

# INTELLECTUAL PROPERTY QUARTERLY UPDATE



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CENTER FOR INTERNATIONAL  
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## THE INTERNATIONAL MEDICAL PRODUCTS ANTI-COUNTERFEITING TASKFORCE (IMPACT): IS THE WHO ON THE RIGHT TRACK?

### I. Introduction

The past issue of the IP Quarterly Update warned of a new threat to access to medicines. A number of events in recent years indicate that discussions regarding protecting the public from counterfeit medicines are shifting away from instituting effective regulatory measures and towards strengthening the enforcement of intellectual property rights.<sup>1</sup>

<sup>1</sup> See, South Centre – CIEL IP Quarterly Update, Second Quarter 2008, “The Dangers of Including Patent Infringements in ACTA: Some Implications for Access to Medicines”, [http://www.southcentre.org/index.php?option=com\\_content&task=category&sectionid=8&id=50&Itemid=102](http://www.southcentre.org/index.php?option=com_content&task=category&sectionid=8&id=50&Itemid=102).

In the context of the proposed Anti-Counterfeiting Trade Agreement (ACTA), discussions appear to dangerously conflate two distinct issues: medicines suspected of infringing patents and counterfeit medicines. Counterfeit medicines are also mistakenly confused with the term “counterfeit good”, used vaguely to describe a good that may infringe one or more types of intellectual property rights, in accordance to national intellectual property law. The only internationally-agreed concepts are “counterfeit trademark good” and “pirated copyright good” explicitly defined in the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).<sup>2</sup> The World Health Organization (WHO) has developed a definition for counterfeit medicines that is commonly cited but has not been widely adopted by member countries in national law.<sup>3</sup> According to the

<sup>2</sup> Article 51, TRIPS Agreement.

<sup>3</sup> The WHO defines a counterfeit medicine as one “which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit

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WHO definition, what makes a medicine counterfeit is the deliberate or intentional nature of mislabelling a product.

There is however broad consensus on the need for countries to adequately regulate medicines in order to ensure the safety, quality, affordability and efficacy of medicines. Poor quality, harmful substandard medicines pose a major threat to public health. They can lead to treatment failure, drug-resistance and even death.

The World Health Organization (WHO) has long worked towards ensuring the quality of medicines as a public health concern. The WHO through the Department of Essential Medicines and Pharmaceutical Policies has provided normative support and technical assistance to countries, particularly low-income countries, to increase drug quality and safety. Traditionally the WHO has focused on strengthening the capacity of national drug regulatory authorities,<sup>4</sup> rather than promoting greater involvement of law enforcement agencies, including customs enforcement, and the use of trademark and other intellectual property tools to guard against suspected or infringing uses of pharmaceutical brands.

In this same sense, WHO Member States agreed as part of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property in May 2008 to establish and strengthen mechanisms to improve ethical review and regulate the quality, safety and efficacy of health products and medical devices.<sup>5</sup> The timeframe for implementation of the Action Plan is 2008 – 2015, and the stakeholders identified are governments, the WHO, and others including national and regional regulatory agencies. The WHO has a clear mandate and responsibility to focus and strengthen its work in this regard.

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products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.”

<sup>4</sup> See for example WHO, “Improving Drug Regulation”, Essential Drugs Monitor, Issue No 23, 2003, [http://mednet2.who.int/edmonitor/32/32\\_1.pdf](http://mednet2.who.int/edmonitor/32/32_1.pdf)

<sup>5</sup> See WHA Resolution WHA61.21, Global Strategy and Action Plan on Public Health, Innovation and Intellectual Property, [http://www.who.int/gb/ebwha/pdf\\_files/A61/A61\\_R21-en.pdf](http://www.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf)

As of 2006 the WHO is sponsoring and acting as Secretariat to a new initiative aimed at combating counterfeit medicines. The International Medical Products Anti-Counterfeiting Taskforce (IMPACT), described as a global multi-stakeholder partnership, has rapidly advanced numerous initiatives, including model “Principles and Elements for National Legislation against Counterfeit Medicines”. It is unclear how the IMPACT taskforce relates to the other work being undertaken by the WHO, including the implementation of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property and the other components of the WHO Medicines Strategy 2008 – 2013.<sup>6</sup>

The Discussions at the World Health Assembly (WHA) in May 2008 on a proposed new resolution on counterfeit medicines sponsored by Gambia, Ghana, Nigeria, Tunisia, United Arab Emirates and the European Union put in evidence that the IMPACT initiatives are causing concern among WHO member states.<sup>7</sup> Further discussion on the draft resolution and secretariat report will continue in the 124<sup>th</sup> Executive Board, to be held in January 2009, which in turn will decide on how to refer the matter to the 62<sup>nd</sup> WHA to be held in May 2009.

This Focus Piece analyses the nature, scope and current activities of the IMPACT taskforce, and the link between IMPACT activities and broader trends in the pharmaceutical sector. It highlights the need for the WHO, including its member states, to provide oversight to the work of the IMPACT and its participants to ensure:

- i) transparency in the process of developing IMPACT initiatives and implementing them in national contexts,
- ii) timely and full disclosure of information on IMPACT activities and participants,

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<sup>6</sup> See WHO Medicines Strategy 2008 – 2013, Draft 8 June 2008, [http://www.who.int/medicines/publications/Medicines\\_Strategy\\_draft08-13.pdf](http://www.who.int/medicines/publications/Medicines_Strategy_draft08-13.pdf)

<sup>7</sup> See Third World Network, IP: Counterfeit issue stirs debate among WHO member states, 12 August 2008, SUNS No. 6536, available at <http://www.twinside.org.sg/title2/health.info/2008/twnhealthinfo20080802.htm>

- iii) adequate deliberation among WHO member states regarding the IMPACT initiatives prior to their endorsement,
- iv) proper linkage between IMPACT and other WHO initiatives, particularly the implementation of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.

## II. Assessment of the IMPACT Taskforce

### II.1 Nature, Mandate and Structure

It is worrying that the IMPACT nature, mode of operation and core constituency mirrors other initiatives that take place outside multilateral institutions aimed at strengthening intellectual property enforcement by increasing the role of police and cross-border controls by customs authorities to stop goods suspected of infringing an intellectual property right. This approach is evidenced in the Global Congress on Combating Counterfeiting and Piracy.<sup>8</sup> Elsewhere the concerns on the increasing the involvement of INTERPOL and the World Customs Organization (WCO) on intellectual property enforcement and its impact on legitimate trade have been discussed.<sup>9</sup> The conflation of issues on intellectual property enforcement and public health issues concerning production and distribution of substandard and spurious drugs can hinder the goal of effectively tacking counterfeit medicines.

The Group of 8 in its declaration on trade and counterfeiting, which supports the

creation of stringent intellectual property enforcement norms and their implementation in developing countries, has in this context strongly favoured the creation of IMPACT.<sup>10</sup> Concern for the public health and safety of consumers worldwide does not include the same level of support concerning affordability and accessibility of medicines in poor countries. There is no mention, for example, to the WHO Global Strategy and Action Plan on Public Health, Innovation and Intellectual Property.<sup>11</sup>

The purported aim of IMPACT is to promote and strengthen international collaboration to combat counterfeit medical products. This aim would appear to fall in line with the objectives of various related WHA resolutions, although WHO member states have not given a mandate to IMPACT or collectively endorsed it.<sup>12</sup>

The IMPACT taskforce was not established by WHO member states. It was borne out of a Conference held in Rome in 2006 organized by the WHO under the leadership of Dr. Howard Zucker, former Assistant Director General for Health Technology and Pharmaceuticals, the Italian Medicines Agency (AIFA) and the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).<sup>13</sup>

IMPACT was conceived as a step towards building consensus for an international treaty on counterfeit medicines.<sup>14</sup> The Declaration of Rome which gave rise to IMPACT establishes that the taskforce "...will in the long term explore further mechanisms, *including an international convention*, for strengthening

<sup>8</sup> See "Outcomes Statement from the Fourth Global Congress: Dubai Declaration" and previous declarations, <http://www.ccapcongress.net/archives/Recommendations.htm>. These Declarations are not discussed or adopted by consensus by participants, and are produced after the Congress finalizes. The South Centre attended and reported from the Fourth Global Congress in Dubai. [http://www.southcentre.org/index.php?option=com\\_content&task=view&id=470&Itemid=77](http://www.southcentre.org/index.php?option=com_content&task=view&id=470&Itemid=77)

<sup>9</sup> See for example South Centre First and Second International Symposium on Examining IP Enforcement from a Development Perspective, 9 October 2007 and 16 September 2008 [http://www.southcentre.org/index.php?option=com\\_content&task=view&id=473&Itemid=77](http://www.southcentre.org/index.php?option=com_content&task=view&id=473&Itemid=77).

<sup>10</sup> Munoz and Biadgleng, *The Changing Structure and Governance of Intellectual Property Enforcement*, Research Paper 15, South Centre, pg.28.

[http://www.southcentre.org/index.php?option=com\\_content&task=view&id=614&Itemid=1](http://www.southcentre.org/index.php?option=com_content&task=view&id=614&Itemid=1)

<sup>11</sup> Ibid at 5.

<sup>12</sup> See WHA resolutions WHA 41.16 (1998), WHA47.13 (1994), WHA52.19 (1999), WHA57.14(2004).

<sup>13</sup> *Combating Counterfeit Drugs: Building Effective International Collaboration*, held from 16 to 18 February 2006 in Rome, Italy.

<sup>14</sup> "Combating Counterfeit Drugs, A Concept Paper for Effective International Cooperation", WHO, 27 January 2006 <http://www.who.int/medicines/events/FINALBACKPAPER.pdf>

international action against counterfeit medicines".<sup>15</sup>

The specific objectives of IMPACT are for participants to collaborate in facilitating progress in various areas, including in "securing political will and commitment, adequate legal framework, and implementation commensurate to the impact of [counterfeit medicines] on public health and providing the necessary tools for coordinated and effective law enforcement". The proposals and recommendations that IMPACT may adopt do not commit participants to adopt them but are meant to constitute a reference for guidelines, official policy or any other action.

IMPACT is structured in three main bodies. The General Meeting, composed of all participants, is the highest decision-making body. The General Meeting takes recommendations from the Planning Group, composed of the Chair and Vice-Chair of the General Meeting and the working groups, which oversees the activities of the Working Groups. Currently IMPACT has set up five working groups in the areas of: legislative and regulatory infrastructure; regulatory implementation; enforcement; technology and communication. The chairs of the working groups include representatives from enforcement agencies and pharmaceutical associations, as well as representatives of WHO and health regulatory agencies.<sup>16</sup>

<sup>15</sup> Declaration of Rome: Participants of the WHO International Conference on Combating Counterfeit Drugs: Building Effective International Cooperation, gathered in Rome on 18 February 2006

<sup>16</sup> Current IMPACT chairs include: Chair – Carissa Etienne, Assistant D-G, Health Technology and Pharmaceuticals, WHO (Chair); Vice Chairs - Prof Dora N. Akunyili, D-G, National Agency for Food and Drug Administration and Control (NAFDAC), Nigeria and Ms Ruth Lee, Health Sciences Authority, Singapore, and Member of the Permanent Forum on International Pharmaceutical Crime; Chair of Working Group on Legislative and Regulatory Infrastructure - Dr Konstantin Keller, Federal Ministry of Health, Germany; Chair of Working Group on Regulatory Implementation - Dr Ilisa Bernstein, Food and Drug Administration, USA; Co-Chairs of Working Group on Enforcement - Ms Aline Plançon, Interpol, and Mr Eric McIntosh, Therapeutic Goods Administration, Australia; Chair of Working Group on Technology - Dr Alicia Greenridge, D-G, International Federation of Pharmaceutical Manufacturers and Associations; Chair of Working Group on Communication - Mr Ton Hoek, Secretary-General, International Pharmaceutical Federation; Executive Secretary - Dr Valerio Reggi, Coordinator, Medicines Regulatory Support, Department of Technical Cooperation for Essential Drugs and Traditional Medicine, WHO.

IMPACT is supported by a secretariat based inside WHO in the Department of Essential Medicines and Pharmaceutical Policies.

## II.2 Participation

The question of participation in IMPACT is important in understanding the nature and outputs of IMPACT. According to the WHO, IMPACT is comprised of all 193 WHO Member States on a voluntary basis and includes international organizations, enforcement agencies, national drug regulatory authorities, customs and police organizations, non-governmental organizations, associations representing pharmaceutical manufacturers and wholesalers, health professionals and patients' groups.<sup>17</sup>

The Report on Counterfeit medical products (A61/16) prepared by the WHO Secretariat on IMPACT also pointed to a wide variety of stakeholders participating in the initiative.<sup>18</sup> This information is misleading, as IMPACT is not comprised of all these members, but rather participation is open to them. At the same time, participation in the different structures that make up IMPACT may vary widely. More correctly, the IMPACT terms of reference state that IMPACT is intended to be a voluntary grouping of governments, organizations, institutions, agencies and associations from developing and developed countries aimed at sharing expertise, identifying problems, seeking solutions, coordinating activities and working towards the common goal of fighting counterfeit medical products.<sup>19</sup>

IMPACT is meant to allow participants to voluntarily discuss matters that fall within its terms of reference without committing any participant, whether it is government institutions or agencies, intergovernmental organizations, pharmaceutical and other

<sup>17</sup> WHO Fact Sheet No. 275, revised November 14 2006, <http://www.who.int/mediacentre/factsheets/fs275/en/index.html>.

<sup>18</sup> See WHO document A61/16, Report of the Secretariat on Counterfeit Medical Products, 7 April 2008, at [http://www.who.int/gb/ebwha/pdf\\_files/A61/A61\\_16-en.pdf](http://www.who.int/gb/ebwha/pdf_files/A61/A61_16-en.pdf)

<sup>19</sup> See IMPACT terms of Reference, [http://www.ifpma.org/Issues/fileadmin/templates/ifpma\\_issues/pdfs/IMPACT\\_Terms\\_of\\_Reference.pdf](http://www.ifpma.org/Issues/fileadmin/templates/ifpma_issues/pdfs/IMPACT_Terms_of_Reference.pdf)

international associations, etc. in any way. In practice, the extent to which each of these organizations participates in the various activities of IMPACT varies. They may participate in some, or all, of the five Working Groups and in the General Meeting where IMPACT decision-making takes place and documents and other outputs are approved.

One of the complexities of participating in IMPACT is that IMPACT General Meetings, as well as those of the Planning Group and Working Group can take place anywhere in the world. For example, the WHO IMPACT website has recently announced that the **third General Meeting is due to take place in Hammamet, Tunisia, 3 - 5 December 2008**. The past General Meeting took place in Lisbon, Portugal from 10-14 December 2007. The IMPACT website of the International Pharmaceutical Federation however reports that it is intended that General Meetings take place on the side of IMPACT "Global Forums", the first which is scheduled to be held in Singapore between 13-15 February 2009. The various working groups also meet in numerous locations.

Financing participation is a second issue of concern. Participants finance their own participation. Participants can also provide funding for IMPACT and its activities. This can partly explain why the participation of developing country agencies and organizations so far has been limited. The terms of reference do indicate however that IMPACT will aim to ensure appropriate regional representation, particularly from developing countries. While the WHO does not manage or provide guide the work of IMPACT, its terms of reference indicate that the WHO as the provider of secretarial support to IMPACT can decide to support the participation of developing country representatives or invited experts.

A third issue on participation in IMPACT is the question of the extent of involvement and influence of a few stakeholders, particularly pharmaceutical industry associations. In addition to their involvement in the establishment of IMPACT, industry groups actively participate in the governance structure of IMPACT, including chairing working groups and hence present in the planning group. To date industry is

the most enthusiastic supporter of IMPACT with a focus on increasing global enforcement and criminal sanctions as a means to tackle counterfeit medicines. This coupled with a proposed broad definition of counterfeit medicines (further discussion below) and the linkage to intellectual property enforcement initiatives can have deep and negative repercussions on the production and trade in legitimate drugs. The growing participation of police and customs in the IMPACT also risks stirring the debate away from activities aimed at dealing with counterfeit medicines from a public health perspective towards commercial interests and intellectual property protection.

### ***11.3 Transparency and Disclosure of Information***

The IMPACT taskforce takes place with support of a WHO secretariat but functions outside the purview of member states. It is thus imperative that all relevant information is disclosed and readily available to WHO members and other interested stakeholders. Currently information on IMPACT is publicly available but incomplete.

To begin with, the Terms of Reference of IMPACT are not available on the WHO IMPACT website. It is also unclear why there are two IMPACT websites. According to an IMPACT General Meeting summary report, both websites are credited to the WHO.<sup>20</sup> However, one is powered by the International Pharmaceutical Federation (IPF) and contains information which is not available in the WHO IMPACT website.<sup>21</sup> The information about the structure of IMPACT and how stakeholders may participate is also not available on either website. The Terms of Reference indicate that the WHO secretariat should make public the list of participants to the working groups, as well as the General Meeting. This information, which is the basis for the IMPACT to act as a

<sup>20</sup> See IMPACT General Meeting Summary Report, 12-13 December 2007, <http://www.who.int/impact/events/IMPACTGeneralMeeting2007report.pdf>

<sup>21</sup> The WHO IMPACT website, for example, does not provide information on the "Global IMPACT Forums", or allow registration for this meeting. The IPM website is not referenced in the WHO IMPACT website either. See <http://www.impactglobalforum.org/>.

global partnership, is not published. In the few cases where it is available, participation appears to be core group composed mainly of pharmaceutical industry representatives and associations, lawyer groups and European stakeholders.<sup>22</sup>

The terms of reference also state that all IMPACT documents and other outputs should be issued by the WHO secretariat with the appropriate disclaimers to say that the content does not necessarily reflect the views or stated policy of the participating organizations, agencies and institutions, including the WHO. They should also state that the proposals/recommendations are in no way binding on, nor do they commit the organizations, agencies and institutions to who they are addressed. These disclaimers have not been introduced in any IMPACT document. The WHO in its report on counterfeit medicines and IMPACT, presented to WHO member states during the WHA May 2008 meeting, also did not include any disclaimers.<sup>23</sup>

#### II.4 Activities

The establishment of IMPACT follows the work undertaken previously by the WHO on tackling counterfeit medicines. However the IMPACT approach contrasts with the previous WHO approach. There is no clear linkage between IMPACT and previous WHO activities. For example, while in 1999 the WHO developed Guidelines for the Development of Measures to Combat Counterfeit Drugs,<sup>24</sup> IMPACT does not reference the WHO guidelines as a basis for its work.

IMPACT builds its work upon only selected factors that the WHO had previously established as contributing to the proliferation of counterfeit drugs and

encouraging associated activities. The WHO had previously and correctly noted that when drug prices are high and significant price differentials exist there is greater incentive to supply cheaper counterfeit drugs.<sup>25</sup> Notably, the contribution of high prices for legal drugs to the proliferation of counterfeit drugs is absent from the core of the IMPACT framework.

The main factors that IMPACT highlights as contributing to counterfeit drugs are inadequate regulation and enforcement, including lack of high penalties to act as deterrents to the activity.<sup>26</sup> Accordingly, the focus of IMPACT is on "developing a set of principles for the establishment of appropriate legislation and penal sanctions including a clear legal definition of counterfeit medicines."<sup>27</sup> It also has established that counterfeit medicines should be addressed through different bodies of legislation: on intellectual property protection and enforcement, on pharmaceutical and medical devices regulation and control, and criminal law.<sup>28</sup>

The broad scope of IMPACT dangerously linking intellectual property, regulation and criminal law is of great concern, particularly as an initiative housed and promoted by the WHO. It is widely noted that abating spurious and substandard drugs should not be conflated with intellectual property violations. In particular, when criminal penalties and sanctions for activities related to counterfeit medicines is proposed. It is critical that distinctions are clearly made between "bad medicines" - which have little or no therapeutic value - and "good medicines" - which provide the therapeutic value that they present to.<sup>29</sup>

The WHO also previously emphasized that there is no standard solution or solution applicable to all countries to eliminate the problem of counterfeit medicines. It cautioned that in developing a national strategy, the starting point should be a *national assessment* of the current situation

<sup>22</sup> See Annex 1 containing the list of participants to a meeting of experts that drafted the "Principles and Elements for National Legislation against Counterfeit Medical Products" on 12-13 August 2007. The draft text was endorsed, subject to few modifications, by the IMPACT General Meeting in Lisbon 12 December 2007. <http://www.who.int/impact/events/PrinciplesElementsforNationalLegislation.pdf>.

<sup>23</sup> Ibid at 18.

<sup>24</sup> See WHO, Guidelines for the Development of Measures to Combat Counterfeit Drugs, WHO/EDM/QSM/99.1, <http://www.who.int/medicines/publications/counterfeitguidelines/en/index.html>

<sup>25</sup> Ibid at 24, p. 15-17.

<sup>26</sup> Ibid at 17.

<sup>27</sup> Ibid at 17.

<sup>28</sup> See IMPACT "Principles and Elements for National Legislation against Counterfeit Medical Products", p.3, <http://www.who.int/impact/events/FinalPrinciplesforLegislation.pdf>

<sup>29</sup> K. Outtersson and R. Smith (2006), "The Good Bad and the Ugly", Albany Journal of Science and Technology, Vol. 15.

among all concerted parties, including government agencies, pharmaceutical industries, drug suppliers, health care providers, consumers, etc. to implement and develop the plan, and to evaluate from time to time to identify successes or failures and take timely corrective actions.<sup>30</sup> In contrast, on the basis of a broad, global assessment of the problem of counterfeit medicines, IMPACT has developed and is promoting a one-size-fits-all model of legislation and regulation as the basis for national responses to counterfeit medicines.

The Working Group on Legislative and Regulatory Infrastructure, in less than a year from its establishment in 2006, developed "Principles and Elements for National Legislation against Counterfeit Medical Products" on the basis of a draft text crafted by a limited number of experts.<sup>31</sup> No disclaimer was introduced in this document to state that these in no way binds the parties that agreed to the text to implement it, as is required in the IMPACT terms of reference.

The "Principles and Elements for National Legislation against Counterfeit Medical Products" raise numerous concerns:

#### Scope

As mentioned before, intellectual property protection and enforcement, regulation and criminal law are coupled together as the key legislative measures to combat counterfeit medicines. While noting that infringements of intellectual property rights and parallel imports (in the case where they are sold by or with consent of the right-holder) are not *specifically addressed* in the IMPACT document, it also establishes that the Principles may "need to be expanded and periodically updated in order to take into account other international instruments and to reflect current and emerging situations such as the Internet and medical devices". This could mean that the document may be "updated" in future to specifically address intellectual property issues, and any provision of the proposed ACTA agreement, if concluded, could find its way into IMPACT documents. The linkage made between

intellectual property protection and enforcement, regulation of medicines and criminal law is even more troubling given the new and broad definition that the document establishes for counterfeit medicines.

#### Definition of Counterfeit Medicine

In 1992, a joint report of the WHO and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) developed a definition of counterfeit medicines which is widely cited today.<sup>32</sup> The WHO currently defines a counterfeit medicine as one which is "deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit medicines may include products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients." However, in practice WHO member states define counterfeit medicines in different ways. In the United States for example, it is directly related to a trademark violation.<sup>33</sup> Other countries instead focus on the active pharmaceutical ingredients (APIs) contained in the drug.

Given this diversity, the pharmaceutical industry strongly supports the codification of "counterfeit medicines" in national legislation in accordance to or modelled on the WHO definition. For industry, the key element is that a counterfeit medicine is not defined in relation to whether the medicine is adulterated or substandard. Instead the key

<sup>32</sup> WHO, "Counterfeit Drugs: Report of a Joint WHO/IFPMA Workshop", WHO/DMP/CFD/92, 1-3 April 1992, Geneva. The definition was incorporated in the 1999 WHO Guidelines for the development of measures to combat counterfeit medicines, WHO/EDM/QSM/99.1.

<sup>33</sup> The term "counterfeit drug" means a drug which, or the container or labelling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor. United States Federal Food, Drug, and Cosmetic Act, SEC. 201. [21 U.S.C. 321], G(2)

<sup>30</sup> Ibid at 24, p. 3-4.

<sup>31</sup> Ibid at 24.

feature is the deceptive misidentification of the product.<sup>34</sup> A drug with the correct quality and active ingredients, which may provide a safe and efficient treatment, but is incorrectly mislabelled, is a counterfeit drug.

In November 2007 IMPACT was discussing “the possible revision of the established WHO definition of counterfeit medicine”.<sup>35</sup> By December 2007, IMPACT adopted in the “Principles and Elements for National Legislation against Counterfeit Medical Products” its own definition of counterfeit medicines.<sup>36</sup> The IMPACT definition then surfaced in the negotiations at the WHO Intergovernmental Working Group on Public Health, Innovation, and Intellectual Property (IGWG) during discussions on a proposal to consider developing and strengthening legislative, regulatory oversight mechanisms and other measures against the production, trafficking and use of counterfeit medicines.<sup>37</sup> However, WHO member states did not reach consensus on including the IMPACT definition and hence the relevant provision was not adopted in the final Global Strategy and Plan of Action for Public Health, Innovation, and Intellectual Property.<sup>38</sup>

**Box 1: WHO and IMPACT Definition of Counterfeit Medicines**

WHO Definition “Counterfeit Medicine”	IMPACT Definition “Counterfeit Medical Product”
<p>A counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source.</p> <p>Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.</p>	<p>A medical product is counterfeit when there is a false representation in relation to its identity, history, or source. This applies to the product, its container, packaging or other labelling information.</p> <p>Counterfeiting can apply to both branded and generic products. Counterfeits may include products with correct ingredients/components, with wrong ingredients/components, without active ingredients, with incorrect amounts of active ingredients, or with fake packaging.</p> <p>Quality defects or non-compliance with Good Manufacturing Practices/Good Distribution Practices (GMP/GDP) should not be confused with counterfeiting.</p>

<sup>34</sup> The Pharmaceutical Research and Manufacturers of America (PhRMA) has proposed that the Anti-Counterfeiting Trade Agreement include a definition that adheres to the WHO and US standards, which “includes any deceptively, misidentified pharmaceutical or medical device, without the need to prove physical or qualitative differences”.

See [http://www.ustr.gov/assets/Document\\_Library/Federal\\_Register\\_Notices/2008/July/asset\\_upload\\_file319\\_14999.pdf](http://www.ustr.gov/assets/Document_Library/Federal_Register_Notices/2008/July/asset_upload_file319_14999.pdf)

<sup>35</sup> “IMPACT First ASEAN-China Conference on Combating Counterfeit Medical Products: Summary Report”, Jakarta, 13-16 Nov 2007, at p.2, online: WHO <http://www.who.int/impact/events/IMPACTJakarta07MeetingReport.pdf> (accessed 4 July 2008).

<sup>36</sup> “IMPACT General Meeting: Summary Report”, Lisbon, Portugal, 12-13 Dec 2007, at p. 2, online: WHO <http://www.who.int/impact/events/IMPACTGeneralMeeting2007report.pdf> (accessed 4 July 2008).

<sup>37</sup> The definition appeared in an IGWG 2<sup>bis</sup> document, in a footnote for sub element 39(6.2)(e) in the 19 May 2008 draft text: Report of the Intergovernmental Working Group on Public Health, Innovation, and Intellectual Property, World Health Assembly, 61<sup>st</sup> Sess., A61/9, 19 May 2008, available online: WHO [http://www.who.int/gb/ebwha/pdf\\_files/A61/A61\\_9-en.pdf](http://www.who.int/gb/ebwha/pdf_files/A61/A61_9-en.pdf).

<sup>38</sup> Ibid at 5.

An examination of the differences between the WHO and IMPACT definitions allows for a better understanding the implications of changing the definition and coupling it with a stringent enforcement regime such as that which IMPACT proposes.

The IMPACT definition significantly expands the WHO definition.

- i) It replaces “deliberately and fraudulently” with “a false representation”. A “false representation” can occur independently from whether there was deliberate intent of any person or producer of goods. Even

where there is no consumer deception, a medicine could still be considered as a counterfeit. The burden of proof is shifted away from enforcement officers to the producer or distributor of the counterfeit medicine.

- ii) "False representation" in the IMPACT definition applies to the *history* of a product in addition to its *identity* and *source*. The extended scope of what may constitute a false representation in effect lowers the standard of proof needed by an enforcement officer to make a seizure of suspected medicines.
- iii) The IMPACT definition established that "false representation" applies with respect to "the product, its container, packaging, or other labelling information". Unless it is clearly stated otherwise, in using the IMPACT definition a false representation could be claimed to relate to an infringement of various intellectual property rights including a trademark, a patent, or a design right, even in the case when a suspected intellectual property violation is not related to the product itself or its active ingredients. This is highly dangerous when combined with criminal sanctions for counterfeit medicines and use of customs to control trade in counterfeit medicines. Merely stating the intellectual property infringements and parallel imports are not specifically addressed does not solve the problems created by definitional ambiguities.
- iv) The scope of the IMPACT definition is further broadened by adding "components". Further, "the term 'medical products' is defined as encompassing medicines, vaccines, blood derivatives, other biologicals, diagnostics, medical devices and items, as well as their combinations and their components".
- v) The IMPACT definition states that quality defects or non-compliance with GMP/GDP in legitimate, authorized medical products should not be confused with counterfeiting. This is a welcome addition. Such reference should have also been made to explicitly exclude patent disputes/infringements and potentially other intellectual property right infringements.

If adopted into a drug regulatory regime, the IMPACT definition of counterfeit medicines will favour a heavy-handed approach largely based on intellectual property enforcement and criminalization of activities which may have no public health consequence. Such approach is likely to be less effective in dealing with the real threat of counterfeit medicines as compared to strengthening regulatory regimes to ensure that medicines are of high quality and safe.

Accordingly, the Regional Committee of the WHO Regional Office for South-East Asia has recommended that the definition proposed by IMPACT should not be adopted by WHO.<sup>39</sup> Instead it recommends that any definition of counterfeit medicines or medical products encompass the following:

- Focus of combating counterfeit medicines or medical products is on the protection of public health rather than intellectual property rights or trade-related aspects of counterfeiting, if any
- Recognize main victims of counterfeiters are patients rather than intellectual property right holders
- The definition is not limited to medicines but may also include vaccines, diagnostics and medical devices
- The definition of counterfeit medicines or medical products does not lend itself to legal action or litigation that results in hindering the availability of legitimate generic medicines
- Patent disputes or violations are not to be confused with counterfeiting
- Medicines or medical products, whether generic or branded, not authorized for marketing in a given country but authorized elsewhere are not considered counterfeit but simply unauthorized.

#### Obligations of Governments and other Parties

The "Principles and Elements for National Legislation against Counterfeit Medical Products" were designed to serve as

<sup>39</sup> SEARO Regional Committee, "Counterfeit Medicines", Sixty-first Session, 8-11 September 2008, SEA/RC61/27.

reference for developing national legislation. While some elements may go in the right direction of improving regulation of the supply chain of medicines, the document is overly broad and does not provide alternatives, instead it establishes one-size-fits-all proposals. The lists of government responsibilities and acts to be made illegal in national legislation should be seen only as suggestions to be evaluated carefully before implementation, as there is no evidence on several of the proposed measures that such responsibilities are necessary or effective to deal with counterfeit medicines. For example, the IMPACT proposes that governments establish liability for Internet Service providers (ISP) "in relation to advertisement and trade in counterfeit medicines" when currently there is a wide debate on this issue in multiple jurisdictions.

Moreover, developing countries should focus on key elements of an anti-counterfeit medicines strategy rather than adopting uncertain legislation. Increasing the capability of national regulatory institutions should be a priority.

### Sanctions

The IMPACT recommends introducing severe criminal sanctions related to counterfeiting medicines, including when acts related to counterfeit medicines are committed only by negligence. Such suggestion requires careful ex-ante evaluation. A country should first design and implement a national strategy against counterfeit medicines that is appropriate to its context and responds to the specific problematic that the country faces.

In considering or adopting criminal sanctions with respect to counterfeit medicines or counterfeit medical products, a clear and narrow definition of the term is necessary to ensure that such measures will not act as deterrents to the production and distribution of safe and legal medicines. Intellectual property infringements, particularly patent infringements, legal parallel imported medicines and quality defects or GMP/GDP non-compliance with respect to quality medicines should not be confused with counterfeit medicines.

### III. The European Union and IMPACT

The haste to develop and adopt the text on "Principles and Elements for National Legislation against Counterfeit Medical Products" by IMPACT can be partly contextualized by developments and debates currently taking place on intellectual property protection and enforcement under the mantra of "combating counterfeit and piracy" and eliminating counterfeit medicines.<sup>40</sup> This link can be highlighted by observing trends in the European Union. The European Commission is a leading supporter and enthusiast of IMPACT and provided the funding for the development of the "Principles and Elements for National Legislation against Counterfeit Medical Products".<sup>41</sup>

The developments in the debate Europe with regards to a new EU strategy to tackle counterfeit medicines is likely to shape IMPACT in the same way that IMPACT activities will continue to influence the European process. The European Commission has established that any anti-counterfeiting strategy will build on the results of IMPACT.<sup>42</sup> In the European Union the debate on intellectual property protection and enforcement and counterfeit medicines also entangles the issues of:

- i) reports of sharp increase of counterfeit medicines seized at European customs borders,
- ii) the concerns of the major pharmaceutical companies regarding parallel trade in patented medicines and re-packaging as allowed under European Union Law,
- iii) the patent expiration of some of the major pharmaceutical companies' leading blockbuster drugs and the perceived growing threat of competitors from the generics industry,
- iv) increased outsourcing of manufacturing by the major pharmaceutical companies to emerging pharmaceutical markets.

<sup>40</sup> See Ibid at 1, Table 1, Timeline of Events, pg. 9.

<sup>41</sup> See EC, "Public Consultation in Preparation of a Legal Proposal to Combat Counterfeit Medicines for Human Use", 11.03.08, Brussels, [http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2008/2008\\_03/consult\\_counterfeit\\_2008\\_0307.pdf](http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2008/2008_03/consult_counterfeit_2008_0307.pdf).

<sup>42</sup> Ibid at 32.

Understanding these related debates helps shed some light on the complexity and potential risks that the IMPACT activities may produce if IMPACT fails to adequately incorporate the concerns and interests of the broad number and variety of stakeholders involved in the production, distribution and consumption of medicines, and if IMPACT misguidedly conflates the issues of intellectual property protection and enforcement, counterfeit medicines and use of flexibilities available within the intellectual property system (such as parallel importation of patented drugs) to foster access to medicines.

### ***III.1 The EU Statistics Report and Patent Infringements***

For the year 2006 and 2007 the European Commission Taxation and Customs Union issued a "Report on Community Customs Activities on Counterfeit and Piracy", herein EU Statistics Report.<sup>43</sup> The EU Statistics Report contains yearly statistics about seizures made at European borders by customs which are then used as a basis to quantify the efforts made to combat counterfeit and piracy in Europe. While the TRIPS Agreement only requires that Member States adopt procedures to enable an intellectual property right holder to request customs authorities to seize goods at the border (meant for import) that are suspected of constituting a "trademark counterfeit good" or a "pirated copyright good" as expressively defined in the Agreement,<sup>44</sup> the European Council Regulation No. 1383/2003 extends customs authority to seize for import, export and re-export all counterfeit goods, pirated goods, and goods suspected of infringing certain other intellectual property rights, even when an application has not been lodged by a right holder.<sup>45</sup>

<sup>43</sup>The EC Report on Community Customs Activities on Counterfeit and Piracy is available at [http://ec.europa.eu/taxation\\_customs/resources/documents/customs/customs\\_controls/counterfeit\\_piracy/statistics2007.pdf](http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics2007.pdf)

<sup>44</sup> Ibid at 2.

<sup>45</sup> Council Regulation (EC) No 1383/2003 of 22 July 2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights, OJ L 196, 2.8.2003.

The regulation also covers goods that are suspected of infringing a patent, among other intellectual property rights. Thus, drugs that are suspected of infringing a patent may also be seized by customs and quantified in the customs statistics for seizures under the broad heading of counterfeit and pirated goods. But in order to determine whether or not the drug actually does infringe a patent depends on the national law of the Member State where the supposed violation takes place and requires proceedings to be initiated to this effect, which observe the specific competence of the courts or judicial procedures of each Members State.<sup>46</sup>

The complexity in determining certain intellectual property infringements, particularly patents, and important distinction made between counterfeit good, pirated good and other goods infringing an intellectual property right are not dealt with adequately in the EU statistical reporting system of customs seizures and hence not appropriately reflected in the EU Statistics Report. Any intellectual property infringement falling in the scope of the Customs Regulation 1383/2003 is a measure of the extent of counterfeit and piracy in the EU. This dangerously conflates disputes or infringements of pharmaceutical patents with counterfeit goods and counterfeit medicines.

For many in Europe it came as a shock that the EC Statistics Report 2007 revealed that seizures of "counterfeit medicines" had increased by 380% with respect to the year 2005. Moreover, Switzerland was found to be a major source of counterfeit medicines (followed by India and United Arab Emirates). According to the report, 39.21% of medicines exported from Switzerland which were seized under EC Customs procedures were counterfeit medicines. But the report failed to note that the data was quantifying disputed pharmaceutical

<sup>46</sup> South Centre has published various pieces analysing the problematic trend towards the increased use of customs authorities to enforce intellectual property rights. See for example, South Centre - CIEL IP Quarterly Update, First Quarter 2008 "The World Customs Organization and Border Measures for Enforcement of IP Rights: Setting New Standards of Intellectual Property Enforcement Through the Back Door?" [http://www.southcentre.org/index.php?option=com\\_content&task=view&id=679&Itemid=102](http://www.southcentre.org/index.php?option=com_content&task=view&id=679&Itemid=102)

patents, and in the case of Switzerland mostly referred to a shipment of analgesics containing morphine exported to Germany over which there is a pharmaceutical patent dispute that is not at all related to any alteration of the active ingredients contained in the drug.<sup>47</sup>

The EU Statistics Report is also being used as the basis for the European Commission under the Enterprise and Industry Directorate General to prepare a new "legal proposal to combat counterfeiting medicines for human use" and a related public consultation.<sup>48</sup>

### ***III.2 Parallel Trade in Medicines, Re-Packaging and Technical Solutions***

As part of the EU public consultation on a new "legal framework to better protect patients against counterfeit medicines", the long-debated issue of the pros and cons of allowing parallel trade in genuine medicines has resurfaced. Parallel import medicines are not counterfeit medicines. A "parallel import" medicine refers to a drug that is first sold in another country, and then imported into the national territory.<sup>49</sup> The European Union applies a "regional" exhaustion policy which means that an intellectual property holder's right is extinguished when a good or service is placed in the market in any country of the European Union. Consumers benefit from parallel imported medicines because they are able to get lower priced medicines and thus access to medicines is increased. Distributors, wholesalers and traders also profit from parallel imports as they seek to profit from the price differentials among countries in sourcing the market.

But pharmaceutical manufacturers point that parallel imports reduce their control of the supply chain of their products and potentially allows tampering. In the EU medicines can be re-boxed or re-labelled after production to allow drugs to be sourced from a lower-cost country and re-import them to one which commands higher profits. The pharmaceutical industry is

calling for a ban on re-packaging of drugs along with a harmonized EU-wide identification system to track and trace medicines back to its production site as the most effective way to eliminate counterfeit medicines from the European supply chain.<sup>50</sup>

Parallel distributors are adamantly opposed to the proposed measures which would unfairly push them out of the market. They also point that there is no evidence that parallel trade is an entry point for counterfeit medicines,<sup>51</sup> and warn against allowing the counterfeit debate to be driven by the pharmaceutical industry to justify anti-competitive behaviour at a time when an inquiry by the European Commission into competition in the pharmaceutical sector is ongoing.<sup>52</sup> The preliminary findings of the sector inquiry will be presented on 28 November 2008.<sup>53</sup> The technical solutions proposed by major pharmaceutical companies as a measure to tackle counterfeits are also being opposed by the European generics industry.<sup>54</sup>

Whatever the outcome of this debate in Europe, it is likely to resonate in IMPACT. Already the "Principles and Elements for National Legislation against Counterfeit Medical Products" seem to point in this direction, having identified as one of the factors of inconsistencies among WHO members that "there are no provisions addressing the problem of trade in packaging and labelling materials without the obvious involvement of the companies whose name appears on these materials" and the reference in the proposed new IMPACT definition of counterfeit medicines to the "history" and "source" of the medicine. As noted above, moving in this direction may seriously affect lawful parallel importation and the generics industry and

<sup>47</sup> See Swissinfo.ch, "EU voices concern over Swiss-seized medicine", May 19, 2008

<sup>48</sup> Ibid at 41.

<sup>49</sup> See Frederick M. Abbott, "Parallel Importation: Economic and social welfare dimensions, June 2007, IISD.

<sup>50</sup> See 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.

<sup>51</sup> See In-pharmatechnologist.com, "Parallel Traders EU Counterfeiting Response", 30 June 2008.

<sup>52</sup> See European Association of Euro-Pharmaceutical Companies, Press Release "Open and Honest Debate Key Step in Tackling Counterfeit Risk" 14 May 2007, and "EAEPCC Welcomes Crucial Ruling for Free Movement of Medicines in Europe" 16 September 2008.

<sup>53</sup> European Commission, Sector Inquiry, <http://ec.europa.eu/comm/competition/sectors/pharmaceuticals/inquiry/index.html>.

<sup>54</sup> See In-pharmatechnologist.com, "EU Counterfeiting Response is Far from Generic", 23 June 2008.

would still not eliminate counterfeit medicines.

### ***III.3 Patent Expiration and Generics Industry Competition***

The market exclusivity that patents confer to pharmaceutical companies allows them to control the pricing of medicines. The pharmaceutical industry has long held that patents are the main means by which they are able to recoup their massive investments in research and development (R&D), although studies suggest that a huge chunk of that investment actually goes into marketing.

The fact that the world's largest pharmaceutical company, Pfizer, is expected to lose its top position as a number of its drugs such as Lipitor and Viagra lose patent protection before 2014 will mean a massive loss of company revenues as generic producers of these drugs will be able to enter the market.<sup>55</sup> This is a stark future and wakeup call for the pharmaceutical industry which overall is failing to produce new drugs.<sup>56</sup> Meanwhile the generics industry is rapidly gaining ground offering quality low cost drugs. Generics play a crucial role in providing access to medicines to the world's poor. India is currently the major generics supplier.

The fact that generics are increasingly being scrutinized for quality can be related to these broader trends. Although there are 85 US Food and Drug Administration (FDA) approved active pharmaceutical ingredient (API) and formulation plants located in India, the highest such number outside the US,<sup>57</sup> quality-control inspections of plants by US and EU regulatory agencies in India and elsewhere are on the increase. For example, the importation of 30 products of Ranbaxy, a large Indian generics company, was blocked recently in the United States for alleged extensive deviations from the US current manufacturing practice (cGMP) manufacturing requirements, and other

<sup>55</sup> See In-pharmatechnologist.com, "Pfizer to lose top spot by 2014", 12 August 2008.

<sup>56</sup> See "Big pharma slims down to bolster productivity", Nature Reviews Drug Discovery 6, 173-174, March 2007.

<sup>57</sup> Price Waterhouse Coopers, "Why the world's drug industry is moving East", August 7, 2007.

countries have followed in this trend which led to a huge loss of the companies' profits.<sup>58</sup> Ranbaxy holds that it complies with GMP requirements. Acquisitions of generics are also on the rise. Pfizer was seeking to acquire Ranbaxy, who will market a generic version of Pfizer's' Lipitor from 2010, in order to fend off the competitive threat, settle pending patent litigations, acquire cheap manufacturing facilities and take its share in the growing Indian market.<sup>59</sup>

### ***III.4 Increased Outsourcing to Emerging Markets***

Among the big developments in the restructuring of the pharmaceutical sector is the increased outsourcing of manufacturing and other functions including R&D to lower-cost countries and take advantage of expanding markets such as India and China.<sup>60</sup> The global market for Contract Research and Manufacturing Services (CRAMS) in 2007 is estimated to be USD55.48 billion with contract research growing at a rate of 13.8%.<sup>61</sup>

One of the challenges for multinational pharmaceutical companies is to ensure that the products sourced from third countries are of high quality and comply with regulatory standards in major markets. From their perspective, harmonization of global regulatory standards and quality controls as sought through IMPACT and related activities would facilitate their operations and help protect their branded products. Intellectual property becomes an important issue given that innovation and brand-building constitute their main assets in the increasingly competitive global pharmaceutical market.

Moreover, as the pharmaceutical industry moves activities (and jobs) out of the EU and US, quality standards and controls in third countries increasingly

<sup>58</sup> See In-pharmatechnologist.com, "Health Canada adds to Ranbaxy's woes", 24 September 2008.

<sup>59</sup> See In-pharmatechnologist.com, "Pfizer to hijack Ranbaxy deal", 18 June 2008.

<sup>60</sup> See In-pharmatechnologist.com, "Outsourcing of production gaining pace in big pharma", 27 May 2008.

<sup>61</sup> See Research and Market Reports, "Indian Contract Research Manufacturing and Services", <http://www.researchandmarkets.com/reports/c86978>.

become an issue of concern. While clearly ensuring the safe sourcing of products is an important issue, some proposals in the EU for addressing counterfeit medicines would appear to be directed more to safeguard market share, masked under health and safety concerns. For example, the demand to create more stringent rules for producers of active pharmaceutical ingredients (APIs) producers, such as mandatory GMP certification and wide inspections and audits of API manufacturers in and outside the EU. While the importance of regulation of API manufacturing is recognized globally to ensure the production of quality medicines, these proposals surface in the context of the declining global market share of European API producers to Indian and Chinese producers.<sup>62</sup> The efficacy of such measures is also questioned.<sup>63</sup>

#### IV. Conclusion

Ensuring global availability, accessibility and affordability of safe and effective drugs is a goal shared by all WHO member states. Combating counterfeit medicines should be a part of the broader strategy to achieve this goal. Counterfeit medicines should be dealt with from a public health perspective rather than as a means to promote intellectual property protection and enforcement or mask a pharmaceutical industry protectionist agenda.

The analysis presented herein of the IMPACT taskforce point to deficiencies in the operation and activities currently being undertaken. It is thus suggested that WHO member states should carefully review and deliberate on the IMPACT initiatives prior to considering their endorsement. The issue of counterfeit medicines and IMPACT will be on the agenda of the next WHO Executive Board in January 2009 and it is likely that it will also be on the agenda of the WHA in May 2009, on the basis of a proposed new resolution on counterfeit medicines sponsored by Gambia, Ghana, Nigeria,

Tunisia, United Arab Emirates and the European Union. It will be important for members to highlight concerns and ensure the proper linkage between IMPACT and other WHO initiatives, particularly the implementation of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.

Given that the WHO is acting as secretariat for IMPACT, it is crucial that the WHO keeps a watchful eye on the taskforce. The WHO secretariat for IMPACT should also ensure that participation in IMPACT is adequate and information on the actual participants list to each meeting is available as required in its terms of reference. WHO member states should require the public disclosure of all information related to IMPACT in a timely and transparent manner. This will allow WHO member states and any interested stakeholder to decide how and to what extent they wish to participate in or engage with the IMPACT initiative.

Finally, the WHO should focus its work in the area of combating counterfeit medicines on assisting member states to assess their national situation as the basis to develop an appropriate strategy to address the problems identified, and assisting member states to strengthen their drug regulatory capacity.

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<sup>62</sup> See In-pharmatechnologist.com, "India set to overtake Italy in API production", 10-May-2006.

<sup>63</sup> See Comments by the QP Association on the Public Consultation in Preparation of a Legal Proposal to Combat Counterfeit Medicines for Human Use, [http://ec.europa.eu/enterprise/pharmaceuticals/counterfeit\\_par\\_trade/doc\\_publ\\_consult\\_200803/qpassociation\\_counterfeitmedsurvey\\_comments.pdf](http://ec.europa.eu/enterprise/pharmaceuticals/counterfeit_par_trade/doc_publ_consult_200803/qpassociation_counterfeitmedsurvey_comments.pdf)

**AN OVERVIEW OF RELEVANT DEVELOPMENTS IN THE VARIOUS IP FORA**

The following is an overview of developments in the various fora dealing with intellectual property issues in the third quarter of 2008.

**The World Trade Organisation**

The mini-ministerial convened in Geneva from 21-26 July, failed to arrive at consensus on trade negotiations, mainly due to disagreement over agriculture. The third quarter remained a period of rest as countries retreated to consider the options for going forward.

***Progress in the Council for TRIPS during the third quarter of 2008***

The TRIPS Council did not meet during the third quarter. TRIPS-related issues at the July mini-ministerial were covered in the previous edition of the Quarterly.

The WTO Secretariat communicated to the Council its technical cooperation activities related to the TRIPS Agreement IP/C/W/515 dated 26 September 2008. It covers the period from 1 October 2007 to 30 September 2008. The report indicates that the Secretariat's work related to flexibilities focuses on implementation of the paragraph 6 solution and the 2005 amendment. The report outlines the meetings held but provides no details as to participants, documents used or advice given. Without such information it remains difficult to evaluate both the quality and effectiveness of the assistance and technical cooperation provided by the Secretariat.

Reports on technical cooperation were also received from Japan (IP/C/W/517/Add.1), New Zealand (IP/C/W/517/Add.2), Switzerland (IP/C/W/517/Add.4), and United States (IP/C/W/517/Add.3).

***Implementation of Article 66.2***

Several countries provided their annual updates to their reports on the implementation of article 66.2 pursuant to paragraph 1 of the Decision on Implementation of Article 66.2 of the TRIPS Agreement. The countries included, Japan (IP/C/W/519), New Zealand (IP/C/W/519/Add.1), Norway (IP/C/W/519/Add.2), United States (IP/C/W/519/Add.3)

Norway's report continued the practice of equating investment incentives and simple importation of goods with incentives for technology transfer. While describing useful information on investment support for LDCs, the report did not describe what elements of the programs were focused on technology transfer per se. The Japanese report continued to mistakenly describe assistance with IP legislation as one of the activities covered by article 66.2. The report from the United States presents a step forward from its previous reports by focusing somewhat more on measures specifically directed at LDCs, but also makes the same error as Norway of equating investment with technology transfer.

***Disputes***

There were no communications received from any WTO member states on complaints concerning TRIPS violations during the second quarter of 2008. No disputes involving the TRIPS Agreement was decided by the WTO Panels or the Appellate Body during this period.

***2003 Paragraph 6 Doha Waiver and 2005 Public Health Amendment***

The 2005 amendment to the TRIPS Agreement, which made permanent a decision on patents and public health (adopted in 2003), will be formally incorporated into the TRIPS Agreement when two thirds of the WTO members notify their ratification of the change. While the initial deadline was to expire on 1 December 2007, it was extended by the General Council to 31 December 2009. On 6 August 2008, Jordan notified its acceptance of the 2005 amendment.

**The next meeting of the WTO Council for TRIPS will be held 28-29 October 2008. A Special Session of the Council will be held on 29 October 2008.**

## **World Intellectual Property Organisation (WIPO)**

### ***WIPO General Assemblies (Draft report WO/GA/36/13 PROV.)***

The WIPO General Assemblies met 22-30 September 2008, with the key decision of electing the new Director-General nominated by the Coordination Committee. Francis Gurry, from Australia was elected by consensus, and immediately took up the post. The election of the new Director-General meant that significant decisions relating to the Program and Budget would have to be deferred while the new Director-General chose his priorities and established new directions. The new Program and Budget will therefore be considered for approval at a special session of the WIPO General Assembly on 12 December 2008.

In his acceptance speech, Gurry focused on the need to move towards concrete outcomes on discussions related to Genetic Resources, Traditional Knowledge and Folklore. He expressed concern about what he termed the continuing erosion of intellectual property rights through new technologies and the use of the internet. He reiterated again his commitment to the development Agenda, although he focused on access to patent information as a primary issue he would address.

### ***Report of the Committee on Development and IP***

Discussions on the Committee on Development and IP were based on the recommendations forwarded by the committee and reflected some of the concerns already expressed. Developing countries remained concerned that sufficient funds be made available for full implementation of the Agenda while industrialized countries continued to insist that any decisions relating to funding not deviate from existing budgetary procedures at WIPO. This included the recommendation

for a Donor conference in implementing particularly Cluster A: Technical Assistance of the Development Agenda proposals. The General Assembly decided to approve the recommendations, as contained in paragraph 10 of document WO/GA/36/4 Rev; and also decided to support a Donor conference subject to consultations and a budget approved by the Program and Budget Committee.

The Committee also agreed to discuss at the next session:

- (i) Coordination with relevant WIPO bodies in the implementation of the recommendations;
- (ii) A method of assessing implementation progress

### ***Report of the Standing Committee on Copyright and Related Rights***

Discussions also took place regarding the work of the Standing Committee on Copyright and related rights. After some divergence on how to refer to how the committee should report back to the 2009 General Assembly, mostly related as to whether to specifically single out the broadcasting treaty, the following decisions was adopted:

1. The General Assembly is invited to:
  - (i) take note of the current status of the work of the SCCR;
  - (ii) request the Secretariat to report to the General Assembly at its Session in September 2009 on the deliberations of the SCCR on:
    - (a) the protection of audiovisual performances;
    - (b) the protection of the rights of broadcasting and cablecasting organizations;
    - (c) limitations and exceptions to copyright and related rights protection; and
    - (d) any other matter discussed in the SCCR.

The committee also received progress reports on the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), and the Standing Committee on Patents and took note of a

report from the Advisory Committee on Enforcement.

***Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC)***

The 13<sup>th</sup> session of the IGC met from 13 – 17 October 2008. Due to the unanticipated withdrawal of the former chair Mr. Jaya Ratna of Singapore, Ambassador Rigoberto Gauto Vielman from Paraguay was elected Chair of the IGC.

The meeting was preceded by hopeful signs that progress in finding a way forward might be achieved. An official proposal by the African Group on inter-sessional work was put forward for member states to consider (WIPO/GRTKF/IC/13/10), as well as a document attempting to consolidate viewpoints and suggest points of convergence and divergence (WIPO/GRTKF/IC/13/9).

There was little progress in the substantive discussion of the committee as member states restated positions on the three issues before them: traditional cultural expressions, traditional knowledge and genetic resources. Genetic resources issues received somewhat more discussions in line with the decisions in the 12<sup>th</sup> session to give equal time to the issues. Many responded to the gap analysis that had been requested but most attention was focused on the proposal for inter-sessional work put forward by the African Group. The proposal suggested the establishment of small expert task groups aimed at focusing the discussion on specific elements including: beneficiaries, duration of rights, exceptions and limitations, and prior informed consent. Significant elements had been based on similar such working groups established in the context of Access and Benefit Sharing negotiations in the Convention on Biological Diversity.

The proposal received initial support from the Asian Group and GRULAC, but little response from Group B. Following intense informal discussions, including the intercession of the Chair and of the Director-General, no agreement could be reached despite attempts that lasted well into the evening of the final day. Elements of Group

B remained in opposition to any limited participation in the expert groups or to meeting separately in time from regular meetings of the IGC. No agreement could be reached and the African Group noted that it preferred to leave the issue of future work to the General Assembly to decide, given the lack of progress in deciding on methodologies for future work. The IGC now reverts back to the normal mode of meeting and will have a scheduled IGC meeting early in 2009.

**The next session of the IGC has not been scheduled but will be held in early 2009.**

**Other Multilateral Fora**

***Internet Governance Forum***

The Multistakeholder Advisory Group (MAG) mandate was renewed in August. Nitin Desai remains as Chair of the group which will begin planning for the 3<sup>rd</sup> IGF in Hyderabad, India.

The third meeting of the IGF, hosted by the Government of India will take place in Hyderabad on 3 - 6 December 2008.

***United Nations Framework Convention on Climate Change***

The latest round of United Nations climate change negotiations took place in Accra, Ghana, from 21-27 August 2008. The issue of technology transfer remained high on the agenda, despite the attempt of some industrialized countries to relegate it to a lower level of discussion.

On the last day of the meeting, following discussion in a contact group, the G77 plus China put forward a proposal for a new financing and institutional mechanism for technology transfer under the UNFCCC. The proposal would establish an Executive Body and a Multilateral Climate Technology Fund operating under the Conference of Parties.

**The 14<sup>th</sup> Conference of the Parties of the UNFCCC will meet from 1 – 12 December 2008 in Poznan, Poland.**

## **Regional and Bilateral Trade Agreements with Intellectual Property Provisions**

The following section highlights the latest developments in US and European bilateral and regional trade with developing countries with specific focus on IP issues.

### **Free Trade Agreements (FTAs) Involving the United States**

The US Congress has not moved ahead with any FTA during the third quarter of 2008.

### **Free Trade Agreements (FTAs) involving the European Union**

#### ***EU - ASEAN***

The EU and ASEAN continue to negotiate but progress remains slow, which has prompted the EU to establish a parallel bilateral track, particularly focused on Vietnam and Thailand.

#### ***EU – Andean Community***

In much the same way that negotiations between the CAN and the US broke down over differences between CAN member states, Peru and Colombia are now seeking to negotiate separate agreements with the EU.

#### ***EU-India***

The EU has begun detailed negotiations on and FTA with India, and rounds were held in September. Civil society groups are expressing increasing concerns about the effect of proposed provisions on intellectual property but have yet to have access to the full text to evaluate and analyze it.

The EU also continues negotiations on FTAs with South Korea, but talks with Mercosur do not seem to have progressed.

#### ***EU-ACP***

The EU's Economic Partnership Agreements (EPAs) with the African, Caribbean and Pacific continue to cause controversy. Negotiations continue with the other ACP regions while Cariforum, in October, finally signed the EPA. The Caribbean remains the only region to have signed a comprehensive with IP provisions EPA with the EU.

## ABOUT THE IP QUARTERLY UPDATE

The IP Quarterly Update is published on a quarterly basis by the South Centre and the Center for International Environmental Law (CIEL). The aim of the Update is to facilitate a broader understanding and appreciation of international intellectual property negotiations by providing analysis and a summary of relevant developments in multilateral, plurilateral, and bilateral fora as well as important developments at the national level. In each IP Quarterly Update, there is a focus piece analysing a significant topic in the intellectual property and development discussions.

Today, in addition to the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO), there are other multiple fronts of discussion and negotiation on intellectual property. These other fora range from international organizations, such as the United Nations Educational and Scientific Organization (UNESCO), the Food and Agriculture Organization (FAO), the World Health Organization (WHO), the United Nations Conference on Trade and Development (UNCTAD), the World Customs Organization (WCO), INTERPOL, and the UN human rights bodies to regional and bilateral fora such as in the context of free trade agreement (FTAs) or economic partnership agreements (EPAs). In some cases, national processes or decisions, for example, invalidation of a key patent may have important international ramifications.

Consequently, all these processes constitute an important part of the international intellectual property system and require critical engagement by developing countries and other stakeholders such as civil society organizations. Multiple fronts of discussions and negotiations require a coordination of strategies and positions that is not always easy to achieve. The Quarterly Update is meant to facilitate such coordination and strategy development, and is therefore a vehicle for awareness raising as well as capacity development.



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