

UNAIDS PROGRAMME COORDINATING BOARD

UNAIDS/PCB (39)/16.22
Issue date: 22 November 2016

THIRTY-NINTH MEETING

Date: 6–8 December 2016

Venue: Executive Board room, WHO, Geneva

Agenda item 6

Synthesis report of existing research and literature on intellectual property-related and other factors impacting the availability, affordability, and accessibility of treatment and diagnostics for HIV and co-infections in low- and middle-income countries

Additional documents for this item: none

Action required at this meeting – the Programme Coordinating Board is invited to:

Take note of the report

Cost implications: none

ACRONYMS

AIDS	acquired immune deficiency syndrome
AMRH	African Medicines Regulatory Framework
ARV	antiretroviral
ART	antiretroviral therapy
CEWG	Consultative Expert Working Group
DNDi	Drugs for Neglected Diseases Initiative
FDA	Food and Drug Administration
FTA	free trade agreement
GDP	gross domestic product
Global Fund	Global Fund to fight AIDS, Tuberculosis and Malaria
GNP Plus	Global Network of People Living with HIV
HIV	Human immunodeficiency virus
ICTSD	International Centre for Trade and Sustainable Development
ITPC	International Treatment Preparedness Coalition
MDG	Millennium Development Goal
MPP	Medicines Patent Pool
MSF	Médecins Sans Frontières
NCD	non-communicable disease
NGO	nongovernmental organization
PCB	Programme Coordinating Board
PEPFAR	President's Emergency Plan for AIDS Relief
R&D	research and development
SDG	Sustainable Development Goal
TB	tuberculosis
TRIPS	Trade-related aspects of intellectual property rights Agreement
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
UNIDO	United Nations Industrial Development Organization
UN	United Nations
US	United States
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

“We are engaged in a combat to provide access for all to the most innovative therapies and to do this so that everywhere in the world the price of medicines can be controlled and regulated, so that the sick persons can be treated with dignity and also with hope. In a democracy, you cannot say to a person, whatever their revenue, their origins, their career: you cannot be treated and cured because it costs too much. We must act internationally and that is what we are going to do”.

– François Hollande, President of France¹

BACKGROUND

1. Countries around the world, multilateral agencies, donors, civil society organizations and pharmaceutical companies are engaging with the issues of trade, pricing and other barriers that affect access to medicines. These issues have featured in the World Health Organization (WHO) debates on Universal Health Coverage, in concerns about the preparedness to tackle emerging infectious diseases such as Ebola and the Zika virus, and in global efforts to eradicate or control epidemics such as AIDS, tuberculosis (TB) and malaria. They are also prominent in debates about the lack of funding for the prevention and treatment of neglected tropical diseases, the rising prevalence of non-communicable diseases (NCD) in low- and middle-income countries, the public health challenges posed by antimicrobial resistance, and the need for mechanisms to finance research and development (R&D) in the health sector in ways that afford access to health for all.
2. Many of these topics have commanded attention at the highest levels of global governance. In 2001, the United Nations General Assembly held a special session on the AIDS epidemic and its impact on development,² which was followed by High-Level Meetings on HIV/AIDS in 2006,³ 2011,⁴ and 2016.⁵ World leaders gathered at the UN headquarters in 2011 made recommendations to address the growing challenge of NCDs⁶ and in 2016 issued a political declaration on anti-microbial resistance⁷ and its impact on public health.
3. Similar concerns have been raised by Heads of State and in some of the studies assessed during this literature review. In a special communication entitled “United States health care reform: progress to date and next steps”, published in the *Journal of the American Medical Association*,⁸ the United States (US) President Barack Obama reviewed the factors that influenced decisions to introduce health reforms and recommended actions that could improve the health care system in the US. Those factors included enhancing competition in the marketplace in order to increase access to health providers and services, and reducing prices of prescribed drugs, along with improving the affordability of health insurance.
4. At the end of 2015, there were an estimated 36.7 million people living with HIV worldwide, of whom 17 million people were receiving life-saving antiretroviral therapy (ART). This reflects the remarkable scale-up in the provision of ARV medicines in the past decade. In 2015, WHO revised its HIV treatment guidelines to recommend immediate ART initiation for all people diagnosed with HIV infection. Demand for treatment therefore increased, and global ART coverage at the end of 2015 was 46%. Further rapid expansion of access to ART, particularly in low- and middle-income countries, is crucial for saving lives and preventing new infections, and for reaching the “90-90-90” testing and treatment targetsⁱ of the UNAIDS Fast-Track approach, which would put the world on-

ⁱ By 2020, 90% of people living with HIV know their HIV status, 90% of people who know their status are receiving treatment and 90% of people on HIV treatment have a suppressed viral load; by 2030, 95% of people living with HIV know their HIV

course to end the AIDS epidemic. However, the scale-up of HIV treatment still faces major challenges.

5. High prices of medicines, particularly those under patent protection, can present major barriers to access to health technologies. In addition, there is insufficient R&D of new HIV-related products that could enhance adherence to treatment, limit HIV drug resistance and meet the special health needs of people living with HIV who are ageing thanks to the clinical benefits of treatment.
6. The 1994 Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement⁹ was established as one of the World Trade Organization's (WTO) founding international treaties. The TRIPS Agreement sets minimum standards for the protection of intellectual property rights for industrial products, including health products. Patents grant the inventor exclusive rights to his or her invention, and the exclusivity to market the product and establish its price. According to the TRIPS Agreement, patents are granted for a minimum of 20 years. Such protection, however, can lead to monopolies over certain pharmaceutical products, restricting the market entry of less expensive competitive products, including generics.
7. In 2001, in order to mitigate the negative impact of intellectual property rights on public health, WTO Member States adopted the Declaration on the TRIPS Agreement and Public Health, known as the Doha Declaration.¹⁰ This Declaration was motivated by the high burden of infectious diseases, including the AIDS epidemic, in developing countries. It affirmed the primacy of public health commitments over trade considerations, by reiterating the use of "TRIPS flexibilities". Those flexibilities include parallel importing and compulsory licenses, which grant low- and middle-income countries the policy options for ensuring access to affordable quality-assured health products and for creating conditions to promote further R&D in the pharmaceutical arena.
8. The Doha Declaration stated, for example, that:

We recognize the gravity of the public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.
– WTO Declaration on the TRIPS Agreement and Public Health, 2001¹¹
9. Access to medicines is a specific and important component for fulfilling the right to access health care as a fundamental human right.¹² A large body of work exists setting standards on the right to health. However, reports of the "Special Rapporteur on the right of everyone to enjoy the highest attainable standard of physical and mental health on access to medicines"^{13 14 15} have highlighted the imbalance between states' human rights obligations and actual policy development and implementation. According to those reports, the denial of health and health-related human rights is linked to several barriers blocking access to medicines. They include social and economic factors such as poverty, discrimination and harmful social norms. Laws, policies and administrative structures that restrict access to medicines or fail to address those barriers are additional determinants of poor health. The Special Rapporteur therefore has recommended shifting "*from the*

status, 95% of people who know their status are receiving treatment and 95% of people on HIV treatment have a suppressed viral load.

*dominant market-oriented perspectives on access to medicines towards a right-to-health paradigm in promoting access to medicines”.*¹⁶

10. The human rights debate on access to medicines has highlighted concerns that a growing body of international trade law and the scope of intellectual property protections are impeding the production and distribution of affordable health technologies, including generic drugs. While intellectual property protection is enforced to provide an incentive for innovation, experience has shown that current laws fail to promote innovation that serves the health care needs of all people, especially the poor. This state of affairs, along with attempts to discourage developing countries from using the flexibilities of the TRIPS Agreement, have underlined the negative effects of excessive intellectual property protections on access to HIV treatment and other essential medicines.
11. The interconnections between trade and access to HIV-related medicines, against the background of human rights, have been the subject of several reports and resolutions from the Human Rights Council,^{17 18} including those directly addressing the AIDS epidemic.^{19 20 21} In July 2016, the Human Rights Council adopted a seminal resolution on access to medicines.²² The resolution reaffirms the importance of using the TRIPS flexibilities to advance public health outcomes in the areas of research, development and access to medicines and other health technologies. It also incorporates concepts prominent in the WHO debates around access to innovation, such as the importance of alternative models for financing R&D efforts. The resolution does not affirm the primacy of human rights principles over trade, which the original proposed text had done. However, it attempts to frame the realization of the right to access to medicines in terms of the need for greater policy coherence between trade, public health and human rights, by referring to the mandate of the UN Secretary-General’s High-Level Panel on Access to Medicines (which is discussed later in the current report).
12. The concerns regarding trade-related barriers to access to medicines have been addressed by the UNAIDS Programme Coordinating Board (PCB) at various times, including in the report of the NGO delegation at the 35th PCB meeting.²³
13. Following discussion of the report of the NGO delegation, the PCB requested UNAIDS: *“to produce a synthesis report of existing research and literature on intellectual property (IP)-related and other factors impacting the availability, affordability, and accessibility of treatment and diagnostics for HIV and co-infections in low and middle-income countries, including the following provisions in articles 71 a and b of the 2011 Political Declaration, which state:*
 - a) *The use, to the full, of existing flexibilities under the Agreement on Trade-Related Aspects of Intellectual Property Rights specifically geared to promoting access to and trade in medicines, and, while recognizing the importance of the intellectual property rights regime in contributing to a more effective AIDS response, ensure that intellectual property rights provisions in trade agreements do not undermine these existing flexibilities, as confirmed in the Doha Declaration on the TRIPS Agreement and Public Health, and call for early acceptance of the amendment to article 31 of the TRIPS Agreement adopted by the General Council of the World Trade Organization in its decision of 6 December 2005;*
 - b) *Addressing barriers, regulations, policies and practices that prevent access to affordable HIV treatment by promoting generic competition in order to help to reduce costs associated with life-long chronic care and by encouraging all States to apply measures and procedures for enforcing intellectual property rights in such a manner as to avoid creating barriers to the legitimate trade in medicines, and to provide for safeguards against the abuse of such measures and procedures.”*²⁴

INTRODUCTION

14. This research and literature review covers the period from 2001 to 2016. In the vast majority of documents perused during the review, the Political Declarations on HIV and AIDS (2001,²⁵ 2006,²⁶ 2011²⁷ and 2016),²⁸ the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, and the WTO Declaration on the TRIPS Agreement and Public Health²⁹ are considered cornerstones of the debate regarding policy coherence between access to HIV-related medicines and trade issues.
15. In order to systematize the scope of this review and fulfil the request made by the PCB, three types of literature were assessed:
 - a) Policy literature covering access to HIV-related health technologies, produced by selected intergovernmental organizations working in this field, such as the South Centre, UNAIDS, the UN Conference on Trade and Development (UNCTAD), the UN Development Programme (UNDP), the UN Industrial Development Organization (UNIDO), UNITAID (and the Medicines Patent Pool), WHO, the World Intellectual Property Organization (WIPO) and WTO;
 - b) Policy literature and technical documents covering access to HIV-related health technologies, produced by nongovernmental organizations (NGOs); and
 - c) Academic literature on access to HIV-related health technology published in scientific journals or specialized websites on this topic.
16. The findings of the study are presented below, and are divided into four thematic sections and a conclusion:
 - **Access to medicines and other health technologies in the context of the Political Declarations on HIV and AIDS.** The first section presents the linkages between access to medicines and trade as they are referred in the Political Declarations on HIV and AIDS, issued in 2001, 2006, 2011 and 2016.
 - **Breaking the silence.** The second section discusses the most common barriers to access to HIV-related products as described in the reviewed literature.
 - **Pursuing the right balance – trade, public health and human rights.** The third section identifies the global initiatives described in the literature that were put in place to overcome major barriers to access to medicines and other health technologies.
 - **Access equity rights now.** The fourth section focuses on global initiatives in the field of the HIV epidemic regarding access to HIV-related products.
 - Conclusions and recommendations.

ACCESS TO MEDICINES AND OTHER HEALTH TECHNOLOGIES IN THE CONTEXT OF THE POLITICAL DECLARATIONS ON HIV AND AIDS

“15. (...) access to medication in the context of pandemics such as HIV/AIDS is one of the fundamental elements to achieve progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”
– Declaration of Commitment on HIV/AIDS: Global Crisis, Global Action, 2001³⁰

17. Member States adopted the first UN Political Declaration on HIV/AIDS at the United Nations General Assembly Special Session on HIV/AIDS in 2001. In the introductory section of the Declaration, human rights obligations were deemed to override other interests, including trade. The Declaration noted that the success of prevention and treatment efforts depend on the affordability and accessibility of key health products, such as vaccines, medicines, diagnostics, condoms, sterile syringes and more. However, it also emphasized that prevention and treatment efforts need to be aligned with international trade law:

“26. (...) to promote innovation and the development domestic industries consistent with international law in order to increase access to medicines to protect the health of their populations, and noting that the impact of international trade agreements on access to or local manufacturing of essential drugs and on the development of new drugs needs to be evaluated further”.³¹

18. The concluding paragraph of the declaration recommended that countries:

“103. Explore, with a view to improving equity in access to essential drugs, the feasibility of developing and implementing, in collaboration with non-governmental organizations and other concerned partners, systems for the voluntary monitoring and reporting of global drug prices”.³²

19. In 2006, a second High-Level Meeting adopted a new Political Declaration on HIV/AIDS in which it reaffirmed access to medicines as a major component for fulfilling the right to health as a fundamental human right. Trade matters were explicitly addressed in paragraphs 15 and 24, and reference was made to the WTO Doha Declaration on the TRIPS Agreement and Public Health and the TRIPS flexibilities in paragraphs 43 and 44:

“15. Recognize further that to mount a comprehensive response, we must overcome any legal, regulatory, trade and other barriers that block access to prevention, treatment, care and support; (...) do everything necessary to ensure access to life-saving drugs and prevention tools; and develop with equal urgency better tools – drugs, diagnostics and prevention technologies, including vaccines and microbicides – for the future”;

“24. Commit ourselves to overcoming legal, regulatory or other barriers that block access to effective HIV prevention, treatment, care and support, medicines, commodities and services”;

“42. Commit ourselves also to finding appropriate solutions to overcome barriers in pricing, tariffs and trade agreements, and to making improvements to legislation, regulatory policy, procurement and supply chain management in order to accelerate and intensify access to affordable and quality HIV/AIDS prevention products, diagnostics, medicines and treatment commodities”;

43. Reaffirm that the World Trade Organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights does not and should not prevent members from taking measures now and in the future to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, reaffirm that the Agreement can and should be interpreted and implemented in a manner supportive of the right to protect public health and, in particular, to promote access to medicines for all including the production of generic antiretroviral drugs and other essential drugs for AIDS-related infections. In this connection, we reaffirm the right to use, to the full, the provisions in the TRIPS Agreement, the Doha Declaration on the TRIPS Agreement and Public Health and the World Trade Organization’s General Council Decision of 2003 and amendments to Article 31, which provide flexibilities for this purpose”;

44. Resolve to assist developing countries to enable them to employ the flexibilities outlined in the TRIPS Agreement, and to strengthen their capacities for this purpose (...)³³

20. More recently, the 2011 Political Declaration on HIV and AIDS re-affirmed the human rights dimension of access to medicines and other health technologies, although not in the introductory paragraphs of the document. The references appear in paragraph 32, in the section discussing in some detail the trade-related barriers to access, as described in the paragraphs 35 and 36:

“35. Recognize the critical importance of affordable medicines, including generics, in scaling up access to affordable HIV treatment, and further recognize that protection and

enforcement measures for intellectual property rights should be compliant with the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and should be interpreted and implemented in a manner supportive of the right of Member States to protect public health and, in particular, to promote access to medicines for all”;

“36. Note with concern that regulations, policies and practices, including those that limit legitimate trade in generic medicines, may seriously limit access to affordable HIV treatment and other pharmaceutical products in low- and middle-income countries, and recognize that improvements can be made, inter alia through national legislation, regulatory policy and supply chain management, (...)”³⁴

21. The treatment section of the 2011 Political Declaration noted the interconnections between trade and public health, in addition to making recommendations for supporting countries to reach the target of enrolling 15 million people on HIV treatment by 2015. References to the links between trade and public health were phrased using the language negotiated at the WTO³⁵ and other trade-related forums, as is evident in paragraphs 71 (and its subparagraphs a, b, and c) and 72:

“71. Commit to remove before 2015, where feasible, obstacles that limit the capacity of low- and middle-income countries to provide affordable and effective HIV prevention and treatment products, diagnostics, medicines and commodities and other pharmaceutical products, as well as treatment for opportunistic infections and co-infections, and to reduce costs associated with life-long chronic care, including by amending national laws and regulations, as deemed appropriate by respective Governments, so as to optimize:

(a) The use, to the full, of existing flexibilities under the Agreement on Trade-Related Aspects of Intellectual Property Rights specifically geared to promoting access to and trade in medicines, and, while recognizing the importance of the intellectual property rights regime in contributing to a more effective AIDS response, ensure that intellectual property rights provisions in trade agreements do not undermine these existing flexibilities, as confirmed in the Doha Declaration on the TRIPS Agreement and Public Health, and call for early acceptance of the amendment to article 31 of the TRIPS Agreement adopted by the General Council of the World Trade Organization in its decision of 6 December 2005;

(b) Addressing barriers, regulations, policies and practices that prevent access to affordable HIV treatment by promoting generic competition in order to help to reduce costs associated with life-long chronic care and by encouraging all States to apply measures and procedures for enforcing intellectual property rights in such a manner as to avoid creating barriers to the legitimate trade in medicines, and to provide for safeguards against the abuse of such measures and procedures;

(c) Encouraging the voluntary use, where appropriate, of new mechanisms such as partnerships, tiered pricing, open-source sharing of patents and patent pools benefiting all developing countries, including through entities such as the Medicines Patent Pool, to help to reduce treatment costs and encourage development of new HIV treatment formulations, including HIV medicines and point-of-care diagnostics, in particular for children”;

“72. Urge relevant international organizations, upon request and in accordance with their respective mandates, such as, where appropriate, the World Intellectual Property Organization, the United Nations Industrial Development Organization, the United Nations Development Programme, the United Nations Conference on Trade and Development, the World Trade Organization and the World Health Organization, to provide national Governments of developing countries with technical and capacity-building assistance for the efforts of those Governments to increase access to HIV medicines and treatment, in accordance with the national strategies of each Government, consistent with, and including through the use of, existing flexibilities under

*the Agreement on Trade-Related Aspects of Intellectual Property Rights, as confirmed by the Doha Declaration on the TRIPS Agreement and Public Health (...)*³⁶

22. Adopted in June 2016, the Political Declaration on HIV and AIDS: on the Fast-Track to accelerate the fight against HIV and to end the AIDS epidemic by 2030³⁷ reflects the 2030 Sustainable Development agenda and its target of ending the AIDS epidemic as a public health threat by 2030. The introductory section of the Declaration focuses on the achievements of the AIDS response, the remaining challenges related to the epidemic's impact on development and the interplay between AIDS and poverty.
23. As in the previous Declarations, Member States reaffirmed the importance of access to medicines for realizing access to health as a fundamental human right, this time in the section devoted to reviewing successes since 2011 (paragraph 37). The relevant paragraphs appear under the section entitled "ensuring access to testing and treatment in the fight against HIV and AIDS" (sub-paragraphs 60.a to 60.n), which reiterates the commitments to remove trade-related barriers, using virtually the same language that had been negotiated in the 2011 Political Declaration. There is additional emphasis on access to treatment for other public health concerns such as TB, sexually transmitted diseases, viral hepatitis and opportunistic infections. Concern is also expressed about the threats posed by antimicrobial resistance and the burden of NCDs in low- and middle-income countries.

BREAKING THE SILENCE: MAIN BARRIERS TO ACCESS TO HIV RELATED TECHNOLOGIES

24. The disparities between countries of the North and the South with respect to access to ART were at the heart of the debates at the XIII International AIDS Conference held in 2000 in Durban, South Africa. It was the first time that the conference had been held in a developing country and on the African continent. At the conference, activists, people living with HIV, scientists, government officials and health professionals called for urgent action to close the HIV treatment gap.

"With less than a year to go before 2010, only a third of those who need HIV treatment have access to it. That is in itself a cause for urgent action. However, in our drive to achieve these targets, we must not forget that they do not represent the end of the HIV story. All those millions of people who do get on treatment will need to continue being treated, cared for and supported for many decades to come. The prevention programmes must also continue, because treating ever-growing numbers is unsustainable and only prevention can ensure the spread of HIV is reversed once and for all."
– The treatment timebomb³⁸

25. In 2009, the All-Party Parliamentary Group on HIV and AIDS in the United Kingdom (UK) released a report³⁹ on the challenges faced by developing countries in achieving the Millennium Development Goals (MDG) in relation to access to HIV treatment. With a provocative title – *The treatment timebomb* – the report highlighted the fact that only one third of the people eligible for ART were receiving treatment, and it stressed the need for immediate actions to prevent a dramatic rise in the number of people requiring ART by 2030.⁴⁰ The report concluded by emphasizing the actions needed to rapidly accelerate access to HIV treatment:
- a) Ensure affordability of quality first- and second-line ARVs;
 - b) Scale-up access to medicines for treating co-infections and opportunistic diseases affecting people living with HIV;
 - c) Increase availability of paediatric treatment options;

- d) Enhance affordability of diagnostic tools for children and adults in order to ensure timely initiation of treatment;
- e) Devote greater attention and effort to prevent mother-to-child transmission, by increasing access to ARVs for pregnant women living with HIV.

26. In December, 2014, the same UK All-Party Parliamentary Group released a new report,⁴¹ entitled *Access denied*, which focused on the progress made in the global AIDS response in relation to access to treatment and on the remaining barriers. In the foreword, Michel Sidibé, the UNAIDS Executive Director, anticipated the core element of the HIV-related global commitments in the post-2015 era: ending AIDS as a public health threat by 2030:

“Taking shape before us in 2015 is a historic opportunity – I would say a historic imperative – to end AIDS as a public health threat in the coming years. This opportunity has coalesced from years of hard work, heavy engagement and scientific progress against this epidemic (...) We have seen AIDS transform from a death sentence to a chronic, treatable condition, enabling millions of people to live long healthy lives”
– Michel Sidibé⁴²

27. Despite improvements, especially in access to first-line HIV treatment in low- and middle-income countries, the literature continued to highlight persistent barriers to access to HIV-related products. For example, the 2014 All-Party Parliamentary Group report⁴³ identified major obstacles restricting access to ARV treatment, including:

- high-priced medicines, especially second- and third-line ARV drugs;
- underserved key populations;
- stigma and discrimination;
- poor supply chain management;
- weak health systems;
- lack of access to viral load testing;
- lack of streamlining in drug registration processes;
- lack of investment in R&D, particularly for paediatric medicines; and
- middle-income countries' lack of access to generic drugs.

28. Many of those factors also affect other areas of public health areas. According to WHO, there is no single determinant causing a lack of access to medicines: comprehensive approaches for strengthening public health systems are needed:

It will be impossible to achieve national and international goals – including the Millennium Development Goals (MDGs) – without greater and more effective investment in health systems and services. While more resources are needed, government ministers are also looking for ways of doing more with existing resources. They are seeking innovative ways of harnessing and focusing the energies of communities, non-governmental organizations (NGOs) and the private sector. They recognize that there is no guarantee the poor will benefit from reforms unless they are carefully designed with this end in mind. Furthermore, they acknowledge that only limited success will result unless the efforts of other sectors are brought to bear on achieving better health outcomes. All these are health systems issues.
– WHO's Framework for Action⁴⁴

29. On the subject of access to medicines specifically, WHO, along with WIPO and WTO, prepared a report⁴⁵ which discussed in detail the key policy intersections between trade, intellectual property and public health. Titled *Promoting access to medical technologies and innovation*, the report argued for a thorough understanding of those linkages to

ensure that the discovery, development and delivery dimensions of the innovation and access cycle are fully addressed.

30. The report analysed the potential and actual impact of trade mechanisms on R&D, the pricing of health technologies and access to those technologies. Those mechanisms include taxes and tariffs, intellectual property protection and free trade agreements, all operating alongside regulatory and supply chain frameworks. The report built on a series of key documents which addressed the interfaces between access, trade and development, including the WTO Doha Declaration on the TRIPS Agreement and Public Health,⁴⁶ the WIPO Development Agenda,⁴⁷ and the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property,⁴⁸ as well as a selection of robust policy and academic literature.

Public health now finds itself caught in a cross-current of rising expectations and ambitions, set against rising demands and costs, at a time when funds are stagnant or shrinking. In such a situation, introducing greater efficiency is a far better option than cutting budgets and services.

– Margaret Chan, Director-General of WHO⁴⁹

31. The World Health Assembly's adoption in 2008 of the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property⁵⁰ had paved the way for other important initiatives for overcoming the challenges identified in the 2006 report⁵¹ of the WHO Commission on Intellectual Property Rights, Innovation and Public Health. Prominent among those challenges were the effects of the current intellectual property regime on the innovation cycle (discovery, development and delivery) in developing countries. The WHO Intergovernmental Working Group debated the recommendations proposed by the Commission, and those recommendations were reflected in the eight elements that constitute the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.⁵²

- Prioritizing research and development needs;
- Promoting research and development;
- Building and improving innovative capacity;
- Transfer of technology;
- Application and management of intellectual property to contribute to innovation and promote public health;
- Improving delivery and access;
- Promoting sustainable financing mechanisms; and
- Establishing monitoring and reporting systems.

32. Since the adoption of the TRIPS Agreement, a large number of publications have examined the interconnections between trade (including intellectual property) and access to health technologies. They have also assessed the policy options presented in the WTO Doha Declaration,⁵³ occasionally building on the findings and recommendations of the Commission on Intellectual Property Rights, Innovation and Public Health report.⁵⁴

33. Generally, the assessments apply a public health lens when considering the implications of the TRIPS Agreement for the availability, affordability and accessibility of medical products. Some provide policy makers with guidance and legal advice to overcome potential barriers posed by intellectual property enforcement, and to ensure access to medicines and other health technologies. The great majority of the publications discuss a range of health issues, including AIDS, in relation to trade and intellectual property frameworks.^{55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71}

34. In addition, many authors and organizations have specifically discussed the intellectual property-related barriers affecting access to HIV commodities.^{72 73 74 75 76 77 78} Besides the cooperation between WHO, WTO and WIPO in promoting access to innovation within the health sector, the work of the WHO Consultative Expert Working Group on Research and Development – Financing and Coordination⁷⁹ is regarded as providing an important step towards realizing the R&D-related elements of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. The next section examines these and other initiatives to close the R&D gaps.
35. An increasing number of free trade agreements (FTAs) are affecting interconnections between trade and access to medicines. Most of these FTAs contain intellectual property enforcement clauses that go beyond the parameters established in the TRIPS Agreement, clauses known as “TRIPS-plus” measures. A significant body of literature has assessed the impact of FTAs on access to medicines.^{80 81 82 83 84 85 86 87 88} The Trans-Pacific Partnership, for example, is regarded as one of the most emblematic examples of such challenges. Many resolutions from multilateral bodies, such as the World Health Assembly,ⁱⁱ the UNAIDS PCB,⁸⁹ and successive Political Declarations on HIV/AIDS have raised concerns regarding the impact of trade agreements on health and/or the presence of “TRIPS-plus” provisions in those agreements. The concerns relate especially to provisions that may reduce the policy options for countries to make use of the TRIPS flexibilities in a bid to scale-up access to lifesaving drugs.
36. Middle-income countries can experience specific difficulties in accessing ARV drugs. Drug prices vary widely between middle-income countries, and many of them pay high prices for second- and third-line ARV medicines. The influencing factors include differences in disease burdens, procurement policies, economies of scale, patent legislation and the access policies of pharmaceutical companies.^{90 91 92}
37. Due to the existing criteria for external aid, many middle-income countries find it difficult to access financial support from international development agencies for their treatment programmes. They rely preponderantly on domestic resources to sustain access to those programmes. At the same time, many middle-income countries bear increasing disease burdens. It is estimated that by 2020 the majority of people living with HIV will reside in middle-income countries, many of which also face challenges from other public health threats, such as multidrug-resistant TB, hepatitis C infection and NCDs.
38. The UNAIDS PCB has consistently addressed the issue of access to medicines. At the 25th meeting of the PCB, for example, it was announced that UNDP, on behalf of UNAIDS, would convene a high-level Global Commission on HIV and the Law. That independent body was tasked with examining the role of the law in improving outcomes for HIV programmes, including access to medicines. Concerns about access to medicines were reiterated in the agenda item “Ensuring non-discrimination in responses to HIV” tabled at the 26th PCB meeting.
39. The Global Commission on HIV and the Law addressed the various respects in which legislation can affect AIDS responses, such as reducing stigma and discrimination, protecting the rights of people living with HIV and key populations, and the impact of intellectual property laws on access to treatment. While the Commission’s report⁹³ discussed the legislative measures that could help remove stigma and discrimination-

ⁱⁱ The 59th WHA discussed an agenda item on “International Trade and Health”, and requested the WHO Director-General to “respond to Member States’ requests for support of their efforts to build the capacity to understand the implications of international trade and trade agreements for health and to address relevant issues through policies and legislation that take advantage of the potential opportunities, and address the potential challenges, that trade and trade agreements may have for health”. See http://apps.who.int/gb/ebwha/pdf_files/WHA59-REC1/e/Resolutions-en.pdf?ua=1.

related barriers, it also recognized the impact of intellectual property rights on the pricing of newer commodities for treating HIV infection.

40. The recommendations of the Global Commission on HIV and the Law and the adoption of the 2030 Agenda for Sustainable Development motivated the UN Secretary-General to convene a High-Level Panel on Access to Medicines, to “*review and assess proposals and recommend solutions for 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*”.
41. Released in September 2016, the report⁹⁴ of the UN Secretary-General’s High-Level Panel on Access to Medicines focused on the negative impact of policy incoherence regarding access to health technologies. The panel noted that lack of access to medicines, vaccines, diagnostics and other medical commodities, as well as a lack of new tools for tackling health problems such as antimicrobial resistance, was a problem in both rich and poor countries. Among the concerns was the misalignment between public health priorities and economic, social and political considerations, which creates technical and political obstacles for low- and middle-income countries that seek to use the flexibilities of the current intellectual property regime to protect public health. In addition, the panel assessed the capabilities of such a regime for addressing R&D needs in relation of health technologies that have little or no market interest from the productive sector and/or public health policy makers.

PURSUING THE RIGHT BALANCE BETWEEN TRADE, PUBLIC HEALTH AND HUMAN RIGHTS

42. In 2001, the Secretary of State for International Development from the UK established the Commission on Intellectual Property Rights, comprising members from various countries and areas of expertise. It was tasked with reviewing and proposing recommendations regarding the impact of intellectual property protection in both developed and developing countries. Working against the background of newly adopted Millennium Development Goals, the Commission analysed the ways in which intellectual property rights could promote economic growth and reduce poverty or, conversely, widen gaps between poor and rich nations, by creating obstacles to innovation and to access health and agricultural products. The Commission released its report⁹⁵ in 2002, issuing recommendations to correct the distortions which stronger intellectual property might impose on developing countries’ efforts to promote development and reduce poverty.

“We need to ensure that the global IP [intellectual property] system evolves so that the needs of developing countries are incorporated and, most importantly, so that it contributes to the reduction of poverty in developing countries by stimulating innovation and technology transfer relevant to them, while also making available the products of technology at the most competitive prices possible”.
– Commission on Intellectual Property Rights⁹⁶

43. The report of the British Commission on Intellectual Property Rights influenced the discussions on the impact of intellectual property rights on public health which led to the establishment of the WHO Global Commission on Intellectual Property, Innovation and Public Health by the 56th World Health Assembly in 2003.ⁱⁱⁱ The Commission played an important role in bringing the discussions on intellectual property and public health to the upper levels of global health governance, at the World Health Assembly. The

ⁱⁱⁱ See 53rd WHA, Resolution 27, adopted in 27 May 2003: http://apps.who.int/gb/archive/pdf_files/WHA56/ea56r27.pdf.

recommendations included in its report provided the basis for the establishment of the WHO Intergovernmental Working Group on Intellectual Property, Innovation and Public Health, and the subsequent adoption of the WHO Global Strategy and Plan of Action on Intellectual Property, Innovation and Public Health.

44. As a follow-up of the 2008 WHO Global Strategy and Plan of Action on Intellectual Property, Innovation and Public Health, the 63rd World Health Assembly in 2010 approved a resolution^{iv} requesting the WHO Director-General to establish a Consultative Expert Working Group (CEWG) to further examine and take forward proposals presented to an Expert Working Group. The decision followed discussions at the World Health Assembly on implementation of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, and the deliberations of an expert working group which had been mandated to “*examine current financing and coordination of research and development, as well as proposals for new and innovative sources of funding to stimulating research and development*”.
45. The CEWG report⁹⁷ was completed in 2012. It consisted of a comprehensive description of the evolution of WHO’s internal discussions on the linkages between intellectual property rights and public health, which the Commission on Intellectual Property Rights, Innovation and Public Health had initiated and which were reflected in subsequent decisions of the World Health Assembly. The report discussed options for promoting R&D to address the public health needs of developing countries with respect to access to newer health technologies (including medicines, vaccines and diagnostics). It emphasized the need to examine the areas in which the current intellectual property system was inadequate, for example by failing to promote market interest in R&D for key public health technologies. The CEWG focused on proposals that closely matched its mandate, i.e. innovative and sustainable financing, and coordinating approaches and mechanisms for R&D.
46. One of the approaches informing the CEWG’s recommendations on mechanisms (or incentive schemes) to promote R&D was “delinkage” or “delinking”, which featured among the proposals which the previous Expert Working Group had assessed. “Delinking” implies separating the recovery of R&D expenses from the final price of products. In the current intellectual property system, developers of medical products can recoup R&D investments via the prices they charge to final consumers of the products (whether patients, health insurance companies or governments). An example of “delinking” is when a patent on a given product expires, enabling generic producers to develop manufacture the product and market it at prices that are shaped largely by production costs and desired profit margins.
47. The approaches to R&D which the CEWG recommended were based on proposals characterized by “*research and innovation that generate knowledge which is free to use without legal or contractual restrictions*”.⁹⁸ This referred to open knowledge innovation, such as precompetitive R&D platforms, open source, open access and prizes. Equitable licensing and patent pools were also considered as attractive mechanisms to enhance access to innovation “on equitable terms and/or with low transaction costs”.
48. The CEWG also examined the lack of funds invested in R&D. Although the governments of many developed countries invest consistently in R&D, most of the innovation activities are performed by the private sector. This often leads to a neglect of innovations for public health problems that hold little or no prospect of substantial profits or where the

^{iv} See 63rd WHA Resolution 28, adopted on 21 May 2010: http://apps.who.int/gb/ebwha/pdf_files/WHA63-REC1/WHA63_REC1-P2-en.pdf.

recovery of R&D investments may be unlikely. Public sector expenditures on R&D can be substantial, but they tend to fall far short of actual public health needs, particularly in low- and middle-countries.

49. Regarding financing mechanisms, the CEWG concluded that governments should commit to spend at least 0.01% of gross domestic product (GDP) on public-funded R&D to address types II and III diseases, and type I diseases^v affecting developing countries. In addition, it recommended specific targets for countries to invest on overall health-related R&D needs, according to their level of development: 0.15–0.2% of GDP for developed countries, and 0.05–0.1% of GDP for developing countries.
50. The mobilization of funds for R&D should be accompanied by further coordination at the global level. In that regard, the CEWG recommended the creation of a global health R&D observatory and advisory mechanisms, which would operate under the auspices of WHO. Such an observatory would be tasked to collect and analyse data on financial flows to R&D, monitor areas that are under-served by R&D efforts, and evaluate progress. The advisory mechanisms would ensure a common vision and priorities among the various funders and implementing stakeholders as they worked to promote the global R&D agenda.
51. In order to advance the funding and coordinating mechanisms, the CEWG recommended the negotiation of a global R&D treaty. Based on the processes that led to the adoption of the Framework Convention for Tobacco Control, such a treaty would constitute a binding document. WHO Member States would commit themselves to actions to ensure coordination, secure funding and mobilize technical expertise to create a workable and enabling environment for a sustainable R&D framework. It would focus on addressing the major public health concerns, mainly for developing countries and unassisted populations and diseases.
52. In order to assess the feasibility of the recommendations proposed by the CEWG, WHO invited institutions involved in R&D to develop projects based on the principles explored in the CEWG report. Six demonstration projects are currently in place, most of them focusing on neglected diseases (e.g. visceral leishmaniasis, schistosomiasis and febrile illness), new diagnostic methods or open source collaboration for developing drugs for infectious diseases that disproportionately affect developing countries.
53. It is worth noting that none of the current demonstration projects addresses HIV-related health technologies. Some of the proposals presented to the Expert Working Group and the CEWG did pertain to the AIDS epidemic. They addressed clinical trials for AIDS vaccines; the development of a new generation of ARVs through patent pooling; access to existing, high-priced ARVs using open-access/equitable licensing platforms; and stimulating innovation in the competitive supply of newer HIV products by granting milestone-prizes and/or end-prizes.
54. Another important CEWG recommendation concerning coordination was the establishment of voluntary pooled fund for R&D for some specific diseases. Still in its inception phase, this fund is being co-managed by UNICEF, UNDP, The World Bank, and the WHO Special Programme for Research and Training in Tropical Diseases. It is expected that its forthcoming operational plan will be aligned with the access core

^v **Type I diseases** are incident in both rich and poor countries, with large numbers of vulnerable populations in each; **Type II diseases** are incident in both rich and poor countries, but with a substantial proportion of the cases in poor countries. **Type III diseases** are those that are overwhelmingly or exclusively incident in developing countries. See http://www.who.int/phi/3-background_cewg_agenda_item5_disease_types_final.pdf.

principles of affordability, effectiveness, efficiency, equity, and the CEWG-recommended principle of “delinkage”. A major aim is to achieve sustainable funding.

55. One of the proposals presented to the CEWG involved a form of patent pooling known as “WIPO Re:Search”. WIPO established that initiative in 2011 as a voluntary licensing platform, in collaboration with BIO Ventures for Global Health. The platform presents private and public sector research organizations, including originator and generic companies, with a collaborative environment to harmonize R&D efforts for neglected tropical diseases, TB and malaria. It does so by making available intellectual property, such as patents and patent rights, pharmaceutical compounds and compound libraries, unpublished scientific results, regulatory data, technologies, expertise, and other forms of know-how. A wide range of organizations, from both developed and developing countries, are engaged in the initiative. By the end of 2015, “WIPO Re:Search” providers had made 193 contributions to the initiative and there were almost 100 collaborations in place to tackle those public health concerns in least-developed countries.

56. Since the adoption of the Doha Declaration in 2001, health and access to medicines have featured on the agenda of the WTO TRIPS Council on many occasions, mainly in relation to the implementation of paragraphs 6 and 7 of the document, which state:

(6) We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

(7) We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

– WTO Declaration on the TRIPS Agreement and Public Health⁹⁹

57. In August 2003, following deliberations of the Council for TRIPS, the WTO General Council decided on a mechanism by which a particular type of compulsory licensing could be issued to respond to a request from a country (importer member) with no or low manufacturing capacity to import a patent-protected pharmaceutical product from a country with manufacturing capacity (exporter member). Known as the paragraph 6 system,^{vi} that decision was the subject of further internal discussions¹⁰⁰ among TRIPS Council members. This led to the 6th December 2005 decision of the General Council to amend the TRIPS Agreement by inserting a paragraph (31bis), specifying the scope of compulsory licensing under the system and an annex after article 73, describing the operationalization of the system.

58. According to the WTO website,^{vii} 78 WTO Member States had expressed their acceptance of the protocol by June 2016. The remaining Member States have until 31 December 2017 to follow suit. There is a great deal of discussion in the literature about

^{vi} For further information on the paragraph 6 system, see https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm.

^{vii} See https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm.

the operationalization of such mechanism,^{101 102 103 104} as well as its feasibility and efficiency.^{105 106 107 108} Much of the discussion relates to the bureaucratic burden which the mechanism might impose on both exporting and importing members, and a possible lack of market attractiveness for exporting countries due to limited economies of scale. The system has been used only once thus far, to allow the exportation of a fixed-dose combination of ARVs from Canada to Rwanda. The move did not result in a substantial reduction in the price paid by the importing country when compared with prices offered by generic manufacturers in India, for example.^{109 110} The Global Commission on HIV and the Law has recommended that WTO Member States review the paragraph 6 system in order to propose and establish new mechanisms that can facilitate the importation of health technologies that are produced as a result of the issuing of a compulsory license.

59. The follow-up of paragraph 7 of the Doha Declaration regarding the extension of the exemption period for least-developed country Member States to implement or apply intellectual property protection to pharmaceutical products has also been the focus of debate and resolutions at the WTO TRIPS Council.^{111 112} In 2013, after a request from the least-developed country group to the TRIPS Council,^{113 114} an overall extension was granted until 2021. The group made another request in 2015 to extend the TRIPS exemption period for over pharmaceutical for as long as countries remain classified as “least-developed”.¹¹⁵ The request was supported by a large number of health activists, international NGOs and intergovernmental bodies, such as UNAIDS, UNCTAD, UNDP, UNITAID and WHO, based on the assumption that it would promote access to essential medicines, including ARVs.^{116 117 118} The final decision was made in November 2015, extending the exemption period until 2033.^{viii}
60. Intergovernmental organizations prepare the ground for the establishment of global norms, regulations, and policy and technical standards in their various domains of activity. In partnership with technical agencies, they also play important roles assisting their Member States to adopt and implement resolutions made in their governing bodies and to make use of the policy options that exist in international treaties.^{119 120 121 122 123 124}
^{125 126} Technical support provided by those agencies is therefore vital for the full realization of multilateralism principles. Under the umbrella of cooperation between WHO, WIPO and WTO, staff from the three organizations are providing technical support to Member States to reduce the potential barriers which trade mechanisms might pose to scaling-up access to health technologies. The support is also aimed assisting Member States in making better use of policy options, such as the TRIPS flexibilities. These activities include capacity building and training in areas where public health and trade issues converge (such as intellectual property), as well as in-country technical assistance, workshops and seminars at all levels, and headquarter-based courses.^{127 128}
61. Other multilateral agencies are assisting countries on these matters, though in different respects. The UNDP, for example, assists countries in establishing enabling legislative environments that can foster internal coherence and coordination around trade and development issues to improve public health outcomes generally and access to medicines in particular.^{129 130}
62. Similarly, UNCTAD has been working with other international organizations¹³¹ and countries to assess the potential for improving the use of the intellectual property rights regime, including the TRIPS flexibilities, for local pharmaceutical production in low- and middle-income countries. The improvements have several aims, including creating

^{viii} See https://www.wto.org/english/news_e/news15_e/trip_06nov15_e.htm and <http://keionline.org/sites/default/files/JointNGOStatementLDCwaiver6nov2015.pdf>.

investment opportunities for local production of health technologies and encouraging developing countries to improve their capacities for innovation. They are also aimed at fostering access-to-medicines policies through improved coordination and alignment between public health and trade issues, such as intellectual property management,¹³² investments, tariffs and technology transfers. Access to capital (external investment) and technology are core UNCTAD activities to support countries to create enabling environments for trade and development, including by using intellectual property tools to encourage the development of local pharmaceutical manufacturing capacities.¹³³

Africa remains dependent on imported medicines and other health technologies – a risky situation in a continent with the world's highest prevalence of HIV. The 7.6 million Africans living with HIV now on antiretroviral treatment and millions more waiting depend on 80% of antiretroviral medicines being imported from outside the continent. The local production of medicines and other essential health commodities is important for all health challenges faced by the continent. Demand for health commodities is growing rapidly. The ageing population in Africa requires access to a growing range of medicines and assistive technology that cannot be met with Africa's existing manufacturing capacity and sources of supply.

– Michel Sidibé, Li Young, Margaret Chan¹³⁴

63. Many stakeholders have advocated for the strengthening of local pharmaceutical manufacturing capacities in developing countries to achieve increased affordability, availability, accessibility and quality assurance of medicines and other health technologies. In 2010, a pioneering and influential study produced by the African Union, the Council on Health Research for Development and the New Partnership for Africa's Development Agency¹³⁵ reviewed the challenges and opportunities for strengthening pharmaceutical innovation in Africa in order to achieve greater access to essential medicines.
64. The study linked the principles and elements formulated in the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property with the forward-looking Pharmaceutical Manufacturing Plan for Africa, which the African Union had adopted in 2007. The United Nations Industrial Development Organization (UNIDO) is assisting the African Union in developing a business plan for the Pharmaceutical Manufacturing Plan for Africa,¹³⁶ which gathers concerned stakeholders around this ambitious project.
65. Highlighting the long-term timeframe of the initiative and the need to encourage regional synergies across the continent, the 2010 study covered four areas: implementing innovation, ensuring access, manufacturing, and capacity building. It recommended further continental coordination, and the creation of R&D mechanisms through technology transfer platforms, with a clear and shared strategy among the different actors. Despite the enormous challenges for strengthening local production in Africa,¹³⁷ the agenda has been attracting the interest of many investors from around the world, and is stimulating technological partnerships with pharmaceutical companies, both originator and generic producers, as well as with African institutions. As noted by leaders of UNAIDS, UNIDO and WHO, political will is being mobilized, leveraging the local pharmaceutical production agenda, as expressed in the African Union Roadmap on Shared Responsibility and Global Solidarity for AIDS, Tuberculosis and Malaria Response in Africa.¹³⁸
66. The African Union Roadmap sets out options for reducing the dependency of African countries on external funding and resources, including foreign-produced medicines, by exploring health development models that are closer to African realities and communities. This would strengthen national ownership and health security. The Roadmap rests on

three pillars. One of them involves improving access to affordable and quality-assured medicines. Recalling the commitment of the African Union Member States in relation to the Pharmaceutical Manufacturing Plan for Africa, this pillar describes priority actions to scale-up access to medicines and other health products by:

- facilitating regional manufacture of medicines;
- strengthening regulatory capacities across the continent;
- establishing skills-building platforms through technology transfers, including South-South cooperation;
- and creating legislative environments that allow countries to make full-use of the existing TRIPS flexibilities¹³⁹ and to avoid “TRIPS-plus” measures.

67. In recent years, much progress has been observed in the development of local capacity for quality assurance of medical products in Africa. Building on the Pharmaceutical Manufacturing Plan for Africa and the African Union Roadmap, a consortium led by the African Union Commission began implementing the African Medicines Regulatory Harmonization initiative (AMRH) in 2008.¹⁴⁰ The consortium was set up by the New Partnership for Africa’s Development Agency, WHO, the UK Department for International Development, the Bill and Melinda Gates Foundation, the Clinton Health Access Initiative, and the World Bank.

68. The AMRH provides a platform for collaboration between African countries in order to implement harmonized regulatory norms and standards. The initiative recognizes the weaknesses and obsolescence or absence of legal frameworks for health regulation in individual African countries and the subsequent limited capacity of national regulatory agencies to ensure acceptable standards of quality, safety and efficacy of medical products in local markets. The initiative therefore seeks to establish or improve national and regional capacities for assuring the quality of medicines in countries in Africa. The pace of implementation of the initiative in the regional economic communities of the African Union varies considerably. The Eastern African Community and the Southern African Development Community have made greatest progress in relation to the main objectives of the initiative, compared to other parts of the continent which the consortium is prioritizing.

69. The AMRH initiative has mobilized strong political will from African leaders to strengthen regulatory capacities that can help achieve the global and continental commitments on access to medicines, and, more broadly, the creation of an African Medicines Agency. Such an agency would oversee the registration of essential medical products and coordinate regional regulatory harmonization on the continent. In January 2016, African Union Heads of State and Government officially endorsed the African Union Model Law on Medical Products and Regulations.¹⁴¹ This legal tool was developed in a comprehensive consultative process, through a partnership between the African Union Commission, the New Partnership for Africa’s Development Agency, and the Pan-African Parliament. Other partners included the Secretariat of UNAIDS and co-sponsors, including WHO and UNDP.¹⁴²

70. Community-based approaches for R&D of products to tackle major public health concerns can play an important role in meeting the needs of patients who are not prioritized in the mainstream initiatives of R&D stakeholders. The Drugs for Neglected Diseases initiative (DNDi) is a not-for-profit organization working on R&D of treatments for patients affected by neglected diseases, such as Chagas disease, filariasis, leishmaniasis, mycetoma, sleeping sickness, as well as treatments for hepatitis C, malaria and paediatric HIV.

71. The initiative's starting point is that current R&D incentive models, such as those based on intellectual property and exclusivity rights, do not adequately address the health needs of low- and middle-income countries. As a result, the health problems of many patients are neglected, including infections that have been targeted with R&D efforts in developed countries, such as HIV and hepatitis C. For instance, despite all the achievements in dramatically reducing HIV transmission from mothers to children, there is still a lack of ARV formulations that could be as effective in children as they are in adults. Similarly, the high prices of drugs for treating hepatitis C infection and the lack of generic and less expensive versions of those drugs means that the treatment is out of reach for many patients living in industrialized and middle-income countries. DNDi's framework of action therefore includes not only neglected diseases, but also neglected patients and populations.¹⁴³ To achieve a proper balance between innovation and access, DNDi focuses on the establishment of R&D platforms, closely linked with private sector originator and generic producers, so that the required technology and expertise can lead to the most effective treatment outcomes. In addition, partnerships with the public sector are a key element of the DNDi strategy and allow for timely introduction of the outcomes of R&D efforts. Close contact with affected communities in endemic countries is an important component of the DNDi approach, which seeks to address and prioritize the health needs of patients.
72. R&D gaps continue to widen, however. In recent years, the emergence of Ebola and the Zika virus have challenged the national health systems of affected countries and have raised questions about the capacity of the global health infrastructure to tackle major public health threats. Those threats now include the rapidly growing numbers of NCD cases in low- and middle-income countries. Public health experts insist that it is vital for equitable access to health technologies to be made part of the global health agenda and to be translated into concrete actions at community level. This concern is underscored by the growing threat of antimicrobial resistance. In its Global Action Plan on Antimicrobial Resistance, WHO has warned that, "*without harmonized and immediate action on a global scale, the world is heading towards a post-antibiotic era in which common infections could once again kill.*"¹⁴⁴ DNDi and WHO have joined hands to found a partnership among state actors, pharmaceutical companies, civil society and academia, among others, to address the pipeline gaps for products that are urgently needed to prevent, diagnose and treat pathogens that are already resistant to current antibiotics.
73. Many of the initiatives mentioned above are aimed at advancing the access agenda along separate paths. The world finds itself at a dramatic crossroads. On the one hand, there is the immense potential of science and technology to advance health care and realize the right to health; on the other hand, there exist major gaps and weaknesses that undermine effective actions to address existing and emerging disease burdens in many countries and communities. The pace of achieving change is not matching the urgency of the situation. This was one of the reasons for the establishment of the UN Secretary-General's High-Level Panel on access to medicines. Importantly, the Panel noted the need for increased coherence across the multilateral system and did not restrict the scope of its recommendations to specific types of disease, populations, countries or health technologies.
74. Co-chaired by Ms Ruth Dreifuss, former President of the Swiss Confederation and M. Festus Mogae, former President of the Republic of Botswana, the High-Level Panel was an important and timely initiative, especially against the background of the SDGs. The Panel was convened soon after 193 UN Member States adopted the ambitious 2030 Agenda for Sustainable Development, which recognizes the fundamental interconnections between health and development. The Panel comprised a diverse group of 15 distinguished individuals from varied backgrounds, experiences and continents – though they all have important stakes in the innovation of and access to

health technologies. This diversity informed the Panel's deliberations. The Panel's Expert Advisory Group, for example, included recognized experts in various fields, including representatives from pharmaceutical companies, civil society organizations and academia, and from key UN entities such as OHCHR, UNCTAD, UNICEF, UNIDO, WHO and WIPO. The Panel was skilfully chaired by Panel Member Michael Kirby. Its work benefitted from submissions by diverse stakeholders, contributions from UN and other intergovernmental bodies, and background papers commissioned by the Secretariat and UNDP, in close collaboration with UNAIDS. Also important were the Panel's interactions with representatives of UN Member States, civil society and patient groups, the private sector and academia at two global dialogues in London and Johannesburg.

75. The Panel was tasked with focusing on concrete and actionable solutions. Its report¹⁴⁵ has a simple and powerful message: no-one should suffer because he or she cannot afford medicines, diagnostics or vaccines. The Panel was unanimous on the need to act immediately to improve both health technology innovation and access. It has made significant and concrete recommendations to stakeholders, including UN Member States, civil society, the private sector and international organizations, to accelerate actions that address gaps in health technology innovation and access:
- a) Governments must urgently increase their current levels of investment in health technology innovation to meet unmet needs. They should also enter into negotiations for a binding R&D treaty that “delinks” the costs of innovation from the end prices of health technologies in order to resolve issues which existing innovation mechanisms have failed to address adequately;
 - b) There should be much greater transparency to ensure that the costs of research and development, production, marketing and distribution, as well as the end prices of health technologies, are clear to consumers and governments;
 - c) Governments and the private sector must refrain from explicit or implicit threats, tactics or strategies that undermine the right of WTO Members to use TRIPS flexibilities, as reaffirmed in the Doha Declaration on TRIPS and Public Health. WTO Member States must register complaints against undue political and economic pressure, and take punitive measures against offending Member States; and
 - d) The UN Secretary-General should establish an independent review body tasked with assessing progress on health technology innovation and access and should convene a High-Level Meeting on Health Technology Innovation and Access.
76. The Panel's report generated extensive discussion.^{146 147 148} There were positive reactions from the G77 and China (who welcomed the report in their official statements at the recent UN meeting on antimicrobial resistance), the South Centre and a number of leading civil society organizations such as Médecins Sans Frontières, the Treatment Action Campaign and Health Gap. There were also negative reactions from some industrialized country governments and the originator industry, while some civil society groups felt that the Panel's recommendations were not ambitious enough.
77. Nevertheless, considering that the recommendations of the Panel were built upon existing approaches, many of them described earlier in this paper, the Panel's report can be an important catalyst for attaining the 2030 Agenda for Sustainable Development, including SDG 3 on ensuring health and well-being for all.

ACCESS EQUITY RIGHTS NOW: GLOBAL INITIATIVES TO SCALE-UP ACCESS TO HIV-RELATED PRODUCTS

78. At the start of the 21st century, the UN committed to the MDGs, which included MDG 6, focusing on HIV, malaria and other infectious diseases. Around the same time, a series of similar commitments mobilized both political will from world leaders and financial resources to build a coordinated global response to the AIDS epidemic. The 2001 Political Declaration on HIV/AIDS (and the subsequent Political Declarations in 2006, 2011 and 2016) established measurable and realistic global targets for translating political commitment into concrete actions that would address the impact of the AIDS epidemic on development and pave the way for progress in various aspects of the AIDS response, including access to medicines. Since then a series of initiatives, many of them ground-breaking, have contributed to the progress achieved by the global AIDS response.
79. **The WHO Prequalification Programme.**¹⁴⁹ Assuring the quality of health products that are introduced into the market is vital for achieving effective public health outcomes. Yet many of the countries affected by the AIDS epidemic are struggling to create or strengthen those regulatory capacities. The growing number of generic products that are being brought to the market – which helped reduce the price of ARVs – along with newer products developed by originator pharmaceutical companies have reinforced the need to expedite the introduction of these health products into national markets. This would alleviate the burden of registration processes for national regulatory authorities and pharmaceutical companies.
80. National procurement and supply management capacities vary considerably from country to country and from region to region. Procurement agencies, including those in the multilateral system, sometimes struggle to introduce the health products they procure via international tenders and purchases. These agencies require assistance for assessing a growing range of health products, while many developing countries still require assistance for strengthening their national regulatory systems for the importation of medicines. In order to meet those needs, WHO created the Medicines Prequalification Programme in 2001.
81. The programme focused initially on products to treat HIV, TB and malaria, before expanding its scope to include other areas such as reproductive health. The programme evaluates active pharmaceutical ingredients, final products and manufacturing plants, using stringent criteria on quality, safety and efficacy, including standards of global manufacturing practices. The programme has become a key reference for UN agencies and for countries and other entities involved in bulk procurement of health products. It has made possible the rapid completion of the regulatory steps that enable countries to introduce imported quality-assured drugs, including generics. The initiative also helped optimize the procurement activities that are supported by overarching strategies, such as those undertaken by the Global Fund and the US President's Emergency Plan for AIDS Relief (PEPFAR).
82. **The Global Fund to Fight AIDS, Tuberculosis, and Malaria.**¹⁵⁰ Created in 2002, the Global Fund is considered an outstanding initiative for mobilizing and managing financial resources to fund effective public health responses to the three diseases. Initially hosted and administrated by WHO, the Global Fund became an autonomous entity in 2009. It operates as an international financial organization, bringing together implementing government bodies, civil society organizations, the private sector, multilateral and bilateral agencies, and affected communities. At first, the Global Fund funded proposals presented by country-driven bodies (such as the Country Coordinating Mechanisms), which were then assessed by an ad-hoc technical panel (Technical Review Panel).

Implementation was closely monitored by the Secretariat and by local agents in the field. Since 2012–2013, a new operational model has been implemented, seeking a more integrated and comprehensive approach to national health systems, rather than exclusively funding country proposals focused on single diseases.

83. Global Fund-supported grants have contributed to the major increases in the numbers of people receiving ART. In addition to directly funding local procurement of health products by implementers, the Global Fund has developed and implemented market strategies that are helping reduce the prices of commodities globally. Those initiatives include the voluntary pool procurement mechanism and, most recently, the e-marketplace (wambo.org), which is an on-line platform to assist countries in identifying the best prices for health products used in national programmes.

84. **United States President's Emergency Plan for AIDS Relief (PEPFAR).**¹⁵¹ PEPFAR was created in 2003 and is considered the largest component of the Global Health Initiative of the US Government. Its ambitious targets include securing sustainable access to HIV treatment, and strengthening and consolidating HIV-related programmes in priority countries. The PEPFAR strategy is based on three core principles: country ownership, integration of HIV programmes within a broader health and development context, and building local capacities and increased efficiencies. Working closely with governments, communities, multilateral organizations, technical partners and the private sector, PEPFAR had directly supported 5.7 million people on ART by the end of 2015.¹⁵² Achievement of an adequate balance between rapid scale up of access and quality assurance of purchased health products has been a constant priority: quantity should not come at the expense of quality. Collaboration with the WHO Prequalification Programme has been essential to ensure the availability of safe, effective, quality-assured and affordable generic ARVs.

85. The US Food and Drug Administration (FDA) has played a similarly important role by introducing an expedited "tentative approval" (fast-track) process. This enables ARV manufacturers to have their products and manufacturing processes promptly assessed for quality, and to obtain clearance for purchase by countries using PEPFAR grants. The products used by PEPFAR grantees are therefore subjected to the same quality-assurance procedures as products that are available in the US market. Moreover, an agreement between the FDA and the WHO Prequalification Programme allows for accelerated dossier approval by the Prequalification Programme once the product receives tentative approval from the FDA. The Global Fund also recognizes the approval processes of both the FDA and the WHO Prequalification Programme. Given that PEPFAR and the Global Fund finance large proportions of procured ARVs worldwide, these arrangements have an important impact on the pharmaceutical market. They facilitate substantive increases in the number of patients accessing treatment, while promoting affordable and sustainable prices.

86. **The "3 by 5" initiative.**¹⁵³ Launched by UNAIDS and WHO in 2003, this initiative set a global target to provide ART to three million people living with HIV in low- and middle-income countries by the end of 2005. It was estimated that 40 million people were living with HIV in 2003, 95% of them in developing countries, and that 14,000 people were being newly infected with HIV per day. The benefits of highly-active ART for reconstituting people's immune systems and reducing AIDS-related mortality had been known since 1996. However, the clinical benefits of ART were accessible only to a small minority of people living with HIV, mostly in high-income countries. The high prices of the drugs were the primary barrier. In 2003 it was estimated that fewer than 8% (approximately 400 000) of the 6 million people who were eligible to receive ART in low- and middle-income countries were receiving ART. Analyses done by UNAIDS, WHO and research academics had shown it would be possible to enrol at least three million people

in HIV treatment by 2005. The “3 by 5” initiative focused on mobilizing resources and political will through sustained advocacy, strengthening the capacity of health systems, and establishing and adopting simplified HIV treatment guidelines. Even though the original target of the initiative was only reached in 2007, access to HIV treatment was transformed dramatically. WHO estimated that more than 1.3 million people in low- and middle-income countries were receiving ARV therapy at the end of 2005,¹⁵⁴ three times more than in 2003 when the initiative had been launched. Even more importantly, the initiative proved that providing treatment in resource-limited settings was feasible. ART became an integral part of the comprehensive AIDS response in many developing countries.

87. **Universal access to HIV prevention, treatment and support by 2010.** The “3 by 5” initiative also encouraged national leaders to issue new commitments on expanding access to HIV treatment. In 2005, the G8 group of nations committed to reach universal access to HIV prevention, treatment and support by 2010. The UN General Assembly approved a similar commitment in 2006, and tasked the UNAIDS Secretariat, UNICEF and WHO with monitoring the progress. By the end of 2010, an estimated 6.7 million people were receiving ART in low- and middle-income countries, equal to approximately 47% of people who were eligible for treatment.¹⁵⁵ A major decline in AIDS-related deaths was being observed. In addition, new studies were confirming that HIV treatment has a powerful effect in preventing new HIV infections, thus opening new opportunities for the use of ARVs for prevention.¹⁵⁶
88. **UNITAID.** In 2006, as countries committed to reach the target of universal access by 2010, representatives of the Governments of Brazil, Chile, France, Norway and the UK launched the International Facility for Medicines Acquisition. Known as UNITAID, the new entity is hosted by WHO. It works in partnership with implementing agencies to accelerate the market entry of innovative health products for HIV, TB and malaria. UNITAID has rapidly become a central source of market analysis, publishing systematic market landscape reviews for various products and approaches for procuring health commodities.^{157 158 159 160} By bringing into the market large volumes of strategic products for paediatric treatment and prevention of mother-to-child transmission of HIV, as well as second- and third-line treatment regimens for adults, UNITAID plays a critical role in building markets for niches that are not routinely addressed by other funding initiatives. It also works with the developers of diagnostic and treatment monitoring platforms, such as CD4 and viral load tests, in order to increase the availability and affordability of those products. More recently, and in partnership with UNAIDS, UNITAID has worked to increase the affordability of products to prevent the sexual transmission of HIV, particularly pre-exposure prophylaxis.
89. UNITAID-funded projects have increased the competition offered by generic producers of newer HIV-related products. The prices of key commodities used in HIV treatment have been reduced significantly and these lower prices are also available to countries and procurement agencies that do not directly benefit from UNITAID grants. Since quality-assurance of medical products plays an important role in scaling up access to medicines and regulating the pharmaceutical market, UNITAID is also contributing to the success of activities of the WHO Pre-Qualification Programme.
90. **Medicines Patent Pool.** The impact of intellectual property protection on access to medicines has been a consistent concern of UNITAID Executive Board. UNITAID prepared the ground for the creation of the Medicines Patent Pool (MPP), an independent foundation that is responsible for negotiating the licensing of newer ARVs with patent holders and for establishing licensing agreements with generic manufacturers. Recently, UNITAID extended the mandate of MPP to work on voluntary licensing agreements for other major public health threats, such as TB and hepatitis C infection.

By using a public health approach, the licences negotiated by the MPP promote access to affordable treatment by stimulating competition from generic manufacturers. It also allows for the development of generic fixed- dose combinations and paediatric formulations of patented products.^{161 162 163}

91. The MPP seeks to reduce delays between the approval of new ARVs and their availability as quality-assured generics for use in developing countries. MPP licences are non-exclusive and pro-competitive, while their broad geographic scope enables increased numbers of people living with HIV to benefit. MPP licenses, for example, can include provisions that allow for sales outside the licensing territory under certain circumstances (including in the case of compulsory licences). Transparency is a key feature of the MPP approach, and the licenses themselves are available to the public. The MPP publishes a patent status database that is easily accessed electronically. At the same time, the initiative's success depends on its ability to attract originator companies to deposit their licenses into the pool.¹⁶⁴ Some of the newer products recommended by WHO for use in second- and third-line treatment regimens have not yet been licensed to the MPP. There is also a growing trend of the granting of patents in countries that have manufacturing capacity, such as Brazil, China, India and South Africa, which could create barriers to generic competition regarding patented products. There are concerns that the geographical scope of licenses negotiated through the MPP does not always cover settings with high HIV incidence in key populations, especially in middle-income countries.^{165 166 167}

92. **Treatment 2.0 Framework for Action.** Building on the progresses achieved with the “3 by 5” and the “Universal Access by 2010” initiatives, UNAIDS and WHO in 2010 launched an initiative to support countries to achieve and sustain universal access to ART and to make increased use of ARTs to prevent HIV transmission. The Treatment 2.0 Framework for Action was designed to address the need for innovation and efficiency gains in HIV programmes, with a focus on increased effectiveness, and expanded intervention coverage and impact.¹⁶⁸ The framework rested on five pillars:

- Optimizing drug regimens;
- Simplifying treatment monitoring approaches;
- Reducing costs of treatment;
- Adapting and integrating health service delivery; and
- Mobilizing communities.

93. **Policy guidance and technical support.** As part of ongoing efforts to reduce costs, UNAIDS, UNDP and WHO have developed technical and political guidance for countries to make use of the TRIPS flexibilities, and to avoid TRIPS-plus provisions in trade agreements.¹⁶⁹ Many of the WHO activities in this area occur against the background of the trilateral cooperation between WHO, WIPO and WTO on access to innovation.¹⁷⁰ UNDP carries out wide-ranging activities that provide governments and civil society organizations with technical support for the use of TRIPS flexibilities to enhance public health outcomes. UNDP work with regional and country stakeholders to support capacity building activities has been key for advancing the inclusion of TRIPS flexibilities in ongoing patent law reforms. Collaboration with patent offices is another important aspect of UNDP's work at country level. The work includes regional capacity building activities, such as training patent examiners from pharmaceutical, biological and chemistry divisions of low- and middle-income countries.^{171 172}

94. **The Global Commission on HIV and the Law.** Multiple stakeholder-led initiatives have been created to promote greater policy coherence. Chaired by former Brazilian President Fernando Henrique Cardoso, the Global Commission on HIV and the Law was set up to examine the impact of law on AIDS responses, catalyze action at country level and help

create legal environments that would protect and promote human rights. The Commission's goal was to develop actionable, evidence-based and human rights-based recommendations for effective AIDS responses, including in the domain of intellectual property.¹⁷³ The main findings and recommendations of the Commission were that:

- countries are not sufficiently using TRIPS flexibilities to facilitate treatment access;
- criteria for the issuing of patents should be more stringent;^{174 175}
- "TRIPS-plus" provisions in FTAs have a deleterious impact on access to health, and developing countries should abstain from accepting them;
- the so-called paragraph 6 system should be reformed and replaced in order to effectively resolve the access problems that the system was intended to remedy;
- countries should make greater investments in R&D activities and human rights principles should guide those decisions and prevail over the rights of inventors; and
- there should be a structural review of the current intellectual property system for the health sector.

The UN Secretary-General must convene a neutral, high-level body to review and assess proposals and recommend a new intellectual property regime for pharmaceutical products. Such a regime should be consistent with international human rights law and public health requirements, while safeguarding the justifiable rights of inventors (...) This re-evaluation, based on human rights, should take into account and build on efforts underway at WHO, such as its Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property and the work of its Consultative Expert Working Group.
– Global Commission on HIV and the Law¹⁷⁶

95. **UNAIDS–Lancet Commission.** The UNAIDS–Lancet Commission was established in May 2013 to assess progress in responding to the AIDS epidemic, including in the area of access to ART, and propose scientific and political guidance for ending AIDS as a public health threat in the post-2015 era. Comprising a diverse group of experts in the domains of HIV, health and development, as well as AIDS activists and political leaders, the Commission based its recommendations on modeling exercises that projected the levels of investment required to meet global commitments to prevent new infections, sustain treatment programmes, and maintain and enhance political mobilization. Although the report of the commission¹⁷⁷ did not present specific recommendations regarding trade and access to medicines, a section on commodity security discussed the importance of balanced market approaches for sustaining price reductions of essential HIV-related products, including through generic competition.

96. **Treatment 2015.** Partnerships between multilateral agencies and with Governments and communities constitute the foundation for realizing the global commitments made at high-level forums. The 2011 Political Declaration on HIV and AIDS set a target of having 15 million people on ART by 2015. UNAIDS, partnering with the Global Fund, PEPFAR and WHO, launched the Treatment 2015 initiative which aimed to support the accelerated scale-up of HIV treatment programmes to support achievement of the treatment targets set in the 2011 Political Declaration.¹⁷⁸

97. Informed by evidence of the preventive benefits of ART,¹⁷⁹ Treatment 2015¹⁸⁰ rested on three pillars: greater demand for HIV testing and treatment; strategic investments in evidence-based programmes and innovative approaches; and improved service delivery to people who are not accessing ART, including key populations. Access to commodities was seen as a key factor for achieving the objectives of the initiative. In that respect, the initiative re-affirmed the principles established in the Treatment 2.0 Framework. Those principles included the reduction of treatment costs so that cutting-edge technologies

could be used widely (including optimized treatment regimens, point-of-care of CD4 and viral load tests, and other HIV-related commodities). They also included the need to protect countries' policy options for making appropriate use of the TRIPS flexibilities and for taking advantage of products produced under licensing agreements negotiated through the MPP, so that generic competition could be sustained.

98. The initiative also highlighted other mechanisms such as strengthened procurement and supply management capacities, including forecasting; pooled procurement; the use of competition law; and greater transparency on pricing policies. In addition, the initiative encouraged countries to seek local and regional pharmaceutical manufacturing opportunities in order to reduce their dependency on imported products and increase the long-term sustainability of treatment programmes. That could be done by, for example, leveraging technology transfers through South-South and North-South collaboration, and by pursuing the objectives of the African Union's Pharmaceutical Manufacture Plan for Africa and adhering to the principles of the African Union Roadmap on Shared Responsibility and Global Solidarity. The initiative treatment target was reached ahead of time: by March 2015, an estimated 15 million people were accessing ART.¹⁸¹ By the end of 2015, UNAIDS estimated that 17 million people were receiving HIV treatment.¹⁸²
99. **Equitable Access Initiative.** In 2015, the Global Fund developed a partnership with UNAIDS, UNDP, UNFPA, UNICEF, UNITAID, the Vaccine Alliance (GAVI), WHO and the World Bank to develop a health framework based on a set of economic and health indicators that transcended the classification of countries according to income. The rationale behind the Equitable Access Initiative was that the broader dimensions of development should inform policy decisions and strategies for address health and development issues. According to the current World Bank classification of countries by income, 70% of the global population resides in middle-income countries, which are also home to approximately 75% of people classified as poor and which experience a very large part of the global disease burden.¹⁸³ Paradoxically, the great majority of those countries are not benefiting extensively from assistance provided by international donors, including the Global Fund. The Equitable Access Initiative proposes that a more comprehensive classification should also incorporate indicators such as poverty, inequality and the burden of disease.
100. At first the initiative was perceived by many stakeholders as a narrowly focused attempt to implement a tiered pricing approach to address the access barriers in middle-income countries. There were concerns that it would undermine the policy options for countries to make use of the TRIPS flexibilities.^{184 185} This was clarified in communication from the Global Fund Secretariat to its Board,^{ix} indicating that the scope of the initiative was much broader. The initiative has concluded that, when considered alone, the indicator of gross national income per capita is incapable of capturing the actual health needs of a country or its capacity to invest in health. It recommends that more complex variables should be taken into account to inform decisions on health financing in addition to income. Those variables would include a country's burden of disease and health needs in relation to income levels, and the domestic capacity and policies for investing in health. The findings of the initiative guided the Global Fund Secretariat's proposal of a sustainability, transition and co-financing policy, which the Board adopted during its 35th Session in April 2016.^x

^{ix} See <http://infojustice.org/wp-content/uploads/2014/05/GF-B31-ER8-Board-Update-Equitable-Access-Initiative-Sent.pdf>

^x See <http://www.theglobalfund.org/Knowledge/Decisions/GF/B35/DP08/>

101. **Initiatives led by civil society organizations.** Analyses and reports produced by civil society organizations have had an important impact on the strategic and programming decisions of stakeholders, including government officials and policy makers.¹⁸⁶

- a. With regard to access to HIV-related medicines, the literature covers a comprehensive range of topics. For example, ARV pricing strategies have been assessed in Médecins Sans Frontières' *Untangling the web of antiretroviral price reductions*¹⁸⁷ series which forms part of the organization's Access Campaign. It has published 18 editions since 2001, presenting data on the reference prices from both originator and generic manufacturers of individual products, including fixed-dose combinations, which are used in HIV treatment regimens. The series also analyses trends in terms of use (in line with normative guidance provided by WHO) and price (based on market dynamics).
- b. Many publications have highlighted the concerns of civil society organizations about the impact of intellectual property rights on health commodity prices and access. The current review consulted articles analysing the potential impact of intellectual property provisions in free trade agreements on the policy space that countries have for using the flexibilities of the TRIPS Agreement. The WTO paragraph 6 system has been a focus of analysis by civil society advocates, especially in relation to its feasibility and capacity for effectively enhancing access to affordable medicines. The reform of intellectual property-related legislation in low- and middle-income countries is also regularly discussed in articles and publications. The amendment of the Indian Patent Act in 2005 has received considerable attention, given that the majority of generic pharmaceutical companies are based in that country. WTO negotiations in 2013 and 2015 on the extension of the exemption period for least-developed countries to grant intellectual property protection for pharmaceuticals has also been a major topic of interest for civil society organizations.
- c. Other articles focused on the specific situation of middle-income countries, including the higher prices they typically pay for ARV drugs, their comparative lack of external aid and their need to mobilize domestic funding to purchase and use ARV drugs.¹⁸⁸
- d. Many authors have examined the adoption of the recommendations from the WHO Consultative Expert Working Group on R&D Financing and Coordination, especially in relation to de-linking and the Global Treaty on R&D.
- e. On the advocacy side, civil society organizations have been working at global and local levels to encourage governments to accomplish the commitments made at global level regarding access to medicines. Numerous awareness-building campaigns have been organized.
- f. Some groups, working alone or in partnership with health officials, have sought to oppose the granting of certain patents by national patent offices. As part of a wider strategy to track the use of TRIPS flexibilities at country level, including stricter patenting criteria, patent opposition is an attempt to prevent patents from being granted for products that fail to comply with the patenting standards as defined in the TRIPS Agreement. It is argued that the enforcement of such patents overrides public health interests.

In the context of the 2030 Agenda for Sustainable Development, accelerating the impact of the AIDS response will require mobilizing collective leadership from a broad range of sectors to address links and build political urgency and multisectoral coalitions for action. (...) The Agenda for Sustainable Development further demands action to negotiate and deliver global public goods, such as strengthening disease surveillance and strategic information systems, research and development of health technologies, measures to enhance access to affordable technologies (including overcoming restrictive intellectual property rules and other international trade barriers), civil society activism and promoting health as a political and economic priority.

– UNAIDS 2016–2021 Strategy¹⁸⁹

102. UNAIDS has been centrally involved in efforts to address such concerns in a strategic and programmatic manner. The UNAIDS Fast-Track approach¹⁹⁰ forms part of the organizational strategy to quicken the pace of implementation, focus and change at the global, regional, country, province, district and city levels. It involves setting ambitious targets to place the global AIDS response in relation to the Sustainable Development Agenda and ending AIDS as a public health threat by 2030, by accelerating the delivery of high-impact HIV prevention and treatment services. Those targets were affirmed in the 2016 Political Declaration on HIV and AIDS. It addresses social and legal barriers and advances human rights and gender equality. Expanding access to ART, particularly to newer HIV-related products, is crucial to meet the Fast-Track treatment targets:¹⁹¹ by 2020, 90% of people know their HIV status; of those, 90% access ART; and of those, 90% achieve viral suppression. Aligned with the Fast-Track approach, the Sustainable Development Agenda and the 2016 Political Declaration, removing trade barriers to enhance access to medicines is essential to achieve the targets that underpin the 2016–2021 UNAIDS Strategy, particularly in relation to its vision of “zero AIDS-related deaths”. In addition to measures to strengthen health service delivery and promote universal health coverage, the UNAIDS strategy proposes a set of core actions to address access barriers:

- Fully leverage the use of TRIPS flexibilities;
- Encourage and promote alternative financing mechanisms for R&D to accelerate the introduction into markets of newer HIV-related products; and
- Strengthen regional and local capacities to develop, manufacture and deliver quality-assured medicines.

The work of UNAIDS is essential for continuing to coordinate and catalyze efforts of governments, communities, the private sector and international organizations to remove the barriers that prevent people from getting the drugs and medicines they need.

CONCLUSIONS AND RECOMMENDATIONS

103. Access to quality-assured medicines is a key component of treatment programmes, along with efficient service delivery. With support from international agencies and donor initiatives, substantial progress has been made in improving access to medicines for HIV, TB and malaria. Nevertheless, insufficient availability and affordability of essential medicines in low- and middle-income countries remain major barriers, including for people living with HIV. Access to medicines for co-infections, such as TB and hepatitis, and co-morbidities, such as NCDs, also remains too low, due to high prices and persistent gaps throughout the multiple phases of the drug supply cycle.
104. The supply chains for medicines are lengthy and complex, and range from the development, production and acquisition of health products to their use by individuals, under the framework of rational use of medicines. Unless the structures and processes at each stage work optimally, access to assured-quality medicines will be compromised. If the structures and processes are not transparent and institutional checks and balances are inadequate, the system is vulnerable to failure and wastage of resources. Affordable access to health technologies requires that governments commit to adequately finance health care generally and health products in particular. The careful selection of cost-effective, prioritized health products, and efficient procurement and distribution systems are also priorities. In addition, strengthening regulatory capacities are vital to assure the quality of health products. Managing the costs of health technologies is crucial for achieving equitable and affordable access. Adequate health financing, and, in particular, adequate financing for essential medicines, are major challenges for countries.
105. Equitable access to innovations in public health remains an important challenge for the international community. The AIDS response, however, can be a source for inspiration. Remarkable achievements have been made since the beginning of the AIDS epidemic, so much so that it is now feasible to contemplate the end of AIDS as a public health threat. The clinical benefits of ART are beyond dispute, with widening access to HIV treatment resulting in higher quality of life and longer life expectancy. The effectiveness of HIV treatment for preventing HIV transmission is also well established. Yet, inequities shadow these achievements. In the case of ARVs, important gaps have to be addressed with appropriate and focused public health policies. At the moment, the unsatisfactory scale-up of HIV treatment is leaving groups of people behind. Key populations still lack adequate access to existing medicines and the availability of child-friendly ARV formulations is far from ideal. While first-line ARV drugs are widely available and affordable in most low-income countries, there is an ongoing need to develop fixed-dose combinations that can strengthen treatment adherence. Second- and third-line regimens remain expensive, partly due to fewer opportunities for market competition.
106. Treatment involves more than access to medicines. Technologies for treatment monitoring, such as CD4 and viral load tests, early infant diagnostics, are still in short supply in many resource-limited settings due to high prices and/or complex processes. There is also a need for innovating simpler and more effective treatment options and for averting the emergence of HIV drug resistance. Access to innovation should be a central concern for the global AIDS response. Actions focused on the intersections between intellectual property rights, innovation and public health are vitally important for resolving market failures in medicine development and manufacture, pricing, and unmet needs for R&D.
107. The 2016–2021 UNAIDS Strategy indicates actions to be taken by the Joint Programme in order to address the issues raised in this report:

- Working on and advocating for “the continued innovation and refinement of HIV-related medicines and technologies, and ensuring their availability, quality and affordability”;
- Supporting “countries in adopting and using health-related TRIPS flexibilities and in defending their ability to challenge provisions in trade agreements that impede access to affordable medicines and go beyond the international obligations provided under the TRIPS agreement”;
- Joining “the effort to explore new incentive systems for needed research and development in which research and development costs are delinked from product prices”;
- Supporting “efforts to overcome regulatory barriers that delay market entry of quality-assured medicines and health technologies, including by strengthening local and regional regulatory capacities”;
- Working “with partners in the Diagnostics Access Initiative to fully leverage the potential of laboratory medicine to accelerate progress towards the 90-90-90 treatment target, with particular attention to viral load testing, early infant diagnosis and other health products amenable to greater market influence.”

108. To conclude, this paper makes the following recommendations to guide the global AIDS response in overcoming the barriers to access to HIV-related health technologies:

- a) UNAIDS should explore the recommendations made by the report of the UN Secretary-General’s High-Level Panel on Access to Medicines, and apply them, where appropriate, to the global AIDS response to ensure improved policy coherence across the Joint Programme, in order to support countries to achieve the health-related Sustainable Development Goals, especially those pertaining to access to health technologies and innovation;
- b) UNAIDS should collaborate with and support initiatives, across and outside the Joint Programme, that promote access to medicines and other HIV-related products, especially those described in this report;
- c) UNAIDS should work closely with UNITAID and the Global Fund to strengthen market-shaping initiatives in order to ensure sustained availability, affordability and accessibility of HIV-related products;
- d) UNAIDS should produce reports on the use of intellectual property at country and regional levels, including the use of health-related flexibilities within the TRIPS Agreement, and produce technical papers based on empirical research and analysis of available data, including prices, and published reports, in partnership with relevant stakeholders; and
- e) UNAIDS should coordinate with concerned stakeholders, including civil society, the provision of technical support to countries to create a favourable legislative environment and to implement programmatic actions to remove trade barriers to access to HIV-related products.

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