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Annual report of the United Nations High Commissioner for Human Rights and reports of the Office of the High Commissioner and the Secretary-General

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

Comprehensive report on access to medicines, vaccines and other health products in the context of the right to 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 comprehensive report, prepared pursuant to Human Rights Council resolution 50/13, contains an analysis of good practices and key systemic challenges, including new developments, emerging issues and arising challenges, and outlines a human rights-based approach to ensuring access to medicines, vaccines and other health products as part of realizing the right of everyone to the highest attainable standard of physical and mental health.

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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-ninth session, a comprehensive report, including new developments, 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.

2. The present comprehensive report is the outcome of three expert workshops, the presentation to the Council of a compendium of good practices on access to medicines, vaccines and other health products[1] and an analytical study on key challenges in ensuring access to medicines, vaccines and other health products.[2] Building on previous reports, it identifies and analyses key systemic challenges, as well as new developments and emerging issues, outlining a human rights-based approach to access to medicines, vaccines and other health products.

3. The report benefited from the participation of stakeholders in the online expert workshop on new developments and solution pathways in ensuring access to medicines, vaccines and other health products, held on 21 January 2025,[3] and from their contributions in response to the call for inputs issued on 7 November 2024.[4]

II. Systemic barriers to access to medicines, vaccines and other health products

A. Overview

4. Access to medicines, vaccines and other health products is an essential component of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, as enshrined in international norms and standards.[5] 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 good-quality medicines and vaccines are available, accessible and acceptable for all.[6]

5. Timely, regularly updated data on the global situation of access to medicines, vaccines and other health products are plainly lacking.[7] Sustainable Development Goal indicator 3.b.3, which measures the proportion of health facilities with a core set of relevant essential medicines available and affordable on a sustainable basis, was developed to serve as the global yardstick to monitor progress on access to medicines.[8] However, the indicator has thus far received only 25 contributions from Member States, many outdated, the lowest level of contributions among the 28 Sustainable Development Goal 3 indicators.[9]

6. According to the latest available data from the World Health Organization (WHO), it is estimated that 2 billion people globally have no access to essential medicines.[10] Inequities

[1] A/HRC/53/50.
[2] A/HRC/56/28.
[3] Statements made at the online workshop are available at www.ohchr.org/en/events/events/2025/expert-workshop-new-developments-ensuring-access-medicines-vaccines-and-other.
[4] Submissions are available at www.ohchr.org/en/calls-for-input/2025/call-inputs-comprehensive-report-incl-new-developments-ensuring-access.
[5] E/C.12/2021/1, para. 3.
[6] General comment No. 14 (2000), para. 12.
[7] World Health Organization (WHO), *World Health Statistics 2024*, p. 45; see Kristina Jenei and Veronika J. Wirtz, "Measuring access to essential medicines in the Sustainable Development Goals", *Bulletin of the World Health Organization* (2024), vol. 102, No. 8.
[8] See https://sdg.data.gov/3-b-3/.
[9] See Jenei and Wirtz, "Measuring access to essential medicines in the Sustainable Development Goals".
[10] WHO, "Access to medicines: making market forces serve the poor" (2017), p. 14.

in access disproportionately affect certain population groups and health products. Globally, 1 billion people, including persons with disabilities, older persons and children, are denied access to assistive technologies.[11] While internationally controlled essential medicines[12] play a critical role in the management of pain and palliative care and in anaesthesia, as well as for the treatment of drug use disorders, 85 per cent of the global population lives in countries with little or no access to such medicines.[13]

7. Affordability remains the main barrier to access to medicines, vaccines and other health products.[14] Up to 90 per cent of the population in low- and middle-income countries purchases medicines through out-of-pocket payments.[15] In 2019, about 2 billion people, including 344 million people living in extreme poverty, experienced financial hardship 2019 due to out-of-pocket spending on healthcare. [16] In many countries across regions, out-of-pocket spending for outpatient medicines is the main driver of financial hardship.[17]

B. Medical innovation and the patent system

1. Availability and affordability of medicines, vaccines and other health products

8. Medical innovation rooted in the patent system has undoubtedly contributed to improving the health and lives of millions globally.[18] However, it has also had its limitations in terms of ensuring equitable access.[19] Inadequate investment in research and development for diseases, for which the market provides little financial return, has led to reduced availability, and even unavailability, of products to address the health needs of those with little purchasing power, in particular those in vulnerable and marginalized situations.[20] When pharmaceuticals are available, their generally high prices, aimed at recouping the costs of research and development, sometimes including a monopoly on the exploitation of patents for varying periods, exacerbates the exclusion of the most vulnerable and marginalized from access to medicines.

9. Antimicrobial resistance, which was linked to 4.71 million deaths in 2021 and is predicted to cause 39 million deaths by 2050,[21] disproportionately affects conflict-affected populations, displaced persons, women, children, and people living in extreme poverty, who face barriers to healthcare, leading to infections that are increasingly resistant to treatment.[22] Despite representing one of the most urgent global health threats, the research and development pipeline for new antimicrobials is discouraging, with the number of new antibiotics approved by the Food and Drug Administration of the United States of America declining by 81 per cent between 1987 and 2012.[23]

[11] See www.who.int/news/item/16-05-2022-almost-one-billion-children-and-adults-with-disabilities-and-older-persons-in-need-of-assistive-technology-denied-access--according-to-new-report.

[12] Internationally controlled essential medicines are both listed in the WHO Model List of Essential Medicines and controlled under one of the three international drug control conventions.

[13] Submission of the International Association for Hospice and Palliative Care, para. 7.

[14] E/2023/74, para. 5.

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

[16] WHO and World Bank Group, *Tracking Universal Health Coverage 2023 Global Monitoring Report*, p. 23.

[17] WHO, *Tracking Universal Health Coverage*, p. 23; see also WHO, "Can people afford to pay for healthcare? Evidence on financial protection in 40 countries in Europe" (2023).

[18] *Report of the United Nations Secretary-General's High-level Panel on Access to Medicines* (September 2016), pp. 7 and 13.

[19] E/2023/74, para. 6; and Ellen 't Hoen, *Private Patents and Public Health: Changing Intellectual Property Rules for Access to Medicines* (Amsterdam, Health Action International, 2016), pp. 1 and 2.

[20] WHO, "Access to medicines", p. 16.

[21] Global Burden of Disease (GBD) 2021 Antimicrobial Resistance Collaborators, "Global burden of bacterial antimicrobial resistance 1990–2021: a systematic analysis with forecasts to 2050", *The Lancet*, vol. 404, No. 10459 (2024), pp.1199–1226.

[22] Submission by Médecins Sans Frontières, p. 4.

[23] Center for Global Development, "A new grand bargain to improve the antimicrobial market for human health" (2023), p. 5.

10. Worldwide, 1.65 million people, mostly living in rural, impoverished and marginalized situations, require treatment for "neglected tropical diseases" that are mostly overlooked by research and development funding owing to the low expected profit returns on investment.[24] The vast majority (80 per cent) of the burden of treating neglected tropical diseases is borne by 16 low- and middle-income countries.[25] Despite progress in their control, elimination and eradication,[26] the recent decline in research and development funding may hinder further progress. In addition, it has also become difficult to find funding for rare diseases.[27]

11. Medical research and development also pays unequal attention to the specific medical needs of women and to differences attributable to sex. Higher costs, including at the preclinical stage, are cited among the main reasons for excluding women from clinical trials,[28] leading to gaps in vital data on dosing and on the safety and efficacy of medicines, including among pregnant or breastfeeding women.[29] Similarly, the exclusion of older persons from clinical research and studies results in a lack of data on the effects of medicines on older persons, potentially leading to inappropriate medication and drug prescriptions.[30]

12. Only 7 per cent of the research and development projects assessed in the *2021 Access to Medicine Index* targeted children, owing, in part, to market disincentives.[31] Of the 1.3 million children with tuberculosis across the world, 60 per cent never receive a diagnosis and 96 per cent of children who die from tuberculosis are never given treatment.[32] Although paediatric and child-friendly formulations are now available, diagnostic tests to adequately detect tuberculosis in children remain unavailable.[33]

2. Limitations of voluntary-based approaches to intellectual property management

13. Access-oriented approaches to intellectual property management, including the voluntary licensing of patents and know-how to generic manufacturers in low- and middle-income countries, are good practices that promote the availability and affordability of medicines, vaccines and other health products.[34] However, as highlighted in the *Access to Medicine Index 2024*, there has been a recent drop in voluntary licensing and new non-exclusive voluntary licences.[35] In the absence of voluntary licensing agreements, expensive treatments for the hepatitis C virus or for rare diseases remain out of reach for most people.[36]

14. Existing voluntary licenses mainly focus on infectious diseases, such as HIV, hepatitis C and the coronavirus disease (COVID-19), generally overlooking non-communicable

[24] Sahotra Sarkar and Lauren Gardner, "Zika: the cost of neglect", *Palgrave Communications,* vol. 2, No. 1 (2016), p. 2; WHO, *Global report on neglected tropical diseases 2023*, p. 3.

[25] WHO, *Global report on neglected tropical diseases 2023*, p. 33.

[26] WHO, *World Health Statistics 2024*, p. 28; Butala and others., "Impact of COVID-19 on the neglected tropical diseases: a scoping review", *Infectious Diseases of Poverty*, vol. 13, No. 1 (2024), p. 55.

[27] E/2023/74, para. 15.

[28] Ibid., para. 18.

[29] See www.sciencedirect.com/science/article/abs/pii/S1551714422000441?via%3Dihub; see also https://dndi.org/advocacy/gender-equity-in-drug-development.

[30] A/HRC/45/14, para. 78.

[31] Access to Medicine Foundation, "Closing gaps in access to medicine for children: how R&D and delivery efforts can be ramped up" (2021), p. 2. See also Singh, K., Franson and others, "Breaking the silence: challenges and opportunities in pediatric drug development", *Pediatric Research* (2025), pp. 1–6.

[32] See submission from Médecins Sans Frontières. See also WHO, "Global tuberculosis report 2024".

[33] Médecins Sans Frontières. "Tactic: Test, Avoid, Cure TB in Children: A survey of paediatric tuberculosis policies in 14 countries" (2024), p. 12.

[34] A/HRC/53/50, para. 30.

[35] Access to Medicine Foundation, *Access to Medicine Index 2024*, p. 25. See also the submission of the South Centre.

[36] See Udani Samarasekera, "The changing story of access to medicines", *The Lancet*, vol. 404, No. 10467 (2024), p. 2037; Jonathan Guo and others., "International disparities in diagnosis and treatment access for cystic fibrosis", *Pediatric pulmonology*, vol. 59, No. 4 (2024), pp. 1622–1630. See also the submission of the Third World Network, p. 1.

diseases, which nevertheless account for 74 per cent of global deaths.[37] While the prioritization of voluntary licensing to low-income countries is critical to enhance access, it can lead to the exclusion of middle-income countries with high disease burdens.[38] For example, the recent voluntary licensing agreement for the medication Lenacapavir, which could be a groundbreaking drug for the prevention of HIV, excludes many middle-income countries that, combined, account for 8.7 per cent of new HIV infections.[39] As a result, large numbers of people throughout the world remain unprotected.

15. The often secretive terms and conditions of voluntary licensing agreements can undermine transparency and accountability, especially when they are signed between pharmaceutical companies and publicly funded institutions.[40] Restrictive conditions attached to voluntary licensing agreements, such as different terms between healthcare systems or restrictions on the sources and production of active pharmaceutical ingredients, can also undermine equal access to medicines.[41]

C. Lack of policy coherence

16. Different regimes of public international law, such as trade law, intellectual property law and investment law, as well as the interaction between such regimes, also have a bearing on access to medicines, vaccines and other health products. The operation of bodies of international law in largely self-contained regimes, each with their own norms and dispute-settlement mechanisms, can lead to fragmentation and policy incoherencies, which challenge the ability of States to meet their obligations under the right to health.[42]

1. Agreement on Trade-Related Aspects of Intellectual Property Rights

17. From its inception, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) raised concerns regarding its potential inconsistency with States' obligations under the right to health to ensure access to medicines, vaccines and other health products.[43] Certain safeguards and flexibilities were included in the TRIPS Agreement to address these tensions, including the use of compulsory licensing, which allows governments, under certain circumstances, to grant licences to third parties to produce and sell patented medicines or vaccines without the consent of patent holders.[44]

18. Nevertheless, in practice, States continue to face obstacles to their ability to grant such licences, leading to proposals for a comprehensive review of the TRIPS Agreement.[45] The use of compulsory licensing frequently faces political opposition, retaliatory steps from other States and lawsuits from pharmaceutical companies. Additional obstacles include a dearth of domestic manufacturing capacities, coupled with a rigid importation system, which diminishes for the extent to which compulsory licensing approaches can respond promptly to global health emergencies.[46]

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[37] Medicines Patent Pool, "Voluntary licensing: right for health, smart for business" (2024), p. 8. See also Udani Samarasekera, "The changing story of access to medicines", p. 2037.

[38] Access to Medicine Foundation, *Access to Medicine Index 2024*, p. 25. See also the submission of the South Centre.

[39] Submission by the Joint United Nations Programme on HIV/AIDS (UNAIDS), p. 3. See also https://saludporderecho.org/en/lenacapavir-las-licencias-voluntarias-de-gilead-no-llegan-a-paises-que-las-necesitan.

[40] Médecins Sans Frontières, "Voluntary licenses and access to medicines" (2020), p. 4.

[41] Ibid.

[42] A/HRC/10/5/Add.2, para. 33. See also A/78/168.

[43] *Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines* (September 2016), p. 17.

[44] A/HRC/53/50, para. 29.

[45] See statement of Gita Sen during the online expert workshop, 21 January 2025.

[46] Médecins Sans Frontières, "Compulsory licenses, the TRIPS waiver, and access to COVID-19 medical technologies", Technical Brief (2021), p. 6; and Anna S.Y. Wong, Clarke B. Cole and Jillian C. Kohler, "TRIPS flexibilities and access to medicines: an evaluation of barriers to employing compulsory licenses for patented pharmaceuticals at the WTO", (2022), South Centre Research Paper, Series No. 168, p. 7.

2. TRIPS-plus protections under trade and investment agreements

19. Some States have resorted to bilateral trade and investment agreements to secure stronger protections of intellectual property rights. These "TRIPS-plus" provisions seek to limit, at the bilateral level, the use of TRIPS flexibilities, including compulsory licensing and parallel imports, and can be enforced through investor-State dispute settlement mechanisms.[47] Foreign investors have used such mechanisms to contest public health measures taken by States, including on matters concerning access to medicines.[48] In the light of the significant damages that can be awarded by arbitral tribunals for a successful claim, the mere existence of, let alone the threat to resort to the use of, an investor-State dispute settlement mechanism can have a chilling effect on States in adopting measures to enhance effective access to medicines.[49]

20. In this context, relying primarily on voluntary initiatives to address intellectual property barriers, without robust measures by States, exacerbates existing tensions between immediate corporate interests and the human rights responsibilities of companies.[50] While transnational corporations can benefit from significant investment protection mechanisms, gaps persist with regard to holding them accountable for human rights abuses that they may be involved in.[51] As assessed by the Working Group on the issue of human rights and transnational corporations and other business enterprises, progress on the implementation of the Guiding Principles on Business and Human Rights remains uneven across countries, industries and companies.[52]

3. Reduced fiscal space due to debt distress

21. More than half (55 per cent) of the least developed countries and other low-income countries face high debt distress,[53] diverting resources away from essential investments, including in health. Record levels of debt, limited access to financing and higher inflation have reduced the fiscal space of many countries in debt distress to invest in COVID-19 recovery measures, forcing them to redirect funds towards meeting their debt service obligations.[54] Forty-five developing countries, including 25 States in the Africa region, spend more on debt servicing than on health.[55] Faced with competing priorities, debt servicing can lead governments to deprioritize health spending.[56]

22. The global financial system has thus far failed to provide sufficient debt relief options.[57] While support from international financial institutions to countries in or at high risk of debt distress can contribute to investment in health systems, conditionalities often attached to such support may limit the ability of those countries to allocate sufficient resources to comply with their obligations under the right to health.

D. Inadequate health systems

23. Ensuring access to medicines, vaccines and other health products depends on the components of a well-functioning health system, centred around the key elements of the right

[47] A/HRC/11/12, para. 71.
[48] A.M. Thow and others, "Public health clauses in international investment agreements: sword or shield?", *Global Policy*, London School of Economics and Political Science, vol. 14, No. 2 (2023).
[49] A/78/168, para. 21; and Raymond Yang Gao, "Bridging separate worlds: application of human rights law in investment treaty arbitration" (2021), *Northwestern Journal of International Law & Business*, vol. 42, No. 1 (2021), p. 8.
[50] A/76/238, para. 25.
[51] A/HRC/50/40/Add.3, para. 7.
[52] Ibid.
[53] Financing for Development Office, *Financing for Sustainable Development Report 2024: Financing for Development at a Crossroads*, p. 144.
[54] A/HRC/54/38, para. 5.
[55] *Financing for Sustainable Development Report 2024*, p. 149.
[56] Ibid., p. 15.
[57] A/HRC/54/38, para. 18.

to health.[58] During the COVID-19 pandemic, the most effective responses were mounted in countries with adequate public health infrastructures and healthcare systems that were adequately funded and sufficiently well-equipped in terms of tools, facilities and personnel.[59]

1. Public health financing

24. Government schemes, social health insurance schemes and compulsory private health insurance schemes account for 70 per cent of spending on healthcare in high-income countries, while such schemes represent less than 40 per cent of healthcare spending in low-income countries.[60] In the absence of robust governmental or healthcare insurance schemes, households must depend on discretionary out-of-pocket spending to access medicines, vaccines and other health products. Out-of-pocket spending remains the main means of obtaining healthcare in 30 low- and lower-middle income countries and represents more than half of total spending on healthcare in 20 of those countries.[61]

25. International development cooperation for health is the second source of public health financing in low-income countries.[62] While international donor funding has made a critical contribution to improving public health outcomes, there is concern that the overreliance of health systems in low-income countries on external funding renders them fragile, given its uncertain and often volatile nature and the severe consequences that the phasing out of such aid can cause.[63] Reliance on external aid can also reduce the urgency to mobilize domestic spending for health and can raise issues regarding policy priority setting and accountability.[64]

2. Local manufacturing

26. During the COVID-19 pandemic, the importance of reducing overdependence on imported products and increasing local manufacturing capacities in relevant areas, especially in low-income countries, was highlighted.[65] Efforts to increase local and regional manufacturing capacities often face multiple barriers, including insufficient funding, barriers in accessing technology and know-how protected by intellectual property rights and lack of information on pricing, manufacturing and research costs, access to which are needed to enable fully informed decisions on manufacturing and associated investments.[66] The uneven engagement of companies across countries in the transfer of financial resources, technology and infrastructure is a further barrier to the expansion of necessary manufacturing capacities and to the sustainable availability of products to patients in low-income countries.[67]

3. Discriminatory policies and practices

27. Barriers to access to medicines, vaccines and other health products also often stem from discrimination, which can be multiple and intersectional, compounding differential impacts. As highlighted in previous reports, barriers to access tend to disproportionately affect particular groups, including but not limited to children, women and girls, persons with

[58] A/HRC/23/42, para. 8.
[59] A/HRC/52/56, para. 45.
[60] WHO, “Global spending on health”, p. 20.
[61] Ibid., p. 19.
[62] Ibid., p. vi.
[63] Robert John Fryatt and Mark Blecher, “In with the good, out with the bad: investment standards for external funding of health?”, *Health policy OPEN*, vol. 5 (2023), pp. 1–2; see also UNAIDS, “Impact of US funding freeze on the global AIDS response”, Weekly update – week of 24 February 2025, available at https://www.unaids.org/en/resources/presscentre/featurestories/2025/february/20250226_usfundingfreeze-weeklyupdate_fs.
[64] Fryatt and Blecher, “In with the good, out with the bad”, p. 2.
[65] A/HRC/52/56, para. 19; and A/HRC/53/50, para. 37. See also A/HRC/23/42, paras. 14–15.
[66] Submissions by the South Centre, p. 2, and the Treatment Action Group, p. 9.
[67] *Access to Medicine Index 2024*, p. 26.

disabilities, older persons and persons living in poverty.[68] The effects of such barriers on some groups are described below.[69]

28. Women and girls frequently face systemic discrimination, exclusion and marginalization regarding their right to health, resulting from discriminatory norms, roles, stereotypes and stigma. Moreover, they can face persistent physical and financial barriers, in particular in low- and middle-income countries, to obtaining access to sexual and reproductive health services and products.[70]

29. Lack of access to assistive technologies and controlled medicines for palliative care disproportionately affects older persons,[71] who often encounter obstacles in accessing primary care and care for the prevention of chronic illnesses, compounded by their limited mobility and their socioeconomic vulnerability. In some countries, the cost of prescription drugs generates financial hardship for older persons.[72] In addition, ageism within the health sector can lead to the rationing of care and the denial of medication for older persons.[73]

30. Persons with disabilities, as well as children and older persons, often lack access to assistive technologies, such as prosthetic devices.[74] Levels of access to assistive technologies vary significantly across countries, ranging from 3 per cent to 90 per cent of people in need of assistive products. Persons with disabilities may be excluded from some health coverage programmes on the grounds of pre-existing conditions, forcing them to bear higher out-of-pocket costs.[75]

31. Lesbian, gay, bisexual, transgender and intersex persons face multiple barriers, exacerbated by discriminatory laws and policies.[76] In some cases, they face discrimination in access to healthcare, including refusal by public health facilities to admit them or to provide them with treatment.[77] Transgender persons often face systemic barriers, including financial barriers, to accessing gender-affirming medications, which are banned in certain countries.[78]

32. Unemployed migrants, unsuccessful asylum claimants and migrants in irregular situations are excluded from national health insurance schemes in some countries.[79] Given their vulnerable situation and inability to contract private insurance, they face heightened risk of financial hardship owing to the need to make out-of-pocket payments.

33. Indigenous Peoples are disproportionately affected by infectious and non-communicable diseases.[80] Their access to medicines, vaccines and other health products is often constrained by the limited number or the unavailability of local health facilities, discriminatory practices, racism, lack of health information and provision of health services in Indigenous languages and the unaffordability of health products in countries lacking universal health coverage.[81]

[68] A/HRC/56/28, para. 14.
[69] See also Committee on the Elimination of Racial Discrimination, general recommendation No. 37 (2024), para. 5.
[70] A/HRC/56/28, paras. 20 and 23.
[71] Submissions by the International Association for Hospice and Palliative Care and Pallium India. See also A/HRC/56/28, para. 32.
[72] A/HRC/56/28, paras. 29 and 30.
[73] A/HRC/48/53, para. 59.
[74] A/HRC/56/28, para. 36.
[75] WHO and the United Nations Children's Fund (UNICEF), *Global Report on Assistive Technology* (2022), pp. 23 and 35.
[76] A/HRC/50/27, paras. 9–17.
[77] Submission of the "Coming out" LGBTQ+ initiative, p. 2.
[78] Submission of the Independent Expert on protection against violence based on sexual orientation and gender identity, p. 2.
[79] Submission of the Austrian Ombudsman Board, p. 5.
[80] A/HRC/33/57, para. 71, and Gerard Bodeker and Kishan Kariippanon, "Traditional medicine and Indigenous health in Indigenous hands", *Oxford Research Encyclopedia of Global Public Health* (2020), p. 1.
[81] A/HRC/33/57, paras. 23–26.

III. New developments and arising challenges

A. Emerging technologies and innovation

34. Emerging digital technologies, including artificial intelligence, can contribute to the realization of the right to health and to universal health coverage for all.[82] In a context of rising incidence of non-communicable diseases and an ageing global population, health digitalization, for example, optimized telehealth in remote areas, could produce considerable savings in health spending and boost overall healthcare availability.[83] AI-driven assistive technologies can provide invaluable support to persons with disabilities and older persons.[84]

35. However, artificial intelligence and the use of big data in healthcare settings can also pose significant risks to patients' right to privacy and to informational self-determination over sensitive health data and other personal information.[85] For example, the use of artificial intelligence to infer and predict health conditions that individuals have not voluntarily disclosed could lead to the denial of needed health insurance.[86] Furthermore, artificial intelligence can perpetuate digital divides and different forms of discrimination in the provision of healthcare as the algorithms in digital health tools encode existing human and systemic biases into data sets.[87] The reliance of artificial intelligence-driven assistive technologies in the care of older persons can also pose the risks of dehumanizing care practices and compromising dignity.[88]

36. Neurotechnologies are another emerging area offering promising opportunities in the understanding and treatment of neurological disorders. However, in connecting human brains directly to digital networks, such technologies have significant implications with regard to privacy, autonomy, agency and dignity.[89] Moreover, as most long-term effects remain unknown, they can also pose risks to safety.[90]

37. While technologies are expanding rapidly, the Pact for the Future and the Global Digital Compact, adopted at the Summit of the Future in 2024, affirmed the need for governance and legal frameworks to keep pace with developments in this field, to close the digital divide, to build an inclusive open, safe and secure digital space that respects, protects and promotes human rights and to firmly ground new rules on artificial intelligence in human rights.[91]

B. Regional cooperation

38. The COVID-19 pandemic demonstrated that fulfilling the human rights obligations of international assistance and cooperation are crucial to ensuring that essential medicines, vaccines and health products are widely shared, as a global public good.[92] However, the pandemic also highlighted the potential of regional cooperation to enhance procurement, research and development, technology transfer, manufacturing, technical cooperation, regulatory harmonization and surveillance. That potential has yet to be fully understood and

[82] A/HRC/43/29, para. 19.
[83] Dominique J. Monlezun and others, "Digitalization of health in low- and middle-income countries" *Bulletin of the World Health Organization*, vol. 103, No. 2 (2025), p. 148.
[84] Submission of Third World Network, p. 7.
[85] A/HRC/36/48, para. 54.
[86] A/HRC/43/29, para. 24.
[87] A/HRC/53/65, para. 82.
[88] A/HRC/36/48, para. 41; and A/HRC/43/29, para. 23.
[89] A/HRC/57/61, para. 78 (a).
[90] Ibid., para. 31.
[91] Summit of the Future outcome documents: the Pact for the Future, the Global Digital Compact and the Declaration on Future Generations (September 2024). See also General Assembly resolution 79/1, annex I, objective 3.
[92] A/HRC/53/50, para. 36.

realized as research evaluating the role that regional organizations can play in global health remains limited.[93]

39. For example, in 2020 the African Union established the African Vaccine Acquisition Task Team to pool member States' purchasing power for the procurement of COVID-19 vaccines, which enabled the purchase of 220 million vaccine doses. [94] Similarly, in 2021, the Association of Southeast Asian Nations (ASEAN) established its COVID-19 Response Fund to pool financial resources for the procurement of COVID-19 vaccines.[95] For over 40 years, the Pan American Health Organization (PAHO), through its Revolving Fund for Access to Vaccines, has used bulk-purchasing to access affordable vaccines for its member States.[96] In 2021, the European Union established the Health Emergency Preparedness and Response Authority, which is focused on research and development. The Authority has launched, jointly with the European Medicines Agency, the VACCELERATE clinical research network for the coordination and conduct of COVID-19 vaccine trials.[97]

40. In addition to pooling resources to increase manufacturing capacities, regional organizations can serve as hubs for the sharing of information, expertise, experiences and best practices. [98] Pooling regional information and resources can also contribute to overcoming obstacles to the use of compulsory licensing.[99] By pooling resources for research and development and for technology transfer, regional cooperation can also overcome other intellectual property-related barriers.[100]

41. Regional harmonization of regulatory standards and approval processes can enhance the expeditious availability and the quality of medicines and contribute to pandemic preparedness. The African Medicines Agency has the potential to increase the safety and quality of medicines throughout Africa.[101]

42. The appropriate leveraging of regional cooperation to enhance access to medicines, vaccines and other health products is an important means by which States' obligations can be realized to use the maximum available resources for the progressive realization of the right to health, which includes resources within a State as well as those available through international cooperation and assistance.[102]

C. Increasing attacks on healthcare

43. Barriers to access in times of conflict are exacerbated by attacks on healthcare facilities and personnel, which have risen sharply in recent years. In the absence of a formal global and comprehensive process to ensure monitoring, reporting and accountability, several initiatives have been established to collect data on attacks on healthcare, such as the WHO

[93] Afifah Rahman-Shepherd and others, "Establishing the value of regional cooperation and a critical role for regional organisations in managing future health emergencies", *The Lancet*, vol. 13, No. 3, p. e585.

[94] See https://africacdc.org/news-item/africa-announces-the-rollout-of-400m-vaccine-doses-to-the-african-union-member-states-and-the-caribbean/. See also Afifah Rahman-Shepherd and others, "Establishing the value of regional cooperation and a critical role for regional organisations in managing future health emergencies", p. e590.

[95] See joint communiqué of the fifty-fourth ASEAN Foreign Ministers' Meeting, 2 August 2021, para. 15, available at: https://asean.org/wp-content/uploads/2021/08/Joint-Communique-of-the-54th-ASEAN-Foreign-Ministers-Meeting-FINAL.pdf.

[96] See https://www.paho.org/en/revolving-fund.

[97] Afifah Rahman-Shepherd and others, "Establishing the value of regional cooperation and a critical role for regional organisations in managing future health emergencies", p. e588. See also https://vaccelerate.eu/who-we-are.

[98] Afifah Rahman-Shepherd and others, "Establishing the value of regional cooperation and a critical role for regional organisations in managing future health emergencies", p. e587.

[99] Sisule F. Musungu and others, *Utilizing TRIPs Flexibilities for Public Health Protection through South-South Regional Frameworks*, the South Centre (2004), p. xiv.

[100] Afifah Rahman-Shepherd and others, "Establishing the value of regional cooperation and a critical role for regional organisations in managing future health emergencies", p. e589.

[101] See statement of Lenias Hwenda at the online expert workshop, 21 January 2025.

[102] Committee on Economic, Social and Cultural Rights, general comment No. 3 (1990), para. 13.

surveillance system for attacks on healthcare and the reports of the Safeguarding Health in Conflict Coalition.[103] In 2023, the Safeguarding Health in Conflict Coalition documented 2,562 incidents, which constitutes an increase of 25 per cent over 2022.[104] In 2024, the Coalition documented a further annual increase of 20 per cent.[105] Through its surveillance system for attacks on healthcare, WHO reported 1,623 attacks in 2024.[106] Beyond their direct impacts, such attacks generally disrupt essential health services and pose significant barriers to achieving universal health coverage and upholding the right to health. In addition, data remain incomplete, inconsistent, insufficient and difficult to track and compare, thus impeding opportunities for stronger protection, prevention and accountability.

44. Attacks directed at medical units, medical transports, medical personnel, medical activities and humanitarian relief teams and personnel are specifically prohibited under international humanitarian law.[107] The right to health continues to apply in situations of armed conflict or general emergency.[108] In particular, States cannot, under any circumstances, justify non-compliance of their core obligation to ensure the provision, on a non-discriminatory basis, of available essential medicines, especially for vulnerable and marginalized groups.[109]

D. Protecting traditional knowledge and associated genetic resources

45. Approximately 40 per cent of existing pharmaceuticals are drawn from sources found in nature and from associated traditional knowledge.[110] The traditional knowledge of Indigenous Peoples associated with genetic resources feeds key research on the properties and values of genetic resources and their potential use in the development of new medicines.[111] The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity, which entered into force in 2014, protects Indigenous Peoples' free, prior and informed consent in order to access to their traditional knowledge and associated genetic resources and also requires the equitable mutual sharing of the benefits arising from the utilization of their genetic resources.[112]

46. Indigenous Peoples have the right to maintain, control, protect and develop their traditional knowledge, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, medicines and knowledge of the properties of fauna and flora, as well as the right to maintain, control, protect and develop their intellectual property in those fields.[113]

47. Through the establishment of a disclosure requirement for patent applicants, the recently adopted World Intellectual Organization (WIPO) Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge[114] represents an important step

[103] Simon Bagshaw and Emily Scott, "Talk is cheap: Security Council resolution 2286 & the protection of health care in armed conflict", *Daedalus*, vol. 152, No. 2 (2023), pp. 142–156.
[104] Safeguarding Health in Conflict Coalition, *Critical Condition: Violence against Health Care in Conflict 2023*, p. 7.
[105] See statement of Leonard Rubenstein at the online expert workshop, 21 January 2025.
[106] See the WHO surveillance system for attacks on healthcare dashboard, available at https://extranet.who.int/ssa/LeftMenu/Index.aspx?utm_source=Stopping%20attacks%20on%20health%20care%20QandA&utm_medium=link&utm_campaign=Link_who.
[107] See E/2015/59; common article 3 of the Geneva Conventions of 1949; Additional Protocol I, arts. 12, 15, 16, 70 (4) and 71 (2); and Additional Protocol II, arts. 9 (1), 10 and 11 (1).
[108] E/2015/59, para. 12.
[109] Committee on Economic Social and Cultural Rights, general comment No. 3 (1990), para. 10, and general comment No. 14 (2000), para. 47.
[110] See www.who.int/news-room/questions-and-answers/item/traditional-medicine.
[111] See www.cbd.int/abs/doc/protocol/factsheets/abs-en.pdf.
[112] Nagoya Protocol on Access and Benefit-sharing, arts. 6.2 and 7.
[113] United Nations Declaration on the Rights of Indigenous Peoples, art. 31.
[114] WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge, adopted on 24 May 2024.

forward in efforts to ensure the prevention of and remedy for the misappropriation of genetic resources and associated traditional knowledge.

48. Protecting traditional knowledge and associated genetic resources is at the core of the integrated and unifying "One Health" approach adopted by WHO, which recognizes the critical importance of biodiversity as protection against new diseases and as an element for providing medical responses, while maintaining respect for the rights of Indigenous Peoples.[115]

IV. From commodities to global public goods: towards a human rights-based approach to access to medicines, vaccines and other health products

49. A human rights-based approach treats essential medicines, vaccines and other health products as global public goods. A human rights economy[116] can ensure that the right to health remains at the centre of trade, investment, monetary and intellectual property policies and that pharmaceutical companies and other relevant companies respect the right to access essential medicines, vaccines and other health products. Fulfilling the human rights obligations to international assistance and cooperation can ensure that essential medicines are widely shared as public goods.[117]

A. Policy and legal frameworks relating to access to essential medicines, vaccines and other health products

50. A right-to-health approach requires protecting the right to essential medicines, vaccines and other health products under national legal frameworks.[118] A comprehensive national policy or plan of action to give effect to this right should prioritize the most vulnerable and marginalized and be underpinned by the principles of universality, non-discrimination, participation, transparency and accountability.

51. Establishing a national essential medicines list, which addresses the health needs of the population, is crucial to ensure the availability and affordability of essential medicines and is part of the core obligation of States to provide essential medicines,[119] as listed in the WHO Model List of Essential Medicines. The selection process of essential medicines should be evidence-based, transparent and participatory.[120] Essential medicines lists should be adapted to specific health contexts, taking into consideration the needs of different segments of the population, in particular the most vulnerable and marginalized, and should be updated on a regular basis.[121]

52. Ensuring the availability and accessibility of health products on a non-discriminatory basis requires, more broadly, that underlying cultural, political and legal barriers are addressed, including, for example, the exclusion of essential medicines for palliative care, mental health, drug dependence and sexual and reproductive health from national essential medicines lists, despite their inclusion on the WHO Model List of Essential Medicines.[122]

53. Policy and legal frameworks on the right to essential medicines, vaccines and other health products should take the cultures of individuals, minorities, Indigenous Peoples and communities into account.[123] Indigenous Peoples have specific rights to their traditional medicines and to maintain their health practices, including the conservation of their vital

[115] See https://www.who.int/health-topics/one-health#tab=tab_1.
[116] A/HRC/54/35, para. 23; and A/HRC/56/34, para. 3.
[117] A/HRC/53/50, para. 36.
[118] See statement of Katarina Perehudoff at the online expert workshop, 21 January 2025.
[119] Committee on Economic Social and Cultural Rights, general comment No. 14 (2000), para. 43 (d).
[120] A/HRC/23/42, para. 42.
[121] A/HRC/53/50, para. 49.
[122] Ibid., para. 45.
[123] Committee on Economic Social and Cultural Rights, general comment No. 14 (2000), para. 12 (c).

medicinal plants, animals and minerals.[124] This requires recognition of the inherent connections between the cultural life of Indigenous Peoples, their traditional medicines and their lands and territories and measures to prevent the appropriation and commodification of Indigenous Peoples' traditional medicines by third parties.[125]

54. Monitoring mechanisms of the implementation of national policies should be based on clear targets, time frames and responsibilities.[126] The availability of accountability and redress mechanisms, including judicial and non-judicial mechanisms, is at the core of a human rights-based approach. The right to access medicines, as an essential element of the right to health, should be justiciable under domestic legal systems.[127] Ratifying the Optional Protocol to the International Covenant on Economic, Social and Cultural Rights and other instruments providing competence to international adjudicatory mechanisms offers additional avenues for redress.

55. Access to transparent information, which allows for the documentation of health system deficiencies, awareness-raising on the rights of individuals and the provision of legal support, enables civil society to monitor and hold authorities accountable.[128] Litigation can play a vital role in clarifying the content of rights, reforming outdated laws and ensuring the provision of remedies to victims.[129]

B. Strengthening national health systems

56. In line with the obligation of States to the progressive realization of the right to health, all countries, including those in low- and middle-income brackets, should devote maximum available resources to financing for the health sector, thus ensuring that out-of-pocket spending does not constitute an access barrier and a driver of poverty. States have an obligation to provide those who do not have sufficient means with the necessary protections, including through health insurance schemes and healthcare facilities. Persons living in poverty, older persons and migrants often cannot afford essential medicines, including for managing chronic diseases.[130] Universal health coverage may require the provision of needed medicines, vaccines and other health products free of charge for those segments of the population that are unable to procure them.[131]

57. As affirmed by the Committee on Economic, Social and Cultural Rights, excluding unemployed migrants or migrants in an irregular situation from national health insurance coverage runs contrary to the rights to health and social security.[132] The Committee on the Rights of Persons with Disabilities also noted that the exclusion of persons with disabilities from health coverage programmes, including from private health providers, on the grounds of pre-existing conditions, contravenes the Convention on the Rights of Persons with Disabilities.[133] Assistive devices and technologies should be covered by national health insurance schemes to ensure their affordability to all persons with disabilities.[134] It has also been stressed that gaps in the coverage of the costs of gender-affirming therapy and interventions should be addressed.[135]

[124] United Nations Declaration on the Rights of Indigenous Peoples, art. 24.
[125] Ibid, article 31; Committee on Economic Social and Cultural Rights, general comment No. 21 (2009), para. 36; and A/HRC/33/57, para. 33.
[126] Committee on Economic Social and Cultural Rights, general comment No. 14 (2000), paras. 55–56.
[127] A/69/299, para. 18.
[128] See submission of Ágora, p. 2.
[129] See statement of Katrina Perehudoff at the online expert workshop, 21 January 2025, p. 6.
[130] Committee on Economic Social and Cultural Rights, general comment No. 14 (2000), para. 19; and A/HRC/53/50, para. 7.
[131] A/HRC/56/28, para. 63.
[132] Ibid. See also E/C.12/ALB/CO/4, para. 33; and E/C.12/FRA/CO/5, para. 51.
[133] Convention on the Rights of Persons with Disabilities, art. 25 (e); CRPD/C/JOR/CO/1, paras. 47–48; CRPD/C/PRY/CO/2-3, para. 46 (d); and Committee on Economic Social and Cultural Rights, general comment No. 14 (2000), para. 26.
[134] Convention on the Rights of Persons with Disabilities, art. 20. See also CRPD/C/GHA/CO/1, para. 39 (a).
[135] A/HRC/50/27, para. 30; CEDAW/C/CHE/CO/4-5 and CEDAW/C/CHE/CO/4-5/Corr.1, para. 39 (d).

58. Measures to incentivize manufacturing and efficient procurement include bulk-purchasing, prequalification of suppliers, well-formulated competition laws, relevant tax incentives, revised tariff policies and differential pricing policies, including external reference pricing, therapeutic reference pricing and the appropriate regulation of mark-ups.[136] Pharmaceutical companies should align their pricing and distribution policies with the Guiding Principles on Business and Human Rights, including by adopting transparent pricing strategies and differential pricing.[137]

59. The monitoring and enforcement of quality standards throughout manufacturing and distribution chains is key to ensuring the quality and safety of medicines. Access to transparent information is essential for participatory monitoring efforts and accountability, including combating corruption throughout the medicine chain, which has a negative impact on investments in healthcare and the quality and safety of medicines.[138]

C. Fostering an international enabling environment for access to medicines, vaccines and other health products

60. The fulfilment by States of their obligations relating to international cooperation and assistance is key to fostering an international enabling environment, within which national policies can have a maximum effect. International legal frameworks on intellectual property, trade, investment and finance should be interpreted and applied against the obligations of States to ensure effective access to medicines, vaccines and other health products.[139]

61. The right to enjoy the benefits of scientific progress and its applications requires that States align intellectual property regulations with human rights, ensuring that patents do not block access to life-saving medicines and impede the enjoyment of the right to health.[140] In line with their international obligations under the right to health, States should therefore refrain from invoking and applying intellectual property rights in a manner inconsistent with effective access to medicines, vaccines and other health products in other countries, including with regard to their application of the flexibilities set out in the TRIPS Agreement.[141] Pharmaceutical companies should not seek to limit, diminish or compromise the flexibilities and other features of the intellectual property regime that are designed to protect and promote access to medicines.[142]

62. Current discussions within the Council for TRIPS on a comprehensive review of the implementation of the TRIPS Agreement can serve as an opportunity to comprehensively address persistent intellectual property barriers through international cooperation. Revision of the criteria for patentability and addressing the structural impediments to compulsory licensing are concrete proposals that have been put forward in this context.[143]

63. Stepping up international cooperation and assistance can enhance local and regional manufacturing capacities through financing of support and the transfer of technology and know-how. Leveraging regional cooperation through the pooling of resources at the different stages of the drug development life cycle offers opportunities to strengthen access and build resilience to respond to future global health emergencies.

64. International cooperation and assistance are also crucial to ensuring the financing of health-driven innovation models that incentivize the research and development of essential

[136] See A/HRC/23/42; A/HRC/53/50; and A/HRC/56/28.
[137] A/HRC/53/50, paras. 21 and 24; and A/HRC/23/42, para. 35.
[138] A/HRC/53/50, para. 53.
[139] A/76/238, para. 58; Surya Deva and Tara Van Ho, "Addressing (in)equality in redress: human rights-led reform of the investor-state dispute settlement mechanism", *The Journal of World Investment & Trade*, vol. 24, No 3, (2023), pp. 398–436; and Charter of the United Nations, Article 103, to be read together with Articles 1 (3), 55 and 56.
[140] Committee on Economic Social and Cultural Rights, general comment No. 25 (2020), para. 69.
[141] A/HRC/56/28, para. 71 (g); and Committee on Economic Social and Cultural Rights, general comment No. 14 (2000), para. 39.
[142] A/63/263, annex, paras. 26 and 32.
[143] See statement of Gita Sen at the online expert workshop, 21 January 2025.

new treatments while keeping prices affordable by delinking the price of health products from the full cost of research and development.

V. Conclusions and recommendations

65. **Barriers to access to medicines, vaccines and other health products are complex and multifaceted. They result from issues such as inadequately resourced and functioning health systems, insufficient manufacturing capacities, inadequate governance over the medicine chain, discriminatory policies and practices and international policies that are misaligned with the human rights obligations of States to ensure access to medicines, vaccines and other health products.**

66. **While medical innovation rooted in the patent system has made undeniable contributions to improving public health outcomes, it presents inherent limitations. While access-oriented approaches to intellectual property management represent good practices, given their voluntary nature, they remain unevenly and insufficiently used, thus perpetuating disparities in access.**

67. **Inequities in access disproportionately affect persons in situations of vulnerability and marginalization. An intersectional approach to access to medicines, vaccines and other health products would require further analysis of the differentiated impacts generated by these intersecting forms of discrimination.**

68. **Stark disparities in access remain between and within countries, particularly low- and middle-income countries.**

69. **Different initiatives highlight the value of international and regional cooperation, such as the pooling of resources at different stages of the medicine chain to enhance access to medicines, vaccines and other health products. Expanding regional initiatives could benefit from further understanding of the full potential of leveraging regional cooperation and the role that regional organizations can play in ensuring that public health responses are grounded in human rights. Fostering interregional exchanges of experiences could contribute to this effort.**

70. **The right to health provides an actionable framework for States to enhance the availability, accessibility, acceptability and quality of medicines, vaccines and other health products. The key recommendations set out below are addressed to States, pharmaceutical companies and other relevant companies.**

71. **It is recommended that Member States:**

(a) **Ensure that universal and effective access to essential medicines, vaccines and other health products is protected as a right under domestic legal frameworks;**

(b) **Adopt comprehensive national policies, underpinned by human rights principles, to enhance practical access to medicines, vaccines and other health products, prioritizing the needs of those in vulnerable and marginalized situations and covering the entire life cycle of medicines;**

(c) **Adopt national essential medicines lists, determined and regularly updated through an evidence-based, transparent and participatory process, which reflect the national health context and the particular needs of groups at risk; such lists should guide social protection, procurement, pricing and manufacturing policies;**

(d) **Ensure universal health coverage, including by removing financial and non-financial barriers to access to medicines, vaccines and other health products, including accounting for the specific healthcare needs of marginalized segments of the population and for the coverage of medicines, vaccines and other health products that are specific to certain segments of the population;**

(e) **Advance a human rights economy by ensuring the maximum available resources for public health, including by increasing relevant fiscal space for the realization of the right to health through the generation of corresponding tax and non-tax revenues and human rights-based budget management;**

(f) **Ensure the availability of monitoring and accountability mechanisms, including human rights indicators; the justiciability of the right to health, under domestic legal systems; and access to remedy, including through non-judicial mechanisms.**

72. **In line with their obligations to international cooperation and assistance, it is recommended that Member States:**

(a) **Ensure that intellectual property rights are not invoked and applied in a manner inconsistent with the right to access to medicines, vaccines and other health products or with the exercise by States of the flexibilities of the TRIPS Agreement;**

(b) **Step up collective efforts to establish robust mechanisms for the prevention, monitoring and accountability of attacks on healthcare facilities and healthcare providers during armed conflicts;**

(c) **Advance international human rights-based governance of the use of artificial intelligence and other digital technologies in public health, consistent with the elements of availability, accessibility, acceptability and quality.**

73. **It is recommended that, in line with the Guiding Principles on Business and Human Rights, pharmaceutical companies and other relevant companies respect the realization and enjoyment of the right to access necessary medicines, vaccines and other health products, including by conducting appropriate human rights due diligence to identify, prevent, mitigate and address the negative human rights impacts of their corporate policies and practices on, inter alia, research and development, pricing, intellectual property management, distribution and technology transfer.**