

Comments on the Procedure of *Public Bidding* for *Determining Prices of Medicinal Products*

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American Chamber of Commerce in Croatia *Američka gospodarska komora u Hrvatskoj*

Contents

Introduction 3

- Inadequate transparency of the methodology used to define therapeutic groups 3**
- A short time for collecting data on the consumption of medicinal products..... 3**
- Legal uncertainty regarding the option to appeal..... 4**

Recommendations 4

Introduction

The American Chamber of Commerce in Croatia (AmCham) hereby sets forth its position, i.e. remarks and suggestions for improvements regarding the document laying out the rules and procedure of *Public Bidding for Determining Prices of Medicinal Products*, published by the Croatian Health Insurance Fund on September 28, 2017 (hereinafter referred to as: the Public Bidding).

Specifically, AmCham's remarks on the aforesaid procedure relate to the following elements:

Inadequate transparency of the methodology used to define therapeutic groups

In the published document *Public Bidding for Determining Prices of Medicinal Products*, there are certain ambiguities with regards to defining therapeutic groups. Specifically, the methodology used to define these groups was not explained in a clear and transparent manner, and this leads to the impression that therapeutic groups were not defined in a consistent, systematic, and transparent way.

AmCham believes that such procedure by the Croatian Health Insurance Fund in defining the therapeutic groups does not comply with the *Council Directive 89/105/EEC relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems*.

A short time for collecting data on the consumption of medicinal products

Data regarding the consumption of medicinal products used by the Croatian Health Insurance Fund to establish the reference price (a medicinal product with at least 5% of the market share volume within the reference group, within a period of 3 months prior to the Decision on the Public Bidding), is not publicly available and is therefore not verifiable.

In addition, the 3-month period during which the data is collected is too short to ensure the targeted relevance of the data obtained. Furthermore, setting a reference price on the basis of data collected over such a short time period leaves room for possible attempts of abuse, which consequently may result in supply shortages of medicinal products on the market.

Legal uncertainty regarding the option to appeal

Article 20 of *The Ordinance on the Measures and the Method for Determining the Wholesale Price of Medicinal Products and the Manner of Reporting on Wholesale Prices*¹ also defines the option to appeal against the Decision of the Governing Board of the Fund on defining a reference group with reference prices, to the ministry competent for health care, within 15 days from the date of its publication. In reality, this deadline is practically non-existent since, at the same time, a 30-day deadline is running during which the marketing authorization holder has to declare its final position on the same subject against which the appeal was raised. If the aforesaid position is not stated, all rights in the bidding procedure will be lost regardless of the fact that the previously filed appeal will not be substantively resolved by this point.

Recommendations

Pursuant to the above, and with the aim of improving the relevant Ordinance and the specific Public Bidding procedure, AmCham proposes the following:

- 1) Annulment of the Decision of the Croatian Health Insurance Fund on the Public Bidding procedure;
- 2) Performing a review of the Public Bidding procedure in order to verify irregularities pointed out in this position paper and identify any other potential irregularities;
- 3) Establishment of an expert working group that could correct detected irregularities in the implementation of the Public Bidding procedure, including:
 - clarification and/or revision of the methodology used to define the therapeutic groups;
 - prolongation of the reference period for the collection of data on the consumption of medicinal products, ideally to a year, but not less than six months before issuing the Decision of the Fund on implementing the Public Bidding procedure;
- 4) Establishment of a working group to prepare a draft of the *Amendments to the Ordinance on the Measures and the Method for Determining the Wholesale Price of Medicinal Products and the Manner of Reporting on Wholesale Prices*.

¹ *Official Gazette 83/13, 12/14, 69/14, 22/15 and 84/15*

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