
THE RIGHT TO HEALTH - LESSONS FOR COVID-19 FROM THE HISTORY OF HIV



Preface

In 2020, COVID-19 has wrought global health and economic devastation on a level not seen in our lifetimes. Beyond its immediate and direct effects, COVID-19 could further disrupt health systems by increasing loss of life from HIV, tuberculosis (TB) and malaria by up to 10%, 20% and 36% respectively over the next five years in developing countries with high burdens of these diseases.ⁱ The World Bank also estimates that the pandemic will push between 88 and 115 million additional people into extreme poverty this year, with that number likely to rise.ⁱⁱ In one formulation, COVID-19 has set back global development progress 'about 25 years in about 25 weeks'.ⁱⁱⁱ

Although it is a universal concern, COVID-19 has very different impacts on individuals depending on their citizenship, wealth and existing health status. As everyone, everywhere is feeling its effects, timely and equitable access to COVID-19 Treatment for the greatest number globally will be vital if any nation is to chart a course out of this pandemic.

This report looks back on ongoing pandemics – particularly HIV, but also TB – to see what we can learn from them in relation to the Right to Health and about access to life-saving

medications that could be used in ensuring such access globally for drugs and vaccines to treat and prevent COVID-19.

The report was also prompted by who we are. RESULTS International (Australia) is a movement of passionate, committed everyday people who use their voices to influence political decisions that will bring an end to poverty. We believe that, no matter where people are born, everyone should have equal opportunities to fulfil their potential in life. This means having access to basic health care, quality education and fair economic participation. We, therefore, believe in an equitable, needs-based – rather than purely economically-determined – and global distribution of treatments and vaccines for COVID-19.

We are part of ACTION, a global advocacy partnership that works to influence policy and mobilise resources to fight diseases of poverty and achieve equitable access to health. ACTION works across five continents, with a particular focus on addressing TB and child survival (in particular, immunisation and child malnutrition). Several ACTION partners from countries that feature in this report have provided expert commentary on drafts, and we thank them for their assistance.



Hilda Simon (mother) and her baby Matilda at the Malahang Health Clinic where the Polio Vaccine is administered to children in Lae, Marobe Province, Papua New Guinea. A confirmed Vaccine Derived Polio Virus (VDPV) in Lae was reported to WHO on 21 June, 2018. Four rounds of supplementary immunisation activity (SIA) targeting children less than five years of age were planned from July to October 2018, to combat the virus.

Introduction

COVID-19 pandemic

On 30 January 2020, the World Health Organisation (WHO) declared the novel coronavirus outbreak (COVID-19) a public health emergency of international concern.

Since the WHO's announcement, governments worldwide have been forced to take rapid action to control the outbreak of COVID-19, with different levels of success in lowering (or in some cases, eliminating) community transmission of the virus.

The response to COVID-19 has varied greatly from country to country, but the common theme of unprecedented disruption to everyday life has emerged globally. The UN's International Labour Organization predicts that 1.6 billion informal economy workers could suffer "massive damage" to their livelihoods, and in the second quarter of 2020, COVID-19 may cost the equivalent of 305 million full-time jobs as the travel, hospitality, retail and essential services sectors are forced to cut costs.^{iv} Not surprisingly, COVID-19 has also caused a huge strain on even the most robust healthcare systems.^v

With so much at stake, the race is on to develop pharmaceutical treatments and/or vaccines for COVID-19 (COVID-19 Treatment). A large number of trials are already underway to test the safety and efficacy of COVID-19 Treatment.^{vi} While governments in developed countries have pledged to make COVID-19 Treatment available to the public,^{vii} it remains to be seen whether COVID-19 Treatment will be equally accessible for developing countries. As COVID-19 has now shut down major economies and decimated the travel and tourism industry, it is clear that a national approach to providing access to COVID-19 Treatment is not beneficial for global health or economics, nor advisable.

By examining how governments in developing countries have responded to previous health crises and the interaction between the right to health and protection of intellectual property (IP), this report illustrates some of the most productive pathways by which to advocate for and facilitate equal access to a COVID-19 Treatment. It examines how various countries have dealt with issues arising from access to health, IP laws and management of various health crises (such as HIV) and contextualises a number of possible responses to the COVID-19 pandemic (once a COVID-19 Treatment has been developed). The case studies we will summarise in this report are India, Indonesia, Kenya, Papua New Guinea, and South Africa (Case Study Countries).

Lessons to learn from the HIV/AIDS epidemic

The lack of access to medicines in developing countries is not novel. The HIV epidemic is still one of the world's most serious health challenges to date. As at 13 July 2020, approximately 38 million people are living with HIV and tens of millions of people have died of AIDS-related causes since the beginning of the pandemic.^{viii}

Many people living with HIV or at risk for HIV infection do not know their HIV status and/or do not have access to treatment and care. Although there is still no cure, HIV can be treated and well managed.

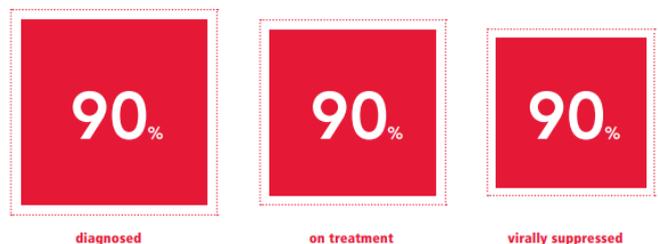
The same goes for TB, which is a treatable and curable disease. In 2019, a total of 1.4 million people died from TB, including 280,000 people who had been living with HIV.^{ix} People living with HIV are more susceptible to TB, which is the leading cause of death for people living with HIV, claiming over one in four lives of people living with HIV.^x

Accessing treatment, whether for HIV, TB or COVID-19, is therefore paramount in countries like South Africa (which historically reports among the highest rates of HIV globally) and India (with the world's highest incidence of TB). This is particularly pertinent since, as of September 2020, both countries ranked amongst the top 10 countries globally for absolute numbers of COVID-19 cases.^{xi}

Since the beginning of the HIV pandemic in 1981, there has been a considerable effort from governments worldwide to lower HIV transmission rates and increase access to HIV drugs and treatment, i.e. antiretroviral therapy (ART).

A number of countries – especially those that have the highest rates of HIV (such as South Africa) – have pledged to achieve the "90-90-90" goal created by UNAIDS, which aims to ensure that, by 2020:

- 90% of all people living with HIV will know their HIV status;
- 90% of all people with HIV will receive sustained ART; and
- 90% of all people receiving ART will have viral suppression (90-90-90 Goal).^{xii}



In fact, although there is no cure or vaccine for HIV, certain countries like India have nevertheless managed to reduce the number of new HIV infections by 56% since 2010.^{xiii}

Examining the successes and struggles faced by governments and advocates in facilitating access to ART and treatments for other epidemic diseases offers us valuable sight for the road ahead to ensure that COVID-19 Treatment (when it is available) is accessible and affordable for all individuals, irrespective of their socio-economic status and geographic location.

The Right to Health

A Human Rights-Based Approach to Health

The notion of a fundamental "Right to Health" (Right to Health) is indivisible from and interdependent on other human rights, such as the rights to food, education and work. This means that achieving the Right to Health is both central to, and cannot be enjoyed without, the realisation of these other rights.^{xiv}

As with other rights, the Right to Health includes both *freedoms* (to control one's own health and body, free from interference) and *entitlements* (for example, to a health system that provides equal opportunities for everyone to enjoy the highest attainable level of health).^{xv}

A *rights-based approach* to health provides clear principles for setting and evaluating health policy and service delivery. Accordingly, health programs should be designed to improve all people's enjoyment of their Right to Health, with a focus on groups that are most disadvantaged, face the greatest obstacles to accessing quality and affordable healthcare, and are thereby prevented from enjoying good health.^{xvi}

The core standards of a rights-based approach are summed up in what have become known as the 'PANEL Principles'.

One of the PANEL Principles articulated is 'Legality'. How then do countries enforce the Right to Health in their legal systems? Several international law treaties have codified the Right to Health, and some of our Case Study Countries have declared that these treaties form part of their domestic legal framework, as outlined in the table below.

If countries recognise the Right to Health as a fundamental human right, it follows that this Right should also be codified within domestic legal frameworks and implemented in practice.



Participation

People should be involved in the decision making which affects their Right to Health



Accountability

Stakeholders should be held accountable when people's Right to Health is being affected



Non-discrimination and equality

All forms of health-related discrimination should be prohibited, prevented and eliminated



Empowerment

Everyone should understand their Right to Health and be fully supported to take part in developing health policy and practices which affect their lives



Legality

The Right to Health should be established in local and international law

International obligations

Universal Declaration of Human Rights (UDHR)

A milestone document adopted by the UN General Assembly in Paris on 10 December 1948, which sets out (for the first time in human rights history) the requirement for fundamental human rights to be universally protected, including the right to life, liberty and security.

Case study countries:

India
South Africa (abstained)

Committee on Economic, Social and Cultural Rights (CESCR)

This committee has stipulated that the Right to Health necessarily includes the right to accessing health facilities, goods and services on a non-discriminatory basis.

Case study countries:

India
South Africa



International Covenant on Civil and Political Rights (ICCPR)

A multilateral treaty adopted by the UN General Assembly in Paris on 16 December 1966, requiring signatory parties to respect the civil and political rights of citizens, including the right to life.

Case study countries:

India (1979)
Indonesia (2006)
Kenya (1976)
Papua New Guinea (2008)
South Africa (1999)

International Covenant on Economic, Social and Cultural Rights (ICESCR)

A multilateral treaty adopted by the UN General Assembly on 16 December 1966, requiring signatory parties to commit to granting economic, social and cultural rights, including the Right to Health.^{xvii}

Case study countries:

India (1979)
Indonesia (2006)
Kenya (1972)
Papua New Guinea (2008)
South Africa (2015)

The connection between intellectual property and the Right to Health



Our access to medicines is directly linked to the way in which medicines and vaccines are made available by the government entities on which we rely. Medicines are produced and distributed globally within the framework of international trade and IP law.

The global IP regime

Prior to the globalisation of IP rights, IP laws and patenting practices differed from country to country and, in particular, between developed and developing countries. The patenting of essential goods such as medicines and foods was considered an act against the public interest.^{xviii}

This all changed in 1995, when the Treaty on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) was introduced, setting out minimum standards for IP regulations amongst participating World Trade Organization (WTO) members. Article 7 of TRIPS provides that the treaty not only serves to protect the private rights of innovators but the broader public interest. Article 7 must also be read alongside the 2001 Doha Declaration (Doha Declaration), which allows countries the ability to implement TRIPS in a manner that takes into account their specific needs with regard to health and access to medicines.^{xix}

TRIPS Flexibilities

There are legal mechanisms built into TRIPS to overcome patent barriers and allow developing countries to acquire the medicines they need for the treatment of high-priority diseases such as HIV (TRIPS Flexibilities). It should be noted, however, that most uses of TRIPS Flexibilities are for HIV medications.^{xx} Despite months of intense negotiation to have the TRIPS Flexibilities included in the 2018 'Political declaration of the high-level meeting of the General Assembly on the fight against tuberculosis', the meeting's final Declaration affirms TRIPS but does not explicitly mention the TRIPS Flexibilities.^{xxi}



Workers look at the filling process of HepB vaccine filled in Uniject syringes at a Bio Farma serum factory in Indonesia.

The TRIPS Flexibilities include the use of Compulsory Licencing (see India below) and parallel importation (see Kenya). Compulsory Licenses in particular have made a considerable impact on the facilitating the production and export of low-cost generic medicines to countries with insufficient or no pharmaceutical manufacturing capacity (previously generic medications were only allowed to be distributed within the domestic market in which the medications were manufactured).^{xxii}

Compulsory Licencing has also been utilised by countries such as Thailand, which have increased access to ART and treatments for cardiovascular disease and cancers. India also allows the production of generic drugs under Compulsory Licence for export to countries without manufacturing capacity within its domestic IP regime, the Indian Patents Act 1970.^{xxiii}

Although the TRIPS Flexibilities seem to offer countries a means to remove barriers to accessing health care, applicants are often inundated by procedural hurdles and delays throughout the Compulsory Licencing application process, leading many to criticise the efficiency and sustainability of the Compulsory Licencing regime.^{xxiv}

For example, if a Compulsory Licence is granted by a government body, TRIPS provides limits on generic manufacturers to producing only the quantities predefined in each Compulsory Licence, which could lead to medicines becoming unaffordable in the long run (see 'Indonesia' and 'South Africa' below).^{xxv} As a result, very few countries have made proper use of TRIPS Flexibilities and Compulsory Licencing is hardly ever recognised as a means to reduce the price of drugs on a broad scale.^{xxvi}

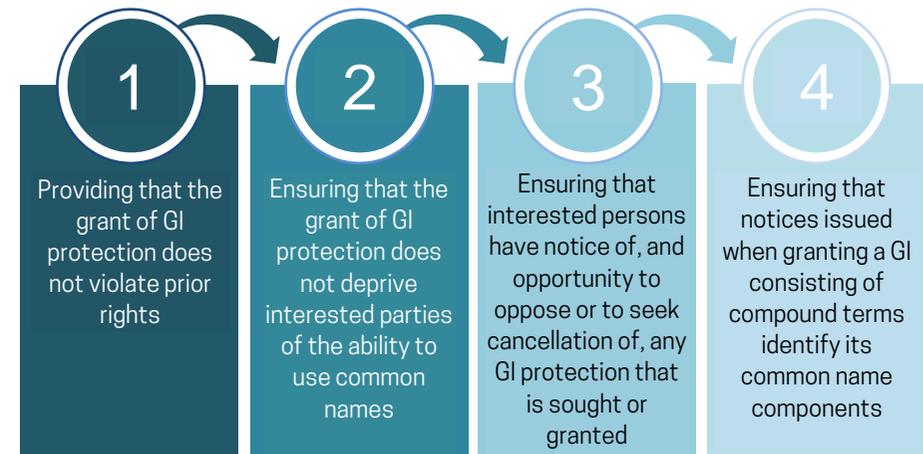
Trade sanctions

Non-compliance with TRIPS may also result in trade sanctions. In 1992, the US carried out a number of trade sanctions by suspending tariff exceptions for Indian pharmaceutical products, which caused a US \$60 million loss in Indian pharmaceutical exports. Thailand has also been pressured by the US and the EU for its issuance of Compulsory Licences in 2006-2007.^{xxvii}

The United States Trade Representative (USTR) is allowed to take action against participating WTO members for failure to protect IP rights. The USTR published the 2020 Special 301 Report (Special Report), which put India and Indonesia on the Priority Watch List for posing the greatest threat to breaches of IP.^{xxviii}

The USTR is also engaging various countries (including South Africa) with respect to protecting its geographical indications provisions (GI) and third-country markets on U.S. producers and traders, specifically regarding trademark rights and the United States.^{xxix} The Special Report provides several goals regarding trade protectionism:^{xxx}

Goals of the Special Report to protect United States Geographical indications in South Africa^{xxx}



The Special Report also provides an overview of key gaps in enforcing IP protection, and discusses ways that governments can combat the trade in counterfeit goods that poses threats to the United States' global supply chains.

Whilst these measures may control corruption, developing countries face greater difficulties as they cannot compete with the heavyweight innovators, such as the United States. Developing countries find themselves having to choose between the expensive original product or an unlawful copy of the original, and therefore are more likely to access the illegal copy.^{xxxi} These enforcement regimes and hard-line approach may deter access to COVID-19 Treatment for developing countries, significantly burdening their economies, especially in places like South Africa, which has one of the world's highest rates of COVID-19.

Effect on drug prices

Another consequence of TRIPS is that it artificially inflates the price of pharmaceuticals during the 20-year period when the patent holder has a monopoly over their invention. This monopoly has been detrimental to facilitating access to ART, and may also be detrimental to facilitating access to COVID-19 Treatment. In fact, there are already reports of pharmaceutical institutions filing for patents on experimental COVID-19 Treatment and subsequent public backlash against these patent applications.^{xxxii} An example of the discrepancy between drug prices in developed vs developing nations include the price of Atripla, a type of ART. Atripla costs approximately US\$1,300 a month, which is only affordable to individuals in industrialised countries with government benefits and robust healthcare systems.^{xxxiii} Further, the story of how the drug sofosbuvir was developed and distributed is a good example of how pharmaceutical companies have profited from the existing global IP regime. The cost of producing sofosbuvir is estimated to be AUD\$101 per treatment, yet the price of the product is AUD\$85,000 for a 12-week course.^{xxxiv}

Consequently while an individual living with HIV in a developed nation can live with their diagnosis and access ART, their counterpart in a developing nation may never be able to access such treatment because their country's health system is not robust or well-resourced enough to subsidise their treatment.

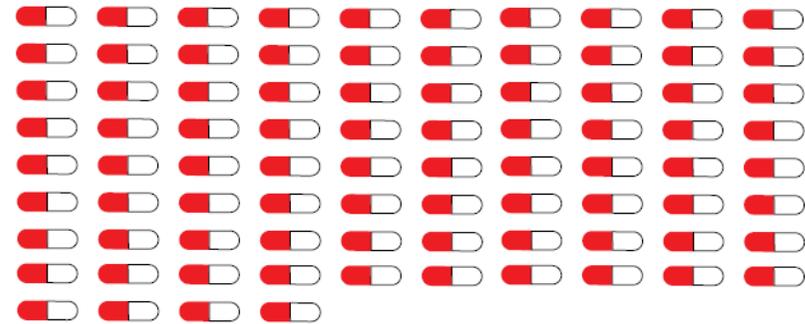
The issue of affordability is not exclusive to developing nations. For example, it is reported that Truvada, a type of ART that is shown to be up to 99% effective at preventing the spread of HIV, is not accessible for more than 90% of the 1.2 million Americans currently at high risk for exposure to HIV.^{xxxv}

The issue of affordability is also constantly evolving, hinging on each country's economic and financial constraints and budget thresholds for HIV treatment^{xxxvi}. Although the price of ART has decreased over the years, our research shows that this price reduction is only in respect of first-line ART. As people living with HIV develop resistance to first-line regimens and many often require newer, second-line and third-line ART, switching to these newer therapies can cost up to triple the price of treatment or a near 18-fold increase over the lowest prices for first-line ART.^{xxxvii}

In light of the various legal barriers to implementing the Right to Health, how then does each Case Study Country deal with the hurdles faced under TRIPS or international trade pressures?

PRICE OF 12-WEEK COURSE OF SOFOSBUVIR IN US:

\$84,000 (84 PILLS)



Source: MSF, "Lives on the Edge: Time to Align Medical Research and Development With People's Health Needs" (May 2016)

Case Study Countries - Asia



- Global powerhouse of generic pharmaceutical manufacturing
- Strong domestic legal framework to enshrine Right to Health, with the enactment of the HIV and AIDS (Prevention and Control) Act 2017
- High threshold for new patents and incorporation of a 'public health safeguard' in IP regime
- Effective utilisation of TRIPS Flexibilities through issuing of Compulsory Licences

India

General

India is one of the world's leading global suppliers of affordable generic medicines. It is reported that India supplies 80% of ART for the developing world^{xxxviii} and supplies products to many countries where these products were not patented (at a fraction of the price being offered by patent-holding multinational pharmaceutical companies) or where Compulsory Licences have been issued.^{xxxix}

Human rights framework

India is able to maintain its position as one of the world's leading global suppliers of affordable generic medicines due to its prioritisation of the Right to Health, its robust national IP regime and careful incorporation of TRIPS, and its mandating in domestic law of the right to ART. India is also a signatory to the ICCPR, ICSECR, CRC and CEDAW.

Human rights framework in India



Constitution of India:

No person shall be deprived of his or her life or personal liberty except according to the procedure established by law.^{xi}

HIV and AIDS (Prevention and Control) Act 2017:

This legislation is the first of its kind. The new Act makes discrimination against people living with HIV/AIDS a punishable offence, prohibits isolation or segregation of a person living with HIV, and importantly, makes receiving ART a legal right for all people living with HIV.^{xii}

Intellectual property framework

The Indian Patents Act 1970 (IPA) abolished product patent protection in pharmaceuticals in order to ensure that medicines were available to the public at reasonable prices.

As TRIPS was being negotiated, India also lobbied against patent monopolies, arguing that TRIPS would likely create serious adverse effects in practice, especially in areas like food production and medicine distribution.

Regardless of such lobbying efforts, the IPA was amended in 2005 to align the patent regime in India with TRIPS. Understandably, there was concern that TRIPS would likely erode India's central role in supplying affordable medicines to developing countries. The Indian government faced domestic and international pressure from politicians, UN officials and NGOs to ensure that changes to the country's IP regime did not adversely affect India's ability and responsibility to continue its role as an international supplier of generic pharmaceuticals.

Incorporating TRIPS into domestic law

In response to TRIPS, the Indian government amended the IPA to incorporate a very high threshold in awarding patents for new products.^{xiii}

Significantly, the IPA:

- allows any person to oppose the granting of a patent,^{xliii}
- continues the production of medicines for which Mail-box Patent Applications were made between 1995 and 2005;^{xliv} and provides that Compulsory Licences shall be available for countries having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems.^{xlv}



Gavi, the Vaccine Alliance and its partners have played a key role in shaping the market conditions that have led to ever-growing demand for the pentavalent vaccine, which offers protection from diphtheria-tetanus-pertussis, Haemophilus influenzae type b (Hib) and hepatitis B (hepB). At present there are at least five Indian companies manufacturing the vaccine, one of them being The Serum Institute of India.

This amendment to the IPA meant that organisations such as the Indian Network of People Living with HIV/AIDS, the Manipur Network of Positive People and Delhi Network of Positive People, were able to oppose a number of patent applications in 2006, including against GlaxoSmithKline's patent application for combivir and tenofovir disoproxil fumarate, which were new types of ART.^{xlvi}

The Indian government also utilised TRIPS Flexibilities by issuing its first Compulsory Licence in March 2012. A cancer drug – which would have cost thousands of dollars a month – was made available to a greater number of people at 3% of the cost.^{xlvii}

The Indian patent regime also has a "public health safeguard" defence, which prohibits the patenting of new forms of existing pharmaceutical substances that do not demonstrate significantly enhanced efficacy, with the key purpose of preventing companies from obtaining subsequent patents for minor improvements to existing drugs before the expiry of the original patent. This public health safeguard defence was upheld by the Supreme Court of India in 2013, in a landmark decision against the pharmaceutical company, Novartis. This decision is widely recognised as a step in the right direction to enabling Indian pharmaceutical companies to continue producing and exporting low-cost generics for life-threatening illnesses like HIV.^{xlvi}

India's national medical programs and advocacy

India boasts the second-largest ART program in the world. Under the National AIDS Control Programme (NACP), the Indian government has been dispensing free ART and diagnostic services through a national network of 510 ART clinics. About 869,000 people living with HIV currently receive first-line and second-line ART through the NACP. The National AIDS Control Organisation (NACO) also provides free ART to people living with HIV^{xlvi} and the Link Workers Scheme reaches 84%^l of sex workers in the rural areas of about 100 districts with peer-led HIV prevention, testing and treatment services.^{li}

Advocacy groups like the Network of Maharashtra People with HIV have also successfully campaigned for the Indian government to provide free second-line ART where people living with HIV have developed resistance to first-line ART.^{lii}

The HIV and AIDS (Prevention and Control) Act 2017 also mandates a new test-and-treat policy that commits to providing access to ART for everyone living with HIV.^{liii}

As a result of ongoing efforts from advocacy groups and government cooperation, India has successfully brought down the rate of new HIV infections in recent years (new infections in 2015 saw a 32% decline from 2007).^{liv}

Case Study Countries - Indonesia



- Stigma and discrimination against people living with HIV in Indonesia is a significant barrier to the Right to Health
- Enforcing anti-discrimination laws is important to ensure change in community attitudes towards HIV/AIDS
- Consistent and accurate information about COVID-19 is important to curb misinformation
- The work of advocacy groups should not be understated

General

At the beginning of the COVID-19 pandemic in early 2020, the WHO's Director-General Dr Tedros Adhanmo Ghebreyesus warned that stigma poses more danger than the disease itself.^{lv}

This statement rings true in the case of Indonesia and its experience with COVID-19. It is reported that people thought to have COVID-19 and their close contacts experience social rejection in Indonesia.^{lvi} Further, testing rates for COVID-19 in Indonesia are among the lowest in the world, as many fear getting tested to avoid the risk of social rejection and exclusion.^{lvii}

Stigma around life threatening diseases in Indonesia (and other parts of the world) is not novel. Historically, people living with HIV and AIDS faced discrimination as a result of their diagnosis. The dangers of unaddressed stigma and discrimination cannot be understated. Indonesia has the world's fourth-largest number of new HIV infections per year: the WHO estimates that 73,000 people contract HIV annually behind only China, India and Russia. Whilst India has brought its HIV rates down, Indonesia is one of the few countries in the Asia-Pacific region where HIV prevalence is still increasing (and any recent decrease to these rates are very minor),^{lviii} concerningly, only 10-20% of Indonesians living with HIV were reported to be receiving ART at the end of 2018^{lix}, and the increase in HIV infection rates in Indonesia correlates with the increasing marginalisation of LGBTQ communities.^{lx}

The law in practice

While the Right to Health is enshrined in the Constitution and legislation, implementation and enforcement of this Right is not always seen in practice.

The Constitution of Indonesia

Every person shall have the right to live in physical and spiritual prosperity, to have a home and to enjoy a good and healthy environment, and shall have the right to obtain medical care.^{lxi}



Unlike India, Indonesia does not codify the requirement for people living with HIV to have access to ART. Although there are anti-discrimination laws in Indonesia that prohibit workplace discrimination and the implementation of punitive laws and policies on the grounds of HIV status, these laws do not always mandate protection nor secure ART access for individuals from all backgrounds who are living with HIV. In fact, Indonesia's former health minister has stated that these anti-discrimination policies were poorly enforced, noting that "*discriminatory treatment against people [living] with HIV in the workplace, especially when they are women*" can be easily identified in everyday life.^{lxii}



Outside of the workplace, HIV and AIDS-related discrimination is also prevalent. There are reports of police brutality against the LGBTQ community, which ultimately deters people who identify as LGBTQ and live with HIV from seeking ART for fear that disclosure of their sexuality or gender identity may lead to discrimination.^{lxiii}

Concerningly, HIV-related discrimination is not limited to key affected populations (i.e. the LGBTQ community). In February 2019, students as young as 14 diagnosed with HIV were expelled from a public elementary school following the demands from parents of other students, who feared that their own children would contract HIV/AIDS from contact with the students living with HIV.^{lxiv} Further, a ban on orphans living with HIV from attending school was also reported in North Sumatra in Indonesia.^{lxv}

Stigma and discrimination against people living with HIV can also occur when they seek healthcare. This is especially problematic given that healthcare providers are in a position of power relative to their patients. Health providers in Indonesia have reportedly minimised contact with patients living with HIV, delayed or denied them treatment, demanded additional payment for services and isolated people living with HIV from others in health-care settings.^{lxvi} Accordingly, people living with HIV may be discouraged from visiting hospitals or general community clinics given the level of stigma they encounter from healthcare providers. Some healthcare professionals in Indonesia also remain ignorant about HIV transmission routes and may hold discriminatory attitudes towards their patients' HIV status, behaviour, sexual orientation or gender identity.^{lxvii}



Local health worker preparing a vaccine at the launch of Indonesia's national measles-rubella immunisation campaign in Madrasah Tsanawiyah Negeri 10 Islamic junior high school in Sleman regency, Yogyakarta. August 2017.

TRIPS Flexibilities and drug prices

Even though the governments in India and Indonesia technically have the same tools to facilitate access to ART (i.e. these countries can utilise the TRIPS Flexibilities), these countries have different attitudes towards facilitating access to ART for people living with HIV. Indonesia was the second Asian country in the post-Doha Declaration period (around 2009) to issue a government-use authorisation in light of the "urgent need of the community in the effort to control the HIV/AIDS epidemic".^{lxviii}

Between 2004 and 2012, the Indonesian government issued Presidential decrees to override patents on hepatitis drugs and ART to pave the way for cheap generic versions.^{lxix}

However, it appears the Indonesian government has not, since 2012, issued further Presidential decrees to override patents on ART. In fact, unlike in India, there are few reports to show that the Indonesian government has historically relied on or utilised TRIPS Flexibilities in order to facilitate greater access to and affordability of ART for people living with HIV.

Further, the price of ART in Indonesia today is amongst the highest in the world.^{lxx} As noted above, even if Compulsory Licencing was utilised, this regime does not necessarily secure long-term access to generic medications at the discounted price, as TRIPS limits the quantities that are produced under each Compulsory Licence. In fact, ART could be purchased almost 400% cheaper outside Indonesia.^{lxxi} However, we do note that HIV treatment is available to the public for free in public referral hospitals and in primary healthcare.

The importance of advocacy

Advocacy groups in Indonesia have been key to the partial alleviation of the widespread stigma and discrimination surrounding HIV and AIDS. For instance, the Indonesia AIDS Coalition has campaigned to lower the price of ART by as much as 48%, resulting in an additional 45,482 people receiving ART.^{lxxii} NGOs have also worked to provide key populations with paralegal support and access to other forms of legal services in order to obtain ART.^{lxxiii} Some individuals living with HIV have also taken to social media, launching digital campaigns and utilising a chatbot run by UNAIDS called 'Tanya Marlo' ('Ask Marlo'), which allows users to ask questions about HIV, link up with a counsellor or even book an HIV test.

Indonesian youth have also stepped up to voice their concerns with stigma and discrimination against people living with HIV and AIDS, with reports of some international students volunteering with children living with HIV to offer them emotional support with their diagnosis.^{lxxiv}

The importance of community engagement in breaking down the barriers of social stigma around COVID-19 therefore cannot be understated.^{lxxv} In Indonesia, progress towards combatting stigma and discrimination, alongside efforts to overcome legal barriers to the Right to Health and 'red tape' around IP in relation to life-saving treatments, will have significant positive impacts for people living with HIV. These steps could also lay the groundwork for the widest possible access to forthcoming COVID-19 Treatments.

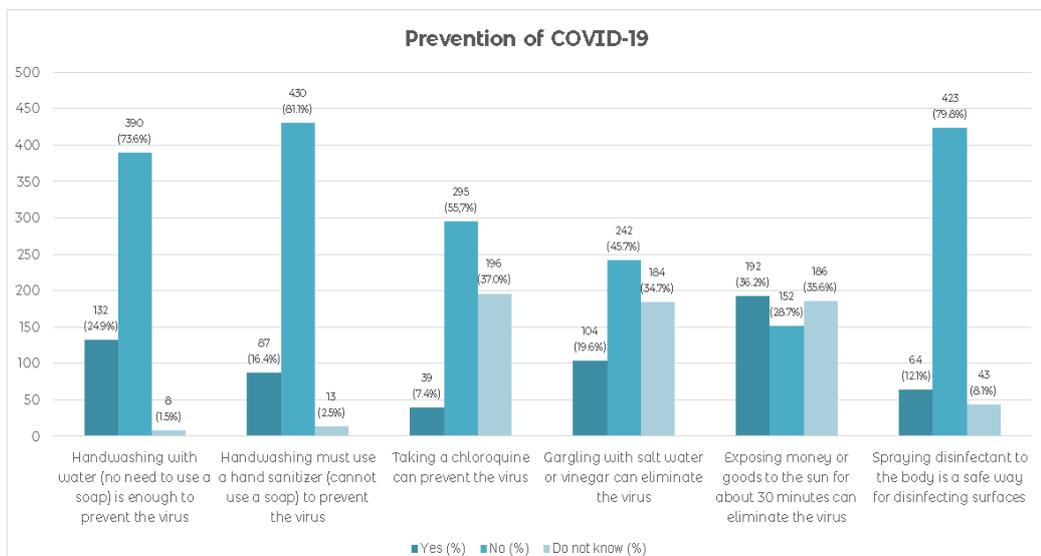
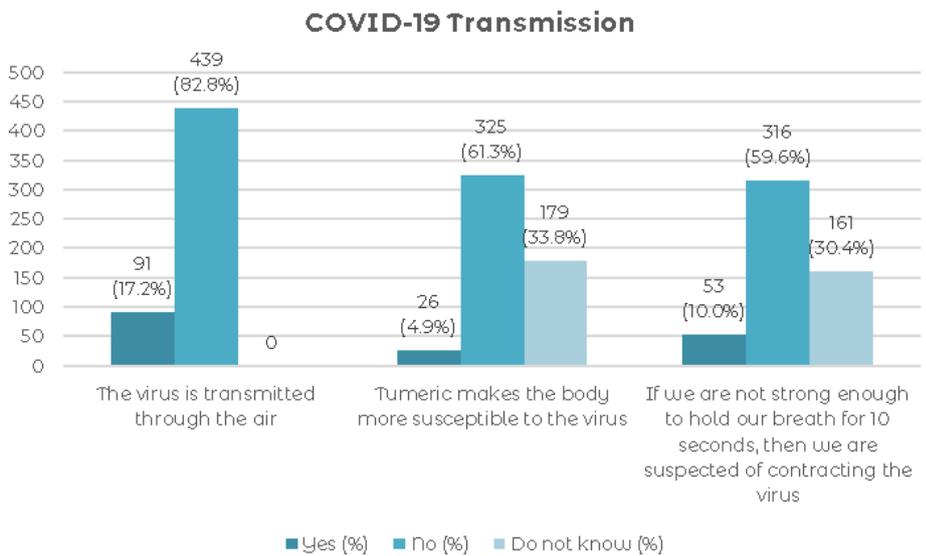
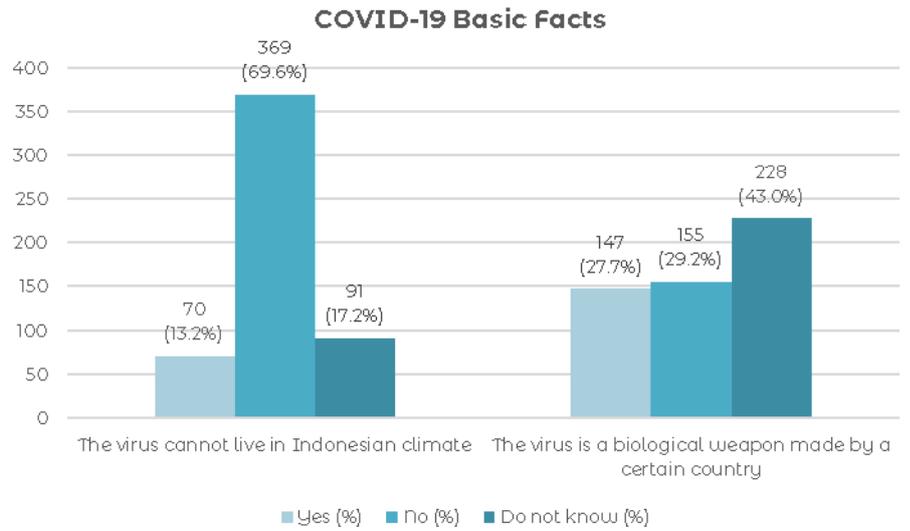
The danger of misinformation

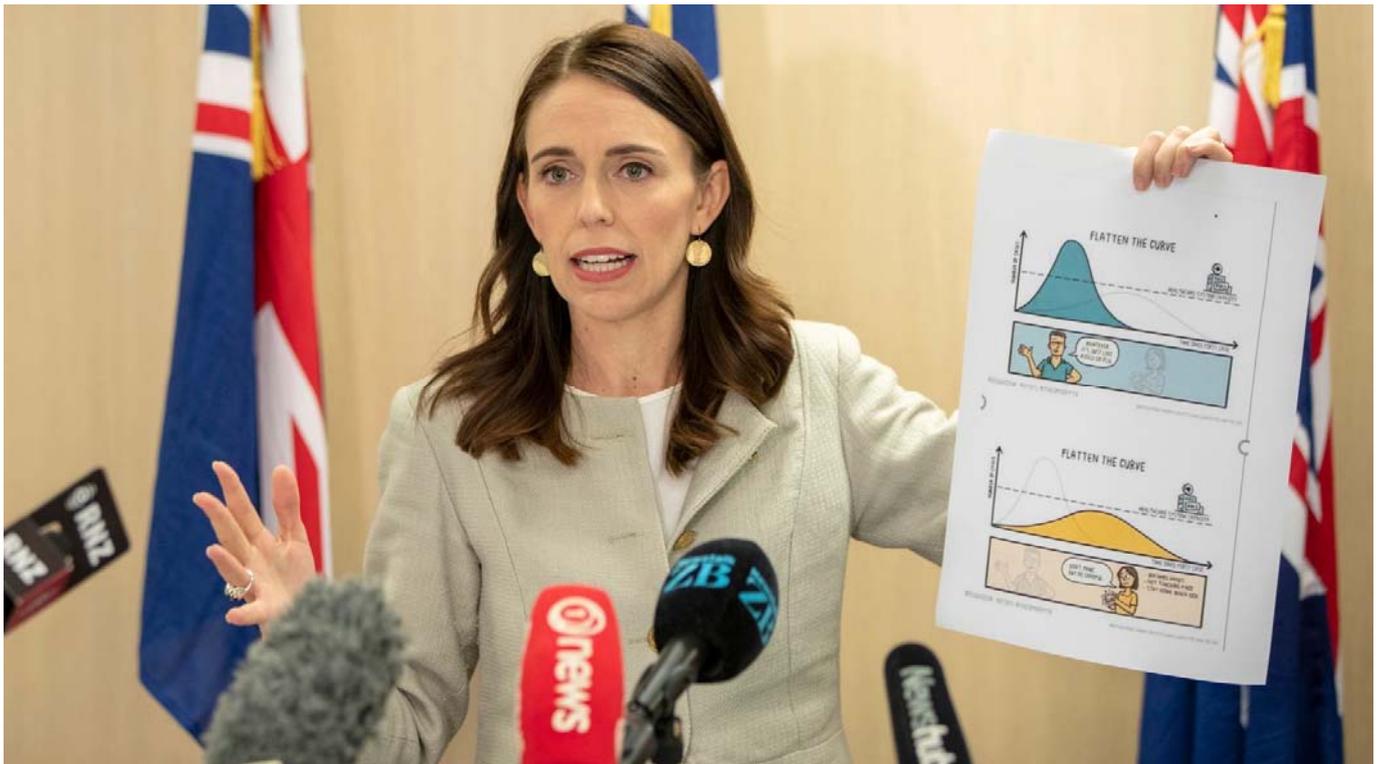
While these digital avenues assist individuals living with HIV get the help they need, any digital tool may be misused to spread misinformation and 'fake news'. Misconceptions around HIV and AIDS continue to circulate on the internet, and recently, anti-ART movements online have tried to peg ART as ineffective or a scam, promoting the use of the herbal tonic Jamu and other palliatives as effective ART alternatives.^{lxvii}

Governments worldwide therefore have a responsibility to play a more active role to ensure accurate and consistent messages to the community at large about COVID-19, its transmission and prevention.

Misinformation about COVID-19, its transmission and prevention is not an issue unique to Indonesia. However, given that Indonesia has the third largest number of Facebook users (120 million) after India and the United States the implications of misinformation about COVID-19 in this forum are serious, as so many individuals would consume news and receive updates on COVID-19 via social media. At the very least, the government can take steps to address the credibility of sources on social media and ensure that the Indonesian public is aware of where to find reliable and accurate information.

While the Indonesian government has taken steps to combat misinformation through the 'hoax buster' section on their official website, the general public appears largely in the dark about COVID-19, its transmission and prevention. The tables to the right show the results of a survey conducted on or around April 2020, and demonstrate the extent of misinformation about COVID-19 in Indonesia.^{lxviii}





Source: Sky News, UK (14 March 2020)

Examples of success stories in combating misinformation and a unified approach towards beating the pandemic is illustrated in countries like Thailand, South Korea, Taiwan and New Zealand.^{lxviii}

Forward thinking strategies around communication, and general cooperation with global public health advice have been proven vital in not only beating the pandemic but also managing stigma or discrimination about individuals who contract COVID-19.



Thailand's forward-thinking public health strategy used a 'whole-of-society' approach to reduce stigma and discrimination against COVID-19.



South Korea has a government 'Office of Communication' that regulates information about COVID-19, sending out messages through multiple channels to ensure the community received the correct information about the transmission and prevention of COVID-19.



Taiwan's emergency Central Epidemics Command Control cooperated with the National Communications Commission to generate materials for social media platforms, and even went so far as to engage with individual concerns via Facebook, instant messaging applications like 'LINE' and a telephone hotline.



New Zealand's response to COVID-19 has been hailed as "crushing the curve" by the WHO. When the WHO first announced the coronavirus outbreak, New Zealand implemented speedy, contact tracing and isolation in accordance with public health guidance.

Case Study Countries – Pacific



- Legal framework provides for improvement in the standard of public health, but the Right to Health is not enshrined directly in law
- Papua New Guinea receives a high level of support from official developmental assistance
- Many people are unable to access health facilities
- Critical shortage of trained health workers and supplies

Papua New Guinea

No Right to health

The Constitution of Papua New Guinea (PNG) does not enshrine the Right to Health principle. The only legislative instruments providing for a notion of health standards are the National Goals and Directive Principles (NGDPs). Sections 25 and 63 of the Constitution direct that the NGDPs and the Basic Social Obligations (BSOs) be given effect by all arms of government. Section 24 directs that an aid to the interpretation of the Constitution is the final report of the drafters Constitution, which contains the NGDPs and section 22 provides for the National Court to intervene and supply where a right or its enforcement is lacking in the Constitution, informed by the NGDPs.^{lxxxix}

Applying the liberal standard of interpretation directed at section 109, Courts have read into these provisions to enforce the NGDPs. On the other hand, some research has noted the NGDPs are merely aspirational statements contained in the Preamble to the Constitution, which provide for improvements in the level of nutrition and standard of public health (although currently only minimal services have been provided).^{lxxx} Access to clean water and general antibiotics are predominantly provided by the government, churches and official developmental assistance (ODA).^{lxxxii} PNG has ratified the international law frameworks on human rights, including the ICCPR and the ICESCR.^{lxxxii}



A young child holds a Polio Vaccine at Wampar Huon Gulf district Health Clinic where the Polio Vaccine is administered to children in Lae, Marobe Province, Papua New Guinea.

Current Health situation

Even before COVID-19, PNG faced a difficult health framework, due to lack of medical resources and the highest prevalence of TB in the Pacific.^{lxxxiii} PNG has a very high level of support from ODA.^{lxxxiv} Many citizens do not have access to a health care facility and there are critical shortages of trained medical staff and supplies.^{lxxxv}

The PNG Government established the National Health Plan 2010-20^{lxxxvi} in order to address the growing need for medical services, however the project is not yet sufficiently resourced to meet its goals.^{lxxxvii} The Australian government also contributed up to \$281 million to the PNG Health Program 2015-2018.^{lxxxviii}

PNG has received support from several NGOs, such as World Vision and Médecins Sans Frontières (MSF).^{lxxxix} The WHO and PNG already work very closely together.

Case Study Countries – Africa

General

Access to medical treatments across Africa has come a long way since the alarming effects of HIV and other epidemics first put enormous pressure on continental health systems and moulded the way governments would respond to future health crises. Parallels can now be drawn from previous government responses in Case Study Countries to how access to COVID-19 Treatments may be provided.

International law obligations require African countries to provide access to medical treatments, however these international law obligations do not provide avenues for specific domestic legal enforcement in African countries. However in 1981 the establishment of the African Charter on Human and Peoples' Rights (African Bill of Rights) provided a higher level of legally-binding and enforceable national protection for accessing necessary medical treatments. The African Bill of Rights was developed by the Organisation of African Unity, now called the African Union (African Union) and ratified by 54 African heads of state and government.^{xc} These provisions are very similar to the international law (see below table).

As the Organisation of African Unity was not a governing body with direct legal power, this led to the creation of the African Court on Human and Peoples' Rights (African Court of Human Rights) and the African Commission, both of which were established to provide enforcement measures to protect these rights.^{xcⁱ} The African Commission is compelled to follow international law and foster, promote and develop the African Bill of Rights while the African Court of Human Rights is empowered to make decisions and provide penalties for any violations of the African Bill of Rights.

Although these legal rights are prescriptive, their practical application to accessing health care is unevenly distributed across Africa. Many African countries have a dual-access health care system (that is, they encompass both public and private health-care provision), and access to private health-care depends on an individual's ability to pay.^{xcⁱⁱ} Roughly 80% of Africans rely on the public health-care services of their countries, and there are not enough health-care professionals in rural areas to meet community need.^{xcⁱⁱⁱ}

African Charter on Human Rights



All peoples shall have the right to their economic, social and cultural development with due regard to their freedom and identity and in the equal enjoyment of the common heritage of mankind.^{xc^{iv}}

States shall have the duty, individually or collectively, to ensure the exercise of the right to development.^{xc^v}

The government must draw from international law on human and people's rights, specifically the provisions of various African instruments on human and people's rights, the Charter of United Nations, the Charter of Organisation of African Unity, the Universal Declaration of Human Rights and other instruments adopted by the United Nations and by African countries in the field of human and people's rights.^{xc^{vi}}

Case Study Countries – South Africa

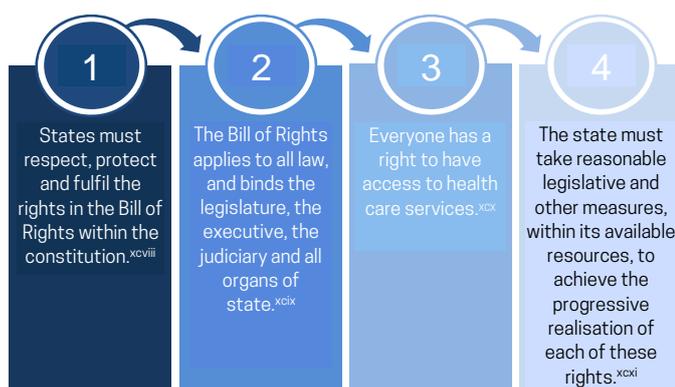


- Landmark civil-society legal action in 2002 mandated access to ART
- Government executed policies that made life-saving drugs available to everyone
- Legal victories and success may assist with facilitating access to COVID-19 Treatment
- Access to critical medicines remains a problem because of shortages and inequities in South Africa's health system (despite ODA investment in health)

Human rights framework

The South Africa Constitution (SA Constitution) provides further Right to Health protection measures in South Africa, on top of those contained in the African Bill of Rights. South Africa abstained from signing the Universal Declaration of Human Rights, however the SA Constitution provides very similar themes and rights as follows.^{xcvii}

South Africa Constitution



The law in practice

A landmark case was brought in 2002 by the Treatment Action Campaign against the South African Minister of Health, where it was argued that the South African government had not provided adequate care in relation to Prevention of Mother to Child Transmission of HIV (PMTCT), resulting in many unnecessary deaths.^{cii}

The Constitutional Court found that:

- the South African government had not adhered to the South African Constitution by not acting reasonably to reduce the spread of HIV from mothers to their children, because the government had refused to make life-saving drugs available to patients in the public health system (where they were prescribed by the attending doctor) and
- the government had also not set out a national program to prevent mother to child transmission of HIV.^{ciii}

This decision was important because it highlighted the movement toward mandating for access to medical treatments, and most notably it required the government to execute policies to make life-saving drugs available to everyone, including in public hospitals.^{civ} Because of this case, the Constitutional Court is obliged to help manage access to COVID-19 Treatment and to develop precedents to force governments to provide lifesaving treatments.

Lessons from HIV epidemic

In 2018, 7,700,000 people were living with HIV and 71,000 people died from an AIDS-related illness in South Africa.^{cv} In comparison, as at 1 December 2020, approximately 790,004 people had been infected with COVID-19 in South Africa and there have been 21,535 deaths.^{cvi} South Africa currently has the largest HIV epidemic in the world, however the country's progress in getting a record number of people tested for HIV has been impressive.^{cvi}

In 2019, the South African government launched two nationwide testing programs, the national HIV testing and counselling campaign and the revitalisation strategy, which predominantly focused on testing a wide range of people, including private-sector employees, farm workers and tertiary students.^{cviii} By 2019, South Africa had also established various prevention programs in order to reduce new HIV infections to under 100,000 by 2022, such as a PMTCT program.^{cix}

Right to Health vs Trade protectionism

Despite South Africa installing legislative regimes to protect the Right to Health, the contrast with IP rights has provided some difficulties. South Africa ratified its *Medicines and Related Substances Control Amendment Act 1997* (South Africa) (Medicines Act) with the objective of providing affordable medicines to South Africa's most impoverished.^{cx}

However the Medicines Act was controversial as it amended the trade patent laws with a goal of reducing the prices of medicines in South Africa.^{cx} In 1998, this led to the Pharmaceutical Manufacturers Association of South Africa bringing a claim against the South African government to prevent the government from using Compulsory Licensing and importation to address the HIV catastrophe, on the basis that the government had contravened its obligations under TRIPS.^{cxii}

The Pharmaceutical Manufacturers Association eventually pulled its claim due to immense pressure from HIV activists and international human rights organisations.^{cxiii} The decision to withdraw the claim is important because it compelled the South African Government to prioritise access to treatments, meaning that the right to health care (and access to an ART) in that country takes precedence over trade mark protection. This precedent may be able to be applied in future cases where there is a dispute between trade protection and the right to access treatments for other disease (such as COVID-19).



In February 2003, the Treatment Action Campaign led a 20 000-strong march to the South African Parliament on the day of the Presidential State of the Nation address to demand a national HIV treatment programme.

Partnerships and national programs



Gavi, the Vaccine Alliance and its partners have played a key role in shaping the market conditions that have led to ever-growing demand for the pentavalent vaccine, which offers protection from diphtheria-tetanus-pertussis, Haemophilus influenzae type b (Hib) and hepatitis B (hepB). At present there are at least five Indian companies manufacturing the vaccine, one of them being The Serum Institute of India.

South Africa has received an immense amount of funding for health care programs from ODA. It is estimated that South Africa received approximately US\$1.1 billion in 2014, with some of the largest donors being the United States Government followed by the Global Fund to Fight AIDS, Tuberculosis and Malaria, the Bill & Melinda Gates Foundation, the German Government, and the European Union.^{cxiv} South Africa has also partnered with many international and domestic organisations, including:

- United Nations (UN) – the UN signed the South-Africa-United Nations Strategic Cooperation Framework 2013-2017;^{cxv}
- WHO - executed the Country Cooperation Strategy Republic of South Africa 2016-2020;^{cxvi}
- USAID – with goals of preventing and controlling drug-sensitive and multidrug-resistant TB;^{cxvii}
- European Union – for assistance in implementing National Health Insurance;^{cxviii} and
- The National Institute for Communicable Diseases of South Africa – focuses on prevention of diseases.^{cxix}

The South African government's goal is to provide universal health care through National Health Insurance (NHI) by 2026, the roadmap for which is set out in the National Development Plan 2030.^{cxx} The main objective is to provide health care to all citizens regardless of their financial status.^{cxxi} However this objective has not been achieved as funding this program has proven to be difficult.

Despite South Africa's National Drug Policy, which was established in 1996 and focuses on providing better access to necessary medical care, access to critical medications is still an ongoing problem due to a variety of issues, which include:^{cxxii}

- excessive waiting times due to shortages of medical staff;
- poor hygiene in medical facilities;
- errors made due to lack of trained staff;
- shortages in medicines and hospital equipment;
- inadequate record-keeping; and
- unequal distribution of resources to poor communities.

Case Study Countries – Kenya



- Legal framework and health policies enshrine Right to Health
- Kenya is also compliant with TRIPS and allows parallel importation of drugs
- Mixed legal outcomes in weighing up importance of Right to Health and medicine patent protection
- Access to critical medicines remains a problem because of shortages and inequities in Kenya's health system (despite ODA investment in health)

Human rights framework

There are several national laws and policies in Kenya providing for the Right to Health:

- Kenya ratified the African Bill of Rights in 1992,^{cxxiii}
- the Constitution of Kenya (2010) provides that every person has the right to the highest attainable standard of health,^{cxxiv}
- the Kenya Public Health Act also imposes several legislative health requirements, for example it provides rules for prevention of diseases,^{cxxv}
- the Kenya National Patients' Rights Charter (2013) aims to provide higher-quality healthcare and promote the right to obtain the highest standard of health for all Kenyans,^{cxxvi}
- the Health Act (2015) establishes a unified health system, to co-ordinate the inter-relationship between the national government and county government health systems,^{cxxvii}
- the aims of the Kenya Health Policy 2014 – 2030 are to provide affordable, equitable and appropriate health services, although implementation will depend on the successful collaboration of all the stakeholders,^{cxxviii}
- Kenya has also committed to the Global Immunization Vision and Strategy (GIV) 2006 - 2015 that was put in place by WHO and UNICEF to combat vaccine-preventable diseases, which kill more than 2 million people globally every year.^{cxxix} The objectives of GIV are to immunise more people and to introduce new technologies and achieve greater integration of critical health interventions.^{cxx}
- the Kenya Ministry of Health National Policy Guidelines on Immunization (2013) provides a guiding framework on the principles on immunisation and policies for current vaccines.^{cxxxi}

IP vs Right to Health

The *Industrial Property Act 2001* (Republic of Kenya) (Kenya IP Act) brought Kenya into compliance with TRIPS.^{cxxxii} The Kenya IP Act provides a controversial flexibility that permits parallel importation of pharmaceuticals (provided the drugs were lawfully and legitimately on the market in the exporting country).^{cxxxiii} The intent of this provision was to assist access to specific medications for HIV.^{cxxxiv}

There are two landmark decisions that show how the Kenyan courts have weighed the delicate balance between Right to Health and protection of patents.

1. The application of 'parallel importation' under the Kenya IP Act was seen in the case of *Pfizer Inc v Cosmos Limited*. In 2008, Pfizer contended that Cosmos had infringed its patent.^{cxxxv} Cosmos alleged that the patented product was already available in Kenya and it had already been imported by India, Bangladesh and China to treat HIV, thereby supporting a fundamental right to health care.^{cxxxvi} However the Tribunal found that the product was not a 'first-line treatment' for HIV and Cosmos had not adhered to the patent rules and arguably downplayed the argument about right to access fundamental healthcare.^{cxxxvii}
2. In 2012, the Kenyan high court revisited the Right to Health debate in the case of *Patricia Asero Ochieng et al. v Attorney General*.^{cxxxviii} This case was brought by people living with HIV who contended that their HIV medications were classified as 'generic drugs',^{cxxxix} which failed to specifically exempt these medicines from the definition of counterfeit goods under the Anti-Counterfeit Act 2008 (Counterfeit Act). The Counterfeit Act was enacted to strengthen enforcement actions for breaches of IP. This placed a considerable burden on the applicants as they contended that, under the Act, their medications would be considered counterfeit goods that they would be barred from accessing. The plaintiffs alleged that sections of the Counterfeit Act were unreasonably harsh in restricting access to affordable and life-saving HIV medications in Kenya. The court held that the relevant sections of the Counterfeit Act were unconstitutional and that the Right to Health in the Kenyan Constitution takes precedence over IP restrictions.^{cxli}



Patients wait at a health clinic to receive the new pneumococcal vaccine. Before the vaccination they are educated by a health worker on the benefits of immunisation and health.

Practical application of the law

Despite the seemingly generous legal provisions, policies and court decision on the importance of the Right to Health, access to general medical treatment is still a problem in Kenya. Several initiatives, such as the Novartis Access Initiative (Novartis Initiative) and the Kenya National Commission on Human Rights (Kenya Commission), have conducted research to understand how to increase access to healthcare for all Kenyans.^{cxli} These Novartis Initiative and Kenya Commission studies each interviewed Kenyan citizens and found that, although government facilities provided medicines that were relatively reasonably-priced (and often free), there were several access-related issues.^{cxliii}

In light of the COVID-19 pandemic, a future COVID-19 Treatment must be subsidised and provided through all public health facilities in Kenya, and not only be accessible to those who can afford it. Furthermore, it is apparent that efforts to improve the training of Kenyan health care workers must continue and the quality of medical products not be compromised.

Partnerships

Unlike South Africa, Kenya has received variable levels of ODA, with investments largely dependent on donors' trust in the government of the day.^{cxliii} As a result, Kenya's dependency on ODA is much lower than that of other African countries.^{cxliv} The Kenyan government has also spent considerable domestic resources on health infrastructure (approximately 5.2% of its GDP in 2015/2016).^{cxlv}

For the 2020/2021 budget, it has been noted that health care funding has not been a priority for Kenya, as the country has allocated 111.7 billion Kenyan shillings (KES) (equivalent to \$1 billion USD) – only about 4% of a total budget of 2.75 trillion KES.^{cxlvi}

Barriers to Right to Health



Availability: There are insufficient health facilities across the country, and often not where most needed.

Affordability: As a result, patients resorted to private clinics at a much higher cost – for example, such clinics might charge up to a month's wages for a seven-day course of a general antibiotic. Thus patients would often not take a complete course of antibiotics, with serious implications for individuals' ability to recover from their illness and for public health, in terms of population-level antibiotic resistance.

Accessibility: There is a shortage of skilled health care workers in several regions.

Quality: Some patients in the study did not receive adequate care from a health care worker, due to lack of training, and availability of counterfeit or unregistered medicines or distribution of medicine by unregulated or informal pharmacies.

Our Findings



Butiban Health Clinic where the Polio Vaccine is administered to children in Lae, Marobe Province, Papua New Guinea.

From our examination of the Case Study Countries, we make the following observations:

Utilising TRIPS Flexibilities

Finding the balance between protecting trade patents and the Right to Health has been controversial in some countries. Many developing countries do not take full advantage of the measures permitted under TRIPS to fulfil the goal of promoting access to medicines for all. This is due to a lack of understanding of the TRIPS Flexibilities, lack of expertise on IP-related issues within government departments, and pressure from developed countries (i.e. from the US) to limit the use of TRIPS Flexibilities in order to protect the patents issued by multinational pharmaceutical companies.

Lack of enforceability of the Right to Health

Governments in the Case Study Countries, with the exception of PNG, by and large enshrine the Right to Health in their respective legal frameworks. However there are different levels of enforcement of the Right to Health in practice owing to government rhetoric and attitudes towards affected groups, who often lack the financial resources and level of knowledge to be able to enforce their Right to Health.

Stigma and discrimination against HIV

Stigma and discrimination against HIV and AIDS, and medical misinformation, can be significant barriers to the Right to Health, and at times, worsen the public health situation. The

spread of misinformation about HIV and/or COVID-19 have greatly impacted the people infected with and affected by these viruses.

Government and ODA

The Case Study Countries will continue to face battles with antiretroviral drug shortages and the cost of life-saving treatments generally. Some countries continue to lean on ODA, such as PNG noting that of the expenditure in the Pacific: ^{cxlvii}

- 82% is paid for by domestic governments;
- 8% is generated from private contributions, or out-of-pocket payments.
- 10% from overseas aid.

Public vs private access to health care

Developing countries with health systems that encompass both public and private care have an unbalanced distribution of health-care resources and marked gaps between health outcomes for the poor and wealthy. In some countries, there is also poor enforcement around ensuring equal access to healthcare, and financial difficulties in supplying affordable medications to the community. Public health care therefore needs to be adequately funded and available to citizens in rural and urban areas. Health care workers also need adequate training in order to ensure individuals from all socio-economic backgrounds receive the same quality standard of healthcare.

Recommendations



This report has referred throughout to human rights and legal rights: the Right to Health, and rights under both national laws and international treaties. A *rights-based approach* which foregrounds the importance of both the content and realisation of these rights, is now seen as key in many areas of social life – including health.

Such an approach is not solely concerned with legal statute, but rather with acknowledgement (of those with rights: the *rights-holders*) and implementation (by those individuals and institutions with the responsibility to do so, who are known as *duty-bearers*).

Deploying a rights-based approach is not an exact science, and many of the issues surfaced in our case studies are not easy to solve.

However, there are lessons we can take from the Case Study Countries' practical and legal responses to HIV and AIDS to help ensure that all individuals will be able to access COVID-19 Treatment.

1. Recognise the Right to Health at a national level

- At a minimum, all countries should implement a national medicines program and mandate in domestic law that COVID-19 Treatment be accessible to all.
- Several countries (such as India, Kenya and South Africa) have continued to lower their HIV infection rates over time by prioritising their citizens' legal right to receive ART within their national legal framework.
- In India, a rights-based approach to care and treatment for people living with HIV and AIDS has been implemented through the HIV and AIDS Act 2017.^{cxlviii}

2. Implement a rights-based approach to health

- A rights-based approach to health aims to ensure that efforts to achieve the right to good health and well-being are grounded in human rights-based principles.
- The core elements of this approach are summed up in the 'PANEL Principles': participation, accountability, non-discrimination and equality, empowerment and legality.

These principles, taken together, will serve as important yardsticks in the implementation of the other Recommendations above – in particular, on community engagement.

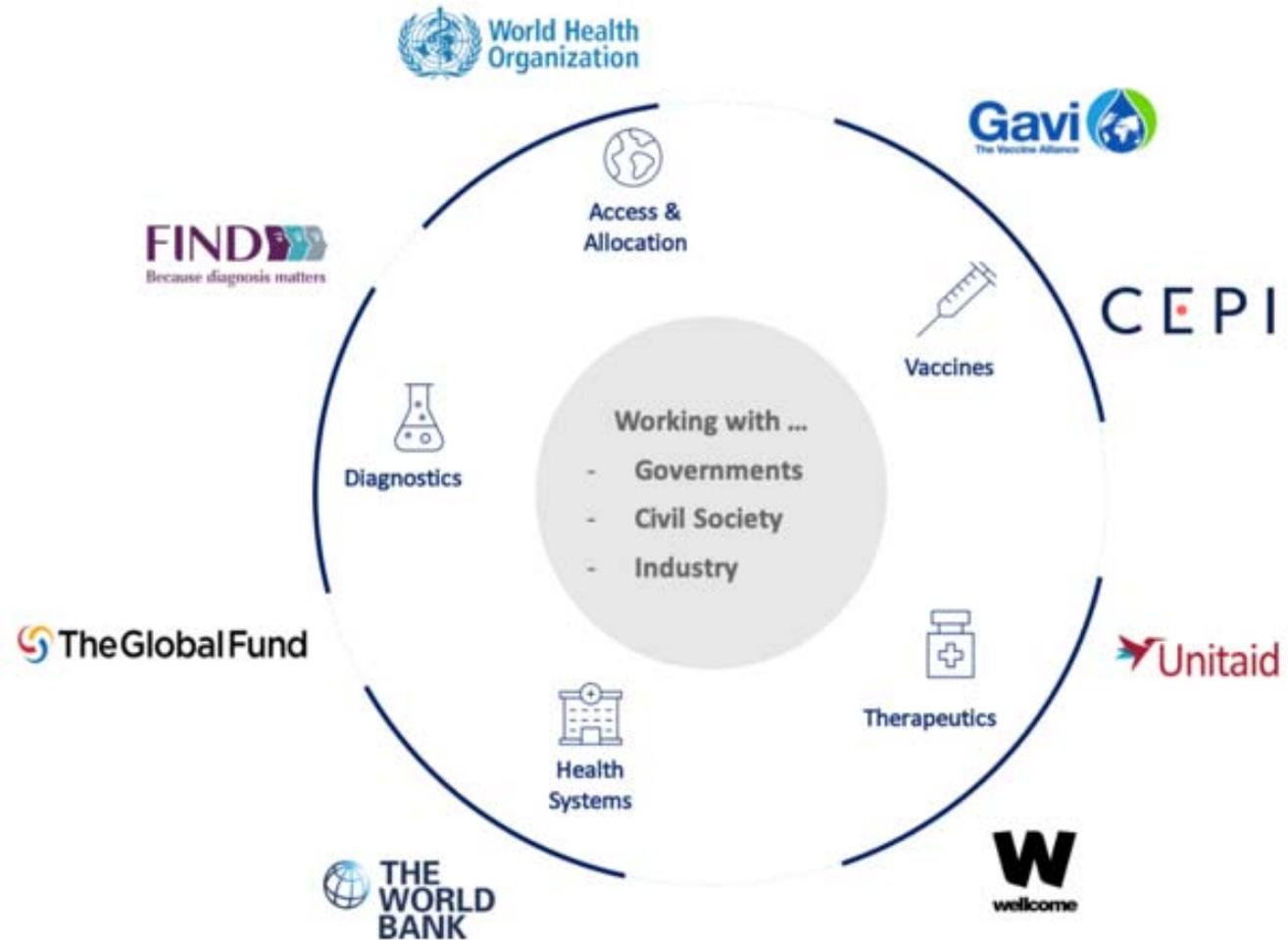
3. Use TRIPS Flexibilities as a public health tool

- WTO members are required to comply with TRIPS, but there are still ways in which they can utilise TRIPS Flexibilities to ensure that public goods (such as a COVID-19 vaccine or ART) are not subject to patent exclusivity.
- Compulsory Licensing is one such public health tool. This regime has been successfully utilised in India and Indonesia to allow use of a patent without authorisation from the patent holder.
- Exceptionally, these licences can also be issued in "national emergencies" and "other circumstances of extreme urgency" – surely situations for which the HIV and COVID-19 pandemics meet the criteria.

Although developing countries face pressure from multinational pharmaceutical companies to limit their use of TRIPS Flexibilities, advocacy groups and government entities need to ensure they are aware of their rights to do so, as WTO Members.

4. Engage with communities and cooperate with global public health organisations

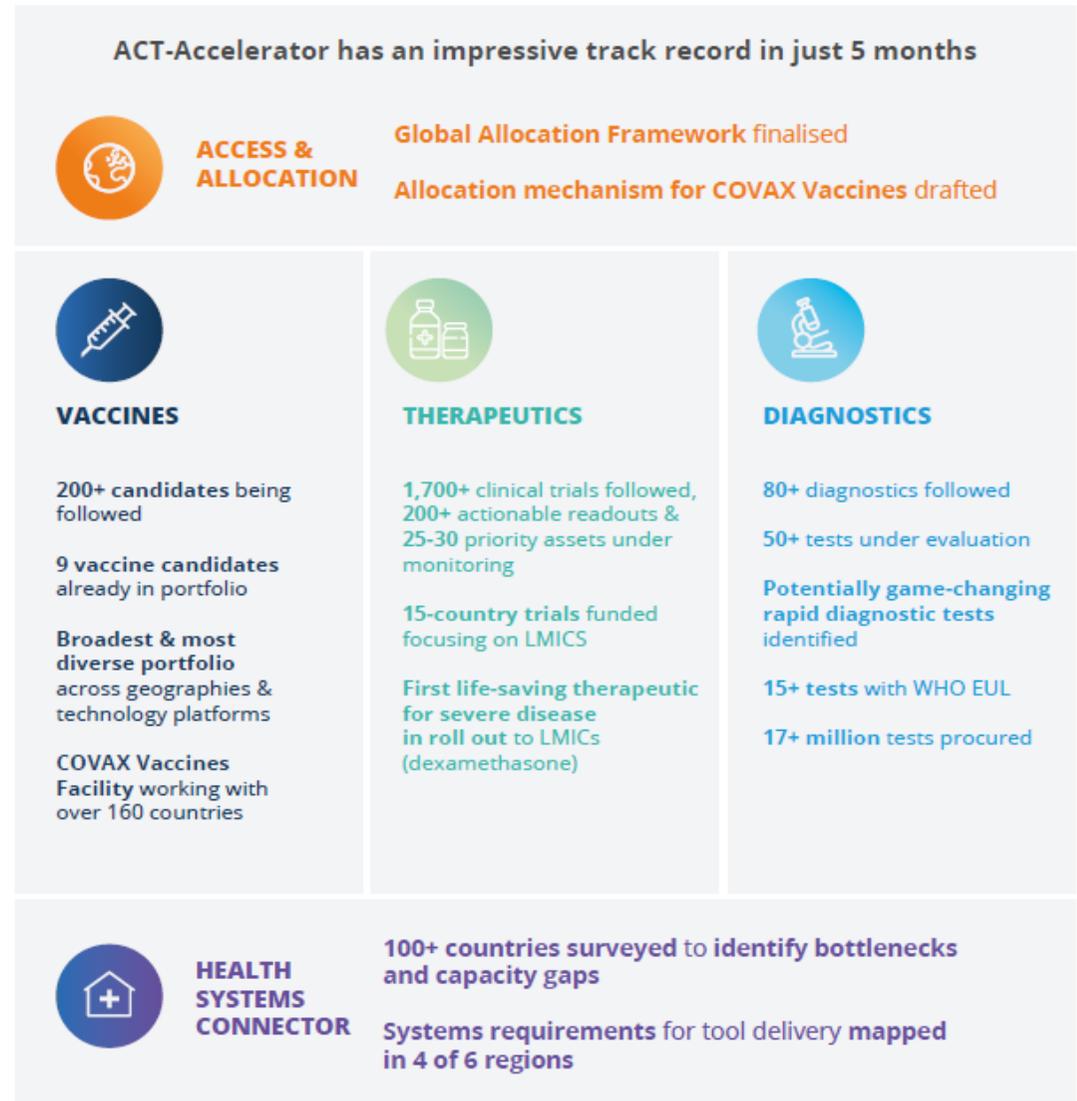
- Engagement with communities and a deep understanding of their attitudes, needs and beliefs is key to ensuring the Right to Health is realised. Effective prevention must be a partnership between experts and communities, with community leaders actively in the response.
- It is also important to mitigate the spread of misinformation about diseases such as COVID-19 and HIV through digital channels. Advocates and civil society can put pressure on governments that are not doing enough – or worse, encouraging blame and false beliefs – to break the cycle of stigma and misinformation.
- This stigma can only be dealt with through increased awareness and accurate, up-to-date information about COVID-19, including facts and figures on new and active COVID-19 cases, the number of cumulative deaths and importantly, the number of people who have recovered, thereby helping to break down the shame and fear associated with contracting COVID-19.
- Community engagement is also central to a rights-based approach to health (discussed further below) – for example, in helping to empower rights-holders and hold duty-bearers to account.



Source: <https://www.who.int/initiatives/act-accelerator>

5. Continue to advocate for affordable access to life-saving treatments

- Beginning with HIV and AIDS in the early 1980s, the work of advocates – particularly people from affected communities – has been central to pushing government, pharmaceutical companies and other stakeholders to improve the standard of health care for people living with HIV, as well as advancing their legal rights and overcoming misinformation and stigma about HIV.
- Building on this history and drawing from its lessons, advocates – in individual countries, regionally and globally – have a central role during the COVID-19 pandemic in ensuring that life-saving treatments are affordable and accessible to all.
- In April 2020, the WHO and other leading global health and financing bodies partnered to create the Access to COVID-19 Tools Accelerator (ACT-Accelerator) to accelerate development of, and provide timely and equitable access to, COVID 19 Treatment globally.
- Following significant advocacy, civil-society representatives have been invited to attend the ACT-Accelerator Facilitation Council, the high-level leadership body that oversees the work of the ACT-Accelerator. Access to COVID-19 Treatment for the most vulnerable or those in most urgent need – regardless of their location or ability to pay – is one of ACT-A's underlying principles.



Source: <https://www.who.int/initiatives/act-accelerator>

Conclusion

The Right to Health should be the backbone of how a future COVID-19 Treatment (including surrounding polices) will be distributed. The final impacts of COVID-19 are still relatively unknown but so far there has been unprecedented disruption in most countries' health care systems as well as in global and domestic economies.

While the WHO has taken proactive steps in collaborating with key organisations like the Bill and Melinda Gates Foundation to create the ACT-Accelerator, the continued support and cooperation of governments worldwide and sufficient funding are paramount for the ACT-Accelerator to have widespread effects. There is also a great deal of uncertainty and much more work to be done.

As the various COVID-19 Treatments are still being tested, a clear and concise plan on how a vaccine will be distributed globally has not yet been set out. Furthermore the ACT-Accelerator requires significantly more funding to achieve its ambitious goals (a total of US\$31.3 billion over the 12 months to June 2021),^{cxlix} and to build on its partnerships with as many countries as possible.^{cl} That being said, the way in which previous health crises (such as HIV) have been dealt with has paved the way for better access to COVID-19 Treatments.

Despite some discrepancies between domestic and international IP laws, what our case study research shows (such as in Kenya) is that courts have recently handed down judgements signalling that a Right to Health will take

precedence over trade protection (as was the case in India and Kenya, as noted above). However the USTR's Special Report 2020 on Trade does blur these lines as it calls for greater enforcement of breaches of IP laws.^{cli} The impacts of this Special Report have not yet been tested.

At a practical level, providing access to health care in developing countries is not always straightforward, even if the Right to Health is mandated in the relevant country's constitution and if that country is a signatory to an international treaty that calls for the protection of human rights. This is mainly because legal proceedings for breaches of law are generally very costly for all parties involved and people living in developing countries (especially people living in rural areas) do not have ready access to legal aid. On top of this, the cost and availability of certain basic medications and health care are beyond the reach of people in poorer areas.

By drawing on past examples of legal victories in the Case Study Countries, the above findings could serve to educate and inform advocate groups in the (hopefully near) future in their fight to ensure all individuals, regardless of socio-economic background and geographic location, have equal access to COVID-19 Treatment. It is in everyone's best interest to ensure that we beat COVID-19, and this pandemic will not be over for everyone until it's over for everyone.



  
A selection of the 42 Heads of State and Government, and leaders from global health, the private sector, vaccine manufacturers and civil society organisations who attended the virtual Global Vaccine Summit 2020, a pledging conference for Gavi, the Vaccine Alliance held in June and hosted by the UK government. The Summit raised US\$8.8 billion, far exceeding its target of US\$7.4 billion. This funding will help to immunise 300 million children in the world's poorest countries over the next five years against diseases like measles, polio and diphtheria. It will also support health systems to withstand the impact of coronavirus and maintain the infrastructure necessary to roll out a future COVID-19 vaccine on a global scale. Celebrating its 20th anniversary in 2020, Gavi is an eminent example of global health co-operation.

Acknowledgements

MinterEllison

For MinterEllison

- Ben Smith, Partner
- Kate Reagh, Associate
- April Wong, Associate
- Christina Plessas, Graduate
- Karen Harrison-Robertson (WP Team Leader), Design



For RESULTS International (Australia)

- Dr Michelle Imison, Policy Advisor (Child Health)
- Negaya Chorley, CEO



For contributions to report content and structure

- Dr Bal Kama - practising lawyer and PNG constitutional law expert
- Rosemary Mburu, Executive Director - WACI Health
- Ntombesizwe Nombasa Gxuluwe, Programme Officer - WACI Health
- Fitsum Lakew Alemayehu, Liaison Officer to the African Union - WACI Health
- Angela Muathe, Communications & Advocacy Manager - WACI Health
- Neil Raw, Policy Advocacy Officer (Child Health) - RESULTS UK



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November 2020

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GLOSSARY

ACT-Accelerator	Access to COVID-19 Tools Accelerator.	Mailbox Patent Application	In IP, a mailbox patent application refers to the requirement for TRIPS to apply to WTO members that do not yet provide product patent protection for pharmaceuticals and for agricultural chemicals. Since 1 January 1995, when the WTO agreements entered into force, these WTO member countries have had to establish a means by which applications of patents for these products can be filed
AIDS	Acquired immunodeficiency syndrome, a disease caused by HIV	MSF	Médecins Sans Frontières, an international and independent medical humanitarian organisation
ART	Antiretroviral therapy	NACO	India's National AIDS Control Organisation
BSO	Basic Social Obligation	NACP	India's National AIDS Control Programme
Case Study Countries	India, Indonesia, Kenya, Papua New Guinea, South Africa	NGO	Non-Governmental organisation
CEDAW	The Convention on the Elimination of all Forms of Discrimination Against Women	ODA	Official Development Assistance, popularly known as 'overseas aid'
Compulsory Licence	When a government allows a third party to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself.	PMTCT	Prevention of Mother to Child Transmission (of HIV)
COVID-19	COVID-19 is a disease caused by a new strain of coronavirus. 'CO' stands for corona, 'VI' for virus, and 'D' for disease. Formerly, this disease was referred to as '2019 novel coronavirus' or '2019-nCoV.'	PNG	Papua New Guinea
COVID-19 Treatment	Pharmaceutical treatments and/or vaccines for COVID-19	Right to Health	The WHO defines the Right to Health as "the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition."
CRC	The Convention on the Rights of the Child	Special Report	United States Special Report 2020 on Trade
GDP	Gross Domestic Product	TB	Tuberculosis is a disease caused by bacteria that most often affect the lungs
GI	means Geographic Indications, which include "place names (or words associated with a place) and identify products as having a particular quality, reputation, or other characteristic essentially attributable to the geographic origin of the product".	Third Country	All countries that are not included in the European Union and European Free Trade Association.
HIV	Human immunodeficiency virus) is a virus that attacks cells that help the body fight infection, making a person more vulnerable to other infections and diseases	TRIPS	The Treaty for Trade-Related Aspects of Intellectual Property Rights (1995)
HIV AIDS Act 2017	The Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Act 2017	TRIPS Flexibilities	Legal mechanisms built within TRIPS to overcome patent barriers and allow developing countries to acquire the medicines they need for high priority diseases
ICCPR	International Covenant on Civil and Political Rights	UN	United Nations
ICSECR	The International Covenant on Economic, Social and Cultural Rights	USTR	United States Trade Representative
IP	Intellectual property	WHO	World Health Organization
IPA	Indian Patents Act 1970	WTO	World Trade Organization
LBGTQ	Lesbian, gay, bisexual, transgender and queer		

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