Access to medicines: human rights and intellectual property-related factors

Statement to UNAIDS Programme Coordinating Board

Geneva, 7 December 2016

The UNAIDS Reference Group on HIV and Human Rights welcomes the opportunity to share its observations with the UNAIDS Programme Coordinating Board (PCB), regarding the issue of intellectual property-related and other factors affecting access to treatment and diagnostics (PCB Thirty-ninth Meeting, Agenda item 6).

At its Seventeenth Meeting (in October 2015), the Reference Group reiterated its deep concern about the ongoing challenge of achieving universal access to quality essential medicines at affordable prices, and noted that "even as UNAIDS and governments commit to prevention and treatment targets that will require further, substantial scale-up of access to ARVs, new barriers are also being raised, including through trade agreements with more restrictive intellectual property rules and other provisions." The Reference Group expressed its concern "that existing action within the UN system has not proven sufficient to date to overcome existing, or forestall new, barriers of this sort." Despite remarkable progress in scaling-up access to ARVs, at the end of 2015, global coverage was 46%, still less than half of those living with HIV.

In light of these concerns, the Reference Group welcomed the prospect of the UN Secretary-General convening a high-level body, as recommended by the Global Commission on HIV and the Law, to explore the tension between human rights and trade rules regarding intellectual property, and to propose measures to remedy or alleviate this tension in ways that protect and advance access to existing and new medicines, as these are essential elements of realizing the right to the highest attainable standard of health. The Reference Group recommended that, should such a body be convened, the Joint Programme should support its work. The Reference Group further recommended that the UNAIDS Secretariat and co-sponsor UNDP support (i) greater flexibility in intellectual property and trade rules for countries, and particularly low- and middle-income countries, to take measures to advance access to medicines, and (ii) the development of an equitable global system for R&D of health technologies, that generates more and better innovation to address global health needs.

In November 2015, the UN Secretary-General Ban Ki-moon convened his High-Level Panel on Access to Medicines, with UNDP serving as the Panel's secretariat in partnership with the UNAIDS Secretariat. In September of this year, the Panel released its report with numerous recommendations, several of them adopted unanimously. In addition, at the request of the PCB, UNAIDS has subsequently prepared a synthesis report on the topic, which is before the PCB for discussion at its current meeting.

One theme recurring in the literature, as summarized in the synthesis report and as also reported by the High-Level Panel, is the reality that countries face barriers in attempting to promote greater, more equitable access to medicines through the effective use of flexibilities regarding intellectual property as stated in international law, such as in the WTO *Agreement on Trade-related Aspects of Intellectual Property Rights* (TRIPS). Another key theme is the need to explore alternative approaches for promoting research and development (R&D) of health technologies, so as to produce greater innovation and to ensure more equitable access to the results of that innovation—including promoting models that "delink" R&D expenses from the final price of the end product. Finally, a third key theme is the need for far greater transparency and accountability on multiple fronts, including in the negotiation of international rules affecting access to medicines and the assessment of their impact on human rights (such as the right to the highest attainable standard of health), as well as the costs of R&D, the patent status and registration status of medicines and other health technologies at country and regional levels, and their pricing and the variability in pricing.

The Reference Group therefore recommends that the Programme Coordinating Board do more than simply *"take note of"* the synthesis report. The Joint Programme and the international community have committed to getting ARV treatment to 90% of those who are diagnosed with HIV and, furthermore, achieving viral suppression among 90% of those on treatment, by the end of 2020. Achieving both the treatment and prevention targets of the "fast-track" approach will require more, and more sustained, attention to the barriers to access to ARVs and other health technologies (including diagnostics). UNAIDS'

governing body cannot in good faith ignore these challenges while reaffirming the 90-90-90 goals. It would be remarkable if, upon receiving the results of the synthesis report it requested, the UNAIDS Programme Coordinating Board did nothing more than simply note the existence of this document. It would be similarly unfortunate if the PCB failed to benefit from, and advance, the analysis and recommendations of the UN Secretary-General's High-Level Panel that are available to it and of direct relevance to UNAIDS' targets.

The Reference Group therefore recommends that the UNAIDS Programme Coordinating Board:

- *Welcome* the synthesis report prepared for the PCB and the report of the UN Secretary-General's High-Level Panel on Access to Medicines;
- *Reaffirm* the critical importance of addressing intellectual property-related factors affecting the availability, affordability and accessibility of treatment and diagnostics for HIV and co-infections, including in low- and middle-income countries, as a necessary element of achieving the fast-track targets and of fulfilling the right to the highest attainable standard of health;
- *Welcome* the commitment of African Union Member States, and steps taken by them in collaboration with various partners, to develop local capacity for the production and quality assurance of medicines and other health products needed to realize the right to the highest attainable standard of health;
- *Encourage* Member States to create legislative environments that allow countries to make full use of the existing TRIPS flexibilities as an important element of their progressive realization of the right to health;
- *Call upon* both Member States and the private sector to refrain from actions that undermine the right of countries to use those flexibilities, including adopting or pursuing "TRIPS-plus" measures that restrict their use, and call upon WTO Members and others to report instances of undue pressure on countries in this regard to the WTO Secretariat and to relevant human rights bodies;
- *Encourage* Member States to review the recommendations of the UN Secretary-General's High-Level Panel on Access to Medicines and to identify which of those recommendations they can and will implement, and to share those conclusions with other Member States and the Joint Programme (both UNAIDS Secretariat and co-sponsor UNDP), as well as with the Office of the UN High Commissioner for Human Rights (OHCHR) and the UN Special Rapporteur on the right to the highest attainable standard of health;
- *Endorse* the recommendations of the High-Level Panel regarding measures to ensure greater transparency, so that the costs of R&D, production, marketing and distribution of health technologies, as well their patent status and end prices, are clear to consumers and governments, and to ensure greater transparency of negotiations of provisions in international agreements that affect access to medicines, including publicly-available assessments of their potential impact on human rights, including the right to the highest attainable standard of health;
- *Request* that, in the spirit of fostering this transparency and facilitating access to health technologies, UNAIDS co-sponsor WHO establish and maintain a database of prices of patented, generic and biosimilar medicines in countries where they are registered, as recommended by the High-Level Panel;
- *Request* that UNAIDS Secretariat and co-sponsors review the recommendations of the UN Secretary-General's High-Level Panel on Access to Medicines and develop proposals for implementing the relevant recommendations in the context of the response to HIV and AIDS;
- *Request* the UNAIDS Executive Director to ensure that the Secretariat and Joint Programme co-sponsors have the necessary resources to implement the recommendations in the synthesis report prepared for the PCB, which are in keeping with the core actions in the 2016-2021 UNAIDS Strategy to address barriers to access to health technologies, including supporting initiatives to: (i) make full use of TRIPS flexibilities; (ii) encourage and promote alternative financing mechanisms for R&D to accelerate the introduction into markets of newer HIV-related products; and (iii) strengthen regional and local capacities to develop, manufacture and deliver quality-assured medicines.