

Friday, 13 October 2017

Dear Dr. Tedros,

Knowledge Ecology International (KEI) welcomes your election as Director-General of the World Health Organization (WHO), predicated upon your vision of achieving universal health care.

INTRODUCTION

In your inaugural address to the staff of WHO on 3 July 2017 you underscored the point that universal health coverage was the overarching priority of the organization. In particular, you noted:

“[A]ll roads lead to universal health coverage. For me, the key question of universal health coverage is an ethical one. Do we want our fellow citizens to die because they are poor? Universal health coverage, as I said earlier, is a human rights issue. And the responsibility of national governments. It’s not only a technical matter but even more so a political one. Countries should compare their results to their peers and learn from each other.

About 400 million people have no access, as you know, to even basic health care. Many more have access but will endure financial hardship. During the coming weeks, we will be looking at how best to implement the relevant Sustainable Development Goal, achieving universal health coverage, including financial risk protection, access to quality essential health care services, and access to safe, effective, quality and affordable essential medicines and vaccines for all.” (Source: Director-General Dr Tedros takes the helm of WHO: address to WHO staff, <http://www.who.int/dg/speeches/2017/taking-helm-who/en/>)

KEI welcomes the opportunity to submit comments on the Draft concept note towards WHO’s 13th General Programme of Work 2019–2023 (GPW). The strategic vision articulated in the draft concept note provides the WHO with a road map to guide its work from 2019-2023 and “serves as the organizing framework for two Programme Budgets 2020-2021 and 2022-2023 as well as the strategic basis for resource mobilization.” (Source: Draft Concept Note towards WHO’s 13th General Programme of Work 2019–2023, http://who.int/about/draft-concept-note_13th-programme-work.pdf?ua=1)

On Thursday, 12 October 2017, in your address to the WPRO region, you identified the Organization’s twin priorities - 1) universal health coverage and 2) health security noting that while the Sustainable Development Goals (SDGs) give the global health community the “political mandate to drive significant change...the clock is ticking...We have just 13 years to

keep the promises we made to the world's people". (Source: Keynote address by Dr Tedros Adhanom Ghebreyesus, WHO Director-General, to the Regional Committee for the Western Pacific, http://www.wpro.who.int/mediacentre/rc_dgspeech/en/)

DELINKAGE

In relation to universal health coverage, KEI welcomes the spirit of change embodied in the Draft Concept Note, but finds it lacking in specificity and avoidant of an explicit recognition of the crisis of high prices for medical technologies, and of the threat that the policy incoherence recognized in the the United Nations Secretary-General's High-Level Panel on Access to Medicines (HLP) places on the ability to actualize universal health coverage.

The UNHLP was tasked to address the incoherence between policies to promote innovation and to achieve universal access. The key to overcoming policy incoherence is to reduce reliance upon and eventually abandon the practice of using high prices and time limited patent monopolies as the incentive to invest in R&D. Delinkage models expand the role of direct funding of research and subsidies for trial costs, and use money, rather than monopolies, as the incentive mechanism. In order to truly fulfill the right to health, it is imperative that the progressive implementation of delinkage becomes a core element of the WHO commitment to achieve universal health coverage. Without delinkage of R&D costs from the prices of drugs, vaccines and other health technologies, access will always be constrained and unequal, an outcome inconsistent with the goals expressed above.

The WHO GPW should envision a pathway to evaluate and implement the alternative business models that are consistent with universal access to products, and that means, in practical terms, progressive implementation of delinkage of R&D costs from the prices of products, something that is essential to reduce prices without undermining innovation.

So long as governments rely upon the grant of a monopoly to induce investments in R&D, there will be monopolies on new drugs and the high prices that come with monopolies.

The first step in implementing delinkage is to undertake serious studies of the feasibility of delinkage in specific cases, such as for specific diseases or technologies, and/or in geographic areas and groups of countries that consider the benefits of delinkage significant, as it relates to their own national interests.

Such a study was proposed as an element in the recent WHA resolution on cancer (WHA 70.12),but not included in the final version of the resolution.

The WHO has a variety of existing mandates that would authorize work on delinkage, including feasibility studies of specific proposed approaches.

The Consultative Expert Working Group on Research and Development: Finance and Development (CEWG), the Global Strategy and Plan of Action on Public Health, Innovation,

and Intellectual Property (GSPOA), and the cancer resolution passed during the most recent World Health Assembly (WHA 70.12) all provide enabling mandates, for example.

The WHO would not be alone in considering the feasibility of delinkage. Several European governments and Members of the European Parliament have supported work within the European Union on this topic, and there are currently 16 U.S. Senators and 18 members of the U.S. House of Representatives calling for a feasibility study or studies by the U.S. National Academies (115th Congress, S.771 and HR 1776, Section 301.j).

Several developing countries have have proposed the creation of large innovation inducement prize funds that would allow countries to take measures to lower drug prices without having an adverse impact on R&D, including several made to the WHO by developing countries during the CEWG process.

Delinkage was one of the options highlighted in the 2017 WHO Fair Pricing Forum in the Netherlands, a key recommendation of the 2017 Lancet Commission report, “Essential medicines for universal health coverage”, and in a number of proposals by other experts from diverse backgrounds and by key stakeholders in public health.

Delinkage is also an important component of proposals to induce the development of, and facilitate access to, new drugs to address antimicrobial resistance (AMR), including for example, a 2017 report endorsed by the U.S. Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB), a September 2016 high level meeting of the United Nations General Assembly on antimicrobial resistance, and an earlier 2015 report by Chatham House.

R&D AGREEMENT

We appreciate that the Draft Concept Note acknowledges the important role that the WHO must play in coordinating collective action, and second the comments of India at the 70th SEARO regional committee meeting in calling for the WHO to lead negotiations on a global R&D agreement, which could provide global norms for funding R&D as a public good (Source: SEARO RC70: India calls on WHO to take the lead in negotiations of the R&D treaty (General Programme of Work debate), <https://www.keionline.org/node/2869>). This can be an important element of a broader strategy to implement the progressive delinkage of R&D costs from product prices, and also to address the need for enhancing R&D in areas of priority and creating more transparency of R&D resource flows and outcomes.

ESSENTIAL MEDICINES

In relation to the WHO Model List of Essential Medicines, we have the following comments. 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.” (Source: The Selection and Use of Essential Medicines - WHO Technical Report Series, No. 914, <http://apps.who.int/medicinedocs/en/d/Js4875e/5.2.html>)

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.

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 drugs affordable.

KEI is completing a review of 56 new anti-cancer drugs approved by the US FDA from 2010 to 2016. 45 of the new drugs received a priority review status by the US FDA. None of the 56 new drugs are on the WHO EML.

In a different analysis, KEI looked at the 28 drugs with unique active ingredients the US National Cancer Institute (NCI) identified as approved by the FDA to treat breast cancer. Of the 28, 18 were registered from 1953 to 1998, and of these, 12 are included in the current 2015 version of the WHO EML. Ten were registered from 1999 to 2016, and of these, none are included in the WHO EML.

A system of medical guidance that is consistently ignoring or excluding 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 welcome the Expert Committee’s decision to create a working group to address the complex and rapidly evolving challenges posed by cancer. This standing group could help identify treatable tumours of public health relevance and prioritize and identify the medicines used to treat these tumours, and also begin to evaluate and contribute to proposals to delink R&D incentives from drug prices, as this is the fundamental policy change that is needed.

TECHNICAL ASSISTANCE

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. Malaysia recently regulated the patent monopoly on hepatitis C medicines under a government use order, 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 licenses.

The WHO should, as you have suggested, be much more active in this regard; rather than waiting passively for countries to approach the WHO for assistance, the WHO could organize a series of regional workshops to share expertise on various technical and practical aspects of compulsory licenses, and other related topics including the ability of Members to implement limitations on remedies for patent infringement, as is done in the United States in the context of cases where courts may and often do deny permanent injunctions even involving medical technologies, but order a reasonable royalty to compensate for the non-voluntary use of the patented invention.

CONFLICTS OF INTEREST - FENSA

We note that the Lancet Editorial reported that you will appoint a “transformation czar and hire McKinsey consultants to manage the change.” (Source: WHO launches new leadership, new priorities, [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(17\)32658-2/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(17)32658-2/fulltext))

In terms of the selection of McKinsey to manage the Organization’s change, what was the process employed by the WHO? Was it FENSA compliant? Did WHO require McKinsey to declare any conflicts of interest? How much will McKinsey receive for its services in relation to change management? Who is paying for the McKinsey work?

KEI is concerned that McKinsey has other clients, most notably research based drug and vaccine manufacturers, the Bill and Melinda Gates Foundation and Microsoft, which create conflicts, as regards certain policies relating to intellectual property rights and drug pricing. For this reason, the relationship with McKinsey needs to be more transparent, and the WHO needs to consider avoiding working with a firm that is not truly responsive to the needs of the WHO, as it also is serving others who have their own interests and values in the global health space.

PREQUALIFICATION

In relation to WHO’s work on prequalification, we welcome the launch of a pilot project for prequalifying two biosimilar medicines - 1) rituximab and 2) trastuzumab. We underscore the important normative role that WHO’s prequalification program (PQP) plays in providing quality assured standards for a suite of health technologies. In order to safeguard the independence of the PQP, WHO should consider funding this work from its core budget, and not make the pre-qualification work excessively subject to the capricious nature of voluntary funding.

TRANSPARENCY

In relation to expanding WHO's work on transparency, we call on Member states to provide the WHO with the mandate to explore norms and mechanisms to enhance the transparency of R&D costs, prices and revenues.

While we acknowledge the importance of public and private sector funding of research and development of pharmaceuticals, vaccines and other health technologies, there is a paucity of data on investment flows and the costs for research and development for specific products.

Of particular interest is data regarding the investments in each clinical trial used to justify the registration of novel drugs, and to approve new indications of older drugs.

We also note the importance of enhancing the public's access to scientific and medical data from clinical trials, including trials that fail. Access to such data is critical to support advances in science, to enable the appropriate scrutiny of trial design, and to evaluate and improve the accuracy of reporting of such results. This has direct and negative consequences for our knowledge about the safety and efficacy of medicines prescribed to patients.

Policies that influence the pricing of health technologies or the appropriate rewards for successful research outcomes can be better evaluated when there is reliable, transparent and sufficiently detailed data on the costs of R&D inputs (including information on the role of public funding and subsidies), the medical benefits, and added therapeutic value of products. The actual access or lack of access to products by patients is highly dependent on affordable prices. In conclusion, access to medicines is the bedrock of universal health coverage.

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