Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION

PRESS RELEASE

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WTO COMPULSORY LICENSES SYSTEM IS UNWORKABLE AND WILL NOT IMPROVE ACCESS TO MEDICINES

The WTO's 2003 August 30 Decision concerning compulsory licenses is complicated, unworkable and unable to deliver any significant improvement in access to medicines. Policy makers should significantly reform the provision as well as concentrate their efforts on reducing threats to access to generic medicines that feature in bilateral trade agreements. This was the key message expressed by Greg Perry, Director General of the European Generic medicines Association (EGA), during his presentation today at the 2008 WTO Public Forum.

"The 2003 August 30 Decision and the implementing EC Regulation 816/2006 on compulsory licenses of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems have been "marketed" as a major breakthrough for access to medicines, but unfortunately this is not the case. The EC Regulation, like similar provisions in other countries, is likely to have only a marginal impact because it is based on the false assumption that companies will be commercially attracted to it as it stands."

Mr Perry went on to explain that he did not intend to undermine the August 30 Decision, but rather "to put it into the context of economic and commercial reality." The provisions he said "act more as a straightjacket than an incentive" since the legal and administrative requirements are extremely complicated and burdensome. Moreover it is unlikely that any company would make major investments to develop, manufacture and market a medicine if it is limited for use in only one country, is restricted by volume and low sales, lacks security of payment, and has no clear long-term market prospect. Originators can at least subsidise their sales to least developed countries by selling the same product in other regions—an option not available to the compulsory license holder. To date no company has used the provision in the EU, while one company in Canada has used the WTO system, only to find the process extremely frustrating and restrictive. In this context, and in order to create a real incentive to improve access to medicines, Mr Perry proposed linking the compulsory licenses to procurement polling and to funding schemes/assistance for the companies wishing to use the system. A regional—as opposed to a country—basis with long-term commitments should also be part of the reform.

Perry added that policy makers should be more concerned by the growing trend to add "TRIPS Plus" provisions[1] such as patent linkage, data exclusivity and patent extensions into trade agreements as was highlighted by European Parliament's Resolution of 12 July 2007 on the TRIPS Agreement and access to medicines[2].

Finally, concerning the ACTA[3] trade agreement, which is currently being negotiated, Mr. Perry pointed out that counterfeiting of medicinal products must be tackled strictly as a public health issue and not as an intellectual property issue, in line with the statements of the WHO. Actions should be aimed at reinforcing controls in the supply chain by regulatory agencies, and not by increasing patent protection or by introducing harsher civil measures to enforce patents. Last but not least, a clear definition of "counterfeiting" based on public health concerns is essential.

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[1] EGA Position Paper, *Access to Generic Medicines and "TRIPS Plus" Provisions*, available on-line at : http://www.egagenerics.com/pol-positions.htm#TRIPS_Doha

[2] Available on-line at: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2007-0353+0+DOC+XML+V0//EN&language=EN

[3] Anti Counterfeiting Trade Agreement- ACTA

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