

WTO Members Agree on TRIPs and Public Health Text

After a flurry of eleventh hour negotiations, WTO Members on 30 August adopted the 16 December Decision on paragraph 6 of the Doha Declaration on the TRIPs (Trade-related Aspects of Intellectual Property Rights) Agreement and Public Health together with a statement by the TRIPs Council Chair Ambassador Vanu Gopala Menon of Singapore. The Decision spells out the conditions under which countries without pharmaceutical manufacturing capacity can import generic versions of drugs still under patent. Earlier attempts to adopt the Decision had foundered due to US opposition arising from pharmaceutical companies' fears that it could be abused. The negotiations were deadlocked, with developing countries adamant that the Decision was as far as they would go and the US insisting on more reassurance to protect research-based pharmaceutical companies.

The Chairperson's Statement, hammered out with the US, Brazil, India, South Africa and Kenya, allowed the 16 December Decision to be adopted without changes. The Statement notes Members' commitment to using the system established by the paragraph 6 Decision "in good faith to protect public health" and not as "an instrument to pursue industrial or commercial policy objectives". This, however is qualified by the phrase that these limitations must be *without prejudice to paragraph 6 of the Declaration on the TRIPs Agreement and Public Health* (see box). The statement goes on to stress the need for preventing diversion of cheap drugs (including active ingredients) to developed country markets, noting Members' understanding that "in general special packaging and/or special colouring or shaping should not have a significant impact on the price of pharmaceuticals". This differs from the Decision, which states that special packaging should only be required "provided that such distinction is feasible and does not have a significant impact on price".

The Statement also notes that Members will seek to resolve any issues arising from the Decision "expeditiously and amicably", including the possibility to call on the Director-General or the TRIPs Council Chair to find a "mutually acceptable solution" in case of concern over its implementation. Neither the Decision nor the Chair's Statement include references to WTO dispute settlement.

The Statement includes a list of 23 developed countries that have decided to opt out of using the system as importers. The 10 countries about to join the EU agree to use the system in case of national emergency only until they become members of the EU after which time they will not use the Decision at all. In addition, the following advanced developing countries have agreed not to use the system except in situations of national emergency or other circumstances of extreme urgency: Chinese Taipei, Hong Kong, Israel, the Republic of Korea, Kuwait, Macao, Mexico, Qatar, Singapore, Turkey and United Arab Emirates.

Developing Countries Wanted Their Interpretations on Record

In meetings before the adoption of the Decision and its accompanying Statement, Venezuela and the Philippines had raised questions regarding the legal weight of the Chair's Statement. Ambassador Sergio Marchi of Canada described it as a "political statement", implying that the text was not legally binding, according to trade sources. During a final informal General Council meeting on 30 August, Kenya and South Africa employed all the eloquence they could muster to convince such developing countries as the Philippines, Argentina, Cuba and others, that the Chair's Statement would not jeopardise their rights. Multiple formal interpretative statements, which a number of developing countries wanted on record when the Statement was first circulated, would only create further uncertainty, they argued. The Philippines, for instance, in an earlier prepared statement had pointed out that the Chair's text did not reflect the draft Decision's 'best endeavour' language regarding measures to prevent diversion. In the end, the Statement was adopted without Member interpretations.

Civil Society Groups, Industry Split over Chair's Text

Civil society groups, including Médecins sans Frontières (MSF), Oxfam, Health Action International, Third World Network, Health GAP and Consumer Project on Technology, strongly rejected the Chair's Statement, denouncing the conditions it imposes as a discouragement for developing countries to use the system. Describing the 16 December Decision as "a monstrosity

that seems to be designed to be a solution that won't work", Ellen 't Hoen from MSF noted that "the proposed deal poses so many hurdles and hoops to jump through that we are really worried it may not work at all". She also pointed out that the TRIPs & health discussion seemed to have lost its focus, being more about giving comfort to the pharmaceutical industry than about access to medicines. Commenting on the Statement, Ms 't Hoen also criticised the apparent assumption that protecting public health and pursuing industrial or commercial objectives were contradictory objectives.

Harvey Bale, Director-General of the International Federation of Pharmaceutical Manufacturers Associations, rejected the groups' criticism, saying the text added "clarity to the focus on the neediest."

"We recognise that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPs Agreement. We instruct the Council for TRIPs to find an expeditious solution to this problem and to report to the General Council before the end of 2002."

Paragraph 6 of the Doha Declaration on TRIPs and Public Health

Such a solution was needed to overcome the limitation in TRIPs Article 31(f), which requires manufacture under compulsory license to be "predominantly for the domestic market of the Member authorising such use."