

Informations on the TRIPS Agreement

- Negotiated under the auspices of the World Trade Organization (WTO) in 1994
- Entered into force in 1995
- It is the only international agreement on intellectual property rights that is part of the multilateral trading system
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What members have to do

- Establish a system of intellectual property rights
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TRIPS

Trade-Related Aspects of Intellectual Property Rights

It is the only international agreement on intellectual property rights that is part of the multilateral trading system.

Parties to the TRIPS Agreement

As of 2023, there are 124 parties to the TRIPS Agreement.

TRIPS Agreement

The TRIPS Agreement is a multilateral treaty that sets out the minimum standards for intellectual property protection that all WTO members must adhere to.

- ### Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)
- 2001 Doha Declaration on the TRIPS Agreement and Public Health
 - 2003 Decision on waiver for new flexibility on access to medicines
 - 2005 Protocol amending the TRIPS Agreement



Working Group on the Interaction between Trade and Competition Policy

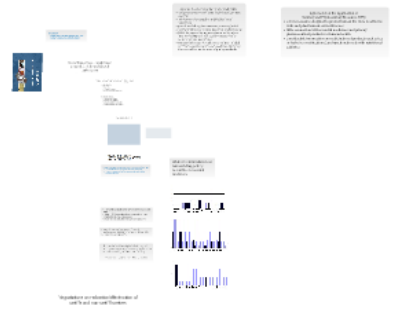
- currently inactive
- from 1997-2003 extensive material on competition and intellectual property
- reports of national experiences

- Canada
- European Union
- Hong Kong, China
- Iceland
- Israel
- Japan
- Korea
- Liechtenstein
- Aruba
- Norway
- Singapore
- Switzerland
- Chinese Taipei
- United States

- ### Agreement on Government Procurement
- principles of openness, transparency and non-discrimination when public money is spent on goods and services
 - cost benefits of open and competitive tendering for public expenditure
 - only applies to scheduled entities
 - many parties have committed cover public health authorities
 - pharmaceutical products are covered unless otherwise specified (only one party excludes a limited list of some medical products, but not medicines as such)

TRIPS Agreement

The TRIPS Agreement is a multilateral treaty that sets out the minimum standards for intellectual property protection that all WTO members must adhere to.



Unpacking access to medicines: a snapshot of the multilateral trade system



'trade related' factors a

at the border:

- tariff -

rational medicines selection

Access?



fair and sustainable
for health care sy

rdable prices
governments,
care providers

two themes:

- **what data can 'the system' offer us?**
- **what's going on out in the field?**

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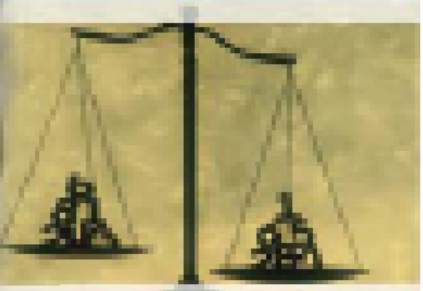
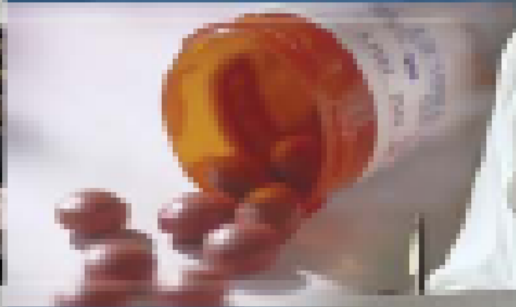


fair and sustainable
for health care sy

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governments,
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WTO AGREEMENTS & PUBLIC HEALTH

A joint study by the WHO and the WTO Secretariat



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fair and sustainable global financial

rational medicines selection

Access?



health and
systems



AC

fair and sustainable financing
for health care systems

rational m

reliable health and supply systems

es selection

SS?



affordable prices
(for governments,
health care providers
and consumers)

rel
ins

Access?



fair and sustainable global financial

to mechanics.

the multilateral system

'trade related' factors affecting prices:

at the border:

- tariffs
- import licences
- quantitative restrictions

behind the border:

Other related factors affecting prices:

at the border:

- tariffs
- import licences
- quantitative restrictions

behind the border:

- standards/regulation
- procurement policies
- pro-competition safeguards
- intellectual property settings

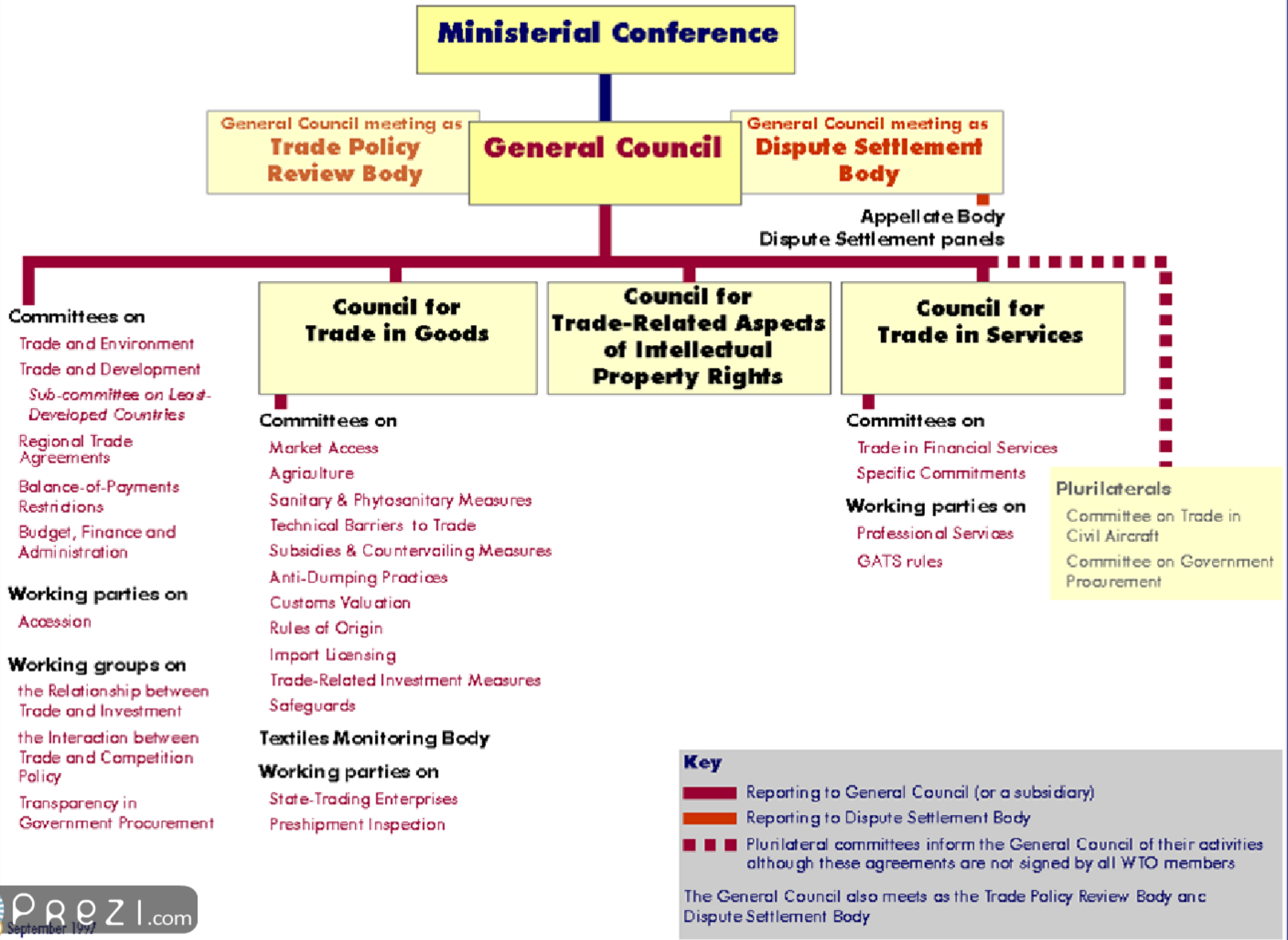
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WTO structure

All WTO members may participate in all councils, committees, etc, except Appellate Body, Dispute Settlement panels
 Textiles Monitoring Body, and plurilateral committees



A glance at tariffs



- Reports ▶
- Queries ▶
- Product Groups
- Download Data
- Printable View
- Help
- About TAO

Currently no query criteria are set.

Applied Duties and Trade (IDB)

Tariff Line Duties

Detailed information on duties by t

Tariff Averages

Simple and trade-weighted tariff a

Principal Suppliers

Imports from all suppliers ranked b

Duties Comparison

Comparison of two duty regimes.

Duties faced in export market

Summary and detailed views of dut

Bound Duties and Commitment

Tariff Concessions

Detailed information on tariff bindin

Total AMS Reduction Commit

The Total Aggregate Measure of S

Select Saved Query or Specify New Selection Criteria

Applied Duties and Trade (IDB) Bound Duties (CTS)

Market and Product Selection Saved Query

Please specify a market by selecting a country and a year.

Reporting country	Year	Imports	Nomenclature
<input type="radio"/> Albania			
<input type="radio"/> Angola			
<input type="radio"/> Antigua and Barbuda			
<input type="radio"/> Argentina			
<input type="radio"/> Armenia			
<input type="radio"/> Australia			
<input type="radio"/> Bahamas			
<input type="radio"/> Bahrain			

Products

Products matching search criteria

30 - PHARMACEUTICAL PRODUCTS

3003 - Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms or packings for retail sale.

3004 - Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale.

300410 - - Containing penicillins or derivatives thereof, with a penicillanic acid structure, or streptomycins or their derivatives

300420 - - Containing other antibiotics

Code	Description
------	-------------

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 - 300420 - - Containing other antibiotics
 - 300430 - - Containing hormones or other products of heading 29.37 but not containing

1. Very high access: above 95% of the population
2. Medium to high access: between 81% and 95% of the population
3. Low to medium access: between 50% and 79% of the population
4. Very low access: less than 50% of the population

5 WTO Members in categories 3 and 4 surveyed (of 8)

- **Low tariff rates on medicines ready for retail sale**
- **Lower on averages than for medicines broadly defi**

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75 WTO Members in categories 3 and 4 surveyed (of 84 in all):

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WTO Member	Average tariff rate HS3004	Average tariff rate All medicines
<u>Low to medium access</u> Between 50% and 79% of the population has access to essential medicines	2.32%	3.91%

WHO recommendation on
national drug policy:
no tariffs on essential
medicines

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- LDCs tend to import medicines (HS3004) free of any duty.
- Many LDCs have reduced or eliminated tariffs on imported medicines in past years.
- Several maintain higher average rates, up to 14%

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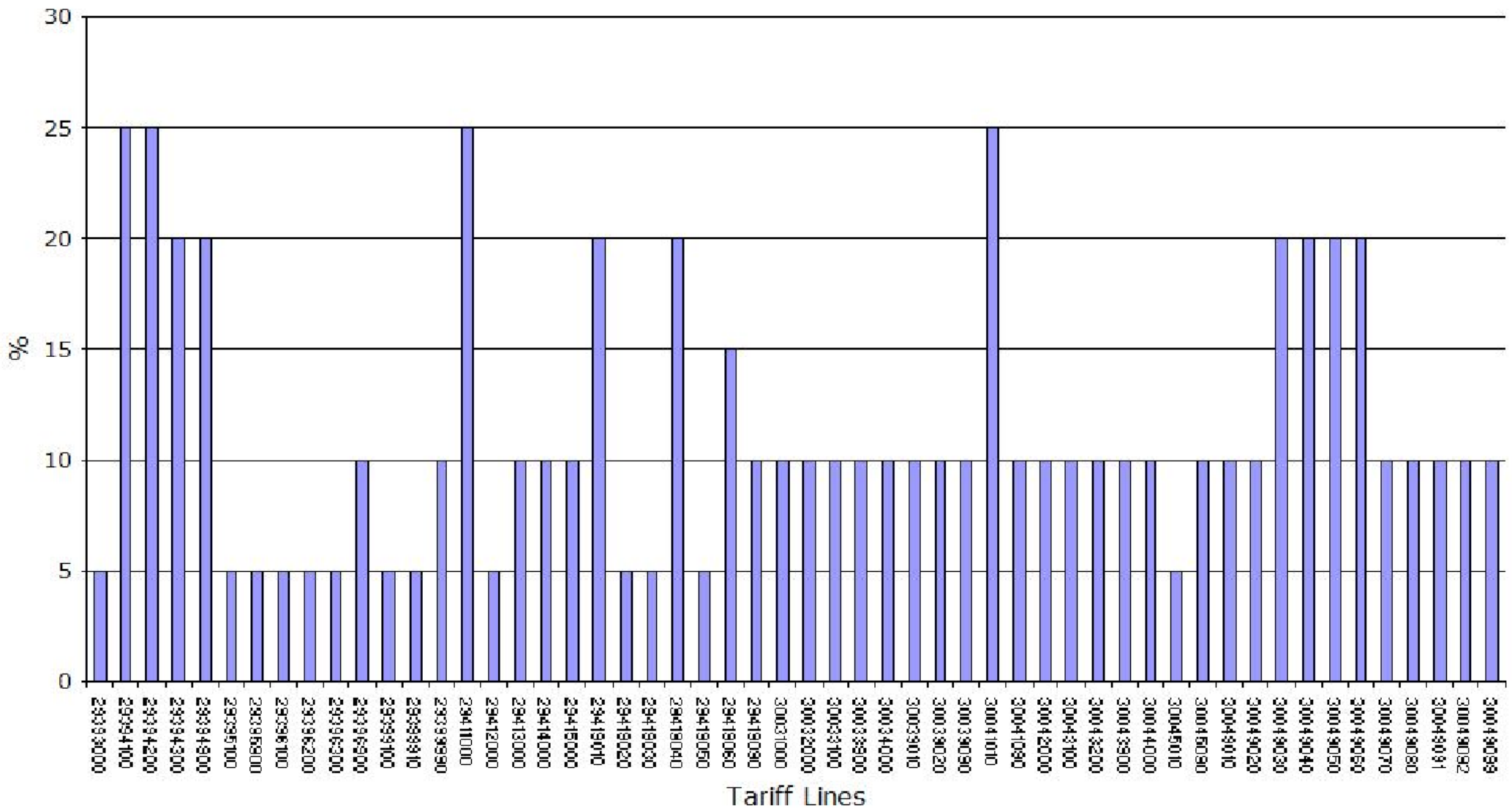
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But low sectoral averages conceal frequent tariff peaks, especially in developing countries with a domestic pharmaceutical industry.

- some tariff peaks from 14% up to 35%



Negotiations on reduction/elimination of tariffs and non-tariff barriers

1) Pharma sectoral initiative:

- negotiated during the Uruguay Round, full liberalisation of over 6,500 pharmaceutical products and inputs covering an estimated 79% of global trade of these products.
- 11 WTO Members have liberalised their pharmaceutical sector under that initiative (or as part of accession commitments): Albania, Armenia,, Canada, EU-27, Japan, Kyrgyz Republic, Macao China, Moldova, Norway, Oman, Switzerland and the United States.
- committed to regular review of coverage for additional pharmaceutical products for tariff elimination. Now entering 3rd review.

2) NAMA Tariff reduction modalities:

- could result in a significant drop in pharmaceutical tariffs.
- developed countries already bound most tariffs in this sector at zero, few remaining peaks would be reduced
- Major developing country markets would also have to reduce pharmaceutical tariffs assuming that they do not choose to apply flexibilities on these tariff lines.

3) NAMA Sectoral initiative for Open Access to Enhanced Healthcare:

- initiative for tariff elimination and reduction in pharmaceutical and medical products proposed by Singapore; Switzerland; Chinese Taipei; and the United States (2006 and 2007).
- Reduce cost of healthcare through the substantial elimination or reduction of tariffs and specific NTBs affecting the trade in medicines, medical devices and "innovative medical technology products".
- Built around the critical mass concept to include the key consumers and producers of these products.

Other related factors affecting prices:

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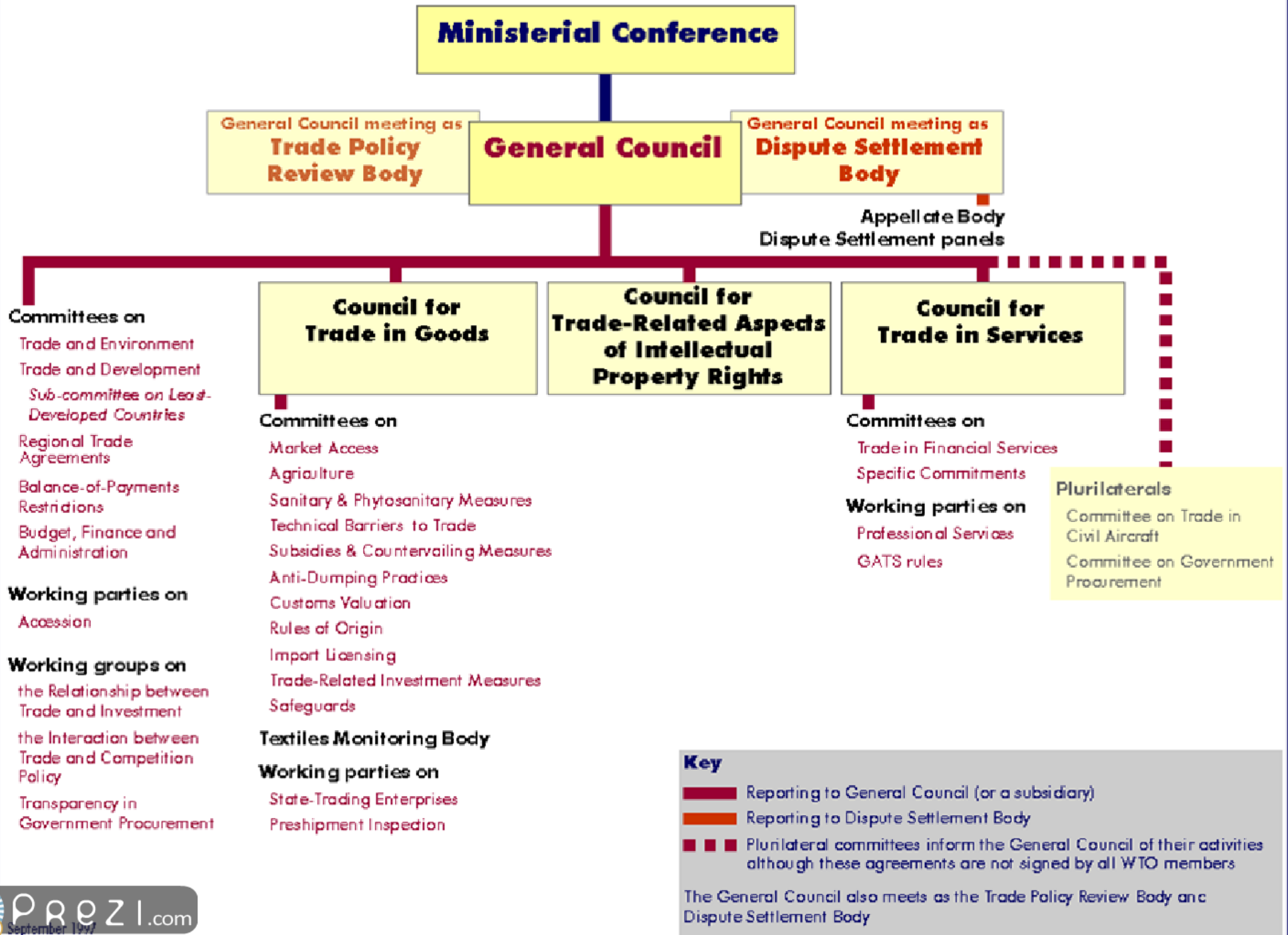
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Agreement on Technical Barriers to Trade (TBT)

- recognizes protection of human health as a legitimate objective
- notification of proposed or modified technical regulations
- 46% of notified regulations aim at protecting health
- relatively few concern pharmaceutical products per se
- TBT Information Management System: 16 Members have notified 115 technical regulations specifically concerning pharmaceuticals
- Discussions on specific trade concerns have included certification and recognition of Good Manufacturing Practice and the maintenance of quality standards

Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)

- covers measures designed to protect human life from food borne risks and plant/animal carried diseases
- little connection with essential medicines and primary pharmaceutical products for human health
- considerable information on medicinal food products such as tea or herbs (177 notifications) and functional foods with nutritional additives

Trade in health services General Agreement on Trade in Services (GATS)

- high flexibility in defining obligations undertaken in a given service sector, whether or not to open market to foreign suppliers at all, scope and conditions; whether to bind such opening in GATS specific commitments.
- maintain the ability to regulate service quality and accommodate other domestic policy concerns.
- emphasizes the need for government regulations to protect the interests of its citizens.

- impact of GATS on trade in health services remains insignificant
- low level of commitments in this sector
- mostly only bind existing levels of market access.

- GATS commitments in health services not an end in itself, one consideration in health policy-making.
- If appropriate regulatory environment is in place, possibility of foreign investment and know-how, wider choice of available services, increase transparency and predictability.
- in some cases, private health facilities are subject to "universal service" obligations with a view to improving access of the poor.
- Assessing risks and opportunities of undertaking GATS commitments requires the involvement of all stakeholders concerned.

principles of openness, transparency and non-discrimination when public money is spent on goods and services

cost benefits of open and competitive tendering for public expenditure only applies to scheduled entities

many parties have committed cover public health authorities

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limited list of some medical products, but

- **Canada**
- **European Union**
- **Hong Kong, China**
- **Iceland**
- **Israel**
- **Japan**
- **Korea**
- **Liechtenstein**
- **Aruba**
- **Norway**
- **Singapore**
- **Switzerland**
- **Chinese Taipei**
- **United States**

Agreement on

- principles of open non-discrimination
- spent on goods and services
- cost benefits of cost tendering for public procurement
- only applies to services
- many parties have health authorities
- pharmaceutical products otherwise specified a limited list of services not medicines as

Working Group on the Interaction between Trade and Competition Policy

- currently inactive
- from 1997-2003 extensive material on competition and intellectual property
- reports of national experiences

WORLD TRADE ORGANIZATION

WT/WGTCP/W/128/Rev.3
27 November 2003

(03-6302)

**Working Group on the Interaction
between Trade and Competition Policy**

OVERVIEW OF MEMBERS' NATIONAL COMPETITION LEGISLATION



WORLD TRADE



ORGANIZATION

WT/WGTCP/W/147
11 September 2000

OVERVIEW OF MEMBERS' NATIONAL COMPETITION LEGISLATION



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11 September 2000

(00-3499)

Working Group on the Interaction
between Trade and Competition Policy

Original: English

COMMUNICATION FROM JAPAN

IPR/Competition Policy and Development

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Article 7

Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

PART V

DISPUTE PREVENTION AND SETTLEMENT

Article 63

Transparency

1. Laws and regulations, and final judicial decisions and administrative rulings of general application, made effective by a Member pertaining to the subject matter of this Agreement (the availability, scope, acquisition, enforcement and prevention of the abuse of intellectual property rights) shall be published, or where such publication is not practicable made publicly available, in a national language, in such a manner as to enable governments and right holders to become acquainted with them. Agreements concerning the subject matter of this Agreement which are in force between the government or a governmental agency of a Member and the government or a governmental agency of another Member shall also be published.

2. Members shall notify the laws and regulations referred to in paragraph 1 to the Council for TRIPS in order to assist that Council in its review of the operation of this Agreement. The Council shall attempt to minimize the burden on Members in carrying out this obligation and may decide to waive the obligation to notify such laws and regulations directly to the Council if consultations with WIPO on the establishment of a common register containing these laws and regulations are successful.

INTELLECTUAL PROPERTY: INFORMATION

Members' transparency toolkit

Members share information on their intellectual property laws, regulations and practices through notifications submitted to the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS). This page contains links to procedures for sharing information, and other aids for members' transparency work on the subject.

What members have notified [back to top](#)

Search Documents Online

These links open a new window: allow a moment for the results to appear.

> [help](#) with downloading these documents

- **Procedures for the notification of national laws and regulations under article 63.2** (Document code IP/C/2) > [search](#)
- **Checklist of issues on enforcement under article 63.2** (Document code IP/C/5) [search](#)
- **Format for listing of other laws and regulations to be notified under article 63.2** (Document code IP/C/W/8/*) > [search](#)
- **Notifications of laws and regulations relating to articles 3, 4 and 5** (Document code IP/C/9) > [search](#)
- **Notifications of laws and regulations under article 63.2** (Document code IP/N/1/*)
 > [search](#)
- **Notifications for copyright and related rights under article 63.2** (Document code IP/N/1/-/C/*)
 > [search](#)

Information on policy and legislative choices on protection of clinical trial data

- Notifications by 120 WTO Members of legislation/ measure dealing with, covering directly or indirectly the protection of pharmaceuticals or other test data.
 - Remainder mostly comprise LDCs, not yet obliged to implement or notify laws in this field
- 59 notify specific legislation on pharmaceutical test data
 - 28 of them also have other legislation/ measures covering protection of test data, e.g. unfair competition legislation, administrative practices to protection of trade secrets in general
- 61 notify more general protection referring to confidential information in general, some adopting TRIPS 39.3 text directly
- Regional Trade Agreement database – means of monitoring policies on data protection agreed in other fora.



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