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cc:

Dr Soumya Swaminathan, Deputy Director-General for Programmes, World Health Organization
Dr Mariângela Batista Galvão Simão, Assistant Director-General for Drug Access, Vaccines and Pharmaceuticals
Dr Bernhard Schwartländer, Chef de Cabinet, World Health Organization

3 August 2018

Dear Dr Tedros Adhanom Ghebreyesus,

In May 2018, the World Health Assembly (WHA) adopted decision WHA71(8)[1] requesting you to "elaborate a roadmap, in consultation with Member States, outlining the programming of WHO's work on access to medicines and vaccines for the period 2019-2023, including activities, actions and deliverables." Decision WHA71(8) requested you to "submit this roadmap report to the Seventy-second World Health Assembly for its consideration in 2019, through the Executive Board at its 144th session."

Process

While we are cognizant of the informal discussion with non-State actors in official relations with the WHO scheduled for 10 September 2018 and the online consultation for Member States (9 July 2018 - 16 August 2018), we request that you establish an online consultation mechanism to gather and reflect contributions from non-State actors in official relations with WHO to provide comments on the Secretariat's zero draft document of the road map on access to medicines and vaccines 2019-2023. In developing the 13th General Programme of Work, you provided non-State actors a platform to provide inputs; we ask that this model be extended to the development of the roadmap on access to medicines and vaccines for the period 2019-2023.

Content

The secretariat report (A71/12) on Addressing the global shortages of, and access to, medicines and vaccines was published on 19 March 2018 and provides the foundation for the World Health Assembly

[1] WHA71(8), 25 May 2018, http://apps.who.int/gb/ebwha/pdf_files/WHA71/A71(8)-en.pdf

decision to create a roadmap on access to medicines. The WHO report was a "comprehensive review of the major challenges to ensuring access to safe, effective and quality medicines and vaccines and analysed progress made to date." (Source: A71/12).

On the basis of this review, the Secretariat identified twelve actions that could be prioritized for implementation. Two of these actions relate to transparency:

- "Support the development and implementation of systems at the national level for collecting and monitoring key data on medicines and vaccines, such as availability, price, expenditure, usage, quality and safety, and ensuring use of these data for better evidence-based policy-making." (Source: Ibid)
- "Develop policies that promote and enhance transparency throughout the value chain, including the public disclosure of clinical trial data, research and development costs, production costs, procurement prices and procedures, and supply chain mark-ups." (Source: Ibid)

A roadmap with robust language on transparency would reinforce the WHO's authority to explore norms and mechanisms to enhance the transparency of R&D costs, prices and revenues.

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 of 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.

The lack of transparency currently impedes or delays many of the policies that would otherwise be available as policy measures to reduce the price of medicines and vaccines. In particular, without reliable information regarding the cost of R&D, the cost and results of clinical trials, private sector expenditure on the development of products, expenditures on marketing and revenues, it is hard to design alternative policy measures to reduce the current prices.

With respect to the overarching theme of achieving universal health coverage (UHC), access will always be constrained and unequal without the delinkage of R&D costs from the prices of drugs, vaccines and other health technologies.

The WHO roadmap on access to medicines and vaccines should envision a pathway to evaluate and implement the alternative business models that are consistent with universal access to products. This 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.

As countries wrestle with affordability and financial sustainability 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 and/or through the use of competition law or other means to remedy excessive prices.

The WHO should 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 and best practices on various technical and practical aspects of compulsory licenses, and other related topics including the ability of Member States to implement limitations on remedies for patent infringement.

In multilateral settings such as the special sessions of the United General Assembly on non-communicable diseases and tuberculosis, WHO should be more vocal in pushing a public health agenda where UHC depends on timely and affordable access to health technologies by, among other means, making use of TRIPS flexibilities and other public health safeguards.

We note that UN Sustainable Development Goal Three seeks to "ensure healthy lives and promote the well-being for all at all ages" and Agenda 2030 target 3.B calls upon Member States to "provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all." The WHO has to take concrete actions to give effect to these goals and targets.

Given the global disparities of access to treatment and the challenge of promoting both innovation and access, it is imperative that the WHO roadmap address the policy incoherence between trade rules, international human rights law, and public health. It is critical for the WHO to stand at the vanguard of the United Nations' (UN) response to the UN High-Level Panel on Access to Medicines (UNHLP) - including the convening of a special session of the UN General Assembly on Access to Medicines and Vaccines in 2019.

We propose the following operational language on: A) Transparency, B) Excessive Pricing C) Biologics drug competition, D) Intellectual Property rights and E) Delinkage, with clear timelines and milestones for key activities - something that is currently missing in the zero draft of the roadmap.

Proposed operational language on transparency for the WHO roadmap

During the period 2019-2023, the WHO secretariat is requested to:

A. Transparency

(1) Collect and analyse and disseminate data on health technologies of public health importance, including but not limited to:

a. Actual costs of R&D on specific drugs and vaccines, including most importantly the enrollment and costs of individual clinical trials, and the degree to which specific products benefit from subsidies provided by governments and charities;

b. Actual manufacturing costs of specific drugs, vaccines and health technologies;

c. The landscape of patents, including information about patent oppositions and other disputes about the validity and/or relevance of asserted patents;

(2) Collect and analyse and make available data on clinical trial outcomes and adverse effects of health technologies;

(3) Create a web-based tool for national governments to share information on drug prices, revenues, R&D costs, the public sector investments and subsidies for R&D, marketing costs, and other related information by the third quarter of 2021;

(4) Create a web-based tool for governments and third parties to provide information on the landscape of patents on medical technologies, including information about disputes about the validity and/or relevance of asserted patents by the first quarter of 2021;

(5) Hold meeting in the first quarter of 2020 to consider measures including but not limited to standards for reporting prices, revenue, R&D and marketing costs;

(6) Create a biannual forum on the transparency of markets for pharmaceuticals, vaccines and diagnostics, to evaluate progress toward the progressive expansion and increasing operationalization of transparency starting in 2019;

(7) Make public any contribution, financial or in kind, from pharmaceutical companies and other for-profit actors, and philanthropic foundations in relation to events, programs and actions implementing this roadmap.

B. Excessive Pricing

The WHO Secretariat is requested to develop a best practices manual on the subject of the control of and remedies for excessive pricing by December 2020. In order to develop the manual, the WHO is requested to organize a series of workshops to share expertise on various legal and technical aspects of excessive pricing, including the context specific methodologies employed by Member States for determining if prices are excessive, and the mechanisms to remedy and control pricing abuses.

No later than the end of 2019, WHO should organize a technical meeting on drug pricing, with contributions from all stakeholders, including academia and civil society, reviewing the conclusions and implementation of recommendations from the Fair Pricing Forum held in Amsterdam in 2017, as well as subsequent work in other fora to address measures to curb excessive prices for medical technologies.

C. Biologic drug competition

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

D. Intellectual Property Rights

During the period 2019-2023, the WHO Secretariat is requested to provide remuneration guidelines in relation to the non-voluntary licensing of health technologies. To this end, the WHO is requested to organize a series of workshops to share expertise and best practices 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, 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.

The WHO Secretariat is requested to produce a report by March 2020 on potential intellectual property and regulatory barriers for gene and cell-based therapies including but not limited to CAR T and CRISPR.

E: Delinkage

The WHO Secretariat is requested to conduct a feasibility study of creating a multi-country push and pull fund for cancer R&D to progressively delink the costs of R&D including the incentives borne by buyers of drugs from product prices, as an alternative to global norms that rely upon time limited monopolies and high prices to induce investments in R&D. The WHO Secretariat is requested to initiate this feasibility study in the first quarter of 2019 and submit the findings of the feasibility study to the Seventy-third World Health Assembly for its consideration in 2020, through the Executive Board at its 146th session.

The suggested operational language for the road map on access to medicines and vaccines would create a clear pathway to have a meaningful impact on the WHO's programme of work for 2019-2023.

Sincerely,

Organizations

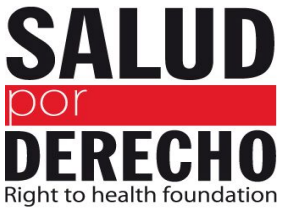

Canadian HIV/AIDS Legal Network
Réseau juridique canadien VIH/sida


Yolse
Santé Publique & Innovation


just TREATMENT


m+
Misión Salud


HEALTH GAP
GLOBAL ACCESS PROJECT


SALUD
por
DERECHO
Right to health foundation


STOP
AIDS.


BUKO
Pharma-Kampagne


Prescrire


KEI Europe

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