

INCEPTION REPORT

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PROJECT:

TA FOR ADVISING ON ESTABLISHMENT OF DRA IN MACEDONIA AND LEGAL ASPECTS OF THE REGULATION ON PRICING POLICY OF PHARMACEUTICALS

I INTRODUCTION

The objective of the assignment according to the terms of Reference (ToR) is to provide Technical Assistance to the Ministry of Health (MoH), Health Insurance Fund (FZOM), and Drug Bureau, working with national experts in establishing DRA (the Agency for Medicinal products and Medical Devices) and in setting a legal frame for a national pricing policy

In order to achieve the stated objectives in the ToR:

- to draft the recommendations in line with the legal provisions for formulating and establishing a national DRA of Macedonia
- to precisely define legal and technical aspects, prerequisites and preconditions for establishment of a DRA and
- to envisage possible obstacles and ways to their overcome in line with legal provisions and EU directives on pricing of medicines.

This is the Inception Report after the 1st in-country visit

II 1 ST IN COUNTRY VISIT

Preparatory work concerned reviewing the Law on Medicinal Products and Medical Devices of Macedonia in light of the objectives of the Project.

1st in-country inception visit was organised in July 2009 and was devoted to analysing the current situation in the area of pharmaceuticals in Macedonia, to discuss legal, political and technical circumstances that may influence future recommendations concerning :

- establishing of the DRA - the Agency for Medicinal Products and medical Devices of Macedonia
- and
- need for introducing changes to the Law on Medicinal Products and Medical Devices in the chapter on Pricing, necessary for proposing the content and structure of implementation regulation on pharmaceutical pricing policy.

The activities during the first in-country visit were organised at the same time and connected with activities carried by the Consultant dr Stanislav Primožič, who will propose the implementation regulation on pricing, due to their content linkage.

The following meetings were organized by prof dr Zora Uzunoska, the Project Coordinator:

- meeting with dr Bujar Osmani, Minister of Health
- meeting with prof dr Vladimir Popovski, deputy Minister of Health, main HSMP coordinator

- meetings with mag Ilčo Zahariev, director of the Drug Bureaux
- meetings with Mr Janez Jelnikar, director of the FZOM (National Health Insurance Fond) and his team
- meetings with the Coordination Working Group established in PEC for coordination activities between the institutions involved in the project outcome
- meeting with prof dr Aneta Dimitrovska, Head of accredited laboratory within Faculty of Pharmacy,
- meeting with Mr Vančo Kargov, director of the National Customs Authority, Chair of the Committee for pricing of medicines.
- meeting with stakeholders: local and foreign manufacturers / their legal representatives, wholesalers and pharmacies

The meetings were aimed to develop an understanding of the existing situation in the pharmaceutical sector, to underline the main concerns and needs.

Minister of Health dr Osmani expressed his support to the project and the European approach, taking into consideration some local specificities, particularly the need for maintaining the stability of the system and the importance of safeguarding the chosen model against possible misuse. Minister was interested in advantages of establishing the Agency for medicinal products and medical devices. It was explained that flexibility, professional independence and international networking as well as appropriate staffing were a main issues.

Deputy Minister prof dr Popovski expressed his full support to the project, particularly the European approach and transparency of the system.

Director of the Drug Bureau mag Zahariev was extremely helpful in providing all the requested information e.g. organizational chart of the Drug Bureau, drug prices approval procedures and criteria, transparency of the Bureau work and other basic information, needed for understanding the existing situation, local specificities, needs and concerns, necessary for achieving the project objectives. Recent deliverables of the legislative, procedural and technical development at the Bureau were presented and e-versions of the legislative texts were provided. It was stressed that uniform prices brought a significant improvement and stability into the system. Since the second visit will be devoted to review the work of the Drug bureau in the light of future Agency needs, the 1st visit was aimed only to review its basic working methods and organization and to review procedures on price approval.

Director of the FZOM Mr Jelnikar was extremely helpful in providing all the requested information, needed for understanding the existing situation, local specificities, needs and concerns, necessary for achieving the project objectives.

He underlined the relation between uniform and referent drug price and need for optimal communication with the Drug Bureau concerning pricing approval. FZOM organized the meeting with stakeholders, but without presence of their representatives that allowed a very direct and helpful debate with consultants. Plans for categorizing medicines paid from FZOM funds were presented: A group with no co-payment (uniform and reference prices are equal), B group with co-payment (uniform prices higher than reference prices), C group of new, expensive medicines. The groups will be defined in details under another TA Project.

The Working Group established in PEC was extremely motivated and helpful in providing necessary information and data that should be taken into account when drafting the recommendations for formulating and establishing a national DRA of Macedonia and setting

legal framework for implementing national pricing policy. They supported establishing the Agency and presented their view on the pricing system in Macedonia. All the WG members supported introducing of uniform prices in Macedonia that helped maintaining of individual pharmacies and allowed pharmacists to turn to patients and to proper planning of orders. They were of the opinion that the existing system is rigid since it is in the Law e.g. it requires Parliamentary procedure to be modified, but that stability of the system requires more rigidity than in some other countries, particularly in EU Member States.

Representatives of industry, wholesalers and pharmacies (ca 30) discussed the most outstanding issues from their point of view. They have all supported introducing of uniform drug prices in Macedonia. They were of the opinion that the existing system was rigid since it was set in the Law e.g. the Parliamentary procedure was required for introducing modifications. At the same time they stressed that stability of the system required more rigidity than in some other countries. They stressed positive and negative sides of the existing solutions on pricing as follows:

- The right for all stakeholders in the distribution chain to have proper conditions for running their business and to make profit has not always been followed because profit margins were sometimes too low
- Profit margins are too low because many expenses were not taken into consideration. Retail margins should be fixed.
- The system of uniform prices allows pharmacists to turn more to patients and to plan pharmacy business properly.
- Since drug prices were set according to tender conditions and quantity, they do not fit to the actual situation. Periodical (at least annual) new setting of prices is necessary for fair business conditions.
- Flexible range of drug prices has the upper limit, but the final price depends on Drug Bureau and unclear criteria
- Requests for changes of drug prices are processed too slow (several months) even if the price is to be reduced
- specificities of small markets concerning fair pricing are to be taken into consideration, otherwise some products or companies will leave the Macedonian market.
- Although the stable system is needed, flexibility of the pharmaceutical market is to be taken into consideration.
- Possible dumping process should be properly identified and prevented.

The meeting was organised by FZOM in their facilities, but FZOM representatives were not present in order to enable the consultants to have an open dialogue with stakeholders.

Mr Kargov explained the role and methods of work of the Pricing Committee that decides only in the cases of requests for changes. Criteria were not publicly available. Mr Kargov stressed a consultative role of the Committee.

III ANALYSIS OF THE CURRENT SITUATION

Main points outlined after reviewing and analyzing the existing legislation and discussion with the interested parties during the first in-country visit are the following:

1. Establishing a national DRA of Macedonia

The Law on Medicinal Products and Medical Devices (The Law) offers the legal basis for establishing the public Agency for Medicinal Products and medical devices (The Agency) as the Competent Authority for medicinal products and medical devices.

The Agency shall begin to operate from 1st of January 2010

Preparation work for establishing the Agency should be of a high priority because of the Agency role in the pharmaceutical and other sectors.

Agency's tasks are set forth in the Art 5. of the Law.

In addition to the tasks in the area of medicinal products and medical devices, the Agency will take over the tasks assigned to the Drug Bureau according to the Law on Narcotics and Law on Chemicals. It should be reflected in the organisational structure of the Agency.

Competences of the Agency in the area of medicinal products and medical devices concern several areas of expertise and operative work. It should also be reflected in the organisational structure of the Agency. It will be discussed in details during the 2nd in-country visit.

Advisory standing and ad-hoc committees are to be established within the Agency. Committees can request the expert support for specific topics not covered by the committee's expertise. Committee's working procedure and membership should be publicly available. It will be discussed in details during the 2nd in-country visit.

Expertises shall be delivered by internal and external experts. The scope of the role of external experts will depend on the size of the Agency e.g. availability of internal expertise and organisation of Agency functions. Pros and cons of developing internal expertise that could in future replace some parts of the external expertise, will be discussed during the second in-country visit.

All the staff and experts should sign the conflict of interest declaration and confidentiality of data declaration. The draft proposal of the declarations will be prepared during in-house work and provided and discussed in details during the second in-country visit.

The content and scope of Agency's tasks should also be set forth in the:

1. Decision on establishing the Agency according the Law that are expected to be issued by the Government of the Republic of Macedonia

and

2. Rules on organisational structure and systematisation of positions within the Agency issued by director of the Agency or Agency Management Board.

Main elements of the Decision on establishing the Agency will be prepared during in-house work, provided and discussed in details during the second in-country visit.

Organisational structure of the Agency, foreseen number of employees and their working positions will be discussed in details during the second in-country visit.

The Agency should make efforts to carry out its tasks in the most systematic, transparent and efficient ways. That should be ensured by clearly stated Agency's mission, vision and strategy. Agency mission, vision and strategy will be discussed in details during the second visit.

Agency mission should clearly reflect the aims of establishing the Agency as a competent authority according to the Law.

Vision and strategy of the Agency depends on the actual management but in any case should reflect the main aims of establishing the Agency having in mind the actual national and international circumstances.

Draft document on basic elements of Agency mission, vision and strategy will be provided after the second in-country visit.

It was stressed during the discussions that a small (cca 35 employees), competent and flexible Agency with highly professional and motivated staff is envisaged. The possibility for achieving all the goals and to perform timely and appropriately all the listed activities with the envisaged number of employees will be discussed in details during the 2nd in-country visit.

Good functioning of the Agency implies the need for management that demonstrates its leadership in appropriate and transparent way, that ensures sufficient resources (financial, human and infrastructure) and the effective use of the available resources. Procedures should be documented to ensure compliance with timelines, consistency, efficiency and control of quality of work. Horizontal and vertical communication channels should ensure spread of information and quick responses. It should be ensured that competence of people that are involved in decision making is adequate for current and future needs. Morale of people should be adequate, mechanism of rewarding should be in place. Current and future needs should be met. All the mentioned issues will be discussed during the 2nd in-country visit.

Agency should ensure effective communication with its stakeholders, so that their needs and expectations are identified, translated, as appropriate, into organisational requirements, and feedback is given. Appropriate level of transparency of work should be ensured.

Systems have to be in place for reviewing the appropriateness of scientific/regulatory decision making.

Systems have to be in place for protecting the staff, premises and property from physical and security threats.

Systems have to be in place for ensuring that risks to the functions, finance, reputation and business processes of the organisation are identified and effectively managed through internal risk management.

Quality system should be set and in compliance with ISO 9000-standard specifications.

The above mentioned issues will be discussed in details with director of the Drug Bureau and his team during the second in-country visit and ways of achieving the goals will be proposed.

2. Drug pricing and possible obstacles and ways to their overcome in line with legal provisions and EU directives

Law on Medicinal Products and medical Devices (herewith: the Law) is not in some provisions in line with EU rules, does not give a sufficient flexibility necessary for adequate response to market dynamics, allows introducing some subjectivity in decision making procedure since decision criteria are not foreseen to be set in a bylaw. There are some good practices, methods and criteria used for price forming, but there's no legal basis for exercising them in practice and there's not enough transparency of work concerning the used criteria. It is necessary to introduce some changes to the Law in order to make it in line with EU rules and to ensure a legal basis for the good practices. All the introduced practices have to be implemented on transparent way.

Gaps in the Law that concern drug pricing are identified as follows:

- art. 107: The Law foresees price control for medicinal products on prescription and for medicinal products that are on the list of essential medicinal product. EU rules allow price control only for medicinal products that are paid from public funds. This is why the scope of the pricing control should be aligned with EU rules

- art. 108: Elements of a drug price are listed. It is not clear how the first element, the production price is to be calculated and what are criteria for acceptance of the stated/proposed production price in applications for price forming. Agency should approve the submitted price but there are no criteria in the Law allowing stakeholders and Agency to do it in line with the Law. There are several possible mechanisms for that, but none of them is in the Law. There is a mechanism of comparative prices in practice, but there's no legal basis in the Law for using it. So, it is necessary to introduce some changes to the Law in order to enable the good practices to be exercised legally. The Law should anticipate the bylaw on price forming with all necessary details.

Wholesale margins are defined "up to" the limit number, but there are no criteria for determining them and subjective approach is a consequential threat. There is a mechanism in practice for limiting "up to" the limit number, but there's no legal basis in the Law to use it in practice. So, it is necessary to introduce changes to the Law in order to enable the good practices to exist legally. The requirements, e.g. the content of the submissions should be clearly defined. All the necessary details should be provided in a bylaw.

The Law is rigid and does not allow changes without Parliamentary procedure. It could be assessed as a deficiency, but it has been explained that the existing situation required more rigid approach in order to ensure stability of the system and predictability for stakeholders. In principle, only a basic requirements and outline of the procedures should be in the Law, all necessary details should be left to its by-laws, so the Law should give the basis for implementation regulations and should not regulate details. The existing Law does not give a legal basis for the needed by-law/s. Although the Law should be open to a wider scope of possibilities for price forming according to the markets needs and should leave decision about the particular model to the Bylaw, it would probably not be accepted due to some stated political and market specificities.

This is why only changes that concern harmonisation with EU requirements will be proposed together with necessary justification.

III PLAN OF THE FUTURE ACTIVITIES WITHIN THE TA

During the at-home work between 1st and 2nd in- country visit the following documents will be prepared:

1. Documents concerning establishing the Agency

- Main elements of the Decision on establishing the Agency
- The draft proposal of the declarations of confidentiality and conflict of interest

2. Changes to the Law: Chapter III.11 Pricing

- Changes that concern harmonisation with EU requirements will be proposed together with necessary justification.

2nd in-country visit is planned and already agreed with Drug Bureau for the week 36 (end of August and the beginning of September) and will be completely devoted to the 1st aim, the establishing of the national DRA of Macedonia, as previously explained. All the proposed and discussed documents will be completed during at-home work after the 2nd in-country visit and sent before the 3rd in country visit and will be a basis for further discussion during the 3rd in-country visit. Presentation for stakeholders on establishing the DRA and presentation on EU approach on pricing as well as proposal for changes to the Law will be prepared during at-home work after the 2nd in-country visit.

Proposal for changes to the Chapter III.11 Pricing will be discussed during the 3rd in country visit with all interested parties and in the Workshop with stakeholders and PEC Working Group. The proposal is to be understood complementary to the future proposal for a Bylaw on drug pricing. Presentation on EU rules and Draft Changes will be sent in advance before the 3rd in-country visit.

3rd in country visit with a workshop/seminar on specific points of the Transparency directive on drug pricing will be organized in October in order to facilitate proper understanding of some provisions proposed in the Draft Changes of the Law. The proposed changes to the Law will be presented article by article with necessary justifications based on EU legislation and specific national situation. PC projector will be used during the visit. Relevant comments arising from discussion will be included in the Draft and will be sent to the WG after the 3rd in country visit as a part of the Draft Final Report.

3rd in country visit will be additional opportunity to discuss all the documents sent after the 2nd visit. Completed documents will be a part of the Draft Final Report.