Consultation Response

To the WHO Discussion Paper *Essential medicines and basic health technologies for non-communicable diseases: towards a set of actions to improve equitable access in Member States*

Submitted by Katrina Perehudoff, Marie Elske Gispen, Brigit Toebes and Hans Hogerzeil on behalf of the Global Health Law Groningen Initiative\(^1\) and with contributions from Jasmin Taylor Garrett and Nikita De Jong

Date: August 31\(^{st}\), 2015

Contact person: Katrina Perehudoff (Katrina.perehudoff@gmail.com)

Contents

1. Introduction .............................................................................................................................. 1
2. Question 1 ................................................................................................................................. 3
   2.1 Rational selection & use ..................................................................................................... 3
   2.2 Reliable health & supply systems ..................................................................................... 4
3. Question 9 ................................................................................................................................... 6
4. Question 10 .............................................................................................................................. 7

1. Introduction

Equitable access to medicines to treat non-communicable diseases (NCDs) is a major public health challenge of our time. Legislation promoting access to medicines exists at various levels and can be an important part of a global response whilst other potentially conflicting laws and regulatory standards may impede efforts to ensure better access For instance, at the international and regional level, the right to health is contained in a wide range of human rights treaties and addresses access to essential medicines.\(^2\) In addition to international treaties, some national constitutions refer to essential medicines, while the standards and conditions of access to essential medicines is also further elaborated in domestic legislation. Both in law and in practice, potential conflicts between, for instance, the condition of realisation of the right to health and international drug control standards, or international


standardisation guidelines, may impede access to medicines to effective NCDs treatment. National laws and policies that reflect international human rights standards can create a framework to guide equitable and responsive health programmes and services, including medicines if understood in light of the legal and practical context in which they have to be implemented. Domestic legislation that expressly enshrines the government responsibility for medicines provision and/or individual entitlements to access medicines may, in some cases, be enforceable before national courts, thereby advancing access by providing a tool to hold governments responsible for the realisation of their obligations under international law.

Much of the human-rights based work promoting access to medicines has been developed around lifesaving HIV/AIDS medicines. At the heart of the issue were expensive medicines that were unaffordable for patients, causing their premature death. The same argument can now be applied to essential medicines for NCDs: In 2013, 8 million people died prematurely (before age 60) from NCDs. Many existing NCD medicines for treatment and secondary prevention are relatively inexpensive but they do need to be taken life-long and, therefore, there is the potential for catastrophic expenditure, possibly leading to patient bankruptcy (e.g. insulin). The case of NCDs again illustrates the importance of equitable medicines supply and non-discriminatory access that can be promoted through government funding and a human-rights approach. Moreover, newer essential NCD medicines (i.e. for Hepatitis C and cancer), the patent holder have additional human rights obligations to take concrete steps towards equitable access, such as through special programmes and differential prices. It is important to stress that a human rights approach requires adequate government funding but not necessarily for governments to pay unnecessary high prices; the pharmaceutical industry also has a responsibility under human rights to take measures to make medicines affordable.

While the context of each domestic legal and health system is unique, certain aspects of domestic law from other jurisdictions may be universally or regionally applicable. The Global Health Law Groningen (GHLG) Initiative investigates legal approaches to promoting access to essential medicines with the ultimate aim of developing and implementing sound legislation in support of universal and equitable access with due respect for country specific context relevant to implementation and realisation.

We welcome the opportunity to respond to the World Health Organization (WHO)’s consultation on Essential medicines and basic health technologies for non-communicable diseases. In our consultation response, we present our key findings to date as strategies to enhance access to essential medicines, including those for NCDs.

---

2. Question 1
Are there specific examples of best practices and successful case studies on country-led initiatives to improve access to essential medicines and basic health technologies for NCDs? What were the critical success factors for these initiatives?

2.1 Rational selection & use
The right to health includes the obligation to ensure access to the medicines listed on the WHO essential medicines list (EML).\(^4\) Due to the varied economic, epidemiological, cultural and other factors of each country situation, the realisation of the right to health can be advanced by establishing a national EML that responds to the local context. A national EML is a valuable tool to promote the rational use of medicines while also achieving the greatest public health impact for the least cost. In spite of its benefits, developing a national EML is not a strict legal requirement and, consequently, only some countries have implemented one. Trends over the last 30 years show that more low- and middle-income countries have an essential medicines list than high income countries.\(^5\) Creating a legal obligation in domestic law to maintain an EML may be an effective way of giving effect to States’ core obligation to provide essential medicines defined by the WHO and to support access in the national context. GHLG’s pilot study of 14 countries has found, in general, that high-income countries tend to have legislative or regulatory provisions for the mandatory selection and listing of medicines to be financed by their public health systems.\(^6\) These lists are often better considered to be reimbursement lists than EMLs. Middle income countries, generally more likely to have a current EML than high income countries, often do not have a legal obligation to establish or maintain an EML. One exception we identified is in Tonga’s Therapeutic Goods Act (2001), which states:

4. Establishment, functions and constitution of committee
(1) There shall be established for the purposes of this Act a Committee to be called the National Drugs and Medical Supplies Committee.
(2) The functions of the Committee shall be—
   (a) to establish, maintain and annually revise and amend the list of medicinal drugs registered for import into the Kingdom;
   ...
   (c) to maintain, annually revise and amend a List of Essential Drugs for the Kingdom which shall be the basis for public sector medicinal drug procurement;\(^7\)

\(^4\) General Comment 14, see note 2.
\(^7\) Therapeutic Goods Act 2001 s 4(2)(c). [Tonga]
7. Criteria for inclusion in the Registered List

A medicinal drug may be included in the registered list only if the Committee is satisfied that the medicinal drug—

(a) is of acceptable quality;
(b) meets an acceptable safety profile;
(c) is of demonstrated efficacy;
(d) is of United States Pharmacopoeia or British Pharmacopoeia standard or proven equivalent standard;
(e) has been proven by the manufacturer to be registered in one of the countries listed in the Schedule or following assessment of a detailed submission by the manufacturer, and payment of the prescribed fee, is found to meet the requirements of subsections (1) to (4); and
(f) would be appropriate for use in Tonga.

This text is favourable for several reasons. In Tonga, a committee, rather than the Minister of Health, is responsible for maintaining an EML using established criteria and within a clearly defined timeframe. The criteria for drug inclusion are medicines quality, safety, efficacy and appropriateness in health context of Tonga. Please consult GHLG’s pilot study in 14 countries for further information.

2.2 Reliable health & supply systems

As mentioned in the introduction, law can be an aid to advance equitable access to medicines for NCDs but also a barrier in itself. Opioid analgesics are priority medicines to provide adequate treatment of NCDs but remain largely and vastly unavailable on a global scale. There is a certain degree of urgency in low- and middle-income countries that increasingly suffer from the threat of NCDs, yet curative care is often unavailable in these countries, leaving palliative treatment, which heavily relies on the use of opioid analgesics, as the only viable therapeutic option. Uganda is often referred to as best practice for their country-led initiative to advance access to pain control medication including liquid morphine. Against the backdrop of the country’s serious HIV/AIDS crisis, structural deficiencies in human resources and deployment, and a culture of preferring home-based over hospital-based care, civil society members and local champions pushed for legislative reform. Since the early 2000s, the country now allows specially trained nurses to prescribe liquid morphine in community settings. In spite of the significant increase to treatment this at first initiated, studies reveal the country still faces inadequate figures of opioid analgesic consumption. Factors contributing to the unavailability of these medicine include potentially conflicting international regulatory standards. In Uganda, the availability and accessibility of opioid

---

8 Therapeutic Goods Act 2001 s 7. [Tonga]
9 Essential Laws for Medicine Access (ELMA) see note 6.
analgesics conform human rights law could conflict with international drug control standards,\textsuperscript{11} whereas the quality and cultural appropriateness of medicines could conflict with international standardisation guidelines.

For instance, recent research demonstrated Uganda has adopted country specific measures to implement the administrative and procedural obligations of the international drug control treaties. These measures include specific class A booklets as the international drug control treaties enshrine the obligation to manage a separate administration. In Uganda, however, managing a separate administration exerts extra pressure on the already overburdened staff, takes up more time which is already very scarce and embeds a certain fear of non-compliance. Although not directly held to obstruct medical access, these additional regulatory standards by all means do make it increasingly complex for a country like Uganda to ensure human rights-conform access to treatment.\textsuperscript{12} Moreover, after the country’s single manufacturer of liquid morphine obtained a public private partnership agreement with the Ministry of Health to supply both the public and private sectors with free liquid morphine, international standardisation guidelines were enforced on this manufacturer because of the production’s commercial nature. The enforcement of these standards resulted in a 20-year practice of colour coded, boiled tap water made medicine bottled in recycled water bottles to be insufficient leading to a significant fall back in production and decrease of availability as a result.

This recent work demonstrates that we should learn from the approaches taken in countries like Uganda but also signals that even such best practice approaches struggle to constructively deal with the difficulty potentially embed in compliance with various international standard setting instruments. In order to reach to a meaningful contribution of country-led initiatives and integrate these initiatives in regional and international standard setting and policy making more research is needed. For it is vital to understand the complexity of service provision in relation to transitioning health systems and compliance with international legal standards, both human rights and other areas of international law, both legal and non-legal.

\textsuperscript{11} See on this for instance M.E.C. Gispen, A human rights view on access to controlled substances for medical purposes under the international drug control framework, (2013) \textit{European Journal of Pharmacology} 16.

3. Question 9

What other measures can be taken to enhance advocacy efforts to improve access to essential medicines and basic health technologies for NCDs in countries?

Access to essential medicines as part of the right to health is well-founded in international law. One study of 59 court cases claiming access to medicines in 12 low- and middle income countries illustrate what this right means in practice. The study showed that international treaties, if supported by constitutional provisions, can indeed promote the realization of individual rights at the national level. The examples, most of which are from Latin America, show that individual cases can generate entitlements across a population group; that the right to health is not restricted by limitations in social security coverage; that government policies have successfully been challenged in court; and that States parties have special obligations towards the poor and disadvantaged. In the countries studied, other success factors are a link between the right the health and the right to life (in case of life-threatening disease) and support by public-interest NGOs.13 When health rights are enforced before domestic courts, judicial decisions can only be given fill effect when they are met with sufficient scale-up of financial resources, technical expertise (i.e. in rational selection of medicines) and other factors enabling their full implementation.

A guarantee of access to essential medicines in national constitutions may create a supportive environment for advocacy efforts. Examples of robust constitutional language can be found in GHLG’s recent global survey of constitutional commitments to create the conditions for access to medicines and provide medicines to those who cannot provide for themselves.14 To this end, model text has been identified in several constitutions. In Ecuador’s constitution (2011), Article 363 states:

“The State shall be responsible for ...

7. Guaranteeing the availability and access to quality, safe and effective medicines, regulating their marketing, and promoting the national production and use of generic drugs that meet the epidemiological needs of the population. With respect to access to medicine, public health interests shall prevail over economic and commercial interests.”15

In Panama’s constitution (2004), Article 110 states:

“In matters of health, the State is primarily obliged to develop the following activities, integrating the functions of prevention, cure and rehabilitation in the:

---

13 Hogerzeil, H. V., Samson, M., Casanovas, J. V., & Rahmani-Ocora, L. (2006). Is access to essential medicines as part of the fulfilment of the right to health enforceable through the courts?. The Lancet, 368(9532), 305-311.

14 Please see our forthcoming publication in Health & Human Rights, Summer 2016.

5. Establishment, in accordance with the requirements of each region, of centers which provide comprehensive health care services, and supply medicines to all the people. These services and medicines shall be given free to those who lack economic means to purchase them.” 16

These texts apply several human rights concepts to access to medicines. First, they explicitly state the government’s responsibility to supply medicines to individuals. Second, attention is paid to the availability, accessibility (i.e. financial accessibility embodied by the phrase ‘medicines shall be given free to those who lack economic means to purchase them’) and quality of medicines. Finally, Panama’s constitution requires that medicines be provided on a non-discriminatory basis ‘to all the people’. This example from Ecuador not only addresses access on the patient level, but also on the level of the health system through the affordability (i.e. ‘regulating their marketing’) and rational use of medicines (i.e. ‘promoting the national production and use of generic drugs that meet the epidemiological needs of the population ’). Other examples of model constitutional text can be consulted online. 17

4. Question 10
What key knowledge gaps are present for NCDs and how can these gaps be bridged using research?

Domestic laws and policies that support universal access to medicines for NCDs from a human rights perspective are an area of much-needed future research. Bearing in mind the unique context of each domestic legal and health system, national law from other jurisdictions may be universally or regionally applicable. Further investigation is needed to scope domestic legislation that promotes access to medicines for NCDs and studies how promising domestic laws about essential medicines function in practice to prevent or control NCDs. The goal should be to provide policy recommendations for governments striving to create a supportive environment in their domestic legislation and for legal reform in areas where legislation is still a major barrier to access to essential medicines and basic health technologies for NCDs.