Standard Project Fiche

1. Basic Information

1.1 CRIS Number: BG 2005/017-353.05.01

1.2 Title: Strengthening of the National Surveillance System for Communicable Diseases

1.3 Sector: Employment, Social Policy and Education

1.4. Location: Bulgaria

1.5 Duration: Phase 1/ Programming year 2004 and Phase 2/ Programming year 2005

2. Objectives

2.1 Overall Objective(s):

To strengthen the CD surveillance system and to establish national early warning system assuring better control of CD in Bulgaria

2.2 Project purpose:

To ensure the integration of the national CD surveillance system into the EU surveillance networks through adopting the EU legislation and strengthening the administrative capacity of the involved institutions.

2.3 Accession Partnership (AP) and NPAA priority (and implementing measures envisaged by the Action Plan for AP priorities related to strengthening administrative and judicial capacity)

The following are quotations from the Accession Partnership

Employment and Social Policy

“Continue to establish a system for the surveillance and control of communicable disease in line with the Community requirements and for health monitoring and information in line with EU standards”

Roadmap for Bulgaria

“Set up a system for surveillance and control of communicable disease in line with the acquis”

2003 Regular Report on Bulgaria’s Progress towards Accession

“With regard to public health, a national communicable disease surveillance and control plan should be developed with a specific focus on building epidemiological capacity. A revision of legislation relevant to communicable diseases surveillance and control is required to align with the principles and methodology of the Community network for the epidemiological...
surveillance and control of communicable diseases. The existing reference laboratory is outdated and lacks resources. Significant capacity building efforts are needed in order to ensure incorporation into the EU system of surveillance and control of communicable diseases.”

2.4 Contribution to National Development Plan (and/or Structural Funds Development Plan/SDP)
Not applicable

2.5 Cross Border Impact
Not applicable

3. Description

3.1 Background and justification:
Is the text copy pasted from fiche 2004/does the text still reflect the current situation? Has there been no update on aspects of Legislation, structure, standards: In particular, the fiche reads “The regulations on CD surveillance are very old and do not respond to the existing EU regulations regarding CD surveillance”.
It would be appreciated to cut down the statements relating to 2004, both in the main text and in the logframe, and instead focus on 2005.

MH justification: The text concerning the analysis of the CD Surveillance in Bulgaria can not be divided for the years 2004 and 2005. The situation in the area has not changed dramatically and the activities concerning programming year 2004 have not yet been performed to reflect some of the results in the project fiche.

The principle health policy visions, as adopted in the Amsterdam Treaty of the EU member states, as well as the Decisions and Directives of the Council of Ministers of the EU have been laid down in the Bulgarian Health Strategy. The National Health Strategy also covers the aims of the EU public health policy: improving the information related to public health development, rapid response to threats to the health system, health promotion and disease prevention and is complying with the aims and values of WHO/EURO “Health for All in the 21st century” Strategy.

All common priority areas of collaboration in the field of public health identified by EC and WHO in December 2000 (health information, communicable diseases, tobacco, mental health, environment and health, nutrition and alcohol) are considered in Bulgarian National Health Strategy.

Public health services are organised, supervised, financed and controlled by the Ministry of Health (MoH). The system retains the basic structure that has existed since the 1950s, when public health concentrated upon eradicating communicable diseases. Since 1992 they are called Hygiene and Epidemiological Inspectorates (HEI) and they exist one for each district. Ministry of Defence and Ministry of Internal Affairs manage and finance their own health care facilities, including PH services. The Ministry of Health recently absorbed their parallel hygiene and epidemiological services. From January 1st 2005 after the adoption of the new Health Law the Hygiene and Epidemiological Inspectorates (HEI) are called Regional Inspectorate for Protection and Control of Public Health (RIPCPH).

Each of 28 District RIPCPH has five operational structures: state sanitary control; communicable diseases control (CDC); disease prevention and health promotion; laboratories (bacteriology, virology and parasitology, which covers the etiological diagnosis); radiology and radiation protection.
In 1999 a functional and structural reorganization was implemented in the HEI system, which defined the current functions of the RIPCPH as follows:

- implementation of state sanitary control;
- coordination and implementation of surveillance, control and preventive measures of infectious and parasitic diseases;
- disease prevention and health promotion;
- Consultations on activities for the protection and promotion of personal and public health.

Actual the CDC Departments represents the operational core of communicable disease surveillance and control.

The structure of the CD surveillance in Bulgaria is based on a vertical exhaustive compulsory notification. Parallel, vertical systems exist for Tuberculosis, Influenza and Acute Respiratory Syndrome, sexual transmitted diseases (including HIV/AIDS), nosocomial infections, immunization coverage and antibiotic resistance. The parallel systems have other flow of information and use other forms and deadlines/timelines. Fifty-three diseases are under compulsory notification (food-borne, air-borne, water-borne, viral hepatitis, diseases of environmental origin, vaccine preventable diseases, diseases covered by the international health regulations, STD, TB etc., including all diseases listed in Annex I of Decision 2003/542/EC). The list of the diseases is fully harmonised with the EU. The new Health Law came into power on January 1st 2005. The Health Law regulates the communicable diseases surveillance framework. A draft regulation has been prepared that regulates the registration and notification of communicable diseases. The Ministry of Health will adopt the draft regulation by May 2005. The EU case definitions will be annexed to the regulation.

The general flow of information is simple and direct – GPs/specialists in outpatient and inpatient health care sector are obliged to report within 24 hours every probable, possible or confirmed CD case to the district RIPCPH by phone, telex, e-mail and every time also on paper by courier or mail. The information includes individual nominative information (name, age, address, profession and workplace, probable source of infection, immunization status and available laboratory results).

RIPCPh immediately start investigation and when is necessary, undertake measures. RIPCPH transmit to the National Centre for Health Information (NCHI) daily aggregated number of cases by disease and place of origin. There is also monthly report from RIPCPH to NCHI based on confirmed diagnosis and is composed of aggregated number of cases and deaths by disease and place of origin. The primary information by the parallel systems comes also from district Tuberculosis and Sexually Transmitted Diseases (STD) Dispensaries and their laboratories. NCHI reports to MoH daily, weekly and monthly aggregated data. RIPCPH is obliged to provide information to MoH immediately at the beginning of a CD outbreak.

The structures involved in the CD surveillance at central level are MoH, National Center of Infectious and Parasitic Diseases (NCIPD) and NCHI.

NCHI only transmitted data regarding CD from RIPCPH to the MoH.

NCIPD is responsible for all referral laboratory services for bacteriology, virology and parasitology, research and technological development in the field of CD, development surveillance analyses, priority setting, planning and implementation of preventive programmes, elaboration and dissemination of guidelines, standards, instructions, manuals. The reference laboratory system strives to achieve quality work, but is outdated and lack resources, computerized archives, specimen bank. NCIPD must pay for the information, coming from NCHI. Only MoH received information for outbreaks and potential outbreaks.

Since January 2003 within the NCIPD is established a new Department of epidemiological surveillance and early warning (ESEW), witch isn’t equipped with appropriate software. The staffs do not have functions in general sanitary control, but deal only with surveillance. They are three epidemiologists and one biostatistician. The role and the responsibilities of the Department are not clear yet. The central operative levels (MoH and NCIPD) are with limited administrative capacity.
At this stage there is absence of a training programme and appropriate PC software for specialists at all levels, especially in the field of prognosis elaboration which could permit the early detection of an important event for the health of the population.

The main problems identified in the current CD surveillance system are as follows:

**Legislation**

- The regulations on CD surveillance are very old and do not respond to the existing EU regulations regarding CD surveillance
- There is no regulation on confidentiality issues related to CD
- There is no separate budgetary line for emergency situations, epidemic preparedness and response at all levels
- There is lack of legislation for laboratory accreditation according to the National Standards of Clinical Microbiology, Medical Parasitology and Medical Virology
- Private labs are not involved in CD surveillance as well as in surveillance of antimicrobial resistance
- There are insufficient funds for sending diagnostic samples and isolated strains to the National Reference labs

**Structure**

- The roles and responsibilities of MoH, NCIPD and NCHI for surveillance are not well defined
- The Department of CD control within MoH and responsible department in NCIPD are inadequately staffed and can not cope with implementation of all surveillance activities at national level
- District epidemiologists are over burdened with control activities and they lack of time for real CD surveillance
- There is insufficient communication between epidemiologists and microbiologists at all levels
- The laboratories are not enough involved in the surveillance process
- The TB and STD labs do not meet the medical standard for clinical microbiology
- There is no National Reference Laboratory for Tuberculosis.

**Standards**

- There isn’t national standard protocol on epidemiological and laboratory surveillance
- All health service providers (GPs and other specialists) lack guidelines and standards for CD surveillance and control and there is poor collaboration and coordination among them
- There are no national standard data management application forms
- There is no national epidemiological software applied in the country
- RIPCPHs staff is burden by too many different reporting forms on various topics to be filled and sent to numerous and different authorities, at different periods of time
The Immediate notification form is old and collect not relevant information regarding immediate notification.

Aggregated data on CD at central level (NCIPD) do not include information on TB and STD.

All laboratories do not collect information for CD surveillance purposes.

**Supply**

Almost all computers in the RIPC PH CDC departments are not accessible for surveillance purposes; do not have internet/e-mails access and appropriate statistical packages for epidemiological surveillance.

There is lack of PCs and there is no access to the existing ones, absence or low level of internet connection in RIPC PH laboratories.

Insufficient and irregular supply with reagents, diagnostic kits and laboratory consumables and lack of reserve of vaccines for epidemic response at all levels.

**Training**

There is insufficient specific training on surveillance and computing at all levels.

Insufficient knowledge of understanding and implementation of analytical epidemiology at district level.

Equipment needed:
The main focus of the project is to strength the system for CD surveillance and control and to include in the national public health legal framework the Decisions 2119/98/EC, 2000/57/EC, 2000/96/EC, 2002/253/EC, 2003/534/EC and 2003/542/EC.

In order to ensure the effective implementation of above legislation it is necessary to take actions as follows:

- Development and enhance the capacity of already existing structures, preparing them for active and effective cooperation in the EU networks through introducing a PC/Internet based epidemiological and laboratory network and respective software for the national CD surveillance network, develop Standard Operating Procedures for the basic components of the surveillance system, coherent with accepted EU standards, elaborate ordinances, instructions and guidelines, equip the national reference laboratories and train all staff in all levels, involved in the CD surveillance.

- This equipment and the trained staff will ensure the national commitment for strengthening public health laboratory services.

The laboratories foreseen to be supported under this fiche are fully ready to accept the equipment (premises and facilities, staff, funding).

3.2. Sectoral rationale: n/a

3.3. Results:

**Programming year 2004:**

- National framework for epidemiological CD surveillance system according to all EU Decisions adopted.
Legislation for standards, regulations and guidelines in the field of CD elaborated
The existing CD epidemiological surveillance system reinforced
Early warning system as a part of the existing CD surveillance system established
Working places for the epidemiologists involved in the CD surveillance equipped
Involved in the CD surveillance epidemiological staff highly trained

Programming year 2005:

- National legislation for the role and responsibilities of the labs in the CD surveillance process developed
- Structures for national laboratory network for the CD surveillance established and reorganized
- Standard Operating Procedures on CD laboratory surveillance developed.
- Laboratories involved in the CD surveillance fully equipped
- Involved in the CD surveillance laboratory staff highly trained

3.4. Activities:

**Programming year 2004:**

1.1. Revision and updating of the existing legislation related to the CD Surveillance system in line with the EU Decisions
1.2. Review the ways of involving both public and private health services and other sectors (Defense, Internal Affairs) in the CD surveillance system
1.3. Development of regulation a confidentiality issues in surveillance and control of CD as separate part of CD surveillance system
1.4. Definition of tasks and description of relationships between authorities and institutions in order to simplify the flow of information in the field of CD surveillance
1.5. Development of information system for the early warning and detection of health threats as part of the overall CDS system, including danger of cross-border spread of CD.
2.1. Updating and simplifying the immediate notification form in order to collect useful and relevant information
2.3. Development of manuals for providing relevant information on CD surveillance at national and district level
3.1. Establishment of a PC network with appropriate software at all levels
3.2. Development of a national standard protocol and national standard data management application form
3.3. Elaboration of guidelines regarding case definitions, outbreak investigation methodology etc.
3.4. Implementation of weekly descriptive analysis on daily notification data and monthly analysis based on monthly data at RIPCPH level (following trends over time, mapping of cases, description by age groups etc.)
3.5. Elaboration of a new immediate notification form for all diseases to reduce the number of forms to be filled
4.1. Establishment of early warning system as a part of the existing CD surveillance system established
5.1. Supply of PCs at all levels only for surveillance purposes
5.2. Ensuring of appropriate statistical packages for CD surveillance
5.3. Supply of fax machines and internet
6.1 Continuous and refresher training of epidemiologists on surveillance and computing at all levels
6.2. Training of RIPCPH epidemiologists in advanced epidemiological analysis (modern surveillance, EPI-INFO, EPI map, basic statistics, other statistical packages, computer use and basic computer skills)
6.3. Training of RIPCPH epidemiologists in descriptive epidemiology, epidemic investigation, study design, emergency response, data accuracy and communication in PH, evidence based prevention, reports and presentations
6.4. Training of all epidemiologists in antimicrobial resistance in order to include them in the surveillance of antimicrobial resistance
6.5. Training of trainers and regular short-term courses for the staff involved in the regional CD surveillance and individual training and practical work for all experts (central and regional level) in the NCDSC.

Programming year 2005:
1.1. Elaboration of regulation according laboratories participation in data collection for CD purpose
1.2. Updating of the existing legislation for Accreditation of labs in collaboration with professional scientific organizations
1.3. Development of Standard Operating Procedures on CD laboratory surveillance coherent with accepted international standards and EU norms
1.4. Elaboration of regulation for involvement of the private labs in the CD surveillance including antimicrobial resistance
1.5. Elaboration of regulation for the supervision and quality control of reference labs to private labs, involved in the CD surveillance including TB, HIV/AIDS surveillance
2.1. Establishment of computerized laboratory network to transmit test results rapidly
2.2. Establishment of a National Reference Laboratory for Tuberculosis
2.3. Reorganizing of TB and STD labs in order to be included in the CD surveillance network
3.1. Elaboration of a special lab reporting form for CD surveillance purposes
3.2. Development of a national standard protocol on CD laboratory surveillance
3.3. Updating of the existing laboratory guideline for specimen collection, packaging and transportation, guide for rapid response etc.
3.4. Adaptation of rapid diagnostic tests and other technologies in order to strengthen the national capacity for laboratory confirmation of priority health events
4.1. Supply labs with basic lab equipment
4.2. Supply of equipment for high quality serological investigations
4.3. Supply of equipment for minimum number of rapid diagnostic techniques
4.5. Establishment of central specimen bank
4.6. Supply of computers, internet connection for all labs
5.1. Training of lab staff on CD surveillance (basic epidemiology and biostatistics)
5.2. Training of lab staff on specific issues concerning sampling techniques, data quality checks, lab safety, transport and storage of biological specimens

3.5. Linked activities:
Since 2001 Bulgaria has participated in three meetings under the Stability Pact for South Eastern Europe for Social Cohesion Initiative. Training of two specialists (epidemiologist and biostatistician) from NCIPD has been conducted in Slovenia 10-22 November 2003. At the last meeting in Brussels, December 2003 in the field of CDS the country achieved the following:
- Multinational team assessment missions
- National Action Plans for CDS
- Strategy for strengthening the national CDS system including portfolio of project proposals
- Harmonised definitions and methodologies
- Increased institutional and human capacities
- Integration of national CDS Systems through a regional network in SEE region

Regarding the WHO project for development of information system “Environment. Health. Communicable Diseases” in part CD software and hardware problems occurred. The parts Environment and Health operate effectively. The developed software in part CD is very labour-intensive and time consuming and requires daily information input for the registered CDs by a technical personnel. The software has been developed on the basis of the existing registration forms. The objective of the project is improving the flow of information i.e. the software has to be adapted to the new registration forms.

It is necessary to assure funds for changing the software in order to meet the requirements on new CD legislation.

3.6. Lessons learned:

Two Peer Review missions, commissioned by DG SANCO and DG ENLARG/TAIEX to assess the CD system have been carried out in June 2002 and 2003 in Bulgaria. The technical assistance needs for the implementation and enforcement of the EU accession with respect to CD surveillance system have been evaluated. Additionally, an assessment of the national surveillance system has been conducted by the experts of WHO-EURO office in May 2003. The main recommendations of the peer reviews were as follows:

- The list of notifiable diseases should be reviewed to include all diseases in EU decisions
- Training of professional applied epidemiologists is required
- Professional Training in modern laboratory techniques is required
- Laboratory equipment and techniques should be updated to meet minimum EU requirements
- Participation in the EU communicable disease networks should be gradually introduced
- A system for early warning needs to be developed.
- The legislation in relation to communicable disease should be urgently updated
- A regular feedback system allowing dissemination of information in the CD Surveillance system should be developed
- Privacy and data protection issues should be addressed

4. Institutional Framework

The NCIPD founded in 1881 is leading national health institution in Bulgaria specialized in the field of CD surveillance and control. The scope of the principle activities of the NCIPD comprises research, postgraduate training, infectious diseases surveillance, development and evaluation of new programs for surveillance, prevention and control of CD.

The national reference laboratories in microbiology, virology and parasitology are responsible for adoption of new lab techniques conducting quality control for HEs labs, as well as participation in lab bases surveillance network.

The Ministry of Health exercises state sanitary control on communicable diseases. The state sanitary control is managed directly by the Deputy-Minister of Health, who is also Chief Sanitary Inspector of the Republic of Bulgaria. At the national level the “Protection and Control of Public Health” Directorate (PCPH) directs, plans, coordinates and controls the activities of the district inspectorates (RIPCPHs) and exercises their methodological guidance in implementing the CD surveillance and control EU legislation.

The 28 District Hygiene and Epidemiological Inspectorates implement the CD surveillance and control measures at local level. The CDC Department and the Laboratory Department of the RIPCPH are structures responsible for and directly involved in carrying out the CD
surveillance and control. The CDC Department in MoH controls at national level the activities of the CD surveillance in RIPCPHs.

5. Detailed Budget

<table>
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<tr>
<th>Year 2004 Phase 1</th>
<th>Phare Support</th>
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<tbody>
<tr>
<td></td>
<td>Investment Support</td>
<td>Institution Building</td>
</tr>
<tr>
<td>Contract 1/ TW</td>
<td>0.9</td>
<td>0.9</td>
</tr>
<tr>
<td>Contract 2/ Supply</td>
<td>0.900</td>
<td>0.900</td>
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<td>Total</td>
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<table>
<thead>
<tr>
<th>Year 2005 Phase 2</th>
<th>Phare/Pre-Accession Instrument support</th>
<th>Co-financing</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>€M</td>
<td>National Public Funds (*)</td>
<td>Other Sources (**)</td>
<td>Total Co-financing of Project</td>
</tr>
<tr>
<td>Investment support jointly co funded</td>
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<td></td>
<td></td>
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<tr>
<td>Contract 2 Supply of equipment</td>
<td>0.900</td>
<td>0.300</td>
<td>0.300</td>
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<tr>
<td>Investment support – sub-total</td>
<td>0.900</td>
<td>0.300</td>
<td>0.300</td>
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<tr>
<td>% of total public funds</td>
<td>max 75 %</td>
<td>min 25 %</td>
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</table>

In case of parallel co-funding (per exception to the normal rule, see special condition as indicated below: Not applicable

<table>
<thead>
<tr>
<th>Year 2005 Institution Building support</th>
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<td>Contract 1 Twinning covenant</td>
<td>0.900</td>
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<tr>
<td>IB support</td>
<td>0.900</td>
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<tr>
<td>TOTAL 2005</td>
<td>1.800</td>
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</tbody>
</table>

(*) contributions form National, Regional, Local, Municipal authorities, FIs loans to public entities, funds from public enterprises

(**) private funds, FIs loans to private entities

Up to 10% of the Twinning project will be covered from the national budget through the National Fund Directorate at the Ministry of Finance. Phare and national co-financing will be tendered and contracted jointly.
6. Implementation Arrangements

6.1 Implementing Agency

The CFCU will be the Implementing Agency responsible for tendering, contracting and accounting with assisting in good project design and implementation and Phare procurement and payment rules. The CFCU (Ministry of Finance) is in charge of the contracting and financial management of the project. The Secretary General of Ministry of Finance will act as PAO of the project. His contact details are:

Secretary General of Ministry of Finance and PAO
☐ Address: 102 Rakovski Str.
☐ 1040 Sofia
☐ Tel: 359 2 9859 2772
☐ Fax: 359 2 9859 2873

6.2 Twinning

The beneficiary Ministry of Health will have the responsibility for technical preparation and control (designing, selecting).

MoH contact point:
Head of Administration and Project Management Department
Address: Ministry of Health
39, Alexander Stamboliyski Blvd
1000 Sofia, Bulgaria
Tel: +359 2 9301202
Fax: +359 2 9875583
e-mail: stodorova@mh.government.bg

The RTA for Phase 1 and Phase 2 should have the following profile:

- experience in epidemiological surveillance of CD
- substantial experience in implementation of the EU legislation in the field of CD surveillance and control
- experience in mutual co-operation with international organizations in the field of public health
- excellent inter-personal communication skills
- initiative and co-operative attitude
- Fluency in English.

Profile of the short and medium term experts

The short- and medium-term experts should have the following profile:

- knowledge of the outbreak investigation and conducting of control measures
- knowledge of early warning and response of health threats in the Member States
- experience in preparing and providing training programs in the field of CD surveillance system
- knowledge of IT (collecting data, analysing data, trends in CD surveillance)
- fluency in English

6.3 Non-standard aspects
The PRAG Procedures strictly will be followed

6.4 Contracts

**Programming year 2004:**

Contract (1) – Twinning covenant 0.9 M € plus national co-financing up to 10%
Contract (2) – Supply of equipment 1.2 M € plus national co-financing 25%

Programming year 2005

Contract (1) – Twinning covenant 0.9 M € plus national co-financing up to 10%
Contract (2) – Supply of equipment 1.2 M € plus national co-financing 25%

7. Implementation Schedule

Programming year 2004

**Contract 1 - TW**
Start of tendering/call for proposals October 2004
Start of project activity September 2005
All activities completed March 2007

**Contract 2 – Supply of Equipment**
TS prepared and verified by June 2005
Start of tendering/call for proposals July 2005
Start of project activity (sign contract) September 2005
Project Completion January 2006

Does this reflects the updated procurement plan? What is the state of play concerning implementation of programming year 2004
Current State of 2004 Phase implementation: TSs will be prepared under PPF 2004 contract, the TW Contract is under preparation

Programming year 2005

**Contract 1 - TW**
Start of tendering/call for proposals May 2005
Start of project activity February 2006
All activities completed February 2007

**Contract 2 – Supply of Equipment**
TS prepared and verified by June 2005
Start of tendering/call for proposals February 2006
Start of project activity (sign contract) May 2006
8. **Equal Opportunity**
All participating Bulgarian institutions are equal opportunity employers. No discrimination of whatever nature will be applied.

9. **Environment**
   - The supplies will be delivered into existing premise. No environmental impact is expected and the supply of equipment falls does not require any sort of environmental assessment.

10. **Rates of return**

    The equipment will not generate incremental costs related to the current running of the laboratories. Staff and premises exist and are running. It will nevertheless generate additional income thanks to the increased quantity/type of samples per year. Non-tangible benefits will be related to increased human health protection.

11. **Investment criteria**

    11.1 Catalytic effect:
    A well functioning surveillance system can facilitate the identification, monitoring and control of communicable diseases. A well developed surveillance system can help Bulgarian Public Health Authorities:
    - To obtain good information for early detection and rapid response to outbreaks or potential outbreaks
    - To identify diseases trends and their risk factors
    - To identify the possible protective measures
    - To obtain appropriate information for priority setting, planning, implementation and resource allocation for preventive programmes and control measures
    - To prepare the Bulgarian System for Epidemiological Surveillance to become part of the Community Network for the epidemiological surveillance and control of communicable diseases
    PHARE support will enable the Bulgarian Public Health Authorities to realize the wider objectives related to the Surveillance and Control Network of Communicable Diseases in Bulgaria and in the EU.

    11.2 Co-financing:

    The National Fund will finance at least 25% of the total contract costs for supply and up to 10% for twinning.

    11.3 Additionality:

    Not applicable.

    11.4 Project readiness and size:

    Technical specifications and tender documentation should be ready at the time of the signature of the Financing Memorandum.

    11.5 Sustainability:
Sustainability of project results is assured through the need and commitment by Bulgaria to implement its CD surveillance and control policy. Staff increased (or decreased) are not expected as a result of the project. The training of the personnel during the implementation of the project will increase the motivation of the staff. The Department of Epidemiological Surveillance and Early Warning in the NCIPD will assure the continuity of the training through elaboration of training programs in CD surveillance, control measures, early warning, etc. All supported investment actions (supplies) are sustainable in the long term beyond the date of Accession. They will comply with the EU norm and standards (accredited), and will be coherent with the sector policies of the EU. Future maintenance and operation costs will be covered by the Bulgarian national budget.

11.6 Compliance with state aids provisions

All investments will respect the state aid provisions of the European Agreement

11.7 Contribution to NDP and/or Structural Funds Development Plan/SPD

Not applicable

12. Conditionality and sequencing

The need assessment for the supply of equipment and the technical specifications for the laboratory equipment for Phase 1 and Phase 2 will be prepared by independent external contracted expert (PPF) by the end of June 2005 IS THIS ALREADY AVAILABLE and if yes what are the results of the assessment? The first Twinning and Supply contracts concern the CD surveillance while the second Twinning and Supply contracts relate to the laboratory surveillance. Both CD and laboratory surveillance are done by different departments within the RIPCPH’s. At the central level the surveillance is concentrated at the MoH and the NCIPD.
ANNEXES TO PROJECT FICHE

1. Logical framework matrix in standard format (compulsory)
2. Detailed implementation chart (compulsory for year/phase 1)
3. Contracting and disbursement schedule by quarter for full duration of programme (including disbursement period) (compulsory for year/phase 1)
4. Feasibility study for the laboratory equipment for the two phases will be performed by an independent expert by the end of May. Terms of Reference have been elaborated and submitted for financing from PPF 2002.
5. List of relevant Laws and Regulations (optional)
6. Reference to relevant Government Strategic plans and studies (may include Institution Development Plan, Business plans, Sector studies etc) (optional) not applicable
7. List of the equipment for the NCIPD and 28 RIPCPHs
8. Needs assessment for the laboratory equipment for NCIPD and 28 RIPCPHs (will be revised after the equipment needs analysis of the PPF consultant is elaborated)
9. Organigramme of the Bulgarian Communicable Disease Surveillance System
### ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>MoH</td>
<td>Ministry of Health</td>
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<tr>
<td>PCH</td>
<td>Protection and Control of Public Health</td>
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<td>NCIPD</td>
<td>National Center of Infectious and Parasitic Diseases</td>
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<td>NCHI</td>
<td>National Centre for Health Information</td>
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<td>HEI</td>
<td>Hygiene and Epidemiological Inspectorate</td>
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<td>RHEI</td>
<td>Regional Hygiene and Epidemiological Inspectorate</td>
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<td>RIPCPH</td>
<td>Regional Inspectorate for Protection and Control of Public Health</td>
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<td>CD</td>
<td>Communicable diseases</td>
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<td>CDC</td>
<td>Communicable Diseases Control</td>
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<td>CDS</td>
<td>Communicable Diseases Surveillance</td>
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<td>SSC</td>
<td>State Sanitary Control</td>
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<td>GP</td>
<td>General Practitioner</td>
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<td>NRL</td>
<td>National Reference Laboratory</td>
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<td>NLN</td>
<td>National Laboratory Network</td>
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<td>SOP</td>
<td>Standard Operating Procedures</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<td>NCDSC</td>
<td>National Communicable Diseases Surveillance Centre</td>
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<td>ESEW</td>
<td>Epidemiological Surveillance and Early Warning</td>
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<td>STD</td>
<td>Sexual Transmitted Diseases</td>
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<td>Tuberculosis</td>
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<td>Resident Twinning Adviser</td>
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### DETAILED IMPLEMENTATION CHART

<table>
<thead>
<tr>
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<th>2005</th>
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<th>2007</th>
</tr>
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<tbody>
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<td></td>
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<td>2 q.</td>
<td>3 q.</td>
</tr>
<tr>
<td>Twinning</td>
<td>T</td>
<td>T</td>
<td>C</td>
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<tr>
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<td>T</td>
<td>C</td>
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<td>Etc.</td>
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*T – Tendering; C – Contracting, I - Implementation; E - End*

Programming year 2005

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<th>2007</th>
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</thead>
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<tr>
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<td>2 q</td>
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<tr>
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<td>T</td>
<td>C</td>
<td>I</td>
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</table>

*T – Tendering; C – Contracting, I - Implementation; E - End*
### CUMULATIVE AND DISBURSEMENT SCHEDULE (MEUR)

<table>
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<th>2007</th>
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<tr>
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<tr>
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### Programming year 2005

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<th>2007</th>
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<td>National co-financing</td>
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<tr>
<td>Contract 2</td>
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<tr>
<td>National co-financing</td>
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<td></td>
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</tr>
<tr>
<td>Disbursed</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>National co-financing</td>
<td></td>
<td></td>
<td></td>
</tr>
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1. Health Act (State Gazette ? 70/10.08.2004)
2. Instruction No 6/21.06.2000 of MoH for notification, registration and reporting of communicable diseases
3. Regulation No 4/21.06.2000 of MoH for notification, investigation and registration of food-born outbreaks
4. Regulation No 13/07.08.1998 of MoH for organization of prophylaxis and control of hospital acquired infections
5. Instruction No 9/25.09.2000 of MoH for control of Influenza and Acute respiratory diseases
6. Instruction No 3/11.02.1997 of MoH for prevention, treatment and control of indigenous parasitic diseases
7. Order No RD-09-111/18.03.2002 of MoH: National standard of clinical microbiology
9. Order No RD-09-211/16.05.2002: National standard of medical Parasitology
10. Regulation No137/19.07.2000 of MoH for border sanitary control in Republic of Bulgaria
12. Ordinance No 2/06.02.2004 defines the list of CD diseases for compulsory notification
13. Decision 2119/98/EC setting up a network for the epidemiological surveillance and control of communicable diseases in the Community
14. Decision 2000/57/EC on the early warning and response system for the prevention and control of communicable diseases under Decision 2119/98/EC
15. Decision 2000/96/EC on the communicable diseases to be progressively covered by the Community network under Decision 2119/98/EC
16. Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision 2119/98/EC
18. Decision 2003/542/EC amending Decision 2000/96/EC as regards the operation of dedicated surveillance networks
Project title: Strengthening of the National Surveillance System for Communicable Diseases

Equipment for the central level

**National CD Surveillance Center**

<table>
<thead>
<tr>
<th>Sort of equipment</th>
<th>Quantity</th>
<th>Unit price (in Euro)</th>
<th>Total price (in Euro)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PC</td>
<td>8</td>
<td>1 500</td>
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</tr>
<tr>
<td>Laptop</td>
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</tr>
<tr>
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<td>8</td>
<td>700</td>
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<tr>
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<td>4</td>
<td>2 500</td>
<td>10 000</td>
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<tr>
<td>Copier</td>
<td>4</td>
<td>2 500</td>
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<tr>
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</table>

**Microbiological reference laboratories (10) - NCIPD**

<table>
<thead>
<tr>
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<tr>
<td>Microscopes-fluorescence</td>
<td>3</td>
<td>15 000</td>
<td>45 000</td>
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<tr>
<td>Microscopes-light</td>
<td>10</td>
<td>10 000</td>
<td>100 000</td>
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<tr>
<td>Incubators</td>
<td>10</td>
<td>3 000</td>
<td>30 000</td>
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<tr>
<td>Sterilisators</td>
<td>10</td>
<td>2 000</td>
<td>20 000</td>
</tr>
<tr>
<td>Incubators-CO₂</td>
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<td>20 000</td>
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<td>40 000</td>
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<td>Refrigerators(-70°C)</td>
<td>4</td>
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<td>40 000</td>
</tr>
<tr>
<td>Centrifuges</td>
<td>10</td>
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<td>30 000</td>
</tr>
<tr>
<td>ELISA readers</td>
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<tr>
<td>Server</td>
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<td>Diagnostic media and reagents</td>
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Equipment for the peripheral level

CD Surveillance Units/Focal Points in RIPCPh

<table>
<thead>
<tr>
<th>Sort of equipment</th>
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</thead>
<tbody>
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Microbiological laboratories – RIPCPh (28)

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<td>120 000</td>
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<tr>
<td>class II</td>
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<tr>
<td>Microscopes-fluorescence</td>
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<td>15 000</td>
<td>120 000</td>
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<tr>
<td>Microscopes-light</td>
<td>15</td>
<td>10 000</td>
<td>150 000</td>
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<tr>
<td>Sterilisators</td>
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<td>2 000</td>
<td>40 000</td>
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<tr>
<td>Incubators</td>
<td>8</td>
<td>3 000</td>
<td>24 000</td>
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<tr>
<td>Incubators-CO₂</td>
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<td><strong>TOTAL ALL YEARS:</strong></td>
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ANNEX 8

NEEDS ANALYSIS FOR THE LABORATORY EQUIPMENT FOR NCIPD AND 28 RIPCPHs

The Ministry of Health exercises state sanitary control on communicable diseases. The state sanitary control is managed directly by the Deputy-Minister of Health, who is also Chief Sanitary Inspector of the Republic of Bulgaria. At the national level the “Protection and Control of Public Health” Directorate directs, plans, coordinates and controls the activities of the regional inspectorates (RIPCPHs) and exercises their methodological guidance in implementing the legislation concerning the CD surveillance.

Due to the budgetary constraints the Regional Inspectorates for Protection and Control of Public Health do not have flexibility and spent money mainly on personnel and consumables. Capital investments have not been registered for the last 10 years as top-level decision makers (Ministry of Finance under the supervision of International Monetary Fund) considers a higher priority for the other health sectors.

Other financing sources for RIPCPHs are: the national and international programmes (CINDI, health promotion, environmental health, etc) and the taxes charged for provided services (preliminary sanitary control, food testing, etc).

There is not a special budget allocated for emergency situations and in case of outbreaks Ministry of Health can not release money from a reserve fund.

- CD surveillance data do not reach directly NCIPD but reach first the NCHI that does not have surveillance and response responsibilities.
- The communicable disease surveillance and the specific disease surveillance systems for TB, STI and HIV/AIDS are not adequately integrated.
- District epidemiologists are over burdened with control activities and they lack of time for real CD surveillance.
- The GPs receive limited feedback and are not well informed about the epidemiological situation outside their service areas.

The NCIPD performs annual analyses of infectious and parasitic diseases as well as of antimicrobial resistance. These analyses are published in the NCIPD informational journal every 2 months, but the regional RIPCPH have not funds to pay for it.

The creation of the NCDSC will increase the efficiency and the quality of the CD surveillance system. Definition of the tasks and description of relationships between authorities and institutions, involved in the system, definition of role and function of national referral laboratories will ensure better CD surveillance management at all levels.

The National centre for infectious and parasitic diseases (NCIPD) has been designated as a national reference laboratory and has capacity to carry out all traditional microbiological and parasitological analyses and most traditional virological analyses. Capacity in molecular biology is not up to date. The laboratories to do not have computerised archives and there is no biological specimen bank.

The laboratory network in Bulgaria is composed of 28 laboratories (with microbiological, virological and parasitological units) one in each RIPCPH area. The virological and parasitological units can make only serological diagnoses.

The district public health laboratories do most of the routine analyses for the surveillance system. Even the labour costs in PH are guaranteed by the state, the budget for supplies (reagents and diagnostic kits) is insufficient. The prohibition of the Ministry of Finance to make capital investments in all RIPCPH structures, including laboratories result in a very old laboratory equipment and facilities.
The project will strengthen the capacity of the laboratories to perform CD surveillance activities:
- standardize laboratory procedures for the CD under surveillance (standardization of specimen collection, preservation, shipment and diagnostic techniques)
- implementation of rapid tests for primary diagnosis
- provide laboratories with equipment and supplies appropriate to the procedures performed
- facilitate communication between laboratory, epidemiology and clinical staff
First step will be the training of the staff in the new established NCDSC (7 specialists) and training for the specialists in MoH (3 specialists). From all 28 RIPCPHs it is foreseen 78 specialists to be trained in CD surveillance (both epidemiologists and microbiologists).

After the independent expert analysis a more objective justification for the need of equipment will be presented to all stakeholders.
Organigram of the Bulgarian Communicable Disease Surveillance System.

Central level

Intermediate level

Peripheral level

Ministry of Health

National Centre of Health Information

National Center of Infectious and Parasitic Diseases

RIPCPh CDC Department Laboratories

Regional Health Centres

General Practitioners

Outpatient Specialized Medical Assistance for Infectious Disease

Outpatient Specialized Medical Assistance for Parasitic Disease

Hospital Wards
- Infectious Diseases
- Other wards
- Laboratories

Tuberculosis Dispensaries

Sexual Transmitted Infections Dispensaries

Measles, Influenza, Polio, AFP, AMR, Rabies, Nosocomial Infections

Parasitic, lice, Rabies, Immunization, AMR

Outbreaks

Reports from National Centres

General Flow of information
Flow of information for specific diseases
Feedback Information

Central level

Intermediate level

Peripheral level
ANNEX 1

**Phare log frame**

- Assumptions in 2005 should include a sentence that implementation of 2004 is progressing as planned or at least no severe backlog.
- Availability of co funding shall be set as a pre-condition

<table>
<thead>
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<th>LOGFRAME PLANNING MATRIX FOR</th>
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<td><strong>Strengthening of the National Surveillance System for Communicable Diseases</strong></td>
<td>Contracting period (year 2) expires on 30 November 2007  Disbursement period (Year 2) expires on 30 November 2008</td>
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<td></td>
<td>Total budget year 2: 2.1 MEUR</td>
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<tr>
<td></td>
<td>Phare budget year 2: 1.8 MEUR</td>
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<table>
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<th>Overall objective</th>
<th>Objectively verifiable indicators</th>
<th>Sources of Verification</th>
<th>Assumptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>To strengthen the CD surveillance system and to establish national early warning system assuring better control of CD in Bulgaria</td>
<td>• Updated, synchronized with the EU requirements surveillance system for CD in place in 2006  • Favourable trends for morbidity in both Bulgaria and EU region</td>
<td>• Reports of the MoH concerning the results of CD  • Epidemiological bulletins  • Annual lab reports</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Project purpose</th>
<th>Objectively verifiable indicators</th>
<th>Sources of Verification</th>
<th>Assumptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ensure the integration of the national CD surveillance system into the EU surveillance networks through adopting the EU legislation and strengthening the administrative capacity of the involved institutions.</td>
<td>• Availability of the adopted by the MoH ordinances, instructions, guidelines, in line with the EU legislation-improved by 2006  • Trained at least 65 experts in the field of epidemiology and laboratory diagnostic</td>
<td>• Official MoH bulletins  • MoH, NCIPD, RIPCPHs</td>
<td>• The drafted legislation is adopted by the relevant bodies  • Necessary human resources available</td>
</tr>
</tbody>
</table>

| Results                                                                 | Objectively verifiable indicators                                                                 | Sources of Verification                                                                 | Assumptions                                   |
| Programming year 2004                                                                                                   | • Trained experts for CD surveillance legislation at all levels                                      | • MoH, NCIPD, RIPCPHs                                      | • Co-operation with other interested parties  • Technical |
| 3.3.1. National framework for epidemiological CD                                                                       |                                                                                                   |                                                                                                             |                                               |
surveillance system according to all EU Decisions adopted
3.3.2. Legislation for standards, regulations and guidelines in the field of CD elaborated
3.3.3. The existing CD epidemiological surveillance system reinforced
3.3.4. Early warning system as a part of the existing CD surveillance system established
3.3.5. Working places for the epidemiologists involved in the CD surveillance equipped
3.3.6. Involved in the CD surveillance epidemiological staff highly trained

Programming year 2005
3.3.1. National legislation for the role and responsibilities of the labs in the CD surveillance process developed
3.3.2. Structures for national laboratory network for the CD surveillance established and reorganized
3.3.3. Standard Operating Procedures on CD laboratory surveillance developed.
3.3.4. Laboratories involved in the CD surveillance fully equipped
3.3.5. Involved in the CD surveillance laboratory staff highly trained

<table>
<thead>
<tr>
<th>Activities</th>
<th>Means</th>
</tr>
</thead>
</table>
| Programming year 2004 | - Twinning contract  
| 3.4.1.1. Revision and updating of the existing legislation related to the CD Surveillance system in line with the EU Decisions | - Supply contract  
| 3.4.1.2. Review the ways of involving both public and private health services and other sectors (Defense, Internal Affairs) in the CD surveillance system |  
| 3.4.1.3. Development of regulation a confidentiality issues in surveillance and control of CD as separate part | 

<table>
<thead>
<tr>
<th>Assumptions</th>
</tr>
</thead>
</table>
| • End of 2006 fully functioning early warning system  
| • End of 2005 NSP to be completed  
| • End of 2006 the data protection system to be established  
| • The bulletin for CD surveillance regularly issued since 2005  
| • Manual for SOP published  
| • Trained 80 laboratory staff for implementation of the CD surveillance process  
| • Draft National legislation for CD surveillance in labs prepared by December 2006  
| • Labs equipped by September 2006  
| • The implementation of activities planned for programming year 2004 is progressing as planned or at least with no severe backlog  
| • Requested budget is provided  
| • Technical specification ready and confirmed  
| • Laboratory premises fully ready and staffed to accept the equipment  
| • Specifications done on time  
| • Needed equipment delivered on time  

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>3.4.1.4.</td>
<td>Definition of tasks and description of relationships between authorities and institutions in order to simplify the flow of information in the field of CD surveillance</td>
</tr>
<tr>
<td>3.4.1.5.</td>
<td>Development of information system for the early warning and detection of health threats as part of the overall CDS system, including danger of cross-border spread of CD.</td>
</tr>
<tr>
<td>3.4.2.1.</td>
<td>Updating and simplifying the immediate notification form in order to collect useful and relevant information</td>
</tr>
<tr>
<td>3.4.2.3.</td>
<td>Development of manuals for providing relevant information on CD surveillance at national and district level</td>
</tr>
<tr>
<td>3.4.3.1.</td>
<td>Establishment of a PC network with appropriate software at all levels</td>
</tr>
<tr>
<td>3.4.3.2.</td>
<td>Development of a national standard protocol and national standard data management application form</td>
</tr>
<tr>
<td>3.4.3.3.</td>
<td>Elaboration of guidelines regarding case definitions, outbreak investigation methodology etc.</td>
</tr>
<tr>
<td>3.4.3.4.</td>
<td>Implementation of weekly descriptive analysis on daily notification data and monthly analysis based on monthly data at RIPCPh level (following trends over time, mapping of cases, description by age groups etc.)</td>
</tr>
<tr>
<td>3.4.3.5.</td>
<td>Elaboration of a new immediate notification form for all diseases to reduce the number of forms to be filled</td>
</tr>
<tr>
<td>3.4.4.1.</td>
<td>Establishment of early warning system as a part of the existing CD surveillance system established</td>
</tr>
<tr>
<td>3.4.5.1.</td>
<td>Supply of PCs at all levels only for surveillance purposes</td>
</tr>
<tr>
<td>3.4.5.2.</td>
<td>Ensuring of appropriate statistical packages for CD surveillance</td>
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<tr>
<td>3.4.5.3.</td>
<td>Supply of fax machines and internet</td>
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<tr>
<td>3.4.6.1</td>
<td>Continuous and refresher training of epidemiologists on surveillance and computing at all levels</td>
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levels
3.4.6.2. Training of RIPCPH epidemiologists in advanced epidemiological analysis (modern surveillance, EPI-INFO, EPI map, basic statistics, other statistical packages, computer use and basic computer skills)
3.4.6.3. Training of RIPCPH epidemiologists in descriptive epidemiology, epidemic investigation, study design, emergency response, data accuracy and communication in PH, evidence based prevention, reports and presentations
3.4.6.4. Training of all epidemiologists in antimicrobial resistance in order to include them in the surveillance of antimicrobial resistance
3.4.6.5. Training of trainers and regular short-term courses for the staff involved in the regional CD surveillance and individual training and practical work for all experts (central and regional level) in the NCDSC.

Programming year 2005
3.4.1.1. Elaboration of regulation according laboratories participation in data collection for CD purpose
3.4.1.2. Updating of the existing legislation for Accreditation of labs in collaboration with professional scientific organizations
3.4.1.3. Development of Standard Operating Procedures on CD laboratory surveillance coherent with accepted international standards and EU norms
3.4.1.4. Elaboration of regulation for involvement of the private labs in the CD surveillance including antimicrobial resistance
3.4.1.5. Elaboration of regulation for the supervision and quality control of reference labs to private labs, involved in the CD surveillance including TB, HIV/AIDS surveillance
3.4.2.1. Establishment of computerized laboratory

- Twinning contract
- Supply contract

- The implementation of activities planned for programming year 2004 is progressing as planned or at least with no severe backlog
3.4.2.2. Establishment of a National Reference Laboratory for Tuberculosis
3.4.2.3. Reorganizing of TB and STD labs in order to be included in the CD surveillance network
3.4.3.1. Elaboration of a special lab reporting form for CD surveillance purposes
3.4.3.2. Development of a national standard protocol on CD laboratory surveillance
3.4.3.3. Updating of the existing laboratory guideline for specimen collection, packaging and transportation, guide for rapid response etc.
3.4.3.4. Adaptation of rapid diagnostic tests and other technologies in order to strengthen the national capacity for laboratory confirmation of priority health events
3.4.4.1. Supply labs with basic lab equipment
3.4.4.2. Supply of equipment for high quality serological investigations
3.4.4.3. Supply of equipment for minimum number of rapid diagnostic techniques
3.4.4.5. Establishment of central specimen bank
3.4.4.6. Supply of computers, internet connection for all labs
3.4.5.1. Training of lab staff on CD surveillance (basic epidemiology and biostatistics)
3.4.5.2. Training of lab staff on specific issues concerning sampling techniques, data quality checks, lab safety, transport and storage of biological specimens

Preconditions

- Existing of the basic national legislation
- Availability of co-funding