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

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The normative framework for access to medicines

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What constitutes 'reasonable' state action on core obligations?

Considering a right to health framework to provide essential medicines

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Abstract

Universal access to essential medicines is both a core obligation under international human rights law and a key component of the Sustainable Development Goal (SDG) for health. In light of the high prices of some essential medicines and finite health budgets, how can States' core obligation to provide essential medicines be interpreted? We propose that the lens of reasonableness offers a deeper understanding of States' minimum core obligation in relation to resources. Enshrined in the Optional Protocol to the International Covenant on Economic, Social and Cultural Rights, the standard of reasonableness suggests that in the context of essential medicines, the right to health may be better fulfilled by applying uniform criteria to set the scope and texture of local minimum standards rather than a one-size-fits-all universal list of medicines. Drawing on authoritative guidance by the UN Committee on Economic, Social and Cultural Rights, this chapter selects four criteria to evaluate the standard of reasonableness: deliberate, targeted, and concrete measures to mobilise State resources; low-cost policy options; international assistance; and non-discrimination. The framework allows policy-makers, judges and civil society to assess States' satisfaction of their core obligations to essential medicines. Examples from domestic law and policy for access to medicines illustrate the potential definition, scope, and value of first three criteria for domestic legislators and judiciaries while depicting how such a consideration could be discharged in practice. This proposal is relevant for progressing towards the SDG target of universal access to essential medicines.

Introduction

High prices of essential medicines threaten patient access and the sustainability of health systems in developing and industrialised countries alike. This phenomenon warrants a thoughtful examination of the feasibility of realising States' core obligation to provide essential medicines under international human rights law. The minimum core was conceived by the United Nations (UN) Committee on Economic, Social and Cultural Rights (CESCR) as the absolute minimum necessary to achieve human dignity, upon which other aspects of rights should be built and progressively realised. (1)

Over the last two decades, a swell of domestic litigation for access to publicly-funded medicines revealed contradictory reasoning by the courts and confusion for patients with regard to core obligations. Divergent domestic application of right to health norms breeds disparate rights enjoyment. For example, the Constitutional Court of South Africa (CCSA) has deemed the need for lifesaving treatment to be insufficient grounds to warrant government-funded emergency care for some patients and not others. (2) Meanwhile the Colombian courts have consistently accepted claims for medicines if the patient's life is allegedly in jeopardy. (3,4) Apart from case law, domestic legislation codifies universal entitlements to a minimum core of essential medicines to varying degrees, if at all. While most aspects of the right to health are subject to differing domestic interpretation, divergent approaches to the understanding of core obligations are of greater consequence because they concern minimum duties that form the basis of the right.

Much medicines jurisprudence has interrogated allegations of discriminatory treatment and unequal allocation of resources while neglecting to examine the sufficiency of public resources. (2,5–7) Such short-sighted examinations presuppose that a State is in fact dedicating a maximum of its available resources to meet all therapeutic needs. It is akin to questioning whether the host has fairly divided the cake among expectant party-goers before asking if the cake was in fact made large enough to satisfy all celebrants. Not to explore the options to maximise resources and leverage efficiencies would be a disservice to the government's capacity to realise rights and to those who stand to benefit from a more targeted and efficient use of resources. At the same time, an emphasis on efficient spending de-prioritises therapies of high cost and low or uncertain benefit, calling into question the right to health of patients needing these treatments.

As we explore in this chapter, principles derived from the human rights framework can guide domestic adjudicators facing queries about how

to fairly and equitably distribute health resources. The human rights framework has been accused of being overly principled and reliant on vague notions of priorities that are divorced from and therefore incapable of adequately responding to the varied contextual domestic realities. (8) This critique is equally, and perhaps especially valid for questions around core obligations.

This chapter adds to existing literature on core obligations by suggesting that the lens of reasonableness offers a more consistent and comprehensive guide for both State action and rights enforcement in relation to resources. Enshrined in the Optional Protocol to the International Covenant on Economic, Social, and Cultural Rights (ICESCR), the standard of reasonableness is a flexible and responsive benchmark to assess State action to realise social rights. A landmark in the international enforcement of social rights, the Optional Protocol, entered into force in 2013, allows individuals to submit complaints that allege a violation of their right to health to an international quasi-judicial body empowered to issue recommendations for national governments. (9) The adoption of the Optional Protocol marked departure from a minimum entitlement, suggesting that in the context of essential medicines, the right to health may be better fulfilled by applying uniform criteria to set the scope and texture of local minimum standards. The Optional Protocol also signals the official endorsement of reasonableness as the threshold against which States' action to realise health rights will be judged.

Part 2 of this chapter examines CESCR jurisprudence regarding States use of a maximum of their available resources to realise core obligations and the implications of moving towards a reasonableness standard for State duties. This chapter selects four criteria from international human rights law and scholarship - the deliberate, targeted, and concrete measures criterion, the low-cost option criterion, the international assistance criterion, and the non-discrimination criterion- to form a framework to allow policy-makers, judges and civil society to assess States' satisfaction of their core obligations to essential medicines. These criteria are drawn from the CESCR's instructive 2007 Statement on a maximum use of State resources. (10) In Part 3, three framework criteria- deliberate, concrete, and targeted measures to mobilise domestic resources, low-cost alternatives, and international assistance- are explored in-depth as means to improve the sufficiency and efficiency of State resources. Examples from domestic law and policy for access to medicines illustrate the potential definition, scope, and value of the framework criteria for domestic legislators and judiciaries while depicting how such a consideration could be discharged in practice.

Building on the examples and explanation provided in Part 3, Part 4 argues for a minimum core framework for essential medicines, based upon the reasonableness standard and relevant criteria, as a universal litmus test of adequate State action.

Nature of States' obligations to essential medicines as part of the right to health

The content and boundaries of core obligations in relation to essential medicines must be examined within international human rights law and specifically the ICESCR, which marked a pivotal step in the protection of health rights. Elaborating on the right to health in the 1946 Constitution of the World Health Organization (WHO) and the 1948 Universal Declaration of Human Rights, the ICESCR framed the right to the highest attainable standard of physical and mental health as an unequivocal element of the human rights spectrum (article 12). In doing so, the international community built on the principle implicitly articulated in the Universal Declaration of Human Rights that health rights are interdependent, interrelated, and of equal value to other human rights.

The ICESCR described two prominent legal obligations on States to realise Covenant rights, which have been subsequently delineated by the CESCR in General Comment No. 3 (1990). On one hand, States have an immediate obligation to take "deliberate, concrete and targeted" steps to meet Covenant obligations "within a reasonably short time after the Covenant's entry into force". (11) Any and all steps States take must not discriminate against individuals on prohibited grounds. On the other hand, States also bear an obligation to achieve results or to progressively realise the rights in the Covenant. This concept recognises that the depth and breadth of social rights can not be fully achieved in a brief period of time. Thus, progressive realisation offers States the flexibility to choose their method, instruments, and pace to "expeditiously and effectively" achieve full realisation of rights. (11)

States are not to misinterpret this latitude as permission to delay rights realisation and to refrain from 'deliberately' retrogressive action that results in denying the enjoyment of rights. (11,12) Either of these actions must be justified in the context of the available resources otherwise either move may constitute a violation of Covenant duties. (12,13)

Essential medicines provision as a minimum core obligation

Drawing on the CESCR's experience evaluating State reports, General Comment No. 3 carved out minimum core obligations incumbent on State parties for the enjoyment of basic essential levels of Covenant

rights. Core obligations indicate the basic minimum duties to realise social rights that must be achieved in order to give meaning to the entitlement against potentially limitless derogations of rights in the name of progressive realisation within resources. (14,15) States failing to satisfy the basic minimum must demonstrate that "every effort has been made to use all resources" at its disposal. (11) This effectively tempers the inviolability of a basic minimum level of health rights and legitimises derogations motivated by insufficient resources despite genuine intentions to use them. (12)

It was not until 2000 that the content and meaning of the right to health was further defined in the non-binding but authoritative General Comment No. 14 which in interpreting the right to health, brought essential medicines defined by WHO into the scope of the core obligations under this right. Also enumerated in the core was a duty to ensure access to health facilities, goods, and services on a non-discriminatory basis and with attention for the needs of the vulnerable and marginalised. (16)

Under the right to health, States bear obligations to respect, protect, and fulfil this right, including through the provision of essential medicines. This chapter focuses on the State duty to fulfil the right to health through positive measures, including the development and maintenance of a health care system through which medicines are continuously available in sufficient quantity, accessible (i.e. affordable, within physical reach, and free of discrimination), acceptable, and of assured quality. (16) States also have the duty to provide medicines to the impoverished and to individuals who cannot otherwise access them, such as prisoners or ethnic minorities. This action may necessitate a health insurance scheme for those who are otherwise unable to afford financial protection, particularly in order to realise the core obligations. (16) In fulfilling their responsibilities, States must "adopt appropriate legislative, administrative, budgetary, judicial, promotional and other measures" to achieve the right to health. (12,16)

Curiously, the CESCR's interpretation of the minimum core under the right to health critically departs from the foregoing notion that its achievement may be resource-dependent. General Comment No. 14 describes minimum core obligations as 'non-derogable', rejecting the notion that State's non-compliance may be defensible. (16) However, in 2008 the CESCR returned to its initial view in General Comment No. 19 on the right to social security. Derogations from the core may be justified by a lack of available resources, provided that the State party demonstrates all efforts have been made with a maximum of available

resources to realise its obligations. (12,17)

General Comments No. 19 (social security) and No. 22 (sexual and reproductive health) also confirmed essential medicines are a part of the State's minimum core duties to these rights. (17,18) In relation to social security, the CESCR affirms that achieving these obligations will necessitate a non-contributory scheme for universal coverage of those who cannot afford to purchase insurance. (17) Recognising that retrogressive measures may be inevitable, the CESCR requires States to demonstrate full use of a maximum of their available resources. Specific points of assessment raised by the CESCR in these authoritative interpretations include a "reasonable justification for the action", a comprehensive examination of the alternatives, whether "the measures were directly or indirectly discriminatory", the temporal nature of the measures, and protection against disproportionate effects on the disadvantaged and marginalised. (17) This justification not only incorporates the concept of reasonableness, but also begins to resemble some of the criteria proposed by the CESCR to evaluate it.

Essential medicines: A flexible concept

Essential medicines are arguably the most precise element of the minimum core as they refer to a WHO concept that gives rise to a finite Model List of Essential Medicines. However, this precision is illusive. WHO's Model List is intended to be further tailored by domestic governments to the local context of disease, infrastructure, and capital, resulting in a national list that is flexible and responsive to local contingencies. (19)

The broader health rights discourse illustrates that basic entitlements better serve functional public health intents and human rights objectives when entitlements are fluid rather than fixed concepts. (1) A prescriptive list of essential medicines would be excessively determinate and insufficient to secure rights realisation in different geographies and populations afflicted by dissimilar diseases. Instead, a minimum core should be seen as a concept to be given domestic content using public health and human rights principles, rather than as offering a finite and universal list of medicines.

A reasonableness standard emerges in domestic law

In 2000, the *Grootboom* ruling by the CCSA- a milestone social rights piece of jurisprudence- laid bare the indeterminacy and impracticality of enforcing minimum core obligations. In *Grootboom*, the CCSA dismissed arguments for the constitutional application of minimum core obligations owing to its lack of definition in international law and

the Court's lack of competence to give content to the core. (2,15,20) Instead, the Court condoned confining a State's responsibility to acting within its available resources. In place of a minimum core, the court affirmed a reasonableness standard whereby "the respondents have a right to reasonable action by the state in all circumstances and with particular regard to human dignity". (2,21) The Court held that the State must adopt a reasonable policy that is consistent with the duty to progressively realise rights and reduce barriers to rights realisation. (2,21) Later, in the *Treatment Action Campaign* case, the court definitively rejected a minimum core approach, and instead the CCSA determined that the reasonableness standard was contravened by the government's restrictions on the provision of prophylactic anti-retrovirals to HIV positive pregnant women before child birth. (5,20)

The standard of reasonableness is viewed by some as a retreat from minimum core obligations, and as such, the rise of indeterminate duties that may evade enforcement with certainty. (15,22) A core offered a fixed minimum of efforts and of results- a line in the sand to which States could be held to account. Reasonableness not only threatens to dismiss the minimum threshold of rights achievement, but also risks predicating social rights realisation on available resources. Commentators worried that the latter danger may prove to be an impossible standard to surmount, particularly in the extremely low-resourced settings where State action is needed the most. (15,23) Moreover, the reasonableness threshold could be met through State efforts towards progressive realisation of core obligations irrespective of the outcome and actual rights enjoyment. This danger is emblematic in the *Mazibuko* decision in South Africa "where the Court found state water policy reasonable, despite recognising that 100,000 city households still lacked access to the most basic water supply." (15,24)

On the other hand, scholars argue that a reasonableness standard can enhance State compliance with and accountability to social rights. Reasonableness can achieve this by contextualising responsibilities to the local reality of policy priorities and resources. In other words, a reasonableness standard is "a measure of compliance with the obligation of progressive realisation". (21) Bruce Porter explains:

> Resource constraints or limits on institutional capacity may justify certain limits to the immediate enjoyment of socio-economic rights, but available budgets and institutional capacity also create obligations on the state to utilise this capacity reasonably in accordance with the priority that must be accorded to human rights. (21)

In this way, reasonableness enhances the specificity of a State's duties, arguably crafting a clearer picture of State obligations than is found in international human rights law. Moreover, Lisa Forman has argued previously that the South African jurisprudence may illustrate that a reasonableness standard does similar work to the minimum core "to the extent that it forces courts to focus on basic and urgent needs of the most vulnerable, marginalised, and poor people in society". (15)

International law transitions to a reasonableness standard

Following much deliberation, in adopting a reasonableness standard, the CESCR now effectively condones a softer approach to enforcing minimum core obligations in the Optional Protocol, which enables the international justiciability of Covenant rights and creates another avenue for their normative development. (15) It is important to note that State commitment to the Optional Protocol is voluntary and only claimants in the 23 ratifying countries (to date) may submit a complaint. Some may argue that the few State parties to the Optional Protocol limit its global applicability and its potential to advance the enjoyment of health rights. Nevertheless, the normative content of the Optional Protocol and its supporting statements can be considered to mark the CESCR's desired 'direction of travel' for social rights interpretation and enforcement globally. The Optional Protocol is therefore an authoritative landmark on the path of social rights adjudication, offering guidance to domestic judiciaries more generally, regardless of the current number of signatories who can make use of the specific complaints mechanisms. (14)

In a new era under the Protocol, fulfilling social rights is contingent upon whether the State has taken sufficiently appropriate measures within the limits of its maximum available resources. (14,25) In doing so, the reasonableness standard further and critically departs from the briefly held notion of core obligations as inviolable, reverting to the earlier suggestion that there may be acceptable circumstances in which States' failure to realise a minimum standard of rights enjoyment is justified. Bruce Porter describes this novel examination as follows:

> Reasonableness is a contextual inquiry into the content of Covenant rights in particular circumstances, attending equally to both the voice and experiences of claimants, and to the realities, restraints, and difficult choices faced by governments. What is reasonable will depend as much on the nature of the interest at stake and the unique circumstances of the particular claimant or group, as on budgetary constraints, competing needs and policy rationale presented by the state. (21)

The contours of the reasonableness standard are still being drawn in legal practice. To date, the most instructive criteria for assessing reasonableness are outlined in the 2007 CESCR Statement on The obligation to take steps to a "maximum of available resources". (10) The criteria in the Statement have since been applied to a limited number of complaints under the Optional Protocol. (26,27) To date, the 2007 Statement remains the most instructive and authoritative account of points to consider when assessing whether States have taken adequate or reasonable measures within their available resources under the Optional Protocol. Selected considerations include (emphasis added):

> (a) the extent to which the **measures taken were deliberate, concrete and targeted** towards the fulfilment of economic, social and cultural rights;
>
> (b) whether the State party exercised its discretion in a **non-discriminatory** and non- arbitrary manner;
>
> (d) where several policy options are available, whether the State party adopts the **option that least restricts Covenant rights**; (10)

The 2007 Statement also includes a second list of objective criteria to assess whether resource constraints may justify regressive action. Criteria for evaluating retrogressive measures relevant to this chapter include (emphasis added):

> (b) the severity of the alleged breach, in particular whether the situation concerned the **enjoyment of the minimum core content** of the Covenant;
>
> (e) whether the State party had sought to identify **low-cost options**; and
>
> (f) whether the State party had sought **cooperation and assistance** or rejected offers of resources from the international community for the purposes of implementing the provisions of the Covenant without sufficient reason. (10)

Framework of assessment

This chapter selects four salient criteria from among those enumerated in the CESCR's 2007 Statement. Two criteria, the principles of deliberate and targeted measures, and non-discrimination, are invoked by the CESCR to assess whether States have reasonably fulfilled their duty of conduct in as far as their resources permit. Two additional criteria, the duties to seek low-cost alternatives and international assistance, are

proposed in the 2007 Statement in relation to retrogressive measures. Although the CESCR suggests that these criteria be applied in different contexts, this chapter proposes to compile these four criteria into a single framework to evaluate State action to provide essential medicines as part of core obligations.

It is notable that the core obligations only appear in the CESCR's statement in relation to regressive measures, and not in relation to reasonableness. This revelation could be interpreted as undercutting the core by using it as a negative bar to retrogression rather than a positive threshold for State action. However, evidence suggests that this is not the definitive location of the core obligations within the reasonableness assessment.

First, General Comments subsequent to the 2007 Statement continue to embrace core obligations as a fundamental element of social rights realisation. If the core obligations were to definitively be relegated to bar retrogression, it would be expected that their formulation would take a significant departure from that in earlier General Comments. However, core obligations are not being rewritten in subsequent CESCR jurisprudence. Ensuring minimum essential levels of Covenant rights as a matter of priority is a key State duty in General Comments Nos. 14 on health (2000), 19 on social security (2008), and 22 on sexual and reproductive health (2016). (16–18)

Second, the principles of non-discrimination and international assistance are both explicitly triggered in the minimum core. Non-discrimination is espoused by the CESCR throughout its jurisprudence on core obligations and again in relation to the reasonableness of States' action within resources. Bruce Porter describes this affirmation as:

> [I]n the CESCR's view, all reasonable strategies must be informed by an equality framework that prioritises the needs of disadvantaged groups, and ensures protection from discrimination. States have an immediate and unqualified duty to ensure both formal and substantive equality in the implementation of policies. (21)

In addition, multiple General Comments identify international assistance and cooperation as a duty of affluent nations in relation to the core duties of less affluent nations.

Third, taking deliberate, targeted, and concrete measures towards the full realisation of the right to health is an immediate legal obligation on States, and therefore of comparable priority to the core obligations. (16)

Fourth, the language of the 2007 Statement indicates that the criteria are discretionary and for use on a case-by-case basis. (10) In this document, the CESCR suggests that in any analysis of reasonableness, these criteria are elective and provisional; they may be complemented by other criteria or disregarded if not applicable to the case at hand. Similar to this observation, the 2007 Statement forwards analogous criteria to evaluate reasonableness and regression. For example, adopting the least restrictive policy option (point 8(d)) as a reasonable state measure is comparable with identifying low-cost options (point 10(e)) to counter retrogressive action. Both criteria seek to secure Covenant rights to the greatest degree and in the least costly or otherwise restrictive manner possible. The emerging reasonableness standard and continued salience of the minimum core therefore permits a flexible application of the CESCR's criteria of assessment.

This chapter examines the first three criteria with specific application to essential medicines by a) taking deliberate, concrete, and targeted measures to mobilise sufficient domestic resources, b) seeking low-cost options and c) pursing international assistance. Giving shape and content to these matters is the main purpose of this chapter and will be discussed in following section (Part 3). The three criteria are each introspective examinations of government action; they query the adequacy of State efforts in the context of its capacities, independent of a specific medicines user. Although the fourth criterion, non-discrimination, is an essential part of the framework for assessing State action, it is more outward looking than the former criteria in that it seeks to nuance and balance State efforts by considering the circumstances of the individuals it is affecting. Refining the assessment of non-discrimination in relation to State resources requires a deeper analysis of human rights principles and precedents beyond what can be accomplished in this chapter; it is an important avenue of future research.

Evaluating a maximum of available resources

Realising universal access to essential medicines is frustrated by insufficient resource allocation, inefficient spending, and a dearth of solidarity within the international community of States. On a global scale, universal access to a basket of essential medicines is estimated to cost between US$77 - $152 billion annually. (28) By comparison, IMS Health uses pharmaceutical sales that forecasts global spending in all markets and by all payers to reach $1.4 trillion in 2020, exceeding this estimate several times over. (28,29) This data suggests that the international community as a whole already allocates sufficient spending to purchasing medicines. However, inefficient prioritisation and a lack of

political will to redistribute funds for basic essential medicines impede universal access. (28) In response to these challenges, the following sections will examine whether States have taken reasonable measures to maximise their available resources, specifically by a) taking deliberate, targeted and concrete measures to mobilise sufficient domestic resources, b) by seeking the lowest-cost therapeutic options, and c) by pursuing international cooperation to provide core essential medicines

Duty to take deliberate, targeted and concrete measures to mobilise sufficient domestic resources

Human rights law indicates that appropriate budgetary measures are of paramount importance for the full realisation of the right to health. (12,16) By extension, sufficient public spending on essential medicines is imperative for States to meet their core obligations. 'Insufficient expenditure' on healthcare that deprives individuals, especially the vulnerable or marginalised, of enjoying their health rights is a clear violation of the right to health. (11,16) This pillar of human rights law is echoed in the *Grootboom* decision in which the CCSA found that the government should not be required to do more than its resources permitted. (2,15) The CCSA recognised that "[e]ffective implementation requires at least adequate budgetary support by national government." (2) It stands to reason that 'adequate' financing must first be achieved before any alleged resource limitations can be assessed. However, the question remains: What scale of investment constitutes deliberate, targeted, and concrete measures for essential medicines provision?

Moving beyond abstract principles in human rights law, political commitments and technical analyses can give shape to budgetary measures for core obligations. Widely acknowledged as a paramount political instrument for health financing, the Abuja Declaration endorsed in 2001 committed members of the African Union to allocate 15% of their gross national product to improve the health sector. (30) A decade later, WHO reports that although 26 of the 46 African nations had increased government spending on health, Tanzania was the only country to achieve the 15% target. (30) However, a deeper analysis of the budget allocation for pharmaceuticals is needed to shed light on core obligations.

Much debate has ensued among public health experts about the potential cost of supplying a basic minimum package of medicines. (31) In 2016, The Lancet Commission on Essential Medicines Policies produced a first-ever estimate of the financing needed to afford a universal package of basic essential medicines; the estimate ranged from US$12.90 to US$25.40 per capita per annum. (28) These figures translate to 25-42%

of spending on a standard universal health coverage (UHC) benefits package, costing $60 per person per annum, being allocated to essential medicines. (32) However, The Lancet Commission also showed that public spending in low- and lower-middle income countries fell short of US$12.90, missing even the lower limit of the medicines spending target in 2010 (year of latest available data). (28) Public financing lessens the need for patients to pay directly out-of-pocket for their medicines, attenuating their financial risk in the event of illness and preventing under-treatment. Failing to reach the minimum spending threshold inevitably leaves the most vulnerable without financial protection, jeopardising their access to medicines in the event of illness or threatening to push them (further) into poverty.

States may fail to meet minimum spending thresholds for two reasons. On one hand, governments may face a genuine and extreme insufficiency of resources, which would be a compelling argument in least developed countries. Legitimate resource limitations do not absolve States of their human rights responsibilities to augment their health financing. Later this chapter will explore how international cooperation and assistance can buoy public budgets for medicines and therefore are part of core obligations.

On the other hand, governments may have deliberately chosen to invest available public funds in non-health sectors. Ruth Sivard's groundbreaking statistical reports from 1974-1996 were the first to compare military and social spending by governments. (33) Robert Robertson quotes Sivard's reports, which illustrate unacceptable trade-offs where staggering military investment dwarfed that in health, such as by a ratio of 20:1 (Sudan, 1993) up to 38:1 (Pakistan, 1993). (34) In these examples, a lack of political commitment and other exogenous factors such as loan conditions from the World Bank and International Monetary Fund may inhibit greater health spending despite the existence of public funds. In recent years, Latin American countries with universal health coverage systems have had much more favourable ratios of military to health spending, such as in Chile (1:1), Mexico (0.2:1), Costa Rica (0:6.3) from 2007-2009, indicating that these governments are taking more effective steps to realise the right to health. (35) These ratios shifted over time as Latin American countries democratised following an era of military dictatorships. (35) Regardless of their motivation, States' core obligations remain unfulfilled as long as governments' domestic spending on pharmaceuticals falls short of the minimum expenditure for a package of essential medicines.

Duty to seek low-cost alternatives

The duty to seek low-cost alternatives was proposed by the CESCR as a point of consideration to judge the reasonableness of State investments for social rights realisation. The criterion itself has no authoritative interpretation in human rights jurisprudence. Despite the CESCR's endorsement, the low-cost option criterion remains riddled with uncertainties. How is the State to demonstrate it has considered more affordable alternatives? In this section, we draw on examples of access to medicines case law to suggest that the potential scope of this duty includes priority setting and price control mechanisms. These measures can use available resources as efficiently as possible, in line with governments' legal obligations in General Comment No. 3. (11)

Priority setting

Priority setting mechanisms are indispensable tools for selecting the most effective and least costly therapeutic options. In doing so, a ranking system highlights those medicines out of entire therapeutic repository that can offer the best health outcomes for the money spent. Prioritising treatments thereby progressively realises the right to health for the largest number of people at the lowest possible cost, freeing up public funding to expand the range of medicine and/or patient coverage. (36) Efficient spending is therefore one policy measure that reduces the need to ration effective treatments. (36)

Transparent and objective criteria (i.e. most often comparative cost-effectiveness), whose weights reflect the societal value each criteria is accorded, is an ethical and fair approach to rank treatments, endorsed by human rights scholars, health economists, and public health experts. (37) The Health Intervention and Technology Assessment Program of Thailand is an example of a body that successfully applies these principles to priority setting tools to reduce the prices of medicines. (28)

Despite its value, priority setting in health is not universally embraced. Barriers in low-resource setting may prevent developing countries from executing a detailed priority ranking; however, these challenges remain unjustified and warrant international cooperation to close this gap. More surprising is the fact that the US Medicare system and the Affordable Care Act do not yet consider the cost-effectiveness of the new therapies they subsidise. Spending on these programmes surges largely due to expensive, branded medicines. (38,39)

Price control

Exerting control over medicines prices is in line with States' duty to provide an environment that facilitates the discharge of human rights obligations of the private business sector. (16) Moreover, human rights law advises that private interests should not impede States' ability to realise their minimum core obligations to the right to health. (40,41) In other words, the right to health empowers governments to take steps to structure and regulate medicines prices in order to ensure all essential medicines are available at a price that the health system and patient can afford. (42) Controlling prices also contributes to the efficient use of available resources and reduces the need for trade-offs between cost containment and access. (43)

Domestic case law and policy illustrate two key messages: One, pricing policy measures concern the allocation of resources for rights enjoyment and therefore fall within the scope of the right to health. Two, abuses of pricing policies equate to a violation of the right. (44) This principle is illustrated in the Colombian case *Asociación Red Colombiana de Personas Conviviendo y Viviendo con el VIH y el SIDA, REOLVIH, y Otros v. Ministerio de Salud y Protección Social* (hereafter the Kaletra case). (45) This case concerns a government policy to reduce the maximum price of a common combination antiretroviral therapy lopinavir and ritonavir (Kaletra(R)) by 54-68% in response to its high price. (46) After the drug manufacturer failed to abide by the pricing order, Colombian civil society organisations filed an accion popular designed to protect collective rights to public health by requesting the government issue a compulsory license to lower prices. (46) A compulsory license is a legal mechanism by which a government may grant a third party or itself the right to produce an invention without the consent of the patent holder; it is a 'flexibility' of the Trade Related Aspects of Intellectual Property (TRIPs) Agreement Agreement, explained further below. (47) The Court held that the right to health has implications for public procurement and financing of pharmaceuticals, stating :

> [O]ne must take into account that the right to health has a compensatory character, and for this compensatory character to be effective, the right to health requires that budgetary and procedural aspects be made viable and balanced. (44,45)

Although the Court did not agree to issue a compulsory license, it did find that the pharmaceutical company and the Ministry of Health "threatened and violated collective rights to public health by maintaining the price of Kaletra above the international reference price". In its decision, the court implored the Ministry of Health to enforce its

pricing policy. Pricing policies are futile without means to enforce the rules on third party producers and to hold governments to account for executing their own policies. (48)

Use of intellectual property flexibilities

Human rights law, and specifically the right to health, justifies government intervention in the face of unaffordable patent-protected essential medicines. When price control measures fail to yield affordable essential medicines, human rights law and domestic policy illustrate that a government can use all means within its legal arsenal to provide essential medicines. (42) This principle is substantiated by General Comment No. 17 that identifies States "have a duty to prevent unreasonably high costs for access to essential medicines,... from undermining the rights of large segments of the population to health…". (40) This principle is illustrated by the policy proposal for government use of patented inventions instigated by the US State of Louisiana to reduce the price of new and highly effective direct-acting antiviral agents to treat hepatitis C, such as sofosbuvir (Sovaldi®) and ledipasvir/sofosbuvir (Harvoni®). (49) Sofosbuvir is therapeutically superior to other treatments for the chronic and debilitating infection Hepatitis C, however the patented medicine commands a high price: $85,000 per patient for a 12-week course of treatment. As a result, publicly subsidised healthcare in the US, such as Medicare Part D and the Affordable Care Act, strive to contain medicines spending by rationing treatment with Sovaldi to patients who meet certain criteria, such as sobriety requirements and/or an advanced stage of disease. (39) In Louisiana, the Medicaid program financed Sovaldi and Harvoni for 324 people in 2016, however, this figure is not even 1% of the 35,000 uninsured and Medicaid-dependent residents infected with hepatitis C who could benefit from government-funded treatment. (49)

The proposal from group of leading health and legal experts, including Kapczynski and Kesselheim, is to invoke the government use of patented inventions codified at 28 U.S.C. Section 1498. (50) Legal scholars Kapczynski and Kesselheim describe this provision as :

> [It] is a form of governmental immunity from patent claims: Under it, patent holders can demand royalties but cannot stop the government from producing the medicine or allowing others (in this case, generic manufacturers) to produce or import the medicine. (39)

Although some discounts and rebates have been granted, government programmes still struggle to finance the high-cost essential medicines,

and any price reduction would relax or obviate discriminatory treatment rationing and allow the medicine to benefit more patients. (39) Kapczynski and Kesselheim appeal to the government to consider invoking this provision when two criteria are met: a substantial disconnect between the costs of research and development and the price commanded by the patent holder, and the potential for considerable public health benefit from the medicine in question. (39) This example illustrates that government policy should consider the fullest use of intellectual property flexibilities when the prices of essential medicines are unaffordable.

In the context of adjudicating the fulfilment of a State's right to health obligations it is legitimate to consider whether the State used all available means, including TRIPs Flexibilities, to provide publicly-funded medicines. TRIPS Flexibilities, secured in the WTO's 2002 Doha Declaration, are policy measures (i.e. compulsory licensing discussed above) that sovereign governments may take in order to protect public health, and in particular access to medicines. (51) This principle is demonstrated in a groundbreaking case from Peru which precisely illustrates how a court, in this case the Constitutional Tribunal, can probe the reasonableness of a State's efforts to maximise its available resources, and specifically query domestic intellectual property rights (IPR) policy. (44,52) In *Azanca Alhelí Meza García v. Ministry of Health* (hereafter García) a woman requested comprehensive care including medicines to treat HIV on the basis of her inability to afford treatment and constitutional protection of the fundamental right to life and the social right to health, as well as supporting domestic legislation including the National Plan to Combat HIV/AIDS. (52) In contrast, the Ministry of Health argued that social rights, including health, are not fundamental but programmatic in nature, representing budget-dependent plan of action and, in this case, no allocations had been made in the national health policy. (52)

What is most striking is how the court decided to evaluate this claim to State resources. The courts acknowledged that the efficient provision of public health services involves and affects the life and integrity of patients. (52) Therefore, judicial claims to such services depends on:

> the severity and the reasonableness of the case, its link or effects on other rights, and the available State budget, provided that concrete actions can be proven for the implementation of social policies. (52)

Drawing on Art 2.1 of the ICESCR, the court asserts that progressive realisation must be accompanied "by concrete actions and reasonable

deadlines". (52)

The court then proceeds to declare:

> without questioning the health policy, per se, we consider it necessary to analyse the performance of the State in the present case, since it was alleged that the violation of the Complainant's rights endangered his own life. (52)

The court fully recognises that the legal question before it does not mandate an examination of the IPR and their exceptions established in international agreements, however, it sees this issue as being fundamentally related to the availability of resources to achieve social policy objectives and secure the right to life. To put this debate in context, in 2003, prices for adult first-line antiretroviral (ARV) treatment regimens in low- and middle-income countries were US $499 per year. (53) At that time less than 8% of the people who required ARVs could access them in developing countries. (54) Ultimately, the court concludes this section by mentioning that the challenges of providing essential medicines to treat diseases like HIV/AIDS and the rights and duties of the state of Peru as a WTO member justify a maximum use of the provisions and measures for a flexible interpretation of IP protection within the margins of the Doha Declaration. (52) The Doha Declaration affirms the right of national governments to implement and interpret the TRIPs Agreement in order to support public health, including through the use of TRIPs Flexibilities. (51) The court sets cautious boundaries to its recommendations and reinforces the responsibility of the State to prioritise collection and distribution of budgets, affirmed in domestic constitutional law. While the final decision carefully navigates within the realm of the legal questions posed in this particular case, the court precedes its findings with the point "[i]t is necessary then, to recommend concrete actions by the State for the satisfaction of these rights, through legislative actions or policy execution." (52)

Duty to seek international assistance & cooperation

Although States hold the primary responsibility to realise their core obligations, this duty is shared by the international community of foreign governments and other actors. (16,55) This duty is vested in CESCR jurisprudence, including as a point of consideration for judging the reasonableness of State action. However, the duty to seek international assistance lacks an instructive definition and boundaries for its implementation and enforcement. This section sketches the potential contours of the international assistance criterion by drawing on examples from domestic law and policy for access to medicines.

International cooperation and technical assistance from foreign governments and others is a significant strategy in the right to health toolbox to achieve a minimum essential level of rights enjoyment, including access to medicines. (16) Yet to date, most prominent domestic medicines litigation have neglected to evaluate the pursuit or receipt of international cooperation and assistance to meet the core obligations. (2,5)

The factual basis of *Mathew Okwanda v. Minister of Health and Medical Services and others* (hereafter Okwanda) before the High Court of Kenya lends itself to a hypothetical examination of how the international assistance criterion could be considered in legal practice. The petitioner, a 68 year old pensioner with diabetes mellitus and a terminal illness, was no longer able to afford the costs of his medication and care at government-funded health facilities. He claimed State support and provision of medicines on the basis of his right to health affirmed in international and domestic constitutional law. (7)

The court found no demonstrable violation of the petitioner's fundamental rights because the State had provided a degree of assistance at publicly run hospitals attended by the petitioner. (7) Nevertheless, a rich vein of potential legal questions could have been examined, such as whether the State's action fulfils its core duties or whether the principle of progressive realisation requires States to provide expensive treatment free-of-charge to the patient. (7,56) If any of these questions would come under closer judicial scrutiny, the reasonableness standard would provoke the question whether the State sought international cooperation or assistance to maximise its available resources. In this particular case, the international assistance criterion may have been a viable option to grow domestic health budgets given that Kenya's annual revenue ranks as a low-income country (in 2012). (57) In general, government expenditure on pharmaceuticals in low-income countries is, on average, demonstrably insufficient to afford a universal basic package of essential medicines. (28) Moreover, Kenya already received international funding to support other areas of healthcare. In 2012-2013, donors financed 72% of health spending on HIV/AIDS, 23% of total expenditures on tuberculosis care, and 18% of all spending on reproductive health. (58) Considering that pharmaceutical treatment accounts for a high proportion of all health spending, these factors suggest that the Kenyan government would be an ideal candidate for international donor funding to buoy its pharmaceuticals budget prior to claiming insufficient resources to provide essential medicines.

Meaningful international assistance may take other forms besides economic support. Exchanging information, cooperative assessments of medicines for reimbursement, and pooling negotiating power for bulk purchasing are forms of international cooperation that can leverage economies of scale and may create downwards pressure on pharmaceutical prices. The facts of a case heard by the Latvian Constitutional Court can be used to illustrate how international cooperation may serve to ease the tension between limited health resources and expensive therapies. In the *G.Z.* case a patient with Gaucher's disease, a rare debilitating condition, sought full reimbursement for the effective but expensive treatment imiglucerase (Cerezyme®). (6) The claimants based their arguments on the constitutional right to health protection and basic medical care for everyone. In this case, the court accepted at face value the State's assertion that its resources were too limited to accommodate full reimbursement of this medicine. (59) An alternative examination, inspired by the reasonableness standard, could investigate whether international assistance had been sought to maximise the available resources. Considering that Latvia is among the smallest EU Member States, it could conceivably cooperate with its neighbours in a number of ways including to negotiate medicines purchases in bulk in order to reduce prices.

Similar steps were taken in 2016 by the European Union Member States, Belgium, the Netherlands and Luxembourg, and later Austria, which pilot the 'Beneluxa' Cooperation for Medicines to exchange information, evaluate the products for reimbursement, and jointly negotiate medicines prices for government reimbursement of expensive medicines. (60) Representatives of those national agencies credited the collaboration as bolstering their leverage opposite pharmaceutical manufacturers by offering them guaranteed access to larger markets, and increasing the likelihood of patient access. (61) Following price negotiations between the drug maker and the Beneluxa Cooperation in 2017, the Dutch and Belgian governments decided not to reimburse the expensive medicine for cystic fibrosis Orkambi (Vertex®). (60) The governments concluded that although Orkambi has added therapeutic value over standard care, if they reimbursed its high cost then their health systems would be precluded from financing other more cost-effective medicines. (60) This example illustrates that although joint negotiations and purchasing has the potential to lower medicines prices, the State must always be mindful of the opportunity costs of funding expensive medicines that can trigger or exacerbate inequalities between patients.

In summary, the CESCR's consideration of international cooperation and assistance instructs governments to use this method to maximise

their resources and fulfil their obligations under a reasonableness standard.

Conclusion

CESCR jurisprudence on the right to health has shifted from an inviolable minimum core to a core that is subject to the State's available resources under certain conditions. This chapter proposes that the reasonableness standard, with its explicit criteria for evaluation, give content to States minimum core obligations, specifically to provide essential medicines. Drawing on the CESCR's instructive statements, we propose a framework of assessment in which States must first mobilise sufficient domestic resources, apply low-cost policy options and pursue international assistance in order to maximise their available resources. Mobilising sufficient domestic resources requires committing adequate government financing to provide at least a basic package of essential medicines to all. Low-cost policy options entail maximising efficiencies, such as medicines provision through universal health coverage, priority setting for reimbursement, the use of low-cost generic medicines and TRIPs Flexibilities. International assistance pertains to both financial assistance and technical support through information sharing and resource pooling. Thereafter, although not explored in detail in this chapter, States must exercise non-discrimination when allocating public funding to provide essential medicines.

This framework can guide the interpretation State duties and adjudication of State action to provide essential medicines within available resources. In doing so, the framework respects the appropriate separation of powers and unique institutional capacity bestowed on each entity, albeit without ceding undue deference to government in its distribution of health resources.

This framework of assessment offers a novel response to ongoing theoretical and practical challenges in matters of core obligations. First, it responds to criticisms that human rights law may be overly principled and vague by successfully distilling the core obligation to provide essential medicines into explicit and tangible legal duties in Part 2, which in turn are delineated by definition, scope, and corresponding domestic policy options in Part 3. In this way, principles of international human rights law respond to the needs of domestic courts and law makers, and forge the bridge between human rights law and policy. Second, social rights draw out the inherent tension between individual and collective rights, and the salience of just resource allocation. With the rise of the standard of reasonableness in the Optional Protocol, the relative importance of efficient State action has been enhanced within

human rights jurisprudence. The framework of assessment navigates this tension using the under-acknowledged principles of sufficiency and efficiency in the field of human rights that manifest here as the duty to maximise resources. Third, applying a reasonableness approach to understand minimum core obligations signals a turning point in the conceptualisation of social rights. The more reasonableness is embedded in the interpretation and enforcement of social rights, the more legitimate it will become as a global social rights norm. Therefore our approach may serve to grow the acceptance and use of reasonableness in social rights jurisprudence, which could result in more consistent protection and promotion of social rights.

The four criteria- measures to mobilise State resources, low-cost policy options, international assistance, non-discrimination- offer a granular roadmap for rights realisation to domestic governments and advocates, and contribute formulae for domestic and international justiciability. Should this happen, then in many countries it will symbolise an improvement in pharmaceutical policy making and rights enforcement for patients.

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