

SCP 27 sharing session:
availability of generic medicines
in developing countries & LDCs





**access to
generic medicines
under the
TRIPS Agreement**



Doha 7:
LDCs

Doha 6:
compulsory
licences for
export

**WORLD TRADE
ORGANIZATION**

WT/MIN(01)/DEC/2
20 November 2001

(01-5860)

MINISTERIAL CONFERENCE
Fourth Session
Doha, 9 - 14 November 2001

DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Adopted on 14 November 2001



1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.
2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.
4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm 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.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

- In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
- Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
- Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
- The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.



WORLD TRADE
ORGANIZATION

IP/C/73

6 November 2015

(15-5882)

Page: 1/1

**Council for Trade-Related Aspects of
Intellectual Property Rights**

**EXTENSION OF THE TRANSITION PERIOD UNDER ARTICLE 66.1 OF THE TRIPS
AGREEMENT FOR LEAST DEVELOPED COUNTRY MEMBERS FOR CERTAIN OBLIGATIONS
WITH RESPECT TO PHARMACEUTICAL PRODUCTS**

DECISION OF THE COUNCIL FOR TRIPS OF 6 NOVEMBER 2015

Ambassador Shameem Ahsan of Bangladesh, coordinator of the LDC group in the WTO, described the decision as “historic,” adding that it “will assure the LDCs the necessary legal certainty to procure or to produce generic medicines for those who need it most but do not have any access.”

This step, responding to a request tabled by LDC members of the WTO ([IP/C/W/605](#)), comes just a month after the UN General Assembly adopted the SDGs as a framework for global action up to 2030.

SDG Goal 3 on ensuring healthy lives and promoting well-being for all at all ages includes the target of providing “access to affordable essential medicines and vaccines”, and in that context recalls the affirmation in the Doha Declaration on the right of developing countries to use to the full the provisions in the TRIPS Agreement regarding flexibilities to protect public health, and, in particular, provide access to medicines for all.



**SUSTAINABLE
DEVELOPMENT
GOALS**

3 GOOD HEALTH AND WELL-BEING



3.B Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all



DG Azevêdo: TRIPS amendment shows that “WTO can negotiate solutions for real problems”



TRIPS amendment is “concrete response” to concerns about public health, says Modest Mero



WHO welcomes additional pathway for access to medicines: Margaret Chan



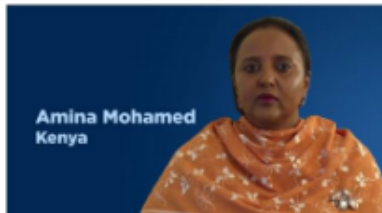
Time to develop national legislation to use new provisions: Nigeria’s Buba



Use new rules in health policy initiative to reap the benefits: Pascal Lamy



Amendment is important because problems have not gone away: Zimbabwe’s Maonera



“African countries played a major role” in TRIPS amendment: Amina Mohamed



TRIPS amendment a “momentous occasion”, says Botswana’s Palai



Supply and prices of medicines should gauge impact of TRIPS reform, says Pérez Motta

[home](#) > [wto news](#) > [2017 news](#) > [news item](#)



WTO: 2017 NEWS ITEMS

23 January 2017

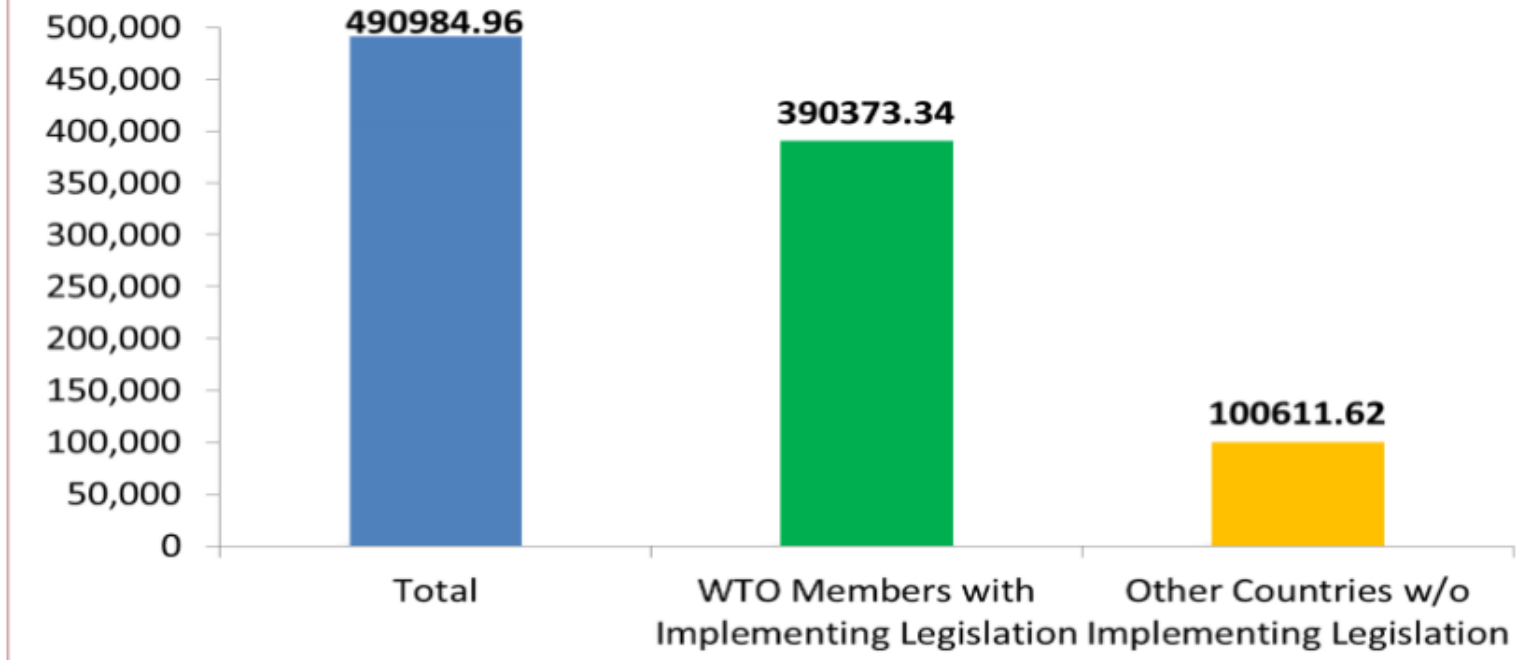
TRIPS

WTO IP rules amended to ease poor countries' access to affordable medicines

An amendment to the agreement on intellectual property entered into force today (23 January) securing for developing countries a legal pathway to access affordable medicines under WTO rules.

The amendment empowers importing developing countries and LDCs facing public health problems and lacking the capacity to produce drugs generically to seek such medicines from third country producers under compulsory licensing arrangements.

Worldwide Pharmaceutical Exports in 2013 for 149 Countries (in US\$MN)



Workshop facilitates understanding the complementarity of trade and health disciplines

Thirty-four government officials from 26 developing country members and three acceding governments attended the thirteenth edition of the Workshop on Trade and Public Health, in Geneva, from 6 to 10 November 2017.



Wednesday, 8 November 2017

Venue: WTO, Room E

Making Effective Use of Special Compulsory Licences for Export: A Procurement Tool for Medicines

09h00 – 09h15 Introduction to the Paragraph 6 System

Speaker: Mr Antony TAUBMAN, WTO

I. Taking Stock

09h15 – 09h30 Overview and Context

- Why was a new TRIPS flexibility adopted?
- What needs does it address?
- When is it intended to be used?

Speaker: Ms Jayashree WATAL, WTO

09h30 – 10h15 Putting the System to Work: Key Practical Steps

- Identification and notification of pharmaceutical needs
- Identification of supply sources
- Compulsory licence procedures

III. Looking at the Way Forward

10h15 – 12h30 Roundtable Discussion

Moderator: Mr Antony TAUBMAN, WTO

Panelists:
Mr Patrick GETHENDU
The Global Fund to Fight AIDS, Tuberculosis and Malaria
Ms Roberta VARGAS DE MORAES
Ministry of Health, Brazil
Mrs Cynthia DAPAH
Food and Drugs Industry, Ghana
Ms Amne Nasser Issa MOHAMED
Zanzibar Food, Drugs and Cosmetics Board - Tanzania
Ms Olena CHUMAKOVA
Ministry of Economic Development and Trade - Ukraine



TALLER REGIONAL SOBRE COMERCIO Y SALUD PÚBLICA

con énfasis en Licencias Especiales Obligatorias
para la Exportación de Medicamentos

con el apoyo de:

Organización Mundial para la Propiedad Intelectual (OMPI)
Organización Panamericana de la Salud (OPS) / Organización Mundial de la Salud (OMS)

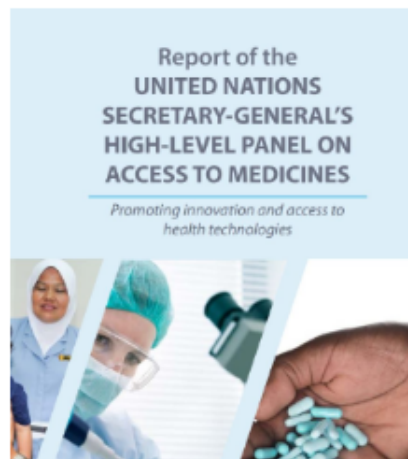
rlish).pdf	
Open with	
Tema V	USO EFECTIVO DE LAS LICENCIAS OBLIGATORIAS ESPECIALES PARA LA EXPORTACIÓN: UNA HERRAMIENTA PARA LA ADQUISICIÓN DE MEDICAMENTOS
	1. BALANCE
9:00 a 9:30	Visión general y contexto <ul style="list-style-type: none">- ¿Por qué se adoptó una nueva flexibilidad en el Acuerdo ADPIC?- ¿A qué necesidades responde?- ¿Cuándo se espera que sea utilizada?- Predicción de posibles escenarios para su utilización- Entrada en vigor de la Enmienda del Acuerdo ADPIC- Labor por delante

Council for Trade-Related Aspects of Intellectual Property Rights

ANNUAL REVIEW OF THE SPECIAL COMPULSORY LICENSING SYSTEM

REPORT TO THE GENERAL COUNCIL

1. Paragraph 7 of the Annex to the TRIPS Agreement as amended by the Protocol Amending the TRIPS Agreement (the "Protocol") and paragraph 2 of the Decision on the Implementation of




UN SECRETARY GENERAL'S HIGH LEVEL PANEL ON ACCESS TO MEDICINES

BUILDING MOMENTUM FOR THE COHERENCE AGENDA ON GLOBAL HEALTH

Background note prepared by the Secretariat of the World Trade Organization (WTO)¹

SCP 27 sharing session:
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in developing countries & LDCs





trade & access

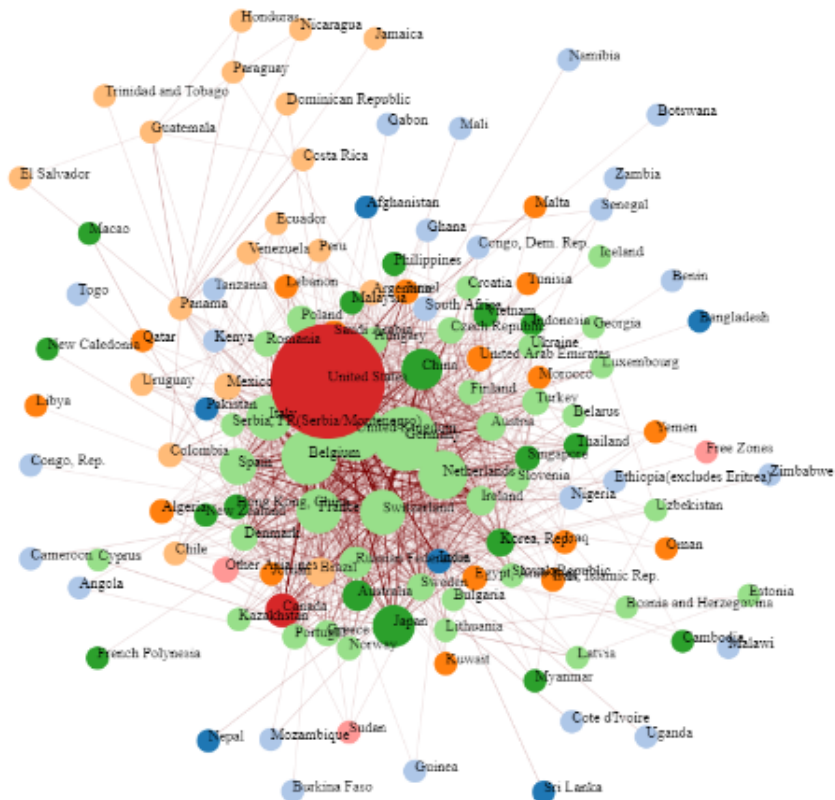
global imports of pharmaceuticals (2016):
524,978,029,000

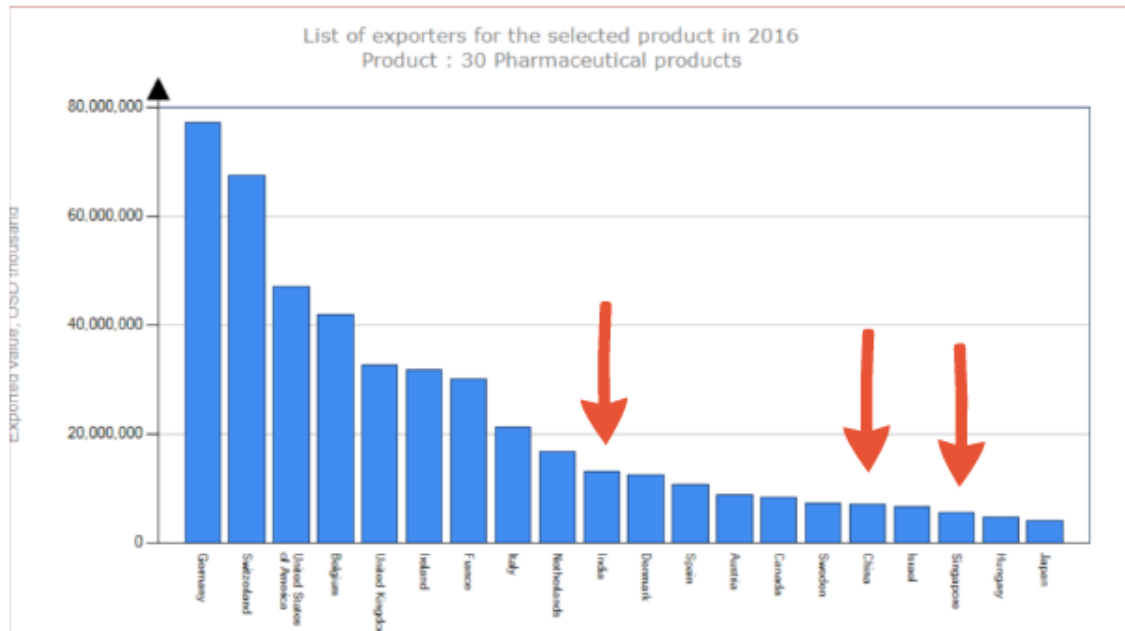
LDCs' imports of pharmaceuticals (2016):
5,283,759,000 (1%)

dimensions
of trade

constraints
on access

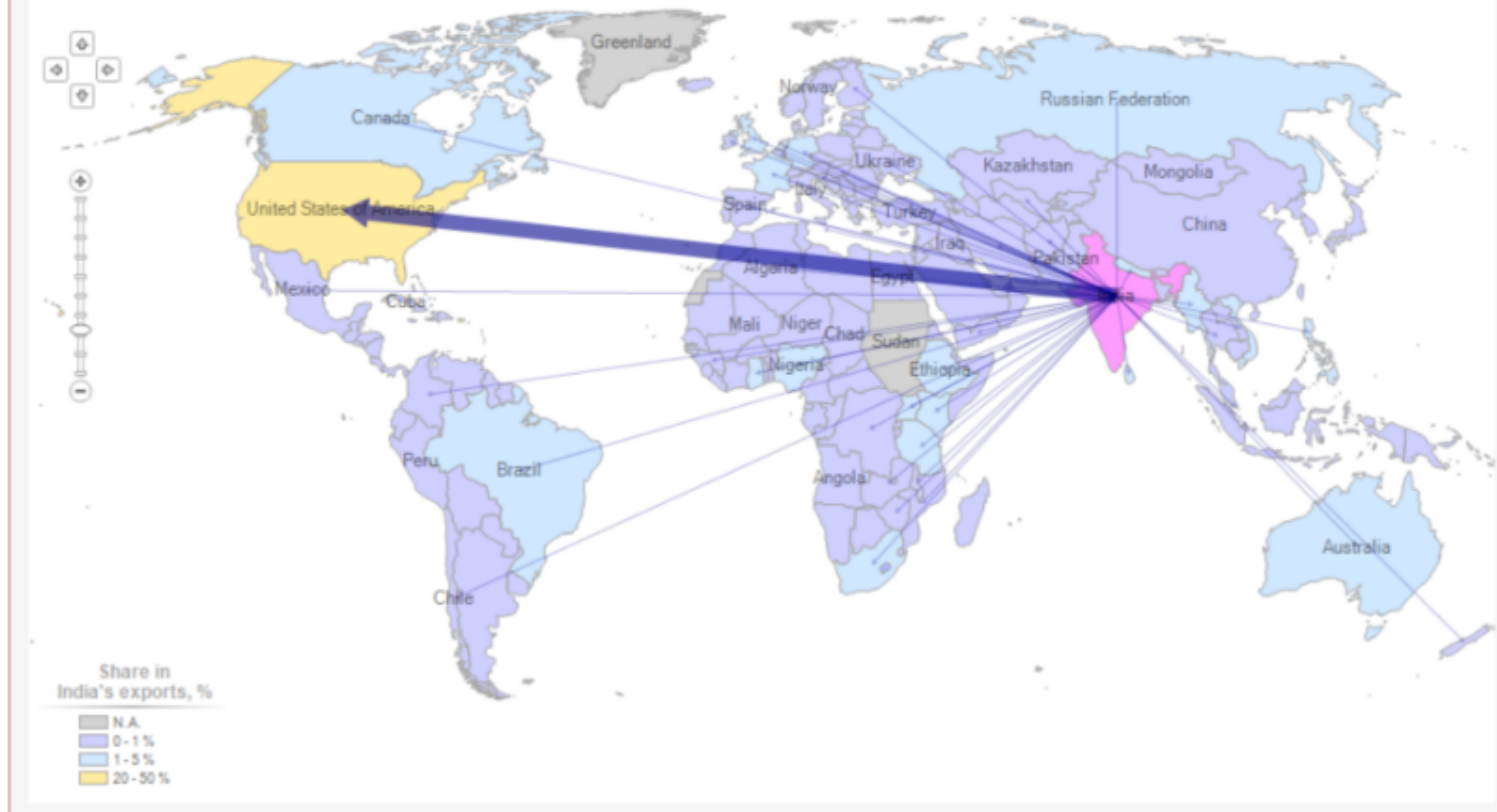
... and the
matter of
tariffs





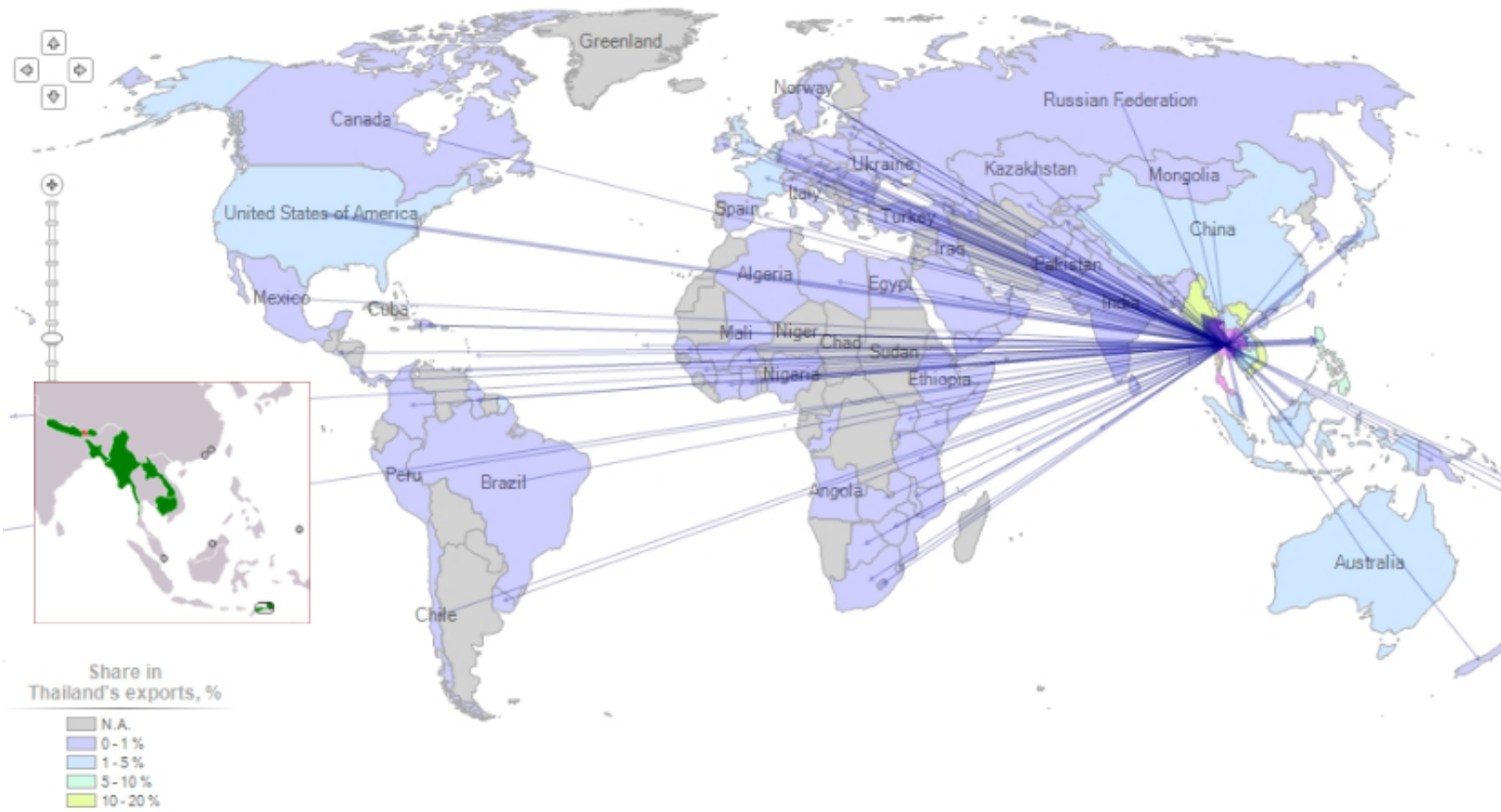
List of importing markets for a product exported by India in 2016

Product : 30 Pharmaceutical products

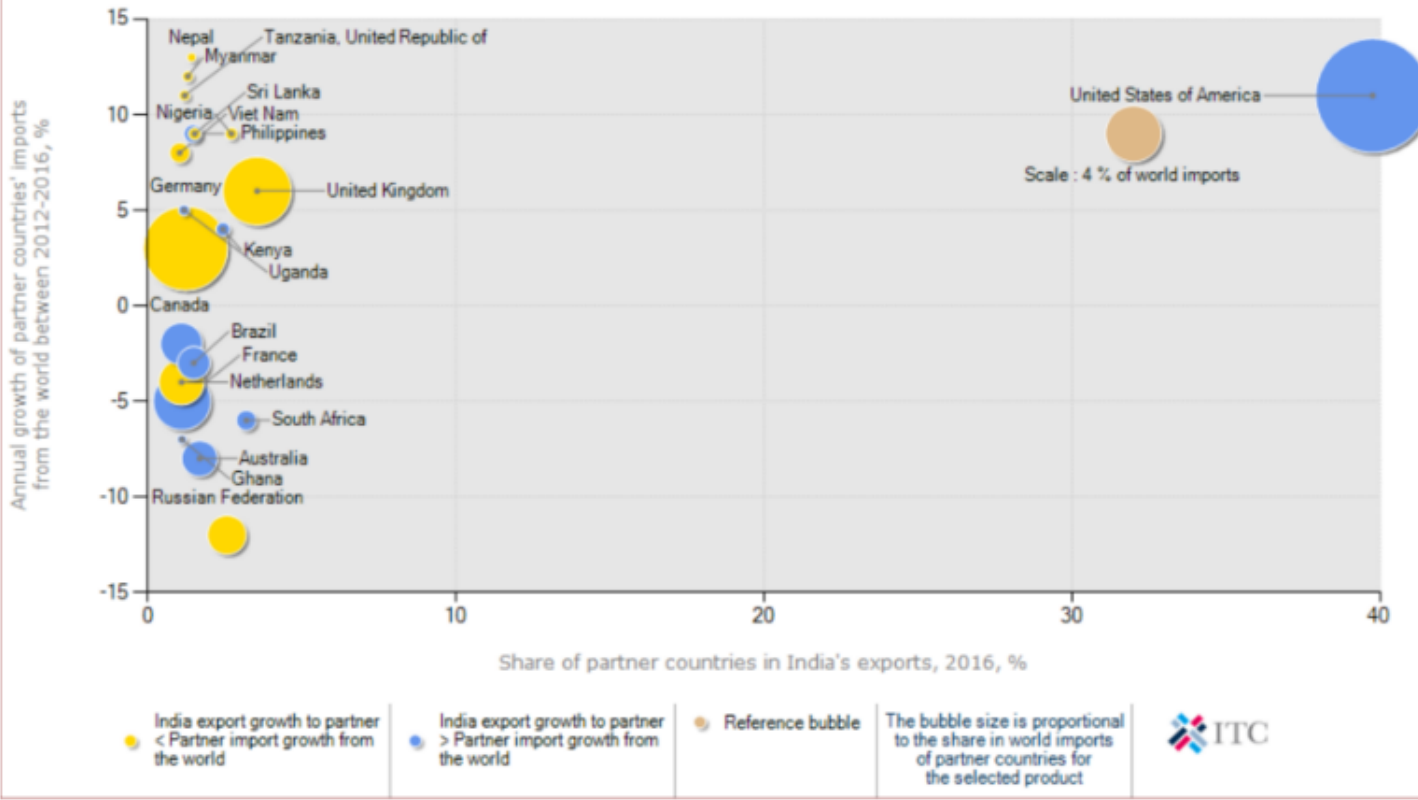


List of importing markets for a product exported by Thailand in 2016

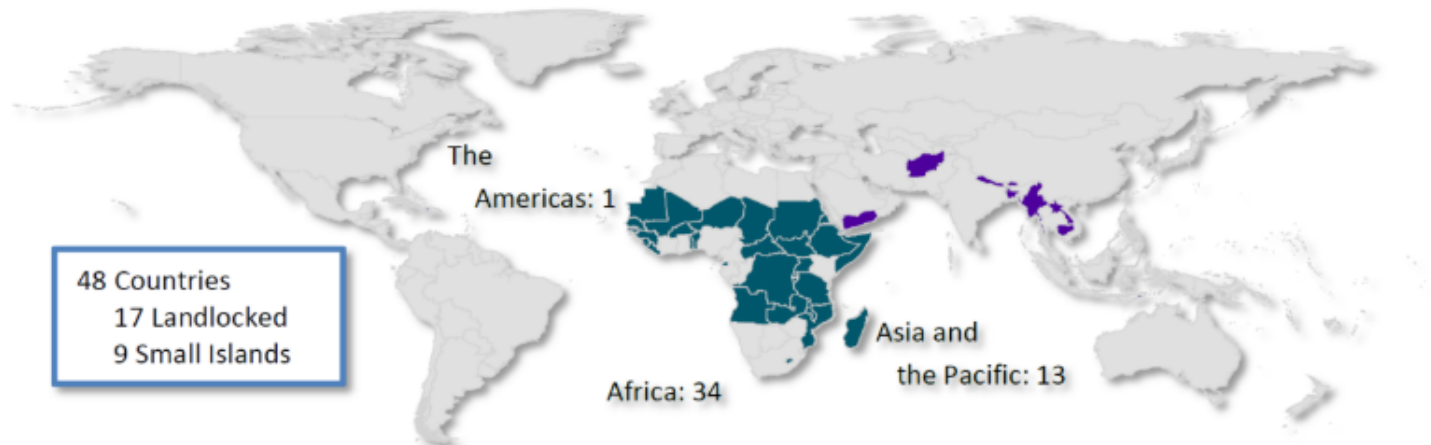
Product : 30 Pharmaceutical products



Prospects for market diversification for a product exported by India in 2016
 Product : 30 Pharmaceutical products



Least Developed Countries (LDCs)



Note: The boundaries and the names shown and the designations used on these maps do not imply official endorsement or acceptance by the United Nations.

Rankings

Rankings Distance to Frontier

Economy Rankings

Economies are ranked on their ease of doing business, from 1–190. A high ease of doing business ranking means the starting and operation of a local firm. The rankings are determined by sorting the aggregate [distance to frontier](#) indicators, giving equal weight to each topic. The rankings for all economies are benchmarked to June 2017. [Recent business rankings and the distance to frontier measure are calculated \(PDF\)](#).

 = Subnational *Doing Business* data available.

Economy ▲	Trading Across Borders DTF	Trading Across Borders rank	Time to export: Border compliance (hours)	Cost to export: Border compliance (USD)	Time to export: Documentary compliance (hours)	Cost to export: Documentary compliance (USD)
◀ Region						
East Asia & Pacific	69.97	102	55.9	387.5	68.2	112.1
Europe & Central Asia	83.96	58	28.0	191.4	27.9	113.8
Latin America & Caribbean	68.71	101	62.5	526.5	53.3	110.4
Middle East & North Africa	58.07	121	62.6	464.4	74.3	243.6
OECD high income	93.92	25	12.7	149.9	2.4	35.4
South Asia	58.32	126	59.4	369.8	77.0	179.5
Sub-Saharan Africa	52.56	137	100.1	592.1	87.8	215.1

Chart 1: Current customs procedures

Customs transactions vary widely from country to country. In 2014, these transactions involved:

← EXPORT →



2-11
documents



6-86
days

→ IMPORT ←

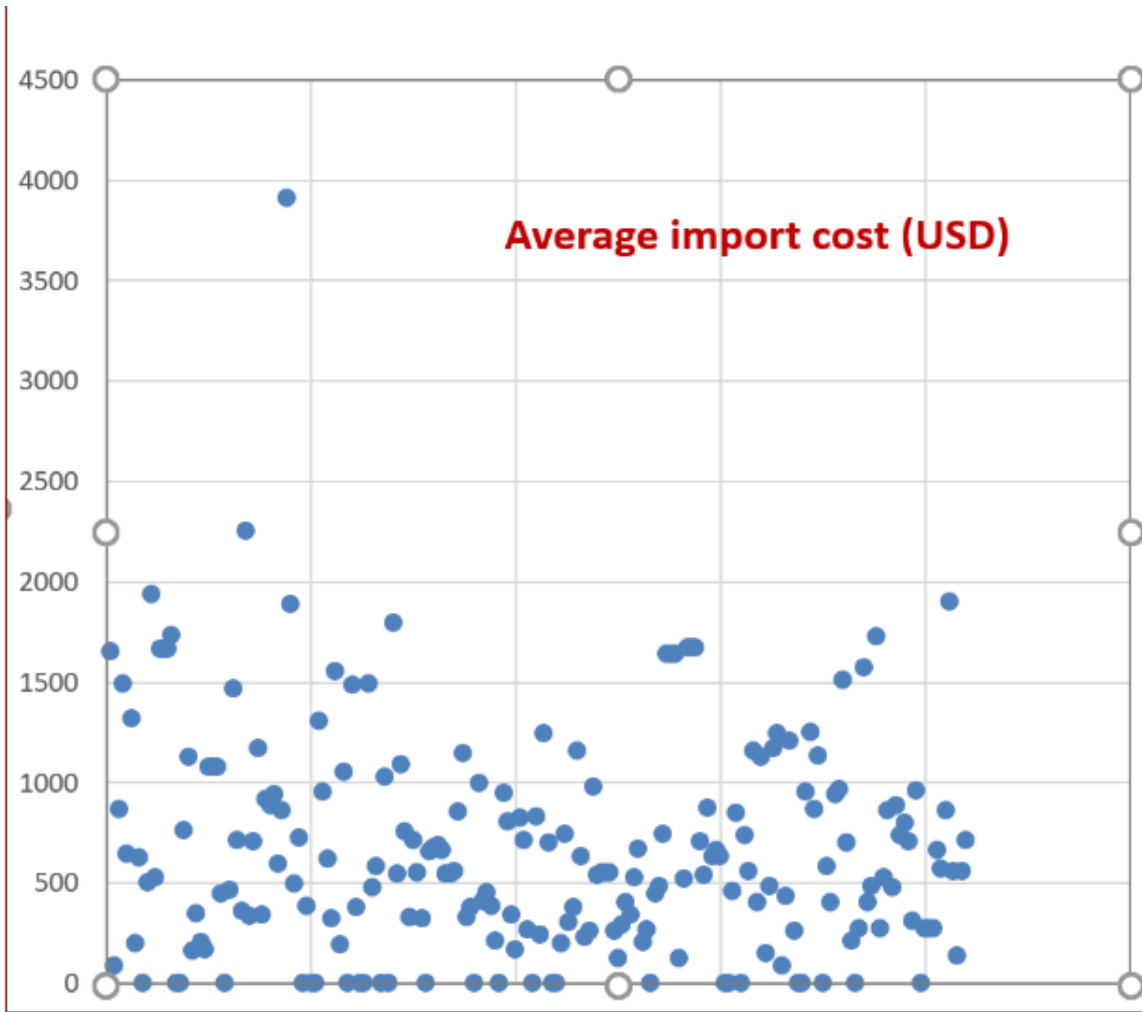


2-17
documents

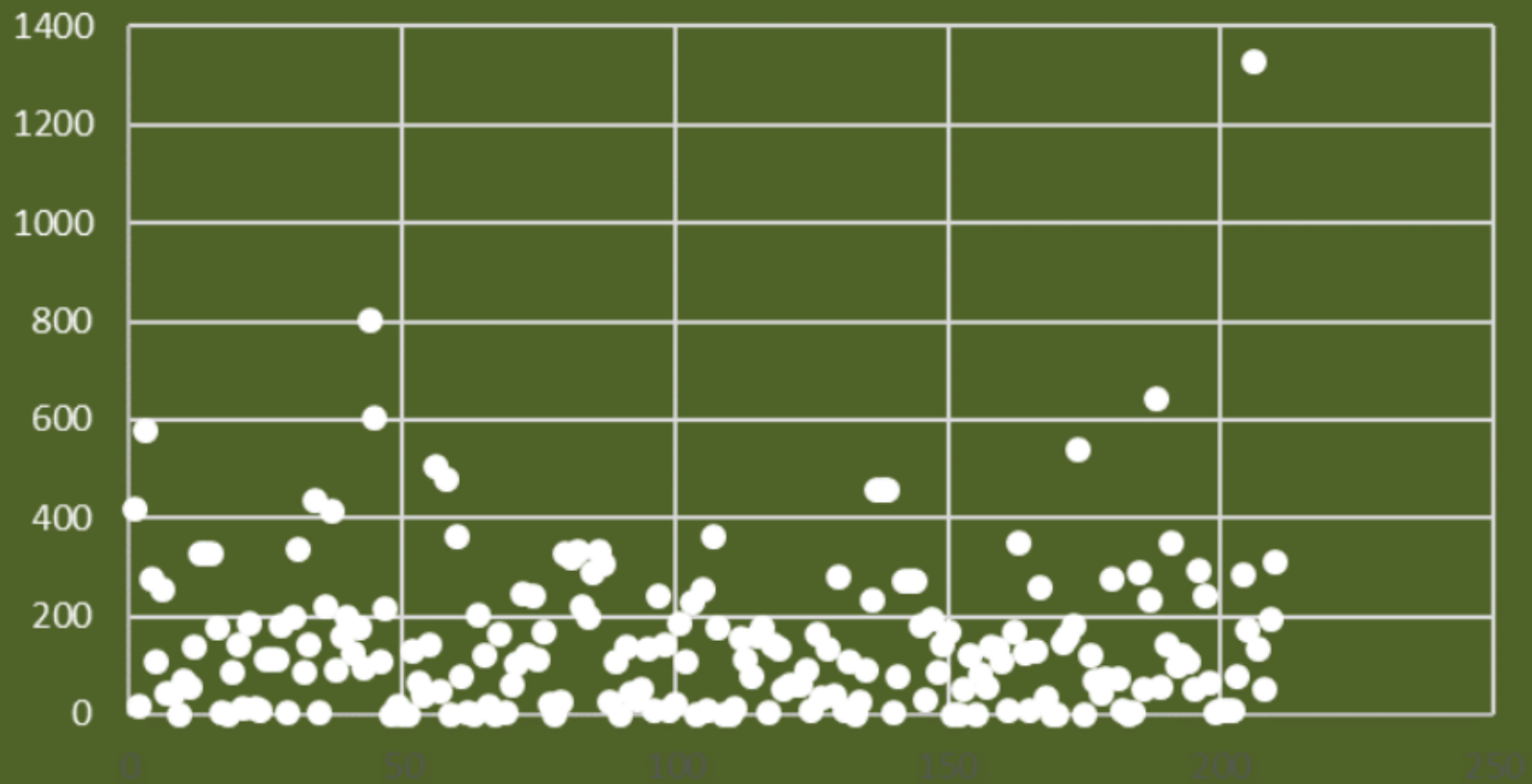


4-130
days

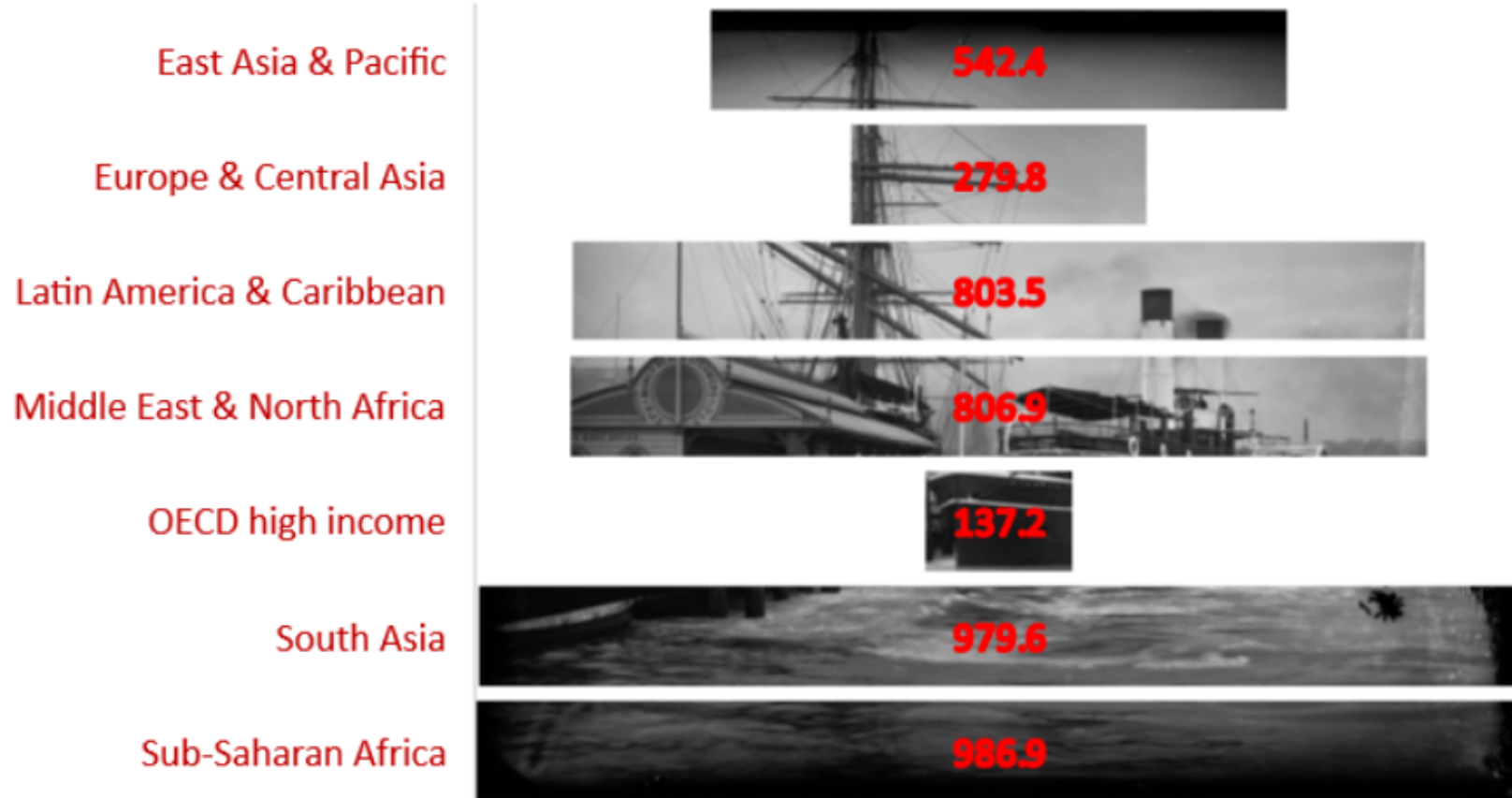
Source: World Bank "Doing Business" project, 2015.

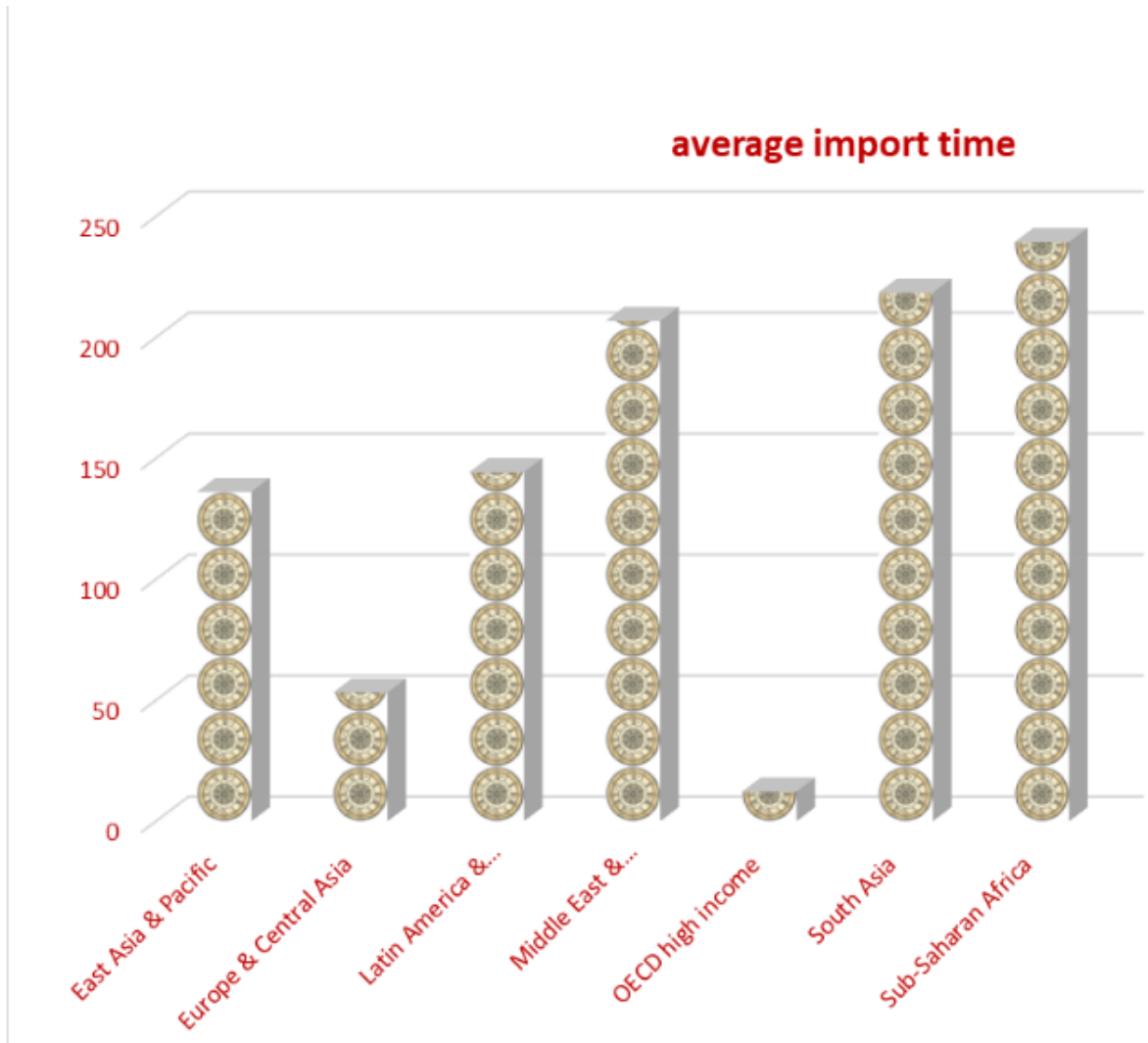


average import delays (hours)



average import costs





costs & delays - documentation & border compliance

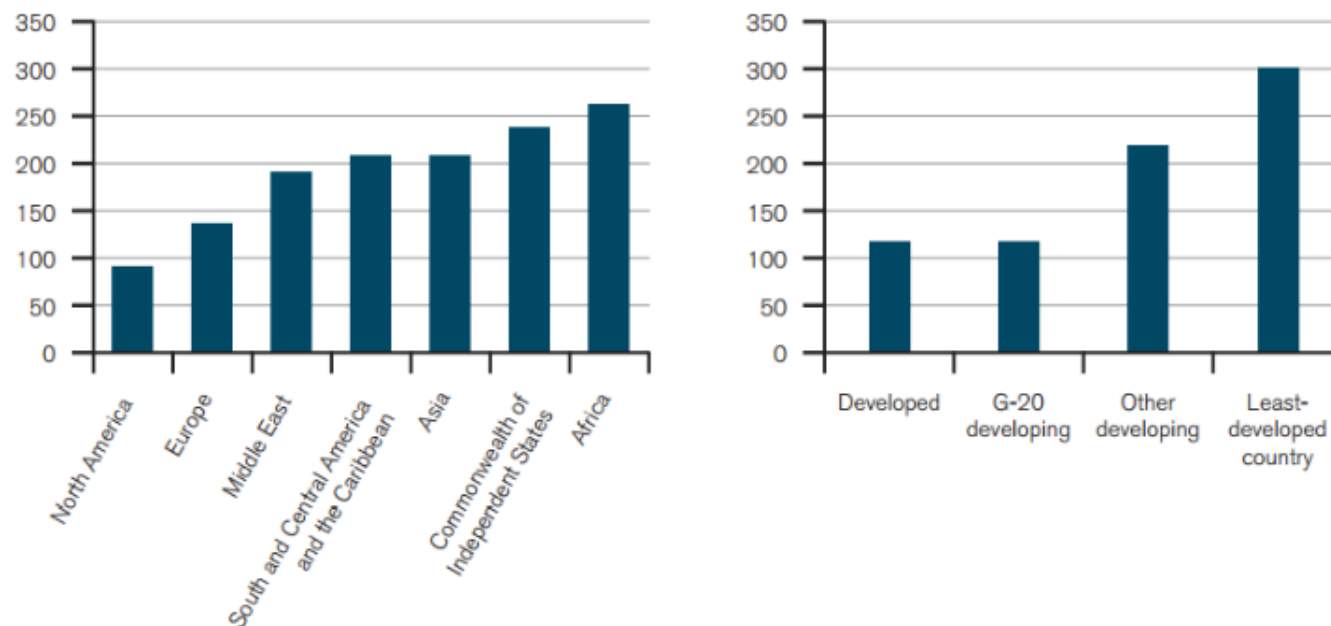
Average trade delays for imports:

- Up to **800 hours** in subsaharan Africa LDCs
- **1 hour** in a number of higher-income countries

Average processing costs for imports:

- Up to **USD 3900** in subsaharan African LDCs
- Reported as **USD 1** in some higher-income countries

Figure D.5: Ad valorem tariff equivalents of trade costs by region and level of development, 2008 (per cent)



Note: For each economy, "the rest of the world" is considered to be the 10 largest importers in 2010. Each group indicates trade costs in 2008 by income group.

Source: WTO Secretariat calculations based on data from Arvis *et al.* (2013).



14.5 %
Expected reduction in total trade costs for low-income countries once the Trade Facilitation Agreement enters into force.

WTO 2017 NEWS ITEMS
TRADE FACILITATION 22 FEBRUARY 2017

WTO's Trade Facilitation Agreement enters into force

A major milestone for the global trading system was reached on 22 February 2017 when the first multilateral deal concluded in the 21 year history of the World Trade Organization entered into force. In receiving four more ratifications for the Trade Facilitation Agreement (TFA), the WTO has obtained the two-thirds acceptance of the agreement from its 164 members needed to bring the TFA into force.

... and the matter of tariffs

**GENERAL AGREEMENT
ON TARIFFS AND TRADE**

RESTRICTED
L/7430
25 March 1994
Limited Distribution
(94-0547)

Original: English

TRADE IN PHARMACEUTICAL PRODUCTS

The following communication concerning trade in pharmaceutical products has been received from the delegations listed below:

RECORD OF DISCUSSION

In the course of the Uruguay Round negotiations, representatives of the following governments discussed the treatment of pharmaceutical products and came to the following conclusions:

Each government will eliminate customs duties on pharmaceutical products, as defined below, recognizing the objective of tariff elimination should not be frustrated by trade restrictive or trade distorting measures. Other governments are encouraged to do the same.

1. With respect to pharmaceutical products (as defined below), they will eliminate customs duties and all other duties and charges, as defined within the meaning of Article II.1 (b) of the General Agreement on Tariffs and Trade (1994), on ALL items in the following categories:

- (i) items classified (or classifiable) in Harmonized System Chapter 30;
- (ii) items classified (or classifiable) in HS headings 2936, 2937, 2939, and 2941, with the exception of dihydrostreptomycin and salts, esters, and hydrates thereof;
- (iii) pharmaceutical active ingredients as designated in Annex I and that bear an "international non-proprietary name," (INN) from the World Health Organization;
- (iv) salts, esters, and hydrates of pharmaceutical products which are described by the combination of an INN active ingredient contained in Annex I with a prefix or suffix as designated in Annex II to this record, as long as such salt, ester, or hydrate is classified in the same HS 6-digit heading as the INN active ingredient;
- (v) salts, esters, and hydrates of INN active ingredients that are separately contained in Annex III to this record and that are not classified in the same HS 6-digit heading as the INN active ingredient;
- (vi) additional products used for the production and manufacture of finished pharmaceuticals as designated in Annex IV to this record.

reported 'applied tariffs' on medicines

HS (Harmonized System) Chapter 30

- reported applied tariffs range from 0% to 51% (ad valorem)
- significant number between 10% and 30%
 - in some cases, this corresponds to domestic production policy
 - in other cases, no major domestic industry

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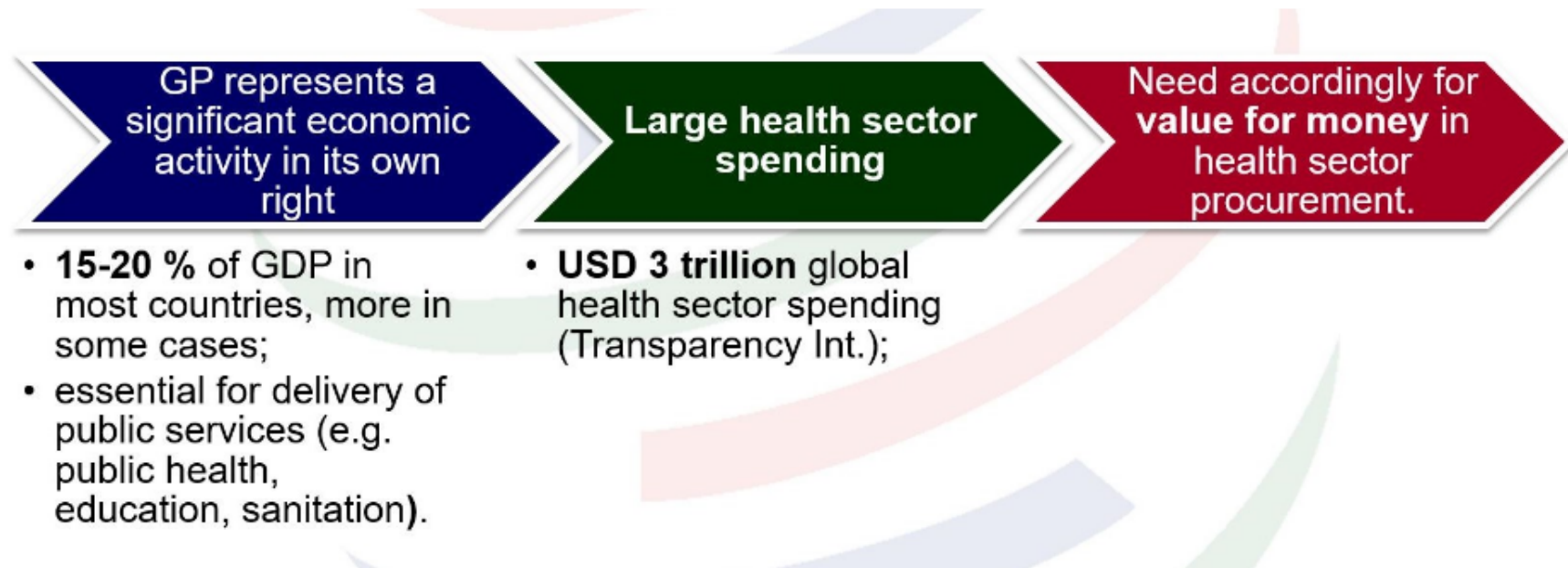
other trade policy questions



procurement
policy

competition
policy

regulation
for public
welfare



Strengthening long term competition



"Public procurement processes that award the whole market for a medicine to a single supplier may result in potential competitors leaving the market and reduce competition in subsequent rounds of tendering. To avoid this problem, South Africa, for example, contracts the two or three lowest-price suppliers and offers to contract other suppliers if they agree to move their prices to this level. Some competition authorities have issued guidance on how to conduct public procurement in a way that strikes a balance between the goal of achieving the lowest prices in a given tender and the goal of maintaining a competitive market structure over the medium to longer term."

Source: Hawkins, L. (2011). WHO / HAI Project on Medicine Prices and Availability. Review Series on Pharmaceutical Pricing Policies and Interventions, Working Paper, 66. Available at <http://www.haiweb.org/medicineprices/24072012/CompetitionFinalMay2011.pdf>.



ASTA INVERSA CORPORATIVA
MEDICAMENTOS



RCOP

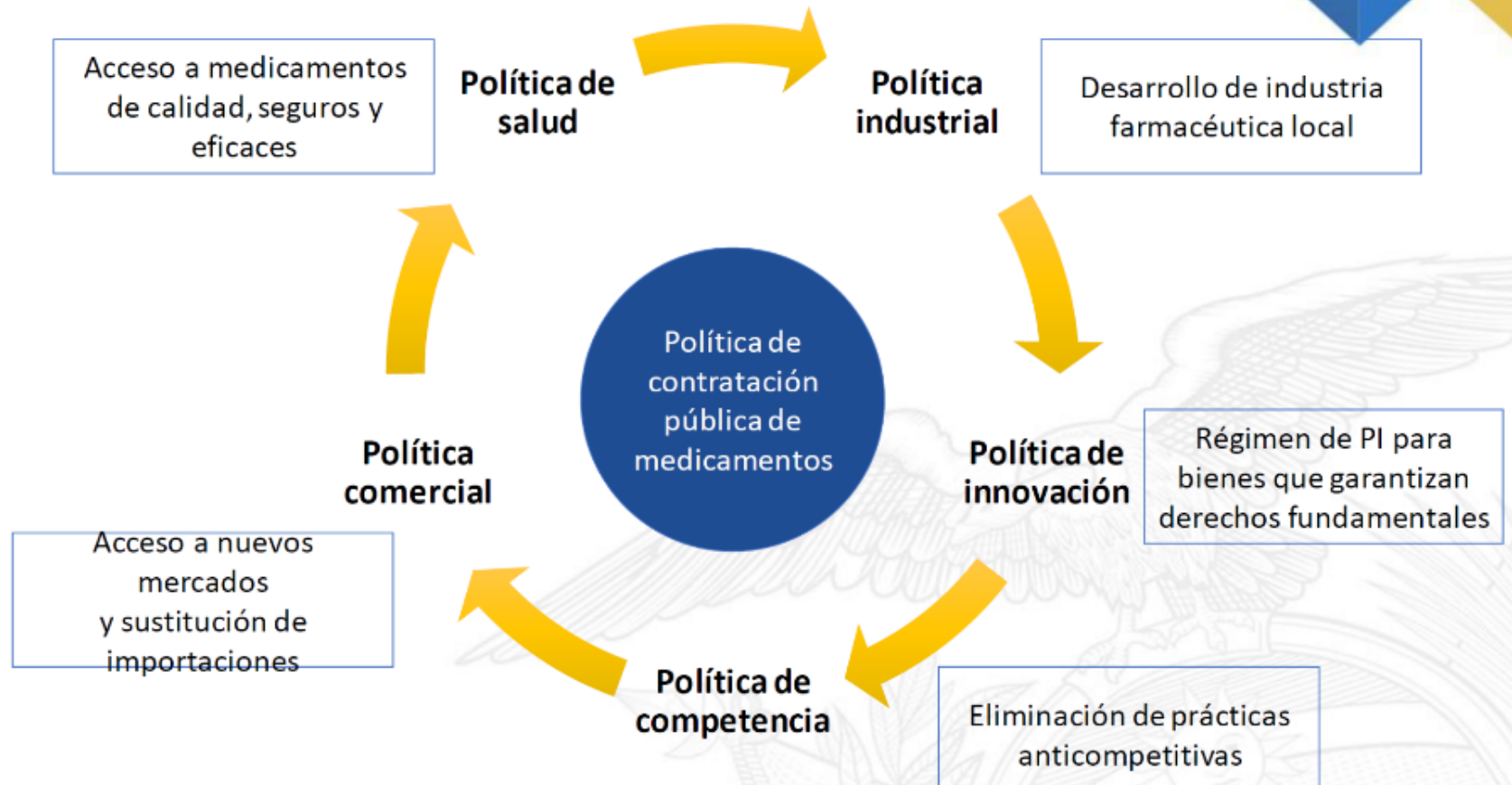


Daniel López Salcedo
Servicio Nacional de Contratación Pública
Taller regional sobre comercio y salud pública
Brasilia D.F., 23 de noviembre de 2017

ARTICULACIÓN PROGRAMÁTICA



SERVICIO NACIONAL DE
CONTRATACIÓN PÚBLICA



EJECUCIÓN PROGRAMÁTICA



PRINCIPIOS ESTRUCTURALES

ETAPAS SICM

Estudio de mercado
+
Márgenes de preferencia
+
Plataforma e-procurement
Módulo PyR – Incentivos puja

1. Etapa Preparatoria

- a. Actualización de información de proveedores
- b. Registro de proveedores internacionales
- c. Elaboración de Reglamento
- d. Elaboración de pliegos
- e. Consejo Consultivo
- f. Adecuación de plataforma virtual
- g. Estrategia de difusión

- a. Publicación
- b. Preguntas
- c. Respuestas
- d. Presentación electrónica de oferta
- e. Calificación automática
- f. Ingreso de OEI
- g. Puja / negociación
- h. Entrega de documentación habilitante
- i. Adjudicación

2. Etapa Precontractual

Adhesión
+
Proceso competitivo
+
Verificación de requisitos sanitarios
RS - BPM

Liquidez
+
Disponibilidad de stock

3. Etapa Contractual

- a. Suscripción de convenios marco
- b. Catalogación (Publicación en Repertorio de Medicamentos)

- a. Evaluación de resultados
- b. Informe de rendición de cuentas
- c. Difusión de resultados

4. Etapa Postcontractual o Evaluativa

Sistema de Control de Calidad
+
Coordinación interinstitucional

PRECIOS ADJUDICADOS



SERVICIO NACIONAL DE
CONTRATACIÓN PÚBLICA



Comparativo de precios unitarios de medicamentos SICM 2011 - SICM 2016

MEDICAMENTO	PRESUPUESTO REFERENCIAL UNITARIO 2011	PRESUPUESTO REFERENCIAL UNITARIO 2015	VALOR UNITARIO ADJUDICADO 2015	PRECIO REGIONAL
Amlodipina 5mg	\$ 0,2300	\$ 0,0100	\$ 0,0070	\$ 2,6700 ^a
Carbamazepina 200 mg	\$ 0,0567	\$ 0,0430	\$ 0,0200	\$ 0,4500 ^b
Enalapril 10 mg	\$ 0,0311	\$ 0,0110	\$ 0,0020	\$ 2,1400 ^c
Gentamicina 10mg/ml	\$ 0,2500	\$ 0,2500	\$ 0,1336	-
Metformina 500mg	\$ 0,3000	\$ 0,0600	\$ 0,0086	\$ 1,1700 ^a

^a Argentina ^b Brasil ^c Chile

Fuente: Sistema Oficial de Contratación del Estado (SOCE).

Elaboración: SERCOP.

- 417 medicines covered (to exceed 500 in 2018)
- Centralized purchasing model saves USD 15-20 million per month.
- Covers 95% of the national supply.
- Interagency monitoring & coordination.
- Standardization of procedures for public health facilities.
- Early warnings for quality control issues to ensure compliance with technical specifications.

WTO - GPA

Agreement on Government Procurement:

- incorporates principles of good governance in procurement
- general coverage of pharmaceuticals procured by government agencies
- plurilateral - 47 WTO Members (19 parties);
- 31 observers



competition policy

Article 8

Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

SECTION 8: CONTROL OF ANTI-COMPETITIVE PRACTICES
IN CONTRACTUAL LICENCES

Article 40

1. Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.
2. Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member.
3. Each Member shall enter, upon request, into consultations with any other Member which has cause to believe that an intellectual property right owner that is a national or domiciliary of the Member



Promoting Access to Medical Technologies and Innovation


Intersections between public health, intellectual property and trade



Competition policy, innovation & access

The importance of competition (antitrust) policy in promoting innovation and ensuring access to medical technology derives from its cross-cutting relevance to all stages and elements involved in the process of supplying medical technology to the patient – from the development and manufacture of such technology to its eventual sale and delivery.

While a full analysis of all competition policy issues involved in that process is beyond the scope of this study, this section outlines a number of areas where competition policy has direct relevance for access to medicines...



regulation for
public welfare

... and
"the right to regulate"

TBT Committee Decision on *Principles for the Development of International Standards, Guides and Recommendations*

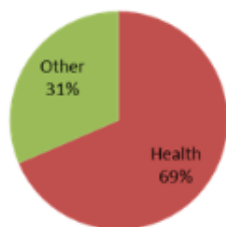
(November 2000, G/TBT/9)

“Six Principles”

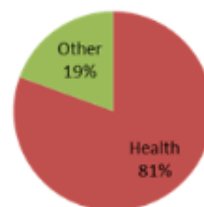
- **Transparency**
- **Openness**
- **Impartiality and consensus**
- **Relevance and effectiveness**
- **Coherence**
- **Development dimension**

Notifications and human health protection

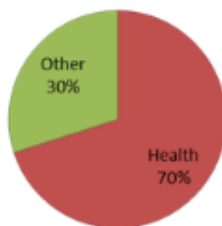
TBT Notifications 2016 (until 20 Oct.)



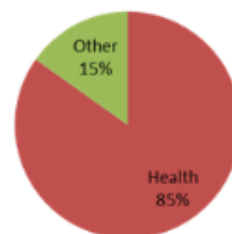
SPS Notifications 2016 (until Oct. 2016)



TBT Notifications 2015



SPS Notifications 2015

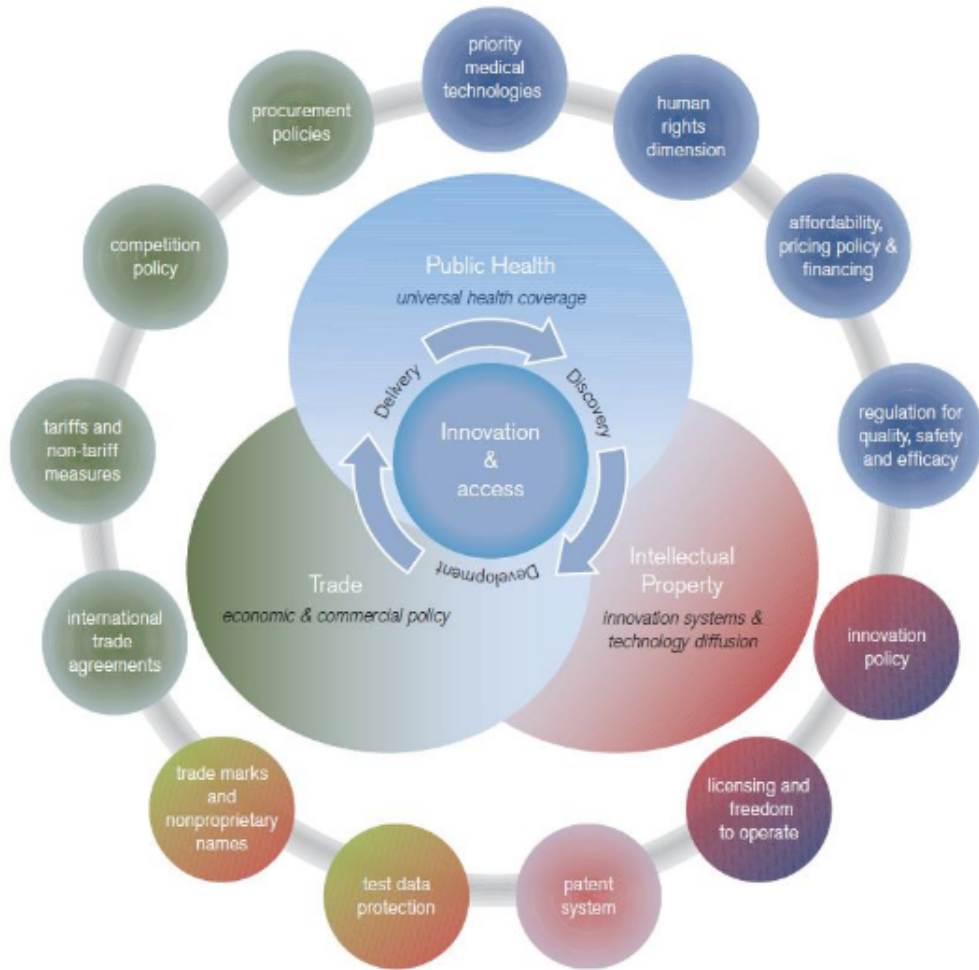


Less than 0.25% of Notifications give right to STCs

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Mapping the policy intersections: key areas of law and policy for innovation and access



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