



TRADE, TRIPS &  
ACCESS TO MEDICINES

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A report for SADC Member States and the future SADC Pharmaceutical Procurement Services (SPPS) based on the lessons learned during the Trade, TRIPS and Access to Medicines project 2012-2014



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*A report for SADC Member States and the future SADC Pharmaceutical Procurement Services (SPPS) based on the lessons learned during the Trade, TRIPS and Access to Medicines project 2012-2014*

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## ***Background***

The SARPAM Trade, TRIPS and Access to Medicines (TTAtM) project received a mandate from SADC Member States in September 2012 to support Member States to optimize their national intellectual property and specifically patent legislation in the context of maximising access to medicines.

Workshops have been held in seven countries: Botswana, Malawi, Zambia, Zimbabwe, Lesotho, Seychelles and Swaziland. The main questions raised were what Member States could do to lower procurement costs of patented medicines in the absence of affordable pricing by the originator company or otherwise.

SADC lawyers' meetings in September 2013 and 2014 formulated solutions for Member States that face patent barriers to procuring low priced medicines. This report summarizes the lessons learned and solutions found if Member States want to procure patented medicines.

The legal pathways described in this document are fully compliant with international rights and obligations of SADC Member States under the rules of the World Trade Organization (WTO). Others have also described the options outlined in this document including the WTO, the World Health Organization (WHO) and the World Intellectual Property Organization (WIPO). On the websites of these organizations additional information is available.<sup>4,5</sup>

Countries in sub-Saharan Africa have extensive experience in the use of legal pathways such as the flexibilities in patent law to assure access to medicines, in particular, in the field of HIV/AIDS.<sup>6</sup> To prevent any controversy over the use of flexibilities such as compulsory licensing, it is important to imbed the use of such mechanisms in procurement practices and in the procedures of the SADC Pharmaceutical Procurement Services (SPPS), as acknowledged in articles 4 and 5 of SPPS Charter.

## ***Procurement of patented medicines***

If one or several SADC Member States need to access a particular medicine (hereinafter medicine A), which is either too expensive or unavailable in the country or region, they have the right, under the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), and as reaffirmed in the Doha Declaration on TRIPS and Public Health, to take the necessary "measures to protect public health". Depending on the patent status of medicine A in each country, whether SADC Member States are classified as least-developed country (LDC) and/or whether

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<sup>4</sup> See for example the WTO site, which also has useful templates for notification:

[http://wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_e.htm](http://wto.org/english/tratop_e/trips_e/public_health_e.htm)

<sup>5,3</sup> See for example: [http://www.who.int/phi/promoting\\_access\\_medical\\_innovation/en/](http://www.who.int/phi/promoting_access_medical_innovation/en/)

production capacity exists<sup>7</sup> in SADC for medicine A, various options are available for SADC Member States to ensure access to medicines needed.

This note outlines how SADC members can make use of TRIPS flexibilities for public health purposes in 3 types of situations:

1. Generic A can be produced in SADC. Use of a compulsory or government use license for regional purposes, based on the regional exception of the WTO Paragraph 6 System, would allow supply to all SADC Member States.
2. Generic A cannot be produced in SADC, but is available from affordable generic source(s) outside SADC. Importation into SADC and re-exportation to other SADC Member States is possible. An ordinary compulsory or government use license may be required.
3. Generic A cannot be produced in SADC, nor seem to be available from affordable generic source(s) outside SADC. Use of compulsory or government use license based on the WTO “paragraph 6 system” may be required to import and re-export within SADC.

## ***1. Production and export within SADC of generic versions of patented medicines***

SADC country X (non-LDC) has manufacturing capacity for medicine A but medicine A is protected by a national or ARIPO patent. Country X can issue a compulsory or government use license in accordance with its own patent regulations to allow production of generic medicine A in its territory.

Further, to harness economies of scale among parties to a regional trade agreement, country X can also use the license to manufacture generic A to address other SADC Members’ needs. This is permitted under the regional waiver of the WTO Paragraph 6 System (see full explanation box on the next page), which specifically allows exports under a compulsory license among countries that belong to a regional trade agreement, of which at least half of the members are LDCs<sup>8</sup>. SADC counts 8 least-developed countries: Angola, Democratic Republic of Congo, Lesotho, Madagascar, Malawi, Mozambique, Tanzania, and Zambia. Therefore, country X, as a SADC Member, can export any quantity of generic medicine A, produced under compulsory license, to any other SADC Member. To make use of this waiver, country X would have to have implemented this WTO flexibility in its national law, i.e. that compulsory

<sup>7</sup> When reference is made to ‘production capacity’ or ‘local production capacity’ it implies that such production can take place in a cost-effective manner.

<sup>8</sup> The TRIPS regional waiver states that “where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory license in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question.”

licenses do not have to be “predominantly for the supply of the domestic market”, if used to supply other SADC Members that share the public health problem(s) in question.<sup>9</sup>

With the establishment of SPPS, regional forecasts should result in joint orders to country X through SPPS.

To import from country X, SADC members without any patent in force on medicine A can simply follow usual import procedures. SADC LDCs may simply indicate intent to use the extended transition period under the TRIPS Agreement, according to which they do not have to enforce patents on pharmaceuticals (see below section on LDCs). SADC members, non-LDC, with a national or ARIPO patent in force on medicine A, need to issue a compulsory or government use license (based on their national patent law) to import generic A from country X. Of note, it could be argued that no remuneration has to be paid under this compulsory license for import if the patent owner has already been remunerated in country X (through the compulsory license for production).

## ***2. Importation in SADC of generic versions of patented medicines***

If there is insufficient or no capacity to locally produce generic A, SADC Members may import generic versions of medicine A from another country where it is readily available. Patents are granted on a territorial basis, nationally or sometimes regionally, such as patents granted by the African Regional Intellectual Property Organization (ARIPO). Therefore, medicines patented in some countries/regions may be available as generic in other countries or regions if there is no intellectual property obstacle, in the form of a patent or other type of exclusivity. For instance, several medicines are generically available in India because India did not grant patents on pharmaceuticals until 2005.

With the establishment of SPPS, SADC Member States would likely pool their demand and jointly import. SPPS will then re-export to individual SADC Member States, based on the TRIPS regional waiver mentioned in the previous section.

Importation into each SADC Member State will always depend on the patent and country status in the country of import:

- SADC Members, where *medicine A is not covered by a national or ARIPO patent* in force can import generic A in accordance with usual import procedures.
- LDCs may simply indicate intent to use the extended transition period under the TRIPS Agreement, according to which they do not have to enforce patents on pharmaceuticals (see below section on LDCs).

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<sup>9</sup> For instance, Botswana Industrial Property Act, Act No. 8 of 2010.

- SADC developing country Members where medicine A is covered by a national or ARIPO patent in force need to issue a compulsory or government use license in accordance with their national patent law to import generic A.

If SADC countries are unaware of an affordable generic source to import medicine A, the WTO Paragraph 6 System may be the optimal way to address the issue.

#### WTO paragraph 6 system

The WTO “2003 August 30<sup>th</sup> decision” also called “[Paragraph 6 system](#)” was adopted by all WTO members, within the legal framework of the WTO system and is therefore available to all WTO members. It created a permanent waiver to Article 31(f) of the TRIPS Agreement that limits compulsory licenses issued by WTO members to override patent rights to be “*predominantly for the supply the domestic market*”. The paragraph 6 system created a special export license according to which WTO members may also issue compulsory licenses *specifically for export* to address needs notified by other countries under the system.

On [6 December 2005](#), WTO members adopted a Protocol amending the TRIPS Agreement to formally include the 2003 August 30<sup>th</sup> decision into the Agreement. This will take effect when [two thirds of the WTO’s members](#) have accepted the change. So far, within SADC, Mauritius, Zambia and Botswana [have accepted the Protocol](#). This does not prevent other SADC members to implement the Paragraph 6 system into their own patent legislation (as did [Botswana](#)) nor to make use of it when required.

As outlined in the [WHO-WIPO-WTO](#) study on *Promoting Access to Medical Technologies and Innovation*<sup>1</sup>, “The special export license is one legal pathway that can be followed when it represents the optimal route to effective procurement [...] Regional approaches to procurement and joint notifications by countries with similar needs for accessible medicines may offer pathways to aggregating demand under the System, thus enabling an effective response to the needs identified.”

### **3. Importation in SADC of generic versions of patented medicines under the WTO Paragraph 6 System**

The WTO Paragraph 6 System may be used for import to remedy the following circumstances:

- one or several SADC countries need access to certain medicines which are either too expensive or unavailable in the country or region;
- the countries in question have established that they have insufficient or no manufacturing capacity in the pharmaceutical sector for the medicine; **and**
- no generic of quality is available to import for the countries in question, e.g. medicines for cancer.

Since the Paragraph 6 System created a waiver to the usual restriction of compulsory licenses, it requires a series of [notifications](#) to the WTO from Member States intending to use the System. Importantly, these notifications are required for transparency purposes only, do not need to be approved by the WTO and do not commit the members to follow through.

SADC members would have to make 2 types of notifications:

- A once-off [notification](#) is required from SADC developing countries only<sup>10</sup> (Botswana, Mauritius, Namibia, Seychelles, South Africa, Swaziland and Zimbabwe) to confirm in general that they intend to use the Paragraph 6 System as an importer. This can be done at any time and it does not commit these countries to use the System. Rather, they reserve the right to do so in the event of potential future need.
- A more specific [notification](#) is then required to signal which drugs are needed in SADC. This notification must outline the names and expected quantities of the pharmaceutical products needed, e.g. "3 million doses of medicine A". SADC members may make such notification of medicines needs individually to the WTO at any time. However, since the Paragraph 6 System recognizes the need for economies of scale in a regional context, it is advised that SADC members make joint notifications through SPPS, once established, to provide a pathway for the establishment of commercially viable levels of demand for production and shipment.

As specified in the WHO-WIPO-WTO study, *"this [product] notification can be submitted at an early stage of the procurement process, before any final decision about preferred sources of supply. It does not create any obligation to use the System should a better alternative emerge. A country is therefore free to notify expected medicine requirements as a routine step in the procurement planning process, thus facilitating assessment of the full range of access options, signalling demand for potential suppliers, and clearing the way for actual use of the System should it present the most commercially viable option."*

The product notification should also include a declaration from SADC developing country members that they have insufficient or no manufacturing capacity in the pharmaceutical sector for the products in question, and that they have granted or intend to grant a compulsory license if the products in question are under patent in their territory. As stated by the WHO-WTO-WIPO trilateral study, *"LDCs may simply indicate an intent to use the extended transition period under the TRIPS Agreement"*<sup>11</sup>. This is based on the fact that the WTO 30<sup>th</sup> August 2003 Decision *"is without prejudice to the rights, obligations and flexibilities that Members have under*

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<sup>10</sup> LDCs are automatically entitled to use the Paragraph 6 System as importing members and need not make a general notification of intent to use it.

<sup>11</sup> Promoting Access to Medical Technologies and Innovation, WHO-WIPO-WTO, Geneva 2012, pp. 225-226.



*the provisions of the TRIPS Agreement [...], including those reaffirmed by the [Doha] Declaration, and to their interpretation”*

These notifications to the WTO aim also at signalling the need for specific medicines to potential generic manufacturers in exporting countries, which can then apply for a compulsory license for export to address SADC members notified needs. For example, India Patents Act (Section 92A) provides for mandatory compulsory licenses for export, to address public health problems of other countries, as is evidenced by the use of the word “shall” in the section below.

**India Patents Act, Section 92A**

*(1) Compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India.*

Before making the order, for example to an Indian generic manufacturer, SADC developing country members in which the medicines are under patent, will need to issue a compulsory license. It is recommended to issue a compulsory license for public non-commercial use, aka government use, which does not require prior negotiations with the patent holder. To avoid double payment of royalties to the patent holder, the Paragraph 6 System provides that the importing country exempts the licensee from the requirement to pay license remuneration if payment has already been made in the exporting country.

LDCs and/or SADC countries in which the medicines in question are not under patent may just order and import the necessary product(s) according to usual procurement processes.

If the products are imported in bulk for the region, for example through SPPS, SADC members may re-export these products to other SADC members without any particular notification (as allowed by the system in the context of regional trade agreements) in situations where: a) there is no patent in force in the importing country, b) the importing country is an LDC not enforcing pharmaceutical patents or c) a CL has been issued by the importing country).

Lastly, the Paragraph 6 System requires importing WTO members to take reasonable measures within their means to prevent re-exportation of the imported generic medicines. It specifies that such measures should be proportionate to these members’ administrative capacity and the risk of trade diversion.

The scenarios described above are summarized in the table below, depending on the patent status situation and whether there is production capacity.



|   | Production capacity for generic A  | No production capacity for generic A   |
|---|--|--|
| Medicine A <b>patented</b> in SADC Member (not LDC)         | CL for production and export within SADC (regional waiver of Paragraph 6 System) | <ul style="list-style-type: none"> <li>- CL for import of generic available, or</li> <li>- WTO notifications + CL for import (Paragraph 6 System)</li> </ul> |
| Medicine A <b>not patented</b> in SADC Member or <b>LDC</b> | No IP obstacle to produce and export   | <ul style="list-style-type: none"> <li>- No IP obstacle to import available generic</li> <li>- WTO notifications if no generic available</li> </ul>          |

### ***Generic production or importation in SADC Least-Developed Countries***

Least-developed countries enjoy important transition provisions under the TRIPS Agreement, based on [two decisions of the Council for TRIPS](#):

- A 2002 decision exempts WTO LDC Members from the obligation to grant or enforce patents on pharmaceutical products, or to protect pharmaceutical test data, until 1<sup>st</sup> January 2016.
- A 2013 decision exempts LDCs from the obligation to implement the entire TRIPS Agreement until July 2021 (with the exception of Articles 3, 4 and 5 related to national treatment and most-favoured nation treatment), or until such a date on which they cease to be a least developed country Member, whichever date is earlier.

As the 2013 decision concerns the entire TRIPS Agreement, it also exempts *de facto* LDCs from their obligations with regards to pharmaceutical patents and data protection until at least July 2021. However, the 2013 decision also specifically exempts LDCs from enforcing granted patents.

In practice, this means that today a SADC LDC may import and/or produce generic versions of any medicine patented in its territory, both for its own needs and for export or re-export within and outside SADC, without IP restriction, as if there were no patent in the country.

### *How to implement the LDC transition provisions*

SADC LDCs would need to publicly indicate that they intend to make use of the LDC transition periods and, if needed, implement appropriate regulations. This is particularly important to allay any concerns producers and suppliers of generic medicines might have about possible patent infringement claims.<sup>12</sup>

This may be done as follows:

(1) The simplest option is that the government authority responsible for intellectual property declares, by decree or other appropriate legal means, that the country will not enforce any national or ARIPO patent claiming a pharmaceutical product, nor that it will protect pharmaceutical test data submitted in the normal course of drug registration process, until the end of the transition period pursuant to the Decision of the Council for TRIPS of 27 June 2002 (IP/C/25). While such a declaration waives the country's obligation to enforce any patents, which have been granted by the national patent office or by ARIPO, its effects are due to expire on 1<sup>st</sup> January 2016 unless LDC WTO Members ask for a further extension of this waiver.

(2) A more sustainable option for SADC LDCs is to introduce a simple amendment to their patent law to specifically exclude pharmaceutical products from patentability, as has been done by Rwanda, Uganda or Cambodia, pursuant to Decisions of the Council for TRIPS of 27 June 2002 (IP/C/25) and of 11 June 2013 (IP/C/64). One advantage of this option is that it would have effect until at least July 2021, and potentially beyond pursuant to the right of least-developed country Members to seek further extensions of the transition period provided for in paragraph 1 of Article 66 of the TRIPS Agreement.

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<sup>12</sup> For a more detailed descriptions on issues related to the implementation of the LDC extensions see:  
<http://www.ictsd.org/bridges-news/bridges-africa/news/the-ldc-medicines-extension-question-contemplating-next-steps>

## Use of LDC TRIPS pharmaceutical exemption by ARIPO Member States

Several SADC LDC Member States are also Contracting States under the Harare Protocol on Patents and Industrial Designs within the Framework of the African Regional Intellectual Property Organization (Lesotho, Malawi, Mozambique, Tanzania, and Zambia). However the Harare Protocol, which predates the more recent WTO decisions affecting LDCs, does not exempt such Contracting States from the processing of patent filings for pharmaceuticals. As with other applications, the ARIPO Office will notify designated offices of its intent to grant the pharmaceutical patents following the application received. It is then up to each Contracting State to communicate their written objection to the grant of a patent, if their national patent law excludes pharmaceutical patents. Failure to communicate a written objection to the ARIPO Office within six months of notification will result in the grant of a pharmaceutical patent extending to all designated Contracting States that did not object.<sup>13</sup>

To create the legal certainty necessary for local production or importation of generic medicines, it is recommended that SADC LDCs, which have excluded pharmaceutical products and processes from patentability in their national patent law, inform ARIPO that patents claiming pharmaceutical products or processes have no effect under the national law of their country.

Under Section 3, sub-section 6 of the Harare Protocol, each ARIPO Member State can make a written communication to ARIPO that “a patent shall have no effect in its territory for the reason [...] that, because of the nature of the invention, a patent cannot be registered or granted or has no effect under the national law of that State”.

The Harare Protocol contemplates such communications on a patent-by-patent basis. However, to avoid having to make a written communication to ARIPO for each patent application claiming a pharmaceutical product or process, it is suggested that such LDCs, which have excluded pharmaceutical products from patentability in their national law, make a general communication to ARIPO that any patent claiming a pharmaceutical product or process shall have no effect in the territory of LDC X for the reason that, because of the nature of the invention, such patents have no effect under LDC X national law.

To further facilitate implementation at the regional level, legal scholars have recommended that the Harare Protocol be revised to “exempt the territory of LDCs from the grant of any pharmaceutical patents. This means, in the event the ARIPO Office grants pharmaceutical patents, such patents will not be applicable to the LDC territories. LDCs that desire for the ARIPO patent to be applicable to their territory would need to communicate so to the ARIPO Office within a specific time-frame of receiving notification from ARIPO of its intent to grant the patent.”<sup>14</sup>

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<sup>13</sup> Shashikant S. The African Regional Intellectual Property Organization (ARIPO) Protocol on Patents: Implications for Access to Medicines. Research Paper 56. South Centre, Nov.2014.

<sup>14</sup> Ibid. 9.

The following is a flow chart detailing options under WTO rules when a needed “Medicine A” is not available or is available only from the originator company and too expensive in a Regional Economic Community (REC). These rules are applicable when a majority of an REC’s member states are Least Developed Countries (LDCs).

