

For the attention of:

First Vice-President Frans Timmermans, European Commission
Commissioner Elżbieta Bieńkowska - Internal market, Industry, Entrepreneurship and SMEs
The Italian Presidency - lead negotiator on behalf of the Council of the European Union
MEP Cecilia Wikström - lead negotiator on behalf of the European Parliament.

Civil Society letter regarding proposed rules for EU trademark legislation

We, the undersigned 50 organisations, community groups, 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 2009¹ 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, seizures which became the subject of a WTO complaint by India and Brazil against the EU and the Netherlands.² That complaint resulted in EU guidelines on dealing with medicines in transit for customs authorities³ and a new customs regulation (No. 608/2013 replacing No. 1383/2003).

¹ European Union Pharmaceutical Sector Inquiry Report, 2009, p.11: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf

² 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; 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.

³ Guidelines available here: 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,⁴ it does state that goods in transit can only be seized if there is evidence of a risk of diversion onto EU markets.⁵ The proposed new legislation therefore seems to directly contravene the existing customs 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 52.⁶

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 overrule 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.

⁴ 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/>.

⁵ 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.

⁶ 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:

Delhi Network of Positive People (DNP+), India

The Southern African HIV Clinicians Society

Action against Aids Alliance, Germany

Thai Network of People living with HIV AIDS (TNP+)

RNP+ São Luis (National Network of Positive People, Brazil)

Oxfam International

AIDS ACCESS Foundation, Thailand

Lawyers Collective, India

Health Action International Europe

Africa Japan Forum

Alianza LAC - Global por el Acceso a Medicamentos

Thai NGO Coalition on AIDS (TNCA)

Médecins Sans Frontières Access Campaign

INESC (National Institute of socio-economic studies, Brazil)

FTA Watch, Thailand

Consumer Association the Quality of Life (EKPIZO), Greece

International Treatment Preparedness Coalition LATCA (Latin American and Caribbean Networks, Guatemala)

SECTION27, South Africa

GRAB (Group of Resistance Asa Branca, Brazil)

Asia Pacific Network of People Living With HIV (APN+)

Salud Por Derecho, Spain

Foundation for AIDS Rights (FAR), Thailand

Cancer Association of South Africa

Restless Development, The United Kingdom
Drug Study Group, Thailand
Universities Allied For Essential Medicines
UAEM Brasil, Universities Allied for Essential Medicines
International Treatment Preparedness Coalition (ITPC) – South Asia
The Rural Pharmacist Association, Thailand
GESTOS, Brazil
The Rural Pharmacist Foundation, Thailand
IBASE (Brazilian Institute of Socio-Economic Analysis)
Knowledge Ecology International Europe
Rebrip (National Network for the Integration of Peoples, Brazil)
Brot für die Welt, Germany
People’s Health System Movement, Thailand
Diamond Life Impact Projects NPC , South Africa
Thai Holistic Health Foundation
The Transatlantic Consumer Dialogue
Foundation for Consumers (FFC), Thailand
Stop Stockouts Project, South Africa
Misión Salud Veeduría Ciudadana, Latin America
Salud y Fármacos, Latin America
IFARMA Foundation
People’s Health Movement,
ABIA (Brazilian Interdisciplinary Aids Association
GIV (Group of Incentive to Life), Brazil
Conectas Human Rights, Brazil
ABGLT (Brazilian Association of Gays, Lesbians, bisexuals, travesties and Transexuals,
Brazil)
ISP/Brasil (International Public Services)

In cc:

Commissioner Neven Mimica - International Cooperation and Development

Cabinet of Vice-President Frans Timmermans

Cabinet of Commissioner Bienkowska

Cabinet of Commissioner Mimica

Members of European Parliament: Mr. Pavel Svoboda (EPP), Mrs. Geringer De Oedenberg (S&D), Mr. Dzhambazki (ECR), Mr. Andersson (Greens) Mr. Mastalka (GUE), Mrs. Ferrera (EFDD)

Council Working Group on Intellectual Property

Council Working Group on Development

Ms. Kerstin Jorna, Director of Directorate D, Intellectual Property, DG Markt

Mr. Luis Riera Figueras, Director of DEVCO B, Human and Society Development

Mr. Gustavo Martin Prada, Director of DEVCO A, EU Development Policy