

**Implementation of the TRIPS flexibilities by
east and southern African countries: Status of
patent law reforms by 2010**

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Executive summary

When the Trade-related Aspects of Intellectual Property Rights (TRIPS) Agreement of the World Trade Organisation (WTO) came into effect on 1 January 1995, it gave transitional periods of five years to developing countries (until 2000) and six years to least-developed countries (LDCs) (until 2006) to reform their intellectual property (IP) systems so that they would conform to the standards set in the TRIPS agreement. In 2005, the year before the transitional period for LDCs was due to expire, the TRIPS Council extended the transitional period by seven years and five months to 2013 (or to the date on which a country ceased to be a least-developed country member, whichever date is earlier). It also extended the transition period to 2016 for pharmaceutical patents. In light of this, only four years are left before the LDCs must reform their IP regimes and enact new patent laws.

The TRIPS agreement has been subject to intense debate and criticism, mostly centred on concerns by developing countries that the agreement failed to promote their efforts at delivering much-needed medical drugs to their citizens. The debate became much more important in the face of the burdens of HIV and AIDS, malaria and tuberculosis, which mostly affect the developing countries and, in particular, the Eastern and Southern African (ESA) countries. The result of this debate was a number of amendments to the TRIPS agreement to introduce some favourable terms – in the form of TRIPS 'flexibilities' – to take care of the health-related concerns of the developing countries.

In the interests of public health, the TRIPS flexibilities provided for:

- **transition periods** for laws to become TRIPS compliant;
- **compulsory licensing** or the right to grant a licence, without permission from the licence holder, on various grounds including public health;
- **parallel importation** or the right to import products patented in one country from another country where the price is lower;
- exceptions from patentability and limits on data protection; and
- early working, known as the **Bolar Provision**, allowing generic producers to conduct tests and obtain health authority approvals before a patent expires, thereby making cheaper generic drugs available more quickly at that time.

Member states have the authority to use these flexibilities when this is necessary to protect public health and to promote access to medicines.

The Southern and Eastern African Trade, Information and Negotiations Institute (SEATINI), under the umbrella of the Regional Network for Equity in Health in East and Southern Africa (EQUINET), carried out an assessment of LDCs in East and Southern Africa with regard to their progress towards the new IP regimes. The study reviewed the situation in sixteen east and southern African countries. It was conducted through a desk review of published and grey literature, including: World Trade Organisation (WTO) documents relating to the negotiations and implementation of the TRIPS agreement; official texts in the economic partnership agreement (EPA) negotiations, including the Cotonou Agreement; regional integration agreements, such as those by the East African Community (EAC), the Common Market for East and Southern Africa (COMESA) and the Southern Africa Development Community (SADC); national laws and policies of the ESA countries, particularly legislation relating to the patenting and exploitation of pharmaceutical products; and, where applicable, judicial interpretations of contested positions on IP rights pertaining to pharmaceutical products.

The study found that most of the IP regimes currently in ESA countries were in existence before the TRIPS agreement was adopted. These included laws that provide some

flexibilities, which were in most cases not being implemented. The constraints that were identified included:

- lack of domestic pharmaceutical research and manufacturing capacities;
- insufficient technical and infrastructural capacities for medicines regulation;
- difficulties in establishing efficient pharmaceutical management and procurement systems;
- bilateral and other political pressures against the use of TRIPS flexibilities;
- lack of capacity to address anti-competitive practices and abuse of patents rights; and
- difficulties in accessing pricing and patent status information.

One major problem is that the public health-related aspects of the TRIPS flexibilities have not been accepted at the WTO level by all the ESA countries concerned, with the exception of only Mauritius and Zambia. In other words, these ESA countries are withholding the critical mass needed to enable a formal adoption of the protocol amending the TRIPS agreement at the WTO. The December 2009 deadline has been further extended to the end of December 2011. It has become crucially important to make sure all countries formally adopt the proposal by then to avoid unnecessary renegotiations of the TRIPS amendments.

This paper recommends that ESA countries prioritise the application and implementation of TRIPS flexibilities, specifically that:

- All ESA countries must endorse the protocol on the TRIPS amendments as a matter of urgency and make the case for this.
- They should focus on implementation of the TRIPS flexibilities through a comprehensive review of laws, policies and capacities to support implementation of the flexibilities, ahead of the deadlines set out in the amendments to the TRIPS agreement.
- They should exploit the relative strengths of different countries in the region to ensure the production and export of medicines within the region.
- In the context of the EPA negotiations, they must create common positions that will enable the adoption of a development co-operation approach to any discussions on IP regimes (IPRs) with the European Union (EU).
- They should resist pressure in the African Growth and Opportunities Act (AGOA), an agreement with the United States, for less government intervention in policy settings and economic affairs and instead emphasise support for public health interventions, even where these relate to a dilution of IPRs.
- They should take note of and implement the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (2008).
- Civil society organisations must provide technical and capacity support to governments and popularise technical information on IPRs. This will advance the debate and encourage contributions by non-technical stakeholders, like parliamentarians and ordinary citizens.

1. Introduction

East and southern African (ESA) countries are involved in the negotiation and implementation of trade agreements at bilateral, regional and the multilateral levels. These negotiations and agreements include those under the World Trade Organisation (WTO), economic partnership agreements (EPAs) between African countries and the European Union (EU), the Common Market for East and Southern Africa (COMESA), the East African Community (EAC) and the Southern African Development Community (SADC). The negotiations include agreements on trade in both goods and services and, if concluded on favourable terms, have the potential to lift the ESA countries out of poverty. One of the indicators of poverty in the ESA countries is lack of access to basic health services and medication. However, the availability of drugs depends on a number of issues. Producers of medical drugs invariably work for profit and, to protect their profits, they usually register patents against their products to ensure that the production of their products occurs under very strict conditions subject to licences. For example, one cannot just manufacture an existing drug because one needs it. Permission must first be sought from the original inventor of the drug if a patent has been registered against that drug.

Medical drugs fall under the category referred to as 'intellectual property'. The protection of intellectual property was deemed very important and this led to the adoption of the Trade-Related Aspects of Intellectual Property Rights, that is, the TRIPS agreement, at the WTO (WTO 1994). The TRIPS agreement has been subject to intense debate and criticism, mostly centred on the concerns by developing countries that the agreement failed to promote their efforts at delivering much-needed medical drugs to their citizens (Correa, 2001). The debate became much more important in the face of HIV and AIDS, malaria and tuberculosis, given their prevalence in and impact on low-income countries, particularly ESA countries.

As a result of this debate, a number of amendments were made to the TRIPS agreement. These TRIPS 'flexibilities' were introduced to take care of the health-related concerns of the developing countries. The full set of flexibilities is further described later on in the paper, in Section 3. EQUINET, through SEATINI and TARSC, carried out a policy analysis on the TRIPS agreement and on the application of its flexibilities in 2006 (Mabika et al, 2006). This analysis found that not all countries in ESA had implemented the flexibilities in their laws, and that those that had implemented them faced serious implementation challenges, even when their laws provided for it. The challenges ranged from information and institutional weaknesses within countries, to international trade and political pressures not to use the flexibilities. The analysis concluded that, for ESA countries to be able to fully utilise the flexibilities, enacting them into legislation and using them needs to be backed by wider political commitment from all the relevant stakeholders. Public and civil society lobbies, parliamentarians, government officials and the media need to understand and defend the reasons for exercising TRIPS flexibilities.

To update this work and to provide policy advice to countries, EQUINET commissioned SEATINI to produce this summary report and policy brief **in non-technical language** that will be accessible to non trade law personnel, parliamentarians, health officials and will give them **practical information** on the current situation with respect to the TRIPS flexibilities in ESA and their use in managing intellectual property regimes.

Consequently, this paper aims to:

- outline the flexibilities in the TRIPS agreement and what needs to be done to apply them;
- outline developments in international EPAs, regional agreements and conventions that affect the flexibilities in the TRIPS agreement and their implications;

- summarise the steps taken in the countries in east and southern Africa to implement the flexibilities in the TRIPS agreements, the challenges faced and how they have been overcome;
- summarise the gaps and challenges remaining in relation to the TRIPS agreements and how they can be overcome; and
- make recommendations, including follow-up actions.

The 'ESA' designation in this paper is not to be confused with the same group of countries that is negotiating EPAs with the European Union. Rather, we use the 'ESA' designation as a loose configuration to describe the SADC-COMESA-EAC states. Also, EPAs refer to the negotiations are taking place between the African-Caribbean and Pacific states and the EU to create new trade relations to replace the historical one-way trade preferences that the EU used to offer to its former colonies.

2. Methods

We included ESA countries that are members of the Southern African Development Community (SADC), the Common Market for Eastern and Southern Africa (COMESA) and the East African Community (EAC), focusing on the 16 countries covered by EQUINET, namely Angola, Botswana, the Democratic Republic of Congo (DRC), Kenya, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, South Africa, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe.

The evidence in the paper was compiled through a desk review of:

- WTO documents relating to the negotiations and implementation of the TRIPS agreement;
- the official texts in the EPA negotiations, including the Cotonou Agreement;
- regional integration agreements (EAC, COMESA and SADC);
- national laws and policies of the ESA countries, in particular, legislation relating to the patenting and exploitation of pharmaceutical products;
- judicial interpretations of contested positions on intellectual property rights pertaining to pharmaceutical products, where applicable; and
- the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.

Particular use was made of the online resources of the World Intellectual Property Organisation (WIPO) and the WTO. We attempted to secure all relevant national laws; however, for four countries – Angola, the DRC, Mozambique and Mauritius – the relevant legislation was either not available online, or was available in French or Portuguese only, and the writers of this study lacked competency in both languages. We relied on the best available information on national legislation, but one must bear in mind that national laws change all the time, and not all governments ensure that such changes are timeously brought to public access and attention. Despite the fact that the WTO requires notification of changes to national laws that have relevance to trade issues, not all countries comply with this requirement, so sometimes the gaps identified in national legislation may have been addressed in very recent legal amendments by the relevant authorities that are not yet available to the public. Also, as this study took the form of a desk review only, we were also not able to observe enforcement in practice or obtain information on barriers or practices not available in literature – this would need to be followed up through country field studies.

3. The TRIPS flexibilities

The TRIPS agreement provides a multilateral framework for the protection and exploitation of intellectual property rights (IPRs). The agreement attempts to strike a balance between

the long-term social objective of providing incentives for future inventions and creations, and the short-term objective of allowing people to use existing inventions and creations. The agreement has obligations for the minimum conditions that must be in place in the WTO members' laws so that each member can comply with the TRIPS regime. WTO members are, in practice, at liberty to impose higher conditions (the TRIPS-plus obligations) for the protections of IPRs. However, WTO members are not under any obligation to implement higher protection than that accorded in the TRIPS Agreement. *Table 1* below shows the subject matter that is protected under TRIPS, the nature of the protection and the relevant exceptions/flexibilities attached to each specific IPR.

Table 1: TRIPS obligations to protect intellectual property rights, with exceptions

Nature of property right	Terms of protection	Limitations/exceptions/flexibilities
Computer programmes and compilations of data	At least 50 years from end of year of authorised publication	Confined to special cases that do not conflict with a normal exploitation of the work – the agreement does not define these special cases.
Performers, producers of sound recordings and broadcasting organisations	For performers, at least 50 years, and for broadcasting organisations, at least 20 years	To the extent permitted by the Rome Convention (1961), governments are permitted to provide exceptions regarding: private use; use of short excerpts in connection with the reporting of current events; ephemeral fixation by a broadcasting organisation by means of its own facilities and for its own broadcasts; and use solely for the purposes of teaching or scientific research.
Trademarks	No less than seven years	Limited exceptions to the rights may be provided, such as fair use of descriptive terms.
Industrial designs	At least ten years	Limited exceptions may be provided, for example those that do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner.
Patents	At least 20 years	Measures may be adopted to protect public health and nutrition, and to promote the public interests. In terms of Article 30, members may provide limited exceptions to the exclusive rights, provided they do not unreasonably conflict with normal use of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the interests of third parties. Governments may also allow someone else to produce the patented product or process without the consent of the patent owner – referred to as 'compulsory licensing'. Compulsory licensing is catered for under Article 31 of the TRIPS agreement. Governments are also authorised under Article 31 to take measures to prevent the use of patents for anti-competitive practices. In other words, a patent is not a licence to abuse the market.
Layout designs of integrated circuits	At least 10 years	Exceptions to the protection are similar to those provided under Article 31.

Source: WTO (1994)

Broadly, in the interest of public health, the flexibilities provided for:

- **transition periods** for laws to be TRIPS-compliant;

- **compulsory licensing**, which occurs when governments allow someone else to produce the patented product or process without the consent of the patent owner;
- **parallel importation**, which is the right to import products patented in one country from another country where the price is lower;
- exceptions from patentability and limits on data protection; and
- early working, known as the **Bolar Provision**, which allows generic producers to conduct tests and obtain health authority approvals before a patent expires, thereby making cheaper generic drugs available more quickly at that time.

Member states have the authority to use these flexibilities when this is necessary to protect public health and to promote access to medicines.

3.1 Time-bound flexibilities

Apart from the above exceptions to the IPR protection obligations, Articles 65 and 66 of the TRIPS agreement also provide for the following flexibilities:

- Developing countries were initially permitted to delay the application of the agreement (apart from Articles 3, 4, 5 concerning non-discrimination) for a period of four years from the date of application (that is, up to 1 January 2000).
- If a developing country member was obliged to extend product patent protection to areas of technology that were not protected in its territory on the general date of application of the agreement, it could delay applying the patents for five years, that is, up to 1 January 2005. This flexibility included all ESA countries.
- Least-developed countries (LDCs) were permitted to delay the application of the agreement (except Articles 3, 4 and 5) by a period of up to ten years, that is, up to 30 November 2005. LDCs included Angola, DRC, Lesotho, Madagascar, Malawi, Mozambique, Swaziland, Tanzania, Uganda and Zambia. This date was extended to 1 July 2013. In addition, the LDCs could request the Council for TRIPS to extend this period even further. For pharmaceutical patents, this period was extended to 2016 by the Doha Declaration on TRIPS and Public Health.

The last time-bound flexibility listed above took into account the specific needs, financial and administrative constraints of LDCs, especially their need for flexibility to create a viable technological base. For example, the implication of paragraph 4 of the same Article 65 was that an LDC that did not provide patent protection for pharmaceutical products in 1995 was allowed to delay the introduction of the protection until 1 January 2005. In the intervening period (1995–2004), the country could allow inventors to file patent applications but only had to consider granting the patent at the expiry of the intervening period, namely 1 January 2005. This process allowed LDCs to store applications for patents for future evaluation under Article 70 of the TRIPS agreement (the so-called 'mailbox' provision).

3.2. Public health-related flexibilities

Low- and middle-income countries face a barrage of public health problems, including pandemics such as HIV and AIDS, tuberculosis and malaria. Although these health problems apply to most developing countries, African countries are particularly hard hit. Access to essential drugs is critical for dealing with these public health problems. Medical drugs are pharmaceutical products, and the production, distribution and other forms of exploitation of pharmaceutical products have to be done within the context of the rules under the TRIPS agreement, as long as a country is a member of the WTO. To protect their profits, drug producers routinely take out patents on their products to prevent third parties from making, using or selling the drugs for a specific period of time.

The exclusive rights enjoyed by a patent holder restrict the free flow of drugs, which helps protect the drug producer's income. However, the public health crisis in the developing countries produced tensions between the TRIPS regime (protecting the profits of patent holders) and the needs of these countries to access cheaper medicines to address their health problems. In 2001, a number of developing countries at the WTO sought clarification on the meaning and actual practice of TRIPS flexibilities. The African Group, for example, was concerned that the TRIPS regime should be utilised in a manner that allowed governments to override private property interests in an effort to combat the HIV and AIDS, tuberculosis and malaria pandemics.

As a result of these concerns, the WTO membership adopted eight decisions (listed in *Table 2*), which created and amplified a set of flexibilities to enable the poorer countries to address their public health crisis. Paragraph 17 of the main Doha Declaration stressed the significance of interpreting the TRIPS Agreement in a manner supportive of public health by promoting access to existing medicines. The decisions adopted by the WTO resulted in the amendment of the TRIPS Agreement – the first ever amendment to a WTO agreement – to include flexibilities for developing countries. However, the adoption of these flexibilities at the WTO level is not enough for the developing countries to resolve their public health crises – these countries need to take specific actions to implement the flexibilities, for example by conducting a general review of the TRIPS flexibilities, including an administrative and regulatory policy needs assessment. *Table 2* contains further details on these actions.

The World Health Organisation emphasised the importance of implementing the TRIPS flexibilities in its 2008 Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. The strategy includes:

“providing as appropriate, upon request, in collaboration with other competent international organisations technical support, including, where appropriate to policy processes, to countries that intend to make use of the provisions contained in the Agreement on Trade-related Aspects of Intellectual Property Rights, including the flexibilities recognised in the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the TRIPS agreement, in order to promote access to pharmaceutical products” (WHO 2008:16).

Table 2: Public health-related TRIPS flexibilities

Decisions and dates taken	Flexibilities	Interventions needed
<p>Paragraph 17 of the main Doha Declaration</p> <p>14 November 2001</p>	<p>The decision reads: 'We stress the importance we attach to implementation and interpretation of the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement) in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines and, in this connection, are adopting a separate declaration.' This flexibility can be used for compulsory licensing and parallel importation.</p>	<p>See the adopted separate declaration on TRIPS and Public Health below.</p>
<p>Declaration on the TRIPS Agreement and Public Health</p> <p>14 November 2001</p>	<p>The declaration reads: 'The Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.' Flexibilities exist to:</p> <ul style="list-style-type: none"> • Apply the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed in its objectives and principles. • grant compulsory licences and the freedom to determine the grounds for this. • determine what constitutes a national emergency or a situation of extreme urgency, which includes public health crises, such as those relating to HIV, AIDS, tuberculosis, malaria and other epidemics. <p>The TRIPS Agreement that are relevant to the exhaustion of intellectual property rights leave each member free to establish its own regime for defining 'exhaustion' without challenge. This is subject to the most-favoured nation (MFN) and national treatment provisions of Articles 3 and 4.</p> <p>The declaration amplified a previous flexibility which noted: 'We also agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of</p>	<ul style="list-style-type: none"> • ESA countries need to conduct a general review of the TRIPS flexibilities, including administrative and regulatory policy needs assessments, to ensure they make full use of the TRIPS amendments to address public health needs. • They must provide the TRIPS Council with 'as much information as possible on their individual priority needs for technical and financial co-operation in order to assist them in taking steps necessary to implement the TRIPS Agreement.' So far the only ESA country to have done this is Uganda. • They should draft and implement laws to enable effective use of compulsory licensing to help deal with public health emergencies. • They must enact laws that encompass the development aspect of IPR policy, including use of competition law and policy to deal with restrictive practices and abuse of patent rights.

Decisions and dates taken	Flexibilities	Interventions needed
Declaration on the TRIPS Agreement and Public Health (continued)	least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.' This amplifies the transitional periods already granted to LDCs in the TRIPS agreement. It was repeated in the Doha Declaration.	
Decision on the Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for LDC Members for Certain Obligations with Respect to Pharmaceutical Products, 27 June 2002	LDCs will not have to protect pharmaceutical patents and test data until 1 January 2016. They have the right to seek further extensions of this period.	<ul style="list-style-type: none"> • ESA LDCs can take advantage of this flexibility by simply not protecting the pharmaceuticals deemed essential to public health up to 1 January 2016. • They will need to prepare requests/negotiating positions for further extension before the due date.
Decision on LDC members' Obligations under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products, 8 July 2002	LDCs do not have to give exclusive marketing rights to pharmaceuticals that are subject to a patent application until 1 January 2016.	<p>ESA LDCs need to</p> <ul style="list-style-type: none"> • fully utilise this waiver by not granting exclusive marketing rights to the use of the 'mailbox' provision. • participate effectively in the Ministerial Conference annual review, and show why the waiver is necessary. • conduct self-assessments and prepare their positions for possible extension of the waiver beyond 1.1.2016 • Develop expertise for, identify and advance the argument for the exceptional circumstances required to persuade the Ministerial Conference to modify or extend the waiver, given the developed countries are likely to demand rigorous criteria. • Know Article IX of the WTO Agreement (the procedure for granting, modification and termination of waivers).
Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, 30 August 2003	This decision removes limitations on exports under compulsory licence to countries that cannot manufacture the pharmaceuticals themselves.	<ul style="list-style-type: none"> • ESA countries that are using compulsory licences to manufacture drugs can assist other ESA countries that are unable to manufacture drugs by exporting the drugs to those countries, ensuring they adhere to the guidelines of the Decision.

Decisions and dates taken	Flexibilities	Interventions needed
Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, 30 August 2003		<ul style="list-style-type: none"> • ESA countries that are not LDCs, such as South Africa and Mauritius, can use the notification system under this Decision to fully exploit their comparative advantage, for example by exporting drugs under compulsory licence production to African LDCs, which have greater health needs.
Decision on the Amendment of the TRIPS Agreement 6 December 2005	This decision removes limitations on exports under compulsory licence to countries that cannot manufacture the pharmaceuticals themselves.	<ul style="list-style-type: none"> • This Decision adopts a protocol of the amendment to the TRIPS Agreement, which will only come into force when two thirds of WTO members have accepted it. ESA countries need to accept this amendment to enable the decision to be fully utilised – it is in their best interest to do so. • ESA countries must acquaint themselves with the procedures for WTO agreements amendments under paragraph 3 of Article X of the WTO Agreement.
Hong Kong Ministerial Declaration (Paragraph 40) on TRIPS and Public Health	Reaffirms importance of Decision of August 30 2003, and of the Amendment to the TRIPS Agreement. The Amendment to the TRIPS Agreement incorporates all the decisions that have been taken on TRIPS flexibilities.	To be effective, the Protocol amending the TRIPS Agreement needs to be accepted by two-thirds of the WTO membership.
Decision of 17 December 2009 to extend the deadline for accepting TRIPS Agreement amendments	This decision extends the period for accepting TRIPS Agreement amendments from 1 December 2007 to 31 December 2009. This has been further extended to 31 December 2011.	<ul style="list-style-type: none"> • To be effective, the Protocol amending the TRIPS Agreement needs to be accepted by two-thirds of the WTO membership, which has unfortunately not happened yet (as evidenced by the extension of the period from December 2007 to December 2009 and, currently, to December 2011). In other words, all ESA countries must accept the Protocol so that the number of countries that have accepted the amendment moves closer to the required two-thirds. • ESA countries need to develop substantive technical expertise to justifying a request for the extension of this period, as justifications will be demanded by developed nations.

Sources: WTO 2001a,b 2002a,b 2003, 2005

The WHO recommended the following specific actions related to this element:

- a) *'consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including those recognized by the Doha Declaration on TRIPS Agreement and Public Health and the WTO decision of 30 August 2003*
- b) *take into account, where appropriate, the impact on public health when considering adopting or implementing more extensive intellectual property protection than is required by the Agreement on Trade-Related Aspects of Intellectual Property Rights, without prejudice to the sovereign rights of Member States*
- c) *take into account in trade agreements the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights and including those recognized by the Declaration on the TRIPS Agreement and Public Health adopted by the WTO Ministerial Conference (Doha, 2001) and the WTO decision of 30 August 2003*
- d) *consider, where appropriate, taking necessary measures in countries with manufacturing capacity to, facilitate through export, access to pharmaceutical products in countries with insufficient or no manufacturing capacity in the pharmaceutical sector in a manner consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights, the Doha Declaration on the TRIPS Agreement and Public Health and the WTO decision of 30 August 2003; and*
- e) *encourage finding ways, in ongoing discussions, to prevent misappropriation of health-related traditional knowledge, and consider where appropriate legislative and other measures to help prevent misappropriation of such traditional knowledge'*(WHO 2008:16).

It is important for ESA countries to implement these recommendations and to advocate for high-income WHO member states to support this implementation.

4. Regional and international agreements influencing the application of TRIPS flexibilities

As noted above, WTO members may adopt stricter requirements on the protection of IPRs but are under no obligation to do so. These TRIPS-plus arrangements may come in the form of a national policy, or they may be influenced by bilateral and regional trade negotiations. Some countries have strengthened their laws in an attempt to attract foreign direct investment (FDI), as stronger property rights (including IPR) laws have been (wrongly) promoted as good for FDI (Smith, 2008). Furthermore, it is possible for a country to adopt TRIPS-plus laws as part of trade policy in exchange for market access in other areas of trade. This trade-off may have positive or negative implications on access to essential medical drugs where TRIPS-plus laws are adopted as part of an economic agreement. In this section, we will discuss the relevant international and regional economic agreements, as well as current positions being developed in the context of negotiations for future economic agreements.

4.1. Negotiating and applying TRIPS flexibilities in EPAs

For ESA countries, the most important international economic agreements are the so-called economic partnership agreements (EPAs). EPAs stem from the Cotonou Agreement between the African-Caribbean and Pacific states and the countries of the European Union (EU). They were put in place to replace the one-way trade deals that the EU historically offered to ACP states. There are a number of ways under which the EPAs may have an effect on access to medicine and the health systems of the ESA states. For example, positions on trade in goods and services have a direct effect on the public health sector

through revenue losses, which may result in governments having less funds to pay for medications, build hospitals etc. These issues have a direct implication on the ability of the ESA countries to utilise TRIPS flexibilities.

Let us start with the Cotonou Agreement as it relates to TRIPS, and then to move to what the EPAs say on the subject. The relevant provision of the Cotonou Agreement is Article 46. Articles 46.1 and 46.6 provide as follows:

'Without prejudice to the positions of the Parties in multilateral negotiations, the Parties recognise the need to ensure an adequate and effective level of protection of intellectual, industrial and commercial property rights, and other rights covered by TRIPS including protection of geographical indications, in line with the international standards with a view to reducing distortions and impediments to bilateral trade.'

The Parties further agree to strengthen their co-operation in this field. Upon request and on mutually agreed terms and conditions co-operation shall inter alia extend to the following areas: the preparation of laws and regulations for the protection and enforcement of intellectual property rights, the prevention of the abuse of such rights by right holders and the infringement of such rights by competitors, the establishment and reinforcement of domestic and regional offices and other agencies including support for regional intellectual property organisations involved in enforcement and protection, including the training of personnel'.

From the above quote, it is clear that the Cotonou Agreement does not oblige the ESA countries to negotiate IPR rules or to create a binding regime for IPRs in the EPAs context – instead, it refers to 'co-operation' in the field of IPR. Furthermore, Article 46 attempts to preserve or respect the positions of the parties, as adopted at the WTO level, as evidenced by the opening words: '*without prejudice to the positions of the Parties in multilateral negotiations...*' The ESA countries are well within their legal rights if they insist on negotiating IPR only in the context of development co-operation, and not for the purposes of developing rules based on possible TRIPS-plus content.

We must also consider the background to Article 46 of the Cotonou Agreement. The focus of the IPR provisions of the Agreement is to ensure the effective protection of intellectual property rights. Article 46 of the Agreement speaks of adherence to WTO TRIPS regime. The language of Article 46 of the Agreement is such that the development-related concerns of the ACP States were never factored in as a necessary dilution of the WTO regime as it stood in 2000 when the Cotonou Agreement was signed.

The WTO decisions on TRIPS flexibilities emerged after the Cotonou Agreement was signed. These include Paragraph 17 of the Doha Declaration (November 2001), the Declaration on the TRIPS Agreement and Public Health (November 2001), the Decision on Article 66.1 of the TRIPS Agreement (June 2002), the Decision on Article 70.9 of the TRIPS Agreement (July 2002) and others, which took place between 2003 and 2008 (WTO 2002a). But we would like to stress here that, although the Cotonou Agreement has been overtaken by events at the WTO, in both spirit and substance it was never meant to cater for the public health concerns of the IPR regime that ACP states were expected to adhere to. It is also important to note that, although the TRIPS flexibilities exist in the context of the EPA negotiations, the very spirit and substance of the Cotonou Agreement can easily allow for negotiating positions that seek to dilute the flexibilities, in particular, from the EU side. Departing from the TRIPS flexibilities and creating a TRIPS-plus regime under the EPAs is a possibility. The Cotonou agreement may not necessarily be aligned to the actual negotiations on the TRIPS provisions of the final EPAs. It is crucial for ESA negotiators to base their positions on Article 46 of the Cotonou Agreement. In other words, the negotiations

on TRIPS under EPAs should be without prejudice to the ESA countries' positions on the multilateral front.

The African configurations are at various stages of negotiating comprehensive EPAs with the EU. The European Community openly states that EU business stands to gain by the opening of new markets for its exports – this was stated in a strategy document on European competitiveness (EC, 2006). The aims expressed in this document are in stark contrast with the 'developmental' language of Article 46 of the Cotonou Agreement. The EC webpage on trade, for example, notes that:

'By negotiating the removal of tariff and non-tariff barriers and ensuring our regulation converges with that of our trading partners, the EU can open new markets for its exporters. The EU does this through the WTO and the ongoing Doha Round of multilateral trade negotiations, through its bilateral trade relations with individual countries and through a market access strategy designed to target and remove individual barriers in key export markets. This includes a tough new approach on intellectual property rights, which are vital for European competitiveness' (EC, 2008).

Quite clearly the EC's approach to the IPR issue under EPAs is part of its global strategy to improve the profits of EU-based businesses (EC, 2006). Stronger IPR rules are a central part of this global strategy, and the aims are listed as follows:

- *'We will require a sharper focus on market opening and stronger rules in new trade areas of economic importance to us, notably intellectual property rights (IPR), services, investment, public procurement and competition;*
- *Free trade agreements (FTAs), if approached with care, can build on WTO and other international rules by going further and faster in promoting openness and integration, by tackling issues which are not ready for multilateral discussion and by preparing the ground for the next level of multilateral liberalisation. Many key issues, including investment, public procurement, competition, other regulatory issues and IPR enforcement, which remain outside the WTO at this time can be addressed through FTAs. ... They [FTAs] are part of our negotiations for Economic Partnership Agreements with the African Caribbean and Pacific countries...*
- *In terms of content new competitiveness-driven FTAs would need to be comprehensive and ambitious in coverage, aiming at the highest possible degree of liberalisation including far-reaching liberalisation of services and investment; and*
- *FTAs should include stronger provisions for IPR and competition, including for example provisions on enforcement of IP rights along the lines of the EC Enforcement Directive'* (EC, 2006:6–8).

The actual texts of the EPAs show ambiguity with respect to the intentions and interests of the EU, but the aims of the EC negotiators are plain in the above quotes, namely as part of the EU global strategy. It is in this context that the European Parliament protested against the EU's imposition of 'WTO obligations on the countries of Africa' (European Parliament, 2007).

ESA negotiators may be strengthened by the fact that the EC accepts that the above aims are *'high levels of ambition. Negotiating bilateral agreements can be complex and demanding... we will need to ensure that we share similar ambitions with our prospective partners at the outset in order to avoid negotiations stalling because of a mismatch of expectations'* (EC, 2006:12). However, ESA states are better off knowing that the EC is approaching the discussions on IPRs in the context of EPAs with the expectation of achieving TRIPS-plus commitments.

Article 2 of the EAC-EC EPA provides that one of the objectives of the agreement is to improve the EAC's capacity in trade policy and trade-related issues. This provision is also to be read with Article 37, which identifies IPRs as one of the areas of future negotiations for a comprehensive EPA. Article 37 does not state in what context the IPRs will be negotiated, whether as a rule-based regime or as simple co-operation. In the light of Article 2, one may safely assume that this is really about development co-operation. What is clear is that there is no requirement under the EAC-EC EPA for the negotiation of rules on IPRs. On this basis there is no need to open negotiations beyond aspects of development co-operation, such as capacity building, as indicated under Article 2 of the EAC-EC EPA.

The EU wants ESA countries to agree on protecting intellectual property especially for the EU companies that are heavily involved in research and development. What this means is that if the ESA countries agree to stronger intellectual property protection in their trade agreement with the EU, they will be required to implement certain provisions that will give EU companies favourable treatment at the expense of the developmental needs of ESA countries. In other words, ESA countries may have to pay heavy royalties for accessing the technology developed by EU companies.

There is no mention of IPRs in the SADC-EC EPA (2009). Article 67, which identifies the areas for future negotiations for a comprehensive EPA, does not even mention IPRs. It is also significant that the SADC group ignored an initial EC text that was meant to be the basis of IPR negotiations in 2007 (EU 2007). SADC was not ready to discuss IPR issues, as they were concentrating on market access of goods only.

4.2. The Africa Growth and Opportunities Act (AGOA)

The African Growth and Opportunities Act (AGOA) of 2000 – formally known as the Trade and Development Act of 2000 – is a unilateral extension of market access by the United States of America (US) to chosen sub-Saharan Africa countries. It commits 41 African countries to take particular positions in support of the US at the multilateral trade level. All countries in ESA are included, except Zimbabwe. The 41 countries were chosen according to eligibility criteria under section 104 of Act. For the purpose of this paper, it is critical to note that one of the requirements for eligibility is that the relevant country should commit itself to eliminating barriers to US trade and investment by 'protecting intellectual property rights'. This requirement is coupled with the requirement that the African governments must desist from interfering in the economy through measures such as price controls, subsidies and government ownership of economic assets.

Section 134 of the AGOA acknowledges the HIV and AIDS public health crisis, but does not attempt to relate this to TRIPS and public health issues. By emphasising the protection of private property and restricting government involvement in the economy, the AGOA eligibility criteria can effectively operate as an external or bilateral pressure on African governments' policy initiatives with respect to the application of TRIPS flexibilities. Here we must note that the AGOA restrictions were set in 2000, before the WTO's decisions on TRIPS flexibilities. To ensure that the TRIPS flexibilities supersede narrowly defined property rights interests, as enshrined in the AGOA, African governments need to insist that the multilateral context (WTO) should govern the IPR eligibility criteria. In the AGOA's current form, its principles run contrary to the practical solutions needed to deal with the public health problems faced by African countries.

4.3. Anti-counterfeit laws in East Africa

Recent developments in East Africa also have the potential to reverse the benefits of TRIPS flexibilities. Kenya passed an Anti-Counterfeit Act in 2009, which seeks to prevent the damage caused by, among others, fake medicines. This also has the potential to limit the legal production and distribution of generic medicines. The Anti-Counterfeit Act defines a counterfeit as “a good that is identical or substantially similar to a good protected by an intellectual property right”. Unfortunately, this definition seems to include legal generic products. Similar moves are underway in Uganda, through its Counterfeit Goods Bill (2009), to introduce anti-counterfeit laws that broadly define counterfeits in a manner that encroaches on the legal trade in generics. Worse, the EAC is considering a Draft East African Community Policy on Anti-Counterfeiting, Anti-Piracy and Other Intellectual Property Rights Violations, which could be as problematic as the Kenyan legislation. Tanzania has also made amendments to its Merchandise Marks Act Regulations (2008) and Zanzibar Industrial Property Act (2008), which are designed to prevent product counterfeiting. It seems that EAC member states have not designed their anti-counterfeit laws to adequately take into account the TRIPS flexibilities.

5. Implementation of TRIPS flexibilities in ESA

Almost all ESA countries had some sort of legal regime dealing with IPRs before the TRIPS agreement was agreed. Laws on IPRs were part of the colonial legal heritage. *Table 3* shows how the 16 ESA countries covered by EQUINET use TRIPS flexibilities. Note how levels of use vary widely from country to country, especially those that have amended their IPR laws to cater for public health emergencies, ranging from Zimbabwe, which makes good use of the flexibilities, to Malawi, which does not.

Current legal practice in ESA countries is mostly based on patent laws that were put in place before the TRIPS agreement was adopted. While some of these laws include provisions that take advantage of the flexibilities, these provisions are not always being enforced.

The most glaring problem is that the public health-related aspects of the TRIPS flexibilities have not been accepted at the WTO level by all the ESA countries concerned, with the exception of only Mauritius and Zambia. In other words, ESA countries are withholding the critical mass needed to enable a formal adoption of the protocol amending the TRIPS agreement at the WTO. The December 2009 deadline has passed and the deadline was extended to 2011 on 17 December 2009 (http://www.wto.org/english/tratop_e/trips_e/wt-l-785_e.pdf). This extension only further delays the process of formally including the flexibilities in the TRIPS agreement that countries fought for at the Doha Ministerial meeting in 2001 (WTO, 2001a).

The TRIPS flexibilities on their own will not deliver the necessary public health outcomes desired by the ESA countries. In *Table 3* we indicated some of the policy interventions that ESA countries will need to take to address the gaps. However, these countries will be constrained in their efforts to address the gaps. South Centre (2004) has identified two levels of constraints. The first level is associated with the incorporation and general implementation of the TRIPS flexibilities. The second relates to constraints in the framing and implementation of supporting legal and policy measures, such as those concerning local innovation and production of pharmaceuticals

Table 3: ESA countries' use of TRIPS flexibilities

Country and legislation	Protocol amending TRIPS accepted?	Exclusion of pharmaceuticals from patenting?	Compulsory licences and other flexibilities	Notification to export or import (August 2003 decision)	Patent duration	Remarks
Angola Industrial Property Law, No. 3 of 1992	No	Yes	N/A	N/A	N/A	The law was passed in 1992 before the TRIPS Agreement was adopted.
Botswana Industrial Property Act 1996, amended 1997	No	N/A	<ul style="list-style-type: none"> • Section 30 allows the government or an authorised agent to exploit a patent without the consent of the patent holder where it is in the public interest or where the patent holder has used their right for anti-competitive practices. • Section 31 allows for the application for compulsory licences at any time after the expiration of three years from the granting of a patent or four years from the date of application on the grounds that the market in Botswana is not being supplied or is not being supplied on reasonable terms. But no compulsory licence has ever been issued. • Also contains exceptions for use of invention for research purposes. • Has an element of competition law so govt can intervene on fair business practices. 	Not yet made use of notification procedure. However, Section 30(2) provides that the exploitation of a patent by the government or other agent should be predominantly for the supply of the domestic market in Botswana.	20 years	<ul style="list-style-type: none"> • Botswana's laws were passed before the WTO decisions on TRIPS flexibilities. • Laws need to be aligned with the flexibilities. • Botswana did not use the transition period available to developing countries to pass patent protection laws by 1 January 2000 its law was passed in 1996.
DR Congo Law No. 82-001, January 1982	No	No	N/A	N/A	N/A	The governing law was passed before the formation of the WTO and is uninformed by TRIPS flexibility developments.

Country and legislation	Protocol amending TRIPS accepted?	Exclusion of pharmaceuticals from patenting?	Compulsory licences and other flexibilities	Notification to export or import (August 2003 decision)	Patent duration	Remarks
Kenya Industrial Property Act, 2001	No	N/A	<ul style="list-style-type: none"> Sections 72–78 provide for the granting of compulsory licences on the grounds that a market is not being supplied on reasonable terms, or where an invention constitutes an important technical advance of considerable economic significance in relation to the invention claimed in the earlier patent. Section 80 allows government to use a patented invention without the consent of the patent holder on grounds of national security, health or nutrition or for the development of a vital economic sector. The Act permits the Bolar Provision limited exception. No compulsory licence has been issued to date. A voluntary licence for the manufacture of anti-retrovirals was issued for territory including EAC. 	<p>The Act does not</p> <ul style="list-style-type: none"> address issues of import, export of drugs. stipulate if compulsory licences can be used to export drugs to other poorer countries in the region that do not have Kenya's productive capacity. 	20 years	Took advantage of the transition period for developing countries to pass TRIPS-compliant patent protection laws, but was too late in doing so because law came into force in 2002 before the August 30 solution of 2003 was adopted.
Lesotho Industrial Property Amendment Act, 1997	No	No	N/A	N/A	N/A	N/A
Malawi	No	No	N/A	N/A	N/A	N/A
Madagascar Law 89-019, Article 27.1.	No	No	N/A	N/A	N/A	N/A
Mozambique Industrial Property Code 2006	No	No	Compulsory licenses may be granted for reasons of public interest (Article 85 of the Industrial Property Code). An invention is of public interest if it is of importance to public health, national defense, economic and technological development (Government of Mozambique 2006).	No	20 years from the date of filing	Mozambique granted in 3.2004 a compulsory licence for local manufacture of a first-line ARV (WHO 2006)

Country and legislation	Protocol amending TRIPS accepted?	Exclusion of pharmaceuticals from patenting?	Compulsory licences and other flexibilities	Notification to export or import (August 2003 decision)	Patent duration	Remarks
Mauritius Patents, Industrial Designs and Trade Marks Act, 2002	Yes (2008)	No	<ul style="list-style-type: none"> • Section 23 allows exploitation of a patent by the government or a person authorised thereby on grounds of national interest or because of the use by the patent holder of the patent for anti-competitive reasons. • Section 24 allows for the application of non-voluntary licences 3 years since granting a patent or four years from the date of patent application on the grounds that the patent is not being sufficiently exploited in Mauritius. 	N/A	20 years	Nil
Namibia Industrial Property Bill, 2008	No	No	<ul style="list-style-type: none"> • Section 17.5 permits the government or an authorised agent thereof to use a patent without the consent of the patent holder where it is in the public interest. • Non-voluntary licences may be granted after three years have expired since the granting of a patent or four years from the date of application on the grounds that the patent holder has failed to sufficiently exploit the invention in Namibia. 	Not utilised.	20 years	Namibia had not by 12.2008 made its IPR regime WTO compliant. Until the Industrial Property Bill is enacted, TRIPS flexibilities are not exploited in Namibia's laws.
South Africa Patents Act, 1978, amended 1988 and 1996	No	No	<ul style="list-style-type: none"> • Section 56 of the Patents Act (1978) permits the use of compulsory licences to remedy abuse, on failure to use the patent, for demand not being met on reasonable terms, and on national security grounds. No compulsory licences have been issued. • Voluntary licences have been produced as a result of pressure from the Competition Commission. 	The law does not explicitly provide for exporting drugs to countries with insufficient manufacturing capacity.	20 years	South Africa has the capacity to assist the region with cheaper drug exports. The law needs to include TRIPS flexibilities for generics to be produced and exported for this purpose.

Country and legislation	Protocol amending TRIPS accepted?	Exclusion of pharmaceuticals from patenting?	Compulsory licences and other flexibilities	Notification to export or import (August 2003 decision)	Patent duration	Remarks
Swaziland Industrial Property Law, No. 6 of 1997	No	No	<ul style="list-style-type: none"> Section 12(6) permits the government or a designated third party to exploit an invention without the consent of the patent holder where it is in the public interest to do so. In April 2004 the government authorised procurement of medicines for HIV and AIDS 'in the best cost-effective way possible on the international market irrespective of the existence of any patent or other intellectual property protection applicable in Swaziland until such a time as it will no longer be considered essential to address the current public health crisis related to HIV and AIDS' (Knowledge Ecology International 2007). 	N/A	20 years	Law adopted relatively early, without full use made of transition period flexibility.
Tanzania Patents Act, 1987	No	No, but Section 13 provides for temporary exclusion by way of statutory instrument. The section is vague, however.	<ul style="list-style-type: none"> Section 52 allows compulsory licences to be issued on four grounds: non-use of the patent, non-reasonable use of the invention for the Tanzanian market demands, patented products being imported into Tanzania and hindering the working of the invention, and the refusal of the owner of the patent to grant licences on reasonable terms. The government may also order the granting of licences for products deemed to be vital to the economy (Section 54). Section 61 permits the government, or a designated third party, to exploit an invention without the consent of the owner on grounds of public interest, public health or national security. The provisions are not being utilised. 	Notification is linked to conditions for granting compulsory licences. Although Tanzania is not making use of this procedure, Section 52 of its law gives a justification for granting compulsory licences in the fact that the patent owner is unfairly and substantially prejudicing the export of the patented invention from Tanzania.	10 years	<ul style="list-style-type: none"> The law came into force in 1994, a long time before the health-related TRIPS flexibilities were even formulated. Tanzania has used its LDC status to keep the patent validity period to up to 10 years (vs 20 years as required by TRIPS Article 33. This is permissible within the context of the Article 66 deadline of 2016.

Country and legislation	Protocol amending TRIPS accepted?	Exclusion of pharmaceuticals from patenting?	Compulsory licences and other flexibilities	Notification to export or import (August 2003 decision)	Patent duration	Remarks
Tanzania continued: Zanzibar Industrial Property Act, 2008	No	Section 3 of the Zanzibar Act provides exclusion until 1 January 2016.	<ul style="list-style-type: none"> The provisions are not being utilised. 		10 years	
Uganda Patents Act, 1993, amended 2002 Industrial Property Bill, 2007	No	No	<ul style="list-style-type: none"> Section 29 allows the government or persons authorised by the government to exploit an invention without the consent of the patent right owner where it is in the vital public interest (this includes public health) for the government to do so. Section 30 allows for the granting of compulsory licences on exactly the same terms as for Tanzania above. Use of these provisions remains limited. 	The same situation to Tanzania also applies to Uganda as mentioned above	15 years	See above comment on Tanzania's use of patent protection term flexibility. The Industrial Property Bill incorporates TRIPS flexibilities (patentability, government use, Bolar Provision compulsory licence, parallel imports and extension of transitional periods).
Zambia Patents Act, 1958, amended 1980 and 1987	Yes (August 2009)	No	<ul style="list-style-type: none"> Section 37 permits the granting of compulsory licences on grounds of insufficient use/ abuse of patent rights. Section 42 permits the government to make use of an invention on grounds of a state of emergency. In 2004, the Zambian government issued a compulsory licence for the manufacture of anti-retrovirals to a local producer. 	Zambia did not notify the WTO.	16 years (S 13). 14 years under Southern Rhodesia law, or terms as in UK law.	The general term of a patent may be within the TRIPS flexibilities for LDCs, however it is far from clear what the special designation for patents granted under UK law means.

Country and legislation	Protocol amending TRIPS accepted?	Exclusion of pharmaceuticals from patenting?	Compulsory licences and other flexibilities	Notification to export or import (August 2003 decision)	Patent duration	Remarks
<p>Zimbabwe</p> <p>Patents Act, 1971, amended 1994</p> <p>Patents Amendment Bill, 2001</p>	No	No	<ul style="list-style-type: none"> • Compulsory licences may be granted under Section 31 for abuse or insufficient use of the invention. • In terms of Sections 34 and 35, the government may use an invention or authorise an agent to do so in a state of emergency. • In 2002, the government declared a state of emergency and overrode patents on anti-retrovirals (ARVs). It issued a compulsory licence to make, use or import ARVs. The period was extended in 2003 up to December 2008. 	Notification not made. However, the Act allows for drugs produced under compulsory licence to be exported on a number of grounds. Section 35 allows export of drugs to address imbalances in trade, to assist a foreign country suffering from war, and to promote industry.	20 years	Nil

More specifically, the gaps include:

- **Lack of domestic pharmaceutical research and manufacturing capacities:** Most ESA countries do not have domestic pharmaceutical research and manufacturing capacity. South Africa has the most advanced pharmaceutical capacity and Zimbabwe and Kenya have some, although their drug research and manufacturing capacity is inadequate.
- **Insufficient technical and infrastructural capacities for medicines regulation:** This applies to the bulk of the ESA countries with the notable exception being South Africa, whose regulatory and infrastructure relevant to medicines is relatively advanced compared to the rest of the region.
- **Difficulties in establishing efficient pharmaceutical management and procurement systems:** TRALAC (2006) considered the potential of Kenya to produce drugs to supply ESA countries like Tanzania and Uganda in the context of the East African regional market. The study noted that the procurement of such drugs from Kenya is made fairly challenging because of differing regulations on the manufacture, import, export and distribution of pharmaceutical products in each of the EAC countries. The study noted that a South African company also faced the same problems when it attempted to export ARVs to Tanzanian and Uganda.
- **Bilateral and other political pressures against the use of TRIPS flexibilities:** In 1997, the South African government amended the Medicines Control Act to allow broader powers for the parallel importation of medicines (Government of South Africa 1965, as amended 1997). This was met by intense lobbying pressure from the large pharmaceutical companies, who attempted to block the operation of the new law. The companies eventually dropped challenges to this law in the face of equally intense domestic and international lobbying by activists opposed to the efforts of the pharmaceutical companies to stifle the new law. Furthermore, the emphasis on the protection of private property rights as a requirement for accessing the US market under AGOA provisions puts both bilateral and political pressure on ESA countries to avoid diluting pharmaceutical patents rights. Most ESA countries are susceptible to this pressure, with the exception of Zimbabwe which is not a beneficiary of the AGOA scheme.
- **Lack of capacity to address anti-competitive practices and abuse of patents rights:** Although the laws of the various ESA countries invariably include a clause on anti-competitive practices, the capacity for the authorities to police and prevent these practices is very limited. A few ESA countries have functioning competition policies and laws. Botswana, for example, is only introducing a Competition Bill in December 2009. A handful of countries, like South Africa, Kenya, Mauritius, Zambia and Zimbabwe, have institutions to enforce laws on anti-competitive practices.
- **Difficulties in accessing pricing and patent status information:** Laws have been developed but, because of the high levels of bureaucracy in government ministries and departments, it has been difficult to access the information. Most of it is not yet available on the internet due to capacity and resource constraints.

These gaps need to be addressed in order to make the TRIPS flexibilities practical and relevant to the needs of the ESA countries. In the context of the EPA negotiations for example, the efforts of the ESA countries should be concentrated on acquiring development assistance to address these gaps in the form of co-operation from the EU.

6. Recommendations and follow-up actions

ESA countries should prioritise the application and implementation of TRIPS flexibilities and focus on the pertinent issues given below.

The protocol on the TRIPS amendments requires endorsement by the ESA countries before December 2011. This process should be led by the relevant line ministries (for example, trade and health ministries). LDCs need to make their case at the WTO for the extension of the exemption on patent protection. They need to participate effectively in the annual reviews by the Ministerial Conference, which means that, where applicable, they must show why the waiver is still necessary. They should also conduct self-assessments and prepare their negotiating positions for possible extension of the waiver beyond 1 January 2016. This requires them to identify and advance the exceptional circumstances required to persuade the Ministerial Conference to modify or extend the waiver. They should acquaint themselves fully with Article IX of the agreement establishing the WTO, namely, the procedure for the granting, modification and termination of waivers (WTO, 1994).

Those countries that have not done so yet, need to **enact laws that encompass the developmental aspect to IPR policy**, and ensure that competition law and policy does not undermine TRIPS flexibilities. This includes drafting and implementing laws to enable effective use of compulsory licensing to help deal with public health emergencies.

It is necessary for ESA countries to focus on the **implementation of the TRIPS flexibilities**. This requires a comprehensive review of each ESA country's policies and capacity needs with respect to the implementation of the TRIPS flexibilities. This has to be done ahead of the deadlines set out in the amendments to the TRIPS agreement. ESA countries need to conduct general review of the TRIPS flexibilities, including administrative and regulatory policy needs assessments, to ensure they make full use of the TRIPS amendments to address public health needs. They should provide the TRIPS Council with as much information as possible on their individual priority needs for technical and financial co-operation in order to assist them in taking steps necessary to implement the TRIPS Agreement. So far, very few African countries have followed this route, with Uganda and Sierra Leone being notable exceptions.

There is a case for better use of the relative strengths of particular ESA countries with respect to the **production and export of medicines** within the ESA countries.

Regional and international agreements should be scrutinised to ensure that they do not erode TRIPS flexibilities. In the EPA negotiations, ESA countries need to create common positions that will enable the adoption of a development co-operation approach to any discussions on IPRs with the EU. Pressure by AGOA for less government intervention in policy settings and economic affairs should be resisted and emphasis placed on the need for ESA governments to be supported in their public health interventions even where these may result in a dilution of IPRs.

ESA countries should take a lead in the **implementation of the recommendations of the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property**. This includes ESA countries advocating for the richer WHO member states to assist in this process by taking the specific actions recommended in the action plan as items for immediate implementation.

For civil society organisations, it is important to help ESA governments with technical skills required to analyse and interpret international IPR laws vis a vis trade policy, as well as

to popularise technical information on IPRs, to advance the debate and contribution of non-technical stakeholders, like parliamentarians and ordinary citizens. Civil society can support capacity building programmes for technical departments to better monitor and manage IPR issues.

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Further useful articles and websites

http://www.iprcommission.org/papers/text/govt_response/govt_response.htm

http://ec.europa.eu/trade/creating-opportunities/trade-topics/european-competitiveness/index_en.htm

<http://www.wipo.int/clea/>

Acronyms and abbreviations

ACP	African, Caribbean and Pacific
AGOA	African Growth and Opportunity Act
COMESA	Common Market for Eastern and Southern Africa
CPA	Cotonou Partnership Agreement
EAC	East African Community
EPAs	Economic Partnership Agreements
EQUINET	Regional Network for Equity in Health in Eastern and Southern Africa
EC	European Community
ESA	Eastern and Southern Africa
EU	European Union
FTA	Free Trade Agreements
IPRs	Intellectual Property Rights
LDCs	Least Developed Countries
MFN	Most Favoured Nation
SADC	Southern African Development Community
SEATINI	Southern and Eastern African Trade, Information and Negotiations Institute
TRIPS	Trade-related Aspects of Intellectual Property Rights
WTO	World Trade Organisation

Equity in health implies addressing differences in health status that are unnecessary, avoidable and unfair. In southern Africa, these typically relate to disparities across racial groups, rural/urban status, socio-economic status, gender, age and geographical region. EQUINET is primarily concerned with equity motivated interventions that seek to allocate resources preferentially to those with the worst health status (vertical equity). EQUINET seeks to understand and influence the redistribution of social and economic resources for equity oriented interventions, EQUINET also seeks to understand and inform the power and ability people (and social groups) have to make choices over health inputs and their capacity to use these choices towards health.

EQUINET implements work in a number of areas identified as central to health equity in the region:

- Public health impacts of macroeconomic and trade policies
- Poverty, deprivation and health equity and household resources for health
- Health rights as a driving force for health equity
- Health financing and integration of deprivation into health resource allocation
- Public-private mix and subsidies in health systems
- Distribution, retention and migration of health personnel
- Equity oriented health systems responses to HIV and AIDS and treatment access
- Governance and participation in health systems
- Monitoring health equity and supporting evidence-led policy

EQUINET is governed by a steering committee involving institutions and individuals co-ordinating theme, country or process work in EQUINET:

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