medical devices. For instance 11% of all occupational diseases registered in 2001 were in Health care sector.

Negative effects can be observed also in business transactions, hence disturbing fair trade practice and principles of free movement of goods. Economic operators are not fully protected from unfair competition. About 10% of medical devices requiring CE marking are imported and put into service not bearing respective marking, which is directly caused by the lack of effective Market surveillance structures. Finally, not completely operational system for Medical devices market surveillance can be a barrier for joining EU.

Proposed project actions

To arrange the medical devices market surveillance there is elaborated Strategy for the further development of Medical devices Market surveillance in Latvia , which will be approved by the Cabinet of Ministers in 2003.

Part of the medical devices market surveillance building activities is expected to be completed until the first half of 2003. Remaining will be implemented during the particular Phare project. The project structure consists of 3 components, which comprise all necessary activities for strengthening Medical devices Market surveillance system:

Component 1 - Improvement of Latvian legislation and strengthening the power of Medical devices Market surveillance structures:
- Improvement of national legislation;
- Development of public structures for market surveillance;
- Approbation of appropriate standards (nomenclature of medical devices).

Component 2 - Development of Medical devices Market surveillance procedures:
- Elaboration and introduction of market surveillance procedures;
- Training of personnel on market surveillance functions.

Component 3 - Capacity building of Medical devices Market surveillance structures:
- Provision of required equipment;
- Development of required information systems and data bases;
- Introduction of market surveillance pilot project for involved institutions, medical devices users and economic operators

The main beneficiaries of the project will be the Ministry of Health (concerning improvement of legislation), and its subordinate institutions – Health Statistics and Medical Technologies Agency (HSMTA), State Pharmaceutical Inspection (SPI) (as core Medical devices Market surveillance structures, medical devices conformity assessment notified body) and National Custom Board on functions capacity advancement.

Component 1 - Improvement of Latvian legislation and strengthening the power of Medical devices Market surveillance structures

Several legislative acts govern safety of Medical devices in Latvia (see Annex 8). Despite provisions partly regulating the Vigilance system in Latvia EU directives concerning Medical devices market surveillance cannot be considered as fully harmonised in national legislation yet. Authority responsible for Market surveillance is not clearly nominated in Latvia and separation of powers among responsible institutions is not defined.

Beside legislative issues, the most important barrier to introduce Medical devices Market surveillance system is lack of common nomenclature of medical devices in Latvia. Existing nomenclature of medical devices in Latvia is rendered in the former Soviet Union and gradually improved during last ten years. In this nomenclature many names of devices are transposed directly from Russian and frequently the brand names of western devices are used as criteria for classification of devices. The ISO/TS 20225 Standard (Global Medical Devices Nomenclature system), which is used in EU, is not incorporated in Latvian standard system.

Several activities on improvement of Latvian legislation and strengthening the power of Medical devices Market surveillance structures are expected to be completed until the first half of 2003:
- Approval of Law on Health care, Regulations of Cabinet of Ministers No100 “On Procedure of realisation, distribution and registration medical devices and medical goods” on the 6 Mart 2001 and Regulations of Cabinet Ministers No78 “On Procedure of exploitation and technical supervision medical devices and medical goods” on the 19 February 2002 (nominating the HSMTA to be responsible for Medical devices Market surveillance in Latvia; defining clear separation of powers among responsible institutions by delegation to the SPI several minority functions of Medical devices Market surveillance).
- Cabinet of Ministers regulations fully transposing EU directives on Medical devices; Including regulation of penalties if the market surveillance and vigilance system is breached by manufactures, organisations and individuals involved in purchasing medical devices and in the provision of health-care.
- Establishment and staffing of Medical devices Market surveillance department in the HSMTA.

- Establishment and staffing of Medical devices sanction administration unit in the SPI.

The particular project should continue above-mentioned initiatives by critical assessment of the existing and newly approved national legislation in order to ensure full compliance. Established structures in the HSMTA and SPI should be further strengthened by adequate power and personnel provision.

Phare program project also will be of crucial significance for introduction of Global Medical Devices Nomenclature, hence establishing effective base for transfer of information and common activities between Latvian and EU institutions. Concerning great dimension and specific terminology of the Global Medical Devices Nomenclature System primary analysis indicated that these competencies were not covered by Latvian public translation services. Project foresees attraction of professional support for translation of Global Medical Devices Nomenclature System and approbation of Latvian version of Nomenclature.

Component 2 - Development of Medical devices Market surveillance procedures

Formerly functions of the HSMTA and the SPI did not include Medical devices Market surveillance. Consequently the knowledge and capacity of Latvian institutions are significantly below required level at the moment. Personnel of HSMTA and SPI are not familiar with surveillance procedures. Only 1-2 persons from each institution have preliminary understanding in market surveillance functions. All documentation concerning Medical devices Market surveillance requirements in EU is available only in English or French. No Latvian guidelines and documentation forms are available.

Even worse is situation with manufacturers, distributors and Latvian hospitals. Duties and rights of the users and economic operators are not known.

Substantial efforts are necessary to develop market surveillance procedures, including all required surveillance documentation forms and guidelines. Competence's of the HSMTA and the SPI should be defined for all surveillance steps, including monitoring of products placed on the market; corrective actions to establish conformity; complementary activities; medical devices Vigilance system and administrative co-operation. Intensive training programme should be introduced for involved institution technical personnel and management to significantly boost the level of qualification. Besides, the training of trainers' model is proposed to ensure sustainability of the Phare programme inputs and broaden spread of training activities also to manufacturers, distributors and Latvian hospitals.

Component 3 - Capacity building of Medical devices Market surveillance structures

At this moment HSMTA maintains two databases - Register of Medical devices and Medical Goods of Ministry of Health and Register of Medical Devices of First Safety Group. These databases do not support real exchange of information among institution dealing with Market surveillance. Moreover, information of EU institutions is not suitable to these registers due to separate classification methods and specific sphere of activities. They are not connected to EU databases and there is no data flow among them neither virtually, nor by means of exchange of data, thus it is impossible to get full information in one concrete place about the life cycle of a certain medical device. Assessment of the existing server and network capacity in HSMTA shows that they do not meet the needs of a new global database/databank that has to be operational for market surveillance, including Vigilance system for medical devices. In parallel to the lack of IT base, there is a weak understating of involved institutions, medical devices users and economic operators on activation of Vigilance system.

HSMTA does not possess a pool of laboratory equipment, which is necessary for Medical device sample examination and testing. Great number of out of date Medical devices on the market in the Republic of Latvia sharpen this problem.

Planned establishment and staffing of Medical devices Market surveillance department in the HSMTA and Medical devices sanction administration unit in the SPI cause additional resources for investments in workplaces and ensuring their mobility with a help of transportation vehicles.

Several activities on capacity building of Medical devices Market surveillance structures are expected to be completed until the first half of 2003:

- Provision of equipment for Medical devices Market surveillance department in the HSMTA and Medical devices sanction administration unit in the SPI, including up-to-date office furniture, telephones, faxes, copiers, stationary and portable computers.
- Provision of transportation vehicles.

Phare programme project starting in the second half of 2003 should support further activities. Databases should be improved, revised and integrated with ISO/TS 20225 Standard to provide the basic information for Medical Devices Market Surveillance and Surveillance system of adverse reaction (Vigilance system). Medical devices Vigilance system should be linked and harmonised with EU databases and national health care system databases. For adequate data base operations it is needed to establish hardware in HSMTA.

For effective monitoring of products placed on the market, HSMTA should be equipped with modern equipment for Medical device sample examination and testing. In transitional period (before investments) and for individual cases, co-operative links for subcontracting with local and foreign testing institutions should be established.

In order to introduce market surveillance mechanisms for larger number of institutions, medical devices users and economic operators on Latvian market, Vigilance system pilot project is planned. It will consist of practice and workshops with participation of relevant institutions: HSMTA, SPI, National Custom Board, at least 3 Latvian hospitals, manufacturers, distributors and notified bodies.

3.2. Linked activities:

EU Phare 2001 Project LE01.09.02 “Improvement of radiation protection in relation to medical exposure”. Project will be implemented during 2002-2003.

- Component 1- Preparation of National technical regulations on technical surveillance of medical radiology equipment in accordance with EU requirements and best practice.
- Component 2 – Strengthening of the unit for conformity assessment of quality assurance and quality control systems in medical radiology.
- Component 3 – Education and training of medical staff, lecturers and technical personnel of radiology in compliance with EC Directive 97/43/EURATOM concerning quality assurance and quality control system.

3.3. Results:

Component 1 - Improvement of Latvian legislation and strengthening the power of Medical devices Market surveillance structures

Twinning should achieve the following guaranteed results:

- Recommendations for adapting national legislation regulating medical devices market surveillance in compliance with European Council directives 90/385/EEC, 93/42/EEC, 98/79/EEC, 97/43/EURATOM

- Recommendations for personnel provision (function, capacity and number) in the public structures for medical devices market surveillance.

Technical assistance results:

- Global medical devices nomenclature translated into Latvian, approbated and enforced in the Republic of Latvia

Component 2 - Development of Medical devices Market surveillance procedures

Twinning should achieve the following guaranteed results:

- Latvian Medical devices market surveillance procedures elaborated and introduced through development of surveillance documentation forms, guidelines and training of personnel and trainers
- Co-operation model and strategy for medical devices notified body involved in Medical devices market surveillance system elaborated
- Compatible system for electronic information exchange among the EU and national institutions involved in Medical devices market surveillance system and vigilance system

Component 3 - Capacity building of Medical devices Market surveillance structures

Twinning should achieve the following guaranteed results:

- Medical devices Market surveillance structures, Latvian hospitals, manufacturers, distributors capacity strengthened through participation in Vigilance system pilot project
- Medical devices market surveillance system elaborated and implemented

Technical assistance results:

- Medical devices Market surveillance structures and conformity assessment notified body strengthened with necessary data bases
- Medical devices testing technical laboratory enlarged and expanded
- Medical devices conformity assessment national Notified Body structure set

Supplies results:

- HSMTA strengthened with necessary Information Technologies network reengineering equipment, hardware – software and access to EU data bases;
- HSMTA strengthened with necessary office equipment, transportation vehicles and medical devices testing equipment and devices;
- National medical devices Notified Body strengthened with necessary equipment, hardware and software

3.4. Activities[1]:

Component 1 - Improvement of Latvian legislation and strengthening the power of Medical devices Market surveillance structures

Twinning (12 months):

- Provision of proposals for changes in the existing Latvian legislation framework/content dealing with Medical devices Market surveillance instruments and regulation mechanisms.
- Provision of advice and guidance on development of necessary amendments of law or regulations. Provision of consultations to the Ministry of Health and working groups.
- Analysis of institutional structure and existing and necessary personnel provision (functions, capacity and number) for implementation of Medical devices Market surveillance, Vigilance system and medical devices conformity assessment notified body functions in project beneficiary institutions:
  - HSMTA;
  - SPI;
  - National Custom Board;
  - Other involved institutions if significant drawbacks are identified.
- Provision of advice on changes in institutional framework (if necessary) and personnel. Assistance to implement proposed changes effectively.

[1] Division of project activities between Twinning instrument and Technical assistance is based on the following principles:

- Twinning instrument is optimal for the adoption of acquis and provision of best policy practice and consultations during day-to-day co-operation with Candidate state authorities.
- Technical assistance is optimal for activities, which needs more technically time-consuming individual preparatory work and involvement of large number of similar experts during implementation (e.g. data bases).

- Supervision of respective Framework contract No.2 activities.

Twinning means

- Contract 1, Twinning Covenant:

  - PAA– (12 man months in total with other components. see profile and tasks of PAA below)
  - Short term twinning expertise on Medical devices Market surveillance and Vigilance system and Notified Body establishment legislation (4 man months)
  - Short term twinning expertise on Market surveillance and Vigilance system and national notified body institutional structures building (4 man months)

Framework Contract No.2

- Screening of National legislation (list of relevant legislation see in Annex 8) for Medical devices Market surveillance sector in compliance with *acquis* (3 man months) under supervision of PAA.

Service contract No.3

- Translation of Global medical devices nomenclature in Latvian.
- Provision of expertise on correction and standard approbation. Approbation should include standard incorporation in:
  - Medical devices registration;
  - Existing counting information in health care institutions, manufacturing and distribution, statistics.
  - Conformity assessment made by notified bodies. Technical surveillance.
  - Medical devices Market surveillance.
  - Medical devices Vigilance system allowing to ensure improved and rapid information exchange and co-operation with EU Vigilance system.
  - Planning and assessment of Medical technology share in different health care service costs.
- Provision of expertise on standard enforcement in national legislation

Component 2 - Development of Medical devices Market surveillance procedures

Twinning (12 months):

- Develop market surveillance procedures for monitoring of Medical devices placed on the market, including surveillance documentation forms and guidelines for:
  - Regular visits to commercial, industrial and storage premises.
  - Regular visits to work places and other premises where Medical devices are put into service.
  - Organisation of random and spot checks.
  - Taking samples of Medical devices, and to subject them to examination and testing.
  - Requiring all necessary information.
  - Checking on the production premises if non-compliance has been discovered
  - Checking trade fairs, exhibitions and demonstrations.
- Develop market surveillance procedures for corrective actions to establish conformity, including surveillance documentation forms and guidelines for:
  - Putting obligation to a manufacturer or authorised representative to make the Medical device comply with provisions.
  - Taking further steps to restrict or prohibit the placing on the market of the Medical device.
- Develop market surveillance procedures for complementary activities, including surveillance documentation forms and guidelines for:
  - Collaboration with manufacturers and suppliers.
  - Warning of persons who might be at risk.
  - Taking appropriate action against the person whom has affixed the CE marking to non-compliant product, and those who are responsible for the non-compliance of the Medical device.
  - Destroying dangerous Medical devices and banning their export.
  - Application of other sanctions.

- Develop market surveillance procedures for, Medical devices Vigilance system (system of notification and evaluation of adverse incidents), including surveillance documentation forms and guidelines for:
    - Responsibilities of users of Medical devices, manufacturers, notified bodies, Medical device Market surveillance structures and other involved parties in the case of adverse incidents.
    - Monitoring the investigation and co-ordination contacts with the manufacturer.
    - Accessing the expertise of relevant Notify body and co-ordinating with other EU Medical device Market surveillance authorities.
    - Discussing with manufacturer the principles of corrective actions to be taken.
    - Disseminating details of incidents to other in EU Medical device Market surveillance authorities and European Commission.
    - Work with EU and local databases.
- Develop market surveillance procedures for administrative co-operation with other EU Medical device Market surveillance authorities and European Commission.
    - Assessment of the existing Medical devices registration procedures and assisting in change implementation (if necessary) in order to comply with EU directives ensuring requirements of free movement of goods
    - 2 one-week study visits (transfer of knowledge and best practice of EU Member state Medical device Market surveillance procedures. Study visits should concentrate on application of the procedures for corrective actions to establish conformity and co-operation with other EU authorities) – training of HSMTA (6 persons) and SPI personnel (2 persons).
    - Local training seminars covering a) monitoring of products placed on the market; b) corrective actions to establish conformity; c) complementary activities; d) medical devices Vigilance system; e) administrative co-operation) – training of HSMTA and SPI personnel.
    - One-week study visit (transfers of knowledge and best practices of EU Member state Vigilance system. Study visit should cover analysis and principles of the co-operation processes with other EU Medical device Market surveillance authorities and European Commission.) – training of trainers from HSMTA (2 persons) and Latvian hospitals (6 persons).
    - Local training seminar on Vigilance system – training of trainers from HSMTA and Latvian hospitals.
    - Organisation of 10 seminars on Vigilance system to manufacturers, distributors and Latvian hospitals provided by trained trainers
- Supervision of respective Framework contract No.2 activities.

Twinning means
Contract 1, Twinning Covenant:

- PAA (12 man months in total with other components. see profile and tasks of PAA below)
- Short term twinning expertise on Market surveillance procedures and Information Technologies for data electronic exchange (10 man months in total);
- Short term twinning expertise on registration and Vigilance system (3 man months in total)
- 2 one-week study visits on Medical devices Market surveillance procedures (8 persons)
- 5 training seminars on Medical devices Market surveillance procedures (8 persons)
- one-week study visit on Vigilance system (training of trainers 12 persons)
- 1 training seminar on Vigilance system (12 persons)
- 10 seminars on Vigilance system provided by trained trainers (Aluksne, Daugavpils, Kuldiga, Cesis)

Framework Contract No.2:
Short term expertise on medical devices market surveillance procedures (10 man months in total) under supervision of PAA

Component 3 - Capacity building of Medical devices Market surveillance structures

Twinning (12 man months)

- Vigilance system pilot project preparation and implementation, by participation of relevant institutions: HSMTA, SPI, National Custom Board, at least 3 Latvian hospitals, manufacturers, distributors and notified bodies.

Pilot project includes following activities – identification of relevant adverse reactions for further analysis, involvement of responsible institutions, leading of vigilance procedures, solving practical cases, organisation of seminars and workshops locally and abroad (see below).

- One-week study visit (workshop on Vigilance system pilot project. Workshop should include all steps of the practical solution of one or several adverse incidents which have occurred in Latvia. Study tour should be organised to the home country of the involved foreign manufacturer), for HSMTA (1 persons), SPI (1 person), Latvian hospitals (2 persons), local manufacturers personnel (2 person).
- 1 local seminar (workshop on Vigilance system pilot project), for HSMTA, SPI, National Custom Board, Latvian hospitals, manufacturers, distributors and notified bodies personnel (20 persons).
- Supervision of respective Framework contract No.2 activities.

Twinning means
Contract 1, Twinning Covenant:

- PAA– (12 man months in total with other components. see profile and tasks of PAA below)
- Short term twinning expertise on Vigilance system pilot project preparation and implementation (3 man months in total)
- one-week study visit (workshop) on Vigilance system pilot project (6 persons)
- 1 training seminar (workshop) on Vigilance system pilot project (20 persons)

Framework Contract No.2

- Short term expertise on Vigilance system pilot project preparation and implementation (3 man months in total) under supervision of PAA.

Framework Contract No.4:

- Reengineering and expanding of the existing Medical devices and Medical devices First Safety Group databases to comprise Market surveillance functions. Development of required information systems compatible with EU databases.
- Development of Medical devices Vigilance system data base for keeping records on:
- Adverse incidents (date, outcome);
- Manufacturer and model, device kind, using appropriate nomenclature.
- Co-ordinating Market surveillance authority
- Corrective actions progress.
- Link and harmonise Medical devices Vigilance system with EU databases and national health care system databases.

Supplies

- Strengthening of HSMTA by provision of required equipment and hardware:
- Supplies of Hardware for databases.
- Supplies of Equipment for laboratory of Medical device sample examination and testing, conformity assessment procedures,
- Supplies of standard office furniture and technical support equipment
- Purchasing of two cars (4WD)
- Training for HSMTA conformity assessment unit and testing laboratory 6 personnel on use of Medical device sample examination and testing equipment.

Means:

- Supply Contract No.5

(Detailed list of equipment see Annex 5)

Twinning arrangements for the project:

The significance of the project as well as the ambitious goals set therein call for involvement of the **Pre-accession Advisor** for the whole duration of the project 12 months to:

- be the head of the all the project's experts and activities, being the leading EU counterpart of the beneficiary
- assist responsible structures for capacity building activities,
- be responsible for management and co-ordination of all the components of the project to ensure that the project proceeds, as planned, in an efficient and orderly fashion
- advice the Project Steering Committee (PSC) on ways to improve design, planning and implementation framework of the project components
- upon request from the head of the PSC, deliver general advisory support to the Ministry of Welfare, other involved institutions
- ensure successful correlation and collaboration of all the institutions engaged in the project activities as far as it is necessary to achieve the project objectives
- follow up on the activities carried out during short-term missions of the expert pool in all the components proposing the PSC any further measures needed to ensure the sustainability of the project
- supervise Framework contract No.2 activities.

The PAA profile should comprise:

- at least 10 years professional experience of working in private or public administration and a good grounding in the fields of:
  - laying down structures and strategic developments in Market surveillance
  - institutional building and Medical devices Market surveillance procedures
  - planning of Medical devices Vigilance system development
  - organisation of Market surveillance data processing activities
  - assistance to governmental bodies and their subordinate institutions for preparation those to their future role in EU.
- experience of working with senior politicians and officials in an advisory role
- Fluent English

Short term twinning experts on:

- Medical devices Market surveillance and Vigilance system and Notified Body establishment legislation (4 man months)
- Market surveillance and Vigilance system and national notified body institutional structures building (4 man months)
- Market surveillance procedures and Information Technologies for data electronic exchange (10 man months in total);
- Short term twinning expertise on registration and Vigilance system (3 man months in total)
- on Vigilance system pilot project preparation and implementation (3 man months in total)

All experts should be experienced in:

- assistance to governmental bodies and their subordinate institutions for preparation those to their future role in EU
- institutional building and Medical devices Market surveillance procedures
- Fluent English

Technical Assistance arrangements for the project;

Framework Contract No.2:

Short term experts on:

- Screening of National legislation (list of relevant legislation see in Annex 8) –for Medical devices Market surveillance sector in compliance with *acquis* (3 man months)
- medical devices market surveillance procedures (10 man months in total)

- Vigilance system pilot project preparation and implementation (3 man months in total)

All experts should be experienced in:
- At least 10 years professional experience of clinical practice
- Drafting national legislation
- Fluent Latvian.

Service contract No3:

- Local 12 different experts expertise on correction and standard approbation (12 man/ months in total)
- Short term local expertise on standard enforcement in national legislation (1 man months)

Framework Contract No.4:

IT expertise

4. Institutional Framework

The responsible institution for the implementation of this project is the **Ministry of Health.** Ministry of Health is as a responsible government body for implementing EU requirements on Medical devices Market surveillance in Latvia. The main tasks of the Ministry of Health in health care sector are:

- To elaborate national policy in the field health protection.
- To manage and solve by political, economic and legal measures health care and protection, as well as public health and pharmacy issues.
- To elaborate national legislation, as well as ensure its harmonisation with the European Council and European Union document requirements.

Involved institutions in the implementation of the project will be:

- **Health Statistics and Medical Technologies Agency** (HSMTA). Current tasks of the Health Statistics and Medical Technologies Agency are: health technologies assessment based on evidence analysis of national health statistics, international databases, medical devices registration, gathers, summarises and distributes the information about legal Medical devices on Latvian market, manufacturers and authorised distributors, according to the legislative regulations, issues importing, transit and distribution certificates of the Medical devices, maintain First Safety Group Medical devices Register.
- **State Pharmaceutical Inspection** (SPI). SPI currently exercises direct oversight and control of the market of medicinal products, inspection of the health cares institutions in respect of the implementation the legislative requirements for medicinal products.will be responsible for: restricting or prohibiting the placing on the market of the Medical device; application of sanctions. Destroying dangerous Medical devices and banning their export.
- National Custom board will be involved in the project to increase its institutional capacity in order to ensure effective control of Medical devices import, export and transit from third countries after joining EU.

Project Steering Committee (PSC) will be establish to monitor project implementation. The PSC will compromise representatives from competent authorities and competent institutions – European Commission Delegation, Ministry of Finance, Ministry of Health, Health Statistics and Medical Technologies Agency, State Pharmaceutical Inspection, National Custom Board and Riga Technical University.

Annex 6 illustrates the core institutions involved in the system and a co-operation mechanism. Medical devices Market surveillance functions will be implemented by 2 institutions, which are subordinated to the Ministry of Health - HSMTA and SPI in cooperation with National Custom Board. It is planned that HSMTA will execute majority of the Market surveillance functions:

Regarding employees of the Medical devices Market surveillance structures HSMTA is staffed partly - with 4 prospective experts. 2 of them are working in HSMTA Medical Devices Registration Section. These experts have basic knowledge in Market surveillance. 1 prospective engineer is currently working in HSMTA

Health Technologies and Standards Section with good knowledge in examination and testing.1 prospective expert is working in HSMTA Medical Devices Testing Unit, dealing with preparatory works for Vigilance system and development of First Safety Group Register. STI may be staffed with 2 employees.

5. Detailed Budget (in euro)

	Phare	**Support**		**National Cofinancing**			
	Investment Support	Institution Building	**Total Phare (=I+IB)**	**Eligible costs**	**Non-eligible costs**	**IFI**	**TOTAL eligible costs**
Contract 1, Twinning Covenant		692 000	692 000	94 200*****			786 200*
Contract 2, Framework contract (service)		48 000	48 000	4 800*			52 800*
Service Contract 3		39 000	39 000	14 200**	2 556		53 200**
Contract 4, Framework contract (service) (Software Development)		139 600	139 600	47 200**			186 800**
Contract 5, Supply	240 000		240 000	219 680**	39 542		459 680**
Total	**240 000**	**918 600**	**1 158 600**	**380 080**	**42 098**		**1 538 680**

∗ Parallel co-financing. Parallel co-financing will be applied for covering of office costs for experts, infrastructure facilities and travel costs for national counterparts.

∗∗Joint co-financing, excluding all taxes and duties.

6. Implementation Arrangements

6.1. Implementing Agency

Implementing agency of the project will be the CFCU, PAO Valentina Andrejeva, State Secretary of Ministry of Finance. CFCU will be responsible for the financial and administrative management of the project in accordance with DIS procurement rules, regulations and procedures.

Programme Authorising Officer - V.Andrejeva, State Secretary of the Ministry of Finance.
1, Smilsu Str., LV-1919, Riga, Latvia
Tel.: +371 7212726, fax: +371 7095413

Central Finance and Contracting Unit - A.Eberhards, Director,
1, Smilsu Str., LV-1919
Tel. + 371 7094344, Fax. +371 7094348

Ms. Ruta Zilvere, Deputy State Secretary of the Ministry of Welfare (28 Skolas str., Riga, LV 1331, Latvia; ph. 371 7021605, fax 371 7276445) is the Senior Programme Officer and responsible for the technical implementation of the project until nomination of the Senior Programme Officer of the Ministry of Health.

The HSMTA as subordinated body of the Ministry of Health will carry out technical implementation of the project. In implementation of the project SPI will be involved actively as well.

6.2. Twinning

The leading PAA will be situated in the HSMTA. Mr. Egils Lavendelis, Director of HSMTA will be the Latvian counterpart of the PAA.

Main Beneficiary institution:
HSMTA
Project leader and counterpart for the PAA
Mr. Egils Lavendelis,
Director of HSMTA,
Tel: +371 7501 590
Fax: +371 7501 591
e-mail: egils@vsmta.lv
12/22 Duntes street
Riga 1005

Other Beneficiary institutions:
Ministry of Health, Riga, Baznicas street 25

SPI, Riga, Jersikas street 15
National Custom board, Riga

6.3. Non-standard aspects

The Contract 3 (Service contract) requires use of simplified procedure, because the technical expertise required (translation of ISO/ TS 20225 Standard (Global medical devices nomenclature) in Latvian and provision of expertise on correction and standard approbation) is not available in the Framework contract.

There will be no non-standard aspects regarding implementation of the contracts No 1, 2, 4 and 5. Standard procedures of the Commission in accordance with Practical Guide to PHARE, ISPA and SAPARD contract procedures will be followed under Extended Decentralised Implementation System (EDIS). Prior to EDIS accreditation, DIS will be followed. EDIS will apply from the date of accession at latest.

The Twinning manual will have to be followed in the case of Twinning.

Ratio: if during project implementation the project cost for some reasons will decrease, the Phare financing will also decrease proportionally.

6.4. Contracts

- Contract No.1: Twinning covenant - 692 000 EUR (parallel co-financing);
- Contract No.2: Framework contract - 48 000 EUR (parallel co-financing);
- Contract No.3: Service contract - 53 200 EUR

(joint co-financing, excluding all taxes and duties)

- Contract No.4: Framework contract - 186 800 EUR

(joint co-financing, excluding all taxes and duties)

- Contract No.5: Supply contract - 459 680 EUR

(joint co-financing, excluding all taxes and duties)

7. Implementation Schedule

Contract No.1: Twinning covenant

- Start of tendering/call for proposals - 3 Quarter 2003
- Start of project activity – 4 Quarter 2003 (duration 12 months)
- Project Completion – 4 Quarter 2004

Contract No.2: Framework contract

- Start of tendering/call for proposals - 3 Quarter 2003
- Start of project activity – 4 Quarter 2003
- Project Completion – 4 Quarter 2004

Contract No.3: Service contract
- Start of tendering/call for proposals - 4 Quarter 2003
- Start of project activity – 1 Quarter 2004 (duration 5 months)
- Project Completion – 2 Quarter 2004

Contract No.4: Framework contract (Software Development)
- Start of tendering/call for proposals - 4 Quarter 2003
- Start of project activity – 1 Quarter 2004 (duration 5 months)
- Project Completion – 3 Quarter 2004

Contract No.5: Supply contract
- Start of tendering/call for proposals - 4 Quarter 2003
- Start of project activity – 2 Quarter 2004 (duration 4 months)
- Project Completion – 2 Quarter 2004

8. Equal Opportunity

When recruiting, promoting and rotating their employees, Latvian public institutions take into account professional qualification, level of competence, compliance with the Law on State Civil Service (when applicable), correspondence to the job description, performance and like factors, not their age, sex or nationality. Equal opportunities for both men and women will also be ensured by other participating institutions.

9. Environment

N/A

10. Rates of return

N/A

11. Investment criteria

N/A

12. Conditionality and sequencing

- Strategy approved for the further development of Medical devices Market surveillance in Latvia.
- Medical devices Market surveillance structures established in HSMTA and SPI before start of the project.
- Power and functions of Medical devices Market surveillance structures defined in national legislation.
- Adequate staffing in the recipient institutions (project coordinators in the Ministry of Health, HSMTA and SPI and project leader in HSMTA) has to be in place for implementation and monitoring of project activities before the start of the project
- Co-financing via national budget ensured

ANNEXES TO PROJECT FICHE

1. Logical framework matrix in standard format
2. Detailed implementation chart
3.. Contracting and disbursement schedule by quarter for full duration of program (including disbursement period)

5. List of equipment to be purchased under investment part of the project
6. Proposed system of the Medical devices Market surveillance and Vigilance system in the Republic of Latvia
7. EU regulations according medical devices and national regulation in force
8. Latvian Legislation on Medical Devices

ANNEX 1 Phare Logical Framework Matrix

LOGFRAME PLANNING MATRIX FOR Project **Medical devices (Market surveillance and Vigilance system)**	Programme name and number	
	Contracting period expires	Disbursement period expires
	Total budget : 1 538 680 EUR	Phare budget : 1 158 600 EUR

Overall objective	**Objectively verifiable indicators**	**Sources of Verification**	
Ensure safety, quality and performance of medical devices	- Decreased number of adverse incidents on 70% (resulting in a death of patient or user, serious deterioration in their state of health) - Prevented import of Medical devices not compliant with EU requirements. Latvian Manufacturers of Medical devices have Certificates of conformity to appropriate EU quality standards	- Regular Progress Report - Information form Latvian health care institutions - Official publications - Report of Health Statistics and Medicine Technology Agency	
Project purpose	**Objectively verifiable indicators**	**Sources of Verification**	**Assumptions**
Development of the market surveillance and surveillance system of adverse reactions for medical devices.	- All medical devices that are in exploitation bear respective conformity marking. - Established and operational Notified body for medical devices conformity assessment	- Final Project Report - Information form Latvian health care institutions - Report of Ministry of Health - Information form National Custom Board - Certificates of conformity - Report of Health Statistics and Medicine Technology Agency - Official publications	- Effective co-operation of institutions involved - Sufficient national financial resources are available
Results	**Objectively verifiable indicators**	**Sources of Verification**	**Assumptions**
- Recommendations for adapting national legislation regulating medical devices market surveillance in compliance with European Council directives 90/385/EEC, 93/42/EEC, 98/79/EEC, 97/43/EURATOM - Recommendations for personnel provision (function, capacity and number) in the public structures for medical devices market surveillance. - Global medical devices nomenclature translated into Latvian, approbated and enforced in the Republic of Latvia - Latvian Medical devices market surveillance procedures elaborated and introduced through development of surveillance documentation forms, guidelines and training of	- National legislation adopted in compliance with European Council directives 90/385/EEC, 93/42/EEC, 98/79/EEC, 97/43/EURATOM - Number of personnel recruited and working in accordance with recommended functions, capacity and number - Nomenclature in use by all involved institutions during 1 year after project completion - Personnel of involved institutions trained and using market surveillance procedures daily.	- Monitoring Project Reports - Decisions of the Cabinet of ministers - Reports form the Ministry of Health, Health Statistics and Medical Technologies Agency and State Pharmaceutical Inspection - Reports from the contracted parties - Assessment reports	- Support from relevant institutions - Appropriate resources allocated

personnel and trainers - Medical devices Market surveillance structures, Latvian hospitals, manufacturers, distributors capacity strengthened through participation in Vigilance system pilot project - HSMTA strengthened with necessary equipment and hardware - Co-operation model and strategy for medical devices notified body involved in Medical devices market surveillance system elaborated - Compatible system for electronic information exchange among the EU and national institutions involved in Medical devices market surveillance system and vigilance system	- Vigilance system operational in the involved institutions - Equipment and hardware supplied and installed - Functional medical devices notified body involved in Medical devices market surveillance - System for electronic information exchange among the EU and national institutions operational		
Activities	**Means**		**Assumptions**
- Screening of National legislation for Medical devices Market surveillance sector in compliance with *acquis* - Provision of proposals for changes in the existing Latvian legislation framework/content dealing with Medical devices Market surveillance instruments and regulation mechanisms - Provision of advice and guidance on development of necessary amendments of law or regulations. Provision of consultations to the Ministry of Welfare and working groups - Analysis of institutional structure and existing and necessary personnel provision (functions, capacity and number) for implementation of Medical devices Market surveillance, Vigilance system and medical devices conformity assessment notified body functions in project beneficiary institutions - Provision of advice on changes in institutional framework (if necessary) and personnel. Assistance to implement proposed changes effectively - Translation and approbation of Global Medical Devices Nomenclature System - Develop market surveillance procedures for monitoring of Medical devices placed on the market, including surveillance documentation forms and guidelines for: - Develop market surveillance procedures for corrective actions to establish conformity, including surveillance documentation forms and guidelines for: - Develop market surveillance procedures for complementary activities, including surveillance documentation forms and guidelines for: - Develop market surveillance procedures for, Medical devices Vigilance system (system of notification and evaluation of	- PAA– (12 man months in total with other components) - Short-term twinning expertise on legislation (4 man months) - Short-term twinning expertise on institutional structures building (4 man months) - Short-term expertise on legislation (3 man months) Service contract for translation - Short-term twinning expertise on procedures (10 man months in total) - Short-term twinning expertise on registration (3 man months in total) - Short term expertise on medical devices market surveillance procedures (10 man months in total) - 2 one-week study visits on Medical devices Market surveillance procedures (8 persons) - 5 training seminars on Medical devices Market surveillance procedures (8 persons)	- Reports form the Ministry of Health, Health Statistics and Medical Technologies Agency and State Pharmaceutical Inspection - Project records - Assessment reports	- Advice/ training is relevant, timely and consistent - All funds available on time - Adequate staff in the involved institutions is recruited - Selected key experts and professionals for training - Established Project Steering Committee

adverse incidents), including surveillance documentation forms and guidelines for: - Develop market surveillance procedures for administrative co-operation with other EU Medical device Market surveillance authorities and European Commission. - Vigilance system pilot project preparation and implementation, by participation of relevant institutions: HSMTA, SPI, National Custom Board, at least 3 Latvian hospitals, manufacturers, distributors and notified bodies. - One-week study visit (workshop on Vigilance system pilot project. - 1 local seminar (workshop on Vigilance system pilot project), for HSMTA, SPI, National Custom Board, Latvian hospitals, manufacturers, distributors and notified bodies personnel - Reengineering of existing Medical devices and Medical devices First Safety Group databases and expanding to Market surveillance functions - Development of software for Medical devices Vigilance system database - Training of databases users (6 persons) - Supplies of Hardware for databases. - Supplies of Equipment for laboratory of Medical device sample examination and testing, conformity assessment procedures, - Supplies of standard office furniture and technical support equipment - Purchasing of two cars (4WD) - Training for HSMTA conformity assessment unit and testing laboratory 6 personnel on use of Medical device sample examination and testing equipment.	- one-week study visit on Vigilance system (training of trainers 12 persons) - 1 training seminar on Vigilance system (12 persons) - 10 seminars on Vigilance system provided by trained trainers (Aluksne, Daugavpils, Kuldiga, Cesis) - Short-term twinning expertise on Vigilance system pilot project preparation and implementation (3 man months in total) - Short term expertise on Vigilance system pilot project preparation and implementation (3 man months in total) - one-week study visit (workshop) on Vigilance system pilot project (6 persons) - 1 training seminar (workshop) on Vigilance system pilot project (20 persons)		

Preconditions

- Strategy approved for the further development of Medical devices Market surveillance and medical devices conformity assessment notified body in Latvia.
- Medical devices Market surveillance structures established in Health Statistics and Medical Technologies Agency and State Pharmaceutical Inspection.
- Power and functions of Medical devices Market surveillance structures defined in national legislation.
- Adequate staffing in the recipient institutions has to be in place for implementation and monitoring of project activities before the start of the project
- Co-financing via national budget ensured

ANNEX 2

DETAILED IMPLEMENTATION CHART

Project N°:
Project Title: Medical devices Market surveillance and Vigilance system

	2003												2004											
	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
Contract 1 - Twinning Covenant																								
Pre-Accession Advisor, Pre-Accession Advisor assistant (12 man-months)												X	X	X	X	X	X	X	X	X	X	X	X	
Provision of proposals for changes in the existing Latvian legislation framework/content dealing with Medical devices Market surveillance instruments and regulation mechanisms.													X	X										
Provision of advice and guidance on development of necessary amendments of law or regulations.														X	X									
Analysis of institutional structure and existing and necessary personnel provision (functions, capacity and number) for implementation of Medical devices Market surveillance functions												X	X											
Provision of advice on changes in institutional framework (if necessary) and personnel. Assistance to implement proposed changes effectively.													X	X	X									
Develop market surveillance procedures, including surveillance documentation forms and guidelines for: monitoring of products placed on the market; corrective actions to establish conformity; complementary activities; medical devices Vigilance system and administrative co-operation.														X	X	X	X	X	X	X	X	X	X	
Assessment of the existing Medical devices registration procedures and assisting in change implementation														X	X	X	X							
2 one-week study visits (transfer of knowledge and best practice of EU Member state Medical device Market surveillance procedures)																	X	X						
Local training seminars (covering a) monitoring of products placed on the market; b) corrective actions to establish conformity; c) complementary activities; d) medical devices Vigilance system; e) administrative co-operation)																		X						
one-week study visit (transfer of knowledge and best practice of EU Member state Vigilance system) – training of trainers																	X	X						
Local training seminar on Vigilance system – training of trainers																		X						
Organisation of 10 seminars on Vigilance system to manufacturers, distributors and Latvian hospitals provided by trained trainers																			X	X	X	X	X	
Vigilance system pilot project preparation and implementation																			X	X	X			
one-week study visit (workshop on Vigilance system pilot project)																				X				
Local seminar (workshop on Vigilance system pilot project)																				X				

Contract 2 - Framework Contract																								
Screening of the existing national legislation for medical devices market surveillance											X	X	X											
Develop market surveillance procedures, including surveillance documentation forms and guidelines for: monitoring of products placed on the market; corrective actions to establish conformity; complementary activities; medical devices Vigilance system and administrative co-operation.													X	X	X	X	X	X	X	X	X	X		
Vigilance system pilot project preparation and implementation																		X	X	X				
Contract 3 - Service Contract																								
Translation of ISO/ TS 20225 Standard (Global medical devices nomenclature) in Latvian.												X	X	X										
Provision of expertise on correction and standard approbation.														X	X	X								
Provision of expertise on standard enforcement in national legislation														X										
Contract 4 – Framework contract (Software Development)																								
Reengineering and expanding of the existing Medical devices and Medical devices First Safety Group databases to comprise Market surveillance functions.													X	X	X	X								
Development of Medical devices Vigilance system data base														X	X	X								
Link and harmonise Medical devices Vigilance system with EU databases and national health care system databases.																X	X							
Contract 5 - Supply Contract																								
Strengthening of HSMTA by Provision of required equipment: Hardware for databases.															X	X								
Seminar for HSMTA personnel on information systems and databases.																X								
Strengthening of HSMTA by Provision of required equipment: Equipment for laboratory of Medical device sample examination and testing.															X	X								
Training for HSMTA personnel on use of Medical device sample examination and testing equipment.																X								

ANNEX 3
CUMULATIVE CONTRACTING and DISBURSEMENT SCHEDULE (by quarters)

			31.12.2003	31.03.2004	30.06.2004	30.09.2004	31.12.2004	31.03.2005	30.06.2005	
Contract 1 (Twinning)*										
Contracted total				**692 000**						
Phare				692 000						
Disbursed total				**553 600**	**622 800**			**692 000**		
Phare				553 600	622 800			692 000		
National			28 000	41 240	54 480	67 720	80 960	94 200		
Contract 2 (FWC)*										
Contracted total				**48 000**						
Phare				48 000						
Disbursed total				**28 800**		**36 000**		**48 000**		
Phare				28 800		36 000		48 000		
National				960	1 920	2 880	3 840	4 800		
Contract 3 (Service)**										
Contracted total				**53 200**						
Phare				39 000						
National				14 200						
Disbursed total				**31 920**		**37 240**		**53 200**		
Phare				23 400		27 300		39 000		
National				8 520		9 940		14 200		

* Parallel co-financing
** Joint co-financing, excluding all taxes and duties

Contract 4 (FWC) – Software Development **				31.03.2004	30.06.2004	30.09.2004	31.12.2004	31.03.2005	30.06.2005	
Contracted total					**186 800**					
Phare					139 600					
National					47 200					
Disbursed total					**112 080**		**140 100**		**186 800**	
Phare					83 760		104 700		139 600	
National					28 320		35 400		47 200	
Contract 5 (Supply) **										
Contracted total					**459 680**					
Phare					240 000					
National					219 680					
Disbursed total					**275 800**	**413 700**	**459 680**			
Phare					144 000	216 000	240 000			
National					131 800	197 700	219 680			

* Parallel co-financing

** Joint co-financing, excluding all taxes and duties

ANNEX 4

INDICATIVE DETAILED BUDGET BREAKDOWN

LV PHARE 2003

MEDICAL DEVICES MARKET SURVEILLANCE AND VIGILANCE SYSTEM

		PHARE			National Co-financing	TOTAL
	Benefici	Investment Support	Institutional Building	**Total Phare**		
Contract 1 - Twinning Covenant*			**692 000**	**692 000**	**94 200**	**786 200**
Twinning arrangements for the whole project	MoH HSMTA SPI					
Pre-Accession Advisor (12 man-months)			180 000			**180 000**
PAA's assistant (12 man months)			12 000			**12 000**
Stationery, communications transportation expences					15 500	**15 500**
Component 1 – Improvement of Latvian legislation and strengthening the power of Medical devices Market surveillance structures	MoH					
Short term twinning expertise on legislation (4 man months)			60 000			**60 000**
Short twinning international expertise on institutional structures building (4 man months)			60 000			**60 000**
Component 2 – Development of Medical devices Market surveillance procedures	HSMTA, SPI					
Short term twinning expertise on procedures (10 man months in total)			150 000			**150 000**
Short twinning expertise on registration (3 man months in total)			45 000			**45 000**
2 one-week study visits on Medical devices Market surveillance procedures (8 persons)			30 000		20 500	**50 500**
5 training seminars on Medical devices Market surveillance procedures (8 persons)			50 000		7 000	**57 000**
		PHARE			National Co-financing	**TOTAL**
one-week study visit on Vigilance system (training of trainers 12 persons)			15 000		19 200	**34 000**
1 training seminar on Vigilance system (12 persons)			10 000		7 000	**17 000**
10 seminars on Vigilance system provided by trained trainers			10 000		14 000	**24 000**
Component 3 – Capacity building of Medical devices Market surveillance structures	HSMTA, SPI					
Short term twinning expertise on Vigilance system pilot project preparation and implementation (3 man months in total)			45 000			**45 000**
one-week study visit (workshop) on Vigilance system pilot project (6 persons)			15 000		9 600	**24 600**
1 training seminar (workshop) on Vigilance system pilot project (20			10 000		1 400	**11 400**

persons)						
Contract 2 - Framework contract*			**48 000**	**48 000**	**4 800**	**52 800**
Short term local expertise on legislation (3 man months)			9 000		900	**9 000**
Short term local expertise on procedures (10 man months in total)			30 000		3 000	**30 000**
Short term local expertise on Vigilance system pilot project preparation and implementation (3 man months in total)			9 000		900	**9 200**
Contract 3 - (TA) Contract**		**0**	**39 000**	**39 000**	**14 200**	**53 200**
Component 1 - Improvement of Latvian legislation and strengthening the power of Medical devices Market surveillance structures	MoH HSMTA, SPI					
Translation of standards					11 000	**11 000**
Local 12 different experts expertise on correction and standard approbation (12 man/ months in total)			36 000		3 000	**39 000**
Short term local expertise on standard enforcement in national legislation (1 man months)			3 000		200	**3 200**
		PHARE			National Co-financing	**TOTAL**
Contract 4 - Framework contract (Software development)**		**0**	**139 600**	**139 600**	**47 200**	**186 800**
Component 3 - Capacity building of Medical devices Market surveillance structures	HSMTA, SPI					
Reengineering of existing Medical devices and Medical devices First Safety Group databases and expanding to Market surveillance functions			110 000		37 000	**147 000**
Development of software for Medical devices Vigilance system data base			20 000		7 000	**27 000**
Training of databases users (6 persons)			9 600		3 200	**12 800**
Contract 5 - Supply contract**		**240 000**	**0**	**240 000**	**219 680**	**459 680**
Component 3 - Capacity building of Medical devices Market surveillance structures	HSMTA					
Supply of hardware for databases		12 000		12 000	40 900	**52 900**
Supply of Equipment for laboratory of product sample examination and testing		228 000		228 000	89 680	**317 680**
Supply office furniture and technical support equipment		0			15 400	**15 400**
Purchasing of two cars (4WD)		0			50 000	**50 000**
Supply of communication equipment		0			3 000	**3 000**
Supply of technical devices and materials for repair of rooms (office and laboratory)		0			20 700	**20 700**
TOTAL		**379 600**	**779 000**	**1 158 600**	**380 080**	**1 538 680**

* Parallel co-financing

** Joint co-financing, excluding all taxes and duties

ANNEX 5

LV PHARE 2003

PHARE SUPPLY CONTRACT 4

INDICATIVE LIST OF EQUIPMENT

Item	Description	Number of units	Unit price, EUR	Total Value, EUR
	Supply of hardware for databases			**52 900**
	Supply of hardware for databases		**Total**	**12 000**
1	IT Web server (to EU MD Databases)	1	12000	12000
	Hardware for Medical devices Market surveillance and Vigilance system experts		**Total**	**40 900**
2	Laptop (Pentium IV (or equal) 1500, 40 G HD, 128 Ram, modem, 15 inch LCD Ethernet 100/modem/CD reader/DVD), Windows XP (or equal), Office Suite Professional. Software in Latvian with also Russian and English Dictionaries, Keyboard Cyrillic qwerty	3	3000	9 000
3	Stationary PCs (Pentium IV 1800, 40 G HD, 256 Ram Monitor 17 inch, 0.22 dpi, 100 network card/CD reader/writer/DVD Windows XP (or equal), Office Suite Professional (Word, Excel, Access, Power Point) Software in Latvian with also Russian and English Dictionaries, Keyboard Cyrillic qwerty	7	1500	10 500
4	Printer (A4 20 ppm BW laser, memory 32 Mega/network card/500 page storage,) 10 toner cartridges, 100 LAN card	3	1200	3 600
5	Printer 12 ppm ink jet colour A3/network card/Memory 32Mega, 10 colour ink cartridges, 10 BW ink cartridges, 100 LAN card	2	1200	2 400
6	Hub speed 100 8 ports minimum for LAN and Internet	1	200	200
7	Internet fast modem connection	1	1000	1 000
8	Copier 20 ppm/auto feeder 2 yr service contract/guarantee	1	4500	4 500
9	A4 Laser Fax, 10 memories, speed dialing, copying, printing	1	500	500
10	Scanner A4	1	200	200
11	Internet modem/server	1	9000	9 000
	Supply of Equipment for laboratory of product sample examination and testing		**Total**	**317 680**
13	Ventilator Testing System	2	14000	28000
14	Electrosurgical Analyzer	2	4000	8000
15	Rigid Endoscope Tester	2	1200	2400
16	Endoscope Testing System	1	46000	46000
17	Gas Flow Analyzer	2	2900	5800
18	Electrical Safety Analyzer	2	6300	12600
19	EGG/Arrytmia Simulator	3	2800	8400
20	Defibrillator Analyzer	2	3600	7200
21	Non-Invasive Blood Pressure Analyzer	3	5400	16200
22	Blood Pressure Analyzer	2	4200	8400
23	Infusion pump tester	3	4100	12300
24	Multiparameter simulator	2	8700	17400
25	Infusion Device Analyzer	1	6500	6500
26	Incubator Analyzer	2	8200	16400
27	Pulse Oximeter Simulator	2	1700	3400
28	Phototherapy radiometer	1	1800	1800
29	Ultrasound Wattmeter	1	3600	3600
30	External Pacemaker Analyzer	1	2900	2900
31	Set of Data loggers for sterilisation with software	1	18100	18100
32	Set of reference materials for laboratory equipment testing	1	32400	32400
33	Conductometer	2	1800	3600

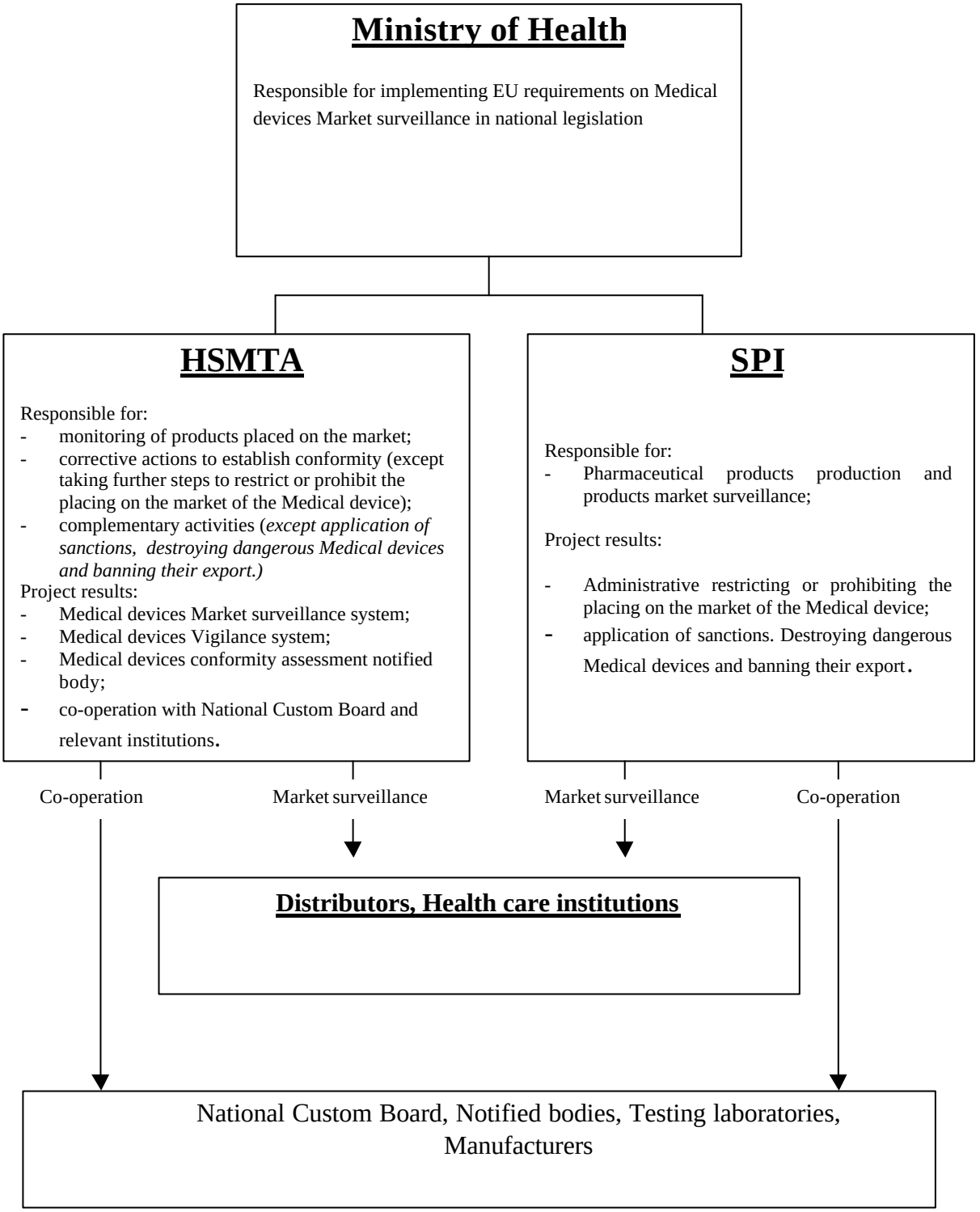
34	Calibrator	2	6800	13600
35	Multiparameter calibrator	2	8200	16400
36	Technical laboratory equipment (reserve)			12600
	Office furniture and equipment		**Total**	**15 400**
37	Desks	10	200	2 000
38	Manager Desk,	3	300	900
39	Buro Roller arm chairs	10	80	800
40	Wood grain, Manager Leather Roller Arm Chair	3	120	360
41	Meeting table	2	500	1000
42	Fixed Meeting Chairs	16	60	960
43	File/Storage Cabinets	5	300	1 500
44	Coat Cabinet	7	250	1 750
45	Desk lamps	13	100	1 300
46	Trash Cans	6	5	30
47	Office technical support equipment			5 200
	Vehicles		**Total**	**50 000**
48	Vehicles 4WD	2	25000	50 000
	Communication equipment		**Total**	**3 000**
36	Set of 5 Phones and mini ATM (4 lines in 6 out)	1	2 000	2 000
37	GSM standard mobile phones	5	200	1 000
	Supply of technical devices and materials			
38	Office and testing laboratory rooms renovation for Medical devices Market surveillance and vigilance system t			**20 700**
			GRAND TOTAL	**459 680***

Justification of Supplies:

Functions of the Medical devices Market surveillance	Required equipment
Monitoring of Medical devices placed on the market: - Regular visits to commercial, industrial and storage premises. - Regular visits to work places and other premises where Medical devices are put into service. - Organisation of random and spot checks. - Taking samples of Medical devices, and to subject them to examination and testing. - Requiring all necessary information. - Checking on the production premises if non-compliance has been discovered - Checking trade fairs, exhibitions and demonstrations.	• Equipment for laboratory of product sample examination and testing • Communication equipment • Vehicles
Corrective actions to establish conformity: - Putting obligation to a manufacturer or authorised representative to make the Medical device comply with provisions. - Taking further steps to restrict or prohibit the placing on the market of the Medical device.	• Hardware for databases • Hardware for Medical devices Market surveillance and Vigilance system experts • Office furniture and equipment
Complementary activities: - Collaboration with manufacturers and suppliers. - Warning of persons who might be at risk.	• Hardware for databases • Hardware for Medical devices Market surveillance and Vigilance system experts

- Taking appropriate action against the person whom has affixed the CE marking to non-compliant product, and those who are responsible for the non-compliance of the Medical device. - Destroying dangerous Medical devices and banning their export. - Application of other sanctions	• Communication equipment • Office furniture and equipment • Vehicles
Medical devices Vigilance system (system of notification and evaluation of adverse incidents): - Monitoring the investigation and co-ordination contacts with the manufacturer. - Accessing the expertise of relevant Notify body and co-ordinating with other EU Medical device Market surveillance authorities. - Discussing with manufacturer the principles of corrective actions to be taken. - Disseminating details of incidents to other in EU Medical device Market surveillance authorities and European Commission. - Work with EU and local databases.	• Hardware for databases • Hardware for Medical devices Market surveillance and Vigilance system experts • Communication equipment • Office furniture and equipment
Administrative co-operation with other EU Medical device Market surveillance authorities and European Commission.	• Hardware for databases • Hardware for Medical devices Market surveillance and Vigilance system experts • Communication equipment • Office furniture and equipment

ANNEX 6 - Proposed system of Medical devices Market surveillance in the Republic of Latvia



ANNEX 7 - EU regulations according medical devices

1. Accession Partnership 2001;

2.90/385/EEC Council Directive from June 20th 1990 on Active Implantable Medical Devices;

3. 93/42/.EEC Council Directive from June 16th 1993 on Medical Devices;

4.98/79/EEC Council Directive from October 27th 1998 on *In Vitro* diagnostic Medical Devices;

5.97/43/EURATOM;

6.ISO/TS 20225 Standard (Global Medical Devices Nomenclature System).

ANNEX 8 – Latvian Legislation on Medical Devices

1. Law on Safety of products and services adopted in 20 June 2000;
2. Cabinet of Ministers regulation No 429 adopted in 12 December 2001, Statutes of Council of market surveillance;
3. Cabinet of Ministers regulation No 83 adopted 27 February 2001, Order how the market surveillance authorities summon and receive samples of goods as well as how them proceed with samples after examination by laboratory or other expertise;
4. Cabinet of Ministers regulation No100 adopted 6 March 2001, Procedures for registration, sale and distribution of medical devices and medical goods;
5. Cabinet of Ministers regulation No 78 adopted 19 February 2002, On Procedure of exploitation and technical supervision medical devices and medical goods.