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INTA Response to DG Enterprise & Industry's Public Consultation in Preparation of a Legal Proposal to Combat Counterfeit Medicines for Human Use: Key Ideas for Better Protection of Patients against the Risk of Counterfeit Medicines

8 May 2008

The International Trademark Association welcomes the opportunity to provide its views to the public consultation on key ideas for amending the European Union's regulatory framework for medicinal products in an effort to combat the counterfeiting of medicinal products.

The sale and distribution as well as the transshipment of counterfeit medicinal products pose a serious and grave threat to public safety and health. INTA takes the view that measures should be taken to strengthen the integrity of the supply.

Our comments are limited to the issues raised in Sections 4.1.3 and 4.2 of the Public Consultation Document. INTA takes no position with respect to issues raised in the Consultation Document that are outside of the context of trademark rights. In particular, INTA will not comment on aspects aiming at securing the integrity of the supply chain: however, INTA generally agrees that certain measures can, and should, be taken to strengthen the supply chain.

General Comments

We agree with DG Enterprise and Industry that the sale and distribution of counterfeit medicines poses a severe threat to public health. The statistics support the notion that the threat is only increasing. The Commission's noted trends should certainly serve to reinforce the severity of this issue and compel the EU to take thoughtful and appropriate action to combat this challenge. The failure to act will only lead to a larger problem which will become more difficult to address.

The Public Consultation Document raises the concern that Member States will soon take individual measures to address this problem, resulting in varying levels of protection and possibly more confusion in the marketplace. INTA also strongly supports the coordination, at the regional and international level, of efforts to combat counterfeit medicinal products. This approach seeks to better align the various legal frameworks and promote best enforcement practices. INTA agrees that any action is more appropriately taken at the EU level to avoid different levels of protection in the different Member States. This approach also avoids the creation of confusion for manufacturers and distributors of medicinal products alike.

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Commission's Proposed Areas of Regulation

The Commission identified three areas of regulation for medicinal products in the Public Consultation Document. INTA only provides comments on the first and second area of regulation, as detailed below.

1. Medicinal Products Placed on the Market

Under the first area of regulation in Section 4.1, the Commission proposes tightening the requirements for manufacturing medicinal products, placing such products on the market and conducting inspections of such medicinal products. As is clear to the Commission, the imposition of additional regulations should involve a careful consideration of the expected benefits of such regulation versus the costs, not only to the manufacturer of the medicinal products, but also the public at large. INTA has long sought to prevent the sale of counterfeit products, in particular counterfeit medicinal products, because of the threat to patients consuming such products.

For the purpose of this proposal, INTA limits its commentary to Section 4.1.3.

Section 4.1.3 seeks to improve product integrity through the utilization of a unique seal on the outer packaging of the medicinal products. This regulation would use a risk-based approach and INTA does not object to this approach. A risk-based approach would utilize a proper cost-benefit analysis to determine the categories of medicinal products that are frequently targeted by counterfeiters. However, INTA provides the following comments regarding this proposal.

The Public Consultation Document states that "the right to open the seal would be restricted to the market authorisation holder and the end user (hospital, health care professional or patient)." INTA is concerned about the use of the phrase "*market authorisation holder*". The market authorisation holder would be allowed to open the outer packaging, thereby breaking the outer seal. It is clear that the end user, whether it is a hospital, health care professional or patient, needs the ability to break the outer seal in order to use the medicinal products. It is equally clear that the trademark owner and other parties with his authorisation (like a licensee) must have the right to break the outer seal. A trademark is a source identifier and the trademark owner needs to control the quality of medicinal products offered under its brand. However, it is not clear why other third parties, without being authorised by the trademark owner, would need the right to break the outer seal.

The term "market authorisation holder" that is currently proposed is not only referring to the trademark proprietor but can be quite broad, including several different participants in the supply chain that are not involved in the manufacturing and first distribution of the original medicines, such as wholesalers and distributors.

By using the broadly defined term "market authorisation holder", the number of participants that are authorised to break the outer seal would be expanded and the supply chain effectively breaks down. This breakdown will certainly weaken the effectiveness of this regulation jeopardizing the health and safety of the public.

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INTA requests that the definition of market authorisation holder be clearly defined and limited, as much as possible, preferably as being the trademark owner and parties with his authorisation. Otherwise, there is a risk that the regulation will not be effective. The Commission rightfully recognised this concern by acknowledging the risks associated with repackaging. In repackaging, the original outer packaging might fall in the hands of and be utilized by counterfeiters.

2. **Medicinal Products Brought into the Community without being placed on the market (Section 4.2)**

The key ideas for changes to EC legislation are to clarify Directive 2001/83/EC *"to the effect that imported medicinal products intended for export…are subject to the rules for imports of medicinal products*." As the Commission is aware, there is a serious influx of counterfeit medicinal products through the EU. As the Commission indicates, the divergent enforcement of current legislation across the EU has led to breaches of legal requirements and has limited its effectiveness to adequately address this problem. INTA views the current situation as an opportunity to introduce new requirements to strengthen the EU's borders and strengthen the rights of brand owners to address the issue of transshipments.

INTA agrees that one way to combat counterfeits more effectively would be to ensure that Directive 2001/83/EC also applies to imported medicinal products intended for export. Placing more strict regulatory rules for such medicines will make it more difficult for counterfeiters to comply and thus will have a discouraging effect.

When starting from a trademark law point of view, counterfeit medicines manufactured *in* the EU and meant for export can be opposed by the trademark proprietor (cf. article 5 section 3 under c of Council Directive 89/104). However, a fast growing problem that by its very nature has a severe impact on health, safety and related consumers' interests is the *transshipment* of counterfeit medicines through the EU – medicines not manufactured in the EU but in a third country and shipped through the EU destined for another third country. The counterfeit goods are put under EU Customs procedures (such as warehousing, external transit or inward processing relief) whereby the counterfeit medicines are, for Customs purposes, deemed not imported in and not placed on the EU market.

Since 2003, Customs have been able to detain and undertake action against such transshipped counterfeits on the basis of Council Regulation 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. Under this Regulation, Customs inform the trademark proprietor of the detention of counterfeit medicines, allowing legal action to be taken resulting in destruction of the counterfeits.

However, the ECJ has recently decided two cases (*Class International*, case C-405/03 of October 18, 2005 and, in particular, *Montex/Diesel*, Case 281/05 of November 9, 2006) from which it seems to follow that whilst Customs are able to detain transshipment of counterfeit medicines on the basis of Regulation 1383/2003 and to inform the brand owner of the detention in order to enable the trademark owner to undertake action, the trademark proprietor can only oppose the offering or the sale of such goods *when it necessarily entails the putting of those goods on the market in the Community*.

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The negative consequence of these ECJ rulings based on the Trademark Directive (Council Directive 89/104) may be very well that in the event of transshipment of counterfeit goods there is no remedy left for the trademark proprietor under Regulation 1383/2003 to undertake action against such infringing goods. These decisions, holding that goods imported for export do not "use" the trademark in that country, have set a threshold for the trademark proprietor which is hardly possible to meet in the action against trade of counterfeit medicines through the EU. In other words, if according to these decisions the trademark is not in use in the EU on transshipped goods, then arguably it cannot be trademark infringement OR a counterfeit, thereby negating application of Regulation 1383/2003 to those goods.

It goes without saying that such transshipped counterfeit medicines may severely jeopardize public health and safety, even if they are not destined for the EU market. In a sense, the good name or "trademark" of the EU is being misappropriated by those who transship counterfeit medicines, by misleading others into believing such medicines originate from the EU. Traders of such counterfeits do benefit from the EU Customs regime and are –in fact- able to trade the counterfeit within the EU Customs zone and are by definition able to change the original destination of such counterfeit medicines. Thus, in that sense the EU Customs framework provides a safe harbor to counterfeit trade. Additionally, this practice also is injurious to legitimate European exporters as the reputation of all European exports may be threatened.

The application of Directive 2001/83/EC to imported medicinal products intended for export will help to close a potential loophole for transshipped counterfeit medicines created by these two ECJ rulings. It will also prevent counterfeiters from taking advantage of the current legal gap and the EU territory as a legitimate hub for their criminal activities with global impact. Where consumer health and safety is at stake as in the case of counterfeit medicines, the EU should not allow any *landing* of counterfeit transshipments into the EU and INTA believes that the EU should close its borders for counterfeit transshipment. In this respect INTA also believes that since illicit trade in medicines is a world wide trade which affects public safety and health globally, the EU should not limit the effective action radius to counterfeit products that are only destined for the EU but should therefore also allow action against counterfeit that during its transshipment benefit from EU Customs provisions.

Further, INTA advocates that both Customs Authorities and Health Authorities should be granted broad competence and responsibilities when dealing with transshipped counterfeit medicines, being assigned the common goal of preventing these goods from being moved through logistic facilities located in the EU.

While we understand that this is not the remit of this consultation, INTA would also support additional legislation clarifying the status of trademark Regulations and Directives for all goods, not just medicines being transshipped. INTA believes that the current transshipment of illicit trade via the EU calls for new additional legislation that allows the trademark proprietor to undertake action against such transshipments.

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About INTA

INTA is a membership association of more than 5,500 trademark owners and professionals, from more than 190 countries including all 27 EU Member States. INTA is dedicated to the support and advancement of trademarks and related intellectual property as elements of fair and effective national and international commerce. INTA has several committees that focus on areas and issues directly related to counterfeiting and medicinal products. INTA's Anti-counterfeiting and Enforcement Committee, Parallel Imports Committee, and Legislation and Regulation Committee-Pharmaceutical Subcommittee have contributed to the comments provided herein.

INTA has consistently provided the European Commission with comments and support on a variety of intellectual property and counterfeit-related issues and we remain at your disposal to provide you with further information on this and other relevant issues.

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