



**PRIORITIZATION OF
HIV, HEPATITIS C
AND TUBERCULOSIS
MEDICINES FOR IN-
LICENSING BY THE
MEDICINES PATENT
POOL - 2018**

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1 INTRODUCTION

Every year, the Medicines Patent Pool (MPP) publishes a list of priority medicines for in-licensing, following a prioritization process that includes consultations with a number of experts, review of the most recent data on each product, and application of a detailed methodology (described in the Appendix). In 2017, several changes were made to the methodology used for prioritization. First, we revised some of the criteria and included additional criteria. Second, quantitative scores were introduced in order to make the assessment more systematic and enable a more objective assessment. Third, the methodology used to prioritize HIV medicines was adapted to hepatitis C medicines, which resulted in the development of disease-specific criteria for the clinical assessment of hepatitis C medicines.

In 2018, the methodology for prioritizing hepatitis C medicines remained unchanged, whereas the methodology for HIV medicines evolved slightly. The main change has been the inclusion of thresholds under certain criteria, which can lead to the de-prioritization of certain products, even if they score highly under other criteria.¹

In addition, for the first time, the MPP has worked on prioritizing tuberculosis (TB) medicines (including drug candidates) for in-licensing. In the field of TB, the approach for the clinical assessment of medicines has been different than for HIV and HCV, particularly in relation to medicines that are still under development. The reasons for this differentiated approach are three-fold. First, new TB medicines have recently received market authorization on the basis of data from Phase 2 (rather than Phase 3) clinical trials. This means that prioritization may therefore also need to commence sooner. Second, in view of the need to facilitate the development of TB medicines in the context of new regimens (rather than as individual compounds), the MPP may be able to play a role more upstream in facilitating regimen development. Finally, a recent process led by the WHO, which resulted in the development of Target Regimen Profiles for TB treatment, provides suitable criteria for the clinical assessment of pipeline medicines, and has therefore been incorporated into the MPP methodology.

The results of the prioritization are provided below for each therapeutic area, with details on the methodology in the annexes. The assessment will continue to be undertaken on an annual basis to re-assess priorities based on new clinical evidence, changes to WHO recommendations, changes in patent status, evolution in licensing practices and changes in prices or market forecasts for HIV and HCV medicines.

It should be noted that the MPP does not include, in its prioritization, medicines for which it has already obtained licences in the past.²

¹ These include: (i) major safety or efficacy issues as compared to the standard of care (ii) contraindication with widely used WHO-recommended medicines for common co-morbidities (threshold applied to medicines with potential for use in 1st line treatment); and (iii) requirements that make a product in its current form difficult to implement in resource-limited settings, such as cold-chain requirements, particularly when there are alternative products that do not have such requirements.

² MPP licences to date are for abacavir (paediatric), atazanavir, bicitgravir, cobicistat, daclatasvir, dolutegravir, elvitegravir, emtricitabine, lopinavir, raltegravir (paediatric), ravidasvir, ritonavir, sutezolid, tenofovir alafenamide, tenofovir disoproxil fumarate and several combinations containing these medicines. In addition, it has obtained a licence on patents that are relevant to darunavir and collaborated on commitments not to enforce patents for darunavir (paediatric) and nevirapine.

2 PRIORITIES IN HIV

One of the medicines identified as a priority for in-licensing in 2017, namely bicittegravir, was licensed to the MPP in October 2017 and obtained regulatory approval as part of a new single tablet regimen in February 2018. Based on the methodology outlined in the appendix, a summary of MPP priorities for in-licensing in HIV are included in Table 1.

Table 1. Summary of Priority ARVs for MPP

ARV	Class	MPP Analysis
Cabotegravir <i>Phase III</i>	Integrase inhibitor	<p>Cabotegravir long-acting injectable (CAB-LAI) is currently in Phase III investigations for treatment maintenance in combination with rilpivirine LAI (RPV-LAI), and separately as a single agent for HIV prevention. CAB-LAI has a shelf life of 3 years at room temperature.³</p> <p>While the combination of CAB-LAI and RPV-LAI could be an option for long-term treatment simplification, the cold chain requirement of the current formulation of RPV-LAI could make this regimen less suitable for use in resource-limited settings. The MPP will continue to monitor the progress with RPV-LAI formulations.</p> <p>Meanwhile, CAB-LAI given bimonthly holds great potential for the prevention of HIV infection, particularly among key populations for whom adherence to daily oral pre-exposure prophylaxis (PrEP) remains challenging.</p> <p>The main patent on cabotegravir has been filed or granted in the leading countries of manufacture of ARVs and expires in 2026. The candidate drug has not been licensed for generic production.</p>

In addition, the following products have been included in an MPP Watchlist. This means that while these products have interesting profiles and may be important targets for future licensing by the MPP, some questions on how these products could be utilized in public health settings to meet the treatment and/or prevention needs in developing countries remain to be clarified.

³ Spreen, B (2016) Cabotegravir long-acting injectable nanosuspension, presented at the 17th HIV-HEPPK

Table 2. Summary of ARVs in MPP Watchlist

ARV	Class	MPP Analysis
Doravirine <i>Filed with FDA</i>	Non-nucleoside reverse-transcriptase inhibitor (NNRTI)	<p>Doravirine (DOR) is a new generation NNRTI anticipated to be effective against a broad panel of NNRTI-resistant viruses, though it has not yet been studied in treatment-experienced patients. At a small daily dose of 100mg taken without regard to food or baseline viral load, DOR has been shown to be as effective as efavirenz or boosted darunavir as part of an initial therapy, with improved safety and tolerability.⁴ However, DOR is anticipated to have drug-drug interactions with rifampicin (an important medicine for the treatment of TB) though the exact impact on clinical use and dosing is yet unclear.⁵ Additional data, particularly in treatment-experienced patients, will be required to inform the best suited application of this novel NNRTI in a public health setting in developing countries.</p> <p>DOR as well as the FDC of DOR/3TC/TDF have been filed with the US FDA, with a target action date of Oct 23, 2018.⁶ DOR is also being studied in combination with EFdA, a promising pipeline medicine currently in Phase II (more below).</p> <p>Patents on DOR are expected to expire in 2031/33 and the candidate drug has not been licensed for generic production.</p>
Fostemsavir <i>Phase III</i>	Attachment inhibitor	<p>Fostemsavir (FOS) is the oral prodrug of temsavir, a first-in-class attachment inhibitor that targets the HIV envelop protein gp120, therefore blocking the very initial interaction between HIV and the host cell. FOS is effective regardless of HIV tropism. Having shown promising results in Phase 2b, FOS is currently being studied in Phase III in heavily treatment experienced patients. Although the clinical impact of gp120 diversity and implication in clinical cutoffs (if any) for use of FOS remain to be elucidated,⁷ FOS could be an important asset to HIV salvage therapies, with potential immune benefits.⁸ Patents on fostemsavir are expected to expire in 2025 and the candidate drug has not been licensed for generic production.</p>
Rilpivirine Long acting	NNRTI	<p>Rilpivirine long-acting injectable is currently in Phase III investigations for treatment maintenance in combination with CAB-LAI. While the combination of CAB-LAI and RPV-LAI could be an option for long-term treatment simplification, the cold chain requirement of the current formulation of RPV-LAI could make this regimen less suitable for use in resource-limited settings. The MPP will continue to monitor the progress with RPV-LAI formulations to explore whether it should become a priority for in-licensing. Patents on rilpivirine expire between 2022 and 2027. Licences have been granted to several generic manufacturers for the oral formulation, but generic products are not yet on the market.</p>

⁴ Squires, KE, Molina, J and Sax, P *et al* (2017) Fixed-dose combination of DOR/3TC/TDF is non-inferior to EFV/F/TDF in treatment-naïve adults with HIV-1 infection: week 48 results of phase 3 DRIVE-AHEAD study, presented at IAS 2017

⁵ Yee, KL, Manthos, H and Khalilieh, S *et al* (2015) The effect of single and multiple dose rifampin on the pharmacokinetics of doravirine, presented at CROI 2015

⁶ Merck & Co. press release, Jan 8, 2018. Available from: <http://investors.merck.com/news/press-release-details/2018/FDA-Accepts-New-Drug-Applications-for-Mercks-Doravirine-the-Companys-Investigational-Non-Nucleoside-Reverse-Transcriptase-Inhibitor-NNRTI-for-Treatment-of-HIV-1-Infection/default.aspx>

⁷ Lataillade, M, Zhou, N and Roshi, SR *et al* (2017) JAIDS

⁸ Ballana, E and Este, JA (2015) BMS-663068, a safe and effective HIV-1 attachment inhibitor. *Lancet HIV*, 2(10): e404-e405

The MPP will also be closely monitoring promising drug candidates that are in earlier stages of development, such as those outlined in Table 3. While some appear promising, there is insufficient data at this stage to be able to prioritize them for in-licensing.

Table 3. Summary of Promising Early Stage ARV Candidates

ARV	Class	MPP Analysis
MK-8591 (EFdA)	Nucleoside reverse transcriptase translocation inhibitor (NRTTI)	EFdA is a novel NRTTI that, unlike any approved NRTTI, inhibits the translocation of HIV reverse transcriptase. Characterized by very high potency and favourable pharmacokinetics, EFdA holds great potential in the prevention as well as treatment of HIV, not only as an oral option given once weekly, but also as long-acting formulations given every six months or longer. ⁹ The oral formulation of EFdA is being studied in a Phase 2 study in combination with lamivudine and doravirine as an initial therapy, followed by maintenance with EFdA and doravirine only. Long-acting parenteral formulations of EFdA are also under development ⁹ but have yet to enter human studies. ¹⁰
ABX464 <i>First-in-class</i>	Rev inhibitor	ABX464 blocks the HIV replication through the novel mechanism of inhibiting an HIV protein named Rev. This compound holds the potential of reducing the size of viral reservoirs in the body, which was observed in over half of the virologically suppressed HIV patients in a recent Phase 2 study. ¹¹ Further studies are warranted to confirm and elucidate its impact on HIV reservoirs, and implications for achieving “functional cure”.
GSK2838232	Maturation inhibitor	Maturation inhibitors disrupt the HIV life cycle by preventing the formation of mature, infectious viruses. The development of prior candidates such as bevirimat and GSK3532795 have been discontinued. GSK2838232 is a second-generation candidate from this unique class of ARVs. Currently being studied in treatment-naïve patients in a Phase 2a study, this compound will likely require pharmacokinetic boosting (e.g. with cobicistat, see NCT03045861) and administration with food. ¹²

Finally, the MPP is also monitoring other scientific advancements that could shift the paradigm in the prevention, treatment and possible cure of HIV, including novel platform technologies and delivery systems, gene and cell therapies, immunotherapies, and various “shock and kill” strategies.¹³ Most of these are in early stages of development and may therefore not be suitable targets for MPP in-licensing at this stage.

However, as was the case with the MPP’s collaboration with the University of Liverpool on reformulating established ARVs using the solid drug nanoparticles technology,¹⁴ there may be instances in which the MPP may take a licence in order to facilitate its

⁹ Grobler, J, Friedman, E and Barrett, SE *et al* (2016) Long-acting oral and parenteral dosing of MK-8591 for HIV treatment or prophylaxis, presented at CROI 2016

¹⁰ www.Clinicaltrials.gov

¹¹ Vandekerckhove, L, Paredes, R and Clotet, B *et al* (2017) ABX464 decreases total HIV DNA and integrated HIV DNA in PBMCs when administered during 28 days to HIV-infected virologically suppressed patients, presented at the 16th European AIDS Conference

¹² Johnson, M, Jewell, RC and Peppercorn, A *et al* (2017) Early Safety, Tolerability and Pharmacokinetic Profile of GSK2838232, a Novel 2nd Generation HIV Maturation Inhibitor, as Assessed in Healthy Subjects, presented at the 18th International Workshop on Clinical Pharmacology of Antiviral Therapy

¹³ Darcis, G, Driessche, BV and Lin, CA (2017) HIV latency: should we shock or lock? *Trends in Immunology*, 38(3): 217 – 228.

¹⁴ <https://medicinespatentpool.org/licence-post/solid-drug-nanoparticle-technology/>

further development and/or to ensure future access in low-and middle-income countries.

3 PRIORITIES IN HEPATITIS C

One of the medicines identified as a priority for in-licensing in 2017, namely ravidasvir, was licensed in by the MPP in April 2017. Results of Phase IIb/III clinical trials on this compound, in combination with sofosbuvir, have just been released and look promising. All the Phase II candidate drugs that were on the MPP Watchlist and that had pan-genotypic potential have been discontinued by their sponsors. As a result, one direct-acting antiviral (DAA) combination regimen remains on the priority list for in-licensing by the MPP.

Table 4 - Summary of Priority DAAs for MPP

ARV	Class	MPP Analysis
Glecaprevir/ pibrentasvir (G/P)	NS3/4A inhibitor + NS5A inhibitor	G/P is a once-daily, pan-genotypic combination regimen approved in 2017. Glecaprevir and pibrentasvir have improved resistance profiles over first-generation NS3/4A and NS5A inhibitors, respectively. Unlike many marketed direct-acting antiviral (DAA) regimens, G/P is safe and efficacious in HCV patients with severe kidney diseases. Contrary to the predominant 12-week treatment duration, GLE/PIB is the only DAA regimen that the FDA has approved as an 8-week regimen for treatment-naïve patients who have no cirrhosis. Patients with compensated liver cirrhosis will require 12-week treatment course, but without the need for adding ribavirin unlike prior generation of DAA therapies. G/P is also approved for salvaging certain treatment-experienced HCV patients. The regimen is also in Phase III development for treating children with HCV. Compound patents on glecaprevir and on pibrentasvir are expected to expire in 2031. The product has not been licensed for generic production.

4 PRIORITIES IN TUBERCULOSIS

The approach undertaken for the prioritization of tuberculosis (TB) medicines is outlined in the annex. The clinical assessment relies heavily on the World Health Organization (WHO) treatment guidelines for already approved medicines and the WHO Target Regimen Profiles for TB Treatment for medicines in late stage development.

On that basis, three medicines were identified as meeting the criteria for prioritization, with some reservations: bedaquiline, delamanid and pretomanid. In view of the ongoing clinical trials for all the medicines identified as priorities for in-licensing in the field of TB, and the upcoming revision of the treatment guidelines by the WHO, the MPP will closely monitor developments and amend priorities as appropriate. While demand for new Multidrug Resistant TB (MDR-TB) medicines has remained low, it is possible that demand may increase in the future as further clinical data becomes available from clinical trials and cohorts. In view of the time required from licensing of a medicine to regulatory filing by generic manufacturers, early licensing by the MPP, under public-health oriented terms and conditions, may be important to enable manufacturers to commence development.

Table 5. Summary of Priority TB drugs for MPP

TB drug	Class	MPP Analysis
Bedaquiline <i>Phase III ongoing</i> <i>Registered with the US FDA and EMA</i>	Diarylquinoline	<p>Bedaquiline (BDQ) was first registered by the USFDA in 2012 for the treatment of MDR-TB. In 2017, it was added to the WHO Model List of Essential Medicines (EML). WHO issued interim guidance for the use of BDQ in 2013 with a further update in 2016.¹⁵ The WHO recommended BDQ may be added to a WHO-recommended longer regimen in adult MDR-TB patients under certain conditions.</p> <p>BDQ is also included in a number of new regimen trials for both Drug Resistant TB (DR-TB) and Drug Sensitive TB (DS-TB), including STREAM 2 (official phase III trial) endTB, PRACTECAL, NiXTB, NeXT and ZeNix.¹⁶ The C211 trial is looking at pharmacokinetics safety and tolerability in HIV uninfected children and adolescents and the ACTG 5343 trial is a drug-drug interaction study with delamanid. The results of these studies are expected from 2021 onwards.</p> <p>The product has been the subject of a donation program that has facilitated its introduction in 64 countries. The compound patent on BDQ is expected to expire around 2023, with secondary patents expiring in 2025 and 2027. A licence has been granted to one company for the manufacture and supply of BDQ in Russia and a number of other countries in that region.¹⁷ An MPP licence with a broader geographical scope under public health-oriented terms and conditions could contribute to making the product available at affordable prices if further data confirms potential importance for TB treatment.</p>

¹⁵ Report of the Guideline Development Group Meeting on the use of bedaquiline in the treatment of multidrug-resistant tuberculosis A review of available evidence (2016) . WHO

<http://apps.who.int/iris/bitstream/10665/254712/1/WHO-HTM-TB-2017.01-eng.pdf?ua=1>

¹⁶ DR-TB Clinical Trials Progress Report. RESIST TB. http://www.resisttb.org/?page_id=1602 Accessed 12th March 2018

¹⁷ <http://www.janssen.com/janssen-broadens-collaboration-russias-pharmstandard-advance-ongoing-efforts-tackle-multi-drug>

<p>Delamanid</p> <p><i>Phase III completed</i></p> <p><i>Registered with the EMA</i></p>	<p>Nitroimidazole</p>	<p>Delamanid (DLM) received approval in Europe and Japan in 2014 and was added to the WHO EML in 2017. The WHO issued interim guidance for DLM,¹⁸ recommending that it “may be added to a WHO-recommended regimen in adult patients with pulmonary MDR-TB”. The phase III results for DLM were released in 2017, which showed no clinically relevant or statistically significant difference between DLM and placebo in terms of efficacy, when used in combination with optimised background regimen but appeared to be protective against the development of additional resistance while on treatment. There were also no major safety concerns with DLM. Following the release of the results,¹⁹ WHO updated its guidance such that “when an effective and well-tolerated longer MDR-TB regimen can be otherwise composed, the addition of delamanid may not be warranted”. There are a number of ongoing clinical trials for MDR-TB including DLM such as the phase II MDR-END trial and the phase III end-TB trial with results expected from 2019. These trials may help to elucidate DLM’s place in treatment, particularly in the context of shorter, more optimised regimens.</p> <p>In 2016, guidance was given for the use of DLM in children older than 6 years old recommending DLM “may be added to the WHO-recommended longer regimen in children and adolescents (6 – 17 years) with multidrug or rifampicin-resistant TB who are not eligible for the shorter MDR-TB regimen, under specific conditions”.²⁰ In 2017, the MPP signed an MoU with Otsuka on paediatric DLM.</p> <p>Compound patents on DLM are expected to expire in 2023, with other secondary patents expiring in 2026, 2028 and 2031. The patent holder has signed agreements for the supply and possible future manufacturing of the product with two companies, covering certain LMICs.²¹ Licences with a broader geographical scope under public health-oriented terms and conditions could contribute to making the product available at affordable prices if further data confirms potential importance of DLM for MDR-TB treatment.</p>
<p>Pretomanid</p> <p><i>Phase IIb regimen trial results available</i></p>	<p>Nitroimidazole</p>	<p>Pretomanid has been developed as part of two regimens from phase II. The phase 2b study on BPamZ²² shows promise to reduce TB treatment time and consolidate treatment regimens for DS-TB and DR-TB. The BPamZ regimen consists of bedaquiline (B), pretomanid (Pa) moxifloxacin (M) and pyrazinamide (Z). A phase III trial is in planning phase.</p> <p>Additionally, pretomanid is part of a phase III trial (ZeNix TB) to evaluate the efficacy, safety, tolerability and pharmacokinetics of bedaquiline, pretomanid and linezolid for 6-9 months in subjects with either pulmonary extensively drug resistant tuberculosis (XDR-TB) and treatment intolerant or non-responsive MDR-TB. Results are expected in 2021. It is likely that this regimen will be submitted for registration with the FDA in 2018.</p> <p>There are patents filed on the combinations of pretomanid expiring in 2036.</p>

¹⁸ http://apps.who.int/iris/bitstream/10665/137334/1/WHO_HTM_TB_2014.23_eng.pdf?ua=1

¹⁹ <http://www.who.int/tb/publications/2018/WHOPositionStatementDelamanidUse.pdf?ua=1>

²⁰ <http://apps.who.int/iris/bitstream/10665/250614/1/9789241549899-eng.pdf?ua=1>

²¹ https://www.otsuka.co.jp/en/company/newsreleases/assets/pdf/20170718_1.pdf and

<https://www.prnewswire.com/news-releases/otsuka-and-mylan-announce-license-agreement-to-commercialize-delamanid-delta-ba-for-multidrug-resistant-tuberculosis-mdr-tb-in-high-burden-countries-300508333.html>

²² Efficacy of Bedaquiline, Pretomanid, Moxifloxacin & PZA (BPamZ) Against DS- & MDR-TB. R Dawson, K Harris, A Conradie, D Burger, S Murray, C Mendel, M Spigelman. Abstract CROI 2017.

http://www.croiconference.org/sites/default/files/posters-2017/724LB_Harris.pdf

A number of other TB drug candidates are in early development and are therefore not yet considered for MPP prioritization. The MPP will closely monitor their progress in development.

Table 6. Summary of TB drugs in Phase 2

Drug	Class	MPP Analysis
SQ109 <i>Phase II</i>	Ethylenediamine	In a 14-day phase I and one phase IIa study SQ109 reported good tolerability, but absence of early bactericidal activity during the 14-day phase IIa study duration. In the recent PanACEA MAMS-TB trial ²³ looking at four new DS-TB regimens (2 containing SQ109) the arms containing SQ109 were dropped as pre-specified efficacy thresholds were not met at the planned interim analysis. There is a Phase IIb/III study underway in Russia.
LCB01-0371 (Delpazolid) Phase II	Oxazolidinone	Enrolling Phase II TB clinical study in Korea ²⁴
Nitazoxanide	Synthetic nitrothiazolyl-salicylamide derivative	Enrolling Phase II TB clinical study in Haiti ²⁵

²³ High-dose rifampicin, moxifloxacin, and SQ109 for treating tuberculosis: a multi-arm, multi-stage randomised controlled trial. Boeree, Martin J et al. The Lancet Infectious Diseases, Vol 17, Issue 1, 39 - 49
[http://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(16\)30274-2/fulltext](http://www.thelancet.com/journals/laninf/article/PIIS1473-3099(16)30274-2/fulltext)

²⁴ <https://clinicaltrials.gov/show/NCT02836483>

²⁵ <https://www.newtbdrugs.org/pipeline/trials/nzt001-14-day-eba>

ANNEX 1 – METHODOLOGY FOR PRIORITIZATION OF HIV AND HCV MEDICINES

The overall methodology has remained unchanged and is available as annexes 1 and 2 at: https://medicinespatentpool.org/uploads/2017/07/MPP-Prioritization-of-HIV-and-HCV-Medicines-for-In-Licensing_V6.pdf

ANNEX 2 - APPROACH FOR PRIORITIZING TUBERCULOSIS MEDICINES FOR IN-LICENSING BY THE MPP

The following outlines the approach applied by the MPP to prioritize TB medicines for in-licensing.

Approved medicines that have already been assessed by the WHO: For the clinical assessment of approved TB medicines that have already been assessed by the WHO in the context of its TB guidelines, the MPP relies on the assessment made by the WHO. Thus, medicines recommended by the WHO are considered to meet the clinical criteria for prioritization by the MPP. Separately, the MPP assesses whether these medicines are patented, are already covered by access-oriented licences and whether there could be a sustainable market with healthy competition for generic manufacturers.

TB drug candidates that are in late-stage development (i.e. phase IIb/III). In this case, the MPP's clinical assessment is based on the minimum and ideal targets established in the WHO's Target Regimen Profiles for TB treatment (2016), referred to as the WHO TRP.²⁶ This publication provides a comprehensive analysis of the desired characteristics of each type of TB regimen (rifampicin-susceptible, rifampicin-resistant and pan-TB treatment regimens), and was developed by the WHO in consultation with a wide range of TB experts and stakeholders. For the purposes of the MPP's prioritization, drug candidates are assessed in the context of the regimens for which clinical data is available. For each candidate drug/regimen, the assessment is made against the appropriate set of targets, depending on whether it is being developed for rifampicin-susceptible, rifampicin-resistant or pan-TB treatment.

For the quantitative assessment of candidate drugs/regimens in late stage development, a candidate drug/regimen receives a low score on any given criterion if it falls below the minimal target as specified in the WHO TRP. It receives medium score if it meets the minimal target and receives maximum score if it meets (or has the potential for meeting) the optimal target. The quality of evidence is reflected in the assessment and scores are multiplied by a coefficient depending on the quality of data available. When there is no data to assess against a given variable, the variable is not considered in the assessment.

²⁶ Available at: <http://apps.who.int/iris/bitstream/10665/250044/1/9789241511339-eng.pdf?ua=1>

Where the assessment against the WHO TRP is negative, but the drug candidate has potential for inclusion in other promising regimens based on feedback from TB experts and stakeholders, the MPP may consider prioritizing them for in-licensing, where such licensing could contribute to the development of such regimens.

TB drug candidates in phase II or earlier. The MPP would monitor the development of TB drug candidates in early phases of development and assess them once phase IIa data becomes available and phase IIb trials are initiated.²⁷ The MPP may also consider the possibility of licensing them at early stages of development, if such licensing could further facilitate their development by other TB drug developers. This may be done, for example, in the context of initiatives aimed at financially supporting the development of new regimens. Opportunities for in-licensing drug candidates in early development would be assessed on a case-by-case basis in consultation with the MPP's Expert Advisory Group for TB.

Marketed or pipeline drug under development for other indications with potential for re-purposing for use in TB. The MPP will consider opportunities for in-licensing such compounds on a case-by-case basis, upon request from stakeholders, in consultation with the MPP's Expert Advisory Group for TB.

The intellectual property, licensing and market criteria mirror those already used by the MPP for HIV and HCV.

MPP priority products for in-licensing focus on individual compounds. However, where appropriate, the MPP would also consider licensing in full regimens rather than individual compounds.

²⁷ An overview of the TB pipeline is available at: <https://www.newtbdrugs.org/pipeline/clinical> and at WHO, Antibacterial Agents in Clinical Development (2017).



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