Dr. Margaret Chan
Director-General
World Health Organization
Avenue Appia 20
1211 Geneva 27
Switzerland

February 18, 2009

RE: SEIZURES OF MEDICINES AS GOODS IN TRANSIT TO DEVELOPING COUNTRIES

Dear Dr. Chan:

Cc: Mr. Kunio Mikuriya, World Customs Organization

Cc: Mr. Francis Gurry, World Intellectual Property Organization

Cc: Mr. Pascal Lamy, World Trade Organization

We are writing about an important issue concerning trade in medicines, vaccines and other technologies that requires your attention.

In recent years there has been a flurry of activity regarding new trade agreements and rules to enforce patents and intellectual property rights. One important aspect of those rules are measures that concern "goods in transit." This term is defined by the WTO General Agreement on Tariffs and Trade (GATT) as follows:

> "Goods . . . shall be deemed to be in transit across the territory of a contracting party when the passage across such territory, with or without trans-shipment, warehousing, breaking bulk, or change in the mode of transport, is only a portion of a complete journey beginning and terminating beyond the frontier of the contracting party across whose territory the traffic passes." (Article V, Freedom of Transit, Paragraph 1).

Under some legal traditions and consistent with WTO rules, goods in transit are exempt from normal restrictions associated with patents or other intellectual property rights, when in route to a market where the use is legitimate. (See for example TRIPS Article 51, footnote 13). This approach is not uniform however, as illustrated recently by several seizures of medicines by Dutch customs officials.

The Dutch cases involved medicines manufactured in India, and then shipped to Brazil, Colombia and Peru, via the Netherlands. The medicines were seized by Dutch customs officials.

According to industry reports, there were at least four cases of generic medicines in transit in the Netherlands that were seized by Dutch customs authorities from October 15, 2008 to December 12, 2008.

1. Date of seizure: October 15, 2008.
   Company: Ind-Swift Laboratories Ltd.
   Product: Clopidogrel Bilsulphate API.
   Destination: Colombia.
2. Date of seizure: November 27, 2008.

Company: CIPLA Ltd through Uni World Pharma Ltd. Dubai.
Product: Olanzapine 10 mg Tabs.
Destination: Peru.

3. Date of seizure: November 27, 2008.
   Company: CIPLA Ltd through Uni World Pharma Ltd. Dubai.
   Product: Rivastigmine 3 mg Tabs.
   Destination: Peru.
4. Date of seizure: December 12, 2008.
   Company: Dr. Reddy's Laboratories Ltd.
   Product: Losartan – API.
   Destination: Brazil.

According to the manufacturers, all products were legitimate generics and did not violate any patent rights in the exporting or the importing countries.

The seizure of the shipment containing Losartan active pharmaceutical ingredients (APIs) destined for Brazil was made in connection with a complaint filed by Merck, as the licensee of European patents and Dutch Supplementary Protection Certificates (SPCs), pursuant to Dutch law and the procedures set out in EU Regulations.[1] In the case of the Clopidogrel Bilsulphate API shipments to Colombia, the Dutch customs authorities reportedly asserted the generic APIs were counterfeits, and Sanofi Aventis sought destruction of the goods.

The European Union is currently seeking very aggressive provisions regarding customs procedures in a number of proposed bilateral and regional trade agreements. The topic of provisional measures is also a key element in the secret negotiations for a new Anti-Counterfeiting Trade Agreement (ACTA). According to some reports, there are proposals in the ACTA negotiations to require the seizure of goods that infringe on patents, even for goods in transit. Whether intentional or not, additional risks to goods in transit are also found in the International Medical Products Anti Counterfeiting Taskforce (IMPACT)'s "Principles and Elements for National Legislation against Counterfeit Medical Products" and World Customs Organization's "Provisional Standards Employed by Customs for Uniform Rights Enforcement (SECURE)."

We are bringing these facts to your attention in part to illustrate how TRIPS plus intellectual property rules can impede access to generic medicines in developing countries. The European Union rules and the actions of the Dutch customs officials are clearly designed to disrupt the supply of legitimate generic medicines to developing countries.

The WTO TRIPS provides the option of exempting goods in transit from the enforcement of patents. The European Union's rules and actions go beyond the required enforcement standards of the WTO TRIPS agreement, and do so in a manner that is clearly inconsistent with the 2001 Doha Declaration on TRIPS and Public Health. The Doha Declaration recognized "the gravity of the public health problems afflicting many developing and least-developed countries" and stressed "the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems." In Paragraph 4 of that Declaration, WTO members agreed that "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." Among other things, the implementation of the WTO's Decision of 30 August 2003 regarding the export of pharmaceutical products to countries with inadequate manufacturing capacity, already seen as complex, will become even

1 COMMISSION REGULATION (EC) No 1172/2007 of 5 October 2007 amending Commission Regulation (EC) No 1891/2004 of 21 October 2004 laying down provisions for the implementation of Council Regulation (EC) No 1383/2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights.

more problematic if patent rights are enforced for goods in transit.

The European Union rules and actions are clearly in conflict with WHO resolution WHA61.21, which states that "international negotiations on issues related to intellectual property rights and health should be coherent in their approaches to the promotion of public health." WHA61.21 further 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."

The importance of this issue is much broader than the cases of four seized shipments of generic medicines to three countries. It presents enormous risks for the WHO, UNAIDS, the Global Fund, UNITAID, and the many development and public health agencies and other entities engaged in the supply of medicines to developing countries that ship medicines through Europe or other countries that sign agreements with anti-goods-in-transit provisions.

We ask that the WHO immediately undertake an assessment of the risks to public health programs presented by such seizures and any anti-goods-in-transit provisions that exist in current or proposed trade agreements, including those relating to anti-counterfeiting initiatives.

In doing this assessment, we ask that the WHO interview developing country governments, UN agencies and other entities engaged in the trans-border delivery of generic medicines to developing countries, to fully document the extent to which medicines in transit are at risk regarding seizure or liability for infringement.

We further ask the WHO, if its own assessment of EU regulations uncovers these threats to public health, to communicate its concerns, and provide relevant technical advice to the European Union with respect to its own customs rules, and to ask the EU to re-examine provisions in trade agreements that present risks to goods in transit.

Article 1 of WHO's Constitution states the WHO's objective "shall be the attainment by all peoples of the highest possible level of health". In this regard the WHO is required to take all necessary action to attain the objective of the Organization including, including, as provided for in Article 2 of the Constitution, to "make recommendations with respect to international health matters, "to provide information, counsel and assistance in the field of health," and to "assist in developing an informed public opinion among all peoples on matters of health."

We trust you will give urgent attention to the issues raised in this letter and to take immediate action to address the problems.

Sincerely,

BUKO Pharma-Kampagne, Christian Wagner-Ahlfs
Consumers International, Bjarne Pedersen
Consumers Union, Chris Murray
Essential Action, Robert Weissman
HAI Africa, , Patrick Mubangizi
HAI Asia Pacific, Kumariah Balasubramaniam
HAI Europe, Teresa Alves
HAI Global, Tim Reed
HAI Latin America and Caribbean, Roberto Lopez.
Health GAP, Brook Baker
IQsensato, Nicoletta Dentico
Knowledge Ecology International, James Love
Medico International, Thomas Gebauer
Oxfam International, Mohga Kamal-Yanni
Third World Network, Sangeeta Shashikant
U.S. PIRG, Edmund Mierzwinski