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Explanatory note on the application of Council Regulation (EC) No 1383/2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights[1]

Customs control over goods which are suspected of infringing intellectual property rights is a key measure to combat such infringements and to respond to growing security and safety concerns linked to international trade.

Certain instances of customs detention[2] of shipments of pharmaceutical products in external transit/transhipment through the EU, which occurred at the end of 2008, have given raise to concerns among certain developing country Members of the WTO, MEPs, NGOs and the civil society. It was claimed that such measures could hamper legitimate trade in generic medicines, thus contradicting the EU commitment to facilitating access to medicines in the developing world.

It is essential to recall that the system of border measures as established under Regulation (EC) No 1383/2003 is primarily intended as an instrument to enable the right holders to initiate proceedings to determine whether an intellectual property right has been infringed. Furthermore, in order to avoid excessively affecting the legitimate trade in goods, the Regulation explicitly foresees the civil liability of entities that use the provisions of the Regulation wrongly or abuse them[3]. The rules governing right holder's civil liability are those defined under national law.

Rules implementing Regulation (EC) No 1383/2003 are laid down in Commission's Regulation (EC) No 1891/2004[4].

Any final decision on the existence of an infringement will be made by national courts and based on the national laws or as appropriate EC legislation that define the scope of protection of the different intellectual property rights. In the case of a suspected patent infringement, it will be up to the judiciary and the legislation of each EU Member State to define whether or not the national patent rights extend patent protection to goods in transit. This means that different Member States may reach different conclusions.

The present explanatory note aims at:

1) Recalling the rules applicable to products protected by intellectual property rights, including pharmaceutical products in transit or transhipment through the EU territory,

2) Clarifying the relationship between the Doha Declaration on TRIPS and Public Health and Regulation (EC) No 1383/2003, and

3) Ensuring that Regulation (EC) No 1383/2003 is not abused in a manner that could become a barrier to legitimate trade in generic medicines.

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[1] OJ L 196 of 2.8.2003, p. 7.
[2] Pursuant to Regulation (EC) No 1383/2003.
[3] Article 19(3) of Regulation (EC) No 1383/2003.
[4] OJ L 328 of 30.10.2004, p. 16.

The Customs Authorities of the Member States are invited to pay particular attention when controlling pharmaceutical products in transit in order to avoid actions that would delay or cause unnecessary disruption of legitimate trade in generic drugs. In all cases, and particularly with regard to pharmaceutical products, when the right holder informs the Customs Authorities that he does not intend to pursue the case, it would be beneficial if the Customs Authorities could act as swiftly as possible to release the goods in order to enable the latter to reach their final destination unless the goods in transit are suspected of breaching another EU or national law.

Furthermore, in the particular case of suspected infringements of the national patent laws by goods in transit or transhipment, it would be useful if the Customs Authorities could be aware of the substantive applicable regime. Indeed, as mentioned above, in several EU Member States national law provides that patent rights protection does not extend to goods in transit.

More generally in the context of pharmaceutical goods, it is recalled that the European Federation of Pharmaceutical Industries and Associations (EFPIA) has made an important statement on 13 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 it the intention of EFPIA members to restrict access to medicines in developing countries*".

This statement is consistent with EU efforts on international level with respect to access to affordable medicines and in particular the Doha Declaration on the TRIPS Agreement and Public Health, and indeed the EC policy on public health (Article 152 EC Treaty).

In practice, this will be particularly relevant in the following situations:

- **Action based upon an application**

Once an application for action has been granted[5], Customs Authorities are required to detain or suspend the release of any goods that are suspected of infringing an intellectual property right covered by the application[6].

Under Article 9(2) of Regulation (EC) No 1383/2003, Customs Authorities are required to give notice of the interception to the right holder, as well as the declarant or holder of the suspected goods. It would be beneficial if such notification could be made as promptly as possible and, if possible, no later than in two working days from the date of the interception.

Strict time limits are imposed on the period for which Customs Authorities are allowed to suspend the release of suspected goods or detain them. This period is initially restricted to 10 working days from the receipt of notification of interception, although it may be extended by a further maximum of 10 working days in appropriate cases[7]. This means that in practice such

[5] Article 8 of Regulation (EC) No 1383/2003.
[6] Article 9(1) of Regulation (EC) No 1383/2003.
[7] Article 13(1) of Regulation (EC) No 1383/2003. For perishable goods, the deadline is reduced to 3 working days.

an extension should not be automatic but based on a duly motivated application by the right holder.

- ***Ex officio* action**

The possibility of *ex officio* action by the Customs Authorities (without prior application by the right holder) is also foreseen by Regulation (EC) No 1383/2003[8]. In such cases Customs Authorities have to have sufficient grounds for suspecting that goods infringe an intellectual property right under national law or EC law.

To ensure compliance with the requirements of Article 4(1) of Regulation (EC) No 1383/2003 Customs Authorities must promptly notify the right holder of the suspected infringement in order to allow the right holder to submit an application for action under Article 5 of the Regulation. The Customs Authorities must also inform the declarant or holder of the goods, if they are known[9].

The period for which goods may be held without an application for action by the right holder is limited to three working days from the moment of receipt of the notification by the right holder.

- **Simplified procedure**

For those Member States which have adopted implementing measures with regard to the simplified procedure, the following rules apply.

A simplified procedure allows Customs Authorities, with the right holder's consent, to have suspect goods abandoned for destruction under customs control without previous judicial determination on whether an intellectual property right has been infringed under EC or national law[10]. If, however, a person with an interest in the goods (i.e. the declarer, holder, or owner of the goods) contests the destruction, it is necessary to follow the standard procedure by instituting proceedings to determine whether an intellectual property right has been infringed[11].

Article 11 provides that the destruction of suspected goods under the application of the simplified procedure shall in principle be applied under the right holder's sole responsibility.

For the simplified procedure to be carried out, the right holder must inform the Customs Authorities in writing within the prescribed period that the goods in question infringe an intellectual property right. The right holder must also provide the Customs Authorities with a written agreement from the declarant, holder or owner of the goods to abandon the goods for destruction.

The agreement is, in principle, to be presumed in cases where the declarant, holder or owner of the goods has not specifically opposed destruction within the prescribed period. The prescribed period for the simplified procedure, as for the standard procedure, is initially restricted to 10 working days from the receipt of notification of interception, although it may

[8] Article 4 of Regulation (EC) No 1383/2003.
[9] Article 9(2) of Regulation (EC) No 1383/2003.
[10] Article 11(1) of Regulation (EC) No 1383/2003.
[11] Article 11(2) of Regulation (EC) No 1383/2003.

be extended by a further maximum of 10 working days in appropriate cases. In the case of pharmaceutical products, if the right holder decides to pursue the simplified procedure without specific reaction from the declarant, holder or owner of the goods, the Customs Authorities are invited to pay particular attention to such a situation and the possible consequences of the destruction of the products.

- **Liability of right holders**

Right holders have to provide to Customs Authorities a declaration accepting liability towards, *inter alia*, the owners of the goods if the goods are found not to infringe an IP right or if the suspension of the goods is discontinued due to an act or omission of the right holder[12]. In these situations the owner of the goods may seek legal redress.

Furthermore and in accordance with Article 19(3), civil liability of the right holder is regulated by the law of the Member State in which the goods in question were placed under suspension.

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[12] Article 6(1) of Regulation (EC) No 1383/2003.