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

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Discussion and conclusion



This thesis aims to identify which legal standards and practical lessons international human rights law can offer national policy makers in low- and middle-income countries for promoting universal access to essential medicines. It explores the written norms and rules embedded in national medicine policies and legislation. The thesis is therefore based on the premise that the wording of national law and policy will influence access to medicines, particularly for the poor and vulnerable who rely on government supplies to meet their health needs.

Human rights have the potential to transform social, political, and legal norms. In 2000, the Committee on Economic, Social and Cultural Rights broke new ground with the publication of its first-ever authoritative interpretation of State obligations towards the right to health enshrined in the 1966 International Covenant on Economic, Social and Cultural Rights (ICESCR). (1) General Comment No. 14 established that State parties have the minimum core obligation to provide essential medicines, as defined by WHO, without discrimination. (2) Despite this development, access to essential medicines for the world's poor and vulnerable has made little progress except for a few specific medicines such as antiretrovirals. (3) The central premise of this thesis is that embedding human rights principles and language in domestic law and policies could be a remedy to the widespread political and legal indifference in attaining universal access to essential medicines, particularly for the most vulnerable. To this end we present the first systematic inquiry into how international human rights law can be translated into policy lessons about access to medicines for domestic law and policy makers.

Research questions

The central 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?

This general question is divided into four specific research questions:

- i. 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?
- ii. 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?

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

iv. 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?

Main findings

Chapter 2 developed a legal framework to evaluate national medicines laws and policies. Chapter 2.1 started to define a common test for determining whether States have satisfied their core obligation towards essential medicines. We examined how the standard of reasonableness - a novel concept enshrined in the 2013 Optional Protocol to the ICESCR - can offer a deeper understanding of a government's minimum core obligations in relation to its resources. We used four criteria from the standard of reasonableness to define the contours of the State's minimum core obligations in a framework for analysis. First, the human rights principle of mobilising a maximum of available resources is consistent with policy measures for sufficient government spending on medicines. Second, the principle of seeking low-cost policy options resonates with policy measures for medicines price control including using the flexibilities to the Trade Related Aspects of Intellectual Property (TRIPs) Agreement. Third, the principle of seeking international assistance relates to two policy measures. One measure is to secure financial assistance (to increase the available resources for medicines) and the other is to engage technical support from the international community (to enhance efficiencies through joint medicines evaluation, price negotiation, and/or procurement). Fourth, although not explored in detail in this thesis, the human rights principle of non-discrimination should also be considered in policy measures. In summary, this chapter delineates States' obligations to provide essential medicines into specific and targeted duties to mobilise resources and maximise efficiencies.

Chapter 2.2 examined how governments can ensure fair access to expensive, new essential medicines as part of the right to health within finite public health budgets. We argued that the human rights principle of progressive realisation justifies priority ranking medicines for reimbursement. Progressive realisation recognises everyone's right to

health, but realises this right in order of a prioritised list of therapies determined (in part) by their cost-effectiveness, in order to achieve maximum efficiency in spending public resources. The human rights principle of efficiency is also consistent with reimbursing medicines based on their cost-effectiveness. Governments employing progressive realisation can guard against 'queue jumping' expensive therapies and can reject patient claims for low-priority, expensive medicines using these human rights arguments. A transparent and objective priority setting process can therefore protect fair reimbursement decisions from being derailed by political and social forces. At the same time, pharmaceutical companies have a duty under human rights to price new medicines affordably for all who need them, thereby increasing access. Ultimately, eliminating excessive high prices, rather than increasing budgets, is the best solution for universal access to new essential medicines.

Chapter 2.3 examined the coherence between WHO's Model List of Essential Medicines and the right to health, through a case study of mifepristone and misoprostol (designated essential medicines for medical abortion). These are the only essential medicines that the WHO recommends to use in line with domestic law or cultural practices. (2) We leveraged the landmark General Comment No. 22 (2016) on the right to sexual and reproductive health to argue that WHO's Model List should not unduly limit the use of mifepristone and misoprostol. We illustrate how this restrictive entry on WHO's Model List is inconsistent with current scientific evidence, with the recently elaborated right to sexual and reproductive health (enshrined in Art. 12 of the ICESCR), and with WHO's own more recently developed policy guidance on safe abortion.

In Chapter 2.4 we concluded that the principles identified in human rights law and WHO's policies for essential medicines can be assembled in a normative framework to evaluate State action to provide essential medicines. The framework consists of 12 principles in 3 domains: legal rights and obligations, good governance, and technical implementation. The arguments and principles presented in Chapters 2.1-2.3 fit in the domains' legal rights and obligations, and technical implementation (see Table 1 in Chapter 2.4). Chapter 2.4 briefly described the arguments and principles included in the good governance domain. (2,4) We also translated the normative framework into a 12-point policy checklist that we applied in our analysis of domestic laws and policies (Chapter 3).

Chapter 3 presented a collection and analysis of legal texts for access to medicines from domestic constitutional law, national pharmaceutical policies, and UHC legislation through a human rights lens.

In Chapter 3.1 we evaluated the evolution of constitutional language referencing access to medicines between 2008 and 2015. We use the tripartite typology (duties to respect, protect, and fulfil) to examine texts in 185 national constitutions and identify comprehensive examples for other countries. We found that since 2008, State duties to fulfil medicines rights have been expanded in five constitutions, maintained in four constitutions, and regressed in one constitution. Notably, terminology used to describe these rights has evolved over time to include more human rights standards. Recently adopted constitutions enshrine the term ‘access to medicines’ and aim to protect the public from access barriers in international trade agreements and/or intellectual property rights. Example texts to protect and to fulfil essential medicines-related rights were identified.

In Chapters 3.2 and 3.3 we executed a cross-national comparison of legal texts using a normative framework developed in Chapter 2 (see Table 1 in Chapter 2.4). In Chapter 3.2 we presented a comparative content analysis of the most recent full-text national medicine policies (NMP) available in 71 countries. Of all 12 principles, NMPs most frequently present measures for medicines selection and efficient spending/cost-effectiveness. Four principles, embedded for the first time in WHO's 2001 guidelines for medicine policies, are significantly more frequent in NMPs adopted in or after 2004. These principles are: the right to health, government financing, efficient spending, and financial protection of vulnerable populations. Six criteria have remained weak or absent in many policies: pooling user contributions, international cooperation, and good governance (transparency; participation of beneficiaries; monitoring; accountability and redress). Commitments to affordability and access are strongest in the policies of South Africa (1996), Suriname (2005), the Philippines (2011-2016), El Salvador (2011), and Somalia (2013).

In Chapter 3.3 we selected domestic UHC legislation from a purposive sample of 16 mostly low- and middle-income countries. Using descriptive content analysis, we found that the principles from our framework most frequently legalised in national law were pooling user contributions (n=10), rights and obligations (n=9 countries), accountability (n=9), and financial coverage for the vulnerable (n=8). The least common principles were related to good governance (i.e. monitoring, transparency, participation, n=2-3) and technical implementation (i.e. international cooperation n=1). Overall, UHC legislation from Colombia, Chile, Mexico, and the Philippines codifies the most principles for access to medicines in their national law.

We also identified the following three legislative trends between the wealthier (upper-middle and high income) and the less affluent (low and lower-middle income) countries that we sampled in Chapter 3.3. In general, laws from wealthier countries described explicit individual rights and State obligations in relation to access to medicines, established clear boundaries to medicines entitlements and State obligations, and codified mechanisms for accountability and redress for all patients. On the other hand, less affluent countries generally refrain from guaranteeing the right to basic healthcare for all, define patients' entitlements to health interventions based on the principle of available public resources, and limit accountability to the (contributing) members of UHC schemes. Some countries showed exceptions to each of these trends. If these differences reflect the development process of realising universal access, then less affluent countries could consider incorporating more explicit provisions for access to medicines earlier in their national law. This hypothesis merits further study.

Chapters 3.2 and 3.3 constitute the first systematic content analyses and examples of essential medicines and human rights principles codified in different legal documents for access to medicines. Innovative ideas for embedding language promoting access to medicines in national medicines policies and UHC legislation are presented in Annexes 1 and 2 of this thesis, respectively.

Chapter 4 addressed the question to what degree governments have achieved their right to health obligations towards essential medicines from a health systems perspective. In 2008, the UN Special Rapporteur on the Right to Health reported on 72 right to health indicators in 194 health systems. We presented a follow-up report of the 8 indicators specifically related to access to medicines in 195 countries. Each of the eight indicators correspond to State obligations under the right to health (Table 1 in Chapter 4).

Only half of the expected data points were retrievable. Between 2008-2015, constitutional recognition of access to medicines increased from 7/190 to 13/192 countries. In this period more countries adopted a national medicines policy (117 to 123) and a national list of essential medicines (78 to 107). Public spending on pharmaceuticals decreased or rose modestly in most of the 44 countries for which data were available. In most low and lower-middle income countries public spending remained below the \$12.90/capita annual minimum threshold for a basket of 201 essential medicines estimated by the Lancet Commission, except in Afghanistan, Morocco, Iraq, and Tuvalu. The median availability of a basket of lowest-priced generics increased in the public (63.2%

to 70.0% n=9 countries) and private (84.2% to 91.5% n=10) sectors in the few countries from which paired data was available. Median global childhood immunisation rates remained constant for measles (around 93% n=114) and improved for 3 doses of diphtheria-tetanus-pertussis (79% to 86% n=82). These median coverage rates approach 95% and 90% required to eradicate measles and diphtheria, tetanus, and pertussis, respectively. Despite the dearth of data, our findings suggest modest progress between 2008 and 2015, and establish an updated reference point to measure future achievements on essential medicines as part of the right to health under the SDGs.

Chapter 5 examined how rights-based language in UHC legislation for access to medicines (analysed in Chapter 3.3) is interpreted by domestic courts in Uruguay. Our study illustrated that Uruguay's circuits of appeal did not consistently interpret patients' rights and the State's legal obligations in line with the right to health in the ICESCR. We also demonstrated that the judiciary's decisions to reimburse expensive medicines contradicted the domestic rules for medicines selection and financing, and sometimes also human rights principles. These findings illustrated that medicines litigation in Uruguay offers relief for some individual claims, but fails to address the structural problems behind high medicines prices.

General discussion

Reflections on the research questions

One key contribution this thesis tries to make to human rights scholarship is to clarify the vagueness surrounding States' core obligation to provide essential medicines under the right to health (Chapter 2). We conclude that governments' abstract human rights duties towards medicines can be translated into concrete policy measures to discharge their core obligations. From a health policy perspective, this thesis developed a normative compass that governments and judiciaries can use to address the ethical and economic challenges of public provision of essential medicines. Besides that, other stakeholders can use these authoritative norms and legal texts as advocacy tools to promote universal access to essential medicines.

Moving one step further, we identified example texts from national laws and pharmaceutical policies that express those duties in legal language (Chapter 3). These practical examples for access to essential medicines show that human rights language - once thought of as a discourse of global health policy and few domestic jurisdictions - has permeated many domestic legal spheres. However, the case study of Uruguay shows

that even the most rights-compliant legislation for access to medicines is subject to the unique interpretation of domestic courts, and that national judiciaries can diverge from authoritative interpretations of the right to health (Chapter 5). In summary, this legislative, policy, and judicial evidence provides the proof of concept that human rights law can yield legally binding standards.

National policy makers can use the example texts in this thesis (found in Annexes 1 and 2) as a starting point for designing medicines legislation and pharmaceutical policy for equitable, transparent, and accountable access to medicines as part of UHC schemes. We have shown that some, but not all, principles in our checklist are embedded in domestic UHC law and national medicines policies. Therefore, more structured guidance is needed to promote the uptake and consistent interpretation of all human rights principles into domestic legal instruments.

Our study measuring States' achievement of their right to health obligations for essential medicines compared data from 2015 with the 2008 report by the UN Special Rapporteur on the Right to Health (Chapter 4). We illustrated that many countries for which data were available have progressed on most of the indicators of access to medicines; yet, most still fail to meet the official targets. The systematic collection and reporting of data is improving, which is the first step towards rights realisation. Nevertheless, we demonstrated that the challenges of monitoring access to medicines globally, highlighted during the tenure of the Millennium Development Goals, regrettably persist in the era of Sustainable Development. (5,6) Our approach contributes to advancing human rights practice beyond its historic methods of “naming, shaming, and litigating” rights violations towards constructive approaches to measuring and monitoring rights realisation. (7) We conclude that a human rights framework is dynamic and can be used to establish or describe norms, and to track real time progress towards those standards.

General reflection on the findings

We have several general reflections on the frameworks we applied and the findings in this thesis.

What lessons have international human rights law and (domestic) pharmaceutical policy learned from one another?

Previously, Hans Hogerzeil has proposed five ‘lessons’ that essential medicines can learn from human rights. (8) These lessons are:

1. Recognise access to essential medicines as part of the right to health;
2. Consult all beneficiaries of the medicines policy or programme;
3. Implement mechanisms for transparency and accountability;
4. Ensure the vulnerable have equal access to essential medicines;
5. Ensure safeguards and redress mechanisms in case of rights violations.

Our study corroborates all five points. First, we offer examples of legal text related to all five points for inspiration and use by domestic law and policy makers. Second, our study examining eight indicators of access to medicines in 195 countries monitors the realisation of points 1 and 2. (These are a constitutional right to health (point 1), the adoption of a national medicines policy (point 2) and an essential medicines list (point 1)) We show that many governments pay lip service to global monitoring of access to medicines, while we could only retrieve half of the expected data points. In 2006 Hogerzeil explained that a human rights approach requires data disaggregated on the grounds of possible discrimination (e.g. sex, tribal background) to monitor access to medicines (points 3 and 4). (8) However, our results show that in practice there are significant gaps in regular monitoring and still little disaggregated data exists for medicines indicators. Third, we show that even in a health system with an enforceable right to health, judicial redress (point 5) does not necessarily protect health rights and the equitable provision of medicines. Therefore, our results suggest that point 5 should encompass both judicial redress and non-judicial mechanisms to address rights violations.

Our research contributes two additional lessons that respond to gaps in WHO's essential medicines policies. The first lesson is that human rights law requires Member States to recognise the right to health in national law. Our study shows that WHO's policies for essential medicines mention the right to health (i.e. in NMPs), yet do not advise Member States to explicitly reference the right; WHO has no guidance for writing legislation to promote universal access to medicines. Only the WHO 2008-2013 Mid-Term Strategic Plan lists a domestic constitutional or legal right to health as an indicator of access to medicines at country level, but does not explain how to embed these commitments in national law. (2) Therefore, our research concludes that WHO should revise its advisory frameworks to include the legal recognition of the right to health (see section below, on Policy implications). In this thesis we also share practical examples of rights-based legal text for policy makers (see Annexes 1 and 2).

The second lesson is that human rights law contributes the principle of progressive realisation to pharmaceutical debates. It introduces the concept that States are obliged to take immediate, deliberate and targeted steps for the provision of essential medicines even if full realisation cannot be immediately achieved. We demonstrated that this principle is not expressly addressed in WHO's policies, nor in Hogerzeil's five points. Our research delineates which policy measures States must take to discharge their right to health obligations towards essential medicines.

Our study leaves an important gap in the translation of human rights principles to lessons for pharmaceutical policy, which is: Which State action and policy measures satisfy the principle of non-discrimination in relation to access to medicines? Our research proposed several policy components that contribute towards non-discrimination, such as the prioritisation of medicines for reimbursement, sufficient State and other funding for essential medicines, especially for the poor and disadvantaged, and the use of low-cost policy options. However, it remains unclear whether these measures are sufficient for a human rights response, or whether other State actions are needed to ensure non-discriminatory access to medicines.

We can also ask whether human rights law offers a complete set of principles required for robust pharmaceutical law and policy making, or whether supplementary standards are needed. For example, one can question whether cost-effectiveness should be a human rights principle. Cost-effective spending is a long-standing pillar of WHO's technical guidance for medicines while the corresponding principle of efficiency is muted in human rights jurisprudence. (9–11) Based on our research we agree with other scholars who frame cost-effectiveness as a tool to achieve efficiency, which in itself should be used to promote equity. (2) In addition, we propose that cost-effectiveness is the practical application of the principle of progressive realisation. In combination with other criteria, cost-effectiveness helps to identify the medicines in which States should invest first to satisfy the health rights for the greatest number of people. We find that human rights law offers a sufficient breadth of principles to support pharmaceutical policy measures.

A human rights framework is the best global consensus of legally-binding norms that we currently have at our disposal. It contributes critical concepts, such as individual rights and State obligations, that other authoritative health frameworks from WHO have generally missed until now. We therefore recommend using human rights law to frame future investigations of universal access to essential medicines. And yet, human rights law is not perfect and researchers should be aware of its

shortcomings.

Is our 12-point policy checklist suited to the task of advancing access to essential medicines?

Throughout this thesis, we have applied human rights law in a way that is useful and relevant for health scientists, health systems analysts, and policy makers in the field of medicines. Our normative framework and 12-point policy checklist is derived from the most authoritative essential medicines and human rights principles. The checklist is an easy-to-use screening tool for access to medicines in national law and policy. Legal scholars may argue that in this process international human rights law was diluted, in the sense that its strength, authority, or full scope of meaning were compromised. For example, the human rights principle of non-discrimination is rather superficially addressed in our policy checklist as “financial coverage for vulnerable groups”. Scholarship has interrogated the complexity of non-discrimination in the context of human rights. (12,13) However, we did not build these intricacies into our policy checklist in order to retain its qualities of simplicity and user-friendliness as a screening tool. We argue that in this thesis international human rights law was instead distilled, that is, refined from abstract universal principles into more practical policy measures that can fit in law and policy makers' tool boxes. In the future we recommend using the 12-point checklist as a departure point to guide the development of domestic law and policy for equitable access to medicines. Our tool, which was developed as a normative framework and checklist for analysing domestic legislation and policy, can also be used as a guide for writing new legislation. It is both a check-list and a wish-list for rights-based domestic pharmaceutical policy making.

What is the role of WHO policy in codifying access to medicines in national law and policy?

We were happy to see that WHO policies for essential medicines, although non-binding, appear to have influenced subsequent domestic laws and policies. The premise of our work on essential medicines for medical abortion (Chapter 2.3) is that WHO's Model List of Essential Medicines is an authoritative guide for national governments. We demonstrated that, since 2008, more countries have adopted a national medicines policy and an essential medicines list (Chapter 4). This finding is consistent with WHO's support for national governments to develop and implement a national medicines policy and an essential medicines list since the onset of its essential medicines programme in the 1970s. (3) Moreover, we show that WHO's 2001 guidelines for developing a national medicines policy introduced and recommended human rights

commitments congruent with our policy checklist (Chapter 3.2), and that some of these principles (but not all) are significantly more frequent in NMPs adopted in 2004 or later.

These results corroborate the authority of WHO as a global normative actor. From a public policy perspective, these findings substantiate our recommendation for WHO to further align its existing guidelines for essential medicines with human rights law. WHO should also develop new guidance specifically for Member States to legislate for access to medicines in UHC schemes.

Our findings have an important implication for legal studies: they suggest that WHO's soft law or non-binding policies are akin to the phenomenon of informal international lawmaking. (14) Informal international lawmaking is informal with regard to its outcomes (i.e. it does not produce a formal source of international law, such as a treaty), its process (i.e. it occurs in a loose network of actors rather than a traditional international organisation governed by a treaty), and/or its actors (i.e. it involves ministries, domestic regulators, independent agencies, and the legislative or judicial branches rather than the usual diplomatic actors). (14) Indeed, Joost Pauwelyn also agrees that much informal international law making has occurred under the auspices of WHO. (14) Our findings suggest that, in the field of pharmaceutical policy, WHO's soft law instruments may hold yet more potential to advance right to health norms than is widely acknowledged.

Are our eight right to health indicators suited to the task of advancing access to essential medicines?

From our follow-up report of eight indicators of access to medicines (Chapter 4) we conclude that the indicators were clear, feasible and informative, but that only few countries reported data. Therefore, we recommend the following adaptations in future monitoring exercises.

Several indicators should be expanded to include sub-indicators offering a more granular view of the real-time situation. One example is expanding constitutional commitments to medicines (indicator 1) to capture the implementation of specific policy measures for medicines affordability and financial coverage. For example, sub-indicators could track whether national legislation requires governments to control medicines prices and to adequately finance essential medicines for the poor and vulnerable. Another sub-indicator could reflect how rights-compliant national medicines policies and national essential medicines lists are (rather than only capturing their existence, as is done now in indicators 2 and 3). Sub-indicators of government spending on pharmaceuticals

(indicator 4) and childhood immunisation rates (indicators 7 and 8) should be disaggregated by wealth quintile, geographic location, and other common grounds of discrimination.

Data for indicators of State effort and results (i.e. government spending on medicines, indicator 4; availability of medicines, indicators 5 and 6) were scarce for many countries, and sometimes of questionable quality. These indicators are valuable snap-shots of government action and patient-level access in the health facilities surveyed. Coordinated efforts are needed to enhance the monitoring and reporting of these indicators in future research.

Is there a relationship between performing well on the eight indicators of access to medicines and commitments to medicines in domestic law and policy?

Unfortunately, we were unable to examine a possible relationship between commitments codified in domestic law and policy (Chapter 3) and country performance on the indicators (Chapter 4) due to a lack of data for the indicators (see Reflections on methodology and Future research sections below).

What implications do these findings have for universal health coverage and sustainable development?

This thesis responds to the dearth of right to health language in the SDGs, and particularly in goal 3 for health. (15–17) We illustrated how the existing UHC monitoring indicators for access to medicines should be adapted to reflect and measure the realisation of human rights, through the use of right to health indicators. Moreover, we demonstrated how governments have embedded human rights language directly into domestic law and policy for access to medicines on the path to UHC. (15) In other words, we offer researchers and policy makers the tools and the examples to introduce a human rights approach to access to medicines into national legal commitments and actions towards SDG Target 3.8.

Reflections on the methodology

This thesis is a multidisciplinary inquiry at the crossroads of the legal and health sciences. It included a normative analysis (Chapter 2) and empirical studies (Chapters 3-5). While this thesis has drawn from the strengths of both disciplines, it also encompassed some of the respective weaknesses that we addressed in the following ways.

In the normative studies in **Chapter 2**, we adhered to the pillars of doctrinal analysis by relying on authoritative legal texts and seeking coherence between legal sources, which are ratified international treaties and non-binding General Comments and Statements by treaty bodies. (18) For example, all sub-sections of Chapter 2 consistently drew arguments from the ICESCR, the International Covenant on Civil and Political Rights (ICCPR, to a lesser extent), and authoritative General Comments and Statements by the Committee on Economic, Social and Cultural Rights. We argued for a coherent interpretation of core obligations through the scope of reasonableness. We also demonstrated coherence between our interpretation of international human rights law and judicial reasoning in domestic medicines litigation (Chapter 2.1). Coherence between international human rights law and authoritative WHO policies for safe abortion and the Model List of Essential Medicines was a cornerstone of our work on essential medicines for medical abortion (Chapter 2.3).

Health scientists may be uncomfortable with the lack of systematic collection and evaluation of data in doctrinal analysis. (18) Some may see it as 'cherry picking' supporting arguments or laws from other jurisdictions without requiring an empirical indication of their frequency of use or impact on public health. We addressed this discomfort in Chapter 2.1 by substantiating our legal arguments for specific government actions through human rights law and with empirical evidence that those efforts support universal access to medicines.

Chapter 3 applied methodologies from the health sciences for policy analysis, where national law and policy were the subjects of study. There are four methodological considerations common to each study in these chapters.

Systematic data collection. The first consideration was the systematic collection of our primary data: domestic laws and policies for medicines. We sourced data from reputable, online repository of constitutional law (Chapters 3.1 and 5). In the absence of a global repository of national health law and policy for medicines (Chapters 3.2 and 3.3), we used an online structured snowball search (i.e. mapping exercise). We also crowdsourced electronic copies of the UHC laws and NMPs in the original language. In our mapping exercise, we used a template to compile in-depth descriptive country profiles detailing the national demographics, health system structure and function, and legislation in relation to UHC and access to medicines. Multilingual researcher assistants - often working in multidisciplinary teams from the Faculties of Medical Sciences and Law - were essential to develop these country

profiles. Research assistants fluent in the national language produced unofficial translations of legislation and policy when official English translations were not available. Where possible, our translations were peer reviewed by a second research assistant. We consulted with at least one local pharmaceutical policy expert per country to verify the accuracy, relevance, and completeness of our primary sources and country profiles. Despite our broad network, we could not locate peer reviewers from Algeria or Nigeria.

Reliability. A second consideration is the reliability of our findings, which is particularly relevant for our analyses that rely on researchers' readings of the legal text in Chapter 3. In all studies we located relevant passages in legislation and policy by using explicit search terms and through a manual search. In Chapter 3.1 we classified the legal text using a list of human rights principles and their definitions that was reviewed by all authors. (The 12-point policy checklist was too specific to be applied to the data in this chapter.) For our qualitative content analyses in Chapters 3.2 and 3.3, two researchers coded the excerpts from national medicines policies and UHC legislation using explicit definitions defined in the 12-point policy checklist and a coding matrix. The researchers deliberated any coding differences until consensus was reached.

Validity. The third consideration is validity or the extent to which our analytical tool (the policy checklist and coding matrix) measures the outcomes of interest. A health scientist would prove validity by showing that these 12 human rights principles are associated with other variables that we expect them to be related to. However, there is little research examining the relationships between human rights principles in domestic law or policy (besides constitutions) and national health or other social outcomes we may expect. (19) Therefore, we can only demonstrate the validity of our studies in Chapter 3 by showing that our measurement tool - the policy checklist - is derived from the essential medicines and human rights principles (proposed in Chapter 2) we seek to study.

Generalisability. The fourth consideration is generalisability or the degree to which these findings can be applied in other contexts. Generalisability depends on the sampling rationale, or which countries we studied and why.

We took a cross-section or global snapshot of domestic constitutional law (Chapter 3.1) and national medicines policies (Chapter 3.2) from as many countries as possible. Our study of constitutional law in 185 countries offers a global overview of medicines provisions from nearly

all 195 WHO Member States. The limited availability of national medicines policies resulted in a greater representation of low and lower-middle income countries than upper-middle and high income countries. Therefore the trends we identify in national medicines policies may be more applicable to less affluent countries than to wealthier nations.

In Chapter 3.3 we purposively sampled 16 mostly low- and middle-income countries to investigate national UHC legislation. These 16 States share important characteristics to study the right to health in the context of UHC. They have a universal health coverage scheme, have ratified the ICESCR, and represent a diversity of legal traditions, income economies and world regions. Health scientists may consider the lack of random selection to be a weakness in this study. However, the 16 cases allowed us to investigate trends and develop hypotheses about legislating in the context of medicines through country comparison. (20,21) From a public policy perspective, other nations can locate relevant examples from this range of 16 countries, thereby facilitating possible policy 'transplants' to other jurisdictions.

Our study of access to medicines indicators in **Chapter 4** benchmarked progress at two time points (2008 and 2015) and describe changes over time. From a public policy perspective, our study builds on the 2008 report by the UN Special Rapporteur on the Right to Health as the baseline measure it was intended as. We reported indicator data from the most authoritative online datasets compiled by the Constitute Project, Health Action International's medicines pricing database, and WHO/UNICEF, among others. (22–24) While this data has its documented flaws, it remains the most reliable and updated information available for these eight indicators of access to medicines.

Due to our large sample size of 195 countries, we accepted a high degree of abstraction in order to investigate systems-level performance, which is a drawback of this design. (25) On the other hand, our comparison over time and geography did permit some statistical evaluation of relationships between variables.

We originally intended to use the results to identify the most improved countries in terms of access to medicines for further study. We hypothesised that countries scoring well on these eight indicators could serve as policy laboratories for our studies of domestic policy and legislation in Chapter 3. However, we lacked data for many countries, and also for some indicators such as government spending on pharmaceuticals and medicines availability. Consequently, our study on indicators did not enable us to identify good candidate countries with advanced UHC schemes where we could study laws and policies

for access to medicines. We then selected the 16 countries on the basis of the selection criteria mentioned above.

We intended the investigation of medicines litigation in Uruguay in **Chapter 5** to be a single-country test of our proposal to apply the standard of reasonableness to essential medicines (from Chapter 2.1). We chose Uruguay as a case study because the right to health is justiciable, its comprehensive UHC legislation includes a right to access medicines on a positive list (Chapter 3.3), and it has ratified the 2013 Optional Protocol to the ICESCR, which enshrines the standard of reasonableness to judge social rights realisation. Despite these promising conditions, we found that the Uruguayan Courts of Appeal pay no deference to the standard of reasonableness, preventing us from testing our proposal.

Policy implications and recommendations

This thesis developed a normative framework of essential medicines and human rights principles for State action on access to medicines. It also collected examples of how these principles are codified for essential medicines in national law and policy. It addressed the central research question:

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?

These results cannot be interpreted in a vacuum divorced from the domestic realities of human rights practice, health systems functioning, or social and political dynamics. In other words, these results do not suggest that legal strategies to improve universal access to medicines in low- and middle-income countries should be exclusively or excessively focused on the introduction of specific text into domestic law. Instead, we propose that legal principles and language - when they conform with human rights standards and WHO's policies for essential medicines - can be an important instrument for promoting equitable access to medicines. These results lead to the following recommendations for pharmaceutical policy stakeholders.

World Health Organization. WHO's guidelines for developing a national pharmaceutical policy and its Model List of Essential Medicines should be revised to reflect the standards in international human rights law (i.e. duty to seek international cooperation, and good governance principles such as transparency, participation, monitoring, or accountability for medicines affordability and access) and WHO's own policies in other fields (i.e. safe abortion). Given its authority and influence on Member States' pharmaceutical policy, WHO should

develop guidelines for national legislators to embed universal access to medicines into domestic legal text. These guidelines can take the 12 principles for essential medicines and human rights, and the examples of legal text from this thesis as a point of departure (see Annexes 1 and 2).

Several UN agencies, such as WHO and the Office of the High Commissioner of Human Rights, should develop guidance for domestic judiciaries ruling on medicines claims. This guidance should take the form of 'points to consider' in relation to human rights rather than fixed recommendations that can not respond to local contingencies. It is important to maintain flexibility when framing how States should discharge their right to health obligations. A degree of flexibility accommodates each jurisdiction's unique legal order encompassing a specific hierarchy of rights and authority of legal texts, and available resources. Nevertheless, this thesis demonstrates a need to inform domestic judiciaries deciding on medicines reimbursement about the key considerations from an essential medicines policy and a human rights perspective. A greater understanding of these global normative standards by judiciaries can enhance the rigour of their interpretation of right to health, and can result in more equitable patient care.

WHO should establish a comprehensive online repository where domestic health law and policy texts can be deposited and publicly consulted. This repository should include texts in their original language and translations in English. If required, WHO could establish a working relationship with higher education institutions training translators from around the world. These professionals may be willing to produce high-quality English translations for WHO's repository. To enhance human rights monitoring and reporting, we recommend that the repository encourage Member States to self-report on two indicators of access to medicines in domestic legislation (described in Chapter 4). This concise self-report can offer a snapshot of legal commitments to essential medicines. It is also less laborious than compiling or reading an entire country profile of domestic medicines law. Moreover, self-reports can be verified by consulting the full text legislation in the repository.

National Ministries of Health and legislators. National Ministries of Health should undertake their own monitoring exercise of national law and policy for medicines, using our 12-point policy checklist. Depending on the nature of the policy gaps/weaknesses and the stage of reform, they could be addressed through government policies or ministerial orders, or large-scale legislative reform. Here national legislators can also include the 12 principles for essential medicines and human rights

in relevant national legislation for medicines. Especially policy makers from less affluent countries can consult the example texts in this thesis when legislating for access to medicines. Legislators should ensure that the law includes both judicial and non-judicial accountability measures to enforce human rights and State obligations towards essential medicines. Moreover, national Ministries of Health should adopt indicators of access to medicines in line with our recommendations and those from the Lancet Commission for Essential Medicines Policies. Areas of deficiency should lead to a documented plan for improvements within a set timeframe.

Domestic judiciaries. Domestic courts should familiarise themselves with the right to health and its operationalisation in international human rights law, including other social rights standards, such as reasonableness. Equipped with this insight, judiciaries should ensure a consistent interpretation of the right to health. Due regard should be given to the concepts of essential medicines selection and progressive realisation (i.e., there is no immediate right to all available treatments but a duty to continuously and gradually expand access). Most importantly, when deciding on reimbursement claims judiciaries should question whether the State has in fact mobilised a maximum of its available resources to provide the medicine(s) in question. Such a reasonableness test should lead to a more objective and systematic assessment of State action.

Public interest, patient, and human rights advocates. Patients, consumers, and other public interest advocates should document and publish government performance on right to health indicators of access to medicines. Civil society groups representing or in contact with vulnerable groups can play an important role in collecting and reporting disaggregated statistics. Enhanced transparency and monitoring is needed to hold governments accountable to their legal commitments. These advocates can also leverage windows of opportunities to advocate for medicines policy reform when influential court cases are decided or progressive laws are passed.

Future research

The findings in our work mark a critical juncture for medicines law and policy making. For the first time they offer legal standards and model language to promote more affordable access to essential medicines for the most vulnerable and a life of dignity for all. Therefore, two areas of future multidisciplinary research emerge from this thesis.

First, we conclude that the eight right to health indicators of access to medicines have been useful and feasible, but also that they can be further strengthened and expanded. Future monitoring exercises should use these indicators as a rights-based screening tool for the commitment, actions, and results of national governments to access to medicines. The larger set of 24 indicators presented by the Lancet Commission on Essential Medicines Policies could then be used for further in-depth analysis and practical guidance for the implementation of national medicine policies. (3)

Second, we can leverage these findings to improve access to medicines in the future. Health scientists, health systems analysts and legal researchers should investigate the determinants / predictors, the implementation, the health impact, and the transfer of rights-compliant legislation and policy for medicines. These studies should document current practices, such as: What factors have led to embedding principles for essential medicines and human rights in domestic law and policy? How are these principles understood and implemented in national health systems? What is their impact on health system function, access to medicines, population health and equity? These topics can shed light on which determinants are important to cultivate in order to legalise human rights principles, and what their expected impacts are. Impacts may be quantified in terms of clearly defined outcomes (i.e. government spending on medicines, lower medicines prices and other systemic efficiencies, the affordability of medicines achieved by the State for patients and communities, and equity of access for vulnerable groups). Impacts may also be studied by social scientists in qualitative terms, such as the views of policy makers, healthcare professionals, patients, and other stakeholders.

Several specific questions emerge about the impact of rights-based legal text on public health practice. One question is: Does codifying a right to health including access to medicines in national law combined with legitimate boundaries to these entitlements (i.e. a right to access medicines on a positive list) result in more equitable access? This question tests the hypothesis arising from this thesis that embedding entitlements with reasonable boundaries could produce more consistent State action to provide essential medicines. This topic is also relevant for law and policy makers reluctant to codify health rights for fear of inducing or sustaining litigation for immediate access to any treatment regardless of its price.

The second question concerns the non-judicial accountability mechanisms (i.e. complaints procedures in health centres, patient

Ombudspersons, etc.) that we identified in domestic law and policy. Future research should ask: Do non-judicial accountability mechanisms effectively resolve illegitimate barriers to medicines access (i.e. unavailable and unaffordable essential medicines) and prevent or attenuate medicines litigation in domestic courts? This topic would offer further insight into how these provisions could most effectively be used. Specifically, studies can determine whether non-judicial mechanisms are capable of rapidly redressing health rights violations for patients and reducing the number of complaints that proceed to the courts.

From these topics scholars can move towards establishing guiding norms and standards (or 'best practices', as policy makers prefer) for navigating the black box of implementation. Drawing on the discipline of political science, further investigations are needed into models of governance that catalyse the translation of law and policy into practice.

From an international relations perspective, researchers could investigate how the 12 principles for essential medicines and human rights develop and move between international and domestic spheres, and between national jurisdictions. Future research can apply Finnemore and Sikkink's model of norm dynamics to study the emergence, international cascade, and acceptance of new norms by State actors. (26) A possible question is: How do the nascent or lesser established human rights norms investigated in this thesis (i.e. reasonableness) migrate from international law and global health discourse to domestic legislation and policy? Chapter 5 was designed to investigate this question in the context of domestic case law.

The examples of legal text in this thesis lend themselves to an investigation of legal 'borrowing' or 'transplantation'. The notion of transplanting legal concepts from the laws of one jurisdiction to another is a contested albeit documented phenomenon. Legal scholars approach legal borrowing cautiously. Different legal systems have different rules of procedure, histories, cultures, and normative standards that can complicate the comparison and interpretation of legal rules between jurisdictions. (27,28) From a public policy perspective, WHO and other advisory organs sometimes advocate that Member States follow a 'model law' to legalise some aspects of pharmaceutical regulation and other areas of health. (3) These different perspectives should collaborate for a robust investigation of the question: What are the conditions for principles for essential medicines and human rights to be successfully transplanted from one domestic jurisdiction to another? The results would establish the strengths and limitations, and necessary precursors for the success of an example law for medicines affordability and financing.

Conclusion

International human rights law imparts important principles that are commonly embedded in the text of national law and policy for access to medicines. These examples are tools to enforce governments' human rights obligations to provide essential medicines to the poor and vulnerable on the path to UHC. WHO should support rights-based legal reform for essential medicines by using these findings to develop guidelines for national legislators. In line with SDG Target 3.8 on universal access to essential medicines, national health policy makers should use these examples to codify legally-enforceable government commitments towards promoting medicines affordability and equitable financing.

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