Making Medicines Affordable

Mr. László Kovács
European Commissioner for Taxation and Customs Union
Directorate General for Taxation and Customs Union
Rue de la Loi, 200
1049 Brussels

Brussels, 20 February 2009

Dear Mr. Kovács,

On behalf of the European Generic medicines Association, I am writing to express the concern of the European generic medicines industry on the recent detention by Dutch customs authorities of medicines in transit in the EU from India to Brazil, for alleged patent infringement on the basis of the Council Regulation (EC) No 1383/2003.

Firstly I would like to state that we fully support seizures of counterfeit medicines and are completely in favour of both criminal and civil sanctions against the organisations responsible for trading such products.

However, alleged patent infringement cannot be confused with counterfeit and public health issues and in this context, the EGA supports the WHO IMPACT definition of counterfeit medicines[1] that was approved in Hammamet (Tunisia) on 7 December 2009 and which received the support of the EU. Whilst we understand that the EU is entitled under TRIPS to detain products under alleged patent infringement, we would ask for caution in this area to avoid detention that has no fundaments and indeed presents no public health risk.

Moreover, whilst we understand too that suspension of release or detention of transit goods is possible under the EC Regulation No 1383/2003, and is allowed under Article 51 of TRIPS, we are equally aware that this goes beyond the obligations required under the TRIPS Agreement which in the footnote of **article 51** says that "*it is understood that there shall be no obligation to apply such procedures to imports of goods put on the market in another country by or with the consent of the right holder, or to goods in transit*".

[1] *The term counterfeit medical product describes a product with a false representation of its identity and/or source. This applies to the product, its container or other packaging or labelling information. Counterfeiting can apply to both branded and generic products. Counterfeits may include products with correct ingredients/components(4), with wrong ingredients/components, without active ingredients, with incorrect amounts of active ingredients, or with fake packaging.*

Violations or disputes concerning patents must not be confused with counterfeiting of medical products. *Medical products (whether generic or branded) that are not authorized for marketing in a given country but authorized elsewhere are not considered counterfeit. Substandard batches or quality defects or non-compliance with Good Manufacturing Practices/Good Distribution Practices (GMP/GDP) in legitimate medical products must not be confused with counterfeiting.*

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Furthermore, Article 41 of TRIPS states that any IP enforcement provisions should "be applied in such a manner as to avoid the creation of barriers to legitimate trade".

We are also concerned that such detention provisions on transit goods are also being requested by the EU to third countries as part of EC Free Trade Agreements. Again whilst we would support this for alleged counterfeit products, we are most concerned that if applied to medicinal goods which are covered by patents in the transit country but patent free in the country of origin and destination, this will effectively create a barrier to the trade in legitimate generic medicines worldwide. This we believe is contrary to Article 41 of the TRIPS agreement.

In this context, we would ask the EU not to apply the provisions of the EC Regulation No 1383/2003 in the case of the legitimate trade of generic medicines in the EU, and neither to include these provisions in the current negotiations of the EC Free Trade Agreements.

We believe that the EU is genuine in its support of a balanced Agreement on Trade and Intellectual Property Rights, of the Doha Declaration and of the WTO August 30th Decision and by no means do we endorse recent criticisms of the EU in this area, however we ask the EU to initiate an open dialogue with other countries and interested parties so as to resolve this situation.

Yours sincerely,

Greg Perry
Director General
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The EGA is the official representative body of the European generic and biosimilar pharmaceutical industry, which is at the forefront of providing high-quality affordable medicines to millions of Europeans and stimulating competitiveness and innovation in the pharmaceutical sector. Generic Medicines account for almost 50% of medicines dispensed in the EU.

CC Mr. David Martin, MEP
Mrs. Catherine Ashton, Baroness Ashton of Upholland*, European Commissioner for TRADE*
Mr. David O'Sullivan Director General of the European Commission for TRADE

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