

SFC & QSE @ WHO (2003-2013)

David G Legge
1 Sept 2013

Introduction

Since 1994 (and the coming into force of the TRIPS (Trade Related Intellectual Property Rights) Agreement) there has been a dramatic strengthening of intellectual property (IP) protection with protection for product as well as process, increasing duration of protection and powerful new sanctions to encourage countries to adopt the new standards. (Scherer and Watal (2001) point out that many of today's developed countries excluded pharmaceutical products from patent protection until quite recently: Germany until 1968; Switzerland until 1977; Italy until 1978; Spain until 1992; Portugal until 1992; Norway until 1992; Finland until 1995, and Iceland until 1997.)

Also launched in 1994 was the NAFTA (North American Free Trade Agreement) which heralded a parallel drive, through the preferential trade agreements (PTA) pathway, for higher levels and wider scope of protection. Since the Cancun Ministerial Conference of the World Trade Organisation (and the deadlock in WTO negotiations) there has been a redoubling of effort into the negotiation of PTAs (such as the proposed Trans Pacific Partnership Agreement (TPPA), the US-EU Transatlantic Trade and Investment Partnership (TTIP), EU-India FTA) and tighter IP protection has been a constant feature of these.

Proponents for increasing IP protection, in particular the research based pharmaceutical manufacturers (RBPM) and their nation-state proxies, argue that it is necessary to support innovation. (Countries such as the US which have exported their manufacturing jobs are increasingly dependent on the export earnings associated with monopoly pricing.)

Opponents to high levels of IP protection argue that:

- monopoly pricing (under patent protection) renders medicines unaffordable for (especially for poor people and low and middle income country (L&MIC) governments); the abuse by RBPMs of their monopoly pricing power (for example with the prices for AIDS drugs determined on the basis of maximising revenues (as when revenue is maximised by higher prices for a smaller number of wealthier families) rather than ensuring access to treatment);and
- funding R&D on the basis of anticipated profit distorts investment in new medicines; manifest in lack of investment in diseases which mainly affect L&MICs and over investment in me-too modifications, disease-mongering therapeutics, and marginal end of life benefits.
- much of the profit garnered through monopoly pricing is misused in marketing with consequences in overuse, irrational use and antibiotic resistance.

The battle is being fought out in several different domains.

The RBPMs have sought to shore up their monopoly pricing powers by lobbying for higher levels of IP protection in PTAs and by attacking the use of generics, including through seizures in Europe, trade sanctions against countries using compulsory licensing and propaganda which conflates questions of IP with issues of quality, safety and efficacy (most notably through the International Medical Products Anti-Counterfeiting Taskforce (IMPACT)).

On the public health side there has been resistance to these strategies including defence of the use of generics and a drive to de-link R&D funding from sales revenues (and therefore IP protection), in particular through alternative ways of funding pharmaceuticals R&D.

These forces are engaging at different levels (global, regional, national), in different institutional settings (eg trade negotiation, public health conferences) and in different countries (eg USA, cf Thailand).

This note reviews decision making in and around the WHO with a focus on the debates around 'counterfeit' medicines and the relationships between IP and affordability, quality, safety and efficacy.

WHO Debate: Impact, Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit Medical Products (SSFFCMP Or Just SFC) And Quality, Safety And Efficacy (QSE)

An item appeared on the [agenda](#) of WHA61 (May 2008) surprised a number of member states. The item, 11.13 'Counterfeit medical products' (with Secretariat paper [A61/16](#)) had not been mandated by any resolution of the Assembly, but had been included on the agenda at the request of UAE and Tunisia (at the EB122 in Jan 2008) without substantive discussion.

Document [A61/16](#) provided a survey of the problem of counterfeit medical products and described with some pride the establishment of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) and the work which had been progressed through IMPACT since its launch in 2006. The document listed the IMPACT 'stakeholders' including strong representation of the RBPMs.

The Taskforce was established in 2006 and work was funded (nearly US\$ 2.6 million) mainly by specified contributions from WHO's Member States through the European Commission and the Governments of Australia, Germany, Italy and the Netherlands (altogether 68%) and by WHO (28%). It also benefitted from significant in-kind support from the pharmaceutical industry.

Of particular interest to many MS was the report on 'Principles and elements for national legislation against counterfeit medical products' endorsed by the IMPACT General Meeting in Lisbon 12 December 2007 ([see](#)). While this report stated that it did not 'specifically address' intellectual property infringements the principles which it recommended be enacted in government legislation included a number of references to ensuring that pharmaceuticals are appropriately licensed and authorised. It is not hard to see the issue of patent linkage (and the criminalisation of IP infringement) being developed.

Pre-Existing Streams of Work in WHO on Medicines

It is important that the debate over the role of IMPACT and the role of WHO in policing IP infringements be seen against the several pre-existing streams of WHO's work in medicines policy. This includes:

- essential medicines lists
- medicines regulation support
- rational use of medicines
- containment of anti-microbial resistance

Essential Medicines

WHO has had an essential medicines program since 1975. See Laing and colleagues (2003) for a detailed history of the essential medicines program. See also the WHO [programs page on essential](#)

[medicines](#). The purpose of the essential medicines list (EML) is to provide guidance to government authorities as to the priority drugs based on health needs, efficacy, safety and cost. These are the drugs which should be given priority in government supply chains, in subsidy and reimbursement programs, and in programs to promote rational use. Of course the obverse of an explicit inclusive list is an implicit list of excluded drugs; not necessarily denied marketing rights but facing an additional hurdle in marketing. In particular big pharma has been and are worried that the concept of a limited list of priority drugs might migrate to the richer countries.

During the discussion of the Executive Board in January 1975, concern was expressed about the pressure exerted on developing countries to purchase drugs. Despite their best efforts, as one African member said, “they were none the less exposed to unscrupulous activities on the part of certain pharmaceutical industries, and he wondered whether WHO could not help in that connexion.” (Third ten years)

The Director-General, in his reply, stressed the problem of sales pressure from drug manufacturers, especially in developing countries. Without unstinting support from the Executive Board and the Health Assembly, the secretariat could do very little to stop that. The Health Assembly would have to consider ways of offering protection that was not merely technical but also political and moral. The global social responsibility that certain members had called for could be exercised only if governments were prepared to limit the activities of the pharmaceutical industry. (Third ten years)

Laing and colleagues (2003) recall that

In 1987, the International Federation of the Pharmaceutical Manufacturers Associations (IFPMA) called the medical and economic arguments for the EML fallacious and claimed that adopting it “could result in sub-optimal medical care and might reduce health standards”. The pharmaceutical industry was concerned that the EML would become a global concept applicable to public and private sectors in developing and developed countries, and were especially opposed to attempts by developed countries to introduce limited medicines lists. In 1982, a spokesman of the US pharmaceutical manufacturers organisation said “The industry feels strongly that any efforts by the WHO and national governments to implement this action program should not interfere with existing private sector operations”.

The current IFPMA paper about essential medicines repeats that view and says that policies extending restrictive drug policies to industrialised countries pose a serious threat to the delivery of effective health care and to investment in drug research

From a public health perspective the idea of an essential medicines list is a foundational principle for a national medicines policy. However, it also constitutes a relative barrier to the unscrupulous marketing of less efficacious or more expensive drugs. The bigger danger is that it could become entrenched in richer countries or affect sales in countries with richer classes.

Statutory Medicines Regulation

Statutory medicines regulation is a core principle of medicines policy and WHO has been involved since the early 1950s.

One of WHO’s earliest projects (from 1948) was assembling an international pharmacopoeia. WHO’s role in assigning non-proprietary names was established in 1955. A study group was convened in 1956 to develop principles which should be expressed in governments approving drugs for marketing. A study group on evaluating the safety and efficacy of drugs was mandated by WHA15 (1962).

WHO’s role in assuring manufacturing standards can be traced back to the early 1950s and guidance around the production of penicillin. (World Health Organization 1958). Work which led to standards for good manufacturing practice was commissioned in WHA20.34 (1967).

The evaluation of efficacy and safety, adverse drug reaction reporting and post-marketing surveillance remained hot topics during the 1970s. The first International Conference of Drug Regulatory Agencies was held in 1976.

Monitoring of adverse drug reactions was a recurring concern in the Assembly after thalidomide in 1961 but effective post marketing surveillance remains weak.

For more see: [medicines regulatory support](#).

Rational Use of Medicines

The explicit focus on the rational use of medicines appears to date back to the mid 1980s. But the national and international investment here is trivial compared with the investment in marketing by big pharma.

See [WHO \(2012\) Technical report on responsible use of medicines](#).

Anti-Microbial Resistance

The rising crisis of anti-microbial resistance (AMR) has been subject to repeated hand wringing at the Assembly but there are powerful forces opposed to any effective action, not least big pharma.

See [WHO topic page](#).

Also [Implementation Workshop on the WHO Global Strategy for Containment of Antimicrobial Resistance \(2002\)](#).

Returning to the Discussion of Counterfeit and Impact

The focus of the World Health Assembly (WHA63, May 2010) returned to 'Counterfeit medical products' as [Agenda Item 11.20](#) supported by [A63/23](#) and [A63/INF.DOC./3](#) in May 2010.

Gambia, Ghana, Nigeria, Tunisia and the United Arab Emirates tabled a resolution congratulating WHO and other IMPACT stakeholders and urging further support for IMPACT (see [Report from page 113](#)). Most of the early speakers in the following debate were positive. However, India and Argentina expressed some concerns about potentially conflicting objectives and Thailand asked how this item had made it to the agenda of the WHA when it had not been mandated by previous resolutions and had not been discussed at the EB. Finally Brazil stated that it did not recognise the legitimacy of IMPACT or of the resolution. It was agreed to defer further consideration and refer it to the EB.

Parallel Developments

Before tracing the further consideration of 'counterfeit medical products' in WHO it is useful to review three parallel initiatives which many of the same parties were driving:

- ACTA: the Anti-Counterfeiting Trade Agreement;
- European seizures of generic pharmaceuticals in transit through European ports;
- patent law revisions in Kenya and Uganda and the East Africa Community Anti-Counterfeiting Policy and Bill; and
- the drive by the USA to include 'patent linkage' in the proposed Trans Pacific Partnership Agreement.

ACTA

While many of the MS delegates at WHA61 were wondering where IMPACT had come from preparations were in full swing for the first formal round of negotiations around the proposed Anti-Counterfeiting Trade Agreement (ACTA).

[Wikipedia](#) reports (Anonymous 2013) that the USA and Japan had been working on the Anti-Counterfeiting Trade Agreement since 2006. This initiative was unambiguously focused on intellectual property infringements. While the above debate was progressing at the WHA (May 2008) the negotiating partners were preparing for the first formal round of negotiations towards ACTA (3-4 June 2008, also in Geneva). Since the negotiations for ACTA were conducted entirely in secret it is not surprising that some delegates to WHA may not have been aware that it was going on. Since big pharma was (a) part of IMPACT, (b) involved in the design of ACTA, and (c) present at the WHA, at least they knew what was going on. (Big pharma's involvement in IMPACT and ACTA was not an isolated initiative. One of the business organisations behind the IP agenda was the International Chamber of Commerce's (ICC) Business Action to Stop Counterfeiting and Piracy ([BASCAP](#)) established in 2004.)

MSF's Access Campaign (MSF 2012) provides an extended analysis of the implication of ACTA for access to medicines (see). Two provisions of particular relevance to the IMPACT saga are the provisions requiring seizure in transit where IP infringements are suspected and the obligation on drug regulatory bodies to have regard to the patent status of medicines.

This latter provision appears to constitute a strategy for linking approval for marketing to inspection of IP status (see below under 'patent linkage').

European Seizures

From October 2008 to May 2009 there were at least six seizures of India generic drugs in transit through European ports but destined for Colombia, Peru, Brazil, Nigeria and Vanuatu (Khor 2009). These were drugs that were legitimate in the source country and the destination country and were not destined for import into the country of transit.

The EU claimed that the seizures were required under a 2003 regulation but after India took the EU to the WTO the EU agreed to amend the regulations (Anonymous 2010) although Baker (2012) believes the amendments don't go far enough.

Kenya Counterfeit Act

In the same year, 2008, Kenya elected to amend its patent laws to put in place much tighter controls over IP. The Kenyan law was challenged in 2009. Christa Cepuch, the director of programs for Health Action International Africa (HAI Africa) [explained](#) that the Act "contains a vague definition of counterfeiting which could be read to include generic drugs". The law makes the manufacturing, importation or sale of "counterfeit goods" a criminal offence rather than a civil matter, which is the usual way in which disputes over intellectual property rights are resolved. The onus to verify whether goods are fakes or not has been put on customs officials and police officers. "We'll have Kenya Revenue Authority officials trying to figure out if drugs are fakes or not. This increases the risk of products being labelled fakes," Cepuch says. "The law further gives these officials excessive powers, making the process difficult and expensive. Moreover, the onus to prove the products are not fakes lies with the accused, a price many will not be willing to pay" (Anyangu-Amu 2009).

In April 2012 the High Court [ruled](#) that the Act was too broad and vague with respect to counterfeit and generic medicines (IP-Watch 2012).

The rise of the counterfeit agenda in Africa was in part due to the agitation of an organisation called the [Investment Climate Facility for Africa](#) which was established "to address key bottlenecks

impeding African countries in improving their investment climates". It is a public-private financial facility involving the UK (\$30 million over 3 years), Royal Dutch Shell and the Shell Foundation (\$2.5 million over 5 years), and Anglo American (\$2.5 million over 5 years). ICF's development partners also include the governments of Germany, Ireland, Netherlands, Norway, South Africa as well as the Africa Development Bank and the International Finance Corporation.

One of ICF's projects has been working with the East African Community to develop an anti-counterfeiting policy and an anti-counterfeiting bill. While EAC officials are upbeat about the need for this bill (see Wambi Michael interview with Juma Mwapachu, secretary general of the East African Community (EAC), [part 1](#) and [part 2](#)). Musungu (2010) provides a detailed critique of the evidence, policy logic and implications of the proposed policy and Herman (2013) [reports](#) that the health departments of the EAC are pushing back.

Patent Linkage

It is evident that patent linkage (actually criminalising IP infringements) is high on the agenda of the RBPMs, industry partners (such as ICC) and their state sponsors. Leaked US negotiating text from the Trans Pacific Partnership Agreement negotiations reveal that the US is seeking to implement 'patent linkage' which means that drug regulatory agencies would be required to ascertain the IP status of any product being brought forward for marketing approval and to notify any parties who may hold IP rights in that product. More from Kiliç and Maybarduk (2012) [here](#).

Returning to WHO Deliberations

EB124 (Jan 2009) considered Agenda Item 4.11 'Counterfeit medical products'. The Board had before it a report from the Secretariat ([EB124/14](#) plus a corrigendum [EB124/14 Corr.1](#) and a note on financial implications, [EB124/14 Add.1](#)) including a draft resolution commending the Secretariat for its work in IMPACT and proposing to continue to work down the same pathway. Not clear where the draft resolution came from.

There was a long vigorous and in-depth discussion with many interventions (see [records from page 146](#)). In the end the DG commented that there was consensus that the Secretariat should focus on the public health concerns and continue to support Member States in strengthening their drug regulatory authorities in that regard. She anticipated a new report for WHA62 (May 2009) addressing the public health dimension of the issue of counterfeit medical products, without a draft resolution. The Secretariat would review the Global strategy and plan of action to identify points that might be relevant to the revised report on counterfeits.

Counterfeit medical products appeared on the WHA62 (May 2009) Agenda Item as 12.9 'Counterfeit medical products' with a new report ([A62/13](#) on counterfeit medical products, and [A62/14](#) on IMPACT). However, owing to the H1N1 influenza epidemic it had been decided to shorten the Assembly and this item was deferred to WHA63 in 2010.

The issue was considered by WHA63 in May 2010 as [agenda item 11.20](#) and with Documents [A63/23](#) and [A63/INF.DOC./3](#). Three draft resolutions were tabled (see [report from page 86](#)) from Latin America, Africa and SEARO (India and Thailand). The UNASUR draft called for an IG WG to work of falsified medical products from a public health perspective, excluding consideration of intellectual property. The African resolution did not mention IMPACT but congratulated the Secretariat for its leadership in these matters and urges continuation. The SEARO draft noted that the TRIPS Agreement defines 'counterfeit' as a trade mark infringement and urges that the term not

be used to refer to medical products compromised in quality, safety and efficacy (QSE). The draft urges WHO cease its involvement in IMPACT and focus on the challenge of QSE compromised medical products. There was a long and interesting debate but no agreement on the three resolutions. The contribution from Kenya was particularly interesting:

Dr YANO (Kenya) said that the issue of the legitimacy of the Taskforce had also arisen at the Sixty-first and Sixty-second World Health Assemblies. The continued use of the WHO logo by the Taskforce and its activities, such as in Kenya where it had assisted the Ministry of Industry to legislate against counterfeits without going through the Ministry of Health, prompted questions about who in the Secretariat persisted in advancing the interests of that entity when its legitimacy was in question, who funded the Taskforce's activities, who were the constituents of the Taskforce and how had they been chosen. The issue should be resolved definitively.

A drafting group was appointed and India (for SEARO) and Ecuador (for UNASUR) submitted a draft decision on SSFFCMPs calling for an OE IG WG (see [discussion](#) at p140, 171, 201) which was adopted as [WHA63\(10\)](#), see [p67](#).

The issues were reviewed at EB128 (Jan 2011) under [agenda item 4.8](#) with the new suit case term 'Substandard/spurious/falsely-labelled/falsified/counterfeit medical products (SSFFCMP). The Sixty-third World Health Assembly had decided in [WHA63\(10\)](#) to establish a time-limited and results-oriented working group on substandard/spurious/falsely-labelled/falsified/counterfeit medical products. The meeting of the working group was scheduled to be held from 9 to 11 December 2010. However, (as the DG [explained](#)) 'following consultations with Member States, the meeting was postponed to early 2011'. The business before the Board was therefore to note the (absence of a) report. Some of the highlights of the [discussion \(from p 94\)](#):

- India comments on the parallel activities of certain MS around the ACTA;
- Bangladesh expressed regret about the deferral of the planned meeting of the WG;
- Mauritania spoke about the great work that IMPACT was doing in Africa;
- Brazil endorsed the comments of India and regretted the delay in getting the WG together;
- The US reaffirmed its strong support for IMPACT;
- Nigeria spoke about the importance of the work that IMPACT is doing;
- South Africa supported India and Brazil and hoped that the report of the IG WG would be available in time before the WHA.

The OE WG of MS on SFC met from 28 Feb-2 Mar, 2011 (see [web page](#)).

WHA 64 (May 2011) received a report from the WG ([Document A64/16](#)) under [agenda](#) Item 13.7 'Substandard/spurious/falsely-labelled/falsified/counterfeit medical products'. The WG reported that it had considered WHO's role in relation to quality, safety, efficacy and affordability; it had considered QSE compromised products such as SSFFCMPs; and it had considered but not achieved consensus on WHO's role in IMPACT. The WG requested an extension of time. In considering this report (see [report from page 174](#)) the Assembly had before it a draft decision tabled by Canada, Monaco, Russian Federation, Switzerland, United States of America and Zambia agreeing to the extension of time. There was a long discussion in which the position of various MSs were elaborated. (The contribution of Canada is particularly staggering, suggesting that IMPACT is the only forum where WHO can work with national drug regulatory agencies, completely ignoring the [International Conference of Drug Regulatory Authorities](#).) The decision was approved.

The second meeting of the OE WG of MS on SFC met in Geneva from 25-28 October 2011 ([see](#)) and reported to EB130 (Jan 2012) under [agenda](#) item 6.13. The report from the WG (Documents [EB130/22](#), [EB130/22 Add.1](#)) contains specific recommendations for the consideration of the Board and the Sixty-fifth World Health Assembly (in line with decisions [WHA63\(10\)](#) and [WHA64\(10\)](#)). The WG proposed (in [EB130/22 page 5](#)) a draft resolution for

the EB to recommend to the Assembly. The resolution would mandate a new Member State mechanism for “international collaboration among Member States, from a public health perspective, excluding trade and intellectual property considerations, regarding “substandard/spurious/falsely-labelled/falsified/counterfeit medical products” in accordance with the goals, objectives and terms of reference annexed to the present resolution”. There was a long debate over the draft resolution (see [report from p191](#)) after which the resolution was adopted as amended, and the Assembly “decides to establish a Member State mechanism”. Some highlights from the debate:

- India reviewed the major issues to be attended to and urged that WHO sever its links with IMPACT;
- Switzerland welcomed the new Mechanism;
- The US welcomed the new Mechanism and announced that it would transfer its support from IMPACT to the new mechanism as soon as it was established;
- The EU reminded the Assembly that the success of the mechanism would depend on the ability of the WHO to mobilise sufficient funds;
- Argentina offered to host the first meeting of the Mechanism provisionally to be held over 3 days in Buenos Aires in October 2012;
- China asked that the resolution be amended to allow that MS would participate in the Mechanism on a voluntary basis;
- Nigeria commended the report but urged that the new mechanism should include the private sector, and NGOs as well as MSs (effectively reproducing IMPACT).

At this point the Board adjourned. When the debate resumed

- Nigeria challenged the offer of Argentina to host the first meeting of the Mechanism;
- Brazil responded, noting that IMPACT remained a highly divisive issue, which unless addressed could threaten the unity of the new Mechanism;
- Bangladesh looked forward to WHO disengaging with IMPACT;
- Thailand endorsed the views of India and Bangladesh and expressed concern about the continuing relationship with IMPACT.

The Board adopted the resolution ([EB130.R13, page23](#)) as amended (the Chinese resolution emphasising the voluntary nature of MS participation).

WHA65 (May 2012) reviewed the resolution as [agenda item 13.13](#) supported by [A65/23](#) conveying the report of the OE WG of MS and the EB’s draft resolution. There was a long and vigorous discussion in Committee B (see [summary records from page 231](#)). The draft resolution was approved.

The MS Mechanism on SFC was [launched](#) in Buenos Aires 19-21 Nov 2012.

The report of its first meeting ([EB132/20](#)) was considered by EB132 (Jan 2013) under [agenda item 10](#). Important points from the report of the first meeting:

- There was agreement on how the MSM would operate but;
- There are a lot of square brackets in the draft Work Plan (Appendix 2);
- The meeting had not been able to establish a Steering Committee (waiting on nominations from each region of two vice-chairpersons) and did not have a Chairperson (emerging as a critical issue);
- The meeting decided to establish an open-ended working group to identify the actions, activities and behaviours that result in SFFC medical products;
- The meeting decided to progress work on those activities under areas 1, 2, and 3 of the workplan that were agreed.

There was a longish debate in the EB in which MSs articulated their perspectives. Some of the highlights (see [records](#) from page 172, then 203):

- The US appreciated the fact that the Vice-Chairpersons had been identified and hoped that the Chairperson would be chosen soon; supported Brazil's offer to chair the OE WG on Actions, Activities and Behaviours;
- Switzerland, on behalf of Europe, was critical of the failure to adopt a workplan and appoint a Chairperson;
- Lithuania, on behalf of the EU, was likewise scathing about the failure to finalise a work plan; WHO's credibility is at risk!
- Panama: serious problem, need to find resources to support WHO's involvement;
- Sierra Leone: serious problem; Africa proceeding with African medicines regulatory agency
- China: keen to be involved; volunteered as a vice-chairman;
- Iran: regret the delay in getting started; priorities for Workplan;
- Lebanon: pricing, technology transfer, generics as well as QSE;
- Australia: regrets delays, counterfeit a big problem; multisectoral approach needed;
- Nigeria: serious problem; Nigeria has much experience to share;
- Brazil: proposes to call the Mechanism 'the mechanism of Buenos Aires';
- India: major exporter; keen to proceed with mechanism;
- Argentina: even tho workplan not finalised, lot of work which can commence;
- UK: regrets delay; supports Australia's concern about AMR;
- Thailand: welcomes report; emphasises need to work on drug regulatory structures at country level as well as through the mechanism internationally.

Dr Kieny (ADG) was keen to organise meeting of SC before WHA. The Board noted the report.

SFC returned to WHA 66 (May 2013) as [agenda item 17.1](#) supported by [Doc A66/22](#) which records that the MS mechanism had met in BA in Nov 2102; that the work plan was not fully agreed upon but that there was a commitment to an OE MS WG on Actions, Activities and Behaviours which drive SFC. A Steering Committee was established but there was no agreement on the chairperson. (Rumor has it that Nigeria wants the Chair and Africa is supporting Nigeria but that Latin America does not accept Nigeria because it has long been a strong supporter of IMPACT.)

An informal meeting of the SC (the two vice-chairpersons from each region) had taken place in Geneva on 11 April 2013, chaired by the Secretariat. The OE WG on Actions, Activities and Behaviours was due to meet in July 2013 and it was anticipated that the second meeting of the MS Mechanism would take place in Nov 2013.

WHA66 saw a long [debate](#) in which many countries reiterated well known positions including variously frustration and vindication regarding the delay in getting started and the deadlock over the position of Chairman. Brazil suggests a rotation among the vice chairpersons so the SC can get started. Doc A66/22 was noted.

The Assembly decided A66(10) that: The Sixty-sixth World Health Assembly, having considered the report on substandard/spurious/falsely-labelled/falsified/counterfeit medical products, decided to recommend that the chairmanship of the Steering Committee of the Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products should operate on the basis of rotation, on an interim basis, without prejudice to the existing terms of reference of the mechanism.

The OE WG of MS to identify Actions, Activities and Behaviours which result in SSFFC MPs was scheduled to meet on 23-24 July 2013.

[Document A/MSM/WG/1/2](#), prepared by the Secretariat for the WG meeting records that Brazil prepared a 'non-paper' on actions activities and behaviours which had been posted on the [web-based platform](#) for internet mediated consultation (not public) and as of 10 July, three countries had posted comments (Argentina, Mali and USA).

Summary

There are two major issues at stake here: first, the project of tightening IP protection, including patent linkage and the criminalisation of IP infringement (and the reaction to this project on the grounds of affordability and innovation); and second, the regulation of medicines supply (nationally and internationally) to guarantee quality, safety and efficacy and the role of IP policing in such regulation.

The RBPMs are central if somewhat shadowy players in both fields. It seems very likely that RBPMs (directly or indirectly) are able to procure the voice of member state representatives. See for example, the intervention of Dr Yano of Kenya at WHA63, May 2010 (see [report of debate, p97](#)) and also the [WHO Watch comment on the Psoriasis case](#).

On regulation for QSE there is wide agreement that the national and regional medicines regulatory authorities (MRAs) should be the central institutions and that WHO, in association with the [International Conference of Drug Regulatory Authorities](#), is the responsible body to support the development of MRAs. However, the RBPMs are conflicted here because MRAs also have a brief to worry about marketing practices and over servicing and even pricing and the last thing RBPMs want is any attention to their marketing practices or any restrictions on overprescribing. The great advantage of IMPACT, from the point of view of RBPMs, was that it could address the IP issues, and perhaps the most egregious sources of rubbish drugs, without any focus on their marketing practices or over-prescribing.

References

- Anonymous (2010). Drug seizure issue settled, EU agrees to amend laws. Economic Times.
- Anonymous. (2013). "Anti-Counterfeiting Trade Agreement." Retrieved 24 August, 2013, from http://en.wikipedia.org/wiki/Anti-Counterfeiting_Trade_Agreement.
- Anyangu-Amu, S. (2009, Dec 21, 2009). "KENYA: Anti-Counterfeit Law "Violates Right to Life and Health"." Retrieved 24 August, 2013, from <http://www.ipsnews.net/2009/12/kenya-anti-counterfeit-law-violates-right-to-life-and-health/>.
- Baker, B. K. (2012). Settlement of India/EU WTO Dispute re Seizures of In-Transit Medicines: Why the Proposed EU Border Regulation Isn't Good Enough. PIJIP (Program on Information Justice and Intellectual Property) Research Papers. Washington, D.C., American University Washington College of Law.
- IP-Watch. (2012, 21 April 2012). "Kenyan High Court's Overturning Of Anti-Counterfeit Law Hailed." Retrieved 24 August, 2013, from <http://www.ip-watch.org/2012/04/21/kenyan-high-courts-overturning-of-anti-counterfeit-law-ailed/>.
- Khor, M. (2009). "Row over European seizures of low-cost drugs." Third World Network Retrieved 24 August, 2013, from <http://www.twinside.org.sg/title2/resurgence/2009/228-229/health1.htm>.
- Kılıç, B. and P. Maybarduk (2012). Comparative Analysis of the United States' TPPA Intellectual Property Proposal and Chilean Law, Public Citizen.
- Laing, R., B. Waning, A. Gray, N. Ford and E. t. Hoen (2003). "25 years of the WHO essential medicines lists: progress and challenges." Lancet 361(9370): 1723-1729.
- MSF (2012). A blank cheque for abuse: the Anti-Counterfeiting Trade Agreement and its impact on access to medicines. MSF Briefing Documents.

Musungu, S. F. (2010). The Potential Impact of the Proposed East African Community (EAC) Anti-Counterfeiting Policy and Bill on Access to Essential Medicines, HIV/AIDS Practice, Bureau for Development Policy (BDP), United Nations Development Programme (UNDP).

Scherer, F. and J. Watal (2001). Post-TRIPS options for access to patented medicines in developing countries. Commission on Macroeconomics and Health Working Paper Series. Geneva, WHO.

World Health Organization (1958). The first ten years of the World Health Organization. Geneva, WHO.