



**EUROPEAN COMMISSION**  
DIRECTORATE-GENERAL  
TAXATION AND CUSTOMS UNION  
Customs Policy  
**Protection of the EU and its citizens**

Brussels, 14/09/2009  
**TAXUD/C3/2114/2009-EN**

## **JOINT STATEMENT**

### **Dialogue between customs administrations of the EU and pharmaceutical companies: - 14 September 2009**

A meeting took place on 14 September 2009, between the European Commission, Customs experts representing the Member States of the EU and private representatives of the European Pharmaceutical Sector. Certain cases involving the detention of shipments of pharmaceutical products in transit through the EU have caused concern, as it was suggested that such measures were hindering legitimate trade in generic medicines. Participants discussed customs measures relating to the enforcement of patent rights at the border, in particular the need to protect such rights effectively, whilst ensuring that the legitimate flow of and access to genuine generic products from manufacturer to customer outside the EU was not restricted.

Participants recalled and welcomed the statement made by EFPIA in March 2009 in which it affirms that "it is neither the policy nor practice of EFPIA members to encourage Member States to use the powers of detention available to them to prevent the flow of legitimate generic products from manufacturer to customer outside the EU. This applies even where goods transit through EU countries where intellectual property legislation could be applied. Nor is the intention of EFPIA members to restrict access to medicines in developing countries".

The participants also recognised the important role Customs Authorities play in the fight against global trade in illegal medicines which also involves controlling goods in transit. On particular occasions this will require the temporary detention of some products for the purpose of verification. Where the temporary detention of a product is strictly required, participants agreed that it is imperative to keep the timeline to a minimum. To this end, both industry and customs commit to ensuring the fast and efficient application of the border measures.

Against a background of ever-increasing trade flows and rapid decision making with limited information, effective and proportionate customs enforcement measures require monitoring their use, as well as strong and dynamic cooperation between all stakeholders. Participants highlighted the role that the owner, the shipper and/or the recipient of genuine products in transit can take in ensuring that all necessary

information is available in order for a rapid decision to be taken regarding the status of the goods in transit.

The outcome of the dialogue is further summarized in the following conclusions:

1. In the context of customs enforcement of patent rights, it is essential to have the correct balance between different interests concerned in the trade of medicines, including generics.
2. It is important to respect the right of Customs Authorities to control goods in transit and ensure that measures can be taken against global trade in pharmaceutical products suspected of infringing intellectual property rights.
3. European Customs Authorities and pharmaceutical companies reaffirm their commitment to continue to apply enforcement procedures in a way as to avoid the creation of undue barriers to legitimate trade.
4. European Customs Authorities will pay particular attention to cases involving the transit of medicines through the Community Customs Territory.
5. European Customs Authorities will ensure regular contacts with all stakeholders.
6. Co-operation and mutual administrative assistance between Customs Authorities is an important tool in combating goods infringing intellectual property rights.
7. European Customs Authorities shall act where there is a suspicion of an infringement of the applicable intellectual property rights law, in accordance with the provisions of Regulation 1383/2003, according to available information provided by the applicant, or otherwise obtained.
8. Where the detention of pharmaceutical products has taken place under EC Regulation 1383/2003, customs and the right holder concerned will act in swift and coordinated fashion.
9. Customs and the right holders will cooperate closely to accelerate wherever possible, the procedures for release of goods where no further proceedings are initiated. To this end:
  - Customs Authorities should immediately notify the right holder by the most expeditious means that the detention has occurred;
  - The right holder should take a decision whether or not to initiate legal actions and notify Customs authorities of any decision not to initiate legal actions as soon as possible and always within the legal deadline from the receipt of notification of detention;
  - Customs Authorities should not grant an extension of the ten working days period automatically, but based on a duly motivated application by the right holder and having in mind the principles underlying this joint statement;
  - If the right holder has no intention to initiate legal actions related to a particular shipment of pharmaceutical products, the right holder should not make use of the provisions implementing the simplified procedure and should

formally notify this circumstance to the Customs Authorities to allow them to release the goods in question;

- Conversely, if the declarant or holder of the goods objects to the simplified procedure, the right holder is expected to initiate legal procedures as soon as possible unless new evidence allows for the right holder to determine that such procedures are not appropriate, in which case the right holder should immediately notify this change in circumstances to the Customs Authorities to allow them to release the goods in question;
- Where the right holder decides not to pursue action, Customs Authorities shall release the pharmaceutical products immediately, insofar as other customs requirements are met.

It is recalled that the owner of the goods may seek legal redress if the goods are found not to infringe an IP right or if the suspension of the goods is discontinued.