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Access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria

Report of the Secretary-General*

* This document is submitted late so as to include as much up-to-date information as possible.

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Summary

Almost 2 billion people have inadequate or no access to life-saving medicines; 80 per cent of these people live in developing countries where inadequate supplies of medicines prevent the enjoyment of the right to the highest attainable standard of health.[1]

In 2007, 33.2 million people were living with HIV out of which 2.5 million people were newly infected. Every day, 5,700 people die from AIDS, primarily due to inadequate access to HIV prevention and treatment services.[2] Of the total estimated number of deaths due to AIDS, 76 per cent occurred in sub-Saharan Africa where AIDS remains the leading cause of death. In 2006 the General Assembly High-Level Meeting on AIDS reaffirmed the 2001 Declaration of Commitment on HIV/AIDS and issued a Political Declaration on HIV/AIDS, annexed to Assembly resolution 60/262. In the Declaration, Member States recognized that HIV/AIDS constitutes a global emergency and poses one of the most formidable challenges to development, where progress requires an exceptional and comprehensive global response as recognized in the Millennium Development Goals.

Although preventable and curable, malaria causes more than 1 million deaths per year worldwide. The Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health has often referred to malaria as a neglected or "poverty-related" disease. The NGO Malaria Consortium notes: "Whilst the disease is in large part determined mainly by climate and ecology, and not poverty per se, the impact of malaria takes its toll on the poorest - those least able to afford preventative measures and medical treatment. The impact of malaria is not only felt in terms of the human suffering and death it causes but also by the significant economic cost and burden."[3]

Tuberculosis is also a neglected disease and a major cause of death worldwide, particularly among persons living in poverty. There were an estimated 8.8 million new cases in 2005, out of which 7.4 million were in Asia and sub-Saharan Africa. Overall, the World Health Organization (WHO) received notification that 26.5 million patients had tuberculosis between 1995 and 2005. A total of 1.6 million people died of tuberculosis, out of which approximately 12 per cent were persons living with HIV.[4]

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[1] *WHO Medicines Strategy: Countries at the Core*, WHO, 2004, http://whqlibdoc.who.int/hq/2004/WHO_EDM_2004.5.pdf; *WHO World Medicines Situation*, WHO, 2004, http://www.searo.who.int/LinkFiles/Reports_World_Medicines_Situation.pdf; UNAIDS, 2006 Report on the Global AIDS Epidemic.

[2] UNAIDS, 2007 AIDS Epidemic Update.

[3] *Neglected diseases: A human rights analysis*, Paul Hunt, WHO, 2007, and www.malariaconsortium.org/data/files/human_rights_malaria_final.pdf.

[4] WHO Report 2007, "Global tuberculosis control - surveillance, planning, financing", WHO/HTM/TB/2007.376.

This report summarizes contributions received from States, intergovernmental and non-governmental organizations on steps they have taken to improve access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria. It highlights that the number of people receiving treatment for HIV, tuberculosis and malaria has increased over the years due to efforts by Governments, civil society, international donors, and multilateral agencies. In some countries, the spread of these diseases has been significantly reduced, custom duties and taxes have been revised to facilitate access to medicines, and progress towards universal access has been made. However, the fact that a large number of people continue to live with, are affected by, and die from HIV/AIDS, tuberculosis and malaria means that renewed efforts are required to ensure better access to medicines especially among vulnerable groups.

The input received for this report highlights the fact that access to medicines is a fundamental human right. The need to overcome legal and regulatory, trade and other barriers that block access to prevention, treatment, care and support is considered critically important to the enjoyment of this human right. In this regard, the value of the World Trade Organization (WTO)'s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and the Doha Declaration adopted in 2001 by the WTO's Fourth Ministerial Conference were noted as essential to facilitating access. Nonetheless, the continued lack of affordable and appropriate drugs, especially for second- and third-line treatment continues to impede access to medicines, together with the unequal geographical spread of health services. Finally, the need to create incentives for research and development into new drugs, vaccines and diagnostic tools for HIV, tuberculosis and malaria was also recognized as essential to saving more lives.

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Introduction

1. In its decision 2/107, the Human Rights Council recognized that access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria is one fundamental element for achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. The Human Rights Council requested the Secretary-General to solicit comments from Governments, United Nations organs, programmes and specialized agencies, and international and non-governmental organizations on the steps they have taken to promote and implement, where applicable, the decision and to report on these to the Council at any session after its fourth session.

2. The present report summarizes replies received from the Governments of Albania, Argentina, Bosnia and Herzegovina, Canada, Croatia, Cuba, El Salvador, Germany, Greece, Mexico, Morocco, Poland, Spain, Thailand, Qatar, as well as from the Office of the United Nations High Commissioner for Human Rights (OHCHR), the World Health Organization (WHO) and the World Trade Organization (WTO). Contributions were also received from AIDS Information Switzerland, Caritas Internationalis and Conectas Direitos Humanos. Complete replies are available for consultation at the Secretariat.

I. CONTRIBUTIONS FROM STATES

3. The Government of Albania reported on its efforts to protect people living with HIV, including through various policies and legislation. An increase in HIV prevalence was noted, with 32 new cases reported as at August 2007 out of a total of 243. There were 500 new cases of tuberculosis in 2006 with regional differences in epidemiology. Over 85 per cent of the new cases of tuberculosis were successfully treated and funding from the Global Fund to Fight AIDS, Tuberculosis and Malaria (The Global Fund) is expected to improve the prevention and treatment of tuberculosis.

4. The Government of Argentina referred to developments in relation to the TRIPS Agreement and the utility of the flexibility it provides to issue compulsory licences. The WTO General Council decision of 30 August 2003 that allows members to import patented products or products manufactured through a patented process in the pharmaceutical sector was also referred to as a useful mechanism for facilitating access to medicines. Argentina has played an active part in these negotiations and is currently considering ratification of the WTO General Council decision. With reference to the WHO's Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, the Government participated in regional discussions on the development of the Working Group's global strategy. Argentina submitted information on human rights in relation to health and the priority that the right to health has over commercial interests.

5. In May 2006, Argentina, together with nine other Latin American countries, signed a declaration on intellectual property, access to medicines and public health in which they reaffirmed their commitment to implement the Doha Declaration, in particular the WTO General Council decision. Argentina also subscribes to the UNESCO Universal Declaration on Bioethics and Human Rights of October 2005, including the principles of full respect for human dignity and priority to the welfare of the individual over the interest of science or society.

6. The Government of Bosnia and Herzegovina reported that full access to medication for HIV/AIDS and tuberculosis is free of charge and guaranteed for those who need it, and that malaria has been eradicated from the country. Medication for those diagnosed with HIV/AIDS is financed by health insurance funds. Additional support from the Global Fund has secured the purchase of equipment for CD4 count testing and viral load testing (polymerase chain reaction). Paediatric forms of HIV treatment have not been secured due to the low prevalence rate of HIV among children.

7. The Government of Canada, through its African Health Systems Initiative, will contribute US$ 450 million over the next decade to support country-led efforts to strengthen health systems, improve health outcomes and make progress towards the Millennium Development Goals. It has supported efforts in West African countries to develop new strategies to improve access to medicines and to take advantage of flexibilities available in the TRIPS Agreement. As the seventh-largest donor to the Global Fund, the Government also supports initiatives that directly target the provision of medicines and/or vaccines to developing countries. The Government also supports organizations such as the Canadian Red Cross, the GAVI Alliance, the Canadian International Immunization Initiative, the Micronutrient Initiative, the Global Tuberculosis Drug Facility, advance market commitments (AMCs) and United Nations agencies to: prevent and control malaria through the distribution of insecticide bed nets; provide new and underused vaccines to developing countries; immunize children; eliminate micronutrient deficiencies in children and women; develop safe, effective, affordable and universally accessible HIV vaccines; provide life-saving drugs to 10 million tuberculosis patients; and accelerate the development of an effective pneumococcal vaccine for developing countries. In 2007, an "Initiative to save a million lives" was announced by the Government to provide funding to train 40,000 health workers and to provide life-saving treatment for mothers and children suffering from malaria, measles and malnutrition.

8. In order to facilitate access, the Government of Canada also instated a new tax incentive to encourage pharmaceutical manufacturers to donate medicines to developing countries. In 2005, the Canada Access to Medicines Regime (CAMR) entered into force and amended the Patent Act. This statutory measure has enabled Canadian pharmaceutical manufacturers to apply for a compulsory licence to export a lower-cost, generic version of patented pharmaceutical products to developing or least-developed countries that are unable to manufacture their own. CAMR recently granted authorization to export a fixed-dose, triple-combination HIV/AIDS drug to a developing country.

9. The Government of Croatia indicated that it had a centralized system of care for people living with HIV who are treated at the HIV/AIDS Centre at the University Hospital of Infectious Diseases in Zagreb. The following antiretroviral drugs are available at the centre: zidovudine, lamivudine, zidovudine plus lamivudine combination treatment, stavudine, didanosine, abacavir, nevirapine, efavirenz, indinavir and lopinavir/ritonavir. Antiretrovirals are provided free of charge through the National Health Insurance system and coverage is universal. The average monthly cost of antiretrovirals for one patient is approximately US$ 950. Through support from the Global Fund, an outpatient centre for HIV/AIDS was established in June 2005 at the University Hospital, which also provides psychosocial support as an integral part of health care. Currently, there are 416 patients at the centre, of whom 342 receive antiretroviral treatment.

10. Cuba recognizes the importance of the highest attainable standard of physical and mental health as a fundamental human right. The Government ensures that access to treatment for HIV/AIDS, malaria and tuberculosis is universal. Cuba has an HIV prevalence rate of 0.09 per cent (among the lowest in the Americas) and currently 7,204 people are living with HIV. With extensive experience in the production of generic medicines, Cuba currently produces six antiretroviral medicines. This enables the provision of free treatment to 2,929 people including for the prevention of mother-to-child transmission. In 2007, Cuba celebrated the fortieth anniversary of the eradication of malaria and in 2006 it succeeded in reducing the tuberculosis prevalence rate to 6.4 per 100,000, which is closer to WHO's indicator of 5 per 100,000 for claiming that an illness has been eliminated as a health problem.

11. In relation to access to medication for tuberculosis, the Government of El Salvador has a policy of universal, free-of-charge, non-discriminatory distribution of medication through the national health system. A national strategy on antiretroviral therapy was developed in 2001 and benefits 4,200 people (an increase from an initial 73 patients). HIV/AIDS related services have also been decentralized to 16 health centres. Accessibility to free voluntary testing facilities and mobile clinics in rural areas has improved, reducing mortality rates and allowing for the identification of new cases of HIV.

12. The Government of Germany underscored the importance of international cooperation in ensuring universal access to health care, particularly to fight pandemics such as HIV/AIDS, tuberculosis and malaria. The 2001 General Assembly Declaration of Commitment on HIV/AIDS was highlighted, with emphasis placed on the need to reduce the cost of treatment. Access to effective medicines to treat HIV/AIDS, tuberculosis and malaria is a top priority for Germany and the Government has devoted specific attention to this through: its support in WTO negotiations for fair regulations in trade law for facilitating access to life-saving medications; and its active involvement in WHO's Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, where it has advocated for the creation of incentives for research and innovation for neglected diseases such as malaria and supported the development of vaccines and other medicines. Germany also participates in the European and Development Countries Clinical Trials Partnerships (EDCTP) and the European Clinical Research Infrastructures Network (ECRIN) to promote the development of new alternative treatments for fighting AIDS, malaria and tuberculosis in developing countries. During its European Union (EU) Presidency, Germany launched an AIDS medication initiative for EU member States and pharmaceutical companies to negotiate country-specific prices for treatment in the EU. The Government is currently looking into the possibility of expanding this initiative to countries outside the EU. In addition, Germany provides funding for projects in Eastern Europe to improve access to preventive care, treatment and health care.

13. Although Greece is not a high-risk country for malaria, anti-malaria drugs and testing facilities are readily available free of charge. The Government has a national vaccination programme to limit and control the spread of tuberculosis and ensures sufficient supplies of tuberculin and the BCG vaccine. Tuberculosis tests, treatment and care are provided free of charge. The cost of HIV/AIDS medicines is usually covered by a patient's health insurance. Specific measures to facilitate access to antiretroviral treatment have been taken for irregular migrants or migrants without health insurance.

14. The Government of Mexico recognizes that HIV/AIDS is an issue of public health and national security. In 2000, a national programme was launched for the gradual provision of universal access to antiretrovirals - this target was met by 2003. HIV prevention campaigns were also designed during this period, including campaigns against stigma and discrimination. Public expenditure has also increased considerably and 60 million pesos were spent on purchasing antiretroviral medication, which covered 1,000 people. An investment in medicines for people without social security meant that, by 2007, it was possible to treat 21,000 people.

15. Since 2000, Mexico has also provided comprehensive quality health care to people living with HIV/AIDS. The number of special facilities for HIV/AIDS patients has grown to 102. Between 2004 and 2006, 52 AIDS prevention and treatment outpatient centres were built and equipped. The largest part of the budget was allocated to antiretroviral medication. This is due not only to increasing demand from persons in need of medication, but also because intellectual property rights have helped pharmaceuticals to maintain prices that pose a serious threat to the right of access to health. Mexico does not have access to generic drugs of proven quality, and thus continues to explore other means of funding medicines to combat pandemics such as AIDS and tuberculosis.

16. In its response the Government of Morocco provided a brief history of its efforts to facilitate access to treatment for people living with HIV. Highlights included the removal of taxes for antiretrovirals, a 60 per cent reduction in the cost of medicines from five pharmaceutical companies that produce antiretroviral drugs in 2001, the establishment of a Department of Infectious Diseases at the University Hospital of Ibn Rochd in 2002, the introduction of HIV triple therapy in 2003, and the decentralization of equipment for CD4 count testing to six regions in 2004. Ensuring access to antiretroviral treatment to those who require it is part of Morocco's National Strategic Plan to respond to AIDS (2007-2011) with due consideration given to the needs of foreign migrants. Currently, information sessions and access to treatment and care are free of charge and includes treatment for opportunistic infections. Government expenditure on the purchase of antiretroviral drugs has steadily increased over the years and has been complemented by funding from the Global Fund. In future, psychosocial support will be made available. Treatment for malaria is available free of charge and in accordance with WHO recommendations. The Government is of the view that in the medium and long terms, the reinforcement of intellectual property standards will lead to the creation of monopolies and an increase in the price of medicines. In drawing attention to this, it urges a global solution for this global problem.

17. The Government of Poland provided details on its HIV, malaria and tuberculosis prevention efforts. There are an estimated 25,000 to 30,000 people living with HIV in Poland. Since 1985 there have been 11,259 registered cases of HIV; half of these are injecting drug users, with a significant increase in heterosexual transmission. The number of deaths due to AIDS has decreased over the years due to the availability of free antiretroviral treatment since 1996. The antiretroviral treatment accessibility indicator amounts to 77 per cent, which meets European standards. Health care includes information sessions to improve patient adherence to treatment and essential medicines can be imported if they are not available in Poland. There are no social groups that are discriminated against in terms of access to treatment and an improvement in reproductive health care has reduced mother-to-child transmission. Every year some 120 HIV-positive pregnant women and their children receive antiretroviral treatment and annual expenditure for this care amounts to US$ 1.3 million. In 2006 the National AIDS

Centre launched a programme for the early detection of HIV among pregnant women on a voluntary basis. This programme is intended to decrease the number of incidents of mother-to-child transmission, increase access to HIV prevention and treatment, and improve the quality of care. For HIV-positive people who are addicted to drugs, substitution methadone therapy has been available since 1997.

18. Tuberculosis prevention and treatment is available free of charge for Polish citizens, foreigners and refugees. People with tuberculosis and HIV co-infection are provided with free anti-tuberculosis and antiretroviral treatment. Prisoners were highlighted as a high-risk group who are also provided with treatment for tuberculosis.

19. The Government of Spain noted that improving access to health care for the population affected by HIV has been addressed in many resolutions adopted by the World Health Assembly, but some countries continue to be largely excluded from the benefits of science. The Intergovernmental Working Group on Public Health, Innovation and Intellectual Property was welcomed as a step forward in creating consensus among countries on how to correct the imbalance in health services between rich and poor countries, taking into account research and development activities, the ability of the developing world to innovate, intellectual property rights and sustainable funding. Spain also emphasized the relevance of the Millennium Declaration in the context of HIV/AIDS, including the new global target of universal access to prevention, treatment and assistance programmes for people living with HIV/AIDS.

20. Reference was made to the value of the Doha Declaration on the TRIPS Agreement in facilitating developing countries' access to cheaper medicines through imports or local production. The Government observed that there is growing consensus among countries to boost public-private contributions in order to increase and ensure sustainable funding. The Government's commitment to double official development assistance in 2008 is expressed in the Master Plan for Spanish Cooperation and is based on the principles of fairness and universal access to basic health services.

21. For the Government of Thailand, improving access to health care by focusing on the poor, the elderly and the disabled is a priority. Since October 2003, universal access to antiretrovirals and associated care has been provided for people living with HIV whose CD4 count is below 200. In addition, the Government has increased its national health-care budget, with an increase of more than 36 per cent for the treatment of HIV and AIDS patients. The Government's use of patents is also a crucial instrument to ensure access to medicines, especially second-line antiretroviral medicines which are expensive and in increasing demand. In line with the 2002 National Health Security Act, which provides universal access for all medicines, the Government announced its intention to implement compulsory licensing for efavirenz (first-line antiretrovirals) in November 2006; and lopinavir, ritonavir (second-line antiretrovirals) and clopidogrel in January 2007. HIV has led to more tuberculosis infections in Thailand. Treatment and access to medicines are free and access to second-line medicines for patients with resistant strains is granted. As required, patients also have access to free anti-malarial medicines and bed nets.

22. With regard to the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, Thailand noted that, although the outcome of session two of the Working Group is still to be determined, it is generally agreed that the main purpose of the

Working Group is to promote innovation, research and development for neglected diseases, focusing on type II and type III diseases, and to promote access to all medicines. Emphasis was placed on the need for all stakeholders to work together to improve the delivery of all health products and medical devices, and effectively overcome the barriers to access.

23. The Government of Thailand was of the view that the scope of this report should include the importance of promoting innovation, research and development for neglected diseases, focusing on type II and III diseases; and promoting universal access to medication including diagnosis, care, treatment and access to medical devices and health products. The need for an innovative financing mechanism that is sustainable, transparent and accountable was also highlighted. It was also suggested that intellectual property rights should not be an impediment to access to medication, health-related research and technology transfer. Universal access requires an expansion and the effective implementation of existing mechanisms such as flexibilities provided in the TRIPS Agreement and the Doha Declaration. The application and management of intellectual property should be supported in a manner that maximizes health-related innovation, especially to meet the research and development needs of developing countries, and protects public health and access to health products for all.

24. The State of Qatar indicated an annual diagnosis of 300 active tuberculosis cases, 198 cases of malaria and 5 to 7 cases of HIV. Treatment for these diseases is available and easily accessible to all citizens and expatriates free of charge. The supply of antiretroviral medication is usually uninterrupted. Anti-tuberculosis treatment, both first-line and second-line, is available free of charge for all patients. Although Qatar does not have a malaria epidemic, anti-malaria drugs are readily available for inpatients and outpatients who require them.

II. CONTRIBUTIONS FROM UNITED NATIONS BODIES

A. Office of the United Nations High Commissioner for Human Rights

25. The Office of the United Nations High Commissioner for Human Rights (OHCHR) continues to address HIV/AIDS prevention, treatment, care and support as a human rights concern in the broader framework of the right to the highest attainable standard of physical and mental health. In collaboration with other United Nations agencies and programmes, the International Guidelines on HIV/AIDS and Human Rights are used both as an advocacy tool and to provide guidance on implementing a rights based response to the pandemic. The human rights treaty bodies and special procedures continue to draw attention to issues relating to access to HIV medications in concluding observations to State parties and in reports and communications made by special procedures. In his report to the General Assembly (A/61/338), the Special Rapporteur on the right to health noted that existing national and international policies, rules and institutions give rise to massive deprivations and inequalities in access to medicines. Combating HIV/AIDS, malaria and other diseases depends upon improving access to medicines. This includes making use of flexibilities in the TRIPS Agreement; developing and making available new drugs, vaccines and diagnostic tools for diseases in developing countries; and economic, financial and commercial incentives to influence research and development into specific health needs. In the view of the Special Rapporteur, access to medicines means medicines that are: accessible to all parts of the country; economically accessible; accessible without discrimination; and accompanied by accessible information about the medicines.

26. Recognizing the profound impact of pharmaceutical companies on Governments' ability to realize the right to the highest attainable standard of health, the Special Rapporteur launched a process for producing Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines. These Guidelines will be finalized in 2008 and will help pharmaceutical companies better understand and discharge their right to health responsibilities (ibid, para. 42).

B. World Health Organization

27. The World Health Organization (WHO) referred to the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, whose task is to draw up a draft global strategy and plan of action aimed at, inter alia, securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries. The Working Group held its first session in December 2006 and, at the request of the 60th World Health Assembly in May 2007, WHO provided technical and policy support to countries that intend to make use of the flexibilities contained in the TRIPS Agreement and other international agreements in order to promote access to pharmaceutical products.

28. At the request of the Working Group and following discussions at the World Health Assembly, the Secretariat prepared a working document of the global strategy and plan of action.[5] Discussions on the global strategy and plan of action continued during the second session.[6] So far, the eight elements of the global strategy cover prioritizing research and development needs, promoting research and development, building and improving innovative capacity, transfer of technology, management of intellectual property, improving delivery and access, ensuring sustainable financing mechanisms and establishing monitoring and reporting systems. In addition, specific actions related to monitoring the impact of intellectual property rights on innovation and access to medicines were also proposed. Consultations were held on the content of the global strategy during August, September and October 2007 and to solicit views on proposals for research and development, including incentive mechanisms that address the linkage between the cost of research and development and the price of health-care products.[7] At the second session of the Working Group, held from 5 to 10 November 2007, drafting groups considered all components of the global strategy. An additional meeting will be convened by WHO to complete this process in early 2008. The final draft global strategy and plan of action is due at the 61st World Health Assembly, to be held in May 2008.

C. World Trade Organization

29. The World Trade Organization referred to its efforts to ensure that WTO rules on intellectual property, as stipulated in the TRIPS Agreement, are part of wider international and national action on access to medication in the context of pandemics such as HIV/AIDS,

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[5] Document A/PHI/IGWG/2/2, issued on 31 July 2007.

[6] Document A/PHI/IGWG/2/3, issued on 24 October 2007.

[7] Document A/PHI/IGWG/2/INF.DOC/7.

tuberculosis and malaria. It called attention to the WTO's Fourth Ministerial Conference held in 2001 at Doha and the adoption of a Declaration on the TRIPS Agreement and Public Health, which supports WTO members' right to protect public health and promote access to medicines for all. Pursuant to the Ministerial Declaration, the WTO General Council adopted, in August 2003, a decision which grants waivers from the obligations set out in the TRIPS Agreement, thereby making it easier for those countries with insufficient manufacturing capacity to obtain cheaper generic versions of patented medicines. The August 2003 decision also called for the TRIPS Council to prepare an amendment to the TRIPS Agreement that would replace the waiver decision. In December 2005, the General Council adopted a Protocol amending the TRIPS Agreement. The Protocol will enter into force upon acceptance by two thirds of WTO members.

30. The WTO continues to organize capacity-building activities in Geneva and in developing countries on the public health-related aspects of the TRIPS Agreement, aimed at ensuring that developing countries have the necessary information to use the flexibilities under the Agreement.

III. CONTRIBUTIONS FROM NON-GOVERNMENTAL ORGANIZATIONS

31. AIDS Information Switzerland provided information on access to medicines in South Kivu, Democratic Republic of the Congo, further to a project it is undertaking on voluntary counselling and testing. They noted that, in Bukavu and Mwenga, 1,500 people were in need of antiretroviral treatment. However, access to treatment is limited and expensive.

32. Caritas Internationalis provided information on access to medicines for children living with HIV. Reference was made to the fact that while an increased number of adults have access to life-saving medications, a much smaller proportion of children living with HIV are receiving paediatric antiretroviral treatment. The current challenges include: lack of research and development of diagnostic tests and treatment adapted for use in children; inadequate capacity to procure and supply medicines; unaffordable cost of paediatric antiretroviral treatment; insufficient numbers of knowledgeable and trained health-care professionals who are aware of the appropriate use of medicines for children and who will ensure adherence to treatment programmes; weak health systems; and lack of scientific information.

33. HIV is often detected in children when it is too late to start treatment. The test that is used to detect HIV antibodies does not produce reliable results for children younger than 18 months. In order to detect the virus in children below this age, virological tests (e.g. polymerase chain reaction) are required, but this technique is expensive and requires sophisticated laboratory equipment and trained staff. Furthermore, this technology is not usually licensed for HIV diagnosis in children. When treatment is available, many antiretroviral drugs used to treat adults do not exist in formulations appropriate for use in children, particularly fixed-dose combinations for children under the age of 12. In low-income settings adult antiretrovirals are often modified (i.e. crushed or broken) for use in children. This carries the risk of over or under dosing making medicines for children less safe than those for adults.

34. Reference was made to a report from UNICEF that indicates that the estimated cost of antiretrovirals for a child in a poor country is US$ 200 per year compared to US$ 130 for an adult. Children's access to second-line medicines is even more problematic; they are more expensive than first-line drugs because most of the time there are no generic equivalents. The

market for paediatric antiretroviral treatment exists mainly in low-income countries because relatively few children are born with HIV in higher-income countries. Pharmaceutical companies have been reluctant to undertake research and development into medicines for children living with HIV.

35. Conectas Direitos Humanos provided information on the challenges in ensuring universal access to medicines in Brazil. Although Brazil is able to produce generic drugs locally and passed an act which guarantees access to treatment, including antiretrovirals and medicines for opportunistic infections, the increase in the cost of treatment for newer medicines due to patent laws remains a challenge. The NGO was of the view that Brazil's success at ensuring universal access to HIV treatment was due to: strong support from civil society in securing compulsory licences; Government commitment to universal access to health and treatment; existing precedents where compulsory licensing was successful; and the availability of more than one compulsory licensed medicine.
