



International Development Law Organization
Organisation Internationale de Droit du Développement

HEALTH IN THE POST-2015 DEVELOPMENT AGENDA

Key theme: Lessons learnt from the health MDGs

THE ROLE OF THE LAW

SUBMISSION BY THE INTERNATIONAL DEVELOPMENT LAW ORGANIZATION

DECEMBER 2012

"The MDGs also did not adequately address issues of ... violence against women, social protection, inequalities, social exclusion, [the]increase in noncommunicable diseases, reproductive health, ... governance, [and] the rule of law and human rights."

United Nations Task Team on the Post-2015 UN Development Agenda¹

"The human rights embedded in the UN Charter and the range of broadly-ratified human rights conventions and treaties are based on fundamental values. These values include equality and non-discrimination, peace and security, ...accountable and democratic governance, and sustainable development. The same values would need to underpin the new transformative development agenda."

United Nations Task Team on the Post-2015 UN Development Agenda²

The important role of the law in protecting and promoting health in economically developed countries is well documented.³ This submission will therefore focus on the integration of the international human rights law and the importance of an enabling legal environment in protecting and promoting health in economically developing countries and transition economies ('developing countries') post-2015.

All UN Member States are bound by customary international law (including, to the extent to which it has incorporated, the Universal Declaration of Human Rights (UDHR)) and relevant international treaties and conventions. These include the Charter of the United Nations, wherein 'promoting and encouraging respect for human rights' is one of the four stated purposes of the Organization. The right to health is affirmed as a fundamental human right in the UDHR (in the context of an adequate standard of living - Art. 25). State obligations have since been codified in international treaty law, and clarified in international case law and the comments of the relevant treaty bodies.⁴

In each of the areas below, the differential impact of the health issue and the legal responses on women and girls, and men and boys, must be taken into account.

1. Lessons from MDGs: integration of international human rights legal frameworks on health

The post-2015 development agenda provides an opportunity to remedy shortcomings in protecting and promoting the right to health which were inherent in the MDGs, and which also persist in international human rights frameworks.

The goals and targets of the MDGs provided a much-needed global monitoring framework for progress in selected health priorities by 2015. However the framework

failed to integrate State obligations under international law on health and development. As a result, the extensive international human rights system, with its multiple entry points (including health, women, children, discrimination...) was not fully engaged.

The international human rights system, on the other hand, has been strong on developing standards and principles, and articulating the importance of accountability and access to justice in the context of health. However, enforcement of these standards and principles remains a challenge. The post-2015 development agenda on health should include a clear reference to the right to health under international law, and linkages with the relevant UN human rights conventions and mechanisms.

2. Lessons from the response to HIV: the importance of an enabling legal environment

An enabling legal environment for health is one in which laws, government policies, and practices of state actors all contribute to attaining health goals. A key factor is the ways in which laws and policies are implemented, and includes legal empowerment and access to justice, particularly for vulnerable and disadvantaged populations. This concept has been explored most fully in the context of HIV, where it includes:

- laws and regulations, including customary and religious laws
- judgments of courts, tribunals and traditional village courts
- management of prison systems and other closed settings such as detention centers for people who use drugs
- programs providing access to justice for communities through legal aid for people living with HIV and education for communities about their rights
- law enforcement practices of police and prosecution authorities.⁵

The role of the police in attaining health goals is gaining more attention. Further lessons from HIV: the criminal law can impede public health interventions; and police policies and practices can determine their success.⁶ The post-2015 development agenda on health should include the promotion of an enabling legal environment for health.

3. Lessons from the response to HIV: addressing discrimination is essential to achieving health goals

Discrimination in the health setting includes the denial of appropriate prevention, treatment and care services to groups such as people living with HIV, injecting drug users, sex workers or men who have sex with men (MSM). It also includes practices such as the coercive sterilization of women with disabilities or women living with HIV, around the use of long-term contraceptive methods.⁷ Discrimination in other contexts also increases vulnerability to illness, such as through reduced economic opportunity, or exposure to violence. Such discrimination undermining public health goals. Appropriate legal frameworks that prohibit such discrimination, and affordable and accessible quality legal services, are required. These frameworks must also consider the different impact of discrimination and proposed remedies on men and boys, and women and girls. The post-2015 development agenda on health should include also strengthen measures to address discrimination.

4. Lessons from the response to HIV: comprehensive and transparent monitoring and reporting frameworks can encourage enabling legal environments

Since 2000, the UN General Assembly has adopted resolutions with specific commitments to action on HIV/AIDS, starting with the Declaration of Commitment on HIV/AIDS. These commitments have been backed by a comprehensive global monitoring and reporting framework which includes a specific reference to human rights and law.

The reporting guidelines developed for this framework include indicators on law reform and HIV-related legal services. All the periodic reports submitted under this framework are accessible on the UNAIDS website. This provides **the opportunity to track States'** compliance with international commitments on HIV, and identify obstacles and areas for increased support. The post-2015 development agenda on health should ensure that such monitoring of the global HIV response continues. It also should provide for comprehensive monitoring and reporting frameworks in other health areas such as NCDs, and which include explicit indicators on legal and policy reform.

5. Lessons from the response to HIV: engage a broad range of development partners

Framing HIV as a broad development challenge, rather than just a health issue, allowed the engagement of a broad range of multi-sectoral partners, including development agencies and civil society organizations. This approach, which included the creation of a joint UN program on HIV outside of WHO, has been hugely successful in engaging multiple stakeholders, raising funds, and coordinating global policy development on HIV.

In the post-2015 context, such an approach to priority health issues will require States, WHO and UN and other international development agencies and civil society organizations to work together in new ways. WHO must become a facilitator and catalyst of a global response, welcoming other development partners, and not limit its role to technical guidance and support.

6. Lessons from noncommunicable diseases: the importance of national public health law capacity

In 2008 over 14 million people aged 30 - 69 years in developing countries died from cardiovascular disease, diabetes, cancer and chronic respiratory disease and other NCDs. Most of these deaths were premature or preventable, and were largely due to four modifiable risk factors: tobacco use, physical inactivity, unhealthy diet, and the harmful use of alcohol. As Magnusson and Patterson noted in 2011 (emphasis added, footnotes omitted):

Priority actions to reduce tobacco use and alcohol consumption include: the restriction of alcohol advertising and sponsorship, and the enforcement of comprehensive bans on tobacco advertising, promotion, and sponsorship; health warnings on tobacco products; higher taxes on tobacco and alcohol; bans on smoking in public places; prohibition of sales to children; and penalties for smuggled and counterfeit tobacco and informally produced alcohol. Restrictions on when retail alcohol can be sold and drink-driving countermeasures are also important interventions. Priority interventions for diet include: the replacement of trans fats with polyunsaturated fats; a reduction in salt content of food; restrictions on the marketing of foods and beverages high in salt, sugar, and fat (especially to children); better food labelling; and the promotion of food reformulation (particularly salt reduction).

A striking feature of these interventions is that legal and regulatory actions by governments are needed for successful implementation. Regrettably, the need for global leadership in public health law has received little attention.

The experiences of high-income countries with tax rises, warning labels, advertising bans, and retail controls on tobacco and alcohol suggest that the implementation of priority interventions in countries of low and middle income will be strongly resisted by industries that benefit from harmful products or harmful rates of consumption. Many countries have outdated public health laws,

insufficient technical capacity to implement interventions, and their governments are vulnerable to inappropriate corporate influence...

... **National governments must also navigate World Trade Organization rules and obligations** under bilateral investment treaties and simultaneously resist pressures from trading partners who act on behalf of tobacco and other business interests domiciled in their territories.⁸

Today, 'public health law' also includes international trade and investment law, constitutional law, and intellectual property law. Governments of many developing countries do not have adequate technical capacity in public health law, which may include resisting legal challenges from the private sector to government sovereignty in public health matters. Civil society organizations in many countries are not equipped to tackle the relevant legal issues. The post-2015 development agenda should include development of broad capacity in public health law – including through South-South learning and other forms of support.⁹

7. Lessons from access to medicines: the importance of national legal and policy coherence on health

Appropriate national and international legal frameworks are needed to ensure access to medicines that are affordable, safe, effective and of good quality.¹⁰

Ensuring access to medicines in the development context will continue as one of the most pressing issues in the post-2015 health and development agenda. In the context of HIV, lower drug prices combined with increased testing to identify persons needing treatment has led to a significant increase in the number of people on antiretroviral treatment in lower and middle income countries. However this progress is under threat from inadequate or overly-restrictive intellectual property laws, new international legal obligations arising from bilateral and multilateral trade and investment treaties, and an unnecessary confusion between quality generic drugs and 'spurious/false-labelled/falsified/counterfeit drugs'.¹¹ As a result, many developing countries and transition economies are not accessing these medications or using them efficiently.

The growth of NCDs also fuels the need for affordable, quality treatment in developing countries. WHO has noted that the costs of NCD treatment already place a considerable burden on household incomes.¹²

Many States are members of the World Trade Organization (WTO) and must implement the Trade Related Aspects of Intellectual Property (TRIPS) Agreement. Others are revising their intellectual property laws in anticipation of WTO membership. However all States should be aware of the flexibilities available in the TRIPS Agreement to protect and promote public health. National policy coherence is essential to avoid conflicts between public health and other national development goals.

In the Rio Political Declaration on Social Determinants of Health, States pledged to "**reach out and work across** and within all levels and sectors of government by promoting mechanisms for dialogue, problem-solving and health impact assessment with an equity focus to identify and promote policies, programmes, practices and legislative measures that may be instrumental for the goal pursued by this Political Declaration and to adapt **or reform those harmful to health and health equity.**"¹³ The post-2015 development agenda on health should encourage a coherent whole-of-government approach to health policy and law reform.

8. Lessons from spurious/falsely-labelled/falsified/counterfeit (SFFC) medicines: need to integrate health with national and global responses to organized crime

SFFC medicines are defined by the WHO as medicines which are “deliberately and fraudulently mislabelled with respect to identity and/or source.”¹⁴ SFFC medicines are more likely to be a problem in countries and regions with weak regulatory and enforcement regimes. They can result in poisoning, avoidable mortality and morbidity from treatable diseases, and erode public confidence in quality medicines and public health initiatives. In many countries, the criminal law and capacity to address SFFC medicines is non-existent, weak, or outdated. The health impacts are disastrous—at a personal and family level and from a public health perspective.

Appropriate criminal legal frameworks and enforcement capacity are essential, both nationally and internationally. If SFFC medicines are only treated as a trademark violation, options for prosecution and punishment are unlikely to be a sufficient deterrent. The post-2015 development agenda on health should explore how SFFC medicines can be addressed through national, regional and international responses to organized crime.

9. Lessons from pain management and palliative care: the need to tailor solutions to local contexts

WHO estimates that 5 billion people live in countries with little to no access to controlled medicines and have insufficient or no access to treatment for moderate to severe pain.¹⁵ Those in need of pain management include people with cancer, advanced stage AIDS, and chronic illnesses. Morphine, the main opioid treatment for pain, is relatively affordable and easy to administer. However, because of its status as a controlled medicine many countries have inappropriate legal and regulatory barriers to access.¹⁶

Burdensome prescription procedures and limits on the length of opioid prescriptions result in repeated visits to doctors by patients or family members, draining human and financial resources. Limiting the right to prescribe opioids to specialists or to doctors undermines access in countries which have a shortage of doctors and rely on mid-level providers, such as clinical officers and nurses, for the majority of healthcare provision.

Invasive and stigmatizing surveillance of patients receiving opioids, and of healthcare workers handling controlled substances, can deter patients from seeking care and healthcare workers from providing it. Legal solutions tailored to national contexts are urgently needed to overcome barriers to access, while reducing the risks of substance abuse. This cannot be done by simply importing legal frameworks from other jurisdictions. The post-2015 development agenda on health should acknowledge that often local solutions must be found through a participatory dialogue between regulatory authorities, patients and their carers and advocates, and the medical profession.

About IDLO (www.idlo.int)

IDLO is an intergovernmental organization that promotes legal, regulatory and institutional reform to advance economic and social development in developing countries, countries in economic transition and in those emerging from armed conflict.

IDLO empowers people and enables governments to reform laws and institutions to promote peace, justice, social development and sustainable economic growth. Our vision is of a world free of poverty where every human being lives in dignity and under the rule of law. Our mission is to strengthen the rule of law, human rights and good governance in developing countries.

Founded in 1983 and one of the pioneers of justice sector reform and development assistance, IDLO's mandate is to strengthen the rule of law by supporting economic and social development that is driven by societal demand. By involving stakeholders from all levels of society in its development programs, IDLO helps develop sustainable, equitable solutions that reflect a country's broad needs and desires.

IDLO has worked with over 20,000 legal professionals in 175 countries. Its network of 47 legally established IDLO Alumni Associations around the world, with membership drawn from legal, business, academic and civil society communities, contribute to the overall impact and long-term sustainability of the Organization's work.

IDLO has its headquarters in Rome, a liaison office for the United Nations in New York, and country offices in Afghanistan, Kenya, Kyrgyzstan, South Sudan, Somalia (based in Nairobi) and Tajikistan.

Authors' statement.

David Patterson, Head, Social Development Programs
Elisa Slattery, Legal Officer, Social Development Programs

The authors are employees of IDLO. They have disclosed no competing interests.
Further information: email: dpatterson@idlo.int

1 UN System Task Team on the Post-2015 UN Development Agenda, *Realizing the Future We Want for All: Report to the Secretary-General*, para.19 (2012).

2 *Id.* at para. 58.

3 See e.g. Gostin L.E *Public Health Law: Power, Duty, Restraint* (University of California Press, 2000)

4 See Leary V.A 'The right to health in international law' in *Health and Human Rights* (1994) 1(1) 24-56.

5 International HIV/AIDS Alliance, *Enabling Legal Environments for Effective HIV Responses: A leadership challenge for the Commonwealth*, (2010) available at <http://www.hivpolicy.org/Library/HPP001810.pdf>

6 In 2012 IDLO was an auspice partner for the First International Conference on Law Enforcement and Public Health. See <http://www.policing-and-public-health.com/>

7 See e.g., Global Commission on HIV and the Law, *Risks, Rights and Health*, July 2012 available at <http://www.hivlawcommission.org/resources/report/FinalReport-Risks,Rights&Health-EN.pdf>.

8 Roger Magnusson, David Patterson. Comment: Role of law in global response to non-communicable diseases, *Lancet* 2011; **378**: 859-60.

9 See also IDLO submissions in 2012 to WHO discussion papers on the global response to NCDs: <http://www.idlo.int/Publications/CommentsWHODiscussionNCD.pdf>

10 See Human Rights Council resolution 'The right of everyone to the enjoyment of the highest attainable standard of physical and mental health in the context of development and access to medicines' A/HRC/Res/17/14 adopted 14 July 2011.

11 See World Health Organization, 'Spurious/falsely-labelled/falsified/counterfeit (SFFC) medicines' <http://www.who.int/medicines/services/counterfeit/en/index.html>

12 World Health Organization, *Global Status Report on Non-Communicable Diseases, 2010, (2011)* available at http://www.who.int/nmh/publications/ncd_report_full_en.pdf, 36.

13 Rio Political Declaration at para. 13(2)(viii), 2011.

14 World Health Organization, Factsheet 275: Medicines: spurious/falsely-labelled/ falsified/counterfeit (SFFC) medicines available at <http://www.who.int/mediacentre/factsheets/fs275/en/>.

15 World Health Organization Briefing Note: Access to Controlled Medications Program, February 2009 available at http://www.who.int/medicines/areas/quality_safety/ACMP_BrNoteGenrl_EN_Feb09.pdf.

16 Human Rights Watch, *Drug Control and Access to Controlled Medicine: A Global View* available at http://www.hrw.org/sites/default/files/related_material/hrw_map_flyer_FINAL3.pdf.