



MÉDECINS SANS FRONTIÈRES POLICY POSITION ON EXPANSION OF THE MEDICINES PATENT POOL MANDATE TO COVER HEPATITIS C AND TUBERCULOSIS May 2015

Médecins Sans Frontières (MSF) supports the Medicines Patent Pool (MPP) playing a key role in facilitating and accelerating entry of new and critical medical commodities into markets, including by reducing intellectual property (IP) barriers that undermine innovation and access. This year, the UNITAID Board will evaluate whether the Medicines Patent Pool should expand its mandate to negotiate voluntary licenses for hepatitis C virus (HCV) and tuberculosis (TB) medicines. MSF supports the proposition that the MPP immediately begin work to facilitate voluntary licenses for TB medicines and to manage an IP pool for development of future TB regimens. The MPP should consider expanding its mandate to HCV only after certain conditions are met and after careful consideration of key issues.

Tuberculosis

The MPP should immediately expand its mandate to include TB, including drug-resistant forms of TB, for the following reasons:

A. Facilitating inclusive voluntary licenses for drugs already under development or on the market

1. Public health-driven voluntary licenses for new drugs – especially bedaquiline and delamanid – are needed due to existing and new concerns around sustainable access to these drugs.
2. Donation programmes for bedaquiline and delamanid – the first new drugs for TB in 50 years – represent a step backwards in access to medicines for affected populations, especially in middle-income countries, which represent the largest number of drug-resistant TB (DR-TB) cases.
3. In addition to concerns around donations, company policies related to registration, pricing and IP risk inhibiting, rather than expanding access.

Generic versions of new TB drugs can facilitate early access for research, registration and public health programmes. To be deemed successful, the MPP must ensure that voluntary licenses for existing TB drugs have a broad geographic scope that should aim to include all low- and middle-income countries (LMICs). MSF originally supported the creation of the Pool as an entity that can benefit all developing countries. If the MPP is unable to secure access for all developing countries under the terms of a voluntary license, such voluntary licenses should be complementary to the use of all TRIPS flexibilities. Voluntary licenses that do not include all developing countries also must not place restrictions on licensees selling drugs into all LMICs that have rejected, removed or not granted competition-blocking patents.

B. Creating a patent pool for research and development of new DR-TB regimens

1. The development of novel combination therapies can be accelerated through open, collaborative research and early access to study drugs.
2. In today's environment, drug developers do not have access to all necessary data or all potential companion drugs (including those still in clinical development) in order to run clinical trials to build optimal regimens.
3. There is a lack of data on the safety and efficacy of combining drugs (drug-drug interactions), which risks undermining opportunities to improve patient outcomes (by not providing the drugs) or negatively affecting patients' health (by combining without having adequate data).
4. Exclusive licensing of potentially promising compounds (e.g. Johns Hopkins University licensing of sutezolid to Sequella) creates upstream monopolies that squander the opportunity to get optimal regimens to market.
5. Downstream pooling of finished products could result in increased access to medicines.

MSF supports the MPP playing a key role for the 3Ps – Push, Pull, Pool project.¹ The 3Ps project would launch a new research and development (R&D) collaboration to develop TB regimens. The MPP could play a key role through negotiating licenses that pool IP at the earliest stages to ensure that open, collaborative approaches to R&D are facilitated. A pool will also ensure that IP for final products is widely available to enable equitable access.

¹ For more information on the 3Ps project, see : <https://www.msfacecess.org/spotlight-on/3p-project-new-approach-developing-better-treatments-tb>

Hepatitis C

The MPP should expand its mandate to include HCV only after the following key issues have been carefully considered and addressed:

1. Consider approaching negotiations for HCV voluntary licenses in a different way to HIV. It will be important to enable more consultations during negotiations and ensure inclusion of governments (including middle-income countries that may be excluded from a voluntary license's geographic scope), patients and civil society in these discussions. Adapting the Expert Advisory Group (EAG) in a different way for HCV may be one way to facilitate this change in approach. Adapting the EAG membership can also help facilitate the sharing of access strategies, including collaboration with those organisations and governments looking to make full use of TRIPS flexibilities.
2. Ensure good internal competency, which can provide some thought leadership on how to best expand access to HCV treatments through voluntary licenses. There are also some practical issues the MPP can start working on now, such as establishing a patent database for HCV medicines as a starting point to help all actors evaluate the value of voluntary licenses for HCV.
3. Observe and evaluate the outcomes of litigation on new direct acting antivirals (DAAs), especially in India, or at least make a technical assessment of the likelihood of success or failure of key oppositions, in particular fordaclatasvir, sofosbuvir and velpatasvir.
4. Allow significant political and popular pressure to build over Gilead Sciences' anti-diversion program and over Gilead's current approach to licensing and pricing – especially those bilateral licensing provisions that block export of generics to excluded countries. Such pressure would improve the MPP's ability to engage in technical negotiations.
5. Make an effort to amend existing provisions in HIV treatment license agreements that leave excluded countries such as Venezuela and Ukraine from access to generics. These agreements have been used as precedent by Gilead in its initial HCV treatment license agreements, and may be used by other companies in bilateral or MPP-led license agreements. Amending these existing HIV license agreements would be a critical first step to successfully negotiate voluntary licensing agreements for HCV. The MPP should ensure that its approaches to voluntary licensing are fully complementary to the use of public health safeguards to expand access to drugs so that all low- and middle-income countries have access to low-cost generic medicines.

When the MPP does expand its mandate to include HCV, it needs to ask the Board for additional conditionalities that define acceptable terms and conditions the MPP could negotiate with HCV patent holders. The MPP may need to be willing to halt negotiations if doing so increases its leverage to secure access for excluded countries and to avoid licensing provisions that may prevent excluded countries from securing affordable access to new DAAs. The MPP should also push back against unwarranted anti-diversion programs that exceed existing HIV medicines anti-diversion programs.

Conclusion

MSF continues to be a strong supporter of the MPP and hopes that alongside ongoing efforts to expand access to HIV medicines, the MPP can ultimately play a critical role to ensure both innovation and access to new medicines for TB and HCV.