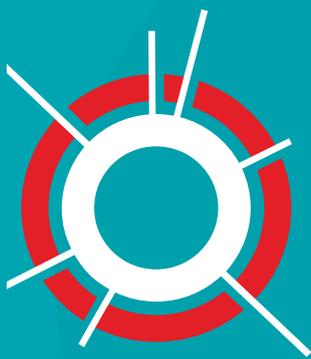


Progress Report 2012-2020



BREAKING IP BARRIERS

Creating Pathways to Medicine Access

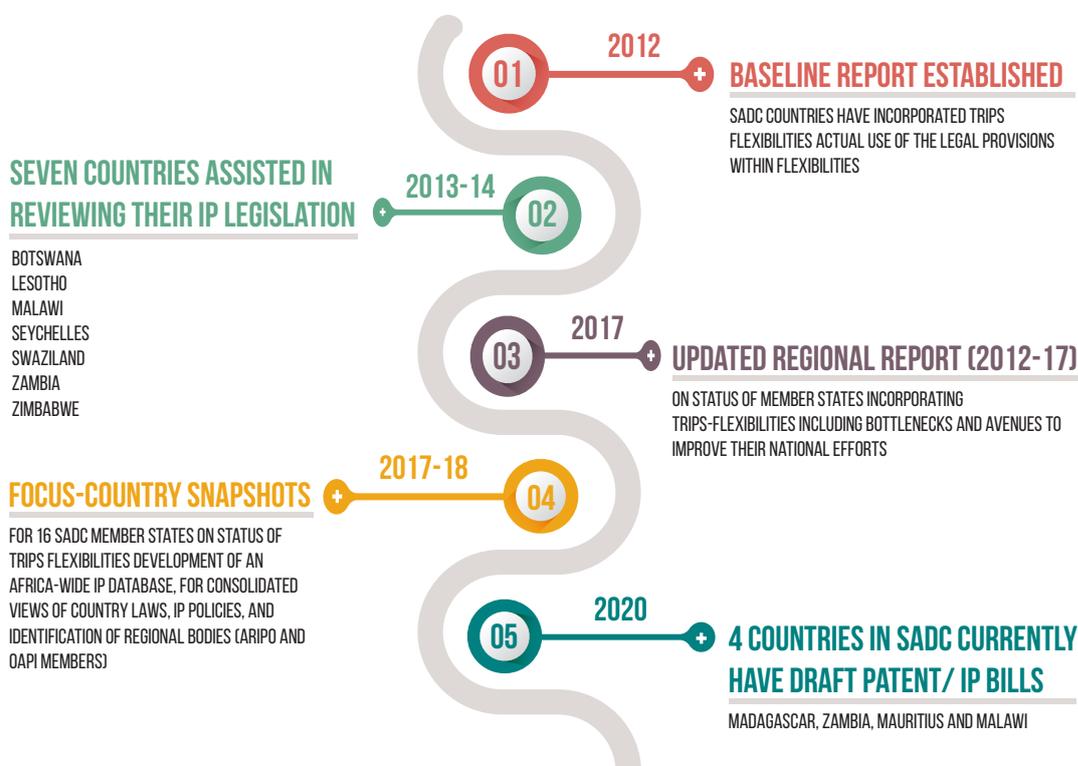


Abstract

Member States (MS) of the Southern African Development Community (SADC) have recognised the importance of Intellectual Property (IP) as an important policy instrument to drive innovation, industrial development, knowledge transfer and regional integration. Harnessing of the flexibilities contained in the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS-Agreement) will go a long way in the protection and promotion of Intellectual Property Rights (IPRs), while safeguarding public health, promoting local infrastructure and manufacturing capability, as well as food security and the protection of indigenous knowledge systems in the SADC.

2012 saw greater momentum within MS leveraging the TRIPS-flexibilities as a strategy to promote access to affordable, safe, and efficacious medicines. Between 2012 and 2014, the Southern African Program on Access to Medicines and Diagnostics (SAPAM), a programme designed by the SADC Secretariat and funded by DFID. This programme provided technical support to Botswana, Zimbabwe, Malawi, Zambia, Lesotho, Seychelles and Eswatini, to incorporate the TRIPS flexibilities into their domestic Patent/Industrial Property and IP legislations. Since then, efforts have been led by SAPAM in collaboration with the AIDS and Rights Alliance for Southern Africa (ARASA) to support the already established multi-disciplinary Technical Working Group (TWG) in these countries; to review and revise their IP/ Patent laws and policies.

This report chronicles progress that has been made by some of the SADC MS in efforts to review, revise and install progressive IP/ Patent laws and national policies. It looks at progress made during the period 2012 - 2020, to advance enabling IP/Patent legislative and regulatory environments, for the improvement of access to essential pharmaceutical medicines and diagnostics. This Snapshot report builds on the 2018 report, the publication entitled: "Progress Report 2012-2020". Moreover, this report provides an overview of the emerging COVID-19 pandemic through the lens of TRIPS flexibilities and details the options available to the MS, to improve access to the COVID-19 therapeutics (diagnostics and vaccines).



Executive Summary

Significant strides have been made in the adoption of comprehensive national IP policies. These have facilitated the revision and adoption of new Intellectual Property (IP)/Patent legislative frameworks. This includes the installation of complementary implementing regulations in some of the SADC countries.

According to the TRIPS, Least Developed Countries (LDCs) are exempted from applying some general provisions of the TRIPS until 2021 and medicines related provisions until 2033. A proposal to extend the general provisions was submitted by the LDC members in October 2020.

It is observed that the period 2018-2020 saw significant progress for the SADC Intellectual Property and Industrialisation agenda. During this period, the Republic of Zimbabwe, South Africa, Namibia, and Malawi approved their national IP policies. Progress was seen in the Republic of Namibia, in that the 2012 Industrial Property Act and implementing regulations were approved by Cabinet in June 2018. Another welcomed development within the region has been the Kingdom of Eswatini tabling the Patent Bill No. 19 of 2018.

The SADC Pharmaceutical Business Plan 2015-2019 (PBP-19) is another strategic tool that has been advanced by SADC MS. The purpose of this PBP-19 was to enhance the capacities of member states to effectively prevent and treat diseases that are of major concern to their national public health.

The PBP-19 was also supposed to address intra-regional pharmaceutical trade matters, in the hopes of facilitating availability and access to quality medicines and diagnostics among SADC MS. It calls on countries to strengthen their domestic IP/ Patent legislations. This is seen as a key strategy for ultimately stimulating SADC's innovation agenda. To achieve this goal, the preparedness of domestic IP/Patent legislative frameworks is prioritised, as a critical path to driving the feasibility of local manufacturing. It is envisaged that these efforts will result in the activation of a research and development into products, and processes that will safeguard SADC countries' public health obligations. The Business Plan is due for another update. At the time of writing, no concrete plans had been shared by SADC Secretariat to facilitate the revision.

The developments documented in this report, continue to contribute towards a solid foundation for an enabling environment for the region's industrialisation agenda, as regulated and supported by the various iterations of the PBP-19.

Section 7 of the SADC Pharmaceutical Business Plan, provides for the Facilitating trade in pharmaceuticals within SADC.

- i) Complete the regional assessment of intellectual property and medicines legislation in MS to determine their TRIPS compliance and adaptability;
- ii) Utilise the legal expertise identified to facilitate the harmonisation of national legislation with TRIPS to incorporate TRIPS flexibilities into national legislation;
- iii) Collaborate with development partners to enable countries to protect, include and take advantage of the flexibilities that exist in the TRIPS Agreement as well as to assist countries in bilateral trade negotiations to conclude agreements that are not detrimental to public health;
- iv) Strengthen the capacity of Intellectual Property (IP) officers, procurement agencies and Medicines Regulatory agencies on issues of intellectual property and public health;
- v) Utilise paragraph 6 system (DOHA Declaration) or article 31bis of the TRIPS

PROGRESS REPORT: INTELLECTUAL PROPERTY (IP) LEGISLATIVE UPDATES

Intellectual Property Acts enacted between 2012 – 2020 by SADC Member States

Four out of the 16 SADC MS have enacted new IP/Patent legislations, incorporating the TRIPS flexibilities. These include the Republics of Botswana, Mozambique, Seychelles and Namibia. The Kingdom of Eswatini and the Republic of Zambia currently have pending implementation regulations for their IP Acts to be enforced. The Republics of Madagascar in 2016 and Mauritius in 2017 developed draft IP bills, but these processes have stalled. The government of Malawi is currently revising their IP/ Patent law in line with their National IP Policy, launched in May 2019.

Incremental changes in the legislative environments of SADC Member States

- The **Republic of Botswana** enacted their Industrial Property Act (Act No. 8 of 2010) in 2012.
- The **Union of the Comoros**, the newest political member of the SADC, is regulated under the Organisation Africaine de la Propriété Intellectuelle (OAPI). Therefore, all IP-related matters in the countries are regulated under this regional intellectual property agreement, which supersedes national IP law.
- The **Republic of Mozambique** enacted the Industrial Property Code (Decree No. 47/2015) on 31 March 2016.
- The **Republic of Namibia** promulgated the Industrial Property Act of 2012 came into effect on 1 August 2018 following the finalisation of the implementing regulations. This new Act repeals the Patents, Designs, Trade Marks and Copyright Act No. 9 of 1916 and Trade Marks in South West Africa (Act No. 48 of 1973).
- The **Republic of the Seychelles** enacted the Industrial Property Act (Act No. 7 of 2014) came into effect on March 2015. This small country also acceded to WTO and the TRIPS agreement within the same period. This IP Act contains all the relevant TRIPS flexibilities.
- The **Republic of Madagascar** has a reformed Intellectual Property Bill No. 043/2017 which was announced on 27 October 2017. The Bill is still under review.
- The **Republic of Mauritius** Draft Industrial Property Bill was sent out for commentary early 2017.

Progress towards creating enabling environment: Implementing Rules/Regulations

One of the impeding factors in the effective implementation of IP/Patent legislation, is often the lack of implementing regulations, which administer and enforce the provisions of the law by providing practical interpretative guidance as to how the law is to be applied. For some MS, it often takes years for the implementing regulations to be developed and adopted, after the Bills have been promulgated into law.

Case studies of delayed implementation regulations in member states:

- The **Republic of Namibia** took six years to develop and consolidate the implementing regulations to the Industrial Property Bill of 2012.
- The **Republic of Zambia** enacted her Patent Act in 2016; the implementation of said legislation has been stalled due to a lack of implementing regulations. Therefore, the country continues to rely on the Patents Act of 1958 (Chapter 400, as amended up to Act No. 13 of 1994). Regulations are still undergoing regulatory process before they can be approved, and the Statutory Instrument signed by the Minister. , The Patents and Companies Registration Agency (PACRA) confirmed that no date has yet to be set for when the regulatory process is finalised.
- The **Kingdom of Eswatini's** Patent Act No 19 of 2018, is not yet in force due to the outstanding regulations. The patent regime continues to be governed by the Patents, Design and Trade Marks Act of 1936.

Consolidation of IP regimes through national Intellectual Property Policies: Progress between 2012 – 2020

A national Intellectual Property (IP) Policy serves as a cornerstone of a country's intellectual property regime. These policies provide a holistic overview of the country's strategic objectives in leveraging IP as a tool for its various spheres of development. MS often have to strike a balance between the formulation of IP policies to support their national developmental goals, strengthened trade positions and safeguarding of domestic Intellectual Property Rights (IPRs) to support innovation and development. Numerous MS have commenced a process of either developing a national IP policy or tabling same in parliament. Quite a few MS have adopted such policies.

- The **Kingdom of Lesotho** has taken an incremental approach in revising her intellectual property policy. The process has been on-going since 2013. As at the time of drafting, no further information was available on developments toward completing the national IP policy.
- The **Republic of Malawi** launched their **National Intellectual Property Policy** in 2019. It mentions that “the current IP legal framework does not provide enough safeguards for public health and access to essential medicines and health technologies in the context of the TRIPS Agreement”. The Republic of Mauritius launched the National Intellectual Property Development Plan in 2017. The plan calls for the incorporation and implementation of TRIPS flexibilities into the country's new Industrial Property Bill.
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- The **Republic of Mozambique** adopted the **Intellectual Property Strategy 2008–2018**. Similar to an IP policy, the strategy mainly addresses issues of innovation, industrial development and scientific advancement, but does not touch on the use of TRIPS flexibilities.
- The **Republic Namibia** approved in October 2019 the **National Intellectual Property Policy and Strategy 2019-2024**. The IP policy touches upon utilising flexibilities: “provide for effective and adequate exceptions, limitations and flexibilities for purposes of safeguarding public interests, promotion of access to medicine, education and information for all Namibians.”
- The **Republic of the Seychelles** does not have an intellectual property policy. The country relies on the **National Health Policy of 2015**, which promotes the use of TRIPS flexibilities and the ‘Seychelles Strategy for the Prevention and Control of Non-Communicable Diseases, 2016-2025’.
- The **Republic of South Africa's** approved the **Intellectual Property Policy Phase I** in May 2018. The policy focus on moving the nation towards a knowledge economy of innovation, local manufacturing and improved productivity at the same time emphasises the importance of access to affordable health care.
- The **Republic of Zambia** Intellectual Property (IP) Policy 2010-2014 remains the country's latest national IP policy.
- The **Republic of Zimbabwe** launched in 2018 **The National Intellectual Property Policy and Implementation Strategy 2018-2022**. The Policy promotes among other things, access to medicines, at affordable prices and through the exploitation of the TRIPs flexibilities. Moreover, it advocates for the use of research and development of pharmaceuticals.

It is envisioned that progress made thus far, will enable SADC countries to harness the flexibilities afforded by the World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS-Agreement) and the Doha Declaration on the TRIPs Agreement and Public Health (2001), to respond to their various communicable and non-communicable disease (NCD) public health concerns.

Intellectual Property (IP) Response to the COVID-19 Pandemic

Introduction

As it stands low- and middle-income countries will be the last to get COVID-19 rapid molecular diagnostics and vaccines. With the advent of 'vaccine nationalism' the initial solidarity seems to have swayed from the notion that "no one is safe unless everyone is safe" to "each country for themselves". This context shows why it is so important that countries have IP policies that lays out how the country will ensure access to medicines.

At the emergence of the COVID-19 pandemic at the beginning of 2020, the Access to COVID-19 Tools (ACT) Accelerator was launched in April 2020. This is a global solution for expediting the end of the COVID-19 pandemic. This collaboration of leading public health agencies has accelerated the development of COVID-19 tests, treatments and vaccines and is positioned to rapidly scale and ensure equitable access to a new generation of COVID-19 tools. ACT-A has four primary pillars, including vaccines, diagnostics, therapeutics and the health systems connector, which all operate in a complementary fashion to facilitate equitable access to the COVID-19 tools. The Vaccines Pillar of ACT-Accelerator, COVAX, is one of the three pillars of the ACT-Accelerator. It is convened by the Coalition for Epidemic Preparedness Innovations (CEPI), Global Alliance for Vaccines and Immunization (GAVI), World Health Organisation (WHO) and other partners. COVAX has accelerated the development and production of vaccines through investments in a broad portfolio, currently including 11 candidates across 4 technology platforms. The facility is financed by higher income economies that brings together governments and manufacturers to ensure COVID-19 vaccines are rolled out.

Most SADC countries, other than South Africa, rely solely on the highly subsidised solidarity mechanism of the COVAX facility. Besides the consignment that has been procurement by the Africa Union through CDC Africa, there little information as to how many of the SADC MS will access the COVID-19 tools. The pandemic highlights the importance of epidemic preparedness by MS and installing progressive IP policies could act as safeguard mechanism to ensure that MS are able to leverage the TRIPS flexibilities as and when these public health emergencies emerge.

Trade-Related Aspects of Intellectual Property Rights (TRIPS) and COVID-19

In October 2020, the Republics of South Africa and India proposed a temporary suspension of patents and other intellectual property (IP) rights on any COVID-19 related novel vaccine, medicine, and testing tools, for the duration of the pandemic. Several high-income countries, including Norway, United Kingdom, European Union together with the pharmaceutical industry opposed this proposal, arguing that it will stifle competition and hamper companies from recouping their research and development costs. Moreover, arguments have been made that within the current IP system consent by pharmaceutical companies already exists for voluntarily data and technology transfer. South Africa and India aver that a suspension of patents related to the COVID-19 response would allow a larger group of manufacturers to produce the much needed vaccines and rapid diagnostic tools, rather than these being in the hands of only a few patent rights holders at higher costs with smaller quantities being manufactured.

According to the provisions of the TRIPS, any pharmaceutical company can voluntarily share its technologies (through a patent pooling mechanism), or it can be forced by government provisions in the country where it has registered its patent for said technology. For pharmaceutical products and/ or processes, this can be in the case of domestic public health emergencies, through 'government use' or compulsory licensure clauses in the country's IP/ Patent law. In the case of the former, voluntary licenses is awarded by the patent pooling mechanism, to countries. This has been the trend with the recent innovative drugs for HIV and Hepatitis C. In the case of the latter, compulsory licenses (non-voluntary) the pharmaceutical company is not required to give the know-how or the test-data of the patent. So instead of getting into a conflict with the pharmaceutical company, it is better to have voluntary mechanisms in place. One recent example is the partnership model that Novavax and AstraZeneca made with the Serum Institute of India for the making of their vaccines.

Bilateral Agreements

Most SADC countries will have to rely on the COVAX facility to ensure access to vaccines. Although given the current trajectory, this is going to be a long process. For domestic distribution, most African countries are privileged in that they have existing vaccination systems in place. Once the vaccines are available, they should ensure that the Covid-19 vaccine rollout strategy piggybacks on their existing national vaccine programs. As it stands, in terms of “vaccine readiness”, the African region has an average score of 33% for the roll-out of COVID-19 vaccine. This is unfortunately below the desired 80% benchmark.

An alternative solution and one that will be more costly for SADC countries, is to have a bilateral agreement together with the COVAX facility. South Africa and Kenya have reached an agreement with the Serum Institute of India and the AstraZeneca vaccine and is expecting to receive a total of 1.5 and 24 million doses (respectively) in 2021. Morocco has ordered 65 million doses of the Chinese Sinopharm and AstraZeneca vaccines. Other SADC member countries could follow the same model and negotiate with the Serum Institute, Chinese Sinopharm or the Russian Sputnik V Vaccine.

Patent Pooling

Another potential solution is to use the regional patent pool. This is when a patent holder shares his patent with several other manufacturers who are then allowed to make the drug for a small fee. The Medicines Patent Pool is an example of a progress pooled procurement mechanism. The MPP has ensured voluntary licenses for many countries for HIV, TB and Hepatitis C. The World Health Organization (WHO) has an existing patent pool (medicines, vaccines and test material) for COVID-19. Unfortunately, no producer has yet signed up to include a patented product in the pool. It is still early, and the patent pool might be a more viable solution to low- and middle-income countries. Working through a regional cooperative strategy or SADC Pooled procurement mechanism would be a viable solution for regional distribution of the COVID-19 vaccine.