

## Draft Recommendations of the AD Hoc Interagency Coordination Group on Antimicrobial Resistance

### Medicines Patent Pool Comments

The Medicines Patent Pool (MPP) would like to welcome this additional opportunity to provide feedback on the draft recommendations of the Interagency Coordination Group on Antimicrobial Resistance (IACG).

#### Access for all to ensure progress

- We are very pleased to see that the first IACG recommendation to accelerate progress in the AMR response is to provide affordable access to new and existing antibiotics, drugs, diagnostic and vaccines at affordable prices for those in need of treatment. Medicines must be available and affordable for biomedical innovation to make a real contribution to global health. In a recent article, Källberg *et al* have found that of the twenty-five new antibiotics introduced between 1999 and 2014 only twelve had registered sales in more than ten countries, and typically with little to no spread to LMICs<sup>1</sup>. With new antibiotics under development being in many cases developed by small companies with limited global reach, there is a risk that this trend continues and that people in need in LMICs will not have access.
- The experience of the MPP in HIV and Hep C has provided a concrete example of how patent pooling can help ensure that new medicines become rapidly available and affordable to people needing them in low- and middle-income countries (LMICs). The MPP model has also demonstrated that it contributes to addressing the need for follow-on innovation in relation to products needed mostly in developing countries, such as new combinations of medicines that are patented by more than one entity. A prime example of implementation of the model is the development of the new fixed dose combination comprising tenofovir, lamivudine and dolutegravir (“TLD”), which is now recommended by the WHO as the preferred first line regimen for HIV treatment.

#### Incentives to promote innovation

- We welcome the recommendation from the IACG asking for global access initiatives like the MPP to consider access to new and existing antibiotics, which is fully aligned with what we are currently exploring. Last May, the MPP released the results of a feasibility study exploring the possibility of expanding its mandate to work on other patented essential medicines, including new antibiotics of public health priority. The feasibility study provided the technical analysis for the MPP to expand its mandate beyond HIV, TB and hepatitis C. Over the coming months, the MPP will be working on prioritizing possible candidates for in-licensing, including exploring its possible role in relation to new

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<sup>1</sup> Cecilia Källberg *et al*, “Introduction and Geographic Availability of New Antibiotics Approved Between 1999 and 2014,” PLOS ONE, Oct. 16, 2018. Available at: <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0205166>

antibiotics for combatting AMR, taking into consideration the AWaRe categorization of the WHO.

- We agree that financial and non-financial incentives should be based on the principles outlined in the 2016 UN Political Declaration on Antimicrobial Resistance. These principles call for the de-linking of the financing of research and development for new antibiotics from the price and volume of sales to facilitate equitable and affordable access and to avoid perverse incentives that may lead to excessive use. The MPP can contribute to the implementation of these principles by supporting efforts to manage IP on new antibiotics in a public-health oriented manner that promotes innovation and facilitates both access and stewardship.
- We agree with the IACG that any financial or non-financial market incentive to address AMR should be aligned with R&D needs and priorities targeting to address the bottlenecks and market barriers across the product cycle. Linking prizes or other incentives offered by different innovative R&D financing mechanisms to MPP licensing could contribute to ensuring that new products become available in LMICs under provisions that consider good stewardship practices.

#### Incentives for manufacturers

- The demand for new antibiotics in LMICs will likely be limited and stewardship requirements that restrict marketing and/or distribution channels may limit further the market attractiveness for manufacturers, even if licences were available. It is therefore important for the IACG to consider whether appropriate incentives may also be needed to ensure that manufacturers remain interested in producing antibiotics of public health significance for LMICs, including those that are meant for Watch or Reserve.
- We support the request to leverage existing global pool procurement initiatives or the promotion of a new global procurement agency to include antibiotics. This would help to secure the supply of quality assured medicines, contribute to good stewardship and may help to enhance predictability of demand for manufactures that supply LMICs.

#### Collaboration among key stakeholders

- As suggested by the IACG, we welcome the request for further collaboration and information sharing between different stakeholders, including the private sector, to ensure affordable access, prudent use and stewardship of antimicrobials. The MPP is keen to work closely in collaboration with the industry and with recent mechanisms established to support R&D for new antibiotics, such as CARB-X or GARDP. CARB-X, an initiative to stimulate the early-stage pipeline for antimicrobials targeting priority pathogens, already requires its grantees to develop an access and stewardship plan for its drug candidates that advance through the pipeline and has indicated that licensing to the MPP could be one option for grantees to fulfil this requirement.

### Licensing to implement stewardship clauses

- As mentioned in our previous submission, the MPP is already implementing, monitoring, and enforcing certain stewardship-related obligations in its current licenses with drug manufacturers. In Tuberculosis (TB) for example, the licence signed by MPP and the Johns Hopkins University on sutezolid, includes provisions to ensure that commercialization of the product follows proper stewardship. The TB Stewardship Report, which we published in 2016, examined how MPP licences could contribute to both affordable access and responsible stewardship for new TB drug<sup>2</sup>. These could be further enhanced in relation to AMR. Through its licensing agreements and careful monitoring of compliance, the MPP can ensure that there are binding obligations in a number of areas in which manufacturers would be expected to contribute to the stewardship of new antibiotics. These could include, for example, licensing provisions that ensure that products comply with quality assurance standards, that there are appropriate controls on environmental discharge from pharmaceutical manufacturing, that marketing practices are appropriate and contribute to appropriate use, or that new antibiotics are sold through appropriate channels to decrease the risk of resistance. The licences can also contribute to ensuring that people in LMICs who need them get access.

### Benchmarks needed for responsible behavior

- In addition to clauses to ensure appropriate marketing of new antibiotics and those to regulate environmental discharges in manufacturing, there is a need to develop appropriate standards that can be expected from manufacturers of antibiotics in a range of other areas. We, therefore, very strongly support the IACG recommendation for the early adoption and implementation of global standards and best practices by the Tripartite+ and other international and national authorities, so that those norms and standards could be used as a benchmark for responsible behaviour from all parties.

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<sup>2</sup> The Medicines Patent Pool Foundation. TB Stewardship Report. 2016.  
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