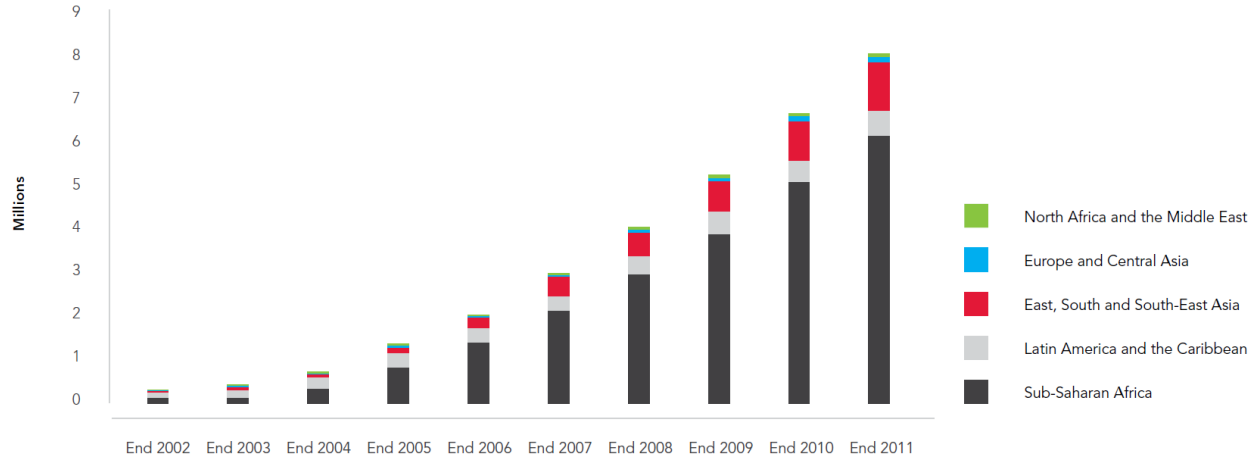
# Policy Position

## Voluntary Licenses and Non-Assert Declarations

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 34 million people live with HIV/AIDS, 1 in 20 adults in sub-Saharan Africa[1]. More people initiated antiretroviral therapy in 2011 than in any previous year, with the number of people living with HIV receiving treatment rising by 21% compared with 2010[2]. Since 1995, antiretroviral therapy has added 14 million life-years in low- and middle-income countries, including 9 million in sub-Saharan Africa[3]. That access has often been achieved through the numerous access initiatives an approaches developed and deployed by the R&D pharmaceutical industry, such as differential pricing, donations, licensing and capacity building.

*Number of people receiving antiretroviral therapy in low- and middle-income countries, by region, 2002–2011*[4]




Some of these access initiatives do not depend on intellectual property rights[5]. For example, differential 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, additional considerations may apply. For some patented products, a differential pricing approach may be the most appropriate and sustainable option. However, many companies also have implemented access models allowing generic pharmaceutical companies to produce and sell patented medicines. Examples of these IP access models include voluntary licensing and non-assert policies.

[1] UNAIDS Report on the global AIDS epidemic (2012), pg. 8
[2] Ibid, p. 50
[3] Ibid
[4] Ibid
[5] For a discussion on the reasons for improved access to medicines, see Wilson *et al* "Evidence on Access to Essential Medicines for the Treatment of HIV/AIDS (2011)

**International Federation of Pharmaceutical Manufacturers & Associations**
Ch. Louis-Dunant 15
P.O. Box 195
1211 Geneva 20
Switzerland
Tel: +41 22 338 32 00
Fax: +41 22 338 32 99
www.ifpma.org

# Policy Position

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

Voluntary License. A voluntary license is an authorization given by the patent holder to a a third party (e.g., a generic pharmaceutical manufacturer), allowing that party to make, use, sell or import the patented article, e.g., a medicine. The licensing terms usually include quality requirements and define the markets in which the licensee can make, use, sell or import the product. The terms of a voluntary license 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. In certain circumstances, the patent holder might consider it appropriate to grant a license to an intermediary sub-licensing agency, such as a patent pool.

Non-Assert Declaration**.** A non-assert declaration (sometimes called a "non-assertion covenant" or "immunity-from-suit agreement"), is where a patent holder commits not to enforce certain patents in certain circumstances and in a defined group of countries. This allows third parties to make, use, sell or import the patented article within the scope of the declaration, including in resource-limited settings, without fear of an infringement suit. Some non-assert declarations may be limited in scope to apply only to those products that meet certain quality requirements, (e.g. those pre-qualified by the WHO or approved 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, if patens were a significant barrier to access, in those countries where patents on a product do not exist, one might expect to see a sustainable supply of cheap generic medicines from a vibrant community of generic competitors. However, that is often not the case. As with any commercial entity, generics companies need economically-viable markets in which to operate. 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, which could be impacted by both supply and demand limitations, 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[6].

IFPMA welcomes the current efforts to create new mechanisms to further improve access to ARVs in resource-limited settings. However, any such mechanism should complement the current and proven initiatives already in place in order to ensure the most effective and efficient use of the resources available.

[6] See IFPMA, The Changing Landscape on Access to Medicines (2012).

**International Federation of Pharmaceutical Manufacturers & Associations**
Ch. Louis-Dunant 15
P.O. Box 195
1211 Geneva 20
Switzerland
Tel: +41 22 338 32 00
Fax: +41 22 338 32 99
www.ifpma.org

# Policy Position

**Selected examples of initiatives to improve access to ARVs through voluntary licenses or non-assert declarations**[7]

**AbbVie** has a voluntary licensing agreement in place with the Medicines Patent Pool (MPP) for paediatric fomulations of lopinavir and ritonavir, WHO-recommended medicines for children living with HIV. The license agreement enables generic and other companies and organizations to re-formulate and manufacture LPV/r and ritonavir paediatric treatments for distribution in low- and middle-income countries where 99% of children with HIV in the developing world live. The MPP-AbbVie agreement covers 102 countries of which more than 65 are classified as middle-income nations and permits manufacture and distribution in countries where AbbVie does not hold patents.

**Boehringer Ingelheim** has granted over the last six years non-assert declarations to generic manufacturers pre-qualified by the World Health Organization (WHO), to manufacture products containing nevirapine as IR and ER, and for production of tipranavir. The policy applies to all low-income countries, all LDCs and all African countries (78 countries in total). This has led to an increase in patients being treated with medicines containing nevirapine. The non-assert policy stipulates that patents will not be enforced, that no royalties have to be paid and, most importantly, that high product quality will be ensured.

**Bristol-Myers Squibb** has License and Technology Transfer Agreements with Africa- and India-based generic manufacturers for its protease inhibitor, atazanavir (ATV). In addition to providing royalty-free licenses and technical documentation, Bristol-Myers Squibb made available its scientific, manufacturing and regulatory experts to support the licensees. The scope of these agreements covers over 80% of people living with HIV/AIDS in low and middle income countries. In 2011, BMS concluded a technology transfer agreement with the Brazilian Ministry of Health to manufacture ATV by Farmanguinhos (Fiocruz) designed to build the capacity and skills required for the Brazilian government to produce a sustainable, high quality supply of atazanavir. BMS has also a policy of not enforcing its patents for HIV products in sub-Saharan Africa and has immunity from suit agreements for atazanavir, stavudine and didanosine with over ten generic manufacturers.

**Janssen** (a J&J subsidiary) has royalty-free agreements for branded HIV medicines in sub-Saharan Africa (SSA) and Least Developed Countries (LDCs). These royalty-free agreements have helped to establish distribution networks, lay the groundwork for the appropriate clinical use of its HIV medicines, and support pharmacovigilance activities. For rilpivirine, its medicine indicated for treatment-naïve adults as part of combination HIV treatment the company has additional licenses, covering as many as 112 countries. Tibotec works with its partners to assist and provide them with the technical information and knowledge ("tech transfer") needed to manufacture both the active pharmaceutical ingredients (API) and the finished products.

**Lilly** does not file, maintain, or enforce patents for any of its products in Least Developed Countries. As a result, generics manufacturers are free to produce and provide generic versions of any Lilly medicine in these countries.

**MSD** has granted royalty-free licenses of its ARV efavirenz to six South African generic manufacturers, of which four are currently on the market. In June 2011, MSD granted two non-exclusive licenses to two Indian generic

[7] More detailed descriptions of the R&D pharmaceutical industry's access initiatives, can be found at: http://partnerships.ifpma.org/

**International Federation of Pharmaceutical Manufacturers & Associations**
Ch. Louis-Dunant 15
P.O. Box 195
1211 Geneva 20
Switzerland
Tel: +41 22 338 32 00
Fax: +41 22 338 32 99
www.ifpma.org

manufacturers for the manufacture and commercialization of raltegravir in 60 LIC and sub-Saharan African countries.

**Roche** does not file any new patents or enforce old patents in LDCs or LICs. In addition, Roche does not enforce existing patents for its antiretrovirals in sub-Saharan Africa. As a result, generic versions of ARVs can be produced in these countries, where an estimated 24.5 million people live with HIV. In 2006 Roche initiated an "AIDS Technology Transfer Initiative", to help local organisations in Least Developed Countries and sub-Saharan Africa that have the manufacturing capacity and capability to reach the right levels of quality and efficacy to manufacture the protease inhibitor Invirase (saquinavir), their second-line HIV medicine. To date, Roche transferred technology and up-scaled capabilities of 13 organisations in six countries so that they are now able to manufacture their own generic versions of saquinavir.

**ViiV Healthcare**, a specialist HIV joint venture between GSK, Pfizer and Shionogi, currently has royalty free voluntary licensing policy for all its medicines for all LICs, LDCs and of Sub Saharan Africa. ViiV Healthcare has given 13 voluntary licences for ARVs to generic manufacturers, based in a broad range of different locations. In 2012, ViiV Healthcare and its licensees supplied an estimated 1.1 billion antiretroviral tablets. This is the equivalent of approximately 12 months' supply for over a 1.5 million people living with HIV. In February 2013 ViiV Healthcare granted the Medicines Patent Pool a voluntary licence for paediatric formulations of the antiretroviral medicine abacavir in 118 countries. Before ViiV's creation in 2009, GlaxoSmithKline had negotiated eight licensing agreements for its ARVs to companies in India, Kenya and South Africa. Pfizer had also granted the non-profit International Partnership for Microbicides a non-exclusive, royalty-free license to develop maraviroc in a vaginal cream or gel for the prevention of HIV infection.

**Last update: 18 February 2015**

**International Federation of Pharmaceutical Manufacturers & Associations**
Ch. Louis-Dunant 15
P.O. Box 195
1211 Geneva 20
Switzerland
Tel: +41 22 338 32 00
Fax: +41 22 338 32 99
www.ifpma.org