

**Topic  
Brief 6**

**AIDS, developing  
countries and  
pharmaceuticals**

## Brief 6



Poverty remains the single biggest barrier to improving healthcare in the developing world.

# AIDS, developing countries and pharmaceuticals

## The underlying healthcare crisis in developing countries

In spite of improvements in recent years, millions of people in developing countries still cannot access the most basic healthcare, including safe and effective medicines. This has led to a continuing healthcare crisis in these countries, many of which are those least able to cope, have to deal with the double burden of infectious diseases such as HIV/AIDS, tuberculosis and malaria and the growing problem of non-communicable diseases such as diabetes, cardiovascular disease, respiratory conditions and cancers.

Poverty remains the single biggest barrier to improving healthcare in the developing world. In many countries people do not have enough food, access to a clean water supply, hospitals or clinics in which to receive treatment, and healthcare professionals to care for them.

## The AIDS epidemic

“AIDS remains one of the world’s most serious health challenges, but global solidarity in the AIDS response during the past decade continues to generate extraordinary health gains. Historic success in bringing HIV programmes to scale – combined with the emergence of powerful new tools to prevent people from becoming infected and from dying from AIDS-related causes – has enabled the foundation to be laid for the eventual end of AIDS.”

### **UNAIDS Report on the global AIDS epidemic 2012 – Introduction<sup>48</sup>**

The response to the epidemic has included working to provide access to appropriate medicines at little or no cost, developing new medicines to overcome disease resistance and provide simpler dose regimes for patients, giving financial and educational support to help develop the basic healthcare infrastructure within developing countries, and ensuring that transmission of the AIDS virus is minimised. Although total financial resources for HIV programmes in low- and middle-income countries rose modestly in 2012, the world’s ability to lay the foundation for an end to the AIDS epidemic continues to be undermined by a major resource gap<sup>49</sup>. Social and cultural considerations relating to sexual behaviour in many developing countries also remain a significant factor impeding expanded success in addressing the AIDS epidemic.

48 [http://www.unaids.org/sites/default/files/en/media/unaids/contentassets/documents/epidemiology/2012/gr2012/20121120\\_UNAIDS\\_Global\\_Report\\_2012\\_with\\_annexes\\_en.pdf](http://www.unaids.org/sites/default/files/en/media/unaids/contentassets/documents/epidemiology/2012/gr2012/20121120_UNAIDS_Global_Report_2012_with_annexes_en.pdf)

49 [http://www.unaids.org/en/resources/campaigns/20121120\\_globalreport2012/globalreport](http://www.unaids.org/en/resources/campaigns/20121120_globalreport2012/globalreport)

## Rationale for patents on pharmaceuticals

Patents are granted for new pharmaceutical developments in much the same way as for other useful inventions i.e. they must be new and inventive. The availability of patent protection continues to stimulate and underpin the production and development of new improved medicines to treat diseases prevalent in developed and developing countries alike, such as non-communicable diseases. Without adequate patent protection and the ability to recoup R&D investment, companies simply would not undertake the long, risky and very expensive process required for new medicines, including extensive safety and clinical evaluation and post launch monitoring.

Only about one in between five to ten thousand candidate molecules developed from a pharmaceutical invention will ever reach the market as a successful medicine, and only one in three of those medicines will “break even” on the cost of its discovery and development. Accordingly, without patents the major source of new medicines would be cut off to the detriment of patients everywhere in the world. Nevertheless, there are those who continue to blame intellectual property, and patents in particular, for the fact that many millions of people are denied access to the medicines they need.

## Comment

Focusing on patents as the barrier to access to healthcare in the developing world is misleading and unhelpful when there are other significant barriers. The access problem stems primarily from poverty and an inability to pay for even the cheapest medicines, including patent free generic medicines. There is often chronic under-investment in healthcare infrastructure resulting in lack of clinics and hospitals, inadequate distribution networks, insufficient trained healthcare providers, and high levels of patient illiteracy. Other factors impeding access are taxes and tariffs that raise prices unnecessarily, and cultural factors such as stigma and discrimination in many parts of the world, and punitive laws deterring those most at risk from seeking essential HIV services.

In fact, few patents exist in many African countries and over 95% of the 300+ drugs on the WHO Essential Drugs List are not patent protected at all. First line treatments for killer diseases like malaria and TB are available as generic products at very low cost, and yet many people are still denied access to them.

A study published in 2002 reviewed the patent position for fifteen anti-retrovirals in 53 African countries and concluded that: “patents and patent law are not a major barrier to treatment access in and of themselves”<sup>50</sup>. Nevertheless, it is true that, unless licensed, a patent can also prevent production or sale of lower cost, generic medicines or development of novel formulations. This is particularly the situation for the more recently introduced anti-retroviral medicines and certain fixed dose combination products.

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50 [http://iipi.org/wp-content/uploads/2010/07/Antiretroviral\\_Article.pdf](http://iipi.org/wp-content/uploads/2010/07/Antiretroviral_Article.pdf)

The research based pharmaceutical companies, sometimes working in partnerships with their competitors, have developed new HIV/AIDS medicines including anti-retrovirals that have helped save millions of lives in the global fight against HIV/AIDS. UNAIDS has reported that in 2012 approximately 35 million people are now living with HIV/AIDS of which 1 in 20 adults are in sub-Saharan Africa accounting for 69% of people living with HIV worldwide. Further, since 1995, treatment with anti-retrovirals has added 14 million life-years in low- and middle-income countries, including 9 million in sub-Saharan Africa<sup>51</sup>.

In addressing the access problem in developing countries, the research based companies have adopted varying approaches to improve access, such as differential pricing, donations, voluntary licensing and capacity building. Some of these, such as differential pricing and capacity building, are relevant whether or not there are patents on the medicines concerned. This is often the case in least developed and low-income countries. A number of global companies have joined in patent pooling arrangements such as the Medicines Patent Pool<sup>52</sup>. This was set up under the auspices of UNITAID<sup>53</sup> working with a range of stake-holders to create a pool of relevant patents for sub-licensing and product development of key HIV therapies as well as fixed-dose combinations and paediatric formulations.

The independent Access to Medicines Index Foundation<sup>54</sup> has recently reported that: “the world’s leading pharmaceutical companies are doing increasingly more to improve access to medicine in developing countries. More companies are experimenting with innovative access-oriented business models, companies are granting more licenses for making and distributing generic versions of their products, and companies continue to improve their oversight of access policies and activities. Yet progress is uneven. The industry struggles to perform well in two important areas: companies remain conservative in their approach to patents, and all but two have been the subject of settlements or decisions relating to ethical marketing, bribery or corruption standards or competition laws in the last two years.”

“There is a fundamental truth about AIDS – new medicines and vaccines are needed. We do not yet have a cure for AIDS. We do not have a vaccine for AIDS. Existing medicines are less and less effective as resistance to them grows. Patent protection is of critical importance to the research based industry. If there is no patent protection, there will be no R&D. And if there is no R&D, there will be no new medicines and vaccines.” – **public policy statements: GlaxoSmithKline**<sup>55</sup>

51 [http://www.unaids.org/sites/default/files/en/media/unaids/contentassets/documents/epidemiology/2012/gr2012/20121120\\_UNAIDS\\_Global\\_Report\\_2012\\_with\\_annexes\\_en.pdf](http://www.unaids.org/sites/default/files/en/media/unaids/contentassets/documents/epidemiology/2012/gr2012/20121120_UNAIDS_Global_Report_2012_with_annexes_en.pdf)

52 <http://www.medicinespatentpool.org/>

53 <http://www.unitaid.eu/en/>

54 <http://www.accesstomedicineindex.org/index-publications>

55 <http://www.gsk.com/media/280860/ip-atm-developing-countries-policy.pdf>

## Suggested further reading:

- “Developing world health partnerships”: International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) – 2012<sup>56</sup>
- “Towards zero infections” – UK position paper on HIV in the developing world – Department for International Development (DfID) – May 2011<sup>57</sup>
- “Patents versus patients: five years after the Doha declaration” – OXFAM paper – Nov 2006<sup>58</sup>
- “Evidence on access to essential medicines for the treatment of HIV/AIDS” – Charles River Associates summary paper – 2013<sup>59</sup>
- UNAIDS reports on the global AIDS epidemic – 2012, 2013<sup>60</sup>
- IFPMA policy position – patent licensing – Feb 2015
- Intellectual Property & Access to Medicines in Developing Countries – Public policy statements – GlaxoSmithKline<sup>55</sup>
- “Access to medicines is a global problem” – Pharmaceutical Journal editorial – 2 Oct 2014<sup>61</sup>

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56 <http://partnerships.ifpma.org/pages/>

57 <http://www.dfid.gov.uk/Documents/publications1/twds-zero-infs-pos-paper-hiv-dev-wrld.pdf>

58 <http://www.oxfam.org/sites/www.oxfam.org/files/Patents%20vs.%20Patients.pdf>

59 [http://www.ifpma.org/fileadmin/content/Publication/2013/web\\_Brochure\\_CRA\\_IFPMA.pdf](http://www.ifpma.org/fileadmin/content/Publication/2013/web_Brochure_CRA_IFPMA.pdf)

60 [http://www.unaids.org/en/resources/campaigns/20121120\\_globalreport2012/globalreport](http://www.unaids.org/en/resources/campaigns/20121120_globalreport2012/globalreport)

61 <http://www.pharmaceutical-journal.com/opinion/editorial/access-to-medicines-is-a-global-struggle/20066682.article>