

Dear Members of the WHO Expert Committee,

The WHO Model List of Essential Medicines (EML) has been used as a public health and advocacy tool to lower medicine prices at global and national levels. The decision to remove medicine price as a criterion for exclusion from the EML was a significant factor in enabling the generic competition that lowered the price of antiretrovirals by ninety-nine percent.<sup>1</sup> We are concerned, however, that some of the proposed medicines may nevertheless be excluded from the EML on the basis of current prices, despite demonstrated efficacy, safety, public health need, and expected prices of generic versions that favour their inclusion.

Reviews for sofosbuvir and simeprevir, as well as commentary by the media, academia, and civil society, emphasize the difference between the prices charged for medicines under monopoly and the manufacturing cost: sofosbuvir is estimated to cost between US\$68 to US\$136 to produce, yet the prices charged by the originator company range from US\$900 to US\$84,000.<sup>2</sup> We urge the committee to take into account various measures that can, and regularly do, secure generic competition, such as compulsory or voluntary licenses, and accordingly define relative cost-effectiveness in relation to existing or estimated generic prices rather than the exorbitant prices protected by monopolies and segmented markets.

Similarly, for several new anti-cancer medicines proposed, peer-reviewers comment that these are “hardly affordable in general and even more so in disadvantaged settings”, and that medicines be considered for the EML based on “how far the WHO considers affordable costs as a requisite for the selection of essential medicines.”<sup>3</sup> Concerns justly arise on the affordability of medicines such as trastuzumab, currently priced between US\$23,000 to US\$78,000 per patient per year, when a potential alternate supplier has suggested that it could be available for US\$248 per patient per year— 1% of the lowest Roche price.<sup>4</sup> We do not believe that it is ethically justifiable to determine how essential a medicine is based upon the level of resources that a particular country may have. We urge this committee to ask why medicines are so expensive in the first instance and what these discoveries mean if patients cannot afford them.

This Expert Committee meeting marks a milestone with the proposed inclusion of bedaquiline and delamanid, the first new tuberculosis drugs developed since the 1977 introduction of the

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<sup>1</sup> MSF Access campaign. Untangling the web of antiretroviral price reductions, 17th edition [Internet]. 2014. [cited 2015 Apr 15]. Available from: <http://msfaccess.org/content/untangling-web-antiretroviral-price-reductions-17th-edition-%E2%80%93-july-2014>

<sup>2</sup> Hill A, Khoo S, Fortunak J, Simmons B, Ford N. Minimum costs for producing hepatitis C direct-acting antivirals for use in large-scale treatment access programs in developing countries. *Clin Infect Dis* [Internet]. 2014 [cited 2015 Apr 15]; 58(7):928–36. Available from: <http://cid.oxfordjournals.org/content/early/2014/02/13/cid.ciu012.full>

<sup>3</sup> WHO peer review group. Metastatic Breast Cancer [Internet]. 2015 Mar [cited 2015 Apr 15]. Available from: [http://www.who.int/selection\\_medicines/committees/expert/20/reviews/MetastaticBreastCancer\\_PeerReviewReport2\\_EXPCOM20\\_3-Apr-15.pdf?ua=1](http://www.who.int/selection_medicines/committees/expert/20/reviews/MetastaticBreastCancer_PeerReviewReport2_EXPCOM20_3-Apr-15.pdf?ua=1)

<sup>4</sup> Knowledge Ecology International, University of California San Francisco, Universities Allied for Essential Medicines, Young Professionals Chronic Disease Network. Proposal for the inclusion of trastuzumab in the WHO Model List of Essential Medicines for the treatment of HER2-positive breast cancer. 2013 Jan [cited 2015 April 15]. Available from:

[http://www.who.int/selection\\_medicines/committees/expert/20/reviews/MetastaticBreastCancer\\_PeerReviewReport2\\_EXPCOM20\\_3-Apr-15.pdf?ua=1](http://www.who.int/selection_medicines/committees/expert/20/reviews/MetastaticBreastCancer_PeerReviewReport2_EXPCOM20_3-Apr-15.pdf?ua=1)

EML. Healthcare providers' advice should be based on which medicines would be best for their patients, rather than medicines' registration status, the existence of compassionate use programs, and prohibitive prices. The inclusion of bedaquiline, delamanid, and linezolid would be a progressive step in addressing these barriers, as the EML influences national essential medicines lists (NEMs), drug procurement, generic manufacturers, and is an eligibility criterion for enrolment in the WHO Prequalification of Medicines Programme (PQP).

While the decisions of this committee will declare certain medicines essential to public health, we should also reflect upon conspicuous absences. Entire categories of diseases lack serious research and development efforts, such as antibiotics and neglected diseases.

When we consider those drugs undiscovered that are absent from this list, cost-effectiveness takes on a new meaning. As long as drug research and development is governed by a logic of profit rather than public health, pharmaceutical companies will continue to focus their investments on drugs that can be sold at high prices rather than those which are most needed to alleviate human suffering. We emphasize the need for new, collaborative, and needs-driven mechanisms of drug research and development, predicated upon the principle of de-linkage, and implore the Expert Committee to lead in highlighting this issue, as addressing these mechanisms is a crucial part of achieving the Expert Committee's goals.