

Annex to the TRIPS Agreement

1. For the purposes of Article 31bis and this Annex:

(a) "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration on the TRIPS Agreement and Public Health ([WT/MIN\(01\)/DEC/2](#)). It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included¹;

(footnote original) ¹ This subparagraph is without prejudice to subparagraph 1(b).

(b) "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification² to the Council for TRIPS of its intention to use the system set out in Article 31bis and this Annex ("system") as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system as importing Members³ and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

(footnote original) ² It is understood that this notification does not need to be approved -(b)2.3 ((a)6.9Tc

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(footnote original) ⁶ This subparagraph is without prejudice to Article 66.1 of this Agreement.

3. On 6 December 2005, the General Council adopted a Decision on the "Amendment of the TRIPS Agreement" to which the Protocol Amending the TRIPS Agreement was attached.³ The purpose was to make the waivers from paragraphs (f) and (h) of Article 31 of the TRIPS Agreement.

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