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
- Only applies to Zanzibar
*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)
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
*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
**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

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<thead>
<tr>
<th>Implementation</th>
<th>Acceptance</th>
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<td>• Optional: no obligation to implement (or use) the System</td>
<td>• Follow-up to political commitment: legally binding commitment to make an additional public health-related flexibility available to Members</td>
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<td>• Provides legal basis for use of System in a given WTO Member, in particular potential exporters</td>
<td>• Permanently incorporates additional CL mechanism in TRIPS</td>
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<td>• Can be done at the same time or separately:</td>
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<td>General trend seems to be to accept amendment first (at least 41 Members) before considering domestic implementation</td>
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*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