

INCEPTION REPORT

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PROJECT:

TECHNICAL ASSISTANCE FOR THE REGULATION ON PRICING POLICY OF PHARMACEUTICALS IN MACEDONIA

List of abbreviations used in the text:

BMP - Bureau for Medicinal Products
FZOM - Macedonian Health Insurance Fund
INN - International Nonproprietary Name of medicinal products, a synonym for a substance
MKD - Macedonian Denar (currency unit)
MoH - Ministry of Health of the Republic of Macedonia
MP - medicinal product
MPA - Medicinal Products Act
NCA - National Competent Authority for medicines
OTC - non-prescription (over the counter) medicines
PEK - Project Coordination Unit at the MoH
PEK WG - PEK Working Group
PoM - prescription-only medicines
RP - reference price of medicinal product
TA - technical assistance
ToR - Terms of Reference of the Project
UP - uniform price of medicinal product

I. INTRODUCTION

The objective of the assignment according to the Terms of Reference of the Project is to provide technical support to the Ministry of Health, Health Insurance Fund and the Bureau for Medicinal Products, working with the national experts in drafting the regulation on pricing policy for pharmaceuticals in Macedonia.

This inception Report contains analysis of current pricing policies in the relevant Laws derived from the activities of the first in-country visit and relevant other sources. It also contains an outline of the placement of the new regulation in the legal framework defining legal provisions and an outline of the methodology that will be advised in the final report.

In order to achieve the following objectives stated specifically in the ToR:

- to draft the regulation in line with the legal provisions for formulating and implementing pricing policy for pharmaceuticals in Macedonia
- to precisely define methodologies used for this purpose and suggest countries for comparison
- to envisage possible obstacles and ways to their overcome in line with legal provisions and EU Directives,

it is necessary to establish and carry out the proposed work plan and methodology as stated in the technical proposal.

II. 1st IN-COUNTRY VISIT

First in-country visit was organized in July 2009 during the 30th week, after signing the Contract for Consulting Services. Due to their content linkage, the activities during the first in-country visit were connected and simultaneous to the activities of another TA project carried out by the Consultant Dr. Vesna Koblar¹. The two consultants participated together in the activities described in this report and intend to interact appropriately during the continuation of both TA projects.

The aim of the activities during the first in-country visit was to develop an understanding of the existing situation in the pharmaceutical sector, to underline the main concerns and to make a detailed work plan as well as deadlines for achievement of foreseen objectives.

The 1st in-country inception visit was intended principally for the analysis of the current situation in the area of pricing regulation of pharmaceuticals in Macedonia, and to discuss legal, political and technical circumstances and anticipated legal development in Macedonia that may influence the content and structure of the pricing regulation. Dialogue on the preferences on methodologies and key characteristics of the national pricing model in line with international recommendations, as well as on the potential obstacles for the implementation of preferred provisions took place. Identification of principal technical requirements and assets for the realization of the pricing model (e.g. external referencing, price regulation structure, reference country basket etc.), were discussed, as well as the main assets that result of the recent activities undertaken in the area of pricing by the authorities.

Working agenda for the visit was prepared by the representative of the PEK, Prof. d-r. Zora Uzunovska who provided a series of meetings and contacts as follows:

- meeting with the Minister of Health Mr. Bujar Osmani, MD (on Day 1)
- meeting with Mr. Ilčo Zahariev, the Director of the the BMP at the Ministry of Health (meetings on Day 1 and Day 3 of the visit)
- meeting with Mr Janez Jelnikar, the Director of the Health Insurance Fund of RoM and his colleagues,(meetings on Day 1 and Day 3 of the visit)
- meeting with PEK Working Group established in MoH for technical collaboration and professional support (the list of participants is given in the Annex I to this Report)
- meeting with stakeholders of the pharmaceutical sector, consisting of approx 20 representatives of local and foreign manufacturers, wholesalers and pharmacist associations, in the presence of the members of the PEK working group (on day 2 of the visit)
- meeting with the Chairman of the Medicinal Products Pricing Committee Mr. Vančo Kargov

II.1 Description of the undertaken activities

The activities undertaken and main points discussed during the first in-country visit are given in the continuation of this report. Review and analysis of the existing Law, identification of gaps is included in the description of the proceedings of the visit. The activities are described in the sequence in which they were performed.

Event 1: First meeting with Mr. Ilčo Zahariev, the Director of the the BMP at the Ministry of Health (meeting on Day 1 of the visit, the first of two meetings)

¹ TA for Advicing on Establishment of DRA in Macedonia and Legal Aspects of the Regulation on Pricing Policy of Pharmaceutical in Macedonia, Dr Vesna Koblar, The Consultant.

Present: I. Zahariev (IZ), Z. Uzunovska (ZU) , V. Koblar (VK), S. Primožič (SP)

IZ welcomed the consultants. After an exchange of views on the aim of the meeting, IZ presented the consultants with the recent deliverables of the legislative, procedural and technical development at the BMP and provided electronic versions of the legislative texts. He presented the list of uniform/unique prices of pharmaceuticals and demonstrated a sample of a decree resulting from an administrative procedure for determination of price of particular medicinal products, containing in the decision part explicitly determined (in MKD currency units) manufacturer price , wholesaler price and retail pharmacy price as well as the retail pharmacy price with VAT. He described the activities of the BMP and expressed his positions and concerns connected to the aims of the project.

In the discussion it was pointed out that the BMP regulates prices on the three above stated price levels of approx. 2700 medicinal products. The type of price is the uniform price that was installed in the country in February 2008. Uniform price establishes the same price for a particular medicinal product in every pharmacy in the country. The current uniform price brought a determinate level of stability for the pharmaceutical sector, while at the same time lowering prices of many MPs, an effect beneficial to the FZOM and the public. In parallel, it preserved the national framework of approx 760 community pharmacies, which otherwise would be to a large part economically endangered from within the sector by the commercially motivated discount prices that were appearing in the vertically integrated local pharmacy chains. These have become characteristic for the Macedonian pharmacy sector since the country's independence. The applications for the initial price determination and the change of price are submitted according to the Articles 107 and 108 of the MPA to the Agency. Whereas the timelines for decision and the appeal procedure are described in the MPA Art 108(4), there seems to be no legislative text on the level of a law or implementation rule that would determine upfront the pricing procedure, as well as the terms of the model determining the particular levels of the price decision criteria, the timelines for decision making, as well as the BMP's obligation to give explanations of reasons for the denial of proposed price. MPA currently contains delineation between regulated and free prices using their legal status (prescription PoM vs. non-prescription OTC). Upon the note of consultants that this is not in agreement with EU legal framework, BMP expressed position that this has been placed for the benefit of the public and should be retained. The consultants explained the EU systems and recommendations of recent European Commission in which this delineation is made on the basis of access to public funds and not on the PoM status of a product itself. It became clear that the new Agency for medicinal products and medical devices which is expected to be formed on 01.01.2010, is to remain the competent authority for pricing of MPs.

The position of the consultants was presented that the two linked Projects are likely to propose the review in the Pricing section of the current MPA which will describe price entities, the requirement and the procedures in broader terms and provide for a minister's implementation rule on pricing. IZ proposed an option of keeping the current law in the present form while at the same time providing a technical instruction for pricing, on the grounds of good experience and effect in the recent period. SP pointed out that the option 'existing MPA - technical instruction' is likely to be legally less appropriate than the 'revised law - implementation rule' combination in terms of alignment to the EU legal framework. It was agreed that a political decision will choose between the options. It was pointed out by the consultants that the country is free to choose the model of pricing of medicinal products as long as it conforms to the four main elements of the Directive 89/105 as described above. The consultants pointed out that the uniform prices represent the state-regulated prices and should be the only regulated prices in the system, whereas the reference prices have to be considered as price standards that represent the amounts paid for the MPs from public funds which in turn can be equal or lower than the regulated prices. Reference prices are therefore legally *pricing standards* rather than *prices per se*.

Event 2: First meeting with Mr Janez Jelnikar, the Director of the Health Insurance Fund (FZOM) and his colleagues, (meetings on Day 1 and Day 3 of the visit)

Present: J. Jelnikar (JJ), Marija Gulija (MG), Vesna Koblar (VK), Stanislav Primožic (SP)

JJ welcomed the consultants and the project and described the current activities in the FZOM mainly from the angle of the system of the reference prices. On the Day 1 of this in-country visit, the new positive list of MPs was approved by the Management Board of FZOM. The positive list currently contains approx 1200 products with approx 470 INNs. The estimate of the national market value is approx. 160 MIO €. There are approximately 750 pharmacies in the country of which approx. 650 have a contract with the FZOM that *inter alia* arranges the remuneration for medicinal products dispensed to the insurees. It appears that for particular medicines, a parallel private market exists with undefined modalities of switching patients between the public and private markets, with certain implications for the price they are paying at the pharmacy. JJ and MG described the development plans to categorize the medicinal products with access to FZOM funds in four groups:

- "A" group: approximately 175 chemical entities (INN-level) with no copayment. Reference prices of MPs in this group are in principle equal to the uniform prices determined by the BMP. There is no copayment. In one INN entity, more than one product can be placed.
- "A1" group: group of MPs similarly structured to A group but with MPs for which the UP is higher than RP and therefore leads to copayment
- "B" group for medicines used in hospital settings. Awareness was made that despite the fact that the hospital medicines are financed differently from the ambulatory used MPs from the Positive List, they nevertheless are also paid from public funds by the FZOM.
- "C" group of expensive medicines. No definition of delineation in terms of what the adjective "expensive" would amount to in MKD currency was given at the meeting but the high cost-medicines prices frequently amount to 1000 € and above.

The mentioned groups are planned to be implemented in the very near future and their formation is likely to be part of another TA project.

The establishment of uniform prices was welcomed by the FZOM. The used-to-be tendering for medicinal products for primary care by the FZOM has been changed concurrently and replaced by the positive list. In this system, the necessity of the continuous information exchange between FZOM and BMP was stressed, as well as the need to appropriately define the ex-factory price and other parameters in the structure of the national pricing model.

Consultants inquired about the frequency of the review/update of the reference prices in the current setting. JJ and MG explained that once or twice a year seems most appropriate for the FZOM and would in their view be acceptable to the stakeholders also for the future. A planned proposal which the consultant is likely to present in the final report and is described above (see the description of the Event 1), was presented by VK and SP to JJ and MG. In their view it seemed to be acceptable, keeping in mind that the regular and technically well defined exchange of price data and other pertinent information is crucial for the functioning of the system on an inter-institutional level.

-Event 3: meeting with the Minister of Health Mr. Bujar Osmani, MD

Present: minister BO, Zora Uzunovska (ZU), VK, SP

Meeting started with VK describing the principal parameters of the current national legislation in view of the EU legal framework. Consultants presented minister with the leading idea of the Project mission, namely to upgrade the current national legislation in the area of pricing of medicines, possibly in the form of an amended MPA and to elaborate the technical content in the implementation regulation. In part, this may require also the adaptation of the national competent authority for medicinal products as the mandates need to be allocated by MPA. Minister stressed the importance of safeguarding the procedures against possible misuse of the system by any involved group. The consultants explained the minister the envisioned lead architecture in terms of the functions that are vested by law to particular subjects in the price regulation. In the proposal, whereas the Ministry remains the sole carrier of the national pricing policy laid down in the MPA and elaborated in detail in the Pricing Regulation, it is the mandate of the NCA (BMP) to perform the administrative procedures and serve as the operational body making administrative decisions as stipulated in the MPA and the Pricing Regulation. Consultant VK also explained to minister the advantages of changing the legal status of the NCA and the necessity of appropriate staffing in accordance with the foreseen tasks of the new Agency. Minister expressed his views about the dynamics of the establishment of the new Agency, and consultants presented some views on the structure and resources of modern EU Agencies. It was agreed that the communication in the continuation of the two projects would directly include the minister.

-Event 4: meeting with PEK Working Group established in MoH for technical collaboration and professional support (the list of participants is given in the Annex I to this Report)

The meeting was intended to establish permanent contact and exchange mechanisms for organizational and technical issues in the project. Representatives of national competent bodies, PEK, BMP, FZOM and academia are included in the Working Group. Essential documents and other necessary information which is important for the formulation of the pricing regulation proposal will be collected with the help of the Working Group. Examples of administrative legal documents, descriptions of standard operating procedures in the processing of the pricing applications were discussed. The exchange between PEK WG and the Consultants will be very important in drafting the technical part of the Pricing regulation proposal as well as for the MPA proposal. The Working Group established in MoH was extremely motivated and helpful in providing necessary information and data that should be taken into account when drafting the Regulation. Contact point for the exchange between the consultants and the WG will be Dr. Zora Uzunovska.

-Event 5: meeting with stakeholders of the pharmaceutical sector

Present: approx 20 representatives of the local and foreign manufacturers, - wholesalers and of pharmacist associations, members of the PEK WG, VK, SP

The meeting took place at the premises of FZOM. Present were approx. 30 representatives of economic and public entities operating in the pharmaceutical sector. The stakeholders welcomed the uniform prices and expressed the support for their further development. The principal UP issue presented by them was that the system is currently lacking a dynamic component of price change. It has been established early in 2008 and prices have generally not changed since then. They expect development of a mechanism for flexibility of prices on ex-factory level and especially that of wholesale and pharmacy margins. They expressed the transitory effect of the initial implementation of uniform prices partly due to the relative large volume of the trade at the time of UP implementation (the system was closing down national tendering setup and switching over to current reimbursement based on positive list). In the time passed, the effect of a small national market has come out more intensely and the

representatives expect more flexible arrangement. In opposite case, some foreign manufacturers do not exclude the possibility of leaving the market and participation in some service functions such as clinical trials of new medicines.

Representatives of manufacturers and wholesalers of MP strongly pointed their concern over the possible dumping prices that are according to them appearing in the Macedonian market. They expect that the national regulator should act as a deterrent to future dumping initiatives. The consultants pointed out the importance of action of the nation's competition bodies with whom the NCA could cooperate on a continuous basis (the detection of dumping element in the pricing application could be treated as preliminary question).

Event 6: meeting with Deputy Minister for Health Prof. Dr. Vladimir Popovski

Present: Present: Deputy Minister, Zora Uzunovska (ZU), VK, SP

The consultants presented the leading idea of the projects and stressed the triple content of the mission: upgrade of the Agency, upgrade of MEP, and preparing a draft regulation on pricing of medicinal products. Deputy Minister stressed the importance of the alignment of the proposals with the EU legal framework. He again pointed out the importance of the system of uniform prices. Consultants presented him with their view that the uniform prices are ceiling prices regulated by the state authorities, whereas reference price are price standards which represent the levels of reimbursement of medicinal products from public sources. Deputy Minister will be continuously briefed on the progress of the project by the PEK.

Event 7: second meeting with Mr. Janez Jelnikar, the Director of the Health Insurance Fund of RoM and his colleagues (meeting on Day 3 of the visit)

Debriefing took place on the content of the meetings with the two directors of FZOM. Once again it was stated that the FZOM will rely on the Agency for establishing and maintaining uniform prices while itself it will develop the system of RP. Prices of medicines to be paid for FZOM either in terms of full or partial reimbursement should be exchanged regularly between the institutions. When distinctly asked whether a proposal would be acceptable for the FZOM in which, all along with the established and valid uniform prices, the FZOM may achieve or be offered agreed prices that are legally valid and in principle equal or lower than the uniform prices, the Directors agreed to the thesis.

Event 8: second meeting with Mr. Ilčo Zahariev, the Director of the BMP at the Ministry of Health (meetings on Day 1 and Day 3 of the visit).

Debriefing on the principal content of the listed events took place with the Director. Mutual commitments were expressed between the Director and the Consultants in order to assure good work and impact of the Result of this project. Director once again expressed high interest in that the proposed legislation would not jeopardize the recent achievements of the BMP in implementing and running the system of unique prices. Commitment was shared from both sides that the technical support would be given by the BMP Staff to the Consultants in the drafting process.

Event 9: meeting with Mr. Vančo Kargov the Chairman of the National Standing Committee on pricing of medicinal products.

The Consultants met with Mr. Kargov, the Head of the Macedonian Customs Authority. He Chairs the Committee established by the Government of the Republic of Macedonia which presents opinions on the appropriateness of the applications for (increased) pricing which are being processed by the NCA. The Committee is a consultative one and oversees mainly the economic impact of the new price proposals. By presenting an opinion the Committee positively influences the decision making by the Agency. The consultants exchanged their views with the Chairman. Again, the mechanisms and criteria for decision taking are not written and publicly accessible and they should be prepared for the new bylaw. The role of this committee could be retained and developed in the new pricing regulation.

II.2 Key findings upon completion of the listed activities

Some findings that are deemed important by the Consultants are presented below:

- regulation of prices of MPs in Macedonia recently benefitted from the introduction of the uniform prices; it is important to keep the system of UP while interfacing it efficiently with the system of reference prices as price standards, and retaining possible price adjustments for the public market (ie. for FZOM as the 3rd Party Payer).
- the legislation currently governs the pricing on the level of the law. While this arrangement provides for extraordinary high (parliamentary) level of a rather technical sector, at the same time it is rigid in terms of ability to include adaptations to the rapid developments in the health care sector and the economy; alternative legal architecture should be considered and will be proposed, and the choice between options should be political;
- in such proposed arrangement, the main concepts introducing EU legal requirements would be built in an upgrade to the 'Pricing' section of the MPA, the competences given to the authorities and introduced implementation regulation; provisions for the timelines for decision, the criteria for decision making, the obligation for authorities to state reasons for negative decision and the possibility of legal appeal for the applicant should be provided;
- at the same time, the MPA should bring the main concepts of the national pricing model, which in turn would use external (interstate) referencing of prices with selected countries while applying appropriate corrective mechanisms necessary for the Macedonian market;
- while the law would become more conceptual and less technical, its concepts would be developed at the level of technical detail in the implementation regulation;
- in any case, a legal instrument is needed containing, where appropriate, the hitherto largely effective and efficient measures and activities undertaken by the authorities in the area of pricing, and containing all necessary elements for adherence to the EU legal framework,

III. Planned Future activities

Activities to follow:

- At home work (6 working days) will follow and will be devoted to preparing the draft regulation on pricing of pharmaceuticals taking into consideration specific national requirements, needs and preferences as well as EU experiences and recommendations, particularly those on assuring cost containment of public funds while at the same time providing for access to important medicines and enabling competitiveness of economic operators on the market as in line with the existing and newly developed national recommendations concerning the necessary legal frame for implementation of pricing policy (objectives of the EU transparency directive).

- 2nd in country visit (2 working days) should be devoted to presenting the Draft regulation and to discuss it with Ministry of health, BMP and other relevant stakeholders. A workshop for approximately 20 key stakeholders should be delivered and aimed to present the content and structure of the Regulation in its pharmaceutical, economic and regulatory aspects. The appropriateness of the precisely defined methodologies in the Draft regulation for reaching the objectives of the project and systemic instruments provided to avoid the anticipated obstacles and risks should be discussed in relation to provisions of EU Directives and in line with the legal draft proposal on pricing of pharmaceuticals, which is assumed to be concurrently developed as a separate project in order to provide the necessary legal basis for the Draft Regulation.

- At home work (3-4 working days) should encompass modifications of the recommendations and regulatory and legal proposals following suggestions that were agreed to be taken into consideration during the 2nd country visit based on final communication with the Ministry of health, Health Insurance Fund and other relevant stakeholders concerning any details of the finally modified Draft Regulation. The Draft Final Report should be prepared

III. Other Remarks

There is a concern that the translation of the Pricing Regulation from English to Macedonian language could be a problem because specific terms are to be used, very sensitive provisions are to be translated in a very short period of time, without possibility to prepare interpreters for the specific task. This is why Dr. Primožič recommended to the WG to review the Draft (0) in English language and to use translated text later after consultation with interpreters.

The Report does not include all details that will reflect changes of the existing provisions or introducing the new provisions into the Law, because all necessary explanations concerning those details will be provided during the consultation procedure.

Prepared by

Dr. Stanislav Primožič
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