

USP Statements to the 71st World Health Assembly

In official comments presented at the 71st World Health Assembly (WHA) in May 2018, USP highlighted the significance of quality-assured medicines in treating both non-communicable diseases (NCDs) and tuberculosis (TB), as well as the critical role public quality standards play in enabling access to quality-assured medicines. The World Health Organization (WHO) solicited comments from non-state actors in preparation for high-level meetings on these topics to be held at the United Nations General Assembly in September 2018.

These remarks are USP's first official statements to the WHA since being granted official relations status by the Executive Board of the World Health Organization in January 2018.

USP statement in response to agenda item 11.7 - Preparation for the third High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, to be held in 2018

USP - a nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements worldwide - commends WHO for prioritizing this critical issue.

Increasingly, access to quality-assured medicines for NCDs is significantly affected by limited access to new medicines, and persisting shortages of existing generic medicines due in part to weak global supply chains and a lack of quality manufacturers.

The need for access without adequate supplies of medicines has driven the rise of substandard and falsified medicines.

Lessons from diabetes can help inform this issue of quality-assured medicines access for NCDs globally. For example, the existence of a robust generics supply of one cornerstone diabetes medicine around the world—metformin—has meant more continuous access to a vital tool to combat the diabetes epidemic in many countries.

This is the result of good policies, smart regulations, and robust public quality standards that support a multi-manufacturer environment—one that can better leverage globalized supply chains to deliver quality-assured medicines to patients.

The US FDA's current strategies to enable generics competition domestically has meant ongoing collaboration with USP to develop more public quality standards for generic medicines. This is but one example of a sensible set of regulatory based solutions to the more intractable problem of quality-assured medicines access for NCDs.

Public quality standards are generated by pharmacopeias. Public pharmacopeial standards come in the form of public documentary and reference standards based on science, and established through stakeholder engagement and rigorous transparent processes.

We remain committed in our support of the ongoing leadership of WHO in this matter, and look forward to serving as a resource in preparation for the upcoming high-level meeting of the General Assembly on the prevention and control of NCDs.

USP statement in response to agenda item 11.8 Preparation for a high-level meeting of the General Assembly on ending tuberculosis

USP applauds WHO's prioritization of this vital issue. Current actions and investments are falling far short of those needed to end the TB epidemic.

Underpinning the holistic, WHO 3-pillar strategy to end-TB is the need to access appropriate diagnostics and quality-assured medicines, so that diagnoses and treatment outcomes are better ensured by the right medicine, at the right dose, at the right time.

On treatment, a key aspect of any regimen is ensuring that the medicines used are quality-assured. How well an antimicrobial treatment in TB works is integrally linked to how well quality is maintained throughout the medicine's life cycle.

Poor-quality medicines can expose patients to sub-therapeutic doses, which can lead to further development of multi-drug resistant TB, a threat that links to broader issues of AMR. Treatment regimens for MDRTB also take substantially longer, have more side effects, yield lower cure rates, and can cost up to 200 times more than treatment of susceptible TB with quality-assured medicines.

The need to expand access to TB treatments in the near future to more patients, as part of ending TB strategies, must not inadvertently increase access to poor quality medicines.

Pharmaceutical quality must be a top priority, as this can directly address key current challenges in TB and other diseases. Efforts should include working with manufacturers to increase the supply of quality-assured antimicrobials, and supporting governments to establish robust pharmaceutical quality assurance and post market quality surveillance systems.

USP has been working with USAID through the Promoting the Quality of Medicines program to increase the supply of quality-assured priority medicines and to strengthen pharmaceutical quality assurance systems.

We commend the U.S. government for its dedication to these investments that have helped save lives globally. Finally, it is critical to include drug quality assurance as part of comprehensive plans to end TB.

Statements by USP and other non-state actors on all agenda items are available [here](#)

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