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Report of the United Nations High Commissioner for Human Rights

Summary

In the present report, submitted pursuant to General Assembly resolution 48/141, the United Nations High Commissioner for Human Rights outlines challenges in relation to access to medicines that arise in the existing system for pharmaceutical innovation, its associated business models and current pricing practices. The prohibitive cost of medicines in poor and wealthy countries alike is a major reason why 2 billion persons lack access to the medicines that they need and thousands of preventable deaths occur every day, raising substantial human rights concerns. The High Commissioner emphasizes that, whereas pricing based on a reasonable rate of return would save thousands of lives, maximizing investor return at all costs demonstrates a systematic lack of compliance with human rights law by Governments and failure by business enterprises to meet their responsibility to respect human rights. It urges State action to respect, protect and fulfil human rights and new business models that reconcile the fiduciary responsibilities of pharmaceutical companies with their human rights responsibilities.

I. Introduction

1. The World Health Organization (WHO) defines essential medicines as those that satisfy the priority health-care needs of a population. They are selected with due regard to disease prevalence and public health relevance, evidence of efficacy and safety and comparative cost-effectiveness, and are intended to be available in functioning health systems at all times, in appropriate dosage forms, of assured quality and at prices individuals and health systems can afford.[1] Today, 2 billion persons are without access to essential medicines and, therefore, to the benefits of scientific and medical advances that could improve health or save or prolong life.[2] The vast majority of the people affected live in low- and middle-income countries.[3] While the context in each country is unique, a reliable, affordable and high-quality supply of health products, such as medicines, is vital for any health system.[4] Similarly, under the right to health framework, affordability and accessibility are indispensable.

2. Evoking one of the central tenets of the human rights framework, the 2030 Agenda for Sustainable Development commits States to ensuring that no one is left behind and to endeavouring to reach first those who are furthest behind. Goal 3 of the Sustainable Development Goals ("ensure healthy lives and promote well-being for all at all ages") is the principal health goal, and its targets focus on a range of health concerns. These targets address: (a) the reduction of the global maternal mortality ratio (target 3.1); (b) preventable death of newborns and children under 5 years of age (target 3.2); (c) AIDS, tuberculosis, malaria and neglected tropical diseases, hepatitis, water-borne diseases and other communicable diseases (target 3.3); (d) premature mortality from non-communicable diseases (target 3.4); (e) universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all (target 3.8); and (f) research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries and access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health (target 3b).[5] Effective access to medicines is necessary for these targets to be met. The impact of prices on access is therefore a critical factor in working towards Goal 3 as a whole.

3. When the availability and economic accessibility of innovations essential for life and health depend on producers whose main or sole purpose is to generate revenue, inevitable tensions can arise between the practical enjoyment of human rights, on the one hand, and the profit motive and associated business models, on the other. This situation is particularly apparent in the area of access to medicines and vaccines, with the coronavirus disease (COVID-19) pandemic continuing to provide one of the clearest examples of the impact of failing to provide access to vaccines. WHO estimates that, globally, there have been 764,474,387 confirmed cases of COVID-19, including 6,915,286 deaths.[6] For some entities in the pharmaceutical industry, however, the pandemic generated extraordinary gains and continues to do so.[7] This windfall was facilitated in large part by patent protections for the

[1] See www.who.int/publications/i/item/WHO-MHP-HPS-EML-2021.02.

[2] WHO, "Access to medicines: making market forces serve the poor – ten years in public health 2007–2017" (Geneva, 2017), p. 14.

[3] Rachel Silverman and others, *Tackling the Triple Transition in Global Health Procurement: Promoting Access to Essential Health Products through Aid Eligibility Changes, Epidemiological Transformation, and the Progressive Realization of Universal Health Coverage* (Washington, D.C., Center for Global Development, 2019), p. xi.

[4] Ibid.

[5] This is a reference to the Agreement on Trade-Related Aspects of Intellectual Property Rights (1994).

[6] As at 26 April 2023. See https://covid19.who.int.

[7] On the profitability of pharmaceutical companies in south-east Europe, for example, see https://top100.seenews.com/pharma-remains-sees-most-profitable-sector. In November 2021, the People's Vaccine Alliance reported that Pfizer, BioNTech and Moderna were making combined profits of $65,000 every minute. One source states that the net profits of Pfizer, BioNTech, Moderna and Sinovac from COVID-19-related sales (vaccines and non-vaccines) were more than $50 billion in 2021 and more than $30 billion in the first three quarters of 2022. See Esther de Haan and Albert ten

new vaccines that were developed, as well as the conclusion of advance purchase agreements. The vast majority of doses were sold to wealthy countries, with low- and middle-income countries being left largely behind, giving rise to what has sometimes been termed vaccine nationalism.[8]

4. The example of the COVID-19 pandemic is instructive as it illustrates some of the complex problems related to access to medicines. These problems have been reviewed over the last few decades from a number of perspectives, including in reports issued by the Office of the United Nations High Commissioner for Human Rights (OHCHR).[9] In the present report, the High Commissioner explores challenges related specifically to the pricing of essential medicines, cost considerations and the impact of the existing pharmaceutical innovation system on access. The High Commissioner proposes possible shifts towards a different paradigm for access, taking into account the extensive work that has already informed evolving thinking at both global and national levels.

II. Key areas where further change is needed

A. Pricing and patents

5. There are several reasons why so many people cannot access the medicines that they need, including inefficient procurement processes and poor distribution infrastructure and practices. Yet, comparatively high prices are arguably the most important barrier to access to life-saving vaccines and other medicines.[10] With health systems frequently constrained to ration medicines based on calculations of cost effectiveness, people living in poverty or who otherwise cannot afford necessary medicines are forced to forgo a vital part of their health care.

6. Innovation in the pharmaceutical industry is rooted in the patent system, which, as explained below, is flawed in significant ways.[11] The Global Commission on HIV and the Law, reporting in 2012, found that excessive intellectual property protections played a central role in exacerbating the lack of access to HIV/AIDS treatment and other essential medicines. The Commission noted that: "[Intellectual property] protection is supposed to provide an incentive for innovation but experience has shown that the current laws are failing to promote innovation that serves the medical needs of the poor."[12] As stated by the Committee on Economic, Social and Cultural Rights, ultimately, 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.

7. The trend towards the high pricing of patented new medicines undermines access in both wealthier and poorer countries.[13] The arrival on the market of highly effective treatments for HIV/AIDS in 1996 transformed AIDS from a terminal condition to a chronic one with prospects for a normal lifespan. The cost of the drugs, however, was prohibitive for most of the developing world where, with 8,000 deaths a day, the burden of HIV/AIDS was the highest.[14] Although the global health community and public and other stakeholders successfully mobilized and forced a change in this situation in which large numbers of people were dying from a condition for which treatment existed but was too costly, the problem of steep prices remains.

Kate, *Pharma's Pandemic Profits: Pharma Profits from COVID-19 Vaccines* (Amsterdam, Centre for Research on Multinational Corporations, 2023), p. 11.

[8] See https://data.undp.org/vaccine-equity/assessment-70-percent-global-goal.

[9] See, for example, A/HRC/49/35 and A/HRC/52/56.

[10] 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.

[11] Ibid., p. 4.

[12] Global Commission on HIV and the Law, *HIV and the Law: Risks, Rights & Health* (New York, United Nations Development Programme, 2012), p. 8.

[13] 't Hoen, *Private Patents and Public Health*, p. 2.

[14] Ibid., p. 1.

8. 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. Medicines for the treatment of cancer provide another example of the use by some pharmaceutical companies of patent protections to artificially restrict access to life-saving medication to the few who have the necessary health coverage or who can afford to pay. One drug used in the treatment of chronic myeloid leukaemia, a rare form of cancer, was priced at nearly $30,000 a year on its release in 2001, with the price reaching $92,000 a year in 2012.[15] However, as noted by experts, the recovery of costs and return on investment had been factored into the original price, which continued to rise even as more people were being excluded from the life-saving treatment.[16] Similar pricing issues have arisen with access to drugs to treat diabetes, hepatitis C and other conditions.

9. In addition to patent-related cost issues, price increases for older off-patent products have sometimes followed the purchase of one company by another or the sale of rights to a drug, with the new owner setting higher prices due to the monopoly that it now enjoys. A case in point is that of the only drug available to treat toxoplasmosis, an infection contracted from cat parasites that can cause birth defects.[17] Its price in the United States rose 5,000 per cent from $13.50 a tablet to $750 a tablet in August 2015.[18] This drug is also used as a co-treatment for HIV infections and malaria, conditions that tend to be overrepresented among people living in poverty or who are vulnerable for other reasons.

10. The justifications typically advanced by the pharmaceutical industry for the high cost of medicines include the costs of research and development, production and commercialization and the need to ensure sufficient returns on their investments. The patent system, it is argued, is necessary to allow manufacturers to recoup these costs and maintain incentives for further investment.[19] However, the effective monopoly created by patents for essential medicines can allow manufacturers to set the price for new pharmaceuticals at price points that solely maximize returns on investment, even when this entails avoidable deaths.[20] The practical impacts on the rights of millions of human beings is often neglected in pricing decisions, with prices frequently unrelated to the value of the product or the cost of research and development. Several studies have found the respective justifications tenuous, with some pointing out that the lack of transparency around the true outlays, for example, for research and development, production and marketing prevented a more accurate understanding of these costs. Some experts have pointed out that the wide variation in cancer drug prices in different geographic regions supports the assertion that prices reflect geopolitical and socioeconomic factors that bear scant relationship to the cost of development.[21]

B. Public funding and private profits

11. Governments have a clear interest in encouraging pharmaceutical research and development, and in many countries the public sector plays a vital role in funding. The discovery and development of new medicines typically involves a “process of basic biomedical research to uncover potential targets for drug action, followed by applied, or translational, research to identify candidate products and establish their effectiveness and

[15] The drug referred to is known as Imatinib or Glivec. See https://ashpublications.org/blood/article/121/22/4439/31343/The-price-of-drugs-for-chronic-myeloid-leukemia.

[16] Ibid.

[17] The drug is known as Daraprim.

[18] See www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html.

[19] See, for example, Olivier J. Wouters and others, “Association of research and development investments with treatment costs for new drugs approved from 2009 to 2018”, *JAMA Network Open*, 26 September 2022, p. 1.

[20] See https://twn.my/title/twr131b.htm.

[21] See https://ashpublications.org/blood/article/121/22/4439/31343/The-price-of-drugs-for-chronic-myeloid-leukemia.

safety", and this renders fair attribution of value realized through each stage a complex question.[22]

12. Nevertheless, according to one estimate, two thirds of the global upfront research and development costs are borne by the public, and approximately one third of new medicines begin their development in research institutions.[23] Many medicines developed by the pharmaceutical industry are the result of a large body of scientific work funded by the taxpayer.[24] The seven largest COVID-19 vaccine producers, for example, received government funding in their respective jurisdictions totalling at least $5.8 billion for research and development. Their revenue in 2021 from COVID-19 vaccines amounted to $86 billion, of which $50 billion represented the net profit realized.[25] Consequently, in cases in which the Government has provided the initial funding as part of efforts to meet its right to health obligations, taxpayers will often have financed the initial outlay before being required to pay the (usually) high cost of the drugs themselves. Without a guarantee that the drugs developed using public funding will be available and affordable and that the data, knowledge and technologies generated will be shared, rights holders lose out on both their investment and on the full realization of the rights to health and to enjoy the benefits of scientific progress and its applications.

C. Impacts of pricing practices, cost considerations and patent protections

13. In this section, the High Commissioner outlines a number of areas in which pricing systems, cost considerations and associated practices have resulted in substantial and avoidable human suffering through adverse effects for particular groups and on specific research areas. The list is illustrative rather than exhaustive, and the impacts are much broader than the areas represented here.

1. Medicines principally needed by poor populations

14. The patent system has delivered such significant financial rewards that incentives to allow competition through the availability of generic products remain few and far between. Moreover, given the focus on ensuring high returns on investment, health products that are too costly to develop or that do not offer high enough returns have often been neglected. This has been the fate of new medicines and other health products for poor populations with limited purchasing power, with the result that research and development to meet the unique health needs of these populations is frequently lacking.[26] The more than 1 billion persons worldwide affected by a group of 20 neglected diseases who live in impoverished, marginalized communities is one such population.[27] As indicated by WHO: "Lack of access to medicines causes a cascade of misery and suffering, from no relief for the excruciating pain of a child's earache, to women who bleed to death during childbirth, to deaths from diseases that are easily and inexpensively prevented or cured."[28]

[22] Ekaterina Galkina Cleary, Matthew J. Jackson and Fred D. Ledley, *Government as the First Investor in Biopharmaceutical Innovation: Evidence from New Drug Approvals 2010–2019*, revised 2021, Working Paper No. 133 (Institute for New Economic Thinking), p. 1.

[23] Dzintars Gotham and others, *Pills and Profits: How Drug Companies Make a Killing Out of Public Research* (London, STOPAIDS and Global Justice Now, 2017), p. 13.

[24] See www.ncbi.nlm.nih.gov/books/NBK50972/#:~:text=While%20basic%20discovery%20research%20is, pharmaceutical%20companies%20or%20venture%20capitalists and www.doctorswithoutborders.ca/issues/medical-rd-and-essential-medicines.

[25] De Haan and ten Kate, *Pharma's Pandemic Profits*, p. 4.

[26] WHO, "Access to medicines: making market forces serve the poor", p. 16.

[27] See www.who.int/news-room/questions-and-answers/item/neglected-tropical-diseases.

[28] WHO, "Access to medicines: making market forces serve the poor", p. 14.

2. Rare diseases

15. Globally, a total of approximately 300 million persons live with a rare disease[29] and the vast majority of rare diseases – 80 per cent – are genetic conditions.[30] Owing to the perceived inadequate returns on investment, this area of disease research suffers from chronic underinvestment and marginalization in terms of research and development, resulting in the inadequate development of diagnostics, therapies and treatments. Although the overwhelming majority of rare diseases have no effective treatment or cure, many patients could still benefit from therapies to extend or improve quality of life. The high cost of some of the drugs needed for rare conditions operates to reinforce barriers to access, with the most pronounced impact in the developing world, in which persons living with rare diseases often lack access to treatments that are routinely available elsewhere. According to the *British Medical Journal*, one gene therapy for spinal muscular atrophy was launched at a price of $2 million for a single-dose treatment in 2019,[31] while another gene therapy for haemophilia B cost $3.5 million for each dose as of November 2022.[32]

3. Antimicrobials

16. Another area affected by the dearth of research and development due to the perceived lack of profitability is antimicrobials, which include antibiotics, antivirals, antifungals and antiparasitics. Specifically, one assessment referred in this regard to inadequate market incentives for companies to invest in research and development and bring new products to market at the right time, to protect these products from overuse and, therefore, premature resistance, and to ensure global access to life-saving antibiotics.[33] As emphasized by WHO, the emergence and spread of drug-resistant pathogens continues to seriously threaten the continuing ability to treat common infections. The rapid global spread of multi- and pan-resistant bacteria (“superbugs”) is responsible for infections that cannot be treated with existing antimicrobials.[34] The research and development pipeline for new antimicrobial products is virtually dry, with shortages affecting both wealthier and poorer countries. The situation has been worsening steadily over the years as the number of people for whom treatment is ineffective grows and, consequently, medical procedures, such as surgery, including caesarean sections and hip replacements, cancer chemotherapy and organ transplantation, become increasingly risky for them.

4. Paediatrics

17. In spite of the very important progress made over the last few decades in reducing child mortality and morbidity, the United Nations Children’s Fund estimates that 5 million children, most of them living in the developing world, died from preventable and treatable diseases in 2021.[35] Children are susceptible to many of the same illnesses as adults; however, only a small proportion of adult medications have been assessed for efficacy, dosing accuracy and tolerability in paediatric populations. Medicines may be absorbed, metabolized and eliminated in different ways in children, which calls for specific research on potential responses in children.[36] One source cites the scarcity of available patient populations, the practical complexities of research and development, and minimal financial returns as factors in the relatively poor availability of therapies for children. In the case of HIV/AIDS, although children should begin treatment with antiretroviral drugs without delay, nearly 50 per cent of

[29] In the United States of America, rare diseases are defined as those affecting 86 per 100,000 persons, while in the European Union a rare disease is one that affects fewer than 50 per 100,000.

[30] 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.

[31] The drug is onasemnogene abeparvovec (Zolgensma).

[32] See http://press.psprings.co.uk/bmj/february/drugprice.pdf.

[33] Kevin Outterson, “New business models for sustainable antibiotics”, Working Groups on Antimicrobial Resistance, Paper 1 (London, Chatham House, 2014).

[34] See www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance.

[35] See https://data.unicef.org/resources/levels-and-trends-in-child-mortality-2021.

[36] See www.sciencedirect.com/science/article/abs/pii/S0149291817308329?via%3.

all children living with HIV were not on treatment in 2018.[37] The failure to fully suppress the virus remains a serious problem among affected children and the lack of appropriate formulations has worsened the situation as the most effective treatments are developed for use by adults.[38]

5. Women and research and development

18. A critical gap in the field of medical research and development is the failure to pay equal attention to the specific medical needs of women. Differences attributable to sex may be observed in prevalence, diagnosis, severity and disease outcomes; some illnesses are more prevalent among women and others may present differently, with dissimilar potential for long-term complications.[39] Nevertheless, women have been underrepresented in clinical trials, and health issues primarily or exclusively affecting women have been marginalized in clinical research.[40] This has led to the development of health products that are primarily responsive to the needs of men and to gaps in vital data on physiological differences, such as data on dosing, and the safety and efficacy of medicines in pregnant or breastfeeding women.[41] One such positive example is the impact of pregnancy on multiple sclerosis, whereby pregnancy has been found to dramatically reduce the likelihood of relapse.[42] Increased cost, including at the preclinical stage involving animals, and complexity are among the reasons advanced for excluding women. The underrepresentation of women among those leading medical research and development is a contributing factor for this exclusion.

III. Applicable human rights norms and standards

19. Business enterprises are expected to conduct human rights due diligence to identify, prevent, mitigate and account for how they address the impacts of their operations on human rights, including the right to health. For their part, in situations in which States have failed to take the necessary steps to ensure that companies respect human rights, including with regard to detrimental pricing practices, this inaction implicates their obligations under international human rights law, as discussed in pillar I of the Guiding Principles on Business and Human Rights. Furthermore, Article 1 (3) of the Charter of the United Nations states as a purpose of the Organization the achievement of international cooperation in solving international problems of an economic, social, cultural or humanitarian character, and in promoting and encouraging respect for human rights and for fundamental freedoms for all without distinction as to race, sex, language or religion. International solidarity and cooperation have a critical role to play in creating an enabling environment for realizing all human rights and fundamental freedoms for all people in all countries. In this section of the report, the High Commissioner considers the key normative standards that apply in relation to access to medicines, with the two most relevant sets of guidelines considered first, given their

[37] See www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/hiv/treatment/treatment-and-care-in-children-and-adolescents.

[38] Ibid.

[39] Katherine A. Liu and Natalie A. Dipietro Mager, “Women’s involvement in clinical trials: historical perspective and future implications”, *Pharmacy Practice* (Granada), vol. 14, No. 1 (January–March 2016), p. 1. See also Susan Christine Massey and others, “Sex differences in health and disease: a review of biological sex differences relevant to cancer with a spotlight on glioma”, *Cancer Letters*, vol. 498; and Franck Mauvais-Jarvis and others, “Sex and gender: modifiers of health, disease, and medicine”, *Lancet*, vol. 396, No. 10250 (August 2020).

[40] See https://acmedsci.ac.uk/file-download/22836484; and Institute of Medicine, *Women’s Health Research: Progress, Pitfalls, and Promise* (Washington, D.C., National Academies Press, 2010), p. 15.

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

[42] Kerstin Hellwig, Elisabetta Verdun di Cantogno and Meritxell Sabidó, “A systematic review of relapse rates during pregnancy and postpartum in patients with relapsing multiple sclerosis”, *Therapeutic Advances in Neurological Disorders*, vol. 14 (November 2021).

overarching scope. The report then considers how these might work in a different paradigm for enhancing the accessibility and availability of medicines.

A. Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines

20. In 2008, the then Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health developed the Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines.[43] The Guidelines reiterate the principle that States have the primary responsibility for realizing the right to the highest attainable standard of health and increasing access to medicines; they note that, in addition, numerous national and international actors share a responsibility to increase access to medicines;[44] and that the business sector, including pharmaceutical companies, have human rights responsibilities applicable to access to medicines.[45] The Guidelines observe that, while pharmaceutical companies are subject to several forms of internal and external monitoring and accountability, these mechanisms do not usually monitor, and hold a company to account, as regards its human rights responsibilities in relation to access to medicines.[46]

21. Guideline 1 calls for the adoption of a human rights policy statement that expressly recognizes the importance of human rights generally, and the right to the highest attainable standard of health in particular, in relation to the strategies, policies, programmes, projects and activities of the company. Guideline 2 calls for the integration of human rights, including the right to health, into these strategies, policies, programmes, projects and activities. The Guidelines cover several substantive areas, such as public commitments to contribute to research and development for neglected diseases; the need to respect the right of countries to make full use of the flexibilities provided for under the Agreement on Trade-Related Aspects of Intellectual Property Rights for promoting access to medicines; pricing; ethical promotion and marketing; transparency; and management, monitoring and accountability.

B. Guiding Principles on Business and Human Rights

22. The guidelines for pharmaceutical companies were followed in 2011 by the Guiding Principles on Business and Human Rights,[47] which the Human Rights Council endorsed the same year.[48] While not focused particularly on business entities in the pharmaceutical industry or on access to medicines, the Guiding Principles on Business and Human Rights apply to all States and to all business enterprises irrespective of size, sector, location, ownership and structure. They are grounded in the existing duties of States to respect, protect and fulfil human rights and fundamental freedoms; the role of business enterprises as specialized organs of society performing specialized functions that must comply with all applicable laws and respect human rights; and the need for appropriate and effective remedies for adverse human rights impacts.[49]

23. Under guiding principle 1, States must protect against human rights abuses within their territory and/or jurisdiction by third parties, including business enterprises, and this requires taking steps to prevent, investigate, punish and redress such abuse through effective policies, legislation, regulations and adjudication. Guiding principle 3 looks at how States might implement their duty to protect, calling for States to: (a) enforce laws that are aimed at, or have the effect of, requiring business enterprises to respect human rights, and periodically to assess the adequacy of such laws and address any gaps; (b) ensure that other laws and policies governing the creation and ongoing operation of business enterprises, such

[43] A/63/263. The Guidelines were attached to the Special Rapporteur's report to the General Assembly.
[44] Preambular paragraphs (f) and (g).
[45] Preambular paragraph (h).
[46] Preambular paragraph (k).
[47] A/HRC/17/31, annex.
[48] Human Rights Council resolution 17/4, para. 1.
[49] Guiding Principles on Business and Human Rights, general principles.

as corporate law, do not constrain but enable business respect for human rights; (c) provide effective guidance to business enterprises on how to respect human rights throughout their operations; and (d) encourage, and where appropriate require, business enterprises to communicate how they address their human rights impacts. Additional steps should be taken to protect against human rights abuses by business enterprises that are owned or controlled by the State, or that receive substantial support and services from State agencies, including, where appropriate, by requiring human rights due diligence.[50] Crucially, States should maintain the policy space that they need to meet their human rights obligations when pursuing business-related policy objectives with other States or business enterprises, such as is the case with investment treaties or contracts.

24. Under the Guiding Principles on Business and Human Rights, business enterprises should avoid infringing on the human rights of others and should address adverse human rights impacts with which they are involved. In order to meet their responsibility to respect human rights, business enterprises should: (a) avoid causing or contributing to adverse human rights impacts and address such impacts when they occur; and (b) seek to prevent or mitigate adverse human rights impacts that are directly linked to their operations, products or services by their business relationships, even if they have not contributed to those impacts.[51] Business enterprises are expected to conduct human rights due diligence to know and show that they respect human rights.[52]

C. Right to life

25. The Universal Declaration of Human Rights and the International Covenant on Civil and Political Rights both guarantee the right to life.[53] The Human Rights Committee, which monitors the implementation of the Covenant, has described the right to life as the supreme right from which no derogation is permitted even in time of public emergency that threatens the life of the nation and has indicated that it should not be interpreted narrowly.[54] Each State party is bound, under article 2 of the Covenant, to respect and to ensure to all individuals within its territory and subject to its jurisdiction the rights recognized in the Covenant, without distinction of any kind, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.[55] Article 2 further provides that, where not already provided for by existing legislative or other measures, each State party undertakes to take the necessary steps, in accordance with its constitutional processes and with the provisions of the Covenant, to adopt such laws or other measures as may be necessary to give effect to the rights recognized in the Covenant.[56] Concerning positive measures to protect the right to life, the Committee highlighted the duty of States to address the general conditions in society that may give rise to direct threats to life or prevent individuals from enjoying their right to life with dignity, including the prevalence of life-threatening diseases, such as AIDS, tuberculosis and malaria.[57] As such, loss of life resulting from the unavailability of access to essential medicines may amount to a violation of the right to life.

D. Right to health

26. The international human rights framework recognizes the right to health through numerous instruments, and these include the Universal Declaration of Human Rights, the International Covenant on Economic, Social and Cultural Rights, the Convention on the Rights of the Child and the Convention on the Rights of Persons with Disabilities. The most comprehensive elaboration of the right to health is found in article 12 of the International

[50] Guiding principle 4.
[51] Guiding principle 13.
[52] Guiding principle 17.
[53] Articles 3 and 6, respectively.
[54] Human Rights Committee, general comment No. 36 (2018), para. 2.
[55] Article 2 (1).
[56] Article 2 (2).
[57] Human Rights Committee, general comment No. 36 (2018), para. 26.

Covenant on Economic, Social and Cultural Rights, which refers to the right to the highest attainable standard of physical and mental health and identifies a number of mandatory measures that States parties should take in order to achieve its full realization. These include measures necessary for the reduction of stillbirth and infant mortality rates, the prevention, treatment and control of epidemic, endemic and occupational diseases and the creation of conditions that assure medical service and medical attention to all in the event of sickness.[58]

27. The interpretation of treaty provisions by the respective monitoring bodies has provided authoritative guidance on normative content, as well as concomitant State obligations and priority interventions. In its general comment No. 14 (2000), the Committee on Economic, Social and Cultural Rights provides extensive guidance on the content of the right to health. The right to health contains freedoms, such as autonomy over one's health and body, and entitlements, such as a system of health protection that provides equality of opportunity for people to enjoy the highest attainable level of health.[59] It is an inclusive right, encompassing access to timely and appropriate health care, as well as the many factors that affect its enjoyment – the underlying determinants of health.[60]

28. A human rights framework for realizing the right to health calls for national Governments to ensure that health facilities, goods and services are available in sufficient quantity, and are physically accessible and affordable on the basis of non-discrimination. Health facilities, goods and services are also required to be gender-sensitive and culturally appropriate, scientifically and medically appropriate, of good quality and respectful of medical ethics. All members of society should be able to participate, through transparent processes, in the development and implementation of health policies. Health authorities and other duty bearers should be held accountable for meeting human rights obligations in the area of public health, including through judicial and quasi-judicial mechanisms or other avenues for effective redress.

29. As is the case with all other rights protected by the International Covenant on Economic, Social and Cultural Rights, the right to health is subject to progressive realization. Nevertheless, States have an immediate duty to take deliberate, concrete and targeted measures to this end, and to guarantee the exercise of the right to health without discrimination. The duty to take immediate action also extends to ensuring the satisfaction of the minimum essential levels of each right. For the right to health, these "core obligations" include ensuring access to health facilities, goods and services on a non-discriminatory basis, especially for vulnerable or marginalized groups; ensuring the equitable distribution of all health facilities, goods and services; implementing and adopting a national public health strategy and plan of action on the basis of epidemiological evidence; and providing essential medicines.[61]

30. Access to medicines has four dimensions: medicines must be accessible in all parts of the country; they must be affordable to all, including those living in poverty; they must be accessible without discrimination on any of the prohibited grounds; and reliable information about medicines must be accessible to patients and health professionals in order to facilitate informed decision-making.[62] Access to medicines and health technologies is a fundamental building block of the right to health, and the obligation to fulfil the right to health includes promoting medical research.[63]

E. Right to enjoy the benefits of scientific progress and its applications

31. The Committee on the Theoretical Bases of Human Rights, convened by the United Nations Educational, Scientific and Cultural Organization in 1947 to work on developing the fundamental concepts underpinning the draft Universal Declaration of Human Rights,

[58] Article 12 (2).
[59] Committee on Economic, Social and Cultural Rights, general comment No. 14 (2000), para. 8.
[60] Ibid., para. 11.
[61] Ibid., para. 43.
[62] A/61/338, para. 49.
[63] A/HRC/11/12, para. 10; and Committee on Economic, Social and Cultural Rights, general comment No. 14 (2000), para. 36.

acknowledged a "right to share in progress", characterized by "the right to full access to the enjoyment of the technical and cultural achievements of civilization."[64] The right to enjoy the benefits of scientific progress and its applications is well established under international human rights law and is recognized in the Universal Declaration of Human Rights (art. 27 (1)) and the International Covenant on Economic, Social and Cultural Rights (art. 15 (1) (b)). Subsequently, the Universal Declaration on Bioethics and Human Rights (2005) acknowledged access to quality health care as a benefit arising from scientific research and its applications that should be shared with society as a whole.[65]

32. One of the most important elements of the right to enjoy the benefits of scientific progress and its applications is that innovations essential for a life with dignity should be accessible to everyone, in particular marginalized populations.[66] The normative content of the right includes access to the benefits of science by everyone, without discrimination; opportunities for all to contribute to the scientific enterprise and the freedom indispensable for scientific research; participation of individuals and communities in decision-making; and an enabling environment fostering the conservation, development and diffusion of science and technology.[67] States should ensure that the benefits of science are physically available and economically affordable to all on an equal footing and the non-discrimination dimension calls for the removal of both de jure and de facto barriers.[68] In particular, positive steps must be taken to ensure non-discriminatory access to scientific information, processes and products for marginalized populations, such as persons living in poverty and persons with disabilities, as well as older persons, women and children.[69]

33. With regard to permissible limitations on the right to enjoy the benefits of scientific progress and its applications, restrictions must pursue a legitimate aim, be compatible with the nature of this right and be strictly necessary for the promotion of general welfare in a democratic society.[70] All limitations on the right should, in any event, be proportionate.[71] Given that medicines are essential for health and life, affordability and availability are also important dimensions of the right to enjoy the benefits of scientific progress and its applications. Where the protection of the rights of inventors operates as a disproportionate limitation on the enjoyment of their inventions and therefore the right to enjoy the benefits of scientific progress and its applications, it becomes and detrimental to general welfare. States parties should ensure that their legal or other regimes for the protection of the moral and material interests resulting from scientific productions do not impede their ability to comply with their core obligations in relation to the rights to health and science.

III. Exploring the path to change

A. The need for new "rules of engagement"

34. The lack of access to medicines has become a global challenge, given that both rich and poor countries are affected (albeit to differing degrees) and that the proportion of the world population living in developing countries, where lack of access to medicines is most problematic, continues to rise and is set to reach 86 per cent by 2050.[72] The existing system for pharmaceutical research and development has significant shortcomings, as outlined above, underperforming in terms of delivering optimum rates of innovation and aligning investments

[64] United Nations Educational, Scientific and Cultural Organization, *Human Rights: Comments and Interpretations*, appendix II, p. 14, para. 15.
[65] Article 15.
[66] A/HRC/20/26, para. 29.
[67] Ibid., para. 25.
[68] Ibid., paras. 30 and 31.
[69] Ibid., para. 31.
[70] International Covenant on Economic, Social and Cultural Rights, art. 4.
[71] A/HRC/20/26, para. 49.
[72] See https://unctad.org/data-visualization/now-8-billion-and-counting-where-worlds-population-has-grown-most-and-why.

in research and development with public health priorities.[73] Moreover, where funding has been provided by the State, the general tendency has been for the risks to be assumed by the public while allowing for business profits to be privatized. According to one view, it is usually assumed that the State will receive some return on its investments through tax revenue or the "spillover" generated in the process; however, the assumption fails to hold when patenting operates to limit spillover or when the investment is made across the whole innovation chain, rather than only at the level of basic research.[74] This is a critical area for government intervention to redress the balance in favour of broader enjoyment of human rights.

35. While the business enterprise is motivated in major measure by profit, States have a non-negotiable duty to respect, protect and fulfil the right to access essential medicines and business enterprises have the responsibility to respect this right. As has been suggested, one problem is that the discourse around research and development is "dominated by studies of private sector investment in the biopharmaceutical industry, the economics of the industry, and the efficiency of the penultimate stages of clinical development, regulatory review, marketing, and sales", while public investment and the role of Governments is less prominent.[75]

36. The global health community and other stakeholders have long called for rules of engagement between Governments, both individually and collectively, pharmaceutical companies and others involved in research and development, and rights holders. Making use of a human rights framework and ensuring that States fulfil their existing obligations and businesses their responsibilities under international human rights law would help address the shortcomings of the current system. Although it is beyond the scope of this report, given the complex technical and other issues arising from this debate, to elaborate a possible model or models, the High Commissioner does propose some "organizing principles", based on the human rights framework, around which dialogue could take place, as well as areas in which existing norms could be strengthened. To this end, the following principles should be reaffirmed and upheld: (a) the role of the State as primary duty bearer in relation to upholding human rights; (b) the duty of business enterprises to respect human rights independently of States' abilities and/or willingness to fulfil their own human rights obligations;[76] (c) respect for human rights as part of respect for the rule of law; (d) there should be no profiteering or speculating where public goods or innovations essential for life, health or dignity are concerned; and (e) international cooperation for the realization of the rights to life, health and the enjoyment of the benefits of scientific progress and its applications as they apply to access to medicines should be understood and given effect as a human rights obligation.

B. Recommendations

37. **Taking into account the above principles and the other human rights norms applicable to access to medicines, the High Commissioner makes the following recommendations as the basis for further stakeholder discussions on how to redress the balance in favour of better protecting the practical enjoyment of human rights:**

(a) **With a view to considering a new paradigm for ensuring access to medicines for all, a collaborative, inclusive network of stakeholders should be established with expertise in the areas covered in this report to consider, among other issues, how to achieve the appropriate incentivization of innovation while avoiding the inequalities of access that are the hallmark of the current system. In addition to the human rights norms and standards covered in this report, and building on the existing body of work both globally and at the national and regional levels, the network should consider what would be required to achieve the following: build capacity to strengthen**

[73] 't Hoen, *Private Patents and Public Health*, p. 131.

[74] Mariana Mazzucato, "From market fixing to market creating: a new framework for innovation policy", *Industry and Innovation*, vol. 23, No. 2 (2016), p. 149.

[75] See www.ineteconomics.org/perspectives/blog/us-tax-dollars-funded-every-new-pharmaceutical-in-the-last-decade.

[76] Guiding Principles on Business and Human Rights, commentary to guiding principle 11.

health research systems within member States; support the setting of research priorities that meet health needs, particularly in low- and middle-income countries; develop an enabling environment for research through the creation of norms and standards for good research practice, and ensure that good-quality evidence is turned into affordable health technologies and evidence-informed policy;

(b) **States should reinforce cooperation in the area of access to medicines, particularly in relation to the exchange of technical know-how and data, research and development into new drugs, vaccines and diagnostic tools, financial support and effective regulation, including with regard to human rights due diligence, to ensure that business enterprises involved in the development, production and distribution of medicines operate in accordance with their human rights responsibilities;**

(c) **Developed States should reaffirm and take action to operationalize their responsibility to take steps towards the full realization of the right to health through international assistance and cooperation. This obligation is especially relevant with regard to the need to support developing States with the economic or technological resources to invest in research and development into the major health issues facing their populations;**[77]

(d) **States, individually and in cooperation with one another, should use the human rights framework, including the Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines and the Guiding Principles on Business and Human Rights, to create law and policy frameworks that ensure that access to medicines is sustainable, equitable and responsive to the needs of their populations, including women, persons living in poverty, persons living with rare or neglected diseases, and children;**

(e) **With the aim of countering the impact of patent monopolies on pricing, especially of new drugs, Governments should be proactive in ringfencing the public interest and human rights using, as the Global Commission on HIV and the Law recommended, other areas of law and policy, such as competition law, price control policies and procurement law that can help increase access to pharmaceutical products. As underscored by the United Nations Development Programme, competition law holds considerable unexplored potential, particularly in low- and medium-income countries.**[78] **Based on the premise that free and fair competition benefits consumers in terms of choice and affordability, competition law could be used effectively to address, for instance, the abuse of dominant market positions by charging unfair prices, imposing other unfair conditions on health-service users or limiting production;**

(f) **States should ensure non-discriminatory access to health education, strengthen the capacities of civil society, community-based organizations and the general public to participate meaningfully in public health decision-making processes and actively promote their engagement in law and policymaking. This involves establishing transparent social dialogue and multi-stakeholder mechanisms at community, subnational and national levels and ensuring that participation outcomes inform subnational, national and global policies and programmes related to public health and, specifically, access to medicines;**

(g) **Public health priorities, including those relating to public investment in research and development, the coordination of research and development for pharmaceutical products and the medicines to be included on national essential medicines lists should be decided in line with the health concerns of the population as a whole in participatory, transparent and inclusive processes. These processes should involve all rights holders, including patient advocacy groups, associations of community health workers, publicly funded research institutes, and groups representing persons living with rare diseases and those affected by conditions prevalent among persons**

[77] International Covenant on Economic, Social and Cultural Rights, art. 2 (1); and Committee on Economic, Social and Cultural Rights, general comment No. 14 (2000), para. 38.

[78] United Nations Development Programme, “Using competition law to promote access to medicines and related health technologies in low- and middle-income countries” (New York, 2017).

living in poverty. They should allow for stakeholders at all levels to participate meaningfully and have their inputs considered. The views and inputs of women, persons living in poverty, persons living with rare or neglected diseases and children should be carefully solicited and reflected;

(h) **States should allocate and govern public funding for research and development in the interests of public health and should ensure that all medicines developed with the financial and other support of the Government are available and accessible to everyone solely on the basis of need. Public interest and human rights conditions, including those derived from the Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines and the Guiding Principles on Business and Human Rights, should be attached to publicly funded research and development. This may be achieved, within a broader regulatory framework, by mandating government bodies to require, monitor and enforce these conditions in all contracts and agreements concluded with public and private sector stakeholders for health research. A framework for ensuring fair returns on public investment through affordable pricing should be underpinned by transparency throughout the research and development process, as well as the principle that recouping research and development costs should equally apply to public investors as well;**

(i) **States should, individually and collectively, work to promote sustainable financing to broaden access to affordable medicines and explore innovative approaches and other methods, such as ensuring that research and development costs for pharmaceutical products considered "non-profitable" are subsidized with revenue from other medicines that have enjoyed more facility in generating revenue. Drawing from good practices, such as the Medicines Patent Pool, should be an integral part of this effort. The Medicines Patent Pool is an example of innovation driving access and saving lives, providing access to antiretroviral therapy in low- and middle-income countries. In partnership with civil society, Governments, international organizations, industry, patient groups and other stakeholders, the Medicines Patent Pool prioritizes and licenses essential medicines and pools intellectual property to encourage generic manufacture and the development of new formulations;**

(j) **In accordance with the Guiding Principles on Business and Human Rights, business enterprises in the pharmaceutical sector should establish policies and processes, including a policy commitment to meet their responsibility to respect human rights; a human rights due diligence process to identify, prevent, mitigate and account for how they address their impacts on human rights, particularly relative to pricing and access to medicines; and processes to enable the remediation of any adverse human rights impacts that they cause or to which they contribute;**

(k) **Business entities involved in the development of medicines in any capacity should integrate human rights standards applicable to access to medicines, including the rights to health and to enjoy the benefits of scientific progress and its applications, into their strategies, policies, programmes, projects and activities. In particular, action to this end should pay special attention to any particular human rights impacts on individuals from groups or populations that may be at heightened risk or vulnerability or marginalization (such as children, older persons, women, persons living in poverty and persons living with rare diseases), and bear in mind the different risks that may be faced by women and men.**

IV. Conclusion

38. **As the primary duty bearer, the State has legal obligations to respect, protect and fulfil the right to access to medicines. The ability of the State to discharge these obligations depends to a great extent on private actors by virtue of their role as producers. This confers power on these actors to wield a very direct influence, negatively or otherwise, on the supply of medicines essential for health or life. This power, however, comes with a responsibility, rooted in the human rights framework,**

not to speculate or profiteer at the expense of human life and health. The exercise of rights and freedoms should be subject only to limitations determined by law for the purpose of upholding the rights and freedoms of others and of meeting the just requirements of morality, public order and general welfare in a democratic society. These are non-negotiable values that should help to shape the societies we build. As such, innovations essential for a life with dignity should be accessible to everyone.[79] However, patent protections, exploitative pricing policies and insufficient regulation of adverse commercial practices have severely restricted access to medicines, including drugs for conditions primarily affecting persons living in poverty, drugs for the treatment of rare diseases, and medicines and formulations for children. This is inconsistent with the human rights principles of equality, non-discrimination and respect for life, health and dignity. The way forward requires proactive State action and concrete measures to ensure access to medicines for all and new business models that allow business enterprises to generate profit while effectively meeting their responsibilities under international human rights law.

[79] A/70/279, para. 3.