

**IPA National Programme 2008 Part II – Bosnia and Herzegovina**

**Fiche 6: Support for the Development of the Health Care Systems**

**1. Basic information**

**1.1 CRIS Number:** 2008/20-339

**1.2 Title:** Support for the Development of the Health Care Systems in Bosnia and Herzegovina

**1.3 ELARG Statistical code:** 02.28 Economic criteria/Consumer and health protection

**1.4 Location:** Bosnia and Herzegovina

**Implementing arrangements:**

**1.5 Contracting Authority:** European Commission

**1.6 Implementing Agency:** European Commission

**1.7 Beneficiary:**

Ministry of Civil Affairs of Bosnia and Herzegovina – Sector for Health, Ministry of Health and Social Welfare RS and Ministry of Health FB&H, District Brčko Government – Department of health and other services, Pharmaceutical Agency of Bosnia and Herzegovina

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**Financing:**

**1.8 Overall cost (VAT excluded):** EUR 2,875,000

**1.9 EU contribution:** EUR 2,850,000

**1.10 Final date for contracting:** Two years following the date of the conclusion of the Financing Agreement

**1.11 Final date for execution of contracts:** Two years following the end date of contracting

**1.12 Final date for disbursements:** One year following the end date for the execution of contracts

## 2. Overall Objective and Project Purpose

### 2.1 Overall Objective

To enhance the efficiency of health care services in Bosnia and Herzegovina

### 2.2 Project purpose:

To assist the B&H Pharmaceutical Agency in becoming a fully functioning institution in accordance with EU standards, implement a system of provider payments that would create incentives for cost containment and improve provider performance as well as to improve the quality of data collection and information flow related to the Public Health Institutes and to harmonize relevant legislation in accordance with EU Directives.

### 2.3 Link with AP/NPAA / EP/ SAA

#### **“Bosnia and Herzegovina European Partnership 2007”**

Short-term priorities, European standards, Internal market:

- Free movement of goods: *“Adopt the State law on pharmaceutical and medical devices and establish the State Pharmaceutical Agency.”*

This will be a precondition for this project. It is expected the Law to be adopted until the end of July 2008.

- Employment and social policies: *“Develop adequate administrative structures and capacity in the field of consumer and health protection.”*

Short-term priorities, European standards, Sectoral policies:

- Statistics: *“Improve the quality and coverage of statistics on consolidated government accounts”.*

Medium-term priorities, European standards, Internal market:

- Statistics: *“Develop reliable economic statistics and build up institutional capacity to produce and publish basic statistical data harmonized with European standards, in particular in the areas of national accounts, agricultural, macro-economic and business statistics, and social statistics, including education, labour and **health statistics.**”*

### 2.4 Link with MIPD

**Multi-Annual Indicative Planning Document for Bosnia and Herzegovina (MIPD) 2008-2010**, Section 2.2.2 - Strategic choices for IPA assistance over the period 2008-2010, Sub-section Socio-economic requirements, it was stated: *“The health sector will be reformed to ease the burden on public finances and to deliver adequate health care to citizens”.*

- Section 2.3 Multi-annual planning component I, Transition assistance and institution building, 2.3.1. Objectives and choices, Axe2: Socio-Economic Criteria: *“Reform of the Public health*

*system to relieve the burden on public finances by assisting in the reconfiguration of the health care delivery system, and in the building of institutional capacities”.*

- Section 2.3, Axe3: Ability to assume the obligations of membership the following was underlined: *“IPA will support the development and the implementation of strategies and policies to establish sectoral policies and a regulatory framework compatible with European Standards. This includes establishing and capacity building of agencies and institutions required for the implementation and enforcement of sectoral policies, including mechanisms for the verification of EU compatibility of government policies and draft plans”.*

## **2.5 Link with National Development Plan**

**Medium-term Development Strategy of Bosnia and Herzegovina (MTDS) - Section Health System, 5.2. EU policy regarding health sector, Functions needed for EU accession:** *“Even though health sector is not directly part of EU legislation, it plays important role in the acquis communautaire. Out of 31 (now 35) chapters of this document, two are directly related to issue of health protection - chapter 23 (new 28) deals with "Consumers and health protection" while chapter 13 (new 19) deals with "Social policy and employment". Certain number of other chapters is directly related to health sector: for instance free movement of goods, persons and services which within health sector is related to free movement of medical equipment, drugs and medicine materials, medical experts, patients and benefits (including benefits of health insurance). Also, issues of health protection are included in number of other chapters such as statistics, agriculture and fishing, science and research, education and training, environment, etc.”*

- **MTDS** also highlighted as priorities the *“Improvement of skills of strategic planning of policy creators and decision makers”* and *“Measure that requires special attention is to build strategy of "new public health"”.*

- Section 5. EU Policy in Regard to Statistics, Activities that Require Special Attention identified following priorities: *“Strengthening of statistics of national accounts”* and *“Strengthening statistics of education and health”*. *“In the area of statistics of education and health statistics it is necessary to introduce monitoring of public expenditures, in accordance with international standards.”*

- Biennial Collaborative Agreement between Bosnia and Herzegovina and the Regional Office for Europe of the World Health Organization for 2008/2009 is referred to the following priorities: (1) *Improving health system stewardship and management information system – (a) Strengthened stewardship and health intelligence function for the strategic health system reform plan implementation; (b) Implementation of national pharmaceutical policy;* (2) *Improving quality and integrating the continuity of care concept in service delivery reforms;* and (3) *Strengthening communicable surveillance and response systems with special emphasis on vaccine preventable diseases and tuberculosis.*

### 3. Description of project

#### 3.1 Background and justification:

According to the administrative constitution there are two entities in Bosnia and Herzegovina – Federation of Bosnia and Herzegovina and Republika Srpska - and the District Brčko, which is independently administered. Since the respective governments are responsible, apart from others, for health sector policies, this implies that Bosnia and Herzegovina's health care systems partially differ each other. According to the Law on Ministries (March 2003), the Ministry of Civil Affairs of Bosnia and Herzegovina is in charge of the overall coordination of health issues at the state level.

In regard to the capacity of existing health systems and health needs of Bosnia and Herzegovina's population, as well as taking into consideration priorities and recommendations contained in "Progress Report for Bosnia and Herzegovina 2007", the following fields could be identified as crucial ones to be established or further developed in the way to EU integration: Pharmaceutical sector; Public health; National Health Account; State obligations in regard to reporting to international organisations; and Harmonization of existing legislation with EU Directives.

According to the existing EU legislation, health care and health care systems are direct responsibilities of each member state. They themselves define how to manage their respective health systems, make decisions on the amount to be spent on health purposes and health care of their citizens, on drugs that will be provided, as well as on technologies to be used in diagnosis and treatment. However, public health and health care issues related to health statistics, science and research, environment protection issues as well the use of informatics technology is of mutual interest to EU member states. Also, contagious diseases, diseases caused by smoking, inadequate food and other risky behaviours (consumption of alcohol and narcotics) are wider than country borders and are of common interest. Furthermore, the single market requiring free movement of people (patients and health experts) and services also requires the free movement and transfer of benefits that follow these rights. The single market demands joint responsibility for drug safety, medical equipment and medical stuff, blood and blood products, as well as tissues used for treatment and transplantation purposes, as defined in Article 152 of EU Amsterdam Agreement (former article 129 of EU Maastricht Treaty).

#### ***Support to Pharmaceutical Agency***

The document "Bosnia and Herzegovina 2007 Progress Report" - European Standards, Free Movement of Goods underlined the following priority: *"The Law on Pharmaceuticals and Medical Devices has not yet been adopted. Consequently, no national agency for medicinal products has been established. This continues to undermine the establishment of a real internal market within Bosnia and Herzegovina in this sector."*

The Ministry of Civil Affairs of Bosnia and Herzegovina, in coordination with entity Ministries of Health and the Department for Health in Brcko District, has been engaged in preparing a Law on pharmaceuticals and medical devices that will, among other issues, provide for the establishment of the B&H Pharmaceutical Agency. The working group tasked with drafting this Law started its work five years ago and its final draft proposal was adopted by B&H Council of Ministers in February 2008 and referred to Parliament for further consideration. According to this Law the Pharmaceutical Agency of Bosnia and Herzegovina will be established as an authorised

body for pharmaceuticals and medicinal devices to be used in B&H medical sector. The main intention of the Law on Pharmaceuticals and Medicinal Devices of Bosnia and Herzegovina is to regulate those issues relating to the manufacturing, sale and use of pharmaceuticals and medical devices according to EU regulations and rules.

The Agency will have rather complex structure since it will comprise three units, as follow: Pharmaceutical Agency, which will also deal with medical devices, Laboratory for Drug Control and Laboratory for Pharmacovigilanca. It could be expected that the Agency would need assistance for adequate administrative organisation and internal and development of set of normative acts assistance in development of adequate communication plan. In addition, there will be need to draft set of different bylaws in order to fully regulate this field in line with EU Directives and requirements.

It will also be necessary to upgrade level of work of the Drug Control Laboratory in order to obtain ISO certificate.

Since the Agency will be newly established institution there will be a need for capacity building of its staff to be ready to deal with highly demanding job.

At the end of the project the Agency should be strengthened enough to became partner of other similar agencies in Europe.

### ***Provider Payment System***

Given that expenditure on the health system in Bosnia and Herzegovina accounts for a considerable level of GDP (9,5%), there is a need for a new system of provider payments in order to achieve more efficient health services.

The “Bosnia and Herzegovina 2007 Progress Report” in regard to Movement of persons, services and right of establishment recommended as follows: “*Ensuring the portability of pension and health benefits between individual social security systems would facilitate mobility within the country.*”

In 2002, the Parliament of BiH endorsed a policy document entitled *Resolution on Health for All*. This document affirms a political commitment of the State to principles which include: solidarity and equity; cross sector cooperation to improve health care provision; establishing the basic health sector functions at the State level; compatible systems of health data collection; and international cooperation.

According to the Dayton Agreement, health care financing and delivery are the responsibility of each Entity, governed by separate health legislation. Under the current system, each Entity has different contribution rates, benefits packages, pricing structures and different reimbursement systems.

Introducing a common revised system of provider payments based on DRG classification (Diagnosis Related Groups) across the country would create incentives for cost containment and improve provider performance. It will help health systems in Bosnia and Herzegovina to increase the efficiency of service delivery and sectoral resource use. DRG system will introduce standards as elements of quality, which will help to value the effectiveness of hospital works.

New system of service provider payment based on Australian Refined - Diagnosis Related Groups (AR-DRG) classification has been pilot tested in four hospitals in Bosnia and Herzegovina. It has been implemented as a project activity of SITAP Project, financed through

the World Bank loan. This project was aimed at rendering technical assistance to social insurance system in developing options for effective formulation and implementation of reforms that are needed to help BH social insurance system to become financially sustainable and more effective. Reforms suggested within the SITAP Project referred to capacity building in relevant ministries, social and health insurance funds to enable them to plan effectively health services, which will fulfil community needs more efficiently and effectively with limited resources.

DRG classification is the most common method of provider payment that is being applied in most European countries. It classifies acute hospital patients into groups requiring similar consumption of hospital resources and having similar clinical specialities.

The main idea of this provider payment method is payment according to episodes, which are defined as time periods in which patients are admitted to and released from hospital.

The introduction of DRG system of classification is aimed at achieving a more equitable allocation of available budget resources in order to improve the efficiency and effectiveness of hospital systems, to initiate planning processes at institutional level, and to ensure approximately equal quality of hospital services. It will enable Bosnia and Herzegovina to compare itself with other countries that have been implementing the DRG system for many years.

This new method of provider payment based on outcomes will provide information on cost-effectiveness of health care system. DRG system will be applied at levels of secondary health care and extended to all B&H health systems using of existing local resources trained in previous pilot-phase. Since DRG method will arrange the health system in B&H, the patients will be able to have better and easier access to health institution. The advantage of this system is to rationalize procedures and improve health care services. Implementation of new DRG system will result in more efficient health care system and rationalize spending of its resources in order to achieve better quality of services that B&H health institutions were not able to provide to their patients previously.

DRG system should be considered as a component of the future hospital information system. It will also introduce new standards in relation to hospital morbidity.

The introduction of new provider payment mechanisms in hospitals throughout Bosnia and Herzegovina will require a change of existing entity legislation on secondary health care services payment.

Health systems of today should have health information system developed including an electronic health card (ECH) as main components of their health strategy. Health information system is still underdeveloped in Bosnia and Herzegovina and there is a need of its informatization as soon possible. Ministry of Health and Social Welfare of Republika Srpska has already developed its electronic health strategy, but it doesn't exist in Federation BH. It is necessary to have the same strategic document developed by Federal Ministry of Health in Federation of B&H, which should be compatible with the one in Republika Srpska As an important precondition for future BH health systems informatization. Since Federal Ministry of Health itself has no capacity to accomplish this activity, the technical assistance will be needed.

Introduction of informatization will be followed up with an introduction of electronic health card, which will make method of following patient more simply and enable all relevant patient data consolidated at one place.

### ***Improved data collection and information flow***

In the EC document “**Bosnia and Herzegovina 2007 Progress Report**” within Section related to **European Standards - Employment and Social Policies**, the following was stressed: “*There is a clear need to improve coordination and governance in the sector (Public Health) as a key element in improving equity and equal access to health care services.*” It was also recommended “*Collection of statistics and reporting of health-related data to international organizations needs also to improve...*”

Bosnia and Herzegovina is faced with the lack of comprehensive and standardised data collection at state level in line with international requirements. The system of providing comparable health data and reporting to international organizations (WHO, EUROSTAT, ILO, etc.) is still fragmented or absent and Bosnia and Herzegovina can't fulfil its relevant reporting obligations. Therefore it is necessary to improve the capacity of the existing network of Public Health Institutes in Bosnia and Herzegovina in order to be able to provide relevant state authorities with reliable data on which they can base policies to adjust the health system to provide the amount, type and quality of health care services to current and future needs. Reform in this field is due to start with an IPA 2007 Project aimed at strengthening Public Health Institutes in BiH.

Institutional capacity development and enhancement are preconditions for high quality performance of core Public Health Institutes functions especially those related to collection of data and establishment of functional data flows.

The aim is to improve the quality of public health practice and the performance of public health systems by providing performance standards for public health systems, improving quality and accountability of public health practice and conducting systematic collection and analysis of performance data.

The production of National Health Account (NHA), as a part of data collection referring to EUROSTAT, is another B&H international reporting obligation that needs to be further developed. The NHA is a process consisted of collecting the data, organizing the data, analysing the results for health policy and disseminating the information to the stakeholders. Its aim is to encompass all expenditures for activities whose primary purpose is to restore, improve and maintain health for the nation and for individuals during a defined period of time.

Within the EC Project “Strengthening of the B&H health systems for EU integrations” (started in 2006, ended in February 2008) certain initial steps were undertaken in regard to NHA function development but these activities were still insufficient to make NHA system fully operated. The working group was established, consisted of representatives of both entities and Brčko District, which will follow up NHA activities as a result of the a/m Project. Its further task will be training of all relevant stakeholders and making NHA system operational.

Since National Health Account (NHA) constitutes a systematic, comprehensive, and consistent monitoring of resource flows in a country's health system for a given period, it will be useful tool to assist policy-makers in their efforts to understand health systems and to improve health system performance.

### ***Harmonisation of legislation***

As a potential candidate for EU membership, Bosnia and Herzegovina is committed to approximate its legislation in the relevant sectors to EU requirements and to implement it effectively.

Apart from the Pharmaceutical Law, the process of harmonisation of legislation in Bosnia and Herzegovina hasn't started yet. As an outcome of the project "Strengthening of the B&H health systems for EU integrations" (referred to above) the document on legal harmonisation was produced and it will be further analysed by a working group established by MoCA which will then identify priorities in accordance with Plan of action for harmonisation of B&H legislation with *acquis communautaire*. Having been introduced with the experience of neighbouring countries that have passed through this process recently and based on existing capacity of health ministries, Bosnia and Herzegovina will certainly need technical support to accomplish such a complex task in the field of approximation of relevant legislation with EU directives.

### **3.2 Assessment of project impact, catalytic effect, sustainability and cross border impact**

Population of Bosnia and Herzegovina will have more benefits if the Project results are achieved as planned. Project will certainly contribute to ongoing health sector reform having catalytic effects to reducing public expenditures. It will enable equal access to health care and better health care quality.

The successful establishment of the Pharmaceutical Agency will ensure that the single market for pharmaceuticals and medical devices, and their availability in the territory of Bosnia and Herzegovina, is properly monitored and enforced. The Agency will protect and promote health by ensuring safe and efficient pharmaceuticals and medical devices of appropriate quality are available to be used in human medicine and to establish functional, co-ordinated and common regulatory system of drugs and medical devices. By implementing its numerous functions, the Agency will directly contribute to the improved health of BH citizens and to progress leading to a single economic space in Bosnia and Herzegovina, which supports free movement of goods, capitals, services and persons.

The introduction of new provider payment mechanisms will increase the efficiency of public expenditure on health.

As regard to Public Health, the Project will ensure preparation of elements for evidence-based planning. Through staff training in public health institutes and relevant ministries, better-planned future actions will be allowed and preventive and promotional activities in health field will be improved. Thus it will help to reduce total population morbidity in B&H and to achieve better health status of population also bringing benefit to B&H economy.

Strengthening institutional capacities in the field of public health, which was planned to start through IPA 2007, will require certain organisational structure and management improvements to be done within PHIs. It will enable better coordination, planning and governance in the sector as a key element for ensuring equity and equal access to health care services. Project will help B&H to fulfil its commitments in regard to collection of statistics data and reporting on health-related data to international organisations.

Introduction of DRG mechanism will positively impact B&H economy contributing to more economic health system financing. Indirect impact will be reflected in reducing investment to secondary health care that will enable better financing the primary health care, which is cheaper and need to be strengthened, as it was not practice so far. In long-term DRG mechanism will contribute to more efficient hospital network since it will indicate their efficiency or capacity utilization.



B&H health legislation will be approximated in line with EU standards. A set of health laws and bylaws will be harmonized with EU directives according to B&H Action Plan.

### **3.3 Results and measurable indicators:**

#### Results and measurable indicators in relation to Activity 1

##### Results

- 1.1 Relevant Agency staff trained according to the best EU practice.
- 1.2 Relevant bylaws and other legal acts arising from the Law on Pharmaceuticals and Medicinal Devices drafted in line with EU legislation
- 1.3 Appropriate structure of the Agency developed within all its units (description of their tasks, organization if needed, certification and implementation of ISO standards requirements for both laboratories drug control and pfarmacovigilanca, fulfilment of all requirements from OMCL network and strengthening of role within OMCL networks etc.)

##### Measurable indicators

- 1.1 Key expert staff (40) from all Agency's units (Pharmaceutical Agency, Control Laboratory and Pfarmacovigilanca) trained.
- 1.2 Set of B&H Pharmaceutical Agency bylaws relevant for drugs import, marketing authorisations, authorisations for clinical trials of pharmaceuticals, monitors adverse reaction of pharmaceuticals etc. published in B&H Official Gazette.
- 1.3 Recommendations report drafted including all elements of further Agency's development.
- 1.4 Laboratories operate in accordance with ISO standards.

#### Results and measurable indicators in relation to Activity 2

##### Results

- 2.1 Analysis and Plan of further extension of AR-DRG provider payment mechanisms approved by Ministerial Health Conference of B&H.
- 2.2 New provider payment mechanisms in territory of Bosnia and Herzegovina developed.
- 2.3 Strategy for electronic health in Federation of Bosnia and Herzegovina that includes overview of current status and need for introduction of hospital information system and electronic health card drafted.

##### Measurable indicators

- 2.1. The number of hospitals in B&H introduced AR-DRG system of classification
- 2.2. Draft strategy prepared and adopted by Federal Ministry of Health

#### Results and measurable indicators in relation to Activity 3

##### Results

- 3.1 Bosnia and Herzegovina as a State ready for membership in public health networks and for appropriate reporting to international organisations (EUROSTAT, WHO, ILO etc.)

3.2 Public Health Institutes developed capacity for policy planning and for drafting relevant strategies for entity Ministries of Health (evidence based planning).

3.3 National Health Accounts (NHA) reporting harmonised with EU requirements

3.4 Relevant Health legislation drafted in compliance with EU Directives.

#### Measurable indicators

3.1 B&H reporting obligations towards international institutions/organisations fulfilled.

3.2. Public Health Institutes reporting list of health indicators harmonised with international requirements.

3.2. NHA reporting set completed.

3.3. A set of health laws and bylaws harmonized with EU directives according to B&H Action Plan.

### **3.4 Activities:**

#### Activity 1 (Twinning contract)

1.1 Expert training of the staff from all Agency's units

1.2 Establishing contacts and partnerships with colleagues from other European Agencies /institutions (conducting two study visits x 6 days x 5 persons)

1.3 Agency's staff participation at international events related to pharmacy issues (conferences, workshops)

1.4 Preparation of Recommendation Report for further improvement of Agency's work (human recourse development, infrastructure etc.)

1.5 Designing of legal acts that are deriving from the Law on Pharmaceuticals and Medical Devices.

#### Activity 2 (Technical assistance contract)

2.1.1 Analysis of existing situation and drafting the plan of implementation

2.1.2 Translation of procedures according to International Classification of Diseases (ICD-10) and instructions for coding

2.1.3 Developing the software for analysis of collected data in local level in accordance with AR-DRG licence.

#### Activity 3 (Technical assistance contract)

3.1.1 Defining set of extended indicators

3.1.2 Trained staff in Public Health Institutes implements new set of indicators

3.1.3 Updating relevant protocols in Public Health Institutes

3.1.4 Developing and installation of software for data intake and reporting purposes

3.1.5 Training staff in all relevant institutions to implement preventive and promotional activities in order to reduce incidence of identified diseases

- 3.2.1 Conducting analysis and drafting gap report
- 3.2.2 Training staff on data collection from financial sources
- 3.2.3 Implementation of extended reporting set
- 3.3.1 Establishing the working group for harmonisation of legislation.
- 3.3.2 Assessment of legislation requirements.
- 3.3.3 Drafting revised legislation.

### **3.5 Conditionality and sequencing:**

Crucial precondition for implementation of Specific objective 1 is to have the Law on Pharmaceuticals and Medicinal Devices adopted by B&H Parliament by the end of July 2008. Unless the relevant Law is adopted, the Pharmaceutical Agency will not be established in Bosnia and Herzegovina.

In order to be able to introduce a new system of provider services payment, Bosnia and Herzegovina will have to provide necessary AR-DRG licence. Activities in that regard are being negotiated with the Australian Government and needed licence will be probably purchased through World Bank loan.

Timely implementation of the previously approved project within IPA 2007 that was also aimed to strengthening the Public Health Institutes in Bosnia and Herzegovina will be precondition to follow up improvement of country's reporting functions in regard to EUROSTAT and other relevant international organizations and institutions. Certain components of public health institutes' work foreseen in IPA 2007 project will be further developed and upgraded (for example health indicators list, data flow etc.) in this project to be funded through IPA 2008. Therefore IPA 2008 Project should be considered as a second phase or follow up of IPA 2007 Project.

### **3.6 Linked activities**

#### **EU involvement in the sector**

**PHARE 1999** - Total amount of the budget allocated was EUR 3.7 million. The budget was allocated to the following projects: (a) Technical Assistance in Public and Environmental Health (EUR 1.25 million). Equipment in the amount of EUR 200 000 has been delivered to the PHIs. (b) Technical Assistance in Health Care Reform (EUR 2.45 million). The project was dealing with: (I) Health Care Management (II) Health Financing - (III) Pharmaceuticals sector development.

**CARDS 2001** - EU/WHO TA to Health Care Reform - the amount of EUR 2 million was allocated to health care reform. The project was co-funded by WHO (in the amount of EUR 0.5 million) and completed in September 2006). The assistance was directed towards: (I) Primary Health Care (PHC), (II) Pharmaceutical Sector, (III) Accreditation and Quality Assurance in B&H, and (IV) Public Health.

**CARDS 2003** - Functional Review of the Health Sector, EUR 0.5 million, the project lasted from April to December 2004 and undertook a review of public administration in 56 institutions in the

health sector and produced a set of recommendations for streamlining the public administration. The final report is available at: <http://www.delB&H.cec.eu.int/en/worddocuments/word251.htm>

**CARDS 2005** - Project “Strengthening the B&H Health Care Systems for EU Integration” (total budget EUR 959.897) ended in March 2008. Its specific goals were: (1) to establish Sector for health within MoCA; (2) to strengthen functions at state and entity levels; and (3) to introduce/establish functions at state, entity and institutional levels related to B&H health systems integration to EU. As a result of the Project three working groups were established to deal with specific health issues (Planning of projects in health and utilization of EU funds; Eurostat; and Coordination of EU integration and legal issues) and will continue work under coordination of MoCA.

### **Involvement of International Donors**

The World Bank (WB) has disbursed four operations (credits):

1. ***The War Victim Rehabilitation Project***, (implemented in FB&H only) – ended in 1999. It was aimed to development of the Physical and mental Rehabilitation Centres.
2. ***The Essential Hospital Services*** - completed in 2002. Its main goal was rehabilitation of hospitals in B&H.
3. ***The Basic Health Project*** (US\$ 10 million) - completed in 2004. This project included following activities: support to development of primary health care system, national capacity for managing health care services, in particular family medicine, development of Centres for Health Care Management, contracting in Primary Health Care and public health institutional support and establishment of Accreditation and Quality Assurance Agencies in both Entities; and
4. ***SITAP Project*** (Social Insurance Technical Assistance Project) became effective in 2003, ended in 2007 (US\$ 9.67 million). The project provided technical assistance to the Ministries of Health, Ministries of Labour, Health Insurance Funds, Pension Funds, Tax Administration Agencies and Ministry of Civil Affairs and supported reform of health insurance and pension funds.
5. The World Bank launched a new ***“Health Sector Enhancement Project”*** in autumn 2005 (US\$ 30 million). Project is primarily focused on development of Family Medicine and its implementation in the country. Additionally it is aimed to further development of strategy and policy for care, training of the health professionals, monitoring and evaluation.
6. WB is preparing ***“Avian Influenza Preparedness Project”*** (US\$ 5 million). The overall objective of the Project is to minimize the threat posed to humans and the poultry industry by the Highly Pathogenic Avian Influenza (HPAI) infection and other zoonoses, by enhancing both animal and human health infectious disease response and control capacities.

Canadian CIDA is investing in primary health care through the project ***“Primary Health Care in Balkan”***. The main goals of the project are following: to contribute establishment of primary health care system in Bosnia and Herzegovina to be able to respond efficiently and effectively, that will resulted in population health improved, to create an environment to enable social, economic and political development.

Canadian CIDA is also implementing another project - ***“Strengthening Balkans' Civil Society Voice for Public Health through Public Health Associations”***. This project started in September 2005 and field activities will end in June 2009. With aim to improve the health of people living in

Bosnia & Herzegovina, the Project is focusing on enhancing the capacity of civil society to advocate for and contribute to the strengthening of essential public health functions thus enabling the health care sector to respond timely and effectively to priority health needs of the population.

Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) is investing USD 4,832,385 in two years starting from 1 November 2006 to “Coordinated National Response to HIV/AIDS” Project. The primary goal is to ensure effective and efficient implementation of the “*Coordinated National Response to HIV/AIDS & Tuberculosis in a War-torn and Highly Stigmatized Settings*” programme implemented by UNDP as the Principal Recipient nominated by the Country Coordination Mechanism (CCM).

UNICEF – There are four projects relevant to health currently implemented within its Programme Cycle 2005-2008, as follow: **Standards and Regulatory Frames of the Project «Health in Early Childhood»** and Project **«Health and Grow in Early Childhood»**, both related to children immunization, as well as **«The HIV/AIDS Standards and Regulatory Frameworks»** and **«The HIV/AIDS Prevention»**. The aim of these projects is to enhance or to improve capacities for development and implementation of bio-behaviour resources, specific health data needed for planning, monitoring and evaluation, etc. These projects involve the MoCA and the entity Ministries for Health and PHIs as partners in their implementation.

### **3.7 Lessons learned**

With aim to achieve the best results of the project as planned, it is necessary to ensure coordination and cooperation of all relevant stakeholders which should be included in all project phases – from its preparation, implementation and evaluation.

When drafting this project we have tried to take into consideration effects and experience of previous projects, especially ones referred to health sector reform process. Having been aware of necessity of reform process continuity we planned the activities to be implemented through this project should be considered as an upgrade of achievements of previous projects (for example SITAP, Strengthening the B&H Health Care Systems for EU Integration, IPA 2007 – Strengthening the Public Health Institutes in Bosnia and Herzegovina – as a first phase of the IPA 2008 Project etc.) accomplished by the EC and other international organizations to achieve the best results as possible.

Since the WB is continuously investing in health sector in B&H there is a need to act in a complementary manner to the activities supported by the WB and to build upon their achievements . It is very difficult to implemented complex projects, such as SITAP, dealing with the social sector in the broader sense (health insurance, pensions, safety nets, hospital network etc.) since many different partners coming from different sectors are needed to implement them in a country with such a fragmented system. Absorption capacity of local counterparts can be a limiting factor as well. In order to avoid this problem the set of project activities is drafted in a straightforward manner in order to get tangible results.

Attempts to implement top down projects in public health (EC funded PHARE project for reform of public health, Basic Health Project funded by WB) do not give some sustainable results if they are not accompanied with some grassroots activities. The approach as suggested in this PF should give more sustainable results since the activities are going in both directions.

We have also taken into account existing local experts and envisaged their maximal inclusion into this project's implementation, especially in its component related to introduction of DRG provider payment mechanism. Local experts should be included adequately in project supervision and monitoring.

Monitoring of project implementation, consideration and adoption of its final report should be committed to B&H Ministerial Health Conference, which was established as a permanent advisory and coordinating body in the country for this important field. Such a practice has shown good results and proven as justified in previous health related projects implemented in Bosnia and Herzegovina and funded by European Union/ European Commission.

#### 4. Indicative Budget (amounts in EUR)

			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)
<b>Activity 1</b> <b>To assist the B&amp;H Pharmaceutical Agency</b>	X		<b>525,000</b>	<b>500,000</b>	<b>95.24</b>	25,000	4.76	25,000				
Contract 1.1 Twinning Contract	-	-	525,000	500,000	95.24	25,000	4.76	25,000				-
<b>Activity 2</b> <b>To implement a system of new provider payment mechanisms and to draft Strategy for Electronic Health</b>	X		<b>1,100,000</b>	<b>1,100,000</b>	<b>100</b>							
Contract 2 Technical assistance Provider payment mechanisms	-	-	1,100,000	1,100,000	100							-
<b>Activity 3</b> <b>To improve Public Health Services and to harmonize relevant legislation</b>	X		<b>1,250,000</b>	<b>1,250,000</b>	<b>100</b>							
Contract 3.1 Technical assistance Public Health services, National Health Account, Harmonization of health legislation	-	-	1,250,000	1,250,000	100							
TOTAL IB			2,875,000	2,850,000	99.13	25,000	0.87	25,000				
TOTAL INV												
<b>TOTAL PROJECT</b>			<b>2,875,000</b>	<b>2,850,000</b>	<b>99.13</b>	<b>25,000</b>	<b>0.87</b>	<b>25,000</b>				

Amounts net of VAT

(1) In the Activity row use "X" 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	1st quarter 2009	4 <sup>th</sup> quarter 2009	4 <sup>th</sup> quarter 2010
Contract 2	1st quarter 2009	4 <sup>th</sup> quarter 2009	4 <sup>th</sup> quarter 2011
Contract 3	1st quarter 2009	4 <sup>th</sup> quarter 2009	3 <sup>rd</sup> quarter 2011

## 6. Cross cutting issues

### 6.1 Equal Opportunity

The Project activities will cover the needs of all relevant population groups without any kind of discrimination. It will pay special attention in addressing gender equity. It will contribute to equal access to medical services all over the country and in all regions, by getting all relevant data about health of population. Based on the results of the Project the Ministries will be able to plan medical service according the real needs of population.

### 6.2 Environment

N/A

### 6.3 Minorities

The Project will be implemented in both entities and cover needs of all citizens of Bosnia and Herzegovina including minorities. System established through new approach should enable the state and entities to measure inequities in health, reduce existing gaps and assure equal opportunities of all B&H citizens to health.

## ANNEXES:

- ANNEX I. Logical framework matrix in standard format
- ANNEX II. Amounts (in EUR) Contracted and disbursed by quarter for the project
- ANNEX III. Reference to laws, regulations and strategic documents:
- ANNEX IV. Details per EU funded contract



## ANNEX I. Logical framework matrix in standard format

<b>LOGFRAME PLANNING MATRIX for Project Fiche</b>	<b>Programme name and number:</b> Support for the Development of the Health Care Systems in Bosnia and Herzegovina  CRIS No:2008/20-339		
<b>Support for the Development of the Health Care Systems in Bosnia and Herzegovina</b>	<b>Contracting period expires:</b> N+2		Disbursement period expires: N+5
	<b>Total budget:</b> 2,875,000 EUR		<b>IPA budget:</b> 2,850,000 EUR
<b>Overall objective</b>	<b>Objectively verifiable indicators</b>	<b>Sources of Verification</b>	
To enhance the efficiency of health care services in Bosnia and Herzegovina	Single internal market of drugs and unique registration procedure for drugs in Bosnia and Herzegovina established AR-DRG system of classification introduced in hospitals throughout B&H B&H prepares annual reports for EUROSTAT and WHO based on extended set of health indicators since 2010 Secondary health care costs reduced	EC Progress Report B&H Pharmaceutical Agency annual reports Annual reports from hospitals and Health Insurance Funds EUROSTAT reports WHO reports B&H Ministerial Health Conference reports	
<b>Project purpose</b>	<b>Objectively verifiable indicators</b>	<b>Sources of Verification</b>	<b>Assumptions</b>
SO1 Assisting the B&H Pharmaceutical Agency in becoming a fully functioning institution in accordance with EU standards;  SO2 Implementing a system of provider payments that would create incentives for cost containment and improve provider performance;  SO3 Improving the quality of data collection and information flow related to the Public Health Services and the harmonisation of relevant legislation in accordance with EU standards and National Health Accounts (NHA).	B&H Pharmaceutical Agency member of the EU network of Pharmaceutical agencies  Provider payment system in place in hospitals in Bosnia and Herzegovina  Protocols on information flow introduced/updated, reporting lines improved. Relevant PHIs staff (250) at all levels trained Health legislation in line with EU Directives/standards.	Annual pharmaceuticals register Register of relevant drug certificates and authorizations issued List of essential drugs  Annual reports from hospitals on types and number services provided Annual financial reports from hospitals  Public Health Institutes (PHIs) protocols and annual reports EUROSTAT/WHO reports B&H Action Plan for harmonization of legislative with EU directives	Law on Pharmaceuticals and Medicinal Devices of B&H adopted by the end of July 2008.
<b>Results</b>	<b>Objectively verifiable indicators</b>	<b>Sources of Verification</b>	<b>Assumptions</b>

R 1.1 Relevant Agency's staff trained according to the best EU practice.	Key expert staff (40) from all Agency units (Pharmaceutical Agency, Control Laboratory and Pfarmacovigilanca) trained.	Training agenda, list of participants at workshops and seminars	Enough number of trained expert staff to cover all organizational units of Agency
R 1.2 Relevant bylaws and other legal acts arising from the Law on Pharmaceuticals and Medical Devices drafted in line with EU legislation	Set of B&H Pharmaceutical Agency bylaws relevant for drugs import, marketing authorisations, authorisations for clinical trials of pharmaceuticals, monitors adverse reaction of pharmaceuticals etc. published in B&H Official Gazette.	B&H Official Gazette	Registers of certificates and authorizations established and run in accordance with bylaws.
R 1.3 Appropriate structure of the Agency developed within all its units (description of their tasks, organization if needed, certification and implementation of ISO standards requirements for both laboratories drug control and pfarmacovigilanca, fulfilment of all requirements from OMCL network and strengthening role within OMCL networks etc.)	Recommendations report drafted including all elements of further Agency's development. Laboratories operate in accordance with ISO standards.	B&H Pharmaceutical Agency report Specification of laboratory equipment OMCL certificate OMCL network's report/database	Budget funds for implementation of project recommendations provided.  All relevant stakeholders engaged.
R 2.1 Analysis and Plan of further extension of AR-DRG provider payment mechanisms approved by Health Conference in B&H.	Health Conference in B&H conclusion made	Analysis and Plan of further extension of AR-DRG	Existing entity legislation on secondary health care services payment changed. Existing local trained staff engaged.
R2.2 New provider payment mechanisms in territory of Bosnia and Herzegovina developed	The number of hospitals in B&H introduced AR-DRG system of classification	Copy of contracts concluded between hospitals and entity health insurance funds	Federal Strategy for Electronic Health compatible with one existing in Republika Srpska.
R 2.3 Strategy for electronic health in Federation of Bosnia and Herzegovina that includes overview of current status and need for introduction of hospital information system and electronic health card drafted	Draft strategy prepared and adopted by Federal Ministry of Health	Strategy for Electronic Health of Federal Ministry of Health.	Basic IT equipment exists.
R 3.1 Bosnia and Herzegovina as a State ready for membership in public health networks and for appropriate reporting to international organisations (EUROSTAT, WHO, ILO etc.)	B&H reporting obligations towards international institutions/ organisations regularly fulfilled	List of indicators PHIs reports MoCA report Eurostat and WHO reports	Cooperation between MoCA, MoHs and State Agency for Statistics well functioning.
R3.2 Public Health Institutes developed capacity for policy planning and drafting relevant strategies for entity Ministries of Health (evidence based planning)	Public Health Institutes reporting list of health indicators harmonised with international		Good cooperation between relevant stakeholders at state and

<p>R 3.2 National Health Accounts (NHA) reporting harmonized with EU requirements</p> <p>R 3.3 Relevant health legislation drafted in compliance with EU Directives</p>	<p>requirements.</p> <p>NHA reporting set completed.</p> <p>A set of health laws and bylaws harmonized with EU directives according to B&amp;H Action Plan.</p>	<p>Eurostat reports</p> <p>B&amp;H NHA report</p> <p>Health legislation published in B&amp;H Official Gazette</p>	<p>entity level exists.</p>
<b>Activities</b>	<b>Means</b>	<b>Costs</b>	<b>Assumptions</b>
<p><b><u>Activity 1</u></b></p> <p>1.1 Expert training of the staff from all Agency units</p> <p>1.2 Establishing contacts and partnerships with colleagues from other European agencies/institutions (conducting two study visits x 6 days x 5 persons).</p> <p>1.3 Agency staff's participation at international events related to pharmacy issues (conferences, workshops)</p> <p>1.4 Preparation of Recommendation Report for further improvement of Agency's work (human recourse development, infrastructure etc.)</p> <p>1.5 Designing of legal acts that are arising/deriving from the Law on Pharmaceuticals and Medical Devices.</p> <p><b><u>Activity 2.</u></b></p> <p>2. 1 Analysis of existing situation and drafting the plan of implementation</p> <p>2.2. Translation of procedures according to International Classification of Diseases (ICD-10) and instructions for coding</p> <p>2. 3 Developing the software for analysis of collected data in local level in accordance with AR-DRG licence.</p>	<p>Twinning contract</p> <p>Technical assistance contract</p>	<p>500,000EUR</p> <p>1,100,000 EUR</p>	

<p><b>Activity 3</b></p> <p>3.1.1 Defining the set of extended indicators</p> <p>3.1.2 Trained staff in Public Health Institutes implements new set of indicators</p> <p>3.1.3 Updating relevant protocols in Public Health Institutes</p> <p>3.1.4 Developing and installation of software for data intake and reporting purposes</p> <p>3.1.5 Training the staff in relevant institutions to implement preventive and promotional activities in order to reduce incidence of identified diseases.</p> <p>3.2.1 Conducting analysis and drafting gap report</p> <p>3.2.2 Training the staff on data collection from financial sources</p> <p>3.3.3 Implementation of extended reporting set</p> <p>3.3.1 Establishing the working group for harmonisation of legislation</p> <p>3.3.2 Assessment of legislation requirements</p> <p>3.3.3 Drafting revised legislation</p>	<p>Technical assistance contract</p>	<p>1,250,000 EUR</p>	
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(1) Law on Pharmaceuticals and Medical Devices of B&H adopted by the end of July 2008; (2) B&H provided AR-DRG licence; (3) IPA 2007 Project in regard to strengthening the PHIs completed as planned.

**ANNEX II. Amounts (in EUR) Contracted and disbursed by quarter for the project**

<b>Contracted (6)</b>	1 <sup>st</sup> quarter 2009	2 <sup>nd</sup> quarter 2009	3 <sup>rd</sup> quarter 2009	4 <sup>th</sup> quarter 2009	1 <sup>st</sup> quarter 2010	2 <sup>nd</sup> quarter 2010	3 <sup>rd</sup> quarter 2010	4 <sup>th</sup> quarter 2010	1 <sup>st</sup> quarter 2011	2 <sup>nd</sup> quarter 2011	3 <sup>rd</sup> quarter 2011	4 <sup>th</sup> quarter 2011	1 <sup>st</sup> quarter 2012
Contract 1				500,000									
Contract 2				1,100,000									
Contract 3				1,250,000									
<b>Cumulated</b>			<b>0</b>	<b>2,850,000</b>									
<b>Disbursed</b>													
Contract 1				400,000				50,000	50,000				
Contract 2				220,000		192,500		192,500		192,500		192,500	110,000
Contract 3				375,000		250,000		250,000		250,000	125,000		
<b>Cumulated</b>			<b>0</b>	<b>995,000</b>	<b>995,000</b>	<b>1,437,500</b>	<b>1,437,500</b>	<b>1,930,000</b>	<b>1,980,000</b>	<b>2,422,500</b>	<b>2,547,500</b>	<b>2,740,000</b>	<b>2,850,000</b>

### **ANNEX III. Reference to laws, regulations and strategic documents:**

Reference list of relevant laws and regulations

#### Bosnia and Herzegovina

- B&H Council of Ministers - Decision on establishment of working groups for the purpose of harmonization of B&H legislation with *acquis communautaire* (“Official Gazette B&H”, No 5/03)
- B&H Council of Ministers - Instruction on drafting method and adoption procedure for technical rules (“Official Gazette B&H”, No 35/06)
- B&H Council of Ministers – Program for takeover the technical regulations (“Official Gazette B&H”, No 35/06)
- Action plan for implementation of Program for takeover the technical regulations (“Official Gazette B&H”, No 89/06)

Reference to AP /NPAA / EP / SAA

STABILISATION AND ASSOCIATION AGREEMENT between the European Communities and their Member States, of the one part, and Bosnia and Herzegovina, of the other part, TITLE VIII - COOPERATION POLICIES, **Article 88, Statistical co-operation:** *“Co-operation between the Parties shall primarily focus on priority areas related to the Community acquis in the field of statistics. It shall notably be aimed at developing efficient and sustainable statistical systems capable of providing comparable, reliable, objective and accurate data needed to plan and monitor the process of transition and reform in Bosnia and Herzegovina. It should also enable the state Agency for Statistics of Bosnia and Herzegovina as well as the entity Statistical Offices to better meet the needs of their national and international customers (both public administration and private sector). The statistical system should respect the fundamental principles of statistics issued by the UN, the European Statistical Code of Practice and the stipulations of the European Statistical law and develop towards the Community acquis.”* and its CHAPTER V - GENERAL PROVISIONS, **Article 63:** *“1.The provisions of this Title shall be applied subject to limitations justified on grounds of public policy, public security or public health. 2.They shall not apply to activities that in the territory of any of the Parties are connected, even occasionally, with the exercise of official authority.”*

Reference to MIPD

Reference to National Development Plan

Reference to national / sectoral investment plans

#### **“EU Integration Strategy of Bosnia and Herzegovina”**

##### Section 1.3 Principles the EU is based on

Relationship between the EU and its member states is based on the principle of fair cooperation and respect of equality of all member states. Competences and cooperation between the EU and member states includes as follows:

- sole competence: customs union, competition regulations, monetary policy, preservation of marine-biology resources, common trade policy, international treaties related to common regulations;
- common competence: social policy, economic, social and territorial cohesion, agriculture, environment, consumer protection, transport, energy, security and justice, public health safety, research and technological development;
- complementary activities; health protection and improvement, industry, culture, tourism, education, youth, sports, civil protection, administrative cooperation, employment policy.

### **Bosnia and Herzegovina 2007 Progress Report**

#### *European standards, Internal market, Employment and social policies*

“The *public health* system in Bosnia and Herzegovina consists of 18 public health institutes at Entity, cantonal and regional level. The capacity of these institutes varies but the system falls short to guarantee appropriate health care to citizens - even if it consumes a very significant part of the country's budget. There is a clear need to improve coordination and governance in the sector as a key element in improving equity and equal access to health care services. Collection of statistics and reporting of health-related data to international organisations needs also to improve. Initial steps to address these issues have been taken by the State-level Ministry of Civil Affairs through the establishment of a new Department of Health.

As regards health protection, limited progress has been made as regards establishing the legal framework and administrative capacity that is in line with EU policy. A regular conference of health ministers of Bosnia and Herzegovina, which will act as a permanent advisory and coordinating body in the country, has been established. Further progress is necessary in the implementation of international commitments in health, in particular the WHO Framework Convention on Tobacco Control (FCTC) and the International Health Regulations (IHR).”

## **ANNEX IV. Details per EU funded contract**

### ***Twinning covenant:***

#### **Contract 1**

- To organise expert training of relevant Agency's staff (workshops, seminars)
- To organise study visits for Agency's staff (2 study visits x 6 days x 5 persons)
- To arrange participation of Agency's staff at international conferences and workshops
- To prepare Recommendation Report
- To draft relevant legislation (bylaws)

### ***Technical assistance contracts***

#### **Contract 2.**

- To conduct analysis and prepare gap report (inception report)
- To prepare Plan of AR-DRG implementation
- To organise translation of Procedures according to ICD-10 and instructions for coding
- To organise training of relevant staff for coding (workshops, seminars)
- To develop appropriate software in accordance with AR-DRG

#### **Contract 3**

- To conduct analysis and prepare inception report
- To define extended list of indicators
- To organise training for PHIs staff (workshops, seminars)
- To update relevant PHIs documents (protocols)
- To develop and install software for data intake and reporting purposes
- To establish working group to harmonise relevant B&H legislation with EU