SAPAM

HEALTH SYSTEMS STRENGTHENING

TRIPS flexibilities in Africa: Are countries equipped to protect public health?

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Presentation to Global Health Centre
Graduate Institute of Geneva
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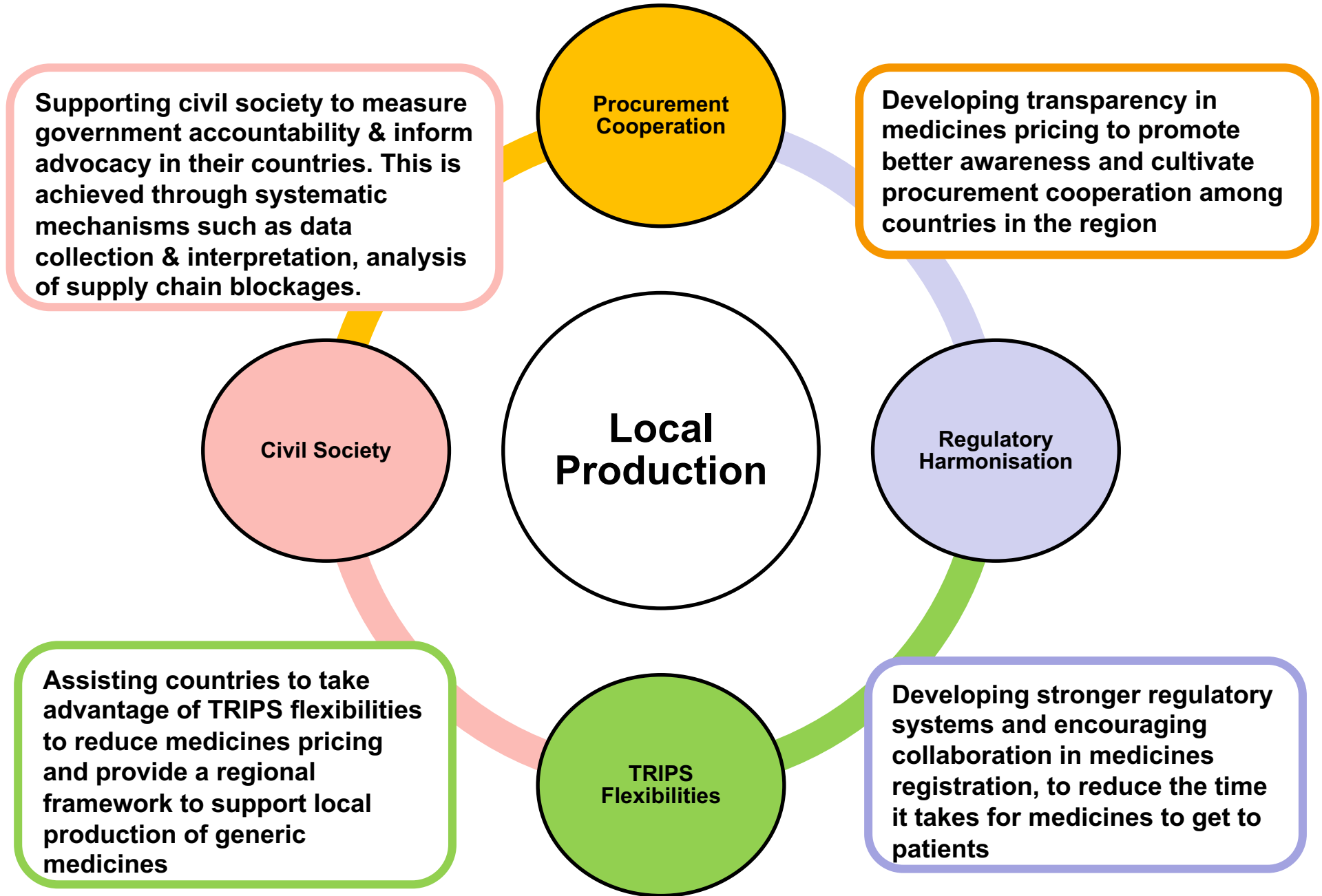
Sustainability – Access to Medicines



Preparing CSOs and affected communities

BREAKING IP BARRIERS
Creating Pathways to Medicine Access

SAPAM with AIDS & Rights Alliance for Southern Africa (ARASA) in collaboration with the Medicines Patent Pool designed an **IP and Access CSO training programme**

Followed similar learning pathway to the 2-week University of Kwazulu Natal (UKZN) Extended Course on IP and Access to Medicines developed by Dr/ Profs. Y. VAWDA & Brook Baker)

Pivoted face-to-face interactions onto online platforms to reach larger CSO cohorts.

Post-training advocacy and retention of CSO interest remain a challenge due to:

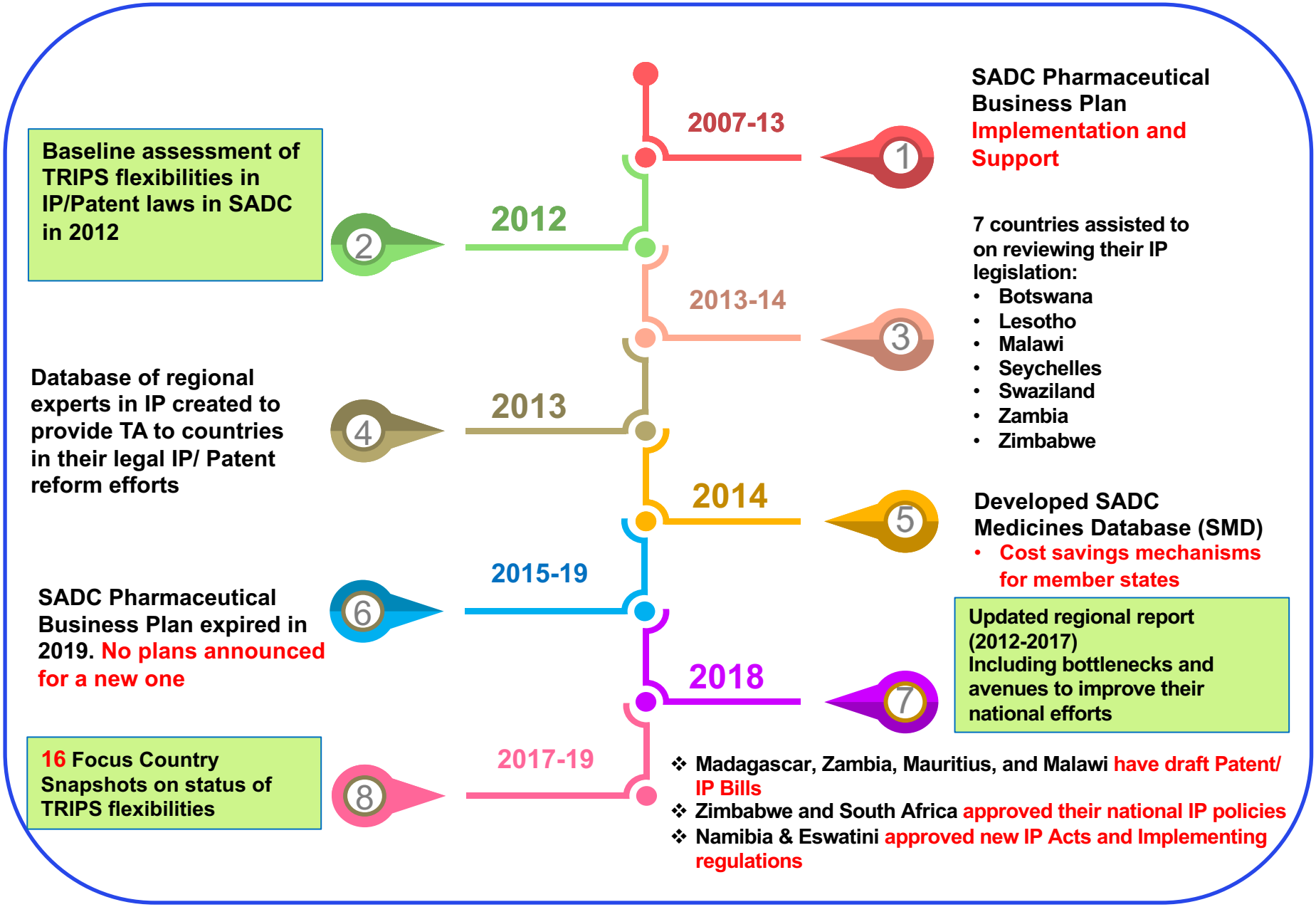
- Lack of sustained funding to support domestic interventions (i.e. only handful of donors)
- Legal reform is tedious and requires large investments (e.g. SA #FixthePatents campaign)
- Low priority area for some CSOs who believe securing affordable access to ARVs is sufficient
- IP& A2M advocacy has become a **"singleDisease-single-Drug"** game. TA required by most CSOs who are invested in working on the agenda

ARASA and SAPAM continue to offer online training for CSOs on IP and Access to medicines on an annual basis (funding support from Aids Fonds)

Strengthened engagement with affected communities and CSOs working on other diseases such as NCDs and Cancer

Working concurrently with other stakeholders - Members of Parliament, govt. Ministries, private sector, academic and research institutes.

Advancements in SADC region



SADC Member Sates Snapshot Report Overview

BREAKING IP BARRIERS
Creating Pathways to Medicine Access

- Renewed political will within SADC to move forward the implementation of the 2015 – 2019 SADC Pharmaceutical Business Plan?

Strategic Priority 7: Facilitating trade in pharmaceuticals within SADC through Intellectual Property legislation review and harnessing TRIPS flexibilities for improved access to medicines

- Calls on countries to strengthen their domestic IP/ Patent legislations
- Critical path to driving the feasibility of local manufacturing
- SADC Regional Industrialisation Strategy (2015-2063):

3 overarching pillars of Industrialisation, Regional Integration and Competitiveness starts with transparency and sharing of information

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www.sapam.net

Republic of Namibia

The Industrial Property Act, (2012) was signed into operation on 1st of August 2018. This repeals the old Patents, Designs, Trade Marks and Copyright Act No. 9 of 1916 and Trade Marks in South West Africa Act No. 48 of 1973. With Act No 1 of 2012 operational, Namibia has a very robust legal grounding to ensure access to essential medicine through the options of utilising flexibilities found in the Trade Related aspects of Intellectual Property Rights (TRIPS). In June 2018, cabinet approved the draft IP Policy and Strategy.* It is uncertain if TRIPS flexibilities are included.

**At the time of developing this Snapshot, a draft copy of the IP Policy and Strategy could not be made available.*

Policy Recommendations

1. Launch a **national IP Policy** framework which integrates TRIPS flexibilities. Such a policy would greatly benefit from having clear guidelines on how Namibia will ensure the access to affordable, quality, safe and effacious medicines.

2. Have a operational online searchable database integrated with BIPO.

Country Indicator

Population (2016): **2,48** m

GDP Per Capita (2016): **4 140 USD**

Health Expenditure of GDP (2014): **8.9%**

Human Development Index (2016): **125**

LDC Status: **No.**

Disease Indicator

Malaria New Cases per 1000
10 (2016)

TB Estimated Cases per 100,000
495 (2015)

HIV Prevalence aged 14-49
13.8% (2016)

Non-Communicable Diseases
43% of total deaths (2014)

Harnessing Trade Related aspects of Intellectual Property Rights (TRIPS) Flexibilities

- Member of World Trade Organisation (WTO): **Yes.** January 1, 1995.
- Acceded to TRIPS Agreement: **Yes.** January 1, 1995.
- Voluntary Licenses: **Yes.** [**Refer to** Medicines Patent Pool (MPP)].
- Past Use of TRIPS Flexibilities: **Yes.** 2005, no patent, all medicines, all diseases.
- Research Exception: **Yes.** Article 43(c), Act No. 1 of 2012.
- Early Working (Bolar) Exception: **Yes.** Article 43(2), Act No. 1 of 2012.
- Compulsory Licenses / Government Use: **Yes.** Article (55)- (63), Act No. 1 of 2012.
- Parallel Importation (International exhaustion): **Yes.** Article 43(1)(a) Act No.1 of 2012 .
- Patentability Criteria: **Yes.** Article 14(1) Act No.1 of 2012.
- Pre and Post patent Grant Opposition Procedures: **Yes.** Article 65, Act No.1 of 2012.
- Importation of HIV, TB and Malaria drugs from SADC member states: **Yes.**
- Pharmaceutical Act: **Yes.** Pharmacy Act, 2004, (Act No.9, 2004).
- Regulatory Authority: **Yes.** Namibia Regulatory Council.

Namibia IP Timeline

01 — 1916 — ACT NO. 9 OF 1916
PATENTS, DESIGNS, TRADE MARKS AND COPYRIGHT ACT, 1916. THE ACT IS STILL APPLICABLE TO SOME INDUSTRIAL PROPERTY RELATED ISSUES.

02 — 1973 — ACT NO. 48 OF 1973
TRADE MARKS IN SOUTH WEST AFRICA ACT, 1973. ENFORCEMENT OF IP AND RELATED LAWS. IP REGULATORY BODY, INDUSTRIAL PROPERTY, TRADEMARKS

03 — 1990 — BERNE CONVENTION
PROTECTION OF LITERARY AND ARTISTIC WORKS

04 — 1995 — TRIPS
THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY (TRIPS)

05 — 2002 — HARARE PROTOCOL
PATENTS AND INDUSTRIAL DESIGNS WITHIN THE FRAMEWORK OF THE AFRICAN REGIONAL INDUSTRIAL PROPERTY ORGANISATION

06 — 2003 — LUSAKA AGREEMENT
THE CREATION OF THE AFRICAN REGIONAL INTELLECTUAL PROPERTY ORGANIZATION (ARIPO)

07 — 2004 — BANJUL AGREEMENT
MARKS WITHIN THE FRAMEWORK OF THE AFRICAN REGIONAL INDUSTRIAL PROPERTY ORGANISATION

08 — 2011 — DOLUTEGRAVIR
VOLUNTARY LICENSE OF DOLUTEGRAVIR IN COMBINATION WITH ABC AND 3TC GRANTED FROM MEDICINES PATENT POOL.

09 — 2012 — INDUSTRIAL PROPERTY ACT, 2012
ACT NO. 1 OF 2012. (NOT YET NOT IN FORCE)

10 — 2016 — BUSINESS AND INTELLECTUAL PROPERTY AUTHORITY ACT
BIP ACT ADMINISTERED BY BUSINESS & INTELLECTUAL PROPERTY AGENCY.

Intellectual Property Policy Environment

- IP/Patent Act: **Industrial Property Act, 2012 (Act No. 1 of 2012)**
- Competition Act: **Competition Act, 2003 (Act No. 2 of 2003)**
- Regional IP Member: **Yes.** African Regional Intellectual Property Organization (ARIPO)
- Regional/ Multilateral Legislation: **TRIPS/Paris/Harare/Lusaka/Banjul**
- IP Policy Status update: **No.**
- Online searchable patent database: **No** National online database, ARIPO online database only

Cost Saving Mechanism

A wide range of medicines can be profitably manufactured at very low cost and /or through the procurement of generic medicines. Should voluntary license options not be available, then governments could consider the use of other TRIPS flexibilities. This is especially urgent as newer and less toxic essential medicines are now needed for diseases such as HIV-Tuberculosis co-epidemics (and their drug-resistant strains), Hepatitis C and other Non-Communicable Diseases (NCD's)such as cancer and diabetes.
It is estimated that on average generics medicines are 20-80% cheaper than originator drugs and often push down price of originator drugs.

Prescription drug cost comparison

Union of the Comoros

The patent regime in the Comoros is governed by the Bangui Agreement of March 2, 1977. Comoros is member of the Organisation Africaine de la Propriété Intellectuelle (OAPI) which have a regional intellectual property agreement which supersedes national IP law. Member states can issue a separate national law that would supersede the Bangui Agreement (so far this has not been done). Patent applications are filed with OAPI at national or at OAPI main office. It has been argued that the revised Bangui Agreement of 1999, missed the opportunity at the time to incorporate all the permissible TRIPS flexibilities at the expense of access to affordable medicine for its member countries and have unecesserily introduced TRIPS-Plus measures. In 2015 OAPI amended the Bangui Agreement to allow its LDC member countries to postpone granting test data until 2033.

Policy Recommendations

1. Move from regional paralell importation to **international exhaustion**. Clearly state the option for **Early working** (bolar) exceptions. Enable **pre grant** opposition application procedures.

2. Avoid **TRIPS-Plus measures**, such as data exclusivity, granting of secondary patents and patent linkages.

3. Deny the granting of patents for **pharmaceutical products**, as per World Trade Organisation's (WTO) waiver on pharmaceutical products until 1 January 2033.

Country Indicator

Population (2016): **795 601**

GDP Per Capita (2016): **616,7 USD**

Health Expenditure of GDP (2014): **6.8%**

Human Development Index (2016): **160**

LDC Status: **Yes.** Observer

Disease Indicator

Malaria New Cases per 1000
1.34 (2016)

TB Estimated Cases per 100,000
35 (2016)

HIV Prevalence aged 14-49
0.1%

Non-Communicable Diseases
37%

Harnessing Trade Related aspects of Intellectual Property Rights (TRIPS) Flexibilities

Member of World Trade Organisation (WTO): **No.** (WTO accession negotiation)

Acceded to TRIPS Agreement: **No.**

Voluntary Licenses: **Yes.** [**Refer to** Medicines Patent Pool (MPP)].

Past Use of TRIPS Flexibilities: **Yes.** 2007, paragraph 7, all medicines, HIV/AIDS

Research Exception: **Yes.** Article 8(c), Bangui Agreement of 1977.

Early Working (Bolar) Exception: **Yes.** Article 8, Bangui Agreement of 1977. Though not specifically mentioned in Article 8, member state courts could broadly interpret the article to allow for the early working (bolar) exception.

Compulsory Licenses / Government Use: **Yes.** Article 46-57, Bangui Agreement of 1977.

Parallel Importation (International exhaustion): **Yes.** (Regional) Article 8 (1)(a), Bangui Agreement.

Patentability Criteria: **Yes.** Article 2-6, Bangui Agreement of 1977.

Pre and Post patent Grant Opposition Procedures: **Yes.** Article, 43-44, Bangui Agreement of 1977. Post grant opposition procedures only by a civil court.

Pharmaceutical Act: **No.**

Regulatory Authority: **No.**

Comoros IP Timeline

01 — 1844 — NATIONAL IP LAW
THE PATENTS ACT OF JULY 5, 1844 WAS REPLACED BY THE BANGUI AGREEMENT OF MARCH 2, 1977 SIGNED BY COMOROS IN 2013.

02 — 1974 — INDEPENDENCE
THREE OF THE ISLANDS MAKING UP THE COMOROS VOTE FOR INDEPENDENCE.

03 — 2005 — 1ST 5 YEAR PLAN
COMOROS LAUNCHED ITS FIRST FIVE-YEAR ANTI-MALARIA PROGRAMME WITH FUNDING FROM THE GLOBAL FUND AGAINS MALARIA, TB AND AIDS.

04 — 2005 — THE PARIS CONVENTION
APPLIES TO INDUSTRIAL PROPERTY IN THE WIDEST SENSE, INCLUDING PATENTS, TRADEMARKS, INDUSTRIAL DESIGNS, UTILITY MODELS, SERVICE MARKS, TRADE NAMES, GEOGRAPHICAL INDICATIONS AND THE REPRESSION OF UNFAIR COMPETITION.

05 — 2005 — PATENT COOPERATION TREATY
THE PATENT COOPERATION TREATY (PCT) MAKES IT POSSIBLE TO SEEK PATENT PROTECTION FOR AN INVENTION SIMULTANEOUSLY IN EACH OF A LARGE NUMBER OF COUNTRIES BY FILING AN "INTERNATIONAL" PATENT APPLICATION.

06 — 2007 — ANTIMALARIAL ARTEQUICK
COMBINATION DRUG THERAPY BASED ON ARTEMISININ AND A SECOND ANTIMALARIAL CALLED PIPERAQUINE. IT IS MADE AND SOLD UNDER THE BRAND NAME "ARTEQUICK" BY ARTEPHARM. THE NUMBER OF CASES IN THE ISLAND OF MOHELI FELL BY 95%.

07 — 2010 — 2ND 5 YEAR PLAN
THE TWO FIVE YEAR PLAN HAS ALL BUT ERADICATED MALARIA THANKS TO A COMBINATION OF PREVENTION, CONTROL MEASURES AND THE USE OF ARTEQUICK.

08 — 2013 — BANGUI AGREEMENT
BANGUI AGREEMENT RELATING TO THE CREATION OF AN AFRICAN INTELLECTUAL PROPERTY ORGANIZATION, CONSTITUTING A REVISION OF THE AGREEMENT RELATING TO THE CREATION OF AN AFRICAN AND MALAGASY OFFICE OF INDUSTRIAL PROPERTY

09 — 2013 — SOFOSBUVIR
FILED WITH MEDICINES PATENT POOL (MPP). IT IS USED FOR THE TREATMENT OF HEPATITIS C. IT IS ONLY RECOMMENDED WITH SOME COMBINATION OF RIBAVIRIN, PEGINTERFERON-ALFA, SIMEPREVIR, LEDIPASVIR, DACLATASVIR, OR VELPATASVIR.

Intellectual Property Policy Environment

- IP/Patent Act: **Bangui Agreement of March 2, 1977**
  Date of entry into force: May 25, 2015.
- Competition Act: **No.**
- Regional IP Member: **Yes.** Organisation Africaine de la Propriété Intellectuelle (OAPI).
- Regional/ Multilateral Legislation: **Paris, Bangui.**
- Online searchable patent database: **No.**

Cost Saving Mechanism

A wide range of medicines can be profitably manufactured at very low cost and /or through the procurement of generic medicines. Should voluntary license options not be available, then governments could consider the use of other TRIPS flexibilities. This is especially urgent as newer and less toxic essential medicines are now needed for diseases such as HIV-Tuberculosis co-epidemics (and their drug-resistant strains), Hepatitis C and other Non-Communicable Diseases (NCD's)such as cancer and diabetes.
It is estimated that on average generics medicines are 20-80% cheaper than originator drugs and often push down price of originator drugs.

Prescription drug cost comparison

Adaptation of advocacy

BREAKING IP BARRIERS
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- Lack of understanding or appreciation of tangible benefits of TRIPS flexibilities
- Conflicting interests between industrial policy, public health and revenue collection
- Lack of clarity about which government agency takes responsibility or lead e.g. Health, Trade & Industry or Finance
- National interests overriding potential benefits from regional cooperation e.g. lack of using LDC status for benefit of region
- Efforts to work with ARIPO to reform the Harare Protocol threatens a lot of countries as they often depend on ARIPO for up-keep of the patent offices.
- Apparent inertia in parliamentary processes in getting to Bill stage then Act of Parliament

Opportunities

BREAKING IP BARRIERS
Creating Pathways to Medicine Access

- Increase **understanding and appreciation** to prioritize TRIPS flexibilities
- Relevant Parliamentary Committees drives process of harnessing TRIPS flexibilities and pharmaceutical waivers
- Generic manufacturers esp. in LDCs team up with experienced manufacturers for **technology transfer** to produce pharmaceuticals that meet WHO pre-qualification standards
- Strengthen linkages between tools in **Procurement Cooperation Strategy** and **Local Production** to maximize TRIPS flexibilities implementation e.g. SADC Medicines Database, Pooled Procurement Network, Regulatory and Review of Patent Legislation in the region
- Minimize disruptions from TRIPS+ arising from **bilateral trade agreements (leveraging perhaps on the Continental FTA being negotiated for COVID-19 & emerging epidemics)**
- Strengthen harmonization/convergence efforts in pharmaceutical value chains of medicines registration, procurement and supply management standards and practices