

## **D1 | WORLD HEALTH ORGANISATION: CAPTIVE TO CONFLICTING INTERESTS**

The World Health Organisation's (WHO) ability to provide leadership in the arena of global health has been seriously compromised because its mandate has been usurped by multiple agencies, such as the World Bank, the World Trade Organization (WTO), and global public private partnerships (PPPs). In *Global Health Watch 1* (GHW1), the process of marginalisation of the WHO was clearly detailed. In its analysis, GHW1 concluded: 'Woefully inadequate resources, poor management and leadership practices, and the power games of international politics are just some of the forces hindering sustainable change in WHO' (People's Health Movement 2005). Consequently, there is an increasing tendency to characterise the WHO as a 'technical' agency that should concern itself only with issues related to the control of communicable diseases and the development of biomedical norms and standards.

The WHO faces three key challenges – related to its capacity, legitimacy, and resources. The WHO's legitimacy has been seriously compromised because of its inability to secure compliance with its own decisions, which is reflected in the various resolutions passed at the World Health Assembly (WHA). Developed countries that contribute the major share of finances for the functioning of the WHO have today a cynical attitude towards the ability of the WHO to shape the global governance of health. They see the member-state-driven process in the WHO (where each country has one vote) as a hindrance to their attempts to shape global health governance, and prefer to rely on institutions such as the World Bank and the WTO, where they can exercise their clout with greater ease.

GHW2 carried a detailed analysis of WHO's funding. It concluded: 'Instead of being funded as a democratic UN agency, it is in danger of becoming an instrument to serve donor interests' (People's Health Movement 2008). WHO's core funding has remained static because of a virtual freeze in the contributions of member states. A large proportion of WHO's expenditure (about 80 per cent) comes in the form of conditional, extra-budgetary funds that are earmarked for specific projects by contributing countries. The 2011 Executive Board of the WHO (in January 2011) discussed a paper by the WHO Secretariat that talked about the crisis in the WHO's finances (World Health Organisation 2010a). Today, the WHO is sustained through a financing system that undermines coherent planning and that forces the WHO departments and divisions to compete with each other (and with other organisations) for scarce



34 Demonstration in Geneva at the World Health Assembly, May, 2008 (Amit Sengupta)

funds. Consequently, health priorities are distorted, and even neglected, to conform to the desires of donors and to the requirement to demonstrate quick results to them. The WHO is in danger of compromising its own mission and principles because of conflict-of-interest issues that arise as a result of contradictions between the constitutional mandate of the WHO and the interests of individual donors. In this context, GHW<sub>2</sub> commented: ‘The WHO must “speak the truth to power”, as its director-general promises it will. But that means standing up to powerful industries and being more prepared to speak out against its most powerful member state’ (People’s Health Movement 2008).

The earlier analysis sounds almost prophetic as we look back at the different controversies that have rocked the WHO in the recent past. We detail below two instances where the WHO was compromised and held captive to the narrow interests of a few powerful countries and to those of private corporations.

### **Negotiations on public health, innovation and intellectual property: how a historic opportunity was hijacked<sup>1</sup>**

The negotiations undertaken by the Intergovernmental Working Group (IGWG) on Public Health, Innovation and Intellectual Property between 2006 and 2008 were the result of a deadlock in the WHA in 2006 where member states were unable to reach an agreement on what to do with the recommendations in the report on Public Health, Innovation and Intellectual Property (also

known as the CIPIH report),<sup>2</sup> submitted to the WHA in the same year by a group of experts designated by the director general of the WHO. The 59th WHA approved Resolution 59.24, which requested that an intergovernmental working group open to all WHO members be established. The resolution also requested the director general to include in the intergovernmental group organisations of the United Nations (World Health Organisation 2007a) NGOs in official relations with the WHO, expert observers, and public and private entities. These negotiations resulted in the ‘Global strategy and plan of action (GSPOA) on public health, innovation and intellectual property’, which was approved by the WHA in 2008 (World Health Assembly 2008).

The intention of the GSPOA was to substantially revamp the research and development (R&D) system of the pharmaceutical companies in view of the findings that the present system, working within the intellectual property-based framework, had failed to ensure access to medical products where they were most required.

The intergovernmental group held negotiations for nearly two years, between December 2006 and May 2008, with three meetings in Geneva, which were attended by representatives from over one hundred countries, as well as several other meetings in all the WHO regions.

As is usual in United Nations negotiations, there were groups, alliances, and mediators that helped build a consensus. A first group, which was led by the United States and Switzerland, was supported by Australia, Japan, South Korea, Colombia, Mexico, and Canada. A second group, which was led by Brazil, Thailand, and India, was supported by a great majority of the develop-



**35** WHO is unfairly characterised as just a technical agency (Indranil Mukherjee)

ing countries. The European Union was led by Portugal during the first part of the IGWG, and then by Estonia, in their capacities as presidents of the EU. The not-for-profit NGOs working in the field of public health played an important role. Representatives and lobbyists of the pharmaceutical industry were permanently present in the hallways and corridors, actively trying to influence the different stakeholders. Unfortunately, several United Nations agencies that fully share a public-health vision, such as UNICEF, UNDP, and UNAIDS, were practically absent from the discussions. WIPO and the WTO participated throughout the negotiations, and the group of industrialised countries, as well as the Secretariat of the WHO, requested their comments and points of view on subjects related to the interpretation and management of intellectual property.

*First meeting in Geneva, 4–8 December 2006* The preparations for this meeting and the documents that were to serve as a reference, were not in the spirit of the recommendations of the CIPIH, which provided the basic mandate for the negotiations. Attempts were made to dilute and hide references to intellectual property, which was supposed to be at the core of the discussions during the negotiations.

When the WHO Secretariat presented the key elements of the proposed strategy at the first meeting, the issue of intellectual property had practically disappeared! During the chaotic discussions that ensued, the developing countries managed to force a consensus on the need to introduce issues related to intellectual property in the text under negotiation. The WHO Secretariat decided to isolate this issue in a separate chapter (element 5: ‘Application and management of intellectual property to contribute to innovation and promote public health’). The fact that intellectual-property-related issues were ghettoised into one section, and were not made part of the discussions of all the elements of the text under negotiation, constituted the most fundamental problem in the negotiations henceforth. Another small success achieved by the developing countries was an agreement to include discussions on the possible negative impact of free-trade agreements.

Throughout the negotiations, a group of industrialised countries questioned the WHO’s authority in the area of intellectual property, insisting that this was an issue that should be dealt with by the WIPO and the WTO. According to these countries, the WHO should only be involved in health care aspects (World Health Organisation 2007a), excluding other decisive aspects influencing the health sector. Nor could agreement be reached on the inclusion of a reference to human rights, or on a statement that public health has priority over intellectual property rights.

The first meeting ended abruptly without any conclusion or consensus being reached. In July 2007, the IGWG Secretariat issued a new version of the GSPOA. An additional column was introduced in the action plan to indicate

the ‘stakeholders’ (WHO member states, Secretariat of the WHO, WIPO, WTO, national institutions, academia, industries, PPPs, NGOs, etc.). This initiative by the Secretariat was later used by certain countries as a means to try to exclude the WHO from certain activities, especially those pertaining to intellectual property.

*Regional consultations and the ‘Rio Document’* Regional and inter-country meetings took place during the second quarter of 2007. The most important of these, in terms of impact on the negotiations, was the one held in Rio de Janeiro, attended by Argentina, Brazil, Chile, Costa Rica, Cuba, Ecuador, El Salvador, Honduras, Mexico, Peru, Suriname, Uruguay, and Venezuela. The meeting produced what was referred to as the ‘Rio document’. The Rio document included the following principles:

- a) The right to health protection is a universal and unalienable right, and it is the obligation of governments to guarantee that the instruments for implementing this right are available.
- b) The right to health takes precedence over commercial interests.
- c) The right to health implies access to medicines.

*Second meeting, 5–10 November 2007* The draft, produced at the end of the second meeting, was clearly influenced by the Rio document. Although substantive progress was made in this meeting, several key points remained in parentheses because no consensus had been reached. A welcome development was an agreement (point 30.2.3.c) to ‘encourage further exploratory discussions on the utility of possible instruments or mechanisms or essential health and biomedical research and development, including, inter alia, an essential health and biomedical research and development treaty’. This is undoubtedly the central and most important point of the Global Strategy, and the one that aroused the most opposition from the pharmaceutical industry, as well as from some industrialised countries. The meeting, however, left unresolved the issue of whether the WHO would be a stakeholder in this project. One and a half years later, at the January 2009 Executive Board meeting, and at the 2009 WHA, a group of nine countries, with the presence of the WHO Secretariat acting as an ‘observer’, used the WTO ‘green room’ technique and agreed to exclude the WHO as one of the stakeholders in this activity of the plan of action. Thus, many of the gains obtained by including this issue in the text were overturned later, as without the WHO as a stakeholder the proposal remains largely toothless and meaningless.

*Continuation of the second meeting, 28 April–3 May 2008* After negotiating one sentence at a time, and sometimes even one word at a time, consensus was reached on four of the seven elements. The elements that eluded a consensus

were *element 4*: transfer of technology; *element 5*: management of intellectual property; and *element 6*: improving delivery and access.

Many of the open points enclosed in parentheses pending consensus had been blocked only by the United States, and several countries requested that ‘pending USA approval’ be indicated in the draft with respect to these elements. The most problematic element for the United States delegation was element 5, in aspects such as ‘the need to find new incentive schemes for research’, the role of the WHO with regard to intellectual property, the protection of test data, and the reference to TRIPS-plus measures in bilateral trade agreements.

*61st World Health Assembly, 24 May 2008* During the 61st WHA, another meeting was held. On the Friday prior to the close of the WHA, the WHO Secretariat authorised a ‘WTO green room’-type meeting (a closed-door meeting with a group of nine countries). This practice, the first one in the history of the WHO (with the exception of some negotiations on the anti-tobacco convention), was strongly criticised by many countries in public, and they even threatened to not recognise the consensus reached by the nine countries. Such a process and similar criticisms were to be repeated during the 62nd WHA in May 2009, when another ‘green room’ manoeuvre led to the exclusion of the WHO as a stakeholder in the activity related to the treaty on R&D.

As this was the final stretch of the negotiations, the Secretariat and the countries wanted to finish the exercise (only a few NGOs tried to extend the IGWG but were unsuccessful). Hence, this was the moment when the technique of referring to ‘previously agreed-to documents and other forums’ was used most often. Since most of the pending elements belonged to element 5 (intellectual property and patents), the topic of intellectual property was the one that most suffered or profited from this technique.

Certain aspects were deleted, and others were adapted with certain changes that weakened the text. References to TRIPS-plus provisions, parallel imports, the concepts of patent expiration and invalid patents, the patentability criteria, and even test data exclusivity were eliminated.

### **Exclusion of WHO as a stakeholder from a proposed R&D treaty**

On the last day of the WHA, and at the last moment, a resolution sponsored by Canada, Chile, Iran, Japan, Libya, Norway, and Switzerland, and with the support of the United States, was approved. This resolution made reference to, and approved, document A62/16 Add.3, which excluded the WHO from future discussions regarding the treaty.

Several developing countries (Argentina, Bangladesh, Barbados, Bolivia, Cuba, Ecuador, Ghana, India, Jamaica, Nicaragua, Suriname, and Venezuela) expressed their disagreement with the way in which the closed-door informal consultations were carried out, as well as with the result of these consulta-

tions to exclude the WHO as a stakeholder in future discussions regarding a possible international treaty.

### **Disappointing outcome of negotiations**

The GSPOA on public health, innovation and intellectual property was approved by the WHA in May 2008. The final wording of the GSPOA is, in many cases, vague, weak, and full of conditions and nuances. Two examples will suffice to show how the final text was weakened to the extent that its meaning became obscure and largely unusable. Instead of a clear recommendation that the WHO should provide technical and regulatory support to make use of the flexibilities contained in the TRIPS agreement, the final text says:

... providing as appropriate, upon request, in collaboration with other competent international organizations technical support, including, where appropriate, to policy processes, to countries that intend to make use of ...

Developing countries were largely united in asking for an international agreement or convention as an alternative form of funding R&D for the pharmaceutical products to be studied. The final text diluted this intent to say:

2.3 (c) encourage further exploratory discussions on the utility of possible instruments or mechanisms for essential health and biomedical research and development, including inter alia, an essential health and biomedical research and development treaty.

Article 19 of the WHO constitution states:

The Health Assembly shall have authority to adopt conventions or agreements with respect to any matter within the competence of the Organization. A two-thirds vote of the Health Assembly shall be required for the adoption of such conventions or agreements, which shall come into force for each Member when accepted by it in accordance with its constitutional processes.

Yet the WHA failed to conclusively ratify an agreement that acted decisively in favour of a process that would look beyond the intellectual property framework to make medical products accessible and to incentivise innovations directed at resolving problems faced by the poor in developing countries. In the case of the IGWG negotiations, this happened in spite of a majority of the countries present being in favour of a decisive agreement. Instead, the WHA chose to arrive at a consensus that was driven, in large measure, by a few developed countries.

It is important to underline the role of several developing countries mentioned earlier, and especially the group of African countries, which struggled in the face of intense pressure from a few developed countries to insert useful language in the final text. Mention should also be made of several not-for-profit NGOs (including Essential Action, Health Action International, Health

Gap, Knowledge Ecology International, Médecins Sans Frontières, Oxfam International, and Third World Network) and some invited experts, who toiled hard to make their concerns heard and who managed to make a substantial impact on the final text. It is a testimony to their efforts that the final text, in spite of all the shortcomings, embodies several positive outcomes that remain with us and have the potential to be built upon. They include:

- The scope of the Global Strategy is not restricted to the three diseases (malaria, AIDS, and tuberculosis).
- A consensus was reached on the need for new mechanisms to incentivise R&D.
- A special group of experts to examine the R&D funding systems was established. This group was supposed to report to the 63rd WHA, but now it will report to the 65th WHA in 2012.
- The topic is still on the agenda, at least until 2015, and the Secretariat will have to report to the WHA every two years.
- Finally, for the third time after the adoption of the anti-tobacco convention and the international sanitary code, the idea of the treaty raised the issue (although without much success) of the need for the WHO to exercise the right conferred on it under Article 19 of its Constitution, which allows its ‘recommendation’ on public health to take on a mandatory character.

### **An unsavoury postscript**

The saga of the IGWG negotiations is followed by a rather unsavoury and bizarre postscript. One of the few tangible outcomes of the negotiations was the decision by the WHO in 2008 to constitute an Expert Working Group (EWG). The EWG was mandated to examine different mechanisms for R&D, financing, and coordination. It was expected that the group would find new ways to pay for, and prioritise, health research and the development of new medical products. In late 2009, Wikileaks carried a story that the report had been leaked in advance to the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) (Lancet 2010). The IFPMA, in its internal communications, had also lauded the EWG report (even before the report was presented to the WHO!) (ibid.). This was subsequently followed by a letter, on 15 January 2010, by a member of the EWG, Cecilia Lopez Montano (also a senator of the Colombian Congress), to the Executive Board members of the WHO, urging the members to refuse endorsement of the EWG’s report, stating that the method of work of the EWG was not transparent or participatory, and that she was used for legitimising the EWG process (Shashikant 2010b).

The reason for the IFPMA’s advance approval of the EWG report was clear when the report was presented before the WHA in 2010. The conclusions of the report failed to address the impact of intellectual property on access to

medicines, and ignored the need to explore financial mechanisms that could overcome the problems posed by a patent-based system for R&D. The report was rejected by member states, and the WHO Secretariat was directed to constitute a fresh working group, which would present its report at the WHA in 2012.

### **WHO's anti-counterfeit policy: the strange case of IMPACT**

WHO's association with the International Medical Products Anti-Counterfeiting Task Force (IMPACT) is shrouded in mystery. Serious concerns have been raised about how IMPACT, a body with a strong pharmaceutical industry presence, has been allowed to dictate WHO's policy, especially in the sensitive area concerning counterfeit medicines. We recount below the IMPACT story, in order to clarify the threat that IMPACT poses to the credibility of WHO (Third World Network 2010).

### **Origins and objectives of IMPACT**

IMPACT is a WHO-hosted 'partnership' set up 'to promote and strengthen international collaboration to combat counterfeit medical products' (World Health Organisation 2006). IMPACT originated in a series of planning sessions, leading to an organising meeting in Rome on 16–18 February 2006. This meeting, 'Combating Counterfeit Drugs: Building Effective International Collaboration', is described in IMPACT literature as a WHO international conference. It was jointly sponsored by WHO and IFPMA.

IMPACT has a policy of keeping the names of attendees at their meetings secret 'for reasons of privacy and security' (World Health Organisation 2010b), so we can only guess at the identity of the attendees of the Rome meeting, and we are equally in the dark as to the actual deliberations. We do know that many pharmaceutical-industry-affiliated groups took part at various stages of the planning and execution of the meeting, including the International Pharmaceutical Federation (FIP), the European Association of Pharmaceutical Wholesalers, the International Federation of Pharmaceutical Wholesalers, the Pharmaceutical Security Institute, the International Alliance of Patients' Organisations (funded in part by Astra-Zeneca, GlaxoSmithKline, Johnson and Johnson, Lilly, Merck, Novartis, Pfizer, and Sanofi-Aventis), the Pharmaceutical Research and Manufacturers Association, and the International Federation of Pharmaceutical Manufacturers and Associations. Representatives of 57 national drug regulatory authorities (DRAs), seven international organisations, 12 international associations of patients, and 'health professionals' were also present (World Health Organisation 2010c).

### **Is IMPACT part of the WHO, or merely 'hosted' there?**

After the Rome meeting, IMPACT became a hosted 'partnership' within WHO, with WHO acting as the secretariat. IMPACT is described variously

in WHO documents as ‘a task force administered by WHO’; ‘IMPACT is a partnership’; ‘not a legal entity’; and ‘guided by the [IMPACT] General Meeting’ (i.e., under separate governance); with ‘secretariat support’ from WHO. An unusual provision in the IMPACT terms of reference requires WHO to ‘take the 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’ (ibid.). This unusual restriction on WHO would logically characterise IMPACT and WHO as separate entities.

IMPACT is a separate entity, with secretariat functions provided by WHO. This is not an unusual arrangement. However, the WHO’s Department of Essential Medicines and Pharmaceutical Policies (EMP) tells us that ‘IMPACT is also part of the department’ (World Health Organisation 2011a). We are also told that IMPACT ‘... has become the main conduit for WHO’s work on counterfeit medicines’ (World Health Organisation 2010d). This suggests that IMPACT has a direct technical and policy role in WHO. Adding to the confusion, some documents bear only IMPACT’s logo in some editions, and both IMPACT and WHO logos in others (World Health Organisation 2007, 2008).

IMPACT partner INTERPOL has no hesitation in describing IMPACT as part of WHO. IMPACT–INTERPOL raids and seizures of ‘counterfeit’ medicines from pharmacies, distributors, and markets in Tanzania and Uganda are described as ‘combined INTERPOL–World Health Organization (WHO) operations’. Similar INTERPOL police actions in several Southeast Asian countries are described as ‘supported by INTERPOL, the WHO and the World Customs Organization (WCO), under the framework of IMPACT’ (INTERPOL 2008a, b).

There are two IMPACT websites (World Health Organisation 2009; IMPACT 2009). One is the WHO site and the other is in a separate non-WHO location. In the non-WHO IMPACT site, a WHO logo appears at the top of the home page, but it is in a separate image file and disappears when the webpage is printed, making it difficult to document this use of the WHO logo, which is probably in violation of WHO guidelines (‘the use of the WHO emblem on non-WHO websites is normally not allowed ...’) (World Health Organisation 2011b).

The ambiguous position of IMPACT within WHO serves several purposes. Two of the heads of IMPACT’s five ‘working groups’ are full-time pharmaceutical industry employees. An IMPACT organogram (Rägo 2010) shows the working groups as outside of WHO, which provides some ‘plausible deniability’ to charges that industry staff have directly infiltrated WHO. It also allows IMPACT to receive financial support from industry in its guise as a separate entity, thus circumventing WHO’s own guidelines (World Health Organisation 2000).

More importantly, this arrangement has made it possible to receive technical documents from industry sources, which can then be ‘sanitised’ before

transmission to WHO proper. An example is the document ‘A Guide to Anti-Counterfeiting Technologies for the Protection of Medicines’. It proposes a variety of high-tech protections, such as holograms, ‘optically variable devices’, colour-shifting security inks and films, and fine-line printing similar to that used on banknotes, all of which might be useful in protecting high-value branded products, but would be unavailable to low-cost generic producers and low-income producer countries. The priority here is obviously intellectual property protection, not counterfeit prevention. This document was prepared by GlaxoSmith Kline and introduced into WHO’s policy process – a process facilitated by the fact that the chair of IMPACT’s Technology Working Group is also the director general of IFPMA (Third World Network 2010). This process appears to be in violation of WHO’s policies on working with the private sector and on partnerships (World Health Organisation 2000, 2010e).

IMPACT’s terms of reference claim that IMPACT was originally ‘proposed by WHO’, citing a paper (Forzley 2006) presented at the Rome meeting. This paper, marked as a ‘background document’, is identified as originating from WHO’s Health Technologies and Pharmaceuticals unit. However, it was not written by WHO. Its author, Michele Forzley, is a US intellectual property lawyer and consultant who was an early advocate of the concept of framing ‘counterfeit’ as a public health issue (Forzley 2003, 2006; Third World Network 2010). The WHO Secretariat claims unequivocally that IMPACT has a legitimate place in the Organisation: IMPACT ‘... has become the main conduit for WHO’s work on counterfeit medicines’. The Secretariat justifies the existence of IMPACT on ‘discussions at the Sixty-first World Health Assembly and the 124th session of the Executive Board’ (World Health Organisation 2010d). However, no resolutions or decisions were taken on IMPACT at either of these meetings.

WHO member states have questioned IMPACT’s role within WHO. At the 63rd WHA, India and Thailand argued that ‘... IMPACT, or its Terms of Reference, has not been approved by any governing body of WHO and ... there are conflicts of interest in its composition’. India added: ‘Clearly, IMPACT is ... an instrument of IPR policy and market access by some of the largest economies of the world’ and it is ‘one of the prongs of the multi-pronged TRIPS+ enforcement drive of some developed countries and originator pharmaceutical companies’. Concerns about IMPACT were also expressed by Kenya, Venezuela, Bolivia, Ecuador, Bangladesh, Egypt, Iran, and Pakistan. On the other hand, the United States, Switzerland, and Spain expressed support for IMPACT (Shashikant 2010a).

### **The policy agenda of IMPACT**

IMPACT’s approach to the definition of ‘counterfeiting’ is revealing.

The WTO treats counterfeiting exclusively as a form of trademark violation. WHO developed a definition of counterfeit medicine in 1992:

A counterfeit medicine is 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 products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging. (World Health Organisation 1992)

While quoting the WHO definition in several documents, IMPACT argues elsewhere that a new definition is needed. In 2007, IMPACT proposed rephrasing the first sentence as follows: ‘A medical product is counterfeit when there is a false representation in relation to its identity, history or source’. In a 2008 IMPACT definition, the words ‘deliberately and fraudulently’ were removed. Both these changes increase the ambiguity and broaden the scope of what is ‘counterfeit’. ‘False representation’ could include trademark or packaging similar to that of a branded product. The word ‘history’ is (deliberately?) imprecise, and could encompass incompletely documented distribution channels. The removal of the words ‘falsely and deliberately’ eliminates the element of intent from the definition, so that a variety of minor or unintentional documentation failures could be considered ‘counterfeiting’, and potentially subject to criminal penalties. Together with the push to criminalise ‘counterfeiting’, these definition changes pose a real threat to small producers, generic producers, and even distributors and sellers, who would become liable to criminal prosecution for relatively trivial procedural errors (WHO South East Asia Regional Office 2008).

Also, in 2008, IMPACT produced another definition of ‘counterfeit’:

A medical product is counterfeit when there is a false representation in relation to its identity (name, composition, strength, or any other element that may influence the judgment of health professionals, patients or consumers about the identity of the product) or source (manufacturer, country of manufacturing, country of origin, marketing authorisation holder), or any other element that may influence the judgment of health professionals, patients or consumers about the source of the product. (World Health Organisation 2007b)

This definition is particularly alarming because it could very easily encompass legitimate generic products and their producers, distributors, and sellers, and because it appears on the WHO website in a document bearing both the IMPACT and WHO logos. This document, titled ‘Principles and Elements for National Legislation against Counterfeit Medical Products’, has been picked up enthusiastically by the European Commission and the World Intellectual Property Organization (Third World Network 2010). It is extraordinary that IMPACT was able to produce a new and radically different definition of ‘counterfeit’, have it legitimised by WHO, and then adopted elsewhere, without the knowledge or approval of WHO’s member states or governing bodies.

IMPACT has taken this document and its expanded definition of ‘counterfeit’ to countries in a deceptive manner. At the 63rd WHA in May 2010, the delegate from Kenya reported that Kenya’s law on counterfeit products was the result of advice given by IMPACT, adding that the law has been problematic in providing health facilities and access to medicine (Mara 2010).

Recent IMPACT documents have claimed that IMPACT does not concern itself with intellectual property matters (World Health Organisation 2010c). However, IMPACT’s claim that it is not concerned with intellectual property matters is half-hearted, insincere, and deceptive. One of the main policy products of IMPACT, the ‘Principles and Elements for National Legislation against Counterfeit Medical Products’, does state that ‘principles set out in this document do not specifically address ... infringement of aspects of intellectual property rights (IPR), including patent rights ...’, but only after stating: ‘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 criminal law. All these bodies of legislation should be in place.’

The role of IFPMA in IMPACT is significant in this respect. IFPMA co-organised and co-funded IMPACT’s organising meeting in Rome, co-chaired IMPACT’s first global technical meeting, ‘Combating Counterfeit Medicines: Where the Regulatory and Technology Roads Meet’ (IFPMA 2008), and continues to play a leadership role – for example, heading the IMPACT working group on technology. IFPMA has a long-standing position on ‘counterfeit’. At the 1992 meeting ‘Counterfeit Drugs: Report of a WHO/IFPMA Workshop’, IFPMA’s executive vice-president clearly stated IFPMA’s view of ‘counterfeiting’ as an intellectual property crime to be controlled through enforcement and prosecution:

Counterfeiting of any type of goods is a crime because it is theft and thus deprives the authentic manufacturer of his just rewards. The main answer to control ... must be application of due processes of law ... detection; prosecution; judgment; punishment. (World Health Organisation 1992)

WHO’s approach is, or was, quite different. While recognising that ‘counterfeiting’ is a crime, WHO and its member states see beyond the limited issue of ‘counterfeits’ to the actual public health problem, which is the elimination of ‘substandard/spurious/falsely-labelled/falsified/counterfeit medical products’ (World Health Organisation 2010d). Protection of private property rights has not been a concern. In line with this understanding, WHO has accorded priority to national DRAs in its recommendations for countering counterfeiting (World Health Organisation 1999). DRAs have responsibility for ensuring the quality, safety, efficacy (QSE) and the correct use of drugs. IMPACT places little or no emphasis on QSE or on the role of DRAs (IMPACT 2008). While other units within WHO’s Essential Medicines and Pharmaceutical Policies

Department continue to work on QSE issues, the creation of a well-funded separate body dealing exclusively with ‘counterfeit’ medicines is an incoherent policy from the public health perspective, and was never authorised by WHO’s governing bodies.

### **Against WHO’s guidelines**

If IMPACT’s Rome meeting was a WHO meeting as claimed, and if IMPACT is indeed a part of WHO, then both the co-funding of the Rome meeting by IFPMA and IFPMA’s continued support to IMPACT’s activities appear to be in violation of WHO’s guidelines on working with the private sector (‘... financing may not be accepted from commercial enterprises for activities leading to production of WHO guidelines or recommendations ... WHO should avoid indirect collaboration particularly if arranged by a third party acting as an intermediary between WHO and a commercial enterprise ... funds may not be sought or accepted from enterprises that have a direct commercial interest in the outcome of the project toward which they would be contributing ... WHO may not cosponsor a meeting being held by specific commercial enterprises [or with] one or more health-related enterprises ...’) (World Health Organisation 2000).

IFPMA certainly qualifies as a ‘third party acting as an intermediary between WHO and a commercial enterprise’, since its membership includes 26 pharmaceutical companies (IFPMA 2010). On the other hand, if IMPACT is considered to be merely a partnership hosted within WHO, the arrangement is probably in violation of WHO’s guidelines on partnerships (World Health Organisation 2010c). (‘... risks and responsibilities arising from public–private partnerships need to be identified and managed through development and implementation of safeguards that incorporate considerations of conflicts of interest ... the partnership shall have mechanisms to identify and manage conflicts of interest ... the Director-General shall submit to the Executive Board any proposals for WHO to host formal partnerships for its review and decision ... fundraising by a WHO-hosted partnership from the commercial private sector shall be subject to WHO’s guidelines on interaction with commercial enterprises ...’). Through its ‘half-in and half-out’ position in WHO, IMPACT attempts to evade one set of restrictions on its activities, but encounters another.

### **Conclusions on the IMPACT Story**

The IMPACT episode is not the first time that private commercial interests have had an undue influence on WHO’s work. However, it is the first time that private industry has penetrated directly into WHO’s operations, with the capacity to insert industry messages, directly and essentially unfiltered, into WHO’s policy and technical documents. Was the insertion of IMPACT into WHO’s policy-making done ‘deliberately and fraudulently’? Certainly, some

IMPACT products appear to be ‘mislabelled as to content and source’. *Can we say, then, that IMPACT is ‘counterfeit’?*

Would the IMPACT fiasco have occurred had the WHO been operating strictly within the ambit of its Constitution and guidelines and relying solely on unconditional funding received as dues payments or other unrestricted grants from its member states? Had it done so, the WHO would be 80 per cent less wealthy, but 100 per cent more credible as ‘the directing and co-ordinating authority on international health work’ (World Health Organisation 1946).

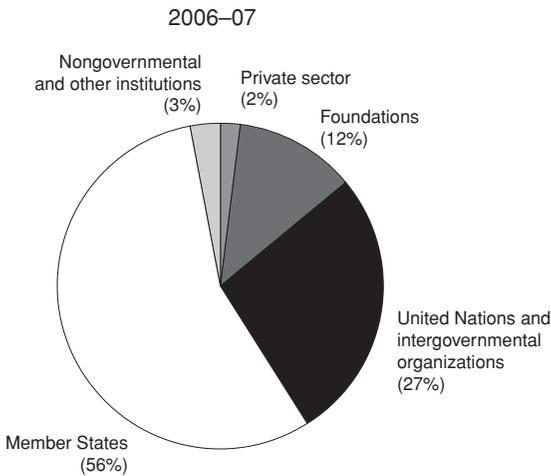
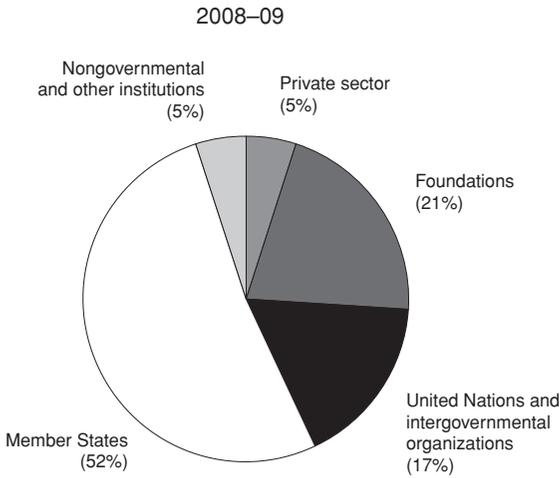
A long-delayed first meeting of an intergovernmental working group to examine, among other things, WHO’s relationship with IMPACT took place in March 2011, but was unable to resolve the issue.<sup>3</sup> It was also revealed that the IMPACT Secretariat has removed itself, mysteriously, from Geneva to the Italian Medicines Agency (AIFA), where it is producing documents bearing the IMPACT and AIFA logos. This leaves us with three separate IMPACT websites, only one of which reveals IMPACT’s present location. It is not surprising to find that one document, ‘IMPACT: the Handbook’, contains one of the many unapproved and potentially harmful definitions of ‘counterfeit’ (Agenzia Italiana del F armaco 2011).

As a first step in recovering from the embarrassment caused by the IMPACT episode, it is hard to improve on the recommendation of India and Thailand made at the 63rd WHA:

... replace WHO’s involvement in the International Medical Products Anti-Counterfeiting Taskforce with an effective programme to address the issues of quality, safety and efficacy ... (World Health Organisation 2010e)

## Conclusion

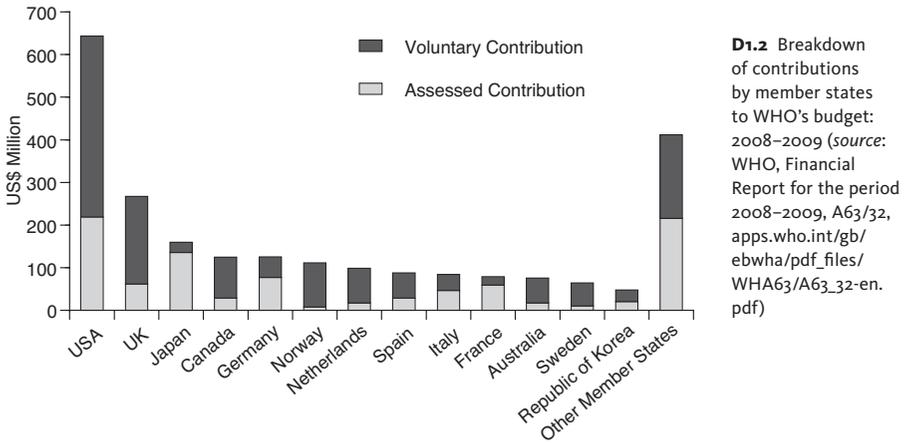
The two case studies discussed here are illustrations of the crisis faced by the WHO today. The crisis in WHO’s finances has reached a stage where only 20 per cent of its budget comes from assessed (i.e. mandatory) contributions from member states (World Health Organisation 2010g). The skewing of WHO’s finances in favour of voluntary contributions (a large proportion of which is not flexible and can be used only for programmes specified by the donors) places the organisation’s role as an independent body at risk. A large proportion of contributions from member states is also ‘voluntary’, i.e. they are for specific programmes (Charts D1.1 and D1.2). The report by the director general of the WHO to the Executive Board says: ‘... given that more than 60% of WHO’s income takes the form of highly-specified funding, an area of work that attracts significantly more, earmarked, voluntary funding than another becomes de facto a priority ...’ (World Health Organisation 2010g). Further, there is a continued push towards restricting the mandate of the WHO to that of a ‘technical body’, with little or no mandate to pursue work in areas seen as ‘developmental’. The director general’s report to the



**D1.1** Sources of voluntary contributions to WHO's budget (source: WHO, Financial Report for the period 2008–2009, A63/32, [apps.who.int/gb/ebwha/pdf\\_files/WHA63/A63\\_32-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_32-en.pdf))

Executive Board of the WHO articulates this tension as follows: ‘The global governance role of WHO in the field of development is much less clear. In recent years, development has attracted growing political attention, increasing resources, and a proliferation of global health initiatives.’

Clearly, there is a need to develop a sustainable financing and strategic plan for the WHO that is premised on increased assessed contributions of member states, with a view to securing the independent role of the WHO, its continuing and expanding role in providing stewardship in dealing with global health issues, and to reversing the present 20:80 division in the WHO’s finances. Such a plan should also propose mechanisms for ensuring that voluntary and donor contributions are not channelled for specified programmes, but are free to be used for promoting the overall goals of the WHO that are collectively decided upon by member states. The plan should also propose a



**D1.2** Breakdown of contributions by member states to WHO's budget: 2008-2009 (source: WHO, Financial Report for the period 2008-2009, A63/32, [apps.who.int/gb/ebwha/pdf\\_files/WHA63/A63\\_32-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_32-en.pdf))

code of conduct on voluntary donations, so as to prevent conflict of interest between donor priorities and the member-state-driven agenda of the WHO. The WHO Constitution mandates WHO to take up the leadership role with respect to the coordination of international decision-making on health matters. This should include holding the large donors to account with respect to the effectiveness and coordination of their technical and funding roles. It cannot be consistent with WHO's mandate to withhold commentary on the large donors because they also provide tied funds to WHO. Health is a political as well as a technical subject. WHO must accept the responsibility of engaging in the politics of health as well as advising on technical issues (People's Health Movement 2011).



**36** WHO's role as an independent organisation is at risk (Indranil Mukherjee)

## Notes

- 1 This analysis draws heavily from a more detailed analysis in Velásquez (2011).
- 2 Public health, innovation, and intellectual property rights: report of the Commission on Intellectual Property Rights, Innovation and Public Health (2006). Geneva, WHO.
- 3 WHO (2011) Working Group of Member States on Substandard/Spurious/Falsely Labeled/Falsified/Counterfeit Medical Products.

## References

- Agenzia Italiana del Fármaco (2011). *IMPACT: the handbook: facts, activities, documents developed by the Assembly and the Working Groups 2006–2010*. www.agenziafarmaco.gov.it/sites/default/files/final\_handbook\_for\_the\_web.pdf (accessed 8 March 2011).
- Correa, C. M. (2004). 'Ownership of knowledge: the role of patents in pharmaceutical R&D'. *Bulletin of the World Health Organization*, 82(10): 784–6.
- Forzley, M. (2003). *Counterfeit goods and the public's health and safety*. Washington DC, International Intellectual Property Institute. www.iccwbo.org/uploadedFiles/BASCAP/Pages/public%20health%20and%20safety%281%29.pdf.
- Forzley, M. (2006). *Combating counterfeit drugs: a concept paper for effective international cooperation*. International conference, 'Combating Counterfeit Drugs: Building Effective International Collaboration'. Rome, 16–18 February 2006. www.who.int/medicines/events/FINAL-BACKPAPER.pdf. (accessed 8 February 2011).
- IFPMA (International Federation of Pharmaceutical Manufacturers and Associations) (2008). *FDA @ IFPMA officials to chair anti-counterfeiting conference on interaction of regulatory @ technological approaches*. www.ifpma.org/News/NewsReleaseDetail.aspx?nID=8907 (accessed 10 February 2010).
- IFPMA (2010). *About us: member companies*. www.ifpma.org/aboutus/index.php?id=2086 (accessed 9 February 2011).
- IMPACT (International Medical Products Anti-Counterfeiting Taskforce) (2008). *Draft principles and elements for national legislation against counterfeit medical products*. www.who.int/impact/news/BonnMeeting-DraftPrinciples.pdf (accessed 7 February 2011).
- IMPACT (2009). *IMPACT*. www.impactglobalforum.org (accessed 21 December 2010).
- IMPACT (2010). *IMPACT: frequently asked questions with answers*. www.who.int/medicines/services/counterfeit/impact-faqwa.pdf (accessed 5 February 2011).
- INTERPOL (2008a). *Operation Mamba (IMPACT) – targeting counterfeit medicines in Tanzania and Uganda*. 29 October. www.interpol.int/Public/News/2008/mambaz0081029.asp (accessed 8 February 2011).
- INTERPOL (2008b). *Tunisia hosts international taskforce meeting supported by INTERPOL in drive against fake medicines*. Media release. 3 December. www.interpol.int/public/ICPO/PressReleases/PR2008/PR200875.asp (accessed 8 February 2011).
- Lancet (2010). 'Editorial: Drug development for neglected diseases: pharma's influence'. *The Lancet*, 375(9708): 2, 2 January.
- Mara, K. (2010). 'Debate erupts over WHO police work against "counterfeit" drugs trade'. *Intellectual Property Watch*. 20 May. www.ipwatch.org/weblog/2010/05/20/debate-erupts-over-who-police-work-against-counterfeit-drugs-trade (accessed 8 February 2011).
- People's Health Movement (2005). *Global Health Watch I*. London, Zed Books.
- People's Health Movement (2008). *Global Health Watch II*. London, Zed Books.
- People's Health Movement (2011) *The future of financing for WHO: statement by PHM to Executive Board of WHO*. 20 January. www.ghwatch.org/sites/www.ghwatch.org/files/PHMStatementOnTheFutureOfFinancing-ForWHO110120.pdf (accessed 14 March 2011).
- Rägo, L (2010). *Counterfeit medical products: anti-counterfeit medicines programme update*. World Health Organisation. www.whcaonline.org/uploads/WHEN%202010/WHEN\_Lembit%20R%C3%A4go.ppt (accessed 8 February 2011).
- Shashikant, S. (2010a). *Clash over WHO's role in 'counterfeits'*. IMPACT. SUNS #6929. 25 May. Geneva, Third World Network.
- Shashikant, S. (2010b). *WHO: expert report on R&D financing triggers inquiry, consulta-*

- tions. SUNS #6847. 22 January 2010. [www.twinside.org.sg/title2/health.info/2010/health20100102.htm](http://www.twinside.org.sg/title2/health.info/2010/health20100102.htm) (accessed 8 March 2011).
- Smith, R. D., C. Correa and C. Oh (2009). 'Trade, TRIPS and pharmaceuticals'. *The Lancet*, 373(9664): 684–91.
- Third World Network (2010). *WHO's 'counterfeit' programme: legitimises IP enforcement agenda, undermines public health*. Briefing Paper 2. 63rd World Health Assembly, 17–21 May. Geneva. [www.twinside.org.sg/title2/briefing\\_papers/nontwn/Briefing.paper.on.WHO.Counterfeits.pdf](http://www.twinside.org.sg/title2/briefing_papers/nontwn/Briefing.paper.on.WHO.Counterfeits.pdf) (accessed 31 January 2011).
- Trouiller, P. et al. (2002). 'Drug development for neglected diseases: a deficient market and a public-health policy failure'. *The Lancet*, 359(9324): 2188–94.
- UK Commission on Intellectual Property Rights (2002). *Executive summary*. London.
- UNAIDS, WHO and UNICEF (2010). *Towards universal access: scaling up priority HIV/AIDS interventions in the health sector*. Progress Report 2009. [data.unaids.org/pub/Report/2009/20090930\\_tuapr\\_2009\\_en.pdf](http://data.unaids.org/pub/Report/2009/20090930_tuapr_2009_en.pdf).
- Velásquez, G. (2011). *The right to health and medicines: the case of recent negotiations on the global strategy on public health, innovation and intellectual property*. Research Paper 35. January. Geneva, South Centre.
- Working Group of Member States on Substandard/Spurious/Falsely Labeled/Falsified/Counterfeit Medical Products (WHO) (2011). *Report of the working group of member states on substandard/spurious/falsely labelled/falsified/counterfeit medical products*. A/SSFFC/IGWG/5. [www.ipwatch.org/weblog/wpcontent/uploads/2011/03/SSFFC\\_Report.pdf](http://www.ipwatch.org/weblog/wpcontent/uploads/2011/03/SSFFC_Report.pdf) (accessed 8 March 2011).
- World Health Assembly (2008). *Global strategy and plan of action on public health, innovation and intellectual-property*. Resolution 61.21. 24 May.
- World Health Organisation (1946). *Constitution of the World Health Organization*. [apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf](http://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf) (accessed 2 February 2011).
- World Health Organisation (1992). *Counterfeit drugs: report of a WHO/IFPMA workshop*. 1–3 April. [whqlibdoc.who.int/hq/1992/WHO\\_DMP\\_CFD\\_92.pdf](http://whqlibdoc.who.int/hq/1992/WHO_DMP_CFD_92.pdf) (accessed 2 February 2011).
- World Health Organisation (1999). *Counterfeit drugs: guidelines for the development of measures to combat counterfeit drugs*. WHO/EDM/QSM/99.1. [whqlibdoc.who.int/hq/1999/WHO\\_EDM\\_QSM\\_99.1.pdf](http://whqlibdoc.who.int/hq/1999/WHO_EDM_QSM_99.1.pdf) (accessed 4 February 2011).
- World Health Organisation (2000). *Guidelines on working with the private sector to achieve health outcomes*. Report by the Secretariat. Executive Board EB107/20, 107th Session, 30 November. Provisional agenda item 8.3. [www.searo.who.int/LinkFiles/Guidelines\\_on\\_Resource\\_Mobilization\\_eezo.pdf](http://www.searo.who.int/LinkFiles/Guidelines_on_Resource_Mobilization_eezo.pdf) (accessed 3 February 2011).
- World Health Organisation (2006). *International Medical Products Anti-Counterfeiting Task Force (IMPACT). Terms of Reference*. [www.who.int/impact/about/IMPACT\\_ToR.pdf](http://www.who.int/impact/about/IMPACT_ToR.pdf) (accessed 2 February 2011).
- World Health Organisation (2007a). *Intergovernmental Working Group on Public Health, Innovation and Intellectual Property*. Report of the first session. Geneva, 4–8 December 2006. A/PHI/IGWG/1/6, 25 January. [apps.who.int/gb/phi/pdf/igwg1/A\\_PHI\\_IGWG1\\_6-en.pdf](http://apps.who.int/gb/phi/pdf/igwg1/A_PHI_IGWG1_6-en.pdf) (accessed 14 March 2011).
- World Health Organisation (2007b). *Principles and elements for national legislation against counterfeit medical products*. Text endorsed by IMPACT General Meeting, Lisbon, 12 December. [www.who.int/impact/events/FinalPrinciplesforLegislation.pdf](http://www.who.int/impact/events/FinalPrinciplesforLegislation.pdf) (accessed 7 February 2011).
- World Health Organisation (2008a). *Global strategy and plan of action on public health, innovation and intellectual property*. WHA, 61.21 (7).
- World Health Organisation (2008b). *Draft principles and elements for national legislation against counterfeit medical products (IMPACT)*. [www.who.int/impact/news/BonnMeetingDraftPrinciples.pdf](http://www.who.int/impact/news/BonnMeetingDraftPrinciples.pdf) (accessed 7 February 2011).
- World Health Organisation (2009). *International Medical Products Anti-Counterfeiting Task Force – IMPACT*. [www.who.int/impact/en](http://www.who.int/impact/en).
- World Health Organisation (2010a). *The future of financing for WHO: report of an informal consultation convened by the Director-General, Geneva, Switzerland, 12–13 January 2010*. Geneva, World Health Organisation.

- World Health Organisation (2010b). Sixty-third World Health Assembly, Provisional agenda item 12.9 30. *Counterfeit medical products: report by the Secretariat*. A62/13, 30 April 2009. [apps.who.int/gb/ebwha/pdf\\_files/A62/A62\\_13-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/A62/A62_13-en.pdf) (accessed 8 February 2011).
- World Health Organisation (2010c). Sixty-third World Health Assembly, WHA 63.10, agenda item 18.1, 21 May 2010. *Partnerships. Policy on WHO engagement with global health partnerships and hosting arrangements*. [apps.who.int/gb/ebwha/pdf\\_files/WHA63/A63\\_R10-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_R10-en.pdf) (accessed 7 February 2011).
- World Health Organisation (2010d). *Counterfeit medical products: report by the Secretariat*. Sixty-third World Health Assembly. Provisional agenda item 11.20 22, April 2010. A63/23. [apps.who.int/gb/ebwha/pdf\\_files/WHA63/A63\\_23-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_23-en.pdf) (accessed 28 January 2011).
- World Health Organisation (2010e). Sixty-third World Health Assembly, Geneva, 17–21 May 2010. *Resolutions, decisions, annexes*. WHA63/2010/REC/1. [apps.who.int/gb/ebwha/pdf\\_files/WHA63-REC1/WHA63\\_REC1-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA63-REC1/WHA63_REC1-en.pdf) (accessed 5 February 2011).
- World Health Organisation (2010f). *Medium-term strategic plan 2008–2013 and proposed programme budget 2012–2013: report by the Secretariat*. Executive Board EB128/24, 128th Session, 16 December. Provisional agenda item 6.3. [apps.who.int/gb/ebwha/pdf\\_files/EB128/B128\\_24-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/EB128/B128_24-en.pdf) (accessed 14 March 2011).
- World Health Organisation (2010g). *The future of financing for WHO: report by the Director-General*. Executive Board EB128/21, 128th Session, 15 December. Provisional agenda item 5. [apps.who.int/gb/ebwha/pdf\\_files/EB128/B128\\_21-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/EB128/B128_21-en.pdf) (accessed 14 March 2011).
- World Health Organisation (2011a). International Medical Products Anti-Counterfeiting Task Force (2010). *IMPACT: frequently asked questions with answers*. [www.who.int/medicines/services/counterfeit/impact-faqwa.pdf](http://www.who.int/medicines/services/counterfeit/impact-faqwa.pdf) (accessed 5 February 2011).
- World Health Organisation (2011b). *About us: WHO medicines: worldwide activities based on a global strategy*. [www.who.int/medicines/about/en](http://www.who.int/medicines/about/en) (accessed 8 February 2011).
- World Health Organisation (2011c). The WHO emblem. [www.who.int/about/licensing/emblem/en/index.html](http://www.who.int/about/licensing/emblem/en/index.html) (accessed 7 February 2011).
- WHO South East Asia Regional Office (2008). *Defining 'counterfeit medicines' from the perspective of public health*. New Delhi, South East Asia Regional Office, World Health Organisation.