

MEMORANDUM OF UNDERSTANDING

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

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,
The Ministry of Health of the Czech Republic,

hereinafter referred to as the “Participants”;

Endeavouring to support their public health objectives through enhanced cooperation in the field of health technology assessment, pricing and reimbursement.

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;

Taking note of the experiences gained in the course of the implementation of the Memorandum of Understanding signed on 3 March 2017 in Warsaw (hereinafter referred to as MoU2017);

Willing to develop methods and modalities of cooperation and including, if appropriate, negotiations with marketing authorization holders concerning pricing and reimbursement of certain medicines, pharmaceutical preparations or medicinal products in their indications;

Desiring to deliver tangible results that can effectively help national pricing and reimbursement activities;

Having regard to the fact the MoU2017 was concluded for two years and it is therefore necessary to conclude a new Memorandum of Understanding setting out the framework of future cooperation;

Have reached the following understanding.

Paragraph 1 – Objective

1. The Participants will encourage mutual cooperation in the field of pricing and reimbursement of medicinal products in order to improve and facilitate access to effective and affordable medicinal products.
2. The Participants will endeavour to share best practices or develop certain modalities on health technology assessment, as well as on pricing and reimbursement of selected medicinal products.
3. The Participants will strive to enhance communication to share voluntarily information on relevant real-world data (including information on patient outcomes, industrial pricing-setting methodology, volume turnover data etc.) necessary for their respective health technology assessment, pricing and reimbursement activities.

Paragraph 2 - Methods

1. The Participants agree to collaborate with each other in order to develop effective methods of achieving the objectives of this Memorandum.
2. 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 voluntarily pilot negotiations with marketing authorization holders.
3. The Participants agree to establish structured and appropriate standardized tools for information exchange.
4. The participants will also seek for enhanced open data sharing among their respective patient registries.
5. The Participants will adopt yearly workplans with measurable deliverables in order to assess effectively the effectiveness of cooperation.
6. The Participants will increase the visibility of the cooperation via adequate communication tools.
7. The Participant will explore, in good faith, feasible avenues of approach in order to ensure the sustainability of cooperation, *inter alia* via financial support and in kind contributions.

Paragraph 3 – Coordination Committee

1. The Participants agree to maintain the Coordination Committee established under MoU2017 – 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 adopt yearly workplans and support its proper implementation.
3. The Coordination Committee shall 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 Coordination Committee may decide to form task groups with specifically designated duties.
5. The Coordination Committee will work in line with its rules of procedure adopted in line with Paragraph 3.7 of the MoU2017.
6. When taking decision, the Committee will endeavour to reach consensus.

Paragraph 4 – Pilot negotiations

1. The Participants interested in taking part in pilot negotiations 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.
2. During negotiations the interested Participants, together with marketing authorization holders, will endeavour to achieve a common position on certain elements or modalities of pricing of medicinal products for the service of efficient public financing system.

Paragraph 5 – Exchange of information

1. The Participants will exchange voluntarily information and documents necessary for achieving the objectives of this Memorandum in compliance with their national law.
2. The Participants will take available 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 their respective national law. At the end of this Memorandum, all commercial information will be protected in accordance with the respective 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 36 months.
2. Every year, 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. The first meeting shall will take place no later than 12 months after signing of this Memorandum.
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

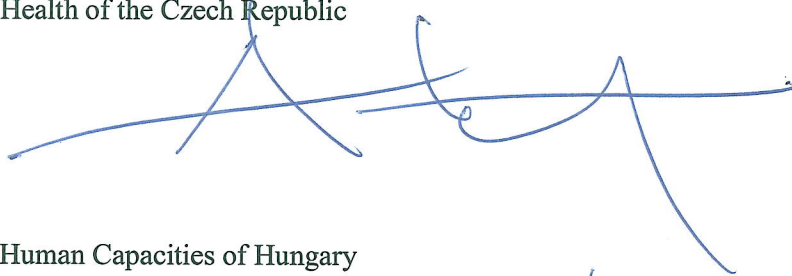
1. After the Memorandum is signed, Ministries of Health or public administration entities interested in cooperation in the field of pricing and reimbursement of medicinal products in order to improve and facilitate access to effective and affordable medicinal products may declare to the

Ministry of Health of the Republic of Poland their willingness to participate in the cooperation framework set by this Memorandum.

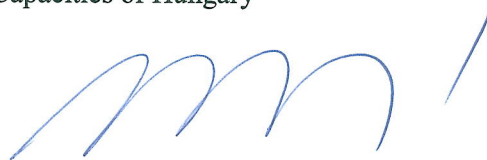
2. The Ministry of Health of the Republic of Poland will circulate the information referred to in section 1 above among all Participants in order to receive comments on the new Participant. If there is no objection, the involvement of the new Participant will become effective as of the date set out in 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.

Signed in Warsaw....., on 15/05/2019....., in English language.

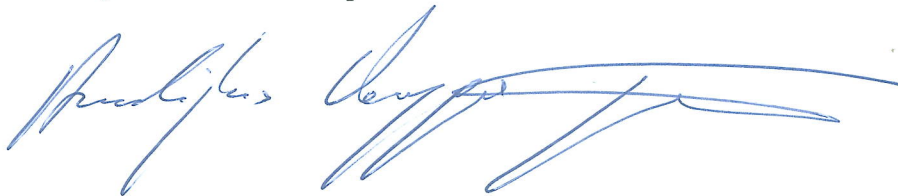
For the Ministry of Health of the Czech Republic



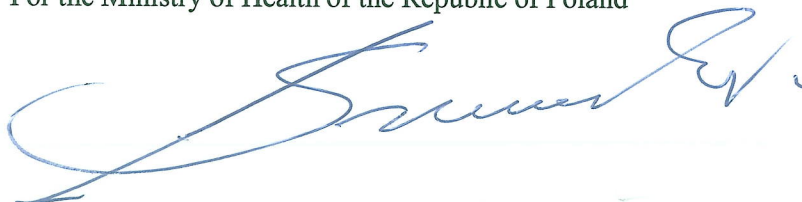
For the Ministry of Human Capacities of Hungary



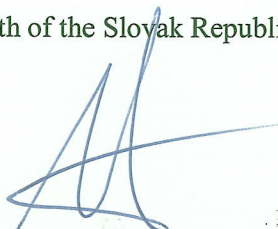
For the Ministry of Health of the Republic of Lithuania



For the Ministry of Health of the Republic of Poland



For the Ministry of Health of the Slovak Republic



Appendix 1

List of experts nominated under Paragraph 3 section 3

Ministry of Health of the Czech Republic:

- 1/ Ministry of Health of the Czech Republic
- 2/ The State Institute for Drug Control

Ministry of Human Capacities of Hungary:

- 1/ Ministry of Human Capacities of Hungary.
- 2/ National Health Insurance Fund of Hungary.
- 3/ National Institute of Pharmacy and Nutrition.

Ministry of Health of the Republic of Lithuania:

- 1/ Ministry of Health of the Republic of Lithuania,
- 2/ National Health Insurance Fund under the Ministry of Health of the Republic of Lithuania.

Ministry of Health of the Republic of Poland:

- 1/ Ministry of Health of Poland,
- 2/ Polish Agency of Health Technology Assessment and Tarification.

Ministry of Health of the Slovak Republic:

- 1/ Ministry of Health of the Slovak Republic.