

## Claiming our space: Using the flexibilities in the TRIPS agreement to protect access to medicines

*In 2001 the Doha Declaration on TRIPS and Public Health provided a landmark political commitment reaffirming the option for World Trade Organisation (WTO) member states to use all flexibilities provided in the TRIPS Agreement to ensure access to affordable medicines, and to prevent patent monopolies stopping access to medicines where they are needed for public health. By 2006, many of these flexibilities are not yet exploited in Africa, despite the massive demand for cheap medicines. This brief outlines the opportunities that African countries have to use these flexibilities and the legal and other changes needed for this. It also outlines the challenges that we may face and the measures to respond to them.*

### What does the TRIPS Agreement provide for?

The Agreement on Trade Related Aspects of Intellectual property Rights (TRIPS) sets out the minimum patent protection requirements for WTO members to enforce through their national laws. Developed and developing countries should by now have made their laws TRIPS compliant. The Least Developed Countries (LDCs) have until 2016. A large number of countries in east and Southern Africa (ESA) are LDCs.

Patents give those who hold them a monopoly on the production and sale of an invention. TRIPS rules oblige states to grant patent owners at least 20 years of exclusive commercial rights to make or sell their inventions, such as medicines. While this aims to protect investments in research and development, it allows patent holders to keep prices of patented drugs artificially high, putting them out of reach of many. Competition reduces prices, such as the 82% fall in the price of antiretrovirals (ARVs) when

Brazil began producing generic ARVs in 2000 (MSF 2005).

Recognising the necessity of generic competition in developing countries to allow access to treatment, and the huge need generated by AIDS, malaria, TB and other public health problems, in 2001 the Doha Declaration provided that the TRIPS Agreement **“can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, access to medicines for all.”** (Article 4).

In particular this gave countries the authority to use the flexibilities provided in the TRIPS Agreement in the interest of public health, including

- Giving transition periods for laws to be TRIPS-compliant.
- Providing for **compulsory licensing** or the right to grant a license, without permission from the license holder, on various grounds including public health.
- Providing for **parallel importation** or the right to import products



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patented in one country from another country where the price is less.

- Exceptions from patentability and limits on data protection
- Providing for early working, known as the **Bolar Provision**, allowing generic producers to conduct tests and obtain health authority approvals before a patent expires, 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.

**Compulsory licensing** was proposed at the WTO General Council in 2003 to enable countries not producing specific medicines themselves to import them, and made a permanent amendment to the TRIPS Agreement in 2005. It is also possible for voluntary licenses to be given by the patent holder for this. Companies can be awarded compulsory licenses if they have tried to obtain a voluntary licence on reasonable commercial terms within a time specified by national law. Governments, in contrast, do not need to seek a voluntary license or the permission of the patent holder if the compulsory licence is for public use or in response to a national emergency relating to urgent and longstanding public health problems (Article 5c of the Doha Declaration 2001), although a market-rate royalty must be paid to the patent holder. This compulsory licence can be used only in the domestic market and for the scope and duration of the purpose authorised. Currently, for example, the drug Varivar is produced under compulsory license in Zimbabwe, as the cheaper generic version of Combivir, whose patent is held by GlaxoSmithKline.

Since permissible grounds for compulsory licensing are not explicitly defined in the

TRIPS Agreement, states need only to demonstrate the compulsory license was issued for public interest reasons. The TRIPS agreement broadly construes public health and the public interest, including national emergencies and matters of extreme urgency, and non-commercial government action to remedy anticompetitive practices (TRIPS Articles 8, 31(b), 31(k).) For example after the Zimbabwe government declared a national emergency with regard to HIV and AIDS in 2002, as provided for in Zimbabwe law, the government issued compulsory licenses to three local companies to either import or produce four varieties of ARVs at about a third of the cost of the patented products, leading to price reductions in the ARV Zeret from US\$400 in 2001 to US\$30 in 2002 (Musungu and Oh 2006). Similarly Mozambique granted a compulsory licence to a local company, Pharco Mozambique Ltd, for the local manufacture of the triple compound of generic ARV drugs.

**Parallel importation** means allows governments to import without permission of the patent holder a product manufactured under a patent held in one country but sold at lower prices in another country.

Price differences for the same drug across different countries can be large, as shown in the table below.

US\$ price of Amoxil in	
Pakistan	\$8
Canada	\$14
Italy	\$16
New Zealand	\$22
Philippines	\$29
Malaysia	\$36
Indonesia	\$40
Germany	\$60

(Source Duckett 1999).

For example azithromycin in Kenya, patented by Pfizer under the trade name Zithromax cost \$2.02 per 250mg capsule in October 2001 and exactly the same drug cost US\$0.84 in India March 2001, 2.4 times cheaper. Importing this from India would have reduced the cost per patient significantly. TRIPS affirms that governments permitting parallel imports cannot be challenged at WTO, provided they do not discriminate on the grounds of the nationality of the patent holder, and treat imported products in a manner not less favourable than the like products of national origin.

These examples indicate that countries that use TRIPS flexibilities gain from price reductions, from opportunities for local industry to produce drugs and from a spread of possible suppliers. The benefits to public health flow from the wider spread of available resources and thus access to treatment, and the increased security of supply.

### ***So what are countries in ESA currently doing?***

The first step is to provide for these flexibilities in national laws. Some countries in ESA do provide for compulsory licensing and parallel importation in their national laws. Many do not. Those that do are shown in the table below.

Incorporating these flexibilities in national law is a bottom line for using them. The table shows those with LDC status whose have to 2016 for their national laws to be TRIPS compliant.

### ***Ensuring flexibilities are provided in national law***

A number of examples of options for legal provision for flexibilities already exist in ESA, as shown below.

Kenya's Industrial Property Act 2001 Sections 58(2), 72 to 78 and 80 provide for parallel importation, compulsory licensing, and government use powers.



Country	LDC – ie option for law to be TRIPS compliant by 2016	Law provides for compulsory license	Law provides for parallel importation
Angola	YES		
Botswana		YES	
D.R. Congo	YES	YES	
Kenya		YES	YES
Lesotho	YES		
Malawi	YES	YES	
Mauritius		n.a	n.a
Mozambique	YES	YES	
Namibia			
South Africa		YES	YES
Swaziland		YES	YES
Tanzania	YES	YES	YES
Uganda	YES	YES	YES
Zambia	YES	YES	
Zimbabwe		YES	YES



16

**Kenya Industrial Property Act 2001 Sec 80 (1) a and b**

*(1a) Upon exercising the powers conferred upon him under subsection (1), the Minister may, notwithstanding any of the measures set out in this section, authorize by written order the importation, manufacture or supply, or authorize the utilization of any molecule or substance whatsoever by any individual, corporation or society as named or described by any individual, corporation or society as named or described in the order without notice to the patent holder or any other notifiable party, and such order shall remain in force until revoked by the Minister in writing, after giving six months' prior notice of his intention of such revocation to the party named or described in the order.*

*(1b) An order made under the subsection (1a) shall not require the payment of compensation to the owner of the patent or license holder or any other party so interested by the Minister in writing, giving six months prior notice of intention of such revocation to the party named or described in the order.*

**South Africa 1997 Medicines Act Sec 15c**

*The minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may-*

*(a) notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act No. 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent;*

*(b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported:*

*(c) prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph (b).*

**Zimbabwe Patents Act Sec 34 on compulsory licensing**

*Notwithstanding anything in this Act, any department of the State or any person authorised in writing by the Minister may make, use or exercise any invention disclosed in any specification lodged at the Patent Office for the service of the State in accordance with this section*

**Sec 35**

*During any period of emergency the powers exercisable in relation to an invention by a department of the State or a person authorised by the Minister under section thirty four shall include power to make, use, exercise and vend the invention for any purpose which appears to the minister necessary or expedient:*

### ***Claiming our space: using TRIPS flexibilities***

Kenyan law Act permits parallel importation of patented medicines previously sold abroad and of generic medicine produced pursuant to a compulsory license as provided for in TRIPS Article 6 . (Musungu and Oh

2006). Kenya applies 'international exhaustion' which implies that the exclusive right of a patent holder to import a product is exhausted and ends when that product is launched on the market.

#### **Kenya Industrial property Act 2001 Sec 58(2)**

*The rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya.*

For example if a patent holder releases a product in South Africa, Lesotho can import that drug from a South African supplier without any interference from the patent holder since he has already obtained the benefit of the right in South Africa.

Countries that do not yet have provisions in their laws for compulsory licensing and parallel importation are encouraged to

- Include these provisions in their law
- Provide for deferred implementation and enforcement of pharmaceutical patents until 2016.
- Specify as many of the possible grounds for the issuing of compulsory licences in order to avoid ambiguity or uncertainty.
- Provide in competition law for the issuing of a compulsory license on the basis of unfair competition in line with Article 31(k) of TRIPS
- Provide explicit provisions for the waiver of negotiations with the patent holder in cases of compulsory licensing for government use or for national emergencies
- Provide explicit provisions for the waiver for remuneration paid to the patent holder in importing countries.
- Provide for time limitations for negotiation for voluntary licences in circumstances where compulsory licenses are *not* applied after which

time the requirement shall be deemed satisfied and a compulsory licence granted.

- Provide for international exhaustion of intellectual property rights
- Provide for swift procedures and clear guidance in law for royalty rates so that the granting of compulsory licenses is not held up in legal appeals and squabbles over royalties
- Make sure other health and pharmaceutical laws are amended if they affect the where application of these flexibilities.

### ***Ensuring flexibilities in practice***

Putting the flexibilities in law is necessary but not sufficient. Countries in ESA face many other challenges to implementing TRIPS flexibilities even when their laws provide for this. These challenges range from information and institutional weaknesses within countries, to international trade and political pressures not to use the flexibilities. Countries in ESA are too small to individually make the issuing of a compulsory license a good incentive for a generic producer to invest in developing generic versions of patented drugs, but have not yet developed a regional protocol for this. Some of these challenges are outlined below, together with possible responses to them.





Some of the blocks lie at national level.

# 16

Challenge	Response
Lack of information about the existing range of options for accessing cheaper generic medicines. Uncertainty about status of patents in importing and exporting countries of particular medicines.	Patents offices in countries to get information on patent status of medicines with support from WHO Essential Drygs programme and Regional patent organisations such as African Regional Intellectual Property Organization. Relevant government departments - patents office, health ministry and trade ministry - to ensure mechanisms for information exchange. For example the Kenya Industrial Property Institute works with the Ministry of industry and trade on issuing compulsory licences in Kenya.

Challenge	Response
Shortfalls in trade, patent and public health law and technical experience and expertise for domestic law amendments and to administer newly enacted flexibilities.	Strengthen working links between relations between government ministries, local industry, national research institutions and technical agencies to support skills pooling and knowledge exchange. Draw on regional, south-south and international capacities to support domestic reforms.

Blocks also exist in the bilateral pressures on Africa countries from wealthy countries.

Challenge	Response
Trade, diplomatic and political pressure from rich countries, through trade-related technical assistance and bilateral trade agreements, to interpret TRIPS flexibilities narrowly and deter countries from using them. This occurred in the US-SACU (Southern African Customs Union) Free Trade Agreement negotiations. Signing agreements with TRIPS-plus rules may undermine the regulatory flexibility needed to ensure access to affordable medicines and available in TRIPS.	TRIPS should be interpreted as a ceiling for intellectual property protections, not a platform for further protections, particularly in the pharmaceutical sector. ESA countries can collectively resist efforts to add TRIPS-plus measures in regional or bilateral trade agreements, and states should seek support from technical and civil society organisations and international partners for this. For example civil society expertise can be used, and civil society can raise awareness in civil society and parliaments of countries applying TRIPS plus pressures to raise concern over these pressures. Countries through regional committees of WHO and regional organisations can adopt formal positions rejecting such agreements that include TRIPS plus clauses, and seek visible support for this from global bodies including at UNAIDS, WHO and WTO.

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Many blocks exist within the wider global environment. Act-up Paris highlight a situation where five years after Doha 75% of ARVs in developing countries are still under monopoly, with no generics available in some countries (Act-up 2006).

New challenges exist: India, the largest producer of generic drugs in the world, was required in January 2005 to grant patent protection to new drugs and to drugs invented since 1995. Subsequent WTO provisions, known as the “August 30th decision”, provided that countries that do not have the capacity to manufacture generics themselves (as is the case in many ESA countries) are permitted to import from another country (such as India) if that country issues a compulsory license and if both parties inform the WTO of the nature and duration of the licence and the product quantities involved. This puts the burden on ESA countries to carry out the legal and institutional reforms to issue compulsory licenses and adds new rules to these transactions. ESA countries can continue to pressure internationally for simplified procedures for such exports, and explore other sources of cheaper generic drugs that are not covered by patents, such as from Brazil and Thailand.

In an environment of strong bilateral pressures, countries may be cautious to act due to concern over disputes under TRIPS and court action. For example, in 2000, 39 pharmaceutical companies, mainly US based, threatened to sue the South African Government for passing the *Medicines and Related Substance Control Amendment Act*, a law that made it possible for South Africa to utilise TRIPS flexibilities. While the legal

amendments to use these flexibilities are enabled by TRIPS, enacting and using them needs to be backed by wider political signals. In South Africa, public and civil society lobby combined with political action. These companies withdrew the case after then US President Bill Clinton issued an executive order stating that US could not support a policy hindering access to medicines by people living with AIDS in Africa.

Within countries these political signals come from building stronger state- parliament- civil society and media lobbies that understand and can defend the basis for exercising TRIPS flexibilities.

Across ESA, countries can use regional frameworks such as COMESA and SADC to share information, resources and expertise, to harmonise legislation, but also to collectively issue compulsory licenses for common public health problems. In Latin America, for example, ten countries joined efforts to get agreements from generic manufacturers and originators. If ESA countries use regional frameworks to collectively issue compulsory licenses for the same drug, this may also build a sufficient market to encourage generic producers to invest in generic versions of these drugs.

Internationally this calls for intensified pressure and visibility of political commitment to move Doha from intent to practice - to make clear at international platforms the rights of countries to implement TRIPS flexibilities; to reinforce capacities of countries to do so and to remove procedural and information blocks to the export and import of generic medicines.



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## FURTHER RESOURCES

For discussions of Intellectual Property and Health Care

Listserve: IP-health: <http://lists.essential.org/mailman/listinfo/ip-health>

For details on Free Trade Agreements, see: [www.bilaterals.org](http://www.bilaterals.org)

For further information on trade and health, see: [www.equinet africa.org](http://www.equinet africa.org)

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Technical edit: R Loewenson TARSC.

Design: Blue Apple Design.

Produced with support from SIDA Sweden

EQUINET is a network of professionals, civil society members, policy makers, state officials and others within east and southern Africa who have come together as an equity catalyst, to promote and realise shared values of equity and social justice in health.

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