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

Perehudoff, Sammi-Jo Katrina

# Normative framework

2.4

In this chapter we briefly explain the development of the normative framework that serves as the assessment tool that we apply in our analysis of domestic laws and policies in Chapters 3.2 and 3.3.

## WHO policy and legal frameworks

We identified overlapping principles in WHO's policies for essential medicines and international human rights law that are relevant for access to medicines, particularly their affordability and the financial protection of vulnerable groups.



We identified principles in the following policies for essential medicines:

- Developing and Implementing a National Drug Policy, second edition (1),
- Equitable Access to Essential Medicines (2),
- Six Building Blocks of a Health System (3),
- Access to Medicines from a Health Systems Perspective (4),
- Good Governance for Medicines programme and Model Framework (5).

We selected principles from international human rights law that concern States' obligations towards social or health rights, the core obligation to provide essential medicines, and/or rights related to good governance. These legal instruments include:

- International Covenant on Economic, Social and Cultural Rights (6),
- International Covenant on Civil and Political Rights (7),
- Optional Protocol to the International Covenant on Economic, Social and Cultural Rights (8),
- publications from the United Nations Committee on Economic, Social and Cultural Rights that interpret the scope and content of Covenant rights and obligations, including:
    - States duties under the Covenant (General Comment No. 3 (9)),
    - the right to health (General Comment No. 14 (10)),
    - authors' and inventors' rights in the context of access to medicines (General Comment No. 17 (11)),

- criteria to evaluate the reasonableness of State action in relation to available resources (2007 Statement (12)),
- the right to social security (General Comment No. 19 (13)),
- the right to sexual and reproductive health, as part of the right to health (General Comment No. 22 (14)).

### Principles for access to medicines in national law and policy



We identified overlapping principles for access to medicines through a multi-step, iterative process. The policy checklist was developed by two researchers (Katrina Perehudoff and Nikita V. Alexandrov) who shortlisted the relevant principles from source documents, independently piloted the short list on UHC laws to determine their applicability and adequacy, and revised the short list. Three right to health and pharmaceutical policy experts (Hans V. Hogerzeil, Brigit Toebes, and Ellen 't Hoen) reviewed the short list to ensure the principles were relevant and correctly defined.

Our final normative framework identifies 12 principles categorised in three domains (described below): legal rights and obligations, good governance, and technical implementation. The domains correspond to the structure-process-outcome framework for monitoring and evaluating the realisation of human rights by the UN Office of the High Commission for Human Rights. (15) Below we describe the principles assigned to each domain.

#### *Legal rights and obligations*

The 'Legal rights and obligations' domain reflects the essence of States' overarching right to health commitments that should be legally recognised in domestic law and policy. This domain consists of the individual entitlement to the highest attainable standard of health (principle 1) and the State's core obligation to provide essential medicines (principle 2). We developed these two principles throughout Chapter 2.

These principles are primarily informed by the International Covenant on Economic, Social and Cultural Rights (ICESCR, art. 12) and the authoritative interpretation of essential medicines as a 'core obligation' of States in multiple General Comments. (6,9,10,13,14) To date, the only reference to human rights in the context of pharmaceutical policy is found in the Access to Medicines from a Health Systems Perspective framework proposed by Bigdeli and colleagues. (4) It includes a weak reference to human rights as a 'value'.

### *Good governance*

The 'Good governance' domain captures principles to guide the processes of State action (i.e. How should States act?). This domain consists of transparency (principle 3), participation and consultation of beneficiaries (principle 4), monitoring and evaluation of State commitment, efforts and results (principle 5), and accountability and redress (principle 6).





From a legal perspective the International Covenant on Civil and Political Rights (ICCPR) offers a firm foundation on which to ground three of our four Good governance principles. (7,16) Transparency corresponds to the right to freedom of expression, including to seek, receive, and impart information (art.19). (7,16) Participation relates to the right to take part in public affairs (art. 15). (7,16) Accountability is derived from the right to an effective remedy for rights violations (art. 2). (7,16)

In addition, the Committee on Economic, Social and Cultural Rights recognises in General Comment No. 14 that "good governance is essential to effective implementation of all human rights, including the realization of the right to health" (§55). (10) All four principles are reflected in General Comment No. 14 of the ICESCR. (10) The participation of beneficiaries is required in relation to health-related decision making and processes for health policy, programming, and the organisation of health facilities goods and services. (§11,17,54) (10) The monitoring and evaluation of State action for the realisation of health rights is a component of the right to health (§57-58). (10) Less specific are references to transparency and accountability in General Comment No. 14. A national health strategy and plan of action should be based on the principles of accountability and transparency (§43(f),55). (10) This concept creates a platform on which transparency and accountability can be related to State strategies and plans to realise the right to health.

From a governance perspective, transparency, participation, and accountability emerge as common elements from the definitions of good governance provided by the International Development Association, the United Nations Development Programme, Office for the High Commissioner of Human Rights, former UN Commission on Human Rights, and other institutions (i.e. international financing institutions). (16) According to a governance approach, monitoring is not an explicit principle because it is considered to be a component of accountability.

From the perspective of WHO policy, we can look to the Good Governance for Medicines programme and model framework. (5) This

framework advances 10 components (based on ethical principles) to guide laws, policies, and procedures to improve the management of and reduce corruption in pharmaceutical systems. Of the 10 components in this Model Framework, several corroborate our four Good governance principles. Transparency corresponds with the principle of "transparent and accountable regulations and administrative internal and external audits" in which transparency is vaguely referenced (p.15). (5) Participation of beneficiaries is not strongly referenced in WHO's Good Governance for Medicines framework. It can be related to "collaboration among anti-corruption and transparency initiatives" that includes civil society (p.15). (5) Monitoring is captured by the principle of "management, coordination, and evaluation" (p.16). (5) Accountability is contained in the ethical principle 'accountable trusteeship' in which public servants are stewards of public resources and therefore accountable to the society they serve (p.12). (5)



### *Technical implementation*

The 'Technical implementation' domain specifies the intermediate steps or policy measures that States should take to discharge their right to health obligations in the context of medicines (i.e. What should States do?). In Chapter 2.1 one of the authors (Katrina Perehudoff) and Lisa Forman extensively examined how some of these principles are derived from international human rights law and WHO's policies. Perehudoff and Forman propose that 'reasonable' State action to provide essential medicines requires governments to:

- ensure sufficient public spending, which is at least the minimum amount required to purchase a basic package of essential medicines for all (principle 8),
- generate efficiencies by seeking international (technical) cooperation and (financial) assistance to support domestic essential medicines programmes (principle 10),
- implement spending efficiencies through price control and use the flexibilities to the Trade Related Aspects of Intellectual Property (TRIPs) Agreement when all other measures fail to yield affordable medicines (principle 11),
- observe non-discrimination in national pharmaceutical policy through the financial protection of vulnerable groups, among other approaches (principle 12).

In addition, two other principles arose from overlapping concepts in WHO's policies and international human rights law: the selection of

essential medicines (principle 7) and the pooling of user contributions to increase the resources available for pharmaceuticals (principle 9).

**Table 1. Normative framework for access to medicines in national law and policy.**

| Principles | Human rights principle | Source of law<br>Hard law is **bolded,**<br>soft law is *italicised* | WHO essential medicines policy | Developed in thesis chapters | Applied in thesis chapters |
|---|---|---|---|---|---|
| **Legal rights and obligations** | | | | | |
| 1. Right to health | Right to the highest attainable standard of health | **ICESCR art. 12**<br>*General Comment No. 14* | Human rights are a 'value'. (4) | Throughout | Throughout |
| 2. State obligation to provide essential medicines | Core obligation to provide essential medicines defined by WHO | **ICESCR arts. 2.1, 12**<br>*General Comment No. 3*<br>*General Comment No. 14*<br>*General Comment No. 19*<br>*General Comment No. 22* | | Throughout | Throughout |
| **Good governance** | | | | | |
| 3. Transparency | Transparency | **ICCPR art. 19**<br>**ICESCR art. 12**<br>*General Comment No. 14* | Information to assess service access and coverage, and publicly available price information for medicines. (1,3) Also an aspect of good governance for medicines. (5) | 2.2, 2.4 | 3.2, 3.3 |

| | | | | | |
|---|---|---|---|---|---|
| 4. Participation & consultation | Participation | **ICCPR art. 15**<br>**ICESCR art. 12**<br>*General Comment No. 14* | Collaboration and accountability of all health systems actors, and stakeholder consultation. (1,3) Also vaguely referenced in good governance for medicines. (5) | 2.4 | 3.2, 3.3 |
| 5. Monitoring & evaluation | Monitoring | **ICESCR art. 12**<br>*General Comment No. 14* | Achieved through explicit government commitment, indicator-based surveys, and independent impact evaluation. (1,3) Also a component of good governance for medicines. (5) | 2.4 | 3.2, 3.3 |
| 6. Accountability & redress | Accountability | **ICCPR art. 2**<br>**ICESCR art. 12**<br>*General Comment No. 14* | Accountability of all health systems actors. (3) Also a component of good governance for medicines. (5) | 2.4 | 3.2, 3.3, 5 |

| Technical implementation | | | | | |
|---|---|---|---|---|---|
| 7. Selection of essential medicines | (Assured) quality of health services (of the AAAQ) | **ICESCR article 12**<br>*General Comment No. 14* | Includes the essential drugs concept, procedures to define and update the national list(s) of essential drugs, explicit, evidence-based criteria that includes cost-effectiveness, and selection mechanisms. (1,2) | 2.3 | 3.2, 3.3, 4 |
| | Duty to adopt appropriate legislative, administrative, budgetary and other measures to a maximum of its available resources.<br><br>Core obligation to provide essential medicines as defined by WHO | **ICESCR arts. 2.1, 9, 12**<br>*General Comment No. 3*<br>*General Comment No. 14*<br>*General Comment No. 19*<br>*General Comment No. 22* | | | |
| 8. Government financing | | | Requires adequate funding and mobilising all available public resources and increase funding for priority diseases, and the vulnerable. (1–3) | 2.1 | 3.2, 3.3, 4 |
| 9. Pool user contributions | | | Medicines reimbursement with user charges is a (temporary) financing option. (2,3) | - | 3.2, 3.3 |

| | | | | | |
|---|---|---|---|---|---|
| 10. International assistance and technical cooperation | Duty to seek international assistance and technical cooperation | **ICESCR art. 12**<br>**Optional Protocol to ICESCR**<br>*General Comment No. 14*<br>*Statement by the CESCR the obligation to take steps to a maximum of available resources* | Includes the possibility of using development loans for medicines financing. (2) | 2.1 | 3.2, 3.3 |
| 11. Efficient and cost-effective spending | Duty for the efficient use of available resources | **ICESCR art. 2.1**<br>*General Comment No. 3* | Includes the efficient use of resources and affordable pricing through: price control; a pricing policy for all medicines; competition through generic policies and substitution; good procurement practices; price negotiation and information; and TRIPs-compliant measures such as compulsory licensing and parallel imports. (1–3) | 2.1, 2.2 | 3.2, 3.3 |
| | Duty to take appropriate steps to ensure that the private business sector is aware of, and consider the importance of, the right to health in pursuing their activities. | **ICESCR art. 12**<br>*General Comment No. 14* | | | |

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|---|---|---|---|---|---|
| 11. Efficient and cost-effective spending (continued) | Duty to prevent unreasonably high costs for access to essential medicines from undermining the rights of large segments of the population to health. | **ICESCR art. 15**<br>*General Comment No. 17* | | | |
| | Duty to seek low-cost policy options | **Optional Protocol to ICESCR**<br>*Statement by the CESCR on the obligation to take steps to a maximum of available resources* | | | |
| 12. Financial protection of vulnerable groups | Duty towards non-discrimination and attention to the vulnerable | **ICESCR arts. 9, 12**<br>*General Comment No. 14*<br>*General Comment No. 19* | Increase government funding for poor and vulnerable groups and reduce the risk of catastrophic health spending. (2,3) | - | 3.2, 3.3, 4 |

Abbreviations used in this table: art.= article; ICESCR=International Covenant on Economic, Social, and Cultural Rights; ICCPR=International Covenant on Civil and Political Rights; CESCR= Committee on Economic, Social, and Cultural Rights; WHO=World Health Organization; TRIPs=Trade Related Aspects of Intellectual Property; AAAQ=Availability, Accessibility, Acceptability, and Quality as elements of health services under the right to health.

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