

## OPEN LETTER TO EUROPEAN TRADE COMMISSIONER KAREL DE GUCHT

Geneva, 8<sup>th</sup> November 2010

Dear Commissioner de Gucht,

We write to you today as a medical organization that is deeply concerned about the damaging impact the European Commission's current trade policies will have on patients' lives. Médecins Sans Frontières relies on affordable generic medicines to treat people in more than 60 countries – over 80% of HIV medicines we use to treat over 160,000 people are from India.

We have previously corresponded with you and our colleagues have met with members of your cabinet. We note that you have made some efforts to address concerns but many areas remain that will create additional barriers to production, distribution and sale of generics. The Commission's policies, despite your assurance to the contrary, also by far exceed international trade rules as set out in the TRIPS agreement.

### **Problems with the EU-India Free Trade Agreement (FTA):**

#### **1) Data exclusivity:**

The Commission claims data exclusivity is required under the TRIPS Agreement. International experts have agreed it is not.<sup>1 2</sup> The Commission claims there will be no harm to access to medicines from data exclusivity. Studies show this is wrong.<sup>3 4</sup> The Commission claims harm will be limited because data exclusivity can be lifted if a compulsory licence is issued. However, even when no patent is granted under Indian law, data exclusivity would create a monopoly that blocks generic producers.

#### **2) Border measures include civil trademark infringement:**

The Commission wants to include civil trademark disputes in the FTA and in ACTA, the Anti-Counterfeiting Trade Agreement. But such disputes do not pose a threat to public health and are purely a commercial matter. The potential access barrier is illustrated by the German customs' detention in 2009 of a drug using the internationally authorized generic name 'amoxicillin' on the assumption that it was infringing GlaxoSmithKline's trademark 'Amoxil.' In the FTA, ACTA and the EU customs regulation 1383/2003, the Commission should therefore limit border measures to willful trademark infringement, i.e. the fraudulent exact copying of the labeling and branding, which can represent a serious threat to health.

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<sup>1</sup> WHO (2006): Public health, innovation and intellectual property rights: report of the Commission on Intellectual Property Rights, Innovation and Public Health.

<sup>2</sup> Carlos Correa (2002) : Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement. South Centre

<sup>3</sup> Health Action International and Oxfam (2010): Trading away access to medicines. How the European Union's trade agenda has taken a wrong turn.

<sup>4</sup> Oxfam, (2007): All costs, no benefits: how TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines.



### **3) Excessively broad enforcement measures:**

The Commission demands mandatory use of court orders (injunctions) to stop production by generic manufactures, even before a case for infringement has been heard in court. This will override the role of the courts in balancing the constitutionally enshrined right to health with the economic interest of the intellectual property owner.

### **Problems with the Anti-Counterfeiting Trade Agreement (ACTA):**

#### **1) The scope of ACTA is too broad and will hurt access to medicines:**

ACTA will widen the intellectual property enforcement net so that legitimate medicines could be detained in transit or destroyed simply because their label looks similar to the originator product. In addition, your negotiators have been pushing to include patents in ACTA. All this has nothing to do with protecting the public from fake medicines.

#### **2) Damages and lack of due process and judicial oversight:**

ACTA opens the door for abuse by permitting the seizure and destruction of medicines without notification of the owner, without providing the owner with the opportunity to respond, and without judicial oversight. Generic companies may even face criminal proceedings merely on the basis of an allegation of infringing a patent or a trademark. This dramatically increases the risks and reduces viability of generic production.

#### **3) Severe penalties for all involved in producing and distributing generic medicines:**

Suppliers of active pharmaceutical ingredients, distributors, retailers, NGOs such as MSF who provide treatment and funders who support health programs will all be at risk of severe penalties, including imprisonment, for patent or trademark infringement by a generic medicine. This will deter anyone involved in the production, sale and distribution of affordable generic medicines.

ACTA's real effect will be to protect the commercial interest of companies. Once ACTA is signed, developing countries will be pressured to join it. Instead, action against unsafe medicines should be developed through a legitimate process involving all countries, not just among a few countries negotiating in secret.

We urge you to change your policies and request to meet with you in person on these critical issues.

Sincerely,

Dr. Unni Karunakara  
International Council President  
Médecins Sans Frontières

Dr. Tido von Schoen-Angerer  
Executive Director  
Médecins Sans Frontières  
Campaign for Access to Essential Medicines

C.C.

- Andris Piebalgs, *Commissioner for Development*
- Jerzy Buzek, *President of the European Parliament*
- MEP David Martin, *Chair of the European Parliament Working Group on Innovation, Access to Medicines and Poverty Related Diseases*
- Mr Vital Moreira, *President of INTA Committee, European Parliament*