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Briefing Paper 2

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WHO's "COUNTERFEIT" PROGRAMME: LEGITIMISES IP ENFORCEMENT AGENDA, UNDERMINES PUBLIC HEALTH

A. INTRODUCTION

Many developing countries have on numerous occasions raised concerns with regard to WHO's programme on "Counterfeit" in particular attempts to redefine the term "counterfeit" (which is already defined in the TRIPs Agreement) and to obtain endorsement of the International Medical Products Anti-Counterfeit Taskforce (IMPACT) and its activities especially its Principles and Elements on Counterfeit Medical Product for National Legislation.

There is fear that WHO and issues of public health are being used as a front by various OECD governments and businesses to strengthen the IP enforcement agenda. These concerns are due to the recent emergence of numerous anti-counterfeiting initiatives that are primarily about pushing for the adoption of TRIPS-plus-plus standards of IP enforcement especially in developing countries. OECD governments in particular the EU countries/European Commission (EC), the US, Switzerland and Japan sponsor these initiatives supported by their industries including the multinational pharmaceutical industry, industry associations and think tanks.

One such recent initiative is the Anti-Counterfeiting Trade Agreement (ACTA), a plurilateral initiative begun in 2007 by the US, EC, Switzerland, Japan and now being negotiated by 13 countries (including 27 EU members) to achieve a common standard for IPR enforcement in the context of counterfeiting and piracy with the final aim of ensuring the universalisation of these standards by forcing developing countries to accept it. While public health consideration is one of the rationale presented for ACTA it is anticipated that ACTA will have detrimental effects on access to affordable medicines.[1]

Various international agencies and organisations such as the Interpol, the World Customs Organisation (WCO), the World Intellectual Property Organisation (WIPO) have been enlisted to advance the IP enforcement agenda. And to give legitimacy to this Agenda, public health concerns over proliferation of medical products with compromised quality and safety are presented as the rationale by exploiting confusion over use of the term "counterfeit".

This has led to real concern that WHO is the latest international organisation to be enrolled to legitimize the TRIPS Plus IP enforcement agenda by conflating issues of public health and IP under the heading of "Counterfeits".

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 will impede developing countries access to affordable, quality generic drugs.

This briefing paper attempts to (i) in Part B provide an understanding of the confusion over use of the term "counterfeit" and how this confusion is being exploited to conflate IP and public health issues and to promote addressing issues of quality, safety and efficacy through an IP enforcement lens; (ii) in Part C, to provide a critical analysis about statistics pertaining to counterfeit medicines; (iii) in Part D highlight issues pertaining to IMPACT and its setup in particular linkages with the IP enforcement agenda and the effect of IMPACT and its outcomes on access to affordable medicines; and finally (iv) in Part E, the Conclusion.

B. CONFUSION OVER "COUNTERFEIT" TERMINOLOGY

The term "Counterfeit" has been used in many different ways resulting in confusion as to what the term really means.

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[1] "Consumer Groups Fear ACTA Could Encourage Generic Drug Seizures", Inside U.S. Trade - 4/30/2010; "ACTA and the Drug Monopoly Enforcement Agenda: A windfall for big drug companies; higher medicine prices for all" available at http://www.essentialaction.org/access/index.php?/archives/213-ACTA-and-the-Drug-Monopoly-Enforcement-Agenda-A-windfall-for-big-drug-companies;-higher-medicine-prices-for-all.html, accessed 1 May 2010; ACTA & Access to Medicines, Sean Flynn (28 April 2010) available at http://www.wcl.american.edu/pijip/go/blog-post/acta-and-access-to-medicines, accessed 1 May 2010.

"Counterfeit" is defined by the WTO-TRIPS Agreement as referring to a specific category of trademark violation. Footnote to Article 51 of TRIPS 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". For violations of counterfeit trademark goods (i.e. literal copying of registered trademarks) heightened measures are prescribed by the TRIPS Agreement such as border measures by customs for importation of such goods and criminal penalties in cases of "*wilful"* trademark counterfeiting on a *"commercial scale"*.[2]

[Note: Cases of counterfeit trademark violation must be distinguished from normal civil trademark violations for which civil remedies (and not criminal sanctions are suitable)[3]. Such cases would include situations where an infringing mark is confusingly similar (but not identical to) to a registered mark or a well-known mark. For example, the Delhi High Court in a civil case in India held that a generic manufacturer's use of the trade name "Meromer" did not infringe the originator's trade name "Meronem", as both names were derived from the INN of the medicine, "Meropenem"[4]. Such situations are a common occurrence in the pharmaceutical field since both the originator and generic companies derive their names from INN and should not be treated as cases deserving criminal sanctions].

Today in some instances, the term counterfeit is used to refer to all other IP violations including patent violations. And under the banner of "Anti-Counterfeiting", OECD businesses and governments are making use of trade agreements, plurilateral government initiatives and programmes in international agencies to set and enforce higher standards of IP enforcement[5]. Such standards have a great potential to undermine access to and production of affordable pharmaceuticals in developing countries.

Against this background, WHO's simultaneous use of the term "Counterfeit" to refer to a range of pharmaceutical quality and safety problems is counterproductive. It enables proponents of an extended IP enforcement agenda to propagate confusion over the term "counterfeit" and to advocate for an IP enforcement framework in developing countries as a way of ensuring delivery of safe pharmaceuticals.

Such confusion is already noticeable in many parts of the world. For instance, in Kenya, Tanzania and Uganda, as well as at the East African Community (EAC) regional level itself several anti-counterfeiting legislations have been, or are in the process of being enacted. **Although the given rationale for such legislations is to protect the public from unsafe products, these legislations are only about protecting the rights of the IP holder. In fact such legislations through their erroneously broad definition of counterfeit makes every generic pharmaceutical a counterfeit.** In Kenya, enactment of the Anti-Counterfeit Act 2008 has been challenged by persons living with HIV/AIDS (PLWHA) on grounds that the Act will deny them access to affordable drugs and thus their Right to Life. More recently, PLWHA won a victory as the High court decided that pending final decision on the case the anti-counterfeit agency of Kenya cannot take action against the import and export of generic medicines.

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[2] See Article 51 and 61 of the TRIPS Agreement.

[3] Articles 15 and 16 of TRIPS make clear, a civil trademark infringement can be established: (1) with respect to a service mark; (2) where the infringing mark is confusingly similar (but not identical to) to registered mark; (3) where the good or service on which the infringing mark is placed is merely similar (but not identical to) to those for which the mark is registered; (4) where the mark is not registered, provided that the mark is "well-known;" and (5) where the goods or services are not similar to those for which a mark is registered, provided that the mark is "well-known". None of these categories of recognised trademark infringements would fall under the definition of counterfeit trademark goods as defined in Article 51 of the TRIPS Agreement.

[4] See Chan Park (2009), "Legal Aspects of Defining Counterfeit Medicines": A Discussion Paper, prepared for WHO SEARO

[5] For an overview of anti-counterfeiting initiatives see Susan Sell (2008), "The Global IP Upward Ratchet, Anti-counterfeiting and piracy enforcement efforts: The State of Play" available at http://www.iqsensato.org/wp-content/uploads/Sell_IP_Enforcement_State_of_Play-OPs_1_June_2008.pdf. See also Ermias Tekeste Biadleng and Viviana Munoz Tellez (2008) "The Changing Structure and Governance of Intellectual Property Enforcement" Research Paper 15, South Centre, p. 25 available at www.southcentre.org

Misusing the term "Counterfeit" (a term defined in the TRIPS Agreement as trademark violation) to also refer to spurious pharmaceuticals is a disservice to public health as it conflates issues of health and IPRs. As a consequence public health problems of QSE will be addressed through an IP enforcement lens.

Such an approach will not deliver the solutions needed to address the proliferation of spurious pharmaceuticals, as IP rights are about protecting the IP holders which are largely MNCs. They are private rights and IP holders have the responsibility of enforcing such rights. **The problem of unsafe pharmaceuticals arises irrespective of IP violations.** A product may be protected by an IPRs (e.g. trademark or patents) but this does not guarantee that it is of quality. **Quality is guaranteed after the approval of DRA. Thus quality, safety issues are distinct from issues of IPRs.**

Moreover **conflating issues of IPRs and public health will only further promote seizures of medical products by customs authorities.** In the recent seizures of safe and legitimate products at European ports, the EU and the European rights-holders invoke public health worries to justify their actions. Although in reality such actions were aimed at protecting the IP rights of their MNCs. **Conflating IPRs with public health also makes it impossible to obtain reliable data on the true extent and nature of the proliferation of spurious pharmaceuticals, data which is presently non-existent (See Part C below).**

For public health oriented solutions, terminology used to describe QSE issues MUST BE DISTINCT from terminology relating to IP violations. The term "counterfeit" must not be equated with proliferation of medical products with compromised QSE, and WHO must advocate that an IP enforcement framework IS NOT suitable to address problems of QSE.

C. THE TRUTH ABOUT "COUNTERFEIT MEDICINES" STATISTICS

All sorts of statistics are bandied about on the extent of the problem of "counterfeit medicines". The often-cited statistic is that of WHO which estimated that more than 10% of the global medicines market is comprised of counterfeits, and that up to 25% of medicines in developing countries are counterfeit[6]. Since then it has emerged that this statistic cannot be supported.[7]

IMPACT presents statistics that counterfeit medicines account for between 10% and 30% of the medicines sales[8]. However in support the document describes a selected number of largely anecdotal accounts that purport to describe the extent of the problem in several developing countries; with no sources provided.[9] In addition, the accounts use the terms "counterfeit", "substandard", "pirated", "adulterated", "forged", "faked" and "expired" interchangeably.[10] For instance, one account quotes a Nigerian government official as stating "approximately 48% of goods and drugs imported into the country are substandard or counterfeit" but conflating "substandard" with "counterfeit", and medicines with all other "goods".[11]

It is common for statistics to conflate the problem of "counterfeit medicines" with substandard medicines as well as with intellectual property infringements.

A recent paper authored by persons from MSF and AEDES Foundation, found that few published reports differentiate between substandard and counterfeit. It mentions that "One WHO study found that almost all (18/19) poor quality medicines were genuine products yet this study has been cited

[6] World Health Organization (2003), Substandard and counterfeit medicines: fact sheet no. 275. Geneva.
[7] World Health Organization (2006). Counterfeit medicines: fact sheet no. 275 (revised 14 November 2006). Geneva: WHO.
[8] International Medical Products Anti-Counterfeiting Taskforce (2006), Counterfeit Medicines: an update on estimates available at http://www.who.int/medicines/services/counterfeit/impact/TheNewEstimatesCounterfeit.pdf – accessed 09 February 2009
[9] Chan Park (2009), see above
[10] Chan Park (2009), see above.
[11] Chan Park (2009), see above.

elsewhere by WHO as evidence of counterfeiting"[12]. The paper also concluded that substandard medicines represent a far larger risk to public health than counterfeit medicines and that substandard and counterfeit drug are regularly conflated and confused.

The British Medical Journal (BMJ) in a study conducted by the European Alliance for Access to Safe Medicines (EEASM) alleged that 62% of drugs sold by online pharmacies were counterfeit or substandard[13] but a review of the study revealed that this figure included "unapproved generic medicines", which were defined as medicines that have "been manufactured by a company who does not have permission from the original developer"[14] (thus not related to the quality of the product).

Another example is the 2007 "Report on Community Customs Activities on Counterfeit and Piracy" that listed Switzerland as the main source of counterfeit medicines with 39.21% of medicines exported from Switzerland and seized under the EC Customs procedures being counterfeit. However the report failed to mention that the seizure was because of a patent dispute, which had nothing to do with the active ingredients contained in the drug.[15]

On counterfeit statistics, Outterson and Smith point out "not only that the evidence for counterfeit drugs is anecdoctal rather than empirical but that the only comprehensive collection point for global data on counterfeiting is the Pharmaceutical Security Institute (PSI) – a trade organization created by the security directors of 14 global drug companies that does not make its data available to the public"[16]. They also point out that "the terms fake or counterfeit have included a wide range of drug products from those resulting in criminal acts of homicide, to placebos, to safe and effective drugs from Canada"[17].

From the above, the truth about "counterfeit medicines" statistics is that reliable empirical data on the extent and nature of the problem is non-existent.

Many of the accounts pertaining to counterfeit medicines conflate substandard with counterfeit medicines or with infringement IPRs. Many of the accounts originate from suspect sources such as industry groups. Also what is apparent is that anecdotal information is being synthesized into an estimate of prevalence of counterfeit medicines in a specific country or in developing countries in general. For example some of the accounts state the number of illegal pharmacies that allegedly operate in a given jurisdiction; others discuss the total estimated amount of economic losses to the pharmaceutical industry from counterfeiting; and still others provide a raw number of seized medicines in a specific country.**[18] Such a method is unreliable for providing a true picture of the counterfeiting problem since "translating or harmonizing such disparate indices to arrive at a common denominator from which to approximate the prevalence of counterfeit medicines in developing countries might well be impossible"[19].**

In the absence of a well-recognised reliable methodology, data on the spread of counterfeit medicines should be treated with scepticism.

WHO in its report for the WHA (A63/23) concurs that no reliable and sound data on counterfeit drugs exist. Despite this recognition, it attempts to paint a picture of massive problem of counterfeits and

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[12] "J.M. Caudron, N. Ford, M. Henkens, C. Mace, R. Kiddle-Monroe and J. Pinel; "Substandard medicines in resource-poor settings: a problem that can no longer be ignored"; Tropical Medicine and International Health, Vol. 13 N0. 8 pp 1062-1072 August 2008

[13] Mayor, S. (2008). More than half of drugs sold online are fake or substandard. *BMJ,* 337:a618.

[14] European Alliance for Access to Safe Medicines (EEASM) (2008). The Counterfeiting Superhighway. Surrey: Medicom Group Ltd, quoted in Chan Park (2009), see above.

[15] See Swissinfo.ch, "EU voices concern over Swiss-seized medicine", May 19, 2008 quoted in South Centre & CIEL IP Quaterly Update, Third Quarterly 2008.

[16] Kevin Outterson and Ryan Smith (2006), "Counterfeit Drugs: the Good, the Bad and the Ugly" 16 Albany Law Journal of Science and Technology 525

[17] Kevin Outterson and Ryan Smith (2006), see above

[18] Chan park (2009), see above

[19] Chan park (2009), see above

attempts to describe the nature of the problem. It does so without providing any concrete evidence to support its claims.

WHO's approach is problematic as intergovernmental organisations are supposed to take policy decisions based reliable and concrete empirical evidence. For instance, contrary to WHO's insistence that counterfeits pose a massive threat many studies including by WHO show that the problem of substandard medicines is much greater than counterfeit medicines. For example a WHO study conducted in Myanmar and Viet Nam concluded that "the prevalence of substandard drugs is in general a much greater problem than counterfeit drugs in both countries", and found no instances of counterfeiting in Viet Nam despite an 11% overall substandard ratio.[20] Another WHO study conducted in Cameroon, Chad and Madagascar found that 17.8% (28 of 157) of the antibiotics and 13% (18 of 138) of antiparasitic products tested were substandard, while only 2.8% (4 of 138) of the antiparasitic products and 7.6% (12 of 157) of the antibiotics contained no active ingredient and were clearly fraudulent.[21]

Thus obtaining reliable evidence based on well-defined and transparent methodology on the extent and nature of the problem is important to have a better understanding of the problem and to enable development of suitable solutions. [**To obtain reliable evidence, there must also be clarity over terminology as explained in Part B above]. In the absence of such evidence and understanding, efforts to deal with the proliferation of medicines with compromised quality and safety is bound to be unsuccessful. Instead wrongful measures could adversely affect access to, and local/regional production of, affordable generic medicines in developing countries.**

D. INTERNATIONAL MEDICAL PRODUCT ANTI-COUNTERFEIT TASKFORCE (IMPACT)

1. IMPACT: ORGANISATIONAL STRUCTURE

IMPACT was launched in 2006 following a conference organised in Rome by WHO supported by the Italian Medicines Agency (AIFA) and IFPMA resulting in a Rome Declaration[22]. The Declaration outlines the objectives of IMPACT as *inter alia* raising awareness among international organisations and other stakeholders about the problem of counterfeit; encouraging coordination among different anti-counterfeiting initiatives; calling for effective legislative measures to combat counterfeit medicines etc. The Declaration also outlines IMPACT's long-term vision on "counterfeiting" i.e. "explore further mechanisms including an international convention for strengthening international action against counterfeit medicines".

Further information about IMPACT's mission, objectives, relationship with WHO, collaborating parties, structure as well as issues of financing and fundraising, is detailed in its Terms of Reference (ToR)[23]. According to the ToR, IMPACT is a voluntary grouping of governments, organisations and institutions from developed and developing countries.

IMPACT is composed of organisation such as the WHO, International Criminal Police Organization (Interpol), OECD, World Customs Organisations (WCO), World Intellectual Property Organization (WIPO), World Trade Organization (WTO), International Federation of Pharmaceutical Manufacturers Association (IFPMA), World Bank, European Commission, Council of Europe, International Pharmaceutical Federation, Pharmaceutical Security Institute.[24]

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[20] Wondemagegnehu, E. (1999). Counterfeit and Substandard Drugs in Myanmar and Viet Nam: Report of a study carried out in cooperation with the Governments of Myanmar and Viet Nam, WHO, Geneva.
[21] World Health Organization (1995); La qualité des médicaments sur le marché pharmaceutique africain. Etude analytique dans trois pays: Cameroun, Madagascar, Tchad. Geneva: WHO.
[22] The Rome Declaration is available at http://www.who.int/medicines/services/counterfeit/RomeDeclaration.pdf, accessed on 6 April 2010
[23] The Terms of Reference of IMPACT is available at at http://www.who.int/impact/about/IMPACT_ToR.pdf , accessed on 6 April 2010
[24] See list of Organizations participating in IMPACT available at http://www.who.int/medicines/services/counterfeit/IMPACTOrgParts.pdf, accessed 9th April 2010

The General Meeting of IMPACT is the highest decision making body and has met 3 times between 2006 and 2008.[25] The General Meeting reviews the reports and proposals presented by the Planning Group, which is the executive arm of IMPACT. IMPACT has also established 5 Working Groups viz. Legislative and Regulatory infrastructure; Regulatory implementation; Enforcement; Technology and Communication.

According to the ToR, IMPACT is a taskforce administered by WHO which also provides secretariat support to IMPACT (See below Part E on Conclusion: WHO's Involvement in "Counterfeits" & "IMPACT").

2. IMPACT & LINKS TO "IP ENFORCEMENT" AGENDA

In discussing IMPACT's work on counterfeit it is important to note the numerous simultaneous anti-counterfeiting initiatives that have emerged motivated not by public health considerations but to promote an IP enforcement framework particularly in developing countries[26]. The holders of IP are powerful multinational companies (MNCs) of developed countries. The origins of the WTO-TRIPS Agreement can be traced back to a push by such MNCs (in particular the pharmaceutical industry) for countries to adopt minimum IP standards. Following adoption of the TRIPS Agreement concerns arose about developing countries' access to affordable generic medicines as IP standards required by the TRIPS Agreement would make production and thus availability of generic medicines difficult. And affordable generic medicines play a pivotal role in increasing access to medicines in developing countries.

In recent years, attention of MNCs (including the pharmaceutical industry) has shifted to IP enforcement. According to Sell there has been a surreptious campaign to increase IP enforcement beyond the minimum standards set in the WTO in ways that are "TRIPS-Plus-Plus" using concepts such as "anti-counterfeiting" and "piracy"[27]. Sell notes that to achieve this purpose, "*advocates of the IP enforcement agenda have engaged in a shrill public relations campaign to frighten people into accepting their agenda*" adding also that the IP enforcement campaign is "*characterised by strategic obfuscation; its message is intentionally misleading*".

Sell's investigation concluded: "*The IP Anti-counterfeiting and enforcement agenda involves hundreds of OECD-based global business firms and their foreign subsidiaries. It includes a number of initiatives including: the Anti-Counterfeiting Trade Agreement (ACTA); Interpol; the US Chamber of Commerce's "Coalition against Counterfeiting and Piracy Intellectual Property Enforcement Initiative: Campaign to Protect America"; the Security and Prosperity Partnership of North America; the WHO's IMPACT; WIPO's ACE discussions; and many bilateral and regional Free Trade Agreements, Investment Treaties, and Economic Partnership Agreements*."

The recent IMPACT FAQ denies any involvement in IP issues. It states "Issues related to intellectual property (IP) protection are not within the scope of the task force"[28]. Further WHO's report on IMPACT prepared for the WHA (A63/INF.DOC./3) states in paragraph 10 that "WHO is working on the issue of counterfeit medical products from a public health perspective".

However evidence available suggest otherwise. See paragraphs 2.1 – 2.4 below.

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[25] General Meeting held in Bonn (Germany), 25-26 November 2006; General Meeting held in Lisbon (Portugal), 10-14 December 2007; General Meeting held in Hammamet (Tunisia), 3-5 December 2008.

[26] For more information on the IP enforcement agenda see Ermias Tekeste Biadleng and Viviana Munon Tellez (2008) "The Changing Structure and Governance of Intellectual Property Enforcement" Research Paper 15, South Centre, available at www.southcentre.org

[27] Susan Sell (2008), "The Global IP Upward Ratchet, Anti-counterfeiting and piracy enforcement efforts: The State of Play" available at http://www.iqsensato.org/wp-content/uploads/Sell_IP_Enforcement_State_of_Play-OPs_1_June_2008.pdf. Susan Sell is the Director of the Institute for Global and International Studies and Professor of Political Science and International Affairs at George Washington University in the United States

[28] See FAQ with Answers prepared by WHO & IMPACT, distributed at an Open Forum on IMPACT on 26th March 2010, available at http://www.who.int/medicines/services/counterfeit/impact-faqwa.pdf, accessed on 5th May 2010

2.1. Many of the organisations participating in IMPACT are widely known to be active promoters of strong IP enforcement measures under the heading of "anti-counterfeit" using public health as a front. For instance:

- ***Interpol:*** is an active player in IP enforcement, focusing on IP crime[29] and views dealing with medical products with compromised quality and safety issues through an IP enforcement lens. This is explicitly evidenced by Interpol's 2008 annual report which explains its IP crime activity as follows: "The Intellectual Property (IP) Crime Programme focuses increasingly on counterfeit goods, especially medical products, which pose a threat to the health and safety of consumers"[30] and in this description reference to IMPACT is made. The same report also mentions an IP crime training course in Nairobi organized jointly with the Kenyan police on counterfeit medical products.[31] From this it is obvious that Interpol sees solutions pertaining to quality and safety in the context of dealing with violations of IPRs. Concern has also been raised that the scope of the definition of counterfeit relied on by Interpol may be so wide as to include legitimate uses of works.[32] It is noteworthy that Interpol has one officer full-time in WHO working on IMPACT & counterfeit issues.

- ***WCO:*** is an active proponent of IP enforcement as a solution to dealing with consumer health. It has developed model legislation related to border measures and customs legislation to deal with infringement of IPRs.[33] In 2006, WCO launched "Provisions Standards Employed by Customs for Uniform Rights Enforcement" (SECURE) to disrupt trade in IPR infringing goods.[34] This initiative was disbanded following criticism by developing countries and public interest NGOs for advocating TRIPS plus standards as the benchmark for IP enforcement related issues and for the lack of transparency and accountability.[35] These and other activities on IP enforcement take place under the banner of "anti-counterfeiting", and one of the rationales for such initiatives is protection of public health.

- ***WIPO*****:** an intergovernmental organisation concerned with IP protection and enforcement. WIPO's Advisory Committee on Enforcement (ACE) established in 2002 is industry dominated and has devoted its efforts to discussing strengthening enforcement and problems that right holders face in third countries without giving much attention to public interest considerations or right holders' obligations.

- ***Big Pharma:*** is represented in IMPACT *inter alia* through IFPMA & the Pharmaceutical Security Institute (PSI).

    - Big Pharma has long been known for advocating strong IP protection and enforcement to protect its profits. In a background paper written for the WHO Commission on Macro Economics and Health, the then IFPMA Director General Dr. Harvey Bale, proposed that "in order to counteract the proliferation of counterfeit drugs, all countries, and particularly developing countries, need to implement an appropriate legislation which actively utilizes

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[29] Susan Sell (2008), see above

[30] See Interpol 2008 Annual Report, pg. 31 available at http://www.interpol.int/Public/ICPO/InterpolAtWork/iaw2008.pdf, accessed 1 May 2010

[31] See Interpol 2008 Annual Report, pg. 22 available at http://www.interpol.int/Public/ICPO/InterpolAtWork/iaw2008.pdf, accessed 1 May 2010

[32] Ermias Tekeste Biadleng and Viviana Munoz Tellez (2008), see above

[33] See http://www.wcoipr.org/wcoipr/Menu_ModelLegislation.htm, accessed 1 May 2010

[34] See Li, X (2008): *Secure*: *A Critical Analysis and Call for Action*, South Bulletin, May, Issue 15.

[35] See Shashikant S., (11 August 2008), "Controversy on proposed IP rules at World Customs Organisation" published in SUNS #6535, available at http://www.twnside.org.sg/title2/intellectual_property/info.service/2008/twn.ipr.info.080802.htm; See also Shashikant, S., (6 October 2008), "Countries call on World Customs Organisation to be member-driven, transparent), published in SUNS #6561, available at http://www.twnside.org.sg/title2/intellectual_property/info.service/2008/twn.ipr.info.081004.htm; See NGO Open Letter to the World Customs Organisation (October 2008) available at http://www.twnside.org.sg/

patent system"[36] a strong indication that Big Pharma sees a link between IPRs and quality, safety issues.

- US based Big Pharma (whose interest is also represented by IFPMA) provided to the USTR recommendations on ACTA aimed at strengthening the legal framework with regard to trade in counterfeit medical products[37]. These recommendations are similar to/drawn from, IMPACT's Principles and Elements for National Legislation against Counterfeit Medical Products, with US Big Pharma endorsing IP enforcement framework as providing the solution.

- ***European Commission:*** is an active participant and funder of IMPACT. At the same time it also has a keen interest in anti-counterfeiting initiatives in the context of protecting and enforcing IPRs. The EC/EU has always presented IPR enforcement as a solution for dealing with quality and safety issues[38].

  - The EC is one of the sponsors of ACTA.

  - The EC in its "Strategy for the Enforcement of Intellectual Property In Third Countries" makes clear of its intention to deal with IPR violations in third countries under the pretext of dealing with public health.[39]

  - A 2006 resolution of the European Parliament on counterfeiting of medicinal products is most revealing of the EC/EU agenda.[40] This Resolution recalls the Rome Conference that launched IMPACT and stresses on the scourge of counterfeit medicines. However this same resolution refers to EC's initiatives on enforcing IPRs and in this context its action plan on counterfeiting and piracy, and calls on the EC to go beyond its "Strategy for the Enforcement of Intellectual Property In Third Countries" to deal with the problem.

  - In another official communication the EC points out that it is losing ground in pharmaceutical innovation to US and Asia. The same communication speaks of dealing with illegal medicinal (including counterfeit medicines) through effective enforcement of IPRs and to this end EC will fund implementation of IMPACT's Principles & Elements for National Legislation in third countries.[41]

  - The European Council Regulation No. 1383/2003 on "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"[42] speaks of the need to deal with counterfeit goods for public health purposes. However provisions of this same Regulation is the cause of the recent seizures of quality medicines at European ports on suspicion of IP violation (not because of quality concerns), thus delaying treatment for developing country patients.

- ***Council of Europe:*** Council of Europe views IPR protection as a way of dealing with quality issues. For instance the "Draft Council of Europe convention on the counterfeiting of medical products and similar crimes involving threats to public health" refers in its introductory section to

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[36] See Harvey E Bale, Consumption and Trade in Off-Patented Medicines, Working Paper no.65, Indian council for Research on International economic relations, 2001, available at http://www.icrier.org/pdf/bale65.PDF, accessed 7 April 2010.
[37] See http://keionline.org/content/view/193/1
[38] See Communication From the Commission to the European Parliament, The Council, and the European Economic and Social Committee: An Industrial Property Rights Strategy for Europe available at http://ec.europa.eu/internal_market/indprop/docs/rights/communication_en.pdf, accessed 7 April 2010
[39] See http://trade.ec.europa.eu/doclib/docs/2005/april/tradoc_122636.pdf, accessed 7 April 2010
[40] See http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+MOTION+P6-RC-2006-0467+0+DOC+PDF+V0//EN&language=EN, accessed 1 May 2010
[41] See Communication From the Commission to the European Parliament, The Council, The European Economic and Social Committee and the Committee of the Regions: safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector.
[42] See http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:196:0007:0014:EN:PDF, accessed 1 May 2010

instruments such as the Parliamentary Assembly Recommendations 1673 (2004) on "Counterfeiting: problems and solutions", the declaration of the G8 Summit in St. Petersburg entitled "Combating IPR piracy and counterfeiting" of 16 July 2006, the declaration of the International Conference "Europe against counterfeit medicines" held in Moscow on 23 and 24 October 2006. These instruments take a view of tackling public health issue from an IP perspective[43].

2.2 Several key IP enforcement initiatives have also identified WHO & IMPACT as part of the IP enforcement agenda. For example:

- The 2007 G8 Summit Declaration on "Growth & Responsibility in the World Economy" noted the importance of IP protection and enforcement including "harmonizing the international patent system in order to improve the acquisition and protection of patent rights world-wide." It further states that the "benefits of innovation for economic growth and development are increasingly threatened by infringements of intellectual property rights worldwide. We therefore strongly reaffirm our commitments to combat piracy and counterfeiting. Trade in pirated and counterfeited goods threatens health, safety and security of consumers worldwide particularly in poor countries". Against this context the Declaration welcomed "the work on the WHO initiative to implement international medical product anti-counterfeiting Taskforce (IMPACT)".[44]

- The OECD report on "The Economic Impact of Counterfeiting and Piracy" under the heading "Summary of Intergovernmental IPR activities" lists WHO & IMPACT as initiatives linked to IP enforcement[45].

- The European Observatory on Counterfeiting and Piracy created by the EC, which serves as a platform to exchange experiences and information and to share best practices on IP enforcement identifies IMPACT as one of the organisations involved in IP enforcement[46].

- WIPO only deals in IP issues and has listed IMPACT's Conference on Developing Effective Legislation to Combat Counterfeit Medical Products (10-12 December 2007) & Meeting of Jurists and Experts on Legislation to Combat Counterfeit Medical Products (12-13 July 2007) as "WIPO's enforcement-related training and awareness-raising activities and cooperation with intergovernmental and non-governmental organisations"[47].

2.3. The origins of IMPACT is also rooted in the context of IPRs

The concept paper for IMPACT *"Combating Counterfeit Drugs: A Concept Paper for Effective International Cooperation"*[48] was drafted by Michele Forzley, a US-based lawyer and a public health representative to the US Department of Commerce Industry Trade Advisory Committee 15 on Intellectual Property on behalf of the Global Health Council"[49]. Her biography states that her study *"Counterfeit Goods and Public's Health and Safety"(Forzley 2003)*[50] became *"the basis for the "Concept Paper on a Framework Convention on Counterfeit Drugs" the recommendations of which are now implemented in IMPACT"*.[51]

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[43] See http://assembly.coe.int/Documents/WorkingDocs/Doc10/EDOC12130.pdf, accessed 13 May 2010
[44] See G8 Summit Declaration on "Growth & Responsibility in the World Economy" (2007) available at http://www.g-8.de/Webs/G8/EN/G8Summit/SummitDocuments/summit-documents.html, accessed 7 April 2010
[45] See OECD report on "The Economic Impact of Counterfeiting and Piracy", pg. 186 available at http://www.oepm.es/cs/OEPMSite/contenidos/ponen/InformeOCDE26feb09/2009_03_03_OECD_Study_on_Counterfeiting_and_Piracy.pdf, accessed on 7 April 2010
[46] See http://ec.europa.eu/internal_market/iprenforcement/observatory/index_en.htm#what
[47] See http://www.wipo.int/enforcement/en/activities/activities_07.html, accessed 7 April 2010
[48] Michele Forzley (2006) "Combating Counterfeit Drugs: A Concept Paper for Effective International Cooperation", available at http://www.who.int/medicines/events/FINALBACKPAPER.pdf
[49] See Michele Forzley's biography available at http://www.micheleforzley.com/sections/mf_about.html, accessed on 7 April 2010
[50] Michele Forzley (2003), "Counterfeit Goods and the Public's Health and Safety" available at http://www.iipi.org/reports/Counterfeit_Goods.pdf, accessed on 7 April 2010
[51] Michele Forzley's biography, see above.

The *"Counterfeit Goods and the Public's Health and Safety"* (2003) study by Forzley was supported by the US Patent and Trademark Office (USPTO),[52] while copyright to the paper is owned by the International Intellectual Property Institute (IIPI), an industry funded NGO that has at the core of its focus the promotion and enforcement of IPRs. This means that ideas expressed in Forzley (2003) study done for a pro-IP industry funded NGO and supported by the USPTO form the foundation of IMPACT.

The Forzley 2003 study states clearly 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" adding that "To reframe the policy perspective is fundamental to the success of any strategy on counterfeit goods". The same paper states "what havoc counterfeits might wreck….if resources devoted to intellectual property seizures are redirected towards other objectives".[53] The paper continues to add that public health problems arise when developing countries do not have an adequate IP legal system in place.

From this it is apparent that institutions concerned about IPR violations have made a conscious and deliberate attempt to link IP infringement to public health problems through use of the term "counterfeit" so that public health problems can be used as a front to promote IP protection and enforcement.

2.4. IMPACT's funders also fund and promote anti-counterfeiting activities in the context of IP enforcement as a solution to quality and safety problems.

IMPACT is funded by the EC, Australia, Germany, Italy and Netherlands. Germany, Italy and the EC are part of G8 Countries that are very concerned with IP infringements and believe IP enforcement to be pivotal in dealing with quality and safety issues and in this context promotes the IMPACT initiative[54]. Meanwhile all of the abovementioned funders are involved in negotiating ACTA, over which there is already significant concern that trade in generic medical products will be targeted.[55] It is also noteworthy that USA, Germany and Australia (also countries participating in ACTA negotiations) hold the Chairman to 3 of the 5 Working Groups of IMPACT. Interpol and IFPMA described above as having an interest in IP enforcement are also funders of IMPACT.

2.5. IMPACT's Rome Declaration is mandated to coordinate various IP enforcement initiatives.

One of the objectives of IMPACT as outlined in the Rome Declaration is to encourage coordination among different anti-counterfeiting initiatives. As noted above, the many recent anti-counterfeiting initiatives aim to promote a *"TRIPS plus plus"* IP enforcement framework. Thus IMPACT's objective makes it a role of IMPACT to not only be involved in such initiatives but also to encourage co-ordination of such activities although such activities are anticipated to be detrimental for public health.

3. PARTICIPATION, TRANSPARENCY, ACCOUNTABILITY & CONFLICTS OF INTEREST

3.1 Participation

Several observations can be made with regards to participation in IMPACT:

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[52] See http://www.iipi.org/reports/Counterfeit_Goods.pdf
[53] Michele Forzley (2003), p. 18, see above
[54] See G8 Summit Declaration on "Growth & Responsibility in the World Economy" (2007) available at http://www.g-8.de/Webs/G8/EN/G8Summit/SummitDocuments/summit-documents.html, accessed 7 April 2010
[55] "Consumer Groups Fear ACTA Could Encourage Generic Drug Seizures", Inside U.S. Trade - 4/30/2010; "ACTA and the Drug Monopoly Enforcement Agenda: A windfall for big drug companies; higher medicine prices for all" available at http://www.essentialaction.org/access/index.php?/archives/213-ACTA-and-the-Drug-Monopoly-Enforcement-Agenda-A-windfall-for-big-drug-companies;-higher-medicine-prices-for-all.html; accessed 1 May 2010; ACTA & Access to Medicines, Sean Flynn (28 April 2010); available at http://www.wcl.american.edu/pijip/go/blog-post/acta-and-access-to-medicines; accessed 1 May 2010

(a). **Information about participation in IMPACT's activities is conspicuously missing.** WHO's report for WHA (A63/INF.DOC./3) attempts to paint a picture of wide acceptance by member states but the numbers given indicate that only a handful of member states may have participated in some of IMPACT's meetings. In addition there is hesitance to reveal the participants on grounds of "privacy and security".[56] There is also no clarity about the basis on which WHO member states were invited to participate in IMPACT since the ToR of IMPACT requires that there be balanced representation[57] as well as who participated (and the extent of member states' participation) in the Planning Group and the Working Groups as well as other expert groups which are the most important components of IMPACT.

(b) **IMPACT is not a WHO member-driven organisation** *and* consists of a wide range of stakeholders many with conflicting vested interests. For instance as noted above many of the entities that participate in and fund IMPACT are also promoting an IP enforcement agenda under the "anti-counterfeit" heading.

(c) **There is extensive private sector involvement in IMPACT's activities.** The IFPMA that represents the interest of multinational companies plays a central role in IMPACT's activities including by funding its activities. In particular its Director General heads the Working Group on Technology. Pharmaceutical MNCs also participate in IMPACT through the Pharmaceutical Security Institute (PSI), an entity made up of 24 pharmaceutical MNCs. It is well known that the pharmaceutical industry has a strong interest in ensuring strong IPR protection and enforcement in developing countries as well as in undermining use of generic pharmaceuticals and production of such products in developing countries, as generics undercut their profits. Thus **participation of the private sector in IMPACT's activities to the extent it relates to WHO raises serious concerns about the influence that MNC drug companies exert over IMPACT particularly in standard-setting, and about conflicts of interests.**

(Note: Despite the conflicting interests, WHO has admitted that the issue of conflicts of interests has never been dealt with. See below section on conflicts of interest).

(d) "Organisations participating in IMPACT" are largely developed country organisations or represent interest of entities based in developed countries[58]. Apart from this, 3 of the 5 Chairs of the Working Groups are from Germany, USA, Australia, while 2 of the Chairs are from the IFPMA, Interpol and the International Pharmaceutical Federation. The Vice-Chairs are from Singapore and Nigeria.

3.2 Transparency & Accountability

On the issue of transparency and accountability, the following observations can be made:

(a) There is very little information available on IMPACT and its activities (as noted above).

(b) In relation to financing of IMPACT, WHO's report on IMPACT (A63/INF.DOC./3) states that between 2006 and 2008 its activities were financed by the EC, Netherlands, Australia, Germany, Italy, and by WHO. The report also states (in para 12) that IFPMA and Interpol have made direct contributions to IMPACT's meetings and activities as well as that additional in-kind contributions have been made by member states and stakeholders but no further information is provided as to this list of contributions, the amounts and the purpose for which it was made.

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[56] See FAQ with Answers prepared by WHO & IMPACT, distributed at an Open Forum on IMPACT on 26th March 2010, available at http://www.who.int/medicines/services/counterfeit/impact-faqwa.pdf, accessed on 5th May 2010

[57] See Para. 5.2 of IMPACT's Terms of Reference available at http://www.who.int/impact/about/IMPACT_ToR.pdf , accessed on 6 April 2010

[58] See list of Organizations participating in IMPACT available at http://www.who.int/medicines/services/counterfeit/IMPACTOrgParts.pdf, accessed 9th April 2010

(c) WHO Sect. also appears to be under an obligation not to share information about IMPACT since IMPACT's ToR states that WHO should take *"necessary measures to ensure the confidentiality and protection of materials and information that are provided to WHO with the request to keep them protected from unauthorized access"*.[59]

(d) **A key concern is that IMPACT operates outside the purview of WHO member states and has not been accountable to WHO member states in relation to its operation and activities although WHO Secretariat is involved in IMPACT's activities** – WHO Secretariat funds and fundraises for IMPACT, provides secretariat support to IMPACT, has its logo on most of IMPACT's document; is pushing for the adoption of IMPACT's principles & elements for national legislation (See below, section on standard-setting). **Noting the wide-ranging activities of IMPACT in particular standard-setting with the aim of promoting legal instruments in developing countries, the lack of transparency and accountability is simply unacceptable in the context of a member-driven intergovernmental forum such as WHO.**

(e) **There is also the issue of whether and the extent to which there has been compliance with "*WHO Guidelines on Working with the Private Sector to Achieve Health Outcomes*"[60] which is supposed to be applicable as an internal management tool at WHO.** This document is intended to help *"WHO staff interact appropriately with commercial enterprises in order to achieve positive outcomes on health"* and also applies to associations representing commercial enterprises. Therefore, any partnership with the private sector including the IFPMA, PSI would come under the purview of these guidelines.

3.3 Conflict of Interest (COI)

Conflict of interest occurs when an individual or organization has multiple interests, one of which could *possibly* corrupt the motivation for an act in the other[61]. **IMPACT's setup raises many issues of such COI.** Particularly concerning is the involvement of the pharmaceutical industry and entities (e.g. the European Commission) in IMPACT that have an interest in propagating confusion over use of the term "counterfeit" to promote adoption of an IP enforcement framework or undermining use of generics and/or local production of generics in developing countries or an interest in all of the above.

Despite the existence of such COI WHO has admitted this issue has never been dealt with. WHO argues that "participation in meetings of the Taskforce has not required declarations of interests because participants are clearly identified by their affiliation and thus represent the view of their respective organizations"[62]. **This admission reinforces criticisms that IMPACT and its outcomes such as "Principles and Elements for National Legislation against Counterfeit Medical Products" lack legitimacy. IMPACT is a forum wherein entities with COI have been allowed to participate and shape the agenda, and thus the forum and its outcomes are obviously inappropriate tools to deal with issues of QSE.**

4. IMPACT & STANDARD SETTING ACTIVITIES

IMPACT's General Meeting endorsed in 2007 a text on "Principles and Elements for National Legislation against Counterfeit Medical Products" ("Model Elements"), which contains WHO and IMPACT's logos[63]. At IMPACT's General Meeting in Tunisia in December 2008 the Model Elements were revised to include counterfeit medical devices. These Model Elements cover issues of scope; definitions including a definition on "counterfeit"; obligations of government institutions,

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[59] See para 5.5 of Terms of Reference of IMPACT available at http://www.who.int/impact/about/IMPACT_ToR.pdf, accessed 9th April 2010

[60] See "*WHO Guidelines on Working with the Private Sector to Achieve Health Outcomes"* contained in EB 107/20 (13 November 2000) available at http://apps.who.int/gb/archive/pdf_files/EB107/ee20.pdf , accessed 5th May 2010

[61] See wikipedia at http://en.wikipedia.org/wiki/Conflict_of_interest

[62] See WHO Doc. A63/INF.DOC./3

[63] See http://www.who.int/impact/events/FinalPrinciplesforLegislation.pdf, accessed 7th April 2010

manufacturers, operators of the distribution chain, retailers and other operators; acts that are illegal; sanctions; nature of sanctions, etc. The aim of the Model Elements is to serve as a "reference for developing ad hoc legislation aimed at effectively combating counterfeit medical products within their jurisdiction".[64]

These Model Elements have never been scrutinized or approved by WHO member states and yet the text is legitimized with WHO's logo.[65] In fact many member states have repeatedly objected to WHO's involvement in IMPACT and its endorsement of the Model Elements. **However, WHO Secretariat has simply ignored these concerns and is pushing for the adoption of the Model Elements by seeking comments on the Model Elements[66] and suggesting that these Model Elements will be adopted through expert committee processes bypassing scrutiny of the World Health Assembly.[67]**

The Model Elements raise several concerns:

- **Model Elements on a highly complex and technical matter were finalised after 2 expert meetings.**[68] There is little information volunteered about participation in these meetings. A list of participants of the first expert meeting suggests that only 6 of the 32 participants were from developing countries.[69] However it is not clear whether the participation was in their personal capacity or as government representatives. The rest of the participants represented pharmaceutical companies and associations, lawyer groups, European entities (e.g. European Commission, Council of Europe), WIPO, WTO etc.

- **The Model Elements are not backed by any concrete evidence.** As noted in Part C above, there is lack of reliable data on the extent and nature of problems pertaining to QSE. Thus the need for such Model Elements is in question.

- **The Model Elements have not emerged from a member driven process, but from an initiative that lacks credibility** because issues of conflicts of interest have not been addressed and it is participated by entities that conflate IP and health issues and that also seek to address QSE issues through an IP enforcement lens.

- **IFPMA being the Chair of Working Group on Technology plays a central role in the overall standard-setting functions of IMPACT.** On this its mandate includes assessing technologies to prevent, deter, or help to detect counterfeit products and disseminating information and recommendations on the merits and limitations of technologies.[70] To this end, Glaxo Smith Kline has prepared a paper on "Anti-Counterfeiting Technologies for the Protection of Medicines" and this paper contains the logos of WHO as well as of IMPACT. Interestingly the paper states "some of these [technologies] are protected by international patents and may only be available from licensed suppliers, subject to appropriate royalties or license fees".[71] Thus it is IFPMA that will

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[64] See http://www.who.int/impact/events/FinalPrinciplesforLegislation.pdf, accessed 7th April 2010
[65] See http://www.who.int/impact/events/FinalPrinciplesforLegislation.pdf, accessed 7th April 2010
[66] See WHO website - http://www.who.int/impact/news/en/, accessed 7th April 2010
[67] See FAQ with Answers prepared by WHO & IMPACT, distributed at an Open Forum on IMPACT on 26th March 2010 wherein it is states that "IMPACT documents could become a WHO document if they undergo WHO procedures including review by the relevant WHO Expert Committee processes", available at http://www.who.int/medicines/services/counterfeit/impact-faqwa.pdf, accessed on 5th May 2010 See also WHO's website at http://www.who.int/impact/news/en/ <http://www.who.int/impact/news/en/> wherein comments are being sought on IMPACT's Draft Principles & Elements for National Legislation Against Counterfeit Medical Products"
[68] A meeting of experts took place in Brussels on 12-13 July 2007 and prepared a preliminary document. A revised version was discussed at a second experts meeting, which took place in Lisbon on 10-11 December 2007. The result of this second meeting was discussed and finalized at the 2007 IMPACT General Meeting held in Lisbon from 10-14 December 2007. Once finalized, the text was revised to include modifications specific to medical devices. See http://www.who.int/impact/news/BonnMeetingDraftPrinciples.pdf, accessed on 7 April 2010.
[69] See http://www.who.int/impact/events/PrinciplesElementsforNationalLegislation.pdf, accessed on 7 April 2010
[70] See Terms of Reference of IMPACT and attached presentation of Valerio Reggi at the Third Global Conference on Counterfeit and Piracy, January 30-31, 2007,Geneva, , available at http://www.ccapcongress.net/archives/Geneva/Files/Reggi.pdf, accessed 7th April 2010
[71] G Power, "Anti counterfeiting Technologies for the Protection of Medicine" , p.2, http://www.who.int/impact/events/IMPACT-ACTechnologiesv3LIS.pdf, accessed 7th April 2010

determine the level and types of technology to be used for anti-counterfeit purpose and access to the technologies would be subject to payment of royalties if it is IPR protected.

- Documentation by IMPACT: The ToR of IMPACT states 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).[72]

  It is strange that the ToR requires that all documents be issued by WHO particularly since IMPACT is not an initiative endorsed by the WHA. Moreover, the WHO Secretariat has made clear that IMPACT's documents are distinct from WHO's documents.[73] **Unfortunately WHO's logo is visible on many IMPACT's documents, and such documents do not contain the abovementioned disclaimer.**[74] **Failure to do so raises speculation as to whether there exists some hidden motive to encourage WHO member states to accept IMPACT's documents and represent them as reflecting the position of WHO Secretariat and its member states.**

- **IMPACT's definition of counterfeit is problematic** as it conflates issues of IP and health in one definition thus enabling proponents of IP enforcement to use public health concerns as a pretext for pushing for the adoption of an IP enforcement framework. Additionally the broad scope of IMPACT's counterfeit definition could be interpreted to include legitimate quality medicines.

4.1 IMPACT's Model Elements & links to Intellectual Property:

The recent FAQ prepared on IMPACT states "Issues related to intellectual property protection are not within the scope of the taskforce".[75] **This statement is misleading and inaccurate.**

IMPACT's Model Elements found on WHO's website very clearly state that "Counterfeit medical products need to be addressed through different bodies of legislation: on *intellectual property protection and enforcement*, on pharmaceutical and medical devices regulation and control; and on criminal law….". It adds "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, which are intended to complement or strengthen other legislation and not to replace it."[76] It is noteworthy that the words "established or enhanced" have in the most recent version of Model Elements on WHO's website been changed to *"may need to be enriched by or established"*.[77]

The Model Elements then state that the principles *"do not address"* infringement aspects of intellectual property, including patent rights, parallel importation of original goods from a country where they have been sold by or with the consent of the right holder; etc. This statement seen in context of the earlier statement i.e. that IP laws may need to be enhanced means that although that the Model Elements may not specifically address IP infringements, this does not exclude the possibility that the Model Elements can be directed towards dealing with infringement of IP rights.

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[72] See http://www.ccapcongress.net/archives/Geneva/Files/Reggi.pdf, accessed 7th April 2010
[73] See FAQ with Answers prepared by WHO & IMPACT, distributed at an Open Forum on IMPACT on 26th March 2010 that points out that IMPACT documents are different from WHO documents; available at http://www.who.int/medicines/services/counterfeit/impact-faqwa.pdf, accessed on 5th May 2010
[74] See for example Principles & Elements for National Legislation against Counterfeit Medical Products available at http://www.who.int/impact/events/PrinciplesElementsforNationalLegislation.pdf, accessed 7th April 2010 and G Power, "Anti counterfeiting Technologies for the Protection of Medicine" , p.2, http://www.who.int/impact/events/IMPACT-ACTechnologiesv3LIS.pdf, accessed 7th April 2010
[75] See FAQ with Answers prepared by WHO & IMPACT, distributed at an Open Forum on IMPACT on 26th March 2010, available at http://www.who.int/medicines/services/counterfeit/impact-faqwa.pdf, accessed on 5th May 2010
[76] See http://www.who.int/impact/events/FinalPrinciplesforLegislation.pdf, accessed 7th April 2010
[77] See http://www.who.int/impact/news/BonnMeetingDraftPrinciples.pdf

Noting the confusion that has arisen with use of the term "counterfeit" which refers to IP violations, and the fact that many of IMPACT's partners are actively funding and pushing an IP enforcement agenda, the proposal to enhance/enrich IP laws as a method of dealing with quality and safety is most concerning from a development and public health perspective.

It is also noteworthy that the Model Elements do not explicitly mention use of TRIPS flexibilities or other methods to enhance access to affordable and quality generics, which is key to dealing with proliferation of spurious pharmaceuticals.

4.2 TRIPS-plus Implementation:

There are several provisions proposed in the Model Elements that could result in TRIPS plus implementation. For example the Model Elements proposes that Governments should apply legal basis to all medical products in transit/trans-shipment, bonded warehouses, free trade zones and all situations of the international trade.

This element is worrying for several reasons. As noted above, the Model Elements call for an enhancement of IP legislation. According to Article 51 of the TRIPS Agreement[78], border measures by customs is only required for "importation of counterfeit trademark goods". There is no obligation for border measures to be applied to all other IPR violations or to goods in transit or goods to be exported. **The Model Elements' proposal is thus promoting TRIPS-plus implementation**. **Such TRIPS plus measures are the cause of the many seizures of good quality medicines in transit at European ports on request of MNCs on suspicion of IP violations that has resulted in delayed treatment for developing country patients.**

Even the UN Special Rapporteur on the Right to Health, Anand Grover has objected to such provisions. In his report he has points out that "TRIPS-plus IP enforcement can adversely impact access to medicines". He further adds that "Customs regulations of some countries allow the seizures of goods suspected of IP infringement even if they are only in transit. Such regulations impose a far higher standard of IPR enforcement than that required by TRIPS which requires that IP enforcement measures should not create barriers to legitimate trade. In effect, such actions can bring to naught TRIPS flexibilities exercised by developing countries and LDCs, and de facto impose IP protection on LDCs that are not yet required to comply with TRIPS as generic medicines they need do not reach them".[79]

Other provisions in the Model Elements that could result in TRIPS plus implementation include:

(a) establish legal mechanisms to allow/improve coordination and information exchange among health, regulatory, police, customs and other enforcement officers/authorities at a national, regional and international level, including the ability to use the information exchanged in legal/regulatory /investigative actions;
(b) take measures to enforce effective compliance with documented procedures to ensure the appropriate destruction of counterfeit products; this includes the identification of operation and financial responsibilities;
(c) permit investigators, as per appropriate guidelines, to conduct effective investigations including undercover operations, in which samples can be obtained anonymously;
(d) ensure that non-compliance with anti-counterfeiting laws and regulations results in prosecution and severe penal sanctions including the confiscation, forfeiture and destruction of the counterfeit medical products as well as equipment and other materials used in conjunction with their manufacture.

[78] Article 51 of TRIPS states: "Members shall, in conformity with the provisions set out below, adopt procedures to enable a right holder, who has valid grounds for suspecting that the importation of counterfeit trademark or pirated copyright goods[78] may take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation of such goods."
[79] Human Right Council, doc. No. A/HRC/11/12 dated 31 March 2009

(e) that criminal offences related to counterfeit medical products should also be prosecuted by a country if committed abroad by a citizen of that country.

Several of the abovementioned elements can already be found in recent anti-counterfeiting policies enacted or being enacted in Uganda, Kenya, Tanzania as well as at the East African regional level. These policies are all about IP enforcement but because of the use of the term "counterfeit" (which is used in an IP infringement context as well as in a health context to refer to quality problems) these policies are being pushed by vested interests under the pretext that it will protect public health. What is perhaps most notable is that abovementioned IMPACT Model Elements are found in the new IP enforcement policies of East African countries and these policies have been the subject of strong criticism for their impact on access to affordable generic medicines.[80]

4.3 Non-tariff barriers (NTBs):

Many obligations proposed in the Model Elements could become NTB for trade in medical products, which could undermine access to medicines, become entry barriers for generic industries particularly of developing countries and affect use of flexibilities such as parallel importation of good quality medicines. Some such obligations include:

(a) Regulate the manufacture, importation, exportation, distribution, supply, donation, offer for sale and sale of medical products, thereby ensuring that those who manufacture, import, export, distribute, supply, and perform any transaction related to medical products have a specific license.
(b) Establish regulations aimed at fostering a safe, transparent and secure distribution system by establishing measures for traceability of medical products, as applicable, throughout the distribution channels from the manufacturer/importer to the retailer.
(c) Establish specific import procedures; including designating a limited number of entry points for imported medical products.
(d) Regulate manufacture of active substances and of certain excipients that may pose public health risks;
(e) Regulating international trade of labels and packaging materials for medical products;
(f) Ensure that suppliers of raw, starting and packaging materials are legitimate and finished medical products are delivered to legitimate operators of the distribution chain; this may include conducting audits or verifying the legitimacy of business partners;

For example the Model Elements makes 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" and proposes severe sanctions. Firstly the definition of counterfeit used by IMPACT goes beyond the definition of the TRIPS Agreement and its overbroad scope could include quality generic medicines as "counterfeits". Secondly the measures proposed are problematic in themselves but even more so with the overbroad definition proposed by IMPACT. For instance, the abovementioned measure would impose liability on manufacturers of active pharmaceutical ingredients (APIs) if the APIs are used to make counterfeits (as broadly defined by IMPACT). Such a measure is a major burden on the API maker who would have to verify the validity of manufacturers to whom they sell and to somehow ensure that all use is legitimate. Even where the use is for quality generics the API producer may be liable because of the overbroad definition of counterfeits proposed by IMPACT, that includes quality generic medicines. Further the measure also imposes 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 as defined by IMPACT.

[80] See Wambi, Michael, "Anti-counterfeit laws to limit access to ARVs" Business Daily Africa, available at http://www.businessdailyafrica.com/Company%20Industry/Anti-counterfeit%20laws%20to%20limit%20access%20to%20ARVs/-/539550/892858/-/11a4kmw/-/, accessed 7th April 2010

In addition, regulations such as mentioned in paragraph (a) may push parallel traders out of the system, resulting in budgetary consequences for developing countries.[81] Similar regulations have been proposed in the context of EU since the pharmaceutical industry is calling for an EU wide identification system to track and trace medicines to the production site.[82] 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.[83] The pharmaceutical industry also wants to introduce similar measures into ACTA.[84]

5. "IMPACT": A FAULTY APPROACH, PROLIFERATING CONFUSION OVER "COUNTEREFITS"

Discussion above has raised concerns relating to participation, transparency, accountability, conflicts of interests, involvement of entities with an interest in promoting an IP enforcement agenda, the extensive involvement of the private sector as well as concern over promotion of Model Elements that are problematic from a public health perspective. **These concerns are further compounded by the fact that the approach taken by IMPACT is faulty in that it will not address the problem of proliferation of spurious pharmaceuticals but may undermine access to affordable generic pharmaceuticals and local/regional production of generics.**

IMPACT's approach stresses enforcement and regulatory reform, advocates criminal sanctions and penalties as well as use of anti-counterfeit technology to deal with spurious pharmaceuticals **without addressing the root causes for the proliferation of spurious pharmaceuticals in particular the high price of pharmaceuticals and the lack of regulatory capacity in terms of adequate facilities, human and financial resources**.

Trade in spurious pharmaceuticals is encouraged when quality affordable medicines are not available resulting in a demand which is not satisfied with affordable supply and thus resulting in inequitable access to medicines. **If peoples' demand for access to affordable, effective medicines of assured quality is systematically satisfied there would be little incentive for such trade to exist.** IMPACT also does not stress on measures to improve access to affordable medicines including the use of TRIPS flexibilities nor is there a stress on stimulating and improving local production capabilities in developing countries to ensure access to affordable generics that are of quality and safe.

Further approximately only 20% of countries have fully operational medicines regulatory bodies.[85] Thus strengthening regulatory capacity particularly in terms of ensuring that DRAs are functioning with the necessary facilities, financial and human resources is key to dealing with spurious pharmaceuticals. **IMPACT's approach of promoting regulatory reforms and enforcement measures including strengthening other agencies such as customs, police, etc. without dealing with the problem of weak regulatory capacity is counterproductive (particularly in the long term) as these agencies would not have the expertise to deal with spurious pharmaceuticals.** Moreover, the issue of introducing regulation only arises when the DRA has not been empowered with legal powers to take action. More often than not, it is not the lack of regulation but weak regulatory capacity (in terms of lack of resources, management failure) that hinders proper regulation

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[81] Parallel import refers to a drug that is first sold in a country (country A) and thereafter imported by another country (country B) as the price of the drug is lower in country A than in country B. This is a flexibility recognised by the TRIPS Agreement as well as by Doha Declaration on TRIPS and public health as a measure to promote access to more affordable medicines.

[82] In-pharmatechnologist.com, "EFPIA sparks drug repackaging debate with counterfeit claim". 15 May 2008, and "Repackaging Ban 'most useful' too to prevent counterfeiting in Europe", 24 June 2008

[83] In-pharmatechnologiest.com "Parallel Traders EU Counterfeiting Response", 20 June 2008.

[84] See "Counterfeit Trade Deal May Hurt Generics: Activists" (Ed Silverman, September 17th, 2008) reporting on Rob Weissman on ACTA: "He also maintains that the pharmaceutical industry is trying to use ACTA as a way to prevent parallel trade/reimportation, and notes PhRMA's submission to the US Trade Rep also says: "ACTA members should also be required to prohibit the distribution of medical products diverted from legitimate distribution channels and such distribution of diverted products should be treated as a counterfeiting offense," available at http://www.pharmalot.com/2008/09/counterfeit-trade-deal-may-hurt-generics-activists/

[85] Effective medicines regulation: ensuring safety, efficacy and quality. WHO Geneva 2003, available at http://apps.who.int/medicinedocs/pdf/s4921e/s4921e.pdf, accessed 5 May 2010

of medicines.

In addition, IMPACT stresses anti-counterfeit technologies without giving due attention to the fact that these technologies would simply not be affordable or useful for most part of the developing world and that use of such technologies will also increase the cost of medicines, which in any event are already beyond the reach of most patients. A technological approach would also be inadequate to address the variety of problems faced in relation to QSE of medicines (e.g. false labelling: products with wrong information about the side-effects of a medicine).

IMPACT's activities also propagates confusion over use of the term "counterfeit". Its definition of counterfeit goes beyond the counterfeit definition found in the TRIPS Agreement, and conflates IP issues with legitimate public health issues such as false labelling, spurious and substandard drugs. **Such an overbroad definition strengthens the agenda of entities interested in IP enforcement** since they can legitimately use quality and safety issues as a front to push for the adoption of an IP enforcement framework. **The extensive links between IMPACT and organisations promoting an IP enforcement agenda suggests that the resulting effect will be public health concerns being addressed through an IP enforcement lens**.

E. CONCLUSION

1. WHO'S INVOLVEMENT IN "COUNTERFEITS" & "IMPACT"

From the above discussion it is evident that WHO's involvement in "anti-counterfeiting" activities particularly through IMPACT legitimises the IP enforcement agenda and threatens to undermine WHO's credibility and public health considerations.

WHO Secretariat is involved in IMPACT's activities without any approval from WHO member states. WHO Secretariat funds and fundraises for IMPACT, host IMPACT's website[86], provides secretariat support to IMPACT, allows use of WHO's logo on most of IMPACT's document[87] (without any disclaimers although required by IMPACT's ToR) even when the document is prepared by industry[88] and is pushing for the adoption of IMPACT's principles & elements for national legislation bypassing scrutiny of the World Health Assembly.

WHO Secretariat justifies its actions on the basis of WHA resolution 41.16 adopted in 1988 and WHA 47.13 adopted in 1994.

However looking at the nature of WHO's involvement in IMPACT as well as IMPACT's focus on standard setting with aims of pushing legislation in developing countries and involvement with entities interested primarily in IP enforcement, it is simply untenable that WHO Secretariat did not see the need to obtain an endorsement of the WHA and justifies its actions on the basis of resolutions adopted decades ago. In addition, while WHO justifies its work on counterfeit, it has not clarified whether there is an independent work program on falsely labelled or on spurious medicines, also mentioned in WHA 41.16. Further, the mandate of all the earlier resolutions is to work on "medicines" and not "medical products". Hence there needs to be an explanation of the expanded approach undertaken by the WHO, without approval of WHO member states.

At this point it is important to recall WHO's Constitution that WHA (and not the Secretariat) "*shall determine the policies of the Organization*".[89] The WHO Constitution also clearly states that it is the

[86] See http://www.who.int/impact/en/index.html.
[87] See IMPACT's documents available at http://www.who.int/impact/activities/meet_reports/en/index.html, accessed 9th April 2010
[88] See paper by on "Anti Counterfeit Technologies for the Protection of Medicines" prepared by a Director from GSK, G Power, available at http://www.who.int/impact/events/IMPACT-ACTechnologiesv3LIS.pdf, accessed 7th April 2010
[89] WHO Constitution, Article 18 (a)

task of the Health Assembly to "*establish such other institutions as it may consider desirable*"[90] and to "*take any other appropriate action to further the objective of the Organization*"[91] Further Article 37 of the Constitution clearly points out that "*in the performance of their duties the Director General and the staff shall not seek or receive instructions from any government or from any authority external to the Organization*" and "*shall refrain from any action which might reflect on their position as international officers*".

WHO's Constitution is clear that the Secretariat should only act as directed by the WHA and in accordance with policies set by the WHA including in relation to establishing other institutions. And WHO Secretariat should not receive instructions from authorities external to WHO as it has been doing with regard to IMPACT.

Whatever the case may have been, it is crucial that WHO member states reconsider WHO's involvement in IMPACT, particularly noting that IMPACT's agenda is tainted with various interests that is likely to be detrimental for public health.

In view of the above it is recommended that:

- **WHO drops use of the term "counterfeit" (which is already defined in the TRIPS Agreement) and explores use of other terminologies through a member-driven process to capture the problem of pharmaceuticals with compromised QSE such as "falsely labelled", "spurious" and "substandard" (also referred to in WHA 41.16) [***Falsely labeled products* are in violation of labelling requirements set by the DRA. *Spurious products* are the result of intentional acts contrary to the prescriptions of the DRA that compromises QSE and would include manufacturing of medicines containing no or inadequate active ingredients or use of contaminated materials. *Substandard products* are products that do not meet the standards set by the national DRA due to unintentional acts e.g. poor storage facilities**].**

- **WHO reorient its programme towards addressing the real causes and solutions to pharmaceuticals with compromised QSE in particular focusing its action on promoting measures: to improve access to affordable medicines; to stimulate local/regional production of generic medicines; and to strengthen regulatory capacity of developing countries to improve the QSE of medicines available in developing country.**

- **WHO distances itself from IMPACT, its activities and outcome documents especially its "Principles and Elements for National Legislation against Counterfeit Medical Products" as well as stops functioning as the Secretariat of IMPACT as well as withdraws its logo from all IMPACT documents.**

- **WHO promotes intergovernmental discourse on medicines quality, safety, and efficacy;**

- **WHO actively advocates that protection and enforcement of IP and health issues are distinct and that an IP enforcement framework is NOT the appropriate approach to deal with QSE problems.**

- **WHO does not endorse any other activities that promotes the IP enforcement agenda;**

- **WHO collects reliable, impartial empirical data based on agreed methodology on the nature and extent of the problem of proliferation of products with compromised quality and safety to inform policy making and allocation of resources.**

[90] WHO Constitution, Article 18 (l)
[91] WHO Constitution, Article 18 (m)