

**TECHNICAL ASSISTANCE ON
PRICING AND REIMBURSEMENT POLICY
OF PHARMACEUTICALS IN MACEDONIA**

INCEPTION REPORT

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Introduction

The objective of the assignment according to the Terms of Reference (ToR) is to provide technical support to the Ministry of Health, Health Insurance Fund and the Bureau of drugs, working with the national experts in defining the prices of drugs on the level of “unified prices” and reimbursement policy on the level of “reference prices” of drugs.

The consultancy should cover several important aspects:

- To draft/develop methodology for calculation of prices of drugs on the level of “unified prices” and reimbursement level for “reference prices”
- To advise on reference countries model which should be used for comparison when defined comparative prices
- To advise on defining methodologies in calculation of comparative prices
- To advise methodologies when calculating “reference prices” of reimbursable drugs
- To estimate financial expenditures in accordance to the suggested methodology (financial simulation on expenditures for the Positive list of drugs (PLD), reimbursement fiscal analysis on yearly basis)
- To advise in adjustment of prices in accordance with the suggested methodology
- To advise the system for regular adjustment of the pricing and reimbursement methodology
- To advise options for sustainability of the pricing policy (“unified prices” and “reference prices”)
- To envisage possible obstacles and ways to their overcome in line with legal provisions and EU Directives.

This is the Inception Report after the 1st in-country visit end of July 2009.

First in-country visit

Previous analysis of the current pricing models in place in Macedonia was performed. Analysis concerned reviewing the existing system of prices of drugs, especially “reference prices” defined by the Health Insurance Fund (HIF) and “unified prices” defined by the Bureau for Drugs.

First in-country visit was organised 28.-31. of July 2009. Main objective of this visit was to make brief analysis of the current situation regarding pricing practices and to discuss legal, political and technical possibilities and options for implementation of pricing policy in Macedonia.

In accordance to the ToR, several major issues, in line with pricing practices were discussed:

- current situation with the legal framework and legal provisions for Positive list of drugs: Law on health insurance, Law on health protection, Law on medicines and medical devices,
- current situation with existing Regulations and related by-laws,
- current situation with the Positive list of drugs (PLD), list of drugs financially covered by the HIF,
- current situation with the List of reference prices (LRP), list of prices of drugs financially covered by the HIF,
- current situation regarding expenditures on drugs financially covered by the HIF (PLD drugs)
- current situation regarding participation in cost of the reimbursement drugs (cost share, participation, co-payment) of insures

The activities during the first in-country visit were organised later, but connected in professional manner and in line with the previous consultancy activities of Dr. Koblar and Dr. Primožic, who will work on establishment of Drug Agency and legal aspects of the pricing policy.

During this brief visit, several meetings with the major stakeholders were organized by Prof. Dr. Zora Uzunovska from the Ministry of Health:

- Meeting Prof. Dr. Vladimir Popovski, Deputy Minister of Health and Principle Project co-ordinator of the Health Sector Management Project (HSMP),
- Meeting Mr. Janez Jelnikar and Mr. Georgi Trenkovski, Directors of the HIF,
- Meeting the Working group (WG) on co-ordination of the consultancy on pricing policy (MOH),
- Meeting the Working group (WG) on reference prices (HIF),
- Meeting the Pharmaceutical department of the HIF,
- Meeting Mrs. Mejrem Haxihamza, President of the Committee of the selection of the PLD.

The purpose of the meetings was to get acquainted with the current situation of the pricing practices, problems faced and different obstacles in implementation. Defined main concerns in implementation should enable understanding the possibilities for improving pricing practices relevant to the needs of the country.

Deputy Minister of health, Prof. Dr. Popovski expressed his full support to the project activities. Especially he was interested in relevant transparency of the process and development of fully transparent system, where all involved parties (MOH/Bureau of Drugs and the HIF) should collaborate and share information and responsibility.

Dr. Popovski expressed interest about the plan and the content of the project on introduction of reference prices of drugs and expected benefits for the health care system of Macedonia, as well as for the financial projections of expected changes which will occur after defining the levels of reference pricing (levels of referral).

Directors of the FZOM Mr. Jelnikar and Mr. Trenkovski, were very helpful in providing information regarding the legal aspects (current legislation in use), regulations (by-laws) and existing practices of pricing for reimbursable drugs (drugs from the PLD, financially covered by the HIF). Also, Mr. Jelnikar stressed the urgent need for developing of a nation wide system on drug pricing. It was pointed out, that revision of the current List of reference prices should be done asap, in line with the recent development in pharmaceutical sector, but still following the global economic recession and its influence on national economy.

The WG on co-ordination of the consultancy on pricing policy (MOH) was informed about different aspect in implementing pricing policy in country, especially regarding reference prices of drugs and the need of defining transparent and adequate methodology for pricing. Information was shared by the members of the WG and they all strongly supported the need of transparency in the processes of pricing (legal aspects, co-ordination of the work, transparent methodology). It was clearly stated that strong coordination, collaboration, share of information and expertise between the two leading institutions (MOH/Bureau for Drugs and the HIF) is required.

The WG on reference prices within the HIF was very helpful in providing in depth information: all recent developments in drug selection (defining the PLD), pricing in line of unified prices (MOH/Bureau for drugs), legislation and regulations, prescribing practices in PHC, issues concerning drug use in hospitals, drug consumption (data from the HIF), expensive drugs and other relevant issues.

Special emphasis was placed on the existing methodology for defining reference prices according to the Regulation on defining criteria and procedures for classification of reference prices (Official Gazette 8/2008), as well as the mechanisms of categorization of the co-payment or participation of ensures in the overall price of drug.

For both WGs (MOH and HIF) presentation on detailed planned project activities regarding implementation of reference prices in Macedonia was made. In the introduction, major factors for increasing costs of drugs and most common P&R mechanisms (measures) for regulation of expenditures, as well as major objectives in placing system of reference prices were stressed. Further on, plan on project activities was discussed, regarding separate phases and elaboration of needed activities in each phase separately. With the WG of the HIF the patterns and preparation of needed information and data for the second visit were agreed, relevant for preparation of the solid basis for implementation of reference prices.

Pharmaceutical department of the HIF explained all difficulties and obstacles they are facing in pricing practices. Also, all other relevant information regarding LRP and reimbursement practices were stressed.

Mrs. Mejrem Haxihamza, President of the Committee of the selection of the PLD briefly explained the process of drug selection in the country. She was very helpful in drawing the difficulties in selection process and again, pointed out the fragmentation of the process.

Analysis of the current situation and key remarks

After this first in-country mission and discussion with relevant stakeholders and national experts and professionals, several remarks as key issues are relevant:

1. There is existing legal frame on pricing (Law on health insurance) and accompanying by-law. It is still needed to define (on a national basis) the scope of covering and implementing pricing policy for reimbursable drugs.
2. PLD is defined by a National Committee and members of the Committee are relevant experts from the pharmaceuticals sector nominated by the Minister of health. It is practice to have most of the members as clinicians with experience, as well as representatives from the HIF.
3. The process of drug selection is fragmented, not coherent, but in line with the existing documents.
4. It is needed to draw a transparent, clear and understandable methodology on reference prices, taking into consideration the needs of the country and current situation.
5. There are existing practices on pricing used, where unified prices are helpful mechanism in defining the “ceiling” prices of drugs on national level. Reference pricing should be developed in line with the unified prices for reimbursable drugs (covered financially by the HIF).
6. Within the PLD (RPL), there should be corresponding (matching, analogue) prices ratio of different concentration and packages, e.g. corresponding prices ratio of comparative drugs from different suppliers.
7. There is a need to perform detailed analysis on drug expenditure in line with the PLD, oversee the possibilities for savings and perform estimations of impact of the implemented measures.

Future activities

1. During the at-home work between 1st and 2nd in- country visit, detailed **situation analysis** of the existing system in the country, referring on existing/current legislation framework, possibilities and strengths and weaknesses of the system for pricing of drugs in place on a national level will be made.
2. During the second visit and in accordance with the detailed situation analysis of the existing system in the country, including relevant documents and existing **data on prices of drugs**, concrete proposal for changing of the existing legal framework, updating of the medical background for implementation of therapeutic groups of drugs and analysis of the financial data on drug expenditures in Macedonia will be made.
3. After the second in-country visit, in accordance to the relevant and available data, **methodology for implementation** of a national pricing policy (as a system for pricing of drugs on different levels) should be described as well as analysis of the **methodology for defining of reference pricing system** (model for pricing & reimbursement).

4. During third in-country visit **methodology for defining of reference pricing system** (model for pricing & reimbursement) will be defined and proposed. Development of model methodology relevant to the national needs will be drafted, in line with development of appropriate (accompanying) regulation, as a **by-law document**. In line with the proposed Regulation, tables of therapeutic groups with proposed reference prices will be made.
5. Fourth in-country visit should (in accordance to the developed methodology) be followed with financial **estimation-fiscal projection** of planned costs for reimbursable drugs and further on, according to the analysis of cost-estimations, **fine tuning of methodology** should be performed (when needed and where needed).
6. Fifth in-country visit will include approaching the **relevance of the developed methodology**, where proposed methodology which has been tested through financial simulation should be **further discussed** with national authorities. Comments, suggestions and recommendations should be validated and incorporated within the methodology, depending on the national needs and requirements. Other relevant experiences should be taken into consideration (other countries in the Region, EU experiences and recommendations).
7. Fifth in country visit will be in November 2009, including organization of a workshop/seminar on specific issues of pricing and reimbursement policy and systems. Relevant comments from participants at the workshop will be included in the Draft Final Report and will be sent to the WG after fifth in country visit as a part of the Draft Final Report.
8. Sixth in-country visit will consider the **sustainability of the system** with precise advising on the development of a sustainable system for a pricing policy of the country (national level, P&R level); advice on monitoring and evaluation of the reference pricing & reimbursement system; advice on needs for adjustment of the prices based on regulations in place.