
United Nations 2008 High-Level Meeting on HIV/AIDS

Roundtable Discussion on “Universal Access to Affordable HIV/AIDS Diagnostics, Prevention and Treatment: In Search of Sustainable Solutions”

Statement by

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1. Merck is a global research-driven pharmaceutical company dedicated to putting patients first.¹ For more than 110 years, Merck has been discovering, developing, manufacturing and marketing vaccines and medicines to address unmet medical needs. As an integral part of our mission, Merck devotes extensive efforts to improving access to medicines and vaccines through far-reaching programs that not only provide Merck medicines and vaccines at significant discounts or free of charge, but also help to deliver them to the people who need them most. To this end, we promote and participate in public/private partnerships, particularly in the developing world, which help to build health workforce capacity and health system infrastructure and to achieve targeted goals in prevention and treatment of major diseases. We contribute to public health and development especially in areas where we possess particular expertise: through research and development, through clinical training, and through drug delivery and distribution.
2. This statement outlines how the research-based pharmaceutical industry and Merck in particular are working to address sustainable solutions for universal access to affordable HIV and AIDS prevention, care, treatment and support. I will focus on three key issues: innovation, affordability and access.

¹ Merck & Co., Inc., Whitehouse Station, NJ, USA, operates in most countries outside of the United States as Merck Sharp & Dohme, or MSD. For more information, see www.merck.com

Innovation

3. The most sustained way in which the pharmaceutical industry has contributed to the global fight against HIV and AIDS is through our strong commitment to innovation. Since 1983, when the human immunodeficiency virus was first identified, 30 new medicines to treat HIV infection have been discovered and developed by pharmaceutical researchers. (Merck has discovered and developed several of these medicines, including the protease inhibitor CRIVAN (indinavir sulfate), the non-nucleoside reverse transcriptase inhibitor STOCRIN (efavirenz) and the integrase inhibitor ISENTRESS (raltegravir).) There are now medicines that attack the virus via many different routes, interfering with cell entry and with the action of the HIV reverse transcriptase, protease and integrase enzymes. This is critically important, because HIV mutates rapidly and new mechanisms of action help to address the challenges of resistance.
4. Efforts to find new medicines to treat HIV infection and vaccines or microbicides to prevent HIV infection continue apace. According to the most recent survey conducted by the Pharmaceutical Research and Manufacturers of America, in 2007 there were more than 90 new medicines and vaccines in development to fight HIV and AIDS – nearly 50 new antiretrovirals and 20 vaccine candidates.²

Affordability

5. As the Secretary-General's Report on implementation of the Declaration of Commitment on HIV/AIDS and the Political Declaration on HIV/AIDS notes, "prices for many first-line antiretrovirals have fallen sharply over the last decade."³ Indeed, from a cost of roughly US\$10,000 per patient per year in the 1990s, the median cost of combination antiretroviral therapy in low-income and middle-income countries now ranges from about US\$100 – US\$350 per patient per year for first-line therapy and from about US\$620 – US\$3,300 per patient per year for second-line therapy.⁴ To remind ourselves how remarkable a change this is – with prices for first-line therapy now less than 5% of what they were just 10 years ago -- think for a moment of recent trends in the prices of oil and basic foodstuffs.
6. One of the principal ways in which research-based pharmaceutical companies have helped to address affordability of antiretrovirals has been through the Accelerating Access Initiative (AAI). Begun in May 2000, the AAI is a collaboration among UNAIDS,

² Pharmaceutical Research and Manufacturers of America, *Medicines in Development for HIV/AIDS: 2007 Report* (Washington, DC: PhRMA, 2007).

<http://www.phrma.org/files/Meds%20in%20Development%20for%20HIV%20AIDS.pdf>

³ United Nations, "Declaration of Commitment on HIV/AIDS and Political Declaration on HIV/AIDS: Midway to the Millennium Development Goals: Report of the Secretary-General," UN General Assembly Document A/62/780, April 1 2008, paragraph 42 (p. 17).

http://data.unaids.org/pub/Report/2008/20080429_sg_progress_report_en.pdf . Cited below as Secretary-General's Report (2008).

⁴ World Health Organization, UNAIDS, UNICEF, *Towards Universal Access: Scaling Up Priority HIV/AIDS Interventions in the Health Sector* (Geneva, Switzerland: WHO, 2008), pp. 32-35.

http://data.unaids.org/pub/Report/2008/200806_TowardsUniversalAccessReport2008_en.pdf

the World Health Organization (WHO), the United Nations Children's Fund (UNICEF), the UN Population Fund (UNFPA), the World Bank and nine research-based pharmaceutical companies (Abbott, Boehringer-Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, Gilead Sciences, Merck & Co. Inc., Pfizer, Roche and Tibotec (an affiliate of Johnson & Johnson)). All AAI companies have individual programs through which they provide their antiretroviral medicines at more affordable prices in developing countries. As of October 1, 2007, some 830,000 patients in developing countries were estimated to be taking one or more medicines supplied at differential prices by an AAI company.⁵ (In the case of Merck's antiretrovirals, more than 9 out of 10 of those patients being treated with combinations containing CRIVAN, STOCRIN or ISENTRESS live in the least developed countries and those hardest hit by the HIV pandemic.)

7. There is still room for further adjustments in the prices of antiretrovirals. We can expect further competition among pharmaceutical companies – both research-based and generic companies - and it is likely that companies will continue to offer price reductions as the volumes sold increase with the scale-up of treatment programmes. But the price of medicines is just one factor in ensuring access to care and treatment -- a key lesson that has become increasingly clear with the expansion of treatment programs globally in the past several years through the increased funding available from the Global Fund to Fight AIDS, TB and Malaria, the U.S. President's Emergency Plan for AIDS Relief and other multilateral and bilateral aid programs. Collaboration with the public sector on demand forecasting, and in developing a shared understanding of the role of different combinations in the therapeutic preferences of physicians and patients, will help manufacturers to plan production accordingly and to supply necessary treatments affordably and sustainably.

Access

8. In addition to providing antiretroviral medicines at differential prices to least developed countries, land-locked developing countries and small island developing states, research-based pharmaceutical companies are working together with partners to address additional factors that improve access to antiretroviral medicines and enhance prevention efforts. Chief among these are initiatives to license antiretrovirals to generic manufacturers and to provide technology transfer; to register the products widely among developing countries; and to help build capacity for improving access to HIV and AIDS prevention, care and treatment by providing support for the training of healthcare workers and broader health system strengthening.

9. ***Licenses.*** In many developing countries, there are few patents on antiretrovirals to begin with, so, in those cases, intellectual property protection cannot be a barrier to access. And where patents do exist, companies individually have taken steps to ensure that patients will have broad access to the medicines they need, in some cases by agreeing

⁵ International Federation of Pharmaceutical Manufacturers and Associations, *Partnerships to Build Healthier Societies in the Developing World* (Geneva, Switzerland: IFPMA, 2008), p. 12.
http://www.ifpma.org/documents/NR9598/IFPMA_Partnerships_Book_2008.pdf

not to enforce patents in developing countries, in others by providing licenses to generic producers and offering technology transfer assistance to help meet the growing demand for quality antiretrovirals. The pharmaceutical industry is also on record as supporting the flexibilities in the TRIPS agreement that enable countries with little or no capacity in the pharmaceutical sector to ensure that they can obtain necessary HIV medicines when facing public health emergencies.⁶

10. As a recent analysis of antiretroviral licenses granted by research-based to generic manufacturers shows, more than 50 licenses had been granted through mid-2007.⁷ For example, in 2006, Bristol-Myers Squibb concluded technology transfer agreements with generic companies Aspen PharmaCare (South Africa) and Emcure Pharmaceuticals (India), for its newest antiretroviral, atazanavir (sold as Reyataz® in the US). Gilead has also partnered with Aspen Pharmacare to manufacture and distribute branded and generic versions of Viread® and Truvada® in Africa; Gilead has also entered into non-exclusive licensing agreements with 10 Indian generic companies, allowing them to distribute generic versions of tenofovir in 95 developing countries. GlaxoSmithKline granted its first license in 2001 and has now negotiated eight licensing agreements for its ARVs in Kenya and South Africa; in 2007, GSK licensees supplied more than 180 million tablets of their versions of Epivir® and Combivir® to Africa. Merck & Co., Inc., has granted non-exclusive, royalty-free licenses to Adcock Ingram, Aspen Pharmacare, Aurobindo and Cipla Medpro for the manufacture and supply of a generic form of efavirenz for southern Africa, including South Africa. And in 2006 Roche announced a technology transfer initiative to help local firms in least developed countries and sub-Saharan Africa to manufacture second-line HIV medicines; to date, agreements have been signed with nine companies in Bangladesh, Ethiopia, Kenya, South Africa, Tanzania and Zimbabwe, with expressions of interest received from 36 more companies in 16 eligible countries.⁸

11. **Building capacity.** As indicated in the Secretary-General's report, "acute shortages of health-care professionals impede the scale-up of HIV treatment and prevention services in many countries heavily affected by the epidemic." In addition to building human capacity in healthcare settings, "comparable work is needed to strengthen national capacity for drug regulation and the procurement and supply management of drugs and diagnostics."⁹ Pharmaceutical companies are also offering assistance in these areas. Let me provide one example from Merck's experience.

12. The African Comprehensive HIV/AIDS Partnerships (ACHAP) was established in 2000 by the Government of Botswana, The Merck Company Foundation/Merck & Co., Inc. and the Bill & Melinda Gates Foundation.¹⁰ The partnership works to support and

⁶ See, for example, IFPMA, "TRIPS amendment permanently resolves export compulsory licensing issue," Press release, December 6, 2005, <http://www.ifpma.org/News/NewsReleaseDetail.aspx?nID=3951>.

⁷ Robert Dintruff (Abbott Laboratories), "Licensing of generic antiretroviral drugs in the developing world," Presentation to World Bank – Pharma Industry Meeting, 21 June 2007.

⁸ IFPMA, *Partnerships to Build Healthier Societies in the Developing World* (2008), p. 15.

⁹ Secretary-General's Report (2008), paragraph 49 (p. 18).

¹⁰ For more information on the ACHAP program and Botswana's response to HIV/AIDS, see www.achap.org.

enhance Botswana's response to HIV and AIDS through a comprehensive approach to prevention, care, treatment and support. Among other things, ACHAP works to strengthen healthcare infrastructure, promote behavior change and de-stigmatize HIV and AIDS. Most importantly, partnership programs are enhancing local capacity by strengthening healthcare infrastructure and transferring technical skills. To assist *Masa*, the Government's antiretroviral treatment program, ACHAP has supported the development of laboratory capacity to test and monitor patient response to treatment. Information technology systems are being developed to track patient adherence. The partnership joined with Harvard University and the Botswana Ministry of Health to provide training for more than 3,900 of Botswana's health care workers on the first of eight core modules on AIDS clinical care fundamentals, while more than 3,200 physicians, nurses and other health care professionals have received hands-on, clinic-based training from international AIDS experts through the partnership's preceptorship program. These efforts have contributed to ART coverage rates in Botswana exceeding four out of five of those people who need treatment, with adherence rates equal to or higher than many countries in the West.

Lessons learned

13. These examples of innovation, affordability and access are instructive in considering how to find sustainable solutions to ensure access to affordable medicines as we move toward universal access. As I've indicated through the examples noted, fighting the global AIDS pandemic has required robust and creative public/private partnerships. Such partnerships should embrace all stakeholders with resources and expertise to contribute. The challenges faced by developing countries are so daunting, and the resources required so substantial, that new ways of working are essential. Public/private partnerships have a key role to play in marshalling the necessary resources and expertise, particularly when those partnerships are country-led and fully integrated with the national health system (in the spirit of the "three ones").¹¹

14. Collaboration is critical, and success should be based on common objectives, mutual respect, clear shared targets and agreed metrics to monitor progress, with transparency for all stakeholders involved. Working in this way builds trust and confidence among the partners.

15. Building local capacity is also a critical element. When we began some of our partnerships, we thought that the major challenges would relate to money and access to medicines. But in fact, public officials were more concerned with training physicians and nurses with the skills to treat and care for HIV-positive patients; with building hospitals, treatment centers and diagnostic facilities; with educating teachers and their students

¹¹ UNAIDS, *The "Three Ones" in Action: Where We Are and Where We Go From Here*, UNAIDS/05.08E (Geneva: UNAIDS, 2005) http://data.unaids.org/publications/irc-pub06/jc935-3onesinaction_en.pdf ; Jeffrey L. Sturchio, "Business and global health in an era of globalization: reflections on public/private partnerships as a cultural innovation," in D. Held and H. L. Moore, eds., *Cultural Politics in a Global Age: Uncertainty, Solidarity and Innovation* (Oxford, UK: Oneworld Publications, 2008), pp. 270-277.

about healthy behaviors; and with finding the means to care for AIDS orphans. Investing in human resource capacity and health infrastructure also were the primary building blocks of success, not just money and medicines.

16. Finally, in reflecting on the 3 million people in developing countries now receiving antiretroviral therapy, it's important to note that progress is possible, with the right level of political commitment, the right policies, and the right partners – including the private sector.

17. By working in this spirit – finding new approaches that work, building trust through cooperative action, and harnessing the expertise and commitment of the private sector and other constituencies in civil society – together we can find innovative solutions to catalyze the movement toward universal access to HIV prevention, treatment and care by 2010.