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# IFPMA Statement

## Voluntary Licenses and Non-Assert Declarations:

Actions by R&D pharmaceutical companies that facilitate access to medicines

### Background/Rationale:

IFPMA member companies are committed to improving access to antiretrovirals (ARVs) for those who cannot afford them, particularly in Least Developed Countries (LDCs) and low-income countries (LICs). For many years, the pharmaceutical industry has created and delivered ARVs that have saved millions of lives in the global fight against HIV/AIDS. UNAIDS reports that approximately 2.9 million lives have been saved because of access to ARV therapy<sup>1</sup>. About 1.2 million people started treatment in 2009, bringing the total number of people receiving treatment to 5.2 million, compared to 4 million at the end of 2008<sup>2</sup>. That access has often been achieved through the numerous access initiatives developed and deployed by the R&D pharmaceutical industry, such as preferential pricing, donations, licensing and capacity building.

Most of these access initiatives do not depend on intellectual property rights. For example, preferential pricing and capacity building are relevant whether or not there are patents on pharmaceutical products. This is often the case in the LDCs and LICs. Where patents do exist, many companies have gone beyond preferential pricing initiatives to implement access models allowing generic companies to produce the patented medicine. Examples of these IP access models include voluntary licensing and non-assert policies.

### Voluntary Licenses and Non-Asserts: What they are, how they work:

Voluntary License. A voluntary license is an authorization given by the patent holder to a generic company, allowing it to produce the patented article, such as a medicine, as if it were a generic. The license usually sets quality requirements and defines the markets in which the licensee can sell the product. The decision to grant a voluntary license, and the terms therein, can be tailored to account for many factors, including the nature of the epidemic/disease, social factors, economic considerations and the capacity of the licensee to meet and maintain quality standards for the product.

Non-Assert Declaration. A non-assert declaration (sometimes called a “non-assertion covenant”), is where a rights holder commits not to enforce certain patents in a defined group of countries allowing a generic version of a patent-protected article to be produced in a resource-limited setting. Some non-assert declarations may require a party wanting to make the product to meet certain quality requirements e.g. being pre-qualified by the WHO or being granted approval by a Drug Regulatory Agency (DRA).

Voluntary licenses and non-assert declarations build on other industry-led access initiatives enabling generics manufacturers to serve the market. However, in countries where IP rights are rarely sought, one might expect to see a sustainable supply of cheap generic medicines from a vibrant community of generic competitors, but that is often not the case. Generics companies need economically-viable markets in which to compete. These observations lead to the conclusion that the barrier is not IP, but the inability of generics manufacturers to operate sustainably, either because there is no commercial market or because the cost of doing business is too high. This problem is particularly acute when medicines are difficult and/or expensive to manufacture. Other major factors, such as the condition of infrastructure and/or health care systems, also play a crucial role in enabling access to medicines. If these factors are not in place, or fail to operate effectively, then the objective of medicine access is significantly undermined.

The IFPMA welcomes the current efforts to create “innovative mechanisms” to further improve access to ARVs in resource-limited settings. However, any such mechanism should not undermine the current and proven initiatives already in place in order to ensure the most effective and efficient use of the resources available.

Geneva, 28 July 2010

<sup>1</sup>UNAIDS Report on the global AIDS epidemic, 2009, p.17

<sup>2</sup>[http://www.unaids.org/en/KnowledgeCentre/Resources/FeatureStories/archive/2010/20100719\\_Vienna\\_PR\\_WHO.asp](http://www.unaids.org/en/KnowledgeCentre/Resources/FeatureStories/archive/2010/20100719_Vienna_PR_WHO.asp)

## **Annex: Non-exhaustive list of examples of access initiatives undertaken by the R&D Pharmaceutical Industry to tackle the HIV/AIDS epidemic<sup>3</sup>.**

### **Voluntary licensing**

**Merck & Co.** has granted royalty-free licenses of its ARV efavirenz to five South African generic manufacturers, of which four are currently on the market. All but one licensee donates a percentage of efavirenz net sales to the MSIZI Trust, which has been established to support the fight against HIV and AIDS in South Africa ([www.merck.com](http://www.merck.com)).

**GlaxoSmithKline** granted its first voluntary license in 2001 and has now negotiated eight licensing agreements for its ARVs to companies in India, Kenya and South Africa. Following the launch of ViiV Healthcare, a specialist HIV company created as a joint venture with Pfizer, these licences have transferred to ViiV. These agreements are now all royalty free and cover all of sub-Saharan Africa. ViiV's licensees supplied 439 million tablets of their versions of Epivir® and Combivir® to Africa in 2009. This represents more than 50% growth over 2008 and 140% more than in 2007. This initiative gives customers in sub-Saharan Africa greater choice and contributes to better security of supply ([www.gsk.com](http://www.gsk.com)).

**Gilead** Gilead has partnered with Aspen Pharmacare, South Africa, to manufacture and distribute branded and generic versions of Viread® and Truvada® in Africa. Gilead has entered into non-exclusive licensing agreements with 13 Indian generic companies, allowing them to distribute generic versions of tenofovir and tenofovir-based regimens in 95 developing countries, including India, South Africa and Thailand. The agreements include technology transfer to ensure high-quality products and the generic companies are free to establish their own pricing for their products ([www.gilead.com](http://www.gilead.com)).

**Pfizer**, prior to the creation of the new HIV company ViiV, granted the non-profit International Partnership for Microbicides ([www.ipm-microbicides.org](http://www.ipm-microbicides.org)) a non-exclusive, royalty-free license to develop maraviroc in a vaginal cream or gel for the prevention of HIV infection.

### **Non-assert declarations**

**Roche** has halted patent filing and enforcement in LDCs. It will also not enforce existing patents for its antiretrovirals in sub-Saharan Africa. As a result, generic versions of ARVs can be produced in these countries, encompassing 70% of all people living with HIV. In 2006, Roche committed to an "AIDS Technology Transfer Initiative", to help local firms in Least Developed Countries and sub-Saharan Africa to manufacture second-line HIV medicines. Agreements have been signed with 10 companies in Bangladesh, Ethiopia, Kenya, South Africa, Tanzania and Zimbabwe ([www.roche.com](http://www.roche.com)).

**Boehringer Ingelheim** offers a non-assert declaration for its ARVs to all WHO pre-qualified manufacturers, stating that it will not enforce its nevirapine patent rights in LDCs, low income countries and all countries in Africa, in order to ensure supply at lowest possible cost. To date, seven generic producers have accepted the non-assert declaration (<http://www.boehringer-ingenelheim.com>).

**Bristol-Myers Squibb** has a policy of not enforcing its patents for HIV products in sub-Saharan Africa and has immunity from suit agreements for stavudine and didanosine with five African generic companies. In February 2006, it concluded technology transfer agreements with the generic companies Aspen PharmaCare (South Africa) and Emcure Pharmaceuticals (India), for its newest antiretroviral, atazanavir (sold as Reyataz® in the US) ([www.bms.com](http://www.bms.com)).

### **Preferential pricing and product donations**

**Abbott** made a commitment in 2002 to sell its HIV medicines at USD 500 per patient per year in Africa and LDCs. Abbott later expanded its preferential pricing program to create a new tier for low and lower middle-income countries. In 2006, Abbott announced that the heat-stable lopinavir/ritonavir tablet would also be priced at USD 500 per patient per year in Africa and the LDCs. This approach has consistently provided lopinavir/ritonavir at a price below that of generic products<sup>4</sup>. A further reduction in price for lopinavir/ritonavir occurred in 2009 ([www.abbott.com](http://www.abbott.com)).

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<sup>3</sup> For a more detailed list of industry's access initiatives, see : <http://www.ifpma.org/Healthpartnerships> and <http://www.globalhealthprogress.org>

<sup>4</sup> Veronika J Wirtz, Steven Forsythe, Atanacio Valencia-Mendoza, Sergio Bautista-Arredondo, Factors influencing global antiretroviral procurement prices, *BioMed Central, Ltd.*, 18 November 2009, <http://www.biomedcentral.com/1471-2458/9/S1/S6>

**Pfizer** created the Diflucan® Partnership in 2000 to provide treatment for two AIDS-related fungal infections in developing countries. Pfizer and its program partners distribute millions of Diflucan® (fluconazole) treatments free of charge to governments and NGOs in developing countries. Since 2000, Pfizer has donated medicine worth more than USD 840 million to more than 2,000 sites in 60 countries in Africa, Asia, the Caribbean and Latin America and has provided training and education materials to more than 20,000 healthcare professionals ([www.pfizer.com](http://www.pfizer.com)).

**Johnson & Johnson's** Tibotec subsidiary makes Tibozole™ Miconazole MAT, a muco-adhesive buccal tablet that can treat oral thrush in AIDS patients. Over two million patient treatments of Miconazole nitrate 10 mg MAT Tibotec have been donated or sold at cost in sub-Saharan Africa. Of these, more than 1,300,000 treatment units have been sold to international procurement agencies for distribution in resource poor settings, through Tibotec's Cost recovery distribution program ([www.inj.com](http://www.inj.com)).

**GlaxoSmithKline** introduced not-for-profit pricing for all its ARVs in all the LDCs and the countries of sub-Saharan Africa in 2001. This commitment continues under ViiV Healthcare's stewardship.

Geneva, 28 July 2010