

MEMORANDUM OF UNDERSTANDING

ON COOPERATION IN THE FIELD OF FAIR AND AFFORDABLE PRICING OF MEDICINAL PRODUCTS

The Ministry of Health of the Republic of Croatia,
The Ministry of Human Capacities of Hungary,
The Ministry of Health of the Republic of Lithuania,
The Ministry of Health of the Republic of Poland,
The Ministry of Health of the Slovak Republic,

hereinafter referred to as the "Participants";

Acknowledging the necessity to enhance mutual cooperation in the field of fair and affordable pricing of medicinal products for the service of efficient public financing system;
Willing to develop methods and modalities of cooperation and negotiations with marketing authorization holders concerning pricing of certain medicines, pharmaceutical preparations or medicinal products in their indications;

Have reached the following understanding.

Paragraph 1 – Objective

1. The Participants will encourage mutual cooperation in the field of pricing of medicinal products in order to improve and facilitate access to effective and affordable medicinal products.
2. The Participants will endeavour to develop certain modalities on pricing of selected medicinal products.
3. The Participants agree to collaborate with each other in order to develop effective methods of achieving the objectives of this Memorandum, in particular the Participants will endeavour to develop an international agreement concerning fair pricing.

Paragraph 2 - Methods

1. The Participants will endeavour to achieve objectives set out in Paragraph 1, *inter alia*, by participating in expert meetings, exchanging information and general knowledge and organizing pilot negotiations with marketing authorization holders.
2. The Participants will endeavour to develop a Guidance describing in detail the process of joint negotiations.

Paragraph 3 – Coordination Committee

1. The Participants agree to establish a Coordination Committee – an expert body responsible for achieving objectives of this Memorandum and in charge of any matters related to the subject matter hereof.
2. The main task of the Coordination Committee is to develop the procedure of joint negotiations, the Guidance document, organize pilot negotiations and coordinate further development of an International Agreement concerning fair pricing.
3. The Coordination Committee will consist of up to 5 experts from each Participant, who have knowledge on pricing and reimbursement of medicinal products. The list of nominated experts will form an Appendix to this Memorandum.
4. The Participants agree to establish the following Task Groups:
 - a. Scope Group – which will be responsible for selecting and proposing specific medicinal products for joint negotiation process.
 - b. Analytical Group – which will be responsible for conducting analysis of medicinal products, which are considered for negotiation process and providing analytical support for purpose of creating negotiation strategy.
 - c. Legal Group – which will be responsible for providing legal support for Coordination Committee and coordinating the process of developing Guidance, mentioned in Paragraph 2, section 2, and International Agreement, mentioned in Paragraph 1, section 3.
5. The Coordination Committee may decide to form other task groups with specifically designated duties.
6. The first Coordination Committee meeting will be organized by the Ministry of Health of the Republic of Poland within two months upon signing this Memorandum.
7. The Coordination Committee will adopt its own rules of procedure.
8. When taking decision, the Committee will endeavour to reach consensus.

Paragraph 4 – Pilot negotiations

1. The Participants will strive to achieve the objectives of this Memorandum by encouraging and organizing pilot joint negotiations between the interested Participants and holders of marketing authorization for orphan medicinal products, expensive medicinal products and for other products which pose a significant burden to national health funds. The scope of the products concerned can be further specified by the Scope Group.
2. During negotiations the interested Participants, together with marketing authorization holders, will endeavour to achieve a common position on certain modalities of pricing of medicinal products for the service of efficient public financing system.
3. The pilot negotiations will allow to develop effective procedures of negotiations and identify elements, that can be included in the International Agreement, mentioned in Paragraph 1, section 3.

Paragraph 5 – Exchange of information

1. The Participants will exchange information and documents necessary for achieving the objectives of this Memorandum.
2. The Participants will take necessary measures to safeguard the confidentiality of information and documents that may contain privileged information and trade secrets. Any information and documents exchanged under this Memorandum, will be disclosed only as needed by the persons involved in the performance of this Memorandum. Any public access to information will be assessed by the Participants in accordance with national laws. At the end of this Memorandum, all commercial information will be protected in accordance with the national laws of the Participants.

Paragraph 6 – Legal status

1. This Memorandum is not intended to create any legal obligations under domestic or international law. It will not affect rights and obligations of the Participants, arising from the international agreements, signed by the Participants and other international obligations which Participants have accepted in accordance with the international law.
2. This Memorandum will be carried out within the framework of the respective laws and regulations of each Participant and subject to the availability of appropriated funds and personnel of the Participants.

Paragraph 7 – Validity and evaluation

1. This Memorandum will become effective on the date it is signed and will be valid for 24 months.
2. No later than 12 months after signing of this Memorandum the Participants will organize a meeting and review the level of accomplishment of the objectives set out in Paragraph 1, and decide on further steps to be taken, in particular on the feasibility of concluding the international agreement as provided for in Paragraph 1, section 3.
3. This Memorandum may be terminated by written declaration of all Participants. In this case this Memorandum is terminated on the date stated in the declaration.
4. Every Participant may give a written withdrawal from the cooperation under this Memorandum. The withdrawal from the Memorandum becomes effective on the day it is delivered to the Ministry of Health of the Republic of Poland. The Ministry of Health of the Republic of Poland will immediately notify all Participants on the withdrawal of the Participant.

Paragraph 8 – Amendments

1. Any amendment to this Memorandum requires written declaration of all Participants (consensus).
2. Amendments referred to in section 1 above will become effective in line with Paragraph 7, section 1, and remain effective as long as the Memorandum remains effective.
3. The Appendix referred to in Paragraph 3 section 3 may be updated through notification of the Participant concerned to the Ministry of Health of the Republic of Poland which will circulate such information among all Participants.

Paragraph 9 – New Participants

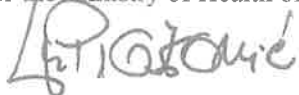
1. After the Memorandum is signed, Ministries of Health or public administration entities interested in cooperation in the field of pricing of medicinal products in order to improve and facilitate access to effective and affordable medicinal products may declare to the Ministry of Health of the Republic of Poland their willingness to participate in the cooperation framework set by this Memorandum.
2. The Ministry of Health of the Republic of Poland will circulate the information referred to in section 1 above among all Participants in order to receive comments on the new Participant. If there is no objection, the involvement of the new Participant will become effective as of the date set out in the Ministry's response. Written declaration and written

consent of accession of the new Participant to the Memorandum will be an integral part of the Memorandum.

3. The declaration referred to in section 1 above can be made no later than 11 months after signature of this Memorandum.

Signed in Warsaw, on 3 March 2017, in English language.

For the Ministry of Health of the Republic of Croatia



For the Ministry of Human Capacities of Hungary



For the Ministry of Health of the Republic of Lithuania



For the Ministry of Health of the Republic of Poland



For the Ministry of Health of the Slovak Republic

