

Standard Summary Project Fiche – IPA centralised program

1. Basic information

- 1.1 CRIS Number:
- 1.2 Title: **Support to the Health Sector**
- 1.3 ELARG Statistical Code – **03.28**
- 1.4 Location: **Kosovo**

Implementing arrangements:

- 1.5 Contracting Authority: **The European Commission Liaison Office to Kosovo.**
- 1.6 Implementing Agencies: **The European Commission (EC) Liaison Office to Kosovo**
- 1.7 Beneficiaries: **Ministry of Health; Health Institutions; Kosovo Medicines Agency**

Project activity	Beneficiary	Contact point responsible for activity coordination
1. Component 1: Sector Wide Approach in Health: feasibility study & mapping	Ministry of Health (MOH)	Focal point is Permanent Secretary of MoH
2. Component Capacity Building of the Kosovo Medicines Agency	Kosovo Medicines Agency	Arian Ahmet Head MA Dep. Email: arian@k-ma.org

Financing:

- 1.8 Overall cost (VAT excluded)¹: 1.5 million Euro
- 1.9 EU contribution: 1.5 million Euro
- 1.10 Final date for contracting:
Three years after the signature of the financing agreement between the European Commission and the Kosovo Authorities.
- 1.11 Final date for execution of contracts:
Two years after the final date for contracting.
- 1.12 Final date for disbursements:
One year after the final date for the execution of contracts.

2. Overall Objective and Project Purpose

2.1 Overall Objective:

To improve the Health service delivery in Kosovo, through the strengthening of the Kosovo Health Sector, its respective institutions and the strengthening of coordination of the principle health institutions and stakeholders together with the international Donors.

¹ The total cost of the project should be net of VAT and/or other taxes. Should this not be the case, the amount of VAT and the reasons why it should be considered eligible should be clearly indicated (see Section 7.6)

2.2 Project purpose:

This project will work to strengthen the institutional capacity and technical skills of the health sector institutions through the promotion of and improving inter-departmental, inter-Ministerial and donor coordination. It will build the institutional and human resource capacity of the KMA in order that it can meet all the European Medicines Agency standards and will provide up-to-date information on the current status of health care delivery in Kosovo. This project will examine the possibilities for the advancement of a SWAP in the health sector by means of a feasibility study.

2.3 Link with AP/NPAA / European Partnership / SAA:

Component 1: Sector Wide Approach in Health: feasibility study & mapping

The Project responds to priorities presented in the European Partnership Action Plan in its interest to improve the efficiency and sustainability of public services, the advancement of self-government, to increase administrative capacity and to facilitate the decentralisation process. This will be done through the review of the existing framework in order to recommend improvements to the quality of Health service delivery and in the drafting and updating of the Health Strategies and the development of health systems, in particular for a Health Information System.

Component 2: Capacity Building of the Kosovo Medicines Agency

This project is consistent with the priorities identified in the European Partnership for Kosovo in its calls for support for the meeting of European Standards and the effective implementation of European legislative frameworks as well as the reinforcement of structures dealing with European approximation.

2.4 Link with Multi-Annual Indicative Planning Document (2007-2009)

The projects are consistent with the objectives of the MIPD to promote good governance and the improvement of performance of the Kosova public institutions, alignment of Kosova legislation with EU acquis and the plan to undertake a functional review of the health system in Kosovo to enhance service delivery and financing.

Component 1: Sector Wide Approach in Health: feasibility study & mapping

The studies and the activities proposed in this Project link to some of the proposals included in the Multi Annual Indicative Planning Document with regards to the development of the Kosovo Health System to:

- Give a special focus to the Health Sector, as a cornerstone of future economic growth.
- Complete a functional review of Health System to enhance service delivery.
- Promote a more effective coordination of donors' activities.
- Consolidate the development of the Health System in line with European standards.
- Support Health Institutions strategy making and coordination capacities.
- Focus on the normative framework to promote an operational health system.
- Develop the Health Information System to reduce the inefficiencies of the Sector.

Component 2: Capacity Building of the Kosovo Medicines Agency

This project is consistent with MIPD calls to improve the good governance of public utilities and develop infrastructures in order to promote and enhance the quality of public goods and services including in the areas of health.

It is consistent with the call to build the strategy-making capacity of public health institutions and to conduct an impact assessment of financing systems for public health;

2.5 Link with National Development Plan (where applicable)

Component 1: Sector Wide Approach in Health: feasibility study & mapping

This initiative is in accordance with some Health Sector Goals to improve strategic and operational management of the Sector, and responds to a number of priorities foreseen in the Medium Term Expenditure Framework 2008-2010:

- Better allocation of resources through an improved donor coordination
- Promotion of better service quality and efficient delivery
- A certain development and training of human resources
- Integration of information systems of data within the Health Information System

Component 2: Capacity Building of the Kosovo Medicines Agency

The Medium Term Expenditure Framework 2008-2010 has emphasised the need to enhance both administrative and operational management in the health sector and in health service delivery. Human Resource Development is presented as one of the priority measures of the MTEF and the KMA capacity building initiative is, therefore, consistent with this HRD support prioritised by the Kosovan Government.

The project is consistent with the Strategy for Kosovo Health (2005-2015) which calls for

- Improved management of drugs and medical supplies (objective 23)
- Strengthening of the legal and regulatory framework (objective 22)
- Improved financial management and procurement of the health sector (objective 21)
- Development of Human Resources in the Health Sector (objective 8)

2.6 Link with national/ sector investment plans

The Strategy for Kosovo Health 2005-2015, drafted by the MOH, aims at making sure that health services are directed to benefit the Kosovan population and at focusing on inequalities in the health sector. This Project responds to these goals with activities that aim at:

- Training and development of Health Sector human resources.
- Promoting institutional reforms and improvement of management practices in Health system in the areas of legal and regulatory framework, planning capacity, and health services delivery quality.
- Integrate a functioning Health Information Systems into the Health Sector.

3 Description of project

Component 1: Sector Wide Approach in Health: feasibility study & mapping

3.1 Background:

The United Nations set up an Interim Administration Mission in Kosovo (UNMIK) in June 1999 under the authority of Security Council Resolution 1244. In 2002 UNMIK transformed the Joint Interim Administrative Structure (JIAS) into the Provisional Institutions of Self Government (PISG) and the Department of Health Social Welfare and Spatial Planning into the Ministry of Health (MOH).

The MOH is responsible for the implementation and supervision of the Kosovo Health Strategy with the collaboration of the Municipal Health Directorates (MHD). The MOH and the MHD cooperate for the preparation of tasks and activities, the implementation of plans, and the delegation of responsibilities. The Institute of Public Health (IPH) has the task to guarantee integration and coordination in the flow of health information and analyze the health of the population and the performance of the Health sector.

The Kosovo Health Law was approved by the Assembly of Kosovo of PISG on February 2004. In this law the Municipalities are responsible for the provision of primary health care (PHC) services and the MOH for the secondary and tertiary Health Care Institutions. The health system comprises 63 institutions, of which 26 are of the first level and the rest are of the second and third level directly under MOH. The Municipal Assembly approves the operational plan for the development of PHC in accordance with the mid-term plan approved by the Government of Kosovo.

The difficult health situation in Kosovo was worsened further by the conflict in 1999. In the recent years considerable efforts have been made to improve the health system, nevertheless the life expectancy in Kosovo is put at 69 years² and the mortality rates of mothers and newborns remain among the highest in Europe. The health status of persons in Kosovo is the poorest in the West Balkans Region. Health service delivery, according to the Kosovo Development Strategy, is ineffective and inefficient and has led to a growing system of informal payments and growth in private sector health care delivery which people in Kosovo are ill able to afford.

Human Resource Management and HR development in the health service is inadequate and has led often to a mismatch between staff hired and skills required. There is a need for capacity development of health service staff and staff in the Health Ministry which also needs to be addressed.

The Strategy for Kosovo Health for the period 2005 -2015 published by the MOH in June 2004 defines the platform of the health activities of the Ministry of Health and the Government. Among its priorities the Health Strategy sees the need for the development of human resources in the health sector and institutional reforms and improvement of management practices. Goals which this project seeks to achieve.

Justification

Donors' support to the Health Ministry and to the health sector has been piecemeal and uncoordinated which adds to the administrative burden and complexity of demands on the Ministry. There is a lack of information on the status and effectiveness of donor support to the Health Sector and a lack of systematic communication and coordination among donors and the beneficiary, the Ministry of Health and other relevant Ministries, to ensure that the most appropriate support is given to bring about improvements in health service delivery.

The adoption of a Sector Wide Approach (SWAP) could overcome these problems. It consists mainly in the establishment of an alternative aid mechanism by which both Donors and recipient Countries coordinate their activities in specific sectors, as opposed to the traditional mechanism whereby donors give support to projects in an uncoordinated way with no overarching framework.

² Source: Progress Report 2007 & MTEF 2008-2010

This initiative will have the added value of strengthening the policy-making within and across all levels of government and ensure inter-ministerial policy making and coordination.

The project will examine and extend across the broad range of managerial functions, including policy definitions, planning, financial management, procurement and human resources development and will, thereby, examine the possibilities, pros and cons, for the roll-out of a Health SWAP in Kosovo.

A mapping and feasibility study for SWAP in Health is needed as a preliminary step. Implementation of SWAP in Kosovo can be done only with a proper mapping of the health system at the central, regional and municipal level to include identification of current financial support of the donors, the current interaction between the MOH and the other Ministries involved in health issues, means to establish a proper health information system and the revision of the health sector development strategy to give it a more realistic perspective.

Component 2: Capacity Building of the Kosovo Medicines Agency

The Kosovo Medicines Agency (KMA), originally known as the Kosovo Drug Regulatory Authority, was established in 2000 and came into full legal existence as an independent executive agency in 2001 in accordance with United Nations Mission in Kosovo (UNMIK) Regulation No. 2001/19³. The work of the KMA is governed by the 'EU Regulation on Medicinal Products and Medicinal Devices'. This law was adopted by the Kosovo Assembly and promulgated by the SRSB in July 2004.

The KMA is responsible for ensuring the quality, safety and efficacy of human medicinal products and medical devices placed in Kosovo. It achieves this task via implementation of regulations and administrative instructions concerning marketing authorization, licensing and inspection, narcotics and psychotropic quality control, pharmaco-vigilance and clinical trials. The KMA is, therefore, responsible for issuing market authorisations and important licenses for drugs and medical devices as well as licensing and monitoring of pharmaceutical manufacturers, wholesalers and pharmacists.

Work is needed to develop the capacity of the KMA as an institution, to develop its human resource capacity and to go forward with the drafting and adoption of Secondary Legislation necessary to implement the European Regulations on Medicinal Products and Medicinal Devices. Until this work is done the Kosovo Medicines Agency will not be in a position to meet the criteria and standards necessary to become officially recognised by the international bodies and the KMA is not yet eligible to become member of the European Medicines Authority (EMA)⁴.

The general public in Kosovo are at risk in this situation, in particular because local manufacturers are producing products which are not manufactured according to modern international quality criteria. Their products are not subject to the Good Manufacturing Practice (GMP) procedures defined by WHO and by the EU as the KMA does not yet have the capacity to under-take this GMA Certification process. Furthermore a number of non-registered products directly imported from neighbouring countries are also being circulated inside Kosovo. There is no information service about medicines available and the follow-up on adverse reactions is very fragmented.

³ 'On the Executive Branch of the Provisional Institutions of Self Government in Kosovo' and Administrative Instruction (Health) 7/2000 'On the Establishment of Kosovo Drug Regulatory Agency'. On 04/12/2003, Medicines Law No. 2003/26 'On Medicinal Products and Medical Devices', in harmonization with EU Directives, was adopted by Kosovo Assembly and promulgated by the SRSB on the 07.07.2004.

⁴ <http://www.emea.europa.eu/>

As the Kosovo Medicines Agency is not yet an internationally recognised body (ie. member of EMEA and international authorities), the pharmaceutical industry (consisting of two manufacturers in Kosovo) is not able to license their products or certify the quality of their operations and, therefore, their products are unable to reach markets in Europe and America.

This project will bring about the development of institutional and human resource capacity the Kosovo Medicines Agency requires in order that it may become a fully fledged member of the EMEA and the international authorities⁵. This will put the KMA in a position to provide a full and complete service to the general public of Kosovo of ensuring safer, quality pharmaceuticals and at a cheaper affordable price.

In particular this project will provide the KMA with the skills and capacity it needs to carry out the Good Manufacturing Practice (GMP) certification process in accordance with internationally recognised inspections as well as adherence to the Good Distribution Process (GDP) and Good Laboratory Process (GLP) in Kosovo; processes which are required by international standards bodies and mandatory for the safety and security of Kosovo's general public. They are also required if the pharmaceutical industry in Kosovo is to survive.

3.3 Assessment of project impact, catalytic effect, sustainability and cross border impact

Component 1: Sector Wide Approach in Health: feasibility study & mapping

The project addresses both the needs for improving the capacities of the Kosovo MOH, the needs for an integrated, heightened cooperation between the MOH, the other relevant Health Sector stakeholders, and the Donors interested to support the Health Sector in Kosovo.

The Project, to assess and analyse the feasibility of pursuing a SWAP in the Health Sector in Kosovo, will build understanding of SWAP in the Health Sector, across line Ministries and Donors and facilitate its advancement and the take-up in Kosovo in so far as it is possible.

The Project will have a relevant impact on the activities of the Health Sector in Kosovo, and specifically on the activities of the MOH, insofar as the preparedness and eventually implementation of a SWAP in Health in Kosovo, or elements of a SWAP Health approach in Kosovo, will be successful.

Catalytic effects arise from the fact that the Ministry of Health will be able to use the information collected and the analysis carried out during the Project, in order to enhance its efficiency following the completion of the project.

Component 2: Capacity Building of the Kosovo Medicines Agency

The project will serve to improve the institutional structure and guidelines for governance of the KMA as well as considerably enhance the training and competencies of KMA staff in

⁵ International bodies: Official Medicines Control Laboratory (OMCL) Network; European Directorate for the Quality of Medicines – EDQM; Certificate ISO/IEC 17025:2005 (requirements of ISO/IEC 17025:2005 are examined by the experts from EDQM); The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme jointly referred to as PIC/S (are two international instruments between countries and pharmaceutical inspection authorities, which provide together an active and constructive co-operation in the field of GMP); KMA is a collaborative member of CADREAC (New Collaboration Agreement between Drug Regulatory Authorities in Central and Eastern European Countries, <http://www.newcadreac.org>) but not a full member

order that they may deliver more numerous and better quality services to the benefit of the Kosovan health sector and to the benefit of the public at large.

The project's catalytic effect will be brought by actions supporting a 'training of trainers' approach which will ensure trained staff members will be in a position to train others and thereby improve overall efficiency of the KMA over the longer term. By increasing the capacity and effective operations of the KMA in order that it is eligible to join the EMEA, this will, in turn lead to further opportunities for building of relations with international experts, benefiting from training and exchange opportunities, information and knowledge development of the Agency, the institution and the staff, and thereby lead to an ever-increasing capacity building/development cycle.

Project Sustainability will arise from actions to bring about the self-financing operation of the KMA (as is the case for most other Medicinal Agencies) by means of more efficient, effective and rapid service delivery linked to an appropriate fee structure. By building the capacity of the KMA staff there will be an increase in the number of services which the KMA can provide which in turn increases the profit margins of the KMA in order that it can eventually become self-financing and able to invest properly in building up the quality of KMA operations.

3.4 Results and measurable Indicators:

Component 1: Sector Wide Approach in Health: feasibility study & mapping

Expected Results:

- 1.1 Feasibility Study for analysing and evaluating the health sector for a SWAP approach completed including mapping and legal analysis of the Health system undertaken at the primary, secondary and tertiary level;
- 1.2 Weaknesses and strengths of the institutional capacities, the current legislation, and the health information system identified and assessed; Health Sector Development Strategy revised and updated.

Measurable Indicators:

- Feasibility Study for Health Sector SWAP in Kosovo produced, including recommendations concerning the extent to which SWAP is currently applicable.
- All Kosovo existing medical facilities of primary, secondary and tertiary level visited, medical equipment and services checked, patient numbers, defined and quantified. Report prepared with all the findings.
- Report prepared on MOH human resource and managerial capacity with Recommendations, presented to MOH and Donors
- Official Report prepared and submitted to MOH and Donors, with discrepancies between Kosovo and European Law and regulations regarding health related issues.
- Technical equipment & financial resources (including running costs) necessary to establish an efficient running Kosovo Health Information System assessed, costed and listed
- Health Sector Development Strategy revised and brought up to date, prepared with action plan and costings - approved by MOH

Component 2: Capacity Building of the Kosovo Medicines Agency

Expected Results:

- 2.1 The internal structure of KMA reviewed and strengthened;
- 2.2 Pharmaceutical Regulatory System in Kosovo strengthened: an assessment of the Pharmaceutical Regulatory system in Kosovo; legal framework reviewed and advanced

- with regard to its alignment with EU legislation and standards for the pharmaceuticals and medicinal products sector;
- 2.3 Inspection and supervision activities carried out according to EU standards
- 2.4 KMA eligible to join EMEA

Measurable indicators:

- Improved service quality and expanded KMA service delivery as measured by increased number of services delivered with improved response times; Improved operational effectiveness of the KMA including profit margins (baseline currently is 1.1meuro per annum), training and accreditations of staff (at a minimum there will be training of staff of the seven KMA Departments- the Head of the Departments plus at least 3 high officers from each department adoption of secondary legislation;
- Updated pharmaceutical policy including financing policy and development plan for I.T support system adopted by KMA;
- Membership to EMEA

3.5 Activities:

Component 1: Sector Wide Approach in Health: feasibility study & mapping

Contracting Arrangements: The project will be implemented through a service contract. A Project Coordinator will be appointed and established in MOH for 12 months.

Activity 1.1:

- Feasibility Study for a SWAP in Kosovo for the Health Sector undertaken and will involve the drafting of recommendations concerning the extent to which such a SWAP is applicable in Kosovo at this time.
- Mapping of the Health System at primary, secondary and tertiary level, to include a description and listing of existing facilities, medical equipment and services provided, defining the main pathologies treated in each speciality.
- An assessment of the clinical capacity of the Primary Health Care Centres, the different departments/medical faculties of secondary and tertiary level, the annual number of patients per pathology referred to the University Hospital in Pristine and the financing arrangements.
- Evaluation of the level of job satisfaction of medical and paramedical personnel employed in each health facility and of the beneficiaries perception of the quality of services provided in each health facility.

Activity 1.2:

- Identify weaknesses and strengths of the existing Human Resources of the Kosovo MOH in the areas of managerial capacity.
- Draft the necessary requirements in terms of activities and costs for appropriate trainings.
- Analysis and report of the discrepancies between Kosovo and European laws and Regulations regarding health related issues.

- Ascertain which methodology has been used so far for the data collection, analyze and evaluate if its extended application will be capable of satisfying the needs of a modern, efficient Health Information System in Kosovo.
- Assess and list what technical equipment, financial resources are necessary to complete the establishment of an efficient and running Kosovo Health Information System.
- Define the detailed costs for completing the Health Information System.

- Revise the HSDS on the base of the current financial situation of the Sector, and in the perspective of the budget evolution in the short term.
- Prepare and provide, in close collaboration with key MOH officials, a list of detailed prioritizations of activities for the Health Sector Development Strategy, with action plan, and detailed costing.
- Finalize the findings in a formal Report with Recommendations and present it to the MOH and the Donor Community for feedback and endorsement.

Component 2: Capacity Building of the Kosovo Medicines Agency

Contracting Arrangements: The preferred implementation instrument for this project is through a Twinning. Ideally, the Twinning Partner(s) would be an EU Medicines Agency operating in a territory of comparable size to the KMA, a twinning partner(s) which is/are self-financing and operating effectively, delivering quality services and, thereby, can provide a good practice model for the KMA. The Twinning partner(s) will be assisted by at least one full-time expert known as a Resident Twinning Adviser from a member state who will work on a day-to-day basis with the beneficiary.

RTA profile:

- Experience in implementation of EU Pharmaceutical legislative framework and operations with an European Medicines Agency;
Experience in the management [programming, monitoring, evaluation, implementation and control] of development programs in this field.
- Fluency in English;
- Relevant education in the area of health and pharmaceuticals

Activities for achieving Results 2.1: Internal structural review of KMA

2.1.1 - Internal structural review of KMA undertaken to improve management and operational capacity of KMA

- Working with European partners in the review & (re)defining of the KMA Vision, Mission Strategy and Development Plan to ensure it is aligned with the needs of Kosovo as well as that of the European Medicinal Agencies;
- Revisit (and revise) organisational structure of the KMA using the experience of European partners to develop a more efficient and effective organisational structure to meet the service demands.
- Develop / review recruitment policy for KMA staff
- Develop / review a quality management system of internal operations, including reporting and specific standard operational procedures (SOPs)
- Develop a short and long-term business plan in order to secure a self-financing operation for the KMA to include a review of the fee structures in light of increased capacity and expanded service delivery of KMA and in keeping with EU best practice on pricing, public financing and reimbursement system.
- development of I.T support system

2.1.2 Staff capacity building and training programme to be done by means of:-

- i) preliminary staff assessments and assessment of training needs;
- ii) development of tailored training measures in accordance with assessment of needs;
- iii) short study visits to Twinning Agencies
- iv) training seminars and workshops delivered by experts (EU and local experts) and Twinning partners as well as study programme with twinning partner(s) to include mentoring, coaching and on-the-job training within Twinning Partner Agencies

v) course work and documentation (staff required to complete course work and undertake a test(s) to assess knowledge and understanding acquired – test results lead to accreditation and certification).

2.1.3 - Relationship building with relevant partners and stakeholders

- i) Establish working relations with advisory bodies and external experts (activities to include developing expert database and network of advisors)
- ii) Build-up relations with, eligibility and application for membership to, the international networks and organisations⁶.
- iii) Build-up communication structures with the pharmaceutical industry with the development of protocols and guidelines for working with pharmaceutical industry including in particular the adoption of the Good Manufacturing Practice Regulation in Kosovo which enables the KMA to establish working operations with the local pharmaceutical industry
- iv) Build-up communication structures with distributors and pharmacies organisations
- v) Advance cooperation with other Governmental bodies in addition to Ministry of Health

Activities for achieving Results 2.2

Legal framework reviewed and advanced with regard to its alignment with EU legislation and standards for the pharmaceuticals and medicinal products sector

Advance and improve alignment and compliance with EU and international rules and standards
-An assessment of the Pharmaceutical Regulatory system in Kosovo: drafting of a status report on existing situation regarding EU and international compliance (strengths and weaknesses)

-Training and information exchange by/with EU institutions (in particular European Commission DG Health) and twinning partners (European Medicines Agencies).

-Introduce and advance adoption of secondary legislation on pharmaceutical products and devices in Kosovo in order to secure compliance with EU-rules and international guidelines.

Activities for achieving Results 2.3: Inspection and supervision activities carried out according to EU standards

-Training and information exchange by/with EU institutions (in particular European Commission DG Health) and twinning partners (European Medicines Agencies).

-Introduce and advance adoption of secondary legislation on pharmaceutical products and devices in Kosovo in order to secure compliance with EU-rules and international guidelines.

-Improvements to Monitoring and Inspection process: training delivery to KMA staff on Good Manufacturing Practice and the process of GMP Certification; Good Distribution Process and Good Laboratory Process necessary to comply with and attain standards for membership to the EMEA.

-Capacity building measures to establish functioning Quality Control Laboratory.

Activities for achieving Result 2.4: KMA's eligibility to join EMEA

-Legal framework review & capacity building activities as outlined in Activities 2.1, 2.2 and 2.3

3.6 Conditionality and Sequencing

For the project to be successful it is necessary to have full commitment and endorsement of the project by Kosovo MOH, key stakeholders and Donors. There needs to be adequate

⁶ EU, EMEA, WHO, CADREAC, PIC, Balkan Council

participation by Kosovo MOH, key stakeholders and Health Donors. It will be important to assure consensus between Donors and Government on Project objectives and means. MOH support must be given in terms of appointing one of its officials of intermediate level as the National Counterpart to the Project Coordinator.

In the case of capacity building of the KMA there will need to be willingness from other EU Member State(s) and Medicinal Agencies to be involved in a twinning project with KMA. Also important will be the high level of commitment and engagement of KMA staff.

The KMA will need to provide office accommodation and appropriate ICT equipment and support to meet the needs of the expert(s) and for KMA to ensure a designated staff member is available to support and work directly with the expert(s) to facilitate and implement the project activities. There must also be engagement of, coordination and cooperation with other donors and stakeholders in the field.

3.7 Linked activities

The project has been designed and will be implemented in coordination with the government and other donors. This project builds-on previous EC and other donors' assistance in the health sector, particularly the following projects:

<i>EC funded (current)</i>	The current EC funded project 'Technical Assistance to Kosovo Development Strategy and Plan (Contract No. 04KOS01/05/03/001)' has the overall aim of helping develop a strategic policy function in the key line Ministries and their capacity to identify, plan, prioritise and budget for important future projects. A prime output is the preparation of sector strategies for 2009-2014 for each of these Ministries, including the Ministry of Health. Its sector strategy is planned to be completed by May 2008.
<i>EC funded (past)</i>	<ul style="list-style-type: none"> • Assessment of Health Information System Project 2006 • Ensuring the distribution of essential drugs through state health facilities all over Kosovo • Capacity Building for medical training and health service management • Upgrading of Health Care Systems • Establishment of a new college of nursing • Project on "Strengthening the Sustainability of Quality Health Care in Kosovo" • Training programmes in health services management, master courses for health experts, training in Project to strengthen the legal capacity within the MoH <p>Support to Kosovo Pharmaceutical Sector: Development of sustainable Pharmaceutical Sector (CARDS 2000)</p>
<i>The World Bank (€3 million)</i>	<ul style="list-style-type: none"> • Support the development of a health care financing system • Restructuring of the Primary Health Care Restructuring in Kosova • Development of a Master Plan to inform capital investment possibilities, develop infrastructure planning for health sector and build up of health policy and a health planning unit • Sector Analysis of Kosovo Pharmaceutical Sector – leading to report 'Kosovo Pharmaceutical Sector Analysis – 4 May 2007'
<i>Luxembourg</i>	Health information System in the Prizren Region
<i>DFID</i>	Support to legislative review
<i>ECHO (€19.2 million)</i>	Rehabilitation of health facilities, and training of health professionals. Support was chiefly provided through NGOs, WHO and Belgium Red Cross.

Foundation Partnership For Health	Trainings for HIV/Aids
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3.7 Lessons learned

The following lessons have been learned from past projects in the health field:

- the importance of ownership and commitment of the Ministry of Health and relevant stakeholders to the project and its activities;
- The importance of clear communication and transparency between the beneficiaries (the health institutions) and the technical assistance experts;
- the importance of linking the training directly to the work activities of the beneficiaries

4. Indicative Budget (amounts in €million)

			SOURCES OF FUNDING									
			TOTAL EXP.RE	IPA COMMUNITY CONTRIBUTION		NATIONAL CONTRIBUTION					PRIVATE CONTRIBUTION	
ACTIVITIES	IB (1)	INV (1)	EUR (a)=(b)+(c)+(d)	EUR (b)	% (2)	Total EUR (c)=(x)+(y)+(z)	% (2)	Central EUR (x)	Regional/Local EUR (y)	IFIs EUR (z)	EUR (d)	% (2)
Activity 1	X		0.5	0.5	100							
contract 1.1			0.5	0.5	100							
Activity 2	X		1.0	1.0	100							
contract 2.1			1.0	1.0	100							
TOTAL IB			1.5	1.5	100							
TOTAL INV												
TOTAL PROJECT			1.5	1.5	100							

Note:

- (1) In the Activity row "X" is used to identify whether IB or INV
- (2) Expressed in % of the **Total** Expenditure (column (a))

5. Indicative Implementation Schedule (periods broken down per quarter)

Contracts	Start of Tendering	Signature of contract	Project Completion
Contract 1.1 SWAP Health: Mapping & Feasibility Study	Q4 2008	Q2 2009	Q2 2010
Contract 2.1 'Capacity Building of the Kosovo Medicines Agency'	Q4 2008	Q3 2009	Q2 2011

All projects should in principle be ready for tendering in the 1ST Quarter following the signature of the FA

7. Cross cutting issues (where applicable)

1.1 Equal Opportunity:

Equal Opportunities and non-discrimination is to be given attention by the project in respect of MOH and KMA recruitment policy and practice and management delivery – how it respects EU and Kosova equal opportunity and non-discrimination legislation and best practice. Assessment and capacity building will also be undertaken in respect of equality of access to health care services in Kosovo (for example in respect of access to pharmaceuticals).

1.2 Environment

The Project implementation should contribute to the development of a new understanding of the importance of the connections between Health and Environment. A fully functioning Kosovo Health Information System will be capable of producing data on environmental hazards and their effects on Health. An understanding of the necessary interaction between MOH and Ministries involved in health related issues, such as Occupational Health, Environmental Health, Hygiene regulations for food production, will put forward the debate on these issues. The discrepancies between Kosovo and European Law and Regulations regarding health related issues, will show the health related risks which are currently not fully covered by the existing legislation.

The KMA policy and operational plan will take into consideration measures to promote and advance respect for the environment in particular in respect of pharmaceutical waste disposal.

6.3 Minorities

Assessment and capacity support of MOH and KMA will be provided in respect of recruitment: how it should be developed in accordance with equal opportunities of minorities and respect and adherence to non-discrimination legislation and best practice (includes in particular the Serbian minority population as well as other minorities Turkish, RAE and other minority groups including people with disabilities). This will include staff training on equal opportunities and non-discrimination in the work place.

MOH and KMA institutional and capacity building measures to be delivered; such as the development of policy and operational plans, to take into consideration measures to ensure improve and promote equal access to health care services by minorities and other disadvantaged groups.

ANNEX 1: Logical framework matrix in standard format

LOGFRAME PLANNING MATRIX FOR Project Fiche	Programme name and number	
	Contracting period (See section 1.11)	Disbursement period(see section 1.12)
	Total budget : 1.5 €million	IPA budget: 1.5 €million

Overall objective	Objectively verifiable indicators	Sources of Verification	Assumptions
Improve the health service delivery in Kosovo, through the strengthening of the Kosovo relevant institutions and the coordination of the stakeholders together with the international donors, in the perspective of a Sector Wide Approach.	Increase life expectancy of 5 years and decrease overall morbidity by 5 % in 10 year	Health Statistics; Eurostat.	Project approved in time.
Project purpose	Objectively verifiable indicators	Sources of Verification	Assumptions
This project will strengthen the institutional capacity and technical skills of the health sector institutions through the promotion of and improving inter-departmental, inter-Ministerial and donor coordination. It will build the institutional and human resource capacity of the KMA in order that it can meet all the European Medicines Agency standards and will provide up-to-date information on the current status of health care delivery in Kosovo through a detailed mapping process & a SWAP feasibility study.	Establishment of the SWAP approach for health. Participation of donors to SWAP -improved quality and rate of service delivery by KMA -expansion of services available -improved sense of job satisfaction among KMA staff & MOH and KMA clients in service	-MOH -EC -Health Donors -auditors reports of KMA -KMA reports on service output -feedback from KMA staff -feedback from KMA clients -KMA financial reports	-Project approved and financial means / TA disbursed in time. -Full commitment and participation of KMA Senior Management in all aspects of the project; -Full engagement of KMA Staff -Engagement of MOH and other relevant organizations and stakeholders in the sector
RESULTS: COMPONENT 1 – SWAP HEALTH MAPPING & FEASIBILITY STUDY	Objectively verifiable indicators	Sources of Verification	Assumptions
Result 1.1: SWAP Feasibility Study undertaken:	Feasibility Study for Health Sector SWAP in Kosovo produced	MOH	Donors and MOH agree on SWAP implementation and its timeframe
Mapping of the Health system at the primary, secondary and tertiary level	-All Kosovo existing medical facilities, equipment and services of primary, secondary and tertiary level visited, checked, listed, defined and quantified	Experts reports prepared with the findings	MOH Support Government and Municipalities support to experts in accessing all Data
Legal Analysis: Analysis undertaken on the level of alignment and non-alignment of Kosovan and European Law in the field of Health	-Official Legal Analysis Report prepared and submitted to MOH and Donors.	Experts reports	MOH Support access of experts to all Data

Result 1.2: Weaknesses and strengths of MOH Human Resources in managerial capacities identified	-Report prepared with all the findings and Recommendations & taken forward by MOH with donor support and involvement.	Experts reports	Donors Support in accessing all the Data MOH staff cooperation and engagement
Current status of Kosovo Health Information System assessed. Methodology used so far for data collection by the System analyzed, and its efficiency for Kosovo Health Information System evaluated.	-Technical equipment and financial resources, running costs necessary to establish an efficient running Kosovo Health Information System assessed and listed.	Experts reports	MOH Support access of experts to all Data
Health Sector Development Strategy of June 2004 revised and brought up to date using the information acquired from the Feasibility Study	-HSDS revised & revision formally approved by MOH. -Sector Strategy Development detailed prioritizations of activities prepared, and provided with action plan, and detailed costing. HSDS formally approved by MOH. -Report with recommendations on the Kosovo Health Sector Strategy Development finalized.	MOH	MOH Endorse: Revised HSDS Sector Strategy Development Report and Recommendations presented by the expert
Results - COMPONENT 2: CAPACITY BUILDING OF KOSOVO MEDICINES AGENCY	Objectively verifiable indicators	Sources of Verification	Assumptions
Result 2.1: Internal structure of KMA reviewed and strengthened	-improved service quality and expanded KMA service delivery;	Ministry of Health Audit of the KMA -Accreditation of KMA staff -I.T development plan published and disseminated; -Application of electronic registration system by KM	MOH and KMA commitment and engagement-particularly management level Twinning partners commitment and engagement Clear communication between MOH, KMA, KMA staff and twinning partner(s) Access to documents and data from Government, MOH, KMA as required
Result 2.2: Review and Strengthened Pharmaceutical Regulatory system in Kosovo	-Adoption of secondary legislation on medicinal products and medicinal devices; -Improvement in application & compliance with EU legislation -Updated pharmaceutical policy	Texts of laws and secondary legislation -Ministry of Health Audit of the KMA -Training participation register test results-staff accreditation	
Result 2.3: Inspection and supervision activities carried out according to EU standards			
Result 2.4: KMA eligible to join the EMEA as full member and to join as member of other international bodies in the field	-Membership to EMEA and other international platforms -Enhanced relationships and communication with relevant partners and stakeholders	EMEA Membership papers Strategic Plan Experts reports	
Activities COMPONENT 1 – SWAP HEALTH MAPPING & FEASIBILITY STUDY	Means	Costs	Assumptions

Activity 1.1: SWAP Feasibility Study undertaken analyzing the implications of the SWAP adoption in the Kosovo Health Sector	Technical Assistance-Service Contract	0.5 €million	-The MOH will ensure participation of all the Key personnel. -Donors participation to activities related to SWAP -Municipalities will guarantee access to all existing documentation including all the financial documents. -The Government of Kosovo will guarantee full access to all documents. -MOH will collaborate and actively participate
Activity 1.2: Identify weaknesses and strengths of the existing Human Resources of the Kosovo MOH in the areas of managerial capacity			
Activities COMPONENT 2: CAPACITY BUILDING FOR THE KOSOVO MEDICINES AGENCY	Means	Costs	Assumptions
Activity 2.1: Internal structural review of KMA Includes activities to: -improve management and operational capacity of KM -Staff capacity building and systems support -Development & implementation of staff training programme	Twinning Contract is preferred	1.0 €million	-Commitment and cooperation of KMA management and staff Member states' relevant institutions interested in establishing a twinning arrangement. -commitment and active engagement of twinning partners
Activity 2.2: -Assessment of the Pharmaceutical Regulatory System in Kosovo; measures to advance and improve alignment and compliance with EU and international rules and standards Activities for achieving Results 2.3: Inspection and supervision activities carried out according to EU standards -Training and information exchange by/with EU institutions -Improvements to Monitoring and Inspection process -Capacity building measures Activities for achieving Result 2.4: KMA's eligibility to Join EMEA -Legal framework review & capacity building activities as outlined in Activities 2.1, 2.2 and 2.3			

Pre-conditions:

For the project to be successful it is necessary to have full commitment and endorsement of the project by Kosovo MOH, key stakeholders and Donors. There needs to be adequate participation by Kosovo MOH, key stakeholders and Health Donors. It will be important to assure consensus between Donors and Government on Project objectives and means. MOH support must be given in terms of appointing one of its officials of intermediate level as the National Counterpart to the Project Coordinator.

In the case of capacity building of the KMA there will need to be willingness from other EU Member State(s) and Medicinal Agencies to be involved in a twinning project with KMA. Also important will be the high level of commitment and engagement of KMA staff. The KMA will need to provide office accommodation and appropriate ICT equipment and support to meet the needs of the expert(s) and for KMA to ensure a designated staff member is available to support and work directly with the expert(s) to facilitate and implement the project activities. There must also be engagement of, coordination and cooperation with other donors and stakeholders in the field.

ANNEX II: amounts (in €million) Contracted and disbursed by quarter for the project

[This table should be consistent with the table in section 5 in the fiche main text]

	2008				2009				2010				2011				2012			
Contracted	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Sector Wide Approach Health						0.5meuro														
Capacity Building to Kosovo Medicines Agency						1.0meuro														
Cumulated Total						1.5meuro														
	2008				2009				2010				2011				2012			
Disbursed	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Sector Wide Approach Health						0.2		0.25		0.05										
Capacity Building to Kosovo Medicines Agency							0.4	0.08	0.08	0.08	0.08	0.08	0.1	0.1						
Cumulated Total						0.2	0.6	0.93	1.01	1.14	1.22	1.3	1.4	1.5						

ANNEX III: description of the Institutional Framework

Health Sector in Kosovo

The United Nations set up an Interim Administration Mission in Kosovo (UNMIK) in June 1999 under the authority of Security Council Resolution 1244. In 2002 UNMIK transformed the Joint Interim Administrative Structure (JIAS) into the Provisional Institutions of Self Government (PISG) and the Department of Health Social Welfare and Spatial Planning into the Ministry of Health (MOH).

The MOH is responsible for the implementation and supervision of the Kosovo Health Strategy with the collaboration of the Municipal Health Directorates (MHD), particularly for Primary Health care (PHC) activities. The MOH and the MHD cooperate for the preparation of tasks and activities, the implementation of plans, and the delegation of responsibilities. The Institute of Public Health (IPH) has the task to guarantee integration and coordination in the flow of health information and analyze the health of the population and the performance of the Health sector.

The Kosovo Health Law was approved by Assembly of Kosovo of PISG on February 2004. In this law the Municipalities are responsible for the provision of PHC services and the MOH for the secondary and tertiary Health Care Institutions. The Municipal Assembly approves the operational plan for the development of PHC in accordance with the mid-term plan approved by the Government of Kosovo.

The Kosovo Medicines Agency

The Kosovo Medicines Agency KMA, originally known as the Kosovo Drug Regulatory Authority, was established in 2000 and came into full legal existence as an independent executive agency in 2001 in accordance with United Nations Mission in Kosovo (UNMIK) Regulation No. 2001/19⁷. The work of the KMA is governed by the 'EU Regulation on Medicinal Products and Medicinal Devices'. This law was adopted by the Kosovo Assembly and promulgated by the SRSB in July 2004.

The KMA is responsible for ensuring the quality, safety and efficacy of human medicinal products and medical devices placed in Kosovo. It achieves this task via implementation of regulations and administrative instructions concerning marketing authorization, licensing and inspection, narcotics and psychotropic quality control, pharmaco-vigilance and clinical trials. The KMA is, therefore, responsible for issuing market authorisations and important licenses for drugs and medical devices as well as licensing and monitoring of pharmaceutical manufacturers, wholesalers and pharmacists.

⁷ 'On the Executive Branch of the Provisional Institutions of Self Government in Kosovo' and Administrative Instruction (Health) 7/2000 'On the Establishment of Kosovo Drug Regulatory Agency'. On 04/12/2003, Medicines Law No. 2003/26 'On Medicinal Products and Medical Devices', in harmonization with EU Directives, was adopted by Kosovo Assembly and promulgated by the SRSB on the 07.07.2004.

Annex IV: Reference to laws, regulations and strategic documents:

i) Reference list of relevant laws and regulations

Kosovo Health Law (approved on 20 August 2004)

Law on Kosovo Sanitary Inspectorate (approved November 2003)

Law on the Executive Branch of the Provisional Institutions of Self Government in Kosovo and Administrative Instruction (Health) 7/2000

Law on rights and duties of citizens receiving health care

Law on the Establishment of Kosovo Drug Regulatory Agency (04/12/2003) Medicines Law No. 2003/26

Law on Medicinal Products and Medical Devices (Law no. 2003/26), in harmonization with EU Directives adopted by Kosovo Assembly and promulgated by the SRSG on the 07.07.2004.

ii) Reference to AP /NPAA / European Partnership (EP) / Stabilisation and Association Process (SAA)

European Partnership

This project would be consistent with the priorities identified in the European Partnership for Kosovo in advancing progress on the meeting of European Standards and effective implementation of legislative frameworks and the need to undertake a functional review of the health system to enhance service delivery.

Component 1: Sector Wide Approach in Health: feasibility study & mapping

The Project responds to some of the priorities listed in the European Partnership Action Plan in the:

- Review the existing framework to enhance quality of Health service delivery.
- Draft a comprehensive strategy for Health System, in particular for a Health Information System, for a more effective provision of health services.

Component 2: Capacity Building of the Kosovo Medicines Agency

This project is consistent with the priorities identified in the European Partnership for Kosovo which calls for support the meeting of European Standards and the effective implementation of European legislative frameworks as well as the call for a functional review of the health system in order to enhance service delivery.

European Commission Progress Report 2007

This project is consistent with Progress Report concerns on the need to advance conformity with European Standards, promote consumer protection and to improve efficiency in public administration and service provision.

iii) Reference to Multi-Annual Indicative Planning Document (2007-2009) (MIPD)

Component 1: Sector Wide Approach in Health: feasibility study & mapping

The studies and the activities proposed in this Project link to some of the proposals included in the Multi Annual Indicative Planning Document with regards to the development of the Kosovo Health System:

- Give a special focus to the Health Sector, as a cornerstone of future economic growth.
- Complete a functional review of Health System to enhance service delivery.
- Promote a more effective coordination of donors' activities.
- Consolidate the development of the Health System in line with European standards.
- Support Health Institutions strategy making and coordination capacities.
- Focus on the normative framework to promote an operational health system.
- Develop the Health Information System to reduce the inefficiencies of the Sector.

Component 2: Capacity Building of the Kosovo Medicines Agency

This project is consistent with MIPD calls to improve the good governance of public utilities and develop infrastructures in order to promote and enhance the quality of public goods and services including in the areas of health.

It is consistent with the call to build the strategy-making capacity of public health institutions and to conduct an impact assessment of financing systems for public health;

iv) Reference to National Development Plan

Component 1: Sector Wide Approach in Health: feasibility study & mapping

The Health Sector Goals of the Kosovo Development Strategy are to improve strategic and operational management of the Sector. This initiative responds to a number of priorities foreseen in the Medium Term Expenditure Framework 2008-2010:

- Better allocation of resources through an improved donor coordination
- Promotion of better service quality and efficient delivery
- Limited development and training of human resources
- Integration of information systems of data, within the Health Information System

Component 2: Capacity Building of the Kosovo Medicines Agency

The Kosovo National Development Plan has emphasised the need to enhance both strategic and operational management in the health sector and in health service delivery.

Human Resource Development is presented as one of the priority measures of the Kosovan National Development Plan and the KMA capacity building initiative is, therefore, consistent with this HRD support prioritised by the Kosovan Government.

The Strategy for Kosovo Health (2005-2015) calls for

- Improved management of drugs and medical supplies (objective 23)
- Strengthening of the legal and regulatory framework (objective 22)
- Improved financial management and procurement of the health sector (objective 21)
- Development of Human Resources in the Health Sector (objective 8)

v) Reference to national / sectoral investment plans

ANNEX V: details per EU funded contract (*) where applicable:

Component 1: Sector Wide Approach in Health: feasibility study & mapping (

Contracting Arrangements: The project will be implemented through a service contract. A Project Coordinator will be appointed and established in MOH for 12 months.

Tasks under this component include:

- SWAP Feasibility Study undertaken; analyzing the implications of the SWAP adoption in the Kosovo Health Sector
- Mapping of the Health system at the primary, secondary and tertiary level, with reference to all the data published by the Statistical Office of Kosovo:
- Identify weaknesses and strengths of the existing Human Resources of the Kosovo MOH in the areas of managerial capacity
- Analyze existing laws and regulations regarding current interaction and legislative framework between MOH and other Ministries involved in health related issues
- Assess the current status of the Kosovo Health Information System:
- Revise the Health Sector Development Strategy in a more realistic perspective:

Component 2: Capacity Building of the Kosovo Medicines Agency (Twinning)

Contracting Arrangements: The preferred implementation instrument for this project is through a Twinning. Ideally, the Twinning Partner(s) would be an EU Medicines Agency operating in a territory of comparable size to the KMA, a twinning partner(s) which is/are self-financing and operating effectively, delivering quality services and, thereby, can provide a good practice model for the KMA. The Twinning partner(s) will be assisted by at least one full-time expert known as a Resident Twinning Adviser from a member state who will work on a day-to-day basis with the beneficiary.

RTA profile:

- Experience in implementation of EU Pharmaceutical legislative framework and operations with an European Medicines Agency;
Experience in the management [programming, monitoring, evaluation, implementation and control] of development programs in this field.
- Fluency in English;
- Relevant education in the area of health and pharmaceuticals

Tasks under this component include support and guidance on:

- Internal structural review of KMA & Staff capacity building and systems support
- The strengthened of Pharmaceutical Regulatory system in Kosovo; to advance and improve alignment and compliance with EU and international rules and standards
- Measures required for KMA to meet eligibility criteria to EMEA