



BREAKING IP BARRIERS

Creating Pathways to Medicine Access

ARASA AND SARPAM REGIONAL POLICY DIALOGUE on
Minimizing intellectual Property Barriers to Access to HIV,
TB and Hepatitis C Medicines in Botswana, Mauritius
and Zimbabwe

12-13 October 2015

Aviator Hotel, Johannesburg, South Africa



BREAKING IP BARRIERS is jointly implemented by:



and supported by:



In January 2015, the **AIDS and Rights Alliance for Southern Africa (ARASA)** and the **Southern African Regional Programme on Access to Medicines and Diagnostics (SARPAM)** secured funding from AIDS Fonds, to jointly implement a programme to advance regional strategies aimed at minimizing intellectual property barriers that prevent access to medicines – entitled, “Influencing policymaking on minimizing Intellectual Barriers in the SADC region for People Living with HIV, TB and Hepatitis C”. The programme focuses specifically in the following countries: Botswana, Mauritius and Zimbabwe. The ultimate outcome from this 3-year programme will be to promote improved access to new TB, MDR and XDR-TB, Hepatitis C and HIV treatment for people living with HIV in these countries, by addressing intellectual property (IP) barriers.

Meeting Report

ARASA and SARPAM Regional Policy Dialogue on Minimizing Intellectual Property Barriers to Access to HIV, TB And Hepatitis C Medicines In Botswana, Mauritius And Zimbabwe



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1. Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
ARASA	AIDS and Rights Alliance for Southern Africa
BONELA	Botswana Network on Ethics, Law and HIV/AIDS
HIV	Human Immunodeficiency Virus
IP	Intellectual Property
LDC	Least Developed Countries
TRIPS	Trade-Related Aspects on Intellectual Property Rights
SADC	Southern African Development Community
SAGMA	Southern Africa Generic Manufacturers Association
SALC	Southern African Litigation Centre
SARPAM	Southern African Regional Programme on Access to Medicines and Diagnostics
SRHR	Sexual and Reproductive Health and Rights
TB	Tuberculosis
WTO	World Trade Organisation
ZLHR	Zimbabwe Lawyers for Human Rights

2. About ARASA and SARPAM

Established in 2002, the AIDS and Rights Alliance for Southern Africa (ARASA) is a regional partnership of 89 non-governmental organizations working together to promote human rights-based approaches to HIV/AIDS, SRHR and TB in east and southern Africa; through capacity building and advocacy.

The Southern Africa Regional Programme on Access to Medicines and Diagnostics (SARPAM) was designed in consultation with the SADC Secretariat and other stakeholders, to respond to identified gaps in the pharmaceutical markets of Southern Africa, including practices which result in uncompetitive, inconsistent medicine pricing and the poor supply chain management of medicines. The programme engages both public and private sector stakeholders to ensure improved access to medicines across the region.

The two organizations are collaborating for the following reasons:

ARASA's value proposition: A strong regional civil society partnership driven 'voice' on rights-based responses to HIV and TB in East and Southern Africa, including articulating rights-based arguments to access to essential medicines as a basic human right. Access and reach of civil society partners in 18 countries, including advocacy and community mobilization.

SARPAM's value proposition: Uses collaborative and innovative tactics to assist countries tackle regulatory and policy barriers to communities accessing medicines and seeks to enable member states of SADC, to partner together in finding solutions to existing challenges. SARPAM has been implementing the TRIPS, Trade and Access to Medicines regional project over the last five years.

3. Executive Summary

ARASA and SARPAM are jointly implementing a three-year programme, which started in January 2015 focusing on minimising intellectual property barriers to access to HIV, TB and Hepatitis C medicines. This programme focuses in three countries: Botswana, Mauritius and Zimbabwe.

3.1 The main objectives of this programme are grouped as follows

1. Sustained engagement of SADC member states by civil society for increased visibility of challenges presented by IP barriers, to encourage (medicines-friendly) regional agreements that do not conflate IP enforcement detrimental to public health within the SADC region
2. Strengthened regional approaches in responding to IP barriers by encouraging non-IP centred registration of 2nd & 3rd line ARVs, TB, MDR and XDR-TB, as well as Hepatitis C medicines (i.e. implementation of regional guidelines, within the Pharmaceutical Business Plan and the SADC Protocol on Health
3. Enhanced civil society capacity in Zimbabwe, Mauritius and Botswana to undertake national advocacy and mobilisation campaigns to advocate for IP law review and reform, which is aligned with policies that promote systematic improvements for issuing of the compulsory licensing
4. Strengthened engagement between civil society and policy makers at national level for the implementation of the regional guidelines, as well as national accountability for accelerated domestic implementation



The specified objectives of this programme are relevant to its broader outcomes of achieving access to medicines in the broader Southern African Development Community. While this is appreciated, there is a need to monitor and evaluate progress against agreed methodology such as the theory of change model agreed upon, in order to demonstrate the impact of the advocacy being undertaken in the focus countries and regionally, to minimize IP barriers as they impact access to affordable and safe medicines.

3.2 Technical approach

This is being done through:

1. Stakeholder (especially government) engagement
2. Public advocacy & mobilisation using existing structures
3. Gathering evidence for advocacy through a TRIPs mapping exercise by regional TRIPS experts
4. Civil society capacity building on TRIPs and status of country IP policy and Bills; equipping through training activities
5. Networking nationally & regionally
6. Scaling up systematic advocacy on TRIPs flexibilities



3.3 Programme Management Approach

The implementation approach includes engaging and collaborating with partner organizations with detailed knowledge of the communities in their respective countries. This includes ensuring a regional focus is maintained. Continuously improve systems and developed infrastructure and apply learning's and growth.

3.4 Key Emerging Issues from the Regional Dialogue

- Lack of understanding, appreciation and application of TRIPS flexibilities by the various national government stakeholders as well as civil society organisations
- Lack of the necessary skills in-country to fully use TRIPS flexibilities as a tool to increase access to second and third line HIV and TB, as well as Hepatitis C medicines
- The need to build the capacity of and bridge the gap between IP lawyers, and experts; as well as and civil society organizations and government stakeholders
- The need to promote coordination between Ministries of Health, Finance and Trade at a national level



4. Aim of the Dialogue

SARPAM and ARASA convened a two-day Regional dialogue with 16 delegates from the focus countries on the 12th and 13th of October 2015 in Johannesburg, South Africa.

The aim of this dialogue was to engage on a more direct basis with the three focus countries (Botswana, Mauritius and Zimbabwe) that have registered patents with the African Regional Intellectual Property Organisation countries (ARIPO). In these countries, the programme will focus on ensuring access to some of the drugs listed below, by focusing on the IP related barriers as well as advocacy on price reduction for some of the medicines.

In terms of second line HIV drugs: *Dolutegravir, Ritonavir, Lopinavir, Etravirine and Raltegravir*. In terms of TB, the programme will focus on *Bedaquiline, Linezolid and Sutezolid*, for which there is currently national and regional level advocacy for price reduction. For Hepatitis C, the following drugs will be targeted; *Sofosbuvir, Boceprevir, Telaprevir and Ledispavir*.

The workshop intends to leverage the outcomes achieved in these focus countries for sharing for the purposes of providing technical support and building the capacity for civil society in other countries within the Southern African Development Community (SADC), to undertake similar advocacy aimed at reviewing and amending their IP laws and policies. The regional component of the programme will develop tools for evidence gathering and advocacy for use in all 15 countries, as well as at regional fora, including SADC and the African Union.

4.1 Objectives of this Dialogue

This regional meeting sought to achieve the following objectives:

1. Discuss and reach consensus on the results from the three country Assessment Report & Policy Briefs, which looked at the existing intellectual property gaps in Zimbabwe, Botswana and Mauritius
2. Develop in-country focused advocacy strategies to advance national mobilisation campaigns by civil society, to advocate for IP law review and reform, which is aligned with policies that promote systematic improvements for issuing of the compulsory licensing
3. Encourage a tripartite discussions (between government, private sector and civil society) in order to strengthen engagements at national level for the implementation of the regional guidelines, as well as national accountability for accelerated domestic implementation
4. Reach consensus on the Theory of Change (ToR) to complement in-country discussions and national 2016 work plans

4.2 Outcomes

The ultimate outcome from this 3-year programme is to promote improved access to new TB, MDR and XDR-TB, Hepatitis C and HIV treatment for people living with HIV in these countries, by addressing intellectual property (IP) barriers.

The participating countries developed working plans as follow on activities from this Dialogue.



PROCEEDINGS OF DAY 1

12 October 2015

5. Opportunities and challenges in using TRIPS flexibilities in the SADC region

Intellectual property rights in health in the context of medicines and pharmaceutical products, refers to utilising TRIPS flexibilities in order to work around the exclusion from making, using, or selling an invention (medicine).

In 1994 all members of the World Trade Organisation (WTO) adopted the Agreement on Trade-Related Aspects on Intellectual Property Rights known as the TRIPS Agreement. The TRIPS Agreement obliged all WTO members, including developing countries, to grant patents on, among other fields of technology, pharmaceutical products. This Agreement disadvantaged developing countries which could not access or manufacture medicines for HIV and AIDS.



In 2001 the WTO countries adopted the Doha Declaration on the TRIPS Agreement and Public Health, known as 'the Doha Declaration'. The Doha Declaration acknowledged the rights of countries to protect public health in the light of the HIV/AIDS pandemic, as a 'national emergency'. In the area of health, these flexibilities have come to be commonly known as "public health TRIPS Flexibilities". There was a particular emphasis on the need to promote wider

availability of lower cost generic medicines to ensure sustained availability and access. The Doha Declaration confirmed that public health considerations can and should condition the extent to which patents on pharmaceuticals are enforced and that flexibilities in *the TRIPS Agreement should be used to improve access to medicines for all*.

The Declaration also gave guidance on how to interpret the provisions of the TRIPS Agreement when dealing with health generally and specific clarifications on compulsory licenses and exhaustion of rights. In addition, the Declaration recognised, under Paragraph 6, the challenges related to using compulsory licenses by Members with insufficient or no manufacturing capacity in the pharmaceutical sector and the need to address these challenges. In addition, the Declaration, in paragraph 7, addressed the special case of Least Developed Countries (LDCs). Since the Doha Declaration, the WTO has adopted a series of other decisions to implement the Declaration.

Member states can therefore circumvent the provisions of the TRIPS Agreement by utilising flexibilities in addressing epidemics, including HIV, TB and malaria.

TRIPS flexibilities refer to the following key areas:

- Compulsory and Government use licences
- Bolar exceptions (or early working exceptions)
- Definition of patentable subject matter

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- Exclusion from patentability
- Waivers and transitional periods
- Parallel importation

See presentation “T Kujinga presentation 1” for further detail of 5: Opportunities and challenges in using TRIPS flexibilities in the SADC region.

5.1 Challenges raised within the presentation

- There is a definite reluctance to utilise TRIPS flexibilities at national and regional level due to various reasons, including the fact that parties do not have updated IP legislations - which incorporate the TRIPS flexibilities.
- This is coupled with some confusion as to where the TRIPS agenda resides within ministries at a national level – Ministry of Health, Justice, Trade and/ or Finance. Due to the fact that there is never consultation between the various ministries/ departments at national level the on ‘Agreements’ being negotiated these have the potential to impact how countries utilise existing legislation, as well as the TRIPS flexibilities to increase access to medicines.
- A lack of knowledge on the actual use or how to use TRIPS flexibilities at national level is evident
- There are further limiting factors within bilateral and multilateral agreements being negotiated at regional level, such as the Southern Africa Customs Union Free Trade Area.

Participants discussed the following issues, which hinder the implementation of the TRIPS flexibilities in the region:

- Ever greening of patents is an ongoing practice without the necessary awareness at country level. This includes technology and diagnostics.
- More capacity strengthening efforts are required to increase knowledge and implementation of these flexibilities.
- A knowledge gap in the region includes areas such as implementation of Paragraph 6 and Article 31 bis of the Doha Declaration on TRIPS.
- Existing case studies and functional models from other regions on the use of the media to expose inconsistencies or gain coverage for advocacy purposes (*Peru was cited as an example*)

5.2 Opportunities presented by the Southern African Development (SADC)



SADC has committed itself to utilizing TRIPS flexibilities in addressing access to medicines. This commitment is dictated by the SADC Treaty provides the overall structure and mandate for working towards regional integration, and has inspired the Protocols on Trade and Health.

The SADC Secretariat is playing a supportive role in clarifying and articulating the regional approach, while increasing national level involvement of state members. SADC Regional policies and

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frameworks are in line with the 'African Union Pharmaceutical Manufacturing Plan for Africa' (PMPA), its 2012 Business Plan, the 2015 update report, the AU Accelerated Industrial Development of Africa, and the 'Agenda 2063'. These all provide evidence for a broad continental level consensus on prioritising industrialisation and pharmaceutical manufacturing.

Countries such as Zimbabwe, Zambia and Mozambique have issued compulsory licences for the manufacture of generic ARVs, before. All the countries in the region now seem to import generic ARV medicines for their national HIV treatment programs.

Between 2012 – 2014, SARPAM convened national workshops on TRIPS, Trade and Access to Medicines in 8 Southern African countries, which aided in stimulating interest in the discussions with national government stakeholders, around the use of TRIPS flexibilities. As a result of this process, Malawi, Botswana and Zambia have commenced with legislative amendments of the Intellectual Property Laws, to incorporate and articulate the use of the TRIPS flexibilities.



Through the SARPAM programme, there is now a pool of expertise on Intellectual Property (IP), TRIPS and Trade, which can be mobilised to provide technical expertise for member states.

There is limited manufacturing capacity available in the region. Countries such as South Africa, Zimbabwe, Zambia, Malawi, DRC, Tanzania, Mauritius and Botswana have existing capacity, although that too comes with its own set of challenges. Process are underway to increase generic

pharmaceutical manufacturers; and these efforts are coordinated by the Southern Africa Generic Manufacturers Association (SAGMA).

SADC is currently working on a process to provide a conceptual framework, in order to "Develop the pharmaceutical manufacturing economy in the Southern African Development Community (SADC) to become a viable and competitive supporter of public health programmes for HIV/AIDS, TB and malaria". The vision points to the interrelation between industrialisation and health objectives, which both will have to be achieved. SADC has embraced this vision by putting the focus for the regional production feasibility study on three diseases with considerable public health relevance (HIV/AIDS, TB, and malaria).

The region has a vibrant civil society that arose from the HIV pandemic. These pioneers need to be the voices that play an active role in articulating issues to access to medicines and in demanding that their national governments accelerate access to newer, more affordable and safer HIV, TB, Malaria and Hepatitis C medicines.



6. Presentation on the research findings of the in-depth Mauritius, Botswana, Zimbabwe assessment reports on TRIPS challenges, opportunities and avenues of advocacy

See full Research Finding of the in-depth Assessment of Mauritius, Botswana , Zimbabwe on TRIPS, Challenges, Opportunities and Avenues of Advocacy Report for further details.

Delving into some of the major access barriers to HIV, TB and Hepatitis C facing Mauritius, Botswana and Zimbabwe (in the contexts of intellectual property laws and policies) the participants explored:

- What are the key human rights issues to be considered in the context of access to medicines and the law: Where should the focus be?
- Current and projected challenges to accessing affordable HIV, TB and Hepatitis C medicines in the next 10 years
- What opportunities are presented by exploring TRIPS flexibilities and amendments of IP legislations?

See presentations: Mauritius, Botswana and Zimbabwe for further detail.

6.1 Country experiences with TRIPS flexibilities

Zimbabwe

Capacity building remains as a significant issue that needs to be addressed. One example that poses a strain on resources is the limited 6 month period allowed for testing and running pilots for new products. A more realistic period of 60 months would allow resource scarce bodies to amply undertake the necessary testing and pilot stages required.

Furthermore provision should be made for stock piling (not currently in the Acts). This goes hand in hand with available procurement data, which at this stage is not publically accessible. This points to a lack of transparency in the supply chain process, which subsequently impacts upon applying TRIPS flexibilities.

From the Mauritius example there is a mutual benefit to be achieved by incorporating an understanding of human rights in conjunction with intellectual property. Intellectual property strategy needs to be operationalised, along with tribunals within government structures.

ARASA and SARPAM were propositioned to commit to push these IP barriers.

Botswana

The participants discussed that although there is clear broad objectives in place from government, there is a need to break this down into clear specific milestones with timelines in place.

Through working and sharing information with other Member States, the government will be able to measure performance on increasing access to medicines.



Mauritius

Mauritius is at an advanced stage of tackling Hepatitis C with available treatment options provided. This comes in the form of the fixed-dose combination ledipasvir-sofosbuvir (*Harvoni*) which was approved by the FDA for the treatment of chronic hepatitis C.

There are already two pharmacy laboratories operating that undertake testing. Medicine procurement for the public sector is undertaken by the government tender process.

Intellectual property legislations add provision for the need to strengthen the Regulatory authority. It can be said that although there is a willingness to utilize TRIPS flexibilities in Mauritius the need has not yet risen. Thus, areas for advocacy would point to developing regulations for implementation, which currently seem to be only at a policy level.

6.2 Group Discussions on the country experience - presentations above



Participants stressed the importance of access to medicines as human rights issue. Thus, articulating 'access' using the human rights framework, requires us to recall various resolutions and declaration that have been signed by member states. Reference was made to the 2008 African Commission for Human and Peoples Rights' Resolution 141: Resolution on Access to Health and needed Medicines in Africa among others which articulated the need for African countries to commit to acceleration of access to medicine for their

citizens. The promoting of judicial activism on issues of access to medicines, as articulated in individual countries' Constitutions at a national level, was definitely an entry point.

The need to improve and simplify implementation of Paragraph 6 rules and regulations is important. This process needs to be driven and supported from the level of the national stakeholders and the various governmental departments in order to succeed. Colleagues discussed the practicality of using the Paragraph 6 solution given the complications that arose when Rwanda tried using it to use this system to get medicines from Canada. It was stressed though, that failure by one country to utilize this system, should not hinder countries within the SADC using same, especially where there is a possibility of importing medicines between two Least Developed Countries. This could be an avenue to create appetite for harmonization in the SADC. While agreed that this is a terrain that should be carefully explored, Paragraph 6 has not been implemented in countries, like Zimbabwe, for instance and on a practical level - it has limited extent of use.

The low hanging fruit would be to get governments to incorporate TRIPS flexibilities into legislation.

There are two obvious focus areas, adoption of TRIPS flexibilities and then actually implementing the legislations, which seems to be the bigger challenge. One suggested approach was to transition and share successes at each national level through making use of regional harmonization approaches.

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PROCEEDINGS OD DAY 2

13 October 2015

7. Overview of in-country civil society partners focusing on the need to increase from visibility of IP challenges to access to HIV, TB and Hepatitis C medicines

7.1 The challenges faced by civil society in working to promote access to HIV, TB and Hepatitis C medicines through the use of intellectual property legislation

Civil Society plays a crucial role in pushing new laws, programmes, policies or strategies that promote enabling legal and policy environments, which hold governments accountable. Advocacy at a national level has the power to influence even regional and international processes. As part of the advocacy processes, organizations such as BONELA (Botswana Network on Ethics, Law and HIV/AIDS), would be critical for tackling IP barriers to access lifesaving medicines.

Some existing issues highlighted

- Intellectual property lawyers tend to have little involvement with human rights law, and few human rights specialists deal with science and technology or IP issues.
- Most active civil society organisations that could actively participate in breaking IP barriers to accessing medicines take the human rights approach, just like BONELA. This is hindered though by a general lack of expertise in dealing with the technical aspects of Intellectual Property law and provisions therein, which act as a barrier to access medicines.
- It is recommended that for civil society to make meaningful contributions, they have to have the relevant skills to appreciate the field of IP law, which in turn allows for advocacy on TRIPS flexibilities. A need thus arises to capacitate Civil Society lawyers to enable them to influence policies and law at in-country level and also international processes.

See presentation “Civil society challenges in working to promote access to HIV, TB and Hepatitis C medicines - Botswana Network on Ethics, Law and HIV/AIDS Case Study” for further detail.

7.2 Is it only TRIPS-related or should we consider competition law as an avenue for strategic impact litigation

Competition law promotes or seeks to maintain market competition by regulating anti-competitive conduct by companies. The relationship between IP and competition law has economic justifications necessary for regulated markets and innovation.

Competition regulation is contemplated within the TRIPS regime:

- **Article 8:** Broad categories of permissible regulations that could overlap with competition regulations (unreasonable restraint of trade / adverse effect on technology transfer).
- **Article 40:** Contractual / voluntary licensing; specific mention of competition regulation.
- **Article 31:** Compulsory licensing, creates exceptions to requirements to seek voluntary licenses 1stand to use licenses for domestic market only in cases of anti-competitive conduct.



Opportunities	Challenges
Competition authorities bear the brunt of the cost, investigations, and burdens of going up against big pharmaceutical companies	Identifying cases.
Potential to work with government (need for broad cooperation)	IP / procurement/ donor procurement transparency constraints.
Pro-capital ideology: using the unsettled presumption of R&D feedback in southern African economies.	Externalities.
Remedies: <ul style="list-style-type: none">• Settlement• Interdicts / injunctions (e.g. to license a 3rdparty, price controls etc.)• Broader compulsory licensing powers when anti-competitive conduct.(e.g. Italy in 2007 Merck was ordered to grant free licenses for the production of the active ingredient Finasteride).• Damages.• Merger and acquisition controls.• Criminal penalties and fines.	Absence of generic manufacturing base (vulnerable to dominance abuse and certain licensing flexibilities less effective in reducing prices) / new and under-resourced competition authorities

See presentation "Competition litigation as a strategic intervention: TRIPS flexibilities and beyond-Southern Africa Litigation Centre (SALC)" for further detail.

8. Breakaway Groups and Country Plans

The participants held working groups to review and propose the way forward through firm actions and planning. The plans for 2016, included:

- Meeting frameworks for 2016 between civil society, IP Experts and the relevant national stakeholders
- Media material such as t-shirts, posters etc. and advocacy campaigns around the targeted medicines.
- Increased capacity of Civil Society organizations engaged or trained through ARASA's online short course on Intellectual Property and Access to medicines, starting in November 2015
- Press statements on topical matters
- Drug litigation case preparation research. Drafts can be prepared.
- Further consultation by SARPAM with Civil Society groups in their own countries over the next two months. Firstly, to assist them in articulating the Theory of Change in their 2016 workplans and secondly, to set timelines for when such work plans will be completed



During the last day of the Dialogue, it was also agreed that a statement would be sent to the World Trade Organisation (WTO) Council on TRIPS, in support of the European Commission's call for an indefinite and unconditional exemption on patents and test data protection for pharmaceutical products to Least Developed Countries (LDCs). On the 9th of November 2016, an exemption of 17 years only has been granted.

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9. Annexure A: Agenda

MEETING GUIDE

ARASA and SARPAM Regional Policy Dialogue on Minimizing intellectual property barriers to Access to HIV, TB and Hepatitis C Medicines in Botswana, Mauritius and Zimbabwe

DATE: 12-13 October 2015
VENUE: Aviator Hotel,
Kempton Park,
Johannesburg



DAY 1 : 12 October 2015

TIME	SESSION OUTLINE	FACILITATOR
8:30 - 9:00	Registration of participants	ARASA/SARPAM
9:00 - 9:15	Welcome remarks and purpose of the meeting	Celestine Kumire Director Southern African Regional Programme on Access to Medicines and Diagnostics (SARPAM)
9:15 - 9:30	Introductions	Meeting participants
9:30- 9:45	Brief overview of the ARASA / SARPAM Programme on Minimizing intellectual property barriers to Access to HIV, TB and Hepatitis C Medicines in Botswana, Mauritius and Zimbabwe	Lynette Mabote Regional HIV, TB and Human Rights Advocacy Team leader AIDS and Rights Alliance for Southern Africa (ARASA)
9:45 - 10:30	Opportunities and challenges in using TRIPS flexibilities in the SADC region <i>Plenary Q & A on presentation</i>	Tapiwanashe Kujinga IP Expert Zimbabwe
10:30 - 11:00	HEALTH BREAK & NETWORKING	
11:00 - 12:00	<p>EXPERT PERSPECTIVES ACCESS NEEDS: Delving into some of the major access barriers to HIV, TB and Hepatitis C facing Mauritius, Botswana and Zimbabwe (in the contexts of intellectual property laws and policies)</p> <ul style="list-style-type: none"> What are the key human rights issues to be considered in the context of access to medicines and the law: Where should the focus be? Current and projected challenges to accessing affordable HIV, TB and Hep C medicines in the next 10 years What opportunities are presented by exploring TRIPS flexibilities and amendment of IP legislations 	<p>Moses Nkomo Intellectual Property Expert Zimbabwe</p> <p>Roopanand Mahadew IP Expert Lecturer University of Mauritius</p> <p>John Botsang Focal Point Lead, Intellectual Property Rights & Access to Medicines Permanent Secretariat, Ministry of Health, Botswana</p>
11:30- 12:00	Plenary Discussions on the issues raised in the Perspectives on Access Needs	Plenary Discussion
12:00 - 13:00	<p>Presentation on the research findings of the in-depth Mauritius, Botswana, Zimbabwe Assessment Reports on TRIPS challenges, opportunities and avenues of advocacy</p> <p><i>Plenary/open discussion of the TRIPs report (comments/inputs)</i></p>	Presentation & Conversation facilitated by Tapiwanashe Kujinga
13:00- 14:00	LUNCH BREAK	
14:00 - 14:45	BREAK AWAY GROUPS: COUNTRY TEAMS: Discussions on aspects of the report, recommendations	Country Group
14:45 - 15:30	BREAK AWAY GROUPS REPORT BACK PRESENTATIONS	Country Group
15:30 - 16:00	HEALTH BREAK & NETWORKING	
16:00 - 16:30	Plenary discussion: Q&A on group presentations	ALL
16:30 - 17:00	Closing Remarks	Washington Matika CS PACT Lead Southern African Regional Programme on Access to Medicines and Diagnostics (SARPAM)

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**MEETING GUIDE**

ARASA and SARPAM Regional Policy Dialogue on Minimizing intellectual property barriers to Access to HIV, TB and Hepatitis C Medicines in Botswana, Mauritius and Zimbabwe

DATE: 12-13 October 2015

VENUE: Aviator Hotel,
Kempton Park,
Johannesburg

**BREAKING IP BARRIERS**

Creating Pathways to Medicine Access

DAY 2 - 13 October 2015

TIME	SESSION OUTLINE	FACILITATOR
8:30 - 9:00	Recap of proceedings of Day 1	Washington Matika CS PACT Lead Southern African Regional Programme on Access to Medicines and Diagnostics (SARPAM)
9:00 - 10:00	<p>Welcome remarks and purpose of the meeting PANEL DISCUSSION: In-country civil society partners focusing on the need to increase from visibility of IP challenges to access to HIV, TB and Hepatitis C medicines</p> <ul style="list-style-type: none"> The challenges faced by civil society in working to promote access to HIV, TB and Hepatitis C medicines through the use of intellectual property legislation Is it only TRIPS-related or should we consider competition law as an avenue for strategic impact litigation Considerations current threats to access to medicines, can we leverage on declarations and commitments in Africa? 	<p>Lynette Mabotel ARASA</p> <p>Tinashe Mundawarara Programmes Manager Zimbabwe Lawyers for Human Rights</p> <p>Phazha Molebatis Attorney at Law, Botswana CSO Representative BONELA</p> <p>Annabel Raw Project Attorney Southern African Litigation Centre</p>
10:00 - 11:00	Q&A / Plenary discussion on avenues to consider given current threats to access in the region	Nelago Amadhila HIV, TB and Human Rights Advocacy Team Officer ARASA
11:00 - 11:30	HEALTH BREAK & NETWORKING	
11:30 - 13:00	<p>BREAK AWAY GROUP: Planning of 2016/2017 advocacy roadmap activities to expedite integration of TRIPS flexibilities in legislations in Mauritius, Botswana and Zimbabwe:</p> <p>Groups tasked to discuss:</p> <ul style="list-style-type: none"> What actions can we move forward in each country in 2016? Which strategic ministries and avenues should be targeted? Which key strategic dates need to be priorities for in-country actions? What resources are required to move this action plan forward in 2016? 	BREAK AWAY GROUPS
13:00 - 14:00	LUNCH BREAK	
14:00 - 15:00	GROUP REPORT BACK: Partners 2016/2017 Action plans, with plenary inputs	BREAK AWAY GROUPS
14:45 - 15:30	<p>Plenary discussion: Programmatic Outputs:</p> <ul style="list-style-type: none"> Regional Response to proactively promote medicines-friendly regional agreements that do not conflate IP: Developing an early detection system Inputs on the name and logo of the programme / Branding Way forward on planning and next steps 	Country Group
15:30 - 16:00	Closing Remarks	Celestine Kurime SARPAM

MEETING ENDS**Meeting Report**

ARASA and SARPAM Regional Policy Dialogue on Minimizing Intellectual Property Barriers to Access to HIV, TB And Hepatitis C Medicines In Botswana, Mauritius And Zimbabwe

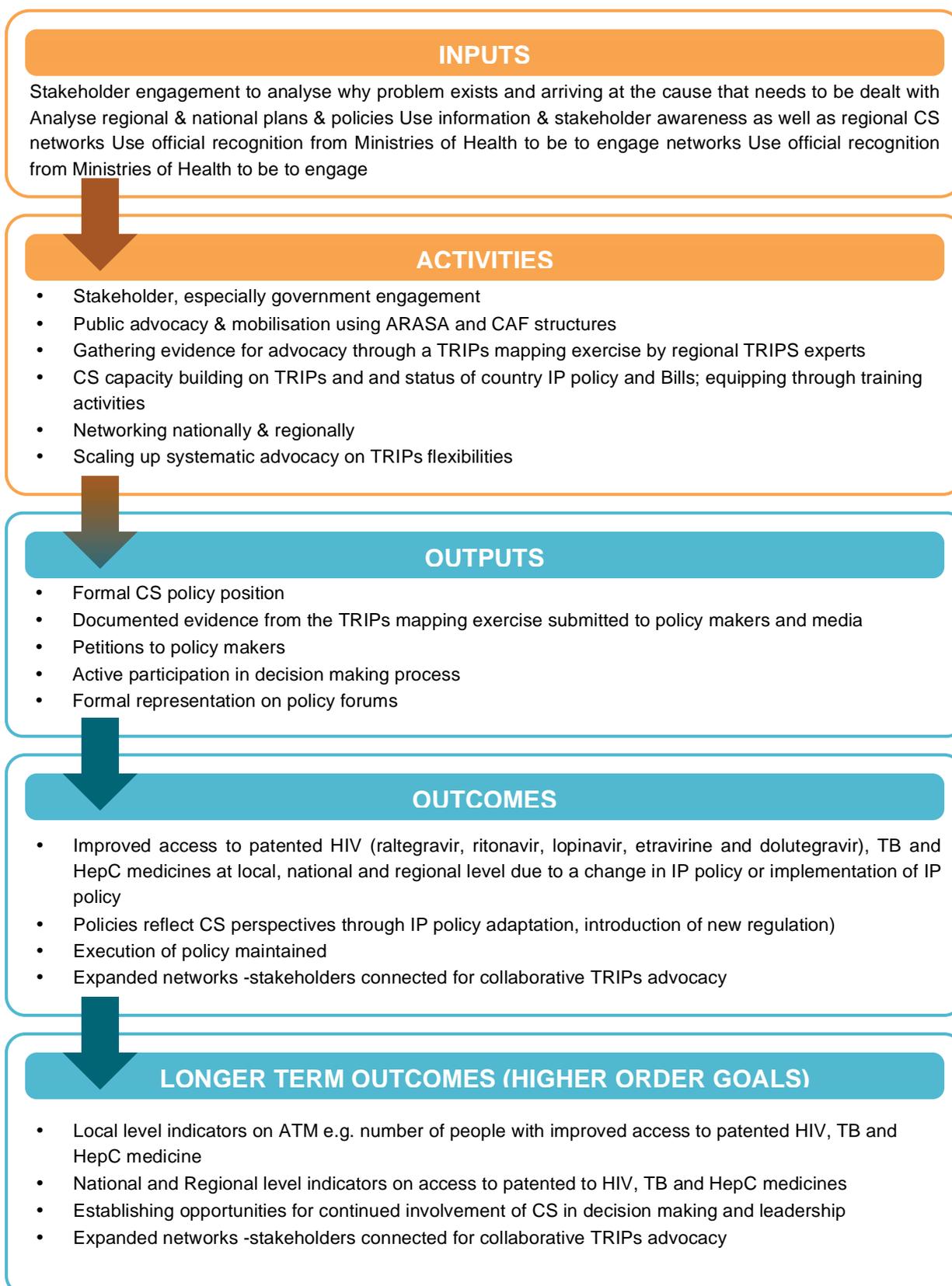


10. Annexure B: Participants and Contact List

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11. Annexure C: Theory of Change Framework for TRIPs





12. Annexure D: Reference Document List

1. Theory of change framework
2. Theory of change Zambia example
3. UNDP Guidebook Using competition law to promote access to health technologies in LMIC settings
4. Civil society challenges in working to promote access to HIV, TB and Hepatitis C medicines” Botswana Network on Ethics, Law and HIV/AIDS Case Study By Phazha Molebatsi (*On Behalf of Bonela*)
5. ARASA & SARPAM overview presentation
6. Competition litigation as a strategic intervention: TRIPS flexibilities and beyond Annabel Raw (*Health Rights Lawyer, SALC*)
7. Dialogue On Minimizing IP Barriers To Access To Medicines By Botsang John
8. Major barriers to access to medicines – IP law and policy perspectives from Zimbabwe
9. Opportunities and challenges in using trips flexibilities in the SADC region – Tapiwanashe Kujinga
10. Research findings on the in-depth country assessments – Tapiwanashe Kujinga