

**CO-OPERATION AGREEMENT IN THE FIELD OF MEDICINES, MEDICAL DEVICES AND
OTHER HEALTH TECHNOLOGIES BETWEEN THE MINISTRY OF HEALTH OF THE
PORTUGUESE REPUBLIC AND THE MALTA MEDICINES AUTHORITY**

Whereas:

The Ministry of Health of the Portuguese Republic, hereby represented by INFARMED – Autoridade Nacional do Medicamento e Produtos de Saúde, I.P. (National Authority of Medicines and Health Products) and the Malta Medicines Authority, hereinafter referred to as ‘Parties’,

Considering the mutual interest between both Portugal and Malta in several areas of their bilateral relations;

Committed to consolidate the existing basis for mutual co-operation in matters relating to health as a fundamental factor contributing to the development and wellbeing of their people;

Taking into account that the development of new technological tools in scientific and technical co-operation requires the exchange of experiences and information;

Aware of the mutual interest in fostering and promoting co-operation ties between both states in the field of medicines, medical devices and other health technologies;

Guided by the willingness of both parties to develop, within the areas of their own competence, fruitful collaboration in the pharmaceutical sector and medicines policy;

Desirous of further developing the fruitful collaboration already existing between the two Parties through the network of EU Medicines Regulatory Agencies and to deepen their existing links, cooperation and interoperability in such areas;

Conscious that such enhanced collaboration may contribute to the improvement of the health of their populations;

Have agreed as follows:

ARTICLE 1

Purpose

This Agreement establishes the cooperation between the Parties in the field of medicines, medical devices and other health technologies on the basis of reciprocity and taking into account the mutual interests.

ARTICLE 2

Co-operation Areas

The Parties, in accordance with international standards and national regulations in force, shall promote co-operation initiatives between them in the following areas:

1. Medicines and medical devices policy;
2. Good regulatory practices in the field of medicines and medical devices ;
3. Information systems and eHealth scientific and regulatory information;
4. Health technology assessment and sustainability of health systems;
5. Training and Education.

ARTICLE 3

Forms of co-operation

1. Co-operation under this Agreement shall be implemented mainly in the following ways:
 - a) Exchanges of scientific and regulatory information
 - b) Promotion of best practices
 - c) Training and education activities
 - d) Exchange of experts
 - e) Any other form of co-operation as may be mutually agreed upon.
2. The co-operation may be specified in programs for co-operation to be agreed by a Joint Committee for Co-operation covering agreed periods, in accordance with Article 4 of this Agreement.

ARTICLE 4

Collaboration in regulatory science and research by the Medicines Authorities

1. Notwithstanding articles 2 and 3, the Medicines Authorities of both Parties, respectively INFARMED - Autoridade Nacional do Medicamento e Produtos de

Saúde, I.P. and MMA-Malta Medicines Authority, will enhance their collaboration in terms of regulatory science, particularly by means of specific expertise focusing on areas of interest such as biological and biosimilar medicines, medical devices, pharmacovigilance, clinical trials, inspections and real world data.

2. This cooperation will be developed in close conjunction to existing training schemes and capacity building activities to be developed, including the ongoing plan by INFARMED.
3. The Medicine Regulatory Authorities in both countries will develop working collaboration towards bilateral and multilateral joint assessment teams, with a view to contribute to work sharing in the EU network.
4. The Medicine Regulatory Authorities in both countries will cooperate in order to facilitate that medicines registered in Portugal are also registered in Malta.

ARTICLE 5

Joint Committee for co-operation in the field of medicines, medical devices and other health technologies

1. The Parties shall set up a Joint Committee for Co-operation in the field of medicines, medical devices and other health technologies composed of representatives designated by the Parties to which delegate the practical implementation of this Agreement. The Parties shall notify each other about the composition of the Joint Committee.
2. Within the terms of this Agreement, the Committee shall take into account the appropriate procedures and regulations of each of the Parties:
 - a) Develop programmes of co-operation;
 - b) Evaluate and analyze the results of this co-operation;
 - c) The committee shall consist of representatives of INFARMED – National Authority of Medicines and Health Products, I.P. of the Portuguese Republic and of the Medicines Authority of Malta, or other organisations at the discretion of both Parties, and shall meet in Portugal and Malta alternately.

ARTICLE 6

Expenses

Each Party shall bear its own expenses resulting from the co-operation undertaken under the present Agreement, in accordance with their respective internal law.

ARTICLE 7 Entry to force

The present Agreement shall come into effect from the date of its signature, and will remain effective for a period of three (3) years from that date. This Protocol shall be further renewed for a successive period of three (3) years unless either Party notifies the other in writing of its intention not to renew the Protocol at least six (6) months prior to the date of its expiry.

This Protocol may only be modified by mutual consent of the parties.

The Signatories may make further arrangements which will be attached as annexes to this Collaboration Agreement.

Signed in Portugal and Malta on 20 November 2017, in two original copies, in the English language.

Maria do Céu
Lourinho Soares
Machado

Assinado de forma digital por Maria do Céu Lourinho Soares Machado
DN: c=PT, o=Infarmed - Autoridade Nacional do Medicamento e Produtos de Saúde, IP, cn=Maria do Céu Lourinho Soares Machado
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Maria do Céu Machado
President of the Executive Board
INFARMED - Autoridade Nacional
do Medicamento e Produtos de Saúde, I.P.



Anthony Serracino Inglott
Chairman
Malta Medicines Authority