



What next for east and southern Africa after the TRIPs Waiver agreement?

Technology transfer in the manufacture of essential health products (EHPs) remains one of the critical enablers of local production. Eastern and Southern African (ESA) countries, together with others beyond the region have over the past two years intensified global demand for constraints to access of key health technologies to be addressed while the COVID-19 pandemic still puts their populations at risk, including at the World Trade Organisation (WTO). The 12th WTO Ministerial Conference (MC12) held from 12-17 June 2022 in Geneva, concluded with the adoption of the so called “Geneva package” that includes a [waiver](#) of certain requirements under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) concerning the use of compulsory licences to produce COVID-19 vaccines. This brief unpacks the waiver and discusses some key options ESA countries may take following the adoption of the TRIPs waiver.

Background

The application for a waiver in 2020 at the WTO TRIPs Council, termed in this brief the ‘Waiver,’ was driven by the need to rapidly access affordable medical products to prevent, diagnose and treat people affected by COVID-19. The pandemic led to a rapid increase in global demand for medical products. Acute shortages were reported, constraining the ability of countries affected by shortages to effectively respond to the outbreak. India and South Africa, in their proposal for a waiver noted that “...shortages of these products has put the lives of health and other essential workers at risk and led to many avoidable deaths. It is also threatening to prolong the COVID-19 pandemic. The longer the current global crisis persists, the greater the socio-economic fallout, making it imperative and urgent to collaborate internationally to rapidly contain the outbreak.” The collaboration they were arguing for was for WTO members to come together and agree on the proposed waiver of constraints to access and distributed production of the key diagnostics and products needed, amongst other issues.

In the face of rising demand and shortages, many countries initiated domestic production of these essential health products (EHPs). EHPs include include medicines, vaccines, therapeutics, diagnostics and other health technologies/ equipment, such as ventilators and personal protective equipment (PPE). In some countries, production lines were switched to meet demands for EHPs, or existing medical products

modified to treat patients with COVID-19. East and Southern African (ESA) countries, along with others, identified rapid scale-up of manufacturing of EHPs in their region as crucial to ensure the timely availability and affordability of EHPs for all populations in need. However, as noted in the original proposal for a time limited waiver, “intellectual property rights [were] hindering ... timely provisioning of affordable medical products to the patients” (WTO, 2020). TRIPS Article 28.1 provides for example for inventors of processes or products to patent technology inventions and receive royalty payments for their intellectual property for a minimum of 20 years.

Some WTO members had urgently amended their domestic patent laws to expedite their issuing compulsory/government use licenses to manufacture these EHPs. Patents have been applied for or granted across production, development and delivery processes of these different EHPs. Patents on these products increased uncertainty and costs, delayed competition and kept prices high, particularly for low- and middle-income countries, hindering people’s access to them. Beyond patents, intellectual property rights issues presented a potential barrier to cheaper products entering the market, delaying or preventing people’s access to effective medical care.

The TRIPs Waiver agreed in June 2022

After prolonged negotiations, notwithstanding the urgency, the waiver adopted at the June 2022 WTO Ministerial Conference grants





eligible members the legal rights to “limit” the application of provisions of Article 28.1 of the TRIPs agreement, noted above, “by authorizing the use of the subject matter of a patent required for the production and supply of COVID-19 vaccines without the consent of the right holder to the extent necessary to address the COVID-19 pandemic” (WTO, 2022). A patent ‘subject matter’ included ingredients and processes necessary to manufacture COVID-19 vaccines.

In clarifying the use of the waiver, the WTO noted that an eligible member state may authorize the use of the subject matter of a patent without the right holder’s consent through any instrument available in the member state’s law or constitution, such as by using executive orders, emergency decrees, government use authorizations, and judicial or administrative orders. For example, when Zimbabwe declared AIDS a national disaster in the 1990s, a Presidential emergency powers executive order gave the local manufacturer, Varichem, a compulsory licence to manufacture generic anti-retroviral treatments, despite their still being under patent.

The gap between the proposed and agreed Waiver

The June 2022 TRIPs Waiver provides some temporary reprieve to low and middle income countries with no manufacturing capacity. It is, however, limited in many ways.

Firstly, the waiver only covers the production and supply of COVID 19 vaccines. It does not extend to other EHPs, such as therapeutics and diagnostics. For the latter, the decision states that “no later than six months from the date of this Decision, Members will decide on its extension to cover the production and supply of COVID-19 diagnostics and therapeutics.”

Secondly, the provisions of the June 2022 decision may only be applied for up to 5 years from June 2022, ie: up to July 2027. Whilst the WTO General Council has the opportunity to extend the period, there is no certainty of an extension, as it needs to be negotiated.

Thirdly, the decision only applies to “eligible” members. The classification of eligibility covers ‘developing countries’.

However, the decision goes further to urge eligible countries with existing capacities to not use the waiver. It says “Developing country Members with existing capacity to manufacture COVID-19 vaccines are encouraged to make a binding commitment not to avail themselves of this Decision.”

Fourthly, the June 2022 decision does not eliminate the obligation to pay royalties to the patent holder. Paragraph 2 (d) of the waiver states that “determination of adequate remuneration under Article 31(h) may take account of the humanitarian and not-for-profit purpose of specific vaccine distribution programs aimed at providing equitable access to COVID-19 vaccines...” .

The implications of the gap for ESA countries

The challenges ESA countries face with respect to accessibility and affordability of EHPs, including medicines and vaccines, goes beyond those used to manage COVID-19. The challenges relate to systemic issues that have blocked local production of EHPs that existed long before the pandemic. If the waiver was to be fully useful to ESA countries, and other low and middle income countries, it should have addressed the barriers to production and supply of EHPs beyond vaccines, such as therapeutics and diagnostics. Postponing negotiations on this for six months to December 2022 limited the opportunity for ESA countries to access technology and expertise to produce these other EHPs, delaying access to them by ESA populations.

The five year period given for operation of the waiver is not enough for countries that have no prior infrastructure for vaccine production and supply. Vaccine production is generally a long process that takes between 5-10 years for the process to develop, test and approve a vaccine for human use and to build the manufacturing capacities and processes to produce it. Evidence presented in 2021 by the African Union and the Developing Countries Vaccine Manufacturers Network on current sites of vaccine manufacture in Africa showed that there is limited ongoing research and development (R&D) activity by those manufacturers. Further the manufacturing process is complex: about 90% of vaccines produced by local companies have bioreactor-based platforms, requiring relatively complex engineering tasks.



The exceptional circumstances leading to COVID-19 vaccines being developed, tested and produced in under a year after the onset of the pandemic were, to a large extent, facilitated by the existence of prior R&D and existing infrastructure for such production in certain countries. The contribution of longer term R&D is signalled by current reports of a legal suit between two pharmaceutical companies for one having appropriating technology developed over 10 years by the other for vaccine production.

There are multiple established vaccine manufacturers in other parts of the Global South. Some have experience in South-South collaboration and knowledge transfer, that may facilitate African vaccine development and production. However, the decision ‘encouraging’ developing countries with existing capacity to not use the June 2022 waiver may limit such opportunities for south-south cooperation. This is the case, even though bilateral arrangements could support technology transfer without the need for this waiver.

A further limitation above on the waiver is the requirement to continue to pay royalties to the patent holder. While the June 2022 decision makes reference to the level of royalty payment taking into account the humanitarian, population health and not-for-profit purposes of the use of the vaccine in question, ambiguity on this leaves it open to negotiation with the patent holder and wide interpretation. In practice this may thus lead to unaffordable royalty fees preventing a developing country from using the waiver.

Given the above, the absence of a predictable and stable intellectual property regime will discourage and constrain ESA countries from investing in vaccine R&D and production capacities. Uncertainty undermines confidence in public or private investment for these capacities and has implications for sustaining investments over the longer term needed for the economies of scale for cost effective vaccine production and the return on investments.

Can ESA countries use the waiver?

ESA countries have a duty to protect public health. Health systems in ESA countries have been weakened over the years, including by macro-economic policies that have reduced social spending and a globalisation that has favoured transnational corporations. The June 2022 waiver, whilst it has limitations, can still be used by ESA countries to reclaim the policy space and rebuild the public infrastructure supporting the provision of EHPs for population health. For example, as noted earlier, ESA countries have already used executive orders, emergency decrees, government use authorizations, and judicial or administrative orders, particularly to manage HIV and AIDS, as shown in *Table 1*.

In addition to the above, in 2007 Rwanda took advantage of the WTO mechanism for compulsory licenses for countries with insufficient or no manufacturing capacity to use a compulsory license for importation of medicines for HIV and

Table 1: Compulsory licenses and government use orders issued by African countries

Country and date	Type of licence and generic name of medicine	Duration	Remuneration
Zimbabwe May 2002	Government declared emergency. Compulsory license to make/use/import seven first-line antiretroviral therapies, given to a local generic producer	Initially six months, then emergency extended until 31 December 2008	Not in compulsory licence
Mozambique April 2004	Compulsory license to a local generic producer Pharco for antiretroviral therapy	Until situation changes (triple combination was not being sold on the Mozambique market)	Royalty payment to patent owners to not exceed 2%.of total turnover at the end of each fiscal year
Zambia September 2004	Compulsory license to a local generic producer Pharco for a two types of triple combination fixed dose antiretroviral therapy	Until situation changes	Royalty payment to patent owners to not exceed ≤ 2.5% of total turnover at the end of each fiscal year

Sources: Gov of Zimbabwe 2002; Gov of Mozambique 2004; Gov of Zambia 2004.



AIDS. There were complications in applying this WTO mechanism leading to the medicines taking almost a year to arrive in Rwanda from Canada. This exposed the challenges in applying TRIPS flexibilities related to regulatory issues, including government procurement rules, and to practices, including the procedures for notifying the WTO.

Nevertheless ESA countries can draw on this earlier precedent in the use of executive orders and flexibilities. While this can be currently used to progress plans for local production of COVID-19 vaccines, ESA countries can put in place plans for production of other COVID-19 EHPs beyond vaccines, given the further negotiation on extension of the waiver to other EHPs.

What else can ESA countries do?

Given the challenges noted in this brief with the WTO waiver adopted in June 2022, ESA countries may consider the following steps moving forward.

ESA countries can widen information on and understanding of ways of using the TRIPs waiver through regional forums, such as those convened by the East African Community and the Southern African Development Community, involving stakeholders from government, private sector, civil society, and relevant UN technical agencies. These forums can promote understanding of the provisions of the waiver, together with its implications and how to use it to plan for and enable local production of EHPs in the region. Such forums can advance strategies for pooling and making more effective use of regional resources and roles to support national awareness; mapping and building local institutional capacities for implementation; and getting a buy in for executive orders/government authorisation to start the setting up of local production processes.

ESA countries can use the provisions of the waiver to pool resources to establish regional vaccine manufacturing plants and associated R&D. A regional approach is critical. Having larger regional markets is essential for developing and sustaining a manufacturing sector that can produce EHPs to respond to currently unmet needs of people in the region. Pooling resources and capacities also shares risks and minimises the potential economic impact.

On the obligation to pay royalties when using the waiver, there are provisions in the TRIPs agreement in Article 44.2, which states that member countries may limit the remedies available against such use to payment of remuneration. ESA countries may use this option in the application of the waiver by using their own laws and legal systems to limit compensation and avoid high royalty payments.

Invoking Article 73 of the TRIPs Agreement

Beyond the TRIPs waiver, ESA countries may invoke the provisions of Article 73 of the TRIPs agreement based on “Security Exceptions”. Failure to access EHPs for the prevention and treatment of major disease burdens in the region may be legal basis for an ESA country to use this article in the TRIPs agreement to override patents as an “action which it considers necessary for the protection of its essential security interests...taken in time of...other emergency in international relations”. This will send a clear message internationally that access to EHPs should be made a priority particularly for low and middle income countries in ESA and globally.

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