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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

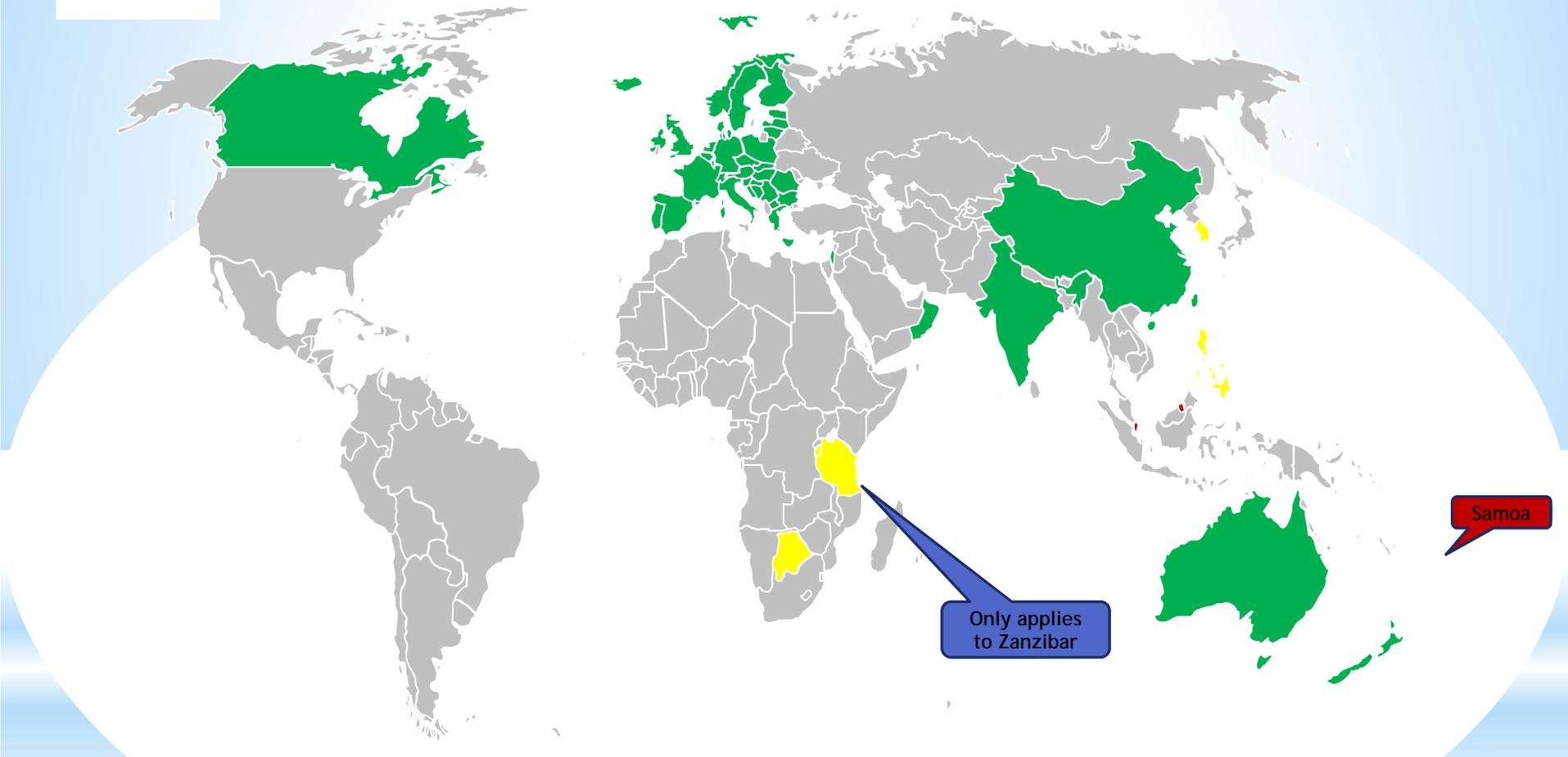
- * BUT: only 16 Members have formally notified measures to TRIPS Council

- * See regularly updated webpage:

- https://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm



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

- 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