Intellectual Property Rights Series 13

The IMPACT Counterfeit Taskforce, Intellectual Property Rights Enforcement and Seizure of Medicines

Edited by Sangeeta Shashikant

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Third World Network

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1 Introduction

Sangeeta Shashikant

IN recent years, proponents of a "maximalist agenda" on intellectual property (IP) have launched a major campaign to increase IP protection and enforcement far beyond the standards set in the World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). These more stringent norms are commonly referred to as "TRIPS-plus standards".

For this purpose the proponents, mainly global business firms and developed-country governments, are making use of trade agreements, plurilateral government initiatives and programmes in international agencies to push forward their agenda to set or enforce higher IP standards, using the concepts of "counterfeiting", "piracy" and "enforcement".

This book is a compilation of news reports on the debate during the World Health Organisation (WHO) Executive Board meeting in January 2009 on the issue of "counterfeit medical products" and on a counterfeit taskforce called "IMPACT" (International Medical Products Anti-Counterfeiting Taskforce).

Members of the Executive Board that met from 19-27 January 2009 considered a WHO Secretariat report with an attached draft resolution (EB124/14) that proposed dealing with health problems through concepts and mechanisms linked to enforcement of intellectual property rights (IPRs). The proposals contained in EB124/14 sought to bundle legitimate quality, safety and efficacy concerns under the rubric of "counterfeit", a term used in connection with IPRs, as well as to obtain endorsement for IMPACT.

These proposals resulted in many developing countries voicing concerns, in particular that the term "counterfeit", used in connection with IP violations particularly trademark infringements, would result in WHO addressing health concerns through IP enforcement measures.

Concerns were also raised over the anti-counterfeit taskforce IMPACT, which many countries felt was unsuited to address the issue of the quality, safety and efficacy of medical products for the following reasons:

- its establishment lacked a mandate from WHO's governing bodies;
- its emphasis on "counterfeits";
- the involvement of the private sector in its activities, thus raising issues of conflicts of interest; and
- lack of transparency.

IMPACT is also known to have links with organisations and initiatives engaged in IP enforcement and in pressuring developing countries to adopt standards of IP protection and enforcement that are "TRIPS-plus".

The discussion on the use of the term "counterfeit" and on IMPACT took place following seizures of quality medicines by European customs authorities, thus heightening developing countries' concerns. Prior to the Executive Board meeting, a number of shipments of quality medicines en route to several developing countries were seized by European customs authorities on suspicion of violation of IPRs. The seizure by the Dutch port authorities of an Indian shipment of the generic drug losartan (which is used to treat arterial hypertension) to Brazil, while it was in transit, was highlighted during the Executive Board meeting as a concrete example of the negative impacts of the relationship between health issues and enforcement of IPRs.

Developing countries that objected to WHO's approach of attempting to deal with the quality and safety of medicines under the rubric of "counterfeits" at the Executive Board feared that the real effect of the WHO document EB124/14 would be to undermine production of and trade in good-quality generic medicines, and, consequently, access to generic medicines.

However, the Executive Board agreed that more efforts need to be made to strengthen the drug regulatory authorities – which tend to be weak in developing countries – to address the issues of quality, safety and efficacy through WHO with guidance from its member states.

Strong views were expressed against the Secretariat's document EB124/14, resulting in rejection of the document and an agreement that the WHO Director-General Dr Margaret Chan would prepare a new report (without a resolution) for member states' consideration at the next World Health Assembly in May 2010, which would address the public health dimension of the issues and what WHO is doing to strengthen national drug regulatory authorities. Dr Chan also agreed to prepare

another report that would investigate issues of conflicts of interest among members of IMPACT.

The issue of counterfeit medical products will be addressed once again during the 2010 World Health Assembly. The Assembly is WHO's highest decision-making body.

The news reports in the following chapters will take readers through the problems of using the term "counterfeit" to refer to quality, safety and efficacy issues against a background of anti-counterfeiting initiatives aggressively being pushed by businesses and governments from the industrialised OECD (Organisation for Economic Cooperation and Development) countries. The news reports also provide information about IMPACT and its activities, and draw attention to concerns about IMPACT pertaining to legitimacy, transparency, accountability, links to IP enforcement, and creation of barriers to trade in, and access to, affordable medicines.

The reports also provide readers with information on the circumstances surrounding the seizure of losartan and other generic medicines by European authorities. In addition, the reports cover discussions on IMPACT, IP enforcement and seizures of medicines that ensued in the WTO's TRIPS Council.

Most of the news reports in this book were published in the *South-North Development Monitor (SUNS)*, a daily bulletin that specialises in news and analysis of international negotiations on development issues. *SUNS* is published in Geneva by Third World Network.

2 Counterfeit issue stirs debate among WHO member states

Published in* SUNS *#6536 dated 12 August 2008

Geneva, 11 Aug (Sangeeta Shashikant and Riaz K Tayob) – The jurisdiction of international organisations over the enforcement of intellectual property rights has also become a controversial issue in the World Health Organisation, as it has in other agencies recently.

In the World Customs Organisation (WCO), attempts to push through a new uniform set of standards on intellectual property (IP) enforcement by customs authorities have resulted in developing countries asking for a review of a misleading Secretariat report alleging consensus for adopting the standards.

The Universal Postal Union, which is holding its Congress in Geneva, has also been discussing resolutions aimed at involving postal authorities in raising awareness to prevent illegal circulation of counterfeits as well as supporting efforts to combat counterfeiting and piracy. In the course of the discussion, many countries have made clear that the postal authorities have no competence in this area.

Developed countries have also attempted in the past two years to place enforcement of IPRs as an item on the agenda of the Council for TRIPS at the WTO, but this has faced objections by developing countries which argue that enforcement comes under the jurisdiction of national authorities and parties that are dissatisfied can have recourse to the dispute settlement system of the WTO.

A similar debate on the content and mandate of IP enforcement also took place at the World Health Assembly (WHA), which is the annual forum for WHO member states to discuss health policies.

A draft resolution on counterfeit medical products presented at the 61st World Health Assembly in May 2008 was the subject of intense discussion, as was a WHO Secretariat report (A61/16) on this issue.

After many member states raised concerns about the implications of the draft, it was decided to defer a decision on it. Instead, the next meeting of the WHO Executive Board in January 2009 will discuss the draft, and another discussion will be held at the next WHA in May 2009.

Both the draft resolution and the Secretariat's report essentially sought to legitimise an initiative known as the "International Medical Products Anti-Counterfeiting Taskforce" (IMPACT), its activities and documents.

The draft resolution (A61/A/Conf. Paper No.1) was initially sponsored by Gambia, Ghana, Nigeria, Tunisia and the United Arab Emirates. During a meeting at the committee level, the European Union also became a co-sponsor.

During the debate at the WHA (23 May), several developing countries raised concerns over several issues, including:

- the composition of IMPACT, whose members comprise industry representatives as well as law enforcement organisations;
- the hasty push to endorse the IMPACT initiative; and
- the definition of counterfeiting proposed by IMPACT and the principles and recommendations developed by IMPACT without any prior deliberations of member states, while sidelining previous WHO guidelines on counterfeiting, without adequate explanation.

Countries also objected to the Secretariat's report for endorsing IMPACT and its activities and for addressing counterfeiting as an end in itself rather than as a public health issue.

A major underlying concern of the countries is that legitimate generic medicines may get caught up in the web of definitions and enforcement of "counterfeit products", with adverse consequences for access to medicine as well as legitimate trade. India, for example, stressed that generic and branded medicines that are not registered but that are available are not counterfeits.

After a lengthy discussion on the subject, the WHA in May agreed that the Secretariat's report and the draft resolution will be considered further by the 124th session of the Executive Board (in January 2009), for a decision on how to refer the matter (including the draft resolution) to the 62nd World Health Assembly in May 2009.

According to the Secretariat report, WHO launched IMPACT in 2006 following a conference in Rome, which emerged with a "Rome Declaration". IMPACT's stakeholders include Interpol, the OECD, WCO, World Intellectual Property Organisation (WIPO), WTO, European Commission (EC), Council of Europe, United States Pharmacopoeia, Commonwealth Secretariat, Association of Southeast Asian Nations Secretariat, and International Federation of Pharmaceutical Manufacturers & Associations (IFPMA – the representative association of multinational pharmaceutical companies).

According to the report, there are five working groups under IMPACT, on (1) Legislative and Regulatory Infrastructure; (2) Regulatory Implementation; (3) Enforcement; (4) Anti-Counterfeiting Technologies; and (5) Communication.

The report states that IMPACT has developed: "Principles and elements for national legislation against counterfeit medical products"; recommendations for strengthening WHO's Good Distribution Practices (and submitted them for consideration and appropriate action to WHO's Expert Committee on Specifications for Pharmaceutical Preparations); and a guide to investigating counterfeiting of medical products and other pharmaceutical crimes (for training regulatory and enforcement officers). According to the report, IMPACT has also drawn up a communication strategy for creating awareness of the risks created by counterfeit medical products in the supply systems, and published a summary assessment of existing technologies used to protect medical products.

The draft resolution, inter alia, urges member states to: (1) establish and enforce legislation and regulations that prevent counterfeit medical products from being manufactured, exported, imported or traded in international transactions and the regulated distribution system, taking into account the principles and recommendations developed by IMPACT; (2) establish effective mechanisms of coordination and collaboration amongst health enforcement and other authorities as well as appropriate mechanisms enabling international cooperation; and (3) promote awareness among health professionals and consumers of the risks posed by counterfeit medical products.

The draft resolution also requests the WHO Director-General, inter alia, to: (1) support member states to develop and implement policies aimed at combating counterfeit medical products including facilitating and exchanging information at the international level, developing tools, guidelines, training and awareness initiative, and methodology for evaluation and monitoring; (2) strengthen the Secretariat of IMPACT; (3) seek extra budgetary resources in addition to those in the regular budget to this end; and (4) continue the development and dissemination of independent information on instances of counterfeits.

Essentially, the draft resolution and the Secretariat's report sought to legitimise IMPACT, its activities and documents.

Some delegates as well as several independent experts following the issue say that member states should critically analyse IMPACT and its activities, including possible conflicts of interest as well as implications of the definition and measures proposed by IMPACT on developing countries, before deciding on the endorsement of the initiative, its activities and the two documents.

According to experts, several of the measures proposed by IMPACT appear to be burdensome, financially and otherwise, on governments, impinge on sovereignty, go beyond requirements of the TRIPS Agreement, promote purchase of IPR-protected technologies (to combat counterfeiting) and have the potential of hampering legitimate trade.

A delegate from an African country, speaking privately, said that the problem with the draft resolution was that it took power away from the regulatory agencies and placed it in the hands of the law enforcement agencies that had no clue about quality, safety and efficacy of medical products.

The delegate added that he had participated in the IMPACT meetings, but representatives of big pharmaceutical companies prepared all the documents in advance. There was hardly any deliberation during the meetings on the documents, which were then just presented for quick endorsement by participants.

Another concern of experts is the definition of "counterfeiting", and the related mixing up of two separate issues – the counterfeiting of products and the quality of drugs.

These issues were captured well in an article in the Delhi-based *Times of India*, which said: "WHO defines counterfeit medicines as those which are deliberately and fraudulently mislabelled with respect to identity or source. At the same time, products with correct ingredients but fake packaging bring trademark infringement within the scope of the definition. Thus, the definition mixes issues of spurious drugs and substandard drugs with intellectual property infringement."

IMPACT provides another definition, i.e., that "a medical product is counterfeit when there is a false representation in relation to its identity, history, or source", and this applies "to the product, its container, packaging or other labelling information". According to the definition, it applies to "both branded and generic products.''

According to the *Times* article, although "the term counterfeiting has different definitions around the world, it is often defined as a trademark infringement". It quotes an expert from the Delhi-based Centre for Trade and Development (CENTAD) as saying: "The adoption of the IMPACT definition will have adverse impact on the access to drugs by branding legally produced generic drugs as counterfeit drugs." The article also reported on fears that "with such regulations, customs authorities across the world will seize or delay the transit of legitimate generic medicines on suspicion of their being counterfeit".

Several of the concerns above were also voiced by some member states during the debate on the draft resolution and the Secretariat's report during the WHA last May, while some other member states supported the draft resolution and the report.

Nigeria, in support of the resolution, said that counterfeiting poses serious threats and is detrimental to public health. It however added that the resolution was not intended to address intellectual property rights issues. Factors that contribute to counterfeiting include lack of appropriate legislation, weak penalties and absent or weak regulation, Nigeria said, adding that counterfeiters make huge profits.

Slovenia, on behalf of the European Union, said that a study by the European Commission demonstrated a 51% increase in seized counterfeits. It said that it actively supported IMPACT.

The US commended IMPACT on its strategy, guidance, information and efforts, and urged continued support and commitment from member states and WHO. It supported the resolution and proposed several amendments including a new paragraph to control the transhipment of pharmaceutical products, active pharmaceutical ingredients and exipients used in the production of counterfeits.

Morocco and Japan also supported the resolution. The United Arab Emirates, for the Eastern Mediterranean Region (EMRO), pushed for more financing for the initiative.

India, on behalf of the South East Asia Region (SEARO), objected to the draft resolution and the Secretariat's report as both had not been considered or deliberated upon by the Executive Board. It said that it did not know what "principles and recommendations" were being referred to in the draft resolution as it had not seen them, and this may be true for other regions as well. Thus, how could these be taken into account, it asked.

India said it recognised the magnitude of spurious and poor-quality medical products and was fully committed to combating those that did not conform to quality standards. It added that it was important to state up front (in the resolution) that the aim was to protect public health, not trade interests.

India also recalled another WHO initiative, i.e., the "Guidelines for the development of measures to combat counterfeit medicines" (WHO/EDM/QSM/99.1), which, it said, provided an overview of the problem and the factors contributing to counterfeiting, and steps and specific measures to be taken to combat it. The Guidelines provide that member states take their own measures to combat counterfeits, India said, adding that WHO should provide a status update on the outcome of the Guidelines.

India also raised concerns over the "counterfeiting" definition proposed by IMPACT. It said this definition has never been used before. Any change in the definition whenever it is considered should state that generics do not entail patent infringement.

India emphasised that generic and branded medicines that are not registered but that are available are not counterfeits. It sought to defer the matter to enable member states to consider all aspects since the nuances, implications and scope of the issues have yet to be discussed.

Brazil expressed alarm that IMPACT's international stakeholders included WIPO, the WTO, the Council of Europe, IFPMA, the European Commission and Interpol. It said that WHO had a crucial role in public health but it was concerned about how this role was now mixed with law enforcement mechanisms that could drive out legitimate generic producers.

Brazil said that it was not in a position to even "note" the report and requested further discussions. It added that the results from IMPACT had political consequences for developing countries and for legitimate producers. Brazil said that it did not recognise the legitimacy of IMPACT and its reports and thus saw no reason to discuss the resolution.

Argentina said that it could not support the contents of WHO's report as it focused the discussion on combating counterfeits as an end in itself rather than as a public health effort. It stressed that counterfeits should not be dealt with by WHO, adding that Article 1.1 of the TRIPS Agreement of the WTO states that member states can establish the mechanisms they see fit to implement the agreement.

Thailand also called for further discussions on the draft resolution and the Secretariat's report. It said WHO should explain how the IMPACT initiative was different from (or similar to) the 1999 WHO Guidelines. If it was different, it should show the difference and explain the rationale for the change in WHO's strategy.

Venezuela supported the interventions by India and Thailand, and said that there was a need to further analyse the causes of counterfeiting. Chile said that the Secretariat's report focused on counterfeits as a problem in and of itself and not as a public health problem. It said that the documents produced by IMPACT did not have the mandate of the WHA. It also supported interventions by Thailand and India and said that it did not agree with the resolution.

Cuba said that not adopting the resolution did not mean that a country would not act against counterfeit goods as Cuba was doing a great deal in this regard.

Indonesia also agreed with others that the principles and recommendations developed by IMPACT and mentioned in the Secretariat's report needed further exploration. Since these had implications beyond the health sector, more time was needed for national consultation.

Jamaica, on behalf of the CARICOM grouping of Caribbean countries, welcomed the IMPACT initiative but cautioned that expanding the nomenclature to other products should not divert attention from counterfeits. Counterfeits are sold with the intent to deceive with respect to origin, source or insufficient or incorrect ingredients that may or may not be harmful.

A drug that had not received regulatory approval was not necessarily harmful. The manufacture of counterfeits was not limited to developing countries but also included Canada, Belgium, the Netherlands and Portugal, amongst others. Generics were not counterfeits, it added.

Jamaica clarified that not all infringements of IPRs could be described as counterfeit and often it was a matter of controversy. It also stated that the relationship between rights and the exceptions to rights was complex. Sometimes cheaper products were also sold under the exhaustion-of-rights principle (parallel importation) or through the use of IPR exceptions, such as voluntary or non-voluntary licences, and these were not counterfeits, it added.

3 Approach to "counterfeit" drugs may affect access to medicines

Published in* SUNS *#6618 dated 15 January 2009

Geneva, 14 Jan (Sangeeta Shashikant) – A WHO Secretariat report and the attached draft resolution (EB124/14) prepared for the WHO Executive Board (EB) meeting starting 19 January propose resolving health problems through mechanisms related to enforcement of intellectual property rights (IPRs).

Some experts are concerned that this is a wrong approach as it may end up negatively affecting the legitimate use of generic drugs and thus become an obstacle to access to medicines.

The mechanisms include bundling legitimate health concerns under the rubric of "counterfeit", a term used in connection with IPRs, wherein the numerous anti-counterfeiting initiatives that have emerged endorse solutions oriented towards protecting and enforcing the rights of the IP holders.

Another linked mechanism is the International Medical Products Anti-Counterfeiting Taskforce known as IMPACT. The Secretariat's report and draft resolution seek WHO member states' endorsement for IMPACT and its activities.

There are legitimate health concerns pertaining to the quality, safety and efficacy of medicines as there are problems concerning products with wrong information on the label with regard to the content, date of manufacture, place of manufacture and date of expiry (known as false labelling); products which contrary to the label contain no active ingredient or a wrong active ingredient or an insufficient amount of active ingredient (known as spurious drugs); and low-quality drugs caused by poor manufacturing practices, poor transportation techniques or poor storage facilities (substandard drugs).

The initial mandate given to WHO through resolution WHA41.16 on rational use of drugs in 1988 was for WHO not only to initiate programmes on "counterfeit" but also to address problems of "falsely labelled", "spurious" and "substandard" drugs. However, while the term "counterfeit" appears to have been given momentum by interests in WHO, other concepts have been sidelined.

Thus, the WHO Secretariat's report and attached draft resolution titled "Counterfeit medical products" may come under scrutiny and debate at the EB meeting as the stakes involve the continued right of developing countries to have access to good-quality, safe and affordable generic medicines.

According to experts, the documents before the EB could result in negative implications for access to medicines and hamper the development of generic drug industries in developing countries.

The report and draft resolution use highly politicised terminology, i.e., "counterfeit", and present this term as a central health problem, distinct from IP issues. In paragraph 5, the Secretariat's report states, "Often no distinction is made between patent violations, patent or trademark disputes, copyright violations and actual counterfeiting." Para 12 says that "[t]he intellectual property rights approach identifies the rights holder as the main victim of counterfeiters and as the main trigger of enforcement and prosecution while, in the case of medical products, the real victim of counterfeiting is the patient".

The Secretariat's report seems to disregard the numerous international documents and national laws that use "counterfeit" in connection with IPRs, particularly trademark violations, and the numerous anti-counterfeiting laws that are focused on IP protection and enforcement.

For example, the TRIPS Agreement in the WTO refers to "counterfeit" in its preamble, i.e., "Recognizing the need for a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods", and further refers to "counterfeit" in the context of trademark violations about seven times.

In fact, Article 51 of the TRIPS Agreement defines the term "counterfeit trademark goods" as "any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation".

A similar definition of counterfeit goods is used in "The EC Regulation concerning customs action against goods suspected of infringing certain IPRs and measures to be taken against goods found to have infringed such rights (Council Regulation (EC) No. 1383/2003)" in the European Union (EU) as well as in other national legislations.

The US Food, Drug, and Cosmetic Act defines a counterfeit drug as "a drug which, or the container or labelling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint or device or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed or distributed such drug and which thereby falsely purports or is represented to be the product of or to have been packed or distributed by such other drug manufacturer, processor, packer, or distributor".

Numerous anti-counterfeiting initiatives have recently emerged, for example, the Anti-Counterfeiting Trade Agreement (ACTA) (a plurilateral initiative of the EU, Japan, United States and Switzerland); the World Customs Organisation's "Provisional Standards Employed by Customs for Uniform Rights Enforcement (SECURE)"; G8 Countries' Initiative on Counterfeits; the World Intellectual Property Organisation's Advisory Committee on Enforcement (ACE); the Security and Prosperity Partnership (SPP) (between Canada, Mexico and the US); Interpol's initiatives on IP crime and other initiatives in the US as well as in the EU, all geared towards strong protection and enforcement of IP.

One of the main aims of these initiatives is to export legislation to developing countries to get them to take on TRIPS-plus enforcement. Broadly some of the prescriptions in these anti-counterfeiting initiatives include:

(1) an extensive legal framework designed to ensure that the authorities and the rights holders have the appropriate tools for strong IPR enforcement;

(2) shifting the burden of protecting IP rights to governments and reducing the burden on IP holders to protect their rights;

(3) extensive powers to customs authorities to seize imports, exports and transhipments of goods suspected of infringing IP;

(4) authority to take action against suspected infringers even in the absence of complaint by rights holders;

(5) enhancing penalties including imposing criminal sanctions (in addition to civil or, where applicable, administrative liability);

(6) extensive powers to the authorities to seize documentary evidence relating to the suspected infringement and the suspected goods themselves and for the granting of preliminary injunctions;

(7) seizure of the alleged infringer's bank accounts and other assets and profits to ensure payment of damages; and

(8) destruction of IPR-infringing goods and seizure of equipment and materials used to make IPR-infringing goods.

The WHO Secretariat deals with and uses the term "counterfeit" in a confusing manner. Such confusion could be damaging for access to medicines in a climate where major industrial countries, in particular the US and the EU, are on a rampage to promote IP protection and enforcement that goes beyond the TRIPS Agreement through many methods, including influencing programmes in UN and other international agencies.

Legitimate health concerns pertaining to quality, safety and efficacy of medicines do exist, as noted above. However, when some of these concerns are packaged under the term "counterfeit", a term used in the context of IP, the likely prescription is bound to be oriented towards protecting and enforcing the rights and interests of the IP holder to such an extent that it may damage access to medicines.

A case in point is Kenya's recent anti-counterfeiting legislation adopted by parliament in 2008 amidst publicity on how the consumer must be protected against counterfeit medicines. However, the bill has little to do with protection of consumers or public health and more to do with protecting the rights and interests of IP holders.

The scope of the bill includes a wide range of IP including plant breeders' right (under the Seeds and Plant Varieties Act), trademarks, patents and other IP rights protected under the Industrial Property Act. The bill contains obligations exceeding those that developing countries are required to fulfil to comply with the TRIPS Agreement, while making no explicit accommodation for the legal limitations and exceptions usually found in IP laws.

The bill defines counterfeiting as "taking the following actions without the authority of the owner of intellectual property right subsisting in Kenya or elsewhere in respect of protected goods". This paragraph applies to actions of (a) manufacture, production, packaging, re-packaging, labelling or making, whether in Kenya or

elsewhere, of any goods whereby those protected goods are imitated in such manner and to such a degree that those other goods are identical or substantially similar copies of the protected goods; (b) manufacture, production or making, whether in Kenya or elsewhere, of the subject matter of that intellectual property, or a colourable imitation thereof so that the other goods are calculated to be confused with or to be taken as being protected goods of the said owner or any goods manufacturer, produced or made under his licence; and (c) the manufacturing, producing or making of copies, in Kenya or elsewhere, in violation of an author's rights or related rights.

The effect of such legislation is the protection of an IP right even when it does not subsist in Kenya. Thus, IP rights related to a product patented in another country but not in Kenya would still be enforced in Kenya.

In view of the detrimental effects of such legislation, non-governmental organisations (NGOs) working on access to medicines in Kenya battled to include a provision to limit damage to access to medicines and damage to the use of flexibilities (such as parallel importation and compulsory licensing) that are contained in the Kenyan Industrial Property Act. Thus, the final bill includes an additional paragraph on medicines: "in relation to medicine, ['counterfeiting' means] the deliberate and fraudulent mis-labelling of medicine with respect to identity or source, whether or not such products have correct ingredients, wrong ingredients, have sufficient active ingredients or have fake packaging: Provided that nothing in this paragraph shall derogate from the existing provisions under the Industrial Property Act."

This definition is from a definition worked out in 1992 in a workshop organised by WHO and the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA). There are problems with this definition; for example, the terms "identity" and "source" are not explained. In the absence of such an explanation, "identity" could also refer to the trademark or the trade name of the drug, which means that a drug of good quality but having a close similarity with another trademark or trade name can be termed as a counterfeit drug. The term "source" could be interpreted to mean the patent holder of that product or the chemical entity. In both cases the definition would address IP issues and not health issues.

However, the exception is somewhat of a victory for health groups particularly since it clearly safeguards, at least in the context of medicines, the exceptions and limitations as well as other flexibilities in the Kenyan Industrial Property Act.

The bill also promotes the protection of IPRs, a private right, more directly through publicly funded protection institutions and measures. For example, the bill

establishes an Anti-Counterfeiting Agency to combat counterfeiting and their trade by receiving complaints regarding protected goods. The Agency shall also appoint inspectors with extensive powers to take action against goods suspected of infringing IPRs (with or without a complaint by the IP holder), including the right to enter and inspect any place reasonably suspected for counterfeit goods and to make arrests without warrants.

Other measures allow a customs office to seize products at the border on complaint by an IP holder. The process for complaint is simple in that the owner of an intellectual property right that has valid grounds for suspecting that the importation of counterfeit goods may take place, can make an application for seizure of the product to the relevant authority. The IP holder has to provide some evidence of an IP right subsisting, and the relevant authority has to consider and deal with the application in three working days to be satisfied that there are reasonable grounds that the applicant is prima facie the owner of the IP right. The seizure may also take place on the initiative of the inspectors.

The Kenyan bill is one concrete case that shows how a term such as "counterfeit", when used to address health problems, can result in national legislation aimed towards protecting the interests of IP holders, with potential damaging effects on access to medicines.

The latest definition for "counterfeit", proposed in the context of IMPACT in a meeting held in Hammamet, Tunisia on 3-5 December 2008, suffers from the same problems. The WHO Secretariat's report, by referring to the definition in para 10, seeks the endorsement of WHO member states for the definition concerned.

The definition proposed is as follows:

"The term counterfeit medical product describes a product with a false representation(a) of its identity(b) and/or source(c). This applies to the product, its container or other packaging or labelling information. Counterfeiting can apply to both branded and generic products. Counterfeits may include products with correct ingredients/components(d), with wrong ingredients/components, without active ingredients, with incorrect amounts of active ingredients, or with fake packaging."

"Violations or disputes concerning patents must not be confused with counterfeiting of medical products. Medical products (whether generic or branded) that are not authorized for marketing in a given country but authorized elsewhere are not considered counterfeit. Substandard batches of, or quality defects or non-compliance with Good Manufacturing Practices/Good Distribution Practices (GMP/GDP) in legitimate medical products must not be confused with counterfeiting."

The notes referred to above are as follows:

(a) "Counterfeiting is done fraudulently and deliberately. The criminal intent and/or careless behaviour shall be considered during the legal procedures for the purposes of sanctions imposed."

(b) "This includes any misleading statement with respect to name, composition, strength, or other elements."

(c) "This includes any misleading statement with respect to manufacturer, country of manufacturing, country of origin, marketing authorization holder or steps of distribution."

(d) "This refers to all components of a medical product."

As with the IFPMA-WHO definition, one of the most problematic aspects of the new definition on "counterfeit" is that it contains within its definition IP issues as well as health concerns such as false labelling and spurious drugs.

For example, the term "identity" is explained as including "any misleading statement with respect to name", which could also mean brand name, which is usually protected under trademark. Thus, a drug containing correct active ingredients but having a close similarity with another trademark or trade name can be termed as a counterfeit drug.

Similarly, in the new definition, false representation of identity and source applies not only to labelling but also to the "product, its container or other packaging". Thus, false representation with regard to any of those elements would make the product a "counterfeit" within the scope of the definition.

This means that a product also may be classified as counterfeit, for example, when the shape or colour scheme of the product is similar to that of the competing product, irrespective of correct labelling information and contents. This is particularly problematic since presently the scope of trademark protection covers not only traditional trademarks like words, signs or combinations of both but also non-traditional trademarks such as taste, shape, colour, touch and feel, smell, etc. Thus, in this case the definition is more about protection of IP elements.

The definition also states that patent violations and disputes must not be confused with counterfeits, but this means that the definition includes other IP violations such as trademark violations.

The definition also includes some health elements of false labelling and spurious drugs. As mentioned, an approach that combines IP and health issues under the rubric of "counterfeit" can then be used by proponents of "anti-counterfeiting" initiatives motivated to achieve a strong IP enforcement agenda and not by public health considerations. Thus, the resulting effect is the protection of the interests and rights of the IP holder rather than the patient, which could undermine access to medicines and nascent pharmaceutical industries in developing countries.

The inclusion of IP elements in the definition together with IP enforcement prescriptions such as seizures at the border (promoted by the World Customs Organisation, Interpol, the EU and the US) will result in seizures that have more to do with IP violations (with no relevance to quality, safety and efficacy) but are cloaked under the rubric of public health protection.

Evidence of this taking place is already emerging as shipments of drug products of Indian companies meant for other countries are being seized at European ports on charges of so-called counterfeiting and patent infringement. India is one of the few countries with an advanced generic manufacturing sector and is a major supplier of generic medicines to developing countries. According to a news report, the Indian Pharmaceutical Export Promotion Council (Pharmexcil) has requested the Commerce Ministry to ask the European Commission to relax its regulations on patent and trademark issues so that drug shipments in transit are not seized.

Another concern in relation to the definition is the scope of the definition, i.e., it relates to "medical products" covering a broad range of items encompassing drugs, vaccines, diagnostic kits, medical devices (such as surgical devices, scanners, X-ray machines) as well as the raw material used for production. It is not clear from where WHO derives its mandate to deal with "medical products". WHA resolutions 41.16, 47.13 and 52.19 referred to in the draft resolution only refer to medicines, drugs and pharmaceutical preparations. They do not provide a mandate to deal with "medical products".

The definition speaks, in note (a), of counterfeiting as an act done "fraudulently and deliberately", thus implying the presence of the element of intention; it also states that "criminal intent and/or careless behaviour" should be considered for purposes of imposing sanctions. This means that even in the absence of intention (for example, in cases of careless behaviour), an act could amount to counterfeiting.

This is contradictory and confusing. If an act is done fraudulently and deliberately, then the issue of "careless behaviour" for purposes of sanction should not arise. Also, the second sentence of the note speaks of criminal intent "and" careless

behaviour, which is also contradictory since an act cannot be careless and intentional at the same time.

In addition, according to the note, the element of intent will be considered for the purpose of imposing sanctions. This implies that the element of intent will only be assessed at the trial stage in court. This does not prevent measures such as seizing goods at the border on the basis of a complaint by an IP holder on mere suspicion of "false representation" (be it intentional or unintentional). Secondly, it implies that the court will only consider the element of intent for purposes of deciding the nature of sanctions.

There is also concern over the imprecise and open-ended nature of the definition, in particular explanations to the terms "identity" and "source", which provide scope for further addition of any other elements and thus abuse. Further, in the pharmaceutical context one is not clear regarding the meaning of the terms "country of manufacturing", "country of origin", "marketing authorization holder" and "steps of distribution". For instance, the term "country of origin" can mean the country of origin of the formulation or the country of origin of the active pharmaceutical ingredient. The implication of such open-ended terms is that good-quality products could end up being deemed counterfeits.

Further, national laws, especially drug regulatory laws, already address the quality and safety of drugs from a public health angle. These laws use terms like "misbranded drugs", "spurious drugs" and "adulterated drugs". Adoption of the new definition may lead to complications at the national level and require amendments to present laws.

Using the term "counterfeit" to ensure good-quality, safe and effective medicines could ironically become an obstacle blocking access to and availability of generic medicines in developing countries. Thus, the consequences of such an approach have to be seriously examined. Instead of using terminology as controversial and politicised as "counterfeit", it may be better to list public health problems and deal with these problems directly from a public health perspective.

Legitimate health concerns pertaining to quality, safety and efficacy of medicines that exist with regard to false labelling, spurious and substandard drugs have to be addressed through a public health lens rather than being confused and complicated by using the perspective of IP rights holders and IP enforcement.

4 WHO/Big Pharma counterfeit plans receive harsh criticism

Published in* SUNS *#6620 dated 19 January 2009

Geneva, 16 Jan (Riaz K Tayob) – Small pharmaceutical manufacturers and civil society groups that support equitable access to medicines have joined hands in their opposition to the World Health Organisation's International Medical Products Anti-Counterfeiting Taskforce (IMPACT).

The next session of the WHO Executive Board (19 to 27 January) is to consider a report and draft resolution (EB124/14) on "Counterfeit medical products" driven mainly by the work of WHO in relation to IMPACT.

In a 15 January letter to Indian Prime Minister Manmohan Singh, the Small and Medium Enterprise Pharma Confederation of India calls for the total rejection of the work of IMPACT. It regards the WHO Secretariat proposal on counterfeit medicines as a serious move at the international level which threatens exports from India particularly to developing countries.

Neither IMPACT, the taskforce partnership between WHO and "stakeholders", nor its work is acceptable, the letter from the Indian small-scale pharmaceutical producers says. It advises that India should not fall into the trap of negotiating any definition of the term "counterfeiting" as it is driven by multinational pharmaceutical industry interests.

Under the garb of coining a new definition, multinational companies should not be allowed to bring in issues of quality, adulterated and spurious drugs solely to muddle facts and surreptitiously use it to curtail Indian exports.

First, the letter cites the dominant influence of multinational pharmaceutical companies in IMPACT. The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) has played and is playing a leading role;

it is the head of IMPACT's technology working group and, more importantly, is a part of the planning group, the main decision-making body of IMPACT.

Second, through leadership and funding, the European Union is pushing its agenda to promote its own pharmaceutical industry via intellectual property rules. The EU is trying to translate their national policy into an international norm through IMPACT.

Specifically, the letter states, the EU has given significant funds to IMPACT and particularly to the promotion of IMPACT's "Principles and Elements for National Legislation against Counterfeit Medical Products" which proposes an international criminal regime for so-called "counterfeit" drugs for enforcement by both customs officials and drug regulatory authorities.

The letter refers to cases of drug shipments seized by EU customs officials under their laws, even though the drugs are safe and efficacious. Multinational pharmaceutical companies could try and raise complaints about intellectual property rights infringement to effectively stop the supply of medicines from India.

According to the *Mint* newspaper, a $500,000 consignment from the Indian manufacturer Dr Reddy's Laboratories to Brazil was seized while in transit in the Netherlands recently. This follows previous seizures of the exports of small manufacturers.

Mint reports India's Commerce Secretary GK Pillai as saying that the department has taken up the matter with the European Commission (EC, the EU's executive arm) and that "this is an act of piracy by the European Union. The consignment was going to Latin America and was seized in Europe ... This is a dangerous thing happening, which is totally uncalled for. It is part of the strategy by these countries to target generic drugs from India."

According to Zee News, India's Commerce Secretary has said that "we may have to take the issue to the WTO and challenge it ... we would be seeking consultation with the EU."

Mint reports that Leena Menghaney of Medecins Sans Frontieres (MSF) in India said that the EC regulations which have led to the seizure of Indian generic drugs in transit to Brazil have created barriers to the export of affordable, quality, low-cost generic drugs from India to other developing countries. This is part of the IP enforcement agenda, she said.

The letter also charges that IMPACT "has taken shelter behind the WHO Secretariat which has given them the cloak of legitimacy when it is actually nothing more than a multinational industry and developed country agenda to stop exports of medicines."

The letter also refers to a national initiative at the behest of Big Pharma which burdened local industry with several measures but which led to no extra purity of medicines. It notes the multinational takeover is imminent as India is the biggest market in the world. It calls on the government to take immediate action if affordable medicines are to be made continuously available in the country in the future.

In a letter to the Indian Ministry of Health, the New Delhi-based non-profit think-tank CENTAD states that there are grave concerns presented by conflicts of interest in the constitution and processes of IMPACT.

It says that many developed-country pharmaceutical industry organisations have actively participated in formulating the definition. IMPACT promotes stringent intellectual property enforcement to circumvent fair competition in generic pharmaceuticals trade in and from developing countries.

The consequences that flow from the IMPACT definition, which conflates issues and has many ambiguities, may have serious legal and economic implications and could undermine flexibilities prevailing in current international IPR agreements, CENTAD states.

The concern regarding falsifying medicinal products is limited to the issue of spurious and substandard drugs. It proposes that both the draft report and the resolution be opposed. The WHO Secretariat should be requested to start the process afresh by adopting a legitimate member-state-driven agenda.

5 Counterfeit taskforce may block legitimate access to generics

Published in* SUNS *#6623 dated 22 January 2009

Geneva, 21 Jan (Sangeeta Shashikant) – An anti-counterfeit taskforce set up under the World Health Organisation could be used by multinational drug companies to place obstacles to the trade in generic drugs in developing countries, thus affecting access to medicines.

This potential problem is expected to be a source of contention when the WHO Executive Board (EB) meeting, which started on Monday (19 January), discusses this issue later this week.

The discussion will take place under an agenda item related to the WHO Secretariat's report and draft resolution on "Counterfeit medical products" (contained in EB124/14).

The documents present counterfeiting as a severe health problem and as an issue that is distinct from intellectual property right issues; endorse the establishment of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) and indirectly its activities; and encourage WHO member states to adopt national legislation and regulations to combat counterfeit medical products presumably on the basis of documents issued by IMPACT.

They also provide freedom to WHO to link up with any institution/entity on this issue, including outsourcing technical assistance, notwithstanding the special interests that entity might have. They further empower IMPACT by leaving implementation of the resolution to IMPACT as well as allowing IMPACT to make recommendations to WHO member states.

Ahead of discussions on the agenda item, several African country delegates participating in the EB meeting have privately pointed out that in using the term

"counterfeit", their intention is to protect against medicines with no or wrong active ingredients (spurious medicines) and medicines of low quality (substandard medicines) and not to protect or enforce IP rights.

Other delegations and experts have however pointed out that "counterfeit" is a term used in connection with IP rights, particularly trademark infringements. They find it perplexing that WHO is stressing on "counterfeits" instead of directly addressing health concerns such as spurious and substandard medicines.

These delegations are also concerned that health is being used as a front through the use of the term "counterfeit" to facilitate and expedite the IP enforcement agenda.

Delegations have also privately confided their concerns about the use of IMPACT as a vehicle to push forward the IP enforcement agenda and to put in place measures to squeeze out the generic industry, in an attempt by drug multinationals to retain market competitiveness in the pharmaceutical sector.

These concerns have been heightened with the issuance of a corrigendum EB124/14 Corr. 1 by WHO. The initial draft resolution states, in the preamble, "Recognizing that disputes about, or violation of, intellectual property rights are not to be confused with counterfeiting". The corrigendum corrects this to "Recognizing that disputes about, or violations of, patents are not to be confused with counterfeiting".

The effect of the corrigendum is to ensure that other IP violations, particularly trademark violations, are covered by the counterfeit definition put forward in the Secretariat's report.

There are also many questions surrounding IMPACT in relation to its role in IP enforcement and creating barriers that would impede the development of generic manufacturers of developing countries.

The origins of IMPACT can be traced to a concept paper, "Combating Counterfeit Drugs: A Concept Paper for Effective International Cooperation", drafted by Michele Forzley, a US-based lawyer and a representative to a US Commerce Department Advisory Committee on Intellectual Property.

This paper was in turn based on a 2003 study, "Counterfeit Goods and the Public's Health and Safety", supported by the US Patent and Trademark Office (USPTO) and whose copyright is owned by the International Intellectual Property Institute (IIPI), an industry think-tank. It focused on promotion and enforcement of IPRs.

The 2003 study states that the goal "is to begin the process of shifting the policy perspective on counterfeit goods to an understanding that counterfeits are not only an intellectual property legal problem, but also a very real public health problem". It added that "To reframe the policy perspective is fundamental to the success of any strategy on counterfeit goods".

The study remarks, "what havoc counterfeits might wreck [sic] ... if resources devoted to intellectual property seizures are redirected towards other objectives", and that "often in the developing/underdeveloped world public health surveillance is inadequate or non-existent, … particularly in those with no developed intellectual property legal system."

IMPACT was launched in 2006 following a conference organised in Rome by WHO. It was supported by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA, an association of multinational corporations (MNCs)), resulting in the Rome Declaration.

The Chair of the taskforce when it was initially launched was Dr Howard Zucker, at that time a WHO Assistant Director-General in charge of Health Technology and Pharmaceuticals. He has been criticised by health NGOs and even within the WHO Secretariat for slowing down WHO's work on access to medicines, particularly where it relates to the use of flexibilities allowed under the TRIPS Agreement.

Objectives outlined in the Rome Declaration include promoting coordination among different anti-counterfeiting initiatives and raising awareness of the need for legislative measures at national level. The long-term aim of IMPACT is to "explore further mechanisms, including an international convention, for strengthening international action against counterfeit medicines".

IMPACT: Issues of Participation and Transparency

There is concern over the influence that multinational drug companies exert over IMPACT, particularly in norm-setting. IFPMA plays a central role in the activities of IMPACT as its Director General (presently Alicia Greenidge) heads the Working Group on Technology. The MNCs also participate in IMPACT through the Pharmaceutical Security Institute (PSI), which was established by 14 pharmaceutical MNCs to work on counterfeit drugs.

This direct participation of the private sector in a WHO initiative raises serious issues of conflict of interests and whether there has been compliance with the WHO Guidelines on Working with the Private Sector to Achieve Health Outcomes.

Also, the ad hoc participation of selected WHO member states in IMPACT raises questions as to the extent of participation of WHO member states and the basis on which they are chosen to participate in IMPACT's activities. Another transparency concern is that IMPACT has been operating outside the purview of WHO member states.

IMPACT and Norm-Setting

IMPACT's 2007 General Meeting endorsed a text on "Principles and Elements for National Legislation against Counterfeit Medical Products" ("2007 Model Elements"), which contains the WHO and IMPACT logos. This text covers scope; definitions; obligations of governmental institutions, manufacturers, operators of the distribution chain, retailers and other operators; what amounts to an illegal act; sanctions; and nature of sanctions.

A December 2008 General Meeting of IMPACT in Tunisia revised the text to also include medical devices. More than half the participants (mentioned in the participants' list) were from organisations with a strong interest in IP protection and enforcement.

The Model Elements are meant to serve as a "reference for developing ad hoc legislation aimed at effectively combating counterfeit medical products within their jurisdiction". In fact, they clearly recognise that "Specific national and/or regional bodies of criminal, pharmaceutical, administrative, intellectual property and civil legislation may need to be established or enhanced on the basis of the principles described in this document..."

It is also noteworthy that the Model Elements for national legislation do not explicitly recognise the use of parallel importation and other TRIPS flexibilities. The Model Elements contain a wish list of obligations that governmental institutions, manufacturers, operators of the distribution chain, retailers and other operators should undertake. They list more than 28 responsibilities for the government, nine responsibilities for the manufacturers, eight responsibilities for the retailers and five responsibilities for other operators.

The responsibilities are lopsided and place a heavy burden on the governments. Many of the obligations mentioned are the subject of much debate and dispute in

other fora such as the World Customs Organisation (WCO) and the Anti-Counterfeiting Trade Agreement (ACTA), an initiative on IP enforcement launched by developed countries.

IFPMA, being the Chair of the Working Group on Technology, plays a central role in the overall standard-setting functions of IMPACT (since Chairs of Working Groups are also members of the Planning Group of IMPACT), with a mandate to assess technologies to prevent, deter or help to detect counterfeit products and disseminate information and recommendations on the merits and limitations of technologies. Thus, it is the pharmaceutical industry that will determine the level and types of technology to be used for anti-counterfeit purposes.

For this purpose as well, the pharmaceutical MNC GlaxoSmithKline has prepared a paper on "Anti-Counterfeiting Technologies for the Protection of Medicines", and this paper contains the logos of WHO as well as IMPACT. Interestingly, the paper states that "some of these [technologies] are protected by international patents and may only be available from licensed suppliers, subject to appropriate royalties or license fees".

The Terms of Reference of IMPACT clearly state that all IMPACT's documents and other outputs will be issued by WHO and will be disseminated with appropriate disclaimers, including that the content does not necessarily reflect the views or state policy of the participating organisations, agencies and institutions (including WHO).

However, IMPACT documents available on websites (e.g., the 2007 Model Elements) do not contain this disclaimer, although the WHO logo is visible on IMPACT documents. This has given rise to concern that there is a presumption that IMPACT's documents reflect the position of the WHO Secretariat and its member states.

IMPACT and Barriers to Trade

Many obligations in the 2007 Model Elements could create non-tariff barriers to trade in medical products and become possible entry barriers for the generic industries particularly in developing countries.

Some of these elements include: (a) regulating the manufacture, importation, exportation, distribution, supply, donation, and sale of medical products, thereby ensuring that those who perform any transaction have specific licence or are authorised to do so; and (b) establishing regulations for a distribution system

including measurers for traceability of medical products throughout the distribution channels.

Other elements are to establish import procedures (including designating a limited number of entry points for imported medical products); to regulate manufacture of active substances and certain experiments that may pose public health risks; to regulate international trade of labels and packaging materials for medical products; to ensure that suppliers of raw, starting and packaging materials are legitimate and finished medical products are delivered to legitimate operators of the distribution chain, including verifying the legitimacy of business partners; and to document the origin of all materials used in the manufacture of authorised products.

Several of the above can be considered non-tariff barriers to trade in medical products. Besides this, the measures raise other concerns.

The measures may affect TRIPS flexibilities such as parallel importation of good-quality medicines, which is recognised by the WTO members as a measure to promote access to more affordable medicines. Regulations such as those mentioned in paragraph (b) may push parallel traders out of the system, resulting in budgetary consequences for developing countries.

Similar regulations have been proposed in the EU. The pharmaceutical industry is calling for an EU-wide identification system to track and trace medicines to the production site. Parallel distributors are opposed to such measures, also pointing out that there is no evidence that parallel trade is an entry point for counterfeit medicines.

The abovementioned measures may also undermine access to medicines as well as nascent generic pharmaceutical industries.

For example, the Model Elements make it illegal to "manufacture, transport or distribute any equipment, materials, components (including genuine ones) or documentation used in the production or to accompany the distribution of counterfeit medical products with the knowledge or intent that they be used for such purposes". Thus, such a measure would impose liability on manufacturers of active pharmaceutical ingredients (APIs), if those APIs are used to make counterfeits. This places a major burden on the API maker as it would have to verify the validity of the manufacturers to whom it sells and to ensure that all use is legitimate.

The measures also impose liabilities on the transport companies, the makers of labels and all other entities that are directly or indirectly related to the manufacture, transport and distribution of the so-called counterfeits.

Ultimately, such measures would result in entities refusing to deal or trade with generic manufacturers and would thus undermine generic industries in developing countries and undermine access to medicines.

Generic drug industries in developing countries are already adversely affected by the TRIPS Agreement. Any additional standards required with regard to import and export, including adoption of technology standards, would further hamper the attempts of many developing countries to develop their pharmaceutical manufacturing capacity.

IMPACT and the IP Enforcement Agenda

Compounding the problems of lack of participation and transparency is the fact that intergovernmental organisations and the industry associations with which IMPACT is linked are engaged in an aggressive IP protection and enforcement agenda, including establishing TRIPS-plus standards. These organisations include Interpol, WCO, the World Intellectual Property Organisation (WIPO), the European Commission, IFPMA and PSI.

In fact, IMPACT's meetings such as the Conference on Developing Effective Legislation to Combat Counterfeit Medical Products (10-12 December 2007) and Meeting of Jurists and Experts on Legislation to Combat Counterfeit Medical Products (12-13 July 2007) are listed as "WIPO's enforcement-related training and awareness-raising activities and cooperation with intergovernmental and non-governmental organisations".

The G8 major industrialised countries also identify IMPACT as part of their IP enforcement agenda and in this regard would like to strengthen cooperation with WHO.

Susan Sell of George Washington University in a paper identifies Interpol, WCO, WIPO and IMPACT with the IP anti-counterfeiting and enforcement agenda which "involves hundreds of OECD-based global business firms and their foreign subsidiaries."

IMPACT and Technical Assistance

Endorsement of IMPACT in the Secretariat's report and in the draft resolution would set a significant precedent in WHO in that norms set essentially by the private sector will then become the basis for technical support at the national level.

There is evidence that some developed-country members have such intentions. A recent European Commission paper on "Safe, Innovative and Accessible Medicines: A Renewed Vision for the Pharmaceutical Sector" states its intention of using IMPACT to develop and enforce legislation against third countries. The same paper describes how the EU is losing market share in the pharmaceutical industry to emerging market economies. The EC is a key funder of IMPACT.

The report estimates that $20 million will be needed for supporting activities at regional and country levels and $10 million for global coordination, policy guidance and the IMPACT secretariat's costs.

Establishing and enforcing national legislation particularly in developing countries through any agency (notwithstanding their vested interest) that is able to provide funding is a key aim of the draft resolution in EB124/14.

However, many developing countries have privately raised concerns that the authority to deal with quality and safety issues for medicines is being taken away from drug regulatory authorities and placed in the hands of law enforcement agencies which have little idea about such issues.

6 Concerns voiced over IMPACT, Secretariat's role on "counterfeits"

Published in* SUNS *#6627 dated 28 January 2009

Geneva, 27 Jan (Sangeeta Shashikant) – Many developing countries voiced concerns at a meeting of the Executive Board of the World Health Organisation (WHO) over the Secretariat using the term "counterfeit" to describe problems relating to the quality, safety and efficacy of medical products, and addressing such problems through the International Medical Products Anti-Counterfeiting Taskforce (IMPACT).

At a meeting of the Executive Board on 23 January, Latin American and Southeast Asian countries (grouped in the GRULAC and SEARO groupings respectively) as well as Iran and Egypt were concerned that the term "counterfeit", used in connection with IP violations particularly trademark infringements, would result in WHO addressing health concerns through IP enforcement measures.

Concerns were also raised over WHO's anti-counterfeit taskforce IMPACT, which many countries felt was unsuited to address the issue of quality, safety and efficacy (QSE) of medical products because of the lack of a mandate for its establishment from WHO's governing bodies; its emphasis on "counterfeits"; the involvement of the private sector in its activities which raises issues of conflicts of interest; and lack of transparency.

The Africa Group of countries, recognising alarm among some countries over the use of the term "counterfeit", recommended improving its definition.

Malawi spoke of the need perhaps to come out with another word to replace "counterfeit". It also recognised concerns raised about IMPACT but stressed the need to come up with measures to deal with substandard medicines.

Strong views were expressed against the Secretariat's report and draft resolution attached to the report contained in EB124/14 entitled "Counterfeit medical products". This resulted in the rejection of the documents.

The documents presented by the Secretariat featured counterfeiting as a severe health problem distinct from IP issues and sought endorsement for IMPACT and its activities.

Analysis of the Secretariat's report and attached draft resolution suggests that the documents may potentially affect the prompt availability of affordable generic medicines.

The debate at the Executive Board resulted in significant convergence among most developing countries present that more efforts need to be made to strengthen the drug regulatory authorities (DRA) – which tend to be weak in developing countries – to address QSE through WHO with guidance from member states.

Noting the unease and dissatisfaction with the approach taken by the report and draft resolution, on the suggestion of WHO Director-General Dr Margaret Chan, it was agreed that WHO would prepare a new report (without a resolution) for member states' consideration at the World Health Assembly (WHA), which would address the public health dimension of the issues and what WHO is doing to strengthen the DRA. In this regard, it would also look at the Global Strategy and Plan of Action (GSPOA) on Public Health, Innovation and Intellectual Property.

At the request of Thailand, Dr Chan also agreed to prepare another report that would investigate issues of conflicts of interest among members of IMPACT.

However, the agreement was preceded by a push from the Chair of the meeting (Sir Liam Donaldson of the UK), the EU and the Swiss delegation for either an informal working group or some outcome on the issue of counterfeits, despite the apparent dissatisfaction among Executive Board and non-Executive Board members with document EB124/14 prepared by the Secretariat.

Sir Liam on one occasion drew parallels with the draft resolution on "The grave health situation caused by Israeli military operations in the occupied Palestinian territory, particularly in the occupied Gaza Strip", and said that sometimes content did not matter and that agreement was needed more for its symbolism so as not to give comfort to counterfeiters. He argued that it might be possible to agree to a shorter resolution.

Hungary, on behalf of the EU, the UK and Switzerland showed strong support for setting up an informal working group to work out an outcome for the Executive Board. The US suggested the possibility of an intergovernmental meeting prior to the WHA to take the issue forward.

However, such a push was resisted, and resulted in sharp responses from many of the developing countries participating in the meeting as Executive Board members and observers.

Paraguay, on behalf of GRULAC, issued a declaration reiterating its readiness to deal with the medicines policy as WHO is the appropriate forum for QSE of medical products as long as it respects national legislation. It added that adulteration of medicines, absence of objective measures and non-compliance with good manufacturing practices are themes of concern and must be dealt with based on scientific and health evidence to ensure QSE of medical products.

However, it stressed that WHO is not the appropriate forum for observance of IPRs; "counterfeit" pertains to infringement of IPRs, particularly trademarks, and has nothing to do with health concerns. WHO should guide discussions on health issues and not deal with issues that are the purview of other fora. It further stated that actions should be adopted after a process of negotiations among member states that includes the strengthening of the health authorities responsible for regulation of medicines.

Brazil, in opposing the draft resolution, voiced deep concern over the QSE of medical products, adding that it has been working to combat falsification and all forms of illegality. It emphasised that WHO is the forum for debate of methodologies focused on QSE of medical products and should help member states to strengthen their DRA. WHO is not a "forum for discussions on enforcement of intellectual property rights". It said that any norms or definitions set to deal with QSE of medical products have to be inclusive, evidence-based and done through a member-state-driven process.

Brazil highlighted the recent seizure by the Dutch port authorities of an Indian shipment of the generic drug losartan (for treating arterial hypertension), while it was in transit to Brazil, as a concrete example of the negative impacts of the relationship between health issues and enforcement of IPRs.

In relation to this case, Brazil also read a joint statement by its Minister of Foreign Relations Celso Amorim and Minister of Health Dr Jose Gomes Temporao, which states: "The decision to retain the shipment – which was not, at any moment, brought

onto Dutch territory – was undertaken as a result of an administrative request from a third company (therefore, without the official endorsement of the local judiciary system) which allegedly owns intellectual property rights over LOSARTAN in the Netherlands." The statement added that this "process imposes on the supplier, and not on the company which requested the intervention, the responsibility to prove the legality of the transaction, essentially an inversion of the universally accepted juridical concept that the accusatory party must present the evidence."

The statement said: "Irrespective of the value or volume involved, or of the fact that the shipment was returned to the country of origin (India), the Brazilian Government considers that the decision by the Dutch authorities to detain an input which is strategic to public health in a developing country, and exported in conformity with the existing international norms, represents a grave drawback in the treatment of the issue of the universal access to medicines" and "represents a distorted use of the international intellectual property system, supposedly upheld by European Union legislation, and contrary to the spirit and provisions of the Doha Declaration on [the] TRIPS [Agreement] and Public Health." The statement added that "this is the sort of procedure that this Organization should oppose firmly".

Brazil said that the case must be seen in light of the direction which the IMPACT initiative has taken, i.e., under the pretext of a fight against counterfeit medicines, it attempts to impose a revision of WHO's position on the issue, with a view to inhibiting the legitimate commerce of high-quality, competitively priced generic drugs. Brazil stressed its dissatisfaction with the action undertaken in the port of Rotterdam, which it said raised doubts with respect to the commitment of European countries to the issue of access to medicines by developing countries. It added that the action may also be taken up in the WTO.

Brazil also stressed the primacy of health over trade, as well as the right of countries to fully use the flexibilities of the TRIPS Agreement to guarantee universal access to medicines, as reaffirmed in WHO's GSPOA on Public Health, Innovation and IP.

Indonesia, on behalf of SEARO countries, also could not accept document EB124/14. While fully committed to combating drugs that do not conform to QSE, Indonesia questioned the legitimacy of IMPACT, adding that "we are still unclear if the Rome Declaration was subsequently discussed, recognised and endorsed by the EB and WHA to frame the terms of reference or decide on the establishment of IMPACT's function and membership".

Indonesia said that SEARO countries "do not accept" particularly the Principles and Elements for National Legislation (Model Elements) produced by IMPACT, since the process has not been inclusive, and it is the "sovereign" right of countries. It also stressed that the focus should be on the strengthening of the DRA and any discussion on this should be intergovernmental in nature.

Bangladesh also expressed concerns about treating "counterfeit", a term used in relation to IP violations particularly trademark violations, as a public health issue. It added that there was a need for better understanding of the problem and its root causes. It also said that without independent verified data, it may be premature to consider the issue. It further said that the approach to the issue, i.e., taking authority away from the DRA and placing it in the hands of the law enforcement agencies which have no idea or capacity to evaluate QSE of medical products, may in fact affect drug supply.

Expressing concerns over IMPACT and its activities, Bangladesh said these are not sufficiently member-driven and have a high involvement of the private sector. This raises issues of conflicts of interest, especially since organisations participating in IMPACT are also engaged in IP protection and enforcement.

Bangladesh also voiced apprehension with regard to the new definition that emanated from the recent IMPACT meeting in Tunisia, adding that the definition lacks precision and may well have serious adverse impacts on access to drugs since it may include legally produced generic drugs.

It further stated that any definition should exclude all IP infringements. It referred to the Secretariat's report which states that the proposed definition "will serve as a model text for national legislation", adding that if so it has to be a definition by member states and not by IMPACT since an inaccurate or misleading definition could have an impact on developing countries and industries.

It stressed the importance for developing countries to retain as much policy space as possible, and concluded by stating that it could not support WHO's report and the draft resolution as it focuses on combating counterfeits as an end in itself rather than as a public health effort.

Niger, on behalf of African member states, pointed to the difficulty in getting the right information about the magnitude and extent of the "counterfeit" problem. It added that most low-income countries do not have DRA. It also stressed the need for a better definition and exchange of information.

[Several African country delegates participating in the Executive Board meetings have privately pointed out that in using the term "counterfeit", they intend to protect against medicines with no or wrong active ingredients (spurious medicines) and medicines of low quality (substandard medicines) and that their intention on this issue is not to protect or enforce IP rights.]

Hungary, on behalf of the EU, said that this issue was a "priority" for the EU, adding that the new EU draft legislation is based on IMPACT's Model Elements and that the fight against counterfeit required international action based on clear principles and cooperation between the police, banks and customs. In this regard, WHO has the coordinating role.

The US showed strong support for IMPACT.

The UAE spoke in favour of the report and draft resolution while Oman sought clarification as to whether one of the causes for the increase in counterfeits was the patent system which allows patents to be valid for 20 years.

Switzerland said that while it was better to change the term "counterfeit", it wondered whether this was politically feasible. It stressed that one must use "counterfeit medical products", which is not the same as "counterfeits". It further said that it did not hear criticisms on the quality of the technical work of IMPACT.

Sir Liam, the Chair of the Executive Board, brought up the possibility of a small informal drafting group and sought to push it forward. However, the Chair's push for a small drafting group and a short resolution was resisted, and in fact resulted in sharp responses from many of the developing countries participating in the meeting as Executive Board members and observers.

India, aligning itself with the SEARO statement, reiterated concerns of how non-tariff barriers are used to obstruct access to good-quality and affordable medicines. It opposed the formation of any group to discuss the issue until WHO came out with documentation with regard to medicines which are "substandard", "falsely labelled" and "spurious".

Iran also voiced strong concerns over document EB124/14, saying that if considered, it will result in a strong mandate on "counterfeit" in relation to IP and an endorsement of IMPACT. It added that it could not accept either outcome.

It also reiterated that "counterfeit" which pertains to IP violations is not per se a quality problem and not an issue for WHO. It stressed on the need to focus on the

issues of false labelling and substandard and spurious medicines and avoid issues of IP enforcement.

Iran also asserted that the IMPACT definition of "counterfeit" in the Secretariat's report opens the possibility of using health concerns as a means for IP protection and enforcement, and that IMPACT's Model Elements would hamper access to medicines and the achievement of self-sufficiency in manufacturing.

Iran further raised the issue of the highly unbalanced participation in IMPACT and the lack of full transparency, stressing that members need to avoid hasty action amounting to endorsement of IMPACT and its views on counterfeit.

Venezuela voiced objection to the use of the term "counterfeit" on the basis that its connotation can be misleading. It added that IMPACT's definition and proposals can be used as a front for protectionism and might amount to a barrier to countries wishing to develop self-sufficiency in manufacturing. It expressed the view that direct financing by special interests and the stress on law enforcement interfered with sovereign matters. It rejected outright IMPACT's policies.

Thailand also said that it could not support EB124/14 and especially IMPACT's Model Elements. It however added that it could support strengthening DRA and having a discussion on this issue.

Argentina also mentioned that WHO was not the appropriate forum for enforcement of IP rights, adding that the TRIPS Agreement contained a definition on "counterfeit" and that it was not appropriate for WHO to draw up an additional definition. It also said that it did not support harmonisation on this issue and urged the Executive Board not to recommend to the WHA the adoption of the resolution.

Ecuador raised similar concerns, adding that WHO should direct its work towards QSE within the context of public health and respecting national legislation, as it was not the appropriate forum for enforcement of IP rights.

Egypt said that recently there has been a lack of clarity as to what WHO's activities have been and should be in relation to QSE of medical products. There is a growing sense of unease about IMPACT, an initiative which does not enjoy a mandate from WHO's governing bodies.

It asked Executive Board members: "Are we discussing public health problems, or are we, as has recently been witnessed in other intergovernmental fora in specialised

agencies of the United Nations and other IGOs [intergovernmental organisations], witnessing an importation of a specific IP enforcement agenda into the WHO?"

Ensuring the quality of drugs requires utmost attention and should be handled through DRA and WHO has a role to play in supporting DRA, it added. On the other hand, counterfeit is a trademark violation, which should be dealt with under relevant IP laws. It further stated that WHO should pay attention to finding solutions, not through the lens of IP but health.

It also said that substandard products represent a far larger risk and these classes (i.e., counterfeit and substandard) must not be confused particularly at WHO.

Egypt also highlighted concerns over IMPACT regarding questions of representation, and on the quality and objectivity of data including statistics used. It added that IMPACT has no mandate to pronounce on issues which are the prerogative of national legislation and that neither the draft resolution nor the report is a positive way forward.

Egypt also responded to the Chair's remarks on the Gaza draft resolution, stating that the resolution is a valid contribution that it expects WHO to work on.

Chile said that on substance this is not an IP problem but one of poor-quality, substandard, falsely labelled and unapproved products not in compliance with QSE.

As to form, it alluded to the problem of transparency, insufficient documents and unclear funding as well as IMPACT meetings held everywhere except in Geneva, adding that to give legitimacy to the issue it has to be dealt with in WHO or at least a group established by the EB or WHA.

It referred to a definition that emerged in 1992 but was not adopted by member states and spoke of the need for a definition which would be to everyone's satisfaction, adding that this issue cannot be resolved in a working group in an EB session.

The Bahamas said there were many assumptions made about regulatory capacity in EB124/14, stressing that it was important to know what WHO was doing to focus on public health aspects particularly as it relates to member states' regulatory capacities. Neither criminal nor trade activities are managed by health, it added, and there was a need to remove all references to criminal and trade aspects from the report.

Dr Carissa F Etienne, WHO Assistant Director-General for Health Systems and Services, attempted to reiterate the same old arguments of WHO found in the Secretariat's report in response to many of the interventions made, i.e., that counterfeiting is a public health problem and that there were statistics on it, adding that counterfeit in WHO referred to patients that were the victims.

Dr Etienne also said that IMPACT's secretariat lies in WHO and attempts to bring stakeholders together, and that the Secretariat will make IMPACT more transparent.

However, countries simply could not accept Dr Etienne's explanation.

The Bahamas said that it expected a more specific response as to what WHO itself has been doing to provide technical support to countries in the region.

Bangladesh, responding to the suggestion of the Chair on an informal drafting group and to the WHO Secretariat, said that since it does not accept the underlying premise of EB124/14, there cannot be an effective discussion on the matter. It urged the Chair to recognise its unease and dissatisfaction with EB124/14.

In response to Switzerland, Bangladesh said it was questioning the legitimacy of IMPACT; thus, how was it able to critique IMPACT's work?

Brazil also expressed its dissatisfaction with EB124/14, adding that the issue was not about whether the resolution was big or small, but it was not clear what was meant by "counterfeit" in the context of WHO's mandate.

It also said that the Secretariat's report builds on the technical work done by a group which is not a member-driven group. Member states don't know whether IMPACT takes into consideration in its deliberations the relevant guidelines and issue such as high prices and the impact on counterfeits.

It also cautioned the Secretariat that it would not like to see WHO being taken over by Interpol or the police.

7 Developing countries attack Dutch seizure of generic medicines

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Geneva, 4 Feb (Sangeeta Shashikant) – Developing countries at the WTO General Council on 3 February launched a scathing attack on the action by the Dutch government in seizing a cargo of generic medicines in transit in Rotterdam (en route from India to Brazil) for alleged patent infringement.

The seizure of 500 kilograms of losartan potassium, an active pharmaceutical ingredient (API) used in the production of medicines for arterial hypertension, was instigated by an administrative request lodged by the corporation which holds the patent on the API in Holland. The API is not patented in either India or Brazil.

The Dutch action was taken in line with procedures set out in the EC Council Regulation 1383 of 22 July 2003 which empowers EU member states' customs authorities to detain goods in transit on suspicion of an infringement of intellectual property rights.

This case is the latest in a recent spate of seizures of several consignments of generic drugs produced by Indian companies by the Dutch customs authorities on the ground of alleged IP violations.

The strong criticisms at the WTO's General Council were made by Brazil and India, the countries most affected by the Dutch seizure, and supported by more than 15 other developing countries. They fear that the Dutch action is an example of increasing attempts to put in place measures that go beyond the TRIPS Agreement and that result in extraterritorial enforcement of IP rights.

According to a diplomat, the EU response to the criticisms at the WTO was "defensive in an offensive way". The EU said that it was ready to engage bilaterally on the issue but also spoke of the need to enter into a "non-emotional" debate

about it. The EU also remarked, jokingly, that if one got emotional, it had a non-generic medicine to treat that.

The heated discussion at the WTO followed an equally controversial session at the World Health Organization's Executive Board meeting last month wherein developing countries strongly criticised the WHO Secretariat for its report and draft resolution on "Counterfeit medical products".

At the 19-27 January Executive Board meeting, the developing countries objected to WHO's approach of attempting to deal with the issue of medicine quality and safety under the rubric of "counterfeits". They feared that the real effect of the WHO documents would be to undermine the production of and trade in good-quality generic medicines and, consequently, access to generic medicines.

The attempt by developed countries to make use of international agencies, standards and agreements to mandate the use of national customs, health, police, postal and other government agencies to enforce the rights of IP holders has become a controversial subject. This is especially since the effect may be to adversely affect the public's access to medicines, as the actions proposed for IP enforcement are intended to protect the interests of multinational companies holding the patents even as they endanger the viability of generic drug producers.

The developed countries have been attempting to use various international forums such as the World Customs Organisation, WHO, the Universal Postal Union and WIPO to further their IP maximalist agenda.

On 3 February, the controversy surrounding this issue finally erupted at the WTO, the home of the TRIPS Agreement.

The incident that sparked off the outrage felt on this issue was the seizure by Dutch customs authorities on 4 December 2008 of a cargo of 500 kilos of losartan potassium in transit in Rotterdam, en route from India to Brazil. Losartan potassium, an active pharmaceutical ingredient, is used in the production of medicines for arterial hypertension. The substance was being exported by the Indian company Dr Reddy's and imported by the Brazilian company EMS.

The cargo was detained at the request of a company which allegedly holds the patent on losartan potassium in the Netherlands, pursuant to procedures set out in the EC Council Regulation 1383, wherein the EU customs authorities are empowered to detain goods in transit on suspicion of an infringement of IPR.

Losartan is not patented in Brazil or in India. According to news reports, it is patented in the Netherlands by DuPont, while US-based company Merck and Co. holds the marketing rights.

According to reports, the cargo was held back by the Dutch authorities for 36 days, after which it was released for return to India.

As a result of the Dutch authorities' actions, the medicines critically required by patients with hypertension – a common, serious disease that often leads to death – never reached Brazil.

This case is the latest in a recent spate of seizures of consignments of generic drugs of Indian companies on the grounds of alleged IP violations. Brazil and India have protested against the seizures at the WHO Executive Board meeting as well as at the recent World Economic Forum in Davos.

During the WTO General Council meeting, the ambassadors of Brazil and India called on the EU to urgently review the relevant regulations and the actions of the EU's national authorities based on such regulations, and to bring them into conformity with the letter and spirit of the TRIPS Agreement and the WTO system. Their call was strongly echoed by many other developing countries.

Brazil's Ambassador, Roberto Carvalho de Azevedo, said that the measure taken by the Dutch authorities clearly violates the freedom of transit, which is a right enshrined in Article V of the General Agreement on Tariffs and Trade (GATT), wherein only very exceptional circumstances warrant restrictions on that freedom. He added that Brazil was not aware of any such circumstance in the losartan case.

He said that the decision to impede the transit of a cargo of generic medicines which was not headed for the Dutch market was "unacceptable" and "sets a dangerous precedent", adding that "whether or not the medicines were generic under the law of the country of transit is an irrelevant question".

The concept of "generic" must not be mistaken with "counterfeit" or "pirated", and generic medicines are not substandard or illegal, said Brazil. The Dutch customs authorities' decision to block transit impeded Brazilian hypertension patients' access to safe and price-competitive generic medicines, and hypertension is a common, serious disease that often leads to death.

Brazil also expressed grave concern over the setting of a precedent for extraterritorial enforcement of IP rights, adding that such attempts have "critical systemic implications" and "affront fundamental canons of the multilateral trade system, in

particular the well-established principle of territoriality", a fundamental pillar of the international IP regime.

It further said that extraterritorial enforcement of patent rights cannot be reconciled with the terms of the Doha Declaration on the TRIPS Agreement and Public Health. The protection of public health and the promotion of the public interest are still part of TRIPS fundamental principles.

The undue interference of Dutch authorities with the transit of the generic medicines may have other serious systemic consequences, particularly that it could undermine countries' ability to address public health needs by means of cross-licensing arrangements, Brazil added. In this regard, it referred to the "Paragraph 6 system" (i.e., the 30 August 2003 Decision of the WTO General Council/Article 31bis of TRIPS) which permits a WTO member state without manufacturing capacity to import medicines from other members under a compulsory cross-licensing arrangement.

Brazil asked: "What would happen to the Doha Declaration on TRIPS and Public Health and, in particular, to the Paragraph 6 system if the denial of transit to generic medicines becomes a systematic and widespread practice and if countries commence to create impediments to the legitimate trade of generic medicines based on the wrongful allegation that it violates national patent rights? In such cases, trade in generic medicines would be rendered virtually impossible."

Brazil stressed that IP protection cannot supersede protection of life and the right to promote public health, which are more fundamental values.

Brazil also pointed out that application of enforcement procedures to goods in transit is being advocated in the World Customs Organisation and in WHO. It added that in the WCO, some countries were pushing for the adoption of standards that would give customs the authority to seize goods in transit suspected of infringing IP rights. Similarly, in WHO, the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) initiative claims that national legislation should provide for enforcement procedures over goods in transit, it said.

Brazil cautioned that "neither the WCO nor the WHO are adequate fora for discussing IP rights enforcement". In WHO, the focus should be on the quality, safety and efficacy of medicines, as well as on the issues of access, while the WCO should concentrate on developing methodologies to enhance customs' performance, rather than venturing into TRIPS-plus norm-setting.

Brazil stressed that interfering with the freedom of transit for the sake of enforcing IP rights violated trade disciplines negotiated by WTO members. IP rights can and should be enforced in a member's own market, but such enforcement cannot reach goods that are not intended for that market.

Brazil called on the Netherlands and/or the EU to clarify the circumstances and legal basis for the Dutch authorities' decisions and stressed that the Netherlands and the EU should bring their legislation into conformity with multilateral trade disciplines.

India's Ambassador Ujal Singh Bhatia recalled the seizure of not only losartan potassium but also other Indian shipments by the Dutch customs on grounds of alleged IP violations, adding that such instances cause great concern due to their systemic and far-reaching implications. He said that such acts represent a distorted use of the international IP system and circumscribe the flexibilities in the TRIPS Agreement.

India also stressed that the "WTO rule-based system provides for freedom of transit by the most economical and convenient routes and without unnecessary delays and restrictions", and that the acts of the Dutch authorities are therefore "a denial of the rule-based system".

It further added that the concept of "territoriality" is a keystone in the edifice of the TRIPS Agreement and that there are no indications that the drug consignment was meant for the markets of the EU. Thus, the seizure and initiating procedures for destruction of such consignments violate this key principle.

India stressed that WTO members have strived for a balance between public health concerns and protection and enforcement of IPRs, and that the public health decisions are a valuable part of the WTO acquis which needs to be adhered to in letter and in spirit.

Ambassador Bhatia added that it was ironical that while on one hand, the WTO has taken steps to promote access to affordable medicines and remove obstacles to the proper use of TRIPS flexibilities, on the other hand, some members seek to negate the same by seizing drug consignments in transit.

He emphasised the importance of generic drugs, adding that their essentiality may vary in inverse proportion to the level of development of a country. Barriers to legitimate trade in generic drugs will seriously impair the efforts of organisations like Medecins Sans Frontieres, the Clinton Foundation, the Bill and Melinda Gates Foundation and many other organisations engaged in providing medicines and improving public health in the least developed parts of the world.

He also drew attention to the emerging trend of efforts "to implement the protection and enforcement of IPRs in a maximalist manner and thereby upset the delicate balance between rights of IPR holders and the public policy objectives under the TRIPS Agreement".

India said that a coordinated approach being witnessed in several international fora like the WCO, WHO and the Universal Postal Union aims to promote the IP maximalist agenda. It noted with dismay the efforts by some members to link safe and efficacious but low-cost generics with counterfeit medicines, which is essentially an IPR issue.

"There is an attempt to enlarge the definition of counterfeits beyond its definition in the TRIPS Agreement, to set maximalist enforcement norms, and to include TRIPS-plus provisions in RTAs [regional trade agreements]," said India.

It added that these are "subtle and concerted ways of circumscribing the flexibilities of the TRIPS Agreement". They not only "run counter to the spirit of the TRIPS Agreement which is a minimum standards agreement but [are] counter to the understanding given to developing countries when the TRIPS Agreement was being negotiated".

India cautioned that "efforts to enshrine new, maximalist TRIPS-plus provisions in other forums will seriously undermine the delicate balance in the TRIPS Agreement and raise systemic issues".

It called on the EU to "urgently review the relevant regulations and the actions of the national authorities based on such regulations, and bring them in conformity with the letter and spirit of the TRIPS Agreement and the rules-based WTO system".

Many other developing countries spoke at the General Council in support of Brazil and India.

Nigeria registered its "expectation that the balance between public health concerns and enforcement of IP rights should be respected" and said that the "importance of generic drugs for countries that have no capacity to manufacture pharmaceutical products cannot be over-emphasised".

It urged countries "to ensure that the enforcement of IP rights is not used to impede legitimate trade" and specifically "to avoid taking measures that would adversely affect the freedom of transit by the most convenient and economical routes". It also encouraged the Netherlands and/or the EU to clarify the circumstances and legal basis of this case.

Pakistan stressed that recent "IP maximalist" attempts and "forum shopping" have triggered a dangerous trend that could undo most of what WTO members have gained so far. It called particular attention to the application of extraterritoriality of IPRs, which it said was alarming for developing countries which are producing the generic drugs.

Adding that the action was against the spirit of the Doha Declaration on the TRIPS Agreement and Public Health, it called on members to respect TRIPS provisions and maintain a fair system devised through multilateral negotiations rather than defining their own standards and applying them at the cost of other members.

According to the IP Watch news service on intellectual property issues (3 February 2009), the EU Ambassador Eckart Guth responded that the Dutch seizure is allowed by the TRIPS Agreement and is based on provisions in EU customs law that allow the customs authorities to temporarily detain any goods if they suspect that these goods infringe an intellectual property right. As soon as the goods were eventually determined not to be headed for the EU market, they were returned to the owner.

Guth said it would have been preferable for Brazil and India to first raise the issue bilaterally in order to clarify facts "before triggering a highly emotional debate." Guth also referred to Article 51 of the TRIPS Agreement, which allows customs authorities to suspend the release of goods, and he said that under EU law, companies whose goods are wrongly detained are eligible for reimbursement.

"Let me make it very clear that the EU has absolutely no intention to hamper any legitimate trade in generic medicines or to create legal barriers to prevent movement of drugs to developing countries, nor have our measures had this effect," Guth said. "We are absolutely committed to all the efforts that are being made to facilitate access to medicines."

In addition to Brazil and India, those voicing their concerns about how the customs authorities' actions could hamper access to medicines were Argentina, Bolivia, Burkina Faso, China, Costa Rica, Cuba, Ecuador, Egypt, Indonesia, Israel, Nigeria, Pakistan, Paraguay, Peru, South Africa, Thailand and Venezuela.

Some sources say that there is another unsavoury twist to the story. They say that there was a possibility that the IP holders in the Netherlands forced the Indian company to agree to return the goods to India (rather than to send them on to Brazil) on the ground that they would otherwise be destroyed in the Netherlands.

8 NGOs voice concerns to WHO, WTO on seizure of generic drugs

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Geneva, 19 Feb (Kanaga Raja) – Sixteen public health, consumer and development groups have sent separate letters to the heads of the World Health Organisation (WHO) and the World Trade Organisation (WTO) voicing their concerns over recent seizures by Dutch customs authorities of Indian generic drugs shipped through the Netherlands en route to Brazil, Colombia and Peru.

In their letter dated 18 February to WHO Director-General Dr Margaret Chan, the non-governmental organisations (NGOs) asked her to "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 conducting the assessment, WHO is asked to "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."

In a separate letter to WTO Director-General Pascal Lamy, the groups called on him to "explore with the European Union the extent to which its customs rules and provisions in trade agreements present risks to goods in transit, and undermine the commitments made in 2001 in the Doha Declaration on TRIPS and Public Health concerning access to medicines."

The 16 NGOs that signed both the letters are BUKO Pharma-Kampagne; Consumers International; Consumers Union; Essential Action; HAI Africa; HAI Asia Pacific; HAI Europe; HAI Global; HAI Latin America and Caribbean; Health GAP; IQsensato; Knowledge Ecology International; Medico International; Oxfam International; Third World Network; and US PIRG.

"In a world with territorial patent rights, it is important that the rules for 'goods in transit' permit the transport of medicines from places where they can be made to places where they will be used. The Dutch seizures have drawn attention to this issue, as has the recent disclosure of MSF [Medecins Sans Frontieres] that they regularly transport and temporarily store medicines in Europe, in route to users in developing countries. We expect the leaders of the WHO and the WTO to lead on this issue," said James Love of Knowledge Ecology International.

"It is time that the World Health Organization, the institution that we look to for a lead in international health and development gave strong and clear guidance on the interpretation of international trade agreements that so adversely affect health. The health of millions of people worldwide who depend on life-saving quality assured generic medicines will be in jeopardy unless action is taken now by the World Trade Organization to give clear guidance to its Members on goods in transit. This situation cannot be allowed to continue," said Tim Reed of HAI Global.

In their letter to WHO Director-General Dr Chan, the groups said that 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." 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 en route to a market where the use is legitimate.

"This approach is not uniform, however, as illustrated recently by several seizures of medicines by Dutch customs officials," said the letter to Dr Chan.

The groups noted that 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.

Citing industry reports, the letter noted at least four cases where Indian generic medicines in transit in the Netherlands were seized by Dutch customs authorities from 15 October 2008 to 12 December 2008: clopidogrel bilsulphate API (to Colombia); olanzapine 10 mg tabs (to Peru); rivastigmine 3 mg tabs (to Peru); and losartan API (to 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 groups said that the seizure of the shipment containing losartan 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.

In the case of the clopidogrel bilsulphate API shipment to Colombia, the Dutch customs authorities reportedly asserted the generic APIs were counterfeits, and Sanofi Aventis sought destruction of the goods.

The letter to Dr Chan said that 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, said the NGO letter, 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 the World Customs Organisation's "Provisional Standards Employed by Customs for Uniform Rights Enforcement (SECURE)."

The groups said that they were bringing these facts to the WHO chief's 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."

Noting that the WTO TRIPS Agreement provides the option of exempting goods in transit from the enforcement of patents, the groups said that the European Union's rules and actions go beyond the required enforcement standards of the TRIPS Agreement, and do so in a manner that is clearly inconsistent with the 2001 Doha Declaration on the TRIPS Agreement and Public Health.

Among other things, said the groups, 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 more problematic if patent rights are enforced for goods in transit.

The groups also underscored that 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," said the letter to Dr Chan.

The groups called on WHO to "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."

The groups further asked 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 EU 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.

In a separate letter to WTO Director-General Lamy, the groups, referring to the recent seizures of in-transit medicines by Dutch customs authorities, including cases where medicines manufactured in India were en route to destinations in Brazil, Colombia and Peru, said that there are longstanding traditions to provide exceptions to patent rights for aircraft and marine vessels en route to markets, and for goods in transport, including, for example, the specific exemption of goods in transit from the provisions of Article 51 of the TRIPS Agreement, concerning "Suspension of Release by Customs Authorities."

According to the groups, the TRIPS Agreement does not require Article 51 to apply to patented goods, and the exception for goods in transit is discretionary rather than mandatory. In addition, TRIPS is part of a larger plan to "reduce distortions

and impediments to international trade", and seeks to "ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade."

Article 41.1 of the TRIPS Agreement provides that enforcement procedures "shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse", and Article 41.2 provides that the procedures shall be "fair and equitable."

Article V of the GATT defines goods in transit, and provides that "There shall be freedom of transit through the territory of each contracting party, via the routes most convenient for international transit, for traffic in transit to or from the territory of other contracting parties."

The letter to Director-General Lamy said that this provision extends to all goods in transit, and provides that "all charges and regulations imposed by contracting parties on traffic in transit to or from the territories of other contracting parties shall be reasonable, having regard to the conditions of the traffic."

The letter also noted that with regard to trade in medicines, the 2001 Doha Declaration on the TRIPS Agreement and Public Health recognised "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."

The letter also voiced concerns that the implementation of the WTO's Decision of 30 August 2003 regarding the export of pharmaceutical products to countries with inadequate manufacturing capacity will become even more problematic if patent rights are enforced for goods in transit.

Noting that the Dutch seizures of medicines in transit from India to South America were made under the European Union's rules regarding customs measures, the groups expressed concerns that these rules, and many other rules being proposed in a plethora of new trade agreements, do not protect legitimate sellers and buyers of generic medicines when those goods move in global trade.

"There are reports that the current drafts of the proposed plurilateral Anti-Counterfeiting Trade Agreement (ACTA) [do] not provide adequate protections for goods in transit, and we are also concerned about many of the proposals regarding provisional measures and customs practices that are seen in bilateral trade agreements."

"Should countries be free to aggressively enforce patent and other intellectual property claims against goods in transit, or should goods in transit be protected when they are clearly intended to markets where their use is legitimate?" the groups asked.

This issue is particularly relevant to the challenge of providing "access to medicine for all", a central objective of the Doha Declaration on the TRIPS Agreement and Public Health, and the World Health Organization's recent Global Strategy on Public Health, Innovation and Intellectual Property Rights, said the letter to Lamy.

Given the importance of this issue, the groups requested the Director-General to explore with the European Union the extent to which its customs rules and provisions in trade agreements present risks to goods in transit and undermine the commitments made in 2001 in the Doha Declaration on the TRIPS Agreement and Public Health concerning access to medicines.

Meanwhile, the medical humanitarian organisation Medecins Sans Frontieres had earlier sent a letter to Laszlo Kovacs, European Commissioner for Taxation and Customs Union, and Baroness Catherine Ashton, European Commissioner for Trade, following the seizure of medicines in transit in the EU to developing countries for alleged patent infringement.

In its letter, the group expressed concern over the potential consequences of the recent seizure on the basis of the Council Regulation (EC) No 1383/2003 by Dutch customs authorities.

Citing the recent case involving the 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's and in transit to Brazil, MSF expressed concern 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.

It pointed 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 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, said MSF.

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, 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, said MSF.

MSF was concerned that its 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."

It called 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 Regulation on the supply of legitimate medicines, given the EU's stated commitment to the full implementation of the Doha Declaration on the TRIPS Agreement and Public Health and the WTO August 30th decision; and clarify whether such provisions are proposed for inclusion in the EU's Economic Partnership Agreements and in the current negotiations of the EU free trade agreements.

9 WHO Director-General willing to drop "counterfeit", stresses on "substandard"

Geneva, May 2009 (Sangeeta Shashikant) – WHO's Director-General, Dr Margaret Chan, offered to drop the term "counterfeit" in favour of other terms such as "substandard" amidst concerns from several developing countries during the World Health Assembly (WHA) that in using the term WHO was endorsing the developed countries' and Big Pharma's agenda on IP enforcement.

Interventions by some developing countries during discussions on WHO's Medium-Term Strategic Plan 2008-2013 (MTSP) raising concerns over the use of the term "counterfeit" prompted Dr Chan to state, "If you don't like the term, we can use another term."

Dr Chan also stressed on the need to address the public health dimension of substandard products.

WHO's keen focus on the issue of "counterfeit" medical products, as opposed to legitimate public health concerns of falsely labelled, substandard and spurious products, had been heavily questioned by many developing countries during the January Executive Board meeting.

The concern is that using the term "counterfeit" (a term used in connection with IP violations particularly trademark infringements) to describe problems relating to the quality, safety and efficacy of medical products would result in WHO addressing health concerns through IP enforcement measures.

During the January EB meeting, developing countries also questioned the legitimacy of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT), particularly with regard to its composition and the issue of conflicts of interest. IMPACT is being pushed by the WHO Secretariat as the vehicle for implementing programmes to combat counterfeit medicines.

This controversial issue, although initially on the agenda of the WHA, was later postponed to next year for discussion as a result of the shortening of the WHA due to the swine flu outbreak.

Although off the agenda, the issue of counterfeits was raised on two occasions by several developing countries at the WHA during discussions on WHO's MTSP.

The MTSP document contains three references to counterfeit medicines under Strategic Objective (SO) 11 that pertains to "ensur[ing] improved access, quality and use of medical products and technologies".

The MTSP states that "Globalization allows for an unprecedented growth in counterfeit medical products" and that "attention should focus on reliable procurement, combating counterfeit and substandard products, cost-effective clinical interventions, long-term adherence to treatment containing antimicrobial resistance".

It further speaks of "providing support to countries for producing, using and exporting products of assured quality, safety and efficacy through strengthening of national regulatory authorities and an international programme to combat counterfeit medicines".

Under SO 11.2, the "Organization-wide expected results" relate to the following: "International norms, standards and guidelines for the quality, safety, efficacy and cost-effective use of medical products and technologies developed and their national and/or regional implementation advocated and supported".

References to international norm-setting include activities related to "combating counterfeit" and IMPACT's norms as WHO's draft Medicines Strategy (2008-2013) which elaborates on SO 11.2 refers to "supporting countries in implementing the IMPACT strategy".

The corresponding budget document shows a projection of $50 million for these activities.

On SO 11, Thailand said that since "IMPACT was questioned during the last EB meeting in January 2009 in terms of conflict of interest and its composition", reference to IMPACT in the draft Medicines Strategy should be removed. It added that this was in line with "WHO's promotion of good governance and transparency".

It further added that WHO, by its constitutional mandate, is required to disassociate and delink itself, on the issue of pharmaceutical quality which is a health threat to the population, from the issues of intellectual property rights violation, which are the explicit goals and ambitions of IMPACT.

Thailand also said that the scale of counterfeiting is unclear as the results of studies are based on selection-biased samples in favour of showing a high problem of counterfeit medicines. "WHO should reference its work from reviewed published

literature for which authors had clearly indicated no conflict of interests and free from sponsors from [the] pharma industry," it added.

Thailand also said that "limited public health resources should be allocated to the real prioritised problems".

Brazil expressed great concern over the use of the expression "counterfeit medicines".

Brazil said that it was deeply concerned about the quality, safety and efficacy of medicines and other medical products and that it was working to combat the practice of falsification of medicines and to hinder all forms of illegality related to those products, taking into consideration the protection of public health and the promotion of access to medicines.

Brazil recalled that during the January EB meeting, GRULAC members presented a statement expressing concerns on this issue.

It voiced concern over the idea of having WHO focus its work on "an international programme to combat counterfeit medicines" as mentioned in the MTSP.

It emphasised that counterfeit products were defined in the TRIPS Agreement and related to "trademarks".

With regard to IMPACT, Brazil said the programme "attempts to impose a revision of WHO's position on the issue of counterfeiting, in order to inhibit the legitimate commerce of good-quality and affordable generic drugs".

Brazil underlined the role of WHO in helping member states to strengthen their regulatory capacities based on concerns of health surveillance and regulation, and stressed that "WHO should not promote the enforcement of intellectual property rights, since it does not fall under the mandate of the Organization".

Brazil defended the primacy of public health over trade. It requested the Secretariat to revise the present version of the MTSP in order to incorporate a more precise picture on how the debate about the quality of medicines stood in the Organization and to delete all the references to counterfeiting in the text.

India said that since the EB had asked the WHO Secretariat to prepare reports for consideration of the WHA and since these reports had not been considered by the WHA, a line to the effect that members' views on these issues should not be prejudged should be added to the MTSP.

Suriname also agreed to the removal of IMPACT as its strategy and composition had been questioned.

Ambassador Angelica Navarro of Bolivia also expressed concern about the inclusion of topics that were not discussed by members. Bolivia further said that it did not think there should be a reference to an international programme to combat counterfeit medicines.

Dr Chan said she was mindful that the term "counterfeit" had created concerns and reassured members that WHO would not implement anything related to IP enforcement. "If you don't like the term, we can use another term," she said, adding that she would avoid using the term "counterfeit" for substandard as the latter was a huge problem.

WHO will address the problem created by substandard medicines in developing countries with a weak drug regulatory authority, she added. Substandard medicines can cause resistance and can compromise the authority and credibility of health agencies; thus, the public health dimension of substandard medicines would be addressed, she further said.

She reassured WHA participants that WHO's role is to provide public health advice.

On another occasion during the WHA, as the resolution endorsing the MTSP came up for consideration, Brazil, supported by Thailand, sought clarity as to whether its amendments to the MTSP were included. The Secretariat responded to the query by stating that amendments as requested would be made.

Removal of references to "counterfeit" from the MTSP should have the effect of ensuring that WHO's resources are not used to fund activities to combat counterfeit medicines as well as the IMPACT initiative.

According to sources, a few hours before the close of the WHA, the US, which had failed to raise any objections during the interventions on the MTSP, revealed its unhappiness with the outcome on the MTSP to the Secretariat and several delegations.

It is unclear how the Secretariat intends to manage the matter. Sources say the US as well as the industry are likely to keep the pressure up on the Secretariat on this matter.

The exact text of the revised MTSP incorporating the amendments was not available during the WHA.

10 Concerns voiced at TRIPS Council over seizure of drugs

Published in* SUNS *#6717 dated 11 June 2009

Geneva, 10 Jun (Sangeeta Shashikant*) – The repeated practice of EU customs officials seizing shipments of medicines in transit to developing countries on grounds of alleged IP violations has once again come under sharp criticism in the WTO.

The criticism this time, with a range of developing countries protesting the EU customs actions, came over the recent seizure of the generic antibiotic amoxicillin by customs officials while in transit in Frankfurt and destined for the Republic of Vanuatu in the Pacific.

The protest by the developing countries came at a formal session of the TRIPS Council on 8 June, where Brazil and India raised the issue under the agenda item of "Other Business." They were supported by several other developing countries.

The concerns were over the seizure by customs officials on 5 May of a shipment of the generic amoxicillin (manufactured in India) while in transit through the EU, specifically in Frankfurt, on its way to Vanuatu, a least developed country.

According to trade officials, the developing countries expressed concern over the EU's commitment to the Doha Declaration on the TRIPS Agreement and Public Health and the flexibilities inscribed in the TRIPS Agreement. They also said that the EU was confusing legitimate generic medicines with counterfeit fakes. Furthermore, the EU was also undermining poor countries' ability to obtain cheaper generic medicines.

Amoxicillin is an essential medicine used to treat a wide range of bacterial infections. The shipment that was seized comprised 3,047,000 tablets of amoxicillin (250 mg), worth approximately €28,000. This is equivalent to 76,000 courses of treatment.

The batch was detained on grounds of alleged trademark violation, but was released after four weeks. The German customs authorities had informed GlaxoSmithKline (GSK), the former patent holder for Amoxil, a brand name for amoxicillin, but GSK subsequently informed the authorities that there was no trademark infringement.

(In a press release on 5 June, Health Action International (HAI), Oxfam International, BUKO Pharma, Medico International and Third World Network urged the German customs authorities to provide full and transparent information about this seizure. They called on the European Commission to take immediate steps to ensure that its regulations and laws do not deny developing countries timely access to essential medicines.)

(Sune Sveningsen, Supply Chain Director of Missionpharma, the agency responsible for the amoxicillin shipment, was quoted in the press release as saying: "These random seizures seriously impact our ability to service the healthcare needs of people living in developing countries in a timely manner, forcing us to consider re-designing our entire supply chain to avoid any transit through European territories.")

News of this latest seizure comes just as it was also revealed by a Freedom of Information Act request filed by Health Action International that the Dutch authorities in 2008 conducted 17 seizures of medicines bound for Brazil, Peru, Colombia, Ecuador, Mexico, Portugal, Spain and Nigeria. The drugs were for diseases such as cardiac ailments, AIDS, dementia and schizophrenia. Of these, 16 consignments originated from India and one from China.

These seizures were taking place pursuant to the EC Council Regulation No 1383/ 2003 of 22 July 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).

They have sparked anxiety among developing countries and civil society alike. It is anticipated that more such seizures are likely, particularly as developed countries continue their strong push for a so-called "anti-counterfeit agenda" in international forums such as the World Health Organisation (WHO) in the context of IMPACT (an anti-counterfeit taskforce), the World Customs Organisation (WCO), the World Intellectual Property Organisation (WIPO), as well as in plurilateral forums such as the Anti-Counterfeiting Trade Agreement (ACTA).

In its statement at the TRIPS Council, Brazil said it believes that the seizure of goods in transit on grounds that they might be violating IP rights conferred by a patent registered in the country of transit is a serious violation of WTO disciplines.

"The decision to impede the transit of cargoes of generic medicines violates the freedom of transit, a right enshrined in GATT Article V. Only very exceptional circumstances warrant restrictions on that freedom," Brazil said, adding that it is not aware of any such circumstances in the concrete cases that it has brought to the attention of the Council.

It said that its inquiries led to the identification of more than a dozen seizures of consignments of generic drugs in transit through Dutch territory in the last year. The medicines had been directed to at least seven different developing countries in South America and Africa. "Now, we face a new seizure on German territory." It is clear that the losartan case, contrary to EU assertions, was not a "minor, exceptional and inconsequential" incident. In fact, "it seems like the tip of an iceberg", said Brazil.

It reiterated that trade in generic medicines is perfectly legal from the intellectual property point of view. Generic products must not be mistaken for counterfeit or pirated products. Generic medicines are not substandard or illegal.

Brazil recalled that the EU, in its response to Brazil and India at the last session of the TRIPS Council, had affirmed its commitment to "facilitating access to medicines for countries in need". Unfortunately, Brazil said, that doesn't seem to be in line with the concrete actions. It noted that the Dutch seizures of the dozen-plus consignments and the recent seizure at Frankfurt airport of the amoxicillin consignment seem to move in the opposite direction to the objective of "facilitating access to medicines for countries in need".

(At the last TRIPS Council meeting on 3 March, the Council discussed the issue of the seizure by Dutch authorities of the generic medicine losartan on its way to Brazil.)

The EU claimed to be "one of the main promoters of the Doha Declaration and the TRIPS flexibilities". Rather than TRIPS flexibilities, however, the EU has actively promoted TRIPS-plus standards in non-specialised multilateral agencies such as WHO (through the IMPACT initiative) and the WCO, as well as in plurilateral fora such as ACTA or in bilateral and plurilateral agreements such as Economic Partnership Agreements, said Brazil.

On the EU claim that the customs actions have "saved lives in final destination countries – often developing countries", Brazil said that this is a blatant attempt to confound the issue. EU customs authorities' apprehensions have actually hampered the developing world's access to affordable life-saving generic medicines.

Brazil also called into question EU statistics about seizures of fake medicines. The losartan and other episodes suggest that EU numbers may lack accuracy, as EU customs authorities may mistake legitimate generic medicines for fake products.

It recalled that the mere seizure of goods in transit – any good, be it a medicine or not – on grounds that they may be violating IP rights registered in the country of transit is, in itself, a violation of GATT Article V and other GATT obligations.

"The TRIPS Agreement does not allow the detention of goods in transit. The seizure of goods in transit on grounds that they may be violating IP rights in the country of transit violates the principle of territoriality, a keystone of the international IP system."

Brazil also sought clarification on the following questions: (a) how the European authorities' actions can be reconciled with WTO disciplines; (b) whether EC Council Regulation 1383/2003 requires or justifies such actions from the EU customs authorities; and, above all, (c) how the EU will ensure that such actions do not happen again.

In its statement, India said that when both it and Brazil raised the issue of generic drug seizures at the TRIPS Council meeting of 3 March, they did not foresee that they would need to raise the issue again in the 8 June meeting. "Going by [the EU'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," India said, adding that it has also not received a satisfactory response to its formal communication to the European Commission in Brussels, nor has it seen any review of the relevant EU regulation or actions by customs authorities.

With respect to the seizure of amoxicillin, India said that there seems no valid reason for detaining these medicines especially since the name "amoxicillin" is an international non-proprietary name (INN).

India said that it has followed closely the different grounds mentioned by the EU for such seizures. The grounds stated by the EU include counterfeits, fake drugs, substandard, potentially dangerous products, patent violations and so on. The EU has 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 [is] proof that the allegations were baseless," India argued.

Seizures have continued to take place at EU ports. The multitude of allegations and the spread across several EU ports imply an emerging pattern to disrupt and create barriers to legitimate trade in generic drugs and to challenge the Doha Declaration on the TRIPS Agreement and 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.

According to India, the EU 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 [EU] authorities that IP violative products are synonymous with potentially dangerous substances. This clearly is an untenable logic. We doubt such simplistic linkages," said India.

India reminded the EU that the concept of "territoriality" is a keystone in the edifice of the TRIPS Agreement and a widely understood and accepted principle. In India's 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 far-fetched to claim that the country of transit will have sound understanding of the IPR laws of the 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, said India, an information-sharing mechanism is what is needed and definitely not action under the laws of the country of transit. If there is a reason to doubt the quality of goods, enforcement action should follow from domestic regulations in the importing country and not from WTO rules, which do not provide for the same, or from rules of a third country.

India also drew attention to the report of the UN 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 UN Human Rights Council last week. The Rapporteur had expressed concern over "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 [least developed countries]."

Widespread and repeated seizures have an adverse systemic impact on legitimate trade in 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, said India.

"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."

India further reminded the EU that trade in generic drugs is perfectly legitimate. Moreover, it is also desirable from the perspectives of public health and access to medicines. "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."

India pointed out that 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". It again called upon the EU to urgently review the Regulation and the actions of the national authorities based on the Regulation, and bring them into conformity with the letter and spirit of the TRIPS Agreement, the rules-based WTO system and the Doha Declaration on the TRIPS Agreement and Public Health.

According to trade officials, Brazil and India were supported by China, Cuba, Colombia, Ecuador, Egypt, Argentina, Venezuela and South Africa.

The EU responded by saying that it remains fully committed to ensuring access to affordable medicines in developing countries. The EU maintained that it is important to continue to allow the customs authorities to control goods in transit and ensure that measures can be taken against global trade in counterfeit products, and in particular, fake medicines whose effects mainly hit developing countries. The EU further maintained that the customs Regulation is fully in line with WTO/TRIPS requirements, in terms of scope and coverage of customs intervention.

According to trade officials, the US, referring to the need to crack down on counterfeits, said that brand names are a guarantee of quality, whereas fakes mislead consumers and can be dangerous. It called for cooperation between countries and between the private and public sectors to deal with counterfeit trade.

Trade officials also said that the main focus is now on consultations chaired by WTO Director-General Pascal Lamy. Some members said that the full membership should be informed as to what is happening in the consultations, which are taking place among a smaller group of members.

(With inputs from Kanaga Raja.)*

11 TRIPS Council takes up public health, drug seizure issues

Published in* SUNS *#6806 dated 3 November 2009

Geneva, 2 Nov (Kanaga Raja) – WTO members, at meetings of the regular TRIPS Council on 27-28 October, amongst others, agreed to recommend extending by another two years an end-of-year deadline for members to accept an amendment to the TRIPS Agreement in relation to TRIPS and public health.

The Council also heard concerns from India over the European Union's seizure of generic drugs while in transit in EU ports and bound for developing countries.

According to trade officials, on 27 October, WTO members agreed to extend for another two years the 31 December 2009 deadline for members to accept an amendment to the TRIPS Agreement concerning the issue of patents and public health. The recommendation to extend the deadline until the end of 2011 will now have to be formally agreed by the WTO General Council.

According to trade officials, since the last TRIPS Council meeting in June, five more members have reported that they have accepted the amendment: Macao-China, Canada, Bahrain, Colombia and Zambia. Pakistan said that it has ratified the amendment and will formally notify the WTO soon. A number of delegations urged all members to accept the amendment.

Canada reported a second and final shipment to Rwanda of medicine made under compulsory licence. According to trade officials, while some members said that the Canada-Rwanda example shows that the system can work, some other members said the fact that the system has only been used once shows that it might be inadequate.

It was agreed at the meeting that the TRIPS Council Chairperson, Ambassador Karen Tan of Singapore, should consult with members on how well the system is working.

Under the agenda item of "Other Business", India voiced its concerns over the seizure by EU member states of generic medicines in transit through EU ports and destined for developing countries.

In a statement at the Council, India, referring to 17 seizures by the Dutch authorities in the year 2008 on the basis of EU Regulation 1383/2003, said it thought that the Dutch seizures were the last because the EU had been giving assurances that they are putting in place systems to ensure that generic medicines are not seized.

However, in May, a consignment 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 while in transit through Frankfurt, Germany, India said. The seizure was made on grounds of alleged trademark violation although GlaxoSmithKline (GSK) had confirmed to the German authorities that GSK is the former patent holder for Amoxil, a brand name for amoxicillin, it added.

India said that it was alarmed to get information of yet another drug seizure. It has been informed by customs authorities at the Paris-Roissy airport that they have seized a shipment of 1,740,000 tablets of clopidogrel, an anti-platelet drug used to prevent strokes and heart attacks in patients at risk for these problems. The consignment was in transit from Mumbai to Caracas, Venezuela, and was seized on the ground of alleged patent violation.

India said that it has continued its bilateral efforts with the EU at the level of senior officials, ministers and formal communications. However, in spite of its persistent urging, "nothing concrete has been done". There are as yet no signs of review of EU customs Regulation 1383/2003, in spite of its inconsistency with provisions of GATT, the TRIPS Agreement and the spirit of the Doha Declaration on the TRIPS Agreement and Public Health.

Referring to an "Explanatory Note" dated 31 July issued by the EC to member states on the application of the EC Regulation 1383/2003, India said that the Note shifts the blame to member states for applying their national laws and the responsibility for interpretation to the national courts. The Note totally disregards the permissiveness of the EC Regulation itself.

Prior to 2003, said India, the scope of EC Regulations covered only trademark and copyright infringements. The EC Regulation 1383 has expanded the scope to additionally cover patents and other IPRs and also extends to goods in transit; as shown by the drug seizures, it has provided a basis for member states to apply IPRs extraterritorially and to goods in transit. The EC's Explanatory Note also repeats

the timelines indicated in Article 55 of the TRIPS Agreement ("Duration of suspension") which were hardly followed by customs authorities in the various drug seizures in 2008.

Noting the EU claims that there have been no drug seizures since December 2008, India said that these claims have been proven hollow with the Frankfurt and Paris seizures.

Further noting that the EU has attributed the seizures in part to its operation MEDI-FAKE, India said that here lies another of the roots of the problem, i.e., dealing with substandard and spurious medicines through border measures and customs officials who can hardly be expected to be experts in public health issues.

Underlying the drug seizures is also a deliberate mixing up of the issue of spurious/ substandard drugs etc with IPRs. India emphasised that the seizure cases involved legitimate generic medicines which are neither fake, nor counterfeit, nor pirated medicines. Moreover, the Frankfurt and Paris seizures happened much after operation MEDI-FAKE.

India said that the seizures, and the consequent denial of access, run counter not only to the spirit of the TRIPS Agreement but also to UN Commission on Human Rights resolution 2002/31 on the right to enjoy the highest standards of physical and mental health.

India also noted that while on the one hand developing countries, including the LDCs, are still adjusting to the TRIPS Agreement, on the other hand, "we are witnessing an increasing spiral of ever-increasing levels of protection, thereby reducing the flexibilities and policy space left open under the TRIPS Agreement particularly for developing countries and LDCs".

"We also witness an orchestrated campaign for TRIPS-plus enforcement norms by deliberately confusing quality issues with IPRs in international organisations (WHO), other TRIPS-plus initiatives in WIPO, WCO and UPU [Universal Postal Union], insistence on TRIPS-plus elements in FTAs [free trade agreements] being negotiated and to top it all, negotiating the ACTA amid secrecy and exclusion of a vast majority of countries including developing countries and LDCs," said India.

India further said that the widespread and repeated seizures under EC Regulation 1383 have an adverse systemic impact on (i) the principle of universal access to medicines, (ii) national public health budgets, (iii) legitimate trade in generic medicines, (iv) South-South commerce, (v) use of TRIPS flexibilities, and also

(vi) the efforts of civil society organisations engaged in providing medicines and improving public health in the least developed parts of the world.

It called upon the EU to urgently review the Regulation and bring it into conformity with WTO provisions including GATT, the TRIPS Agreement and the letter and spirit of the Doha Declaration on the TRIPS Agreement and Public Health.

According to trade officials, countries that supported India included Brazil, China, Peru, Ecuador, South Africa, Argentina, Chile and Egypt (African Group).

According to trade officials, the EU said that its commitment to access to medicines was well illustrated and that this policy had not changed. While not hindering trade in generic medicines, it was important to stop dangerous fake medicines and for that purpose, detention by customs to allow verification of the product by the rights holder was legitimate and necessary, said the EU.

The discussion concerned a few cases of temporary detention of medicines, and all the consignments had ultimately been returned to their importers, the EU said. It further said that it had reacted effectively to India's and Brazil's concerns, as patent right holders had publicly committed themselves not to seize generic medicines for patent infringements, and no new cases had occurred.

The EU said that the regular review of Regulation 1383/2003 was open and could address any concerns that India and Brazil might still have.

THE IMPACT COUNTERFEIT TASKFORCE, INTELLECTUAL PROPERTY RIGHTS ENFORCEMENT AND SEIZURE OF MEDICINES

There has in recent years been a major push to set restrictively high standards of intellectual property (IP) protection and enforcement internationally. Driven by large corporations and governments of industrial countries, this push extends even to the critical medicines and medical products sector.

In this sector, the introduction of stricter IP enforcement measures is sought, among others, through pursuing the agenda of combating "counterfeits". This book looks at recent moves at the World Health Organisation (WHO) to seek endorsement of an initiative called the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) and its proposed definition of counterfeits. This approach has drawn criticism from many developing-country WHO members for seeking to address health issues relating to the quality and safety of medical products through an IP framework.

Concerns over the focus on counterfeits have been heightened by a spate of seizures by European customs authorities of generic medicines in transit to developing countries on grounds of IP infringement. These seizures have further fuelled fears that linking health and IP issues would impede production of and trade in affordable, good-quality generic drugs – and poor countries' access to them.

This book is a compilation of articles – most of which appeared in the *South-North Development Monitor (SUNS)*, a daily bulletin on development issues published by the Third World Network – which examine the concerns expressed by developing countries and civil society over the anti-counterfeit drive and medicine seizures, and report on the lively recent debates on these subjects at WHO and the World Trade Organisation (WTO).

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