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**Human Rights Council**

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Agenda items 2 and 3

**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**

Analytical study on key challenges in ensuring 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[[1]](#footnote-2)\*

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| *Summary* |
| The present report, prepared pursuant to Human Rights Council resolution 50/13, contains an analysis of key challenges and pathways to ensure the availability, accessibility and acceptability of good quality medicines, vaccines, diagnostics and therapeutics and other health products and technologies as part of realizing the right of everyone to the highest attainable standard of physical and mental health. |
| It addresses key challenges to the realization of the right of everyone to the highest attainable standard of physical and mental health, such as rising inequalities and discrimination and systemic access barriers and access challenges in emergency situations. The study is the second in a series of three reports, to be read in a complementary manner with the compendium of good practices related to access to medicines, vaccines and other health products (A/HRC/53/50), also mandated by the Council in resolution 50/13. |
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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-sixth session, an analytical study on key challenges pertaining to access to medicines, vaccines, diagnostics and therapeutics and other health products and technologies in the context of the right of everyone to the highest attainable standard of physical and mental health.

2. The lack of sufficient, adequate and timely access to medicines, vaccines and other health products[[2]](#footnote-3) is a complex and multifaceted issue, and remains a major obstacle to the realization of the right to health. Ensuring access to medicines and vaccines requires a functioning health system that encapsulates the key elements of the right to health, as well as collaborative efforts by Governments, pharmaceutical companies, health-care providers and international organizations.[[3]](#footnote-4)

3. In the present study, OHCHR outlines key elements of the access to medicines, vaccines and other health products, including through the commitments enshrined in the 2030 Agenda for Sustainable Development. It identifies and analyses key challenges to maximize availability and accessibility for different populations and groups, including children, women and girls, older persons and persons with disabilities, and outlines systemic challenges, and its conclusions and recommendations to improve access to medicines, vaccines and other health products. The study, the second in a series of three reports, should be read in conjunction with the compendium of good practices on access to medicines, vaccines and other health products.[[4]](#footnote-5)

4. The study was prepared taking into account information contained in the written submissions received from various stakeholders, including Member States, United Nations agencies and entities, national human rights institutions, international non-governmental organizations, civil society organizations and academic institutions, in response to the call for inputs issued on 15 September 2023.[[5]](#footnote-6) It also takes into account the findings of an expert workshop on key challenges in ensuring access to medicines, vaccines and other health products held on 16 February 2024.[[6]](#footnote-7)

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

5. Access to medicines and vaccines is an essential element of the right to health,[[7]](#footnote-8) as enshrined in international human rights law. It is guaranteed in the Universal Declaration of Human Rights and international human rights treaties,[[8]](#footnote-9) including the International Covenant on Economic, Social and Cultural Rights, the Convention of the Rights of Persons with Disabilities, the Convention on the Rights of the Child and the Convention on the Elimination of All Forms of Discrimination against Women.

6. States must take measures to secure functioning health systems that take into consideration the key elements of the right to health.[[9]](#footnote-10) This includes ensuring the right of access to health facilities, goods and services on a non-discriminatory basis, especially for persons who are members of vulnerable or marginalized groups.[[10]](#footnote-11) Health facilities, goods and services should be gender-sensitive and culturally appropriate, scientifically and medically appropriate, of good quality and respectful of medical ethics.[[11]](#footnote-12)

7. While the realization of the right to health is to be achieved progressively, States have a specific and continuing obligation to move as expeditiously and effectively as possible towards the full realization of the right to health.[[12]](#footnote-13) States are required to take deliberate, specific and targeted steps to achieve the right to health and to deliver immediately on minimum requirements, such as access to essential primary care and medicines without discrimination.[[13]](#footnote-14) Focused efforts are essential to remove barriers, pre-empt potential discrimination and monitor distribution of medicines, vaccines and other health products to avoid discrimination.[[14]](#footnote-15)

8. The right to health is also applicable in situations of armed conflict or general emergency.[[15]](#footnote-16) States have a core obligation under the International Covenant on Economic, Social, Cultural Rights to ensure the satisfaction of at least minimum essential levels of each of the rights enshrined in the Covenant. The non-derogable core obligations[[16]](#footnote-17) include the obligation of States parties to ensure equitable distribution and access to health facilities, goods and services on a non-discriminatory basis, especially for vulnerable or marginalized groups and to provide essential medicines.[[17]](#footnote-18)

9. As part of the 2030 Agenda and the Sustainable Development Goals, all Member States committed to achieving universal health coverage by 2030. The commitment to such coverage was reiterated in 2023 at the high-level meeting of the General Assembly on universal health coverage.[[18]](#footnote-19) Universal health coverage aims to ensure that all persons within a State have access to essential health services, of sufficient quality, without suffering financial hardship, and to safe, effective, quality and affordable essential medicines and vaccines for all.[[19]](#footnote-20) It covers the full continuum of essential health services, from health promotion to prevention, treatment, rehabilitation and palliative care.[[20]](#footnote-21)

III. Key challenges in ensuring access to medicines, vaccines and other health products

1. **Overview**
2. Access to medicines, vaccines and other health products is deeply unequal in many countries owing to structural barriers, social determinants of health and other factors affecting various populations that are marginalized. These inequalities are further aggravated in contexts of fragility, conflict and violence.[[21]](#footnote-22) Moreover, the rise of non-communicable diseases and mental health-related conditions are putting increasing pressure on people and the health-care systems that support them around the world. Given that they frequently require treatment for a long period of time,[[22]](#footnote-23) non-communicable diseases and mental health-related conditions tend to have a particularly detrimental effect on household resources.[[23]](#footnote-24) This impact is most dramatic in low- and middle-income countries, where 90 per cent of the population has to pay full price for medicines out-of-pocket. For many in such circumstances, adequate treatments are financially out of reach. Others are forced to adopt detrimental coping strategies, such as withdrawing children from school, that reinforce patterns of intergenerational poverty.[[24]](#footnote-25)
3. Children, women and girls, older persons, migrants, persons in geographically remote areas and persons with disabilities are among those who are disproportionately affected by limitations on access to medicines.[[25]](#footnote-26) Frequently, intersectional and multiple discrimination has a compounded differential impact. There are different factors that may impede directly or indirectly access to health services by laws, policies and practices, such as migration status, lack of nationality, criminalization affecting specific segments of the population, for example LGBTIQ+ individuals and persons who use drugs.[[26]](#footnote-27)
4. Improving access to medicines, vaccines and medical products is a multidimensional challenge requiring a set of targeted measures to address the specific challenges that different groups face. These should be complemented by other measures to address systemic barriers. Ensuring access to health products depends on the components of a well-functioning health system.[[27]](#footnote-28) It is also essential that comprehensive national policies, strategies and regulatory frameworks cover the entire product life cycle, from research and development to quality assurance, supply chain management and use.[[28]](#footnote-29)
5. The disproportionate impact of the coronavirus disease (COVID-19) pandemic on persons in situations of vulnerability or marginalization[[29]](#footnote-30) reflects the urgency to move towards universal health systems that provide protection to all.
6. **Group-specific barriers to access**
7. The section below draws from submissions by various stakeholders and the expert workshops organized to form the analysis of the present report. It centres on how barriers to access affect particular populations and groups in vulnerable and marginalized situations, including, but not limited to, children, women and girls, older individuals, and persons with disabilities, such as those with albinism, among others.

1. Children

1. Children are susceptible to many illnesses that affect adults, yet only a small fraction of medicines intended for adults have undergone an assessment for effectiveness, appropriate dosing and tolerability in paediatric populations.[[30]](#footnote-31) According to some submissions, the exclusion of children from trials and licensing of development of medicines and vaccines, and limited public and private investment in research and development for children’s medicines, may make availability of medicines particularly challenging for this population group.[[31]](#footnote-32)
2. In some countries, there are no paediatric formulations for many approved drugs, which results in difficulties in pharmacotherapy.[[32]](#footnote-33) For example, tuberculosis diagnostic tests available for adults are not adapted to children, anti-tuberculosis medicine does not have suitable formulations for children,[[33]](#footnote-34) and there are wide disparities between children and adults in global responses to HIV and tuberculosis. According to 2022 data, only 57 per cent of children under the age of 15 living with HIV had access to treatment compared with 77 per cent among adults.[[34]](#footnote-35)
3. Further challenges include stigma and discrimination in health-care settings, and within the community and the family, which act as a barrier to children’s access to the medicines, vaccines and other health products they need.[[35]](#footnote-36) Some households may prioritize the treatment of an employed family member over that of those who do not contribute financially.[[36]](#footnote-37) Children may lack access to support services and caregivers necessary to complete health treatment schemes.[[37]](#footnote-38) In addition, children and caregivers should receive sufficient health-related education and information about treatments to help to promote adherence to treatment programmes and secure long-term health outcomes.[[38]](#footnote-39)
4. The United Nations children’s Fund (UNICEF) estimates that 67 million children missed out entirely or partially on routine immunization from 2019 to 2021 during the COVID-19 pandemic.[[39]](#footnote-40) In many countries, millions of children have passed the age of the routine vaccination schedule set by WHO and are at a high risk of contracting life-threatening diseases that could be prevented by vaccines, including measles, diphtheria or pneumonia.[[40]](#footnote-41)
5. Approximately 300 million people worldwide have a rare disease,[[41]](#footnote-42) 80 per cent of which are genetic[[42]](#footnote-43) and 70 per cent starting in childhood.[[43]](#footnote-44) While 50 per cent of these diseases disproportionately affect children, around 30 per cent of affected children may not survive past the age of 5 years.[[44]](#footnote-45) Rare diseases are plagued by marginalization and chronic underinvestment in research and development, culminating in inadequate treatment options,[[45]](#footnote-46) with children bearing the brunt. Children with rare diseases continue to face marginalization and lack of access to treatment due to inadequate development of diagnostics, therapies and treatments, resulting in elevated costs.[[46]](#footnote-47) Even the experimental treatment available is focused mainly on adults.[[47]](#footnote-48) The cost of medicines in developing countries often prevents children with rare diseases from access to medicines.[[48]](#footnote-49) In high-income countries, such as those in the European Union, even while access to medicines is being further developed, only 56 medicines for rare diseases are approved for paediatric use.[[49]](#footnote-50)

2. Women and girls

1. Women and girls continue to face systemic discrimination, exclusion and marginalization with regard to their right to health, [[50]](#footnote-51) such as through discriminatory norms, roles, stereotypes and stigma,[[51]](#footnote-52) reflected in, for example, spousal consent laws that inhibit a woman’s autonomy to seek medical care without a man’s permission,[[52]](#footnote-53) or limits on a woman’s ability to make health-seeking decisions within households.[[53]](#footnote-54)
2. A critical gap in the field of medical research and development can be seen in the unequal attention paid to medical needs specific to women. In addition to differences attributable to sex that may be observed in prevalence, diagnosis, severity and disease outcomes, some illnesses are more prevalent among women and others may manifest themselves differently, with dissimilar potential for long-term complications.[[54]](#footnote-55) Women face difficulties in their access to medicines in cases of breast, cervical and uterus cancers, particularly in developing countries, owing to unaffordability.[[55]](#footnote-56) Given the longer life expectancy of women, it is essential that their medical needs are met.[[56]](#footnote-57)
3. Women have often been underrepresented in clinical trials, and health issues primarily or exclusively experienced by women have been frequently marginalized in clinical research;[[57]](#footnote-58) as a result, data on the safety and adequate dosing of medicines for pregnant and lactating women are very limited.[[58]](#footnote-59) This has led to gaps in the development of medicines and health products that are primarily responsive to the needs of women.[[59]](#footnote-60)
4. Women and girls in all their diversity continue to face barriers in their access to sexual and reproductive health and other health services and products, such as those to prevent and treat sexually transmitted infections.[[60]](#footnote-61) It is estimated that 214 million women in low- and middle-income countries have different barriers to access to contraception.[[61]](#footnote-62) In high-income countries, marginalized groups may face physical barriers, with health services often being physically out of reach, or financial barriers that hinder access to contraceptives.[[62]](#footnote-63)
5. Gender and poverty intersect and, among historically marginalized and disadvantaged groups of women, result in a lack of access to pre-natal care, leading to high rates of maternal and infant mortality.[[63]](#footnote-64) Women also continue to face barriers in their access to menstrualproducts[[64]](#footnote-65) and to treatment for women undergoing menopause.[[65]](#footnote-66)
6. Women’s vulnerability to economic insecurity and gender-based violence in the home significantly hinders their access to medicines, vaccines and other health products.[[66]](#footnote-67) For instance, the disproportionate burden of unpaid care and domestic work limits women’s ability to seek gainful employment and to enjoy equal access to the right to social security. This disparity can be exacerbated by the lack of or limited participation of women in the labour markets, in particular in a number of developing economies, where women have less access than men to financial institutions, including bank accounts. The socioeconomic fallout of the COVID-19 pandemic has further aggravated the existing inequalities that women face.[[67]](#footnote-68)

3. Persons with albinism

1. Persons with albinism are particularly vulnerable to developing life-threatening skin damage, including cancer, owing to a condition characterized by a deficit in the production of melanin.[[68]](#footnote-69) Skin cancer is however highly preventable if a person with albinism has access to regular health checks and, in particular, early-stage detection, which is more widely available than treatment.[[69]](#footnote-70) While the regular use of sunscreen, sunglasses and sun-protective clothing play a critical role in the prevention and reduction of prevalence of skin cancer in persons with albinism, they are often unavailable, inaccessible or of poor quality.[[70]](#footnote-71) Limited access to sunscreen for persons with albinism in a number of countries, especially in low- and middle-income countries, results in preventable deaths, including among those between 30 and 40 years of age.[[71]](#footnote-72)
2. Only a few countries include sunscreen in their national essential medicines list. The Independent Expert on the enjoyment of human rights by persons with albinism and various partners requested that sunscreen be restored to the WHO Model List of Essential Medicines after its removal in 2005, request which was, however, rejected.[[72]](#footnote-73)

4. Older persons

1. Older persons often face a number of obstacles in relation to their access to primary health care and to the quality of health-care services provided, including for instance access to primary care and the prevention of chronic illnesses.[[73]](#footnote-74)
2. In certain contexts, access to primary health-care services can also be impeded by both physical and financial obstacles. Health-care facilities might be situated far from an older person’s place of residence, while transport might be too expensive, inadequate or simply unavailable. Compounding this problem is the limited mobility of older persons.[[74]](#footnote-75) Such challenges can be further exacerbated by the socioeconomic vulnerability of older persons, especially as access to health care is often subject to receiving a pension or to paying fees out of pocket. Living in poverty can also be a root cause of deterioration in an older person’s health; with limited access to safe drinking water or adequate nutrition, older persons face a high risk of contracting diseases.[[75]](#footnote-76)
3. The lack of affordable medicines, vaccines or health products for older persons can furthermore deepen disparities. For example, during the COVID-19 pandemic, millions of older persons in low- and middle-income countries, despite being at risk of severe disease and death from the virus, faced challenges in their access to vaccines, tests and treatments; in some countries, less than 5 per cent of older persons were vaccinated as at May 2022.[[76]](#footnote-77) In some countries, the cost of prescription drugs generates financial hardship for older persons.[[77]](#footnote-78) In certain cases, the high costs deny older persons access to prescription drugs.[[78]](#footnote-79) Medicines, vaccines and assistive technologies must be available and accessible to people of all ages to support healthy ageing, including those that address non-communicable diseases, age-related conditions and disability.
4. Stigma is another hurdle that can lead to the rationing of care, where treatment is restricted or denied according to the age of the patient rather than anticipated effectiveness of treatment. The COVID-19 pandemic further showed the dilemmas for older persons that resulted when they were without access to health-care products, such as medicines. A systemic review by WHO in 2020 showed that, in 85 per cent of 149 studies, age determined who received certain medical procedures or treatments.[[79]](#footnote-80) With regard to the obstacles that older persons face in their access to medicines or treatment, the Department of Economic and Social Affairs found that older persons are less often recommended for surgery or chemotherapy.[[80]](#footnote-81)
5. Assistive technologies are essential for supporting people’s intrinsic capacity, functional ability and quality of life. While WHO estimates that 2.5 billion older persons in need of one or more assistive products, such as wheelchairs and hearing aids, among others, nearly one million of them are denied access to them in low- and middle-income countries.[[81]](#footnote-82)

5. Persons with disabilities

1. Compared to the general population, persons with disabilities are significantly more likely to experience stigma and discrimination in the context of health,[[82]](#footnote-83) and encounter barriers in their interaction with various building blocks of the health system.[[83]](#footnote-84)
2. Service delivery may not be suited to the specific needs of persons with disabilities. The health and care workforce may prioritize an exclusive medical approach to health, without taking into account a human rights-based approach to disability, such as full respect for autonomy, dignity and equality enshrined in different treaties, as laid out in the Convention on the Rights of Persons with Disabilities. This lack of a human rights-based approach to disability, including lack of information systems, can contribute to a lack of prioritization of persons with disabilities and, in turn, perpetuate inequality and discrimination.[[84]](#footnote-85)
3. Persons with disabilities may moreover be excluded from health coverage programmes on the grounds of pre-existing conditions, and they often bear higher out-of-pocket costs to cover various health services and the additional cost of living associated with disability.[[85]](#footnote-86)
4. As noted in previous reports, the lack of equitable access to medicines, vaccines and other health products disproportionately affects certain groups, including persons with disabilities. They, together with children and older persons, often lack access to assistive technologies, such as prosthetic devices.[[86]](#footnote-87) The lack of or disruption to human rights-based support and care systems,[[87]](#footnote-88) such as support services, products, infrastructure[[88]](#footnote-89) and financial support, undermines access to various services, including health services, by persons with disabilities. These gaps can be further exacerbated during times of crisis, such as a pandemic.

C. Challenges to access in emergency situations

1. Emergency situations, whether caused by conflict or disasters, invariably result in or exacerbate challenges in ensuring access to medicines, vaccines and other health products.
2. Physical barriers in times of conflict can severely affect access to health facilities and treatment. Various actors in conflict-affected areas can at times prevent access of civilians to medical goods, including life-saving medicines and supplies, by obstructing, restricting, limiting or diverting them.[[89]](#footnote-90)
3. In addition to conflict- or disaster-related injuries, persons who require continuous care have particular health needs which, if unaddressed, can increase the number of unnecessary deaths during conflict; for example, an acute shortage of essential medicines causing interruption to treatment may render pregnant women,[[90]](#footnote-91) newborns and children,[[91]](#footnote-92) older persons,[[92]](#footnote-93) persons with disabilities, people living with HIV, tuberculosis and cancer, more vulnerable to ill-health. The lack of availability of medicines and psychosocial services can likewise prove especially detrimental to persons with mental health conditions,[[93]](#footnote-94) some of whom may require continuous treatment.[[94]](#footnote-95) Shortage of medical supplies particularly affect persons with chronic illnesses[[95]](#footnote-96) and non-communicable diseases.[[96]](#footnote-97)
4. Access to medicines, vaccines and other health products may also deteriorate in conflict-affected areas because of disruptions in supply chains, looting of health facilities, or the destruction of clinics and hospitals, which may in turn lead to shortages of essential medicines, equipment and health products.[[97]](#footnote-98)
5. States, as the primary duty bearers, have an obligation under international human rights law and humanitarian law to respect, protect and fulfil the right to health, including access to essential medicines at all times. [[98]](#footnote-99) According to international humanitarian law, State and non-State actors party to a conflict have an obligation to respect and protect medical services, such as hospitals, clinics and pharmacies, whether military or civilian, fixed or mobile, permanent or temporary, and medical equipment and supplies and/or personnel, in all circumstances.[[99]](#footnote-100)

D. Systemic barriers to access

1. Legal and regulatory challenges to ensure access to quality, safety and efficacy of medicines and medical products.

1. States are required to ensure quality assurance for medicines and to protect the population from unsafe and poor-quality medicines.[[100]](#footnote-101) They should also ensure post-marketing surveillance approaches to address the underreporting of adverse drug reactions and events.[[101]](#footnote-102)
2. Many low- and middle-income countries face capacity challenges in their regulatory systems for assessing and authorizing health products owing to a lack of technical expertise, shortages of qualified staff, resource limitations, insufficient infrastructure or inadequate policy frameworks. These challenges can result in extended processing periods that obstruct access to new medicines, also because major pharmaceutical firms frequently postpone introducing products in such countries, which struggle to adapt to evolving health technologies.[[102]](#footnote-103) Sudden emergencies, such as pandemics or natural or man-made disasters, may represent a great challenge to public authorities engaged in setting legal and regulatory frameworks, such as regulatory entities or parliaments.[[103]](#footnote-104)
3. The circulation of unregistered and/or illegal medicines can pose another challenge, especially in countries with more limited regulatory capacity.[[104]](#footnote-105) Illegal medicines sometimes include registered ones that are imported from countries where they are more affordable; unregistered medicines, such as expensive and new-generation medicines that have special storage requirements and transportation conditions; or medicines that have not been granted a marketing authorization for the retail market.[[105]](#footnote-106)
4. Lack of regulatory oversight poses another challenge contributing to the circulation of counterfeit and low quality medicines. WHO has estimated that this issue affects one in every 10 medicines in low- and middle-income countries, leading to patient harm and fostering scepticism or hesitancy towards non-branded medicines. Such hesitancy can exacerbate lack of affordability, as patients choose higher-priced branded medicines, pushing more families into poverty.[[106]](#footnote-107)
5. Some countries may face significant obstacles in their access to medicines due to regional or State legal frameworks[[107]](#footnote-108) that hinder the processes involved in the acquisition, registration, pricing and reimbursement of medicines and the distribution of vaccines[[108]](#footnote-109) affecting the accessibility of medicines, vaccines and other health products. Limited regulatory harmonization and reliance at the national, regional and international levels could result in wasted resources and prolonged approval timelines,[[109]](#footnote-110) exacerbating these difficulties.
6. Overly restrictive guidelines for health services and products included in national lists of essential medicines, vaccines and other health products also pose a challenge to access to medicines, vaccines and health products. One example can be seen in the case of punitive policies that limit the availability of medicines for treatment of pain and drug dependence to persons in need of palliative care or receiving substance abuse treatment,[[110]](#footnote-111) or for care for low-incidence diseases or gender-affirming treatment.[[111]](#footnote-112)
7. Community health workers are an essential part of the wider health system and are often better placed to reach people who are marginalized or disadvantaged.[[112]](#footnote-113) Challenges may also arise if community health workers are not included in registries as part of the workforce under the Ministry of Health.[[113]](#footnote-114)
8. States should strengthen their legal and regulatory frameworks to ensure the quality and safety of medicines, including 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.[[114]](#footnote-115)
9. Without a strong legal and regulatory framework that includes flexible guidelines, countries risk delays in delivery of medicines or finding themselves with a stock of medicines with a short shelf life or that have already reached their use-by date.[[115]](#footnote-116) Furthermore, the lack of a robust system of pharmacovigilance may hinder the timely detection of quality or safety concerns.[[116]](#footnote-117) The public authorities responsible for assessing and monitoring the safety, effectiveness and quality of medicines and vaccines must be properly resourced,[[117]](#footnote-118) with the appropriate skills and up-to-date training,[[118]](#footnote-119) and a well-equipped quality-control laboratory to ensure the quality and safety of products and adequate cold room for vaccines and storage facilities.[[119]](#footnote-120)
10. The WHO Prequalification of Medicines Programme was designed to improve public health outcomes and reduce health disparities by ensuring access to high-quality medicines and vaccines in low- and middle-income countries.[[120]](#footnote-121) States should therefore consolidate their efforts in international global regulatory cooperation and address the challenges posed to the rigorous evaluation processes required by the Programme, and ensure an efficient system where the implementation of those processes is rooted in human rights, remains transparent, is impartial and effective,[[121]](#footnote-122) and is aimed at reducing costs and improving access to medicines, vaccines and other health products.

2. Research and development

1. The current biomedical innovation system is often driven by commercial interests. Most pharmaceutical companies develop medicines based on the likelihood of profitability. The result is a severe lack of investment in medical tools – medicines, diagnostics and vaccines – to meet the needs of people who do not constitute a sizeable or lucrative market. It also has implications for prices, which may not be affordable for a part of the population.[[122]](#footnote-123) This is not only for treatment of neglected diseases, but also for other major global health problems.[[123]](#footnote-124) Infectious diseases, vaccines and antibiotic resistance are examples of key public health areas where pharmaceutical companies are withdrawing their research and development efforts out of profit considerations, thereby reinforcing existing inequalities.[[124]](#footnote-125) Without strong public engagement, the strategic focus and investments of manufacturers will remain limited in relation to the need for an ambitious immunization agenda, and will rather continue to concentrate on more profitable pharmaceutical interventions and on high-income market vaccines.[[125]](#footnote-126) To secure access to medicines, vaccines and medical products for all people, States must reverse this trend.
2. In the context of the COVID-19 response, public-private partnerships played a critical, positive role in facilitating rapid vaccine development, incentivizing it through significant investment in research and development efforts, particularly in the early and risky stage of vaccine development. The COVID-19 response also showed, however, important shortcomings in public-private partnerships. Companies benefiting from research funding were not required to prioritize reasonable returns on investment and undergo evaluations of their pricing practices and their impact on access to medicines, vaccines and other health products;[[126]](#footnote-127) as a result, intellectual property supported at least in part by the public funds ended up in private hands.[[127]](#footnote-128) A key lesson learned from the COVID-19 response is that when States introduce measures for public investments in research and development, they must ensure that the resulting medical technologies that receive public subsidies in their development process are made available and accessible to those in need, domestically and globally.[[128]](#footnote-129)
3. A further drawback in market mechanisms during the research and development stage is the fact that reliance on market exclusivity drives scientists and companies to work in isolation from and in competition with one another. Information on research and development costs and methods are not disclosed, which discourages follow-on innovation, which could drive prices down or improve health outcomes. The lack of transparency also inhibits the ability of companies to learn from each other, leading to poor investment decisions being replicated simultaneously by multiple companies.[[129]](#footnote-130) States should regulate in a way that promotes cooperation and exchange.

3. Impact of intellectual property on pricing of medicines, vaccines and health products

1. According to the Committee on Economic, Social and Cultural Rights intellectual property “is a social product with a social function, and States parties have a duty to prevent unreasonably high costs of essential medicines from undermining the right to health”.[[130]](#footnote-131)
2. There is an increasing need to ensure the sustainable availability of health products through careful management of affordable and fair pricing for health systems and producers.[[131]](#footnote-132) The price of new medicines and vaccines should be affordable to all patients and health systems, while allowing for a reasonable profit margin for pharmaceutical companies to act as a stimulus for further innovation.[[132]](#footnote-133)
3. According to principle 11 of the Guiding Principles on Business and Human Rights,[[133]](#footnote-134) business entities, including the pharmaceutical industry, have a responsibility to respect human rights in the conduct of their business activities. Businesses should avoid infringing on the human rights of others and should take action to address any negative impact on human rights resulting from their actions.This responsibility includes conducting appropriate human rights due diligence to identify, prevent, mitigate and address any risk or actual impact on human rights of their activities and operations.[[134]](#footnote-135) The pharmaceutical industry should assess the main human rights risks throughout their value chain, both upstream and downstream,[[135]](#footnote-136) and consider the adverse consequences that pricing and distribution decisions may have for equal access to medicines and vaccines, particularly for those in vulnerable and marginalized situations.[[136]](#footnote-137)
4. The pharmaceutical industry and innovations are rooted in the patents system, which often leads to monopolies, limiting competition and resulting in high prices, ultimately impeding the availability and affordability of medicines.[[137]](#footnote-138) Poor populations are consequently left with limited purchasing power and their needs unaddressed, as in the case of, for example, neglected tropical diseases. The majority of persons most at risk of and severely affected by life-threatening neglected tropical diseases live in regions without quality health care, in rural and remote areas, conflict zones or areas where the rights to water and to sanitation are neglected.[[138]](#footnote-139)
5. States must find ways to encourage the development of generic drugs that makes medicines accessible to all. Patent pooling systems are one option to increase access to vaccines and medicines. Through patent pooling, entities holding patents for a particular technology or product cooperate to share their intellectual property rights. This collaborative effort enlarges the pool of intellectual property, streamlining the process for generic manufacturers to produce and disseminate crucial medicines and vaccines.[[139]](#footnote-140)
6. The agreement on trade-related aspects of intellectual property rights (TRIPS) 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.[[140]](#footnote-141) Those provisions can help to increase access to essential medicines and vaccines in underserved areas.
7. The discussion on trade-related aspects of intellectual property rights regarding vaccines and medicines in the context of the COVID-19 pandemic has generated varying views with regard to the appropriate balance between protecting intellectual property and ensuring access to affordable medicines and vaccines, particularly in low- and middle-income countries.[[141]](#footnote-142) While companies are legitimately entitled to reasonable rates of return on their own investments, what is considered reasonable should be subject to the test of accessibility of medicines.[[142]](#footnote-143) 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 existing medicines.[[143]](#footnote-144) According to the Committee on Economic, Social and Cultural Rights, business entities, including pharmaceutical companies, have the obligation, at a minimum, to respect economic, social and cultural rights; they have specific responsibilities regarding the realization of the right to health, including in relation to access to medicines and vaccines. It also noted that, in the framework of the COVID-19 pandemic, business entities should also refrain from invoking intellectual property rights in a manner that is inconsistent with the right of every person to have access to a safe and effective vaccine or the right of States to exercise the flexibilities of the TRIPS agreement.[[144]](#footnote-145)

IV. Strengthening health systems to maximize access to medicines, vaccines and other health products

1. To deliver on the promise of the 2030 Agenda and the commitment to universal health care for all by 2030, health-care systems should be designed with the explicit purpose of improving access to essential health services for excluded and marginalized populations. This goal should ensure access to needed health services of sufficient quality to ensure that the use of these services does not expose people to financial hardship.[[145]](#footnote-146) The WHO Consultative Group on Equity and Universal Health Coverage[[146]](#footnote-147) outlined a process for ensuring the fair progressive realization of universal health care. There is no single path to universal health care; the health needs and preferences of populations, the organization of the health system, the resources available, institutional and legal arrangements and existing health financing systems vary widely, requiring each State to address and overcome unique challenges and chart its own path.
2. While approaches to reaching universal health care vary, equity considerations should guide all decision-making about populations and services to be covered and about financing mechanisms. The universal health care package should ensure that any user payments, either through pre-payment schemes or at the point of service, do not render services unaffordable.[[147]](#footnote-148) In this regard, establishing risk pools becomes essential; they allow the financial burden of health services to be spread across larger populations and ensure more equitable distribution, whereby the higher costs incurred by those with greater health needs are balanced by the relatively lower expenses of others.[[148]](#footnote-149) For the poorer segments of the population, ensuring universal access may mean that physical and mental health services and medicines, vaccines and other health products are provided free of charge.[[149]](#footnote-150) Ensuring that medicine, vaccines and medical products are affordable is particularly important in low- and middle-income countries, many of which still rely heavily on out-of-pocket expenses to finance health care, which can account for as much as 55 per cent of total health financing.[[150]](#footnote-151)
3. Universal health care cannot function if it fails to mobilize adequate resources to meet the essential health needs of the population. The Committee on Economic, Social and Cultural Rights has outlined options for Governments to expand the fiscal space for social protection, including by reallocating public expenditure with a renewed focus on social spending, increasing tax revenues, reducing debt or debt servicing, adapting the macroeconomic framework, fighting illicit financial flows and increasing social security revenues.[[151]](#footnote-152) Countries can use the WHO Health Financing Progress Matrix to assess their health financing system[[152]](#footnote-153) and the handbook for parliamentarians published by WHO and the Inter-Parliamentary Union, *The path towards universal health coverage*, which provides guidance on revenue raising, efficient use of resources and financial protection.
4. The current global context is making it very challenging for countries, in particular low- and middle-income countries, to secure sufficient fiscal space to make the investment necessary to achieve universal health coverage. Currently, approximately 60 per cent of developing countries (52 States) face high risk of or are experiencing debt distress, leaving many middle-income countries with no access to debt relief or concessional finance for COVID-19 recovery.[[153]](#footnote-154) Governments are frequently confronted with the difficulty of choosing between allocating adequate resources for health and social protection, fulfilling their human rights obligations or servicing their debts.[[154]](#footnote-155) National action will have to be matched by increased solidarity and cooperation.[[155]](#footnote-156) Addressing these systemic issues is also critical to mobilize the financing necessary to achieve universal health care, which is critical for ensuring access to medicines, vaccines and medical products.
5. Effective health financing also requires that funds are used efficiently, by effectively pooling resources. Health financing for universal health coverage implies mobilizing and raising sufficient funds, to pool them effectively, and to allocate the resources efficiently by purchasing health services strategically. Effective utilization of health resources remains a challenge in many countries owing to inefficient processes to use the funds and to corruption.

V. Pandemic treaty to strengthen pandemic prevention, preparedness and response

67. In December 2021, at its second-ever special session, the World Health Assembly established the Intergovernmental Negotiating Body to draft and negotiate a convention, agreement or other international instrument under the WHO constitution to strengthen pandemic prevention, preparedness and response.

68. As at 7 March 2024, the Bureau of the Intergovernmental Negotiating Body had produced six draft texts. OHCHR has repeatedly stressed the need for the incorporation of a human rights-based approach into health emergency preparedness, response and recovery.[[156]](#footnote-157) In particular, it is important that the treaty ensure that public health interventions take into account the social and economic context, including inequalities and structural barriers for some individuals and communities in their access to health goods, facilities and services.

69. Throughout the process, OHCHR has emphasized that human rights should be an integral part of any future accord, placing emphasis on certain issues, including the need for a truly participatory, inclusive and transparent negotiating process; meaningful stakeholder participation in pandemic prevention, preparedness and response; strengthened multilateralism and international solidarity, and the importance of ensuring equitable access to vaccines, medicines and other health products; and equality and non-discrimination.

VI. Conclusions and recommendations

70. **It is essential that States guarantee the right to health in compliance with their obligations under international human rights law, including providing access to medicines, vaccines and other health products. Business entities, including pharmaceutical companies, have, at a minimum, the obligation to respect the right to health. Furthermore, they have specific responsibilities regarding the realization of the right to health, including in relation to access to medicines and vaccines.**[[157]](#footnote-158)

71. **Overcoming challenges to access to medicines, vaccines and other health products requires urgent action in many areas. Key recommendations within this report include the need:**

1. **To promote collaborative efforts between States, the private sector, civil society and other stakeholders to improve access to medicines, vaccines and other health products, thereby** **ensuring the effective participation of communities and affected populations in decision-making processes; and greater transparency, especially in the selection, pricing, procurement and registration of medicines, vaccines and other health products;**
2. **To strengthen global, regional and local health governance through active international cooperation involving States, the private sector and civil society;**
3. **To strengthen the national capacity of countries, in particular in low- and middle-income countri**es**, to put in place and implement a robust regulatory system relating to medicines;**
4. **To bolster investment in the research and development of new medicines and vaccines; in this regard, public-private partnerships, such as innovative funding mechanisms, can help to provide incentives that can accelerate research and development;**
5. **To take measures to promote research and development in advancing access to medicines, vaccines and health products against health challenges with a limited market, such as neglected tropical diseases and other global public health challenges;**
6. **To take measures to encourage the mutual learning and the transfer of technology to ensure the widest possible access to medicines, vaccines and other health products, in full respect of international law, including international human rights law;**
7. **To ensure that intellectual property rights are not invoked and applied in a manner that is inconsistent with the right to health, including access to medicines, vaccines and other health products, or the right of States to exercise the flexibilities of the TRIPS agreement;**
8. **To move towards health-care systems that ensure universal access to medicines, vaccines and other health products**.

1. \* The present report was submitted to the conference services for processing after the deadline for technical reasons beyond the control of the submitting office. [↑](#footnote-ref-2)
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 (Geneva, 2019), p. 2. [↑](#footnote-ref-3)
3. A/HRC/53/50, para. 3. [↑](#footnote-ref-4)
4. A/HRC/53/50. [↑](#footnote-ref-5)
5. See www.ohchr.org/en/calls-for-input/2023/call-contributions-ohchr-analytical-study-key-challenges-ensuring-access. [↑](#footnote-ref-6)
6. See www.ohchr.org/en/events/events/2024/expert-workshop-key-challenges-and-new-developments-ensuring-access-medicine. [↑](#footnote-ref-7)
7. See E/C.12/2021/1. [↑](#footnote-ref-8)
8. See Universal Declaration of Human Rights, art. 25;; International Covenant on Economic, Social and Cultural Rights, art. 12; Convention on the Rights of the Child, art. 24; Convention on the Elimination of All Forms of Discrimination against Women, art. 12; and Convention on the Rights of Persons with Disabilities, art. 25. [↑](#footnote-ref-9)
9. A/HRC/53/50, para. 3. [↑](#footnote-ref-10)
10. Committee on Economic, Social and Cultural Rights, general comment No. 14 (2000), para. 12 (b) (iii). [↑](#footnote-ref-11)
11. Ibid., para. 12 (c). See also [E/2023/74](https://documents.un.org/doc/undoc/gen/g23/093/49/pdf/g2309349.pdf?token=Rqab7xtfrbGWcUj4eN&fe=true), para. 28. [↑](#footnote-ref-12)
12. Committee on Economic, Social and Cultural Rights, general comment No. 14 (2000), para. 31. [↑](#footnote-ref-13)
13. Ibid., paras. 43 and 44. [↑](#footnote-ref-14)
14. A/HRC/49/35, para. 11; E/2019/52. [↑](#footnote-ref-15)
15. E/2015/59, para. 12. [↑](#footnote-ref-16)
16. Committee on Economic, Social and Cultural Rights, general comment No. 3 (1990) on the nature of States parties’ obligations, para. 10; general comment No. 14 (2000), para. 47; and general comment No. 15 (2002) on the right to water, para. 40. [↑](#footnote-ref-17)
17. General comment No. 14 (2000), para. 12. [↑](#footnote-ref-18)
18. See General Assembly resolution 78/4, annex. [↑](#footnote-ref-19)
19. WHO, “Universal Health Coverage”, available at <https://www.who.int/health-topics/universal-health-coverage#tab=tab_1>. [↑](#footnote-ref-20)
20. Even though there is no single universally accepted definition of universal health coverage, global organizations like the International Labour Organization (ILO), the World Bank and WHO all identify the key common elements of ensuring access to essential health services to all and protecting individuals and families from suffering financial hardship as a result of seeking such services. [↑](#footnote-ref-21)
21. Submission by the United Nations Entity for Gender Equality and the Empowerment of Women (UN-Women). [↑](#footnote-ref-22)
22. WHO, “Noncommunicable diseases”, 16 September 2023, available at www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases. [↑](#footnote-ref-23)
23. See for example A/HRC/53/50, para 9; A/HRC/17/43, para. 32; WHO, *Access to NCD Medicines: Emergent Issues during the COVID-19 Pandemic and Key Structural Factors* (Geneva, 2023); and submission by Mexico (in Spanish). [↑](#footnote-ref-24)
24. A/HRC/53/50, para 9. See also submission by the Third World Network. [↑](#footnote-ref-25)
25. See for example expert workshop mandated by Human Rights Council resolution 50/13 on key challenges and new developments in ensuring access to medicines, vaccines and other health products, 16 February 2024, available at www.ohchr.org/en/events/events/2024/expert-workshop-key-challenges-and-new-developments-ensuring-access-medicines; A/HRC/53/50; andE/2023/74. [↑](#footnote-ref-26)
26. Submissions by Salud por Derecho – Right to Health Foundation and Mexico (both in Spanish). [↑](#footnote-ref-27)
27. See submission by WHO. [↑](#footnote-ref-28)
28. Ibid. [↑](#footnote-ref-29)
29. See A/HRC/47/23, A/HRC/49/34, A/HRC/49/35, A/HRC/52/56 and A/HRC/53/50. [↑](#footnote-ref-30)
30. E/2023/74, para. 17. [↑](#footnote-ref-31)
31. See Christina Bucci-Rechtweg, “Enhancing the pediatric drug development framework to deliver better pediatric therapies tomorrow”, *Clinical Therapeutics*, vol. 39, No. 10 (2017), cited in E/2023/74, para. 17; see also submissions by the Elizabeth Glaser Pediatric AIDS Foundation and the Coalition for Epidemic Preparedness Innovations. [↑](#footnote-ref-32)
32. Submissions by Poland, Salud por Derecho – Right to Health Foundation. [↑](#footnote-ref-33)
33. Submissions by Guatemala and Médecins sans Frontières. [↑](#footnote-ref-34)
34. Submission by the Elizabeth Glaser Pediatric AIDS Foundation. [↑](#footnote-ref-35)
35. Ibid. [↑](#footnote-ref-36)
36. Submission by Guatemala. [↑](#footnote-ref-37)
37. Submissions by the Elizabeth Glaser Pediatric AIDS Foundation and Guatemala. [↑](#footnote-ref-38)
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40. Submission by Médecins sans Frontières. [↑](#footnote-ref-41)
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42. M.C. Letinturier-Valencia and others, eds., *State of Play: Rare Diseases – Research Initiatives 2019–2021* (Ivry-sur-Seine, International Rare Diseases Research Consortium, 2022), p. 12. [↑](#footnote-ref-43)
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46. Ibid. [↑](#footnote-ref-47)
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49. See Philippe Pakter, “Rare disease care in Europe – gaping unmet needs”, *Rare*, vol. 2 (2024). [↑](#footnote-ref-50)
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52. Helena Nygren-Krug, “The right(s) road to universal health coverage”, *Health and Human Rights Journal*, vol. 21, No. 2(December 2019); submission by Guatemala. [↑](#footnote-ref-53)
53. Submission by UN-Women. [↑](#footnote-ref-54)
54. See [www.who.int/initiatives/beijing25](http://www.who.int/initiatives/beijing25) [↑](#footnote-ref-55)
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62. Submission by the national human rights institution of Slovakia. [↑](#footnote-ref-63)
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73. A/HRC/18/37, para. 38. [↑](#footnote-ref-74)
74. Ibid., para. 40. [↑](#footnote-ref-75)
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86. A/HRC/53/50, para. 7. [↑](#footnote-ref-87)
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99. Geneva Convention for the Amelioration of the Condition of the Wounded and Sick in Armed Forces in the Field, art. 35; Geneva Convention relative to the Protection of Civilian Persons in Time of War, art. 21; Protocol Additional to the Geneva Conventions of 12 August 1949, and relating to the Protection of Victims of International Armed Conflicts (Protocol I), art. 21; Protocol Additional to the Geneva Conventions of 12 August 1949, and relating to the Protection of Victims of Non-International Armed Conflicts (Protocol II), art. 11 (1); and Jean-Marie Henckaerts and Louise Doswald-Beck, *Customary International Humanitarian Law: Volume I – Rules* (Geneva, International Committee of the Red Cross; Cambridge, United Kingdom, Cambridge University Press, 2005), rule 29. [↑](#footnote-ref-100)
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150. Christoph Strupat and others, “Health financing in times of multiple crises: analysis and recommendations”, Policy Brief 11/2023 (German Institute of Development and Sustainability, 2023), pp. 3 and 5. [↑](#footnote-ref-151)
151. E/C.12/2015/1. [↑](#footnote-ref-152)
152. See www.who.int/teams/health-systems-governance-and-financing/health-financing/diagnostics/health-financing-progress-matrix. [↑](#footnote-ref-153)
153. See concept note for the Joint High-level Thematic Debate convened by the President of the General Assembly and the President of the Economic and Social Council, 31 May 2022, available at www.un.org/pga/76/wp-content/uploads/sites/101/2022/05/PGA-and-P-ECOSOC-Joint-HLD-on-Debt-Concept-Note.pdf; and George Gray Molina and Lars Jensen, “Building blocks out of the crisis: the UN’s SDG Stimulus Plan”, Development Futures Series (United Nations Development Programme, 2023). [↑](#footnote-ref-154)
154. A/HRC/54/38, para. 20. [↑](#footnote-ref-155)
155. See A/HRC/51/22. [↑](#footnote-ref-156)
156. A/HRC/49/35, para. 67. [↑](#footnote-ref-157)
157. See [A/63/263](http://undocs.org/en/A/63/263), annex. [↑](#footnote-ref-158)