

INTERVENTION by INDIA – TRIPS Council June 2009

Agenda item 'M' – OTHER BUSINESS – Seizure of generic drug consignments at EC ports

Madame Chair,

When India and Brazil raised the issue of seizure of generic drug consignments at EC ports in the TRIPS Council meeting of March 3, we did not foresee that we will need to raise the issue again in today's meeting. Going by EC's intervention at the last TRIPS Council meeting, confirming their commitment to the Doha Declaration on Public Health, we thought that the matter will get the attention it deserves and get resolved. **Regrettably, this has not happened and we are compelled to raise the issue in this meeting.** We have neither received a satisfactory response from the EC to our formal communication to them in Brussels, nor have we seen any review of the relevant EC regulation or actions by Customs authorities. Seizures have continued with the latest one being at Frankfurt last month.

We have received information that a shipment of a generic antibiotic, Amoxicillin, manufactured in India and destined for a **Least Developed Country, the Republic of Vanuatu in the Pacific, was seized by customs officials on 5 May, 2009, while in transit through Frankfurt, Germany.** Amoxicillin is an essential medicine used to treat a wide range of bacterial infections. We understand that the consignment worth approximately 28,000 Euros consisted of 3,047,000 tablets of Amoxicillin (250 mg), equivalent to 76,000 courses of treatment. The seizures were made on grounds of alleged trademark violation although GlaxoSmithKline (GSK) has confirmed to the German authorities that GSK is the former patent holder for "Amoxil", a brand name for amoxicillin. There seems no valid reason for detaining these medicines especially since the name "Amoxicillin" is an international nonproprietary name (INN).

In the last TRIPS Council meeting, and subsequently in our formal communications to Brussels, we had asked the EC to provide details of all drug consignments seized by customs authorities and the grounds of such seizures. We have not yet received such information from the EC so far. However, in response to a request made by Health Action International (Europe) under the Freedom of Information Act, the Dutch government have provided limited information. The information shows that the case of Losartan exported from India to Brazil, and seized at Amsterdam, was just the **tip of the iceberg. We have come to know that there have been 17 seizures by the Dutch authorities in the year 2008 on the basis of EU regulation 1383/2003.** Of these 16 consignments originated in Indian and one in China. These consignments were bound for Brazil (1 consignment), Peru (x5), Colombia (x4), Ecuador (x2), Mexico (x2), Portugal (x1), Spain (x1) and Nigeria (x1). The drugs were for diseases such as cardiological ailments, AIDS, dementia and schizophrenia. It needs to be noted that all 17 consignments originated in developing countries and 15 of the 17 were destined for developing countries.

We have followed closely the different grounds mentioned by the EC for such seizures. **The grounds stated by EC include counterfeits, fake drugs, substandard, potentially dangerous products, patent violations and so on.** The EC have also made allegations of **drug trafficking** after three months of seizure of a particular consignment. These are serious allegations and **we take serious exception to such unsubstantiated and wild allegations. The fact that the drugs were subsequently released are a proof that the allegations were baseless.**

Seizures have continued to take place at EC ports. The multitude of allegations and the spread across several EC ports, imply **an emerging pattern to disrupt and create barriers to legitimate trade of generic drugs and to challenge the Doha Declaration on Public Health. The basic principle of transparency of procedures has also been violated** by the inability of the authorities to share and explain the specific cause of action under EU regulations.

EC has sought to justify the action of customs authorities to control goods in transit suspected of infringing IPRs as a means to stop “traffic of potentially dangerous products, such as fake medicines, even when the shipments were destined for any country.” It seems that it has been ingrained very deeply within the EC authorities that **IP violative products are synonymous with potentially dangerous substances**. This clearly is an untenable logic. We doubt such simplistic linkages. Moreover, we are talking about generic medicines, which neither infringe IPRs nor are they ‘potentially dangerous’. EC takes pride in its claim that “EU customs actions in the past had saved lives in the final destination countries which were often developing countries.” We wish to remind the EC that the concept of **'territoriality' is a key stone in the edifice of the TRIPS Agreement** and a widely understood and accepted principle. In our view, sovereign functions of the country of destination should be exercised by the country itself and other countries may assist in enforcement of their law, if requested. It may be farfetched to claim that the country of transit will have sound understanding of the IPR laws of country of destination or origin and will have the authority to enforce them during transit. It would also be incorrect to presume that the sovereign countries, to which pharmaceutical goods are consigned, are not responsible for ensuring health, safety and expectations of consumers in their countries. In such situations, **an information sharing mechanism is what is needed and definitely not action under the laws of the country in transit**. If there is a reason to doubt the quality of goods, enforcement action should follow from domestic regulations in importing country and not from WTO rules, which do not provide for the same or from rules of a third country.

The seizures run counter to the spirit of the TRIPS Agreement and the resolution 2002/31 of the Commission on Human Rights on the right to enjoy the highest standards of physical and mental health. In this context let me draw Members’ attention to the **report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health** submitted to the 11th Session of the Human Rights Council last week. I quote - “The Special Rapporteur is concerned with reports of IP enforcement measures that have resulted in multiple seizures at some ports of shipments of generic medicines heading to developing countries and LDCs.”

Widespread and repeated seizures have an **adverse systemic impact** on legitimate trade of generic medicines, South-South commerce, national public health policies and the principle of universal access to medicines. The importance of generic drugs to public health in developing countries and particularly in the LDCs is obvious. Such barriers to legitimate trade of generic drugs will also seriously impair the efforts of civil society organisations engaged in providing medicines and improving public health in the least developed parts of the world.

I would like conclude by reminding the EC that trade of generic drugs is perfectly legitimate. Moreover, it is also desirable from the public health and access to medicine perspective. It is ironical that while on one hand WTO has taken steps to promote access to affordable medicines and remove obstacles to proper use of TRIPS flexibilities, on the other hand **some Members seek to negate the same by seizing drug consignments in transit and creating barriers to legitimate trade**.

Since seizures have been recurring at different ports and on different grounds, it is therefore clear

that rather than just being a problem of implementing a law by Dutch Customs authorities, it is the **EC regulation 1383/2003 itself that is problematic and can be misused, and has been misused, to create barriers to legitimate trade. We, once again, call upon the EC to urgently review the Regulation and the actions of the national authorities based on the Regulation, and bring them in conformity with the letter and spirit of the TRIPS Agreement, the rules based WTO system and the DMD on Public Health.** Madame Chair, India attaches the highest importance to protection and enforcement of IPRs in accordance with the TRIPS Agreement. However, we do not see the Agreement as divorced from the Objectives and Principles set out in Art 7 and 8 of the Agreement. Enforcement of IPRs in disregard of these Objectives and Principles and efforts to enshrine new, maximalist TRIPS plus enforcement provisions in other multilateral forums will seriously undermine the delicate balance in the TRIPS Agreement and raise systemic issues, particularly for developing countries.

Madame Chair, my delegation will like this Council to take note of these points.