TERMS OF REFERENCE OF THE EXPERT ADVISORY GROUP

First Adopted November 2011

Last version 25 January 2017

The establishment of the Expert Advisory Group of the Medicines Patent Pool

1. Introduction

The Business Plan and the Statutes of the Medicines Patent Pool Foundation (MPP) foresee the establishment of an Expert Advisory Group (EAG) to provide input in the decision making of the Governance Board and the Executive Director.

On 13 May 2011 the Governance Board decided to move ahead with the establishment of the EAG with the specific mandate to provide advice, upon request, to the Governance Board and the Executive Director related to on-going negotiations and final decisions on licence agreements.

The advice of the EAG with respect to on-going and concluded negotiations is intended to serve several critical factors. For one, the wealth of expertise that would ideally be contained within the EAG could be an invaluable resource for developing and refining negotiation strategies, and for suggesting creative solutions to what may have previously been thought to be irreconcilable positions.

In addition, the members of the EAG would be individuals of recognised expertise who enjoy the confidence of a broad range of stakeholders. Having such a body assess the licence agreements negotiated by the MPP would bring an added measure of legitimacy to the operations of the MPP. Finally, the EAG would serve as a critical check against the possibility of the MPP concluding less than optimal licence agreements.

In August 2016 modifications were introduced to the By-Laws with the aim of adapting the working procedures of the EAG with the expansion of MPP's mandate into hepatitis C and tuberculosis.

This paper outlines the Terms of Reference of the EAG, following the amendment of the By-Laws of August 2016.

2. Terms of Reference of the EAG

The EAG will provide the Governance Board and the Executive Director with advice regarding Patent Pool licence negotiations and assessing whether the terms and conditions of the proposed licence agreements meet the key requirements as set out by the Medicines Patent Pool statutes and MOU.

The key questions for the EAG to address while assessing negotiation interim and final results are:

1) Do the results sufficiently meet the requirements set out in the MOU with UNITAID and Statutes?

2) Do the negotiation results offer "sufficient added value" over the status quo?

The Executive Director will present the EAG with results of the negotiations along with a preliminary assessment. Based on the material presented, the EAG will assess the terms and conditions of the proposed licence agreements, and provide advice regarding whether the terms and conditions satisfactorily meet the stated objectives of the MPP. This may include advice on how negotiation results can be improved. The advice of the EAG is not binding, but will be taken into account in the Board's decision-making. The timing and conduct of the EAG meetings will be in accordance with the procedures as set out in Articles 14-16 of the By-laws of the Patent Pool (see Annex III).

3. Appointment and Selection of the EAG

3.1 The Board may appoint any number of individuals who support the mission of the MPP, enjoy the confidence of a broad range of stakeholders and have expertise in key disciplines to serve within the EAG. The Governance Board shall appoint the Chair and the Vice-Chair of the EAG.

3.2 A list of potential candidates will be drawn up by the Executive Director. Once the Governance Board has made a selection of potential members, the Executive Director will manage the recruitment of EAG members and the organization of the EAG meetings, in accordance with the procedures as outlined in the By-laws.

3.3 In selecting the members of the EAG, the Board shall seek to achieve appropriate gender and geographical balance in its representation, and include experts from the following fields:

- Regulatory
- IP licensing and law
- Expertise in treatment provision of the particular disease area covered by the Foundation
- Public health in developing countries/medicines policy
- Communities/Non-Governmental Organisations
- Science/ research & development

Members of the EAG will function solely in their personal capacity. The members will have relevant expertise in at least one of the areas listed above.

4. General rules and procedures

The rules and procedures under which the EAG will operate will be detailed in the By-laws of the Medicines Patent Pool, which will be subject to approval by the Governance Board.

General policies regarding conflict of interest, code of ethics, whistle-blower policy, confidentiality, transparency and reimbursement of costs will be applicable to the EAG and its members.

5. Working processes

5.1 The EAG will operate in different and independent working groups representing each disease area covered by the Foundation.

- When reviewing proposed licence agreements, drafts will be shared (on a confidential basis) with all EAG members.

- Each sub-group will be independent of the other and be the sole source of advice for their disease area.

- Individuals in other sub-groups shall have the opportunity to comment, but these comments will be for observation only, by the respective sub-group. These observations will be sent separately by the Management to the Governance Board for their information.

- The report of the respective sub-group will be the only document submitted to the Board and ultimately published, should the proposed agreement proceed to execution.

5.2 The Management will periodically inform the respective EAG groups of developments in MPP work in their respective areas, seek advice and share term sheets or draft of licences as appropriate.

5.3 Either the Chair or the Vice Chair, or if possible both of them, shall attend all meetings and discussions from the each working group of the Expert Advisory Group. The Chair, or the Vice Chair on behalf of the Chair, shall guide each working group deliberations' and sign the written report containing EAG's recommendations to the Board.

5.4 There will be 1 annual in-person meeting of the entire EAG; with potential in-person meetings of individual sub-groups around major international events (e.g., HIV at IAS, TB at Union Conference, etc).

Annex I - Relevant Excerpts of Statutes

Art. 4 of the Statutes "Means"

The Foundation may pursue all such lawful activities as may be appropriate to attain its purpose. The Foundation shall operate a Patent Pool through which intellectual property is made available, in order to reduce prices, improve access and facilitate the development and production of quality, safe and efficacious health products for use in low- and middle-income countries, considering the importance of technology transfer mechanisms, capacity building and local manufacturing in developing countries.

In this context, the Foundation may *inter alia* pursue the following activities:

a. Negotiating terms and conditions of license agreements which aim to maximize public health benefits, taking into account the World Health Organization's Global ("**WHO**") Strategy and Plan of Action on Public Health, Innovation and Intellectual Property and consistency with other access to medicines-related multilateral instruments and declarations, such as the World Trade Organization Declaration on the TRIPS Agreement and Public Health and;

b. Entering into license agreements with patent holding entities, and sub-license agreements with generic manufacturers and other appropriate sub-licensees on a non-exclusive and non-discriminatory basis;

c. As and when necessary, enforcing the terms and conditions of license agreements;

d. As and when necessary, assisting in dispute resolution procedures between licensors and sub-licensees. License agreements should contain provisions that specify an alternative dispute resolution mechanism, actionable by all signatories to the license agreements;

e. Ensuring that contracts with sub-licensees specify that products produced under sub-licence from the Patent Pool must obtain approval from a stringent drug regulatory authority or WHO prequalification, as applicable, with adequate provision for alternative temporary arrangements through a WHO Expert Review Panel in case such approvals are not yet available;

f. Safeguarding against the diversion and ensuring the traceability of products produced under sub-licence from the Patent Pool in accordance with the guidelines as set out in Art. 2(b)(ii) of the World Trade Organization's Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health;

g. Liaising with stakeholders to understand and address concerns and garner support for the Patent Pool (communication and advocacy);

h. Responding to opportunities that may arise to maximize the uptake and health benefits of the Patent Pool.

The Foundation may hold intellectual property rights, as well as participations in Swiss or foreign entities or any asset it may deem useful or necessary to pursue its purpose. The revenues that may be realized by the Foundation shall be used exclusively in furtherance of the Foundation's public utility aim.

The Foundation shall not participate in, or intervene in any political campaign on behalf of or in opposition to, any candidate for public office.

- **Art 8 of the Statutes on EAG**

The Governance Board may appoint individuals who support the principle of the Patent Pool and have expertise in key disciplines, such as public health in developing countries, law, economics, management and pharmaceutical science to serve within the Expert Advisory Group.

The Expert Advisory Group shall deliberate and provide advice to the Governance Board and the Executive Director, upon request, with regard to general strategy and key management decisions.

The Expert Advisory Group shall have a consultative function. Its organisation shall be set out in the By-Laws.

The Chair of the Expert Advisory Group may attend the Governance Board meetings of the Foundation without voting right.

Annex II – Relevant Excerpts of Memorandum of Understanding with UNITAID

MOU with UNITAID, Annex 1 "Project Plan", Point 14 "APPENDIX 4 LIST OF PUBLIC HEALTH ORIENTATED TERMS AND CONDITIONS IN MPP LICENCES"

The Medicines Patent Pool aims to improve access to appropriate, affordable HIV medicines in low- and middle-income countries (LMICs) through voluntary licensing and patent pooling[i]. The MPP negotiates licensing terms and conditions from a public health perspective to deliver medicines to the highest possible percentage of people living with HIV in countries hardest hit by the epidemic.

Thus, among other features, MPP licences are non-exclusive, transparent and pro-competitive. They seek to ease and speed generic manufacture and registration; encourage the development of new fixed-dose combinations (FDCs) — two or more medicines in a single pill — and special formulations for children, and maintain countries' ability to procure drugs under compulsory licences. Finally, MPP licensing agreements provide incentives to industry through fair royalty payments.

1. Broad geographical scope

- MPP licences provide access to generic medicines for countries that are home to up to **93.4%** of people living with HIV and **99.3%** of children living with HIV in low- and middle-income countries
- Licences currently include all 34 low-income countries and between **55-80%** of World Bank classified middle-income countries
- MPP has expanded benefits of voluntary licensing to middle-income countries through innovative provisions such as differential royalties[ii] and public-private market segmentation

2. Access to medicines through TRIPS[iii] flexibilities and other mechanisms

- The MPP negotiates provisions that enable licensees to sell outside the licensed territory under certain circumstances, such as, for example:
    - In the event of a compulsory licence being issued
    - In the event that sales do not infringe on any granted patents or patent challenges are successful (e.g. licence on dolutegravir)
    - By allowing generic manufacturers to terminate licences for which they no longer need a licence, thereby allowing them to sell in additional countries (e.g. licence on tenofovir disoproxil fumarate)
- MPP agreements also provide licensees the freedom to challenge the validity of the licensed patents

3. Prompt availability of quality, low cost generic medicines

- Ensure the speedy registration of licensed products through a waiver of the licensor's data exclusivity rights (where applicable)
- Generic company products must meet internationally-recognised quality standards
- MPP's generic partners must adhere to strict timelines for development and regulatory approval of products or face licence termination

4. Promote robust generic competition

- Licences are non-exclusive, pro-competitive and encourage the participation of a broad range of generic manufacturers — in most cases from anywhere in the world — in order to ensure sustained and effective competition
- Potential generic manufacturers must demonstrate their ability to develop and manufacture quality-assured, affordable products promptly

5. Development of adapted medicines and FDCs

- Generic manufacturers can combine different medicines to develop appropriate FDCs

6. Better-adapted HIV treatment for children

- Patent holders have waived any royalties for paediatric formulations
- The geographical scope of paed specific agreements is broader, covering MPP has countries where 98-99% of children with HIV live
- These licences promote the development of needed paediatric FDCs and many allow generic companies to reformulate for child-friendly combinations easily administered in resource-poor settings

7. Transparency of patent and licensing information

- All MPP licences contain provisions to ensure that the MPP may publish the licences in full on the MPP website
- Patent holders provide patent disclosure of relevant patents within (and sometimes outside) the licensed territory.

Annex III – Relevant Excerpts of By-laws

IV Expert Advisory Group

Article 14 Appointment of Expert Advisory Group

14.1 The Board may appoint any number of individuals who support the mission of the Foundation, enjoy the confidence of a broad range of stakeholders and have expertise in key disciplines to serve within the Expert Advisory Group.

14.2 In selecting the members of the Expert Advisory Group, the Board shall seek to achieve appropriate gender and geographical balance in its representation, and include experts from the following fields:

- Regulatory
- IP licensing and law
- Expertise in treatment provision of the particular disease area covered by the Foundation
- Public health in developing countries/medicines policy
- Communities/non-governmental organisations
- Science/research and development

14.3 Members of the Expert Advisory Group may be appointed by a simple majority vote of the Board members present at the Board meeting.

14.4 The Chair and Vice Chair of the Expert Advisory Group may be appointed by a simple majority vote of the Board members present at the Board meeting.

14.5 The Expert Advisory Group will be divided and operate in different and independent working groups representing each disease area covered by the Foundation. The functioning of each working group and its relation to the Expert Advisory Group as a whole shall be set out in detail within the Terms of Reference for the Expert Advisory Group.

Article 15 Term of Office of Expert Advisory Group Members

15.1 Members of the Expert Advisory Group shall serve a three-year term. Expert Advisory Group members may be elected for a maximum of two consecutive terms or six years. Members of the Expert Advisory Group may be appointed to serve in one or in several working groups.

15.2 In the event an Expert Advisory Group member is unable to complete his or her term, the Board shall appoint a replacement to serve until the end of the term.

15.3 The Board may revoke the membership of any Expert Advisory Group member by simple majority vote of the Board members present at the Board meeting, where valid grounds for revocation exist.

15.4 Valid grounds for revocation of membership in the Expert Advisory Group include the neglect of one's obligations towards the Foundation, or the inability to fulfil the duties of one's office, including permanent conflict of interest.

Article 16 Operations and Functions of the Expert Advisory Group

16.1 The Expert Advisory Group shall have a consultative function. Each applicable working group of the Expert Advisory Group shall deliberate and provide advice to the Board and the Executive Director, upon request, with regard to ongoing negotiations and final decisions on licence agreements negotiated by the Foundation for the disease area of its interest.

16.2 The Expert Advisory Group shall meet at least once a year, in accordance to a schedule as set by the Board. Members of the Expert Advisory Group may also be consulted on an individual or collective basis, as deemed required by the Executive Director or the Board.

16.3 The meetings of the Expert Advisory Group shall be organised by the Executive Director. The Executive Director shall propose the agenda of the Expert Advisory Group meetings, to be sent to the Members at least seven days in advance of each meeting. There shall be no quorum for meetings of the Expert Advisory Board.

16.4 The Expert Advisory Group, through its applicable working group, shall submit its recommendations to the Board in a written report. Each working group of the Expert Advisory Group shall make best efforts to decide its recommendations by consensus. To the extent that consensus cannot be reached, the differing viewpoints expressed shall be detailed in the report to the attention of the Board. The report of the Expert Advisory Group on the results of the final negotiations, together with the Board's final decision, shall be made publicly available on the website of the Foundation.

16.5 The working language of the Expert Advisory Group shall be English.

16.6 Members of the Expert Advisory Group shall be allowed reimbursement for reasonable expenses relating to the work of the Foundation, including travel expenses, in accordance with the Foundation's Travel and Expense Policy.

[i] The licensing of products for generic manufacture is often part of companies' commercial strategies and bilateral agreements between originators and generic manufacturers exist in various non-exclusive and exclusive forms. Such agreements are generally confidential and number of licensees, geographical scope and pro-access provisions may in many cases be limited.

[ii] Sliding scale royalties based on countries per capita income.

[iii] The agreement on Trade-Related Aspects of Intellectual Property includes flexibilities intended to create safeguards for the protection of public health.