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## TRIPS & Public Health: Implementation of the Paragraph 6 System

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# Who Has Implemented the System?

\* Scope of the survey:

\* Only covers Members with specific implementing legislation

\* Not specifically addressed: general provisions in domestic laws that may serve to either import or export under CL

\* Implementing measures in at least 50 Members and 1 Observer (July 2014), including:

\* 34 industrialized country Members

\* 2 transition countries

\* 11 developing countries

\* 3 LDCs

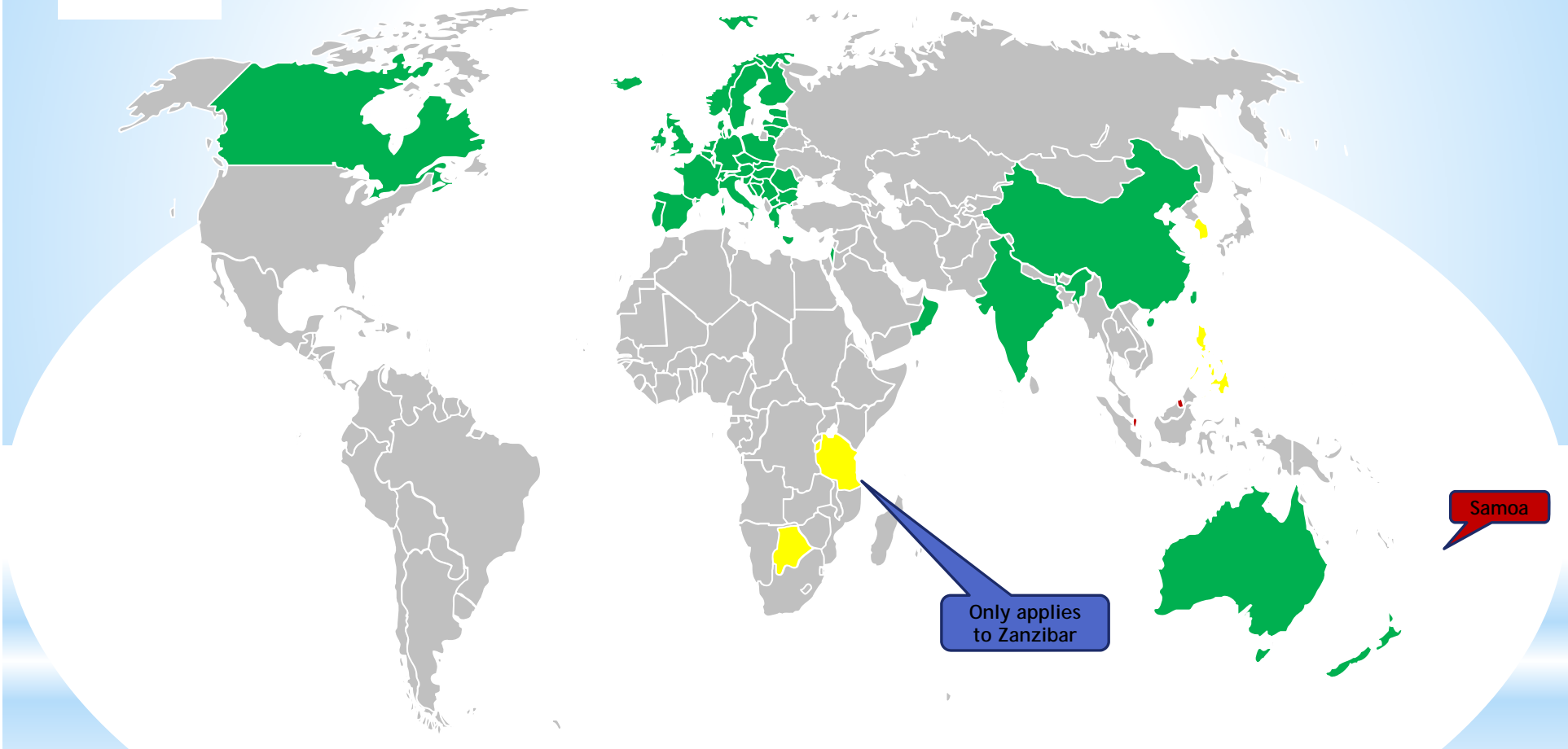
\* BUT: only 16 Members have formally notified measures to TRIPS Council

\* See regularly updated webpage:

[https://www.wto.org/english/tratop\\_e/trips\\_e/par6laws\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm)



# WTO Members' and Observer Implementing Measures



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



# Selected Key Features (1)

- \* Key features:

- \* Overview of how they have been handled in existing measures
- \* Also: issues for consideration in Members that wish to adopt implementing legislation

- \* Scope of specific implementing measures - three categories:

- \* Exclusively for export:

- \* Albania; Australia; Canada; China; EU (Regulation directly applicable in 28 member States); FYROM; Iceland; India; Jordan; New Zealand; Norway; Oman; (Serbia); Switzerland

- \* For import purposes only:

- \* Limited to situations of extreme urgency: Brunei Darussalam; Singapore
- \* Samoa

- \* For import and export purposes:

- \* Botswana; Burundi; Hong Kong, China; Korea; Philippines; Chinese Taipei; Tanzania (limited to Zanzibar)



## Selected Key Features (2)

- \* Diseases:

- \* Most measures refer to “public health problems” in general

- \* Products:

- \* Covered by product or process patents

- \* Where applicable, covered by SPC

- \* Some laws explicitly include active ingredients and diagnostic tool kits

- \* Eligible importers:

- \* WTO Members: LDCs and others that have notified intention to use Para.6 System

- \* Non-WTO Members: included by majority of implementing measures



## Selected Key Features (3)

### \*Pre-grant conditions:

- \* Almost all measures: prior efforts to obtain voluntary licence
- \* Notification by importing country in line with para.2(a) of 2003 Decision
- \* Where patent exists in importing country: (intention to) grant CL

### \*Quantity:

- \* In most cases: not to exceed importing country needs
- \* In some cases: to take account of CL granted elsewhere

### \*Duration:

- \* In one case: limited to two years, once renewable
- \* In some cases: limited to purpose for which CL was granted
- \* In some laws: possibility to terminate CL earlier



## Selected Key Features (4)

### \* Remuneration:

- \* No specific rules
- \* In line with para.3 of 2003 Decision
- \* Specific calculation methods:
  - \* <4% of price paid by importing country
  - \* Link to importing country level of development, contract value, humanitarian and non-commercial circumstances

### \* Regulatory approval:

- \* No specific laws in most WTO Members
- \* Canada: SQE standards as for domestic consumption
- \* EU: scientific opinion procedures, test data exclusivity waived
- \* CH: manufacturing approval
- \* Philippines: conformity with international quality standards; WHO prequalification for imported medicines



# Implementation ≠ Acceptance

Implementation	Acceptance
<ul style="list-style-type: none"><li>• Optional: no obligation to implement (or use) the System</li></ul>	<ul style="list-style-type: none"><li>• Follow-up to political commitment: legally binding commitment to make an additional public health-related flexibility available to Members</li></ul>
<ul style="list-style-type: none"><li>• Provides legal basis for use of System in a given WTO Member, in particular potential exporters</li></ul>	<ul style="list-style-type: none"><li>• Permanently incorporates additional CL mechanism in TRIPS</li></ul>

- Can be done at the same time or separately:  
General trend seems to be to accept amendment first (at least 41 Members) before considering domestic implementation





# Final Observations

- \* Implementing legislation adopted by major potential exporters makes sources of affordable medicines available to countries in need
- \* Implementation of the System can support local production in circumstances where the RTA waiver applies
- \* Members with implementing legislation: notify measures to TRIPS Council to enhance transparency and support capacity building
- \* Members considering adoption of implementing measures:
  - \* Consider how best to implement key features into domestic law
  - \* Compare with approaches taken by other Members
  - \* Aim for simple implementation
- \* Link to TRIPS amendment: acceptance creates legal certainty for Members that wish to implement the System into national law
- \* Link to use: dedicated WTO webpage offers model notifications to facilitate use of the System based on implementing legislation