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Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health

Expert consultation on access to medicines as a fundamental component of the right to health

Summary

The present report contains a summary of the discussions held and the recommendations made at the expert consultation on access to medicines as a fundamental component of the right to health, held in Geneva on 11 October 2010, in accordance with the Human Rights Council resolution 12/24.

Under the main themes of access to medicines as a fundamental component of the full realization of the right to health, and emerging issues and existing obstacles to providing access to medicine as a fundamental element of the full realization of the right to health, the expert consultation heard presentations from experts, complemented by an interactive exchange of views and concerns, and made various recommendations relating to the realization of the right to health and access to medicines. The issues discussed included the need for States to develop suitable national health legislation and policies and to strengthen their national health systems. States were called upon to ensure the sustainable financing, availability and affordability of medicines, and to establish monitoring and accountability mechanisms.

Contents

I. Introduction

1. The expert consultation on access to medicines as a fundamental component of the right to health was held on 11 October 2010, in Geneva, pursuant to Human Rights Council resolution 12/24 on access to medicines in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. In the resolution, the Council invited the Office of the United Nations High Commissioner for Human Rights (OHCHR) to convene an expert consultation for an exchange of views on human rights considerations relating to the realization of access to medicines as one of the fundamental elements in achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, and requested the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health to present a summary of the discussions held during the expert consultation.

2. The expert consultation featured a variety of participants, including representatives of Member States, international organizations, independent experts and a number of non-governmental and civil society organizations. Regrettably, neither patients' organizations nor pharmaceutical companies attended the consultation. However, Novartis, a pharmaceutical company, submitted a letter in which it regretted not being available to participate in the consultation, and reported on its work on a statement of intent under the auspices of the Gates CEO Roundtable, to be launched on 8 and 9 November 2011 in Washington, D.C..[1]

II. Organization of the expert consultation

3. The expert consultation was organized in close cooperation with Member States and other relevant stakeholders, and focused on the elements identified in Council resolution 12/24, namely, access to medicines as a fundamental element of the right to health, and emerging issues, existing obstacles to providing access to medicines and ways forward.

4. The consultation aimed at gathering and discussing expert opinions on the interpretation of the above-mentioned human rights obligations. It also sought to encourage a greater policy coherence between human rights obligations and other areas of government policymaking, as well as to strengthen the global partnership for development, institutional coordination and collective action towards enhancing access to medicines.

III. Summary of proceedings

A. Panel 1: Access to medicine as a fundamental component of the full realization of the right to health

5. In his opening remarks, the Special Rapporteur on the right of everyone to the highest attainable standard of physical and mental health, Anand Grover, reminded participants of the current world situation with regard to access to medicines. Despite recent progress, massive inequalities remained in access to medicines around the world, as nearly

[1] The Gates CEO Roundtable consists of 10 chief executive officers of the largest pharmaceutical companies, and aims, among other things, to improve access to medicines.

2 billion people[2] (or one third of the world's population) lack such access. Furthermore, more than 100 million people fall into poverty annually because of high health-care costs. In low- and middle-income countries, 50 to 90 per cent of the cost of medicines is paid by the patient, even though medicines account for 20 to 60 per cent of the health-care budget. The median coverage of health insurance is 35 per cent in Latin America, 10 per cent in Asia, and less than 8 per cent in Africa.[3] Furthermore, only 5.2 of the 15 million persons living with HIV receive antiretroviral treatment.

6. The Special Rapporteur pointed out the positive examples of domestic courts in Latin America, South Asia and South Africa, which have abolished the distinction between civil and political rights, on the one hand, and economic, social and cultural rights, on the other, by recognizing the individual's right to have access to medicines. He recalled the importance of the availability, accessibility, acceptability and quality of medicines, as well as equality and non-discriminative approach, indicating that special attention needed to be paid to women, children and marginalized groups.

7. The Special Rapporteur recalled that some issues relating to intellectual property laws threatened access to medicines. Current health inequalities demonstrated that States had to respect their obligations under international law, including laws and practices relating to intellectual property, and take into consideration the need to ensure access to affordable medicines for all. In this respect, the Special Rapporteur warned that the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), or at least its application by certain States, remained an impediment to greater access to medicines. In this respect, he noted the pressure of developed countries on least developed and developing countries to refrain from using the flexibilities that TRIPS provides for. He cautioned against new standards in the area of patent law in free-trade agreements such as TRIPS-plus, which threatened to compound this problem even further. He concluded that developing and least developed countries should be allowed to use TRIPS flexibilities.

8. Other issues brought up by the Special Rapporteur as crucial to facilitating access to medicines were calls to resist the establishment of anti-counterfeiting laws, rules and measures, and the setting-up of border controls. He noted the need to ensure that medicine-related health priorities were not weakened in exchange for investment, and ensuring adequate drug regulations. In addition, he warned against the reduction of funding for medicines at the international and national levels, and lamented the lack of technology transfer, which is crucial for the long-term development of least developed countries.

9. Following the Special Rapporteur's opening remarks, Stephen Marks of the Harvard School of Public Health recalled Commission on Human Rights resolution 1999/49 on the protection of human rights in the context of HIV/AIDS, in which the Commission reaffirmed that international agreements should not prevent Governments from taking measures to protect public health but rather encourage them to do so. Dr. Marks, who also chaired the High-level Task Force on the Implementation on the Right to Development, had been in charge of informing the Task Force on the attainment of Millennium Development Goal 8 on the development of global partnership development. He noted that the Task Force had devoted particular attention to target E on access to essential medicines, and had positive interaction with all stakeholders involved in this issue, including pharmaceutical

[2] World Health Organization (WHO), *The world medicines situation*, World Health Organization, 2004, (WHO/EDM/PAR/2004.5), pp. 61–63. See also WHO, *WHO Medicines strategy countries at the core 2004–2007*, p. 2.

[3] World Health Organization, "Equitable access to essential medicines: a framework for collective action", leaflet No. 8, WHO Policy Perspective on Medicines, Geneva, March 2004. Available from http://apps.who.int/medicinedocs/pdf/s4962e/s4962e.pdf.

companies and the World Intellectual Property Organization (WIPO). Finally, he pointed out that access to medicines derived not only from article 12 of the International Covenant on Economic, Social and Cultural Rights, but also from article 15.1.b., which implied that everyone had the right to enjoy the benefits of scientific progress and its applications.

10. Following this presentation, Chandrashekhar Dasgupta, member of the Committee on Economic, Social and Cultural Rights, mentioned the obligation of States, including through international assistance, to achieve the full realization of the rights in the International Covenant on Economic, Social and Cultural Rights, including the adoption of legislative measures to that effect. This obligation stemmed from articles 2.1 and 12 of the Covenant, as elaborated in general comments Nos. 3 and 14, in which the Committee emphasized States parties' important role in international cooperation. Mr. Dasgupta also cautioned about the existing gap in access to medicines between developed and developing countries, which was both politically and socially unacceptable.

11. Mr. Dasgupta reiterated that States parties should ensure that the right to health, including access to medicines, is given due attention in international agreements, as detailed in general comment No. 14, and that States parties should ensure that laws and practices were consistent with the provisions of the Covenant. He shared the assessment of the Special Rapporteur regarding generic medicines, and concluded that TRIPS-plus standards that denied countries the flexibilities to which they are were otherwise entitled were unacceptable if they had an adverse impact on access to medicines.

12. Richard Laing from the World Health Organization (WHO) contributed to the discussion by stressing the importance of measuring access to medicines as a very clear and relatively robust way of measuring a Government's commitment to fulfilling the right to health. He noted, for instance, that the availability of generics in the public health sector was much lower (30 to 40 per cent) than the availability of generics in the private sector (60 per cent). As a result, many patients living in poverty and used public facilities had limited access to medicines. He underlined the fact, however, that contrary to popular opinion, Governments were performing very well, as in most countries, public sector procurement obtained medicines at very reasonable international prices. This was not the case in the private sector, where prices were 10 to 20 times higher and driven by taxes, markups and other determining factors. Mr. Laing pointed out that, for many chronic diseases, such as asthma and diabetes, people were asked to spend up to 30 per cent of wages just to obtain medicines needed daily. Chronic disease often led to unsustainable levels of expenditure, and situations in which people had to choose between buying food or medicine.

13. Access to medicines was also affected by the use of retrogressive measures used in times of economic recession, when Governments often increased taxes on medicines, decrease co-payment and access to health insurance and cut subsidies, which consequently impeded access to medicines.

14. The creation of a new website with data on access to medicines-related case law was one of the most recent awareness-raising activities of WHO. Many examples from Latin America proved that laws could be used to improve access to medicines. In that context, WHO has also analysed constitutions worldwide and found that 135 of 186 national constitutions included provisions relating to health or the right to health. Of these, 95 mentioned the right to access to health facilities, goods and services, while only 4 recognized access to essential medicines as a fundamental right (Mexico, Peru, the Philippines and the Syrian Arab Republic).

15. Mr. Laing also noted the responsibility of multinational and national generic companies for increases in the price of medicines. In that context, WHO recalled the access

to medicine index of 2008,[4] which ranked 20 pharmaceutical companies according to their performance in ensuring access to medicines, and which demonstrated a high variation among them.

16. In conclusion, Mr. Laing recommended that Governments should incorporate a rights-based approach to national health policies, emphasizing the importance of collecting disaggregated data. He furthermore called upon States to specify their obligations relating to provision of health-care services and access to essential medicines. He also urged Governments to endorse a selection of essential medicines to be covered by social security, to establish monitoring and accountability mechanisms and mechanisms of redress, and to report regularly on the progressive realization of the right to health.

17. The presentation delivered by Dr. Zafar Mirza (WHO) focused on essential medicines for non-communicable diseases. He emphasized that essential medicines were a major component of the treatment of diseases, such as cardiovascular disease, diabetes, asthma, many types of cancer, tobacco dependency, depression and epilepsy. Recent surveys in over 40 low- and middle-income countries showed that generic medicines for the treatment of acute diseases were only 56.1 per cent available in the public sector and 65.6 per cent in the private sector. For chronic diseases, the figures were even lower: 36 per cent were available in the public sector, and 54.7 per cent in the private sector. The main causes for low availability in the public sector were lack of public resources or under-budgeting, inaccurate demand forecasting and inefficient procurement and distribution. This in turn forced patients to buy these medicines from the private sector at a much higher price.

18. Dr. Mirza raised concerns about the increasing presence of counterfeit or falsified medicines for chronic diseases on the market owing to unregulated Internet sales used by patients treated for chronic diseases. He also noted the need to develop evidence-based clinical guidelines for non-communicable diseases, including diagnostic standards and international agreements on when to start medicine treatment. Since such diseases had a long-term market potential for chronic treatments, the pharmaceutical industry was heavily engaged, and potential conflicts of interest between the industry, patient organizations, professional associations, health insurance and public sector organizations needed to be carefully identified and adequately addressed. This also applied to low- and middle-income countries, where many locally produced “branded generics” were aggressively marketed.

19. Parra Vera, Senior Attorney from the Inter-American Court of Human Rights, noted that litigation could and should be used to improve access to medicines, and emphasized the importance of having in place mechanisms for monitoring and accountability. Colombia and other Latin American countries had tried to reform their health sectors in the 1990s by unifying two systems of distribution of health services and medicines, to those in the labour market versus those who had no means to pay. This distinction had led to discriminating effects, and thus forced the poor to resort to legal redress in order to have access to health care. For example, in Colombia, between 1999 and 2008, more than 600,000 cases were filed to ensure access to medicines and health care. As a result of the litigation, judges ordered the State to provide funds for certain medicines. In some countries, the prices of medicines were exorbitant, as the State had left prices up to the market. In Colombia, the deregulation of price controls over medicines in 2006 (letting pharmaceutical industries establish their own price according to market laws) was ultimately paid by the State budget. There was thus a need for oversight and control over the price of medicines on the basis of international law. Moreover, health rights litigation played an important role, but if the protection implied greater entitlements of those already covered in the health system, it could lead to inequitable protection. Legal protection had to be harmonized, as distinctions

[4] See www.accesstomedicinesindex.org.

could lead to inequality and discrimination. For that reason, it was important to use strategic litigation and judicial decisions to make structural changes in the policies on access to medicines, rather than to benefit a single individual in a case.

20. Leah Hoctor from the International Commission of Jurists highlighted the importance of bringing the international legal requirements of equality and non-discrimination in the enjoyment of rights to bear in efforts to address and improve access to medicines. She pointed out that place of birth, gender, ethnicity, age, level of education and employment were all factors that had a significant impact on access to medicines. She underlined the importance of ensuring a particular focus on the access to medicines of women as work on this issue moved forward. Women and girls faced significant discrimination and inequality in their access to medicines on grounds of sex and gender, but their access was often affected also by intersectional and multiple forms of discrimination, for example on the grounds of social status and age. She emphasized the fact that States must take a number of steps to ensure women's right to equal access to medicines. Such steps included ensuring that essential medicines women need are both listed on the essential medicines list of countries and available in practice, including reproductive health medicines, contraceptives, drugs that prevent transmission of HIV from mother to child, and drugs that treat and palliate breast cancer. Ensuring that women have effective access to these medicines means taking into account economic factors, since women represent the majority of the poor. Fulfilling the right of women and girls to access to essential medicines may mean making them available for free or subsidized by national health services. Meanwhile a range of indirect factors must be taken into account: for example, improving education and combating illiteracy are key steps in improving access to medicines. Legal prohibitions of certain family planning drugs and health-care services or laws that affect women's legal status also hinder access to medicines and health services. In conclusion, Ms. Hoctor urged that, in their efforts to improve access to medicines, stakeholders take not only a right to health approach but also a broader holistic human rights one that acknowledges that human lives are multifaceted, not one dimensional, and facilitates the identification of the range of interconnected realities that combine to limit access to medicines in women's daily lives.

21. Participants discussed existing obstacles, their causes and possible remedies regarding access to medicines. A number of State representatives expressed their concern regarding the great number of people who lacked such access. They also expressed concern about developing countries being pressured not to use TRIPS flexibilities and the repercussions of the TRIPS-plus standards, which were essentially aimed at strengthening the protection of patents. The impact of poverty and pricing, and the problem of research that prioritizes diseases in the developed world as opposed to the developing world, were also raised. This resulted in the creation of a vicious circle, whereby poor countries relied on the research and technology of rich countries to produce the medicines they need, while remaining unable to develop their own production of medicines. This could, however, be overcome by establishing worldwide cooperation in investment in research and technology in poor countries.

22. Counterfeit and falsified medicines were another issue discussed at the meeting. A number of State representatives stressed the importance that the concept of the right to access to medicines should not be used to undermine the international intellectual property regime and its built-in flexibilities or as an excuse to introduce new legislation in the name of addressing the falsification of medicines. While remaining fully committed to the realization of the right to health, State representatives of some developed countries highlighted the need to ensure that the concept of the right to medicines was not used to undermine intellectual property rights or resulted in tolerance of sometimes dangerous counterfeit medicines, although these two issues should not be confused. In that context, the need of a functioning health system that ensured the provision of health care for all,

including for particularly vulnerable groups, such as women, children, drug addicts and people living with HIV-AIDS, was underlined. Lengthy and cumbersome registration procedures for medicines should be simplified to facilitate and allow timely access to medicines, without compromising their quality and safety. Some representatives reiterated the need for coherence in discussions among OHCHR, WHO and WIPO to avoid duplication, and recommended that more empirical studies should be carried out in order to evaluate the realization of the right to access to medicines in practice. States agreed that the international community should do more to ensure that people have unhindered access to medicines, and that the approach should be preventive rather than curative.

23. In response to the above issues, Dr. Mirza drew attention to the WHO Global Strategy and Plan of Action, which covers the transfer of technology at the global, regional and national levels. While the national medicines list should be the basis for discussion, the WHO medicines list had 17 patent-protected medicines in 2003, and the list would be expanded in cooperation with WIPO. He noted the importance of ensuring the quality and public availability of simple generic medicines.

24. A number of State representatives requested to be part of WHO-WIPO talks on intellectual property and to participate in the deliberations, and expressed interest in learning what the consequences would be for States that were not a party to the International Covenant on Economic, Social and Cultural Rights.

B. Panel 2: Emerging issues and existing obstacles to providing access to medicine as a fundamental element of the full realization of the right to health

25. The Special Rapporteur opened the second panel and again emphasized the most significant obstacles to access to medicines, namely, issues relating to intellectual property rights and competition seen as the most important element in the reduction of prices and making medicines affordable to all. He referred to 2001, when the HIV crisis was at its peak, and when the prices for antiretroviral medicines dropped from $15,000 to less than $400 per patient per year. The availability of cheaper generic antiretrovirals from developing countries inevitably led to competition and price reduction. The Special Rapporteur stressed that the only effective competition was that provided by generic medicines.

26. The need to ensure that multinational companies adopt a corporate social responsibility approach was becoming increasingly urgent. It was of particular importance in the context of the right to health; while States had primary responsibility to ensure the enjoyment of the right to health, this responsibility was shared with other national and international actors, such as pharmaceutical companies. Although pharmaceutical companies had the legitimate aim of improving shareholder value, their main societal goal must be to improve access to medicines, which had to be considered in the context of other social and development objectives, as well as human rights.

27. The Special Rapporteur also cautioned that more stringent measures regarding patents had been introduced. Until recently, patents violations were not subject to criminal procedures (as opposed to trademark or copyright). However, criminal remedies were envisaged to be introduced in patent law, thus shifting the decision of whether patents were infringed to customs inspectors and drug regulators. Moreover, adoption of so-called anti-counterfeiting measures might further limit access to medicines. Although the actual number of counterfeit medicines was very small, the conflation between generic drugs and

counterfeit drugs was, however, being strongly supported by developed countries and multinational companies.[5] The so-called "bottom measures", such as the ones applied by the Netherlands, on medicines exported from India to Brazil and Latin American countries had long-reaching effects on access to medicines.[6] If medicine is not patented in either country, the shipment may be seized and the transport subject to criminal procedure.

28. Dr. Hans Hogerzeil stated that some 30,000 children die every day owing to lack of access to essential medicines, which are largely available in generic form; he stressed the importance of holding Governments accountable for this lack of access. In addition, there was an increasing problem with access to new essential medicines that were still covered by a patent, such as second-line medicines for the treatment of AIDS. This aspect of the problem was largely due to newer and stricter patent laws, making this one of the key public health issues of our times.

29. Dr. Hogerzeil called upon States to publicly commit to universal access and recognize the enjoyment of the right to health and access to medicines in their constitutions or other laws of major importance. He also urged them to commit to ensuring full accessibility to medicines by establishing monitoring and accountability mechanisms and focusing on the poorest and most disadvantaged groups.

30. In that context, Dr. Hogerzeil noted that the creation and adoption of good policies to promote the use of good-quality generic drugs were possible and would be most useful. These guidelines would enable Governments to identify which patented drugs were really necessary or whether a generic drug would be just as effective. By regulating the price of patented medicines and managing competition through generic policies where possible, Governments could ensure that medicines would be affordable and accessible to all, including persons living in poverty.

31. Dr. Hogerzeil called upon OHCHR to contribute to the development of standardized indicators for human rights reporting, which would include reporting on the right to health and access to essential medicines. Lastly, Governments should report on activities that they undertook in order to ensure the enjoyment of the highest attainable standard of health.

32. Dr. Annemiek van Bolhuis, also from WHO, focused on non-communicable diseases, such as cardiovascular diseases, diabetes, asthma and mental health diseases. She reiterated that, for the treatment of these diseases, access and affordable, good-quality medicines was a prerequisite. Access to essential medicines for non-communicable diseases was even lower than those for communicable diseases, in both the public and private sectors. Moreover, if available, many medicines for treating non-communicable diseases (such as insulin) have to be taken for life, and thus have a severe impact on household expenditure, pushing many families below the level of poverty. In tackling this issue, all actors should be involved, including pharmaceutical companies, health insurance and public health organizations, as well as patients' organizations, provided that careful management of any conflict of interests is taken into account.

33. Following the above presentation, Huong Ha of the Global Fund to fight AIDS, Tuberculosis and Malaria presented the approach that the fund uses to address the various challenges to access to medicines, including patent issues facing grant recipient countries.

[5] In Kenya, for example, anti-counterfeiting law equates qualified generic drugs sent by Indian or Brazilian generic companies to Kenya with counterfeit drugs. This practice is now spreading throughout East Africa.

[6] According to the Special Rapporteur, the seizure of these goods by the Netherlands had no legal justification, as medicines were in transit and patent laws are territorial, and do not extend beyond borders.

Ms. Ha discussed procurement and supply management challenges, and underlined the importance of having a transparent, competitive and fair procurement system that ensured quality, availability and affordability of medicines. She explained that the Fund provided procurement supply management assistance to countries and facilitates access to technical assistance and capacity-building services in recipient countries in partnership with technical agencies. It spends around 37 per cent of its budget on medicines and health products, and 15 per cent on human resources. She also pointed out that strengthening health systems was fundamental to achieve the goal of ensuring access to medicines and the full enjoyment of the right to health. The Fund spent 6 per cent of its budget to support health system-strengthening-related activities. She highlighted the need of a sustainable solution for the production of lower priced generic drugs in adequate formulations; to simplify intellectual property management to ensure that countries were able to take full advantages of TRIPS flexibilities as well as to comply with those flexibilities; and lastly, to provide an incentive mechanism to facilitate the arrival of new drugs on the market. She pointed out the various harmonization steps and initiatives taken by the Fund, and also highlighted the fact that human rights principles of equality, non-discrimination, participation, transparency and accountability were reflected in the work of the Fund.

34. Tido vos Schoen-Angerer and Emmanuel Tronc from Médécins sans Frontières, raised several crucial questions that had been previously mentioned, namely, that some States pursued policies that directly undermined access to medicines and were often unwilling (or unable) to provide care of adequate quality; and the fact that the prevalence of diseases in developing and developed countries could change the world's perspective on the importance of access to medicines. The necessity to ensure access to new medicines, where to produce them and how to enable their importation to countries where they were most needed, as well as how to provide patients with the latest recommended treatment, was again underlined. Médécins sans Frontières welcomed the WHO Global Strategy and Plan of Action for Public Health, Innovation and Intellectual Property, as it could fundamentally change the way health research and development was conducted and financed, in order to ensure that medicines were made accessible to those who needed them. This was a historical change, but its implementation depended on the willingness of States to translate the Strategy into action. It was noted that particularly vulnerable groups, such as undocumented migrants, were subject to additional obstacles in the context of access to medicines owing to their uncertain legal status, cultural and linguistic differences and exclusion from health insurance schemes and social security systems, as well as lack of community support.

35. In the interactive debate following the panel discussion, many substantive issues were raised, including the concern that the adjective "essential" medicines may lead to the exclusion of other much-needed medicines. Regarding the responsibility of Governments, some State representatives were of the opinion that the Governments of developing countries were being too harshly judged, and that otherwise responsible Governments sometimes simply did not have the means to provide access to medicines. This was, in turn, due to the fact that patents — imposed by pharmaceuticals and developed countries — increased the prices of medicines. As a result, the Governments of developing countries were not only unable to afford these medicines, but because of the long terms of patents, they were also unable to benefit from the knowledge of developed countries, which they needed in order to produce cheap generic medicines. Moreover, if the duration of patents was extended for an additional five years, as had been proposed by certain pharmaceutical companies and developed countries, the situation would further deteriorate.

36. Essential medicines should not be patented. When TRIPS flexibilities were again raised, some State representatives insisted that issues such as the protection of private sector industries by the developed countries, which caused vast injustice to poor people, should also be discussed in other forums, such as the Human Rights Council and the World

Trade Organization. Panellists were requested to share views on how the Council could take forward recommendations from the special procedures. Concern was also raised that many of the efforts discussed during the expert consultation could be nullified by the attempts of developed countries and the private sector to circumvent the flexibilities available in the TRIPS agreement. There was general agreement that the discussions and negotiations on TRIPS-plus standards should be monitored closely. In this respect, it was suggested that more information be circulated on the legitimacy for making use of TRIPS flexibilities.

37. In their response to some of the concerns raised by representatives of States, and non-governmental and other organizations, the panellists made further clarifications. Regarding the confusion between national essential medicines and the international essential medicines list developed by WHO, Dr. Hogerzeil stated that any national list was more important, as it referred to the specific needs of the country; he also cautioned, however, that, in circumstances where a large country with many health problems had only some 30 essential medicines on its list, this was clearly not enough and, in such cases, the WHO list should perhaps be taken as a reference. With regard to promoting generic policies, he noted several important measures that countries could take: to create an adequate legal framework; to publish price information and inform which generics were available; and to ensure that generics were of good quality. By creating financial incentives, especially for pharmacists, Governments could also raise the interest of and include the private sector in the promotion of generic policies.

38. With regard to patents, while agreeing that pharmaceutical companies should not extend patents beyond reason, Dr. Hogerzeil emphasized that pharmaceutical companies should go beyond, by also promoting and protecting human rights. Regarding the protection of nationally produced medicines in government procurement, Dr. Hogerzeil suggested that, if locally produced medicines were given favourable treatment by the Government while cheaper medicines could be found outside the country, the Ministry of Trade (not the Ministry of Health), as part of its industrial policy, should pay for the price difference with the lowest price good quality generic medicine that could be imported.

39. Dr. Hogerzeil also explained the selection process for essential medicines and the changes that WHO had made in this process since 2002. Before then, affordability and patent status were a selection criterion; today, it was effectiveness, safety and cost effectiveness (within their group). There are many options for reducing prices, namely by reducing import taxes, decoupling them from prescriptions, substituting a specific medicine that is patented with something equally efficient, and negotiating prices. Moreover, States could negotiate for a lower price for a specific medicine with a pharmaceutical company on the basis of price differentiation, or opt for voluntary licensing, while ensuring that such price differentiation was not abused by re-exporting the same medicine. Furthermore, countries could support incentives for innovations by differential pricing and streamlining regulation.

40. On the question of innovation, the Special Rapporteur stated that, while research and development was important, there was a need to differentiate between a completely new drug, a “new molecule” and a drug that had only been slightly changed, namely a “new form”. The majority of pharmaceutical patents were actually new forms and not new molecules, yet both categories were being patented. Only 15 per cent of new drugs approved by the United States Food and Drug Administration from 1989 to 2000 were for

highly innovative priority new medical entities.[7] Medicines were thus insensibly modified, and thereafter patented, needlessly making them more costly. In this respect, the patent system needed to change, to prevent the overpricing of drugs that were only slightly different from already existing ones.

41. During the discussion, some State representatives expressed concern that too much responsibility was placed on Governments, and too little on international organizations and pharmaceutical companies. It was especially difficult for developing countries to reconcile human rights with trade concerns, while developed countries pressure them not to use the flexibilities provided for in trade agreements. On the other hand, it remained unclear whether pharmaceutical companies had a true incentive to fulfil human rights, and this, according to some countries, was an overarching issue. Other State representatives still emphasized the important role of generic medicines in setting the price and opening the floor to competition, and wondered whether the time frame for patents could not be reviewed in the interest of public health. In addition, some State representatives underlined the importance of traditional medicine. Drug supply chains, insufficient and inequitable pricing, inappropriate prescriptions, poor medicine selection and information on access to medicines, weak accountability and low public participation were all sources of considerable concern. Several countries noted that price differentiation should also take into account that some countries that were not considered least developed should nevertheless enjoy price differentiation, owing to the high prevalence of a disease tied to their climate or other unique factors.

42. In response to these observations, Dr. Marks reiterated the potential role and function of regional organizations, some of which had already noted and discussed all the issues considered during the expert consultation. He agreed with the fact that, while 90 per cent of the poor lived in low-income countries, they were dispersed, and three quarters actually lived in middle-income countries and Europe. Thus, the differentiation not only between poorest countries on the international level but also between rich and poor on the country level needed to be taken into account.

43. In his concluding remarks, Mr. Dasgupta raised the issue of the impact of climate change on health and the fact that some countries in North America could be facing malaria, dengue fever and other diseases commonly thought of as “third world” diseases or diseases prevalent in least developed and developing countries. This “migration” of diseases could change the world’s perspective on the importance of access to medicines, their price and patent-related context.

IV. Conclusions and recommendations

44. **The right of everyone to the enjoyment of the highest attainable standard of health encompasses access to medical services and the underlying determinants of health, such as water, sanitation, non-discrimination and equality. As access to medicines is an integral and fundamental part of the right to health, Governments and the international community as a whole have a responsibility to provide access to medicines for all. Yet massive inequalities remain in access to medicines around the world, as up to 2 billion people (or one third of the world’s population) lack access to essential medicines. Most of them live in low- and middle-income countries, where the needs of persons living in poverty, women, children and undocumented migrants, as**

[7] National Institute for Health Care Management Research and Educational Foundation, Washington, D.C. “Changing patterns of pharmaceutical innovation”, May 2002, p. 3. Available at nihcm.org/pdf/innovations.pdf.

well as other marginalized and vulnerable groups who are often discriminated against in terms of access to medicines, are ignored or underestimated.

45. **States have the primary responsibility for enhancing access to medicines; as the Millennium Development Goals recognize, however, this is a shared responsibility. If there is to be an increase in access to medicines, numerous national and international actors have a role to play. Pharmaceutical companies are among those who share this responsibility owing to their evident impact on the ability of Governments to realize the right to the highest attainable standard of health.[8] The expert consultation identified the need for a reliable system for the supply of good-quality medicines that are affordable to all, including those living in poverty and other disadvantaged groups.**

46. **From the right to health perspective, access to medicines must be equitable. Additionally, more research and development is needed to promote the availability of new drugs for those diseases causing a heavy burden on developing countries. Within a framework of international assistance and cooperation, States should resort to a variety of incentives to influence research and development for these specific health needs.**

47. **While intellectual property rights have the important function of providing incentives for innovation, they can, in some cases, obstruct access by pushing up the price of medicines. The right to health requires a company that holds a patent on a lifesaving medicine to make use of all the arrangements at its disposal to render the medicine accessible to all. As patents create monopolies, limit competition and allow patentees to establish high prices, they consequently have a significant impact on access to medicines. While some countries lack sufficient awareness about the use of TRIPS flexibilities and have limited technical capacity to implement them, others have not streamlined their patent laws sufficiently to facilitate use of such flexibilities. Furthermore, pressure from developed countries and multinational pharmaceutical corporations have played a prominent role in shaping the implementation of TRIPS flexibilities in developing and least developed countries. For example, a number of developing countries, while attempting to implement TRIPS flexibilities to address public health concerns, have experienced pressures from developed countries and multinational pharmaceutical corporations.**

48. **A new challenge for the health sector is ensuring access to medicines for non-communicable or chronic diseases. As for any other general essential medicine, equitable access (including rational selection of medicines, affordable prices, sustainable financing and reliable health systems), availability, safety and quality must also be ensured for medicines for non-communicable diseases. Another challenge for these drugs is the creation of clinical guidelines for them, including diagnostic standards and an international agreement on when to start medical treatment. The international pharmaceutical industry is heavily engaged in non-communicable diseases owing to the long-term market potential of chronic treatments. For this reason, a potential conflict of interests between industry, patient organizations, professional associations, health insurance companies and public sector bodies must be carefully indentified and managed. This also applies to low- and middle-income countries, where many locally produced and branded generic medicines are aggressively marketed.**

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

49. **On the basis of the presentations and discussions, the Special Rapporteur believes the expert consultation suggests that States should:**

(a) Establish an adequate legal framework for the realization of the right to access to medicines;

(b) Ensure that medicine-related health priorities are not weakened in favour of investment or industrial priorities;

(c) Take measures to ensure equality for all individuals and groups, such as disadvantaged minorities;

(d) In formulating national health and medicines policies and programmes, ensure the active and informed participation of all concerned – not only of professional organizations and universities, but rural communities, civil society organizations and patients' and consumer organizations as well;

(e) Establish a regulatory system to ensure the safety and quality of medicines;

(f) Establish a national medicine supply system that includes programmes specifically tailored to reach vulnerable groups;

(g) Establish monitoring and accountability mechanisms for access to medicines;

(h) Ensure price and quality control of medicines, and establish dosage standards and ensure the efficacy of medicines;

(i) Ensure that procurement practices and procedures are transparent, fair and competitive;

(j) Establish mechanisms to limit the impact of intellectual property rights and protect unhindered access to medicines;

(k) Ensure that countries are able to take full advantage of TRIPS flexibilities, and to comply with them;

(l) Enhance the transfer of technology and investment in research and development to developing countries;

(m) Strengthen the effectiveness of national and international measures to ensure access to medicines for all.

Annex

List of participants and panellists

The expert consultation was attended by representatives of approximately 60 Governments and a handful of regional and international organizations, as well as several civil society organizations.

The following panellists were asked to present their research and views:

Dr. Annemiek van Bolhuis, Non-Communicable Diseases and Mental Health, World Health Organization, Geneva

Mara Bustelo, Chief of Section, Special Procedures Branch, Office of the High Commissioner for Human Rights, Geneva

Chandrashekhar Dasgupta, Member of the Committee on Economic, Social and Cultural Rights

Special Rapporteur on the right of everyone to the highest attainable standard of physical and mental health, Anand Grover

Leah Hoctor, Legal Adviser, International Commission of Jurists, Geneva

Dr. Hans Hogerzeil, Director, Essential Medicines and Pharmaceutical Policies, World Health Organization, Geneva

Thuy Huong Ha, Director, Global Fund to Fight AIDS, Tuberculosis and Malaria, Geneva

Richard Laing, Coordinator, Medicines Information and Evidence for Policy, Essential Medicines, World Health Organization, Geneva

Dr. Stephen Marks, Professor, Harvard School of Public Health, Boston, United States of America

Dr. Zafar Mirza, Coordinator, Department of Public Health, Innovation and Intellectual Property, World Health Organization, Geneva

Craig Mokhiber, Officer in Charge, Development and Economic and Social Issues Branch, Office of the High Commissioner for Human Rights, Geneva

Oscar Parra Vera, Senior Staff Attorney, Inter-American Court of Human Rights, San José, Costa Rica

Abu Saleh, Pharmaceutical Management Unit, Global Fund to Fight AIDS, Tuberculosis and Malaria, Geneva

Tido von Schoen-Angerer, General Director of the Access Campaign to Essential Medicines, Médécins sans Frontières, Geneva

Emmanuel Tronc, Policy and Advocacy Coordinator, Médécins sans Frontières, Geneva