Para.6 of the Doha Declaration on TRIPS and Public Health
A South Centre Side Event

Geneva, 8 November 2016

Special Compulsory Licences for Export of Medicines

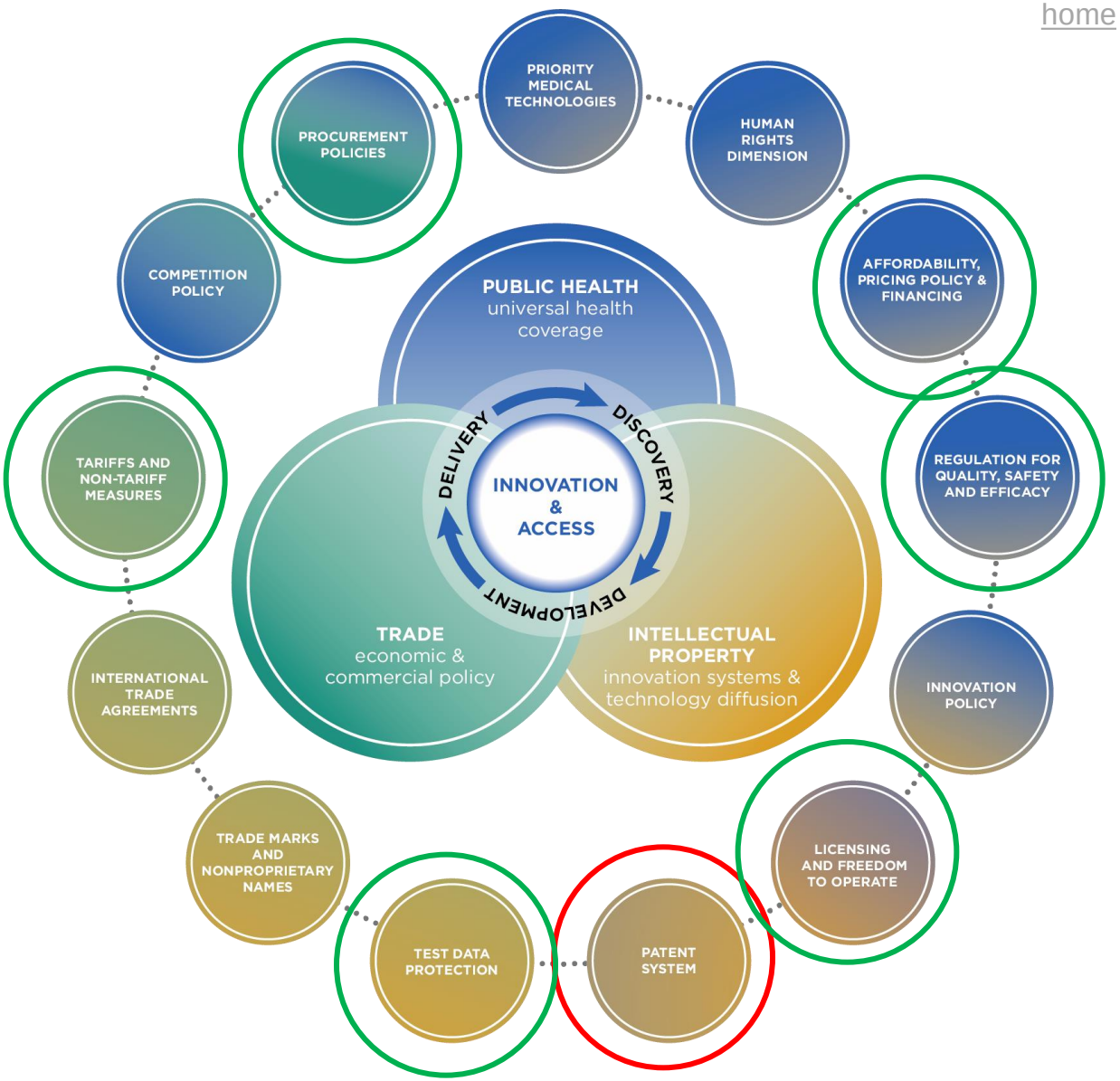
Roger Kampf, WTO Secretariat

I.

Putting the System Into Context

Para.6: Part of a Holistic Approach

home



II.

Where the System Finds its Roots:

The Doha Declaration on the TRIPS Agreement and Public Health

A Blueprint for Policy Coherence on Public Health

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

What Doha Achieved

- Shapes framework for multilateral cooperation on IP and public health (in particular: **trilateral study**)
- Clarifies flexibilities (**exhaustion** and **compulsory licensing**)
- Helps governments to make full use of TRIPS flexibilities
- Reinforces understanding that TRIPS supports balanced and flexible IP framework responsive to broader policy agenda
- Extended LDC transition period
- Led to adoption of **Paragraph 6 System**

Selected WTO Members' Role and Views

- Process initially led by EU
  - 2002 concept paper and subsequent communications (IP/C/W/339, 352, 416)
- African Group and individual members
  - Presented several proposals as of 2002 (IP/C/W/351, 437, 440)
  - Welcomed adoption of 2003 waiver decision as "historic moment" (WT/GC/M/82)
  - Subsequently called for "legally permanent and multilateral solution" (IP/C/M/39, 47)
    - Supported by LDC Group and ACP Group
- Flexibilities offered by the System:
  - "great assistance for developing countries in having access to affordable medicines" (IGDC, WTO General Council, 20 Feb. 2015)

What Multilateral Institutions Have Been Saying

- **WHO:**
  - **Global Strategy and Plan of Action, Element 5.2**
  - **Called for stable international legal framework, (IP/C/M/37)**
  - **Noted full commitment to the Decision and its implementation (IP/C/M/45)**
- **Widespread calls within multilateral system for acceptance and implementation, e.g.:**
  - **UN Political Declaration on HIV/AIDS (7 June 2016) called "for early acceptance of the amendment to article 31 of the TRIPS Agreement…"**

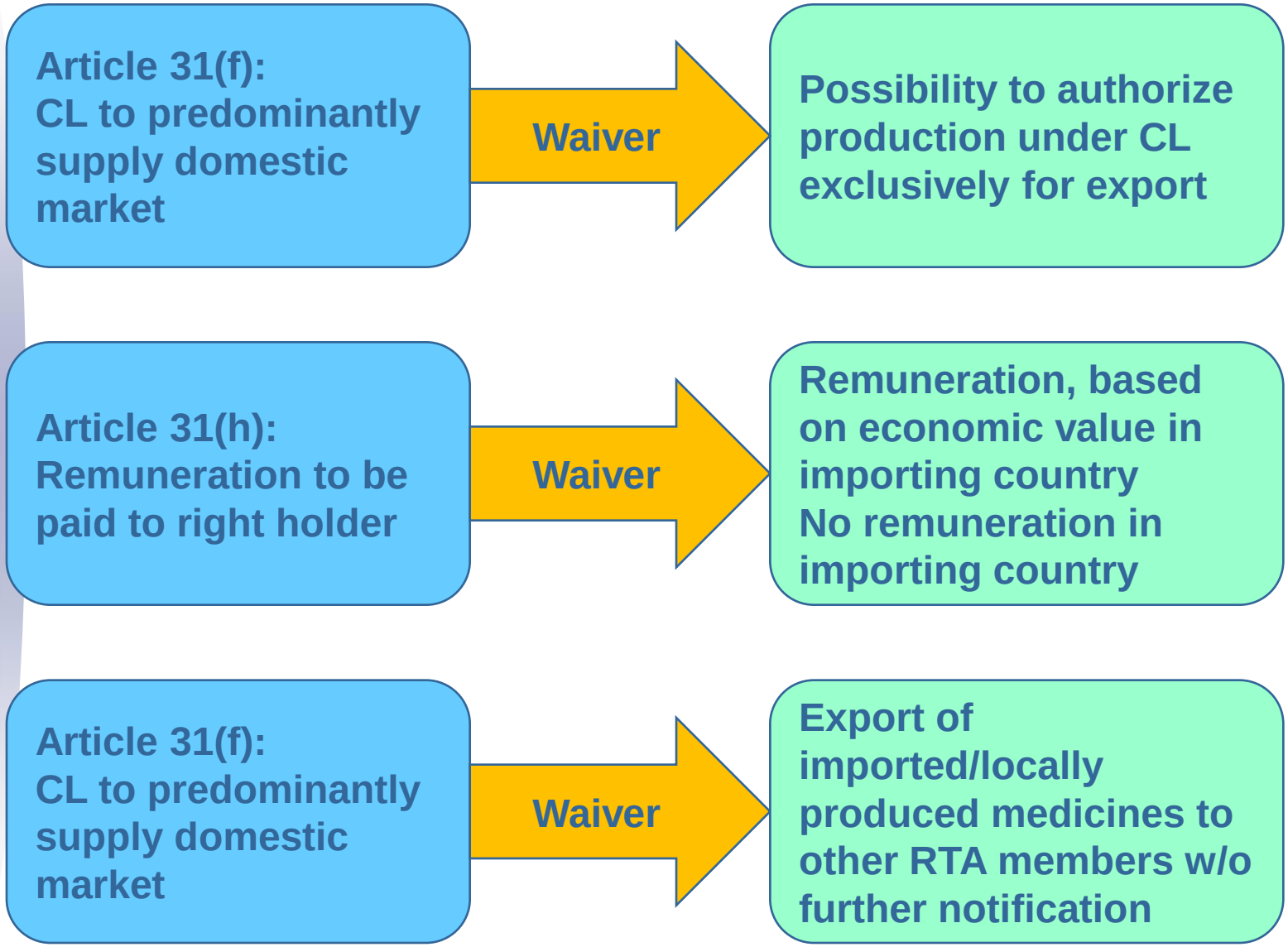
III.
What the System Does and How it Works

The Para.6 System Has Been Conceived to Address...

...a *health* problem in the importing Member

...and a *legal* problem in the exporting Member

How the Para.6 Waivers Work



IV.
Why and How to Accept the Protocol Amending TRIPS

Why to Accept the Protocol

WORLD TRADE ORGANIZATION

WT/GC/W/696

23 February 2015

(15-1055) Page: 1/7

General Council

**PROTOCOL AMENDING THE TRIPS AGREEMENT:
EXPECTED BENEFITS OF THE PARAGRAPH 6 SYSTEM OF SPECIAL LICENCES FOR EXPORT OF MEDICINES[1]**

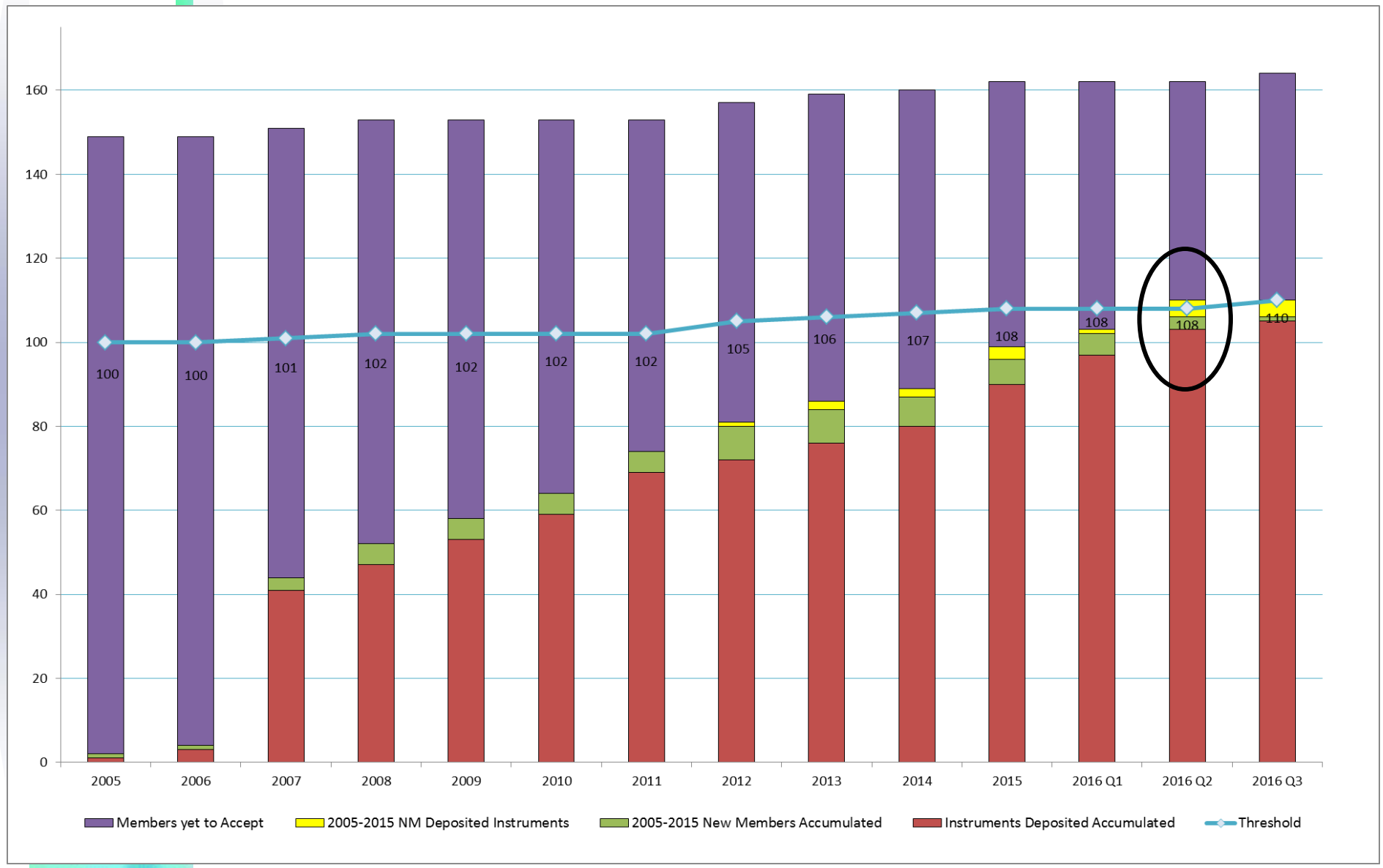
AIDE MÉMOIRE[2]

- **Formal consent to be bound by amendment**
- **Transforms political commitment by all Members into permanent part of TRIPS**
- **Signalling function: first ever amendment to WTO agreements, reflecting importance attached to public health**
- **Supported by the international community, including UN organizations**

How to Accept the Protocol

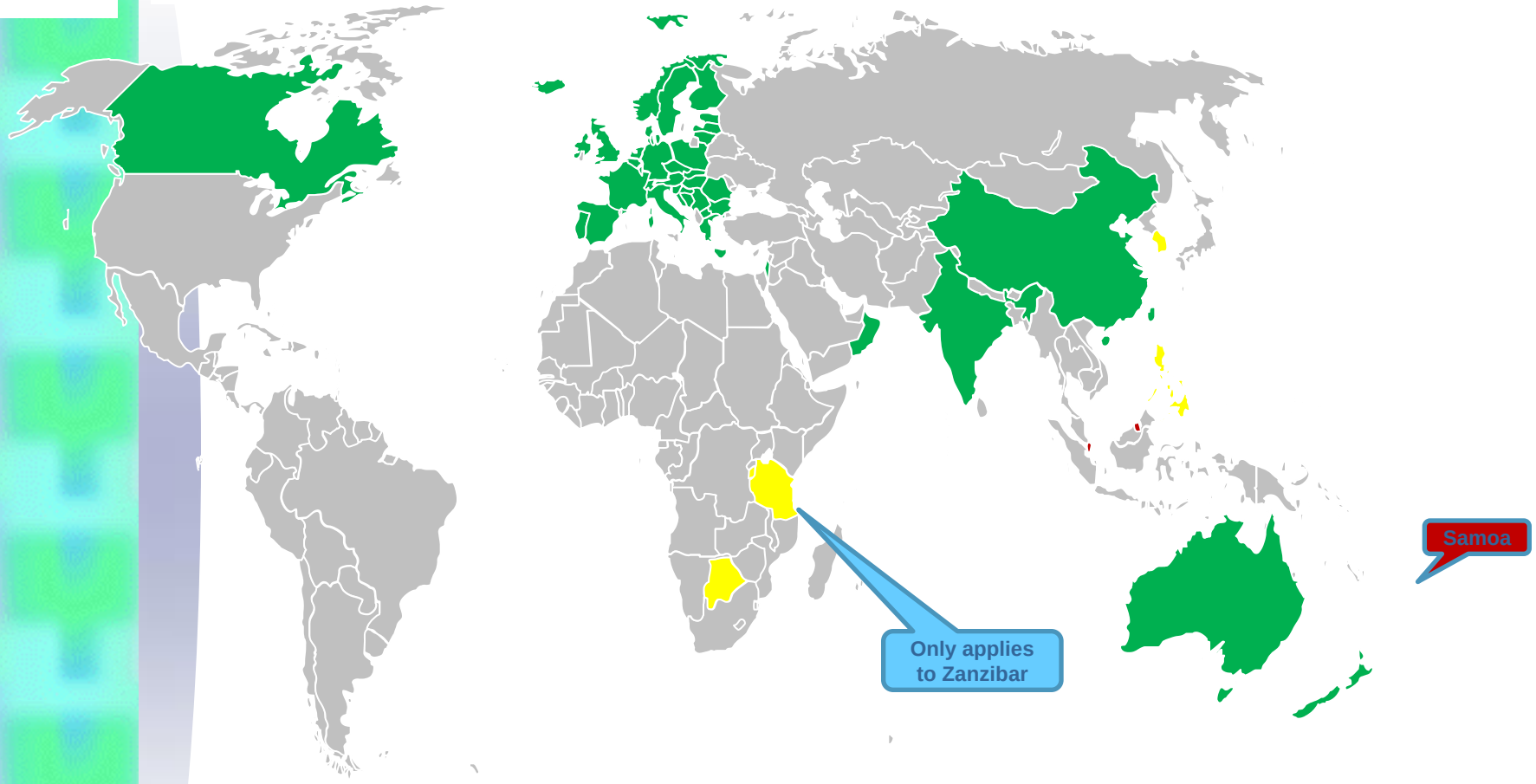
- Submitted to Members for acceptance
  - How to accept the Protocol depends on domestic constitutional requirements
  - WTO notification to meet formal requirements
  - See hand-out on « how to accept TRIPS amendment »
- Period for acceptance runs until end 2017 (can be further extended if necessary)
- Takes effect upon acceptance by two thirds of membership

Two Third Threshold: A Moving Target



V.
By Whom and How Has the System Been Implemented?

Who Has Implemented the System?

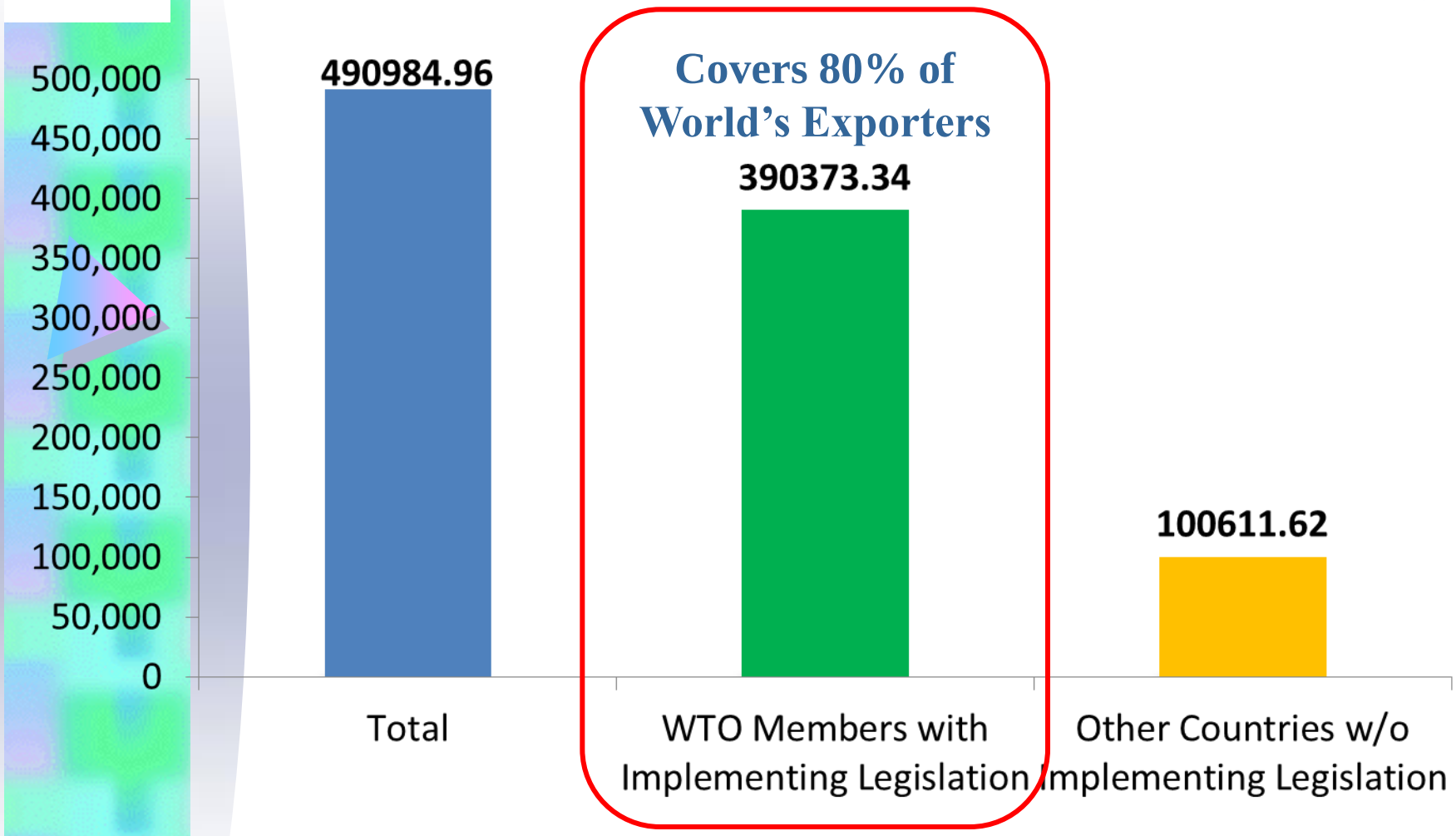


WTO Members / Observer with ***specific*** legislation to act as exporters

WTO Members with ***specific*** legislation to act as exporters and importers

WTO Members with ***specific*** legislation to act as importers

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



Source: IFPMA, The Pharmaceutical Industry and Global Health, Facts and Figures 2014
(http://www.ifpma.org/fileadmin/content/Publication/2014/IFPMA_-_Facts_And_Figures_2014.pdf)

Comparing Regular and Special CL

Selected Conditions	Reg. CL	Spec. CL	+ Para.6 Implementing Measures (IM)
Pre-grant Conditions			Some IM: limit negotiating period (28 days to 6 months)
Prior efforts to obtain VL, except extreme urgency/public non-commercial use	√	√	
Within reasonable period of time	√	√	
Quantity			One IM: accelerated procedure to adjust quantities
Limited to purpose of authorization	√		
Limited to needs of importing country (IC)		√	
Duration			One IM: simplified procedure to review One IM: limited to two years, once renewable
Limited to purpose of authorization	√	√	
Can be terminated earlier	√	√	
Remuneration			Some IM: specific guidance how to calculate remuneration
Based on economic value of authorization	√		
Based on economic value in IC		√	
Not to be paid by IC		√	
Regulatory Approval	Ø	Ø	Some IM: set regulatory requirements Two IM: no data exclusivity

VI.
Use of the System and Its Operation

Use of Paragraph 6 System: Example of Rwanda-Canada

WTO OMC

Regulatory

Paragraph 6 System

Procure ment

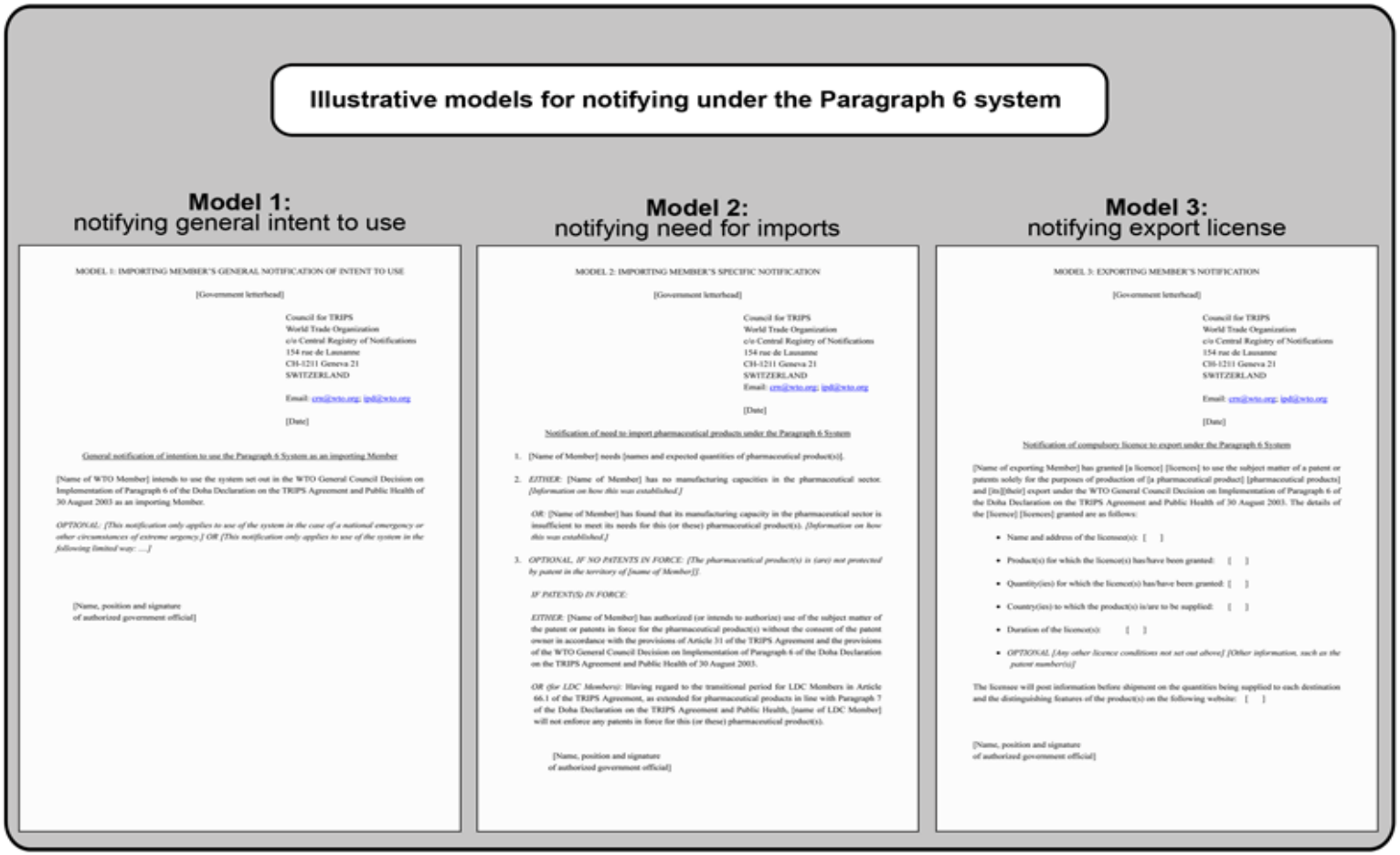
June 06	→	Health Canada approves Apo-Triavir
To July 07	→	No request for Apo-Triavir
July 07	→	Apotex seeks VL from right holders to use patents
July 07	→	Rwanda notifies its intention to import under Para.6
Sept. 07	→	Apotex files CL application to produce/export to Rwanda
Sept. 07	→	CL granted by Patent Commissioner in Canada
Oct. 07	→	Grant of CL notified to WTO by Canada
May 08	→	Apotex announces it has won public tender in Rwanda
Sept. 08-09	→	Shipment of medicines to Rwanda

Use of Paragraph 6 System: Is It Functioning Well?

- TRIPS Council looks into narrow (e.g. annual review 2015) and broader aspects (e.g. annual review 2010)
- Concerns expressed:
  - Too complex and bureaucratic, including as regards certain implementing legislation
  - Limited number of acceptances of the Protocol
  - Political and trade ramifications
- Others argue that:
  - Rwanda/Canada example shows that System can work
  - Less need to use System due to other measures enhancing access to medicines
  - No member has demonstrated obstacles to use of the System

To Facilitate Use: Model Notifications

- **See illustrative guide on dedicated WTO webpage: http://www.wto.org/english/tratop_e/trips_e/par6_modelnotifs_e.htm**



Illustrative models for notifying under the Paragraph 6 system

Model 1:
notifying general intent to use

MODEL 1: IMPORTING MEMBER'S GENERAL NOTIFICATION OF INTENT TO USE

[Government letterhead]

Council for TRIPS
World Trade Organization
c/o Central Registry of Notifications
154 rue de Lausanne
CH-1211 Geneva 21
SWITZERLAND

Email: crn@wto.org; ipd@wto.org

[Date]

General notification of intention to use the Paragraph 6 System as an importing Member

[Name of WTO Member] intends to use the system set out in the WTO General Council Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health of 30 August 2003 as an importing Member.

OPTIONAL: [This notification only applies to use of the system in the case of a national emergency or other circumstances of extreme urgency.] OR [This notification only applies to use of the system in the following limited way: ....]

[Name, position and signature
of authorized government official]

Model 2:
notifying need for imports

MODEL 2: IMPORTING MEMBER'S SPECIFIC NOTIFICATION

[Government letterhead]

Council for TRIPS
World Trade Organization
c/o Central Registry of Notifications
154 rue de Lausanne
CH-1211 Geneva 21
SWITZERLAND
Email: crn@wto.org; ipd@wto.org

[Date]

Notification of need to import pharmaceutical products under the Paragraph 6 System

1. [Name of Member] needs [names and expected quantities of pharmaceutical product(s)].
2. *EITHER:* [Name of Member] has no manufacturing capacities in the pharmaceutical sector. *[Information on how this was established.]*

   OR: [Name of Member] has found that its manufacturing capacity in the pharmaceutical sector is insufficient to meet its needs for this (or these) pharmaceutical product(s). *[Information on how this was established.]*
3. *OPTIONAL, IF NO PATENTS IN FORCE: [The pharmaceutical product(s) is (are) not protected by patent in the territory of [name of Member]].*

   IF PATENT(S) IN FORCE:

   EITHER: [Name of Member] has authorized (or intends to authorize) use of the subject matter of the patent or patents in force for the pharmaceutical product(s) without the consent of the patent owner in accordance with the provisions of Article 31 of the TRIPS Agreement and the provisions of the WTO General Council Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health of 30 August 2003.

   OR (for LDC Members): Having regard to the transitional period for LDC Members in Article 66.1 of the TRIPS Agreement, as extended for pharmaceutical products in line with Paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health, [name of LDC Member] will not enforce any patents in force for this (or these) pharmaceutical product(s).

[Name, position and signature
of authorized government official]

Model 3:
notifying export license

MODEL 3: EXPORTING MEMBER'S NOTIFICATION

[Government letterhead]

Council for TRIPS
World Trade Organization
c/o Central Registry of Notifications
154 rue de Lausanne
CH-1211 Geneva 21
SWITZERLAND

Email: crn@wto.org; ipd@wto.org

[Date]

Notification of compulsory licence to export under the Paragraph 6 System

[Name of exporting Member] has granted [a licence] [licences] to use the subject matter of a patent or patents solely for the purposes of production of [a pharmaceutical product] [pharmaceutical products] and [its][their] export under the WTO General Council Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health of 30 August 2003. The details of the [licence] [licences] granted are as follows:

- Name and address of the licensee(s): [ ]
- Product(s) for which the licence(s) has/have been granted: [ ]
- Quantity(ies) for which the licence(s) has/have been granted: [ ]
- Country(ies) to which the product(s) is/are to be supplied: [ ]
- Duration of the licence(s): [ ]
- *OPTIONAL [Any other licence conditions not set out above] [Other information, such as the patent number(s)]*

The licensee will post information before shipment on the quantities being supplied to each destination and the distinguishing features of the product(s) on the following website: [ ]

[Name, position and signature
of authorized government official]

VII.
Way Forward

Selected Issues for Consideration

- How to:
  - use the System as a practical procurement tool
  - integrate Ministries of Health and procurement agencies more actively in process
  - ensure that national implementing measures put in place an easy to use system
  - make best use of information resources
  - make participation economically viable and sustainable for potential suppliers
  - clarify that the use of the System is widely supported
- What kind of additional guidance is needed in order to facilitate implementation and use
- What concrete lessons can be drawn from past experiences

Possible "Sources of Inspiration"

WTO OMC

WORLD TRADE ORGANIZATION

IP/C/W/439
23 February 2005

(05-0748)

Council for Trade-Related Aspects of Intellectual Property Rights

Original: English

REPORT ON THE WORKSHOP ON THE WTO DECISION[1] ON ACCESS TO MEDICINES AT AFFORDABLE PRICES FOR COUNTRIES WITH NO OR INSUFFICIENT MANUFACTURING CAPACITIES, ORGANIZED BY THE COMMONWEALTH SECRETARIAT IN CO-OPERATION WITH THE ACP GENEVA OFFICE AND THE AGENCY FOR INTERNATIONAL TRADE INFORMATION AND COOPERATION (AITIC) (GENEVA 12-14 OCTOBER 2004)

The following communication, dated 9 February 2005, is being circulated at the request of the Delegation of Barbados on behalf of the Group of Commonwealth Developing Countries and the Commonwealth Secretariat.

WORLD TRADE ORGANIZATION

IP/C/W/618

1 November 2016

Page: 1/15

r Trade-Related Aspects of
al Property Rights

WTO SECRETARIAT TECHNICAL COOPERATION IN THE TRIPS AREA

NOTE BY THE SECRETARIAT

king Paper ERSD-2015-07 **31 July 2015**

World Trade Organization
Economic Research and Statistics Division

s://www.wto.org/english/res_e/reser_e
aps_e.htm

SPECIAL COMPULSORY LICENCES FOR EXPORT OF MEDICINES: KEY FEATURES OF WTO MEMBERS' IMPLEMENTING LEGISLATION

To Be Considered in Practice

- **Early notification of anticipated needs to share information about procurement:**
  - **No obligation to use System in the end**
- **Notification to increase bargaining power:**
  - **Example of Rwanda**
- **Measures to make System commercially viable:**
  - **Regional approaches and joint notifications to enhance economies of scale**
- **Potentially increasing need for the System:**
  - **New generations of patented medicines**
  - **In the event of a global pandemic**
- **For RTA waiver:**
  - **Possibility to support local production**