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

Summary of the panel discussion on access to medicines

Report of the United Nations High Commissioner for Human Rights

Summary

The present report was prepared in accordance with Human Rights Council resolution 32/15, in which the Council decided to convene, at its thirty-fourth session, a panel discussion to exchange views on good practices and key challenges relevant to access to medicines as one of the fundamental elements of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. The Council also requested the United Nations High Commissioner for Human Rights to prepare a summary report of the panel discussion, for consideration at its thirty-sixth session.

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I. Introduction

1. Pursuant to its resolution 32/15, the Human Rights Council convened, on 8 March 2017 during its thirty-fourth session, a panel discussion to exchange views on good practices and key challenges relevant to access to medicines as one of the fundamental elements of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. In the same resolution, the United Nations High Commissioner for Human Rights was requested to prepare a summary report of the discussions for submission to the Council at its thirty-sixth session.

2. The panellists were: Ruth Dreifuss, former President of Switzerland, Chair of the Global Commission on Drug Policy and Co-Chair of the Secretary-General's High-level Panel on Access to Medicines; Michael Kirby, former Justice of the High Court of Australia and member of the Secretary-General's High-level Panel on Access to Medicines; Marie-Paule Kieny, Assistant Director-General for Health Systems and Innovation of the World Health Organization (WHO); Antony Taubman, Director of the Intellectual Property Division of the World Trade Organization (WTO); Thomas Bombelles, Head of Global Health at the Global Issues Sector of the World Intellectual Property Organization (WIPO); Carlos Correa, Special Adviser on Trade and Intellectual Property at the South Centre; and James Zhan, Director of the Division on Investment and Enterprise at the United Nations Conference on Trade and Development (UNCTAD). The discussion was moderated by the Permanent Representative of Brazil to the United Nations Office and other international organizations in Geneva, Maria Nazareth Farani Azevêdo.

3. During the panel discussion, the panellists made brief opening statements that were followed by a debate chaired by the Vice-President of the Human Rights Council, Mouayed Saleh. States, national human rights institutions, non-governmental organizations (NGOs) and other Observers were encouraged to intervene through questions, comments and the sharing of good practices, challenges and recommendations on the way forward.

II. Background

4. Recognizing that, in spite of the progress made in health care and treatments, millions are being left behind because of limited access to medicines and health technologies, in November 2015 the Secretary-General convened a High-level Panel on Access to Medicines "to review and assess proposals and recommend solutions to remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies".[1]

5. In its final report,[2] the High-level Panel on Access to Medicines (hereafter "Panel") called on WTO Member States to respect the letter and spirit of the Doha Declaration on the TRIPS Agreement[3] and Public Health and refrain from any action that limits its implementation and on Governments: to increase their current levels of investment in health technology; to test and implement, with relevant stakeholders, new and additional models for financing and rewarding public health research; to review, at regular intervals, access to health technologies in their respective countries in the light of human rights principles and their obligations to fulfil them, with assistance from the Office of the United Nations High Commissioner for Human Rights (OHCHR); to require manufacturers and distributers of health technologies to disclose information on research and development costs and any public funding received; and to ensure that bilateral and regional trade and investment treaties do not interfere with their obligations to realize the right to health. In the

[1] See "Terms of Reference", para. 3. Available from www.unsgaccessmeds.org/reports-documents.

[2] See "Report of the United Nations Secretary-General's High-level Panel on Access to Medicines: promoting innovation and access to health technologies". Available from www.unsgaccessmeds.org/final-report.

[3] WTO Agreement on Trade-related Aspects of Intellectual Property Rights.

report, the Panel recommended that the Secretary-General initiate a process to negotiate global agreements on coordinating, financing and developing health technologies, including a convention on research and development that delinked the costs associated with such activities from end prices to promote access to good health for all. It also recommended that the Secretary-General establish an inter-agency task force on health technology innovation and access in order to help increase coherence among United Nations entities and relevant multilateral organizations, such as WTO.

III. Summary of the discussion

A. Opening statement

6. In her opening remarks, the Deputy United Nations High Commissioner for Human Rights emphasized that the right to health requires States to ensure universal access to good quality health care, including essential medicines, on the basis of equality and non-discrimination. While that meant that innovations essential for a life with dignity should be accessible to everyone without discrimination, currently, millions were living without access to essential medicines. That was not due to an inherent lack of commodities, but entirely to policy deficits and entrenched practices. The Deputy High Commissioner drew particular attention to the situation of women and girls who, despite being old enough to acquire a sexually transmitted infection or become pregnant, were denied the autonomy to access the necessary services and medicines for treatment and to control their own fertility.

7. States needed to shift from a dominant market-oriented perspective on access to medicines towards one in which there was a focus on ensuring the right to health. Powerful commercial and other interests should not be allowed to dictate public health policy to the detriment of human rights. That meant recognizing, and responding to, a number of challenges, including a disproportionate protection of intellectual property rights, which limited the policy space available necessary to Governments to take the measures to protect the right to health and which restricted access to medicines by expanding monopolies, maintaining high prices for longer periods of time and delaying the availability of generic medicines. Trade and investment agreements should be negotiated with human rights in mind and the availability, accessibility and acceptability of good quality medicines for all without discrimination should be integrated into all public policy frameworks. She highlighted the importance of empowering rights-holders to be partners in health, to claim their health and health-related rights and to enable policymakers on health to make people-centred decisions and hold them accountable for delivering on those.

8. In conclusion, ensuring access to health care was more than a matter of States' political will, it was also a question of health economics, a matter of the ethics of the pharmaceutical industry, and a responsibility of health-care providers and health professionals. She called on all those authorities and actors to stand up for the right to health. Powerful interests should not dictate health policy to the detriment of human rights and protection of intellectual property rights could not trump the right to health.

B. Overview of presentations by the panellists

9. Ms. Dreifuss introduced the work and report of the Panel, emphasizing that it addressed just one part of the problem of accessing medicines, and that there were many other obstacles, such as a shortage of health and transport infrastructure, a lack of financing for public health care, expensive health insurance systems and bureaucracy. She also highlighted that the Panel's mandate concerned access to health technologies, which included not only medicines, but also vaccines, diagnostic tools and various types of medical equipment.

10. She underscored the shortcomings of biomedical research and the development of medicines based on the incentives provided by the present intellectual property regimes, which were founded on the existence of viable markets rather than an assessment of needs.

Such an approach led, for instance, to the neglect of many tropical diseases. Moreover, the monopoly afforded by patents and licensing led to prices that prevented many people from benefiting from progress in science. That resulted in health systems being forced to introduce restrictions and rationing.

11. Intellectual property rights were not the same as the legitimate rights of inventors. The purpose of trade rules and intellectual property rights was to promote economic growth and stimulate innovation, but those could be an impediment to public health. In that regard, while the Panel welcomed the Doha Declaration affirming the right of States to have recourse to the flexibilities available under the TRIPS Agreement in order to take measures to protect public health, it criticized the continuing incoherence of policies, particularly those resulting from the pressure intended to dissuade countries from invoking those flexibilities.

12. Mr. Kirby emphasized that the issue under discussion was not just a matter of ethics but also of international law, which had also been prioritized in the 2030 Agenda for Sustainable Development. The realization of the right to health was greatly hindered by policy incoherence and the weaknesses of the market mechanisms in stimulating invention and in promoting just distribution in accordance with international human rights law.

13. He highlighted the consultative process in drafting the Panel report, particularly the voices of those who had participated in the Panel's public hearings who had been left behind, including women and girls forced to beg for access to life-saving drugs and those from Asia or Africa with drug-resistant tuberculosis who could not afford new therapies. He also noted the challenges faced by the health systems in wealthier countries in acquiring increasingly expensive medicines. Unless the Human Rights Council — and, more generally, the United Nations — acted immediately, Sustainable Development Goal 3 would not be achieved, and millions would be left behind or die.

14. While some of the Panel members might have gone further in the report, they all agreed on the core conclusions and recommendations: WTO members should respect the flexibilities in the TRIPS Agreement and respect the human rights protection embedded in the Doha Declaration; there should be no more pressuring of countries to surrender their rights to contest "evergreening"[4] and other misuse of market powers; and the Secretary-General should initiate an independent review body on innovation in health technologies with a high-level meeting by 2018 to address weaknesses in the global markets.

15. Ms. Kieny drew attention to the long tradition of WHO in supporting access to medicines as a fundamental element of the right to health. She particularly underscored recent initiatives, such as a WHO report on access to hepatitis C treatment,[5] which mapped global access to medicines to treat hepatitis. The report contained detailed information on the patents and regulatory status of new hepatitis C treatments, the pricing of all drugs and ways to access those treatments at affordable prices. Other initiatives included the WHO global price reporting mechanism, which provided: pricing and procurement data for HIV, tuberculosis, malaria and hepatitis C treatments; a comprehensive web platform offering information on vaccine products, prices and procurement data; and the new initiative on fair pricing that assessed the production costs of essential medicines. All of those initiatives fitted well with the Panel's call for more transparency on prices.

16. With regard to technical support for its Member States, WHO had worked closely with the Government of Egypt in 2016 to ensure early and affordable access to hepatitis C treatment. Also in 2016, WHO had advised Colombia on using TRIPS flexibilities to make cancer treatment more affordable, and helped the Government of Ethiopia to develop and implement its national strategy and plan of action to expand pharmaceutical manufacturing. At the regional level, in 2016, WHO, WTO, WIPO and others had jointly advised on the

[4] The practice of extending patents without always making substantial changes to the product in question.

[5] "Global report on access to hepatitis C treatment: focus on overcoming barriers" (Geneva, WHO, 2016).

reform of the intellectual property regime of South Africa, in particular on how to implement TRIPS flexibilities to expand access to medicines.

17. Lastly she underscored the Panel's calls for Governments to review the situation of access in their countries in the light of human rights standards and principles and States' obligations to fulfil them.

18. Mr. Taubman highlighted how, for the WTO, the Doha Declaration was a milestone in placing the legal, practical and policy implications of TRIPS squarely within the public health setting. It still remained an important benchmark for policymakers, particularly given the Sustainable Development Goals, and the growing network of regional and bilateral trade agreements. However, he also highlighted how the practical question of how best to navigate through that policy space and to flex those flexibilities was still open.

19. To address that, he stressed the need to further strengthen coordination and collaboration across the multilateral system. He drew attention to the importance of trilateral cooperation among WHO, WIPO and WTO to develop policy and practical coherence on public health, including recognition of the human rights dimensions of access to medicines and health technologies. Important initiatives undertaken so far included the WTO annual flagship capacity-building workshop on trade and health that addressed both the need for accessibility and innovation.

20. He also emphasized the need for greater transparency, referring to the above-mentioned WHO report on access to hepatitis C treatment as a good example. He underlined the importance of an information platform that supported all Governments to make effective use of the rights and flexibilities within the system and to fulfil their related human rights responsibilities.

21. Mr. Bombelles underscored the mission of WIPO to lead the development of a balanced and effective international intellectual property system that enabled innovation and creativity for the benefit of all. Intellectual property had transcended the confines of legal issues relating to patents, copyrights and trademarks, and touched on many of the most important public policy issues of our time, including health, environment and food security.

22. The activities of WIPO in addressing access to medicine, in the broader context of innovation, technology transfer and capacity-building, included: updating the patent status of products on the WHO Model List of Essential Medicines; catalysing more research and development for neglected diseases; and using trilateral cooperation to drive policy coherence on innovation, trade and health. The WIPO Standing Committee on the Law of Patents commissioned empirical studies on a diverse range of patent-related issues, including exceptions and limitations to patents. At the request of Member States, WIPO also provided legislative and policy assistance within the framework of the multilateral system. He drew attention to the WIPO databases that provided access to information on the many forms of intellectual property rights, including patents, trademarks and copyrights. WIPO experts also prepared patent landscape reports on a diverse range of medicines and other technologies, including on medicines to treat HIV/AIDS, vaccines and selected medicines for non-communicable diseases.

23. Mr. Correa described actions that had been taken at the national level to overcome the incoherence between intellectual property policy and human rights law, with a focus on the role of human rights and public health impact assessments, as recommended in the Panel report. He highlighted examples, such as the study carried out by the National Human Rights Commission of Thailand on the potential impact on public health of the intellectual property provisions of the free trade agreement that Thailand had been negotiating with the United States of America before those talks stalled. He suggested that the Human Rights Council could develop guidelines and methodologies for such impact assessments, which should not just be designed for implementation before the negotiation of bilateral or regional agreements to increase intellectual property protection, but also to introduce appropriate methodologies that address the consequences of the adoption of certain intellectual property rights protections.

24. That overprotectionism in the area of intellectual property rights was not irreversible. Governments and international organizations should work together in order to review and revise national laws and international agreements and treaties to see if there was any inconsistency between intellectual property rights and the realization of the right to health.

25. Mr. Zhan highlighted the need to build capacity to produce medicines in the low-income countries, and outlined several challenges and policy recommendations. The challenges included: weak regulatory frameworks; insufficient financing partly because of poor risk-return profiles and the market sizes of individual countries; lack of policy coherence and fragmented institutional set-ups; lack of coordination and synergies among investment, health and trade and authorities; ineffective facilitation, often with no incentive and investment programmes; weak local productive capacity and supply networks to support investment; and, lastly, inadequate international support measures.

26. In response to those challenges, he discussed some of the policy recommendations that had been made by UNCTAD, which included: seeking new sources of financing, including social investment and partnerships between the development assistance agencies and the private sector, including generics producers; helping developing countries take advantage of TRIPs flexibilities; developing a new generation of investment promotion facilitation strategies and institutions; promoting regional cooperation for production and distribution in order to build economies of scale and to enlarge the market for consumption; and, lastly, forging partnerships with investors, Governments and international organizations.

C. Interventions by representatives of Member States, Observer States and other Observers

27. During the ensuing discussion, statements were made by representatives of: Brazil, both on behalf of the Community of Portuguese-speaking Countries and on behalf of the country; Cuba; El Salvador, both on behalf of the Community of Latin American and Caribbean States and on behalf of the country; European Union; Fiji; Indonesia, on behalf of Brazil, China, Egypt, Senegal, South Africa and Thailand; Iran (Islamic Republic of); Kuwait; Libya; Malaysia; Mexico; Pakistan, both on behalf of the Organization of Islamic Cooperation and on behalf of the country; Portugal; Qatar; Republic of Korea; Russian Federation; Sierra Leone; Sudan; Togo; Tunisia, on behalf of the African Group; and United States.

28. Representatives of the following NGOs also contributed to the discussions: American Association of Jurists; Caritas Internationalis (International Confederation of Catholic Charities); Conectas Human Rights; Iraqi Development Organization; Réseau international des droits humains; and Swedish Association for Sexuality Education.

29. Many of the representatives of States reaffirmed their commitment to ensuring access to medicines as a fundamental element of the right to health. One such representative drew attention to the adoption of five resolutions by the Human Rights Council since 2009 that recognized such a commitment. Representatives underscored the importance of access to medicines for all in efforts to achieve Sustainable Development Goal 3, namely to ensure health and well-being for all, at every stage of life. The United Nations had an important role to play in addressing the lack of access to medicines. Several representatives took the opportunity to highlight some good practices in their own countries to promote access to medicines. Those included developing domestic capacity in health technology, facilitating South-South cooperation, providing technical training, promoting the marketing of generic medicines, and regulating and controlling prices.

30. In general, however, representatives of States painted a dire picture, highlighting that access to medicine and high-quality medical technology depended on where one lived. Several representatives drew attention to the fact that hundreds of millions of people, particularly women and children, were currently denied lifesaving health services. Lack of access to many medicines was not just confined to developing countries. All countries

faced problems, with many medicines being unaffordable even in rich countries, threatening the sustainability of universal health systems.

31. Following the focus by many of the panellists on the Panel report, most representatives of States highlighted problems with the intellectual property regime and the current innovation model. Several representatives of States acknowledged that while the current model had led to progress, including extended life expectancy, there were a number of challenges, such as: high prices; market failures in addressing specific public health needs, particularly in developing countries; and the need for coherence among human rights law, intellectual property rights and trade and investment regimes. Many blamed policy incoherence for the disparities in access to medicines. As several delegations underscored, that was heightened by the limited production capacity of many developing countries and their subsequent dependence on foreign pharmaceutical companies.

32. Echoing some of the views of the panellists, several representatives highlighted the unaffordable prices of many medicines, particularly those used in the treatment of cancer and hepatitis C, which, as well as impeding individual access, threatened the sustainability of many health-care systems. Governments needed to continue to work with the industry and regulators to ensure that the development and use of new health technologies was accompanied by the delivery of more affordable treatments. They asked the panellists how they could pursue more transparency with regard to costs and pricing.

33. A number of representatives of States expressed strong support for TRIPS flexibilities, as had been affirmed in the Doha Declaration, which included the right to grant compulsory licences on a number of different grounds, such as public interest, and provided special treatment for least developed countries. Participants heard for instance how the Parliament of Fiji had just approved the ratification of an amendment to the Protocol amending the TRIPS Agreement. However, several representatives, including one from an NGO, drew attention to ongoing cases in which States were being pressurized because they were taking advantage of the flexibilities provided for in the Doha Declaration. The representative of the NGO specifically highlighted the impact of "evergreening" patents on reducing the enjoyment of human rights. The representative observed that the Panel report contained essential recommendations to address that and that countries should set vigorous standards to protect public health concerns regarding inventions and patents. Many representatives of States also asked the panellists to describe how the developing world could utilize TRIPS flexibilities to ensure the affordability of medicines and how their recommendations could be used to support ongoing cases in which the use of flexibilities by some States was under attack.

34. Representatives of several States also raised the issue of the difficulty of raising funding for certain medicines, particularly since the market-driven system failed to deliver treatments and diagnostics for "unprofitable" diseases that affected only a small section of the population or least developed countries. They spoke of the decline of global access to adequate sustainable and equitable financing of medicines, particularly in Africa. They asked the panellists for examples of possible actions or schemes that could finance medicines through public partnerships, improve the transfer of key technologies and investment to developing countries, and increase the demand for medicines through economies of scale to strengthen the global market and reduce prices.

35. In general, most representatives of States supported the Panel report, and they explicitly encouraged countries to implement its recommendations. According to one representative, the European Parliament had welcomed the Panel report and called on the European Union institutions and member States to take steps to implement its recommendations. Representatives of several States requested the Human Rights Council to call for the implementation of the Panel's recommendations through enhanced cooperation among all United Nations funds and programmes, as well as specialized agencies, in order to support Governments to apply public-health-service criteria in ensuring access to medicines. Several representatives expressed appreciation for the recommendation for Governments to review, at regular intervals, the situation of access to health technologies in their countries in the light of human rights principles and State obligations, and the important role of the Council and OHCHR in following up on this. Many also reiterated the Panel's recommendation that the Secretary-General initiate a process for Governments to

negotiate global agreements on the coordination, financing and development of health technology. That included negotiations for a convention on research and development that delinked the costs associated with such activities from end prices in order to promote access to health technologies. A number of representatives suggested that more attention should be given to engaging the pharmaceutical companies in efforts to ensure greater access to medicines.

36. Shadowing the concerns of the Panel report, many representatives of States underlined the importance of cooperation and coordinated action at all levels to ensure access to medicines. Several delegations urged UNCTAD to continue its cooperation programmes with small vulnerable economies. They also highlighted that countries should cooperate, and there needed to be a call on pharmaceutical companies to cooperate with United Nations agencies.

37. A few representatives, however, regretted the panellists' strong focus on the Panel report. They pointed out that access to medicines, as covered in Human Rights Council resolution 32/15, was broader than the issues that had been raised in the Panel report. One representative argued that the panellists' narrow focus deprived States of an opportunity to consider the reasons why essential medicines that were off-patent were not reaching patients in certain countries. Other possible barriers to consider included inappropriate tax and tariff policies, inadequate health systems, insufficient access to financing and lack of procurement systems.

38. Among some of the general challenges limiting access to medicines that were mentioned were lack of staff, discrimination, stigma, exclusion, limited supply chains, conflict zones and the related problems of providing humanitarian assistance to stricken communities. One representative drew attention to the imposition of unilateral coercive measures and the impact that had had on people who were in vital need of medicines. The representative asked panellists to address how such measures and/or sanctions had violated the right to health.

IV. Conclusions

39. **In their concluding comments, the panellists again focused on the intellectual property regime and the need for more coherence so that the right to health was respected and protected. While stressing the importance of the intellectual property system in ensuring innovation, some panellists articulated the need to "flex the flexibilities". In demonstrating the benefits that competition could bring, Mr. Kirby cited the example of HIV/AIDS antiretrovirals, which had initially cost each patient $10,000 a year. The price had substantially decreased once competition had been introduced by allowing generics to be legally produced.**

40. **Several panellists highlighted the need to make sure that economic considerations were no longer prioritized over human rights. They also highlighted the need for improved transparency of both costs and pricing, and called on States to require health technology companies to reveal their actual investment in research and development. They asked Governments to disclose the price they paid for medicines and health technologies. Ms. Kieny noted the phenomenon of social value-based pricing when prices were not based on cost but on perceived social value. The prices of drugs to treat hepatitis C, for instance, were not indexed to research and development but to the cost of a liver transplant.**

41. **With regard to the possible convening of a special session of the General Assembly on that topic, Mr. Zhan stressed that there was a need to gather the views of stakeholders, including Governments and pharmaceutical industries, on the fundamental changes that needed to be made to the current model. He asked, for instance, what other models of funding were possible, such as push mechanisms (for example, grants) and pull mechanisms (for example, tax breaks). Panellists reiterated the call for the Secretary-General to establish an inter-agency task force on health technology innovation and access.**

42. **Panellists were unanimous on the importance of that issue and the need for a human rights-based approach that both promoted innovation and secured the right to health for all, and achieved the 2030 Agenda for Sustainable Development and prevented people from being left behind.**