SFMPs @ WHO (1992-2025)[1]

David G Legge
1 Sept 2013
Revised 22 Apr 2025

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 (2002) 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 to strengthen IP rights through 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); 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 earnings from the 'export of services' including monopoly pricing enabled by IP protection.)

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);
- 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; and
- 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

1. Work in progress. Currently undergoing further revision

questions of IP with issues of quality, safety and efficacy (QSE) most notably through the International Medical Products Anti-Counterfeiting Taskforce (IMPACT), (more below).

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. Research for this review draws heavily on the WHO Tracker, maintained by the People's Health Movement. See Tracker links to discussions of substandard and falsified medicines in the Executive Board and the World Health Assembly.

Counterfeit: Conflating QSE with IP status

In April 1992 WHO and IFPMA conferred regarding 'counterfeit drugs'. Ostensibly the focus of the meeting was on substandard and falsified medicines and the need to regulate for quality, safety and efficacy. The use of the term 'counterfeit' was accepted by meeting attendees as referring to substandard and falsified medicines, although WHO had previously used the term 'quality' in commenting on these issues.

It is clear that IFPMA representatives were fully aware that the term 'counterfeit' was also used to apply to breaches of intellectual property rights. Indeed, the report of the meeting records that:

> "A discussion was held on the GATT proposals for the protection of intellectual property rights and for control of all types of counterfeiting, and the potential application of these proposals for the control of counterfeit pharmaceuticals at an international level."

While the WHO representatives at the meeting may have believed that 'counterfeit' unambiguously connoted shortfalls in quality, safety and efficacy, the IFPMA representatives would have been very aware that in trade law the term referred to breaches of intellectual property rights. Indeed by 1992 Big Pharma in the US had been deeply engaged in the development of the TRIPS Agreement through their relationship with the US Trade Representative (Drahos 1995):

> "In the 1980s those parts of U.S. business involved in the global trade of information, like the movie industry, the pharmaceutical industry, and the computer industry, had campaigned successfully to link intellectual property protection to trade. Their efforts saw the inclusion in the GATT of a code on intellectual property, known as TRIPS. TRIPS was in many ways a remarkable achievement, but it was not the main aim of the committee that had been responsible for some of the strategic thinking on the intellectual property issue. This committee, known as ACTN (Advisory Committee for Trade Negotiations), was staffed by CEOs of various U.S. companies like IBM, DuPont, and Pfizer. Its task was to provide the U.S. Trade Representative with advice on trade negotiations. During the 1980s ACTN had argued that the United States should in the forthcoming GATT negotiations strive toward getting an agreement on the liberalization of investment. One consequence of investment liberalization would be that intellectual property protection would have to be strengthened so that information-based industries could invest anywhere in the world."
>
> "Particularly influential was the work of the Intellectual Property Committee (IPC). It was formed in 1986 with the specific purpose of improving intellectual property protection. Its members were Bristol-Myers Squib, Digital Equipment Corporation, FMC, General Electric,

Hewlett Packard, IBM, Johnson & Johnson, Merck, Pfizer, Procter & Gamble, Rockwell International, and Time Warner."

The preambulatory paragraphs of the TRIPS Agreement 1994 articulate clearly 'the need for an agreement dealing with international trade in counterfeit goods' and recognise the policy objectives of protecting intellectual property.

In hindsight it appears that the conflation of breaches of IPRs with shortfalls in quality, safety and efficacy in the use of 'counterfeit' was a deliberate strategy of Big Pharma. It appears that the WHO representatives at the workshop were somewhat naïve in accepting this conflation.

The 1988 version of WHO's Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce (revised at WHA41 in 1988) does not use the term counterfeit; it speaks about the quality of pharmaceutical products. However, resolution WHA41.16 adopted in May 1988 introduces the term 'counterfeit' in the new portmanteau term 'falsely labelled, spurious, counterfeited or substandard pharmaceutical preparations'.

Tortured terminology

In 1988 and 1992 the WHA agenda items dealing with these issues were headed, 'Rational use of drugs' and 'Safety and efficacy of pharmaceutical products'. However, by 2008 when the International Medical Products Anti-Counterfeiting Taskforce was introduced to the Assembly, the item was headed, 'Counterfeit medical products'. The corresponding agenda item at WHA63 (2010) was headed with the same title but the decision adopted, WHA63(10), in May 2010, was headed, 'Substandard/spurious/falsely-labelled/falsified/counterfeit medical products' (SSFFCMP) reflecting an impasse over whether to exclude or include considerations of IP infringement in discussions (and regulation) of quality, safety and efficacy.

This term, SSFFCMP, was kept in use until 2017 when WHA70 adopted the advice of the Member State Mechanism (more below) to adopt a new set of definitions and "to replace the term "substandard/spurious/ falsely-labelled/falsified/counterfeit medical products" with "substandard and falsified medical products" (SFMPs) as the term to be used in the name of the Member State Mechanism (MSM) and in all future documentation on the subject of medical products of this type" (WHA70(21)) as recommended in the fifth report of the MSM, A70/23) .

It appears that the impasse about terminology reflected a reluctance on the part of certain member states to cease using the term 'counterfeit' because of its relevance to IP infringements. Japan was explicit about its wish to keep IPR infringement on the table during WHO considerations of quality, safety and efficacy (see Japan intervention in the debate regarding the move from SSFFCMP to SFMP).

IMPACT: The International Medical Products Anti-Counterfeiting Taskforce (IMPACT)

An item appeared on the agenda of the World Health Assembly in May 2008 which 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 among the IMPACT 'stakeholders' a 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%) (was this the US contribution laundered through the WHO Secretariat?). It also benefitted from significant in-kind support from the pharmaceutical industry.

Of particular interest to many member states 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. 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" (which could refer to marketing authorisation and/or IP licensing).

Systems of patent linkage (the harnessing of drug regulatory authorities in the policing of IP rights) were pioneered in the US with the Hatch-Waxman Act of 1984 and were included, at the behest of the US, in a number of bilateral and plurilateral trade agreements to which the US was a party.

Bringing the term counterfeit into WHO usage may have been directed to clearing the way for WHO to endorse a patent linkage role for drug regulatory agencies.

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
- medicines certification scheme
- rational use of medicines
- ethical practices in drug marketing
- 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. National regulatory agencies focusing particularly on marketing approval and post-marketing surveillance play a critical role in manging quality, safety and efficacy. WHO provides ongoing support to the development and operation of national and regional medicines regulatory agencies. At a global level the International Conference of Drug Regulatory Authorities (ICDRA) (first held in 1976) provides an important forum for sharing experience and expertise among national, regional and global officials.

The central importance of the ICDRA is challenged by the International Conference on Harmonisation which also discusses regulatory norms and mechanisms (see https://www.ich.org/ and /about ICH/history). The difference between ICH and the ICDRA is the inclusion of the global pharmaceutical corporations in the former. Not surprisingly this is their preferred forum.

Medicines certification

A medicines certification scheme was introduced in 1975 as part of a suite of new policies encouraged by the new (1974) DG, Halfdan Mahler. (The package included guidelines around good manufacturing practice, rational use and an essential medicines list.)

The medicines certification scheme was directed to regulating the quality of medicines being exported and involved the regulatory authority in the exporting country certifying that:

> (a) the product being exported is authorized for sale or distribution within the exporting Member State (if not, the reasons therefore would be stated on the certificate); and
>
> (b) the manufacturing plant in which the product is produced is subject to inspections at suitable intervals to show that the manufacturer conforms to requirements for good practices in manufacture and quality control, as recommended by the World Health Organization in respect of products to be sold or distributed within the country of origin or to be exported.

The scheme was voluntary and it appears that take up was slow.

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.

Ethical criteria for medicinal drug promotion

Following the WHO Conference of Experts on the Rational Use of Drugs held in Nairobi in November 1985, WHO prepared a revised drug strategy which was endorsed by the Thirty -ninth World Health Assembly in May 1986 in resolution WHA39.27. This strategy included, among other components, the establishment of ethical criteria for drug promotion based on the updating and extension of the ethical and scientific criteria established in 1968 by the Twenty -first World Health Assembly in resolution WHA21.41.

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 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 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). Herman (2013) reports that the health departments of the EAC are pushing back.

Patent Linkage

It is evident that patent linkage (harnessing drug regulatory authorities in policing 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 revealed that the US was 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 Kılıç and Maybarduk (2012) here.

Returning to WHO Deliberations on IMPACT

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 WG of MS on SSFFCMPs 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);
- Japan supported action on SSFFCMPs but emphasised that the Japanese Government's concerns about such products "were not limited to safety and quality but included issues concerning the violation of trademarks and design rights".

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 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 as WHA65.19.

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 SSFFC 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.

SDFFCMPs returned to WHA 66 (May 2013) as agenda item 17.1 supported by A66/22 which records that the MS mechanism had met in BA in Nov 2012; 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. (Nigeria wanted the Chair and Africa was supporting Nigeria but that Latin America did not accept Nigeria because it had 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.

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. 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 Open Ended Working Group on Actions, Activities and Behaviours met in 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). The report of the OE WG was considered by the second meeting of the MSM in A/MSM/2/2. The WG presented a useful list of actions, activities, and behaviours that result in SSFFCMPs. The MSM Workplan in Appendix 2 of EB134/25 was noted.

The MSM has operated since November 2012 with 13 meetings to Nov 2024 (see webpage). The name change, from SSFFCMP to SFMP, took place in 2017 (MSM/6). The trajectory of the MSM can be reviewed in the sequence of MSM reports to the governing bodies from MSM/1 to MSM/13: A/MSM/1/4, A/MSM/2/6, A/MSM/3/3, A/MSM/4/10, A/MSM/5/8, A/MSM/6/4, A/MSM/7/6, A/MSM/8/4, A/MSM/9/7, A/MSM/10/11 Rev.1, A/MSM/11/6, A/MSM/12/10, A/MSM/13/8.

The MSM has been evaluated twice. The 2017 report (summarised in A70/23 Add.1). This report provides a useful overview of the work of the MSM from 2012-2016. It is unfortunate that the full report appears to have been removed from the WHO website.

Gaps identified in the evaluation included an unfinished technical agenda; limited coordination processes among the different actors involved in the work of the mechanism; and the inadequate systems of communication and dissemination of information between the mechanism and Member States, as illustrated by the limited reach of the products and activities of the mechanism.

The second review was undertaken in 2023-24 and reported in October 2024 (Executive summary in EB156/12 (Jan 2025) and full report here). The report was reviewed at the 13th meeting of the MSM in November 2024 and the MSM decided that they needed more time to consider recommendations 1 & 5 (A/MSM/13/8). In EB156(25) the Board recommended that the WHA defer acting on the recommendations of the evaluation until WHA79. Extracts from the findings:

> The Member State mechanism's format and governing structure initially worked well but are now less suited to its operational focus. The mechanism enjoys important strengths: potential for consensus-building; relevant objectives; a reach beyond the health sector; and visibility at the World Health Assembly. It also faces major challenges: most Member States are not active; some working groups lack both participation and expertise; working group and plenary meeting participation is limited; and very few Member States offer funding
>
> … Key factors that have hindered Member State mechanism progress and effectiveness include: suboptimal Member State participation; variable effectiveness of working groups and lack of accountability; limited engagement with other (non-State) stakeholders; and lack of funding. Country-specific factors, some of which are outside the control of the Member State mechanism, include limited leadership and commitment, weak capacity of regulatory and health systems, and poorly enforced laws.

Summary

There are two major issues at stake here: first, the project of tightening IP protection, including patent linkage and the harnessing of drug regulatory agencies in the policing of IP rights (a Big Pharma objective); 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 (a public health objective).

The surprise announcement of IMPACT in 2008 elicited a strong response from Asian and Latin American member states (the response from African member states was mixed). IMPACT was widely

seen as a strategy (of Big Pharma and its host member states) to prevent or slow the introduction of generic medicines into pharmaceutical markets through the use of the term 'counterfeit' to conflate of QSE issues with the protection of IPRs. This would have a serious impact on access and affordability. The generics are generally cheaper; the brand name drugs are forced to compete on price, and where national pharmaceutical subsidy programs operate the generics could displace the brand name drugs.

It would seem self-evident that regulation for QSE should be centred around national and regional medicines regulatory authorities (MRAs) and that WHO, in association with the International Conference of Drug Regulatory Authorities, should be the responsible body to support the development of MRAs.

WHO has a broad agenda in relation to drug regulation, including rational use, ethical marketing, essential medicines lists, and pricing and affordability as well as QSE. The items on this agenda carry risks for Big Pharma. WHO also has privileged access to ministries of health and drug regulatory personnel, both through regional and country offices and through the ICDRA.

Further empowerment of WHO in support of DRAs is not in Big Pharma's interests. The advantage of IMPACT, from the point of view of Big Pharma, was that it could help to harness the authority of drug regulators in protecting IP rights without any focus on marketing practices, over-prescribing or price gouging.

The creation of the MSM was a rearguard action, following the rejection of the IMPACT, designed to prevent the full empowerment of the WHO Secretariat in relation to QSE regulation. Notwithstanding the rejection of IMPACT, several powerful member states were still seeking to harness the medicines regulatory system (including both WHO and the DRAs) in the policing of IP infringement. Japan spoke on at least two occasions of keeping IPRs on the WHO agenda. The US continued to advance the patent linkage project through the negotiation of such provisions in preferential trade agreements.

The work of the MSM has demonstrated the breadth and complexity of combatting SFMPs and regulating for QSE. (See the MSMs 13th Report (A/MSM/13/8) which lists the current 'prioritised activities' including the chairs of each working group and recent progress.) However, the MSM system with this wide range of 'activities' each with particular member state sponsors, lack of participation by many member states, lacking in program wide coherence (across the various 'activities'), underfunded, and operating at a distance from DRAs.

Recommendation 1 of the 2024 evaluation is that "member States should consider revising the format of the Member State mechanism to benefit from more relevant technical expertise; better collaboration with external stakeholders; and potentially increased funding and Member State participation". The evaluation offers two options to achieve this, either dissolving the MSM and returning SFMP regulation to the Secretariat or increasing the involvement of 'technical experts' in the work of the various working groups who carry out the work of the mechanism. The evaluation judges that the first option would have the best chance of success over the long term.

PHM strongly supports Option A, dissolving the MSM and returning SFMP regulation to the Secretariat with appropriate engagement of member states and technical experts and adequate funding.