Making Medicines Affordable

EGA COMMENTS ON THE CONCEPT PAPER ON THE DELEGATED ACT ON THE CRITERIA TO BE CONSIDERED AND THE VERIFICATIONS TO BE MADE WHEN ASSESSING THE POTENTIAL FALSIFIED CHARACTER OF MEDICINAL PRODUCTS INTRODUCED IN THE UNION BUT NOT INTENDED TO BE PLACED ON THE MARKET.

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FURTHER INFORMATION:

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1. Introduction

The EGA[1] supports the European Union and other international initiatives in their fight against counterfeit and falsified medicines. The EGA has been at the forefront of the fight against counterfeiting, taking an active role with different initiatives such as participation in the "EC Observatory of Piracy and Counterfeiting" (2009), and joining forces with UNICRI (SAVEmed, 2011), WHO (IMPACT, 2006), and the Council of Europe (2004).

Counterfeiting is a serious economic problem in today's world. Furthermore, counterfeiting of pharmaceuticals is a criminal and reprehensible crime: it puts people's lives at risk and undermines the confidence of the public in the world's vital healthcare systems. The EGA believes that proper anti-counterfeiting verifications should be put in place by authorities around the world to increase patients' safety and to remove the potential economic benefit from illegal trade.

In this context, any additional or existing rules and requirements proposed in relation to products or shipments in transit should be shown to adequately address the problems at stake (i.e. the counterfeiting of medicines, or avoiding any misuse of IP rights by certain companies aimed at stopping or delaying generic medicines from reaching patients) and to lead to the enhanced protection of patients.

It is also important to consider that the ECJ has repeatedly declared – most recently in 2011 in the Philips and Nokia cases – that in-transit products placed under a suspected customs procedure cannot, by the mere fact of being held in transit, infringe IPR in force in the EU. A specific product that is in transit may well comply with IP rules in both the countries of exportation and importation; therefore the European Court of Justice declared that it is "essential that those goods be able to pass in transit, via the EU […], without that operation being hindered, even by a temporary detention, by Member States' customs authorities". The ECJ hereby also clarified that the so-called manufacturing fiction – the premise that goods in transit may be considered to have been manufactured in an EU Member State, applied by inter alia the Netherlands – can no longer apply to products in transit.

[1] 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. Companies represented within the EGA provide over 150,000 jobs in Europe. Cost-effective generic medicines save EU patients and healthcare systems over €30 billion each year, thus helping to ensure patient access to essential medicines and providing urgently needed budget headroom for the purchase of new and innovative treatments.

2. EGA's Views on the Consultation Items

1. Consultation item N°1

Please comment on this abovementioned possibility for checks and verifications.

Paragraph 14

Any verification should not go beyond what is strictly mandatory by law in case of a suspicious shipment. Providing a potential waiver from verifications that could potentially cause delays in delivering medicines to patients should be considered for reliable, certified, well known or bona fide logistics partners.

EU responsible authorities should consider as exempt from verification shipments in transit destined for other markets that have similar border controls to the EU. This would create a more efficient system and focus authorities on countries where anti-counterfeiting controls are weaker or non-existent and a real danger of counterfeiting exists.

Before engaging in any action aimed at verifying the legitimacy of a shipment, EU authorities should establish a minimum level of proof that would have to be met before the right to inspect can be triggered. An even stricter level of proof should be required if the request comes from a third party, including originator medicines companies.

Paragraph 15

A physical examination in any form may not be feasible for products in transit. Often they only remain in transit for a few hours as they are booked on the next available flight considering the nature of the products. This extends to inspection, not just analytical testing, as shipments would still need to be unpacked and broken down to allow inspection.

This level of examination is only acceptable if the customs officer has strong suspicions regarding the authenticity of the product/declaration. Furthermore, this procedure requires owner company consent and explicit instructions on appropriate handling.

Paragraph 16

Today, legitimate shipments already have documents available including the origin, packing list, invoice and certificate of analysis. This should be sufficient for authorities to verify the source of the shipment and products included in it.

In suspicious cases, responsible authorities could request up-front the above-mentioned documents, possibly through an initial bona fide check on the shipper of a shipment that has not yet passed through an EU port.

Paragraph 17

This information can be made available via in-transit reports from external logistics providers, but should only be requested in cases of reasonable doubt, in order to avoid unnecessary delays for patients receiving their medicines.

2. Consultation item N°2

Do you consider that all the verifications mentioned in paragraphs 15,16 and 17 should be carried out? If not, in which cases it would not be necessary to check all these verifications?

In paragraph 18 where it is stated, *"The level and range of controls and verifications should be governed by the principle of proportionality to avoid unjustified disruptions of trade flows."* the following should be included:
"Applying the principle of proportionality, products introduced in the union but not intended to be placed in the market could actually be classified in 2 categories:

- *Products in transit only*
- *Products that will be packed/repacked in EU before being shipped again to a third country, outside EU."*

Verifications mentioned in paragraph 15 (physical examination) should not be carried out for products in transit only (not intended to be packed or repacked in EU). Provided that all the documentation required is available, products in transit represent a minimal risk for patients in the Union.

In cases where the goods are declared as clinical trial materials, the inspection should concentrate on the shipping documents and labeling confirming this status and all other measures should be disregarded. In suspicious cases the sponsor of the clinical trial or the manufacturer of the CTM should be consulted without delay.

3. Consultation item N°3

Please comment on this consultation topic.

The EGA believes that it is vital to avoid the misuse of the law by citing IP rights as has occurred in the past, when several shipments of legitimate generic medicines were seized.

Checks and verifications performed by competent authorities should not only include border controls and authorities as currently stated in the law, but also IP experts able to assess and prevent any unfair potential linkage between generic medicines and counterfeiting or other IP related issues. This would strengthen the authorities' capability and resources while increasing efficiency to focus on real counterfeiting cases.

Furthermore, as these products are not being imported into an EU member state, but are in-transit, it is questionable whether the authorities in fact should have the right to interfere with an in-transit shipment.

Regarding Paragraph 21, as stated in our previous answers, additional procedures should require reasonable doubt of authenticity before any verifications can be enforced. This necessitates the shipper's consent and instructions.

In its concept paper the European Commission and Member States should consider the need for a broader scope of competences within authorities that will be participating in the verifications and include IP experts as part of the core personnel that assesses the legitimacy of a shipment.

4. Consultation item N°4

Please raise any other issue or comment you would wish to make which has not been addressed in the consultation items above.

The EGA considers that special training of customs personnel is indispensable to avoid overreactions. In cases of verification of suspected falsified medicines the involved companies (sender, recipient, manufacturer, etc.) should be immediately and directly informed on putative delays for this shipment.

Special care is required for cooled and frozen shipments. Such goods have to be properly stored during the whole period of verification. Unnecessary delays have to be avoided. The delivering transport company has to be informed in advance about delays.