



Making Medicines Affordable

Presentation by Greg Perry, Director General of the European Generic medicines Association (EGA) to the European Parliament's Mini-Hearing on TRIPS and Access to Medicines – 5 June 2007 Brussels

In my short presentation I would like to focus on two issues:

- a) The lack of applicability of both the Paragraph 6 Doha Agreement and the corresponding EU Regulation,¹
- b) The danger of TRIPS-Plus provisions and why these must not be part of European bilateral trade agreements.

The Paragraph 6 Agreement and the implementing EU Regulation have been “marketed” as a major breakthrough for access to medicines. Unfortunately this is not the case and, as our Association indicated during the adoption of the Regulation, it is likely to have only marginal impact. This is because it is based on a false assumption that companies will be commercially attracted to the Regulation as it stands.

The provision, and more importantly the implementing Regulation, have many intrinsic flaws:

- Firstly, it only provides a legal framework - nothing more i.e. on its own it means very little.
- Secondly, the formula for using the Regulation is very legally complicated. The Regulation looks like it has been designed to put off, rather than attract, alternate manufacturers. The European Commission told us that they had little room for manoeuvre since they had to follow closely the text of the Paragraph 6 Agreement. If so, that questions the applicability of Paragraph 6 itself.
- Thirdly, the Regulation is not based on economic reality. It is unlikely that any company in Europe would develop, manufacture and market a product if it is restricted for use in only one country, with restricted volume and low sales, lack of security of payment, and with no clear long-term market prospect. At least originators can subsidise their sales to least developed countries by selling the same product in other countries - an option not available to the CL holder.
- Fourthly, the Regulation is not linked to any incentive or funding scheme. It is a stand-alone Regulation. For the system to create a real incentive to improve access to medicines then the CL should be linked to funding and/or assistance to encourage manufacture and guarantee payment.

¹ *EC Regulation 816/2006 of 17 May on compulsory license of patents relating to the manufacture of pharmaceutical products for the export to countries with public health problems*

It is not my aim to undermine the Paragraph 6 Agreement. My intention here is to put Paragraph 6 and the current Regulation into the context of economic and commercial reality.

It is also important to realise that if Paragraph 6 has any hope of success then the pre-existing provisions within Article 31 of TRIPS, which allows any WTO country to issue a compulsory licence at any time for domestic use and /or import, must also be fully supported by developed countries. Significantly, in the case of national emergency it must be understood by policy makers that there is no requirement under TRIPS for prior negotiation with the patent holder and the country itself defines what constitutes an emergency. The lack of support among many western policy makers for these pre-existing provisions adds further to the lack of confidence in Paragraph 6 and in the Regulation.

However, possibly of greater concern is the growing trend to add TRIPS Plus provisions into trade agreements. This has a major negative impact on access to medicines. The trend is led by the USA, who have sought to:

- Accelerate the introduction of product patents before the required date of implementation;
- Introduce data exclusivity provisions to compensate for lack of product patent;
- Introduce patent linkage with the registration of generic medicines, which would prevent the registration and authorisation of generics until after the expiry of patents, which would considerably delay generic market entry;
- Introduce patent extensions beyond the current 20 years agreed in TRIPS.

All these provisions essentially damage the balance that was carefully negotiated in TRIPS and clearly limit access to health in economically vulnerable countries. From our own standpoint as European generic medicine manufacturers, such TRIPS Plus policies if introduced in Russia and CIS countries, Middle East and Asian markets would damage our own efforts to develop markets in these developing economies.

It is very significant that the new leader of the US House of Representatives has launched a Bill in the USA to bring an end to several of these TRIPS Plus conditions in future US Free Trade Agreements. It would therefore be appropriate that the European Parliament and Commissioner Mandelson also made such a clear statement on this issue as well as ensuring the productive use of the FTAs to encourage the full implementation of the Doha declaration on TRIPS and Public Health. It should be recalled that former Commissioner Lamy also made such commitment during his term of office.