

**Att:**

**Responsible Commissioner Biénkowska + cabinet.**

**Italian Presidency - lead negotiator on behalf of the EU Member states**

**MEP Cecilia Wikström - lead negotiator on behalf of the European Parliament.**

**cc:**

**all EU Member States representations,**

**all MEP shadow rapporteurs,**

**all relevant European Commission DGs (Development, Customs, Public health)**

### **Civil Society letter regarding proposed rules for EU trademark legislation**

We, the undersigned organisations, global health experts and activists from the global South and North, are writing to strongly urge the European Commission and Members of the European Parliament to refrain from introducing new barriers to the legitimate flow of generic medicines in transit through the European Union (EU). By introducing a right to enforce European trademark rights on goods in transit through the EU, the European Union is about to take an unacceptable step beyond the internationally agreed WTO trade rules to the detriment of affordable access to medicines in low and middle income countries.

Instituting the proposed IP enforcement policies increase the risk of harmful delays, seizures or even the destruction of legitimate generic medicines in-transit through Europe on their way to health authorities in third countries. Substantial evidence already exists that IP right holders' apply their IP enforcement rights to deter competition from generic manufacturers. This was acknowledged by the EU's own 'Pharmaceutical Sector Inquiry' from 2009<sup>1</sup> and has also been demonstrated by the seizures of at least 20 known shipments of legitimate generic medicines in-transit through the EU in 2008-09, which seizures became the subject of a WTO complaint by India and Brazil against the EU and the Netherlands.<sup>2</sup> That complaint resulted in EU guidelines on dealing with medicines in transit for customs authorities<sup>3</sup> and a new customs regulation (No. 608/2013 replacing No. 1383/2003).

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<sup>1</sup> European Union Pharmaceutical Sector Inquiry Report, 2009, p.11: [http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication\\_en.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf)

<sup>2</sup> European Union and a Member State [India] – Seizure of Generic Drugs in Transit: DS408, [http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds408\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds408_e.htm); European Union and a Member State [Brazil] – Seizure of Generic Drugs in Transit: DS409, [http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds409\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds409_e.htm).

<sup>3</sup> Guidelines available here: [http://ec.europa.eu/taxation\\_customs/resources/documents/customs/customs\\_controls/counterfeit\\_piracy/legislation/guidelines\\_on\\_transit\\_en.pdf](http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/legislation/guidelines_on_transit_en.pdf).

Although the new customs regulation still has numerous problems,<sup>4</sup> it does state that goods in transit can only be seized if there is evidence of a risk of diversion onto EU markets.<sup>5</sup> The proposed new legislation therefore seems to directly contravene the existing custom legislation.

Against this background, we are deeply concerned that no meaningful safeguards against the very real risk of over-enforcement and abuse by right holders have been proposed by the European legislators in the trademark enforcement negotiations.

Even if enforcement is limited to counterfeit trademark infringement, the risk of confusing similarly named, coloured or shaped medicines with counterfeits is high. Especially because ill-equipped customs agents will be asked to evaluate complex trademark violation issues and will wrongfully do so based on the trademark status of the goods in the EU rather than in their place of destination. This is in direct contravention of the relevant WTO TRIPS Agreement Article 52.<sup>6</sup>

Wrongful seizure and detention of generic medicines in transit can lead to harmful and even fatal delays for people who need access to life-saving medicines. In addition, the detention and risk of destruction of medicines in transit may have a chilling effect on trade in generic medicines, and increase costs for generic manufacturers and suppliers, which are then required to take costly steps to avoid running afoul of overzealous IP enforcement. A resulting unnecessary increase in prices can also be a barrier to access to medicines.

For these reasons we believe that by adopting the proposed provisions the EU will send a clear signal that the interests of European rights holders overrules the public health interests of patients in developing countries.

The EU will not protect public health anywhere by using excessive IP enforcement for medicines in transit as a tool to combat counterfeit medicines. Instead, the EU should invest its efforts into improving the quality of medicines exported from the European Union to third countries, by increasing support for drug regulatory authorities in third countries and by strengthening the WHO pre-qualification program.

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<sup>4</sup> Catherine Szez, New EU Customs Regulation Might Allow Wrongful Seizure of Generic Drugs in Transit, NGOs say, IP-Watch (Oct. 17, 2013): <http://www.ip-watch.org/2013/10/17/new-eu-custom-regulation-might-allow-wrongful-seizures-of-generic-drugs-in-transit-ngos-say/>.

<sup>5</sup> This position is in line with established case law from the European Court of Justice (ECJ Nokia/Philips C-446/09 C-495/09) which establishes that only when there is a risk of diversion of goods into the EU market, in transit enforcement can be allowed.

<sup>6</sup> The right holder seeking seizure of goods in transit must “provide adequate evidence to satisfy the competent authorities that, under the laws of the country of importation, there is *prima facie* an infringement of the right holder's intellectual property right.”

In the interest of the people who depend on affordable, life-saving generic medicines in developing countries, we ask that you reverse your positions in these negotiations and remove any provisions allowing for IP enforcement on medicines-in-transit.

Reversing your position on this critical issue will ensure that the EU truly supports access to affordable medicines for all.

**Signatories:**

**Oxfam International**



**Health Action International Europe**



**MSF Access Campaign**



**Salud Por Derecho,  
Right to Health Foundation**



**Restless Development**



**Transatlantic Consumer Dialogue**

