

FINAL REPORT

TECHNICAL ASSISTANCE ON PRICING AND REIMBURSEMENT POLICY OF PHARMACEUTICALS IN MACEDONIA

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Introduction

This document is the Final Report from consultancy, after the finalization of the assignment objectives, distribution and acceptance of the Draft Final Report in December 2009 and starting the implementation of the proposed model as of 1st of May 2010.

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 covered 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
- 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 advice options for sustainability of the pricing policy
- To envisage possible obstacles and ways to their overcome in line with legal provisions and EU Directives.

Structure and organization of performed activities

The Report is result of six in-country visits and discussions at two workshops with the relevant stakeholders, including authorities (Ministry of Health, Health Insurance Fund, Bureau for Drugs), professional society (Faculty, Chambers, Associations) and pharmaceutical industry. Activities during the six in-country visits are described in details (see *Draft Final Report, December 2009*).

1. First in-country visit was organised from 28-31 of July 2009. Main objective of this visit was to make brief situation analysis regarding pricing practices and to discuss legal, political and technical possibilities and options for implementation of pricing policy in Macedonia.
2. Second in-country visit was organised from 28-31 of September 2009. Main objective of this visit was in accordance with the detailed situation analysis of the existing system in the country, including relevant documents and existing data on prices of drugs, to discuss in details proposal for changing of the existing legal framework, update the medical background for implementation of therapeutic groups of drugs and analyse the financial data on drug expenditures in Macedonia.
3. Third in-country visit was organised from 19-23 of October 2009. Main objective of this visit was to propose specific methodology for defining of reference pricing system (model for pricing & reimbursement). Development of model methodology relevant to the national needs was drafted, in line with development of appropriate (accompanying) regulation, as a by-law document.
4. Fourth in-country visit was organised from 8-13 of November 2009. Main objective of this visit was to perform financial estimation-fiscal projection of planned costs for reimbursable drugs and further on, according to the analysis of cost-estimations, fine tuning of methodology (when needed and where needed). New draft Regulation was proposed, in line with the legal framework, current situation and the needs of the country.
5. Fifth in-country visit was organised from 14-18 of December 2009. Main objective of this visit was to discuss further on with national authorities the relevance of the developed methodology and its testing through financial simulation. Comments, suggestions and recommendations were validated and incorporated within the methodology, depending on the national needs and requirements. The Regulation for reference prices was adjusted and presented for comments and further adaptation.
6. Sixth visit was organized from 19-22 March 2010. Main objective of this visit was to analyze received comments from producers on proposed reference prices in accordance with the Regulation adopted. During this visit the final proposal of the list of drugs with reference prices was defined, after receiving anticipated comments (statements) and implementation of the needed adjustments.

Every follow-up in-country visit was step ahead aiming in establishment of a system which should in best possible way enhance access to drugs of the population, without major destabilisation of the supply policies in place.

During the project implementation activities and in accordance with 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 (Law on drugs),
- 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 insurees

The purpose of meetings organized was to get acquainted with the current situation of the pricing practices, problems and different obstacles in implementation and to discuss and propose solutions for improving pricing practices relevant to the needs of the country.

Ministry of Health high officials expressed their full support to the project activities. Emphasis was placed in adequate transparency of the process itself and development of fully transparent system, where all involved parties (MOH/Bureau of Drugs and the HIF) should collaborate and share information and responsibility.

HIF high officials provided 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). It was pointed out the need for revision of the current List of reference prices, in line with the recent developments in pharmaceutical sector.

The WG on co-ordination of the consultancy on pricing policy (WG/MOH) was informed in details about different aspects in implementing pricing policy in country, especially regarding reference prices of drugs and the need of defining transparent and adequate methodology for pricing. Members of the WG strongly supported the need of transparency in the processes of pricing & reimbursement.

The WG on reference prices within the HIF (WG/HIF) provided detailed information: all issues regarding 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 insurees in the overall price of drug.

During each visit, for both WGs presentations on detailed planned project activities regarding implementation of reference prices in Macedonia were made.

Pharmaceutical department (Department for drugs) of the HIF actively participated in all phases of development and implementation of project activities.

Meetings with the Minister of Health and the Director of the Bureau for drugs, meetings with the HIF's Directors, meetings with the WG/MOH and WG/HIF, meetings with the Legal department of the HIF, were organized to discuss and argue about the proposed new Regulation on reference prices of drugs and make corrections of (if) any problematic provisions. Therefore, draft proposed Regulation was sent to all mentioned interested parties (stakeholders) of the health sector related with drugs.

Follow up activities were the workshops with producers and professional organizations (chambers, associations, Drug Bureau, Committee for Drugs). Major objective of the workshops was to provide adequate and sufficient information on the processes undertaken, to give detailed description of measures undertaken and to discuss, comment and open the floor for suggestions and experiences for improving the proposed system. At the workshops, detailed analysis of the current situation regarding all three important (major) aspects of drug prices (legal, financial and medical) were discussed; most important issues were stipulated, results of the analyses made were presented, and proposed model for defining drug prices was explained in details. Further on, all comments were discussed and answers were given to the questions set. Presented proposals were reviewed, out of which some were accepted and incorporated within the final proposal Regulation.

Situation analysis and key remarks

With the analysis of the situation based upon adequate information collected and discussion with the 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 regarding the existing documents transparent.
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.

Description of activities undertaken

In brief – why a new system for reference prices?

- Advantages:
 - establishment of pricing and reimbursement system with clear, simple, equal and transparent rules for all
 - establishing an efficient system which enables the national insurance (HIF/state budget/public resources) to pay for:
 - only up to the needed maximum level
 - same for the same therapeutic value
 - not pay the difference in price for the equivalent drug
 - more drugs without co-payment for the patients with less expenditures for the state
- Possibility of choice:
 - for the patients to more drugs without co-payment, or co-payment for the difference in price if patients requires
 - for the drug producers possibility to decrease the price on reference level or additional payment for the difference in price

Findings and system requirements

Regarding the analysis of the existing system, basic requirements and data needed for system development related to price definition are described through the following (contexts):

- Regulation (legal) context
 - Financial context
 - Medical context.
1. Legal context includes all relevant Laws and Regulations important for defining the content of the existing lists of drugs and systems for defining prices of drugs, i.e. authority of specific bodies in defining lists and prices of drugs.
 2. Financial context provides information on drug expenditure (consumption) on national level, including expenditures covered by the basic health insurance and special programmes of the Ministry of Health, as well as consumption distribution and the participation of the insurees in the expenditures.
 3. Medical context involves procedures and scientific basis related to defining the content of drug lists and ways of price formulation for each drug.

The following problems and deficiencies of the system were noticed:

- Inconsistent legal basis among Law on health protection, Law on drugs and Law on health insurance
- Incomplete Positive list of drugs which lacks defined prices of drugs
- Rules for inclusion of drugs on the List of drugs are incomplete (not harmonized with the EU Directive for transparency)
- Clear methodology for calculation of reference prices is not established (mixture of several different methodologies in existing Laws and Regulations)

- Inconsistent ratios of drug prices on prescription (Rp) based on indications and proportion of doses
- Rules for calculation of prices of drugs used in hospitals are not established
- Lack of reliable data on drug expenditures (consumption), especially expenditures in hospitals
- Influence of insureds excluded (released) from co-payment (participation) is not analysed

Definition of problems and deficiencies of the existing system requires the following necessary activities to be performed:

- Shortfalls within the existing legal basis should be specified and corrections should be suggested
- Detailed analysis of the financial data and distribution of the drug consumption (expenditures) should be prepared
- Updated positive list of drugs including all valid prices (unified prices, reference prices) should be prepared
- In accordance with the length of the process, new calculations of prices on level of average (100%) price, according to the wholesale prices in comparative countries, all in line with the legitimate Law on Health Insurance should be initiated
- Coefficients for correction of prices, related to comparative analysis based on ratio GDP/PPP in accordance with the official Law on Health Insurance, should be defined.

Proposed were possible concepts of the model for defining comparative prices, and based on comparative prices - model for defining reference prices. Also, concrete necessary changes have to be made in accordance with the legal provisions and adoption of new Regulation on defining reference prices were proposed. The new Regulation should be rearranged in a way to precise mentioned important issues and stipulates.

Basic definition and description of the proposed model

The model of reference prices consists of two steps of calculation, where the first step is definition of the comparative price and the second step consecutively derives the reference price (based on coefficients calculated and previously agreed) from the comparative price.

1. Comparative prices:
 - Calculation of comparative prices on level of two lowest wholesaler's prices
 - Countries of comparison are: Bulgaria, Serbia, Croatia and Slovenia
 - Precise definition of sources of information: publications, official gazettes, web sites
 - Defined general coefficients for calculation in accordance with the ratio of GDP (PPP) in percentages (%)
2. Reference prices (based on comparative prices):
 - Levels of calculation of comparative prices for three categories of drugs:
 - original or licensed drugs, specific drugs
 - original or licensed drugs, not specific
 - generics

- Establishing rules for defining of reference prices for:
 - original or licensed drugs, specific drugs
 - original or licensed drugs, not specific
 - generics
- Establishing rules for defining of reference prices for:
 - new drugs
 - new generics
- For equivalent prescribing drugs (Rp) define:
 - therapeutic groups
 - reference prices on level of doses (DDD)
- For hospital drugs, comparative price is reference price
- Exclusions, if there are remarks and requests

Proposal (draft) Regulation on reference prices was drafted and basic model of defining new drug prices has been conceptualized (see *Draft Final Report, December 2009*). Regarding the methodology developed and described in the Regulation, following activities were undertaken:

1. Calculation of the final coefficients for defining levels of reference prices
2. Calculation of the ratio of current unified and reference prices compared (in relation) with the average comparative (100%) price in countries of reference
3. Deployment of the model of therapeutic groups and unique price for the group was started

After basic calculations and comparison, the results were as follows:

1. Some of the prices of drugs are over 100%, some even over the level of 300% of the existing (current) reference prices and all those prices are not justified
2. Several prices are below the lowest level of 51.46%, for which there is no logical explanation for such a price
3. Special problem are the reference prices which are lower from the lowest unified price and for which insurees pay additional costs
4. Several prices are not logical and are irrational within therapeutic groups of equivalent drugs, therefore the scope (extent) of the prices for equivalent drugs vary up to ten times

All information mentioned above were used as grass root for the proposal of the final model for calculation of the prices, namely as basis for précising of some provisions of the new Regulation.

Additional analyses of the prices were undertaken, in line with the coefficients, aiming in précising financial implications of the proposed model. Also, additional therapeutic groups (in count) were defined with possible levels of the unique price within the group.

Implementation of the Regulation for reference prices

The Regulation was presented, adjusted and further on accepted by the Managerial Board of the HIF for starting the first phase of implementation of defining drug prices.

First phase of implementation of the Regulation will cover the following:

1. All prices above 100% average comparative price to be placed on this level

2. All prices below the level of unified price and below level of the coefficient 0.5146, to be increased on the level of lowest unified price
3. Rest of the prices (between this two levels) not to be changed at this point of time
4. Several trial models of therapeutic groups to be made and the prices within the group to be identified
5. To publicly announce proposed prices and give a period of 15 days for manufacturers to comment
6. Define the prices of drugs of which the reference price is not announced

After the Regulation was adopted by the Managerial Board of the HIF and control of reference prices calculated was finalized, reference prices were published on the web site of the HIF. This was a starting point for time frame given to producers to comment (declare their statements) on published prices. After receiving of the anticipated comments (statements), analysis of received comments and definition of the final proposal of the list of drugs with reference prices was performed.

HIF has received in total 19 comments (declared statements) from producers. Performed analysis showed that comments, regarding their context could be grouped in the following categories:

- Mistakes in calculation
- Comments regarding unification of the prices by doses
- Changes of the unified price, regarding the decision from the Bureau for Drugs
- Requested exceptions for:
 - age (children)
 - specific indications
- Drugs without published reference price
- Offer to include cheaper generic parallels

Based on the declarations received, 13 producers have been invited for a meeting, aiming in final unification of listed prices, and for six comments, written replies should be send.

Regarding received comments, criteria for defining the final decision, are as follows:

- Problem calculations have been controlled again and all relevant comments due to mistakes in price calculations were accepted and corrections undertaken, where for inappropriate comments additional explanations on calculations were provided
- Comments on unification of the prices on doses were accepted and corrections were undertaken for all producers for the same INN and dose
- Changes of the unified price as per the Decision of the Bureau for Drugs was accepted, but it didn't apply to instant change of the reference price
- Requested exemptions were accepted, regarding:
 - age (children): for syrups as first line of antibiotic treatment, basic neurological drugs, vitamin drops.
 - essential specific drugs in sensitive indications: oncology, transplantation, neuropsychiatry, cardiology, hormones, corticosteroids.
- For drugs without published reference price and submitted farmaco-economic analysis, adequate reference prices were determined within the therapeutic group or in line (in accordance with) the adequate parallel
- All offers for inclusion of cheaper generic parallels, for which there is a Registration (Marketing authorization), have been accepted and included in the List of drugs.

Recommendations

1. LEGAL BACKGROUND TO BE COMPLETED:
 - Drug Agency actively performing registration and control
 - Methodology for defining unified prices developed
 - Procedures for pricing and reimbursement (P&R) adjusted and harmonized with the EU requirements
2. MONITORING OF CONSUMPTION AND EXPENDITURES OF ALL DRUGS FINANCIALLY COVERED BY THE HIF:
 - Regular analysis of the trends on drug consumption and expenditures, and consequently introducing adequate measures, as per changes of the situation
 - Monitoring consumption and expenditures of the expensive hospital drugs and introduction and implementation of additional measures for their rational prescribing
3. DEFINITION OF NEW COMPARATIVE PRICES, INCLUDING HOSPITAL DRUGS:
 - All comparative prices which by calculation are lower than the existing unified prices, to be offered (considered) as reference prices
 - After comments (declarations) to perform negotiations on final prices of hospital drugs
4. ESTABLISH MORE THERAPEUTIC GROUPS FOR PRIMARY HEALTH CARE:
 - It is possible and recommended to establish (define and introduce) new therapeutic groups for PHC prescription drugs
 - Besides rationalization, it is needed for unification of the prices, wherever possible
5. BACKGROUND FOR POSSIBLE ADDITIONAL (SUPPLEMENTARY) HEALTH INSURANCE TO BE PREPARED:
 - Instead of the co-payment model, enable access to policies for supplementary insurance, and introduce social solidarity for drugs with co-payment.