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Current Experience with Differential Pricing: Accelerating Access Initiative and the Viramune® Donation Program

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During my presentation today, I will provide you with some of the experiences to-date from both the Accelerating Access Initiative and Boehringer Ingelheim's Viramune® Donation Program as they relate to the issue of accessibility to medicines for the treatment of HIV/AIDS. As has been stated at many times during this meeting, prices matter. But the experiences to-date with both programs demonstrate that prices matter only to a certain point. And that point is where the ability of the existing health care capacity is able to deliver these medicines in a safe and reliable manner.

The Accelerating Access Initiative is an innovative public-private partnership launched by five UN agencies and five of the world's leading pharmaceutical companies in May of 2000. The goal and aim of this initiative is to enable and accelerate the sustained access to appropriate interventions for the prevention, care and treatment of HIV/AIDS related illnesses and prevention of mother-to-child transmission. Sustainable success can be achieved by working in partnership, each contributing their own specific expertise. For their part, the pharmaceutical companies have individually committed to make their drugs available at significantly more affordable prices relative to those in the industrialized world.

Let's review, for a moment, the process of involvement in this initiative. The first principle is that countries drive the process; the countries themselves are responsible for making this happen. Correspondingly, the first step begins with an „expression of interest" from a government to the UN. The UN then dispatches missions to countries in order to evaluate local capacity and skills,

and perform needs assessment. Countries actively work with UNAIDS/WHO to develop comprehensive national HIV/AIDS policies and create national implementation plans. Resources, including financial, must be mobilized. Only when all of this has been achieved, and at the request of the governments, are the pharmaceutical manufacturers invited to dialogue with a country regarding access to antiretroviral therapies.

To-date, six countries, Senegal, Uganda, Rwanda, Ivory Coast, Cameroon and, most recently, Mali have formally announced their preparedness to introduce antiretroviral treatment at the significantly reduced costs. Several more countries will be announced in the coming weeks, and there are over two dozen other countries in various stages of developing their national plans in cooperation with the UN. We look forward to the future involvement of private employers and NGOs with the capacity to deliver these medicines. Clearly, the initiative is gaining momentum.

Each additional country that comes forth publically in announcing that there is the local political will to address the HIV/AIDS crisis is a source of encouragement and hope. But the reality is that even with antiretrovirals available at drastically reduced prices, today only a few thousand patients in Africa are actually receiving treatment. And the answer to why that number is so disappointingly small has been referred to several times in this meeting: it is the devastating lack of health care capacity.

But let's look at the countries that have demonstrated success. Senegal has one of the most consistent records of political engagement in the fight against HIV/AIDS of any African country. It has the unparalled energy and determination of a tireless fighter in Dr. Ibra Ndoye. The National AIDS Strategy and, in particular, the guidelines for the use of antiretroviral drugs, are comprehensive, clear and up-to date. The price of antiretrovirals has been significantly reduced. Any yet, the target number of patients who potentially could access treatment in 2001, by my calculation based on figures provided by Dr. Ndoye, are only on the order of 2400, approximately 3% of the estimated total number infected.

Uganda is another country that represents a model of success for dealing with the HIV/AIDS crisis within it's borders. At the heart of their success is the countrywide HIV awareness and condom distribution programs. The treatment experience and expertise at Mulago Hospital in Kampala is almost unparalled owing to it's long standing record of academic alliances with institutions such as Johns Hopkins University. The study conducted by the McKinsey Consulting Group, referenced yesterday by Peter Piot, suggests that expansion of treatment from the current 1400 or so to a target of 5000 patients can be achieved with the current price reductions and without further investments in capacity building.

The potential, however, to expand beyond 5000, to numbers perhaps to 10,000 or 50,000 is directly linked to further investments in health care capacity and infrastructure, and only to a minor degree to further reductions in current prices.

In countries with per capita GDP of less than US$300 and per capita health care spending of US$6 a year, affordability (and it's surrogate, price) is an issue. But, at the same time, we must face the reality that in the absence of concentrated and massive investments into the development and expansion of health care capacity, price is not the major obstacle to achieving the aim of significantly expanding access to treatment today.

As further illustration of this point, I would like to provide the experience to-date with the Viramune® Donation Program. Landmark clinical trials have now demonstrated that significant reductions in the transmission rate of HIV from mother to child during the labor and birth process can be achieved with Viramune® in developing world settings. The efficacy of this treatment is seen following the administration of a single tablet to the mother during labor and a couple of drops of suspension to the newborn. Given the unprecedented public health consequences of this treatment, in July of last year, Boehringer Ingelheim offered Viramune® free of charge for a period of five years for use in this specific indication in developing countries.

To-date, only two countries, Republic of Congo (Brazzaville) and Senegal have indicated their preparedness to participate, and shipments of 3000 treatments each have been sent to these countries. This number of treatments represent what the countries themselves requested, based on their estimates of how many treatments could be used in a one year period. 3000 treatments in countries with estimated numbers of 140,000 and 90,000 births to HIV infected mothers in Congo and Senegal, respectively. Here is a drug treatment that offers the hope of prevention of infection for countless numbers of infants. The price of the drug is not a barrier. Yet, precious few are realizing the benefits.

Boehringer Ingelheim believed that immediately following the announcement last year that we would be overwhelmed by requests for the donation. Nothing has been further from the truth. To realize our company's goal of making this treatment available to as many patients as possible, we have hired an external consulting company to assist us with our outreach efforts. We are in discussions with UNAIDS, UNICEF, World Bank, and USAID to encourage use of the donation by countries in their respective programs. I have personally undertaken trips to many African countries, meeting with representatives from Health Ministries and local treatment groups, attempting to put a face on this Program, to answer questions, and, hopefully, to stimulate participation. The answer I hear is disappointingly the same almost universally: The offer is

appreciated, but we have no capacity to deliver even this simple treatment in the context of a comprehensive mother-to-child transmission prevention program.

The slow uptake of the Donation Program to-date, however, is not reason for losing hope. As with the Accelerating Access Initiative, there will be a lag time, as governments and health care providers understand how to take advantage of the offer. But the reality is that capacity building for the prevention of mother-to-child transmission requires investment. As illustration, Boehringer Ingelheim is cooperating with the German government to establish de novo comprehensive mother-to-child treatment programs, including the use of Viramune®, in 6 clinics, two each in Uganda, Tanzania and Kenya. The cost of the drug (assuming that the drug would have had to be purchased at the developed world prices) amounts to 1.2% of the total investment necessary to establish these programs.

Price reductions and affordability does offer hope, and by my statements, I in no way wish to diminish the hope that that individual patient can enjoy due to current and, hopefully, future further reductions in price. The sharp reductions in price have stimulated local governments and the international community to take action. But decreasing prices in the absence of adequate health care capacity and in the face of continued poverty will not lead to significant increases in the number of patients receiving treatment.

So what can we learn from the experiences to date in the context of achieving a measure of success that history will judge as adequate?

First and foremost, take head-on the difficult and oftentimes unspoken reality that the obstacle to real success is the question of how to develop and deliver competent and reliable health care in the face of countless years of overwhelming poverty.

Second, encourage individual companies to embrace differential pricing as a way of expanding access to drugs by enacting appropriate public policy and legislation to ensure that the drugs reach the patients for whom they are intended.

Third, begin to set realistic goals for the number of patients that can be treated. Set target numbers of patients, define and measure the investments necessary to achieve those targets, mobilize the resources, and be prepared to face the politically difficult issue that some will benefit and some will not.

Fourth, take stock of the results that have been achieved in the Accelerating Access Initiative and other successful public-private partnerships and build more of these alliances based on clearly defined common goals. These partnerships

represent the best way to move forward into an uncertain future that holds tremendous obstacles.

Fifth, ensure continued investment into research and development that will lead to the introduction of new and innovative medicines for the prevention and treatment of mother-to-child transmission, HIV infection and AIDS related diseases through strong protection of intellectual property rights. The reality is that the current antiretrovirals are not very good with regard to adherence, side effects and efficacy, especially with drug resistant viral populations. Boehringer Ingelheim is investing hundreds of millions of dollars into research and development of next generation antiretrovirals. Other companies are investing in the development of new strategies, including fusion inhibitors, integrase inhibitors, and vaccines, to name just a few. This investment must continue unabated and, indeed, with increased vigor. Without these innovations, indeed, there will nothing for the generic industry to copy.

In the debate and search for successful measures, we must never loss the long-term perspective that will allow for truly sustainable, affordable and effective solutions.