TAC and SECTION27 urge Parliament not to ratify WTO decision on Paragraph 6 of the Doha Declaration on TRIPS and Public Health

Organisations call on the DTI to prepare an amendment to the Patents Act to increase access to essential medicines

Cabinet recently resolved to ask Parliament to take the necessary steps to enable South Africa to ratify a decision taken by the World Trade Organization (WTO) on intellectual property (IP) and access to medicines. At its meeting held on 16 March 2011, Cabinet decided to request Parliament to –

- ratify the WTO decision on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health; and
- deposit "an instrument of ratification ... with the WTO.

As organisations that are committed to ensuring universal access to essential medicines, as an integral part of the constitutional right to have access to health care services, TAC and SECTION27 call on Parliament not to ratify the decision. In this press statement we explain why we make this call.

Background to the Cabinet decision

Before explaining our call, let's consider the following questions:

- What is the TRIPS Agreement?
- That is paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health ("the Doha Declaration")?
- What is the WTO decision on the implementation of paragraph 6 of the Doha Declaration ("the December 6" decision")?

What is the TRIPS Agreement?

The Agreement on Trade-related Aspects of Intellectual Property Rights ("the TRIPS Agreement") is one of a number of documents that were adopted as part of new international trade rules that came into force with the establishment of the WTO in 1995. Amongst other things, the TRIPS Agreement requires all WTO members to align their IP laws – including legislation dealing with patents, copyright and trademarks – with minimum levels of protection. In return, WTO members were promised the benefits of a regulated global trading regime, such as increased market access for developing countries.

Before the WTO was established, countries were – in the main – free to determine the nature and extent of IP protection offered. In the field of medicines, for example, some countries offered no patent protection whatsoever. Others, including India, only recognised process – but not product – patents. The evidence shows that the Patents Act of 1970 was central to the development of a world-class, competitive generic medicines industry in India. To this day, India remains the supplier of much of the developing world's medicine needs, as well as active pharmaceutical ingredients imported by generic manufacturers worldwide.

What is paragraph 6 of the Doha Declaration?

The coming into force of the TRIPS Agreement changed all of this. All WTO members became obliged to amend their IP laws to give effect to their new obligations. But the language of the agreement came to mean different things to different people: developed country governments read its terms broadly; their developing country counterparts sought to read its terms narrowly. In the field of patents, the global north sought to impose high levels of protection; the global south sought to retain as much flexibility as the language of the text could reasonably bear. Predictably, these conflicting positions lead to a showdown – at the WTO's meeting in Doha in 2001.

In the months leading up to the Doha meeting, AIDS activists across the world drew increasing attention to the negative impact of high levels of patent protection on access to essential medicines. They argued convincingly that the developed world's interpretation of the TRIPS Agreement, if imposed on all WTO members, would undermine efforts to address urgent public health needs. South Africa's united stand against the drug industry, which saw the Treatment Action Campaign and the state on the same side in a court challenge to medicines legislation, paved the way for a groundbreaking agreement on patents and public health in Doha.

Amongst other things, the Doha Declaration notes that "the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health." It recognises that "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." Importantly, it also recognises that each WTO member "has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted." Compulsory licences authorise the early market entry of generic competition.

In respect of compulsory licensing, paragraph 6 of the Doha Declaration provides as follows:

We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

What is the December 6th decision?

The December 2002 deadline was never met. On 30 August 2003, the WTO adopted an interim solution to the problem ("the August 30th agreement"). This took the form of a waiver from the ordinary rules. The December 6th decision, which was adopted at a WTO meeting in Hong Kong on 6 December 2005, seeks to amend the TRIPS Agreement to give final effect to the interim solution adopted on 30 August 2003. For all practical purposes, there is no

difference in substance between the August 30th agreement and the December 6th decision; and the former remains in force for as long as the latter takes to be approved.

The proposed amendment to the TRIPS Agreement only comes into force once two-thirds of WTO members have deposited instruments of ratification. The new deadline for ratifications is 31 December 2011. Thus far, only 34 members of the WTO – some 22% – have ratified the decision, with Bangladesh (on 15 March 2011) becoming the most recent addition to the list. Interestingly, Bangladesh – as a least-developed country – has no obligations under TRIPS to offer any protection to pharmaceutical patents until 1 January 2016.

What is the problem with ratifying the December 6th decision?

While we welcome Cabinet's apparent commitment to increasing access to medicines, we have a number of concerns:

- The so-called "Paragraph 6 system" which is set out in the August 30th agreement and the December 6th decision is deeply flawed, arguably incapable of properly solving the problem identified in paragraph 6 itself;
- It is unclear what benefits if any arise from formal ratification of the proposed amendment to the TRIPS Agreement, given that
 - The December 6th decision offers nothing more than the August 30th agreement; and
 - The August 30th agreement will remain in place for as long as it takes to implement an amendment to the TRIPS Agreement.

Ratification is unnecessary and possibly harmful. Formal adoption of the proposed amendment will effectively cement in the flawed Paragraph 6 system, making any further amendment highly unlikely. In its 16-year existence, the WTO has yet to amend the TRIPS Agreement. The historic significance of a first amendment does not shift the balance in favour of the ratification of the December 6th decision. If anything, it should be reserved for something more deserving. In addition, Cabinet has remained silent on domestic implementation of the Paragraph 6 system, a matter not yet addressed by the Department of Trade and Industry ("the dti").

What should government be doing instead?

Notwithstanding our concerns about the Paragraph 6 system, the solution it offers – whilst flawed – is still better than what was available before 30 August 2003. In addition, the Doha Declaration provides significant guidance to WTO members on what other legislative steps may be taken to ensure access to medicines. As we have argued before, the state is constitutionally obliged to ensure that our law takes full advantage of the flexibilities and public health safeguards in the TRIPS Agreement. We therefore call on the dti to take urgent steps to prepare an amendment to the Patents Act 57 of 1978 that –

- Incorporates the Paragraph 6 system into South African law, covering both the importation and exportation of generic medicines; and
- Takes full advantage of all other TRIPS flexibilities and public health safeguards, including but not limited to those addressed in the Doha Declaration of 21 November 2001.

For more information, contact Jonathan Berger on berger@section27.org.za or 083 419 5779