

## **Open Letter to Dr. Margaret Chan, Director General of the World Health Organization**

Tuesday, 11 May, 2010

We, the undersigned organizations are very concerned about the nature and extent of WHO's involvement in issues pertaining to counterfeit medical products. We recognize that work must be undertaken under WHO's leadership to ensure availability of quality, safe and efficacious pharmaceuticals but we fear that WHO's involvement in the issue of "Counterfeits" will have adverse consequences for access to affordable medicines while failing to address the very real problem of proliferation of pharmaceuticals with compromised quality, safety and efficacy.

The term "Counterfeit" is defined by the WTO-TRIPS Agreement as referring to a specific category of trademark violation<sup>1</sup> and in some legislation to all other intellectual property (IP) violations as well. Today it is widely known that business interests and governments in OECD countries that represent them are making use of trade agreements, plurilateral government initiatives (e.g. the Anti-Counterfeit Trade Agreement) and programmes in international agencies to set and enforce higher IP standards under the heading of "Counterfeiting".<sup>2</sup>

It is against this background that WHO's use of the term "Counterfeit" to refer to a range of pharmaceutical quality and safety problems is most concerning. Not only has this resulted in confusion but also offered a convenient route for proponents of an extended IP agenda to press for inappropriate IP enforcement standards in developing countries under the false premise that such standards will deliver quality assured pharmaceuticals to the people.

For instance, in the East African region several anti-counterfeiting legislation have been enacted or are in the process of being enacted. Whilst the proclaimed rationale for such legislation is to protect the public from unsafe products, these legislations are in actual fact only about protecting the rights of IP holders to the detriment of access to affordable generic pharmaceuticals. Most of these legislations define "Counterfeit" products as being substantially similar or identical to IP protected products, which effectively makes every generic pharmaceutical a counterfeit. In Kenya, enactment of the Anti-Counterfeit Act 2008 has been challenged by people living with HIV/AIDS on the grounds that enforcement and application of the Act will deny them access to affordable essential medicines and thus deny their Right to Life.

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<sup>1</sup> Footnote 14(a) to Article 51 defines "counterfeit trademark goods" shall mean 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"

<sup>2</sup> 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.iqnsato.org/wp-content/uploads/Sell\\_IP\\_Enforcement\\_State\\_of\\_Play-OPs\\_1\\_June\\_2008.pdf](http://www.iqnsato.org/wp-content/uploads/Sell_IP_Enforcement_State_of_Play-OPs_1_June_2008.pdf). See also Ermias Tekeste Biadeng 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](http://www.southcentre.org)

Equating “Counterfeit” (a term defined in the TRIPS Agreement) to spurious (i.e. products with no or insufficient or toxic active ingredients) and falsely labelled pharmaceutical products not only undermines confidence in much-needed affordable quality generic products but also results in public health problems being addressed through an IP enforcement lens. Such an approach will not deliver the solutions needed to address the proliferation of spurious and falsely labelled pharmaceuticals, which arise irrespective of whether there is an IP violation.

Moreover confusion over the use of the term “Counterfeit” makes it impossible to obtain data on the true extent of the proliferation of medicines which do not meet quality, safety and efficacy standards because the data on “Counterfeit” would also refer to situations involving IP infringements. We would also point out that empirical, reliable and transparent statistics about “counterfeit drugs” is non-existent and that the only comprehensive global collection of data on drug counterfeiting is held by the Pharmaceutical Security Institute (PSI), an industry body that fails to make information available for public scrutiny.<sup>3</sup>

In addition, we are troubled by WHO’s engagement in the International Medical Product Anti-Counterfeit Taskforce (IMPACT) and share concerns of the many member states that have questioned the legitimacy of IMPACT.<sup>4</sup> In particular concerns have been raised about participation in IMPACT’s activities especially the central role played by the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) in IMPACT’s activities, lack of transparency surrounding IMPACT’s activities, and lack of accountability as IMPACT has operated outside the purview of WHO member states.<sup>5</sup>

Concerns have also been raised about IMPACT’s link to entities which are very much engaged on matters pertaining to IP enforcement under the banner of “anti-counterfeiting activities” such as the Interpol, OECD, the World Customs Organisation (WCO), the World Intellectual Property Organization (WIPO), the European Commission and the multinational pharmaceutical industry. This further raises concern about conflicts of interests, about which WHO by its own admission, has taken no measures to address.<sup>6</sup> It is also particularly noteworthy that IMPACT has been identified as an initiative involved in IP enforcement<sup>7</sup>.

Another key concern is IMPACT’s Principles & Elements for National Legislation Against Counterfeit Medical Products which are not only problematic because they emerge from an initiative whose legitimacy is in question but also because - it includes a call for addressing counterfeit medical products

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<sup>3</sup> See Kevin Outterson and Ryan Smith (2006)., “Counterfeit Drugs: the Good, the Bad and the Ugly” 16 Albany Law Journal of Science and Technology 525

<sup>4</sup> See “Concerns voiced over IMPACT, Secretariat’s role on “counterfeits” available at [http://www.twinside.org.sg/title2/intellectual\\_property/info.service/2009/twn.ipr.info.090201.htm](http://www.twinside.org.sg/title2/intellectual_property/info.service/2009/twn.ipr.info.090201.htm);

<sup>5</sup> See South Centre & CIEL IP Quarterly Update, Third Quarter 2008, available at [http://www.southcentre.org/index.php?option=com\\_content&view=article&id=955%3A2008-3rd-quarter-ip-quarterly-update-&catid=50%3Aintellectual-property-quarterly-update&Itemid=102&lang=en](http://www.southcentre.org/index.php?option=com_content&view=article&id=955%3A2008-3rd-quarter-ip-quarterly-update-&catid=50%3Aintellectual-property-quarterly-update&Itemid=102&lang=en)

<sup>6</sup> See FAQ with Answers prepared by WHO & IMPACT, distributed at an Open Forum on IMPACT on 26<sup>th</sup> March 2010 wherein it is states that “To date, participation in task force meetings has not required any declaration of interests.”

<sup>7</sup> 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>; See OECD report on “The Economic Impact of Counterfeiting and Piracy”, available at

[http://www.oepm.es/cs/OEPMSite/contenidos/ponen/InformeOCDE26feb09/2009\\_03\\_03\\_OECD\\_Study\\_on\\_Counterfeiting\\_and\\_Piracy.pdf](http://www.oepm.es/cs/OEPMSite/contenidos/ponen/InformeOCDE26feb09/2009_03_03_OECD_Study_on_Counterfeiting_and_Piracy.pdf) ; See also [http://ec.europa.eu/internal\\_market/iprenforcement/observatory/index\\_en.htm#what](http://ec.europa.eu/internal_market/iprenforcement/observatory/index_en.htm#what)

*inter alia* by establishing or enhancing intellectual property legislation; contains provisions that could result in TRIPS plus implementation as well as non-tariff barriers for trade in medical products which could undermine access to affordable medicines, become entry barriers for generic industries particularly of developing countries and affect use of flexibilities such as parallel importation of good quality medicines.

These elements also promote measures that have led to seizures/detainment of good quality pharmaceuticals in transit at European ports on request of MNCs on suspicion of IP violations, which resulted in delayed treatment for developing country patients.<sup>8</sup>

Moreover the approach adopted by IMPACT is faulty as it fails to address the root causes for the proliferation of pharmaceuticals with compromised quality and safety in particular the high price of pharmaceutical products which results in inequitable access and the problem of weak regulatory capacity in developing countries in terms of facilities, financial and human resources.

The above mentioned concerns raised by Member states have been largely ignored with the WHO continuing to promote use of the term “Counterfeit”, and to endorse IMPACT including by allowing IMPACT to use WHO’s logo on its documents, even where such documents are prepared by the pharmaceutical industry.<sup>9</sup> Moreover despite repeated objections to IMPACT and its Principles & Elements, WHO also appears to be pushing for the adoption of such elements as a WHO document bypassing scrutiny of the World Health Assembly<sup>10</sup>.

We are of the view that WHO’s continued involvement in IMPACT threatens to undermine WHO’s credibility as an organisation that is impartial and that upholds the interests of public health.

**In view of the above we urge the WHO Secretariat:**

- to explore use of other terminologies through member-driven process to capture the problem of pharmaceuticals with compromised quality, safety and efficacy substituting the term “Counterfeit” which is already defined in the TRIPS Agreement<sup>11</sup>;
- to distance itself from IMPACT, its activities and its Draft Principles & Elements and to stop functioning as the Secretariat of IMPACT;
- to withdraw WHO’s logo from all IMPACT documents and to ensure that WHO does not endorse any other activities that promotes the IP enforcement agenda;

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<sup>8</sup> For example IMPACT’s Principles & Elements propose that Governments should apply legal basis to all medical products in transit/trans-shipment, bounded warehouses, free trade zones and all situations of the international trade.

<sup>9</sup> G Power, “Anti counterfeiting Technologies for the Protection of Medicine”, p.2, <http://www.who.int/impact/events/IMPACT-ACTechnologiesv3LIS.pdf>

<sup>10</sup> See FAQ with Answers prepared by WHO & IMPACT, distributed at an Open Forum on IMPACT on 26<sup>th</sup> March 2010 wherein it is stated that “IMPACT documents could become a WHO document if they undergo WHO procedures including review by the relevant WHO Expert Committee processes”. See also WHO’s website at <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”

<sup>11</sup> Other terminology mentioned in WHA resolution 41.61 to refer to the problem of pharmaceuticals with compromised quality, safety and efficacy are: “falsely labeled”, “spurious” and “substandard”.

- to reorient its programme towards addressing the real causes and solutions to pharmaceuticals with compromised quality, safety and efficacy in particular focus its attention to dealing with high prices of pharmaceuticals, ensuring timely availability of affordable pharmaceuticals, as well as strengthening the capacity drug regulatory authorities.

## **SIGNATORIES**

1. Asian Community Health Action Network (ACHAN), Sri Lanka
2. All India Drug Action Network (AIDAN)
3. Asia Pacific Network of People Living with HIV/AIDS (APN+).
4. Berne Declaration, Switzerland
5. Brazilian Interdisciplinary AIDS Association (ABIA), Brazil
6. Butere Focused Women in Development (BUFOWODE), Kenya
7. Centre for Trade and Development (CENTAD), India
8. Coalition for Health Promotion and Social Development (HEPS-Uganda)
9. The Cut the Cost Cut the Pain Network, Philippines
10. Damien Foundation, Belgium
11. Delhi Network of Positive People (DNP+)
12. Diverse Women for Diversity, India
13. Drug Action Forum - Karnataka, India
14. Economic Governance for Health, UK
15. Ecumenical Pharmaceutical Network, Kenya
16. Edmonds Institute, US
17. EMPOWER, India
18. Egyptian Initiative for Personal Rights (EIPR), Egypt
19. Health Action International Africa (HAIA)
20. Health Action International Asia Pacific (HAIAP)
21. Health Action International Europe
22. Health Action International Global
23. Health Action International Latin American & Caribbean (HAI LAC)
24. Health GAP, USA
25. Healthy Skepticism Inc
26. HealthWrights (Workgroup for People's Health and Rights), US
27. IP Justice, USA
28. Intal, Belgium

29. International Baby Food Action Network (IBFAN)
30. International Peoples Health Council (South Asia), India
31. Initiative for Health Equity and Society, India
32. Low Cost Standard Therapeutics (LOCOST), India
33. Lokoj Institute, Bangladesh
34. MEDACT, UK
35. Medical Action Group, Philippines
36. Medico International, Germany
37. National Association of People Living with HIV/AIDS in Nepal
38. Oxfam International
39. Peoples Health Movement Global
40. Policy Research for Development Alternative, (UBINIG), Bangladesh
41. Research Foundation for Science Technology and Ecology, India
42. Southern and Eastern African Trade, Information and Negotiations Institute (SEATINI), Uganda
43. Third World Network
44. Third World Relief Fund, Belgium
45. Kevin Outterson, Associate Professor of Law & Co-Director of the Health Law Program  
Boston University School of Law, Faculty Advisor - American Journal of Law & Medicine,  
Editor in Chief - Journal of Law, Medicine & Ethics
46. Sean Flynn, Associate Director, Program on Information Justice and Intellectual Property  
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47. Ska Keller, Green MEP, Germany