KEI remarks to WHO EML open session - 21 June 2021

Dear Members of the Expert Committee,

The creation of the first essential medicines lists took place in the 1970s. The WHO's original list included 204 medicines. The list has grown, relatively slowly, over the years. The limited number of the drugs on list was a policy objective in the 1970s, when the supply chain of the medicines was considerably more constrained. In resource poor countries health authorities were not only constrained by low budgets, but by the number of products that could be stored for use. Drugs on the early lists were chosen for a combination of the affordability, efficacy and number of patients who would benefit.

Howard and Laing's history of the Essential Drug List (it's original name), published in 1991, reported that from 1977 to 1990, only 12 of the new drugs added to the list were "new clinical entities or to have new indications." They noted that "The original purpose of the essential drug list was to itemise the minimum number of essential drugs."[1] The desire to avoid costly medicines was illustrated by Paul Miano's study on cancer drugs in the 2011, 17th Edition of the WHO Model Essential Medicines List (EML), which found that the newest cancer drug was first registered 15 years earlier by the US FDA.[2]

Since 2000, there has been pressure to add newer patented medicines, and to consider inclusion of medicines for rare diseases. There has been some, very slow progress in this regard, but very little fundamental reflection about the modern role of an essential medicines list.

KEI's position is that the earlier framework for the EML needs to be completely re-evaluated to take into account changes in the health infrastructure worldwide, the disparity of resources between developing countries, scientific progress, and new global norms to "promote access to medicines for all."[3]

Among the changes in the political landscape is a growing belief that inequalities of access to newer medicines is both a moral and a policy failure, that the prices of newer medicines can be lowered through policy interventions, in order to make access more equal, and that the treatment of rare diseases is not unimportant in developing countries.

Today the EML often plays a negative role in debates over access to medicines. The low number of patented medications on the EML is frequently cited as demonstrative that patents are not a barrier to global access to essential medicines. It is not surprising that many patients and patient advocates chafe at the paucity of newer drugs on the EML as a result of this policy tension.

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. A pathway for

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[1] N.J. Howard, BA and R.O. Laing, MD Changes in the World Health Organisation essential drug list, VOLUME 338, ISSUE 8769, P743-745, September 21, 1991, *The Lancet.* https://www.thelancet.com/journals/lancet/article/PII0140-6736(91)91455-4/fulltext

[2] Paul Miono. Approval, ownership, market structure, and placement on WHO EML for 100 new cancer NMEs on NCI alpha list. August 4, 2011. https://www.keionline.org/21644

[3] Declaration on the TRIPS agreement and public health, Doha WTO Ministerial, 2001: TRIPS WT/MIN(01)/DEC/2, Adopted 14 November 2001. Paragraph 4.

affordable antineoplastics would expand treatment options for patients, including the inclusion of second-line treatments.

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. 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 WHO 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.