Text of letters sent by Medecins Sans Frontieres to
Mr László Kovács, European Commissioner for Taxation and Customs Union, and to Baroness Catherine Ashton, European Commissioner for Trade, following the seizure of medicines in transit in the EU to developing countries for alleged patent infringement.

Geneva, February 12th,2009

Dear Commissioner,

On behalf of Medecins Sans Frontieres (MSF), we are writing to express our concerns about the potential consequences of the recent seizure of medicines in transit in the EU to developing countries for alleged patent infringements on the basis of the Council Regulation (EC) No 1383/2003 by Dutch customs authorities.

From our understanding, the recent case involves seizure by customs authorities in Holland of losartan potassium, a generic version of the active ingredient for a patented drug used to treat high blood pressure, manufactured in India by the generic company Dr Reddy and in transit to Brazil. It was not for use within the EU. The drug in question is not under patent in India or Brazil but is under patent in the Netherlands.

MSF is concerned that the establishment of a precedent in EU countries to use such provisions to intercept legitimate trade between generic manufacturers and developing countries could severely impact the affordability and availability of medicines in developing countries.

We are aware of the statement by the European Union at the WTO General Council on February 3rd, 2009:

'In the present case, it appears that, following a request by a company which has patent rights over the medicine in question in the Netherlands, the Dutch authorities temporarily detained (which does not mean seize, confiscate or destroy) a small shipment of drugs worth 55.000 euros in a Dutch airport, in order to control it. This action is allowed by TRIPS and is based on provisions in EU customs law that allow customs to temporarily detain.'?

We would like to point out that the EC Regulation No 1383/2003 goes beyond the obligations required under the TRIPS Agreement in relation to customs authorities as set out in Article 51 of the TRIPS Agreement. The footnote of the same article states that 'It is understood that there shall be no obligation to apply such procedures to imports of goods put on the market in another country by or with the consent of the right holder, or to goods in transit.'? The EC Regulation No 1383/2003 nonetheless applies such procedures to goods in transit. Any implementation of TRIPS obligations or provisions which exceed those obligations must be assessed in light of the 2001 Doha Declaration on TRIPS and Public Health - signed by the members of the European Union - notably in the light of the paragraph 4 of that Declaration, according to which 'the [TRIPS] Agreement can and should be

interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.'? In addition, article 41 of the TRIPS Agreement states that any intellectual enforcement measures should 'be applied in such a manner as to avoid the creation of barriers to legitimate trade.'?

The World Health Organisation resolution WHA61.21, calls upon member states to 'take into account, where appropriate, the impact on public health when considering adopting or implementing more extensive intellectual property protection than is required by the Agreement on Trade-Related Aspects of Intellectual Property Rights.'?

Many countries do not have manufacturing capacity to produce medicines, or rely on importing more affordable generic medicines from abroad in order to treat their population. As such, the trade in legitimate medicines between countries is fundamental to ensuring access to medicines for millions.

Provisions to ensure such countries can access medicines, enshrined in the Doha Declaration and the WTO August 30th decision, provisions cannot be implemented effectively if on key transit routes the risk exists that supplies can be regularly subject to interception based on assertion of patent infringement in the transit country.

We are concerned that MSF's own medicine procurement activities may be affected by the EU customs authorities use of the Regulation. Such actions may have a chilling effect on exporters and require alternative and potentially more expensive transit routes to be used that would inhibit the supply of generic medicines both to developing countries and to humanitarian organisations such as MSF who have logistical centres based in Europe.

We, therefore, call on the European Commission to:

Clarify its position regarding the implementation of the EC Regulation No 1383/2003 with regard to pharmaceutical products;

Review the effect of the EC Regulation No 1383/2003 on the supply of legitimate medicines, given the EU stated commitment to the full implementation of the Doha Declaration on TRIPS and Public health and the WTO August 30th decision;

Clarify whether such provisions are proposed for inclusion in European Partnership Agreements and in the current negotiations of the EU Free Trade Agreements.

We look forward to hearing your response as soon as possible.

Yours sincerely,

Kris Torgeson
Secretary General
MSF International

Tido von Schoen-Angerer

Executive Director
Campaign for Access to Essential Medicines

CC
Mr Louis Michel, European Commissioner for Development
Ms Androulla Vassiliou, European Commissioner for Health and Consumer Protection
Mr Günter Verheugen , European Commissioner for Enterprise and Industry
Mrs Morgantini, Member of the European Parliament, Vice President of the European parliament
Mr Markhov, Member of the European Parliament, Chair of the INTA Committee,
Mr Borrell Fontelles, Member of the European Parliament, Chair of the DEVE Committee
Mr Martin, Mr Susta, Mr Arif, Mr Agnoletto, Mr Schlyter, Mrs Corbey, Mrs Kinnock, Members of the European Parliament,