The AIDS Institute
Public Comment on the Recommendations of
The World Health Organization Intergovernmental Working Group (IGWG) on
Public Health, Innovation and Intellectual Property

The key recommendations from the Commission on Intellectual Property, Innovation can be separated into the areas of discovery of new health-care products; drug development; delivery; and fostering innovation in developing countries. The recommendations put forth in the plan seek to promote access to affordable medicines for all. At the outset, it must be stated that The AIDS Institute has been a longtime supporter of the goal of universal access. The action plan set forth by the Intergovernmental Working Group (IGWG) is ambitious – and it needs to be – to address conditions that disproportionately affect developing countries. The AIDS Institute has championed the elimination of all barriers to care on both the domestic and global level and we are encouraged by the effort of the WHO to achieve this Millennium Development Goal. However, we have several concerns relative to the implementation of the plan:

- First, we have a concern that the plan has placed too much emphasis on the role of Intellectual Property Rights on drug development and access in the developing world. In the debate over access to medicines in developing countries, patents are often blamed for making essential drugs unaffordable. Yet, The World Trade Organization (WTO), the Food & Drug Administration (FDA), and the US Patent & Trademark Office all acknowledge that 90 per cent of the 319 drugs on the World Health Organization's (WHO) list of essential medicines are not under patent. A recent analysis of patent protection in developing countries showed that on average, only 4 or the 319 drugs on the essential medicines list were under patent in any of 65 low income countries. The AIDS Institute is mindful of the fact that a strong patent system encourages the research and development of new medicines to treat or prevent neglected diseases that are prevalent in the developing world.

- We have a concern that the plan emphasizes the flexibilities of the Doha Declaration on the TRIPS Agreement without consideration of the limited capacities of the health care infrastructure in many developing countries. The TRIPS allows member countries to issue compulsory licenses to make generic versions of drugs "to protect public health and, in particular, to promote access to medicines for all". There does not seem to be adequate concern about the safety and efficacy of drugs produced without any regulatory supervision and quality control. The Kaiser Family Foundation reported on September 12, 2007, that Zimbabwe's Medicines Control Authority was investigating allegations that unlicensed drug importers were illegally selling antiretroviral drugs in the country at unregulated locations like flea markets and hair salons. According to the AP/Google.com, some of the anti-retrovirals were counterfeit, diluted or

contaminated. According to some health professionals, the circulation of illegal medication is a reflection of the collapse of the government's health care infrastructure, as well as severe deficiencies in controlling the drugs' manufacture and importation.

- We are concerned that the plan's emphasis on Type II and III diseases could threaten research and development of medicines for those affected by Type I diseases. As more people in developing countries become affected by Type I diseases, we cannot support any plan that blocks the flow of innovation. We believe it is crucial that a balance be found between the market forces of developed countries and the humanitarian needs of developing countries. We believe it is incumbent upon the scientific community, governments, pharmaceutical, and biotechnology companies to focus energy and commit resources to address the health care needs of developing countries. We support developing countries engaging in research, development, clinical trials, and pharmaceutical manufacturing, but only when the infrastructure is adequate to support and implement guidelines that ensure patient safety in-country and worldwide.

- Lastly, we are concerned that there has not been wider consultation to identify the most appropriate way forward with the plan. It is important that the contributions of all stakeholders be taken into account so that their respective energies can be mobilized towards the achievement of a common goal: an enhanced and sustainable basis for research and development relevant to the health needs of developing countries. The plan at present, does not provide a framework (short-, medium-, or long-term) for action by the various respective partners, nor does it set forth clear objectives, priorities, or a realistic estimation of funding needs if the goals are to be achieved. Case in point, the IGWG draft was developed without consultation or involvement of any patient organizations whose constituents, ultimately, represent the beneficiaries of any plan. This omission is troubling because the draft fails to recognize or acknowledge the importance of the patients' perspective in the development of health care policy.

The AIDS Institute supports investment by the world community – at the governmental, business, and individual levels that would support the development and implementation of the needed infrastructure to support medical research, development, innovation, clinical trials, and an effective delivery system.

Respectfully submitted,

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