

PROPOSAL FOR THE CHANGES TO THE LAW ON MEDICINAL PRODUCTS AND MEDICAL DEVICES - CHAPTER - PRICING

INTRODUCTION

Pricing of medicines is a national competence, but common objectives of all national pricing policies are

- ensuring the access to the necessary medicines
- control of health budget and ensuring sustainability of the health system
- creating end/or maintaining incentives for innovations.

Not all the objectives are equally prioritized because priorities depend on available resources, health needs and structure of the pharmaceutical industry in the Country.

Any national measure to control prices of medicines must comply with requirements of dir. 89/105/EEC:

- should concern only medicines covered by national health insurance
- should be non discriminatory
- all the decisions are to be taken in a transparent manner and concern:
 - clear timelines
 - decisions based on objective and verifiable criteria
 - decisions accompanied with appropriate justification particularly in the case of negative decision
 - opportunity to appeal

Review of the Chapter III. 11 Pricing of the Law on Medicinal Products and Medical Devices (herewith: the Law) shows that not all the provisions of the Chapter are in line with EU rules. Besides, the Law does not give a sufficient flexibility, necessary for adequate response to the market dynamics.

Price regulation does not concern only medicinal products covered by public funds as requested by EU legislation.

The Law also allows some subjectivity in the decision making procedures, since decision criteria are neither set adequately in the Law or foreseen to be set in a bylaw. That is not in line with EU requirements. For example wholesale margins are defined in the existing Law "up to" the limit number that is to be defined by Competent Authority, but there are no objective and measurable criteria for determining them by the Competent Authority 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. Besides, some stakeholders and the Agency representatives shared the opinion that fixed margins would better reflect the needs in this stage at least at the wholesale level. The way of or the need for regulation of wholesale margins will depend on the chosen level of marketing at which the price is regulated and principal parameters of the national pricing model. The need for flexibility should be taken into consideration when deciding if the wholesale and retail sale margins are to be regulated in the Law or in the bylaw. In any case transparent criteria should be used in order to avoid subjective approach.

Review of the procedures that are running in practice, shows that there are some good practices, methods and criteria in use for price forming, but there's no legal basis for exercising them and that there is lack of transparency concerning their use.

This is why it is necessary to introduce some changes to the Law in order to bring it in line with EU rules, to ensure a legal basis for transparent use of the good practices and to allow a sufficient flexibility, necessary for adequate response to the market dynamics.

The issue was discussed in details with stakeholders in the system

This proposal will follow EU good legislative practices that enable a sufficient degree of flexibility for pharmaceutical markets.

It is necessary to stress that national pricing policies always refer to both, supply side practices (the price levels and the reimbursement level) and demand side practices (restrictions on doctors, pharmacists and patients). Since the laws reflect the national policy as a whole, final tuning of the wording in the Law will depend on political decision on the chosen level of stability/rigidity of the system and the policy and provisions on reimbursement of medicines.

The following proposal for changes to the Law in the Chapter III. 11 Pricing is aimed at

- filling the gaps concerning EU requirement and
- making the system more flexible and transparent.

Proposal for the changes to the Chapter III. 11 Pricing according to the EU requirements taking into consideration flexibility, necessary for adapting to the market dynamics and challenges.

Chapter III. 11 Pricing

Article 1.

The following terms and definitions will apply for the area of regulation of prices of medicinal products:

1. Manufacturer's price (hereinafter ex-factory price) is administratively determined price that reflects officially recognized ex-factory costs based on the principal parameters of the national pricing model.
2. The wholesale price of the medicinal products shall be considered as a sum of the ex-factory price and wholesale margin.
3. The retail price of the medicinal product shall be considered as sum of the wholesale price and administratively recognized share or a fixed amount intended to cover costs of retail.

4. Maximum allowed price is a regulated ceiling price of a medicinal product determined by the Competent Authority based on the principal parameters of the national pricing model.
5. Approved price is a regulated ceiling price of a medicinal products determined by the Competent Authority based on applicant's submission and the principal parameters of the national pricing model. It can be equal or lower than the maximum allowed price.
6. Uniform price is the price at which the product financed from public funds must be sold in pharmacies in the country.
7. External referencing of prices of medicinal products is a parameter of the national pricing model which involves determining national price relative to the prices of the same or related medicinal products in a set of other countries.

Justification:

Definitions are necessary for proper understanding of the used terms.

Article 2.

The prices of medicinal products shall be formed freely according to the market conditions except for medicinal products financed from public funds for which the maximum allowed price and approved price shall be determined by the Agency for Medicinal Products and Medical Devices as the Competent Authority.

Maximum allowed price and approved price can be determined at any level of trade by Minister of Health according to Art. 9 of the Chapter (*Art. XX of the Law*).

Justification:

Art 107 of the existing Law foresees price control for medicinal products on prescription and for medicinal products that are on the list of essential medicinal product.

EU rules e.g. dir 89/105/EEC allow price control only for medicinal products that are paid from public funds. Other medicinal products that are not paid from public funds are to be freely priced.

The discrepancy between the Art 107 and dir 89/105/EEC should be solved by introducing the EU criteria for defining the scope of medicinal products that are subject to price control according to the Law.

Pricing criteria concern all medicines covered by national insurance system, so it is irrelevant whether a medicinal product is on the list of essential medicinal products or not. So, establishing of a list of essential medicines concerns

policy and professional aspects is not an issue that should be addressed under the Chapter on pricing.

Article 3

Maximum allowed price and approved price of medicinal products formed according to the Law are ceiling prices.

The applicant chooses to apply for the ceiling price at the level of the maximum allowed price or a lower level.

If the applicant applies for a ceiling at the level of a maximum allowed price for his product, the approved price will be equal to the maximum allowed price.

If the applicant applies for a ceiling at the level lower than a maximum allowed price for his product, the approved price will be lower to the maximum allowed price.

The level of trade and other principal parameters of the national pricing model will be determined by Minister of Health according to Art.9.

Justification:

The Law regulates only ceiling prices. Maximum allowed prices can be calculated by using different models (e.g. cross border reference to set of chosen countries, control of profitability etc) and on different levels of trade (e.g. wholesale, retail sale level etc.). Although there is the view of majority of stakeholders in the system that the cross border reference and a wholesale level of regulating prices should be principal parameters of national pricing model, the Law leaves the decision to the Bylaw following the principles of EU good legislative practice, that sets only the main requirements in the Law and leaves the rest to the bylaws and enables sufficient flexibility, necessary for adequate response to the market dynamics or dynamics of development of the state-of-the-art science and technology. The Law is now open to a wider scope of possibilities for price forming according to the market needs

Article 4.

The provisions on pricing in this law have no prejudice to subsequent measures e.g. negotiations on discounts, rebates or to agreements which may be made between suppliers of medicinal products and the health insurance fund or purchasers which perform health services financed by public funds which result in an agreed lower price established according to the rules that govern mutual obligations between the parties entering the agreements.

Justification:

The Law determines only ceiling prices. Suppliers of medicinal products and health insurance fund or health care institutions can enter into agreements that result in an agreed lower price, but those agreements are out of the scope of this Law. It is necessary to underline that double price regulating is not in line with EU requirements. This is why the provision underlines that mutual agreements are not obligatory ("may be made") and are not under the scope of this Law.

Article 5

Medicinal products financed from public funds shall be traded at the retail sale level e.g. in pharmacies using uniform prices that are for that level of trade based on the approved price of the product.

Notwithstanding the provisions of the former paragraph of this Article, medicinal products financed from public funds shall be traded the end users who are insured of the health insurance fund, at the retail sale level e.g. in pharmacies that perform health services financed by public funds, with uniform prices that are for that level of trade based on the agreed lower price of the product, if such price exists.

Justification:

There is a common view that uniform prices are to be maintained because of their benefits to patients and to the pharmaceutical market, but the scope of the use of uniform prices and the linkage to the approved and agreed prices should be defined more precisely.

Uniform prices concern retail trade level e.g. trading to patients as end users.

Uniform prices can concern only medicinal products that are covered (partially or totally) by public funds, because uniforming the prices is a way of regulating them.

The uniform price of medicinal product has its structure, so regardless of the level of regulating prices, uniform prices shall depend on the approved price, but if the agreed lower price resulted from agreements between suppliers of medicinal products and the health insurance fund or purchasers which perform health services financed by public funds, then the structure of the uniform price shall reflect it.

Article 6

Medicinal products that are not financed by public funds shall be traded in wholesale and retail trade with prices set freely.

Justification:

According to EU rules e.g. directive 89/105/EEC, regulation of prices concern only medicinal products covered by national public funds.

Medicinal products that are not covered by public funds are to be traded with prices that are set freely.

Article 7

Minister shall determine:

- principal characteristics of the national pricing model which may be based on external referencing and/or other mechanisms of demand and supply side measures;
- level of marketing at which the price is regulated;
- applicants for the determination of the maximum allowed price and approved price
- the criteria, methods and technical details of the procedure for the determination and amendment of the maximum allowed and approved price and approved price of medicinal products financed from public funds;
- obligatory components of the application for the determination of the maximum allowed and approved price of medicinal product;
- period for which the maximum allowed price is determined;
- the level of wholesale margins and the type and level of the administratively; recognized share or a fixed amount intended to cover costs of retail trade
- the method of publishing and communicating the information on regulated prices of medicinal products and

Minister shall determine and may periodically review those parameters of the national pricing model that reflect the macroeconomic characteristics of the national medicinal products market such as size of the market and purchasing power, as well as public health priorities in the field of medicinal products.

For the determination of values of parameters from the previous paragraph of this article and for advice on other relevant systemic economic issues, the opinion may be obtained from the Committee for the proposals on the opinion on prices of medicinal products that shall be established by Governmental Decree.

Justification:

As already explained, according to EU good legislative practices and taking into consideration market dynamics, the Law should not be rigid and should set only principal rules. Principal characteristic of the national pricing model may vary according to the market needs and should be sufficiently flexible, so it should be left to the Bylaw. The Law should anticipate the bylaw on price forming with all necessary details concerning the application for determination of prices according to the Law, necessary technical details, time-frames and way of obligatory communication between stakeholders as well as wholesale margins and the type and level of the administratively; recognized share or a fixed amount intended

to cover costs of retail trade that depend on the market dynamics. If the level of marketing at which the price is regulated as well as the level of wholesale margins and the mechanism of remuneration of retail sale (margins or service fees or a combination thereof) are stipulated by the Law, the approach will be too rigid and will not allow changes without Parliamentary procedure.

Since the values of parameters of the national pricing model concern economic issues, the newly established Committee may be asked for the advice.

Article 8

The completed application for the determination of the maximum allowed price and approved price of medicinal products should be resolved by the competent authority for medicinal products within 90 days of its receipt by issuing a decision.

In the case of negative decision, the competent authority for medicinal products should specifically substantiate the justification which should be based on the previously set objective and measurable criteria.

If the decision is not issued within the period referred to in the first paragraph of this Article, the application shall be considered granted and the applicant is allowed to market the day following the expiry of the deadline stated in the first paragraph of this Article the medicinal product at the price submitted in the application.

Justification:

The procedure and a time - lines are in line with EU requirements. It is possible only to shorten the period necessary for determination of the maximum allowed price and approved price of medicinal products. The directive 89/105/EEC requires that procedure for determination of prices and procedure for decision on reimbursement of medicines do not exceed 180 days (although regulated by two different laws).

EU legislation requires negative decision to be justified and justification to be based on objective and measurable criteria. According to EU legislation, the applicant is allowed to market his product at the price submitted in application according to the Law if decision is not issued within the period of 90 days.

Article 9

An increase in the maximum allowed or approved price of a medicinal product is permitted only after prior approval has been obtained from the Competent Authority for medicinal products.

The completed application for increase of the determined price of medicinal products should be resolved by the competent authority for medicinal products within 90 days of its receipt by issuing a decision. This period may be prolonged once by 60 days

due to the excessive amount of applications for the determination of the extraordinary maximum price.

In the case of negative decision, the competent authority for medicinal products shall specifically substantiate the justification which should be based on the previously set criteria.

If the decision is not issued within the period referred to in the second paragraph of this Article, the application shall be considered granted and the applicant is allowed to start marketing the medicinal product at the price submitted in the application on the day following the expiry of the deadline stated in the second paragraph of this Article.

Justification:

It is possible to apply for the increase in the ceiling price of medicinal products. According to EU requirements the decision shall be issued within 90 days (or can be prolonged once by 60 days in case of the excessive amount of applications).

EU legislation requires negative decision to be justified and justification to be based on objective and measurable criteria. According to EU legislation, the applicant is allowed to market his product at the price submitted in application according to the Law if decision is not issued within the period of 90 days.

Article 10

A decrease in the maximum allowed or approved price of a medicinal product is permitted based on the application for decrease of the approved price that can be submitted any time.

The completed application for decrease of determined price of medicinal product should be resolved by the competent authority for medicinal products within 30 days of its receipt by issuing a decision.

In the case of negative decision, the competent authority for medicinal products should specifically substantiate the justification which should be based on the previously set criteria.

If the decision is not issued within the period referred to in the second paragraph of this Article, the application shall be considered granted and the applicant is allowed to start marketing the medicinal product at the price submitted in the application on the day following the expiry of the deadline stated in the second paragraph of this Article.

Justification:

A decrease in the ceiling price should be allowed any time because of benefits for patients and public funds, but should be based on prior approval. The analogy concerning the use of the submitted price in the case that the decision is not

issued within the set time-frame and the need for justification of negative decisions is followed also in this case.

Article 11

An appeal against the decisions of the Competent Authority for medicinal products stated in Articles 8, 9 and 10 may be submitted by the applicant within 30 days of the receipt of the decision. The appeal shall not prevent the execution of the decision. The decision on the appeal shall be reached by the Minister within 60 days of the receipt of the appeal. The applicant may bring an action against the decision of the Minister within 30 days of the receipt of the decision by means of administrative dispute at the Administrative Court of Macedonia.

Justification:

EU legislation requires that the possibility for appeal is defined in the Law as well as the procedure together with the time-lines.

Article 12

Notwithstanding with Art.2 , Minister of Health may in exceptional cases of public health concern and under macroeconomic circumstances that justify such measure and are recognized as such by the Government, decide to freeze or to control prices of any medicinal products or groups of products.

Justification:

The article allows the possibility, according to EU rules, for introducing more strict measures e.g. to freeze or to control prices of any medicinal products or groups of products if it is properly justified by macro economic circumstances.

Article 13

In the event of price freeze imposed on all medicinal products or on certain categories of medicinal products by Minister of Health, the Ministry of Health shall carry out a review, at least once a year, to ascertain whether the macro-economic conditions justify that the fixing be continued unchanged. Within 90 days of the start of this review, Ministry of Health shall announce any increases or decreases in price that are being made.

Suppliers of medicinal products may address to the ministry competent for price control an application for derogation from a price freeze, together with the reasoned explanation. The Ministry of Health shall be obliged to resolve the application within 90 days of receiving the completed application.

Justification:

In the case of introducing more strict measures described in the previous article, EU legislation requires at least annual review of the macro economic circumstances necessary to ascertain if the reasons for having more strict measures still exist.

In the case of introducing more strict measures described in the previous article, EU legislation requires from a body competent for introducing such strict measures (e.g. Ministry of Health) makes these findings publicly accessible within 90 days

In the case of introducing more strict measures described in the previous article, EU legislation requires the possibility for marketing authorization holders/suppliers to apply for derogation and to get answer/decision in 90 days.

(Competences for price freeze and the procedures can be raised to Governmental level or be given to the Ministry of finance. It depends on national choice)

Article 14

Legal entities and natural persons authorized to market medicinal products must submit to the Competent Authority for medicinal products all data on the prices of medicinal products marketed in Macedonia at request.

Justification:

Competent authority should have a possibility to monitor prices in Macedonia regardless whether they were regulated or not.

Sum and substance of the proposal is that the proposal for the changes to the Chapter III. 11 Pricing is:

- The Law (proposal) is in line with EU requirements because it regulates only medicines covered by public funds, is not discriminatory, introduces clear timelines and procedures in line with EU dir. 89/105/EEC, requires decisions based on objective and verifiable criteria and accompanied with appropriate justification and gives the applicants the opportunity for appeal.

- The Law (proposal) regulates only ceiling prices for medicinal products, maintains unique prices and leaves the door open for subsequent negotiations or agreements between Health insurance, HC institutions and companies. It foresees the Bylaw that will define principal characteristics of the national pricing model, level of marketing at which the price is regulated, the level of wholesale margins and the type and level of the administratively recognized share or a fixed amount intended to cover costs of retail trade as well as other technical details necessary for proper and transparent functioning of the system. That is in line with good EU legislative practices and gives a sufficient flexibility, necessary for adequate response to the market dynamics.