

# 02

## The Problem of Patents and Access to Medicines in Middle Income Countries

**Middle Income Countries are today bearing the brunt of increasingly strong international trade rules that govern how these countries design and implement intellectual property (IP) regimes. These are countries where the World Trade Organisation (WTO) Agreement on intellectual property (TRIPS) is fully implemented creating barriers to access to generic medicines.**

### Understanding the Terminology

**Middle Income Countries:** The phrase “middle income countries” originates from the World Bank classification of countries. It was introduced nearly three decades ago and is meant to inform World Bank lending, financing and other policies. For the current 2018 fiscal year, low-income economies are defined as those with a Gross National Income (GNI) per capita of \$1,005 or less in 2016; lower middle-income economies are those with a GNI per capita between \$1,006 and \$3,955; upper middle-income economies are those with a GNI per capita between \$3,956 and \$12,235; high-income economies are those with a GNI per capita of \$12,236 or more.<sup>1</sup> It is notable that several Least Developed Countries (LDCs) also feature in the list of lower middle-income countries; this is due to the sole focus of this classification being on income to the exclusion of all other economic, social, political and other indicators such as the fact that one-third of people living in middle-income countries survive on less than US\$2 per day; according to the World Bank itself 73% of the world’s poor people live in middle income countries.<sup>2</sup>

**Developing Countries:** The phrase “developing countries” used by the WTO applies to two-thirds of the membership of the WTO. There is no methodology at the WTO to classify developed or developing countries; countries choose the classification they want. Being a developing country at the WTO provides certain concessions or transition periods. LDCs within the WTO are however based on the UN classification discussed below. Apart from the LDCs below and the countries that have opted for the developed country classification all other countries at the WTO are developing countries.

**Least Developed Countries:** “Least Developed Countries” (LDCs) represent the poorest countries in the world. Based on three criterion administered by the United Nations (UN) including low income, human resource weakness and economic vulnerability, 47 countries are currently designated LDCs.<sup>3</sup> Of these, 36 are members of the WTO.<sup>4</sup> Although several LDCs are now classified by the World Bank as being “Lower Middle Income,” as long as these countries remain on the UN’s LDC list, they are entitled to various transition periods and other flexibilities within the WTO rules including in relation to patents.

**For the purposes of this briefing document, the phrase ‘middle income countries’ refers to those countries classified as developing countries at the WTO.**

### Health Burdens in Middle Income Countries

Middle-income countries are home to almost half of the world’s population, and have a large and growing share of HIV infections (62%). They have lower rates of antiretroviral treatment coverage than low-income countries. For instance, around 2.1 million people living with HIV in the Asia–Pacific region had access to antiretroviral therapy in 2015, which accounts for approximately one in three people living with HIV.<sup>5</sup> Eastern Europe and central Asia is the only region in the world where the HIV epidemic continued to rise rapidly, with a 57% increase in annual new HIV infections between 2010 and 2015.<sup>6</sup> In the case of hepatitis C, the overwhelming burden of disease lies in middle

1. [<https://blogs.worldbank.org/opendata/new-country-classifications-income-level-2017-2018>].

2. [<http://www.worldbank.org/en/country/mic/overview>].

3. [<https://www.un.org/development/desa/dpad/least-developed-country-category/ldcs-at-a-glance.html>].

4. [[https://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org7\\_e.htm](https://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm)].

5. [<http://www.aidsdatahub.org/#tabs-3>].

6. [<https://www.avert.org/professionals/hiv-around-world/eastern-europe-central-asia>].

income countries. The incidence of non-communicable diseases (NCDs) is also on the rise in middle income countries. "Developing countries now account for around 70% of all cancer deaths. Many of these people die without treatment, not even pain relief."<sup>7</sup>

### TRIPS Implementation

Since 2005, all developing countries who are members of the WTO are implementing the TRIPS Agreement and granting 20 years patents on pharmaceutical products.

### High Prices of Patented Medicines

The impact of the resulting high priced patented medicines is being felt directly by patients and government programmes. A 2014 WHO report found widely varying prices for HIV medicines in middle income countries impacted by their patent status and licensing deals.<sup>8</sup> Middle income countries outside Africa are facing particularly high prices. "Pharmaceutical companies are selling antiretrovirals to non-African middle-income countries at prices 74–541% higher than African countries with similar gross national incomes."

### Exclusion from voluntary licenses and price discounts

For middle income countries in Latin America and Asia, multinational pharmaceutical companies are withdrawing<sup>9</sup> lower prices for their medicines and excluding<sup>10</sup> several of these countries from voluntary licenses with generic companies including those being negotiated by the Medicines Patent Pool (MPP) and UN agencies.

A clear example has been the case of the new HIV drug dolutegravir. Patented by ViiV Healthcare, this drug is very effective in reaching viral suppression quickly, has a high genetic barrier to drug resistance, and requires very low dosage, making it safer and, interestingly, cheap to produce. A voluntary licence issued by ViiV to the Medicines Patent Pool (MPP) (VL) in 2014 excludes 48 upper-middle income countries meaning approximately 3.5 million people living with HIV are blocked from accessing generic dolutegravir. In countries including China, Columbia, Kazakhstan, Malaysia, Moldova and Peru, ViiV Healthcare has successfully filed patents blocking access to affordable generic versions of dolutegravir. To make matters worse for the excluded countries, in 2017 a pricing agreement was announced by several development agencies including UNAIDS and WHO of USD 75 per person per year but limited this to only those countries included in the ViiV-MPP VL.<sup>11</sup>

### Disappearing International Aid

Access to international aid for middle income countries, particularly from the Global Fund, is decreasing<sup>12</sup> According to a 2016 report by UNAIDS and the Kaiser Foundation, "donor government disbursements for HIV fell for the second year in a row, dropping from US\$7.5 billion in 2015 to US\$7.0 billion in 2016 (a \$511 million or 7% decline), in current USD, bringing disbursements to their lowest level since 2010."

### Increasing pressure from lobbying, litigation and trade agreements

Any use of TRIPS flexibilities in developing countries attracts lengthy litigation from patent holders and unilateral trade pressures from developed countries like the annual US Special 301 Report.<sup>13</sup> Many of these countries are also in FTA negotiations or have already signed FTAs with developed countries that impose even greater IP protection requirements than the WTO or what are often referred to as TRIPS+ provisions.

### Importance of TRIPS flexibilities

Across Asia and Latin America, and even some parts of Africa, countries are facing the full force of cynical patenting, pricing and licensing policies of patent holders on the one hand and trade pressures of developed countries on the other. To deal with the high prices of patented medicines, several developing countries are using TRIPS flexibilities like compulsory licenses and strict patent criteria to ensure continued access to affordable generic medicines. The right of all WTO members to use these flexibilities was reiterated in 2001 in the Doha Declaration on TRIPS and Public Health which stated that "the (TRIPS) Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all".<sup>14</sup> The reality is that over 15 years after the Doha Declaration most countries have yet to include the full extent of these flexibilities in their national laws. Middle income countries should commit to the inclusion to the full extent of TRIPS flexibilities in the laws and their consistent and routine use to ensure access to affordable medicines.

7. [<http://www.who.int/dg/speeches/2014/wha-19052014/en>].

8. [[http://www.who.int/phi/publications/WHO\\_Increasing\\_access\\_to\\_HIV\\_treatment.pdf?ua=1](http://www.who.int/phi/publications/WHO_Increasing_access_to_HIV_treatment.pdf?ua=1)].

9. [<https://www.theguardian.com/global-development/2011/jul/22/hiv-aids-antiretroviral-drugs-pricing>].

10. [[http://msmgf.org/wp-content/uploads/2015/09/Access\\_Challenges\\_for\\_HIV\\_treatment\\_RAPs.pdf](http://msmgf.org/wp-content/uploads/2015/09/Access_Challenges_for_HIV_treatment_RAPs.pdf)].

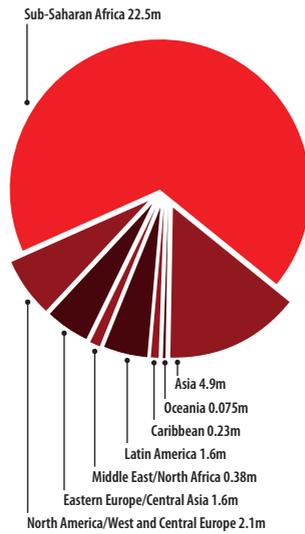
11. [[http://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2017/september/20170921\\_TLD](http://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2017/september/20170921_TLD)].

12. [[http://www.globalfundcommunitiesdelegation.org/wp-content/uploads/2016/09/Myths-Facts\\_Donor-Funding-for-Global-AIDS.pdf](http://www.globalfundcommunitiesdelegation.org/wp-content/uploads/2016/09/Myths-Facts_Donor-Funding-for-Global-AIDS.pdf)].

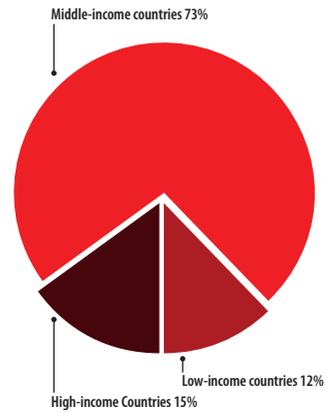
13. [<https://ustr.gov/issue-areas/intellectual-property/Special-301>].

14. [[https://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/minded\\_trips\\_e.htm](https://www.wto.org/english/thewto_e/minist_e/min01_e/minded_trips_e.htm)].

**FIGURE 1** People living with HIV



**FIGURE 2** Distribution of people living with HCV in low-income countries, middle-income countries and high-income countries



Argentina has around 126,000 people living with HIV, of which fewer than 70,000 people are on antiretroviral therapy. The high prices of drugs limits the number of people who can get treatment.



In Brazil, 780,000 people are living with HIV; 405,000 are on HIV treatment. All patients get treatment free from the public health system which, as a result of the high price of drugs, is under severe strain.



An estimated half a million people live with HIV in Thailand. Of these people almost 300,000 are on HIV treatment under a national health insurance scheme paid for by the government.



Ukraine has over 250,000 people living with HIV, of which around 61,000 people are on antiretroviral therapy. According to the National Treatment Program over 118,000 people will be receiving treatment by 2018.