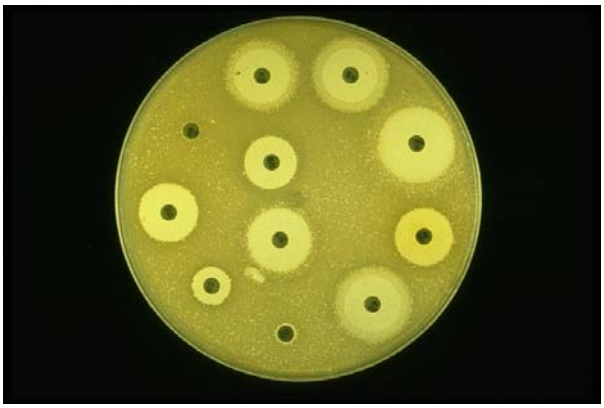

Inception Report

Draft 31 March 2006

Antimicrobial Resistance Surveillance in Human Medicine

Consortium

Interaction in Health / Public Health Consultants
IDA Solutions
Trnava University

Date: March 2006 - draft

Reference: MAT05/HR/9/2

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Acronyms

ABRES	Antibiotic Resistance (coordinating committee)
AGREE	Appraisal of Guidelines, Research and Evaluation
AR	Antimicrobial Resistance
ARC	Antimicrobial Resistance Control
CBO	Institute for Quality in Health Care (the Netherlands)
CLSI	Clinical and Laboratory Standards Institute
CME	Continuing Medical Education
DDD method	Defined Daily Dose
EARSS	European Antimicrobial Resistance Surveillance System
EU	European Union
EUCAST	European Committee on Antimicrobial Susceptibility Testing
ESCMID	European Society of Clinical Microbiology and Infectious Diseases
ESGAP	European Study Group on Antibiotic Policies
ESGNI	European Study Group on Nosocomial Infections
EVD	Economsiche Voorlichtings Dienst
FDA	Food and Drugs Agency
GPs	General Practitioners
ICM	Intersectoral Co-ordination Mechanism
ICT	Information and Communication technology
IDA	International Dispensary Agency
ISKRA	Intersectoral Society for Control of Resistance of Antimicrobials.
LIS	Laboratory Information System
MAFWM	Ministry of Agriculture, Forestry and Water Management
MHSW	Ministry of Health and Social Welfare
MPAP	Matra Pre-Accession Programme
MRSA	Methicillin Resistant Staphylococcus Aureus
NEQAS	National external Quality Assessment Services
NHG	Dutch Society for General Practitioners
RIVM	Dutch National Institute for Health and Environment
SIGN	Scottish Intercollegiate Guideline Network
SWAB	Dutch Working Party for Antimicrobial Policy
TB	Tuberculosis
TOR	Terms of Reference
VWS	Dutch Ministry of Health Welfare and Sport
WHONET	World Health Organisation Network

1 Introduction

1.1 Terms of Reference and Consortium

The project Antimicrobial Resistance Surveillance in Human Health is financed by the Netherlands Ministry of Foreign Affairs through the EVD agency MPAP programme. The project started on 1 January 2006 and will last until 31 December 2007. The project aims to contribute to the accession of Croatia to the European Union. In particular, the project aims to assist Croatia in implementing EU-directives and recommendations in the field of antimicrobial resistance and the sound use of antibiotics.

The purpose of the project is strengthening the Croatian institutional structure engaged in surveillance of antimicrobial resistance.

The following project results are anticipated to be achieved:

1. An Intersectoral Co-ordination Mechanism (ICM) in the field of antimicrobial resistance established and functional;
2. A surveillance system for antimicrobial resistance and use of antibiotics established, based on national policy that is in line with the EU strategy for antimicrobial resistance;
3. Guidelines for sound use of antibiotics in the human sector formulated and implemented.

According to the Terms of Reference, the Ministry of Health and Social Welfare (MHSW) is the counterpart of the project and the National Reference Centre for Antibiotic Resistance Surveillance of the Ministry of Health and Social Welfare is the beneficiary of the project.

A consortium consisting of Public Health Consultants/Interaction in Health, IDA Solutions and Trnava University (Slovak Republic) is providing consultancy services, in collaboration with the Dutch Working Party for Antimicrobial Policy (SWAB), the Dutch National Institute for Health and Environment (RIVM) and the Dutch Ministry of Health Welfare and Sport (VWS).

1.2 Structure of the inception report

The next section describes the activities during the inception phase and key issues which were discussed between consultants, counterpart and beneficiaries.
Section 3 gives information on the final project model, as formulated jointly in the inception phase. In that section and overall work plan is presented, as well as suggestions for human resources input and project management.
Section 4 provides detailed plans for the next quarter, specified per expected result.
In the annexes a logical framework and Gantt chart are incorporated.

2 Progress in the inception phase

2.1 Activities planned for inception phase

Activities inception phase related to result 1 Intersectoral Co-ordination Mechanism (ICM)

During the Inception Phase an inventory will be made of views on the functioning of the ICM. The context of control of infectious diseases will be discussed, and interrelations between disease control and reduction of antimicrobial resistance will be brought forward.
An inventory will be made of possible participants in the ICM and the institutional contributions which can be made in the ICM. Especially further debate with the Ministry of Agriculture, Forestry and Water Management (MAFWM) on the contribution to the ICM will take place.
Tentative preparations for a study visit to the Netherlands should be made.

Activities inception phase related to result 2: Surveillance System

During the inception phase a mapping will be done of all relevant players in the field (both at national level and local level), relevant surveillance activities and research projects. Also the routine activities and present reporting systems will be mapped.
Special attention will be given to the Referral Centre for Antibiotics Resistance Surveillance. What are the available capacities, competencies and technical possibilities? The status of the Information and Communication Technologies will receive extra attention, in respect of the formulated needs in the TOR.

Activities Inception Phase related to result 3: guidelines

During the Inception Phase an inventory will be made of local, national and international initiatives in this field. This will provide the necessary information on the starting of guideline development, training and introduction.
During the Inception Phase a mapping will be made of scientific organisations, universities and training institutions which play a role in guideline development and training.

2.2 Missions and preparatory activities

During the Inception Phase Dr. Jaap Koot, project coordinator, visited Croatia twice. In January a first inventory was made of key issues to be addressed during the project. He met with experts from the MHSW, the Reference Centre and different medical societies and associations participating in antimicrobial resistance surveillance. He also met the representative of the Ministry of Agriculture, Forestry and Water Management (MAFWM). He had meetings with the Royal Netherlands Embassy and the Ministry of European Integration. With the information collected during the first mission, he had meetings with the SWAB, the RIVM, the Health Inspectorate and the Ministry VWS to discuss the contributions of these partners. In March he visited Croatia for the second time. He attended a symposium on antimicrobial resistance and introduced the project. He discussed the final work plan with the beneficiaries.
Dr. Maja Vucetic, consultant, visited Croatia in March and gave a presentation during the symposium on antimicrobial resistance. She contributed to the formulation of the final work plan.
Dr. Martin Rusnak visited Croatia in March and studied operations of various laboratories in Zagreb, Rijeka and Cakovec, especially assessing the automation in the labs. He discussed automation issues with the IT expert who developed the lab information system (LIS), which is now in use in 10 microbiology labs in Croatia. He contributed to the formulation of the final work plan.
Dr. Jan Prins, Secretary of SWAB, intended to contribute to the symposium on antimicrobial resistance. Unfortunately, due to air travel delays, he could not reach Zagreb in time and had to cancel the participation in the symposium.

2.3 Key Issues

2.3.1 Intersectoral Coordination Mechanism

One of the expected results of the project is to assist the Croatian MHSW in initiating an Intersectoral Coordination Mechanism (ICM) for control of antimicrobial resistance.

In Croatia there is already an ICM between MAFWM and MHSW for zoonoses, called Inter-ministerial Committee for Zoonoses. This committee has been set up under an Ordinance of the MAFWM by the MHSW and has – amongst others –as a task to oversee antimicrobial resistance. This committee was formed last year. From the side of the MHSW the Institute of Public Health and the Head of the Sanitary Inspection participate in this committee.

There is also a Ministerial Committee for Nosocomial Infections, which has been constituted through an Ordinance of the MHSW. This committee already exists for some time. The committee produces annual reports. Dr. Stamenic and Dr. Skrlin-Subic are members of this committee. The committee is now trying to set priorities for its activities, and develop activities, topic by topic, starting sampling from CV catheters.

The Croatian stakeholders think it is best to create a separate ICM on the control of antimicrobial resistance. The working name for this committee is ISKRA, which means "sparkle" in Croatian. The acronym stands for Intersectoral Society for Control of Resistance of Antimicrobials.
The provisional committee is based on members of those heads of microbiology labs in Croatia, who are active in the field plus representatives of several other professional associations (Croatian Academy of Medical Sciences; Croatian Society for Microbiology; Croatian Society for Infectious Disease and the Croatian Society for Chemotherapy). However, after series of discussions it was agreed, that it would be beneficial to extend the membership with representatives from:

- Ministry of Health and Social Welfare
- Ministry of Agriculture Forestry and Water Management
- Croatian Society for General Medicine
- Croatian Medical Chamber
- Croatian Institute for Veterinary Medicine
- Croatian National Public Health Institute
- National Health Insurance Company.

The ICM could start as an informal working group under auspices of the MHSW, define its terms of reference and the composition. In a later stage this could be sanctioned by an Ordinance of the MHSW. One of the tasks is to demarcate responsibilities of this ICM vis-à-vis the Inter-ministerial Committee for Zoonoses and the National Committee for Nosocomial Infections.

2.3.2 Policies antimicrobial resistance in human health

The Intersectoral Coordination Mechanism should, according to the TOR produce a policy document for containment of antimicrobial resistance. During the missions the most important topics were discussed with the counterparts in Croatia. The recent working document of the EC on antimicrobial use could serve as a guideline for policy development.[1]

The policy document should tackle a series of topics:

- <u>The surveillance of antimicrobial resistance in humans</u>

[1] EC: Commission Staff Working Document, Detailed Analysis of Member States' reports on the implementation of the Council recommendation (2002/77/EC) on the prudent use of antimicrobial agents in human medicine, COM (2005)684 final, SEC (2005)1746, Brussels, 22.12.2005

The policy should give an official backing to the already existing voluntary system of surveillance. The way the surveillance is organised now should not change too much. The major innovation required is to establish electronic communication between laboratories and central data analysis with adequate interpretation of findings. Another point of interest is establishing the communication between reporting organisation and MHSW, for taking necessary containment measures.

- The surveillance of antimicrobial resistance in animals
  Presently, there is nothing in place in this area. However, it is important to regulate something in line with EU policies. (See below description of practice.)

- The surveillance of use of antimicrobials
  In 2005 a piece of legislation has been adopted by MHSW, which regulates the monitoring of utilisation of antimicrobials. This part is now covered, but could be described in further details in the policy part.

- Essential drug list
  Croatia has an essential drug list and the National Health Insurance Company indicates on the list under which conditions certain drugs can be prescribed. Reference could be made in the policy.

- Prevention measures
  Proposing measures for prevention of antimicrobial resistance in human medicine and in veterinary medicine, including mandates of different government and professional bodies.

- Guidelines and training
  The policy should give suggestions for a methodology for guideline development and capacity building in this area, for both professionals and general public

- Financing mechanisms for surveillance of antibiotic resistance (AR) and for measures for containment of AR.

The project will start making a base-line survey of the Croatian situation with regard to containment of antimicrobial resistance, using the questionnaire in the above mentioned EC document.[1]

2.3.3 Present situation in antimicrobial resistance surveillance in Croatia

The present surveillance system for antimicrobial resistance works with about 30 out of total 34 laboratories in the country. Most of these laboratories are public health laboratories, attached to the regional public health institutes. Some laboratories are attached to hospitals. There is however ongoing political dispute on the position of those laboratories. The laboratories work voluntarily in the antimicrobial surveillance and decide together on the methodology to be applied, and exchange views on quality assurance. There is a high sense of ownership of the system among the participating labs.

In principle, the routine tests for culture and sensitivity are used for the testing on antimicrobial resistance. Results of those tests are mostly reported in qualitative way. This is one of the obstacles for implementation of WHONET and the introduction of MIC. One step toward the solution will be a donation of electronic callipers for those labs, which will start using the WHONET. Additional antibiotics are added to assess a wider range for susceptibility. (Until now, the extra costs are covered by the laboratories themselves. Changes in the financing system by the National Health Insurance of laboratory tests may necessitate additional financing in the future).

For quality testing strains from WHO-CDC are used. These are distributed free of charge by the Reference Centre to the labs. Some labs use NEQAS strains. These are expensive and not affordable for all labs. CLSI guidelines or EUCAST guidelines for quality control are used. The system works well, and does need much external advice.

Most laboratories have a laboratory information system (developed in Croatia), whereby data of all tests are entered into the computer. The reporting to the Reference Centre is done on paper, because it is not possible to export data from this information system. For this reason only samples of three months are taken, and extrapolated for a one-year's period. Manual reporting over the whole year would demand too much work from the labs. However, whole year reporting would greatly enhance the possibilities for detailed analysis of resistance patterns.

Some labs are using the software programme developed by WHO (ftp://ftp.who.int/medicines/WHONET/). Some are using the lab-info system and WHONET in parallel, entering data twice. One laboratory is using WHONET fully, but has no callipers for automated measurement of results. In 2001 the designer of the WHONET system (Dr. John Stelling) has given courses in the use of the software system. He could be consulted for further advice.

Presently the Reference Centre has a simple database system for entering data from labs. This is done by Dr. Tambic and Dr.Pleskova. The manual data entry has as an advantage that data errors are quickly detected. However, it is time consuming. Automation would enable sampling over the whole year. This allows for more detailed analysis, e.g. levels of resistance per region.

In the project the automated data transfer between labs and Reference Centre and linkage of data systems has a priority. The WHONET software seems to offer good possibilities. If callipers were available for routine practice then the translation of the user interface (not reporting) into Croatian would be required. The budget for hardware and software in the project could be used for improving the ICT in the Reference Centre and selected labs, as well as the introduction of WHONET in more labs in Croatia.
Data analysis and reporting could be further developed. When better data transfer is possible, the Antimicrobial Resistance Committee has to define priorities for data sets and type of analysis to be done.

2.3.4 Surveillance of the use of antimicrobials

Recently (March 2005) the MHSW has issued an ordinance, which regulates the monitoring of use of antimicrobials in human health. The Food and Drugs Agency now receives from all pharmacy sales data and that information can be used for analysis. The Public Health Institute of Zagreb has been contracted by the FDA to perform the analysis. Now the standardised DDD method of analysing the use of antimicrobials is applied.
According to Dr. Tambic Croatia has now a reliable system of surveillance of use of antimicrobials, that can be linked to the surveillance of antimicrobial resistance.
In the project there is no need for additional activities in this area.

2.3.5 Nosocomial infections

As mentioned above there is a National Committee on Nosocomial Infections, in which some of the contacted persons participate. All hospitals should have a nosocomial infection committee and a committee for chemotherapy. 90% of the hospitals indeed have these committees (some as a part of general quality of care management). All hospitals with more than 250 beds have an infectious disease control nurse. The possibilities to reduce nosocomial infections are limited. Older hospitals have limited possibilities to isolate patients and to take proper hygienic measures. Under the present insurance system, hospitals do not get extra payment for isolation of patients; hence there is no incentive to containment of nosocomial infections.
In the project, attention could be given to the control of MRSA, which is measured through the EARSS surveillance system. It could be a kind of test case how concrete control measures could be developed in a resource constrained environment and closely monitored in the surveillance system. The approach which was followed in the UK could serve as an example. There it was possible to bring the level of MRSA down considerably.

2.3.6 Guidelines and other measures

At present, in Croatia there are several clinical guidelines with regard to policies on antimicrobial use. Intensive care physicians have produced guidelines. ENT specialists, infectiologists, intensive care units and individual hospitals have produced guidelines as well. The problem is that guidelines, developed by one group, are not accepted by other groups.
In Croatia there is not a national institute for guideline development (like CBO in the Netherlands), or an accepted methodology of consensus building on guidelines. However, there is a programme for quality assurance and many hospitals have quality managers in place.
It will be an important activity in the project, to propose a methodology of guideline development for reduction of AR, which is acceptable for all professionals.
The first step in the project will be an inventory of existing guidelines and protocols with regard to antimicrobial policies. These will be assessed with the AGREE instrument, which is internationally recognised as suitable for this purpose. There will be training in guideline development, where potential stakeholders will be asked to participate. Not only the hospital doctors, but also the general practitioners will be involved into the guideline development.

In the project, there should be an attention given for training in guidelines implementation and dissemination of guidelines. Publication of guidelines on websites is one of instruments to be applied. The website of the National Academy of Medical Sciences could be a suitable place for publication. Also dissemination through publications is important.
In the past there has been training in the rational prescription of antibiotics and reduction of antimicrobial resistance. Six years ago there was a programme, during which 2700 GPs were – obligatory – trained in this area. The impact was very positive. However, over the years prescription habits have gradually deteriorated. Present CME programmes, e.g. in the area of TB, are making less impact; fewer doctors attend.

2.3.7 Veterinary use of antimicrobials

The MAFWM does not have a policy on testing for antimicrobial resistance. This does not have a priority (and many say it does not have any relevance). In Croatia, there is a list of permitted drugs for animals, and the conditions under which drugs may be given.

There are two types of testing in veterinary health:
- before slaughter;
- annual sampling of health of animals.

Testing before slaughter is paid by the government and concentrates on presence of certain microbial organisms, residuals of antibiotics, pesticides and heavy metals. Antimicrobial resistance is not tested, as there should be no organisms at all. For veterinary services, this testing has no added value.
Testing for live animals has limitations in sampling methods. Also in this sampling there is no antimicrobial resistance testing.

The MAFWM has designed a pilot study on use of antimicrobials in poultry. This study has not yet been implemented due to lack of funds. If money could be made available through the project, antimicrobial resistance testing could be included in the pilot. Technically, the veterinary labs are capable of doing this testing. The vet labs are in a process of standardisation through ISO and accreditation.
Experiences on standardised testing for antimicrobial resistance could be shared with the working group on human AR.

2.3.8 Financial aspects of surveillance

As mentioned above, surveillance is paid by laboratories from the reimbursements made by the National Health Insurance Company for routine testing. Recently, the reimbursement system has been changed, leading to lower payments. The management of labs may decide that surveillance activities should be discontinued if not reimbursed.

The Reference Centre distributes strains for quality testing, which are donated by CDC under the WHO quality programme. If commercial quality testing strains have to be procured, it will be too expensive for most labs.
Data aggregation and analysis is done in the Reference Centre without any payment by government. Publications and meetings are sometimes subsidised by pharmaceutical companies.
In the project detailed budgeting of costs involved in surveillance should be done, resulting in a proposal to MHSW (and maybe National Health Insurance Company) for financing the necessary surveillance.

2.4 Coordination and Programme Management

2.4.1 The Netherlands Nominated Organisations

During the Inception Phase the project coordinator discussed the project with representatives of SWAB, the RIVM, the Health Inspectorate and the Dutch Ministry of Foreign Affairs. The organisations are all very positive with regard to this project and want to give their support. The SWAB has indicated it will contribute according to the proposal and has nominated five persons to participate (see below). However, both the Ministry of Health and RIVM have indicated their time constraints. At this moment these institutions cannot make any commitment for the current year, apart from receiving the guests during the study visit.
Also for SWAB it is impossible to indicate exactly availability of experts for the coming two years.
The inputs of the nominated partners will be proposed during every quarterly planning.

2.4.2 European activities in reduction of antimicrobial resistance

ESCMID and ESGAP will provide training and support in the context of its European Programme. On 19 – 20 May 2006, there will be a training programme for Croatian physicians in improving antimicrobial prescribing.
Dr. Inge Gyssens, who is both involved in ESCMID and SWAB will provide coordination of activities in the Matra programme and ESCMID programme.

2.4.3 Programme management

The consortium of Interaction in Health/Public Health Consultants, IDA Solutions and Trnava University will provide the technical assistance to the project. Dr. Jaap Koot will coordinate the consortium and will liaise with the EVD, financing the project.
The MHSW is the counterpart in the project and Dr. Stamenic will be the contact person. The Reference Centre is the beneficiary. Dr. Tambic-Andrasevic, the director of the Department of Microbiology, will coordinate the project.
The ISKRA (Intersectoral Society of Control of Antimicrobial Resistance) will start as a working group and gradually develop into an Intersectoral Coordination Mechanism, as defined in the TOR for this project. This committee will give guidance to the project development.

3 Final Project Model

3.1 Project purpose and expected results

The purpose of the project is strengthening the Croatian institutional structure engaged in surveillance of antimicrobial resistance.

The following project results are anticipated to be achieved:

1. an Intersectoral Co-ordination Mechanism (ICM) in the field of antimicrobial resistance established and functional;

2. a surveillance system for antimicrobial resistance and use of antibiotics established, based on national policy that is in line with the EU strategy for antimicrobial resistance;

3. guidelines for sound use of antibiotics in the human sector formulated and implemented.

The project purpose and project results as formulated in the Terms of Reference are appropriate for this project, with the following observations:

- Under expected result 1 the formulation of the national policy is planned, which is alluded to under expected result 2
- The surveillance system for antimicrobial resistance and use of antimicrobials is well-established in Croatia. The emphasis in expected result 2 will be more on improvement of data communication and analysis.
- Guideline development and introduction of a methodology of design of guidelines and protocols will receive much attention. A larger part of the budget will be allocated for this result than foreseen in the project proposal.

3.2 Project implementation

3.2.1 Overall work plan

Result 1 : Intersectoral Co-ordination Mechanism (ICM) in the field of antimicrobial resistance established and functional						
		Expected starting date	started	Completed	In progress	Expected completion date
1.1	"zero" assess of implementation of EU recommendations on Antimicrobial Resistance Control	14/04/06				30/04/05
1.2	Study visit to the Netherlands	08/05/06				13/05/06
1.3	Proposal for structure and mandate of the ICM	01/06/06				01/07/06
1.4	Conference on control of antimicrobial resistance, presentation of design structure and discussion	23/09/06				27/09/06
1.5	Presentation of the proposal to the MHSW, legal instruments for backing up the ICM	01/10/06				31/10/06
1.6	Outline document on policy development: topics and set-up of the document	01/05/06				31/05/06

1.7	Round table discussions with prospective members of the ICM on policy development	01/06/06				30/06/06
1.8	Draft policy and circulation among relevant stakeholders	01/07/06				31/07/06
1.9	Presentation policy during conference	23/09/06				27/09/06
1.10	Final version of policy and presentation to MHSW	01/10/06				31/10/06
1.11	Develop budgets for surveillance activities	01/12/16				31/12/06
1.12	Formulate financing proposals to relevant institutions	01/01/07				31/01/07
1.13	Develop growth scenarios based on available funding	01/05/07				31/05/07

Remarks:

- Assessment of implementation of EU recommendations: see annex 3 questionnaire
- Study visit: see annex 4 for programme and suggested participants
- The ISKRA will start as a working group, before official endorsement by the MHSW will be in place.
- In agreement with Prof. T. Jeren, President of the Croatian Society of Infectious Diseases, the during the 5th Croatian congress on infectious diseases the project will be presented at a plenary session and workshops on AGREE guidelines evaluation, AR policy development and WHONET introduction will be given by project consultants in close cooperation with local experts;
- The policy will encompass all elements listed in paragraph 2.3.2
- Formulating mechanisms of financing surveillance, reporting, guideline development and training is important for the sustainability of the project

Expected result 2: Surveillance system for antimicrobial resistance and use of antibiotics established						
		Expected starting date	Started	Completed	In progress	Expected completion date
2.1	Inventory of automation in laboratories, information and communication	15/04/06				30/06/06
2.2	Study visit to the Netherlands	08/05/06				13/05/06
2.3	Plan for Improving ICT in Reference centre and labs	01/06/06				31/06/06
2.4	Improving ICT in Reference centre	01/07/06				31/08/06
2.6	Presentation of communication strategy during national conference	23/09/06				27/09/06
2.7	Implementing new communication system between labs	01/10/06				31/12/06
2.8	Testing of new communication system labs	01/01/07				31/07/07
2.9	Evaluation of new communication system	01/10/07				31/10/07
2.10	Final report National Surveillance System	01/10/07				31/10/07

Remarks:

- Automation will be the main activity in the area of surveillance
- Collaboration with WHO will be sought to establish possibilities of integrating WHONET in the Laboratory Information System

- In the process of introduction training activities may be planned for labs.

Expected result 3: Guidelines for sound use of antibiotics in the human sector formulated and implemented						
		Expected starting date	Started	Completed	In progress	Expected completion date
3.1	Study visit to the Netherlands, discuss guideline development with NHG, SWAB	08/05/06				13/05/06
3.2	Inventory of existing clinical practice guidelines and protocols available in Croatia	01/06/06				01/06/06
3.3	Testing guidelines with AGREE instrument, workshop during conference, selection of priority guidelines	23/09/06				27/09/06
3.4	Workshop on guideline development with working groups	01/10/06				31/10/06
3.5	Development of pilot guidelines	01/11/06				31/01/07
3.6	Feed back on pilot guidelines from various stakeholders	01/02/07				30/04/07
3.7	Formulating of final versions of guidelines	01/05/07				30/09/07
3.8	Publication of guidelines and implementation tools	01/11/07				30/11/07
3.9	MRSA reduction strategy in collaboration with national nosocomial infection committee	01/10/06				31/10/06
3.10	Introduction of MRSA reduction measures and quality control in selected hospital	01/01/07				30/09/07
3.11	Evaluation of MRSA reduction strategy	01/11/07				30/11/07

Remarks:

- In agreement with Prof. T. Jeren, President of the Croatian Society of Infectious Diseases, during the 5th Croatian congress on infectious diseases in September 2006, the project will be presented by Dr. Tambic, and two workshops will be given by project consultants, one on the AGREE instrument and one on MRSA containment.
- The guideline development will follow principles as developed by SIGN and CBO. However, for saving time, the procedures may be shortened.
- Electronic exchange in the guideline development process is important. It is proposed that the website of the Croatian Academy of Medical Sciences is used for this purpose.
- MRSA containment will be incorporated in the project, as it offers a possibility to link the surveillance to actual measures.

3.2.2 Human Resources

The consultants' team

In the consultants' team changes are proposed in comparison to the proposal. Dr. Liskova's services are not required, as the Croatian counterparts have indicated that the laboratory procedures and quality mechanisms are in place. Dr. Inge Gyssens has been incorporated in the consultants' team, to coordinate with international projects in Europe. Dr. Johan de Koning's services will be programmed under the RIVM, if there is need for his input.

Dr. Jaap Koot, MD MBA representing Interaction in Health, will act as project coordinator. He is a medical doctor specialised in public health and management. He has worked on development quality systems in health in Slovakia. He will be working all three expected project results.

Dr. Maja Vucetic MD MPH is a medical doctor (University of Zagreb), specialised both in public health (University of Zagreb) and family medicine (University of Amsterdam). She will concentrate on guideline formulation and introduction.

Prof. Martin Rusnak, M.D. CSc. Trnava University will work in the organisational set-up of the ICM, data communication between labs and the formulation of guidelines. He is a medical doctor experienced in public health, health systems research, health and medical informatics, statistics, modelling, project management, computer applications, hospital and national information systems.

Prof. Vladimir Krcmery, MD, DrSc, FRCP, FACP will concentrate on the ICM formation and guideline development. He is a medical doctor board certified in Internal Medicine, Medical Oncology, and Infectiology. Diseases, FRCP Edinburgh. He has been involved in projects on antibiotic policies in Europe as chief advisor for antibiotic policy of the Ministry of Health Slovak Republic - ESGARS (Verona) ESGNI (Madrid) - European Surveillance of Nosocomial Infections.

Prof. Jos van der Meer, MD PhD will concentrate on the coordination mechanism. He is Professor of Internal Medicine and Chairman of the Division of General Internal Medicine at Radboud University Nijmegen Medical Centre. He is member of the Royal Netherlands Academy of Arts and Sciences. From May 2005 onward he serves as the chairman of the Department of Natural Sciences of the Academy. He is expert in the area of infectious diseases and non-infectious diseases with fever.

Dr. Heather Houlihan, PharmD representing IDA Solutions will act as specialist in pharmaceutical aspects of guideline development. Dr Houlihan has provided training and in service guidance on antimicrobial utilisation to pharmacy students and medical doctors.

Dr. Inge Gyssens is an infectiologist, working the Erasmus University Hospital. She is chair of the Study Group on Antibiotic Policies (ESGAP) of the European Society of Medical Microbiology (ESCMID). She is also part of SWAB. She has a special task in the project to coordinate with international projects in Europe.

Ms. Anna Grgurevic will work as local project assistant. She has a Master's diploma in food technology, with specialty in microbiology. She has experience with laboratory technology and is knowledgably in the area. She is Croatian, and lives in Zagreb. She will be responsible for liaising between consultants and the Croatian counterparts.

Nominated partners

The **Ministry of Health, Welfare and Sports** in the Netherlands defines policies and legislation for prevention and control of infectious diseases. As such it creates the conditions for other organisations to implement activities in the field of antimicrobial resistance. The

Dutch MVWS manages the interdepartmental coordination mechanism (ABRES) for antimicrobial resistance.
The MVWS is requested to assist in developing an appropriate structure for the ICM in Croatia. The Consortium has contacted Ms. Trudy van Dijk, in the Public Health Directorate, who is responsible for antimicrobial policy.

The **Working Party on Antibiotic Policy** (SWAB) is a foundation in which all important organisations and individuals in the field of antimicrobial resistance collaborate. SWAB has since 2001 been designated by the MVWS to co-ordinate the surveillance of antibiotic resistance. In addition, the SWAB participates in the realisation of the surveillance of the use of antibiotics. The following expertise from SWAB will be provided:

- Intersectoral Coordinating Mechanism: prof Degener, UMC Groningen
- Surveillance Resistance: dr E.E. Stobberingh, medical microbiologist, AZM, Maastricht
- Surveillance use of Antibiotics: dr.P. Filius, hospital pharmacist, Erasmus MC Rotterdam
- Guideline development: dr. I.C. Gyssens, infectiologist, Erasmus MC Rotterdam
- Guideline development: dr. J. Prins, infectiologist, AMC, Amsterdam

The CVs of the proposed consultants are attached to this inception report.

The **National Institute for Public Health and the Environment** (RIVM) functions as a research institute and centre of expertise in the Netherlands to support policy-makers and professionals in various fields of work. The institute monitors national and international data on infectious diseases, making it possible to signal potential epidemics in an early phase (early warning). The RIVM coordinates the EARSS project, which is described earlier.
The role of the RIVM in health and disease covers research and advice on new infectious diseases, protection against infectious diseases through vaccination and risks due to poisonous substances and exposure to radiation. RIVM also examines the most common causes of death in the Netherlands.
In this project – besides the experiences of EARSS – the RIVM could share experiences on the CIB (new Centre for Disease Control), the automated data transmission from laboratories the ISIS programme, the STUF (standardisation of laboratory reporting), standardisation of susceptibility testing and guideline development, and national coordination structure infectious diseases with protocols.
The consortium would like to see the following contributions from the RIVM

- Expertise on laboratory data collection, standardisation and monitoring of quality
- Expertise on national coordination (CIB, LCI)
- Expertise on guideline development and preventive measures

The contribution of RIVM experts will be discussed on a quarterly basis, dependent on the planning of the project.

3.2.3 Project Management Organisation

Project coordination

Dr. Jaap Koot of Public Health Consultants/Interaction in Health will coordinate the project on behalf of the consultants. He will liaise with the nominated partners VWS, SWAB and RIVM. He will be responsible for quarterly reporting and planning.
Dr. V. Stamenic will represent the MHSW, the counterpart in the project. She will be responsible for those activities, which resort under the prerogative of the MHSW, like producing the ordinance for the ICM, etc.
Dr. A. Tambic-Andrasevic, head of the Reference Centre for Antimicrobial Resistance, will represent the beneficiary of the project. She will coordinate closely with the stakeholders in the project, especially the collaborating laboratories and professional societies under the Croatian Academy of Medical Sciences.

Assistant project coordinator

The tasks of the Assistant Project Manager are defined as follows:

- Ensure proper co-ordination between the various (sub-)components and activities of above mentioned project (e.g. training, development of guidelines, implementation of guidelines, coordination of stakeholders);
- Ensure proper co-ordination between the international consultants, the counterpart and beneficiaries;
- Perform tasks in translation and interpreting between consultants and beneficiaries and other contacts in Croatia;
- Perform tasks in organisation of logistics and support in the project (agenda, minutes, location, participants);
- Monitor project progress and provide the Principal with information on issues arising;
- Manage financial inputs into the project, provide reports on expenditure to the Principal;
- Contribute to project reporting; and
- Perform any other duty necessary for the implementation of the project.

Project Advisory Committee

The project advisory committee could consist of the following persons:

- Mr. C. Baaré, EVD, chair person
- Dr. V. Stamenic, MHSW, counterpart
- Dr. A. Tambic, Reference Centre, beneficiary
- Ms. S. Covik, Ministry of Foreign Affairs, Croatia
- Ms. E. Verschuur, Royal Netherlands Embassy, Croatia

And in addition:

- Dr. Separovic, Ministry of Agriculture, Forestry and Water Management

As observers could be invited:

- Members of the Intersectoral Coordination Mechanism

The tasks of the Project Advisory Committee are as defined in the EVD project implementation guidelines, i.e. monitoring progress and approving adjustments in project implementation.

3.3 Assumptions, pre-conditions and risk analysis

The Consortium would like to emphasise the assumption made in the Terms of Reference with regard to the government's commitment to improvement of antimicrobial resistance monitoring and measures to reduce the incidence of antimicrobial resistance.
The EU has formulated recommendations and has produced a working document which provides necessary steps to be taken in improving control of antimicrobial resistance. It is assumed that the Government of Croatia in the coming project period will follow these EU recommendations.

The Consortium assumes that stakeholders are willing to discuss the control of antimicrobial resistance in a broader context of infectious disease control. Many of the control measures for resistance to antimicrobials are similar to control measures to reduce nosocomial infections and epidemics. The consortium assumes that the sanitary inspection and health inspection are willing to play their role in enforcement of legislation in this area.

The Croatian Academy of Medical Sciences and branch organisations have shown their responsibility by initiating a voluntary surveillance system. The initiatives are still dependent on few motivated individuals, but the awareness is spreading under professionals. It is assumed that this project will facilitate a platform for exchange and collaboration.

There are numerous international initiatives in the field of infectious diseases, by professional organisations, by EU, by World Health Organisation, etc. which are very eager to bring Croatia on board. From these sides, there is some funding available for projects and capacity building. Networking with these international initiatives is important. Consortium members are part of those initiatives and can lobby for inclusion of Croatia in those projects. The consortium assumes that international networks welcome this project as an addition to their work.

The major risk is related to financing of the surveillance and capacity building. In the project budget, the MHSW has allocated a small amount to the ICM, which could be a start. The national health insurance could be convinced if economic justification can be shown. Without additional funding from government or insurance, maybe some international subsidies can help to sustain small scale surveillance. For this reason it is important to develop scenarios, whereby fall back mechanisms are put in place, in case insufficient funding can be raised.

An assumption of another order is the collaboration between nominated partners and the Consortium. The consultants assume that the experts from nominated partners will fully collaborate within the project as defined in the inception phase and stick to agreed tasks and time schedules.

3.4 Sustainability

Sustainability in this project is not a major area of concern. There is a vital network of laboratories which implement surveillance. Professional organisations have indicated they are ready to contribute to the project. The project will enhance the quality of the ongoing activities and will produce a coordination mechanism.
Sustainability can be achieved because some tangible products will be created:

- ICM structure, with government decree or regulation for legal backing;
- Surveillance structure with electronic networking;
- Methodology for surveillance of antimicrobial resistance and use of antibiotics;
- Laboratory procedures for quality assurance;
- Series of guidelines and intervention measures to reduce resistance;
- Concrete measures to contain the spread of the MRSA bacteria.

4 Plans for the next reporting period

4.1 Detailed work plan

4.1.1 Result 1 ICM

In April the questionnaire of the EU which was used for assessing the state of affairs in Europe with regard to antimicrobial policies will be filled in. (See annex 3 for a copy of this questionnaire.) This will provide a "zero" assessment of the situation in Croatia and will also give priorities to be achieved in the project.
In May the study visit to the Netherlands is planned. In the study visit proposed members of the Intersectoral Coordination Mechanism will participate. (See 2.3.1) The proposed programme for the study visit is attached as annex 5. Through the study visit the Croatian experts will learn how the intersectoral collaboration in Croatia can take shape, based on the ABRES model, as well as SWAB and VENTURES collaboration.
In May a first outline of a policy for antimicrobial resistance will be drafted. (Suggestions for the outline of the policy are given in paragraph 2.3.2.)
In June there will be round table meetings with stakeholders, especially the proposed members of ISKRA, discussing what will be the ideal set-up of the ICM, learning lessons from other countries. The same meetings will be used to come to a first draft of a policy for Croatia.

4.1.2 Result 2 Surveillance

The emphasis in the expected result of surveillance will be on automation, data communication and analysis. The first step in the process, in April, will be to develop a questionnaire, in which all laboratories in the surveillance network indicate the state of affairs in their lab. As concluded in the inception phase, the levels of automation differ widely among labs in Croatia. The aim is to bring the most backward laboratories on an acceptable level, so that better surveillance can be achieved. The inventory should help to define priorities in this process.
The study visit to the Netherlands in May will offer participants an opportunity to see how in the Netherlands automation, data communication and data analysis is done.
In June, on the basis of the inventory and on basis of the findings of the study visit a plan will be made on how to improve automation in the labs, especially in the Reference Centre. In data communication and data analysis, the application of WHONET might be proposed (see 2.3.3). For implementation of the automation part of the project budget is reserved.

4.1.3 Result 3 Guidelines

For this result the first activity will be the study visit to the Netherlands. During the study visit the Netherlands approach of guideline development will be highlighted. Important issues are the AGREE approach, interdisciplinary collaboration, involvement of the stakeholders, etc. The information from the Netherlands will be used to develop a methodology of guideline development in Croatia.
In June an inventory will be made of existing Croatian guidelines, produces by different clinical societies, hospitals and other organisations. These guidelines will later be analysed using the AGREE instruments. They will constitute a reference base for developing new guidelines in the area of antimicrobial policy in Croatia.

4.2 Human resources allocation

4.2.1 Result 1 ICM

	Home	Croatia
Dr. Jaap Koot	4	5
Prof. Martin Rusnak	2	5
Prof. V. Krcmery	1	4
Prof. J. van der Meer	1	4
SWAB	4	4

4.2.2 Result 2 Surveillance

	Home	Croatia
Dr. Jaap Koot	See under 1	See under 1
Prof. Martin Rusnak	See under 1	See under 1
RIVM	1	4
SWAB	1	4

4.2.3 Result 3 Guidelines

	Home	Croatia
Dr. Jaap Koot	See under 1	See under 1
Prof. Martin Rusnak	See under 1	See under 1

Annex 1 Logical Framework

LOGFRAME PLANNING MATRIX FOR PROJECT: Antimicrobial Resistance Surveillance in Human Medicine MAT05/HR/9/2			
Project duration: 1 January 2006 – 31 December 2007	Date of drafting: March 2006		Total budget: EUR 307.955,=
Overall Objective	**Objectively Verifiable Indicators**	**Means of Verification**	
The project aims to contribute to the accession of Croatia to the European Union. In particular, the project aims to assist Croatia in implementing EU-directives and recommendations in the field of antimicrobial resistance and the sound use of antibiotics.	Implementation of the Council recommendation (2002/77/EC) on the prudent use of antimicrobial agents	Questionnaire from EU document, COM (2005)684 final, SEC (2005)1746, Brussels, 22.12.2005	
Project Purpose	**Objectively Verifiable Indicators**	**Means of Verification**	**Assumptions and risks**
Strengthening the Croatian institutional structure engaged in surveillance of antimicrobial resistance and responsible for measures to reduce antimicrobial resistance	Indicators using in international projects, like EARSS and ESAC, data over 2007 compared to data over 2005	Official annual reports EARSS and ESAC, benchmarking against other European countries	Commitment of government, insurance and professional organisations toward structure, availability of funding

Results	**Objectively Verifiable Indicators**	**Means of Verification**	**Assumptions and risks**
1. an Intersectoral Co-ordination Mechanism (ICM) in the field of antimicrobial resistance established and functional;	Government MHSW ordinance for ICM, with composition, terms of reference and funding mechanism Policy document approved by Cabinet	Legal document (ordinance) issued by MHSW Budget for 2008, compared to 2005 increased Policy document published	MHSW is cooperative in establishing an ICM and other stakeholders are ready to participate in this structure
2. a surveillance system for antimicrobial resistance and use of antibiotics established, based on national policy that is in line with the EU strategy for antimicrobial resistance	National Surveillance System document approved Automated data communication in place, data collection of full year's samples, and data analysis	Documentation of National Surveillance System publication of annual reports	Financing for surveillance system made available during project period. Hospitals and general practices are willing to collaborate
3. guidelines for sound use of antibiotics in the human sector formulated and implemented.	Series of guidelines developed, piloted and final versions published	Documentation on guidelines on official website Inspection reports by sanitary inspection	Willingness of stakeholders to collaborate in developing guidelines, piloting and publication. Capacity of hospitals to implement MRSA containment measures

Activities Result 1 **Intersectoral Co-ordination Mechanism (ICM) in the field of antimicrobial resistance established and functional**		**Input (human resources + total man days)**		**Assumptions and risks**
1.1	"zero" assess of implementation of EU recommendations on Antimicrobial Resistance Control	Dr. Jaap Koot 16 days Dr. Martin Rusnak 9 days Prof. Krcmery 4 days Prof. van der Meer 9 days		Willingness of stakeholders to collaborate in round table discussions and conferences. Possibility to come to agreement on mandate, composition of ICM. Agreement among stakeholders on policy issues and readiness among health service providers to implement policy Readiness of MHSW and insurance company to contribute to financing surveillance activities
1.2	Study visit to the Netherlands			
1.3	Proposal for structure and mandate of the ICM			
1.4	Conference on control of antimicrobial resistance, presentation of design structure and discussion			
1.5	Presentation of the proposal to the MHSW, legal instruments for backing up the ICM			
1.6	Outline document on policy development: topics and set-up of the document			
1.7	Round table discussions with prospective members of the ICM on policy development			
1.8	Draft policy and circulation among relevant stakeholders			
1.9	Presentation policy during conference			
1.10	Final version of policy and presentation to MHSW			
1.11	Develop budgets for surveillance activities			
1.12	Formulate financing proposals to relevant institutions			
1.13	Develop growth scenarios based on available funding			

Activities Result 2 **Surveillance system for antimicrobial resistance and use of antibiotics established, based on national policy that is in line with the EU strategy for antimicrobial resistance**		**Input (human resources + total man days)**		**Assumptions and risks**
2.1	Inventory of automation in laboratories, information and communication	Dr. Jaap Koot 13 days Dr. Martin Rusnak 10 days		Financing will be available for improvement of automation in reference centre and other laboratories. Laboratories will be capable of improved data collection and data communication to the reference centre. In the reference centre capacity will be available for data analysis
2.2	Study visit to the Netherlands			
2.3	Plan for Improving ICT in Reference centre and labs			
2.4	Improving ICT in Reference centre and improving communication			
2.5	Presentation of ICT strategy during national conference			
2.6	Implementing new communication system between labs			
2.7	Testing of new communication system labs			
2.8	Evaluation of new communication system			
2.9	Final report National Surveillance System			

Activities Result 3 guidelines for sound use of antibiotics in the human sector formulated and implemented		**4.2.3.1.1 Input (human resources + total man days)**		**Assumptions and risks**
3.1	Study visit to the Netherlands, discuss guideline development with NHG, SWAB	Dr. Jaap Koot 14 days Dr. Maja Vucetic 8 days Dr. Martin Rusnak 7 days Dr. Heather Houlihan 14 days Dr. Inge Gyssens 12 days Prof. Krcmery 6 days		Willingness of professional organisations to collaborate in guideline development. Possibilities to implement guidelines in hospitals and clinics. Financial means for capacity building and dissemination of guidelines
3.2	Inventory of existing clinical practice guidelines and protocols available in Croatia			
3.3	Testing guidelines with AGREE instrument, workshop during conference, selection of priority guidelines			
3.4	Workshop on guideline development with working groups, that will formulate guidelines			
3.5	Development of pilot guidelines			
3.6	Feed back on pilot guidelines from various stakeholders			
3.7	Formulating of final versions of guidelines			
3.8	Publication of guidelines and implementation tools			
3.9	MRSA reduction strategy in collaboration with national nosocomial infection committee			
3.10	Introduction of MRSA reduction measures and quality control in selected hospital			
3.11	Evaluation of MRSA reduction strategy			

Annex 2 Gantt Chart

	Antimicrobial Resistance Surveillance in Human Medicine	**Matra Project MAT05/HR/9/2**

	Gantt Chart and consultants contribution	**2006**												**2007**											
		J	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**	**J**	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**
	Inception phase																								
1	**Intersectoral Co-ordination Mechanism (ICM) in the field of antimicrobial resistance established and functional**																								
1.1	"zero" assess of implementation of EU recommendations on Antimicrobial Resistance Control																								
1.2	Study visit to the Netherlands																								
1.3	Proposal for structure and mandate of the ICM																								
1.4	Conference on control of antimicrobial resistance, presentation of design structure and discussion																								
1.5	Presentation of the proposal to the MHSW, legal instruments for backing up the ICM																								
1.6	Outline document on policy development: topics and set-up of the document																								
1.7	Round table discussions with prospective members of the ICM on policy development																								
1.8	Draft policy and circulation among relevant stakeholders																								
1.9	Presentation policy during conference																								
1.10	Final version of policy and presentation to MHSW																								
1.11	Develop budgets for surveillance activities																								
1.12	Formulate financing proposals to relevant institutions																								
1.13	Develop growth scenarios based on available funding																								
	Dr. Jaap Koot																								
	Dr. Martin Rusnak (partly combined with result 3)																								
	Prof. Krcmery (partly combined with result 3)																								
	Prof. Van der Meer (partly combined with result 3)																								
	SWAB																								

	Antimicrobial Resistance Surveillance in Human Medicine	**Matra Project MAT05/HR/9/2**
	Gantt Chart and consultants contributions	**2006** J F M A M J J A S O N D **2007** J F M A M J J A S O N D
	Inception phase	
2.	**Surveillance system for antimicrobial resistance and use of antibiotics established, based on national policy that is in line with the EU strategy for antimicrobial resistance**	
2.1	Inventory of automation in laboratories, information and communication	
2.2	Study visit to the Netherlands	
2.3	Plan for Improving ICT in Reference centre and labs	
2.4	Improving ICT in Reference centre	
2.6	Presentation of ICT strategy during national conference	
2.7	Implementing new communication system between labs	
2.8	Testing of new communication system labs	
2.9	Evaluation of new communication system	
2.10	Final report National Surveillance System	
	Consultants input to result 2	
	Dr. Jaap Koot (combines with other results)	
	Dr. Martin Rusnak (combines with other results)	
	RIVM	
	SWAB	

	Antimicrobial Resistance Surveillance in Human Medicine																									
	Gantt Chart and consultants contribution		**2006**												**2007**											
			J	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**	**J**	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**	**O**	**N**	**D**
	Inception phase																									
3	**guidelines for sound use of antibiotics in the human sector formulated and implemented**																									
3.1	Study visit to the Netherlands, discuss guideline development with NHG, SWAB																									
3.2	Inventory of existing clinical practice guidelines and protocols available in Croatia																									
3.3	Testing guidelines with AGREE instrument, workshop during conference, selection of priority guidelines																									
3.4	Workshop on guideline development with working groups, that will formulate guidelines																									
3.5	Development of pilot guidelines																									
3.6	Feed back on pilot guidelines from various stakeholders																									
3.7	Formulating of final versions of guidelines																									
3.8	Publication of guidelines and implementation tools																									
3.9	MRSA reduction strategy in collaboration with national nosocomial infection committee																									
3.10	Introduction of MRSA reduction measures and quality control in selected hospital																									
3.11	Evaluation of MRSA reduction strategy																									
	Dr. Jaap Koot																									
	Dr. Maja Vucetic																									
	Dr. Martin Rusnak (partly combined with result 1)																									
	Dr. Health Houlihan																									
	SWAB																									
	Dr. Gyssens																									

	Programme activity of several weeks/months
	Single event during project
	Mission by consultant (mostly 5 days)

Annex 3 Questionnaire EC on ARC

Commission of the European Communities
Implementation of the Council recommendation (2002/77/EC) on the prudent use of antimicrobial agents in human medicine,
COM (2005)684 final, SEC (2005)1746, Brussels, 22.12.2005

TABLE 1 NATIONAL STRATEGIES & INTERSECTORAL MECHANISMS

A. Does your country have a national strategy targeted to contain the problem on antimicrobial resistance? If yes, does this strategy comprise measures in relation to: - Surveillance of antimicrobial resistance, - Surveillance of antimicrobial use, - Prudent use of antimicrobial agents, - Other control and preventive measures, - Education and training, - Research.	
B. Did your country formulate a national action plan?	
C. Are the differences among regions (Länder/cantons) in your country in the strategy taken to contain the problem on antimicrobial resistance?	
1. ICM: Intersectoral co-ordinating mechanism: **1:1** Is such a mechanism in place in your country	
1.1.d Please provide a short description of the organisation of the ICM: (1) AMR surveillance, (2) Antibiotic consumption surveillance, (3) Guidelines on prudent antibiotic use, (4) Education of health professionals, (5) Public education.	
1.1.e How is the ICM composed?: (1) Department of Health/Government, (2) Medical Societies/Associations, (3) Veterinary field/Agriculture, (4) Pharmaceutical Industry, (5) Patient Groups/General Public, (6) Medicines regulators, (7) Surveillance institute(s).	
1.1.g What is its legal status?: (1) IM structure/function governed by ministerial order of specific legislation, (2) IM part of government/department of health but no specific legislation governing IM, (3) IM is advisory body with no legal standing.	

TABLE 2: RESPONSES ON SURVEILLANCE SYSTEMS FOR ANTIMICROBIAL RESISTANCE

2.1 Is the ICM co-ordinating activities on antimicrobial resistance surveillance?	
2.1.a If yes, is the ICM actively: -Collecting data, -Analysing data, -Proposing actions on basis of findings, -Disseminating data.	
2.2 Is ownership of antimicrobial resistance data clearly defined?	
2.3 Are there obstacles (e.g. legal, financial) in obtaining antimicrobial resistance data?	
2.4 Are antimicrobial resistance data collected in national reports?	
2.5 Is the structure of antimicrobial resistance surveillance systems: -Governmental and continuously implemented, -As research projects funded by governmental grants, -Performed by scientific medical societies, -Performed by industry.	
2.6 Is there formal collaboration with veterinary surveillance for antimicrobial resistance?	
2.7 Do you have a laboratory bases surveillance system?	
2.8 What organisms are covered by this system and what is the population coverage *(percentage*) of the data available for analysis?	
2.8.a. Does surveillance include hospital isolates?	
2.8.b Does surveillance include community isolates?	
2.8.c Does surveillance differentiate between hospital vs. community acquired isolates?	
2.9 Are external quality assurance systems routinely in place in all participating laboratories to verify validity of microbiological and susceptibility test results?	
2.10 Are surveillance data reported to EARSS?	

TABLE 3: RESPONSES ON SURVEILLANCE SYSTEMS FOR ANTIMICROBIAL USE

3.1 Is the ICM co-ordinating activities on antimicrobial consumption surveillance?	
3.1.a If yes , is the ICM actively: (1) Collecting data, (2) Analysing data, (3) Proposing actions on basis of findings, (4) Disseminating data.	

3.2 Is ownership of antimicrobial consumption data clearly defined?	
3.3 Are there obstacles (e.g. legal, financial) in obtaining antimicrobial consumption data?	
3.4 Are antimicrobial consumption data collected in national reports?	
3.5 Is the structure of surveillance systems for antimicrobial consumptiondata: -Governmental and continuously implemented, -As research project funded by governmental grants, -Performed by scientific medical societies, -Performed by industry.	
3.6.a Are these bodies reporting to the ESAC project (European Surveillance of Antimicrobial Consumption)?	
3.7 Are data available : (1) For total antibiotic consumption, (2) Separately for ambulatory care, (3) Separately for hospitals.	
3.7.a Are data available based on: (1) Reimbursement system or (2) Distribution system.	
3.7.b Can available data be broken down by age and sex?	
3.7.c Can available data be broken down by indications?	
3.7.d Can available data for hospitals be broken down by: (1) Ward or (2) Speciality.	
3.8 Can you link your surveillance data on antimicrobial consumption with indications for antimicrobial prescriptions?	
3.9 Can you link your surveillance data of antimicrobial consumption and resistance?	
3.10 Have you developed indicators to monitor prescribing practices of antimicrobial agents: (a) In ambulatory care? (b) In hospitals?	
3.11 Are you co-ordinating actions for improvement in prescribing practices? (a) In ambulatory care? (b) In hospital? (c) Towards the general public?	
3.12 Do you provide feedback to prescribers and aim for improvement in prescribing practices?	
3.13 Is there formal collaboration with veterinary surveillance for antimicrobial consumption?	

TABLE 4: RESPONSES ON CONTROL & PREVENTIVE MEASURES

4.1 Are antimicrobials sold without prescription believed to be a relevant source of inappropriate antimicrobial use in your country?	

4.1.a have studies been undertaken on the proportion of antimicrobials sold without prescriptions?	
4.1.b Are there reports/estimates on the proportion of systematic antimicrobials sold without prescription?	
4.1.c Are there reports/estimates on the proportion of non-systematic (e.g. topical) antimicrobials sold without prescription?	
4.2 Are there measures in place to enforce regulations for prescription-only use of systematic antimicrobials?	
4.3 Do you have guidelines for the use of other antimicrobial agents not subject to requirements for prescription-only use?	
4.4 Are there regulations about sponsoring of, and/or gifts or inducements to, prescribers by the pharmaceutical industry?	
4.4.a Is it allowed to give free antimicrobial samples to the prescriber?	
4.4.b Are gifts/inducements for the prescribers allowed in phase 4 trials?	
4.5 Is there a system in place to monitor whether sponsoring regulations are respected?	
4.5.a Is there a disciplinary system in place to enforce these regulations?	
4.7 Is there a control system on good practice of marketing of antimicrobial agents in place?	
4.8 Are there nationally accepted guidelines on appropriate use of antimicrobials in: (SP) Surgical prophylaxis, (OM) Otitis media, (S) Sinusitis, (TP) Tonsillopharyngitis, (CAP) Community acquired pneumonia, (AECB) Acute exacerbation of chronic bronchitis, (AB) Acute bronchitis, (C) Common cold, (UTI) Urinary tract infection, (M) Meningitis, (O) Others	
4.9 Did you evaluate/audit the impact of any of the guidelines on antimicrobial prescribing practices?	
4.10 Do you have a national programme for hospital hygiene and infection control in place?	
4.11 Is it mandatory for each hospital to have an infection control committee?	
4.12 Are there legal requirements /recommendations for the number of infection control nurses per hospital bed?	
4.13 Does your country have an accreditation procedure for hospitals*/nursing homes?	
4.13.a Is infection control part of the accreditation procedure for hospitals ?	
4.13.b Is infection control part of the accreditation procedure for nursing homes?	
4.14 Do you have national guidelines for control of multi-resistant pathogens?	
4.15 Have you initiated activities (at national level) aimed at evaluating and, as necessary, updating the product information (SPC) for antibacterial medicinal products particularly related to indications, dose and dose	

regimen and prevalence of resistance?	
4.15 v. Are you planning any co-operation with other countries?	
4.15 vi. Would you agree to develop a common approach to national updates?	

TABEL 5.1: RESPONSES ON EDUCATION & TRAINING (1)

5.1 Do all relevant health-professional-undergraduates receive education on appropriate use of antimicrobials?	
5.2 Is continuing education available /mandatory for prescribers on: -The problem of antimicrobial resistance, -Appropriate use of antimicrobials, -vaccination programmes and their role in preventing infection, -Hygiene and infection control	
5.2.a through -Non-sponsored continuing education, - Sponsored by the pharmaceutical industry	
5.3 Have there been any reports/studies in your country on the knowledge and perception of the general public and health professionals on topics related to antimicrobial resistance?	
5.4 Has there in the last 5 years been a campaign (regional/national) in your country (and to whom was it directed) to raise awareness on topics related to antimicrobial resistance?	

Annex 4 Tentative Programme Study Visit

MAT05/HR/9/2
Antimicrobial Resistance Control in Human Medicine

Study Visit The Netherlands
Tentative Programme

Date time	Activity	Remarks
Monday 8 May morning	Arrival	Amsterdam Hotel
Monday 8 May afternoon	SWAB AMC Amsterdam	The work of SWAB, general introduction, different components
Monday 8 May afternoon	Microbiology lab AMC Amsterdam	Short visit and introduction Electronic communication with referral and surveillance centre
Tuesday 9 May morning	Ministry of Health, Welfare and Sport	Ministry's policy on antimicrobial resistance ABRES Financing mechanisms
Tuesday 9 May afternoon	Ministry of Health Health Inspectorate	Role of Health Inspectorate in control of antimicrobial resistance
Tuesday 9 May afternoon	Ministry of Agriculture	Policy Antimicrobial use in animal health
Tuesday 9 May afternoon (late)	City Centre	sightseeing
Wednesday 10 May morning	RIVM	Surveillance activities • ISIS • EARSS • Electronic communication between laboratories • Nethmap
Wednesday 10 May afternoon	RIVM	CIB and LCI • Protocols for infectious diseases
Wednesday 10 May evening	Dinner	
Thursday 11 May morning	SWAB	Detailed information on elements of work • Guidelines and protocols • Education and training
Thursday 11 May afternoon	WIP Hospital	MRSA policy the Netherlands (and possible interventions in Croatia)
Friday 12 May morning	CIDC Lelystad	VANTURES
Friday 13 May afternoon	GP clinic NHG	Visit to clinic patient information Discussion NHG standards
Saturday 14 May afternoon	Departure	