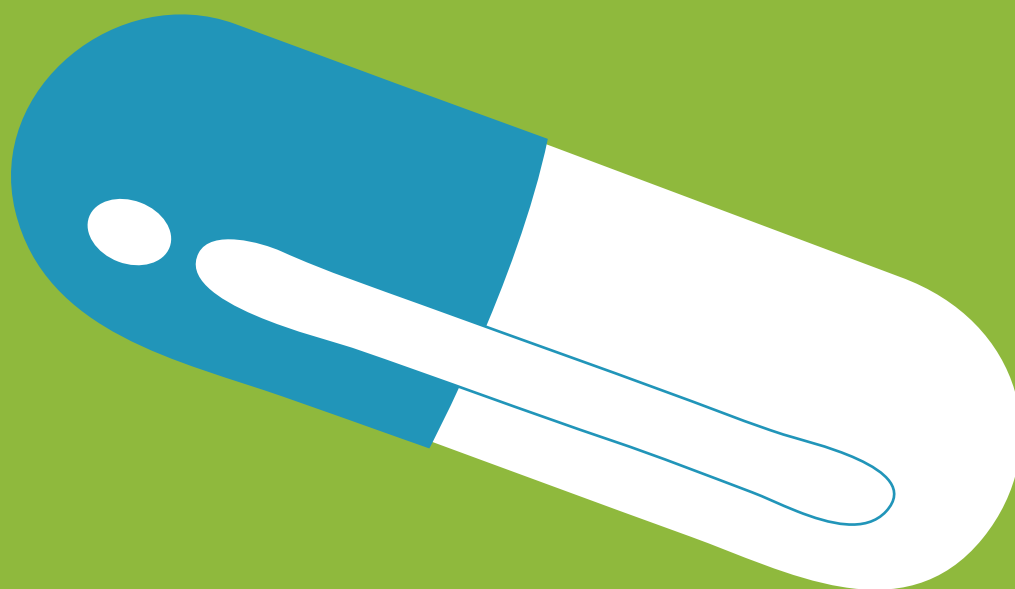




*Empowered lives.
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INTELLECTUAL PROPERTY RIGHTS AND ACCESS TO AFFORDABLE ARVS IN CHINA



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INTRODUCTION

The paper attempts to document the recent developments, opportunities and challenges in intellectual property rights and access to affordable medicines in China. The structure of the paper is as follows. Firstly, the paper starts with the epidemiological situations on HIV and hepatitis B in China (section A) and briefly describes the national response to the problem of access to antiretrovirals (ARVs) (section B). Secondly, it analyzes the situation of local production and exports of finished ARVs and active pharmaceutical ingredients (APIs) (section C). Thirdly, the importance of flexibilities allowed under the Agreement on Trade Related Aspects of Intellectual Property Rights ('TRIPS Agreement') is highlighted (section D), followed by an analysis of such flexibilities in China's intellectual property regime (section E). Finally, the role of civil society in improving prevention and treatment of HIV and access to ARVs is discussed.

A PREVALENCE OF HIV IN CHINA

A.1 How large is the epidemic?

The first case of HIV in the People's Republic of China was reported in 1985. According to the *2012 China AIDS Response Progress Report* by the Ministry of Health, by the end of 2011, the cumulative reported number of people living with HIV (PLHIV) was about 445,000 cases (up from 230,643 cases at the end of 2007). Of these 174,000 were AIDS cases. The number of cumulative AIDS-related deaths was reported to be 93,000.¹

Case reporting data shows that from 2007 to 2011, the number of reported HIV and AIDS cases (including people living with HIV who have developed AIDS) has increased each year, with the figures for each year standing at 48,161, 60,081, 68,249, 82,437 and 92,940 respectively. The numbers of newly diagnosed cases and deaths also increased each year, with the figures standing at 10,742, 14,509, 20,056, 34,188 and 39,183, as well as 5,544, 9,748, 12,287, 18,987 and 21,234 respectively.²

In recent years, the proportion of reported cases accounted for by homosexual and heterosexual transmission has increased year on year. The proportion of cases resulting from sexual transmission increased from 33.1 percent in 2006 to 76.3 percent in 2011. The proportion arising from homosexual transmission increased from 2.5 percent in 2006 to 13.7 percent in 2011³.

Epidemic estimates show that at the end of 2011, the estimated number of PLHIV in China stood at 780,000 people. Of these, 28.6 percent were women. There were 154,000 cases of AIDS among the total estimation and the overall prevalence stood at 0.058 percent. The estimated number of new infections in 2011 was 48,000 and the estimated number of deaths was 28,000. Of the 780,000 people estimated to be living with HIV, 46.5 percent were infected through heterosexual transmission, 17.4 percent through homosexual transmission, 28.4 percent through injecting drug use, 6.6 percent were former blood donors or transfusion recipients, and 1.1 percent were infected through mother-to-child transmission⁴.

1 UNAIDS, 2012 AIDS Response Country Progress Report: <http://www.unaids.org/en/dataanalysis/monitoringcountryprogress/progressreports/2012countries/>

2 Ibid.

3 Ibid.

4 Ibid.

PLHIV account for 0.058 percent (0.046-0.070 percent) of the total population making China still a low-prevalence country. However the epidemic is severe in some areas. At the end of December 2011, 31 provinces (or autonomous regions, municipalities) had reported HIV cases. 93.2 percent (2,885 of 3,095) of counties (or districts) had reported HIV cases. Variations in reported numbers of cases were quite significant between provinces. The six provinces with the highest number of reported HIV cases (from highest number: Yunnan, Guangxi, Sichuan, Henan, Xinjiang, Guangdong) accounted for 75.5 percent of the total number of reported cases nationwide. The seven provinces with the fewest reported cases of HIV (Tibet, Qinghai, Ningxia, Inner Mongolia, Gansu, Tianjin, Hainan) accounted for 1.2 percent of the total number of reported cases nationwide. The 20 counties (or districts, cities) with the highest number of reported cases of HIV were all located within Yunnan, Guangxi, Xinjiang, Henan and Sichuan.⁵

The *2012 China AIDS Response Progress Report* describes China's HIV epidemic as exhibiting five major characteristics: i) national prevalence remains low, but the epidemic is severe in some areas; ii) the number of PLHIV continues to increase, but new infections have been contained at a low level; iii) there is gradual progression of HIV to AIDS resulting in an increase of the AIDS-related deaths; iv) sexual transmission, particularly among men who have sex with men, is the primary mode of transmission, and continues to increase; v) China's epidemics are diverse and evolving.

One of the major challenges that emerged in this context is the high cost of antiretroviral medicines (ARVs), the bulk of which continues to be imported today, due significantly to patent protection granted to foreign manufacturers. As discussed below, today there is the dichotomy of China being the world supplier of active pharmaceutical ingredients for ARVs, without a corresponding production of generic ARVs for its citizens and millions of patients in other developing countries.

Interface between HIV and tuberculosis (TB)

HIV and TB are so closely connected that they are often referred to as co-epidemics or dual epidemics. There is growing concern that successes in battling TB are being undermined and may even be negated by co-infection of HIV and TB, as well as increasing resistance to TB drugs. People living with HIV are 21-34 times more likely to develop TB in a given year than HIV-negative people. TB is a leading killer of people living with HIV, causing one quarter of all deaths. In 2010 and 2011, the proportions of people estimated to be co-infected with HIV and TB who received combined treatment for HIV and TB stood at 44.8 percent and 35.6 percent respectively.⁶

China was one of the 22 countries with the highest TB burden as identified by the WHO in 2008. China, however, has made dramatic progress in TB control. Between 1990 and 2010, the TB death rate in the country fell by almost 80 percent and the total number of people ill with TB dropped by half.⁷ It also has the largest DOTS (Directly Observed Treatment, Short-course) programme, a

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