16.3 Substandard/ spurious/ falsely-labelled/ falsified/ counterfeit medical products

Contents

In focus

The Assembly will consider A69/41 which conveys the report of the fourth meeting of the Member State mechanism on substandard/spurious/falsely labelled/falsified/counterfeit medical products, which met in Geneva on 19 and 20 November 2015. See SFC MSM page for more context.

The Executive Board at its 138th session considered and noted this report. See report of EB discussion at PSR11(8).

The papers prepared for the Steering Committee of the MSM in March 2016 (see yellow highlight below) do not appear to have been published.

Background

The bottom line

At the heart of this item are two issues which in theory are quite unrelated: first, the quality of medicines (including spurious and substandard medicines) on the market; and second, the assertion and protection of intellectual property rights associated with particular medicines. These two issues might have remained separate except for the adoption, by WHO, of the term ‘counterfeit’ (which legally refers to trademark violations), to refer to spurious and substandard medicines. The continuing use of the term counterfeit conflates the public health problem of spurious and substandard medicines with the tort (civil wrong) of breaches of intellectual property rights (IPRs), including patent rights as well as trademark rights, and thus links spurious and substandard regarding quality with generic status.

Advocates for generic competition, as a means to reduce the prices of drugs, including the full use of TRIPS flexibilities (including compulsory licensing and parallel importation), have been concerned that propaganda, largely emanating from big pharma, which conflates

quality with IP status through the use of the term ‘counterfeit’, has been directed to encouraging countries to adopt medicines laws which are TRIPS + in the sense that they preclude the use of TRIPS flexibilities.

The term SSFFCMP (or SFC) has come into use because agreement on an alternative definition regarding spurious medical products has not been achieved. The Member State Mechanism (MSM) is the latest structure established within WHO to drive action on quality of medicines whilst not creating new barriers to the entry of generics.

The MSM is governed by a set of Objectives (in Annex 2 to WHA6.19), an Agreed Workplan (Annex 2 to A/MSM/2/6, Nov 2013), and a list of prioritised activities (Annex 3 of A/MSM/3/3).

[The following summary of the issues up for consideration at WHA69 should be read as a continuation of the previous sequence, summarised under time lines below.]

Papers from the fourth meeting of the MSM

The fourth meeting of the MSM for SFC medical products was held in Geneva, Switzerland on 19 and 20 November 2015. The Mechanism discussed the range of prioritised activities (here) from the agreed workplan, including:

- Activity A. Recommendations for Health Authorities engaged in the detection of SSFFC medical products (draft discussed (Annex 1 to A68/33 appears to be the most recent public version), training resources sought, one year extension decided);
- Activity B. Focal point network for the exchange of information among Member States and ongoing virtual exchange forum (draft TOR discussed and adopted (Appx1) as amended);
- Activity C. A working group to survey “track and trace” models (survey of existing models adopted as amended (see Appx2), one year extension agreed to allow time for further sharing of experiences around authentication and detection);
- Activity D. WHO work on access to quality, safe, efficacious and affordable medical products (review presented (A/MSM/4/4), concept note requested before SC meeting in March 2016 regarding element 8(c):
    - Increase the knowledge and understanding about the links between the lack of accessibility/affordability and its impact on the emergence of SSFFC medical products and recommend strategies to minimize that impact;
- Activity E. Communication and awareness raising materials (see UK submission (A/MSM/4/5)) info on WG to be posted before SC in March 2016;
- Activity F. Economic impact of falsified and substandard medicines (report (A/MSM/4/6) discussed, cost estimates controversial - see TWN); second draft to be circulated for March SC meeting;
- Activity G. Budget and prioritised activities for MSM5
    - Secretariat to provide budget update for March SC;
    - Expert working group on definitions; see TWN; Expert Group on definitions to be set up; Secretariat to report on modalities and progress to SC in March;

    - Activities which fall outside the SFC mandate (existing contested document (Appx3) reviewed); to be resumed 'at a future point in time';
    - The issue of **transit** to be considered by Steering Committee of the MSM for discussion at MSM5 (see WHO Watch review here; also Abbott (2009), Seuba (2009), Baker (2012), Saez (2013), Chee (2014));
- Other issues;
    - WHO participation in global steering committee for quality assurance of health products (A/MSM/4/8); Secretariat to provide more details about GSC;
    - Update provided on WHO work on regulatory system strengthening;
    - Methodology for review of MSM (A/MSM/4/9); further report due for SC in March
    - Terms of office (and rotations) of Chair and Vice-Chairs decided;
    - Next meeting (MSM5) scheduled for Oct or Nov 2016; unresolved debate about scheduling a panel discussion of national regulatory authorities - deferred to a future meeting of the SC.

The record of EB138 discussion of this report is in PSR11(8). MS comment on various aspects of the MSM process.

Useful links

Previous PHM commentaries on SFC discussions

- WHA68 (May 2015) here (includes report of 3rd meeting of MSM & postponement of review of MSM)
- EB136 (Jan 2015) here (considered report of 3rd meeting of MSM)
- WHA67 (May 2014) here (considered report of 2nd meeting of MSM)
- EB134 (Jan 2014) here (considered report of 2nd meeting of MSM)

WHO web pages

- WHO GB SFC page; includes links to
    - WG of MS on SFC (2011)
    - OEWG on activities, actions and behaviours (July 2013)
    - meetings 1-4 of MSM on SFC (including papers circulated for each meeting)
- WHO SFC home page, includes links to
    - MSM page
    - WHO surveillance and monitoring for SFC products (here)

TWN reports (thanks to KEIOnLine)

- 26 Nov 2015 Expert working group on SSFFC definitions established (here)
- 20 Nov 2015 Socio-economic impact study of SSFFC medicines is "propaganda", says South (here)
- 6 June 2014 Governmental pushback on industry role in medical product regulation (here)
- 30 July 2013 Members agree to list of behaviors linked to compromised medical products (here)
- 24 July 2013 Slow progress in WHO Open Ended Working Group on SSFFC medical products (here)

- 30 July 2013 Members agree to list of behaviors linked to compromised medical products (here)
- 6 June 2013 South to introduce resolution on access to medicines (here)
- 26 Jan 2012 New compromised medicines mechanism agreed, some concerns remain (here)
- 10 Nov 2011 'Member State' mechanism on comprised medical products (here)
- 9 March 2011 QSE Working Group divided, IMPACT Secretariat moves to Italy (here)
- 8 Mar 2011 Members meet to shape role in QSE, examine IMPACT (here)

TWN documentation of IMPACT saga

- Sangeeta Shashikant (2010)

The pre-history of the SFC saga

The pre-history of the SFC saga (from WHA68)

Time lines

IMPACT was established in 2006 with WHO Secretariat support and participation.

A report regarding WHO's role in IMPACT appeared on the EB agenda in Jan 2009 (EB124/14) with a draft resolution endorsing WHO's involvement in IMPACT.

Two further reports were submitted to the WHA62 (May 2009), A62/13 on 'counterfeit medical products', and A62/14 on IMPACT, but these were not discussed owing to the H1N1 epidemic.

The issue returned to WHA63 in May 2010 with Documents A63/23 and A63/INF.DOC./3.

OE IG WG

WHA63 adopted WHA63(10) which called for an open ended intergovernmental working group (OE IG WG) on SSFFCMPs. The OE WG of MS on SFC met from 28 Feb-2 Mar, 2011 (see web page) but in its report to WHA64 (WHA64/16) it sought an extension of time for a further meeting which 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) in Document EB130/22). The WG proposed (in EB130/22) a draft resolution for the EB to recommend to the Assembly which would mandate a new Member State Mechanism (MSM) 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". The draft resolution was adopted as amended (EB130.R13) and forwarded to WHA65 in May 2012.

WHA65 (May 2012) reviewed the resolution as proposed in A65/23 and after a long and vigorous discussion the draft resolution, establishing a Member State mechanism (MSM) on

substandard/spurious/falsely-labelled/falsified/counterfeit medical products (SSFFC), was approved (as WHA65.19).

1st meeting of MSM

The MSM on SFC was launched in Buenos Aires 19-21 Nov 2012 and the report of its first meeting (EB132/20) was considered by EB132 (Jan 2013). 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;
- 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 (which was 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.

SFC returned to WHA66 (May 2013) supported by A66/22 which records that the MSM had met in Buenos Aires 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.

A66/22 was noted and the Assembly decided in A66(10) to recommend that the chairmanship of the Steering Committee of the Member State Mechanism should operate on the basis of rotation, on an interim basis, without prejudice to the existing terms of reference of the mechanism.

2nd meeting of MSM

The Assembly in May 2014 considered A67/29, (which forwarded EB134/25 from the EB to the Assembly) conveying the report of the second meeting of the MSM, held in late November 2013.

The MSM had:

- considered and adopted the report of the OEWG on actions, activities and behaviours (Appendix 1 of EB134/25);
- reviewed the Secretariat's global surveillance and monitoring project (here);
- approved continuing discussion on strategies for regulating actions, activities and behaviours;
- adopted the revised work plan (Appendix 2);
- noted the budget shortfall (Appendix 3) and asked for a full report to the WHA67;
- authorised an EWG, to be led by Argentina, "to continue the work of the Open-ended working group on actions, activities and behaviours that result in SSFFC medical products" (here);

- authorised an EWG, to be led by India, to focus on element 5(b) of the work plan on the identification of activities and behaviours that fall outside the mandate of the Mechanism (See Appendix 2 of WHA67/29);
- agreed that next interim Chair would be Argentina;
- agreed to hold "an informal technical meeting, open to all Member States, to finalize the outcomes of the electronic consultations would be held before the third meeting of the Member State mechanism"; and
- agreed that the third meeting of MSM would be in the week of 27 October 2014, to be preceded by a meeting of the Steering Committee and continue the system of chairing through the rotation of vice chairs;

Issues discussed at 3rd meeting of MSM

The 68th Assembly reviewed A68/33 which had been considered by the EB in January, and also Decision EB136(1), in which the Board recommended to the Assembly, in accordance with the request of the Member State Mechanism (MSM), that the review of the Mechanism be postponed by one year to 2017.

A68/33 includes the report of the third meeting of the Member State Mechanism for SSFFCMPs, which was held in Geneva, Switzerland 29 October to 31 October 2014.

The third meeting of the MSM reviewed (and apparently approved) the outcome of the informal technical meeting on recommendations for health authorities to detect and deal with actions, activities and behaviours that *result in SSFFC,* reviewed the outcome of the informal technical meeting on element 5(b) of the work plan on the identification of activities and behaviours that *fall outside the mandate* of the mechanism, and reviewed a proposal by the Steering Committee on proposals and priorities for implementation of the work plan.

Annex 1 (to A68/33) is the outcome document from an informal technical meeting designed to provide advice to national and regional regulatory authorities regarding actions, activities and behaviours which result in SSFFCMPs. It is a revision of an earlier document shared with the EB in Appendix 1 of EB134/25. The revised document covers monitoring, detection, assessment, investigation and prevention. It appears to have been adopted by the MSM and will inform further activities in the workplan of the MSM, in particular Activity A (Annex 3).

Annex 2 (to A68/33) is a report to the MSM from an informal technical meeting tasked with revising the list of actions, activities and behaviours that fall outside the mandate of the mechanism. The informal technical group did not reach consensus on the title, a paragraph in the introductory section nor clauses 3 and 7 of the document.

The debate over the introductory paragraph appears to involve words suggesting that actions, activities and behaviours which fall outside the mandate of the Mechanism "will not face unjustified regulatory actions, in order not to hamper access to quality, safe and efficacious medical products".

The debate over Clause 3 appears to focus on whether deviations from GMP “which do not compromise the quality or which do not pose a health risk” should lie within or beyond the mandate.

The debate over Clause 7 is about the seizure of medical products in transit. It appears that the critics of the EU seizures (see below) want to declare the seizure “of medical products in transit, which are in compliance with the regulatory requirements of the country of export and the country of final destination” as outside the mandate and therefore not justified on the grounds of SSFFC.

The MSM requested the Steering Committee to undertake further consultations on the document with a view to proposing language for the remaining issues in the paper for submission to the fourth meeting of the Member State Mechanism on SSFFC.

The mechanism revised and agreed the list of prioritized activities for 2014–2015 (Annex 3). This annex needs to be read in conjunction with paragraph 7 of the main MSM report which indicates which countries or the Secretariat will lead the various activities. It also refers to the agreed workplan previously shared with the EB in EB134/25 Appendix 2.

The report notes that the MSM ‘expressed concern over the unfunded activities in the budget’.

[Now return to in focus to pick up the threads under discussion at this Assembly.]

Record of EB138 debate at PSR11(8)

PHM comment

The bottom line

The SFC struggle is critical with respect to affordable access to quality, safe and efficacious (QSE) medicines.

The big pharma strategy is:

- first, to conflate the issue of QSE-compromised medicines (SSFFCMPs in WHO speak) with asserted breaches of IPRs;
- second to create a global panic around the fear of ‘counterfeit medicines’ based on the (real) problem of QSE compromised medicines; and
- third, encourage countries to adopt laws and treaties which have the effect of reducing and restricting access to cheap (quality, safe and efficacious) generic medicines (eg through in transit seizure, patent linkage, and domestic laws which preclude the use of TRIPS flexibilities).

Big pharma is supported in this campaign by the governments of the rich countries, in part because they are IP exporters, but in part because of their commitment to corporate globalisation.

The countries, NGOs and social movements working towards access to affordable safe and efficacious medicines are seeking to:

- achieve a practical definition of SFC medicines which clearly distinguishes between QSE risk and IP status;
- establish technologies and regulatory structures which prevent QSE compromised medicines from accessing medicines markets.

While the fundamental issues are simple the policy development and political maneuvering is taking place around the 'prioritised activities' (activities A-G, here) referred to above, within an almost impenetrable snowstorm of processes, bodies, acronyms and documents.

While the WHO processes grind slowly, big pharma, and its various supporters and cheerleaders, are pursuing their extreme IP agenda through trade agreements (including the TTP and TTIP) and national / regional regulations (notably the EU regulations directed to seizure of medicines in transit on suspicion of their breaching IPRs in the countries of transit).

PHM urges MS representatives to keep the fundamental issues (summarised above) uppermost in mind in evaluating the report from the MSM and participating in the debate and keep in mind also SDG Goal 3 (Ensure healthy lives and promote well-being for all at all ages) including Target 3.8: 'achieve universal health coverage (UHC), including financial risk protection, access to quality essential health care services, *and access to safe, effective, quality, and affordable essential medicines and vaccines for all*'.

Critical issues which may be highlighted in the debate at WHA69 include:

- where is the Concept Note on the links between accessibility and affordability and the emergence of SFC products?
- in transit seizure (links above) and whether it falls outside the mandate of the MSM (Appx3);
- membership, procedures and funding of the EWG on definitions (para 15(ii) of EB138/40);
- recommendations for regulatory authorities (Annex 1 to A68/33);
- 'track and trace' technologies (Appx2); links to in transit seizure; integrity and security of data systems;
- communications and awareness raising (Activity E); what progress has been made with regard to the Working Group?
- 'socio economic impact' (Activity F); where is the current draft of this report?
- update on global steering committee for quality assurance of medical products?
- continued funding of the MSM process;
- methodology for the scheduled review of the MSM process.

PHM urges NGOs and community organisations and networks to disseminate, publicise and advocate around the issues at stake in this SFC struggle and in particular to hold MS representatives accountable for the policy positions advanced in the governing bodies of WHO.

PHM urges NGOs and community organisations following the SFC struggle within the WHO to strengthen the links with those activists who are mobilising against the extreme IP agenda in the context of trade agreements and EU regulations.

Notes of discussion at WHA69