Open session - 22nd Expert Committee on the Selection and Use of Essential Medicines

Statement of Knowledge Ecology International

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At the outset, I would like to highlight one element from the Report of the WHO EML Cancer Medicines Working Group (CMWG).

The report states,

"The CMWG discussed that maybe one important element limiting access and affordability of essential medicines concerns the granting of exclusive rights to make, use and distribute medicines, excluding generics from the market. Restrictive interpretations of international trade agreements continue to limit the availability of some medicines in developed and developing countries, even when these medicines would respond to primary public health needs... *Against this background, new policies that de-link research and development costs from product prices could present a solution to expand access to new products* [Emphasis added].

Traditionally, the World Health Organization (WHO) has defined essential medicines as those that "satisfy the health care needs of the population…and are intended to be available within the context of functioning health systems at all times…and *at a price the individual and the community can afford* [Emphasis added]."

In 2015, the WHO announced the inclusion of costly treatments for hepatitis C, cancer (including trastuzumab and imatinib) and tuberculosis (including bedaquiline) on the WHO Model List of Essential Medicines (EML), reflecting the importance of their clinical benefits, even though in many countries, the prices were high, due to patent and other IPR protections.

As the Committee once again deliberates the inclusion of medically effective but costly medicines, it is time to more explicitly acknowledge the need to address the practical issues that governments face. Resources are limited, and expensive therapies can divert resources from more cost effective products. It is not surprising that many dedicated public health professionals are opposed to including expensive patented drugs on the EML. It is also not surprising that many patients and patient advocates chafe at the paucity of newer drugs on the EML.

The WHO Expert Committee has been asked, several times, to create a category in the EML for products that would be essential, if available at affordable prices.

New medicines are expensive due to policies, not physics, chemistry or biology. A policy to grant an IPR monopoly, through patents, data exclusivity or other IPR mechanisms, is designed solely to induce investments in R&D. Countries can regulate or eliminate monopolies, and some do. India broke the monopoly for sorafenib, for example, because of excessive pricing. As

countries wrestle with affordability issues, they can seek technical assistance from the WHO or other entities in order to use lawful pathways to ensure treatments are affordable and widely available — including through the granting of compulsory licences and/or through the use of competition law or other means to remedy excessive prices.

If drugs are medically effective, but expensive, they should be placed in an EML category for drugs that are medically essential but face challenges regarding affordability. Governments and patients would take this as a signal to implement policies to make these medically effective therapies affordable. A system of medical guidance that consistently ignores or excludes new drugs for cancer needs to be reformed, and new options for dealing with affordability and access are needed if we are serious about achieving equality of health outcomes.

We request the WHO Secretariat to organize workshops to consider new policies and guidelines that can enhance competition for biologics, including greater transparency of know-how and access to materials in order to create highly competitive markets for biologics.

We call upon the Expert Committee to renew the mandate of the WHO EML Cancer Medicines Working Group (CMWG). The CMWG could help identify treatable tumours of public health relevance and prioritize and identify the therapies used to treat these tumours. The Committee should cast its nets more widely to examine cell and gene therapies including but not limited to CAR T and CRISPR. On a closing note, I would highlight that in 2013, the USPTO granted four patents on CAR T. In 2018, the USPTO granted 195 patents on CAR T.

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Thiru Balasubramaniam
Geneva Representative
Knowledge Ecology International
41 22 791 6727
thiru@keionline.org