

**APPENDIX II:  
PATENT LEGISLATION REVIEW**

The tables below indicate the findings of the patent legislation review, in which the patent law of a country is assessed against a number of key public health-related TRIPS flexibilities, in order to show the extent to which countries have incorporated the TRIPS flexibilities. Review asked the following questions:

1. Are pharmaceutical products patentable subject matter?
2. Are new use or 2<sup>nd</sup> use patents excluded under the patent law?
3. Is the early working exception specifically provided for in the patent law?
4. What other exceptions to exclusive patent rights are provided for in the patent law?
5. Which exhaustion regime is adopted in the patent law?
6. What are the grounds for the grant of compulsory licenses?
7. Is there a provision for government use or public non-commercial use of patents?
8. Is there a provision for data protection in the patent law?

The review is based the current laws in force.

**The total number of countries reviewed**

Asia	13	
Latin America/Caribbean		19
<u>Africa</u>	<u>17</u>	
<u>Total</u>	<u>49</u>	

**1. Are pharmaceutical products patentable subject matter?**

Pharmaceutical products	Asia		Latin America Caribbean		Africa		Total	% of Total
Yes	10	(77%)	18	(95%)	11	(65%)	39	80%
No	3	(33%)	0	(0%)	1	(6%)	4	8%
Unknown	0	(0%)	1	(5%)	5	(29%)	6	12%

**2. Are new use or 2<sup>nd</sup> use patents excluded under the patent law?**

Patentability: New use or 2 <sup>nd</sup> use patents	Asia		Latin America Caribbean		Africa		Total	% of Total
Excluded	2	(15%)	8	(42%)	0	(0%)	10	20%
Specifically allowed	2	(15%)	0	(0%)	1	(6%)	3	6%
Not excluded	7	(54%)	10	(53%)	11	(65%)	28	57%
Unknown	2	(15%)	1	(5%)	5	(29%)	8	16%
Allowed plus not excluded	9	(69%)	10	(53%)	12	(71%)	31	63%

**3. Is the early working exception specifically provided for in the patent law?**

Early working exception	Asia		Latin America Caribbean		Africa		Total	% of Total
Yes	4	(31%)	6	(32%)	5	(29%)	15	31%
No	7	(54%)	12	(63%)	11	(65%)	30	61%

Unknown	2	(15%)	1	(5%)	1	(6%)	4	8%
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**4. What other exceptions to exclusive patent rights are provided for in the patent law?**

Other exceptions specified:	Asia		Latin America Caribbean		Africa		Total	% of Total
Broadly worded provision*	3	(23%)	1	(5%)	5	(29%)	9	18%
Experimental/Scientific research	11	(85%)	19	(100%)	10	(59%)	40	82%
Education/Teaching	3	(23%)	14	(74%)	2	(12%)	19	39%
Private and non-commercial use	2	(15%)	14	(74%)	3	(18%)	19	39%
Use of patented self-reproducing biological material	0	(0%)	5	(26%)	1	(6%)	6	14%
None specified	1	(8%)	0	(0%)	3	(18%)	4	8%
Unknown	0	(0%)	1	(5%)	1	(6%)	2	4%

\*Broadly-worded provisions are those that provide for a limitation of patent rights to "acts done for industrial or commercial purposes".

**5. Which exhaustion regime is adopted in the patent law?**

Exhaustion regime	Asia		Latin America Caribbean		Africa		Total	% of Total
International	6	(46%)	13	(68%)	7	(41%)	26	53%
National	2	(15%)	4	(21%)	6	(35%)	12	24%
No explicit provision	3	(23%)	1	(5%)	1	(6%)	5	10%
Unclear/unknown	2	(15%)	1	(5%)	3	(18%)	6	12%

**6. What are the grounds for the grant of compulsory licenses?**

Compulsory license grounds	Asia		Latin America Caribbean		Africa		Total	% of Total
Failure to work/exploit	10	(77%)	14	(74%)	15	(88%)	39	80%
Anti-competitive practice	5	(38%)	14	(74%)	5	(29%)	24	49%
Dependent patents	7	(54%)	10	(53%)	10	(59%)	27	55%
Demand not met on reasonable terms	3	(23%)	6	(32%)	13	(76%)	22	45%
Public interest/ public non-commercial use	10	(77%)	15	(79%)	8	(47%)	33	67%
National emergency/ Extreme urgency	5	(38%)	11	(58%)	6	(35%)	22	45%
No provision	2	(15%)	0	(0%)	0	(0%)	2	4%
Unknown	0	(0%)	1	(5%)	0	(0%)	1	2%

\* This includes grounds listed under government use

\*\* Statistics on countries requiring delay before CL may be applied for on ground of failure-to-work: (9 Asia) + (13 Latin America/ Caribbean) + (13 Africa) = 35 countries

This represents, 71% of all countries, or 88% of countries with failure-to-work provisions.

**7. Is there a provision for government use or public non-commercial use of patents?**

Government use	Asia		Latin America Caribbean		Africa		Total	% of Total
Yes	7	(54%)	9	(47%)	17	(100%)	33	67%
No explicit provision	5	(38%)	8	(42%)	0	(0%)	13	27%
Unknown	1	(8%)	2	(11%)	0	(0%)	3	6%

**8. Is there a provision for data protection in the patent law?**

Data protection	Asia		Latin America Caribbean		Africa		Total	% of Total
Yes	6	(46%)	16	(84%)	6	(35%)	28	57%
No explicit provision	7	(54%)	3	(16%)	8	(47%)	18	37%
Unknown	0	(0%)	0	(0%)	3	(18%)	3	6%

Country response to question in TRIPS Council review of implementing legislation: "May later applicants rely on previous test data?"	Asia		Latin America Caribbean		Africa		Total	% of Total
Yes (or probably)	3	(23%)	4	(21%)	4	(24%)	11	(22%)
No, later applicants must supply "new" data	3	(23%)	5	(26%)	0	(0%)	8	(16%)
Not Answered/Unclear/ No WTO interview	7	(54%)	10	(53%)	13	(76%)	30	(61%)