

***Benchmarking AIDS: Evaluating Pharmaceutical Company Responses to the HIV-TB-Malaria Pandemics***

**Response from Merck & Co., Inc.  
September 11, 2006**

Thank you for the opportunity to respond to *Benchmarking AIDS: Evaluating Pharmaceutical Company Responses to the HIV-TB-Malaria Pandemics*, published recently by the Interfaith Center for Corporate Responsibility (ICCR) and noted in the Business & Human Rights Resource Centre *Weekly Update* of August 23, 2006 (<http://www.business-humanrights.org/Links/Repository/370507>).

For nearly 20 years, Merck has sought to make a difference in the fight against HIV/AIDS, from the discovery and development of antiretroviral drugs to our continuing efforts to find new ways to treat and prevent HIV/AIDS. Since our HIV products first reached the market a decade ago, we have worked to expand access to them -- particularly for patients in countries that are the poorest and hardest hit by the pandemic.

We welcome the ICCR's inquiry into the corporate response to the HIV/AIDS, TB and malaria epidemics, and we met with ICCR representatives this spring to review many of the issues discussed in *Benchmarking AIDS*. We believe that open dialogue among all stakeholders is important, which is one of the reasons that Merck has begun to publish a *Corporate Responsibility Report* (see [http://www.merck.com/cr/docs/Merck\\_Corporate\\_Responsibility\\_Report\\_2005.pdf](http://www.merck.com/cr/docs/Merck_Corporate_Responsibility_Report_2005.pdf)) and to report additional information on our HIV/AIDS and other access initiatives on our Web site (see [www.merck.com/about/cr](http://www.merck.com/about/cr) for the most up-to-date information).

However, relatively little of the information we provided in our conversations and correspondence with ICCR seems to have made its way into the final publication. Instead, the ICCR study relies heavily on reports, often outdated, by those who have been critical in the past of Merck and the pharmaceutical industry, without updating the information or making use of relevant and readily available reports from such organizations as e.g., the International Federation of Pharmaceutical Manufacturers and Associations<sup>1</sup>; the Global Business Coalition on HIV/AIDS<sup>2</sup>; or the Global Health Initiative of the World Economic Forum<sup>3</sup>. We leave it to interested observers to make up their own minds about the impact of Merck's efforts in this area – but we do think this should be done in light of a balanced assessment of available information.

---

<sup>1</sup> See, for example, *Partnerships to Build Healthier Societies in the Developing World* (Geneva, Switzerland: IFPMA, September 2006); or *Research and Development for Neglected Diseases: Lessons Learned and Remaining Challenges* (Geneva, Switzerland: IFPMA, August 2005), both available at the IFPMA Web site ([www.ifpma.org](http://www.ifpma.org)).

<sup>2</sup> [www.businessfightsaids.org](http://www.businessfightsaids.org)

<sup>3</sup> <http://www.weforum.org/en/initiatives/globalhealth/index.htm>

In that spirit, we offer the following comments to correct and clarify the profile of Merck & Co., Inc. on pages 55-58 of *Benchmarking AIDS*.

### Research: Neglected Diseases

ICCR does correctly mention that Merck recently introduced ROTATEQ®, a new vaccine against rotavirus, the most common cause of severe dehydrating diarrhea in infants and young children. In developing countries, an estimated 20% to 70% of hospitalizations and 800,000 deaths per year from diarrhea are caused by rotavirus, according to the CDC.<sup>4</sup> Earlier this year, Merck also won approval for GARDASIL®, the first and only vaccine to prevent cervical cancer and vulvar and vaginal pre-cancers caused by the most common types of Human Papillomavirus. Cervical cancer is the second most common cause of cancer death in women worldwide, resulting in nearly a half-million diagnoses and 240,000 deaths each year.<sup>5</sup> Many of these deaths are in the developing world where access to preventive screenings is often rare and a vaccine could make a measurable impact on women's health. Merck is actively working to accelerate the availability of GARDASIL in the developing world: in December, Merck announced a partnership with India's Council of Medical Research to study GARDASIL. Merck is also working with the global non-profit PATH and the Bill & Melinda Gates Foundation to develop HPV vaccination programs that will facilitate the introduction of GARDASIL to the most impoverished nations.

In addition to these recent vaccine introductions, one of the most significant initiatives undertaken by Merck to help improve access to medicines for neglected diseases in developing countries is the MECTIZAN Donation Program. Established nearly 20 years ago, the MECTIZAN Donation Program is the single largest, longest-standing public-private partnership of its kind and is widely regarded as one of the most successful public-private health collaborations in the world.<sup>6</sup> In 1987, Merck announced that it would donate MECTIZAN® (ivermectin), our breakthrough medicine for the treatment of onchocerciasis, to all who needed it, for as long as needed. More commonly known as "river blindness," onchocerciasis is transmitted through the bite of black flies and can cause intense itching, disfiguring dermatitis, eye lesions and, over time, blindness. The disease is one of the leading causes of preventable blindness worldwide and mainly exists in Sub-Saharan Africa and remote parts of Central America. Since the program's inception, Merck has donated more than 1 billion tablets of MECTIZAN through the partnership, with more than 350 million treatments administered since 1987. The program currently reaches more than 45 million people in Africa, Latin America and the

---

<sup>4</sup> <http://www.cdc.gov/ncidod/eid/vol14no4/parashar.htm>

<sup>5</sup> [http://www.who.int/vaccine\\_research/diseases/viral\\_cancers/en/index3.html](http://www.who.int/vaccine_research/diseases/viral_cancers/en/index3.html)

<sup>6</sup> Ruth Levine et al., *Millions Saved: Proven Successes in Global Health* (Washington, DC: Center for Global Development, 2004), pp. 57-64; Jeffrey L. Sturchio and Brenda Colatrella, "Successful Public-Private Partnerships in Global Health: Lessons from the MECTIZAN Donation Program," in B. Granville, ed., *The Economics of Essential Medicines* (London: Royal Institute of International Affairs, 2002), pp. 255-274. See also [www.merck.com/cr/enabling\\_access/developing\\_world/mectizan/home.html](http://www.merck.com/cr/enabling_access/developing_world/mectizan/home.html) and [www.mectizan.org](http://www.mectizan.org).

Middle East (Yemen) each year. In 1998, we expanded the Merck MECTIZAN Donation Program to the prevention of lymphatic filariasis (LF), commonly referred to as elephantiasis, in African countries where the disease co-exists with river blindness. An estimated 300 million Africans are at risk, and another 40 million are infected by this disease. Currently, an estimated 25 million people in 10 African countries are receiving MECTIZAN for lymphatic filariasis through Merck's work with the Global Alliance to Eliminate Lymphatic Filariasis.<sup>7</sup>

### **Pediatric Needs: Price Cuts**

Based on Merck's HIV pricing policy, introduced on March 7, 2001, we offer differential pricing for all of our antiretroviral formulations, including the pediatric formulations of STOCRIN™ (efavirenz).<sup>8</sup> This includes STOCRIN oral solution (30 mg/ml – bottle of 180 mg) and 50 mg capsules. The actual annual cost for pediatric patients receiving the 30mg/ml oral solution varies depending on the weight of the patient, due to the fact that dosing requirements are weight-dependent up to 40 kg. Using the same parameters as for the adult formulations -- specifically the United Nations Development Program (UNDP) Human Development Index (HDI) and the severity of the HIV epidemic in countries as measured by adult prevalence rates reported by UNAIDS -- the pediatric formulations of STOCRIN oral solution are priced as follows:

- All low HDI countries and all medium HDI countries with an adult HIV prevalence rate of 1 percent or greater qualify for a CIF price of US \$16.96 per bottle, at which Merck makes no profit.<sup>9</sup> The annual cost of therapy for children prescribed STOCRIN oral solution thus ranges between US \$229- US \$459. For children prescribed the 50 mg capsules, the annual cost ranges from US \$168 – US \$ 336. (Annual prices for adult formulations in these same countries are: US \$349 per patient per year for STOCRIN 200 mg capsules, and US \$277 per patient per year for STOCRIN 600 mg tablets.)
- Countries in the medium HDI category with an adult HIV prevalence of less than 1 percent qualify for our discounted CIF price of US \$27.22 per bottle of STOCRIN oral solution. The annual cost of treatment with the oral solution will range between \$368-\$736, based on the weight of the patient (13 – 40 kg). For children prescribed the 50 mg capsules in these countries, the annual cost comes to between \$310 and \$ 621 per patient per year. (Annual prices for adult formulations in these same countries: US \$821 per patient per year for STOCRIN 200 mg capsules, and US \$697 per patient per year for STOCRIN 600 mg tablets.)

---

<sup>7</sup> [www.filariasis.org](http://www.filariasis.org).

<sup>8</sup> [http://www.merck.com/cr/docs/Mercks\\_HIVAIDS\\_pricing\\_policy.pdf](http://www.merck.com/cr/docs/Mercks_HIVAIDS_pricing_policy.pdf)

<sup>9</sup> CIF refers to the terms of sale, i.e., cost, insurance and freight included; see <http://www.iccwbo.org/incoterms/understanding.asp>

This clarifies the picture on the pricing of pediatric formulations of STOCRIN in developing countries and corrects the inaccurate information on page 56 of *Benchmarking AIDS*. Given that the annual price of therapy with STOCRIN for children is actually less expensive in many cases than for adults in comparable settings, we were puzzled by the ICCR's assessment of our record in this area.

It is also important to note that Merck is a founding member of a new public-private partnership for pediatric AIDS treatment established earlier this year through President Bush's Emergency Plan for AIDS Relief. The partners will work to identify scientific obstacles to treatment for children, to take practical steps and share best practices on the scientific issues surrounding dosing of ARVs for pediatric applications, and develop systems for clinical and technical support to facilitate rapid regulatory review, approval, manufacturing and availability of pediatric ARV formulations.<sup>10</sup>

### **Accessibility: Licensing & Technology Transfer**

Here the ICCR notes the license for efavirenz we have already granted to Aspen Pharmacare, as well as the licenses granted to the International Partnership for Microbicides for a number of CCR-5 blockers that have potential as microbicides. But the statement that "Merck will be under increasing pressure to issue voluntary licenses" in Africa because generic companies have recently lowered their prices on their versions of efavirenz (p. 56) defies logic: as the ICCR notes in the next section, there are no patents on efavirenz in 52 of 53 African countries, so there is nothing to license and nothing to stop generic companies from making and selling versions of efavirenz throughout the continent.

### **Accessibility: Patent Enforcement Regulation**

As ICCR correctly points out, Merck has patents on STOCRIN in only one of 53 countries in Africa (South Africa) and on CRIXIVAN (indinavir sulfate) in only two of 53 countries (South Africa and the Democratic Republic of Congo). In South Africa, we have issued a license for efavirenz to Aspen Pharmacare. The important point to keep in mind is that the prices for STOCRIN and CRIXIVAN delivered to patients in Africa are cheaper than or comparable to generic versions of these products. As of mid-2006, through our efforts and those of partners in government, multilateral organizations and civil society, nearly 500,000 people living with HIV/AIDS in 76 developing countries are being treated with regimens containing either STOCRIN or CRIXIVAN.<sup>11</sup>

### **Accessibility: Differential Pricing**

The ICCR report refers to the Accelerating Access Initiative, a collaboration among seven research-based pharmaceutical companies and five UN agencies (UNAIDS, WHO, UNICEF, UNFPA and the World Bank) initiated in May 2000 to help improve access to

---

<sup>10</sup> For additional background, see <http://www.state.gov/s/gac/rl/fs/2006/62974.htm>

<sup>11</sup> Note that this is an update from the March 2005 number cited on p. 57 of *Benchmarking AIDS*.

care and treatment for HIV/AIDS in developing countries. Merck was a founding member and continues to be engaged in this initiative, together with Abbott, Boehringer-Ingelheim, Bristol-Myers Squibb, Gilead Sciences, GlaxoSmithKline and Hoffmann – La Roche.<sup>12</sup> However, the characterization of the AAI, based on unexamined claims by “some non-government organizations,” is misleading. As the World Health Organization indicated in its March 2006 report of the 3 x 5 initiative, by the end of 2005, more than 716,000 people living with HIV/AIDS in developing countries were being treated by antiretrovirals provided by AAI companies – more than half of the estimated 1.3 million people then receiving treatment throughout the developing world.<sup>13</sup>

### **Accessibility: Registration:**

In this section (p. 57), the ICCR again relies on outdated claims about the alleged slow pace of registration of STOCRIN in developing countries without checking to learn what is currently taking place.

As of June 2006, the 600 mg tablet formulation of STOCRIN had been registered in 96 countries worldwide. Of these, 55 countries received discounted prices (36 at prices at which Merck does not profit, 27 of which were in sub-Saharan Africa). The 600 mg formulation of STOCRIN was also available in another 12 developing countries through temporary import authorizations or other mechanisms, and registration is pending in 16 other countries. As the ICCR points out, there are about 40 sub-Saharan countries in the low and medium HDI categories: STOCRIN 600 mg tablets are now registered or otherwise available in 33 of the 40 countries and pending approval in 3 more.

For the 200 mg capsule formulation of STOCRIN, the picture is similar. As of June 2006, the 200 mg formulation of STOCRIN had been registered in 101 countries worldwide. Of these, 60 countries received discounted prices (38 at prices at which Merck does not profit, 26 of which were in sub-Saharan Africa). The 200 mg formulation of STOCRIN was available in two additional developing countries through temporary import authorizations or other mechanisms, and registration is pending in 6 other countries.

Merck remains committed to providing our HIV/AIDS medicines in the poorest countries and those hardest hit by the AIDS epidemic at prices at which we do not profit, and to working with other stakeholders to improve access to our medicines in the developing

---

<sup>12</sup> For background on the history and early accomplishments of the AAI, see Jeffrey L. Sturchio, “Partnership for Action: The Experience of the Accelerating Access Initiative, 2000-04, and Lessons Learned,” in A. Attaran and B. Granville, eds., *Delivering Essential Medicines: The Way Forward* (London: Royal Institute for International Affairs, 2004), pp. 116-151; available at [http://www.who.int/hiv/amds/AAI\\_chapter6.pdf](http://www.who.int/hiv/amds/AAI_chapter6.pdf).

<sup>13</sup> World Health Organization, *Progress on Global Access to HIV Antiretroviral Therapy: A Report on “3 by 5” and Beyond* (Geneva, Switzerland: WHO, March 2006), p. 21, available at <http://www.who.int/hiv/mediacentre/news57/en/index.html>. See also the AAI fact sheet, providing a complete analysis of treatment numbers and geographic distribution from 2000 through the end of 2005, at [http://www.who.int/hiv/AAI\\_fs\\_4Q2005.pdf](http://www.who.int/hiv/AAI_fs_4Q2005.pdf).

world. We welcome the opportunity for dialogue on these issues with key stakeholders, and look forward to continued engagement with the ICCR and others on the issues addressed in *Benchmarking AIDS*.

Dr. Jeffrey L. Sturchio

Vice President, External Affairs, Europe, Middle East Africa & Canada

Merck & Co., Inc.

Ms. Maggie Kohn

Director, Corporate Responsibility Communications

Merck & Co., Inc.