Standard Summary Project Fiche for the Transition Facility

1. Background information
1.1 CRIS number: 2005/017-464.04.03
1.2 Title: Strengthening national monitoring of drugs and drug abuse
1.3 Sector: Health
1.4 Location: Bratislava, Slovakia

2. Objectives

2.1 Overall objectives:

High quality monitoring and reporting of the required “Drug Related Deaths and Mortality of Drug Users”, which is one of five Key-Indicators established by the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA).

2.2 Project purposes:

Adjust and strengthen the Laboratory of the Forensic-Medical Toxicology (within the Institute of Forensic Medicine in Bratislava – Petržalka) to be established and accredited as the National Reference Laboratory - the main institution responsible for the necrotic toxicology within the established nationally coordinated system of the forensic medicine.

2.3 Justification

This project will help to achieve the principles and objectives of The EU drug strategy 2005 – 2012:

„better understanding of the drugs problem and the development of an optimal response to it through a measurable and sustainable improvement in the knowledge base and knowledge infrastructure...in the field of drugs and consolidating the drug information systems and tools developed over the 2000-2004 period, making full use of the EMCDDA and Europol.”

Furthermore, in the field of the drug demand reduction:

„Measurable reduction of the use of drugs, of dependence and of drug-related health and social risks through the development and improvement of an effective and integrated comprehensive knowledge-based demand reduction system.”

At the same time the project will take into consideration provisions of the 2003 Concil Recommendation (OJ L 165 of 18 June) on the prevention and reduction of health-related harm associated with drug dependence, namely in its operative paragraphs 2 and 3, which concerns drug related deaths and set up principles of sound measures how to tackle this problem.

3. Description

3.1 Background and justification

As a member of the EU, the Slovak Republic is obliged to fulfill the requirements related to monitoring of the drugs-related deaths and the deaths of drugs abusers. There had been several activities in the past to implement the Drug Related Deaths (DRD) indicator in the Slovak Republic, as a part of the Phare project on Drug Information System (1994 - 2000). EMCDDA was also involved in this project. The
establishment of the structures similar to the National Focal Points of the REITOX network in the group of countries acceding to EU was one of the main objectives of that project. That included introduction of five key epidemiological indicators (the Drug Related Deaths indicator including) and related activities. Strong efforts had lead to the creation of a reporting system based on co-operation between the Ministry of Health SR, especially its section of forensic medicine, and the national Statistical Office. Within the framework of this earlier system, annual reports on the total number of deceased persons in the Slovak Republic were modified retrospectively according to certified number of drug related deaths proved on the basis of confirmative results from forensic examination. The data from such system was not sufficient and reliable and DRD numbers were apparently underestimated; furthermore, the data provision was delayed due to waiting for results of forensic examinations and for finishing a process of the final mortality data file adjustment. The system faded when support from the DIS project had been stopped.

Last year, activities were resumed. Slovakia became a member of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and the key indicators became an obligatory part of the National Focal Point agenda as stated in the documents adopted by two statutory bodies of the EMCDDA: the Operating Framework of Reitox, and the 3 Years Work plan. These documents of the Management Board and the Scientific Committee are considered as binding for National Focal Points, including DRD and other four key indicators. The way of introduction of the indicator is determined by the methodological documents provided by the EMCDDA. In general, two sources of information are accepted as valid ones for DRD reporting: one source is the General Mortality Register, which is available in all Member States. Data from this source is well comparable within Member States. However, obtaining data from the General Mortality Register has some weaknesses (death certification procedures, ICD coding, binding with forensic examination etc.), and therefore the data is usually underestimated. Another source of information on drug related deaths, according to the EMCDDA guidelines, is a special register. The special register is defined like either a register on drug related deaths administered by the police, or a forensic register on drug related deaths. This second source (i.e. special register) provides more accurate data and higher numbers of drug related deaths compared to the first one, however there are no special registers established in all countries so data are therefore less comparable at the international level. Furthermore, special registers only comprise cases that passed forensic examination (poisonings, suspect causes…). Concept of creation of special forensic registry on drug related deaths was outlined during negotiations initiated by the National Monitoring Centre for Drugs (NMCD) with experts of the Ministry of Health SR. A meeting was held at the end of the year 2004 with experts in forensic medicine, toxicology, health statistics, general statistics and others, to consider possibilities of DRD indicator development in the Slovakia:

- A National Working Group of relevant experts will guarantee expert angle of introduction and development of the DRD indicator in the Slovak Republic. The head of this working group is in a position of an external expert for DRD indicator at the Slovak National Focal Point (“National Monitoring Centre for Drugs”). A secretary of this group, who organise their regular meetings, is an internal employee of the National Monitoring Centre for Drugs (an epidemiologist).
• Creation of the Special Forensic Register is priority task during the first phase of the DRD indicator development. Information circle of the General Mortality Register will be built up in parallel activities; collaboration between both information circuits (General Mortality Register and Special Register) will be developed after the GMR circuit is fully functional (with respect to the data on DRD provision). However, experts from the area of GMR data on DRD are members of the working group from the beginning. Interconnection between those two circuits is very complicated and is only possible by retrospective reporting from forensic field on suspected cases after finishing of investigation and forensic examination. After that retrospective reporting to GMR it is possible to adjust GMR data on drug related deaths. This assumes that the information from forensic expert is valid and reliable, based on scientific and proper toxicological data.

• Czech partners will provide their computer programme to simplify input of the data at forensic medicine workplaces.

• To improve quality of forensic data on drug related deaths and their toxicological details it is necessary to improve standard of toxicological analyses by establishing at least one European-level-standard reference toxicological laboratory in Slovakia. The idea of this last task has been elaborated further into the concept of the project presented here.

The role of NFP is:

• to co-ordinate collection of the data on DRD indicator accross the network of forensic/toxicology laboratories;

• to ensure that the data meets EMCDDA standards with respect of the quality of the data, correctness of the data collection and processing, geographical and case coverage etc.;

• to deliver the data on DRD indicator in required format to the EMCDDA database;

• to provide feedback from the site of EMCDDA to experts involved;

• to provide administrative support for running the system of data collection and indicator development.

External expert on DRD indicator at NFP (an expert from the field of forensic medicine) is contracted by NFP as a person responsible for the quality of the data (including toxicological details on respective cases of death). Depending on data quality some rewards from NFP could be negotiated for forensic and toxicology experts who are directly involved in data provision.

Currently, in the Slovak Republic there are eleven toxicological laboratories making up the forensic medicine network. The network is managed by the Health Care Surveillance Authority.

The level of technical status and staff education within the system of laboratories is rigid and insufficient. Out of the eleven labs, in seven practical forensic-medical toxicology is performed on minimum or standard range.

Recently, out of those seven laboratories only three are partially (depends on laboratory equipment and calibration standards availability) able to perform valid quantitative analysis of the monitored Narcotic and Psychotropic Substances (NPS).

Recently topmost actual problem is the issue of drugs (the NPS) using and abusing and the related deaths. The only exact basis for any relevant statements and deductions
is a result of qualitative and/or quantitative toxicological-chemical analysis. Without that exact entry, any diagnosis, statistical processing or prognosis remains on the level of theoretical qualification and speculation.

To meet the responsibilities arising from EU membership, it is, in the first place, necessary to improve the toxicological-chemical analytical basis, including its quality control. What this requires in practical terms is the establishment of at least one National Reference Laboratory of the Forensic-Medical Toxicology, which would assure quality control in the field of qualitative and quantitative monitoring of the NPS.

Establishment of the National Reference Laboratory of the Forensic-Medical Toxicology would represent the basic and the initial step of realization of the long-run national conception in scope of:

- quality management and control according to the STN ES ISO/IEC 17025 European and Slovak standard valid for the control and calibration laboratories - preparation of accreditations and certifications of the forensic-medical toxicology laboratories in the Slovak Republic
- continuous postgraduate education and professional analytical skills development of the toxicologists - responsible investigators as well as the laboratory technicians level executive staff
- cooperation with daughter foreign laboratories focused on:
  - active participation on quality management and control of the EU standard level
  - harmonization of the standard laboratory procedures used for the NPS monitoring
  - sharing professional experience by the following alternative forms: short-term reciprocal fellowships; professional training under supervision of prestigious specialists; active participation on professional actions (conferences, professional meetings and seminars, professional skills improvement courses, etc.);

Laboratories of the forensic-medical toxicology and chemistry represent the basis for exact monitoring and diagnosing of the NPS in biological materials taken at autopsy of human body. Those are methodically, methodologically and from the executive staff experiences and qualification points of view prepared to provide valid qualitative-identificational, semi-quantitative and quantitative analytical results. Processing and analysis of the autopsy biological materials is the typical scope of the forensic-medical toxicology. Those materials do not represent the standard biological materials. Due to saprogenic changes, thermal changes - fire influence, changes after maceration - water influence in case of drowning, etc. they more or less differ from clinical biological materials. Thereof, the forensic-medical toxicology methods of the samples pre-analytical processing and analysis itself are specific. Mostly they are much complicated and difficult, than it is either in the case of dealing with the standard clinical biological matrices (the typical subjects for the clinical toxicology), or in the case of identification of the original forms of chemical individuals not-bonded on biological matrices(for instance, pure drug substances, drugs abused the typical subject of interest, for instance, for the Criminalistic-Expertise Institute of the Slovak Police Corps analytical laboratories).

Typical for the clinical biochemistry laboratory practice is processing of samples in large series. While clinical biochemistry prevalently uses automatized analytical systems, each of the forensic-medical samples taken at autopsy require individual investigative approach of sufficiently educated and experienced investigator -
toxicologist. Essential is to have available broad range of the traditional, but mainly the up-to-date techniques of the "wet" chemistry and the physical-chemical instrumental analytical methods. The needs are based on professional evaluation of the actual situation, very often based on availability of literally none preliminary anamnesis information about the investigated case.

Specific and important rule of the forensic-medical toxicology in the system of institutions involved in fighting against the NPS substances abuse is evident. However, the technical capability of the related laboratories in Slovakia is close to the critical limit of acceptance. In general, it is required to improve: material conditions and instrumentation, availability of scientific information sources and level of professional education of the forensic-medical toxicological laboratories staff.

### 3.2 Linked activities

The project is related to:

PHARE 2000 Twinning Project SK00 / IB/ JHA/ 02 “Fight against Drugs,” which provided a number of conclusions and recommendations for the reinforcement of the Slovak Government’s action and programmes on fight against drugs. These conclusions were ratified by the findings of the international conference UNDCP - Groupe Pompidou, which was realized by the Board of Ministers for the Drug Dependencies and Drug Control with a cooperation of the concerned government departments. The total budget of the project was divided as follows: 1,0 mil EUR from PHARE and 0,12 mil EUR national co-financing.

PHARE 2003 UIBF Project 2003-004-995-0104 “Social and Economic Costs of Illicit Drugs Used in SR”.

The project has been signed with the ECO company and started in July 2004 with the expected end in September 2005. Total budget of the project is 0,2 mil EUR.

The current financial flows related to social and economic costs of illicit drugs used in Slovak Republic should be analysed and the EU standards for the calculation of the costs of illicit drugs used in Slovakia should be implemented within this project. In this framework Slovak experts will be trained in usage of the EU methodology and a manual for the calculation of the social and economic costs of illicit drugs used in Slovak Republic will be developed. Also the recommendations for the implementation of the analysis results into the National programme for the fight against drugs for the year 2004-2008 will be produced.

The project is now in its implementation phase and the objectives performance are fully in compliance with the time frame.

Transition Facility 2004 Project 2004/016-764.03.02 “Support to the Implementation of the National Programme for Fight against Drugs 2004 – 2008”.

Expected starting of the project is June 2005 with the expected end in March 2007. The total budget has been approved in the amount of 1,5 mil EUR from TF and 0,7 mil EUR Slovak national co-financing.

This project aims at building up and strengthening the institutional, administrative and professional capacities at all levels of Slovak Public Administrations and Public Services concerned with the fight against drugs, as well as in third sector organisations involved – as partners of the public administrations - in the implementation of the projects and activities envisaged in the National Programme.
Besides this, is is dealing with the institutional and professional capacities building and strengthening in the field of drug demand and drug supply reduction and with an improvement of the quality and reliability of the information available in the field of drugs and drug addictions in the SR, as well as the enhancement of the communication and sharing of information between institutions dealing with data collection, their analysis, evaluation and presentation. This project is in its inception phase.

3.3 Results

The project realization should meet the following results:

3.3.1. Necessary equipment for acquisition of high quality information provided.

To make monitoring of the deaths related to drugs and drugs abusers efficient and effective, it is necessary to support the National Reference Laboratory of the Forensic-Medical Toxicology (part of the Institute of Forensic Medicine in Bratislava – Petržalka) with specialized equipment. It will help to provide high quality and reliable analyses of non-standard biological samples for all Slovak forensic-medical institutions. (Annex 4)

The National Reference Laboratory of forensic-medical toxicology will ensure qualitative and quantitative monitoring of the NPS. Therefore, the laboratory staff also needs to have access to all necessary and most recent information (newest edition books, publications).

3.3.2. Theoretical background and practical analytical skills of the high quality of the Slovak forensic-medical toxicological laboratories improved.

The executive toxicologists - investigators and their qualified laboratory technicians make up the staff of the Slovak forensic-medical toxicological laboratories located in the cities Bratislava, Banská Bystrica, Košice, Martin, Nové Zámky, Nitra, Žilina, Trnava, Lučenec, Prešov and Poprad. To improve its theoretical background and practical analytical skills the staff will receive a set of specialized trainings focusing on the presentation of standard laboratory procedures, quantification of drugs, recent techniques in forensic toxicology, quality assurance and the laboratory of forensic-medical toxicology and toxicological analysis quality control. In total, there are about 20 employees together (taken from all eleven Slovak forensic-medical toxicological laboratories) to be trained.

3.3.3. Pilot monitoring and reporting of the deaths related to drugs and drugs abusers successfully executed

In the project’s final phase the National Reference Laboratory of the Forensic-Medical Toxicology will be able to assure validity and reliability of the required data and will provide it in the appropriate format required by the EU standards, elaborated by the EMCDDA, to the National Focal Point in Slovakia.

3.4 Activities

3.4.1. Procurement of the special equipment for the National Reference Laboratory to ensure the production of high quality information for monitoring of the deaths related to drugs and drugs abusers

The National Reference Laboratory will be technically strengthened by acquisition of inevitable, special equipment. (Specification in annex 4) Strictly in compliance
with legal Act No. 581/2004 about health insurance companies and health care surveillance as amended, the equipment will be used only for analyzing of the autopsy biological samples.

The support will also include the acquisition of all necessary and most recent information material relating to forensic medicine (last editions of books, publications). However, given that the National Reference Laboratory has to ensure the qualitative and quantitative monitoring of NPS, it requires the access to the most up-to-date information. The required sources of theoretical and experimental (practical) information are mostly issued abroad and are hardly available in sufficient range to the Slovak experts.

3.4.2. Provision of a set of seminars and workshops for 20 employees of all Slovak forensic-medical toxicological laboratories

The trainings (seminars and workshops together) are designed to upgrade the professional knowledge and practical skills to ensure provision of valid analytical results for the EMCDDA key-indicator „Drug related deaths and mortality of drug users“.

MS experts in the second phase of the project will provide a set of 5 specialized trainings on the following topics:

1. Standard laboratory procedures in the forensic-medical toxicology; pre-analytical and analytical processing of the autopsy biological matrix

   Theoretical 3-days seminar focused on the harmonization of the standard procedures used in the Slovak forensic-medical toxicology with the standard procedures of the EU.

2. Quantification of drugs and abused drugs in blood and hairs

   4-days workshop focused on dealing with important sources of toxicological information related to monitoring of drugs and abused drugs. It will consist of a theoretical section (presentations, discussions) and be directly followed by practical laboratory training/demonstration focused on the actually lectured topics.

3. Recent isolation, separation and purification techniques in the forensic medical toxicology; pre-analytical approach to non-standard biological materials processing for the purposes of capture, identification and quantitative analysis of drugs and abused drugs

   4-days workshop focused on dealing with difficult biological matrixes (decayed, burned, macerated etc.) with the goal to produce successful, loss-less capture and high-yield quantitative analysis of drugs and abused drugs. It will consist of a theoretical section (presentations, discussions) and be directly followed by practical laboratory training/demonstration focused on the actually lectured topics.

4. Quality assurance and quality control in the forensic-medical toxicology analysis and laboratory practice following the STN EN ISO/IEC 17025 standard principles

   Theoretical 3-days seminar focused on quality assurance related to professional processing and analyzing of undefined, non-standard autopsy biological materials.
5. Pre-analytical and post-analytical pharmacokinetic and pharmacodynamic aspect of toxicological analysis

Theoretical 3-days seminar focused on the rules of pharmacokinetics and pharmacodynamics of drugs and abused drugs application and interpretation to make right decisions in the process of the toxicological results evaluation.

General comment to all workshops:

Following the Slovak forensic-medical toxicology harmonization with the laboratory procedures in the EU institutions in accordance with the related actual standards (GLP, ES 17025, etc.), MS experts will elaborate recommended standard procedures in printed form (in English and Slovak language) for all participants of the workshops. (about 20 working days together for all MS experts).

For the courses needs, the required equipment (activity 1) is not a pre-condition for the launch of the training activities. However, its availability during the training courses combined with the presence of experienced lecturers and supervisors able to demonstrate its advantages in toxicological analyses, would significantly improve the quality and usefulness of the practical trainings. Hence, the equipment will be supplied in the first phase of the project to ensure its functioning and availability for the planned courses.

3.4.3. Pilot testing of data collection system on Drug Related Deaths indicator

Pilot testing will be provided by employees of the National Reference Laboratory of Forensic-medical Toxicology together with other Slovak forensic medical toxicological laboratories. During 3 months of pilot testing the biological materials will be collected by all laboratories. Biological samples, potentially containing the drugs will be sent to National Reference Laboratory of Forensic-medical Toxicology for analysis using new methodologies acquired during activity 3.4.2. and the new equipment. Analyzed data will be passed to the forensic doctor of the relevant forensic medical toxicological laboratory to complete the analysis of the samples. Particular analysis from each forensic medical toxicological laboratory will be sent to National Reference Laboratory for completion. Complete results in required template will be transferred to National Focal Point and consequently to EU.

The MS input in this activity will be regular consultations and advice to the NRL employees during the analysis of the samples and completion of results made by National Reference Laboratory.

Means:

Activity 3.4.1 will be implemented in the framework of one supply contract (equipment, books and publications)

Activities 3.4.2. and 3.4.3. will be implemented in the framework of one twinning light contract.

In the framework of the twinning light contract one TWL expert is envisaged to be supported by a pool of short-term experts.

The expert required must be a civil/public servant of the relevant MS administration or a permanent staff member of its authorized mandated bodies.
The TWL expert should fulfill the following criteria:

**TWL expert – MS Project leader – II. class**

- he/she must have university education in chemical or pharmaceutical field
- must have at least 8 years of experience in toxicology
- must have experience with harmonization of national forensic-medical toxicology standard procedures with the EU standards
- must have proven team leading experience in working with international teams
- should come from an equivalent institution to beneficiary
- a good command of English is required (spoken, written)
- should have good communication skills
- should have proven lecturer skills

The TWL expert should be responsible for:

- professional and managerial supervision over the entire project
- coordination of partial tasks of the project, sequencing of their realisation
- coordination of pool of STEs
- coordination and professional participation in trainings
- with cooperation of pool of STEs – elaboration of all training materials and recommended standard procedures
- together with STEs – provision of all training requested
- consultation during the pilot testing

With respect to activity 3.4.2. the TWL expert will be supported by the following pool of short-term experts:

**Two short-term experts – class II:**

- they must have education in chemical or pharmaceutical field
- 8 years experience in the field of quality control and assurance in toxicological-medical laboratory, with regard to processing non-standard biological materials;
- should come from equivalent institution to beneficiary
- a good command of English is required (spoken, written)
- should have good communication skills
- should have proven lecturer skills

These experts will be responsible for the following issues:

- in cooperation with the TWL expert – provision of theoretical seminars on selection of a suitable method for toxicological analysis required, used analytical systems optimization (activity 3.4.2.)
- as well as workshops (practical solutions to specific problems, determination of amphetamines in blood serum, quantification of opiates in bile etc.)
- in cooperation with the TWL expert – elaboration of all training materials and recommended standard procedures
### 3.5 Lessons learned:

Within the *Phare 2000 – Twinning Project SK00/IB/JHA/02 – Fight Against Drugs*: to develop and strengthen governmental anti-drug policy of the Slovak Republic the following recommendations have been implemented into the Transition Facility 2004 Project – to improve the co-ordination on the horizontal level between the ministries involved into the drug problems solutions, to improve professionalism in the social care in the field of fight against drugs, to improve the institutional and professionals networks as well as the quality of the statistic data, which depends on the institutional and administrative capacities.

PHARE 2003 UIBF Project 2003-004-995-0104 "Social and Economic Costs of Illicit Drugs Used in SR". The project aims to strengthen the Slovak Government’s programmes and actions in the field of combating drug addiction and ensuring control of illicit drugs in the SR. It will give rise to carrying out the first comprehensive analysis of the social and economic costs of illicit drugs in the Slovak Republic as a pre-step to establish a system of monitoring of the social and economic costs of illicit drug use that might well contribute to a model for the rest of the EU.

The MoH SR has serious experience with managing and coordinating of PHARE projects. The managing structure that was successfully tested is to have overall coordination at the ministerial level (also because the recipient institutions are subordinate of the MoH SR) and the professional guidance is on the recipient level. Project managers from Project Unit of Foreign Aid of MoH SR actively manage and in close cooperation with MS experts and Slovak recipient institutions prepare and ensure all activities and organizational issues. Projects, which MoH managed were successfully finished and objectives and results were achieved, e.g. PHARE No. 2002/000.610-02 “Ensuring Preparedness of the Slovak Public Health Insurance System to apply to Acquis on Coordination of Social Security Schemes” etc

There were no recommendations made during previous interim evaluation that might be applied to this project.

### 4. Institutional framework

The Ministry of Health SR (MoH SR) will be the beneficiary institution and partner in the project. It will have the overall responsibility for the management and control of the
project. The National Reference Laboratory of the forensic-medical toxicology at the
Institute of forensic medicine in Bratislava - Petržalka through its superior Health Care
Surveillance Authority will be the final recipient of the project benefit.

Monitoring of and supervision over the progress and development of the entire project
will be provided by a Steering committee (SC), which will include representatives of
the MoH SR, the Health Care Surveillance Authority, the CFCU and the National Focal
Point for Drugs. The General Secretariat of the Board of Ministers for Drug
Dependencies and Drug Control established by the Government Office SR will take part
as observers.

The Project leader on the Slovak side will be:
Ms. Zuzana Škublová
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The Project manager will be:
Dipl.Eng. Juraj Mlynár, PhD.
Health Care Surveillance Authority
Forensic-Medical and Pathological-Anatomical Institute Petržalka
Antolská 11
851 07 Bratislava
Tel. 00421/2 68673936, Fax: 00421/2 63812217
E-mail: mlynar@npba.sk

5. Detailed budget

<table>
<thead>
<tr>
<th>€M</th>
<th>Transition Facility support</th>
<th>Co-financing</th>
<th>Total cost (TF plus cofinancing)</th>
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<tr>
<td></td>
<td>Investment Support</td>
<td>Institution Building</td>
<td>Total Transition Facility (=I+IB)</td>
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(*) contributions form National, Regional, Local, Municipal authorities, FIs loans to public entities, funds from public enterprises
(**) private funds, FIs loans to private entities
The national joint co-financing was already requested by the MoH in the first draft of the State budget document prepared by the Ministry of Finance SR for 2006.

6. Implementation Arrangements

6.1 Implementing Agency
PAO: Mrs. Silvia Czuczorova
Director of CFCU
Ministry of Finance SR
Štefanovičova 5
817 82 Bratislava
Slovak Republic
tel.: + 421 2 5958 2546
fax: + 421 2 5958 2559
e-mail: cfcu.czuczorova@mfsr.sk

6.2 Twinning
The institutional twinning light partner will be the Ministry of Health of the Slovak Republic, responsible for the overall supervision of the project.

National Contact Point for Twinning involved in Twinning projects management:
Mrs. Jana Minarovičová
Office of Government SR
Námestie slobody 1
813 70 Bratislava
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E-mail: jana.minarovicova@government.gov.sk

The Ministry of Health will cooperate in project implementation with the Health Care Surveillance Authority – and its subordinate institution, the Institute of Forensic Medicine Bratislava – Petržalka, which will be the recipient of the project.
The twinning light experts will be deployed at the office of the – Institute of Forensic Medicine Bratislava – Petržalka.

Contact person:
Dipl.Eng. Juraj Mlynár PhD.
Health Care Surveillance Authority
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E-mail: mlynar@npba.sk

6.3 Non-standard aspects
N/A

6.4 Contracts
The project will be implemented with the following contracts:
Twinning light arrangement: 0,120 mil €
Supply contract (equipment, books): 0,380 mil € (including national joint co-financing)

7. Implementation Schedule
   7.1 Start of tendering/call for proposals: 4th Q 2005
   7.2 Start of project activity: 1st Q 2006
   7.3 Project completion: 3rd Q 2006

8. Sustainability
   Relevant policies and regulations of the Slovak Government ensure that all activities funded under the scheme will yield results that comply with the European Union norms and standards. Governmental funding of the operation and maintenance of the project is ensured.

9. Conditionality and sequencing
   The project implementation will include the following milestones:
      - technical specification developed
      - supply of the equipment and information sources needed;
      - training of relevant staff;
      - provision of pilot monitoring and reporting
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. Description of equipment required
5. List of publications and books needed
## Transition Facility log frame

<table>
<thead>
<tr>
<th>LOGFRAME PLANNING MATRIX FOR Project</th>
<th>Programme name and number</th>
<th>2005/017-464.04.03</th>
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<tr>
<td>Strengthening national monitoring of drugs and drug abuse</td>
<td>Contracting period expires</td>
<td>15 December 2007</td>
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<td>Disbursement period expires</td>
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<td>Total budget: € 0.500 million</td>
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### Overall objective

High-quality monitoring and reporting of the required “Drug Related Deaths and Mortality of Drug Users”, which is one of five Key-Indicators established by the European Monitoring Centre for Drugs and Drug Addictio (EMCDDA).

### Project purpose

To adjust and strengthen the Laboratory of the Forensic Medical Toxicology (within the Institute of Forensic Medicine in Bratislava – Petržalka) to be established and accredited as the National Reference Laboratory - the major institution responsible for the necrotic toxicology within the established nationally coordinated system of the forensic medicine.

### Objectively verifiable indicators

- **2006 National Data on Drug Related Deaths** at the standard as required by EMCDDA produced

### Sources of Verification

- National Report & Standard Tables quality assessment

### Objectively verifiable indicators

- **Fully functional (Equipment, Staff, Quality) National Reference Laboratory**, providing on routine basis information on direct drug deaths according to NFP specification/EMCDDA standards by the end of 2006
- **continuous participation at international testing of laboratory practice quality**

### Sources of Verification

- Agreement on Data provision for Drug-Related Deaths Indicator between Min. of Health and NFP
- Regular reports elaborated by National Reference Laboratory and Laboratories of Forensic Medical Toxicology

### Assumptions

- Good cooperation with National Focal Point for Drugs in Slovakia
- Financial support to Nat. Ref. Laboratory for Quality Assurance Programme and for participation in international quality testing
<table>
<thead>
<tr>
<th>Results</th>
<th>Objectively verifiable indicators</th>
<th>Sources of Verification</th>
<th>Assumptions</th>
</tr>
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<tbody>
<tr>
<td>1. Necessary equipment for acquisition of high quality information for monitoring of the deaths related to drug and drugs abusers ensured</td>
<td>- Routine general drug screening in 100% cases of forensic medicine examination</td>
<td>• monitoring reports • minutes • interim report • final report • evaluation reports • Implementation Status Report (submitted twice a year by NAC)</td>
<td>• staff remained on the positions that was trained</td>
</tr>
<tr>
<td>2. Theoretical background and practical analytical skills of the staff of the Slovak forensic-medical toxicological laboratories improved</td>
<td>- 20 employees of eleven Slovak forensic medical toxicological laboratories trained by the end of the project</td>
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</tr>
<tr>
<td>3. Pilot monitoring of reporting of the deaths related to drug and drugs abusers successfully executed</td>
<td>- Pilot reporting of the deaths related to drugs and drugs abusers executed until October 2006</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Activities</th>
<th>Means</th>
<th>Assumptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Procurement of the special equipment for the National Reference Laboratory to ensure the production of high quality information for monitoring of the deaths related to drugs and drugs abusers</td>
<td>Supply contract /equipment, publications/</td>
<td>• Effective cooperation between all stakeholders</td>
</tr>
<tr>
<td></td>
<td>One Twinning light contract</td>
<td>• The staff of forensic-medical toxicological laboratories adequate prepared for trainings</td>
</tr>
<tr>
<td></td>
<td>The same Twinning light contract</td>
<td>• Technical equipment on place in time</td>
</tr>
<tr>
<td>2. Provision of a set of seminars and workshops for 2 employees of all Slovak forensic-medical toxicological laboratories</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Pilot testing of data collection system on Drug Related Deaths indicator</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Preconditions</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• The Establishment of the National Reference Laboratory fully supported by Health Care Surveillance Authority</td>
<td></td>
</tr>
</tbody>
</table>

**Time Implementation Chart**

Project title:
Strengthening national monitoring of drugs and drug abuse

<table>
<thead>
<tr>
<th>Project component</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1st Q</td>
<td>2nd Q</td>
<td>3rd Q</td>
</tr>
<tr>
<td>Twinning light</td>
<td></td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Elaboration of specification</td>
<td></td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Supply of the equipment needed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Training of relevant staff</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pilot monitoring and reporting</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Supply of the related newest edition</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>books, publications</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Cumulative Contracting and Disbursement Schedule**

Project title:
Strengthening national monitoring of drugs and drug abuse

<table>
<thead>
<tr>
<th></th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contracted</td>
<td>0.280</td>
<td>0.400</td>
<td>0.288</td>
</tr>
<tr>
<td>Disbursed</td>
<td>0.168</td>
<td>0.240</td>
<td>0.288</td>
</tr>
</tbody>
</table>
Annex No. 4

Equipment required:

High Performance Liquid Chromatography with a tandem Mass Detector (LCMS-MS) is:

- unavoidable for analysis of non-standard, multiplex biological samples (a characteristic subject of the forensic-medical toxicology investigation); especially for identification, qualification and quantification of drugs, drugs abused and other active and potentially toxic organic substances (natural forms and metabolites)
- designed for analysis of the liquid samples; analytically covers app. 70% of all actually known active and potentially toxic organic substances; i.e., from a practical point of view, the system is equivalent to the system of gas chromatography in combination with the mass detector (GCMS) analytically covering the gas samples (app. 30% of all actually known active and potentially toxic organic substances)

The LCMS-MS system specification:

The LCMS-MS integrated system is the analytical equipment designed for qualitative and quantitative analysis of multiplex chemical substances.

Typical examples of such organic mixtures are the analytical samples isolated from biological matrices. Analysis of such mixtures requires a specific analytical approach in two main steps:

- separation of a mixture to chromatographically pure individual components and
- consecutive one-by-one analysis of the separated chemical individuals.

The LCMS-MS system integrates instrumentation for both of the required procedural steps:

- a high performance liquid chromatograph (LC) for a mixture separation and
- a tandem mass detector (MS-MS) for specific detection - identification and quantification - of the separated substances. The stated tandem MS detector is unavoidable specifically in toxicology for identification and quantification even unknown chemical compounds, as for instance metabolites of drugs and drugs abused and so far unknown chemical compounds are.

Required is one integrated system, which the actual market price is cca. 375.000.- EURO
Annex No. 5

List of publications and books needed

- the books, publications and journals focused to toxicology in general, toxicology forensic-medical and the sciences related to toxicology, i.e. chemistry, pharmacy / pharmacology (pharmacokinetics, pharmacodynamics), biology and the related interdisciplinaries;
- literature related to relevant storing, organizing, evaluation and statistical processing of analytical data with regard to provision of valid results for the required “Drug Related Deaths and Mortality of Drug Users” key-indicator for the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA);
- the literature describing laboratory technique and analytical procedures conformable to the ISO Good Laboratory Practice standard;
- the literature dealing with the problems of quality control and assurance, matching the valid European standard EN ISO/IEC 17025;

The required resources for the hereinbefore specified literature and other scientific data sources purchase are cca. 5.000.- EURO.