

Will Stephens
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Peter Maybarduk
Global Access to Medicines Program
Public Citizen
1600 20th St NW, Washington, DC 20009

Re: Your letter to Alex Gorsky

Dear Peter,

I am writing in response to your letter to Mr. Gorsky regarding the Medicines Patent Pool.

As you know, Janssen and the Medicines Patent Pool share a common vision and desire to expand the availability of life-saving HIV medicines worldwide. This goal has been the driver of our numerous conversations for the past several years and regular engagement with the Medicines Patent Pool on best practices, new approaches and potential collaborative opportunities for our two organizations to work together to address areas of high unmet medical needs in the field of HIV.

Specifically, our global HIV medicines access program is making progress in ensuring access to Janssen HIV medicines in resource-limited countries, as follows:

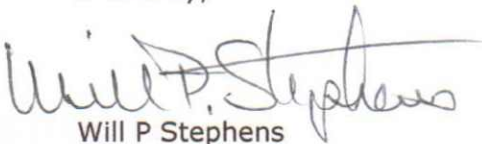
- Licenses to five generic manufacturers for our HIV medicines, five of which allow for generic versions of our HIV medicine *rilpivirine* and formulation as fixed-dose combinations (FDCs) in 112 low and middle-income countries.
- Policy not to enforce our patents on medically acceptable generic versions of the antiretroviral (ARV) drug *darunavir* used in sub-Saharan Africa (SSA) and Least Developed Countries (LDCs). This policy covers manufacture in any country regardless of *darunavir* patent status as long as the product is used only in SSA and LDCs. Moreover, the use of the product in countries outside of SSA and LDCs where there is no *darunavir* patent is not restricted provided the product has been manufactured in a country where there is no *darunavir* patent. Thus, the product potentially can be made much more widely available at the discretion of generic manufacturers.
- Launch of a pediatric HIV treatment donation program for our approved ARVs for HIV treatment-experienced children and adolescents in sub-Saharan Africa. We are currently evaluating expressions of interest and expect to initiate local delivery of donated product to eligible countries in May 2014.

- Successful inclusion of three tablet strengths our HIV medicines PREZISTA® – (*darunavir*) – 600 mg for adults and 75 mg and 150 mg for pediatric patients – and two tablet strengths of INTELENCE® (*etravirine*) – 100 mg for adults and 25 mg for pediatric patients – in the World Health Organization (WHO) List of Prequalified Medicinal Products.
- Clinical study to determine appropriate and optimal use of *rilpivirine* – a low dose, low-cost potential first-line treatment – for resource-limited settings. We have enrolled over half the required patients for this trial globally.
- Research collaborations with other pharmaceutical companies and product development partnerships (PDPs) to develop new FDCs with our HIV medicines to help simplify treatment for patients. For example, we are currently working with PATH, an international non-profit organization that transforms global health through innovation, for the early development of *rilpivirine* in a long-acting injection as potential pre-exposure prophylaxis (PrEP) against HIV infection.
- Integration into the new Janssen Global Public Health group to drive innovative access strategies for a portfolio of health solutions for HIV, multi-drug resistant tuberculosis (MDR-TB) and neglected tropical diseases.

As a result of this work and the current clinical indication of *darunavir* and *etravirine* for HIV treatment-experienced patients (third-line), our focus remains on new opportunities, innovative strategies and collaborations that will create positive change in areas of high unmet medical needs such as in the field of HIV pediatrics and treatment optimization.

Again, rest assured that we are steadfast in our commitment to patients. Our access efforts continue to evolve as we strive to cultivate new solutions and collaborations to address unmet public health needs.

Sincerely,



Will P Stephens

Vice President, HIV Access and Partnerships, Janssen Global Public Health