



## Non-Communicable Diseases & Access to Medicines Recommendations for Member States to Control NCDs in Low and Middle-Income Countries

Ensuring a steady supply of affordable, appropriate and good quality medicines, vaccines and diagnostics via the public and private sectors to people in low- and middle-income countries (LMIC) is a critical component of the international response to Non-Communicable Diseases (NCDs). The Moscow Ministerial conference provides a valuable opportunity to highlight issues of **access to medicines and health-related technologies**, which is a critical but under-discussed issue in the lead-up to the United Nations High-Level Meeting on NCDs.

The World Health Organisation/Health Action International Project on Medicine Prices and Availability has documented the limited availability and affordability of NCD medications in both the private and public sectors.<sup>1</sup> Even for medicines that are off-patent, generic production is increasingly threatened due to demands by high income countries to include data exclusivity in free trade agreements<sup>2</sup>. Of great concern is the insufficient research and development being carried out to adapt NCD health technologies to low resource settings. Drawing on the lessons from the struggle to increase the availability of medicines for infectious diseases such as HIV/AIDS, our coalition of civil society leaders with historical and contemporary leadership in the access to medicines movement call on WHO Member States to adopt the following recommendations in the context of NCDs:

**1. Safeguard generic production:** Member states should ensure equitable and affordable access to essential health technologies for NCDs and support generic production as the most effective method to lower prices. Member States should make use of flexibilities enshrined in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and affirmed by the Doha Declaration on TRIPS and Public Health to ensure generic production and refrain from promoting or adopting TRIPS-plus measures such as data exclusivity that could limit the affordability even for off-patent medicines. Furthermore, Member states must ensure that all medicines are affordable and available to all. In this regard, and in addition to all other steps taken to make medicines affordable, governments that fund medical R&D should ensure that health-related technologies developed through publicly subsidized research are affordable and available from competitive generic suppliers in LMICs in accordance with the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.

**2. Incentivize research and innovation:** Member states should explore and promote a range of incentive schemes for the research and development of medicines for non-communicable diseases as promoted by the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. In particular, member states should: adopt strategies which (i) de-link the cost of medicines and health related technologies from the cost of research and development, (ii) apply the concept of prizes as one form of incentive mechanism for innovation in new cancer treatments and (iii) provide funding for the feasibility studies for cancer prize funds in developed and developing countries.

**3. Support quality assurance:** Member states should ensure that all health technologies including those addressing NCDs are quality assured. In addition to strengthening national medicine regulatory agencies, exporting countries must ensure that medicinal products produced in and exported from their territory meet WHO quality standards. Procurement agencies, distributors and purchasers, as the main actors purchasing medicines on behalf of developing countries, should be certified by a centralised neutral body, potentially hosted by WHO, on the basis of existing WHO standards. All donors should set a clear quality assurance policy in accordance with the WHO.

<sup>1</sup> [http://www.who.int/medicines/areas/access/Medicine\\_Prices\\_and\\_Availability/en/index.html](http://www.who.int/medicines/areas/access/Medicine_Prices_and_Availability/en/index.html)

<sup>2</sup> Kesselheim AS, Solomon DH. Incentives for drug development--the curious case of colchicine. *N Engl J Med.* 2010; **362**(22): 2045-7.