

# INTERNATIONAL LAW ASSOCIATION

## SYDNEY CONFERENCE (2018)

### GLOBAL HEALTH LAW

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### I. Global Health Law as a field of international law

1. Over the course of the past several decades, the attention of policymakers at the national and international level has increasingly focused on the protection and promotion of human health, and the legal rules that influence the availability of and access to healthcare. The HIV-AIDS epidemic that killed or threatened millions of individuals, with devastating consequences in countries where treatment was unavailable or unaffordable, illustrated that viruses and other diseases-bearing pathogens have little regard for borders. A coordinated international response helped to contain that epidemic. Subsequent threats arising from pandemic influenza, and the willingness of some developing countries to withhold access to virus samples, forced an overdue re-thinking of the international regime for pathogen-sharing, and negotiation of a new framework mechanism. Efforts by national governments to constrain the consumption of tobacco products met with objection on trade and investment law grounds, requiring the substantial expenditure of resources to address these objections in dispute settlement fora established to address economic issues. This despite an existing multilateral Tobacco Convention calling for the types of measures that were challenged. A major Ebola outbreak in West Africa revealed institutional weaknesses in the global mechanisms for response. New institutional mechanisms are gradually being built to improve this situation. National and international policymakers today focus on environmental pollution and climate change as threats to public health, a recent change in perspective that enhances the role of the WHO.
2. Global society is interconnected. For a very substantial part of humankind, access to healthcare is a more important issue than the state of the international financial system or whether tariffs are moving up or down. Laws, including international agreements, that affect the promotion and protection of human health must have effective authority equivalent to laws designed to govern economic affairs. The Global Health Law Committee was established in recognition of the important role that health law and policy plays in the international arena, and to further the idea that global health law should take its place among the established fields of international law. Global health law has moved beyond characterization as an “emergent” field, and has established itself as a field of international law, even if identification and clarification of basic principles is less well-settled than in some other areas. This Committee has as one of its important goals to make progress in that identification and clarification.

#### *Global Health Law in Historical Perspective*

3. With the exception of the fight against the international spread of infectious diseases, the protection and promotion of human health has not been considered as an issue area ripe for treaty-making until the 1990s. With the exception of normative developments at the regional level in Europe and the Americas, the sole global binding legal instruments wholly dedicated to the health were two WHO regulations, the so-called Nomenclature Regulations<sup>1</sup> and the International Health Regulations.<sup>2</sup> Regulations are binding on WHO Member States under Articles 21 and 22 of the WHO Constitution.

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<sup>1</sup> Resolution WHA9.29, WHO Official Records 13, Annex 1, pp. 349-352. The Regulations were revised in 1967 by moving the actual classification of diseases to a different document, the International Classification of Diseases. Resolution WHA20.18, WHO Official Records 160, p. 9.

<sup>2</sup> [http://www.who.int/topics/international\\_health\\_regulations/en/](http://www.who.int/topics/international_health_regulations/en/)

4. Why such a dearth of dedicated global instruments? And why has WHO been historically reluctant to use international law as a tool to discharge its mandate? This report is not the place for an in-depth historical analysis, but two main considerations may help placing this section of the report in perspective. The first is that the regulation of health has focused for the longest time on health care and public health measures, i.e. two essentially domestic issues, again with the exception of the fight against epidemics. It is only from the 1990s that the consequences of the HIV/AIDS pandemic, the effects of globalization and economic liberalization (e.g. the proliferation of investment agreements and the establishment of the WTO) and the increasing perception of diseases as national security threats focused scholarly and policy attention on the “determinants of health” – non-health factors that have a significant direct causal effect on health outcomes such as economic, social and security policies. Those factors were often already highly regulated at the international level, e.g. through international economic law or environmental law; this may explain the reluctance of many states to accept new and partly overlapping or conflicting obligations. The second is that WHO focused throughout its first five decades on diseases and public health issues of high importance to its developing country members but that – with few exceptions – did not warrant the adoption of treaties. Where a normative approach would have been justified, e.g. for the regulation of the marketing of breast-milk substitutes, overwhelming economic interests militated against a legally binding approach. For these and other reasons, WHO did not fulfil the expectations reflected in its Constitution to be an active normative organization.<sup>3</sup>

#### *Taxonomy of Global Health Law*

5. The body of international norms dealing specifically with the protection and promotion of human health (including the regulation of directly related issues such as medicines or medical devices) has to be seen holistically, extending the analysis to non-binding instruments adopted by international organizations and increasingly to international standards of a largely private character. Without prejudice to the ontological question whether the international legal system is evolving to encompass non-binding sources and whether the latter can be considered of a legal nature,<sup>4</sup> the empirical consideration of the impact and influence of soft norms on health outcomes and their complex interactions with existing treaties warrant their inclusion into a broad taxonomy of the field.
6. The core of the field is comprised of instruments adopted by WHO under its Constitution.<sup>5</sup> The World Health Assembly has the authority to adopt regulations on prescribed subject matter to be given effect by Member States,<sup>6</sup> and to adopt conventions<sup>7</sup> and recommendations.<sup>8</sup>
7. The first instrument adopted by WHO in 1951 were the International Sanitary Regulations, renamed International Health Regulations (IHR) in 1969 and largely overhauled in 2005.<sup>9</sup> The IHR provide the only global legal framework for the prevention and control of the international spread of diseases. Under their authority, the WHO Director-General can declare public health emergencies of international concern and issue temporary recommendations to facilitate a coordinated international response.
8. The WHO Framework Convention on Tobacco Control (FCTC)<sup>10</sup> imposes obligations on its Parties designed to reduce demand and supply of tobacco products through a variety of measures. The FCTC

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<sup>3</sup> On the divergence between the initial assumptions about WHO’s normative role and its historical development, see G.L. Burci, C.H. Vignes, *World Health Organization*, (The Hague, Kluwer Law International, 2004), pp. 153-155.

<sup>4</sup> J. Klabbbers, “The Redundancy of Soft Law”, *Nordic Journal of International Law* 65 (1996), p. 65.

<sup>5</sup> Constitution of the World Health Organization, as amended, first entered into force 7 April 1948, [http://www.who.int/governance/eb/who\\_constitution\\_en.pdf](http://www.who.int/governance/eb/who_constitution_en.pdf).

<sup>6</sup> Article 21, id.

<sup>7</sup> Article 19, id. Such conventions are subject to acceptance by Member States.

<sup>8</sup> Article 23, id.

<sup>9</sup> <http://www.who.int/ihr/publications/9789241580496/en/>. FIDLER 2005 ARTICLE

<sup>10</sup> Entered into force 27 February 2005. [http://www.who.int/tobacco/framework/WHO\\_FCTC\\_english.pdf](http://www.who.int/tobacco/framework/WHO_FCTC_english.pdf). The WHO FCTC was developed in response to the globalization of the tobacco epidemic. The core demand reduction provisions in the WHO FCTC are contained in articles 6-14. The core supply reduction provisions in the WHO FCTC are contained in articles 15-

established a Conference of the Parties (COP) with authority that extends to proposing and adopting amendments to the Convention.<sup>11</sup> The COP has been developing the normative framework of the FCTC through the adoption of guidelines as well through a Protocol on Illicit Trade in Tobacco Products adopted in 2012 but not yet entered into force as of June 2018.<sup>12</sup> The FCTC was adopted with limited mechanism for resolution of disputes, with provision for future consideration of proposals by the Conference of the Parties.<sup>13</sup>

9. The “soft” instruments adopted by the WHA include the 1981 Code of Marketing of Breastmilk Substitutes,<sup>14</sup> the 2011 Pandemic Influenza Preparedness Framework (PIP Framework)<sup>15</sup> and the 2010 Global Code of Practice on the International Recruitment of Health Personnel.<sup>16</sup> The PIP Framework, in particular, is an innovative instrument that regulates the sharing of pandemic influenza viruses and related benefits, thus ensuring equity in the pursuit of global health security. The WHO Secretariat also issues recommendatory instruments with a clear normative function, e.g. the 2015 Guidelines on sugar intake,<sup>17</sup> the Model List of Essential Medicines<sup>18</sup> and the recommendations on the level of control of narcotic drugs and psychotropic substances under the relevant UN conventions.<sup>19</sup> Particular attention must be paid to the standards, guidelines and other instruments adopted by the Codex Alimentarius Commission – a joint FAO-WHO programme on food standards - given their status under the WTO Agreements on Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT), respectively. Pursuant to Article 3.2 and Annex A of the SPS, in particular, states that base their national measures on Codex standards and recommendations are presumed to be compliant with their obligations under the SPS and GATT.
10. From the perspective of binding instruments, the field also arguably includes global treaties adopted by other international organizations whose main object and purpose is the protection or promotion of particular aspects of human health. Treaties falling within this group may include the United Nations (UN) conventions on the control of narcotic drugs and psychotropic substances<sup>20</sup> and treaties of the International Labour Organization (ILO) on occupational health such as the 1981 Occupational Safety and Health Convention<sup>21</sup> or the 1995 Safety and Health in Mines Convention.<sup>22</sup> Health is so intrinsic to the purposes and functions of environmental law that several environmental conventions with a more direct connection with the protection of human health may also be included within the core of global health law. This point is dealt in more detail later in this report, with a list of relevant conventions.
11. One should also not overlook the important normative developments happening at regional level, in particular in the Americas and Europe. The Pan-American Sanitary Code, for example, is one of the

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17. The Convention is the inclusion of a provision that addresses liability. Mechanisms for scientific and technical cooperation and exchange of information are set out in Articles 20-22.

<sup>11</sup> Such amendments are subject to acceptance by Member States through their constitutional processes. Articles 28 & 29, FCTC.

<sup>12</sup> Protocol to Eliminate Illicit Trade in Tobacco Products, adopted on 12 November 2012.

<sup>13</sup> Issues related to implementation of the WHO FCTC and settlement of disputes concerning the implementation or application of the Convention, Report by the Convention Secretariat, FCTC/COP/7/20, 27 July 2016. This report prepared by the Convention Secretariat of the FCTC takes note that dispute settlement bodies established under international economic agreements may interpret the FCTC.

<sup>14</sup> WHO ‘International Code of Marketing of Breast-Milk Substitutes (entered into force 21 May 1981).

<sup>15</sup> WHO ‘Pandemic influenza preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits’ (PIP Framework) (adopted 24 May 2011).

<sup>16</sup> WHO ‘Global Code of Practice on the International Recruitment of Health Personnel’ (adopted 21 May 2010).

<sup>17</sup> [http://www.who.int/nutrition/publications/guidelines/sugars\\_intake/en/](http://www.who.int/nutrition/publications/guidelines/sugars_intake/en/)

<sup>18</sup> <http://www.who.int/medicines/publications/essentialmedicines/en/>

<sup>19</sup> <http://www.who.int/medicines/access/controlled-substances/ecdd/work-on-ecdd/en/>

<sup>20</sup> Single Convention on Narcotic Drugs (adopted 30 March 1961, entered into force 8 August 1985) 520 UNTS 151; Convention on Psychotropic Substances (21 February 1971, entered into force 15 August 1976) 1019 UNTS 175; United Nations Convention Against Illicit Traffic In Narcotic Drugs And Psychotropic Substances (adopted 20 November 1988, entered into force 11 November 1990) 1582 UNTS 95.

<sup>21</sup> ILO, Convention (No. 155) Convention concerning Occupational Safety and Health and the Working Environment (adopted 22 June 1981, entered into force 11 August 1983) 1331 UNTS 22345.

<sup>22</sup> ILO, Convention (No. 176) Convention concerning Safety and Health in Mines (adopted 22 June 1995, entered into force 5 June 1998) 2020 UNTS 207.

oldest health treaties even though partially overtaken by the IHR.<sup>23</sup> In the European context and besides the growing *acquis* of the European Union, the normative production of the Council of Europe on health matters spans from the harmonization of specifications for medicinal substances and the Convention on the Elaboration of a European Pharmacopoeia and its protocols,<sup>24</sup> to the very important instruments in the field of human rights and biomedicine<sup>25</sup> and finally to the recent convention on counterfeiting of medical products (“Medicrime Convention”).<sup>26</sup>

12. Besides soft instruments adopted by intergovernmental bodies, one of the most striking developments of contemporary global health governance is the proliferation and impact of international standards and guidelines adopted by institutions and networks comprising public and private, or only private, members, whether representing corporate or social interests. Examples range from the guidelines adopted by the International Standardization Organization (ISO) and the International Council for Standardization of Technical Requirements for Pharmaceuticals for Human Use (ICH) to standards on medical devices – for example the International Medical Device Regulators Forum –<sup>27</sup> and food safety – for example Global G.A.P.<sup>28</sup> The proliferation of international hybrid and private standards is a manifestation of what has been seen as a trend towards “informal international law-making” and raises delicate questions of legitimacy, accountability and privatization of public functions.<sup>29</sup> This topic deserves more attention and the GHLC could return to it in a subsequent report.

#### *Health as a normative value or a field of international law?*

13. Besides a core of hard or soft instruments for which the protection of health is an integral part of their object and purpose, the international regulation of health issues and in particular of the “determinants of health” is shaped by the role of health as a normative value in many international legal regimes, from trade, investment and intellectual property to human rights and humanitarian law, and from arms control law to environmental law. Given the particular nature of health as an intrinsic status of individuals and communities, it is evident that most human activities regulated under international law have a direct or indirect impact on various aspects or determinants of human health and, conversely, are influenced by the need to better protect or promote health with regard to the design, implementation and interpretation of their respective international regulations.<sup>30</sup>

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<sup>23</sup> Pan-American Sanitary Code (adopted 14 November 1924, entered into force 26 June 1925).

<sup>24</sup> Convention on the Elaboration of a European Pharmacopoeia, (adopted 22 July 1964, entered into force 8 May 1974) ETS No. 51.

<sup>25</sup> Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (adopted, entered into force) ETS No.164; Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (adopted 12 January 1998, entered into force 1 March 2001) ETS No. 168; Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (adopted 24 January 2002, entered into force 1 May 2006) ETS No.186; Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research (adopted 25 January 2005, entered into force 1 September 2007) CETS No.195; Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes (adopted 27 November 2008) CETS No. 203.

<sup>26</sup> Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (MEDICRIME Convention) (adopted 28 October 2011, entered into force 1 January 2016) CETS No.211.

<sup>27</sup> International Medical Device Regulators Forum (IMDRF), <<http://www.imdrf.org/>>; The IMDRF is made up of a voluntary group of medical device regulators who aim to harmonize regulatory requirements for medical devices. Their work builds upon the Global Harmonization Task Force on Medical Devices (GHTF).

<sup>28</sup> Global G.A.P. (Good Agricultural Practice), <[https://www.globalgap.org/uk\\_en/](https://www.globalgap.org/uk_en/)>, Global G.A.P. is a farm assurance program with the objective of creating safe and sustainable agriculture worldwide. Global G.A.P. aims to harmonize standards for the certification of agricultural products by setting voluntary standards. Despite being voluntary, these standards are widely recognized and increasingly complied with by producers, suppliers and buyers.

<sup>29</sup> J. Pauwelyn, R.A. Wessel, J. Wouters (eds.), *Informal International Lawmaking* (Oxford, Oxford University Press 2012).

<sup>30</sup> This indeed is the approach of the forthcoming book Gian Luca Burci and Brigit Toebes, *Research Handbook on Global Health Law*, (Cheltenham, Edward Elgar 2018). For a survey of the scholarly literature on different fields of international law from a health perspective, see G.L. Burci (ed.), *Global Health Law* (Cheltenham, Edward Elgar research collection, 2016).

14. As discussed in more detail later in this report, the discourse about the role of health in international law is driven by the vision of health as an individual entitlement grounded normatively in human rights law, in particular the right to health enshrined in a number of global and regional human rights instruments.<sup>31</sup> There is consequently a strong normative and moral imperative behind much scholarly literature and policy discourses on the need to secure a better protection of health against politically and normatively stronger values. This is evident in the constant controversies pitting patents as a tool to promote pharmaceutical innovation against access to affordable essential medicines as a key component of the right to health; the report of the United Nations High-Level Panel on Access to Medicines, for example, criticizes the “power differential” between trade and investment law to enforce economic rights on the one hand, and human rights law as the normative basis to secure equitable access to medicines.<sup>32</sup> Also this point is dealt with later in this report, in particular with regard to the use of litigation as a way to enforce access to medicines. The presence of a relatively narrow core of dedicated international health instruments on the one hand, and the pervasive influence of health considerations in the design and implementation of many other international legal regimes on the other hand, result therefore in a complex overall normative landscape characterized by an extreme fragmentation. Health constitutes at times a normative limit to the implementation and enforcement of certain international rules while forming part of the object and purpose of other rules. The fragmentation is increased by the fact that many of the rules in question are managed by dedicated international institutions – e.g. WTO, the Human Rights Council, UNEP and the conferences of the parties established by environmental conventions – that use specific concepts, mechanisms and processes for their interpretation and enforcement.
15. In the light of the foregoing overview, it seems clear that global health law is not a “field” of international law comparable to other broad issue areas on which states have adopted a relatively large number of dedicated treaties with a coherent object and purpose - for example, human rights law, environmental law or international economic law. Toebes defines it as “a disjointed field with unclear boundaries consisting of hard and soft law standards”, but expresses optimism at the “clear movement toward global health law within international law”.<sup>33</sup> At the same time, global health law can be seen holistically not only from a positivist perspective as a set of international rules and standards sharing a coherent object and purpose, but also from a normative perspective as an approach to international law aiming at placing human health interests on the same plane as other recognized international interests, including security, international monetary system, international economics and trade, and international environmental regulation. Gostin defines global health law as “the study of and practice of international law – both hard law (e.g. treaties that bind states) and soft instruments (e.g. codes of practice negotiated by states) – that shapes norms, processes and institutions to attain to attain the highest attainable standard of physical and mental health for the world’s population.”<sup>34</sup> Navigating global health law therefore largely means analyzing the relations of health with international legal and policy regimes with different objects, purposes and functions, their mutual interactions (e.g. those between intellectual property rights and the right to health) and their interactions with the core of global health law (e.g. the relationship between the PIP Framework and the Convention on Biological Diversity).

## **II. Health and Human Rights - Progress toward embedding the right to health as an international human right**

### *The role of human rights in global health law*

16. One of the four tracks that the GHLC settled upon in 2015 concerned State obligations in the field of health and links with human rights law, including in the fields of noncommunicable diseases (including

<sup>31</sup> L.O. Gostin, *Global Health Law* (Cambridge, MA, Harvard University Press, 2014), pp. 243-269.

<sup>32</sup> *Report of the United Nations Secretary-General’s High-Level Panel on Access to Medicines* (2016), at <http://www.unsgaccessmeds.org/news-blogs/2016/9/13/united-nations-secretary-generals-high-level-panel-on-access-to-medicines-calls-for-new-deal-to-close-the-health-innovation-and-access-gap>

<sup>33</sup> Brigit Toebes, ‘Global health law: identifying the field’, forthcoming in Gian Luca Burci and Brigit Toebes, *Research Handbook on Global Health Law*, 2018.

<sup>34</sup> Lawrence O. Gostin, *Global Health Law* (2014), 59.

tobacco control) and also (progressively) sustainable development (e.g. obligations to assure access to clean air and water, and to address climate change).<sup>35</sup> In its 2015 report, the GHLC identified the scope of the right to health, suggesting that this framework may inspire many of the topics addressed by this Committee. Specific attention was paid in the report to the human right to essential medicines.<sup>36</sup> In the current report, we offer some reflections on the overall role of the right to health and other human rights in global health law (section II), and with regard to access to medicines, humanitarian intervention, tobacco control and environmental health specifically (sections II-V).

17. Several authors have advanced the idea that human rights play a foundational role in global health law.<sup>37</sup> By placing the dignity, health, and wellbeing of individual right-holders at the centre of the debate, human rights standards may offer protection against the powerful needs and demands of international trade and commerce including excessive patent protection and aggressive marketing of unhealthy products, as well as the devastating effects of warfare.<sup>38</sup> However, the precise role and position of human rights in global health law is still debated. There is concern that human rights law is perceived as a field that is congruent to global health law.<sup>39</sup> It is important to emphasize that human rights law is a distinct branch of international law which has a number of specific characteristics and tools that can inform global health law in important ways.<sup>40</sup>

#### *Access to medicines through litigation*

18. The right to access to essential medicines is a derivative but important component of the human right to health. Its fulfilment depends on several factors, such as the production, distribution, and pricing of medicines, on the incentives for research and development of drugs needed to treat diseases in developing countries, functioning health systems so that drugs are part of a rational system of quality treatment and care, and on infrastructure so that they can be delivered to all areas where they are needed.<sup>41</sup>

19. In spite of its crucial role as a component of the right to health, access to medicines in the global south still faces big challenges, such as the underfunding of the health sector and inadequate national commitment. In the last years many initiatives and strategies have been adopted to tackle these challenges at the international level, such as the inclusion of access to medicines in the Millennium Development Goals (MDG 8, Target 8.E), in the Sustainable Development Goals (Target 3.8), and in a recent Resolution from the United Nations Human Rights Council.<sup>42</sup> Nevertheless, data from the World Health Organization (WHO) on access to essential medicines between 2007–2014 still indicate that the median availability of selected essential medicines was only 60% and 56% in the public sector of low-income and lower-middle-income respectively.<sup>43</sup>

20. Parallel to these international strategies, the development of a rights approach in relation to the right to health at the national level enabled the advancement and legal enforcement of health rights in several low and middle-income countries. In effect, the constitutions promulgated in the late twentieth and early twenty-first centuries, particularly in the developing world, have enshrined the right to health (and, consequently, to

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<sup>35</sup> See Global Health Law Committee (GHLC), *First report of the Committee*, Johannesburg Conference 2016, 1-2.

<sup>36</sup> GHLC first report, 2 and 9-10.

<sup>37</sup> Eg. Lawrence O. Gostin, *Global Health Law*, (Harvard University Press 2014), xv, and Brigit Toebes, 'Global health law: identifying the field', forthcoming in Gian Luca Burci and Brigit Toebes, *Research Handbook on Global Health Law*, 2018.

<sup>38</sup> Toebes, 2018.

<sup>39</sup> As also expressed by John Tobin and Thérèse Murhpy in the forthcoming *Research Handbook on Global Health Law*, 2018.

<sup>40</sup> Toebes, 2018.

<sup>41</sup> S. P. Marks, "Access to Essential Medicines as a Component of the Right to Health" (2009), in A. Clapham and M. Robinson (eds.), *Realizing the Right to Health*, Zurich, Switzerland: Rüfer & Rub, the Swiss Human Rights Book Series, pp. 82-101.

<sup>42</sup> United Nations Human Rights Council Resolution A/HRC/35/RES/25/23 (23 June, 2017) <https://documents-dds-ny.un.org/doc/UNDOC/GEN/G17/190/18/PDF/G1719018.pdf?OpenElement>

<sup>43</sup> WHO, *World Health Statistics 2017: monitoring health for the SDGs, Sustainable Development Goals* (Geneva: World Health Organization; 2017), p. 11. Available at <http://apps.who.int/iris/bitstream/10665/255336/1/9789241565486-eng.pdf?ua=1>

healthcare) as a fundamental right.<sup>44</sup> They are considered transformative constitutions in that the protection of such a right expresses a commitment to overcoming a past of poverty and social inequities.<sup>45</sup>

21. These Constitutions have settled the legal framework for the development of healthcare rights litigation in some low and middle-income countries in Latin America. Despite the different models for enforcing healthcare rights, the most prevalent form of enforcement in some Latin American countries has been the individual model, especially when it comes to access to medicines claims.<sup>46</sup> This model of litigation consists of lawsuits brought by individual plaintiffs represented by private or public attorneys against public authorities claiming the provision of a specific medication or treatment.<sup>47</sup> The effects of these decisions apply *inter partes*. This is in effect the case of the Brazil.

22. This model requires a low threshold to accessing courts insofar as the individual litigant must simply prove that a health need (access to medication or treatment), as described in a doctor's prescription, was not met. Brazil, for instance, is a paradigmatic case where this model of litigation is prevalent. In this country, the doctor's prescription (from a state or private health facility) is the only relevant document necessary for a court to render a decision imposing on the state the obligation to provide a particular medication or treatment to a particular individual.<sup>48</sup>

23. The use of individual litigation to enforce social rights has been heavily criticized for rendering public health systems less fair, since it does not do much for the poorest individuals; a minority of upper- and middle-class people who have access to lawyers, courts, and very often, to private health insurance, benefit the most from it.<sup>49</sup> Therefore, this judicialization could widen the social gap, diverting public resources from the most deprived individuals and from other important areas of the healthcare field. However, the premise of the use of individual litigation by elites has been contested by scholars who argue that "judicialization may serve as a grassroots instrument for the poor to hold the state accountable."<sup>50</sup>

24. Despite these contrasting views over the individual model of litigation, there is already some evidence that in Brazil this model has contributed to advancing health technology assessment (HTA) and healthcare governance in the country.<sup>51</sup> This is in effect quite relevant in the context of low and middle-income countries where the institutionalization of HTA is still considered immature.<sup>52</sup> The establishment of a more transparent, participatory and accountable decision-making process regarding HTA may contribute to the advancement of fairness in the health system, as health technology assessment is considered an important tool in this regard: it not only sets more transparent rules and procedures for allocating health resources but also promotes fairness by making drugs available to the population at large and not only to individual claimants.

#### *Human rights, humanitarian assistance and epidemics*

25. By increasing the volume and speed of exchanges of people and goods, globalization has increased the interdependence of states towards pathogens. But globalization also allowed for an increase in the volume and

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<sup>44</sup> M. Tushnet, *Weak Courts, Strong Rights: Judicial Review and Social Welfare Rights in Comparative Constitutional Law* (Princeton, NJ: Princeton University Press, 2008).

<sup>45</sup> C. R. Sustain, *Designing Democracy: What Constitutions Do?* (Oxford; New York: Oxford University Press, 2001).

<sup>46</sup> D. W. L. Wang, *Courts as Healthcare Policy-Makers: The Problem, The Responses to the Problem and Problems in the Responses*, Direito GV Research Paper 75 Direito GV Research Paper Series – Legal Studies (São Paulo: Direito GV, 2013). Available at

[http://bibliotecadigital.fgv.br/dspace/bitstream/handle/10438/11198/RPS\\_75\\_final.pdf?sequence=1&isAllowed=y](http://bibliotecadigital.fgv.br/dspace/bitstream/handle/10438/11198/RPS_75_final.pdf?sequence=1&isAllowed=y).

<sup>47</sup> L. Reveiz; E. Chapman, R. Torres *et al.* "Right-to-health litigation in three Latin American countries: a systematic literature review", *Revista Panamericana de Salud Publica* 33/3 (2013), pp. 213-222.

<sup>48</sup> O. M. Ferraz, "The Right to Health in the Courts of Brazil: Worsening Health Inequities?" *Health and Human Rights Journal* 11/2 (2009), pp.33-45.

<sup>49</sup> O. M. Ferraz, "Harming the Poor through Social Rights Litigation", *Texas Law Review* 89 (2011), pp. 1643-1668.

<sup>50</sup> J. Biehl, M. P. Sochal and J. J. Amon, "The Judicialization of Health and the Quest for State Accountability: Evidence from 1,262 Lawsuits for Access to Medicines in Southern Brazil" *Health Hum Rights* 18/1 (2016), pp. 209-220.

<sup>51</sup> D. C. L. Borges, "Individual healthcare litigation in Brazil through a different lens: strengthening health technology assessment and new models of healthcare governance", *Health and Human Rights Journal*, Forthcoming.

<sup>52</sup> R. Kuchenbecker and C. A. Polanczyk, "Institutionalizing Health Technology Assessment in Brazil: Challenges Ahead," *Value in Health Regional Issues* 1 (2012), pp. 257-261.



speed of information and expertise on infectious diseases. This knowledge is shared through many efficient networks such as the Global outbreak alert and response network (GOARN), the Global influenza surveillance and response system (GISRS), the new born Emerging diseases clinical assessment and response network (EDCARN) or the network for the epidemiological surveillance of the European Union. All these networks are international structures serving the world community and global health. Although states have not yet fully implemented the 2005 International Health Regulations (IHR) yet, the international community as a whole has the tools and human resources to be promptly informed of an infectious disease event and to evaluate it.

26. Yet, as the 2014-2016 Ebola epidemic in West Africa showed, people die on a large scale of sudden outbreaks because of a lack of assistance. This reveals a persistent discrepancy between the means that are conceived and employed to address interdependence among states, and the means that are implemented to provide assistance to people. This Ebola outbreak was so devastating that it not only challenged the right to health and the right to life. It jeopardized human dignity and the enjoyment of certain human rights such as the right to education or the right to private and family life<sup>53</sup>. Thus, prompt assistance to the victims of an epidemic is important from a human rights perspective.

27. In its 2003 resolution on “Humanitarian assistance”,<sup>54</sup> the Institute of International Law (IIL) (*Institut de droit international*) considers that the principles outlined in this resolution apply to epidemics. In particular, in the name of the protection of fundamental rights, victims of epidemics would have a right to humanitarian assistance<sup>55</sup> and there would exist a correlative duty of states other than the affected one to offer humanitarian assistance to the victims.<sup>56</sup> On such a basis, it has been argued that, during the Ebola outbreak, states that were in a position to undertake international assistance did not or only partially fulfilled their obligation.<sup>57</sup> However, this alleged “right to assistance” and the correlative “duty to offer assistance” are not mentioned in the General Assembly resolutions on humanitarian assistance<sup>58</sup>. This absence suggests that states are not ready to recognize these two IIL proposals as customary international norms.

28. More realistically, it is widely recognized that the assistance to victims of an epidemic falls primarily within the responsibility of the affected state.<sup>59</sup> Interdependence and the concept of global health do not abolish basic principles of the world order and international law. When the affected state is unable to provide sufficient assistance to the population placed under its jurisdiction, other states cannot provide assistance without its consent.<sup>60</sup> Thus, the appeal for assistance by the affected state is of utmost importance. During the Ebola epidemic, the mainly affected states only openly sought assistance through a letter dated 29 August 2014 addressed to the Secretary-General by the Presidents of Liberia, Sierra Leone and Guinea.<sup>61</sup> By 29 August, the total number of probable, confirmed or suspect cases was already 3052, with 1546 deaths.<sup>62</sup> This formal demand undeniably had a positive impact. On 17 September, the Secretary-General transmitted the 29 August letter to the Security Council and expressed his intention to establish the United Nations Mission for Ebola Emergency Response (UNMEER). The following day, the Security Council adopted resolution S/RES/2177 (2014). Together with General Assembly resolution A/RES/69/1 adopted on 19 September, this resolution was the starting point of mass-funding, bilateral assistance and a coordinated international response through UNMEER. In this perspective, the formalized call for

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<sup>53</sup> High-Level Panel on the Global Response to Health Crises, “Protecting humanity from future health crises”, A/70/723, 9 February 2016, p. 63, para. 161.

<sup>54</sup> IIL, Resolution on “Humanitarian assistance”, Bruges session, 2003, Article I(2).

<sup>55</sup> Article II of the resolution.

<sup>56</sup> Article V of the resolution.

<sup>57</sup> Physicians for Human Rights, *International Cooperation and Assistance in the Context of the Ebola Outbreak in West Africa*, 2014, p. 2.

<sup>58</sup> For instance, see A/RES/43/131, A/RES/45/100, A/RES/46/182, A/RES/71/127 and A/RES/72/133.

<sup>59</sup> IIL, Resolution on “Humanitarian assistance”, Bruges session, 2003, confirmed by A/RES/43/131, A/RES/45/100, A/RES/46/182 (guiding principle 4), A/RES/68/103.

<sup>60</sup> IIL, Resolution on “Humanitarian assistance”, Bruges session, 2003, Article IV(2), confirmed by A/RES/46/182 (guiding principle 3).

<sup>61</sup> Letter dated 29 August 2014 from Ernest Bai Koroma, President of the Republic of Sierra Leone, Ellen Johnson Sirleaf, President of the Republic of Liberia, and Alpha Condé, President of the Republic of Guinea, annexed to a letter dated 15 September 2014 from the Secretary-General addressed to the President of the Security Council, S/2014/669.

<sup>62</sup> WHO, “Ebola Response Roadmap Situation Report 1”, 29 August 2014.

assistance by Guinea, Sierra Leone and Liberia was late, not to mention that these states were reluctant to notify the first cases, for fear of being penalized economically.<sup>63</sup>

29. Considering that humanitarian assistance should be provided with the consent of the affected country and in principle on the basis of an appeal by the latter,<sup>64</sup> and considering the positive effects of the August 29 formal call for assistance on the international response, states should not delay in asking for assistance when they cannot handle an epidemic. WHO should not hesitate to suggest to that state that it should ask for assistance. Consistent with Article 12(1) of the International Health Regulations (2005), the Director General of the WHO declared the Ebola outbreak was a public health emergency of international concern on 8 August, three weeks before the three presidents formally requested assistance through the UN Secretary-General. None of the recommendations adopted by the WHO Director General dealt with humanitarian assistance. This approach seems consistent with Article 15(2) of the IHR (2005), which rather calls for more “technical” recommendations.<sup>65</sup> However, considering Article 2(d) of its constitutive Charter, whereby “the functions of the Organization shall be (...) to furnish (...), in emergencies, necessary aid upon the request or acceptance of Governments”, part of this aid should consist of raising awareness of the affected states on their need of humanitarian assistance.

30. Additionally, it must be underlined that international assistance regarding epidemics cannot be limited to emergency assistance. Long-term action, whose goal is to ensure development, must be a priority.<sup>66</sup> This is supported by numerous legal or political instruments. First of all, this approach is consistent with the view of the General Assembly that “emerging assistance should be provided in ways that will be supportive of recovery and long-term development”.<sup>67</sup> Secondly, the Committee on Economic, Social and Cultural Rights considers that international cooperation for development and thus for the realization of the rights guaranteed by the Covenant (these include the right to health) is an obligation incumbent upon all states.<sup>68</sup> Thirdly, the inclusion of epidemics and pandemics in the Sendai Framework on Disaster Risk Reduction for 2015-2030<sup>69</sup> and in the Sustainable Development Goals (SDGs) for 2030 (Target 3.3) requires placing public health and crisis prevention among the priorities of development cooperation programs. Lastly, the “New Way of Working” developed in 2016 aims to overcome the cleavage between humanitarian action and development, so that a health crisis such as an epidemic is not isolated from its causes. This new way of working aims to respond to immediate humanitarian needs while reducing risks and vulnerability over several years to end the need for humanitarian assistance. The UN Secretary-General and the leaders of several organizations involved in humanitarian aid and development accepted this new approach by signing “Commitments to Action” at the first World Summit on Humanitarian Action held in May 2016.<sup>70</sup> It will be implemented as part of the work of the Inter-Agency Standing Committee whose aim is to coordinate humanitarian assistance among UN and non-UN partners.<sup>71</sup> WHO, as a signatory of these commitments, refers to this approach in the new edition of its *Emergency Response Framework*.<sup>72</sup>

### III. Health and Tobacco Control

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<sup>63</sup> High-Level Panel on the Global Response to Health Crises, “Protecting humanity from future health crises”, A/70/723, 9 February 2016, p. 33, para. 46.

<sup>64</sup> A/RES/46/182 (guiding principle 3).

<sup>65</sup> Article 15(2) of the IHR (2005) states: “Temporary recommendations may include health measures to be implemented by the State Party experiencing the public health emergency of international concern, or by other States Parties, regarding persons, baggage, cargo, containers, conveyances, goods and/or postal parcels to prevent or reduce the international spread of disease and avoid unnecessary interference with international traffic.”

<sup>66</sup> Supporting this view, see Independent Panel of Experts on the Cholera Outbreak in Haiti, *Final Report*, p. 29; High Level Panel on the Global Response to Health Crises, “Protecting Humanity from Future Health Crises”, A/70/723, 9 February 2016, para. 176; Report of the WHO Director-General, A/70/9, Annex 2, para. 3.

<sup>67</sup> A/RES/46/182 (guiding principle 9).

<sup>68</sup> Committee on Economic, Social and Cultural Rights, *General Comment No. 3: The nature of States Parties’ Obligations (Art. 2, Para. 1, of the Covenant)*, 1990, para. 14.

<sup>69</sup> Sendai Framework on Disaster Risk Reduction for 2015-2030, para. 6 and 28.

<sup>70</sup> See the report of the Secretary-General of the United Nations, A/71/353, para. 33 et seq. For a critique of this new approach, which led Doctors without Borders (MSF) to withdraw from the World Summit on Humanitarian Action, see MSF, “MSF to pull out of the World Humanitarian Summit”, 5 May 2016, <<http://www.msf.org/en/article/msf-pull-out-world-humanitarian-summit>>.

<sup>71</sup> IASC, *Background Note for the IASC Principals, Update on the “New Way of Working”*, 6 December 2016, 2 p.

<sup>72</sup> WHO, *Emergency Response Framework*, 2<sup>nd</sup> ed., 2017, pp. 12-13.

### *Recent developments in tobacco control and the interface with human rights*

22. Tobacco control regulation cuts across international, regional and domestic law. At the international level, the 2003 WHO Framework Convention on Tobacco Control (FCTC) is a key instrument, not only because it regulates tobacco consumption and exposure to second hand smoke (SHS) as a crucial public health concern, but also because it is the only treaty ('framework convention') thus far adopted by the WHO. As the first treaty adopted by WHO, it generates a 'wealth of knowledge, experience, expertise, practice and jurisprudence' that will have 'profound significance far beyond tobacco and tobacco control for years to come'.<sup>73</sup> Its success is also evidenced by an increasing worldwide incorporation of its provisions into domestic legislation.<sup>74</sup>

23. Several studies have addressed the interaction between human rights law and tobacco control.<sup>75</sup> The Preamble to the FCTC provides a basis for this interaction with its reference to the right to health in Article 12 ICESCR. While the human rights standards are open-ended and do not mention tobacco explicitly, their focus on the protection of the individual and his or her vulnerability, in particular children, provides an important additional framework and reference point. The best-interest norm, in an interaction with the right to health and healthy development of the child, holds clear obligations for governments to protect children against environmental tobacco smoke (ETS) and harmful marketing, and to regulate the tobacco industry.<sup>76</sup>

### *Soft law instruments concerning Tobacco-Free Initiative*

24. Soft law plays a vital role in tobacco control regulation, and this is clearly exemplified by the Tobacco Free Olympics. There are several non-binding instruments in addition to the FCTC and its guidelines that require host governments to make best efforts towards Tobacco Free Olympics, including the WHO-IOC Memorandum of Understanding to improve healthy lifestyles (including Tobacco Free Olympics)<sup>77</sup> and WHO's 'A Guide to Tobacco-Free Mega Events'.<sup>78</sup> These documents may strengthen or substantiate the obligations under the FCTC. For instance, the 'Guide' states "[t]he policy should refer to the WHO FCTC and any smoke-free law and ban on tobacco advertising, promotion and sponsorship, as well as any law banning sales to minors. (Such laws should be considered by the host government if not in force. Parent organizations should favour selection of hosts of these policies)".<sup>79</sup> As such, these Tobacco Free Olympics instruments are clearly based on the FCTC guidelines. For instance, the 'Guide' states that "WHO FCTC Article 8, 12, 13 and 16, and the guidelines to Article 8 and 13, have application to these recommendations" for tobacco free environments. Thus the FCTC guidelines and the Tobacco Free Olympics instruments are working together and complementing each other.

25. Such soft law instruments are unique in two respects. First, these instruments involve not only governments but also host cities, event organizers and venue managers. They are required to set up their tobacco-free policy and carry it out. Second, these instruments are highly effective for host states. Since 2008, all the host states or cities enacted strict regulations of banning SHS.<sup>80</sup> These international events set an important international example of how soft law functions in this field. For the Tokyo 2020 Olympic Games, the Japanese government is now making a more serious effort to strengthen its tobacco regulations than at the time of its

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<sup>73</sup> Contribution by Liberman in Burci and Toebe, 2018, section 7.

<sup>74</sup> Monique E. Mugli et al, Tracking the relevance of the WHO Framework Convention on Tobacco Control in legislation and litigation through the online resource, Tobacco Control Laws, *Tobacco Control*, Volume 23, Issue 5.

<sup>75</sup> Carolyn Dresler & Stephen Marks, *The Emerging Human Right to Tobacco Control*, 28 HUMAN RIGHTS QUARTERLY 599 (2006); Brigit Toebe, Marie Elske Gispén, Jasper Been and Sheikh Aziz, A missing voice: The rights of children to a tobacco-free environment, *Tobacco Control*, 2017, 27(1), 3-5.

<sup>76</sup> Marie Elske Gispén and Brigit Toebe, The Human Rights of Children in Tobacco Control, forthcoming in *Human Rights Quarterly* in 2019.

<sup>77</sup> WHO-IOC Memorandum of Understanding, [http://www.who.int/mediacentre/news/releases/2010/ioc\\_20100721/en/](http://www.who.int/mediacentre/news/releases/2010/ioc_20100721/en/)

<sup>78</sup> Guide to Tobacco-Free Mega Events, [http://www.wpro.who.int/publications/PUB\\_9789290614982/en/](http://www.wpro.who.int/publications/PUB_9789290614982/en/)

<sup>79</sup> *Ibid.*, p. 3.

<sup>80</sup> Slides of Dr Douglas Bettcher (Director, Prevention of Noncommunicable Diseases, WHO), Olympic Games in a City with No Passive Smoking - Leadership Caring for People, <http://smokefree-giren.net/wp/wp-content/uploads/2015/03/en.pdf>.

ratification of the FCTC. The government has explained to lawmakers that other countries hosting the Olympics had actually achieved strict regulations.

*Normative tension arising from the clash between tobacco control and freedom of trade and investment*

26. Investment arbitral cases have arisen from the implementing regulatory measures taken by certain Contracting Parties of the FCTC. Two of these disputes have been brought before investment treaty-based arbitration tribunals, specifically one against Australia, because of its 2011 ‘Plain Packaging’ law, before a UNCITRAL arbitral tribunal,<sup>81</sup> and one against Uruguay, because of its Law No. 18.256 on tobacco labelling,<sup>82</sup> before an ICSID arbitral tribunal.<sup>83</sup> In both cases the respondent States had enacted the challenged domestic tobacco control regulatory measures when the claimants had already made their investments. In both cases the claimants belonging to the Philip Morris corporate group were not successful.

27. The arbitral tribunal established by the Permanent Court of Arbitration on request of Philip Morris Asia Ltd. against Australia, in accordance with the Arbitration Rules of the UN Commission on International Trade Law (UNCITRAL), did not deal with the legitimacy, under the applicable international investment treaty, of the 2011 Australia’s plain packaging legislation. The Tribunal declined its jurisdiction in applying the standard that “the commencement of treaty- based investor-State arbitration constitutes an abuse of right (or abuse of process) when an investor has changed its corporate structure to gain the protection of an investment treaty at a point in time where a dispute was foreseeable.”<sup>84</sup>

28. The tribunal of the *Philip Morris Brands Sarl, Philip Morris Products S.A. and Abal Hermanos S.A. v. Uruguay* case decided that the domestic anti-tobacco legislation was not “arbitrary and unnecessary” but rather [...] potentially “effective means to protecting public health,” [...], in accordance with statements by the World Health Organization and by the Pan American Health Organization (PAHO), and was “a valid exercise by Uruguay of its police powers for the protection of public health”.<sup>85</sup> The Concurring and Dissident Opinion by Arbitrator Gary Born “makes clear that Uruguay possesses broad and unquestioned sovereign powers to protect the health of its population, both in the context of tobacco regulation and otherwise” and that “[n]othing in the BIT prevents Uruguay from exercising these powers”.<sup>86</sup>

29. The reference by the arbitral tribunal to the host State’s ‘police powers’ for the protection of public interests may be an important ‘turning point’ in the alleged pro-investor approach of investment arbitral tribunals. However, such references have not been consistent so far. A relevant general trend has not been detected.<sup>87</sup>

30. In June 2018, a WTO dispute settlement Panel issued a Report on the complaints filed with respect to Australia’s Tobacco Plain Packaging (TPP) legislation by Cuba, the Dominican Republic, Honduras and Indonesia.<sup>88</sup> The Panel rejected all claims of WTO inconsistency in an 880+ page decision. There were two main

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<sup>81</sup> See *Philip Morris Asia Ltd. v. Australia*, PCA Case No. 2012-12, UNCITRAL Award on Jurisdiction and Admissibility, 17 December 2015.

<sup>82</sup> Enacted on 6 March 2008 and entered into force on 1 March 2010.

<sup>83</sup> See *Philip Morris Brands SARL, Philip Morris Product S.A. and Abal Hermanos S.A. v. Uruguay*, ICSID Case No. ARB/10/7, Award, 8 July 2016.

<sup>84</sup> See the UNCITRAL Award on Jurisdiction and Admissibility, (quoted at footnote 9), Para. 389. As to the position of the claimant, see particularly Paras. 265-266, 281 ff.

<sup>85</sup> See the Award quoted at footnote 28, Paras. 306-307.

<sup>86</sup> See the Concurring and Dissident Opinion by Arbitrator Gary Born, 28 June 2016, especially Paras. 90 and 197.

<sup>87</sup> See, in particular, Boute, “The Potential Contribution of International Investment Protection Law to Combat Climate Change”, 27 *Journal of Energy & Natural Resources Law*, 2009, p. 333 ff., especially p. 352 ff.; Ranjan, Anand, “Determination of Indirect Expropriation and Doctrine of Police Power in International Investment Law: A Critical Appraisal”, in Choukroune (ed.), *Judging the State in International Trade and Investment Law: Sovereignty*, Springer International Publishing AG, Heidelberg, 2016, p. 127 ff., and; P. Acconci, “The Integration of Non-investment Concerns as an Opportunity for the Modernization of International Investment Law: Is a Multilateral Approach Desirable?”, in *General Interests of Host States in International Investment Law* edited by Sacerdoti, co-edited by Acconci, Valenti, De Luca, Cambridge University Press, 2014, especially 185-189.

<sup>88</sup> Australia – Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging, Reports of the Panels, WT/DS435/R, WT/DS441/R, WT/DS458/R, WT/DS467/R, 28 June 2018.

sets of claims, those under the Agreement on Technical Barriers to Trade (TBT Agreement), and those under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). For the Sydney Biennial the Committee organized an expert panel to assess the Panel Report. This was a timely and “geographically appropriate” occasion given Australia’s central role in the dispute. The panel included several individuals who directly participated in the dispute settlement process, both from a legal and scientific angle.<sup>89</sup> The WTO Panel reached the right operative result. This was to be expected in light of the weakness of the complaining parties’ position -- which weakness was manifest already from the outset of the case back in 2012. One question discussed by the panelists was whether the tobacco producers enjoyed some success by virtue of the 6-year time span for issuance of the panel report, exceeding WTO procedural rules by five years (though somewhat less by customary practice), thereby potentially delaying adoption of similar TPP legislation by other countries. Opinions were mixed on that, with some expressing the view that after about two years countries contemplating new legislation had stopped worrying about the WTO. Others thought that there were concrete examples of government delays awaiting the outcome. The case illustrated the complex science surrounding smoking cessation, and the importance of a multipronged approach to reducing tobacco use. It demonstrated that the TBT Agreement is not a “model of clarity”, particularly regarding some rules surrounding burden of proof, and the disputing parties spent considerable time debating which WTO Member had the burden, and what were the potential consequences of burden shifting. Considerable attention was paid to the WTO Panel determination that the WHO Framework Convention on Tobacco Control did not constitute a “relevant international standard” for purposes of establishing a rebuttable presumption that Australia’s legislation did not constitute an unnecessary obstacle to trade, and whether that determination raised questions regarding WTO’s approach to public health matters. On the TRIPS Agreement, the “main” question was whether Australia’s TPP legislation “unjustifiably” encumbered the rights of trademark owners under Article 20. Again, the WTO Panel reached the operative right (i.e. “no”) result, but there was some discussion in Sydney about the multi-part analytic framework employed. Interestingly, the complaining countries generally conceded that the TRIPS Agreement does not establish a “right to use” trademarks yet sought in various ways to infer positive from otherwise negative rights. The WTO Panel rejected those efforts. An appeal of the Panel Report was initiated by the time of the Sydney Biennial (Honduras, more recently followed by Dominican Republic), and Prof. Voon discussed the issues raised in the Honduras appeal filing. A number of insightful interventions were made from the floor as part of the follow-on Q & A.

#### **IV. Health and the Environment**

##### *Introduction*

31. The report issued by the WHO in 2016 on *Preventing Disease through Healthy Environments: A Global Assessment of the Burden of Disease from Environmental Risks*<sup>90</sup> states that 23% of global deaths (26% of deaths among children under age 5), an estimated 12.6 million every year, are due to preventable environmental risks factors such as air, water and soil pollution, chemical exposures, climate change, and ultraviolet radiation which contribute to more than 100 diseases and injuries. Stroke, heart disease, unintentional injuries, cancers and chronic respiratory infections are the top five causes of environmental-related deaths. Children under 5 and older adults between 50 and 75 are most affected by the detrimental effects of environmental degradation, while low- and middle-income countries bear the greatest share of environmental disease. Environmental health interventions can make a valuable and sustainable contribution towards reducing the global disease burden, improving the well-being of people worldwide and achieving all Sustainable Development Goals. In this respect, intersections and synergies between international environmental law and global health law should be thoroughly examined and fostered.

*The international law dimension: interaction between international environmental law and global health law*

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<sup>89</sup> The Sydney panel was comprised of Jonathan Liberman (McCabe Centre for Law and Cancer, Australia), Edward Kwakwa (World Intellectual Property Organisation, Switzerland), Natasha Spisbah (Department of Foreign Affairs and Trade, Australia), Prof. Brigit Toebe (University of Groningen, Netherlands) and Prof. Tania Voon (University of Melbourne, Australia). Prof. Abbott chaired this expert panel session.

<sup>90</sup> WHO, Annette Prüss-Ustün and others, *Preventing Disease through Healthy Environments: A Global Assessment of the Burden of Disease from Environmental Risks* (2016).

32. The importance of safeguarding human health in the context of environmental protection is evidenced by several agreements of international environmental law, whose stated aim is the protection of both public health and the environment. These include the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes,<sup>91</sup> the Rotterdam Convention on Hazardous Chemicals and Pesticides,<sup>92</sup> the Stockholm Convention on Persistent Organic Pollutants,<sup>93</sup> and the Minamata Convention on Mercury.<sup>94</sup> These treaties establish an international regime for the control of cross-border movements and international trade in toxic and bioaccumulative products and substances, creating an integrated system of protection of human health from the damages caused by exposure to such harmful agents.

33. Air pollution is another major threat to public health owing to the severe respiratory (lung diseases and cancer) and cardiovascular diseases caused by air pollutants (both outdoor and indoor). The impact of air pollution on human health is currently at the top of the WHO agenda and will be discussed in the first world conference on air pollution, climate change and human health, organized by the WHO in collaboration with the United Nations Environmental Programme (UNEP), the World Meteorological Organization and the Secretariat of the Framework Convention on Climate Change.<sup>95</sup> In this field, there are several important treaties combating air pollution and protecting health, first and foremost the Convention on Long-Range Transboundary Air Pollution and its eight protocols, negotiated by the United Nations Economic Commission for Europe.<sup>96</sup> These treaties aim to improve air quality on the local, national and regional levels, gradually reducing and preventing air pollution through the identification of specific measures to cut emissions of air pollutants.

34. With regard to climate change, it is imperative to mention the 2015 Paris Agreement, whose preamble emphasizes for the first time the relationship between climate change and the right to health.<sup>97</sup> However, the impact of climate change on human health is currently the object of scientific investigation in order to clarify its possible negative effects, also in terms of increased spread of new pathogens that lead to the multiplication of infectious diseases.<sup>98</sup>

35. In the field of water pollution and waterborne diseases, the UNECE Protocol on Water and Health is of special significance.<sup>99</sup> The Protocol deals with the management of water resources and access to drinking water and its aim is to protect human health, prevent the spread of infectious diseases and diseases associated with water through better management of water resources and the protection of aquatic ecosystems. The Protocol is the first international agreement specifically adopted to reach a suitable supply of safe drinking water and adequate sanitation for all. The implementation of the Protocol requires close inter-sectoral collaboration based on an integrated approach and the alignment of policies and strategies in various sectors, ranging from health protection to environmental management, regional development, investment, infrastructure and education.

36. Moreover, in the field of biodiversity protection, one specifically relevant agreement is the Nagoya Protocol on Access to Genetic Resources.<sup>100</sup> The Protocol provides regulatory instruments to promote an effective and equitable international access to pathogens and the sharing of related benefits (including through the

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<sup>91</sup> Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, Basel, 22 March 1989, in force as of 5 May 1992, ratified by 186 States.

<sup>92</sup> Rotterdam Convention on Hazardous Chemicals and Pesticides (PIC Convention), Rotterdam, 10 September 1998, in force as of 24 February 2004, ratified by 160 States.

<sup>93</sup> Stockholm Convention on Persistent Organic Pollutants (POP Convention), Stockholm 22 May 2001, in force as of 17 May 2004, ratified by 182 States.

<sup>94</sup> Minamata Convention on Mercury, Geneva, 19 January 2013, in force as of 16 August 2017, ratified by 89 States.

<sup>95</sup> WHO News Release, [www.who.int/airpollution/events/conference/en/](http://www.who.int/airpollution/events/conference/en/).

<sup>96</sup> Convention on Long-Range Transboundary Air Pollution, Geneva, 13 November 1979, in force as of 16 March 1983, ratified by 51 States. See at [www.unece.org/env/lrtap/welcome.html](http://www.unece.org/env/lrtap/welcome.html).

<sup>97</sup> Paris Agreement, adopted by the UNFCCC Conference of the Parties (COP21) on 12 December 2015, in force as of 4 November 2016, ratified by 174 States.

<sup>98</sup> See at [www.who.int/globalchange/en/](http://www.who.int/globalchange/en/) (last accessed 15 April 2018).

<sup>99</sup> UNECE Protocol on Water and Health, London, 17 June 1999, in force as of 4 August 2005, ratified by 26 States.

<sup>100</sup> Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, Nagoya, 29 October 2010, in force as of 12 October 2014, ratified by 104 States.

development of specific international instruments), the assessment of the existence of emergencies that threaten human health and the promotion of international collaboration. In a recent study by the WHO Secretariat, the implications of the application of the Protocol for the sharing of influenza and non-influenza pathogens are explored, and it is concluded that the Protocol can play an important role, also in support of *Pandemic Influenza Preparedness Framework* and the *Global Influenza Surveillance and Response System*.<sup>101</sup>

37. Although the treaties mentioned so far represent major examples of IEL conventions setting the protection of public health as one of their main objectives, the number of relevant legal instruments (both soft and hard) is much broader and there is a strong need for a comprehensive review and coherent framework. The Committee on Global Health Law could engage in this systematic review and analysis, and also better explore the possible interactions between international environmental law and global health law (for example, between the Protocol on Water and Health and the International Health Regulations,<sup>102</sup> or the Nagoya Protocol and the Pandemic Influenza Pandemic Framework).

#### *The role of the WHO in environmental health*

38. The WHO has over time become an important global player in the field of environmental health and safety. Article 2(i) of the WHO Constitution confers on the Organization the function ‘to promote, in co-operation with other specialized agencies where necessary, the improvement of nutrition, housing, sanitation, recreation, economic or working conditions and *other aspects of environmental hygiene*’.<sup>103</sup> This provision contains the only reference *lato sensu* to the environment to be found in the constitutional text of the Organization and represents the legal basis for the remarkable work accomplished by the WHO in environmentally related matters impacting on public health.

39. Environmental hygiene is broadly understood as encompassing all measures undertaken to keep the human environment safe and healthy to live in, including waste disposal, clean water supplies, food safety controls, and good housing. The commitment of the Organization to environmental health has progressively gained momentum, in line with the ever-increasing evidence of the interconnections between the environment and human health and a growing concern for the threats posed by environmental hazards to human life.

40. The WHO’s activities in this field are led by the *Department of Public Health, Environmental and Social Determinants of Health* and cover a broad range of topical issues, including climate change, water quality and safety and sanitation, outdoor and indoor air pollution, chemical safety, ionizing and ultraviolet radiations, electromagnetic fields. The role of the Department is to promote a healthier environment, intensify primary prevention, and influence decision-makers and public policies in all sectors by assessing and managing risks, formulating evidence-based norms and guidance on major environmental and social hazards to health, creating guidance, tools, and initiatives to facilitate the development and implementation of policies that promote human health in priority sectors.

41. Noteworthy is the Health and Environment Linkages Initiative, a joint WHO-UNEP initiative which aims at providing policy-makers, especially in developing countries, with a number of resources and tools that can help them in shaping environmentally friendly policies especially with regard to given areas of priority risks.<sup>104</sup> On 10 January 2018, both the WHO and UN Environment signed an agreement to foster cooperation and joint actions aimed at combating environmental health risks posed by air pollution, climate change, antimicrobial resistance, waste and chemicals management, water quality, and food and nutrition issues. This agreement has been

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<sup>101</sup>WHO, Implementation of the Nagoya Protocol and Pathogen Sharing: Public Health Implications, Study by the Secretariat, 18 November 2016, available at [www.who.int/influenza/pip/2016-review/NagoyaStudyAdvanceCopy\\_full.pdf](http://www.who.int/influenza/pip/2016-review/NagoyaStudyAdvanceCopy_full.pdf); see also Review of the Pandemic Influenza Preparedness Framework, Report by the Director-General, EB140/16, 29 December 2016, Annex: Report of the 2016 PIP Framework Review Group.

<sup>102</sup> See, for example, Negri, *Waterborne Disease Surveillance: The Case for a Closer Interaction Between the UNECE Protocol on Water and Health and the International Health Regulations 2005*, in *International Community Law Review*, 2010, pp. 287-302.

<sup>103</sup> Emphasis added.

<sup>104</sup> See [www.who.int/heli/en/](http://www.who.int/heli/en/) (last accessed 15 April 2018).

welcomed as ‘the most significant formal agreement on joint action across the spectrum of environment and health issues in over 15 years’.<sup>105</sup>

42. All this notwithstanding, the WHO’s action in environmental health seems to lack coherence and is scattered in diverse areas of the Organization’s activity, also appearing somewhat incidental to other overarching health goals. For these reasons the WHO’s contribution in this field risks being underestimated or even going unnoticed. Taking water quality as an example, it has to be stressed that the WHO is committed to improving environmental health and preventing public health hazards in a number of ocean-related matters. It has in fact contributed to setting goals for overall marine ecosystem health and environmental quality standards in the following areas: standards and guidelines on water quality, especially referred to coastal waters; standards and codes on seafood safety; prevention and control of foodborne and waterborne diseases; and ship sanitation.<sup>106</sup> However, WHO action in this field lacks a systematic approach and is also almost invisible to the general public. In fact, the WHO website offers no clear and direct link to the Organization’s work in the field of ‘ocean health’ and all relevant information are retrievable only after a well-targeted and patient research throughout the other areas of intervention which are more or less strictly related to it. In this respect, a report commissioned by the IMO has recently surveyed the role of the WHO in global ocean governance and has shown that there still seems to be potential to improve and strengthen such a role and also to make it better known and accessible to the general public.<sup>107</sup>

43. As is the case with ocean health, there is a strong need for systematisation and dissemination of the WHO’s contribution in the field of environmental health in most of its sectors of intervention. The Committee on Global Health Law could engage in surveying the wealth of guidelines and standards and provide a systematic framework to this important, though sometimes neglected, section of global health law. The Committee could also write a report for the WHO and offer the *Department of Public Health, Environmental and Social Determinants of Health* some proposals to improve the visibility and impact of the Organization’s work.

#### *The links between the environment and human rights*

44. There is an increasing consensus that human rights and environmental protection are closely intertwined.<sup>108</sup> It has been asserted that proper and full enjoyment of existing (substantive) human rights – such as the right to life, private life, health, food, water and proper sanitation, housing, work and development – cannot take place without taking into account adequate protection of the environment. Likewise, particular (often procedural) human rights, including access to information, freedom of expression (public participation in

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<sup>105</sup> See *UN Environment and WHO agree to major collaboration on environmental health risks*, WHO News Release, 10 January 2018, available at [www.who.int/mediacentre/news/releases/2018/environmental-health-collaboration/en/](http://www.who.int/mediacentre/news/releases/2018/environmental-health-collaboration/en/) (last accessed 15 April 2018).

<sup>106</sup> See, e.g., WHO, ‘Guidelines for Safe Recreational Water Environments. Volume 1: Coastal and Fresh Waters’ (2003); WHO, ‘Guidelines for Safe Recreational Water Environments. Volume 2: Swimming Pools and Similar Environments’ (2006); Joint FAO/NACA/WHO Study Group on food safety issues associated with products from aquaculture. WHO Technical Report Series No. 883, 1999; WHO-FAO (Codex Alimentarius Commission), ‘Code of Practice for Fish and Fishery Products’ CAC/RCP 52-2003; WHO, ‘Sustainable Development and Healthy Environments: Sanitation on Ships: Compendium of outbreaks of foodborne and waterborne disease and Legionnaires’ disease associated with ships, 1970-2000’ (WHO/SDE/WSH/01.4, 2001); WHO, ‘International Health Regulations Guide to Ship Sanitation’ (3rd ed., October 2007); WHO, ‘Guidelines for Drinking-water Quality’ (4th ed. 2011); WHO, ‘Guidelines for the Safe Use of Wastewater and Excreta in Agriculture and Aquaculture. Measures for Public Health Protection’ (1989); ‘Guidelines for the Safe Use of Wastewater, Excreta and Greywater’, Volume III: ‘Wastewater and Excreta Use in Aquaculture’ (2006).

<sup>107</sup> See extensive discussion and proposals in Negri, ‘Healthy Oceans for Healthy Lives: The Contribution of the World Health Organization to Global Ocean Governance’, in Attard (ed.), *IMLI Treatise on Global Ocean Governance*, Volume 2: *UN Specialized Agencies and Global Ocean Governance*, edited by Fitzmaurice and Ntovas, OUP, 2018, pp. 261-283.

<sup>108</sup> Stakeholder input by the Dutch Section of the International Commission of Jurists (NJCM) re OHCHR 2011 study on human rights and the environment, June 2011. Available at [https://www.rug.nl/research/portal/files/17685377/Call\\_for\\_input\\_NJCM\\_OHCHR\\_HR\\_and\\_Environment\\_DEF.pdf](https://www.rug.nl/research/portal/files/17685377/Call_for_input_NJCM_OHCHR_HR_and_Environment_DEF.pdf). Accessed March 2018. This study recognises five dimensions which have been integrated into this text.



decision-making) and the right of access to justice can be used by individuals to achieve greater protection of the environment as such.<sup>109</sup>

45. In connection to this, there is a clear movement towards the recognition of a separate right to environment.<sup>110</sup> To some extent, such a right already exists. For example, both the American and African regional human rights systems recognize a right to environment. In addition, according to Boyd 182 of the world's 193 UN member nations recognized this right by 2013, 'either through their constitution, environmental legislation, court decisions, or ratification of an international agreement'.<sup>111</sup> In March 2018, the UN Special Rapporteur on Human Rights and the Environment called for the global recognition of the right to a safe and healthy environment.<sup>112</sup> His report affirms the increasing call over the last decennia for a firm recognition of a right to an environment, as also advanced by several scholars.<sup>113</sup>

46. Furthermore, human rights and the environment are related through the concept of 'sustainable development', which requires that all efforts for development should be geared at equitably meeting the social (human rights), environmental and economic needs of present generations whilst not compromising the ability of future generations to meet their need.<sup>114</sup> Human rights and environmental protection also come together in the emerging concept of 'human duties to protect the environment as such', i.e. for the benefit of nature in its own right and not necessarily to the benefit of humankind.<sup>115</sup>

#### *Justiciability of environmental health concerns*

47. The link between health and the environment has been directly addressed by international human rights bodies. These bodies have generally approached environmental protection as being one of the underlying determinants of health.<sup>116</sup> Unlike environmental harm in general, which can be, and has been the object of impersonalized state-to-state claims at e.g. the International Court of Justice,<sup>117</sup> the link to health is based on a human-centered perspective. According to a human rights approach, environmental damage is legally enforceable to the extent that it has an impact on a person's health –sometimes with deadly consequences. If there is no such impact, it is to be addressed through state-to-state dispute settlement, if compensation is to be pursued.<sup>118</sup>

48. Concerning interpretative steps taken by judicial and quasi-judicial human rights bodies to clarify obligations for states under international law, these have varied due to divergences in applicable primary law. For instance, on several cases, the European Court of Human Rights (ECtHR) has framed the relationship between

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<sup>109</sup> See e.g. Dinah Shelton, 'Human Rights and the Environment: What specific environmental rights have been recognized?', *Denver Journal of International Law and Policy*, Vol. 35, 2006, pp. 130-143. See also NJCM, 2011.

<sup>110</sup> African [Banjul] Charter on Human and Peoples' Rights, Banjul, adopted by the Organization of African Unity on 27 June 1981, OAU Doc. CAB/LEG/67/3 rev. 5., Article 24; Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights, San Salvador, adopted by the Organization of American States, 17 November 1988, OAS Treaty Series No. 69, Article 11; See Annex II for a list of constitutions currently explicitly recognizing rights to environment. See also NJCM study, 2011, 8.

<sup>111</sup> David R. Boyd, *The Effectiveness of Constitutional Environmental Rights*, Yale UNITAR Workshop, April 26/27, 2013.

<sup>112</sup> UN Office of the High Commissioner of Human Rights, <http://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=22755&LangID=E>. Accessed April 2018.

<sup>113</sup> Shelton, 2006, 16.

<sup>114</sup> Principle 3 of the 1992 Rio Declaration on Environment and Development; Paragraph 5 of the 2002 Johannesburg Declaration on Sustainable Development; Principle 7 ILA New Delhi Principles on Sustainable Development. NJCM, 2011, *supra* note 21.

<sup>115</sup> Shelton, 2006, 130-132.

<sup>116</sup> Committee on Economic, Social and Cultural Rights, General Comment 14, 'The Right to the Highest Attainable Standard of Health', adopted on the 22nd session, E/C.12/2000/4, para. 11; Human Rights Council Resolution 34/20, 'Human rights and the environment', A/HRC/RES/34/20, para. 5(a), adopted on 24 March, 2017; also, African Commission on Human and Peoples' Rights, Principles and Guidelines on the Implementation of Economic, Social and Cultural Rights in the African Charter on Human and Peoples' Rights, November 2010, paras. 61 & 63.

<sup>117</sup> Recently, *Certain Activities Carried out by Nicaragua in the Border Area/Construction of a Road in Costa Rica Along the San Juan River (Costa Rica v Nicaragua/Nicaragua v Costa Rica)*, Merits, Judgment of 16 December 2015, ICJ Reports 2015, p. 665.

<sup>118</sup> *Certain Activities/Construction of a Road*, Judgment on Compensation, paras. 41-43.

the environment and health as part of the right to life<sup>119</sup> when it concerns very dangerous industrial activities that may put a person's health at risk;<sup>120</sup> or as part of a right to private and family life,<sup>121</sup> which may not necessarily entail direct risks for health.<sup>122</sup> Contracting Parties have been found to be in breach of their human rights obligations when activities occurring within their jurisdiction with a negative impact on the environment also hinge upon applicants' 'well-being', a term not strictly limited to health matters. It should be noted that the ECtHR specified that a breach occurs in cases of 'severe' environmental pollution. Whether the threshold of 'severe' is met can only be determined on a case-by-case analysis. On the other hand, the right to a healthy environment has been directly addressed by the European Committee of Social Rights, which included it as a component of the right to health under Article 11 of the European Social Charter.<sup>123</sup>

49. In turn, the African Commission on Human Rights has also framed the quality of the environment as an underlying component of the right to health,<sup>124</sup> as well as this provision's link with the distinct right to a satisfactory environment.<sup>125</sup> According to this regional body, obligations of states have a negative dimension, namely to refrain from causing harm, as well as a positive one, i.e. to protect their population from activities undertaken either by the state itself or by private companies.<sup>126</sup>

50. The Inter-American Court of Human Rights (IACtHR) has repeatedly ruled that a healthy environment is part of an expansive interpretation of the right to a dignified life<sup>127</sup> and to personal integrity,<sup>128</sup> with an emphasis on indigenous communities. More recently, the IACtHR dealt with the possibility of extraterritorial human rights obligations in case of transboundary environmental harm.<sup>129</sup> This means, in practice, that if state A causes an environmental damage that leads to a negative impact in a person or group of persons living in state B, these affected persons should have access to justice in state A. Thus, there is an extension of jurisdiction beyond the territorial confines of a state, in order to encompass instances where a state does not exert 'effective control' over the territory of another state. In this sense, the IACtHR can be seen as developing an idea of 'diagonal environmental rights'.<sup>130</sup> Yet pending questions of causality remain, given the difficulties for proving a link between harmful activities which take place on state A and the damage to a person's health in state B.

51. Albeit on different legal grounds, these three regional human rights bodies have also identified general obligations on the part of states, *inter alia*, to provide access to information; undertake environmental impact

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<sup>119</sup> European Convention for the Protection of Human Rights and Fundamental Freedoms, as amended by Protocols Nos. 11 and 14, adopted by the Council of Europe, November 1950, Article 2 (hereinafter European Convention on Human Rights).

<sup>120</sup> *Case of Öneriyıldız v. Turkey*, ECtHR, App. No. 48939/99, Judgment, 2004, paras. 71 & 90.

<sup>121</sup> European Convention on Human Rights, Article 8.

<sup>122</sup> *Case of López Ostra v. Spain*, ECtHR, App. No. 16798/1990, Judgment, 1994, paras. 51 & 58; *Case of Guerra and Others v. Italy*, ECtHR, App. No. 116/1996/735/932, Judgment, 1998, para. 60; *Case of Taşkın and others v. Turkey*, ECtHR, App. No. 46117/99, Judgment, 2005, para. 113.

<sup>123</sup> *Marangopoulos Foundation for Human Rights (MFHR) v. Greece*, European Committee on Social Rights, Complaint No. 30/2005, 6 December 2006, paras. 194-221.

<sup>124</sup> African Charter on Human and Peoples' Rights, Article 16, as interpreted in *Sudan Human Rights Organisation & Centre on Housing Rights and Evictions (COHRE) v. Sudan*, African Commission on Human and Peoples' Rights, Communications No. 279/03-296/05, 27 May 2009, para. 210; also, see the *Principles and Guidelines on the Implementation of Economic, Social and Cultural Rights in the African Charter on Human and Peoples' Rights*, para. 63.

<sup>125</sup> African Charter on Human and Peoples' Rights, Article 24, *Social and Economic Rights Action Centre and Centre for Economic and Social Rights v. Nigeria*, African Commission on Human and Peoples' Rights, Communication No. 155/96, 27 October 2001, paras. 50-54.

<sup>126</sup> Manisuli Ssenyonjo, 'The Protection of Economic, Social and Cultural Rights under the African Charter' in Danwood Mzikenge Chirwa and Lilian Chenwi (eds), *The Protection of Economic, Social and Cultural Rights in Africa. International, Regional and National Perspectives* (Cambridge University Press, 2016), 107-110.

<sup>127</sup> American Convention on Human Rights, Article 4.1., as interpreted in *Caso Comunidad Indígena Yakye Axa v. Paraguay*, IACtHR, Merits, Judgment of 17 June, 2005, paras. 163 & 167; *Caso Comunidad Indígena Xákmok Kásek v. Paraguay*, IACtHR, Merits, Judgment of 24 August, 2010, para. 187.

<sup>128</sup> American Convention on Human Rights, Article 5.1., as interpreted in *Caso Pueblo Indígena Kichwa de Sarayaku v. Ecuador*, IACtHR, Merits, Judgment of 27 June, 2012, para. 249; *Caso Pueblos Kaliña y Lokono v. Surinam*, IACtHR, Merits, Judgment of 25 November, 2015, paras. 172 & 222.

<sup>129</sup> *Medio Ambiente y Derechos Humanos*, IACtHR, Advisory Opinion OC 23/17, 15 November 2017, paras. 95-103 & 238-240.

<sup>130</sup> John Knox, 'Diagonal Environmental Rights', in Mark Gibney and Sigrun Skogly (eds), *Universal Human Rights and Extraterritorial Obligations* (University of Pennsylvania Press, 2010), 82.

assessments that include health-based indicators; consult individuals possibly affected by an activity with negative effects on the environment; monitor activities by private actors; and to provide access to an effective judicial remedy in case of harm. The link to health could thus provide distinctive avenues in human rights cases. Namely, individuals have legal standing in regional human rights courts if their health has been directly impacted by activities that harm the environment. In turn, within the aforementioned regional jurisdictions, states would have to prove they followed the necessary procedural steps for ensuring they fulfilled prevention and due diligence obligations. Future work in this field could further explore whether these converging regional developments point towards an emerging consensus regarding (procedural) obligations for states in international environmental law, particularly when the health of individuals has been negatively affected.

### *The uneasy intersection of health, environment and trade rules*

52. The potential for conflict between health and environmental policies, on one side, and trade policies, on the other, is evidenced by the decision of the WTO Appellate Body in the 2016 *India-Solar* case.<sup>131</sup> This involved a complaint brought by the United States against India for adopting domestic content requirements connected to purchases of equipment to produce solar energy to supply India's power grid. The Indian government adopted an ambitious program to transition toward renewable energy sources, including a substantial government financial commitment to purchase energy delivered from those sources. The Appellate Body upheld a finding that India's domestic (local) content requirements were inconsistent with the GATT national treatment rule that generally precludes favoring locally-produced products over imported products, and that GATT rules allowing exceptions or deviations, in this case for addressing supply shortages (GATT art. XX(j)), did not authorize India's favoritism toward domestic production.

53. As a matter of legal interpretation, the AB was correct. But, from the standpoint of health and environmental policy, the decision raises serious concerns. India has very serious environmental problems (e.g., the WHO has ranked New Delhi's air pollution the worst in the world), Indian expenditures on imported sources of energy are a major budgetary issue, and India has a large population in need of employment. If the government is going to make a major commitment to alternative energy sources, it seems to make good sense to do so by encouraging the development of a local solar power equipment industry, as opposed to purchasing American or Chinese-made solar generation equipment. It is not that the WTO Appellate Body made the wrong decision, but that WTO law does not provide adequate space for a large developing country with enormous employment and energy needs to deploy its own resources toward addressing environmental issues that are strongly connected to human health. A WTO policy that placed an emphasis on human health might well allow for India to develop its own resources toward achieving a healthier environment.

## **V. Transparency**

### *Transparency as a norm in international law*

54. Transparency has been identified as an important norm in international law.<sup>132</sup> Transparency may be defined in terms of openness or accessibility of information.<sup>133</sup> International agreements addressing a range of subject matter incorporate rights and obligations with respect to transparency.

55. International agreements in the field of trade and investment routinely incorporate obligations on governments to provide accessible information with respect to rules, regulations and

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<sup>131</sup> *India-Certain Measures Relating to Solar Cells and Solar Modules*, AB-2016-3, WT/DS456/AB/R, 16 Sept. 2016.

<sup>132</sup> See JOHN BRAITHWAITE AND PETER DRAHOS, *GLOBAL BUSINESS REGULATION* (Cambridge 2000); *TRANSPARENCY IN INTERNATIONAL LAW*, eds. A. Bianchi and A. Peters (Cambridge 2013). Braithwaite and Drahos observe: "Transparency is the principle that has most consistently strengthened in importance in regulatory debates. It is an emergent property of globalization, a meta-principle in the sense of revealing the operation of all other principles." *Id.* at 29.

<sup>133</sup> According to a widely used definition, 'transparency' means "that information is freely available and directly accessible to those who will be affected by such decisions and their enforcement. It also means that enough information is provided and that it is provided in an easily understandable forms and media". United Nations Economic and Social Commission for Asia and the Pacific, *What is Good Governance?*, p. 2. Available at <http://www.unescap.org/resources/what-good-governance> (accessed March 2018).

practices that may affect interested persons.<sup>134</sup> Such transparency provisions are enforceable, typically through the mechanisms for dispute settlement incorporated in such agreements. Such provisions have routinely been invoked and applied in dispute settlement proceedings.<sup>135</sup>

56. International agreements in other subject matter fields, including with respect to the environment<sup>136</sup> and financial regulation<sup>137</sup> incorporate transparency obligations, and decisions of international regulatory and dispute settlement bodies interpreting and applying those agreements have recognized transparency obligations.
57. While transparency is a widely adopted norm in international agreements, it is also recognized that there is not a uniform approach among subject matter fields regarding how transparency obligations should be defined and implemented. In a variety of contexts, interests in openness and access to information must be balanced against countervailing interests. Information in the context of security and defense matters,<sup>138</sup> or in relation to individual personal interests (e.g., personal health data), may be subject to limitations in respect to openness. In this regard, we do not speak of a universally applicable principle of transparency, but rather approach subject matter from a contextual perspective.
58. International agreements in the field of global health law incorporate transparency obligations. The Constitution of the World Health Organization incorporates among functions of the organization “to provide information, counsel and assistance in the field of health”, and “to assist in developing an informed public opinion among all peoples on matters of health”.<sup>139</sup> Chapter XIV of the WHO Constitution obligates member states to report a range of information to the organization, including “action taken with respect to recommendations made to it by the Organization and with respect to conventions, agreements and regulations” (Article 62) and “important laws, regulations, official reports and statistics pertaining to health which have been published in the State concerned” (Article 63), as well as incorporating a general obligation to respond to requests from the Board for additional information (Article 65).
59. The International Health Regulations (2005), application of which is obligatory, imposes a wide range of reporting requirements on state parties, including to designate or establish national focus and contact points (Article 4), and in Part II - Information and Public Health Response - an obligation to develop and maintain the capacity to detect, and report events (Article 5), to notify (Article 6), share information (Article 7), consult (Article 8) and provide other reports (Article 9).<sup>140</sup> It further imposes obligations on the WHO to provide certain information (which may be subject to confidentiality) (Article 11). Various other reporting obligations are established in the IHR, including with respect to private parties (e.g., from vessels in transit).

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<sup>134</sup> See relevant provisions in WTO Agreements, including GATT Article X, GATS Article III and TRIPS Agreement Article 63, and Revised Agreement on Government Procurement, adopted 30 March 2012 (GPA/113), at Article XVI; Regarding the European Union, see, e.g., Directorate General for Internal Policies Policy Department C: Citizens' Rights and Constitutional Affairs, Petitions, Openness, Transparency and the Right of Access to Documents in the EU, PE 556.973 (2016), [http://www.europarl.europa.eu/RegData/etudes/IDAN/2016/556973/IPOL\\_IDA\(2016\)556973\\_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/IDAN/2016/556973/IPOL_IDA(2016)556973_EN.pdf).

<sup>135</sup> See, e.g., cases listed in Repertory of Appellate Body Reports 1995-2013, Publication and Administration of Trade Regulations, [.wto.org/english/tratop\\_e/dispu\\_e/repertory\\_e/p5\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/repertory_e/p5_e.htm).

<sup>136</sup> See Jutta Brunnée and Ellen Hay, *Transparency and International Environmental Institutions*, in Bianchi and Peters, *supra* note 1, at 23.

<sup>137</sup> See Braithwaite and Drahos, *supra* note 1, at 88-142.

<sup>138</sup> See Orna Ben-Naftali and Roy Peled, *How Much Secrecy does Warfare Need?*, in Bianchi and Peters, *supra* note 1, at 321.

<sup>139</sup> [http://www.who.int/governance/eb/who\\_constitution\\_en.pdf](http://www.who.int/governance/eb/who_constitution_en.pdf).

<sup>140</sup> <http://www.who.int/ihr/publications/9789241580496/en/>.

60. Health treaties contain transparency obligations of vertical, horizontal and interpersonal nature. The WHO Framework Convention on Tobacco Control (FCTC) is an example.<sup>141</sup> In vertical provisions, states agree to regulate their relations with legal or natural persons in a specific manner. For example, the FCTC establishes that people should be informed about the health consequences and addictive nature of tobacco products, and that states must undertake legislative, executive, administrative or other measures for that purpose.<sup>142</sup> Horizontal provisions rule the relations between contracting Member States. The mechanisms for the exchange of information between states set out in the FCTC, dealing with measures taken and constraints identified, belong to this group.<sup>143</sup> Interpersonal obligations obligate states to shape the relationship between private parties in a particular fashion. In this sense, the FCTC obliges states to require tobacco producers to publicly disclose information about the toxic constituents of the tobacco products and the emissions that they may produce, and to ban tobacco advertising, promotion and sponsorship.<sup>144</sup>
61. The WHO Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits (PIP Framework), adopted as a recommendation to the WHO and Member States,<sup>145</sup> provides that member states should share PIP biological materials from influenza viruses with human pandemic potential (para 5.1), as well as genetic sequence data and analysis from that data (para 5.2). The PIP Framework also establishes a “transparent traceability mechanism”, and related reporting systems (para 5.3). Other parts of the PIP Framework require exchanges of information, including making available to the public certain information (e.g. on the health regulatory approval of vaccines, diagnostics and pharmaceutical products) (para 6.7). There is a provision that the WHO Director General shall inform the World Health Assembly, through the Executive Board, of the status and progress on implementation of the PIP Framework (para 7.4).
62. Almost all environmental law treaties identify among their principal objectives the protection of human health,<sup>146</sup> and reflect the close correlation between health and environment.<sup>147</sup> At the same time, a recurrent provision in environmental conventions prescribes the exchange of information regarding environmental hazards or threats.<sup>148</sup> Either autonomously<sup>149</sup> or as

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<sup>141</sup> *WHO Framework Convention on Tobacco Control (FCTC)*, WHA 56.1, 22 May 2003. Reporting, exchange of information and transparency are also central in the International Health Regulations, which provide the legal framework to coordinate disease detection and reaction against disease outbreaks.

<sup>142</sup> Article 4.1. *See*, also in this context, the education, communication, training and public awareness obligations enshrined in Article 12 of the FCTC.

<sup>143</sup> Article 21.

<sup>144</sup> Articles 10 and 13, respectively. This obligation is subject to potential national constitutional limitations.

<sup>145</sup> The technical legal status of the Framework, adopted by consensus of WHO members, is the subject of some ambiguity.

<sup>146</sup> For instance, the objective of the Stockholm Convention on Persistent Organic Pollutants is “to protect human health and the environment from persistent organic pollutants” (Art. 1). Health occupies also an important place in, among other, Art. 1.2 of the Vienna Convention for the Protection of the Ozone Layer; Para 1-4 of the Preamble and Art. 2.2(c) of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal; Art. 1.1(4) United Nations Convention on the Law of the Sea.

<sup>147</sup> Y. von Schirnding, W. Onzivu, A. O. Adede, “International environmental law and global public health”, *Bulletin of the World Health Organization*, 2002, vol. 80, n° 12, pp 970–974; S. Atapattu, “The public health impact of global environmental problems and the role of international law”, *American Journal of Law and Medicine*, 2004, vol. 30, n° 2-3, pp. 283-304.

<sup>148</sup> *See* P.N. Okowa, “Procedural Obligations in International Environmental Agreements”, *British Yearbook of International Law*, vol. 67, 1996, p. 200.

<sup>149</sup> According to D. Partan, “Due to the fact that much of the state practice evidence supporting the ‘duty to inform’ exists in treaties, there is substantial reason to doubt that the ‘duty to inform’ can be established, in classical terms, as customary international law”. D.G. Partan, “The Duty to Inform in International Environmental Law”, *Boston University International Law Journal*, vol. 6, 1988, p. 88; According to Dupuy, regular exchange of information by means of permanent regional institutions ‘seems to be the most appropriate way of establishing a reasonable and equitable use of shared natural resources, “as is required by international law”. *See* P.M. Dupuy, “Overview of the Existing Customary Legal Regime Regarding International Pollution”, in D.B. Magraw, *International Law and Pollution*, Philadelphia: University of Pennsylvania Press, 1991, p. 60.

procedural step of the customary principle of cooperation,<sup>150</sup> this is considered customary international law. Hence, protection of health by means of exchange of information regarding environment related threats, as well as in the context of the notification of disease outbreaks,<sup>151</sup> may be considered a customary norm of public international law.<sup>152</sup>

63. The right to health is also relevant when discussing transparency. The Committee in charge of monitoring Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR)<sup>153</sup> on the right to health, has addressed the relationship between right to health, access to information and transparency. The Committee has emphasized that access to information is an underlying determinant of health,<sup>154</sup> that population must participate in health-related decision-making,<sup>155</sup> that transparency should be a pillar of the national health strategy<sup>156</sup> and that ensuring transparency is a core obligation when reviewing the national health strategy.<sup>157</sup> Particularly important is the reference to the “interrelated and essential elements” of the right to health, one of them being *accessibility*. One among the overlapping dimensions of accessibility is access to health information, and the right to seek, receive and impart information and ideas concerning health issues.<sup>158</sup> Also of interest from a transparency point of view is the obligation to protect the right to health, pursuant to which states should “ensure that third parties do not limit people’s access to health-related information and services.”<sup>159</sup>
64. An area of contention relates to the management of transparency in international negotiations. Secrecy and discretion used to be the pattern -and regarded as virtue- of diplomacy and international relations.<sup>160</sup> However, criticism towards lack of transparency has become recurrent in respect to contemporary trade and intellectual property negotiations, in substantial part directed toward measures impacting health.<sup>161</sup> Criticism, however, is not unanimous.

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<sup>150</sup> The duty to inform would be a procedural stage in the fulfillment of the obligation of prevention. The International Court of Justice has held that the principle of prevention is a customary rule, has its origins in the due diligence and is now part of the corpus of international law relating to the environment. See, ICJ, *Pulp Mills on the River Uruguay (Argentina v. Uruguay)*, Judgment, I.C.J. Reports 2010, paras. 101-102, p. 14.

<sup>151</sup> D. Fidler, *International Law and Infectious Diseases*, Oxford: Clarendon Press, 1999, p. 100.

<sup>152</sup> This is in line with the fact that “Transparency is of particular relevance to international health law-making, given the history and importance of surveillance in public health”. E.A. Bruemmer, A.L. Taylor, op. cit., p. 272.

<sup>153</sup> International Covenant on Economic, Social and Cultural Rights, General Assembly Res. 2200A (XXI) of 16 December 1966.

<sup>154</sup> Committee on Economic, Social and Cultural Rights, *The Right to the Highest Attainable Standard of Health, General Comment 14*, U.N. Doc. E/C, Dec. 4, 2000, para. 11.

<sup>155</sup> *Id.*

<sup>156</sup> “since good governance is essential to the effective implementation of all human rights, including the realization of the right to health.” *Id.* para. 55.

<sup>157</sup> *Id.* para. 43(f).

<sup>158</sup> *Id.* para. 12.

<sup>159</sup> *Id.* para. 35.

<sup>160</sup> See P. Reuter, “Le droit au secret et les institutions internationales”, *Annuaire français de droit international*, vol. 2, 1956, pp. 46-56; H. Morgenthau, *Politics Among Nations*, New York: Alfred A. Knopf, 1950, pp. 431-433.

<sup>161</sup> A case in point are the ongoing EU-Mercosur trade negotiations, see HAI-EPHA, *Health Action International and European Public Health Alliance reaction to leaked documents from EU-MERCOSUR trade talks*, available at <http://haiweb.org/eu-mercotur-trade-agreement-bad-deal-transparency-policy-coherence-access-medicines/> (accessed March 2018). For a broader perspective on transparency and trade negotiations, see P. Delimatsis “TTIP, CETA, and TiSA Behind Closed Doors Transparency in the EU Trade Policy”, in S. Griller, W. Obwexer, E. Vranes (Eds), *Mega-Regional Trade Agreements: CETA, TTIP, and TiSA: New Orientations for EU External Economic Relations*, Oxford: OUP, 2017, pp. 216-246; P. Roffe, X. Seuba, “ACTA and the International Debate on Intellectual Property Enforcement”, in P. Roffe and X. Seuba (Eds), *ACTA and the Plurilateral Enforcement Agenda*, Cambridge: CUP, 2015, pp. 9-11.

Governmental bodies<sup>162</sup> and judicial institutions,<sup>163</sup> and scholars as well, defend limitations on transparency as a tool to achieve a better outcome, or just to not “make the process entirely unworkable.”<sup>164</sup> In this context, the so-called “deliberation exception” is meant to improve negotiations and decision-making,<sup>165</sup> under the assumption that “there may be an optimal level of transparency that is less than maximum transparency”.<sup>166</sup>

65. Within the broader sphere of global health law, there are issue areas with respect to transparency that have taken on a particular importance because of their direct impact on access to health technologies, and more specifically to pharmaceutical products (including therapeutic drugs, vaccines and diagnostics).

*Transparency in pharmaceutical pricing*

66. Price transparency of pharmaceutical products is globally regarded as an important prerequisite for the procurement of affordable medicines and the wise expenditure of public resources. The WHO website provides a global price reporting mechanism for HIV, TB, malaria, hepatitis and diagnostic tools. For vaccines the WHO has created a database that collects and disseminates vaccine prices and procurement information to assist countries in the procurement of affordable vaccines. The Global Fund maintains a publicly available price reporting mechanism on procurement transactions. Also, NGOs provide medical product pricing information.<sup>167</sup>
67. Achieving price transparency for newer, often patented, medicines however remains a challenge. Secrecy in price negotiations involving pharmaceutical companies has become common practice. Policy makers increasingly find themselves in a situation not being able to report on the results of price negotiations with pharmaceutical companies that demand their prices be kept secret.<sup>168</sup> This raises a number of issues including the question of whether such secrecy is appropriate in democratic government. Price confidentiality allows companies to charge different prices in different markets. Price differentiation is more difficult to sustain if prices are transparent. Price differentiation might perhaps be defended if different price levels reflect differences between countries in their ability to pay. But, in reality, companies pursue a strategy to maximize prices in each market and price differences bear little relationship to the ability to pay. For example, prices for HCV treatment in Europe vary among countries but

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<sup>162</sup> ACTA negotiators held that “it is accepted practice during trade negotiations among sovereign states to not share negotiating texts with the public at large, particularly at earlier stages of the negotiation.” European Commission, *The Anti-Counterfeiting Trade Agreement – Summary of Key Elements under Discussion*, 6 November 2009. See also USTR, *Fact Sheet: Transparency and Trans-Pacific Partnership*, June 2012; ICTSD, “EU Parliament Criticises Secrecy of ACTA Negotiations in Landslide Vote”, *Bridges Weekly Trade News Digest*, vol. 14, n° 10, March 2010.

<sup>163</sup> The Court of Justice of the European Union has held that secrecy is important “to allow mutual trust between negotiators and the development of a free and effective discussion,” because “any form of negotiation necessarily entails a number of tactical considerations of the negotiators, and the necessary cooperation between the parties depends to a large extent on the existence of a climate of mutual trust”. *Case T-301/10*, Judgment of the General court (Second Chamber), 19 March 2013, par. 119.

<sup>164</sup> S. Lester, “Transparency in trade negotiations: How much is enough, how much is too much?”, *Bridges Africa*, vol. 4, n° 7; R. B. Mitchell, “Sources of Transparency: Information Systems in International Regimes”, *International Studies Quarterly*, vol. 42, 1998, pp. 112-113.

<sup>165</sup> A. Peters, “Towards Transparency as a Global Norm”, in Bianchi and Paters, supra note 1, p. 579.

<sup>166</sup> D. Heald, “Transparency as an Instrumental Value”, in C. Hood and D. Heald, *Transparency: The Key to Better Governance*, Oxford: Oxford University Press, 2006, p. 60.

<sup>167</sup> Médecins sans Frontières’ (MSF) *Untangling the Web of Price Reductions* first published in 2001 has been an important guide for finding low cost quality producers of antiretroviral medicines (ARVs) for the treatment of HIV and for documenting the price developments of ARVs over time. Since 1986 Management Sciences for Health (MSH) publishes the *International Medical Products Price Guide* which offers pricing information for a range of pharmaceuticals. The MSH guide is an essential tool in procurement of quality medicines at the lowest possible cost. According to MSH, Comparative price information is important for getting the best price, and this is an essential reference for anyone involved in the procurement of pharmaceuticals.

<sup>168</sup> Accord, Frederick M. Abbott, *Let International Competition Negotiations Sleep a While Longer: Focus on Tools and Capacity*, IIC - International Review of Intellectual Property and Competition Law, March 2018, Volume 49, Issue 3, PP 259–266, [HTTPS://DOI.ORG/10.1007/S40319-018-0683-5](https://doi.org/10.1007/S40319-018-0683-5).

these variations do not reflect national income levels. The same is seen globally where medicines prices in developing countries can even exceed prices in high-income countries.<sup>169</sup>

68. Affordability of new medicines has become a global issue. So has the call for greater price transparency and justification for high drug prices. An analysis of R&D expenditure of 10 cancer drugs showed that R&D expenditure ranged from \$157.3 million to \$1950.8 million. The total revenue from sales of the 10 cancer drugs since approval was \$67.0 billion compared with total R&D spending of \$7.2 billion. These figures indicate that R&D cost does not offer a justification for sustained high pricing of these cancer medicines.<sup>170</sup>
69. The call for greater transparency with regards to how medicines are priced and the cost of research and development is becoming louder. The Council of Europe adopted a resolution regarding public health and the pharmaceutical sector in which it demands greater transparency with respect to pharmaceutical R&D expenses.<sup>171</sup> WHO has embarked on a “Fair Pricing Project” and defines a fair price as “one that is affordable for health systems and patients and that at the same time provides sufficient market incentive for industry to invest in innovation and the production of medicines”.<sup>172</sup> However, in order to assess whether a product is fairly priced requires access to data on the cost of R&D and production which is often not readily available.<sup>173</sup> Access to data regarding R&D costs is also important to assessing whether pharmaceuticals are being sold at excessive prices constituting an abusive practice under competition law.<sup>174</sup>
70. The report of the UN High-Level Panel on Access to Medicines (UNHLP) puts emphasis on the need to ensure good governance and transparency in pharmaceutical policies and practices. The Panel recommends countries “require manufacturers and distributor of health technologies to disclose to drug regulatory and procurement authorities information pertaining to: (1) the cost of R&D, production, marketing and distribution of health technology being procured or given marketing approval with each expense category separated; and (2) any public funding received in the development of the health technology including tax credits, subsidies, and grants.”<sup>175</sup>
71. Also, the Lancet Commission on Essential Medicines Policies puts a strong emphasis on transparency in areas related to pharmaceutical policies including pricing and cost, medicines

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<sup>169</sup> For example, the price of the breast cancer drug trastuzumab:

[https://www.oxfam.org/sites/www.oxfam.org/files/file\\_attachments/rr-access-cancer-treatment-inequality-040215-en.pdf](https://www.oxfam.org/sites/www.oxfam.org/files/file_attachments/rr-access-cancer-treatment-inequality-040215-en.pdf)

<sup>170</sup> Though production costs are only one important part of the cost of a new pharmaceutical, it is useful to note that recent studies of cost of production of HCV medicines, cancer medicines and medicines on the WHO Essential Medicines List show that prices of pharmaceuticals bear little relation to the actual production cost.

<sup>171</sup> EUR. PARL. ASS., Resolution 2071, 30th Sitting (2015) ¶ 1. The resolution provides, “6.2. with regard to research and development for new therapeutic molecules, to: 6.2.1. oblige pharmaceutical companies to ensure absolute transparency regarding the real costs of research and development, particularly in relation to the public research portion.”

<sup>172</sup> [http://www.who.int/medicines/access/fair\\_pricing/en/](http://www.who.int/medicines/access/fair_pricing/en/)

<sup>173</sup> At the Fair Pricing Forum, which brought together member states and other stakeholders held in Amsterdam on 11 May 2017, “promoting transparency of prices paid, R&D costs, production costs, and profit margins” was a recurrent theme. Also at the sub-national level, there are moves to increase pharmaceutical transparency. In California a law, which aims to provide more transparency about pharmaceutical and biotech company pricing methods for their medicines, requires drug manufacturers to give a 60-day notice if prices are raised more than 16 percent over a two-year period. KEI has mapped legislative initiatives aimed at increasing transparency of R&D cost in 13 US states.

<sup>174</sup> See Frederick M. Abbott, *Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health*, 6 UC IRVINE L. REV. 281 (2016), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2719095](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2719095).

<sup>175</sup> President Festus Mogae, co-chair of the UNHLP said at the launch of the report: “A paradigm shift in transparency is needed to ensure that the costs of R&D, production, marketing, and distribution, as well as the end prices of health technologies are clear to consumers and governments. Governments should require manufacturers and distributors of health technologies to disclose these costs and the details of any public funding received in the development of health technologies, including tax credits, subsidies, and grants.” <http://www.unsgaccessmeds.org/news-blogs/2016/9/13/united-nations-secretary-generals-high-level-panel-on-access-to-medicines-calls-for-new-deal-to-close-the-health-innovation-and-access-gap>



quality, procurement practices, conflict of interest management, patent status information and patent licensing. The Commission specifically argues for transparency in the costs of R&D to enable effective dialogue and decision-making on affordable pricing of new essential medicines, and a fair return on R&D investments. It also recognizes the need to “actively manage and protect the public interest in the proceeds of state-funded research” to avoid the public paying twice for innovation, which also requires greater transparency of R&D spending data.

72. Transparency in pharmaceutical pricing, production and R&D cost is emerging as a strong demand in international policy discussions. However, at the national level secrecy prevails in the day-to-day reality of price negotiations and pharmaceutical R&D and production cost. The pharmaceutical industry is opposed to greater transparency of costs and pricing, which underlines the need for public policy development in this area.
73. Concerns regarding lack of adequate transparency with respect to pharmaceuticals is also directed toward information regarding patent status and regulatory-approval based exclusivity determinations. Some steps have been taken to address these concerns,<sup>176</sup> but much remains to be done. Three recent decisions of the General Court of the European Union have highlighted the need to strike a balance between corporate claims of business confidentiality and the interests of the public in accessing information regarding clinical trials and related subject matter.<sup>177</sup>

#### *Recommendations for promoting transparency*

74. The foregoing discussion and analysis suggests the following:

1. Transparency is recognized as a basic principle in international law in the context of guaranteeing access to information regarding laws, regulations and practices;
2. Transparency is essential for enabling proper functioning of government and private sector systems intended to address public health needs;
3. In the context of the pharmaceutical sector, transparency is essential to allowing appropriate regulation of pricing, including by establishing the costs of developing, manufacturing and distributing products, and informing the public regarding the status of exclusive rights granted through patent and regulatory approval processes;
4. In the context of international organizations addressing human health, transparency of information should be the baseline norm, subject to limitations where necessary and appropriate to protect the public;
5. In the context of the health sector, there are circumstances in which exceptions to transparency are appropriate, such as with respect to health information regarding identifiable individuals, and to prevent development and distribution of materials that may pose a significant security risk (e.g., bioweapons);
6. It is appropriate to recognize a general principle of transparency in global health law, subject to limitations and exceptions necessary to protect the public. It is further appropriate to recognize a presumption against the establishment and use of limitations and exceptions in acknowledgment of the foundational role of transparency in promoting and protecting human health interests. Accordingly, any limitations and exceptions should be construed narrowly.

75. The Global Health Law Committee should further pursue a work program regarding transparency that will make specific recommendations for promoting transparency, which

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<sup>176</sup> See for example: [www.medspal.org](http://www.medspal.org) and [http://www.who.int/phi/implementation/ip\\_trade/ip\\_patent\\_landscapes/en/](http://www.who.int/phi/implementation/ip_trade/ip_patent_landscapes/en/)

<sup>177</sup> *Pari Pharma v. EMA*, Case T-235/15, Judgment of General Court, 5 Feb. 2018; *PTC Therapeutics v. EMA*, Case T-718/15, Judgment of General Court, 5 Feb. 2018, and; *MSD Animal Health v. EMEA*, Judgment of General Court, Case T-729/15, 5 Feb. 2018.

include supporting the recommendations of the UN High Level Panel on Access to Medicines regarding transparency.