

# **South Africa's Acceptance of the Protocol Amending the TRIPS Agreement**

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**DDG: ITED**

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Department:  
Trade and Industry  
REPUBLIC OF SOUTH AFRICA

# BACKGROUND

- The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) is an international agreement administered by the WTO.
- TRIPS is the most important and comprehensive agreement dealing with IP rights.
- TRIPS agreement introduced intellectual property law into the international trading system for the first time.
- South Africa is member of TRIPS because of the Single Undertaking Rule in the WTO.



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# KEY OBJECTIVES OF THE FLEXIBILITY

- Addresses the impact of the TRIPS Agreement on access to drugs, local manufacturing capacity and the development of new drugs.
- Africa Group proposal to ensure that the TRIPS Agreement does not undermine the legitimate right of WTO Members to formulate their own public health policies.
- Emphasis on access to medicines and R&D for prevention and treatment of diseases predominantly affecting people in developing and LDCs.



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# KEY OBJECTIVES OF THE FLEXIBILITY

- Initial resistance by developed countries (US, Japan, Switzerland, Australia and Canada) stressing the importance of intellectual property protection for R&D and that IP contributes to public health.
- Despite initial resistance Doha Declaration was adopted by consensus.
- Recognizes that the high prices of medicines caused by patent protection are part of the grave problems that afflict developing countries and LDCs and is a "concern" that needs to be addressed.



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# 2001 DECLARATION

- November 2001 Doha Meeting, developing countries demanded a reassessment of TRIPS
- Purpose:
  - (1) address high prices of medicines charged by developed countries' pharmaceutical companies.
  - (2) ensure that developing countries could either produce affordable generic drugs (compulsory licensing) or buy them from elsewhere (parallel imports) at reasonable prices, especially in a national health emergency situation.



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# DECLARATION CONTENT

- Recognition of the gravity of the public health problems...,especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics
- Recognition that intellectual property protection is important for the development of new medicines and recognise concerns about its effects on prices
- Agreement that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health.
- Reaffirmation that TRIPS can and should be interpreted and implemented in a manner supportive of Members' right to protect public health and, in particular, to promote access to medicines for all.



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# DECLARATION CONTENT cont..

- Clarifies that “public health crises” can represent “a national emergency or other circumstances of extreme urgency”, and that an “emergency” may be either a short-term problem, or a long-lasting situation.
- Places the burden on a complaining Member to prove that an emergency or urgency does *not* exist.
- It is implicit within the Declaration that differentiation in patent rules may be necessary to protect public health - recognition that public health-related patents may be treated differently from other patents.
- Makes it easier for developing countries to adopt measures necessary to ensure access to health care without the fear of being dragged into a legal battle.



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# DECLARATION CONTENT cont..

- Gives Members more flexibility:
  - in utilising parallel import mechanism and in the granting of compulsory licences.
  - to determine through their own national legislations the grounds upon which such licences are to be granted,
  - to decide what constitutes a national public health emergency.
  - to cover any “public health problem” – not limited to specific diseases
- Though access to medicines was preoccupation -covers any product, method or technology for health care. Applies to pharmaceutical products, processes and uses, surgical, therapeutic and diagnostic methods, diagnostic kits as well as medical equipment.





# DECEMBER 2005 DECISION

- 2003 decision which gives effect to the 2001 Declaration and calls for the amendment of the TRIPS Agreement
- 2005 Decision finds its basis from paragraph 11 of August 2003 Decision which instructed TRIPS Council to initiate work on amendment by end 2003 with a view to its adoption within 6 months
- Adopts Protocol Amending the TRIPS Agreement and submits it to Members for acceptance
- Protocol open for acceptance until 1/12/2007
- Period extended a number of times due to low number of instruments of acceptance deposited with the WTO

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# DECEMBER 2005 DECISION

## cont...

- Latest deadline expires 31/12/2015 but will be extended at MC 10
- Takes effect upon acceptance by two thirds of membership



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# CONSTITUTION

- Section 27 (1): Everyone has the right to have access to (a) health care services, including reproductive health care;
- 27 (2): The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.
- Section 27 therefore places a positive obligation on the State to accept the 2005 Protocol
- Acceptance by SA will contribute to the current number of acceptances in order to reach the two thirds majority threshold for the Protocol to come into force (Article X iii)



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# CONSTITUTION cont....

- WTO Agreement falls under section 231(2)
- Section 231(2): An international agreement binds the Republic only after it has been approved by resolution in both the National Assembly and the National Council of Provinces, unless it is an agreement referred to in subsection (3).
- Any amendment to an agreement referred to above will also have to follow the same process
- Legal opinions from DIRCO and DoJ confirm this position
- Instrument of Acceptance to be deposited with the WTO to confirm our acceptance of the amendment

# BENEFITS

- Government will be able to fully implement flexibilities provided by such amendments
- Full and effective implementation of flexibilities will enable Government to provide access to cheaper and better health care
- Work on the IP policy review already underway to come up with proposals on how to effectively take advantage and implement these flexibilities



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