

MEMORANDUM OF UNDERSTANDING

The Joint Research Centre of the European Commission,
represented for the purpose of signing this memorandum by Stephen Quest, Director General of the
Joint Research Centre, duly entitled to sign,

(hereinafter referred to as '**the JRC**'),

and

The Medicines Patent Pool
with the registered address at Rue Varembe 7, 1202 Geneva, Switzerland,
represented for the purpose of signing this memorandum by Charles Gore, Executive Director, duly
entitled to sign,

(hereinafter referred to as '**the MPP**').

Hereinafter referred to individually as '**the Side**' or collectively as '**the Sides**'.



BRIEF EXPLANATION OF THE BACKGROUND

As the science and knowledge service of the European Commission, the Joint Research Centre's mission is to support EU policies with independent evidence throughout the whole policy cycle. Through its Directorate I, Competences, the JRC consists of an array of Competence Centres which provide cross-cutting scientific and technical support in specific fields of relevance for EU policies. The JRC Unit I.4 hosts two centres, namely: i) the European Commission's Central Intellectual Property Service (CIPS), that is mandated by the Commission to manage its intellectual property rights (IPR), such as patents, copyrights, trademark, and to provide legal advice on IP to the Commission services including on in/out licensing of IPR to third parties; ii) the Centre of Competence for Technology Transfer (CCTT) which, provides technology transfer policy related expertise and services to the European Commission and other institutions of the Union and operational support services to a broader range of stakeholders facing technology transfer related challenges and issues. In liaison with other Commission DGs and Services, JRC Unit I.4 is exploring alternative models of voluntary licensing and patent pooling to facilitate global and equitable access of health technologies to prevent, treat and cure COVID-19.

The Medicines Patent Pool (MPP) Foundation is a non-profit organisation founded by UNITAID in July 2010, based in Geneva, Switzerland. Its public health driven business model aims to lower the prices of medicines and facilitate the development of better-adapted treatments through voluntary licensing and patent pooling. MPP has significantly improved access to HIV and hepatitis C medicines in low- and middle-income countries. The organisation has recently temporarily extended its mandate to cover COVID-19 related technologies (not necessarily limited to medicines) on the global scale in response to international calls.

The Sides wish to establish a mutually beneficial cooperation in the field of intellectual property, in particular as relates to the licensing of intellectual property via patent pools with a focus on the health sector both in the EU and beyond, and in order to benefit from their complementary activities and assets and to share among each other the knowledge arising therefrom.

The Sides wish to undertake joint activities of mutual interest in accordance with their specific needs and objectives, and intend, by separate and formal agreements, determine the areas and subject of such joint activities, on the basis of the understanding set out in this Memorandum of Understanding (hereinafter referred to as '**the MoU**').

THE SIDES HAVE ENVISAGED AS FOLLOWS:

SECTION 1 – SUBJECT AND SCOPE OF THE MoU

- 1.1 The subject of the MoU is to establish the basis for future collaboration between the Sides in the field of licensing of intellectual property by setting out the overall framework for such collaboration in terms of general context, technical areas and procedures for entering into formal collaboration agreements, detailing the specifics of the collaboration.
- 1.2 The envisaged collaboration between the Sides is aimed at further exploring the options for co-operation between the Commission and the MPP, to accelerate access to COVID-19 technologies under equitable and affordable conditions, as a component of a wider EU strategy to fight COVID-19, such as the options being briefly presented in the Technical Annex I.

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- 1.3 Each Side intends as a general rule to implement the MoU through the exchange of publicly available, non-proprietary information. Should the exchange of other information be necessary, such exchange will be subject to Section 3.
- 1.4 The Sides do not intend, or expect, to create intellectual property under the MoU. If it appears that intellectual property is likely to be created, the Sides should enter into a collaboration agreement in accordance with Section 1.5.
- 1.5 In case the Sides decide to undertake joint activities in any of the scientific subjects identified in the Technical Annex 1, they should, prior to undertaking such activities, enter into a separate and formal collaboration agreement, covering the technical, legal (including liabilities of each Side and intellectual property rights) and financial aspects of the envisaged collaboration.
- 1.6 The MoU does not establish legally binding obligations on the part of any of the Sides, including without limitation any financial obligation.

SECTION 2 – MODALITIES OF CO-OPERATION

- 2.1 The implementation of the MoU is subject to the availability of funds, personnel and other resources as well as to the applicable laws and regulations, policies and programmes of each Side. The MoU does not represent any commitment with regard to funding on the part of either Side.
- 2.2 Each Side is expected to bear its own costs and expenses incurred or to be incurred in connection with the implementation of the MoU. There will be no transfer of money between the Sides in connection with the MoU.
- 2.3 The exact modalities of cooperation between the Sides on any of the scientific subjects specified in the Technical Annex 1 will be set out in the collaboration agreements related to the particular subject.

SECTION 3 – CONFIDENTIALITY

- 3.1 In case the Sides exchange confidential information under the MoU, either orally or in written form, existing applicable law and internal rules on confidentiality of information applicable to each Side respectively and distinctively shall be observed.

SECTION 4 – ADMINISTRATIVE PROVISIONS

- 4.1 All correspondence concerning the performance of the MoU is to be sent to the following addresses:

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<p><u>For administrative questions</u> European Commission Joint Research Centre Rue Champs de Mars 28, CDMA 05/194 Brussels 1049 Belgium To the attention of the Head of Unit, mail: JRC-A4-Collaboration-Instruments@ec.europa.eu</p>	<p><u>For administrative questions</u> Medicines Patent Pool 7 Rue Varembe 1202 Geneva Switzerland To the attention of Charles Gore, Executive Director cgore@medicinespatentpool.org</p>
<p><u>For technical questions</u> European Commission Joint Research Centre Rue Champs de Mars 28, CDMA 00/139 Brussels 1049 Belgium To the attention of Giancarlo Caratti, Head of Unit, mail: giancarlo.caratti@ec.europa.eu</p>	<p><u>For technical questions</u> Medicines Patent Pool 7 Rue Varembe 1202 Geneva Switzerland To the attention of Esteban Burrone, Head of Policy, eburrone@medicinespatentpool.org</p>

SECTION 5– DATA PROTECTION

- 5.1 Where the JRC processes personal data included in or related to the MoU, it will do so in accordance with Regulation (EU) 2018/1725.
- 5.2 Where the MPP processes personal data included in or related to the MoU, it will do so in accordance with applicable data protection law, namely Swiss Federal Act of 19 June 1992 on Data Protection.
- 5.3 Details concerning the processing of personal data will be made available to data subjects by each Side in the corresponding data protection notices, which may be amended by each relevant Party unilaterally from time to time.

SECTION 6 – ENTRY INTO EFFECT AND DURATION

- 6.1 The MoU will enter into effect on the date of its signature by the last Side and is concluded for a period of 3 years from said date. The MoU may be extended or amended only by written agreement signed by the duly authorised representatives of both Sides.
- 6.2 Either Side may terminate the MoU at any time upon three months prior written notice to the other Side.

SECTION 7 – ANNEXES AND ATTACHMENTS

7.1 The following annexes shall form an integral part of the MoU:

- Technical Annex 1

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7.2 This Memorandum of Understanding contains the following Attachments:

- Data protection notice on processing of personal data by the Unit for Legal Affairs of JRC for contractual purpose
- Data protection notice on processing of personal data by MPP

Signed in two originals in the English language.

For the **Joint Research Centre of the European Commission**

Done in Brussels/ on _____

Signature: _____

Stephen Quest
Director General
Joint Research Centre

For the **Medicines Patent Pool**

Done in Geneva on 17/12/2020

Signature: Charles Gore

Charles Gore
Executive Director

TECHNICAL ANNEX 1

The JRC is a Directorate General of the European Commission whose mission is to provide scientific and technology support across EU policies, by interacting with the relevant different policy services, and it hosts the Central IP service of the European Commission, which has significant experience in the licensing of intellectual property. Among the different actors present on the international scene operating in the health sector, the MPP is the most relevant and experienced public health organisation for the licensing of essential medicines via the instrument of IP pooling. The MPP is a pooling platform that was established by UNITAID in July 2010 to facilitate voluntary licensing between patent right holders and generic companies in low- and middle-income countries with a focus on medical products related to HIV-AIDS, tuberculosis and hepatitis C. To date, MPP has negotiated licences on 18 medicines, with 10 patent holders. MPP licensees have enabled access to 11.7 billion doses of treatment in over 130 countries.

The main objective of this MoU is to lay the basis and establish a channel of direct communication for setting up possible collaborations between the JRC and the MPP in the area of licensing of intellectual property (patents, technologies and know-how) with focus on the health sector in the EU and beyond, with a view to accelerating the deployment, in any country in need, of essential medical products under fair, equitable and non-discriminatory conditions.

In particular, in relation to the COVID-19 pandemic, the JRC has organised from May to June 2020 three rounds of discussions between representatives of MPP and of the relevant Commission services, which have shown its potential usefulness for different EU policies as vehicle for streamlining deployment of COVID medicines. Although, the expertise gained by the MPP during its ten years of operation is in the area of essential therapeutics in low and middle-income countries, MPP has recently been mandated by its Board to temporarily expand its activities to COVID-19 internationally, including on vaccines. It should be noted that MPP is already collaborating with many of the other leading organisations involved in the fight against COVID-19, including the ACT-Accelerator, WHO, UNITAID, the Global Fund, UN Technology Bank, etc. It is likely that a solution to ensure equitable and affordable global access to successful diagnostics, therapeutics and vaccines will be based on collaboration involving several international actors. Global discussions in this respect are ongoing at the time of signing this MoU.

From the EU side, the recent Communication on an EU Strategy for COVID-19 vaccines (COM(2020) 245) reaffirms the Commission's commitment to universal, equitable and affordable access to COVID-19 technologies. It expresses support for voluntary pooling and licensing of intellectual property related to COVID-19 therapeutics and vaccines, also in line with a recent resolution of the WHO (World Health Assembly Resolution 73.1) to promote equitable global access and fair return on investments. Moreover, the possibility to license through a patent pool is being explored as a possible option to ensure broad and equitable access to the results of research for addressing public emergencies, including COVID-19 under Horizon 2020. Within the context, the recently released Pharmaceutical Strategy (COM(2020) 761 final) and the Intellectual Property Action Plan (COM(2020) 760 final) announce that the Commission will analyse tools to better facilitate access to critical IP in times of crisis.

It should be noted that, while COVID-19 constitutes an urgent priority for both Sides, the scope of the MoU should not be limited to COVID-19 but should also investigate other opportunities in a longer-term perspective.

In particular, in the implementation of this MoU the following opportunities will be explored:

- Collaboration in the frame of the fight against COVID-19 pandemic, in particular as regards:
 - the identification and definition of specific co-operation mechanisms and incentives to encourage the beneficiaries of EU funding to make available their IP through the MPP,
 - the implementation of the global dimension of the EU strategy for COVID-19 vaccines (concerning not only vaccines, but also therapeutics and diagnostics)
 - the possible synergies with the ongoing or developing global public health initiatives, such as the ACT-Accelerator.

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- Collaboration beyond Covid-19 in line with relevant Commission policies on access to essential medicines in the post COVID era and the work undertaken by international organisations active in the field of Global Health and IP, such as the WHO, WIPO and WTO.

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ATTACHMENT: DATA PROTECTION NOTICE

**PROCESSING OF PERSONAL DATA BY THE UNIT FOR LEGAL AFFAIRS OF JRC
FOR CONTRACTUAL PURPOSES**

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1. Introduction

This privacy statement explains the reason for the processing, the way we collect, handle and ensure protection of all personal data provided, how that information is used and what rights you may exercise in relation to your data (the right to access, rectify, block, etc).

The European institutions are committed to protecting and respecting your privacy. As this service collects and further processes personal data, Regulation (EU) 2018/1725¹ is applicable.

This statement concerns the establishment and execution of collaboration instruments, undertaken by the Unit for Legal Affairs of the Joint Research Centre of the European Commission.

2. Why do we process your data?

Purpose of the processing operation: The Unit for Legal Affairs of JRC at the European Commission (referred to hereafter as 'controller') collects and uses your personal information to comply with the administrative and legal procedures relevant for the implementation, management and monitoring of collaboration instruments by the JRC (i.e. the establishment and management of their execution, including drafting, approving and ensuring legal execution of the instruments and compliance with ancillary legal obligations, such as archiving or disclosure following requests for access to documents).

3. Which data do we collect and process?

¹ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ L 295, 21.11.2018, p. 39–98

The personal data collected and further processed are:

- Name;
- Function;
- Contact details (e.g. e-mail address, business telephone number, mobile telephone number, fax number, postal address, company and department, country of residence, internet address).

4. How long do we keep your data?

The controller only keeps the data for the time necessary to fulfil the purpose of collection or further processing. In particular:

Data relating to requests for collaboration instruments are processed immediately. Data encoded at the moment of the signature of the collaboration instrument is kept as it was at the time of reception. The updated data - address or contacts - are used for correspondence and exchanges that follow.

Files relating to collaboration instruments procedures and execution including personal data are to be retained in the service in charge of the procedure until the expiry date of the instrument, and in the archives for a period of 10 years following the expiry of the instrument. These files could be retained until the end of a possible audit if one started before the end of the above periods.

After the periods mentioned above have elapsed, the files containing personal data are assessed and chosen files are sent to the historical archives of the Commission for further conservation, other files are destroyed.

5. How do we protect your data?

All data in electronic format (e-mails, documents, uploaded batches of data etc.) are stored either on the servers of the European Commission or of its contractors; the operations of which abide by the European Commission's security decision of 16 August 2006 [C(2006) 3602] concerning the security of information systems used by the European Commission.

In particular, for electronic information, the information is protected by User IDs and passwords. Only designated staff has the possibility to access the data kept for the purpose of administrative or financial processes. For hardcopy documentation, limited number of staff have access to cupboards; the storage offices are always locked when unattended.

The Commission's contractors are bound by a specific contractual clause for any processing operations of your data on behalf of the Commission, and by the confidentiality obligations deriving from the General Data Protection Regulation (EU) 2016/679.

6. Who has access to your data and to whom is it disclosed?

Access to your data is provided to authorised staff according to the "need to know" principle. Such staff abide by statutory, and when required, additional confidentiality agreements. This includes: Staff of Resource Support Units, some Directorate A Units, scientific personnel of the JRC Directorates; Staff of OLAF (European Anti-Fraud Office), IDOC (Investigation and Disciplinary Office of the Commission), IAS (Internal Audit Services), IAC (Internal Audit Control) of the JRC and the Legal Service of the Commission as well as staff of other Commission Services (SG, DG BUDG and clearinghouse) upon request in the context of official investigations or for audit purposes.

Further, access to your data may also be provided to institutions exercising scrutiny and control functions, including both EU bodies (Court of Auditors, European Court of Justice, EPDS, Ombudsman) and national authorities (judicial or administrative). Your data may also be disclosed to the public in the context of specific requests for access to documents in accordance with EU legislation.

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Recipients of personal data may be within the EU and also in third countries and international organisations with which the JRC establishes scientific or administrative collaboration activities.

7. What are your rights and how can you exercise them?

Any person whose personal data are processed by the controller for the purposes stated above has specific rights as a data subject under Chapter III (Articles 14-25) of Regulation (EU) 2018/1725, in particular the right to access, rectify or erase their personal data and the right to restrict or, where applicable, the right to object to processing or the right to data portability.

Should any person whose personal data are processed in relation to this collaboration instrument have any queries concerning the processing of his or her personal data, they may address a request to the controller. The data subject may also address a request to the Data Protection Officer of the Commission. Data subjects have the right to lodge a complaint at any time with the European Data Protection Supervisor (see contacts below).

8. Contact information

If you have comments or questions, any concerns or a complaint regarding the collection and use of your personal data, please feel free to contact the controller using the following contact information:

The controller:

- European Commission
Joint Research Centre
Unit A.4 – Legal Affairs

Email: JRC-A4-COLLABORATION-INSTRUMENTS@ec.europa.eu

Other contacts:

- The Data Protection Officer (DPO) of the Commission: DATA-PROTECTION-OFFICER@ec.europa.eu
- The European Data Protection Supervisor (EDPS): edps@edps.europa.eu

9. Where to find more detailed information?

The Commission Data Protection Officer publishes the register of all operations processing personal data. You can access the register on the following link : <http://ec.europa.eu/dpo-register>

This specific processing has been notified to the DPO with the following reference: **DPR-EC-00454**

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ATTACHMENT: DATA PROTECTION NOTICE

PROCESSING OF PERSONAL DATA BY MPP

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1. Introduction

This privacy statement explains the reason for the processing, the way we collect, handle and ensure protection of all personal data provided, how that information is used and what rights you may exercise in relation to your data (the right to access, rectify, block, etc).

2. Why do we process your data?

Purpose of the processing operation: MPP collects and uses your personal information to comply with the administrative and legal procedures relevant for the implementation, management and monitoring of collaboration instruments by MPP (i.e. the establishment and management of their execution, including drafting, approving and ensuring legal execution of the instruments and compliance with ancillary legal obligations, such as archiving or disclosure following requests for access to documents).

3. Which data do we collect and process?

The personal data collected and further processed may be:

- Name;
- Function;
- Contact details (e.g. e-mail address, business telephone number, mobile telephone number, fax number, postal address, company and department, country of residence, internet address).

4. How long do we keep your data?

MPP keeps the data for the time necessary to fulfil the purpose of collection or further processing. In particular:

- data relating to requests under the MoU is processed immediately upon receipt. Data encoded at the moment of the signature of the collaboration instrument is kept as it was at the time of reception. The updated data - address or contacts - are used for correspondence and exchanges that follow.
- files relating to collaboration instruments procedures and execution including personal data are to be retained in the service in charge of the procedure until the expiry date of the instrument, and in the archives for a period of 25 years following the expiry of the instrument. These files could be retained until the end of a possible audit if one started before the end of the above periods.

After the periods mentioned above have elapsed, the files containing personal data may be sent to archives for further conservation.

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5. How do we protect your data?

All data in electronic format (e-mails, documents, uploaded batches of data etc.) are stored either on the servers of MPP or of its contractors.

In particular, for electronic information, the information is protected by User IDs and passwords. Only designated staff has the possibility to access the data kept for the purpose of administrative or financial processes. For hardcopy documentation, limited number of staff have access to cupboards; the storage offices are always locked when unattended.

MPP's contractors are bound by a specific contractual clause for any processing operations of your data on behalf of MPP and by the confidentiality obligations.

6. Who has access to your data and to whom is it disclosed?

Access to your data is provided to authorised staff and consultants of MPP according to the "need to know" principle. Such staff and consultants abide by statutory, and when required, additional confidentiality agreements.

Further, access to your data may also be provided to institutions providing funding or exercising scrutiny and control functions and national authorities (judicial or administrative). Your data may also be disclosed to the public in the context of specific requests for access to documents in accordance with applicable legislation.

Recipients of personal data may be within Switzerland and also in third countries and international organisations with which MPP establishes collaboration or funding activities.

7. What are your rights and how can you exercise them?

Any person whose personal data are processed by MPP for the purposes stated above has specific rights as a data subject under the Swiss Federal Act of 19 June 1992 on Data Protection, available at <https://www.admin.ch/opc/en/classified-compilation/19920153/index.html>.

Should any person whose personal data are processed in relation to this collaboration instrument have any queries concerning the processing of his or her personal data, they may address a request to MPP as per section 8 below.

8. Contact information

If you have comments or questions, any concerns or a complaint regarding the collection and use of your personal data, please feel free to contact MPP using the following contact information:

Medicines Patent Pool,
Rue de Varembé 7
1203 Geneva,
Switzerland
Email: compliance@medicinespatentpool.org

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