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Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development

Compendium of good practices on access to medicines, vaccines and other health products in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health

Report of the Office of the United Nations High Commissioner for Human Rights

Summary

The present compendium, prepared pursuant to Human Rights Council resolution 50/13, contains an overview of good practices related to access to medicines, vaccines and other health products, including policies and interventions that can contribute to ensuring access to such essential health products.

Ensuring the availability, accessibility, acceptability and quality of medicines, vaccines and other health products requires a collaborative effort by governments, pharmaceutical companies, health-care providers and international organizations. Good practices include access-oriented management of intellectual property rights, strong regulatory frameworks and investment in research and development of new medicines and vaccines, including through public-private partnerships, and policies and measures that encourage the production of generic medicines.

I. Introduction

1. In its resolution 50/13, the Human Rights Council requested the Office of the United Nations High Commissioner for Human Rights (OHCHR) to submit to the Council, at its fifty-third session, a compendium of good practices on access to medicines, vaccines and other health products in the context of the right of everyone to the highest attainable standard of physical and mental health. The compendium will be complemented by an analytical study on key challenges to be submitted to the Council at its fifty-sixth session.

2. OHCHR would like to thank all stakeholders for their participation in the virtual expert workshop on good practices in ensuring access to medicines, vaccines and other health products held on 14 February 2023, and for their contributions in the preparation of the present compendium. Submissions received are available on the OHCHR website,[1] and will also inform the preparation of the comprehensive report on access to medicines, vaccines and other health products that is to be submitted to the Human Rights Council at its fifty-ninth session.

II. Human rights-based approach to medicine and vaccine equity

A. Human rights dimension of access to medicines, vaccines and other health products

3. The lack of access to medicines, vaccines and other health products[2] is a complex and multifaceted issue and a major obstacle to the realization of the right to health.[3] Ensuring access to medicines and vaccines requires a functioning health system that encapsulates the key elements of the right to health. As outlined by the Committee on Economic, Social and Cultural Rights in its interpretation of the normative content of the right to health, this includes ensuring that medicines and vaccines are available, accessible, acceptable and of good quality for all.[4] It also requires a collaborative effort by governments, pharmaceutical companies, health-care providers and international organizations. The purpose of the present compendium is to provide an overview of practices, policies and interventions that may contribute to improving access to medicines, vaccines and other health products.

4. The coronavirus disease (COVID-19) pandemic demonstrated once again the interconnectedness of human health, where the health of an individual living in one country has an impact on the health of a person in another country. Efforts to implement the right to health at the national level need to take into account the fact that decisions of States and businesses affect the rights of people in multiple jurisdictions. In the pharmaceutical sector, which has typically accounted for a significant portion of health budgets globally,[5] the pandemic generated extraordinary gains and continues to do so,[6] while access to life-saving COVID-19 vaccines has remained disturbingly unequal.[7]

[1] See https://www.ohchr.org/en/calls-for-input/2023/call-contributions-good-practices-ensuring-access-medicines-vaccines-and-other.

[2] The World Health Organization (WHO) has described "other health products" as including medical devices, diagnostics, protective equipment and assistive devices. WHO, *Road Map for Access to Medicines, Vaccines and Other Health Products 2019–2023* (2019), p. 2.

[3] See in particular WHO, *Road Map for Access to Medicines*.

[4] General comment No. 14 (2000), para. 12.

[5] Jillian Clare Kohler and others, "Corruption in the pharmaceutical sector: diagnosing the challenges" (Transparency International UK, 2016), p. 4.

[6] Esther de Haan and Albert ten Kate, *Pharma's Pandemic Profits: Pharma Profits from COVID-19 Vaccines* (Amsterdam, Centre for Research on Multinational Corporations, February 2023), p. 11.

[7] See A/HRC/49/35 and A/HRC/52/56.

5. While the pandemic has prompted innovation and cooperation, it has also exposed the significant fault lines in universal and equitable access to medicines and vaccines.[8] It has reconfirmed the significant impact that lack of access to medicine and vaccines has on a range of human rights, including the rights to health, to life, to non-discrimination and to development.[9]

6. Approximately 2 billion people have no access to essential medicines and 80 per cent of the world's population lives in countries with little or no access to controlled medicines for pain relief.[10] About 25 million children missed out on life-saving vaccination in 2021 alone as a result of the COVID-19 pandemic and associated disruptions that have strained health systems.[11]

7. The lack of equitable access to medicines, vaccines and other health products disproportionately affects certain groups, such as persons living in poverty, older persons, persons with disabilities, persons living with chronic illnesses, women and children. Without access to health insurance or social protection, persons living in poverty, older persons and migrants cannot afford even essential medications, including for managing chronic conditions. Women and children often experience a greater burden of disease than men, and may face additional challenges in accessing health care and medications.[12] Almost 1 billion children, older persons and persons with disabilities lack access to assistive technology, such as prosthetics, hearing aids and communication devices.[13]

8. The denial of access to essential medicines, vaccines and other health products creates or perpetuates discrimination and exacerbates existing inequalities in the realization of the right to health. Ensuring that the right to non-discrimination is upheld requires that essential medicines and vaccines are accessible to all. Governments have a primary responsibility to ensure that vaccines and medicines are available and affordable to everyone, and to address the underlying social and economic factors that contribute to health inequities and discrimination.[14]

9. While availability is a precondition for access, affordability is one of the dimensions of access. Up to 90 per cent of the population in low- and middle-income countries purchase medicines through out-of-pocket payments. A household that is forced to sell an asset, such as the family cow, or take children out of school to pay for medicines may be pushed into intergenerational poverty.[15] Other factors, such as gaps in local health systems and infrastructure, determine whether people have access to the medicines, vaccines and health products they need. Access also depends on procurement practices and the strength of national regulatory authorities. While access to essential medicines for non-communicable diseases is lower than that for communicable diseases, many medicines for treating non-communicable diseases have to be taken for life, and thus have a severe impact on household expenditure, pushing many families below the level of poverty.[16] Apart from being affordable and of good quality, medicines must also be safe. Secure supply chain management is needed to protect populations from substandard or falsified medical products.[17]

[8] On the human rights challenges stemming from the lack of universal and equitable access to COVID-19 vaccines, see A/HRC/49/35 and A/HRC/52/56.

[9] Ibid. See also Veronika J. Wirtz and others, "Essential medicines for universal health coverage", *The Lancet*, vol. 389 (January 2017).

[10] WHO, "Access to medicines: making market forces serve the poor" (2017), pp. 14 and 15.

[11] WHO and United Nations Children's Fund (UNICEF), "COVID-19 pandemic fuels largest continued backslide in vaccinations in three decades", 15 July 2022.

[12] See https://www.who.int/health-topics/gender#tab=tab_1.

[13] WHO, "Almost one billion children and adults with disabilities and older persons in need of assistive technology denied access, according to new report", 16 May 2022.

[14] See A/HRC/49/35 and A/HRC/52/56.

[15] WHO, "Access to medicines", p. 15.

[16] A/HRC/17/43, para. 32. See also WHO, *Access to NCD Medicines: Emergent Issues during the COVID-19 Pandemic and Key Structural Factors* (2023).

[17] WHO, "Access to medicines", p. 15. See also the submission from the Syrian Arab Republic (in Arabic).

B. Maximizing availability and accessibility

10. The call to make essential medicines, vaccines and other health products available and accessible to everyone everywhere is rooted in an approach of universal health coverage.[18] Maximizing the availability and accessibility, and in particular the affordability, of medicines and vaccines requires a multifaceted approach that involves increasing funding for research and development, encouraging generic drug manufacturing, implementing price regulation, increasing public awareness and addressing intellectual property issues.

11. It also requires adherence to the Guiding Principles on Business and Human Rights, which require companies to assess the main human rights risks throughout their value chain, both upstream and downstream. Lack of affordability and the resulting impact on the enjoyment of the right to health need to be included systematically in pricing discussions.

12. Medical devices are essential for the prevention, diagnosis and treatment of illness and disease, and for patient rehabilitation. Yet 13 per cent of the world's population accounts for 76 per cent of the use of global medical devices.[19] Even where they are made available, medical technologies are typically designed with little consideration for their use in settings with high temperatures, fluctuating electricity or lack of clean water. Installation, maintenance services and user training are often lacking, leading to the unsafe handling of devices, with potentially harmful consequences, such as misdiagnosis.[20]

1. Funding and partnerships for research and development

13. Public-private partnerships, bringing together governments, pharmaceutical companies and other stakeholders, can facilitate the development and delivery of medicines and vaccines to underserved populations when human rights considerations become intentional outcomes of such partnerships. Such partnerships can facilitate the invention of technologies and the sharing of the costs and risks of research and development, and can help increase the availability of and access to health care. They can play an important role in improving access to medicines and vaccines in low- and middle-income countries by mobilizing additional resources, promoting collaboration, fostering innovation, improving efficiency and ensuring sustainability.[21]

14. A number of public-private partnerships have contributed to the development of medicines and vaccines and to facilitating access for low- and middle-income countries. The development and production of the pneumococcal vaccine, for instance, was made possible through an advance market commitment – an innovative financing mechanism that provides guaranteed funding for the development and production of vaccines, at an affordable price, for diseases that disproportionately affect low- and middle-income countries. Under the advance market commitment, in return for funding from donors, the manufacturers commit to supplying the medicine or vaccine at an affordable price to low- and middle-income countries. This arrangement provides a market for vaccine manufacturers and an incentive for them to invest in research and development.[22]

15. The Gavi Alliance, another example of a public-private partnership, helped to immunize over 822 million children and helped to prevent over 14 million deaths by improving access to vaccines in low- and middle-income countries, and has served as co-lead of COVAX, the vaccines pillar of the Access to COVID-19 Tools (ACT) Accelerator.[23] Similarly, the Global Fund to Fight AIDS, Tuberculosis and Malaria finances and coordinates programmes to prevent and treat disease through public-private partnerships.[24] Medicines for

[18] A/HRC/49/35, para. 45.

[19] Davide Piaggio and others, "A framework for designing medical devices resilient to low-resource settings", *Globalization and Health*, vol. 17, No. 64 (2021).

[20] WHO, *Road Map for Access to Medicines*, p. 16.

[21] Florian Till and others, "Governing the public private partnerships of the future: learnings from the experiences in pandemic times", *Eurohealth*, vol. 27, No. 1 (2021).

[22] See, for example, Ernst R. Berndt and others, "Advance market commitments for vaccines against neglected diseases: estimating costs and effectiveness", *Health Economics*, vol. 16, No. 5 (2005).

[23] See https://www.gavi.org/news/media-room/covax-announces-new-agreement-plans-first-deliveries.

[24] See https://www.theglobalfund.org/en/.

Malaria Venture has contributed to developing new treatments for malaria.[25] In 2008, the Innovative Medicines Initiative was established for the development of new treatments for diseases such as Alzheimer's, diabetes and cancer, building on the collaboration of pharmaceutical companies, research institutions and patient groups.[26] In the area of non-communicable diseases, the Access to Oncology Medicines (ATOM) Coalition,[27] for example, seeks to increase access to essential cancer medicines and the capacity to use them appropriately.[28]

2. Fair and equitable pricing

16. Essential medicines and vaccines should be treated as public goods, yet their current cost represents a significant financial burden for low-income countries and constitutes an important obstacle to medicines and vaccine equity globally. Medicines and vaccines need to be priced in a fair and equitable manner and be affordable so as not to disproportionately burden persons living in poverty. It has been argued that the right to health requires States to regulate private sector production of essential medicines if such production jeopardizes the affordability and accessibility of such medicines.[29]

17. Commercial interests may lead to greater inequalities in access to medicines and vaccines. At the same time, when prices are too low and preclude profits, companies leave the market, resulting in a gap in the availability of quality products.[30] It is essential, therefore, that the price of new medicines and vaccines ensures that they are affordable to all patients and health systems, while allowing for a reasonable profit margin for pharmaceutical companies and acting as a stimulus for further innovation.[31]

18. Based on considerations such as affordability, access and value for money, the World Health Organization (WHO) sets guidelines and makes recommendations for fair pricing of medicines and vaccines. By implementing those, pharmaceutical companies and other stakeholders can work together to ensure that medicines and vaccines are priced fairly and that access to health care is equitable nationally and globally.[32]

19. In line with the Guiding Principles on Business and Human Rights, pharmaceutical companies must respect human rights in the conduct of their business. They must avoid infringing on the human rights of others and should take action to address any negative impacts on human rights resulting from their actions.[33] This responsibility includes conducting appropriate human rights due diligence to identify, prevent, mitigate and address any risk or actual human rights impacts of their activities and operations.[34] It also requires that businesses consider the adverse consequences that pricing and distribution decisions may have on equal access to medicines and vaccines, particularly for those in vulnerable and marginalized situations.[35]

20. Pharmaceutical companies themselves can play an important role in fair pricing by adopting transparent pricing strategies and differential pricing, and collaborating with stakeholders. They should be transparent about the costs of research and development, manufacturing and distribution. It is essential to have a well-established governance structure, and health technology assessments, for value-based pricing, to ensure that processes are transparent; assessment reports and decisions should be disseminated publicly. The

[25] See https://www.mmv.org/.
[26] See https://www.imi.europa.eu/.
[27] See https://globalhealthprogress.org/collaboration/access-to-oncology-medicines-atom-coalition/.
[28] Submission from the International Federation of Pharmaceutical Manufacturers & Associations.
[29] A/HRC/23/42, para. 21.
[30] WHO, "Access to medicines", pp. 15 and 16.
[31] Ibid., p. 24.
[32] See WHO, "WHO guideline on country pharmaceutical pricing policies" (2020).
[33] Guiding Principles on Business and Human Rights, principle 11.
[34] Ibid., principle 15.
[35] A/HRC/49/35, para. 16.

governance structure should include enactment of legislation, regulations or rules to mandate transparent pricing and reporting of prices, where appropriate.[36]

21. Differential pricing allows pharmaceutical companies to price medicines and vaccines based on the purchasing power of the country or region where they are sold. This helps to ensure that low- and middle-income countries have access to affordable medicines and vaccines. The Gavi Alliance, for instance, negotiates prices with vaccine manufacturers based on a country's ability to pay and the volume of doses purchased. Several pharmaceutical companies have also implemented differential pricing for HIV/AIDS medicines, such as tiered pricing models, depending on the country's income level, differential pricing for malaria medicine, and cancer medicine offered at a lower price in low- and middle-income countries.[37]

22. Public-private partnerships can also contribute to delinking the cost of research and development from the price of the final product, by providing alternative funding mechanisms, including public funding through grants or subsidies or other innovative financing mechanisms, such as advance market commitments. Delinking models allows for a health product to be sold at a lower price and can help to incentivize pharmaceutical companies to develop and produce medicines and vaccines for neglected diseases or underserved populations.[38]

23. In the context of the COVID-19 response, public-private partnerships played a critical role in vaccine development, but also showed that publicly funded intellectual property ended up entirely in non-governmental hands, which allowed for the exercise of monopoly rights and the charging of prices for vaccine doses that were much higher than the actual costs of manufacturing.[39] States need to introduce measures for public investments to ensure that the resulting medical technologies that receive public subsidies in their development process will be available and accessible to those in need, domestically and globally.[40]

24. Some countries use pharmaceutical price regulation to ensure access to essential medicines, while still allowing pharmaceutical companies to cover their costs and make a reasonable profit. Examples include reference pricing that involves setting a maximum price for a group of medicines that have similar therapeutic effects,[41] external reference pricing, which bases the price of a medicine on its price in other countries,[42] price negotiations with pharmaceutical companies to ensure that medicines are affordable and accessible to patients,[43] and price controls, established by setting a maximum price for a medicine or a group of medicines that are deemed essential for public health.[44] Concerning external reference pricing, in order to secure the lowest price for medicines and enhance affordable and equitable access to essential medicines, purchasing States should select reference countries whose level of economic development is similar to theirs.[45] Voluntary agreements

[36] See WHO, "WHO guideline on country pharmaceutical pricing policies", and WHO, *Country Pharmaceutical Pricing Policies: A Handbook of Case Studies* (2021).

[37] Suerie Moon and others, "A win-win solution? A critical analysis of tiered pricing to improve access to medicines in developing countries", *Globalization and Health*, vol. 7 (2011).

[38] *Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines* (September 2016), p. 29.

[39] A/HRC/52/56, para. 52.

[40] WHO Council on the Economics of Health for All, "Governing health innovation for the common good", Council Brief No. 1 (2021).

[41] Sabine Vogler and others, "Pharmaceutical policies in European countries in response to the global financial crisis", *Southern Med Review*, vol. 4, No. 2 (2011). See also the submission from the national human rights institution of Argentina (in Spanish) and the submission from Argentina (in Spanish).

[42] Jaime Espin, Joan Rovira and Antonio Olry de Labry, "External reference pricing", Review Series on Pharmaceutical Pricing Policies and Interventions, Working Paper No. 1 (WHO and Health Action International, 2011), p. 1. See also the submissions from Luxembourg and Malaysia.

[43] WHO, report on the 2017 Fair Pricing Forum, p. 7.

[44] See, for example, Sarah L. Barber, Luca Lorenzoni and Paul Ong, *Price Setting and Price Regulation in Health Care: Lessons for Advancing Universal Health Coverage* (WHO and Organisation for Economic Co-operation and Development, 2019).

[45] A/HRC/20/15/Add.2, para. 31.

between pharmaceutical companies and governments or other organizations that set the price of a medicine are often used for new and innovative medicines that are not yet covered by regulations.[46] Tax incentives to manufacturers,[47] wholesalers and retailers and government subsidies for manufacturers are other measures of indirect control to regulate prices of medicines.[48]

25. The inclusion of medicines, such as those referenced in the WHO Model List of Essential Medicines, in social protection schemes is crucial for ensuring access to necessary medications for groups in vulnerable situations, particularly those in low- and middle-income countries; for reducing the burden of disease; and for promoting equitable access to health-care services. The use of health insurance schemes to reimburse patients the cost of essential medicines is also common in some States.

26. Non-governmental organizations have a crucial role to play in ensuring fair prices for medicines and vaccines.[49] By engaging in advocacy, conducting research, collaborating with other stakeholders and building capacity, they can work towards improving access to essential medicines and vaccines for all individuals and communities, particularly for neglected diseases that affect people in low- and middle-income countries.

3. Access-oriented approaches to intellectual property management

27. Access-oriented approaches to intellectual property management include responsible patenting policies, transparency about existing patents and a willingness to engage in non-exclusive voluntary licensing.[50]

28. The continuing discussion on trade-related aspects of intellectual property rights regarding vaccines and medicines has generated varying views on the appropriate balance between protecting intellectual property and ensuring access to affordable medicines and vaccines, particularly in low- and middle-income countries. Article 15 of the International Covenant on Economic, Social and Cultural Rights not only enshrines the right to enjoy the benefits of scientific progress and its applications, but also affirms the benefits to be derived from international scientific cooperation. In accordance with the human right to enjoy the benefits of scientific progress, scientific knowledge, information and advances must be shared and made accessible to all, without discrimination. States should, therefore, direct their own resources and coordinate the actions of others to ensure scientific progress and ensure that the applications and benefits thereof are distributed and are available, in particular to groups in vulnerable and marginalized situations.[51]

29. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) includes provisions for the use of compulsory licensing, which allows Governments to grant licences to third parties to produce and sell patented medicines or vaccines without the consent of the patent holder, under certain conditions.[52] Those provisions can help to increase access to essential medicines and vaccines in underserved areas. While States did not approve the initially proposed waiver of certain protections under the TRIPS Agreement, at the twelfth Ministerial Conference of the World Trade Organization (WTO), held in Geneva in June 2022, they agreed to allow countries to use compulsory licensing not only to produce for their own consumption but also to export.[53] Pharmaceutical companies should not seek to limit, diminish or compromise the flexibilities and other

[46] See, for example, National Institute for Health and Care Excellence, “Patient Access Schemes Liaison Unit”.

[47] Submission from Burundi.

[48] A/HRC/23/42, para. 22.

[49] Non-governmental organizations active in this area include Médecins sans frontières, the Drugs for Neglected Diseases initiative, Health Action International and the Access to Medicine Foundation.

[50] WHO, “Access to medicines”, p. 22.

[51] A/HRC/52/56, para. 50.

[52] *Report of the United Nations Secretary-General’s High-Level Panel on Access to Medicines*, p. 18; see also the Declaration on the TRIPS Agreement and Public Health.

[53] See WTO, Ministerial Decision on the TRIPS Agreement, document WT/MIN(22)/30. See also Gita Sen, statement at the OHCHR expert workshop on good practices in ensuring access to medicines, vaccines and other health products, Geneva, 14 February 2023.

features of the intellectual property regime that are designed to protect and promote access to existing medicines.[54] They should refrain from invoking intellectual property rights in a manner that is inconsistent with the right of every person to have access to essential medicines and safe and effective vaccines.[55]

30. Pharmaceutical companies can voluntarily license their patents and know-how to generic manufacturers in low- and middle-income countries, which can produce and distribute affordable generic versions of medicines and vaccines. The terms of such agreements may include provisions for pricing, distribution, quality control and other aspects of production and sale. Voluntary licensing agreements that are limited in geographic scope can help ensure that the product is targeted to areas of greatest need, while also protecting the market for the branded product in other regions. Non-exclusive voluntary licences have been used, for instance, for HIV and hepatitis, and some companies agreed during the COVID-19 pandemic to issue non-exclusive voluntary licences for their COVID-19 medicines and vaccines. Recently, and for the first time, a company used a voluntary licence for medicine for a non-communicable disease, namely cancer.[56]

31. Patent pooling can be an effective strategy for increasing access to vaccines and medicines, particularly in low- and middle-income countries. In patent pooling, companies or institutions that own patents related to a specific technology or product agree to share their intellectual property rights with each other or with a third party. This creates a larger pool of intellectual property, making it easier for generic manufacturers to produce and distribute essential medicines and vaccines. This approach increases competition and can lower the price of essential medicines and vaccines, making them more accessible to patients, including those who might not be able to afford them otherwise. It can also help to increase innovation and reduce costs.[57]

32. One example is the Medicines Patent Pool, established in 2010 as a public health initiative to promote access to affordable and quality medicines for diseases such as HIV, tuberculosis and hepatitis C.[58] The Pool negotiates voluntary licences with pharmaceutical companies to allow generic versions of patented medicines to be produced and sold in low- and middle-income countries at lower prices.[59] In the context of the COVID-19 pandemic, it reached an agreement with some pharmaceutical companies to issue non-exclusive sublicences to manufacture their antiviral medicines.[60]

33. Through the patent pool mechanism, licensing by patent holders has accelerated, with broader geographical coverage and improved terms and conditions, enabling more robust competition. Patent holders in turn are rewarded with fair royalties that are multiplied as low-priced generics bring a surge in demand. Generic manufacturers benefit from the simplified procedure of dealing with a single negotiating body, as well as the ability to enter the market before patents expire.[61]

34. Access to transparent patent information is a key element in ensuring that the right to health is upheld. Companies that engage with a patent pool are obliged, for instance, to disclose information about their patents, which the pool then makes public.[62] When information about the status and specifics of intellectual property protection is readily available, competitors can confidently introduce affordable health technologies that are

[54] A/63/263, annex, para. 32; see also para. 26.
[55] E/C.12/2021/1, para. 6; and A/HRC/49/35, para. 18.
[56] Access to Medicine Foundation, “First voluntary licence for a cancer treatment is a promising sign for future expansion of access to innovative medicines”, 15 November 2022.
[57] See https://www.wipo.int/patent-law/en/developments/standards.html; and Esteban Burrone, “Patent pooling for global health”, in *The Cambridge Handbook of Public-Private Partnerships, Intellectual Property Governance, and Sustainable Development*, Margaret Chon, Pedro Roffe and Ahmed Abdel-Latif, eds. (2018).
[58] Medicines Patent Pool, “A decade of making medicines accessible: 18 billion doses of treatment in 10 years – annual report 2020”.
[59] WHO, “Access to medicines”, p. 22.
[60] See Medicines Patent Pool, “COVID-19”, and A/HRC/49/35, para. 54.
[61] WHO, “Access to medicines”, p. 23.
[62] Ibid., p. 23.

similar to off-patent products.[63] Additionally, governments, generic companies, researchers, and civil society can more easily monitor and challenge questionable patent applications and approvals. To this end, several countries and organizations have published patent databases and conducted surveys and analyses.[64]

35. The Access to Medicine Index is another example of public scrutiny aimed at improving industry behaviours and responsible management of intellectual property. The *Access to Medicine Index 2022* report showed that more companies were newly engaging in voluntary licences and technology transfers.[65]

36. The COVID-19 pandemic also demonstrated that fulfilling the human rights obligations of international assistance and cooperation is crucial to ensure that essential medicines, vaccines and health products are widely shared as a global public good. The international community must support low-income countries in financing a basic package of essential medicines for all if they are unable to do so domestically.

4. Enhancing regional and local production

37. Among the lessons learned from the response to the COVID-19 pandemic is that the limited number of vaccine manufacturers[66] was a key driver of vaccine inequity.[67] Initiatives aimed at strengthening regional and local production of health products, medicines and vaccines can help to increase access to essential health-care services, reduce dependence on imported products and support economic development in specific regions.

38. Examples of such initiatives include the Pharmaceutical Manufacturing Plan for Africa, under the umbrella of the African Union. Its purpose is to increase local production of essential medicines by promoting investment in local pharmaceutical manufacturing and research and development. The plan has the potential to reduce dependence in Africa on imported medicines and increase access to essential medicines in the region. The purpose of the Access and Delivery Partnership, led by the United Nations Development Programme, is to strengthen local manufacturing and distribution of health products in developing countries. It is focused on building national capacity to produce medicines and health technologies, such as diagnostic tools and medical devices. In the area of vaccine equity, there are valuable lessons to be drawn from the COVID-19 Vaccine Global Access (COVAX) Facility, which aims to ensure equitable access to COVID-19 vaccines by supporting the development of regional and local vaccine manufacturing capacity.

5. Strengthening governance

39. Transparent, competitive and fair public procurement and generic substitution have also proven successful with respect to improving the affordability of essential medicines.[68] In that regard, the Guiding Principles on Business and Human Rights also extend to commercial transactions of States, notably procurement. The Guiding Principles require that States exercise adequate oversight, including by communicating, through contracts or enabling legislation, the need for service providers to respect human rights.[69] The World Bank,

[63] See WHO, World Intellectual Property Organization (WIPO) and WTO, *Promoting Access to Medical Technologies and Innovation*, 2nd edition (2020); and United Nations Development Programme (UNDP), *Patent Information and Transparency: A Methodology for Patent Searches on Essential Medicines in Developing Countries* (2012), pp. 5 and 9–11.

[64] *Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines*, p. 36.

[65] See Access to Medicine Foundation, *Access to Medicine Index 2022*.

[66] Submissions from Australia and from Burundi (in French).

[67] A/HRC/52/56, para. 19; and Victor J. Dzau, Celynne A. Balatbat and Anaeze C. Offodile II, "Closing the global vaccine equity gap: equitably distributed manufacturing", *The Lancet*, vol. 399 (May 2022), p. 1924.

[68] Loraine Hawkins, "Competition policy", Review Series on Pharmaceutical Pricing Policies and Interventions, Working Paper No. 4 (WHO and Health Action International, 2011). See also the submission from the Syrian Arab Republic (in Arabic).

[69] Guiding principle 5. See also Claire Methven O'Brien and others, *Public Procurement and Human Rights: A Survey of Twenty Jurisdictions* (International Learning Lab on Public Procurement and Human Rights, July 2016), p. 19.

for example, is assisting countries globally with vaccine procurement and deployment through vaccine financing operations.[70]

40. Another key element of guaranteeing access to medicines and vaccines is to respect donation standards. A key constraint in achieving universal access to COVID-19 vaccines in the pandemic context, for instance, has been the allocation of doses, with developing countries finding themselves at the back of the vaccine delivery queue.[71] The pandemic also highlighted the need to systematize dose donations with a shelf life sufficient for receiving countries to roll out their vaccination programmes.[72] Implementing the WHO Guidelines for Medicine Donations involves facilitating entry and ensuring equitable distribution of medicines and vaccines.[73]

41. It has been noted that as part of the obligation to address practices that impede equitable access to medicines and vaccines, States must subject the pharmaceutical value chain, both upstream and downstream, to policy regulation that safeguards rights, especially the rights of persons in developing contexts where the costs to the end-user are prohibitive. The value chain includes pricing, research and development, manufacturing, registration, distribution, procurement and marketing.[74]

42. Some States use competition laws to ensure access to medicines, by promoting a competitive marketplace that can prevent monopolies and anticompetitive practices that may restrict or limit the availability of essential medicines. Such approaches include measures against practices such as the charging of excessive prices, restrictions preventing other companies from accessing the market, collusive tender practices and restrictive agreements.[75] For example, competition laws can be used to prevent pharmaceutical companies from abusing their patent rights or engaging in so-called pay-for-delay tactics that delay the entry of generic drugs into the market, thus limiting competition and driving up prices.[76]

43. Well-formulated and enforced competition laws can counter anticompetitive practices at every stage of the pharmaceutical supply chain.[77] Moreover, they can be used to promote innovation and the development of new medicines by ensuring that pharmaceutical companies can compete and invest in research and development without undue restrictions. This can enhance access to essential medicines through a competitive market with fair prices, freedom to choose among various productions, innovation and the availability of high-quality medications.[78]

44. One approach to tackle the problem of complicated and time-consuming medical registration processes is to streamline procedures without compromising on stringent safety and quality standards. States have adopted measures such as reducing redundant paperwork and bureaucratic processes, and streamlining the review and approval process for medicines. Additionally, increasing transparency and stakeholder engagement could help to ensure that the registration process is effective, efficient and responsive to the needs of patients and

[70] See https://blogs.worldbank.org/voices/tackling-vaccine-inequity-africa.

[71] A/HRC/52/56, para. 51.

[72] A/HRC/49/35, para. 53.

[73] Veronika J. Wirtz, statement at the OHCHR expert workshop on good practices in ensuring access to medicines, vaccines and other health products, Geneva, 14 February 2023.

[74] Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, statement at the OHCHR expert workshop on good practices in ensuring access to medicines, vaccines and other health products, Geneva, 14 February 2023.

[75] See, for example, United States of America, Federal Trade Commission, "Agreements filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: overview of agreements filed in fiscal year 2012 – a report by the Bureau of Competition" (2013).

[76] United States of America, Federal Trade Commission, "Pay-for-delay: how drug company pay-offs cost consumers billions" (2010).

[77] Hawkins, "Competition policy", p. 41.

[78] European Commission, "Competition enforcement in the pharmaceutical sector (2009–2017): European competition authorities working together for affordable and innovative medicines" (2019), pp. 19 ff.

health-care providers.[79] National regulatory agencies can also play a role in determining fair pricing by evaluating the safety, efficacy and quality of medicines and vaccines and by setting standards for pricing and reimbursement.[80]

45. Governments can also facilitate the production of generic medicines. This can be through measures such as expedited review processes, flexible regulatory pathways and reliance on data from other regulatory authorities. By reducing barriers to entry for generic manufacturers, governments can promote competition in the market and lower prices for consumers.[81] It is also important to continuously engage with stakeholders to receive feedback on the effectiveness of the regulatory activities.[82]

46. An efficient procurement system relies on transparent management, a limited selection of medicines based on a restricted list, accurate forecasting of demand, competitive tendering, multi-product agreements,[83] bulk purchasing, pre-qualification of suppliers and close monitoring of selected suppliers, along with reliable financing.[84] Bulk purchasing allows governments to negotiate lower prices for essential medicines and vaccines.[85] Quality assurance and good procurement practice require that suppliers are certified for good manufacturing practices. In decentralized systems, some States have centralized price negotiations and require lower levels of government to place orders through the successful bidder at the centrally negotiated price to maintain purchase volumes.[86]

47. Data on purchase prices and quality test certificates are critical for other governments in benchmarking their purchase prices and making good procurement decisions. Examples of public repositories to promote transparency of medicine prices and quality include the Market Information for Access to Vaccines[87] and Global Fund Price and Quality Reporting[88] initiatives.

48. The development of appropriate medical devices that respond to the local context and their accessibility has a direct impact on health-care delivery in low- and middle-income countries. WHO has created a compendium of emerging innovative health technologies for low-resource settings, in order to support non-governmental organizations, governments and other stakeholders in making procurement decisions and to ensure greater investment in health technology towards universal access to essential health technologies.[89]

49. Many governments create a national essential medicines list that covers medicines and vaccines that are deemed essential for the population's health. These lists can be used as a reference for procurement, pricing and reimbursement decisions to ensure that essential medicines and vaccines are always available and affordable. They need to be adapted to the specific health context, taking into consideration the needs of different segments of the population, such as women and children, older persons and persons living in poverty, and must be updated on a regular basis, through a participatory process.[90]

[79] See, for example, the WHO Global Benchmarking Tool for Evaluation of National Regulatory Systems for Medical Products. See also https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation; https://amrh.nepad.org/who-we-are; https://www.paho.org/en/documents/regulatory-system-strengthening-americas-lessons-learned-national-regulatory-authorities; and https://www.fda.gov/patients/learn-about-drug-and-device-approvals/fast-track-breakthrough-therapy-accelerated-approval-priority-review.

[80] See, for example, WHO, *Pricing of Cancer Medicines and its Impacts* (2018).

[81] See TD/RBP/CONF.8/3.

[82] Submission from Australia.

[83] Submission from New Zealand.

[84] WHO, "Operational principles for good pharmaceutical procurement" (Geneva, 1999).

[85] See, for example, the Revolving Fund of the Pan American Health Organization; and submissions from Argentina, Ecuador and El Salvador (in Spanish). See also the submission from Spain (in Spanish).

[86] A/HRC/23/42, para. 51.

[87] See https://www.who.int/teams/immunization-vaccines-and-biologicals/vaccine-access/mi4a.

[88] See https://www.theglobalfund.org/en/sourcing-management/price-quality-reporting.

[89] Available at https://www.who.int/publications/i/item/9789240049505.

[90] See, for example, WHO, *Model List of Essential Medicines*, 22nd ed. (2021).

50. Ensuring a robust, efficient and resilient supply chain is also important to ensuring access to medicines and vaccines for all. Governments can strengthen supply chain management by investing in logistics and distribution systems and ensuring that they are properly staffed and equipped. The Global Fund to Fight AIDS, Tuberculosis and Malaria, for instance, provides countries with assistance for procurement supply management and facilitates access to technical assistance and capacity-building services in recipient countries in partnership with technical agencies.[91]

51. As part of their responsibility to ensure that essential medicines, vaccines and other health products are available and accessible to all, without discrimination, States need to establish effective distribution and monitoring systems. Additionally, health-care providers must ensure that medications are prescribed and dispensed in an equitable and non-discriminatory manner. Some developing countries have successfully adopted certification programmes for distributors.[92]

52. Considering that the distribution chain involves various entities, including private actors, most States have national regulations in place for the distribution of essential medicines in both the public and private sectors. These regulations typically address the storage, transportation and handling of medicines, as well as temperature-sensitive products.[93]

53. Transparency is a core component of good governance. Civil society and patient groups rely on transparent information to hold government authorities, private sector companies and international organizations accountable. Transparency can ensure fairness during negotiations that take place between pharmaceutical companies and procurement organizations. It is also an essential aspect of combating corruption, which can occur at any stage of the medicine chain. Reducing corruption in the pharmaceutical sector can have a direct impact on countries' investment in health care, while improving access to quality medicines.

54. The work of regulatory authorities in enhancing both innovation and access could be significantly supported if accurate information on the costs of research and development, production and distribution of health technologies were available. Most regulatory authorities already mandate the disclosure of information on quality, safety and efficacy of health technologies and some encourage sharing of information on investments made in the research and development of health technologies.[94] However, this information can be difficult to disaggregate.

C. Ensuring quality and safety

55. States are required to protect the population from unsafe and poor-quality medicines. Quality assurance for medicines includes such aspects as registration and marketing of good quality, safe and efficacious products under ethically and medically validated clinical trials, continuous regulation of the quality of production of medicines and prevention of substandard and spurious medicines from being sold on the market after registration.[95] Specific examples include quality control, good manufacturing practices,[96] quality management systems, regulatory oversight and post-market surveillance.

56. Regulatory agencies play a critical role in ensuring the quality of medicines and vaccines. They are responsible for establishing and enforcing quality standards, conducting

[91] A/HRC/17/43, para. 33.

[92] Center for Global Development, "Drug resistance: improving standards in the medicine distribution chain". Available at https://www.cgdev.org/sites/default/files/archive/doc/DWRG/distribution_chain.pdf.

[93] A/HRC/23/42, para. 54.

[94] See, for example, WHO and Health Action International, *Measuring Medicine Prices, Availability, Affordability and Price Components*, 2nd edition (2008).

[95] A/HRC/23/42, para. 61.

[96] See submission from the national human rights institution of Argentina (in Spanish).

inspections and audits of manufacturing facilities and ensuring that products meet all regulatory requirements. It is important, therefore, that they are adequately resourced.

57. Health-care providers, moreover, need to be trained to properly administer medications and monitor patients for adverse effects. Ensuring the safety and quality of medicines and vaccines[97] is essential for promoting trust and acceptability.

58. The WHO Prequalification of Medicines Programme[98] can help improve public health outcomes and reduce health disparities by ensuring access to high-quality medicines and vaccines in low- and middle-income countries. It was created in 2001 to ensure that the large quantities of low-cost treatments for HIV, tuberculosis and malaria produced by generic manufacturers met the need for stringent assessment. It includes a rigorous evaluation process with a review of the manufacturing facilities, testing of the products for quality and safety, and assessment of the clinical data on the product. This process helps ensure that the products included in the prequalification list meet international standards and are suitable for use in low- and middle-income countries. The programme also negotiates with manufacturers to secure lower prices for prequalified products, which contributes to ensuring that these products are accessible to countries with limited resources. There are also some potential limitations of the programme, however, and ongoing efforts are needed to ensure that the implementation remains transparent, impartial and effective in achieving the goals.[99]

59. One detection and reporting tool is the WHO Global Surveillance and Monitoring System for substandard and falsified medical products. Information is collected and analysed in collaboration with national regulatory authorities, international organizations and other stakeholders. The system is designed to improve the accuracy and completeness of data on such products, and to facilitate the sharing of information across countries and regions. When warranted, WHO issues a global medical product alert to warn countries and populations of the existence of a dangerous medical product.

D. Promoting acceptability

60. Promoting good health outcomes necessitates ensuring the acceptability of medicines and vaccines. It refers to the extent to which patients or individuals are willing to adhere to their treatment plan. Acceptability is influenced by various factors, including cultural beliefs, personal preferences, previous experiences with medications or vaccines, access to health care and trust in health-care providers or authorities. For example, a medicine or vaccine may be effective in treating or preventing a particular disease, but if patients or individuals perceive it as unsafe or ineffective, they may be hesitant to use it. Similarly, if a medicine or vaccine is difficult to access or administer, or if it causes significant side effects, patients may be less likely to adhere to the prescribed treatment.[100]

61. Behavioural science plays a key role in ensuring access to medicines and vaccines through the identification and addressing of barriers that may prevent people from seeking or adhering to health-care interventions, including vaccines and medicines. Such approaches can help identify reasons why some people may be hesitant to take vaccines or medicines, which can be used to tailor public health campaigns and messaging to address those concerns. There are also examples of how behavioural science, including social psychology, can help to improve communication between health-care providers and patients, such as through the use of clear and simple language, which can improve patients' understanding of the benefits

[97] See WHO, *Safety Monitoring of Medicinal Products* (2012).

[98] WHO, "Prequalification of medicines by WHO".

[99] Elina Urli Hodges and others, "Navigating complexity to improve global access: supporting a more efficient and effective World Health Organization prequalification program" (Duke Global Health Innovation Center and Global Health Technologies Coalition, 2022).

[100] Kirsi Kvarnström and others, "Factors contributing to medication adherence in patients with a chronic condition: a scoping review of qualitative research", *Pharmaceutics*, vol. 13, No. 7 (July 2021); and K. Rivet Amico and others, "Advantages to using social-behavioral models of medication adherence in research and practice", *Journal of General Internal Medicine*, vol. 33, No. 2 (February 2018).

and risks of vaccines and medicines.[101] The recent adoption by the WHO Executive Board of a resolution on behavioural insights for better health is an important acknowledgement of the centrality of behavioural science in promoting the realization of the right to health.[102]

62. In order to promote acceptability, health-care providers and authorities should consider the perspectives and needs of patients or individuals when developing health-care policies and programmes. This includes addressing concerns about safety and efficacy, ensuring accessibility, and promoting education and awareness about the importance of using medicines and vaccines as prescribed.[103]

63. Providing accurate and accessible information on the safety, effectiveness, and benefits of medicines and vaccines is essential for building trust and increasing acceptability. Health communication should be tailored to different audiences, using culturally appropriate language and messaging that resonates with different communities. To improve levels of acceptance, it is essential that public information campaigns reach all social groups, in particular the most marginalized, to ensure that no one is left behind as part of the obligation to ensure access to vaccines.[104]

64. Similarly, engaging with communities and involving them in the decision-making process is essential to increasing trust in and the acceptability of medicines and vaccines. This can include working with community leaders and faith-based organizations,[105] health-care providers and patient advocates to provide information and address concerns.[106] Information campaigns, surveys, interviews and various research methodologies can help contextualize interventions. Understanding people's concerns allows the design of tailored, behaviourally informed interventions that are multiple, layered and deployed at the local level, taking into consideration the specific context.[107]

III. Conclusions and recommendations

65. **Ensuring access to medicines, vaccines and other health products is an integral and fundamental part of the right to health. Yet massive inequalities remain, as one third of the world's population lacks access to essential medicines. The needs of persons living in poverty, older persons, persons with disabilities, women, children and persons in situations of vulnerability and marginalization are often underestimated, ignored and underserved.**

66. **The COVID-19 pandemic illustrated how access to medicine and vaccines could be facilitated or hindered. Despite the speedy availability of life-saving vaccines in some countries, factors such as cost, patents and national stockpiling determined which populations received them first. The challenges witnessed should serve as a catalyst for creating an enabling global environment free of structural obstacles, in which the right to health, including universal and equitable access to medicines, vaccines and other health products, can be realized for all.**

67. **Governments, national and international actors, the private sector and civil society have a shared responsibility to provide access to medicines and vaccines for all. It is essential that States guarantee the right to health in compliance with their**

[101] For other examples, see A/HRC/52/56, para. 23; Fadi Makki, statement at the OHCHR expert workshop on good practices in ensuring access to medicines, vaccines and other health products, Geneva, 14 February 2023; Malaysia, statement at the expert workshop on good practices in ensuring access to medicines, vaccines and other health products, Geneva, 14 February 2023; and submission from New Zealand.

[102] The resolution will be considered at the seventy-sixth World Health Assembly, which will take place in Geneva in May 2023. See also the submission from Malaysia.

[103] See also the submission from Luxembourg.

[104] See A/HRC/52/56, para. 43.

[105] Submission from Malaysia.

[106] Submission from the Dominican Republic.

[107] A/HRC/52/56, paras. 25 and 26.

obligations under the economic, social and cultural rights framework, and that pharmaceutical companies live up to their responsibility to respect.[108]

68. **Among the few good practices promoting the availability, accessibility, acceptability and quality of essential medicines, vaccines and other health products that have been identified are practices that are underpinned by a human rights-based approach and that ensure meaningful participation of all concerned, including civil society organizations and patients and consumer organizations. They include:**

(a) **Investment in research and development of new medicines and vaccines, through, inter alia:**

(i) **Public-private partnerships, such as innovative funding mechanisms and partnerships to enhance the transfer of technology and investment in research and development, including in medicines and vaccines for non-communicable diseases;**

(ii) **Policies and measures to promote the fair pricing of medicines, vaccines and other health products to ensure their affordability, placing the right to health considerations before profit, such as:**

a. **Inclusion of essential medicines in social protection and reimbursement policies to ensure access to affordable medicines, vaccines and other health products without discrimination, particularly for persons and groups in situations of vulnerability and marginalization;**

b. **Efficient and transparent procurement practices and procedures that are fair and competitive and require stringent prequalification for suppliers;**

c. **Policy frameworks that stimulate the local production of medicines and vaccines to ensure their availability and long-term accessibility and affordability;**

d. **Measures that encourage the production of generic medicines, and innovative models for procurement and distribution;**

(b) **Ensuring access-oriented management of intellectual property rights through:**

(i) **Mechanisms that mitigate the impact of intellectual property rights and promote unhindered access to medicines, vaccines and health products in line with the right to health framework;**

(ii) **Access-oriented approaches to intellectual property management, including patent pooling and the use of non-exclusive voluntary licensing;**

(iii) **Use of flexibilities under the TRIPS Agreement to promote regional collaboration to pool resources and facilitate competitiveness of local production;**

(c) **Strong regulatory frameworks, including:**

(i) **Streamlined review and approval processes to facilitate the production of generic medicines, while maintaining the highest standards of quality and safety of medicines and vaccines;**

(ii) **Procedures for increased transparency and accountability to address corrupt practices, especially in the selection, procurement and registration of medicines;**

(iii) **Competition laws and policies that prevent anticompetitive practices of pharmaceutical companies and promote competitive pricing of medicines, together with strong enforcement;**

(iv) **Disclosure of information on medicine prices and quality, and sharing of information on patents and investments in research and development;**

[108] See A/63/263, annex.

(d) **Measures promoting effective participation and acceptability, such as:**

(i) **Effective participation of communities and affected populations in the decision-making process to increase trust and acceptability of medicines and vaccines;**

(ii) **National essential medicines lists, determined through a transparent and participatory process, that adequately reflect the national health context, particularly the needs of vulnerable groups, and that are regularly updated;**

(iii) **Tailored interventions supported by behavioural, science-informed analysis to ensure the acceptability of medicines and vaccines.**