TWINNING INTERIM QUARTERLY REPORT

No. 7

Strengthening the surveillance and control of Communicable Diseases

Member State Partners

The Netherlands Ministry of Health, Welfare and Sport, The Netherlands School of Public and Occupational Health (NSPOH)

Beneficiary Country Partners

Ministry of Health of the Slovak Republic Public Health Authority of the Slovak Republic

October 2006

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List of abbreviations

BC Beneficiary Country
CC Component Coordinator
CD Communicable diseases

CFCU State Agency "Central Financing & Contracting Unit"

EC European Commission Representation in the Slovak Republic

EPIS Epidemiological Information System EQAS External Quality Assurance System

EU European Union

ISO International Organization for Standardization

KIT BR KIT (Dutch Royal Tropical Institute) Biomedical Research

LCI Dutch National Co-ordination-centre for CD Min VWS Dutch Ministry of Health, Welfare & Sport

MoH Ministry of Health of Slovakia

MS Member State

NRC National Reference Centre

NSPOH Netherlands School of Public & Occupational Health

RTA Resident Twinning Advisor

PL Project Leader
PM Project Manager
PHA Public Health Authority

QA/QC Quality Assurance / Quality Control

RIVM Dutch National Institute for Public Health and the Environment

RPHA Regional Public Health Authority

SAC Sector Aid Coordinator

SNAS Slovak National Accreditation Service

SOP Standard Operating Procedure SPO Senior Programme Officer

SR Slovak Republic
STE Short Term Expert
SW/HW Soft Ware / Hard Ware
WHO World Health Organization

Section 1. Project data

Twinning Contract No. SK03/IB/SO/01

Project title Strengthening the surveillance and control of communicable

diseases

Twinning partners Ministry of Health, Welfare and Sport (NL)

Ministry of Health (SK)

Report No. 7

Period covered by the report 14 August 2006 – 31 October 2006

Duration of the project 21 months

Rapporteur Member State Rapporteur Beneficiary Country

Mr Geert van Etten, project leader Ms Zuzana Škublová, project leader

Section 2. Content

Background

Policy development

The new Decree of the Government of the Slovak Republic no. 337 on further details on prevention and control of communicable diseases from 10th of May 2006 has been approved by the Slovak government. This decree replaced the Regulation of the Ministry of Health of the Slovak Republic no. 54/2000 which changed and supplement the Regulation of the Ministry of Health of the Slovak Republic no. 79/1997 on measurements for prevention from communicable diseases.

Into the Decree was incorporated the request from EU Decrees concerning EWRS, EU Networks for surveillance of communicable diseases (CD) and reporting of CD.

In the Act no. 126/2006 on public health the diseases are grouped and a timeframe of reporting according to the importance of the measures that have to be taken for each of these groups is established (according to EU standards).

NOTE: Instead of three months, this 7th report concerns the reporting period for only two and a half months, i.e. from the 14th of August 2006 until the 1st of November 2006, the 31st of October being the end of the project.

Achievements of mandatory results

The following **Benchmarks** were achieved in the reporting period:

Component I

- Overview of relevant EU networks and the actual participation of BC experts in these networks.
- The new system of data collection is operational in 36 regional PHA's.
- As part of the training programme, about 50 officials from MoH and PHA have participated in a one day conference on intervention epidemiology.

Component II

• Recommendations on how to proceed for the PHA to pass the accreditation.

Component III

• New Standard Operating Procedures for external quality control are operational in 5 pilot regions.

The following **Mandatory Results** were completed in the reporting period:

Component I

 Slovak monitoring system of CD harmonised with EU standards, Early Warning System (EWS) upgraded and staff trained.

Component II

 National Reference Centres (NRC) network extended, existing NRC strengthened, and Laboratory Assurance Quality System in NRC implemented.

This result is partly achieved, with the exception of the accreditation of 6 NRC's (at the Public Health Authority of the Slovak Republic) instead of the 9 NRC's that should have been ac-

credited. Due to the delays with the reconstruction of the building of the PHA SR Bratislava until December 2006, the accreditation for these 6 NRC's will not take place before the end of the project.

It also should be noted here that instead of the 9 NRC's mentioned only 8 existing NRC's were included in the project and 1 new NRC for arboviruses and haemorrhagic fever was planned to be established. However due to lack of competent staff this only has been established as a separate workplace for the moment. However, it functions on a laboratory level.

Component III

 Standard Operating Procedures (SOP) in selected clinical microbiology laboratories implemented based on the new implemented quality assurance system.

This result is achieved, with the exception of the testing in 5 pilot regions. Instead, the testing took place in only 2 pilot regions. Due to organisation changes of laboratory basis at Regional Public Health Authorities during the 3.3 activity, the Component III work plan had to be rearranged and the former idea of a standard EQAS was retained only for salmonella NRC and NRC for resistance to antibiotics (ATB) serving the remaining (about 60) participating clinical microbiology laboratories. Because of lack of target EQAS participating laboratories NRC for measles, mumps and rubella (MMR) and influenza NRC were excluded from EQAS PHA SR. For Polio NRC a relevant simplified system with just 2 participating laboratories at RPHAs was adopted.

Activities in the reporting period

On the 4th of September 2006 a meeting took place between the Director PHA SR Mr. Rovný, the deputy Director Mr. Fitz, RTA Mrs. Aalders, RTA assistant Mrs. Ráčková, STE Mrs. de Schipper, Mrs. Sirotná (replacement of Mrs. Bosá), Mrs. Gavačová and Mrs. Tietzová from the microbiological laboratories at PHA SR.

The reason for this meeting was that Mrs. Bosá, coordinator of component II, resigned from the PHA SR Bratislava at the beginning of September 2006. Therefore, the consequences of her leaving had to be discussed and especially the progress of the mission of Mrs. de Schipper taking place at the 1st week of September. Mr. Rovný offered his support in order to let the project continue. There are no minutes available.

On the 8th of September 2006, the 6th Meeting of the Steering Committee took place at the Ministry of Health of the Slovak Republic. See annex I.1 for the minutes of this meeting for which a draft was first circulated to all members for comments which then were integrated into this new version.

On the 5th of October 2006 (in the morning) the 7th and last Meeting of the Steering Committee took place at the Ministry of Health of the Slovak Republic. See annex I.2 for the minutes of this meeting for which a draft was first circulated to all members for comments which then were integrated into this new version.

On the 5th of October (in the afternoon) the Closing Ceremony of the project took place at the Ministry of Health of the Slovak Republic. Special guests were the Slovak State Secretary of the Ministry of Health Mr. Klačko and the Dutch Ambassador in the Slovak Republic Mr. Swartbol. They both gave a speech. Furthermore, Mr. van Wijngaarden of the Dutch Ministry of Health and Mr. Rovný, Director of the PHA SR, the Slovak and Dutch project leaders Mrs. Škublová and Mr. van Etten and the RTA Mrs. Aalders gave speeches. The project manager Mrs. Krištúfková, the component coordinators Mrs. Avdičová, Mr. Klement and Mr. Nikš all presented evaluations of the project as a whole and of the three components separately. Next to this, two STEs, Mrs. de Schipper and Mr. Otto gave presentations in which they showed the progress made during the project. Afterwards at the Ministry of Health SR a re-

ception was organised by the PHA SR. See annexes II.1 – II.8 for the programme, list of participants and given presentations from the Closing Ceremony.

Because the Closing Ceremony was not budgeted for in the work plan, a Side letter No. 13 had to be drafted in order to be able to invite the two STEs mentioned above, to the meeting. See annex I.3 for concerned Side letter No. 13. Mrs. de Schipper's and Mr. Otto's full mission reports can be found in annex I.4.

Component I

This component is completed.

Extension of activity 1.10 (extra proposal)

To streamline Slovak specific general guidelines for outbreak management with the Dutch National guidelines by translating part of the latter into the Slovak language.

The list of diseases (Dutch National guidelines) selected by the component coordinator will be finalized by mid October 2006.

Activity 1.12 Registration for new memberships of EU networks

This activity was delayed. In September 2006, The RTA office received an updated list with EU networks (see annex I.5) via Mrs. Krištúfková.

In the period of Project preparation (2003) the PHA SR supplied active participation only in the 3 EU Networks for surveillance of communicable diseases – EISS, ESEN, EMGM (see Project Fiche). After the SR became a member of EU, it was asked to nominate the contact points (representatives) for several EU Networks or projects (see 1st Quarterly report / Annex II.6).

Besides PHA representatives, there were representatives from various Slovak institutions, such as Slovak Academy of Science, Faculty hospital, Comenius University, Faculty of Medicine, Slovak Health University, nominated into the networks. These institutions were not included into the project.

In September 2006 the PHA actively participated (regularly sent the data, attended the meetings, shared information, dealt with problems in workgroups) in 12 EU Networks (see annex 1.5).

There were also some changes concerning the networks during the project duration. EURO-HEPNET was a project mapping the surveillance system of viral hepatitis in the EU and it finished in 2005.

Next to this, this activity was put forward as an extra proposal: a 1 day workshop on the use of ENTERNET, a network specialized in communicable diseases, implemented by two Dutch experts.

Mr. Wilfrid van Pelt and Mr. Arjen van de Giessen (NSPOH / RIVM, The Netherlands) were involved in this activity on behalf of the Member State-partner. The visit took place from 4-5 September 2006 at the Public Health Authority of SR in Bratislava.

See annex I.6 for Side letter No. 12 for the approval of Mr. van de Giessen as the second expert to come for this activity.

The one day workshop took place at the Ministry of Health. 152 people were present. They had the following backgrounds: epidemiology, nutritional hygiene, clinical microbiology labs

(private & hospitals), environmental microbiology and staff from Veterinary institutions, laboratories and food hygiene.

During the one day workshop, the following topics were discussed:

- Introduction into ENTERNET.
- Presentation of the Dutch system of surveillance, monitoring and control salmonellas.
- Evaluation of the present system of salmonellas surveillance in the Slovak Republic.
- Examples of detection and recognition of outbreaks of food-borne diseases at the international level.
- Practical use of ENTERNET in the daily work discussion of cases and case management, importance of molecular epidemiology in finding the source of infection.

Main conclusions of the mission according to STE:

- The workshop resulted in a successful exchange of information on the surveillance and control of zoonoses, especially salmonella, both from national and EU points of view;
- Integration of expertise from the Slovakian public health and veterinary and food authorities was successfully realised.

See annex I.7 for the programme of the workshop.

Mr. van Pelt's and Mr. van de Giessen's full mission report can be found in annex I.8.

Activity 1.13 Implementation, testing and evaluation of the new system on data collection in 5 selected pilot regions.

At the request of the component coordinator the STE also concentrated on the following:

- To read and comment the document "Tests for acceptance for the new software EPIS" created by the SOFTEC company.
- Filling in of tests for acceptance.

Mr. Matthias Otto (NSPOH / KinderUmwelt Germany) was involved in this activity on behalf of the Member State-partner.

The 1st part of his visit took place from 9 – 14 July 2006 and was reported in the 6th Quarterly report. The 2nd part of his involvement for this activity took place from 21 - 25 August 2006.

Main conclusions of the mission according to STE:

- The tests of acceptance have to be repeated after installation of a revised / improved version (probably by the end of week 34). The available version allowed for a pre-test only.
- Secure data transmission (VPN, SSL) is a priority issue and has to be solved before data migration and entry of real data (i.e. before the start of the regular operation phase). The same holds for the password problem concerning the login of registered users

Mr. Otto's full mission report can be found in annex I.9.

Activity 1.14 Full systems roll-out in all 36 Regional PHA's

The system is functional in all Regional PHA's. Epidemiologists and other health personnel of the departments of epidemiology have the possibility to work with the system. During the last week of September a training was held for epidemiologists in order to be able to use the new system in an optimal way (27th and 28th of September; Bystrá - hotel Biela Medvedica district Brezno). All participants received detailed instructions about the programme concerning epidemiological aspects. From the 2nd of October the normal use of the software on the national

level will start with parallel using of the old programme. The results will be compared and assistance will be offered to solve faults and mistakes in the new programme.

Activity 1.15 Organization of a one day conference on Intervention epidemiology for surveillance and control of communicable diseases at the national and local level

This activity, which was delayed, took place on the 22nd of September, to finalize the 3 day training of extra activity 1.15 (see below). Around 40 people were present, consisting of epidemiologists and microbiologists.

See annex I.12 for the short report on this activity (written by RTA) annexed to the mission report of Mrs. Jeanette de Boer and Mrs. Hannelore Götz.

During the one day conference the following subjects were discussed:

- Outbreak investigation.
- Risk assessment and risk management.
- The new EPIS system.

Main conclusion of activity 1.15 according to RTA:

• The conference turned out to be a good way to complete the 3 day training and share the results with other people.

Extension activity 1.15 (extra proposal)

4 day training by Mrs. Jeanette de Boer and Mrs. Hannelore Götz on epidemiological principles in general and on risk assessment

Mrs. Jeannette de Boer (NSPOH / RIVM, The Netherlands) and Mrs. Hannelore Götz (NSPOH / GGD, The Netherlands) were involved in this activity on behalf of the Member State-partner. See annex I.10 for Side letter No. 11 for the approval of this visit.

The visit took place from 16 - 22 September 2006 at the Ministry of Health of SR and the Public Health Authority of SR in Bratislava.

Description of activities during mission:

To organize a 5 day training in total (1 day preparation, 3 day training, 1 day conference), consisting of an intensive training course for 10-15 selected epidemiologists on Risk assessment in infectious diseases and epidemiological principles in general. The last day (original act. 1.15) was organised as a conference for a broader public (40-50 people) and was concerned with different aspects of epidemiology (see above).

During the 3-day training the following topics were discussed:

- Risk assessment and –management.
- Different aspects of outbreak investigation (cohort and case control study).

Main conclusions of the mission (extra activity 1.15) according to STE's:

- The participants showed an active attitude and participated with interest.
- At the end of the training it appeared that these kind of epidemiological analytical studies
 were new to the participants but that the basic understanding has been achieved. The
 training enabled participants to translate their daily tasks into the structure of riskassessment.

See annex I.11 for the official programme of the training.

Mrs. de Boer's and Mrs. Götz's full mission report (with Annex by RTA on one day conference) can be found in annex I.12.

Update on SOFTEC

The work with the company SOFTEC continued on a daily basis and according to agreed time schedule stated in the contract and will be finished on time.

- Pilot testing of new software functionality finished on September 8th 2006. After the training of all users, also other Regional PHAs were involved in giving comments.
- Official testing for approval of the new software was held at two PHA's: registering of infectious diseases was tested at the RPHA Banská Bystrica, EWRS and influenza reporting at the PHA SR Bratislava during September the11th-14th.
- A Two day seminar for epidemiologists from all Slovak Regional PHAs and PHA SR was organized, where methods for diseases classification, case management, data collection were explained. Softec company was present at the meeting to give input to the software and to give answers to users about technical difficulties.
- Regular daily use of the new software started on the October 2, 2006.

Component II

This component is completed except for the accreditation of PHA SR Bratislava which will take place in December 2006.

Activity 2.7 Final assessment of the implementation of the new quality control system

Mrs. de Schipper fulfilled this activity, which was delayed, from the 4th of September until the 8th of September 2006 and she combined it with activity 3.4. She wrote one mission report for both activities.

The visit took place at the Public Health Authority of SR in Bratislava and the Regional Public Health Authorities in Banská Bystrica and Košice (Side letter No. 8 and No. 9, concerning this activity, were already added to the 6th quarterly report).

Note: At the beginning of this activity, Mrs. Bosá, coordinator for component II, resigned (see also under Issues).

Main conclusions of the mission according to STE: Bratislava:

- The leave of the coordinator for component 2 is sad especially because thanks to her efforts the process for accreditation is almost finished.
- It has been agreed with SNAS that they will pay their final visit after the reconstruction is finished.
- The quality system at laboratory level is up and running even in the tiresome circumstances during the reconstruction. The performed vertical audit on the process of identification and typing of Salmonellosis gave no nonconformities. Within the process data have to be (re)written in about 5 different registers or sheets this is a potential source for mistakes. Some use of a database to register results is made next to the handwritten registers.
- The newly appointed head of the NRC for Meningococci has nonconformities to solve regarding her own competence, inter- and intra-laboratory control and differential diagnosis. In November she will go for an internship to Praque.
- The NRC's for Poliomyelitis, Influenza and MMR have established themselves in the appropriate international networks.

Banská Bystrica:

- Reaccreditation has taken place and the new certificate is already received.
- The quality system looks very solid with lots of ways of collecting evidence within the system. Continuous improvement could be more emphasised.
- Sample data are registered in a database and also still registered in notebooks.

Košice:

- The SNAS has approved the quality system of the parts that applied for accreditation. The certificate is expected within a month.
- The quality system is described well and implemented in a practical way.
- The NRC for Diphtheria is accepted in the appropriate international network.
- The laboratory did not get much support from the project in setting up the system. However they managed well through their contacts with already accredited laboratories in the area.

Mrs. de Schipper's full mission report on activities 2.7 and 3.4 can be found in annex I.13 together with the "Report on activity 3.4" (written by Mr. Nikš).

Activity 2.8 Passing the accreditation process

Regional PHAs in Banská Bystrica and Košice both have been accredited this year. For PHA SR in Bratislava the process is still running. RTA Mrs. Aalders is keeping track of it until the end of the project (see also below for update on Accreditation process by component coordinator).

Update on the accreditation

It is now clear that due to the delays with the reconstruction of the PHA SR Bratislava the SNAS inspection of the fulfilment of the nonconformities is extended until December 2006. As a consequence of this, the Certificate of Accreditation will not be received by the PHA SR Bratislava before the end of the project.

Update on VITRUM

Because the contract was extended until mid October, estimated delivery finalization will be by the end of October 2006.

Update on reconstruction of PHA SR in Bratislava

The reconstruction is delayed but will be finished by the end of October 2006.

Component III

This component is completed.

Activity 3.4 Implementation and testing in 5 selected pilot workplaces of Standard Operating Procedures for external quality assurance.

Mrs. Karin de Schipper (NSPOH / University Medical Centre Leiden, The Netherlands) was involved in this activity on behalf of the Member State-partner. (Sideletter No. 8 for approval of Mrs. de Schipper was already included in the 6th report)

The visit took place from 3 - 8 September 2006 at the Public Health Authority of SR in Bratislava and the Regional Public Health Authorities in Banská Bystrica and Košice. Mrs. de Schipper combined her work for activity 3.4 with activity 2.7 (see under Comp. II). She wrote one mission report for both activities.

Main conclusions of the mission according to STE:

- Except for ATB suspectibility, the SOP's are still first draft SOP's.
- There are two types of EQAS established:
 - o ATB suspectibility and Salmonella send samples to approx. 50 clinical laboratories.
 - Poliomyelitis, Measles and Rubella send samples to the regional PHA's in Banska Bystrica and Kosice.
- Background and conclusions on these rounds can be found in the report of the component Coordinator on activity 3.4 (see annex to mission report Mrs. de Schipper) and on the explanatory document of my mission report on activity 3.3 (see 6th Quarterly Report).
- Every 3 years the NRC for influenza also sends out a round to the regional PHA's in Banska Bystrica and Kosice, the last one was in 2004.
- EQAS PHASK has proven its use through the pilot in this project.

Mrs. de Schipper's full mission report on activities 2.7 and 3.4 can be found in annex I.13 together with the "Report on activity 3.4" (written by Mr. Nikš), as mentioned under Component II.

The four EQAS PHA-SK test runs (ATB, salmonella, measles-mumps-rubella and polio NRCs) passed successfully and have confirmed usefulness and necessity of organisation of a national EQA system in the Slovak Republic.

Evaluation of test runs of EQAS PHA-SK has documented the need in routine laboratories for an efficient national EQA system oriented first on educational functions. Such system might also help to detect and to solve practical laboratory diagnostic problems in microbiology laboratories in the Slovak Republic. The system in the future might also help to get a general impression of the standard of laboratory practice and to achieve an inter-laboratory comparability. Such system will be a necessary prerequisite if national databases for infection diseases markers will be established in Slovakia, or if Slovakia will join EU networks for surveillance of infectious diseases and will report to central European databases (for more details see annex I.13 for mission report of Mrs. de Schipper with annex written by Dr. Nikš).

Timing & Delays

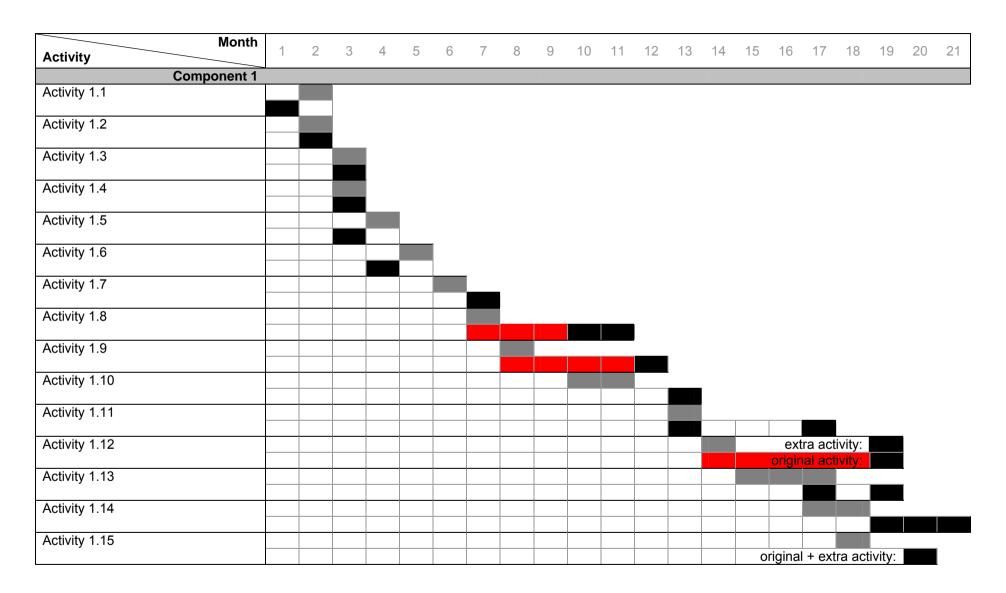
Adherence to time schedule¹

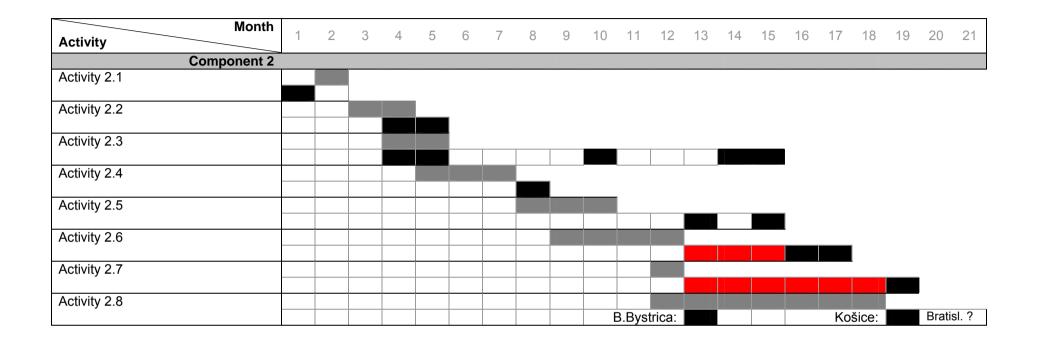
The adherence to the time schedule is expressed in the following table:

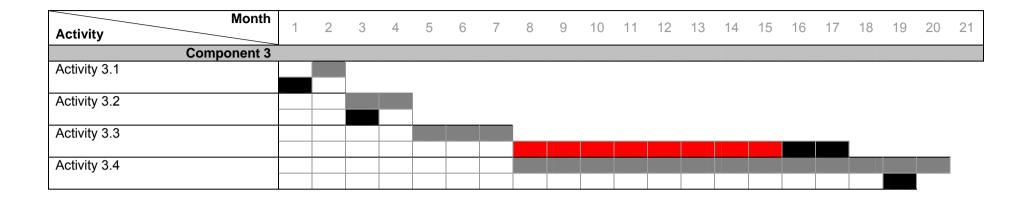
Activity planned
Activity implemented
Activity delayed by more than 3 months

7th Quarterly report

1







Recuperation of delays

All activities that were delayed, have taken place.

Assessment

Overall assessment of progress

Component I

All activities of component I have been completed.

Component II

All activities of component II have been completed. Except: activity 2.8: Passing the accreditation process. This activity is only partly completed because of the fact that the SNAS will only hand out the Certificate of Accreditation to PHA SR Bratislava after the reconstruction of the building is finished, this will not be before the end of the project however. The 2 NRC's in Banská Bystrica and Košice taking part in the Twinning project have both been accredited already.

Component III

All activities of component III have been completed.

Issues

Resignation coordinator Component II

At the beginning of September 2006 Mrs. Bosá, coordinator for Component II, resigned from the PHA SR Bratislava. Mrs. Bosá's leaving caused quite a problem for the Twinning project and the finalization of Component II, because she was completely involved in the reconstruction of the PHA SR Bratislava building and the accreditation process. Next to this, she did not hand over her work to her colleagues properly and she took with her some documents that are of importance to the project (a.o. revised quality manual).

Mrs. Bosá was replaced by Mr. Klement, Head of Section of Medical Microbiology at Regioanl PHA in Banská Bystrica. Mrs. Bosá's resignation also caused some problems for the implementation of the last activity (2.7) for which STE Mrs. de Schipper came to the SR. Fortunately with the help of the director of the PHA SR and some colleagues of Mrs. Bosá, Mrs. de Schipper was able to complete her mission in a satisfactory way.

Recommendations

Component I

For activity 1.12 the following recommendations were made by Mr. van Pelt and Mr. van de Giessen:

- For future workshops, a professional discussion leader would be an improvement.
- Collaboration between experts from the public health authorities and veterinary and food authorities should be further stimulated and facilitated. Also, collaboration between the national public health and the veterinary national reference laboratory should be realised.

For activity 1.13 (2nd part) the following recommendations were made by Mr. Otto:

 In August 2005, workgroups on groups of diseases (virus hepatitis, foodborne diseases, nosocomial infections, STD, zoonoses, diseases preventable by vaccination) had been established. It is strongly recommended to make these workgroups permanent. They should care for a high data quality in their respective field and also for updates in the EPIS menus according to the "state of the art".

For activity 1.15 the following recommendations were made by Mr. de Boer and Mr. Götz:

- Training on these subjects should be continued in Slovakia. Ms. Kristufkova is presently
 giving epidemiological training, an activity which should be continued. It would be preferable to start courses for trainers of trainers (TOT).
- Training of trainers is preferable in order to achieve sustainable results.
- Training parts should be followed by a continuous group of participants.
- Give English courses to professionals in public health.

Component II

For activity 2.7 the following recommendations were made by Mrs. de Schipper:

- Retrieving Quality Manual from former Quality Manager Bratislava.
- Appoint a new Quality Manager Bratislava.
- The Quality Manual will have to be rewritten taken into account the nonconformities of the SNAS, especially on topmanagement, continuous improvement, management of complaints, internal audits, training of personnel and management review.
- Research on a way to implement a Laboratory Information System.

Component III

For activity 3.4 the following recommendations were made by Mrs. de Schipper:

- Still include SOP's on EQAS in system of document control.
- Look into the possibilities to develop a system for EQAS on a national level that's appropriate for public health laboratories as well as private clinics (as recommended by Dr. Nikš).

Section 3. Expenditure

According to the Twinning manual (revision 2004), the total figures of disbursement for key groups of costs are described in this section of the quarterly report. A detailed financial report following the format for financial invoice report is enclosed as annex I.14.

Total figures of disbursement for key groups of costs

Project management Activities component I Activities component II Activities component III	€ 28.637,00 € 28.563,90 € 5.121,66 € 3.406,30
Total budget	€ 505.816,95
Spent 1 st quarter	€ 98.563,43
Spent 2 nd quarter	€ 54.458,57
Spent 3 rd quarter	€ 12.799,05
Spent 4 th quarter	€ 35.813,63
Spent 5 th quarter	€ 55.385,63
Spent 6 th quarter	€ 60.073,68
Spent 7 th quarter	€ 65.728,87
Total spent	€ 382.822,87