The right to health as the basis for universal access to essential medicines

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Introduction

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An estimated 2 billion people lack regular access to essential medicines. (1) Many of these people live in low- and middle-income countries. The political slogan to 'leave no one behind' signals a new era under the 2030 Agenda for Sustainable Development. Among its aims, Target 3.8 on universal health coverage (UHC) seeks to achieve access to safe, effective, quality and affordable essential medicines and vaccines for all. (2) The World Health Organization (WHO) defines UHC as:

> [E]nsuring that all people have access to needed health services (including prevention, promotion, treatment, rehabilitation and palliation) of sufficient quality to be effective while also ensuring that the use of these services does not expose the user to financial hardship. (3)

National governments therefore need to strive for UHC's three related objectives: 1) equity in access to health services, 2) quality health services, and 3) financial-risk protection of users. (3)

Low- and middle-income countries with inadequate UHC schemes often have a large proportion of financially-vulnerable people who are dependent on government-subsidised essential medicines. Frequent medicines stock-outs in the public sector force patients to buy from the private sector, where they often pay out-of-pocket for higher priced products. (4,5,6) Households face potentially catastrophic health spending to buy their essential medicines, or forgo treatment at the expense of their health. (4,7)

Some initiatives to scale-up UHC are associated with increases in medicines sale and use – which can be used as proxy indicators of access. (8,9) Other evidence shows that poorly designed or implemented UHC schemes can also perpetuate health inequities. This can occur when UHC programmes inadequately cover vulnerable populations or the full range of essential medicines for priority conditions, or insufficiently finance health services, burdening users with unaffordable care costs. (10,11) These challenges are compounded by the high prices of new, therapeutically beneficial medicines (i.e. for cancer, Hepatitis C, etc.) that are too costly for many UHC schemes and patients to purchase. (12–15) In brief, the way governments design UHC schemes to finance and supply essential medicines can have a major impact on health equity.

The central assertion of this thesis is twofold. First, we assert that the legislative provisions in national laws and policies frame the government's commitments to essential medicines. ('Legislative provisions' mean the legal language that is used to articulate underlying ethical principles to national law and policy. Legal language for access to

medicines should be interpreted and implemented in line with the right to health.) The scope of national laws and policies in this thesis includes legally-binding domestic law (known as 'hard law', i.e. constitutional law, legislation, case law) that frames obligations for public actors (i.e. governments). (16) This thesis also includes national medicines policies that are prescriptive for action in the national pharmaceutical sector but not (usually) legally enforceable (known as 'soft law'). (16) Second, we contend that this framing will influence how inclusive and responsive UHC schemes are to the medicines needed by the poor and vulnerable. Yet, as long as ethical principles are not legally enforceable, the poor and vulnerable in many low- and middle-income countries must rely on the benevolence of their governments in order to receive essential medicines. Pharmaceutical policy studies over the last decade demonstrate that such government charity alone, without legal obligations, is incapable of remedying the growing disparities in medicines access and health. (3,17)

International human rights law is a promising source of norms that can inform political commitments and legal standards to enhance equitable access to essential medicines. (18–20) First, human rights refocus government commitments, action, and outcomes on individuals and on collective action. As Nixon and Forman argue: "[t]he individual entitlement cannot be met without an adequate collective health care system". (21) The right to health under the International Covenant on Economic, Social, and Cultural Rights (ICESCR) imposes core obligations on State parties.* Core obligations signify the basic minimum level of rights enjoyment that States must attain to give meaning to the right to health. One core obligation under the right to health is to provide essential medicines, as defined by WHO, on a non-discriminatory basis and with attention for vulnerable groups. (22) From an accountability perspective, the right to health can help to address power disparities in global health, supporting the vulnerable to emerge from the margins of health policy. (23)

* Although the right to health is enshrined in other international treaties, we focus on the ICESCR because it includes the most detailed scope and content of the right to health (in General Comment No. 14) that is applicable to all persons. The rights in other international treaties are specific to certain populations such as children, women, racial minorities, migrant workers, or disabled people. Other such treaties codifying the right to health are the Convention on the Elimination of All Forms of Discrimination Against Women (article 12), the Convention on the Rights of the Child (article 24), the Convention on the Elimination of Racial Discrimination (article 5(e)(iv)), the International Convention on the Protection of Rights of All Migrant Workers and Members of Their Families (articles 28, 43, and 45), and the Convention on the Rights of Persons with Disabilities (articles 25 and 26).

Second, the right to health is legally binding on the 165 national governments that have ratified the ICESCR. Consequently these governments are legally obliged to protect and promote health rights in national law and policy. The strength of these legal obligations varies by country, depending on the standing of international law in the domestic legal order, and on the presence and content of national implementing legislation. (21) Statutory right to health commitments in international and domestic law can create a supportive environment to claim and enforce human rights and the provision of essential medicines. (24-28)

While ambitious in many areas, the post-2015 development agenda for health omits right to health language from its rhetoric. (3, 29–33) Moreover, the 2017 UHC monitoring report sidelines access to medicines in Target 3.8. (34) Medicines availability is one of 16 tracer measures of the UHC service coverage index, and will only be included in the index once data become widely available. The result is a global political agenda and monitoring system for access to medicines that is devoid of meaningful human rights commitments and adequate measuring tools.

In the context of national health systems, law is a neglected yet decisive moderator of patient-level access to medicines. Legal rules structure much of our environment from the organisation and provision of health care (i.e. essential medicines) as well as the social conditions that influence wellbeing. (35)

Yet, there is a dearth of WHO guidance to advise its Member States on legislating for equitable access to essential medicines. (36,37) Instead, WHO's policies focus on the holistic management of pharmaceuticals as essential public goods and health system commodities. (38) In 2017 WHO and its partners published guidance for Member States titled Advancing the right to health: Vital role of the law. (19) This initial examination applies human rights principles to a variety of public health laws. While useful, these publications fail to advise Member States on the normative standards and full 'menu' of domestic legal tools for access to medicines. This paucity of evidence and policy advice illustrates how emergent such legal studies are in the field of pharmaceutical policy research.

Scholars, legislators, policy makers, advocates, patients, and the public require - and deserve - an effective roadmap of legally-enforceable government obligations to provide essential medicines. This roadmap should be guided by a human rights compass capable of asserting priority for the poor and marginalised. To address these challenges, this thesis aims to determine the practical lessons that international human rights law offers governments of low- and middle-income countries for

universal access to essential medicines and sustainable development. The thesis focuses on adequate financing of essential medicines and their affordability, as two of the five key challenges to universal access to essential medicines identified by the Lancet Commission on Essential Medicines Policies. (4)

The overarching research question of this thesis is:

> ***How has international human rights law been embedded in national law and policy, and been implemented and enforced in practice to promote universal access to essential medicines?***

Detailed research questions

The overarching research question is examined in four sub-questions addressed in Chapters 2, 3, 4, and 5. Each chapter investigates a step in policy formulation and practice for universal access to essential medicines. First, we develop a normative framework for State action to provide essential medicines, which we use for our subsequent analyses. Second, we collect and evaluate a practical 'menu' of legal texts for access to medicines from national laws and policies from various low- and middle-income countries. Third, we evaluate how States have progressed towards fulfilling their right to health obligations for access to medicines in 195 national health systems. Finally, we analyse how domestic courts interpret these legal texts in the context of medicines litigation.

The four research questions are:

> ***i) Chapter 2: What are States' obligations under international human rights law to provide essential medicines? How can these commitments be translated into a normative framework for domestic health law and policy?***

International human rights law sets globally-endorsed standards and norms for protecting and promoting human dignity. It offers a framework for State commitment and action. Scholarly debate has questioned the contours of States' core obligations under the right to health, particularly to provide essential medicines. (39,40) As it is common in legal research, scholars argue and interpret a legal concept through the lens of other legal frameworks. (41) Common right to health frameworks include the tripartite typology (known as the duty to respect, protect, and fulfil health rights), or the so-called AAAQ (where Availability, Access, Acceptability, and Quality of health goods and services are elements of the right to health). (22) Beyond a general duty to *fulfil* access to medicines and ensure their financial *accessibility*, these

frameworks lack the detail required to further unpack the normative meaning of State obligations with regards to medicines affordability and financing.

Recent developments in human rights law and pharmaceutical policy offer new opportunities to delineate States' core obligation to provide essential medicines. First, the standard of reasonableness is an under-explored human rights concept recently enshrined in the 2013 Optional Protocol to the ICESCR. (42) Reasonableness offers a softer approach to core obligations. It asks whether governments acted reasonably to provide essential medicines based on a set of criteria. Second, in 2016 the right to sexual and reproductive health, a component of the right to health, was defined and operationalised in General Comment No. 22. (43) It reaffirms that essential medicines for sexual and reproductive health constitute a core obligation.

The purpose of Chapter 2 is to take universal human rights principles and make them particular to essential medicines. We use legal analysis to establish what national governments 'ought' to do in the context of essential medicines provision. In Chapter 2.1 we apply the standard of reasonableness in relation to States' core obligations towards essential medicines, resulting in a list of explicit and tangible legal duties and policy measures. In Chapter 2.2 we apply the human rights principle of progressive realisation to the ethical and economic dilemma of reimbursing expensive essential medicines. This section clarifies misinterpretations of the right to health, specifically about individual entitlements, State obligations, and responsibilities of the pharmaceutical industry in relation to high-priced medicines. In Chapter 2.3 we examine the limitations imposed by WHO's Model List of Essential Medicines on essential medicines for medical abortion. We base our argument on international human rights law, WHO's own policies on safe abortion, and the best scientific evidence. (44) Through this case study we address the lack of coherence between the right to health and its application to State obligations in WHO policy guidance for Member States.

Taken together, the findings from Chapter 2 result in an policy checklist composed of 12 principles that should be included in national law and policy for access to medicines (Chapter 2.4), which is applied in Chapters 3.2 and 3.3.

> ***ii) Chapter 3: How have national legislators embedded right to health obligations into the texts of domestic law and policy for medicines affordability and financing? Are these legal texts consistent with the normative framework (developed above) and policy checklist?***

National governments pursuing health reform often lack the evidence and practical examples from other jurisdictions to advance access to medicines as part of UHC. Pharmaceutical policy handbooks lack guidance for legalising rights and State commitments to access to medicines. (45) WHO's rare pharmaceutical policy guidelines for legislators focus on areas unrelated to UHC (i.e. pharmaceutical regulation and good governance) or are outdated (i.e. WHO guidelines for national medicines policies, last published in 2001). (46,47) In response to the dearth of practical examples, in 2010 legal scholars in collaboration with WHO produced a pilot study of national legislation for access to medicines in four countries. (48) This study was an important first step to collect and compare national legislation for access to medicines. However, it did not address UHC neither as a critical concept in essential medicines policy nor as a driver of universal access to medicines. This probably reflects the limited development of the UHC concept at the time.

The purpose of Chapter 3 is to collect and describe the prevalence, scope, and trends of essential medicines and human rights principles for medicines in national law and policy in different jurisdictions. Using a health science methodology, we examine three types of legal tools (constitutional law, pharmaceutical policy, and UHC legislation) that government ministries and legislators have at their disposal for meeting population health needs. Each sub-section of this chapter also reports examples of comprehensive legal texts that are aligned with the normative framework developed in Chapter 2. Chapter 3.1 reports changes in the number of domestic constitutions enshrining right to health language with direct or indirect references to essential medicines and the scope of these commitments since 2008. Domestic constitutional law is the highest and most vital affirmation of State commitments and individual entitlements. Depending on the jurisdiction, constitutional rights can be enforced by domestic courts. Chapter 3.2 examines the essential medicines and human rights principles in the national pharmaceutical policies from 71 countries. A national pharmaceutical policy is a non-binding government commitment and guide to action in the national pharmaceutical sector. (47) Chapter 3.3 is a cross-national comparison of essential medicines and human rights principles in the UHC legislation of 16 mostly low- and middle-income countries. UHC legislation governs the structure, organisation, and function of a range of systems to provide beneficiaries with access to health services in the event of ill health, without incurring financial hardship.

iii) Chapter 4: To what degree do national governments achieve their right to health obligations towards essential medicines? What progress have governments made since 2008?

In 2008 the UN Special Rapporteur on the Right to Health published 72 indicators related to the right to health in 194 health systems. (53) Right to health indicators are selected because they signal the State commitments, efforts and results that are considered relevant from a human rights perspective. However, since 2008, this baseline measurement has not been repeated. As mentioned above, the indicators selected by the new Sustainable Development Goals (SGDs) monitoring system for UHC and access to medicines do not fully reflect a human rights perspective. (3,34)

Chapter 4 presents our follow-up report of the eight right to health indicators that were chosen to reflect access to essential medicines, from 195 countries. These eight indicators serve as a screening tool giving an immediate snapshot of government duties, actions and outcomes that are important for the right to health. Besides reporting progress since 2008, we also establish a reference point for measuring future achievements under the 2030 Agenda for Sustainable Development.

iv) Chapter 5: In the context of domestic litigation for medicines reimbursement, how has the domestic judiciary interpreted the right to health in national law? Is this interpretation consistent with the normative framework (developed above) and policy checklist?

Ambitious legal language for access to medicines should be interpreted and implemented in line with the right to health to advance universal access and equity. Some jurisdictions permit national courts to receive individual or group complaints, and examine whether health rights have been violated. (49) In this process the language in national laws for access to medicines is interpreted by domestic courts; their judgment becomes binding law. Consequently, the process of interpreting and codifying human rights principles for access to medicines extends beyond framing and adopting laws, to include the decisions of the courts (called case law).

One example of the justiciability of medicines-related rights is from Uruguay. Since 2007, the Uruguayan courts have received a wave of patient claims for the reimbursement of specific medicine products. This phenomenon suggests a disconnect between the right to access medicines on a positive list in national law, and its implementation in practice. (50) Medicines litigation in Uruguay provides a potentially

rich case study of the various reasons the judiciary uses to decide which medicines 'ought' to be reimbursed, and for whom, in several ways. First, the constitutional right to health is justiciable and access to medicines on a positive list is protected by national law. (51,52) Second, Uruguay is one of the 23 State Parties to the 2013 Optional Protocol to the ICESCR. The Optional Protocol applies the standard of reasonableness to judge State action on social rights in relation to its resources. We could expect the Uruguayan judiciary to heed the human rights standards in the international law it has ratified. Uruguay is therefore an interesting laboratory to study the interpretation of the reasonableness standard for medicines. Chapter 5 assesses how the Uruguayan judiciary interprets the government's core obligations in the context of domestic litigation for high-priced medicines.

Methodological considerations

In addition to the substantive investigations, this thesis is also an experiment in using hybrid methodologies borrowed from health sciences and law. We approach this experiment differently in each chapter.

Chapter 2 uses a legal methodology. We examine different legal sources to compare, craft, and apply arguments for a desired action or outcome. (41) Following the method of norm setting, we identify relevant principles from authoritative legal sources, such as international human rights law. (41) Then, we argue why and how they apply to specific State actions for access to medicines.

Chapter 3 uses the tools of health science to learn practical lessons about legislation and policy for access to medicines. By taking this approach we diverge from the standard health science study designs and methodologies that test hypotheses about relationships, patterns, or causality, although these are secondary tests in our studies. (54) Instead, our primary aim is to explore, document, describe, and analyse relevant legal texts from a large number of countries ('big N' studies). In this way our research attempts to offer a global overview of current practices for embedding access to medicines in domestic constitutional law and national medicines policies, and in the domestic law of a selection of countries with UHC. (55) This thesis strictly aims to offer first-ever insight into how access to medicines is framed in the legal provisions of domestic law.

Chapter 4 examines right to health indicators, which use public health data to gauge the realisation of human rights standards in a population. (56) The Office of the High Commissioner of Human Rights advises to

use three types of indicators (structural, process, and outcome) to judge State commitment, action, and results. (57) Moreover, each indicator should correspond to a specific State obligation under the right to health, derived from General Comment No. 14. (22) We have observed these considerations in selecting the indicators, collecting data, and reflecting on their suitability.

Chapter 5 is a single-country case study ('small n' study) of how patients' claims for specific medicines are interpreted by domestic courts in relation to national legislation founded on right to health. This study aims to be classic legal analysis of judicial reasoning against the authoritative human rights framework for health and medicines.

References

1. Access to Medicines Index. Methodology 2015. Haarlem: Access to Medicines Foundation; 2015. 64 p.

2. UN General Assembly. Transforming our world: the 2030 Agenda for Sustainable Development [Internet]. 2015 [cited 2018 May 24]. Adopted in Resolution No.: A/RES/70/1. Available from: http://www.un.org/en/development/desa/population/migration/generalassembly/docs/globalcompact/A_RES_70_1_E.pdf

3. World Health Organization. Universal Health Coverage [Internet]. [cited 2018 Jul 16]. Available from: http://www.who.int/healthsystems/universal_health_coverage/en/

4. Wirtz VJ, Hogerzeil H V, Gray AL, Bigdeli M, De Joncheere CP, Ewen MA, et al. Essential medicines for universal health coverage. Lancet [Internet]. 2016 Nov 7 [cited 2018 May 18];74. Available from: http://dx.doi.org/10.1016/S0140-6736(16)31599-9

5. Ewan M, Joosse H-J, Ashigbie P, Beran D, Laing R. Insulin prices profile [Internet]. Amsterdam: Health Action International; 2016 [cited 2018 Jun 3]. 155 p. Available from: http://haiweb.org/wp-content/uploads/2016/04/ACCISS-Prices-report_FINAL-1.pdf

6. Mahmić-Kaknjo M, Jeličić-Kadić A, Utrobičić A, Chan K, Bero L, Marušić A. Essential medicines availability is still suboptimal in many countries: a scoping review. J Clin Epidemiol [Internet]. 2018 Jun 1 [cited 2018 May 24];98:41–52. Available from: https://www.sciencedirect.com/science/article/pii/S0895435617310089

7. Ewen M. Too costly & too scarce: price, availability and affordability of medicines in low- and middle-income countries [Internet]. Amsterdam: Vrije Universiteit Amsterdam; 2016 [cited 2018 May 24]. 171 p. Available from: http://dare.ubvu.vu.nl/handle/1871/54753

8. Nazzal C, Frenz P, Alonso FT, Lanas F. Effective universal health coverage and improved 1-year survival after acute myocardial infarction: the Chilean experience. Health Policy Plan [Internet]. 2016 Jul 1 [cited 2018 May 23];31(6):700–5. Available from: https://academic.oup.com/heapol/article-lookup/doi/10.1093/heapol/czv120

9. Garabedian LF, Ross-Degnan D, Ratanawijitrasin S, Stephens P, Wagner AK. Impact of universal health insurance coverage in Thailand on sales and market share of medicines for non-communicable diseases: an interrupted time series study. BMJ Open [Internet]. 2012 [cited 2018 May 23];2(6):e001686. Available from: http://bmjopen.bmj.com/content/2/6/e001686.long

10. Asante A, Price J, Hayen A, Jan S, Wiseman V. Equity in health care financing in low- and middle-income countries: a systematic review of evidence from studies using benefit and financing incidence analyses. PLoS One [Internet]. 2016 Apr 11 [cited 2018 May 23];11(4):e0152866. Available from: http://dx.plos.org/10.1371/journal.pone.0152866

11. Alshamsan R, Leslie H, Majeed A, Kruk M. Financial hardship on the path to universal health coverage in the Gulf States. Health Policy (New York) [Internet]. 2017 Mar [cited 2018 May 23];121(3):315–20. Available from: http://www.ncbi.nlm.nih.gov/pubmed/28089280

12. Lopes GL, De Lima Lopes G, De Souza JA, Barrios C. Access to cancer medications in low- and middle-income countries. Nat Rev Clin Oncol [Internet]. 2013 [cited 2018 May 24];10(10):314–322. Available from: https://www.canceralliance.co.za/wp-content/uploads/2015/01/Access-to-Medicines-Lopez-29102013.pdf

13. Reich MR, Harris J, Ikegami N, Maeda A, Cashin C, Araujo EC, et al. Moving towards universal health coverage: lessons from 11 country studies. Lancet [Internet]. 2016 Feb 20 [cited 2018 May 24];387(10020):811–6. Available from: https://www.sciencedirect.com/science/article/pii/S0140673615600022

14. Chalkidou K, Marquez P, Dhillon PK, Teerawattananon Y, Anothaisintawee T, Gadelha CAG, et al. Evidence-informed frameworks for cost-effective cancer care and prevention in low, middle, and high-income countries. Lancet Oncol [Internet]. 2014 Mar 1 [cited 2018 May 24];15(3):e119–31. Available from: https://www.sciencedirect.com/science/article/pii/S1470204513705473

15. 't Hoen E. Access to cancer treatment: a study of medicine pricing issues with recommendations for improving access to cancer medication [Internet]. Paris: Oxfam International; 2015 [cited 2018 Jun 3]. 58 p. Available from: http://hdl.handle.net/10546/344070

16. Gersenn J, Posner EA. Soft law: Lessons from congressional practice [Internet]. Stan L Rev. 2008 [cited 2018 Jul 16];61:573-628. Available from: https://chicagounbound.uchicago.edu/cgi/viewcontent.cgi?article=11512&context=journals_articles

17. Cameron A, Ewen M, Ross-Degnan D, Ball D, Laing R, Cameron A. Medicine prices, availability, and affordability in 36 developing and middle-

income countries: a secondary analysis. Lancet [Internet] 2008 Dec 1 [cited 2018 May 24];373(9659):240-249. Available from: https://doi.org/10.1016/S0140-6736(08)61762-6.

18. WHO Consultative Group on Equity and Universal Health Coverage. Making fair choices on the path to universal health coverage [Internet]. Geneva: World Health Organization; 2014 [cited 2018 May 23]. 84 p. Available from: http://www.who.int/choice/documents/making_fair_choices/en/

19. Magnusson RS. Advancing the right to health: the vital role of law [Internet]. Sydney: World Health Organization; 2017 [cited 2018 Jun 3]. 331 p. Available from: http://www.who.int/healthsystems/topics/health-law/health_law-report/en/

20. Frenk J, Gómez-Dantés O. Ethical and human rights foundations of health policy: lessons from comprehensive reform in Mexico. Health Hum Rights [Internet]. 2015 [cited 2018 May 24];17(2). Available from: https://www.hhrjournal.org/2015/11/ethical-and-human-rights-foundations-of-health-policy-lessons-from-comprehensive-reform-in-mexico/

21. Nixon S, Forman L. Exploring synergies between human rights and public health ethics: a whole greater than the sum of its parts. BMC Int Health Hum Rights [Internet]. 2008 Dec 31 [cited 2018 May 24];8(2):1-9. Available from: http://bmcinthealthhumrights.biomedcentral.com/articles/10.1186/1472-698X-8-2

22. UN Committee on Economic, Social and Cultural Rights. General Comment No. 14 on the Right to the Highest Attainable Standard of Health [Internet]. 2000 [cited 2018 May 23]. Document No.: E/C.12/2000/4. Available from: http://tbinternet.ohchr.org/_layouts/treatybodyexternal/Download.aspx?symbolno=E%2fC.12%2f2000%2f4&Lang=en

23. Forman L. What do human rights bring to discussions of power and politics in health policy and systems? Glob Public Health [Internet]. 2017 Dec 13 [cited 2018 May 24];1–14. Available from: https://doi.org/10.1080/17441692.2017.1405457

24. Hogerzeil HV, Samson M, Casanovas JV, Rahmani-Ocora L. Is access to essential medicines as part of the fulfilment of the right to health enforceable through the courts? Lancet [Internet]. 2006 Jul 22 [cited 2018 May 24];368:305–11. Available from: https://doi.org/10.1016/S0140-6736(06)69076-4

25. Yamin AE, Parra-Vera O. How do courts set health policy? The case of the Colombian Constitutional Court. PLoS Med [Internet]. 2009 Feb 17 [cited 2018 May 18];6(2):e1000032. Available from: http://dx.plos.org/10.1371/journal.pmed.1000032

26. Motta Ferraz OL. Health inequalities, rights and courts: the social impact of judicialization of health. In: Yamin AE, Gloppen S, editors. Litigating health rights: Can courts bring more justice to health. Boston: Harvard University Press; 2011. 72-102.

27. Flood C, Gross A. Litigating the right to health: what can we learn from a comparative law and health care systems approach. Health Hum Rights [Internet]. 2014 Dec [cited 2018 May 18];16(2):E62-72. Available from: https://cdn2.sph.harvard.edu/wp-content/uploads/sites/125/2014/12/Flood-final.pdf

28. Machado M, Acurcio FDA, Brandão CMR, Faleiros DR, Guerra AA, Cherchiglia ML, et al. Judicialization of access to medicines in Minas Gerais state, southeastern Brazil. Rev Saude Publica [Internet]. 2011 [cited 2018 May 18];45(3):590–8. Available from: http://dx.doi.org/10.1590/S0034-89102011005000015

29. Forman L, Ooms G, Brolan CE. Rights language in the sustainable development agenda: has right to health discourse and norms shaped health goals? Int J Heal Policy Manag [Internet]. 2015 Sep 29 [cited 2018 May 23];4(12):799–804. Available from: http://ijhpm.com/article_3102_616.html

30. Ooms G, Latif LA, Waris A, Brolan CE, Hammonds R, Friedman EA, et al. Is universal health coverage the practical expression of the right to health care? BMC Int Health Hum Rights [Internet]. 2014 [cited 2018 Jun 3];14(1):3;1-7. Available from: https://doi.org/10.1186/1472-698X-14-3

31. Forman L, Ooms G, Chapman A, Friedman E, Waris A, Lamprea E, et al. What could a strengthened right to health bring to the post-2015 health development agenda?: interrogating the role of the minimum core concept in advancing essential global health needs. BMC Int Health Hum Rights [Internet]. 2013 [cited 2018 Jun 3];13(1):48;1-11. Available from: https://doi.org/10.1186/1472-698X-13-48

32. Ooms G, Brolan C, Eggermont N, Eide A, Flores W, Forman L, et al. Universal health coverage anchored in the right to health [Internet]. Bull World Health Org. 2013 [cited 2018 Jun 3];91(1):1–2. Available from: http://www.who.int/bulletin/ volumes/91/1/12-115808

33. Brolan CE, Hill PS, Ooms G. "Everywhere but not specifically somewhere" : a qualitative study on why the right to health is not explicit in the post-2015 negotiations. BMC Int Health Hum Rights [Internet]. 2015 Aug 21 [cited 2018 May 24];15:22:1-10. Available from: https://doi.org/10.1186/s12914-015-0061-z

34. World Health Organization, World Bank. Tracking universal health coverage: 2017 global monitoring report [Internet]. Geneva: World Health Organization and the International Bank for Reconstruction and Development / The World Bank; 2017 [cited 2018 May 18]. 69 p. Available from: http://pubdocs.worldbank.org/en/193371513169798347/2017-global-monitoring-report.pdf

35. Burris S, Kawachi I, Sarat A. Integrating law and social epidemiology. J Law, Med Ethics [Internet]. 2002 Dec 24 [cited 2018 May 24];30(4):510–21. Available from: http://journals.sagepub.com/doi/10.1111/j.1748-720X.2002.tb00422.x

36. World Health Organization. Health laws and UHC: WHO's work on law and universal health coverage [Internet]. 2016 [cited 2018 May 23]. Available from: http://www.who.int/health-laws/who-work/en/

37. Clarke D, Rajan D, Schmets G. Creating a supportive legal environment for universal health coverage. Bull World Health Organ [Internet]. 2016 Jul 1 [cited 2018 May 24];94(7):482–482. Available from: http://www.who.int/entity/bulletin/volumes/94/7/16-173591.pdf

38. Bigdeli M, Jacobs B, Tomson G, Laing R, Ghaffar A, Dujardin B, et al. Access to medicines from a health system perspective [Internet]. Health Policy Plan. 2013 [cited 2018 May 24];28(7):692–704. Available from: https://doi.org/10.1093/heapol/czs108

39. Chapman AR, Forman L, Lamprea E. Evaluating essential health packages from a human rights perspective. J Hum Rights [Internet]. 2017 Apr 3 [cited 2018 May 22];16(2):142–59. Available from: https://www.tandfonline.com/doi/full/10.1080/14754835.2015.1107828

40. Forman L, Beiersmann C, Brolan CE, Mckee M, Hammonds R, Ooms G. What do core obligations under the right to health bring to universal health coverage? Health Hum Rights [Internet]. 2016 Dec [cited 2018 May 22];18(2):23–34. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5394991/pdf/hhr-18-023.pdf

41. Smits J. Redefining normative legal science: towards an argumentative discipline. In: Coomans F, Grunfeld F, Kamminga MT, editors. Methods of Human Rights Research. Antwerp: Intersentia; 2009. p. 262.

42. General Assembly. Optional Protocol of the Covenant on Economic, Social and Cultural Rights [Internet]. 2008 [cited 2018 May 31]. Adopted in Resolution No.: A/RES/63/117. Available from: http://www.ohchr.org/EN/ProfessionalInterest/Pages/OPCESCR.aspx

43. UN Committee on Economic, Social and Cultural Rights. General Comment No. 22 on the Right to Sexual and Reproductive Health [Internet]. 2016 [cited 2018 May 23]. Document No.: E/C.12/GC/22. Available from: http://tbinternet.ohchr.org/_layouts/treatybodyexternal/Download.aspx?symbolno=E%2fC.12%2fGC%2f22&Lang=en

44. WHO Expert Committee for the Selection and Use of Essential Medicines. WHO Model List of Essential Medicines, 20th List [Internet]. Geneva: World Health Organization; 2017 [cited 2018 May 22]. 604 p. Available from: http://www.who.int/medicines/publications/essentialmedicines/en/

45. Fefer E. Pharmaceutical legislation and regulation (Chapter 6). In: Managing access to medicines and health technologies [Internet]. Arlington: Management Sciences for Health, Inc.; 2012 [cited 2018 May 23]. Available from: http://www.msh.org/resource-center/ebookstore/copyright.cfm.

46. World Health Organization. Good governance for medicines model framework [Internet]. Geneva: World Health Organization; 2014 [cited 2018 May 31]. 54 p. Available from: http://apps.who.int/iris/bitstream/handle/10665/129495/9789241507516_eng.pdf?sequence=1

47. Hodgkin C, Carandang ED, Fresle DA, Hogerzeil HV, editors. How to develop and implement a national drug policy [Internet]. Second edition. Geneva: World Health Organization; 2001 [cited 2018 May 18]. 96 p. Available from: http://apps.who.int/iris/bitstream/handle/10665/42423/924154547X.pdf?sequence=1

48. Forzley M, Walker DM, Gispen ME. Essential laws for medicines access: a pilot study on national legislation [Internet]. Geneva: World Health Organization; 2010 [cited 2018 May 24]. 38 p. Available from: http://www.who.int/medicines/areas/human_rights/ELMA_report_2010_final.pdf

49. Zhang Y. Advancing the right to health care in China: towards accountability. Cambridge: Intersentia; 2018. 373 p.

50. Bardazano G, Caredio V, Cechi P, Ceretta J, Domínguez V, Giudice L, et al. Múltiples miradas a los medicamentos de alto costo: hacia una comprensión integral del tema [Internet]. Montevideo: Universidad de la República; 2017 [cited 2018 May 23]. 127 p. Available from: http://www.proyectomac.hc.edu.uy/images/múltiples_miradas_a_los_medicamentos_de_alto_costo-_hacia_una_comprensión_integral_del_tema.pdf

51. Constitution of Uruguay [Internet]. 1966, last amended 2004 [cited 2018 May 22]. Available from: https://www.constituteproject.org/constitution/Uruguay_2004.pdf?lang=en

52. Decree No. 265/006 of 2006, on the creation of the National Medicines Formulary (Uruguay). 2006.

53. Backman G, Hunt P, Khosla R, Jaramillo-Strouss C, Fikre BM, Rumble C, et al. Health systems and the right to health: an assessment of 194 countries [Internet]. Lancet. 2008 [cited 2018 May 23];372(9655):2047–85. Available from: https://doi.org/10.1016/S0140-6736(08)61781-X

54. World Health Organization. Health policy and systems research: A methodology reader [Internet]. Gilson L, editor. Geneva: World Health Organization; 2012 [cited 2018 May 24]. 472 p. Available from: http://www.who.int/alliance-hpsr/alliancehpsr_reader.pdf

55. Tremper C, Thomas S, Wagenaar AC. Measuring law for evaluation research. Eval Rev [Internet]. 2010 Jun 17 [cited 2018 May 23];34(3):242–66. Available from: http://journals.sagepub.com/doi/10.1177/0193841X10370018

56. Landman T. Social science methods and human rights. In: Coomans F, Grunfeld F, Kamminga MT, editors. Methods of Human Rights Research. Antwerp: Intersentia; 2009. p. 262.

57. Office of the High Commissioner for Human Rights. Human rights indicators: a guide to measurement and implementation [Internet]. 2012 [cited 2018 May 18]. Document No.: HR/PUB/12/5. Available from: http://www.ohchr.org/Documents/Publications/Human_rights_indicators_en.pdf