

**MEMORANDUM OF UNDERSTANDING BETWEEN
THE MEDICINES PATENT POOL (“MPP”)
AND THE ITALIAN NATIONAL AGENCY FOR NEW TECHNOLOGIES, ENERGY
AND SUSTAINABLE ECONOMIC DEVELOPMENT
(“ENEA”)**

This Memorandum of Understanding (“MoU”) is made by and between MPP, a not-for-profit corporation organized under the laws of Switzerland, whose business headquarters is located at Rue de Varembe 7, 1202 Geneva, Switzerland, and ENEA, a public research organization organized under the laws of Italy with its registered office at Lungotevere G.A. Thaon di Revel 76, 00196 Rome, Italy, collectively referred to as the “Parties” and individually as a “Party.”

Background:

ENEA is a public research organization aimed at research and technological innovation as well as the provision of advanced services in the fields of energy and sustainable economic development and is engaged in numerous areas such as Energy Efficiency, Renewable Sources, Environment and Climate, Safety and Health, and New Technologies, promotes technology transfer processes and makes its expertise, experience, technologies and services available for development cooperation with low- and middle-income countries (LMICs).

MPP is a United Nations-backed public health non-governmental organization working to increase access to, and facilitate the development of, life-saving medical technologies for LMICs through patent pooling and non-exclusive voluntary licensing. MPP’s 2023-2025 strategy articulates a commitment to working closely with universities, research institutions, funders and other entities to support the inclusion of terms in licensing and funding agreements for early-stage health technologies that contemplate affordable access in LMICs.

MPP and ENEA recognize that equitable access in LMICs can benefit from close collaboration between research institutions and organizations built expressly for the purposes of facilitating affordable access, such as MPP, and that early consideration of LMIC affordable access in licensing or funding agreements may help facilitate such access once a medical technology is commercialized. ENEA and MPP further agree upon the value in utilizing an affordable access plan provision (AAP) in licences of early-stage medical technologies as one method to further equitable access goals, where such provisions create an expectation of the collaborative development of strategies and timelines to achieve affordable access in LMICs, and where such strategies may include, for example, licensing of intellectual property and technology transfer, or other strategies that may be likely to yield equitable access.

MPP and ENEA further recognize that ENEA and its licensees may benefit from additional global health and access-related expertise that MPP may have relevant to particular technologies, disease fields, and/or other issues important to developing a fuller understanding of specific public health needs in certain countries and/or regions. Such expertise may be valuable in assisting in the evaluation and potential improvement of access plans submitted to ENEA.

NOW, THEREFORE, the Parties agree upon a framework of collaboration (the “Collaboration”) as follows:

- 1. Description of Collaboration.** The Parties wish to accomplish the following objectives through the Collaboration:

- (a) On a semi-annual basis, ENEA will update MPP as to executed licences where the AAP provision has been utilized providing detail as to the identity of the licensee, types of technology at issue, the relevant disease field, any other information that may help provide context into the potential public health applications of the technology, and the current status of development of licensed products deriving from such licences (the “Licensed Products”);
- (b) Where ENEA utilizes the AAP in licences of medical technologies and where the Licensed Products mature to the point that affordable access plans must be submitted to ENEA in accordance with the AAP, MPP can, where appropriate, be available as a “designated entity” to assist ENEA in the evaluation of such access plans, working collaboratively with ENEA and ENEA’s licensees;
- (c) MPP and ENEA will seek to establish an ongoing working relationship to share knowledge and perspectives on access-oriented licensing and other issues relating to affordable access medical technologies in LMICs, and to identify opportunities for further collaboration.

2. Communications. The Parties agree that this MOU may be made publicly available on their respective websites and by other appropriate means. Unless in relation to their cooperation or joint activities under this MOU or otherwise expressly authorized by the other Party in writing in advance, neither Party shall, in any manner whatsoever, use the name, acronym or logo of the other Party in connection with their business or otherwise.

3. Financial Implications. This MOU does not in any way commit either Party to financial or human resource obligations. Each Party will respectively bear its own expenses, costs, risks, and liabilities arising from such Party’s obligations and efforts under this MOU. Implementation of this MOU shall be subject to the availability of funds for these activities.

4. Confidentiality

- (a) During the course of this MOU, the Parties may make available to each other certain Confidential Information (as hereinafter defined), or one Party may otherwise learn of Confidential Information held by the other Party. For purposes of this Section, “Confidential Information” means any and all confidential or proprietary information regarding a Party or its business, including, without limitation, any confidential information that either Party has received from a third party and is authorized to share, all products, patents, trademarks, copyrights, trade secrets, techniques, scientific information, computer programs, databases, software, services, research, development, inventions, financial, purchasing, accounting, marketing, fundraising and other information, whenever conceived, originated, discovered or developed, concerning any aspect of its business, whether or not in written or tangible form; provided, however, that the term “Confidential Information” shall not include information (i) which is or becomes generally available to the public on a non-confidential basis, including from a third party provided that such third party is not in breach of an obligation of confidentiality with respect to such information, (ii) which was independently developed by a Party not in violation or breach of this MOU or any other obligation of such Party to the other Party, or (iii) which was or is rightfully known to a Party.

- (b) The Parties shall hold in strictest confidence any of the other Party's Confidential Information; and shall not distribute, disclose or convey Confidential Information to any third party (it being understood that the employees, officers, directors, supervisory board members, observers, committee members and advisors will not fall under the "third party") and shall not make use of any Confidential Information for its own benefit or for the benefit of any third party. The foregoing notwithstanding, the Parties shall not be in violation of this subsection in the event that a Party is legally compelled, or upon request by the authorities, to disclose any of the Confidential Information.
- (c) Any legally binding documentation entered into by the Parties in relation to this MOU and the Collaboration shall contain relevant clauses relating to confidentiality of information.
- (d) The obligations of this Section 4 shall continue for a period of three (3) years after the termination of this MOU.
- 5. Status of MOU.** The Parties agree to be bound by the provisions of Sections 2, 4, 5, 6 and 7 hereof and agree that the remaining Sections of this MOU are not intended to be legally binding and represent the framework for future discussions between the Parties in relation to the Collaboration.
- 6. Effective Date, Term, and Termination.** This MOU will enter into force on the date of its last signature by the two Parties and continue for four (4) years. The MOU may be modified upon written agreement between the Parties or extended for the same or shorter duration by mutual written consent of the Parties to be made thirty (30) days prior to the expiration date. Either Party may terminate this MOU with a sixty (60) day advance written notice to the other Party or in the event of a breach of any provisions of this MOU by the other Party.
- 7. Dispute Resolution.** In the event of any dispute, controversy, difference or claim arising out of, relating to or in connection with this Agreement (including any question regarding the existence, validity, interpretation, performance, breach or termination thereof or any dispute regarding non-contractual obligations arising out of or relating to it), the Parties first shall try to settle such dispute amicably through consultations; otherwise, they will be settled under the ICC Rules of Arbitration, that shall take place in Brussels.

IN WITNESS WHEREOF, the undersigned, duly authorized thereto, have signed the MOU.

ENEA

Firmato digitalmente da: Giorgio Graditi
Organizzazione: ENEA/01320740580
Data: 28/06/2025 16:54:52

Name: Giorgio Graditi
Title: General Director
Date:

Medicines Patent Pool

DocuSigned by:

Charles Gore

4713D0F59C13482...

Name: Charles Gore
Title: Executive Director
Date: 02 July 2025

Appendix A

Template of an Affordable Access Plan Provision

Within three (3) months of receiving AIFA - Italian Medicines Agency (or its foreign equivalent's) approval of a LICENSED PRODUCT, LICENSEE will provide the ENEA with either (a) an Affordable Access Plan (defined below), or (b) a written explanation as to why such an Affordable Access Plan is not needed or infeasible.

In the case of (b), LICENSEE agrees to discuss such reasoning with the ENEA in good faith within one (1) month thereafter ("Initial Discussion") and, if following such Initial Discussion the ENEA concludes an Affordable Access Plan is reasonable and desired, to provide an Affordable Access Plan to ENEA within three (3) months of such Initial Discussion.

The "Affordable Access Plan" means LICENSEE'S and/or its SUBLICENSEES' plans (including strategies and timelines) reasonably intended to support affordable access in a) Low and Middle Income Countries as defined by the World Bank Group ("LMICs"), and b) vulnerable, underserved, and special needs populations in Italy, as defined by the Ministry of Health, such as through licensing or partnerships including with non-profit organizations. To the extent such Affordable Access Plan includes Proprietary Information, LICENSEE will also provide a non-confidential version or statement of such Plan that the ENEA can make available to third parties:

(a) A specified set of ("LMICs") in which the LICENSEE does not intend to commercialize the LICENSED PRODUCTS (the "Non-Commercialized Territory");

(b) LICENSEE'S and/or its SUBLICENSEES' plans (including strategies and timelines) reasonably intended to support affordable access in LMICs and Non-Commercialized Territories, such as through licensing or partnerships including with non-profit organizations; and

(c) LICENSEE'S and/or its SUBLICENSEE' plans (including strategies and timelines) reasonably intended to support affordable access for the vulnerable, underserved and special needs populations in Italy.

Within thirty (30) days of the ENEA's request (but no more often than once annually), LICENSEE agrees to confer with the ENEA to review LICENSEE'S progress, and to consider in good faith any modifications suggested by the ENEA, with respect to its Affordable Access Plan ("Progress Discussions"). For clarity, while the ENEA may invite a designated entity to join either the Initial and/or Progress Discussions under this Paragraph, such discussions will at all times be made subject to the confidentiality obligations set forth in the "Confidentiality" Article of the agreement.

PROGRESS AND ROYALTY REPORTS

For the period beginning [Date], LICENSEE will submit to the ENEA an annual progress report covering LICENSEE's activities related to the development and testing of all LICENSED PRODUCTS, LICENSED SERVICES and LICENSED METHODS and the obtaining of necessary governmental approvals, if any, for marketing in Italy and in foreign countries. These progress reports will be made for all development activities until the first SALE occurs. Each progress report will be a sufficiently detailed summary of activities of LICENSEE and any SUBLICENSEES so that ENEA may evaluate and determine LICENSEE's progress in development of LICENSED PRODUCTS, LICENSED SERVICES, and LICENSED METHODS, and in meeting its diligence obligations under the "Diligence" article, and will include (but not be limited to) the following:

- summary of work completed and in progress;
- current schedule of anticipated events and milestones, including diligence milestones;
- anticipated market introduction dates for the LICENSED TERRITORIES;
- status of implementation of the Affordable Access Plan and SUBLICENSEE's activities during the reporting period.

LICENSEE also will report to the ENEA in its immediately subsequent progress and royalty reports, the date of first SALE.