medicines patent pool

# WHO Draft Global Strategy for TB Research and Innovation

## Feedback from the Medicines Patent Pool

## Comment Form

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Reviewer's Name in Full, Title, Institution, City, Country, Tel., Email address:

Name: Esteban Burrone

Title: Head of Policy

**Institution: Medicines Patent Pool**

City: Geneva

Country: Switzerland

Tel: +41 22 533 5055

Email Address: eburrone@medicinespatentpool.org

The Medicines Patent Pool (MPP) is grateful for the opportunity to provide feedback on the draft Global Strategy for TB Research and Innovation. We welcome the fact that the Global Strategy acknowledges the critical importance of ensuring that people with tuberculosis (TB) can benefit from advancements in TB research and the need for new models of innovation that are not only needs driven and evidence based, but are guided by the core principles of affordability, efficiency, equity, sustainability and collaboration.

Patent pooling is recognised in the strategy as one possible approach to supporting the development of needed medicines in the context of an enabling environment for TB research and innovation. The MPP is the first patent pool in the field of health and as such welcomes the opportunity to offer its perspective on the potential of the approach in the field of TB.

The MPP was established in 2010 with the support of Unitaid and works to improve access to affordable, appropriate and quality-assured HIV, hepatitis C and TB medicines in low- and middle-income countries (LMICs). It negotiates with patent holders for licences on HIV, hepatitis C and TB medicines. These licences permit generic pharmaceutical companies to manufacture and distribute patented medicines in LMICs. The licences also provide the freedom to develop new treatments such as fixed-dose combinations and special formulations for children.

Some of the new regimens recommended by the WHO for HIV treatment, such as the tenofovir / lamivudine / dolutegravir combination, were developed partly thanks to licences negotiated by the MPP.

Currently, the MPP holds licences on 16 medicines with 9 patent holders and 25 partner generic companies to develop, register, manufacture and supply WHO-recommended products in LMICs.

The experience of the MPP has provided a concrete example of how patent pooling and voluntary licensing can contribute to addressing some of the innovation and access challenges relating to health technologies. To be effective in promoting access and innovation, such licences need to be developed in a manner that is needs driven, evidence based, and based on the principles of affordability, efficiency, equity, transparency and collaboration. They need to respond to public health needs.

In early 2017, the MPP signed its first license for a TB treatment with Johns Hopkins University to facilitate the clinical development of the TB drug candidate sutezolid. The antibiotic sutezolid has long been considered a promising investigational treatment that, if further developed in combination with other drugs, could be used to more effectively treat both drug-sensitive and drug-resistant TB in patients.

Faster acting, better therapies to treat TB are a particularly urgent and global public health priority. The granting of public health oriented licences on TB drug candidates earlier in the development process, coupled with push and pull incentives, and the sharing of clinical trial results data, could help to support the development of faster-acting and more effective regimens to combat the global health threat presented by the TB epidemic. It would also help to ensure that such regimens, once developed, become available at affordable prices in LMICs and high burden TB countries.

The following detailed suggestions for amendments to the draft WHO Global Strategy for TB Research and Innovation build from the MPP experience as an effective mechanism to ensure prompt access to affordable treatment in low- and middle-income countries for HIV and hepatitis C patients.



Rue de Varembé 7 - 1202 Geneva - Switzerland | Tel: +41 22 533 50 50 | office@medicinespatentpool.org | www.medicinespatentpool.org

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| Page 9, Line 18 | As outlined by the 2018 UN Political Declaration on Antimicrobial Resistance, TB R&D efforts should be guided by the principles of affordability and accessibility, among others. | Policies for health innovation must align with the demands of health systems, to ensure that innovation is affordable and accessible, and can be made available equitably and sustainably | |
| Page 12, Line 32 | Lack of affordable access to the newest TB regimens is slowing down the shift to newer and better drugs and the scale-up of the new WHO recommended all-oral regimens. | The TB field still suffers from **lack of equitable and affordable access to medicines and technologies, and low use of services** by populations that need them most. The challenges include lack of legal and regulatory mechanisms for introducing new medicines and technologies, and negotiating price reductions; weak health system infrastructure and social care that limits access to overall care; inadequate financing for health care and medicines; local costs that drive up the price of medicines (e.g. taxes and tariffs on pharmaceutical products); high prices of medicines due to lack of robust competition for certain treatments (particularly for MDR-TB); gaps in procurement and supply chain frameworks; | |

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| | | regulatory deficiencies; and lack of awareness of opportunities to obtain care. | |
| Page 23, Line 74 | Pooling of IP and data can be important to support open collaborative research that facilitates the development of new regimens (as opposed to new individual drugs). | A range of incentives – both financial and nonfinancial – must be initiated and existing initiatives must be strengthened to stimulate innovation, from discovery to diffusion of technologies. Policies that encourage and support new collaborative models for research, data and intellectual property sharing and public–private partnerships (PPPs) are key to leveraging the comparative advantages of various actors to foster R&D, and to facilitate equitable, affordable and sustainable access to medicines and technologies.<br><br>Such incentives should promote TB R&D efforts that are needs driven and evidence based and guided by the principles of affordability, effectiveness, efficiency and equity as outlined by the 2018 UN Political Declaration on Antimicrobial Resistance. | |

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| Page 23, Line 26 | The majority of TB compounds are being developed by public institutions, small companies or PDPs which need mechanisms to support them in the early stages and during preclinical research. Milestones prizes could be a better fit to help filling the gaps in the pipeline compared to some of the other suggested pull mechanisms. | "However, more targeted pull mechanisms, such as milestone prizes awarded on set criteria, volume guarantees or advanced market commitments, would be an important additional incentive mechanism…" | |
| Page 24, Line 78 | The Life Prize project, recently endorsed by the UN High Level Meeting on Tuberculosis in its Declaration, is an example of a new model of innovation for TB that would combine patent and data pooling with push and pull mechanisms. Its aim is to improve financial incentives for TB drug development both at the pre-clinical and clinical stage and ensure access and affordability of new regimens once developed. | Ensuring that all people with TB or at risk of TB can benefit from advancement in TB research requires new models of innovation that are needs driven and evidence based, and are guided by the core principles of affordability, efficiency, equity and collaboration. Putting these principles into practice will require research efforts to anticipate access issues at each stage of the research process. Combining patent and data pooling with push and pull mechanisms could contribute to the development of new regimens that are needed in | |



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| | | the field of TB to improve current treatments and for multi-drug resistant TB in particular. | |
| Page 25, 82 | Licensing on public health-oriented terms and conditions can be one way to maintain the IP incentive for innovation while facilitating the wide dissemination of the technology through competitive supply. This approach has been used in HIV and hepatitis C to great success, with multiple generic manufacturers making the new regimens and supplying LMICs at affordable prices. | The intellectual property (IP) system, and the patent system in particular, can play a pivotal role in incentivizing innovation in the pharmaceutical field and as a policy tool to facilitate diffusion of technology and access to essential medicines and technologies. Conversely, poorly structured IP systems, with an inappropriate balance between innovation and access, can hamper the ability of governments to safeguard the health of their populations. Licensing of patented technologies on public-health oriented terms is one way through which IP can be used to promote innovation and facilitate equitable access. | |
| Page 30, Table 5.1 | The current text reflects the role that patent pooling could have in the field of TB if associated with pull and push | Patent Pools. ~~Often combined with above incentives,~~ Patent pools encourage open, collaborative development | |



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| | incentives, as well as clinical trials data sharing. This is the structure that had been proposed in the Life Prize project.<br><br>To date, patent pooling has facilitated access to new treatments for HIV and hepatitis C in LMICs through the licensing of medicines to multiple manufacturers, thus enabling robust competition and facilitating price reductions. In addition, patent pooling has been used to facilitate the development of new fixed dose combinations (e.g. a recent example is the combination tenofovir/lamivudine/dolutegravir or TLD) or new paediatric formulations needed in LMICs.<br><br>In 2017, the Medicines Patent Pool also announced a royalty free licence agreement with Johns Hopkins University to facilitate the clinical development of TB drug candidate sutezolid to contribute to accelerating its development by facilitating access to the IP by other | through pooling of intellectual property and facilitate access to new medicines through market competition. If combined with push and pull incentives and the pooling of clinical trial data, they could contribute to the development of new needed regimens for the treatment of TB. ~~in exchange for certain awards, incentives or other conditions~~. The Medicines Patent Pool is an example of a mechanism for patent pooling that has played a pivotal role in facilitating access to new medicines in HIV and hepatitis C. It has also supported the development of needed new formulations. It is well positioned to play such a role in TB and could contribute to new innovation models that incentivize the development of new and improved regimens. | |



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| | potential developers, thereby contributing to further innovation. | | |
| Page 34, Line 108 | The licences MPP has negotiated in HIV, hepatitis C and TB have enabled the manufacturing of generic versions of medicines for competitive supply in over 130 LMICs, years before the patents on those drugs were expired. | Some medicines (e.g. clofazimine) are not used to their full potential because of country regulatory frameworks that limit off-label use; also, availability of some medicines (e.g. bedaquiline and rifapentine) is constrained because of delays in registration in countries and high prices. Voluntary initiatives and incentive mechanisms that separate the cost of investment in R&D from the price and volume of sales are key to lowering pricing barriers for access to new medicines, vaccines, diagnostics and technologies *(9, 34)*.<br><br>Additionally, public health oriented voluntary licenses, like those negotiated by the Medicines Patent Pool, can also accelerate availability of quality assured generics for use in low- and middle-income countries, which would bring prices down | |

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| | | and facilitate treatment scale-up. | |
| Page 36, line 104 | By signing the political declaration of the HLM on Tuberculosis in 2018, countries agreed to "support existing and new initiatives that separate the cost of investment in research and development from the prices of sales, to facilitate equitable and affordable access". | Participates in and funds international collaborative research initiatives that separate the cost of investment in research and development from the price and volume of sales, to support the development of new approaches and medical innovations to fight TB, and to facilitate equitable and affordable access as stated in the UN Declaration on TB, including through North–South and South–South, bilateral, regional and global collaborations and research networks. | |
| Page 37, line 106 | Idem. By signing the political declaration of the HLM on Tuberculosis in 2018, countries committed to "promote tuberculosis R&D efforts aiming to be needs-driven, evidence-based and guided by the principles of affordability, effectiveness, efficiency and equity and | Sets global TB research priorities that are needs-driven, evidence based and guided by the principles included in the UN Political Declaration on TB to stimulate the development of evidence for policy around knowledge gaps that are critical for countries and communities, with a view to guiding research financing | |

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| | which should be considered as a share responsibility". | to priorities developed through consensus among relevant stakeholders. | |
| Page 40, line 142 | Most of TB and MDR-TB patients are in middle-income countries, including some upper middle-income countries like South Africa, Russia, China, Brazil or Peru. Therefore, access to TB drugs in those countries should be considered a priority, not only in low- and lower middle-income countries.<br><br>Non-exclusive voluntary licences under public health-oriented terms facilitate generic competition among several generic companies and can contribute to accelerating availability and lowering prices. | Pharmaceutical companies should adopt patent and enforcement policies that facilitate greater access to TB medicines and technologies needed in low- and ~~lower-~~middle- income countries, including high TB burden countries. ~~In low-income countries they should avoid filing patents or enforcing them in ways that might inhibit access.~~ Companies are also encouraged to grant non-exclusive voluntary licences in these countries under public health oriented terms and conditions, such as through the Medicines Patent Pool, where this will facilitate ~~greater~~ more affordable access to medicines, and to accompany this with data exclusivity waivers and technology-transfer activities. | |



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