



## **Expanding Global Access to Affordable Essential Non-communicable Medicines and Technologies A Next Generation Perspective on the WHO Discussion Paper**

### **INTRODUCTION:**

In response to the WHO's invitation for feedback on its discussion paper on "*Improving the availability and affordability of essential medicines and basic health technologies for noncommunicable diseases*," the Young Professionals Chronic Disease Network (YP-CDN) and The Lancet Youth Commission on Essential Medicines Policies (YCEMP) jointly submit the following comment.

YP-CDN is an independent non-profit organization whose mission is to mobilize a global community of young leaders to take action against the social injustice driving non-communicable diseases (NCDs). Members include early career physicians and nurses, public health and public policy professionals, scientists, lawyers and communicators, and people worldwide who have been impacted personally by NCDs, including patients. YP-CDN is the first and largest community of young people devoted to NCDs with over 4,000 global citizens in over 140 countries.

The Lancet YCEMP is a 19-person commission from 16 different countries who have been selected to assess access and promotion policies for Essential Medicines worldwide through the lens of young health providers, researchers and advocates. Building on the analysis on primary and secondary data, the Youth Commission seek both to provide evidence based policy recommendations and raise the awareness of the relevance of Essential Medicines Policies.

The WHO document is helpful in describing the current landscape in global health and NCD control, identifying basic needs, and suggesting goals of the organization in helping member states address their growing NCD burdens. However, the language used does not convey concrete actions and roles in assisting with such objectives as lowering the prices of medicines, nor does it suggest a framework for accountability to achieve targets to improve access to affordable essential NCD medicines. While international attention on NCDs is relatively recent, country case studies and lessons from international movements for such diseases as HIV/AIDS provide sufficient evidence to solidify the WHO's and its member states' commitments to improve access to NCD essential drugs and technologies.

### **METHODOLOGY:**

YP-CDN and YCEMP sent a comprehensive survey regarding pharmaceutical access and procurement policies to their global networks of young professionals as well as relevant pharmaceutical policy listservs (ip-health, e-drug, etc.) in order to gather anecdotal evidence from young people on their experience and views on how to improve access to essential NCD medicines worldwide. We received responses from 11 countries, which included Bangladesh, Cameroon, Liberia, Ethiopia, Egypt, Kenya, India, Pakistan, Rwanda, Uganda, and the United States. Furthermore, a live web-based video consultation was held with participants from Bangladesh, Uganda, Brazil, India, and the United States. A selected number of these responses are detailed and categorized according to the WHO discussion document framework in order to provide guidance for practice steps that the WHO might take to engage Member States in strengthening their NCD control programs.

### **OVERVIEW OF RESPONSES AND DISCUSSION:**

#### **BOTTLENECKS (as identified in the WHO Discussion Paper)**

##### *Unaffordable prices of medicines:*

YP-CDN and YCEMP strongly feel that the WHO discussion paper failed to sufficiently address bottlenecks to accessing essential NCD medicines related to affordability. Specifically, the WHO discussion paper fails to recognize the very real impact of intellectual property rights on affordability of these medicines. While the discussion paper does create an exception for cancer drugs, doing so is short-sighted with cancer contributing to over 20 percent of all deaths due to

NCDs worldwide and estimates from the International Agency for Research on Cancer (IARC) showing an expected doubling of both cancer cases and deaths by 2030. With 80 percent of deaths due to NCDs concentrated in both low- and middle-income countries, the reality is that these large populations will continue to be unable to gain access to these treatments at prices they can afford. A key contributor to this unaffordability is intellectual property rights, which have only increased in recent years due to both national and international legislation to adopt longer periods of monopoly protection through add-on periods to patents such as data exclusivity and lowering patentability standards, allowing companies to obtain patents for minor modifications to already existing treatments.

Moreover, the recent addition of 16 new cancer drugs, including branded medications such as imatinib and trastuzumab, to the WHO Essential Medicines List affirms that the essentiality of a medicine, as defined by the WHO, is based on clinical need. Cost and patent status are not criteria to include or exclude medications<sup>1</sup>. The next step, and a crucial bottleneck, is ensuring that medicines that are deemed essential by the WHO are, in turn, made affordable. Which institution -- or set of institutions -- will take that on?

Both YP-CDN and YCEMP in their comments to the WHO Essential Medicines Committee in 2015 urged the members to further investigate why exactly these medicines are unaffordable to those who need them:

*"... 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." 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. 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."*<sup>2</sup>

In fact, when low- and middle-income countries which have sought to such cancer medicines more affordable to their populations by using TRIPS-flexibilities as supported by the 2001 Doha Ministerial Declaration on Public Health including compulsory licenses, they continue to face unwarranted political pressure from developed countries in various fora. YP-CDN recently joined several civil society organizations in expressing concern over the Swiss government's attempts to directly dissuade the Colombian government from issuing a compulsory licence for the leukemia drug imatinib (brand name: Glivec, produced by Novartis). Imatinib, which was added to the WHO Model List of Essential Medicines in May 2015, currently remains out of reach to many patients worldwide due to its high price. As the joint civil society [Open Letter to the Swiss government](#) states, "Compulsory licenses are an integral part of our internationally agreed patent system. High-income countries, including the United States (US), have also used compulsory licensing as a method to negotiate a lower price for medicines."<sup>3</sup>

Similarly, the United States and other developed countries with support from multinational pharmaceutical companies have sought to ratchet up intellectual property rights across other low- and middle-income countries through free trade agreements. This is exemplified in current negotiations for the Trans-Pacific Partnership Agreement, in which the United States has been actively seeking stronger intellectual property provisions including an additional 12 year data exclusivity period beyond the length of a 20 year patent for all biologic drugs.<sup>4</sup> This provision comes directly from United States legislation under the 2010 Biologic Price Competition and Innovation Act. This legislation continues to be controversial within the United States with various parties calling for a change to the data exclusivity period as evidenced by the Administration's recommendation in the 2016 Presidential Budget calling for the protection period to be reduced to 7 years in order to ensure cost-savings to the health care system.<sup>5</sup> Nevertheless, if such a provision is included within the TPP, not only will the United States be unable to amend current legislation to reduce the data exclusivity period, but other

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<sup>1</sup> <http://www.who.int/bulletin/volumes/93/4/15-154385.pdf>

<sup>2</sup> [http://www.who.int/selection\\_medicines/committees/expert/20/reviews/open-session\\_YCEMP-statement\\_18-apr-15.pdf](http://www.who.int/selection_medicines/committees/expert/20/reviews/open-session_YCEMP-statement_18-apr-15.pdf)  
[http://www.who.int/selection\\_medicines/committees/expert/20/applications/YPCDN\\_CancerReview.pdf?ua=1](http://www.who.int/selection_medicines/committees/expert/20/applications/YPCDN_CancerReview.pdf?ua=1)

<sup>3</sup> <http://ypchronic.org/profiles/blogs/yp-cdn-joins-ngos-expressing-concern-regarding-swiss-government-s>

<sup>4</sup> Luo J, Kesselheim AS. The Trans-Pacific Partnership Agreement and Implications for Access to Essential Medicines. *JAMA*. Published online August 20, 2015. doi:10.1001/jama.2015.10872.

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<http://www.citizen.org/documents/report-biologics-industry-leverages-political-power-to-maintain-monopolies-and-inflate-prices.pdf>

participating countries including those low- and middle-income countries will be required to adopt legislation mandating 12 years of data exclusivity for biologics approved for use by their populations as well. The impact of this provision goes beyond cancer drugs as it encompasses all biologic drugs, which are used to treat other NCDs.

The WHO must cast a light on the role of intellectual property rights on the affordability of essential NCD medicines. The WHO in collaboration with member organizations of the Trilateral Cooperation, WIPO and WTO, must take a strong stance against this practice of forum-shifting where certain countries and companies place pressure on other governments to adopt intellectual property policies in trade negotiations and other agreements that would raise the prices of essential NCD medicines. The WHO must also stand by those resolutions passed by Member States in past World Health Assemblies asserting their right to use TRIPS flexibilities including compulsory licensing and parallel importation. Additionally, the WHO should provide technical support to those Member States in implementing these flexibilities to ensure access to affordable, essential NCD medicines.

### *Poor Health Systems and Supply Chain Governance*

Many of our participants across both developed and developing countries identified weak health care infrastructure as a significant barrier to accessing medicines in their respective countries, and a key barrier that ought to be further emphasized in the WHO discussion paper. Specifically, challenges in the procurement of essential NCD medicines were repeatedly described as a process to which the WHO could lend its technical expertise. For example, a healthcare provider from Uganda stated that his hospital had difficulty estimating how many and which drugs to order. This was further compounded by the fact that the required projects to determine quantity and type exceeded the hospital's budget. Moreover, our consultation suggested that significant financial resources are wasted due to improper management of supplies. A respondent from Brazil, for example, reported that administrative capacity for the supply chain is limited. As a result, in 2014, millions of drugs which should have been sent to hospitals were left in storage centers and eventually discarded because their shelf lives had expired.<sup>6</sup> Similar challenges had been observed in Honduras, where medications for HIV patients among others were not distributed and thus left to expire.<sup>7</sup> These inefficiencies are extremely problematic, particularly in LMICs where health systems are already resource-constrained.

Furthermore, weaknesses in training and capacity building for personnel involved in managing and delivering NCD care, including supply chains and administration of medicines, were described as significant barriers to NCD control.

A major concern and need is also the lack of training, educational programs and resources (both human and material) to build and sustain capacity for effective national surveillance and data collection to forecast medicine needs and document inefficiencies and bottlenecks in the system. A vacuum of capacity for surveillance and data collection is of particular concern in remote and rural areas of countries such as Liberia. A need for greater access to rigorous scientific education and research training was voiced, including wider access to peer-reviewed scientific and medical journals, that would allow country-led research on NCD treatment gaps and innovations.

As mass screening programs for NCDs, such as cervical cancer, are becoming more prevalent, there is often a lack of coordination between public and private actors to integrate information and collect comprehensive and useful data on disease prevalence and treatment needs. Such established weak coordination and feedback systems were further identified as challenges with regards to "quantifying needs" in NCD control. The scaling up of screening programs is undoubtedly important, but comes with critical ethical concerns when treatment is not actually available or affordable to those who receive a positive diagnosis.

Member States must take steps to better equip established educational and training institutes and initiatives in-country to address gaps in health care provider, supply chain management, and research training in relation to NCDs. Successful cross-country partnerships between educational institutions could be built upon or used as examples for new initiatives. For example, the East Africa Social Science Translation (EASST) Collaborative is a multi-institution research network that seeks to build regional leadership in the generation of rigorous, policy-relevant social science research and increase the use of high quality evidence in the design of social policies, programs, and institutions throughout the East Africa region.

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[http://www.em.com.br/app/noticia/politica/2015/04/09/interna\\_politica,635751/milhoes-de-medicamentos-gratuitos-perde-m-a-validade.shtml](http://www.em.com.br/app/noticia/politica/2015/04/09/interna_politica,635751/milhoes-de-medicamentos-gratuitos-perde-m-a-validade.shtml)

<sup>7</sup> <http://www.ajs-us.org/news/ajs-uncovers-medications-left-expire>

The Collaborative is administered by the Center for Effective Global Action (CEGA) at the University of California (UC) and the School of Social Science at Makerere University.<sup>8</sup>

Furthermore, the WHO should explore, promote, and provide training for methods of pharmaceutical inventory management. One such approach is the ABC-VED (vital, essential, and desirable) method of analysis for essential medicines and basic health technologies at the primary, secondary and tertiary levels of health care system. This method identifies drugs that require strict management, and has been used in several inpatient and outpatient pharmacies across India. Descriptions of these programs suggest that usage of ABC-VED has enabled personnel to successfully prioritize management of select drugs, and can thus contribute to cost-savings.<sup>9,10</sup> Such scientific inventory management tools may help protect against stock-outs and minimize wastage of drugs.<sup>11</sup>

Besides the health system and supply chain bottlenecks identified in the WHO discussion paper, respondents to the consultation also identified corruption as another barrier of concern to citizens of various countries in the effort to achieve the 80% availability of affordable NCD medicines and technologies target. Anecdotal evidence from people living with type 1 diabetes in various countries highlights concerns over misallocation of funds intended for improving health systems and essential medicines access for diabetes. Corruption has often been highlighted as a barrier to access to medicines in scientific literature. Bouchard *et al.* (2012)<sup>12</sup>, for example, found that poor leadership in government and corruption were major barriers to access of orthopaedic care and orthopaedic medical devices in Uganda.

We strongly suggest that the WHO note corruption within the health system as another key barrier to access. The WHO should further explore this area in addition to the other bottlenecks mentioned in the discussion paper.

### *Sustainable Financing*

As the discussion paper highlights, the inclusion of both NCDs and essential medicines in the goals and targets of the sustainable development agenda will be an opportunity for governments, development actors and other stakeholders to mobilize resources. The global community must push for adequate and appropriate financing to support the effective implementation of NCD prevention and control initiatives and move toward universal health coverage in countries. Thus far, the financial commitments of governments have fallen far behind population needs and political commitments made at the UN High-level Meeting on NCDs in 2011 and at World Health Assemblies.

We recommend that WHO prioritize efforts to push for adequate global financing and procurement to reach the 80% availability and affordability of NCD medicines. Heads of state and ministries of finance must demonstrate that they value the health of their populations by committing an adequate health budget (such as the 15% agreed upon by the African Union within the Abuja Declaration) that stipulates resources for NCD control.

## **ENGAGEMENT OF THE PRIVATE SECTOR**

Several governments have undertaken initiatives to engage with the private sector to improve delivery of NCD medications. For example, through the Popular Pharmacy program, launched in 2004, the government of Brazil partnered with private pharmacies to distribute subsidized medicines specifically targeted to NCDs. The medicines are distributed either free of cost or with up to a maximum of 10% co-pay to patients. Often, these drugs are produced by government

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<sup>8</sup> <http://www.easst-collaborative.org>

<sup>9</sup> Anand T, Ingle GK, Kishore J, Kumar R. ABC-VED Analysis of a Drug Store in the Department of Community Medicine of a Medical College in Delhi. *Indian Journal of Pharmaceutical Sciences*. 2013;75(1):113-117. doi:10.4103/0250-474X.113543.

<sup>10</sup> Gupta, R et al. ABC and VED analysis in medical stores inventory control. *Medical Journal Armed Forces India* , Volume 63 , Issue 4 , 325 - 327

<sup>11</sup> Devnani M, Gupta A, Nigah R. ABC and VED Analysis of the Pharmacy Store of a Tertiary Care Teaching, Research and Referral Healthcare Institute of India. *Journal of Young Pharmacists : JYP*. 2010;2(2):201-205. doi:10.4103/0975-1483.63170.

<sup>12</sup> Bouchard M, Kohler JC, Orbinski J, Howard A. Corruption in the health care sector: A barrier to access of orthopaedic care and medical devices in Uganda. *BMC Int Health Hum Rights*. 2012; 12: 5.

laboratories. The diseases covered in this program are: hypertension, diabetes and asthma, dyslipidemia, Parkinson's disease, rhinitis, glaucoma, oral contraceptives and geriatric pads for urinary incontinence.<sup>13</sup> According to one of our participants, this program was seen as beneficial to the public, which is able to access chronic disease medications at low cost, and to the pharmacies themselves, as they saw a rise in the number of customers and sales. The WHO may draw from such initiatives to advise countries on how to efficiently and effectively work with private partners to improve access to essential drugs for NCDs.

We look forward to learning further about how WHO will support Member States in navigating private sector engagement that will avoid conflicts of interest and serve the public via the Global Coordination Mechanism on NCDs.

## **THE ROLE OF THE WORLD HEALTH ORGANIZATION**

### **Implementation of WHO Treatment Guidelines**

Consistent with the bottlenecks and challenges identified, we call upon the WHO to provide for supervision and assistance for in-country training of medical personnel for implementation of the WHO treatment guidelines. As our consultation requested, we also see a role for the WHO in assisting in the translation of these guidelines to local settings.

### **Knowledge sharing and price transparency**

The discussion paper touched on the creation of a knowledge-sharing initiative through the WHO that would facilitate the exchange of information on quality and pricing to support procurement processes for medicines and other technologies for NCDs. We believe that this is an important step to build transparency and information for evidence-based advocacy.

Insufficient evidence currently exists on the global availability and affordability of essential NCD medicines and technologies, as well as on the impact of policy interventions to improve access to medicines. The WHO- Health Action International (HAI) methodology has been very useful to capture necessary evidence. A study by Cameron *et al.* in 2008 demonstrated that the mean availability of essential NCD medicines in public facilities was only 36% in the public sector, compared to 54% availability for acute diseases.<sup>14</sup> Further studies such as this are needed across many different settings to collect and analyze medicine prices (patient prices and government procurement prices) across sectors and regions in a country, as well as medicine availability, treatment affordability and all price components in the supply chain from manufacturer to patient (taxes, mark-ups etc.)

Medicins Sans Frontières' *Untangling the Web of Antiretroviral (ARV) Price Reductions* has been a very valuable tool to increase transparency and understanding of ARV prices and build subsequent initiatives to increase medicines access and affordability. A similar tool to map cancer medicine prices would be an important step in increase price transparency.

HAI's Addressing the Challenge and Constraints of Insulin Sources and Supply (ACCISS) study is currently mapping the global insulin market to assess insulin formulations, prices, production scale, distribution channels, trade and regulatory issues.

Furthermore, Member States must be supported to undertake initiatives and set policies that will demand full transparency on drug prices, including R&D as well as marketing and advertising costs in addition to profits from pharmaceutical companies. Such information would allow Member States to engage in informed negotiation on drug pricing. Coupled with competitive tendering systems, Member States would be able to procure these essential NCD

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<http://portalsaude.saude.gov.br/index.php/o-ministerio/principal/leia-mais-o-ministerio/346-sctie-raiz/daf-raiz/farmacia-popular/11-farmacia-popular/18008-programa-farmacia-popular-do-brasil>

<sup>14</sup> Cameron A, Ewen M, Ross-Degnan D, Ball D, Laing RO. Medicine prices, availability, and affordability in 36 developing and middle-income countries: a secondary analysis. *Lancet* 2009; 373: 240–49.

medicines at affordable prices for their population. The WHO could offer support for such initiatives through the development of indicators to further anchor drug prices based on various factors including disease burden, socioeconomic status of populations, and public financing.

### **Civil society engagement and increasing awareness**

The WHO can work with civil society partners to encourage and facilitate effective campaigns and programs that aim to improve access to NCD medications and technologies, particularly those in line with additions to the WHO Essential Medicines List. The WHO can connect with organizations and interested parties already working in health capacity on the ground, to show these 'smaller' stakeholders that they are valued and contribute significantly to government policy. These smaller groups often have a more accurate understanding of the on-the-ground challenges and can more easily connect with patients. They also have the potential to find innovative solutions to issues such as distribution and continued availability of treatment.

As the WHO discussion paper indicates, there is a pressing need for a more vocal and strong civil society at the global, regional and national levels, working together and with the WHO toward affordable and accessible NCD treatment. The lack of resources for NCDs and conflicts of interest within some civil society organizations due to their funding sources are some examples of barriers to building a stronger civil society NCD treatment movement. Nevertheless, efforts are growing-- particularly at the country level, where it matters most. YP-CDN and other civil society organizations are eager to engage with WHO on ways to ensure that medicines on the WHO Essential Medicines List are made affordable and available to the populations that need them.

One scenario in which the benefits of civil society engagement are also apparent is through the establishment of strong partnerships for disaster-prone settings. The WHO should work with emergency and humanitarian organizations and national governments to ensure that access to essential medicines (i.e. insulin) is maintained during emergency situations. Concretely, this means putting regular and NPH (or other commonly used forms) insulin in the emergency kits that go into emergencies with other UN agencies. This role would require the WHO to assume a leadership position in prioritizing and coordinating efforts to plan and implement NCD control programs in the midst of disaster relief. Historically, UN agencies have not prioritized NCDs in emergency settings, as evidenced by the state of diabetes care during the Mali coup.<sup>15</sup>

### **CONCLUSION:**

YP-CDN and YCEMP commend the WHO on prioritizing and publishing a document on access to essential medicines and technologies for NCDs. However, we challenge the WHO to concretely state how it will engage individual Member States, industry, and civil society to achieve specific benchmarks in ensuring access to these treatments. We urge the WHO to act on recommendations based on case studies across Member States and in consultation with local stakeholders. We also urge the WHO to take a strong stance in engaging Member States to adopt policies across different fora that protect public health and access to affordable NCD medicines for their populations. Our consultation provides insights into common challenges faced across countries and several ideas on how the WHO can best assist Member States improve access to care. We request that the WHO continue to engage with civil society in order to further elucidate challenges and establish partnership opportunities to provide technical assistance at both the local and global level.

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<sup>15</sup> <http://www.conflictandhealth.com/content/9/1/15>