

PROPOSAL FOR THE RULES ON DETERMINATION OF PRICES OF MEDICINAL PRODUCTS FOR HUMAN USE

DR STANISLAV PRIMOŽIČ, THE CONSULTANT

PROJECT:

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

Consultant's proposal for "Rules on Determination of Prices of Medicinal Products for human use", intended to serve as implementation rule to the Law on Changes to the Law on Medicinal Products and Medical Devices, which in itself is a subject of a parallel Technical Assistance Project (Dr. V. Koblar, Consultant). The proposal is presented and is expected to be considered simultaneously with the stated proposal of the Law because its provisions are linked to or are determined by the provisions of the proposed Law.

Main characteristics of the proposal for the Rules:

1. The Rules regulate ceiling prices in the form of maximum allowed prices and approved prices and provide for means of establishing the retail prices of medicinal products.
2. Principal parameters of the pricing model used are the following:
 - a. external referencing using 4 comparative countries (BG, HR, SR,SI)
 - b. provisions of external price referencing in other countries in the region and in other EU member states if the product is not present in the 4 comparative countries
 - c. establishment of a comparative wholesale price as the LOWEST price in the set of pertinent countries
 - d. provision for market size adjustment according to the provisions of Article 7(2) of the proposal of the Law, when the lowest price is obtained in a comparative country with at least twice larger population
 - e. determination and efficient means of updating the systemic parameters used for above item d (Annex III)
 - f. specific but technically homologous provisions of the model for price calculations for original, generic, biosimilar and outstanding medicinal products
 - g. safeguard mechanism for the cases where the above item "d" applies: adjustment for market size cannot exceed the average price level observed in the comparative countries
 - h. provision for a user-friendly price calculation tool for applicants and regulators (form A in Annex I)
 - i. provisions for obligatory periodic update of prices twice a year and for facilitation of voluntary lowering of the prices that is based on business interest of the applicants
 - j. provisions for regular publication of prices and inter-institutional communication of data on prices of Medicinal products
 - k. full integration of pricing model with mechanisms leading to agreed lower prices that are provided by the proposal of the law.
3. Proposal contains three Annexes (I-III) that describe or contain the necessary technical tools for the formulation and determination of the abovementioned regulated ceiling wholesale prices of medicinal products. Usage of Form A in the Annex I should be envisaged as an electronic tool (XLS spreadsheet) that will be downloadable from the webpage of the Competent Authority.

Dr. Stanislav Primožič, Consultant
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