Comments on the Draft of the Ordinance Establishing the Criteria for the Inclusion of Medicinal Products in the List of Medicinal Products of the Croatian Health Insurance Fund

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AmCham

American Chamber of Commerce in Croatia Američka gospodarska komora u Hrvatskoj

Contents

Introduction

Determining the prices of medicinal products for human use and deciding on their inclusion in the national health insurance system constitutes the criteria that generally aim to ensure better access to medicinal products for the patients with optimal use of resources of health care funding and encouraging research and development of new medicinal products.

According to the data of the European Federation of Pharmaceutical Industry and Associations (EFPIA), the availability rate of new medicinal products i.e. the medicinal products with an international nonproprietary name (INN), measured according to the share of new medicinal products authorized for marketing in European countries in the period from 2014 to 2016 that are available to patients in 2017, is among the lowest in Europe for the Republic of Croatia – 28%. Also, the Patients W.A.I.T. Indicator, the indicator of average delay, measured by the average period between the marketing authorization and the actual availability of the medicinal product by its inclusion in the basic or supplementary reimbursement list of medicinal products of the Croatian Health Insurance Fund (HZZO), is almost 500 days and it is among the highest in Europe.

The process of drafting the new *Ordinance establishing the criteria for the inclusion of medicinal products in the reimbursement list of the Croatian Health Insurance Fund as well as determining the prices of medicinal products reimbursed by the Fund and the method of reporting* and *Ordinance establishing the highest allowable wholesale price of the medicinal product and exceptional prices exceeding the highest allowable wholesale price of the medicinal product and calculating annual pricing of medicinal products* should be used as an opportunity to address the stated challenges taking into the account the value of the drug market in Croatia that, according to the report by HALMED (Agency for Medicinal Products and Medical Devices) for 2017, amounts to HRK 6,131,627,475.

In the "Recommendations for improving the medicinal product pricing process" from June 2018 AmCham determined the following basic principles that need to be considered when drafting the new Medicinal Products Act and the related Ordinances:

1) Time frames for decision making
2) Transparent decision making
3) Encouraging production, research and development of new medicinal products

In keeping with the above-mentioned principles, AmCham hereby provides comments on the draft of the *Ordinance establishing the criteria for the inclusion of medicinal products in the reimbursement list of the Croatian Health Insurance Fund as well as determining the prices of medicinal products reimbursed by the Fund and the method of reporting* dated January 24, 2019 and published on the e-Savjetovanja web page.

General remarks on the Ordinance on the inclusion of medicinal products on the list of the Croatian Health Insurance Fund (HZZO)

The issue of the purpose of the ordinance and access to modern technologies

While drafting the ordinance, it is necessary to take its purpose into account. New ordinances effectively regulate the market of medicinal products in Croatia as well as the availability of medicinal products to Croatian citizens and, consequently, better treatment outcomes. The intention of the ordinance should therefore be to simplify and reduce the pricing process and the process of including the medicinal products in the list of the HZZO which would provide citizens with faster access to the best and latest medicinal products.

Given the above, further considerations of some provisions of the draft of the ordinance are necessary because they may, contrary to the legislator's intent, slow down the mentioned process.

Transparent decision making

It is necessary to take into account the compliance with the provisions of the Directive 89/105/EEC (Transparency Directive). All the decisions made by the member countries on the prices of medicinal products and their inclusion on the list of medicinal products within the national health insurance system should be based on transparent, objective publicly available criteria that can be verified. Also, descriptive terms should generally not be used in the implementing regulations, but they should be written precisely and accurately. An appropriate publication should be ensured annually in the relevant gazette in accordance with the provisions of the Transparency Directive.

Comments on specific articles of the Ordinance on the inclusion of medicinal products on the list of HZZO

Article 1

Article 1, paragraph 2 of the draft of the ordinance stipulates the following:

(2) Price of the medicinal product within the context if this Ordinance is the wholesale selling price of the medicinal product (hereinafter: price of the medicinal product).

Comment:

AmCham proposes deleting the word "selling" to harmonize the Ordinance with the provisions of the Medicinal Products Act.

Article 3

Article 3, paragraph 1, items 1-9 of the draft of the ordinance stipulate the following:

Criteria for the inclusion of the medicinal products in the list of the HZZO are:

1. importance of the medicinal product from the aspect of public health
2. therapeutic value of the medicinal product in relation to the suggested indication
3. relative therapeutic value of the medicinal product
4. assessment of ethical aspects
5. optimal quantity of the medicinal product for the treatment based on the diagnosis and the stage of the disease
6. price of the medicinal product/pharmacoeconomic analysis
7. marketing authorization
8. number of European Union member states with the marketing authorization and a number of member states
9. of the European Union where the medicinal product is funded by the national health insurance provider.

Comment:

Since the text should be interpreted unambiguously for the sake of clarity of the implementation of the provisions of this Article, adding the words "and/or" after the items 1-8 is suggested. Article 6, item 3 of the Transparency Directive calls for publication of the criteria which are to be taken into account by the competent authorities in deciding whether or not to include medicinal products on the list.
We also propose a correction in Item 8 of "number of member states", which should be part of Item 9.

1. importance of the medicinal product from the aspect of public health and/or,

2. therapeutic value of the medicinal product in relation to the suggested indication and/or,
3. relative therapeutic value of the medicinal product and/or,
4. assessment of ethical aspects and/or,
5. optimal quantity of the medicinal product for the treatment based on the diagnosis and the stage of the disease and/or,
6. price of the medicinal product/pharmacoeconomic analysis and/or,
7. marketing authorization and/or,
8. number of European Union member states with the marketing authorization and/or,
9. number of European Union member states where the medicinal product is funded by the national health insurance provider.

Article 4

Article 4, paragraph 1, items 1-9 of the draft of the ordinance stipulate the following:

In the assessment of the importance of the medicinal product from the aspect of public health from Article 3, item 1 of this Ordinance, the priority tasks of the implementation of health programs shall be considered.

Comment:

In order to avoid any doubt, we propose adding the words "national" before the words "health programs".

In the assessment of the importance of the medicinal product from the aspect of public health from Article 3, item 1 of this Ordinance, the priority tasks of the implementation of ***national*** *health programs shall be considered.*

Article 5, paragraph 2

Article 5, paragraph 2 of the draft of the ordinance stipulates the following:

(2) *In the assessment of the therapeutic value of the medicinal product, the level of recommendation of Croatian clinical guidelines (exceptionally European or American) based on the following evidence will be considered:*

- *class I: the medicinal product is absolutely and undoubtedly effective, therefore it is necessary to use it*
- *class IIa: evidence of the efficacy of the medicinal products is not unambiguous, but there is predominant evidence that the medicinal product is effective, therefore its use is recommended*
- *class IIb: there is insufficient evidence on the efficacy, therefore it is not recommended to use the medicinal product except in special cases*
- *class III: there is no evidence of clinical efficacy of the medicinal product, therefore its use is not recommended.*

Comment:

Given that EMA/HALMED issues a marketing authorization based on the efficacy and safety of the medicinal product, the purpose of this paragraph is unclear.

Therefore, AmCham proposes the following correction of the text:

(2) *In the assessment of the therapeutic value of the medicinal product, the level of recommendation of Croatian clinical guidelines (exceptionally European or American) will also be considered.*

Article 6

Article 6 of the draft of the ordinance stipulates the following:

Given the relative therapeutic value referred to in Article 3, item 3 of this Ordinance, a medicinal product is defined as:

1. a medicinal product with a new therapeutic value when it comes to medicinal products for treatment or prevention of diseases, health conditions or disorders without existing effective treatment,
2. a medicinal product with an added therapeutic value when, in comparison with the standard medicinal product or therapy or if there is no such medicinal product, standard practice, it refers to:
– a more favorable effect on final clinical outcomes,
– a more favorable effect on alternative therapeutic outcomes,
– a more favorable effect on the quality of life,
– efficient treatment of the symptoms of the disease,
– better safety profile of the medicinal product,
– using a medicinal product that suits the patient better, which increases the patient's compliance,
3. a medicinal product with no evidence of new or added therapeutic value.

Comment:

According to the Article 6, item 3 of the Transparency Directive, the criteria which are to be taken into account by the competent authorities in deciding whether or not to include medicinal products on the list should be published, therefore for the sake of relevance, we propose that the criteria that the Fund has to take into account in deciding whether or not to include medicinal products on the list should be published in advance.

Article 7

Article 7 of the draft of the ordinance stipulates the following:

In the assessment of medicinal products intended for the treatment of rare diseases, ethical aspects will also be taken into consideration if there are no other therapeutic

options and if it refers to medicinal products that significantly improve the long-term course of the disease or the patient's quality of life.

Comment:

According to the Article 6, item 3 of the Transparency Directive, the criteria which are to be taken into account by the competent authorities in deciding whether or not to include medicinal products on the list should be published, therefore for the sake of relevance, we propose that the criteria that the Fund has to take into account in deciding whether or not to include medicinal products on the list should be published in advance.

Article 8

Article 8 of the draft of the ordinance stipulates the following:

In the assessment of the criteria referred to in Article 3, item 5 of this Ordinance of the optimal quantity of the medicinal product required for treatment, the following parameters will be considered:

- the adult patient's average weight of 70 kg and/or the body surface area of 1.8 m2
- defined daily dose of the medicinal product (hereinafter: DDD), recommended method of posology from the Summary of Product Characteristics i.e. the usual therapeutic dose of the medicinal product
- 365 days per year if the medicinal product has to be administrated continuously
- the quantity of medicinal product per therapeutic cycle and the number of therapeutic cycles per year for the medicinal product taken in cycles.

Comment:

There is fixed posology for certain medicinal products in the Summary of Product Characteristics.

AmCham proposes the following wording for Article 8:

In the assessment of the criteria referred to in Article 3, item 5 of this Ordinance of the optimal quantity of the medicinal product required for treatment, the posology defined in the Summary of Product Characteristics will be considered.

If the quantity is not defined in the Summary of Product Characteristics, the following items will apply:

- the adult patient's average weight of 70 kg and/or the body surface area of 1.8 m2
- WHO defined daily dose of the medicinal product (hereinafter: DDD)
- 365 days per year if the medicinal product has to be administrated continuously

- the quantity of medicinal product per therapeutic cycle and the number of therapeutic cycles per year for the medicinal product taken in cycles.

Article 9

Article 9 of the draft of the ordinance stipulates the following:

In the assessment of criteria referred to in Article 3, item 6 of this Ordinance the following information will be considered:

- the price of the medicinal product calculated in accordance with the ordinance establishing the highest allowable wholesale price of the medicinal product
- the price of the medicinal product calculated in accordance with this Ordinance
- data from the pharmacoeconomic study/budget impact analysis study.

Comment:

Since the text should be interpreted unambiguously for the sake of clarity of the implementation of the provisions of this Article, adding the words "and/or" after the items 1-2 is suggested (as suggested in Article 3).

The proposed new formulation is as follows:

In the assessment of criteria referred to in Article 3, item 6 of this Ordinance the following information will be considered:

- the price of the medicinal product calculated in accordance with the ordinance establishing the highest allowable wholesale price of the medicinal product and/or,
- the price of the medicinal product calculated in accordance with this Ordinance and/or,
- data from the pharmacoeconomic study/budget impact analysis study.

Article 11

Article 11 currently stipulates that:

the medicinal product will not be included in the list of medicinal products of the Fund if:

- *the medicinal product does not show the same or added value in therapeutic or economic terms as compared to medicinal products in the same therapeutic group that are already included in the list of medicinal products*
- *unacceptably high price is proposed for the medicinal product*
- *the medicinal product is administered for alleviating symptoms and it is less necessary from the aspect of public health*
- *the medicinal product is administered in conditions that can be regulated by lifestyle changes*

- *the medicinal product is classified as over-the-counter.*

Comment:

a) In the article, under the second indent, the phrase "unacceptably high price" is mentioned.

Using such phrases should be avoided in the final version of the document in order to avoid ambiguous and/or arbitrary interpretation of the provisions. Such wording and criteria create a possibility of misuse and they are not transparent enough, because it is unclear which publicly defined criteria determine the "acceptability" or "unacceptability" of the price.

The amount is to be defined and published as required by the Transparency Directive referred to in Article 2.

Therefore, AmCham proposes that the indent is defined more precisely or deleted.

b) The last indent of Article 11 stipulates that the "medicinal product will not be included in the list of medicinal products of the Fund if it is: classified as over-the-counter"

Paracetamol, for example, also belongs to this category of medicinal products, therefore this provision might open-up a practical impossibility of administering this medicinal product to a patient in a hospital, which is why the intent of this indent should be phrased differently in order to preserve the legislator's intent.

Therefore, AmCham suggests that the indent in question is deleted.

Article 14

Article 14, paragraph 5 of the draft of the ordinance stipulates the following:

(5) The proposal to delete the medicinal product, besides the marketing authorization holder, may be also submitted by the Committee.

Comment:

Adding a phrase "with prior notice to the marketing authorization holder" is suggested.

(5) The proposal to delete the medicinal product, besides the marketing authorization holder, may be also submitted by the Committee ***with prior notice to the marketing authorization holder****.*

Article 16, paragraph 1, item 7

Article 16, paragraph 1, item 7 stipulates that with the request for inclusion of a new active substance or a new indication in the list of medicinal products, the following, inter alia, should be attached:

> *7. a statement that it is an original medicinal product with a patent or other protection, indicating what the specific status of the medicinal product refers to and its expiration date.*

Comment:

It is unclear what the phrase "other protection" refers to in the text above.

Intellectual property rights protection is not under the jurisdiction of the Fund but the State Intellectual Property Office, so AmCham proposes for this item to be deleted.

Article 16, paragraph 1, item 8

Article 16, paragraph 1, item 8 stipulates that with the request for inclusion of a new active substance or a new indication in the list of medicinal products, the following, inter alia, should be attached:

> 8. *tabular presentation of the status of the medicinal product in the health insurance systems of other European Union member states, with listed indications and administration criteria, portion of the cash amount covered by the health insurance of each country, the amount of participation in the cost of the medicinal product and other relevant information for funding the medicinal product in a specific state with an indication of the source of information*

Comment:

Since the type of information following the words "with listed indications" is not available, we propose that this part of the item should be deleted.

Item 8 in accordance with the comment would read as follows:

> *8. tabular presentation of the status of the medicinal product in the health insurance systems of other European Union member states, with listed indications*

Article 16, paragraph 1, item 9

Article 16, paragraph 1, item 9 stipulates that with the request for inclusion of a new active substance or a new indication in the list of medicinal products, the following, inter alia, should be attached:

9. *decision or opinion on the funding of the medicinal product by the competent authority in charge of health technology assessment, with listed indications and administration criteria, portion of the cash amount covered by the health insurance of each country, the amount of participation in the cost of the medicinal product and other relevant information for funding the medicinal product in a specific state*

Comment:

Since this type of information is not available, we propose that item 9 be deleted.

Article 16, paragraph 1, item 16

Article 16, paragraph 1, item 16 stipulates that with the request for inclusion of a new active substance or a new indication in the list of medicinal products, the following, inter alia, should be attached:

16. a signed copy of the Agreement between the Fund and the marketing authorization holder

Comment:

We propose regulation of the ethical advertising process through the Agreement on Ethical Advertising in line with current practice.

Item 16 in accordance with the comment would read as follows:

16. a signed copy of the Agreement on Ethical Advertising of Medicinal Products between the Fund and the marketing authorization holder

Article 16, paragraph 2

Article 16, paragraph 2 stipulates the following:

(2)Together with the documentation from paragraph 1 of this Article, a related offer where the request for inclusion of a new medicinal product in the list of medicinal

products of the same authorization holder is connected with a parallel proposal for price reduction i.e. the costs for the medicinal product that is already on the list of medicinal products can be attached to the request for inclusion of a medicinal product with a new active substance or the proposal for expanding the indication of a medicinal product that is already included in the list of medicinal products.

Comment:

Suggested wording is not clear enough, that is, it is not clear enough what was envisaged under the "related offer".

Therefore, AmCham suggests the following alternative wording for Article 16, paragraph 2:

(2) Together with the documentation from paragraph 1 of this Article, ***a request of the marketing authorization holder for inclusion of a new medicinal product in the list of medicinal products connected with a parallel proposal for price reduction i.e. the costs for the medicinal product that is already on the list of medicinal products of the same marketing authorization holder*** *can be attached to the request for inclusion of a medicinal product with a new active substance or the proposal for expanding the indication of a medicinal product that is already included in the list of medicinal products.*

Article 18, paragraph 3

Article 18 paragraph 3 stipulates that the budget impact analysis study of the Fund for including a new medicinal product or for expanding the indication of a medicinal product that is already included in the list of medicinal products *"is done for the period of three years beginning from the first day of the following calendar year"*.

Comment:

This framework is not adequate for, for example, chronical diseases that comprise a high share in the health problems of the population in Croatia. It would therefore be advisable to predict and prescribe the indicative period as a period of *"no less than three years",* but to also allow for the submissions of analyses with different time periods (5, 7, 15 years, or whatever is appropriate).

Item 18, paragraph 3, in accordance with the comment would read as follows:

(3) The study is done for the period ***of no less than three years*** *beginning from the first day of the following calendar year.*

Article 19

Comment:

Regarding the category i.e. list of *particularly expensive medicinal products*, the criteria placing the medicinal product in the stated category should be defined more clearly, given the fact that the current wording allows for the marketing authorization holders to arbitrarily decide if they want the medicinal product to be included in the stated list or not. The criteria for particularly expensive medicinal products should be clearly defined and universally applicable.

Article 19, paragraph 2, indent 3

Article 19, paragraph 2, indent 3 stipulates the following:

(2) The Fund will consider the proposal from paragraph 1 of this Article if with the conditions prescribed by this Ordinance the applicant proposes:
– guideline for prescribing the medicinal product that is strictly defined by the professional association of the Croatian Physicians Association or another appropriate professional association.

Comment:

We propose deleting the word "*strictly"* in indent 3 because the referenced guidelines are changed relatively often, and the treatment algorithms are commonly not exclusively defined.

Article 19, paragraph 2, indent 7

Article 19, paragraph 2, indent 7 stipulates that the Fund is considering a proposal to include the medicinal product in the List of particularly expensive medicinal products of the Fund if together with the conditions prescribed by the Ordinance the applicant proposes:

- *the use of a medicinal product that makes a significant step forward in the risk and benefit ratio of the therapy for the indication in relation to medicinal products that are already included in the list of medicinal products.*

Comment:

It is questionable what constitutes a "significant step forward" in the risk and benefit ratio. There are no criteria for defining a significant step forward for a specific therapy in a specific area (rheumatology vs oncology). A "significant step forward" in this context is a term that is open to subjective interpretation. The criteria should be

defined and published as required by the Council Directive 89/105/EEC referred to in the Article 2.

Therefore, AmCham considers that the indent should be worded differently in order to preserve the original intent.

Article 19, paragraph 5

Article 19, paragraph 5 currently reads:

(5) If there is a medicinal product used for the same indication that is included in the List, the Fund is obliged to harmonize the prices of all medicinal products for the same indication by determining the price per form for each medicinal product on the list by recalculating the prices regarding the use and the necessary quantity of the medicinal product per cycle and/or within a defined time period.

Comment:

Medicinal products included among the particularly expensive medicinal products are approved for various indications, and the medicinal products administered for the same indication are not always equally efficient. Also, guidelines for administering the medicinal products for the same indication can vary significantly.

The Fund bears no risk for uncontrolled consumption for the medicinal products included in the particularly expensive products because of the value-cap contract. The price of the medicinal products and the mechanisms for harmonization and consumption control have already been regulated (Article 32), so this additional mechanism would have unforeseen consequences for the health of patients because they might be denied their effective therapy or the medicinal product with which they started their treatment at one point without an adequate therapeutic substitution.

Patients may not be able to get the appropriate medicinal product if the authorization holder is unable to reduce the price, and the replacement with another medicinal product is not medically acceptable (e.g. biological medications) or other medicinal products are not adequate because of different guidelines or patient's profile. This can consequentially result in the deterioration of the treatment outcomes.

Therefore, AmCham proposes deletion of the Article 19, paragraph 5.

Article 19, paragraph 7

Article 19, paragraph 7 currently reads:

(7) If the authorization holder does not harmonize the price of the medicinal product with the price from paragraph 5 of this Article or if the medicinal product with the

same unprotected name as the medicinal product that is already on the list is included in the list, the Committee can suggest removing the medicinal product from the list.

Comment:

Since this paragraph primarily refers to paragraph 5, and we have proposed its deletion, **we therefore propose that paragraph 7 is also deleted.**

Article 23

Article 23 currently stipulates the following:

The request or proposal referred to in Article 12 of this Ordinance shall be considered by the Committee, except those proposals for which by the General Act of the Fund referred to in Article 44 of this Ordinance it was determined otherwise.

Comment:

From the current wording of the Article it is unclear which Act/document the Article refers to.

Since the document this Article refers to is adopted at the level of the Fund, we would hereby like to stress the importance of commenting on the the stated document with relevant parties in the phase of its drafting.

Article 24

Article 24 currently reads:

(1) The Management Board of the Fund appoints a Committee.

(2) The Committee has nine permanent members. The Management Board of the Fund can, as needed, also appoint additional members.

(3) The Committee shall adopt its Rules of Procedure with the consent of the Management Board of the Fund.

(4) The annual schedule of the regular sessions of the Committee will be published on the Fund's web site by 31 January for the current year.

(5) The Committee can also work in extraordinary sessions. Dates of the extraordinary sessions shall be published on the web site of the Fund in the period of five work days from the date of convening.

Comment:

AmCham proposes adding a new paragraph 6 to the current Article 24 in order to increase the transparency of the Committee's work:

(6) Daily agenda of the sessions shall be published on the web site of the Fund seven days before the session is held.

Article 25, paragraph 2

Article 25, paragraph 2 currently reads:
(2) The Committee may request an additional opinion of a professional association of the Croatian Physicians Association, the reference center of the Ministry in charge of the health care system, the Agency, an assessment by the competent authority for assessing health technologies or from another professional association.

Comment:

Within the Article a time period should be prescribed within which it is possible to request an additional opinion within 8 days from the day of the session at which it was decided that the additional opinion will be requested.

Article 27, paragraphs 2 and 3

Paragraphs 2 and 3 of Article 27 currently read:

(2) The Committee may suggest including the medicinal product in the list of medicinal product with a time limit, if the opinion is given for the medicinal product that the criteria from Article 10, paragraph 1 of this Ordinance refers to, and the authorization holder in that case has to submit a new request for including the medicinal product in the list of medicinal products no later than two years since the day of the inclusion of the medicinal product in the list of medicinal products.

(3) If the authorization holder does not submit a new request within the deadline from paragraph 2 of this Article, the medicinal product shall be deleted from the list of medicinal products.

Comment:
According to other legal provisions and the provisions of this Ordinance the authorization holder must notify the Fund and HALMED about the termination/expiration of the decision or of the shortage of the medicinal product.

In accordance with the above, we propose the amendment of paragraphs 2 and 3 as follows:

(2) The Committee can suggest including the medicinal product in the list of medicinal product with a time limit, if the opinion is given for the medicinal product that the criteria from Article 10, paragraph 1 of this Ordinance refers to, and the authorization holder in that case must ***notify the Fund about the renewal of the marketing authorization decision*** *no later than two years since the day of the inclusion of the medicinal product in the list of medicinal products.*

(3) If the authorization holder does not notify the Fund about the ***renewal of the marketing authorization decision*** *within the deadline from paragraph 2 of this Article, the medicinal product shall be deleted from the list of medicinal products.*

Article 31, paragraph 1

Article 31, paragraph 1 currently reads:

(1) The procedure for determining the price for the list of medicinal products and the price of the medicinal product paid by the Fund and harmonization of the prices on the list of medicinal products is done according to the provisions of this Ordinance.

Comment:

Since the Fund is responsible for determining the price paid from its own budget, while the reimbursement amount should be possible up to the highest allowed price determined by HALMED, we suggest deleting the segment *"for the list of medicinal products and the price of the medicinal product"* from Article 31, paragraph 1. It is stated in accordance with the Medicinal Products Act that stipulates that the Minister will prescribe the manner of "determining the prices of medicinal products paid by the Fund" with an Ordinance.

Article 32, paragraph 1

Article 32, paragraph 1 currently reads:

(1) Price of a medicinal product containing a completely new active substance with significant effect on increasing the possibility of treatment and healing, shall not be higher than 100% of the average comparative price calculated according to the provisions of the ordinance determining the highest allowable price of the medicinal product.

Comment:

Bearing in mind the provided comment related to Article 31, paragraph 1, we propose on the same basis that the wording of Article 32, paragraph 1 be amended to include the words "to be paid by the Fund" in the current proposition.

Amended wording of Article 32, paragraph 1 according to the comment would read:

(1) Price of a medicinal product ***to be paid by the Fund*** *containing a completely new active substance with significant effect on increasing the possibility of treatment and healing, shall not be higher than 100% of the average comparative price calculated according to the provisions of the ordinance determining the highest allowable price of the medicinal product.*

Article 32, paragraph 2

Article 32, paragraph 2 currently reads:

(2) The price of the medicinal product for a medicinal product containing a completely new active substance, when there are comparative medicinal products on the list of the Fund with the same or similar pharmacologic-therapeutic properties (level 4 ATC) cannot be higher than 90% of the price of the comparative medicinal product paid by the Fund.

Comment:

a) Bearing in mind the provided comment related to Article 31, paragraph 1, we propose on the same basis that the wording of Article 32, paragraph 2 be amended to include the words "to be paid by the Fund" in the current proposition.
b) Pertaining to the provision that the price of the medicinal product "cannot be higher than 90% of the price of the comparative medicinal product paid by the Fund", we would like to emphasize that such a provision puts innovative medicinal products that are not the first included in the list of the Fund at the level ATC4 in a less favorable position and consequentially narrows therapeutic options. Furthermore, in the segment of prescription medicinal products, such rule will continue to result in the new innovative medicinal products coming to the market with growing surcharges for the patients.

Therefore, AmCham proposes an amendment of the Article 32, paragraph 2 as follows:

(2) The price of the medicinal product ***to be paid by the Fund*** *for the medicinal product containing a completely new active substance, and there are comparative medicinal products in the list of the Fund with the same or similar pharmacologic-therapeutic properties (level 4 ATC)* ***cannot be higher than 100% of the average comparative price calculated according to the provisions of the ordinance determining the highest allowable price of the medicinal product or 100% of the price of the comparative medicinal product with the same or similar pharmacologic-therapeutic properties (level 4 ATC).***

Article 32, paragraphs 3 and 4

Article 32, paragraphs 3 and 4, currently reads:

(3) Notwithstanding paragraph 2 of this Article, the price of the medicinal product for the medicinal product containing a completely new active substance, and there are comparative medicinal products in the list of the Fund with the same or similar pharmacologic-therapeutic properties (level 4 ATC) can amount to 100% of the price of the comparative medicinal product if the authorization holder proves that the medicinal product has added value as referred to in Article 5 of this Ordinance.
(4) The price of the medicinal product paid by the Fund for the medicinal product with the same active substance that exists on the list of medicinal products of the Fund or for the medicinal product containing a completely new active substance, and there are comparative medicinal products on the list of the Fund with the same or similar pharmacological-therapeutic (level 4 ATC), and including the medicinal product with the improved formulation for administration is suggested, must not exceed the price of 100% of the cheapest comparative medicinal product that is already included in the list of medicinal products paid by the Fund.

Comment:
The medicinal product with added value must be able to achieve a higher price (value -based pricing). If no studies were conducted with the purpose of obtaining an approval for marketing authorization, evidence of added value often become available subsequently.

Therefore, AmCham proposes deleting paragraphs 3 and 4.

Article 32, paragraph 7

Article 32, paragraph 7 currently reads:

(7) The price of each new packaging of the medicinal product with the new form of the medicinal product is determined according to the price determined according to the provisions of this Ordinance and must not exceed the level of 90% of the recalculated price per the form suggested for the packaging for the existing medicinal products with the same unprotected name on the list of medicinal products.

Comment:

The percentage in the mentioned paragraph of Article 32 should be corrected to 100%. Namely, reducing the price of the additional package sizes by 10% will most often result in drug availability only in the size of the package that was initially placed on the market. This reduces the options to the physicians for prescribing the optimal package size and potentially leads to increased costs for the Fund.

Also, the new shape of the medicinal product does not necessarily mean that the administration route is the same. The improved formulation of the medicinal product also results in an increased price of the medicinal product. For example, the price of the SC form of the medicinal product cannot be defined by recalculating to the amount of 90% of the price of the existing IV forms of the same unprotected name of the medicinal product.

According to the above, **AmCham proposes an amendment of the Article 32, paragraph 7 as follows:**

*(7) The price of each new packaging of the medicinal product with the new form of the medicinal product is determined according to the price determined according to the provisions of this Ordinance and must not exceed the amount of **100%** of the recalculated price per the form suggested for the packaging for the existing medicinal products with the same unprotected name on the list of medicinal products.*

Article 32, paragraph 9

Article 32, paragraph 9 currently reads:

(9) The price of the medicinal product for the medicinal product that is suggested to be included in the list of medicinal products, and which contains the same active substance as the medicinal product that is already in the list, must not, for the first such product, exceed the amount of 70% of the price of the medicinal product with the same active substance (with the same unprotected name) that already exists on the list of medicinal products.

Comment:

Bearing in mind the provided comment related to Article 31, paragraph 1, we propose on the same basis that the wording of Article 32, paragraph 2 be amended to include the words "to be paid by the Fund" in the current proposition.

Amended wording of Article 32, paragraph 9 according to the comment would read:
*(9) The price of the medicinal product **to be paid by the Fund** for the medicinal product that is suggested to be included in the list of medicinal products, and which contains the same active substance as the medicinal product that is already in the list, must not, for the first such product, exceed the amount of 70% of the price of the medicinal product with the same active substance (with the same unprotected name) that already exists on the list of medicinal products.*

Article 32, paragraph 12

Article 32, paragraph 12 currently reads:

(12) If there are no equivalent forms and/or equivalent packages in the list of medicinal products to those of the medicinal products that are suggested to be included in the list of medicinal products, the Fund shall calculate the price of the medicinal product for the new form and/or package by logical calculation while taking into account the prices of the equivalent medicinal product in the forms and/or packages that exist in the list on medicinal products.

Comment:

Following the comment provided for paragraph 7, **we propose the deletion of paragraph 12.**

Article 34, paragraph 1

Article 34, paragraph 1 currently reads:

(1) If the authorization holder delivers a request for including a new indication for a medicinal product that is already on the list of medicinal products, the Fund must reevaluate the price of the medicinal product that was determined upon the inclusion of the medicinal product in the list of medicinal products.

Comment:

In the proposed Article and paragraph, we propose deleting the word "must" and replacing it with "may".

Amended wording of Article 34, paragraph 1 according to the comment would read:

*(1) If the authorization holder delivers a request for including a new indication for a medicinal product that is already on the list of medicinal products, the Fund **may** reevaluate the price of the medicinal product that was determined upon the inclusion of the medicinal product in the list of medicinal products.*

Article 34, paragraph 2

Article 34, paragraph 2 currently reads:

2) If it is determined during the reevaluation that the price of the medicinal product that will be paid by the Fund, which was previously determined upon the inclusion of the medicinal product in the list of medicinal products, is unjustifiably higher for the newly proposed indication, and taking into account the prices of medicinal products paid by the Fund for the same indication with comparative medicinal products that

are already on the list of medicinal products with the same or similar pharmacological-therapeutic properties, the Fund is obliged to request from the authorization holder the correction of the suggested price, that is, price harmonization before issuing the final opinion on the inclusion of the medicinal products in the list of medicinal products.

Comment:

The same medicinal product does not have the equal therapeutic value for different indications in terms of clinical outcomes. Inclusion of new medicinal products for the indication is already regulated with Article 32.

We propose deletion of the paragraph 2 of Article 34.

Article 35

Current wording of Article 35 reads:

Harmonization of the prices of medicinal products that are already included in the list of medicinal products refers to:

1. *harmonization of the prices of all medicinal products from the list of medicinal products that are calculated in the annual calculation procedure of the prices of medicinal products that is done according to the ordinance establishing the highest allowable wholesale price of the medicinal product*
2. *harmonization of the medicinal products intended for use in hospital health institutions at level 5 of the ATC classification of medicinal products*
3. *harmonization of the prices of prescription medicinal products prescribed by the Fund through reference therapeutic groups and subgroups.*

Comment:

The prices of medicinal products intended for use in hospital health institutions have already been regulated by tendering in accordance with the Public Procurement Act. The current legal regulation does not provide the option of additional payment in hospitals and the consequence for the authorization holder if he is unable to match the price of the lowest generic/biosimilar medicinal product would be to delete the medicinal product from the list.

On the other side, the consequence for the patient may be frequent changes in therapy with uncertain clinical outcomes (interchangeability of the medicinal product, clinical consequences).

According to the above, **we propose deleting item 2**, whereby item 3 becomes item 2.

Article 37

Current wording of Article 37 reads:

(1) The procedure of harmonization of the medicinal products intended for use in hospital health institutions is done for medicinal products at level 5 of the ATC classification of medicinal products.
(2) The first harmonization of prices for generic and biosimilar medicinal products at level 5 of ATC is performed simultaneously when a second generic medicinal product or a second biosimilar medicinal product is included in the list of medicinal products, when the price of the originator or the first medicinal product with the same active substance that is already on the list is adjusted to the level of the cost of the first generic or biosimilar medicinal product already listed on the list of medicinal products, for which the price was determined in accordance with Article 32 of this Ordinance.
(3) Every subsequent price harmonization for generic and biosimilar medicinal products at level 5 of ATC is performed at each subsequent inclusion of a new generic and/or every new biosimilar medicinal product on the list of medicinal products, i.e. placing the 4th and each of the following medicinal products with the same active substance in a row, by harmonizing the prices of all the medicinal products with the same active substance that have the price that exceeds the price level that the Fund pays for a medicinal product that is on the list of medicinal products with the price of the previous medicinal product that had the lowest price on the list before including the last generic or biosimilar medicinal product on the list of medicinal products.
(4) The Fund is obliged to calculate the price of the medicinal product to be paid in accordance with paragraphs 2 and 3 of this Article and inform the authorization holder of the amount of the calculated price.
(5) The harmonized prices of medicinal products referred to in this Article shall apply simultaneously with the inclusion in the list of medicinal products referred to in paragraphs 2 and 3 of this Article.
(6) For a medicinal product included in the list of medicinal products and intended for use in hospital health institutions, the Fund shall adjust the price of the medicinal product to the price level established in accordance with paragraphs 2 and 3 of this Article, and in such adjustment process that price represents the amount to be paid by the Fund and there is no participation amount in the price for such medicinal product.

Comment:
Applying the same logic as in comment for Article 35, **we propose deleting the entire Article 37.**

If the proposal for deletion of Article 35 is not accepted, it is necessary to amend the procedure for harmonizing the prices of medicinal products at the level 5 of the ATC classification according to the same form, strength and formulation.

Article 38, paragraph 3

Current wording of Article 38, paragraph 3 reads:

(3) The reference groups may include equivalent medicinal products or medicinal products with similar effect and innocuousness considering levels 3-5 of the ATC classification.

Comment:

The level of the ATC classification should be corrected with the emphasis on the fact that only level 5 of the ATC classification is considered. Price referencing at levels 3-5 of the ATC classification is not transparent enough and it opens the possibility of subjectivity in determining the level for referral for particular groups.

Amended wording of Article 38, paragraph 3 according to the comment would read:

*(3) The reference groups may include equivalent medicinal products or medicinal products with similar effect and innocuousness considering the level **5 of the ATC classification**.*

Article 38, paragraph 8

Current wording of Article 38, paragraph 8 reads:

(8) The authorization holder when proposing a medicinal product to be included on the list of medicinal products must state the comparative medicinal product from the list of medicinal products, i.e. the therapeutic group and subgroup that the medicinal product proposed for inclusion on the list belong to.

Comment:
Criteria of the "comparative medicinal product" must be objective. Also, the criteria for inclusion in the groups and subgroups should be objective, based on the ATC classification rather than the subjective assessment of the authorization holder or HZZO.

According to the above, **we propose that paragraph 8 be deleted.**

Article 41, paragraph 2 and the new paragraph 3

Article 41, paragraph 2 currently reads:

(2) The Fund shall submit to the authorization holder the decision referred to in paragraph 1 of this Article to which the authorization holder is obliged to make a written statement within 8 days from the notification.

Comment:

The minimum deadline for the written statement due to the duration of the internal approval procedures for new prices should be 30 days, and we propose an amendment in the text in accordance with the above.

Also, in line with the Transparency Directive, it is necessary to provide for the possibility of an appeal to the decision of the Fund, therefore that should be incorporated into the text of the Ordinance, and we propose an addition of a new paragraph 3 in the same Article. Thereby the existing paragraph 3 would become paragraph 4, and the paragraph 4 would become paragraph 5.

Amended wording of Article 41, paragraphs 2 and **3** according to the comment:

*(2) The Fund shall submit to the authorization holder the decision referred to in paragraph 1 of this Article to which the authorization holder is obliged to make a written statement within **30** days from the notification.*

(3) An appeal can be submitted against the decision of the Fund referred to in paragraph 2 of this Article to the responsible ministry within 15 days from the date of delivery of the decision of the Board of the Fund.

Article 41, paragraph 5

Article 41, paragraph 5 currently reads:

(5) The price of the medicinal product from the list of medicinal products the price of the original package of which exceeds the level of the determined reference price is to be harmonized whereby the Fund determines the amount of participation in the cost of the prescription medicinal product prescribed by the Fund.

Comment:

It is unclear on what grounds the Fund could determine the amount of participation in the price independently in the situations provided for in this paragraph.

Article 41, paragraph 7

Current wording of Article 41, paragraph 7 reads:

(7) For medicinal products with the determined amount of participation in the cost of the medicinal product, if there are no medicinal products with the same unprotected name without the participation in the cost, the price to be paid the Fund does not change for the medicinal product of the same unprotected name that is proposed to be included in the list of medicinal products until the price level for the original

package of the medicinal product is at the level of the cost paid by the Fund or lower, or until a new procedure where the Fund will determine the new reference price is conducted.

Comment:

Current wording of the stated Article is unclear, and it does not clarify the legislator's intent. **We propose that the Article above be rephrased.**

Article 42, paragraph 2

Current wording of Article 42, paragraph 2 reads:

(2) All new decisions of the Management Board to amend the list of medicinal products with new medicinal products or to change the information for the medicinal product already included on the list shall be published on the web site of the Fund.

Comment:

An appropriate publication should be ensured annually in the relevant gazette in accordance with the provisions of the Transparency Directive.

Proposed new wording for Article 42 and paragraphs 2-6:

(2) The decision of the Management Board of the Fund also decides on the amendment or supplement to the list of medicinal products of the Fund for including the medicinal products on the list of medicinal products of the Fund.
(3) The decision of the Management Board of the Fund referred to in paragraph 2 of this Article shall be published on the web site of the Fund, with a brief explanation of the rejected proposals.
(4) The Decision of the Management Board of the Fund accepting the proposals referred to in Article 12 of this Ordinance shall be published on the web site of the Fund.
(5) The decisions of the Management Board of the Fund referred to in paragraphs 3 and 4 of this Article shall be published on the web site of the Fund no later than 8 days after the decision.
(6) The decision shall come into effect within 15 days from the publication on the web site of the Fund.

Article 43, new paragraph 3

Currently paragraph 43 reads:

(1) The Fund is obliged to publish a complete list of medicinal products on its web site.
(2) The list of medicinal products must contain a list of medicinal products paid by the Fund and the amount of participation of the insured person for the medicinal products that are subject to the obligation of participation in the cost according to the law governing mandatory health insurance.

Comment:

In order to increase the transparency of the work of the Fund, it is necessary to incorporate a clause in the Ordinance that obliges the Fund to provide the right to view the prices of medicinal products on the list, with certain exceptions.

Therefore, we propose adding a new paragraph 3 in the Article 43 as follows:

(3) The Fund will provide the authorization holders with the right to inspect the prices of medicinal products from the list of medicinal products upon written request or via electronic database of medicinal products kept by the Fund (apart from medicinal products with a special contract).

Article 44

Article 44 stipulates the following:

The manner of handling and resolving the requests and proposals referred to in Articles 12 and 15 of this Ordinance and the manner of submitting the notifications referred to in Articles 38 and 40 of this Ordinance and the decisions referred to in Article 41 of this Ordinance shall be prescribed by the Fund by a general act.

Comment:

Since the document/general act this Article refers to is adopted at the level of the Fund, we would hereby like to stress the importance of assessing the stated document with the relevant stakeholders in the phase of its drafting.

Article 46, paragraph 2

Article 46, paragraph 2 reads:

(2) The requests received after the Act on Amendments to the Medicinal Products Act (Official Gazette 100/18) enters into force will be resolved in accordance with this Ordinance.

Comment:

Paragraph 2 should include a provision that the legal act should not have retroactive effects, i.e. the procedures started by one ordinance should be carried out completely by the same ordinance in order to ensure legal certainty.

Article 46, paragraph 3

Current wording of Article 46, paragraph 3 reads:

(*3) For medicinal products which are on the list of medicinal products on the day of entry into force of this Ordinance and which are intended for use in hospital health institutions, the Fund shall undertake the harmonization of the prices of such medicinal products in accordance with Article 37, paragraph 1 of this Ordinance within 90 days of the date of entry into force of this Ordinance, if there is a medicinal product on the list of medicinal products with the same unprotected name from three or more different authorization holders.*

Comment:

In accordance with the proposals and comments for deletion of Article 35, paragraph 2 and Article 37, consequentially **AmCham proposes the deletion of current paragraph 3.**

In order to avoid legal uncertainty by the time of the first annual calculation, it is proposed to add a new paragraph 3 for medicinal products that are currently on the list of medicinal products of the Fund which reads as follows:

Request from Article 16 paragraph 1, items 4 and 5 does not apply to medicinal products which, on the date of entry into force of this Ordinance are already included in the list of medicinal products referred to in the Decision on establishing the basic list of medicinal products of the Croatian Health Insurance Fund (Official Gazette, nos. 63/18, 71/18, 98/18, 102/18 and 106/18) and the Decision on establishing the supplementary list of medicinal products of the Croatian Health Insurance Fund (Official Gazette, nos. 63/18, 71/18, 98/18, 102/18 and 106/18) until the annual calculation of medicinal products in accordance with applicable current regulations

For additional information, please contact:
The American Chamber of Commerce in Croatia
Andrea Doko Jelušić,
Executive Director
T: +385 1 4836 777
E: andrea.doko@amcham.hr