

**2011 High-Level Meeting on
the comprehensive review of the progress achieved in realizing
the Declaration of Commitment on HIV/AIDS and
the Political Declaration on HIV/AIDS**

Panel 3: Innovation and new technologies

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**De-Linking R&D costs from drug prices and the sustainability of treatments for
persons living with HIV**

With regard to new medicines for HIV, policymakers need a strategy for making both innovation and universal access feasible. Such a strategy will necessarily involve de-linking R&D costs from drug prices.

Newer HIV drugs are needed to deal with the adverse effects of older drugs and drug resistance, or to achieve better compliance.¹ The system of granting legal monopolies to make and sell HIV medicines in order to stimulate investments in R&D is flawed, and predictably leads to barriers to access.²

High prices for medicines are the enemy of universal access. High drug prices not only limit the drugs you can buy with a limited budget, but they call into question the entire rationale for funding HIV treatment in developing countries.

High drug prices will weaken donor enthusiasm, and undermine efforts to transfer funding of treatment programs from Northern donors to developing country governments.

Under the de-linkage approach, new HIV drugs would be available from competitive generic suppliers at low prices, allowing more patients to participate in treatment programs, and to receive the best drugs.

Rewards for successful investments in R&D would be a separate element of treatment budgets, not linked to the prices of medicines.³

De-linkage of R&D costs and product prices is endorsed in the WHO Global Strategy for Public

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- 1 Sarah Zaidi, "Differential Treatment: Restricted Access to Newer Antiretrovirals," *UN Chronicle*, Vol. XLVII No. 1, 2011 (15.05.2011)
<http://www.un.org/wcm/content/site/chronicle/cache/bypass/home/archive/issues2011/hivaidsthefourthdecade/restrictedaccesstoantiretroviras>
 - 2 2011. James Love, "The production of generic drugs in India: A new trade agreement with the EU would hinder access to drugs in developing countries," *BMJ* 2011; 342:d1694.
 - 3 Joseph Stiglitz, "Scrooge and Intellectual Property Rights: A medical prize fund could improve the financing of drug innovations," *British Medical Journal*, 333:1279-80, December 23, 2006. James Love and Tim Hubbard, "Prizes for Innovation of New Medicines and Vaccines," *Annals of Health Law*, Vol. 18, No 2, pages 155-186, Summer 2009.

Health, Innovation and Intellectual Property,⁴ and is at the center of the Donor Prize Fund proposal being reviewed by WHO experts on R&D,⁵ and a US legislative proposal for a Prize Fund for HIV/AIDS.⁶

In the past two years, Gilead, Johnson and Johnson and Novartis have indicated it may be appropriate to use innovation prize funds as an incentive to openly license drug patents in developing countries, effectively de-linking R&D cost and drug prices for diseases like HIV or TB.

These are four questions that the WHO, UNAIDS, donors, member states, and persons living with HIV need to answer, with data and economic analysis.

- Is it possible to de-link R&D incentives from drug prices?
- How much would this cost?
- What would be the benefits to persons living with HIV?
- Is it possible to obtain and sustain universal access to treatment in the absence of a de-linkage strategy?

De-linkage is a new idea when new thinking is needed.⁷ Embracing de-linkage will show that policymakers are serious about achieving universal access.

4 Sixty-First World Health Assembly, WHA61.21, May 24, 2008. The Annex is the *Global strategy on public health, innovation and intellectual property*. In Element 5, on the “Application and management of intellectual property to contribute to innovation,” paragraph 5.3 (a) calls upon member states and the WHO to “explore and, where appropriate, promote a range of incentive schemes for research and development including addressing, where appropriate, the de-linkage of the costs of research and development and the price of health products, for example through the award of prizes, with the objective of addressing diseases which disproportionately affect developing countries.”

5 Proposal by Barbados, Bolivia, Suriname and Bangladesh, A Prize Fund to Support Innovation and Access for Donor Supported Markets Linking Rewards for Innovation to the Competitive Supply of Products for HIV-AIDS, TB, Malaria and Other Diseases for Humanitarian Uses, Date: 09.04.15, http://www.who.int/phi/Bangladesh_Barbados_Bolivia_Suriname_DonorPrize.pdf.

6 “Senator Sanders introduces two medical innovation prize bills in U.S. Senate to de-link R&D costs from drug prices,” Knowledge Ecology International Blog, May 27, 2011. <http://keionline.org/node/1147>. The Prize Fund for HIV/AIDS: A New Paradigm for Supporting Sustainable Innovation and Access to New Drugs for AIDS: De-Linking Markets for Products from Markets for Innovation, May 26, 2011, http://keionline.org/sites/default/files/big_prize_fund_overview_26may2011_a4.pdf. S. 1138, 112th Congress.

7 Recognizing the shortcoming of the existing frameworks to support innovation, the official “aim” of the WHO *Global strategy on public health, innovation and intellectual property* is “to promote new thinking on innovation and access to medicines.”