



## PHM Commentary on the Agenda of the 68th Session of the World Health Assembly

Geneva: May 2015

The comments set out below have been prepared by the People's Health Movement as a contribution to Member State deliberation during the 68<sup>th</sup> Session of the World Health Assembly.

PHM is a global network of organisations working locally, nationally and globally for Health for All. Our basic platform is articulated in the [People's Charter for Health](#) which was adopted at the first People's Health Assembly in Savar in Bangladesh in December 2000. More about PHM can be found at [www.phmovement.org](http://www.phmovement.org).

PHM is committed to a stronger WHO, adequately resourced, with appropriate powers and playing the leading role in global health governance. PHM follows closely the work of WHO, both through the Secretariat and the Governing Bodies. Across our networks we have many technical experts and grassroots organisations who are closely interested in the issues to be canvassed in the WHA68 debates.

PHM is part of a wider network of organisations committed to democratising global health governance and working through the WHO Watch project. More about WHO Watch at: [www.ghwatch.org/who-watch](http://www.ghwatch.org/who-watch).

The following notes comprise a reduced version of PHM's commentary on the WHA68 agenda. Several Secretariat papers have yet to be published as this edition of the PHM commentary is finalised. The full version, with updates as the final papers become available, can be followed or downloaded from the individual item commentaries linked from [www.ghwatch.org/who-watch/wha68](http://www.ghwatch.org/who-watch/wha68). The full version includes detailed analysis of the agenda items and direct links to the various Secretariat documents. Readers are warmly invited to explore the expanded online version of this commentary.

PHM representatives are attending the Assembly and will be pleased to discuss with you the issues explored below.

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## 11.1 Overview of reform implementation

### In focus

The Assembly will consider [A68/4](#) which is an overview report on the implementation of WHO reform, incorporating the overview provided to the EB in [EB136/7](#).

There is a brief mention of the Member State Consultative Process arising from [EB136\(16\)](#) in January 2015. See below.

### Background

The WHO Reform program is a sprawling multifaceted exercise reaching into many aspects of WHO's work. A68/4 discusses programmatic reform (focusing on budgeting and financing), governance reform (focusing on methods of work in governing bodies, engagements with NSAs, and WHO's role in global health governance) and management reform (focusing on accountability, human resources, evaluation and communication).

[A68/4](#) summarises progress since WHA67 in each of these areas; notes outstanding challenges and summarises plans for continuing the reform.

The report notes that the EVD outbreak has delayed the reform program and also revealed new issues for attention associated with WHO's emergency response preparedness.

### Member State Consultative Process

In Jan 2015, the EB decided ([EB136\(16\)](#)) to establish a Member State Consultative Process ([MSCP](#)) on governance reform which would report to WHA69 in May 2016 (notes of discussion [here](#)). The Decision identified two elements of governance reform as the mandate of the MSCP:

1. the working methods of the governing bodies (including agenda items, resolutions and decisions and the functioning of the officials of the EB and the WHA);
2. the 'alignment of governance' at all three levels of the Organisation.

The process prescribed by the Decision includes two open member state meetings and a working group with representation from each region.

The Decision also requested the DG to establish an online platform to provide access to relevant information and facilitate communication between MS. The Platform so established ([MSCP](#)) includes:

- a compilation of MS comments provided to the WG following the EB discussion,
- a compendium of documents on governance reform,
- a list of inter-governmental meetings (other than assemblies and EB meetings),
- reference documents regarding the election of the DG,
- a 'sub-platform' which provides links to documents and submissions generated in the course of the 2002 Zeltner Review, and
- statistics regarding documentation, agenda items and resolutions over the last ten years.

The first meeting of the WG took place 26-27 March. Their report is included on the agenda for the first Open MS Meeting on Governance Reform (OMSMGR) scheduled for 13 May. See [EB/OMSMGR/1/2](#).

Also relevant, in terms of the deliberations of the current MSCP, are:

- the issues raised in the EBSS/3 meeting on Ebola (see PHM report [here](#)),
- document [EB136/6](#) on methods of work of governing bodies,
- the issues raised during the debate at EB136 ([here](#)),
- the comments made by 9 MS as input to the MSCP in February 2015 ([here](#)),
- the report of the Independent Expert Oversight Advisory Committee to PBAC in Jan 2015 ([here](#)),
- the report of the Independent Evaluation Team considered by EB134 as [EB134.39](#),
- the documents generated during the 2002 Intergovernmental Open Working Group review into the working of the EB (linked from [here](#)).

### Working methods of governing bodies

Many of the issues under consideration by the MSCP are practical administrative issues such as agenda management, session management and capacity building for officers of the governing bodies. See report of [EB/OMSMGR/1/2](#) for a full list of identified issues concerning the working methods of the governing bodies.

### 'Alignment of governance'

There are also some sensitive structural issues, the most sensitive of which concerns the election / nomination of regional directors. This issue simmered below the surface during the EBSS/3 on Ebola and during EB136. At the end of the debate on WHO reform at the EB ([here](#)) the DG berated MS who had implied that there might be a problem regarding the accountability of regional directors (perhaps she protested too much). Nevertheless the mandate given to the MSCP, regarding 'the alignment of governance' across the three levels of the Organisation, implicitly includes consideration of the split accountability of the regional directors to both the DG (and through her to the EB and Assembly) and separately to the regional committees and member states.

See report of [EB/OMSMGR/1/2](#) for a list of the issues identified regarding alignment of governance.

### PHM Comment

Four fundamental issues are not being properly addressed in the current reform program:

1. barriers to coordination and collaboration within the Secretariat arising from the intra-organisational competition for donor attention and donor funding as a consequence of organisational donor dependence due to the freeze on assessed contributions
2. regional dysfunction consequent upon the arrangements under which regional directors are appointed;
3. the lack of accountability of member states for their contribution to and implementation of agreed policies, programs and principles; and
4. WHO's role in the wider structures of global health governance.

## 1. The barriers to coordination and collaboration within the Secretariat arising from the intra-organisational competition for donor attention and donor funding consequent on organisational donor dependence due to the freeze on assessed contributions

WHO's dependence on donor financing has led to donor capture of WHO's operational agenda; with gross misalignments between priorities identified in the Assembly and expenditures underwritten by donors.

Equally destructive has been the competition for donor funds between clusters, departments and regions. Departments are forced to compete for opportunities for visibility, including workshops, publications, projects and governing body resolutions. Not surprisingly collaboration suffer when colleagues are seen as competitors.

Beyond donor capture and the fragmenting effect of internal competition, is the fact that WHO's budget is in absolute terms quite inadequate. [Kickbusch \(2013\)](#) notes that the annual budget of WHO is comparable to that of the Geneva Cantonal Hospital and she compares the miniscule WHO budget to the global cost of SARS, the increased funding which China has allocated to rebuilding rural medical care and the huge budgets of the Global Fund and the Gates Foundation. It is clear that WHO's response to the Ebola crisis was severely restrained by the continuing freeze on assessed contributions ([Gostin and Friedman 2014](#)).

## 2. Regional dysfunction consequent in part on the arrangements under which regional directors are appointed

A draft internal document obtained by Associated Press in 2014 is reported as acknowledging a mishandling of the Ebola outbreak (See [Sara Bosely in The Guardian 17 October](#), [Bloomberg 17 Oct](#)). In the Bosely piece Peter Piot is quoted as criticising the response of the regional office. The Bloomberg piece reports that the DG acknowledges being unhappy with the response of the region and the country offices.

The dysfunctional arrangements for the nomination and appointment of regional directors has been commented upon repeatedly but MSs have repeatedly failed to address it.

WHO's regional system is unique among intergovernmental organisations. Undoubtedly there are important benefits which arise from this decentralisation. However there are also significant disabilities and there have been 'repeated but futile' ([Hanrieder 2014](#)) attempts to reform the way regionalisation works.

The findings of the most recent report of the Joint Inspection Unit ([JIU2012](#)) are worth reviewing:

*The second main challenge to decentralization at WHO is the consistent implementation of policies, routine administrative services and related controls across the Organization. This is often a source of duplication, loss in economies of scale and inefficiency. ...*

*The powers vested by the Constitution in the Regional Directors as elected officials weaken the authority of the Director-General as chief technical and administrative head of the*

*Organization, compared to other United Nations system organizations, and have been a source of tension in their relationship in the past....*

*Better defined monitoring and accountability mechanisms for Regional Directors are needed to monitor the implementation of the authority delegated to them and to assess their performance ... the accountability of managers is a critical issue in the perception of staff....*

*The two previous JIU reports on WHO examined this issue and its implications in detail. Particularly, JIU/REP/93/2 highlights that accountability is better exercised when based on a single, pyramidal chain of command and not with seven “executive heads”. It proposes to change the procedures for nominating Regional Directors – without changing the Constitution – to empower the Director-General to select them and nominate them for confirmation by the Executive Board, following consultations and in agreement with the Regional Committees. ...*

*At WHO ... Regional Directors are not subject to a formal performance assessment. ... The Inspectors are not aware of any performance appraisal of Regional Directors done by Regional Committees either.*

The de facto election of regional directors (RDs) by the regional committees (RCs) is a major factor in the regional dysfunctions to which the JIU refers. The RD has a significant incentive not to challenge national health authorities because the RDs are themselves accountable to MSs for re-election. Ministers of Health may not welcome activist heads of WHO country offices (HWCOs) or RDs because of the risk that they may generate pressures causing political difficulties domestically. Conversely MOH officials may be less than confrontational with the RD if they are anticipating an appointment in the RO after leaving the MOH.

Both RD and MOHs have an incentive to caucus against HQ; arguing for larger share of budget and greater programmatic control. This includes caucusing against institutional reform which might weaken the region vis a vis the centre.

Clearly these dynamics do not operate in the same ways in all the regions. However, there is clearly a prima facie case for looking more closely at the processes for nomination and appointment of regional directors.

A recent review conducted by Chatham House in the UK ([Clift 2014](#)) commented that

*... numerous external reports going back more than 20 years have identified key problems arising from the WHO’s unique configuration of six regional offices, with directors elected by member states, and its extensive network of about 150 country offices. While these reports have recommended sometimes radical reforms, there has been hardly any response from the WHO and its member states. This is because the governance structures in the WHO mean that there is a very strong interest in maintaining the status quo.*

Clift quotes Chow ([2010](#)) as commenting that ‘Regional leadership posts are pursued as political prizes’. Chow comments further

*With competition between branches and body, the assignments of WHO country representatives often involve extensive negotiations between the power in Geneva and the*

*power in the region. Key appointments have many a time been blocked not by qualifications of the individuals but for political reasons.*

Clift refers to the 1993 JIU report which:

*... identified the way in which RDs were elected by their regional committees as the central problem. But the JIU's proposals, seeking to depoliticize the regional committees by reasserting the authority of the EB and the director-general in the appointment of RDs, were not taken up by the EB.*

Chow argues strongly for Country Offices working with a range of stakeholders including local health workers and civil society as well as the ministry of health. It seems that while the RD is beholden to the MOH for election he/she is unlikely to countenance such an extension of country office work, even if it would make the Organisation more effective.

The JIU report of 2012 commented that:

*WHO participation in multi-sectoral health programmes and activities at country level should be rendered more effective. To this end, WHO country offices should be provided with improved guidance, tools and possibilities and HWCOs empowered to be operative and capable partners.*

...

Under the the 'alignment of governance' brief given to the Member State Consultative Process ([MSCP](#)) under [EB136\(16\)](#) the processes for nomination/ election/ appointment of regional directors will be reviewed.

We urge the MSCP to seriously consider the options for reforming the governance of WHO's regions and, in particular, the procedures for nominating and appointing RDs.

### **3. Lack of member state accountability**

Collectively WHO's MSs are responsible for the proper funding of WHO. Collectively they have failed this responsibility. Collectively MSs are responsible for the coherent functioning of all three levels of the Organisation. Collectively they have failed this responsibility.

Individually MSs are responsible for the quality of policy analysis underpinning their contributions to governing body debate. Not all MSs live up to this obligation. More importantly MSs should be accountable for implementation of governing body resolutions, which they are not. The limited implementation of the Code on the Marketing of Breastmilk Substitutes and the continuing gaps in the achievement of core capacities under the IHRs illustrate the point.

In the context of the Ebola crisis the disregard of their obligations regarding 'additional measures' under the IHRs by certain MSs illustrates.

Also in relation to the monitoring of implementation of WHO's Comprehensive Mental Health Plan (see [Item 18A](#)) we comment on WHO's weakness in holding MSs to account for their implementation of agreed global norms.



There has been an extended discussion over recent years of the importance of protecting the integrity of the WHO from conflicts of interest arising from experts who provide advice or the institutions with whom WHO collaborates. However, there have been some quite high profile instances where lack of accountability on the part of MS has significantly undermined the integrity of WHO. See our commentary under NSAs ([here](#)) regarding a number of such cases.

There are models in other intergovernmental organisations which could be used to strengthen the accountability of MSs to their peers, preferably from beyond their region. These include the universal periodic reviews held by the Human Rights Council, the periodic reporting of the World Heritage Committee and IMF, OECD and WTO reports on member countries.

Ultimately the constituency, to which MS officials are presumed to be accountable, is the domestic electorate and there are precedents (NCDs, tobacco control, breastfeeding) which illustrate the possible roles which could be played by professional constituencies and community based organisations in mediating more firmly such accountability.

#### **4. WHO's role in the wider structures of global health governance and global governance for health**

There have been occasional references, during the discussions of WHO reform, to WHO's leadership and coordination role in relation to the various other bodies which participate in global health governance. These include other intergovernmental bodies, global health partnerships and global private sector entities (including philanthropies, corporations and business associations).

The direction of these references range from those who remember the Article 2(a) from the WHO Constitution ('to act as the directing and coordinating authority on international health work') to those who blame WHO for the emergence of various other agencies and organisations.

PHM belongs to the former group and sees WHO as the pre-eminent global health authority, notwithstanding the freeze and some of the organisational dysfunctions referred to above.

WHO's role in the wider structures of global health governance is mentioned in A68/4 but unfortunately the main focus is on coordination within the UN system which is a very narrow construction of global health governance

PHM believes that it is time for WHO to take concrete steps to fulfil the obligations imposed by Article 2(a). We suggest that the adoption by the UN of the new Sustainable Development Goals provides an opportunity for WHO to project such leadership.

We envisage a resolution commissioning the Secretariat to report annually on the health dimensions of each of the 17 new SDGs. This annual report would include:

- a review of the global organisations who are in a position to advance the population health outcomes associated with each of the goals and an assessment of achievements and shortfalls in the work of each of those organisations;
- a review the achievements and shortfalls of member states in relation to the population health outcomes associated with each of the goals with recommendations for strengthening such work.

## 11.2 Framework of engagement with non-State actors

### In focus at WHA68

The Assembly will consider [A68/5](#), which presents the current state of agreement and disagreement regarding the draft Framework of Engagement with NSAs (FENSA). This will be accompanied by further advice from the PBAC.

[A68/5](#) was produced through the Open-ended Intergovernmental Meeting held 30 March and 1 April. In addition it includes the Chairperson's proposals for compromise in relation to the contested passages.

The Open-ended Intergovernmental Meeting had before it:

- [EB136/5](#), as presented to EB136;
- the annex to [EB136\(3\)](#) which lists a range of issues 'which seem to need more work amongst member states';
- textual proposals submitted to the Secretariat by MS before Feb 16 2015, in accordance with Decision [EB136\(3\)](#); see [EN version](#).

### Background

WHO's relationship with various non-state actors (NSAs), including NGOs, private sector entities, academic institutions and philanthropies, has been an important and sensitive element of the current WHO reform program.

The Secretariat provided a detailed paper ([EB133/16](#)) to the EB in May 2013. In response to Decision [EB133\(2\)](#) the Director-General provided a further report to EB134 in January 2014 ([EB134/8](#)) on the development of a framework of engagement with non-State actors.

Paragraph 28, under Next Steps, proposed four adjustments to current protocols to be implemented immediately: prior screening of NGO statements to be dropped; web pages for the posting of NGO statements to be created; NGOs to nominate a head of delegation; and for documentation submitted to the SC on NGOs to be made public. There was general support for these adjustments and they are being implemented. See notes from EB134 debate [here](#).

A further iteration of EB134/8 ([here](#)) was circulated at the March 27-8 Consultation of member states. See PHM's comment on this discussion paper ([here](#)). According to the TWN report of this meeting ([here](#)) the MSs were unable to agree upon key principles regarding NSA relations. Of particular concern were:

- the proposal on secondment (including secondment of staff from private sector entities into the Secretariat),
- a lack of effective safeguards to protect WHO from undue influence of private and philanthropic organisations, and
- the silence of the framework with regard to engagement with philanthropic and academic institutions.

TWN reports that the United States and the United Kingdom complained that the draft policy sets a higher degree of scrutiny for the private sector compared to other NSAs.

Debate at the Assembly in May 2014 was focused around [A67/6](#). Consensus was not achieved at the Assembly. (See PHM's report [here](#)). The basic issue in question is whether the proposed protocols will provide adequate protection from improper influence associated with conflicts of interest (COI). In Decision [WHA67\(14\)](#) MSs were asked to advise the Sect of their concerns in time for a new paper to be prepared for regional committee consideration and for the outcomes of that discussion to be reviewed at EB136.

A summary of the issues raised in and following the WHA67 discussion was prepared by the Secretariat and despatched for the consideration of the Regional Committees. (See for example the Euro version [EUR/RC64/22](#).) The issues raised during regional committee debates were summarised in [EB136/INF./2](#) and the Secretariat's response and revised framework were presented to the Board in [EB136/5](#).

#### [EB136/5](#):

- provided a report on the main issues regarding the framework for engagement with NSAs which were raised by MSs in the consultation after WHA67 ([EUR/RC64/22](#))
- summarised the issues raised during regional committee debates ([EB136/INF./2](#));
- set out the Secretariat's responses to the issues raised; and
- provided a revised draft framework for engagement with NSAs in the Annex to [EB136/5](#).

Consensus was not achieved at the Board (see PHM report of debate [here](#)) and a process decision was adopted ([EB136\(3\)](#)) which:

- invited MSs to submit to the DG specific proposals for amendments, inclusions or deletion of text from the draft overarching framework of engagement and the four specific policies by 16 February 2015;
- requested the Director-General to:
  1. compile these proposals and to make them available to Member States<sup>4</sup> by 9 March 2015;
  2. convene an open-ended intergovernmental meeting from 30 March to 1 April 2015 with a view to discussing the textual proposals submitted by Member States;
  3. submit, based on the outcome of the above intergovernmental meeting, a revised version of the Framework of Engagement with non-State actors to the Sixty-eighth World Health Assembly through the Programme, Budget and Administration Committee.

Some of the issues highlighted in the MS suggestions include:

- management of COI and prevention of improper influence
- support for salaries, secondments, conditions and whether they shall include PSEs and philanthropies
- NSA participation in WHO meetings
- NGO participation in the Financing Dialogue
- conditions for accreditation of NGOs
- proposal that WHO engagement with NGOs be 'on a competitively neutral basis'
- allegedly disproportionate restrictions on engagement with PSEs

- proscription of other industries as well as tobacco and arms, in particular alcohol and food and beverage industries
- proscription of co-sponsorship of meetings with PSEs
- criteria for arm's length relationships between PSEs and other types of NSA
- status of PPPs
- conditions for accepting funding support for clinical trials
- definition of conflicts of 'non-financial' interests
- process for evaluating the framework

## PHM comment

The continuing debate over the FENSA has cost a lot of time and money. However, the underlying issues are quite fundamental. If it came to a vote it is quite likely that the parties supporting a free and easy relationship with corporations would lose the vote. However, it is also quite likely that WHO would be punished through the withdrawal of donor funds.

The main cause of the deadlock are relatively fixed positions regarding the role of private sector entities (PSEs), variously expressed in terms of: denial of the proposition that the pre-eminent risk arises from the commercial interests of PSEs; opposition to a proscription on secondments from PSEs; calls for greater attention to conflicts of non-financial interest affecting other NSAs (including 'strongly held opinions!'); calls for more uniform regulations to apply to all NSAs.

PHM has reservations also about the practicability of the very complex policy guidelines proposed and the failure to explore the structural factors within the Secretariat (in particular the extreme donor dependence) which predispose some officials to turn a 'blind eye' to circumstances which blatantly undermine the integrity of the Organisation.

## **Commercial interests of transnational corporations are the pre-eminent risk associated with WHO's engagement with non-state actors**

There have been several incidents of improper influence in recent years, all involving large transnational corporations, often working with particular member states. These include: the IMPACT debate, Paul Herrling and the EWG, virus sharing in the context of PIP, the case of psoriasis at EB133 and lobbying by the sugar industry and related ultra-processed food industries against the WHO recommendation of a 5% ceiling to sugar as a proportion of daily energy intake.

These provide real life cases for testing the comprehensiveness and practicability of the Secretariat's proposed policy package.

### IMPACT

The IMPACT saga (see TWN report [here](#)) involved certain MSs working with certain Secretariat officials and the IFPMA to set up a Taskforce to be hosted by WHO and funded in some degree by WHO without any reference to WHO GBs, certainly no mandate. It was only after two years of operations that the work of IMPACT was drawn to the attention of the GBs. The concern regarding improper influence centres upon the conflation of IP protection and the regulation of QSE through the use of the term

'counterfeiting'. The strategy of big pharma appears to have been to amplify concerns about substandard medical products and use the urgency so created to persuade countries to implement regulatory strategies which had the effect of harnessing the medicines regulatory agencies in the policing of IP claims. In fact the problematic definition of 'counterfeit' has been traced back to a 1992 meeting between WHO officials and industry representatives. More [here](#). It may be relevant that the establishment of IMPACT coincided in time with the election of a new DG.

Decisions of the GBs since 2008 have made it clear that the original decision to launch IMPACT was ill-considered. Having regard to the widely held concerns regarding the purpose of big pharma in this exercise it appears that there were conflicts of interest at play and that big pharma (and perhaps certain MSs) exerted improper influence.

It is not clear that the procedures outlined in the new policy package would have prevented this episode. What was needed and what was lacking was a high level of awareness of the risks within the Secretariat and a high level of discipline regarding risk control.

### Paul Herrling and the EWG

The case of Paul Herrling and the EWG (see TWN report [here](#)) involved the appointment (to the EWG) of a Novartis employee who was identified with a particular proposal to be considered by the EWG. Despite concerns being expressed by MSs and CSOs, Professor Herrling remained on the EWG but excused himself from the meeting which considered his proposal. Whether EWG deliberations were in fact subject to improper influence remains debatable but clearly there was reputational harm done to WHO.

Clearly Prof Herrling's affiliation with Novartis was known to the Secretariat as was his association with one of the project proposals under consideration. However, we do not know how much pressure was exerted by Switzerland on behalf of the Herrling nomination. Complex bureaucratic policies and procedures seem somewhat irrelevant here. The situation called for judgement and discipline.

### Virus sharing (and PIP)

See debate at WHA60 ([WHA60-REC3/A60\\_REC3-en](#) from page 12; see especially the Indonesian contribution). Indonesia complained that contrary to agreed protocol virus samples collected in and contributed by Indonesia were being provided to vaccine manufacturers without consultation with Indonesia and were being patented and there was no guarantee that Indonesia would have access to the vaccines. This was the beginning of what became the PIP virus sharing and benefit sharing saga which looks to be a positive outcome but it started badly. The episode may be understood as carelessness by the relevant WHO officials, some disregard for any rights which the source country might claim. It seems not unreasonable to conclude that the officials concerned were closer to the vaccine manufacturers than to the sensitivities of the countries. Whether this is improper influence or a failure of administration is open to argument.

## Psoriasis

Psoriasis (see WHO Watch [report](#)). At the EB133 in May 2013 the EB was presented with a proposal that it endorse World Psoriasis Day which is sponsored by and extensively supported by pharmaceutical manufacturers who have much to gain from promoting psoriasis as a treatable disease. The EB members were not alerted to the commercial benefits, to the pharmaceutical manufacturers, of WHO support for World Psoriasis Day nor were they alerted to the substantial support provided to the patients' organisations involved. If there was improper influence in getting this item onto the agenda it appears to have involved member states rather than (or perhaps as well as) Secretariat officials. However, the fact that the EB was not alerted to the commercial dimensions of this resolution appears to be a failure of risk assessment and risk management. The issue of WHO's engagement with NSAs was actually on the agenda of the same meeting.

## Sugar and WHO Guidelines

In March 2014 WHO issued a draft guideline suggesting dropping the recommended free sugar intake from a maximum of 10% of total energy intake to 5%. See the WHO Media Release from March 2014 which announced the draft guideline ([here](#)). This suggestion remained in the final version of the guidelines which were formally published ([here](#)) on 4 March 2015.

On the first day of WHO's Executive Board meeting (EB136, January 2015) a motion from Italy was announced proposing a supplementary item on the agenda aiming to open up WHO's guidelines development processes to interference by member states. See [EB136/1 Add.1](#). The motion was postponed to EB137 (Item 7, see [PHM comment](#)).

[Explaining the Italian decision](#) the Under-secretary for Health, Vito De Filippo, claimed that 'sugar is an essential nutrient' and argued that reducing sugar intake as a proportion of total caloric intake to 5% was 'overly restrictive'. (Mr De Filippo did not mention that Italy is a major sugar producer ([here](#)); nor did he mention that Italy is host to the world's largest chocolate producer, Ferrero, owned by Italy's richest man.)

The world faces an epidemic of NCDs. The [scientific evidence](#) is that excessive sugar intake plays a major role in obesity, diabetes, heart disease, caries and other high burden conditions. In its [comment on the WHO guidelines](#), the European Public Health Association pointed to the forthcoming deregulation of the sugar beet industry in Europe leading to increased production and reduced prices which will flow on to cheaper junk food, further driving the rise in NCDs, obesity and overweight, and heart disease. See also the extensive commentary in support of the WHO guidelines by [Action on Sugar](#).

The sugar industry has form when it comes to interfering in national and international policy formation. They seek to buy the researchers, to buy the regulators, and to buy their way into trade negotiations. See four part series of articles by Jonathan Gornall in BMJ earlier this year: [1](#), [2](#), [3](#), [4](#).

The [processes of setting WHO guidelines](#) has carefully guarded against commercial interference. The Italian motion at the WHO's Executive Board argued that the process of developing WHO guidelines should include opportunities for the 'adequate involvement' of Member States (of the WHO) 'and other

stakeholders' in the development of guidelines. It seems that the motion seeks to make space for the sugar industry to be 'involved' in guidelines development. This is a direct attack on a fundamental pillar of WHO integrity.

This is not to say that the WHO guideline reflects a universal scientific consensus. The Canadian Centre for Science in the Public Interest (CSPI) [was critical](#) of the guidelines development group for conceiving the guideline around the concept of 'total sugars' which includes fruit sugars as well as 'added sugars', sugars added in production. The CSPI argued that the focus of the guideline should be on sugar added in production (which is the health threat) and there should be no suggestion that consumption of sugar-containing fruit and vegetables should be limited.

Interestingly, this argument corresponds to radical [new dietary guidelines developed in Brazil](#). These use a new classification system based not on food groups, but on the nature, purpose and extent of food processing. There are three kinds of processing, the argument goes. The first and oldest is minimal processing, which does not alter the food, such as methods of preservation like drying. The second adds oils or sugar or salt so that foods are modified – preserved, but less healthy. The third, ultra-processing, became the norm as from the 1980s when global corporations mined wonder-foods such as corn for a welter of chemical ingredients and mixed these up with an array of artificial factory-made food-like substances that added colour, flavour, mouth-feel, shelf-life, and extreme convenience. Just as important – and this is where the new classification method confronts transnational corporations – ultra-processed products are rejected because their 'means of production, distribution, marketing, and consumption damage culture, social life, and the environment'.

## **The accountability of Member States for protecting WHO's integrity**

The modalities of influence of non-state actors are not addressed in the current document; in particular they are silent on confidential collaborations between MSs and PSEs such as those summarised above. The proposed protocols say nothing about the accountability of the Member States for protecting WHO's integrity. However, in several of the above cases particular Member States were involved in initiatives which created risks for the integrity and decision making of the Organisation.

## **The role of judgement and culture**

The draft policy does not address the cultural dimensions (awareness, probity, judgement) that were demonstrably problematic in the episodes reviewed above. In a situation where managers at every level are preoccupied with the competition for visibility and donor attention it is not surprising that the risks of improper influence may not be given due attention.

The immediate problem is the culture of management within the Organisation which presently discounts the risk of improper influence because it is over-shadowed by the need to attract donor attention. The long term solution is to free the Organisation from the debilitating donor dependence which so distorts the organisational culture. This will require lifting the freeze on assessed contributions.

The lack of MS accountability is also a barrier to effective action. When improper influence or actions to undermine implementation of agreed norms is facilitated by MSs it is not surprising that Secretariat officials are also ambivalent.

## Operational practicability

The proposed regulatory procedures are very complex. There are four specific policies in the Annex to [EB136/5](#) that deal with four types of non-State actor, which detail specific policy provisions for each type of interaction. The challenge of monitoring the compliance of WHO staff with the provisions of these policies is even more complex. The complexity of these procedures has implications for their operational practicability and the transaction costs involved in their implementation.

For example, the draft policy and procedures regarding private sector entities are complex and will require judgement and information but these kinds of decisions are undertaken in many different offices and programs and there can be no assurance that the spirit of these provisions will be realised in such engagements. Illustrative clauses: Clause 12 and 13, 33 & 34.

## The practice of due diligence

Para 28 & 29 of [EB135/5](#) describe the process of due diligence in theory but there are no mechanisms outlined regarding how it might be institutionalised. The concept of “red lines” in para 30 is illustrated with reference to the tobacco and arms industries but there have been instances of employees and corporations from the food and beverage and the pharmaceutical industries seeking to deploy their engagements with WHO for purposes of advancing their commercial interests in ways which conflict with WHO’s mandate.

Simply delaying the implementation of effective policies in relation to food and nutrition (through claims of impracticability or assurances regarding self-regulation) can have the effect of maintaining profits at the same time as perpetuating high rates of NCDs. This is a high stakes game.

WHO is a large and sprawling organisation. Just because someone somewhere in the Organisation is aware of such instances does not mean that officials in other parts of the Organisation or member state representatives would also know that the red line has been crossed.

## Clarifying the status of commercially sponsored non-profit organisations

PHM appreciates the inclusion of international business associations as private sector entities and subject to the rules applying to PSEs. There remains some uncertainty regarding patient groups sponsored by pharmaceutical companies. [EB135/5](#) appears to deal with this by stating (paragraph 11) that entities which are not “at arms’ length” from their commercial sponsors shall be considered as PSEs. “An entity is “at arm’s length” from another entity if it does not take instructions and is not clearly influenced in its decisions by the other entity”. The framework in [EB135/5](#) does not make it clear how WHO will determine whether an NGO is independent or influenced by private sector funding sources. Some of the MS contributions to the subsequent debate have suggested that more than 30% of income from PSEs would define NGOs as PSEs.

## Due diligence in relation to engagement with academic institutions

The draft policy in relation to academic institutions does not address the situation where researchers or whole units are funded by industry, and institutional engagement is contemplated. Some of the risks of inappropriate influence in this situation will be covered by individual conflict of interest provisions (CI



4.6) of WHO's Regulations for Expert Advisory Panels and Committees ([here](#)) but it is not clear that institutional engagement is so protected.

## Partnerships

It is proposed that the new framework will apply to hosted partnerships but engagements with non-hosted partnerships (para 30 in [EB135/5](#)) will be managed in accordance with a separate policy on global health partnerships. However, for the management of risks, arising from WHO's engagement in these partnerships, the proposed new framework for engagement with non-State actors would apply (Para 48(a) in [EB135/5](#)).

During recent consultations member states have highlighted the risks associated with global health partnerships which involve interactions with alcohol and food and beverage industries and corporations involved in labour law violations and environmental damage. PHM appreciates the decision to list all partnerships and other collaborative arrangements on the WHO website.

An example of the problem of competing interests is on the WHA68 agenda in a recommendation by SAGE on the global vaccine action plan (para 5 of [A68/30](#)) that WHO (as part of GVAP Secretariat) attend Davos World Economic Forum and solicit assistance from various stakeholders, including private sector entities, present at that meeting.

## 12.1 Implementation and financing of Programme budget 2014–2015: update

### In focus

The Assembly will consider progress with respect to the implementation and financing of the Programme Budget for 2014-15 ([PB14-15](#)) which is guided by Twelfth General Programme of Work, 2014–2019 which was set out in [A66/6](#).

The Assembly will consider [A68/6](#) which provides a comprehensive overview at the programme level of the main activities undertaken during 2014; an overview of expenditure and fund raising against budget; and a summary 'self-evaluation', from each of the major offices, of progress with respect to the output indicators for the various categories and programmes.

In its commentary on an earlier version of this report ([EB136/33 Rev.1](#)) in January, the PBAC ([EB136/3](#)) noted malalignments of funding secured as against budgeted expenditure; recognized the vulnerability of some programmes, in view of the economic conditions that would prevail in the coming biennium; and emphasized the need for the report to the Assembly ([A68/6](#)) to provide more information, particularly on progress and challenges in delivery of expected results as well as on the impact of the Ebola virus disease outbreak on the work of other technical programmes and overall funding.

In the discussion of this item at the Assembly, delegates may:

- congratulate or criticise the Secretariat for the reported progress on each programme summarised in paragraphs 9-66;
- comment on the over-funding and under-funding of different programmes as shown in Fig 1 (social determinants, NCDs and 'integrated people-centred health services are all seriously underfunded);
- comment on spending in 2014 as reflected in Figs 2 & 3.

(See also EB137/2 for the advice provided by the PBAC22 regarding this item.)

### Background

The PB14-15 is framed by the Twelfth General Programme of Work, 2014–2019 which was set out in [A66/6](#) and approved through [WHA66.1](#).

Resource allocation for GPW12 is framed by six broad 'categories of work' (para 144) and 30 'programme areas' within categories (see annex to [A66/6](#)). GPW12 uses a matrix approach, six core functions (para 44) against three levels, to identify criteria for determining programmatic allocations across levels.

The Programme Budget 2014–2015 (reviewed in [A68/6](#)) is set out in [A66/7](#) and approved in [WHA66.2](#). The PB is structured around the categories/programmes cross referenced by levels (see page 110 of [A66/7](#)).

Critical to the revenue side of PB14-15 is the success of the so-called 'financing dialogue' (will be reviewed at EB137 as [Item 5](#)). Relevant recent documents regarding the funding dialogue include:

- [EB132/27 Add.1](#) Draft decision (includes outline of FD),
- [A66/48](#) WHO Reform: financing of WHO. Approval of entire budget, modalities for FD, strategic allocation of WHO resources, role of GBs at different stages in budget cycle,
- [A67/7](#) Follow-up to the financing dialogue,
- [A67/8](#) Follow-up to the financing dialogue (Independent evaluation).

A major feature of the PB14-15 implementation has been the impact of the Ebola crisis, in particular on the African region (see para 9-11 in [EB136/33 Rev.1](#)).

For further information see: [Financial and Programmatic Reports](#); and the [Programme Budget Portal](#).

## PHM Comment

[A68/6](#) provides useful information on the implementation of the PB14-15 but it raises more questions than it answers.

The short paragraph reports on individual programs are interesting and clearly good work is being done. However, it is in the nature of such reports that the best picture is put forward (as is the case for the self-evaluation reports in the Annex to A68/6).

Important questions which A68/6 does not answer, include:

- how effectively are the resources flowing to country cooperation being applied?
- how effective are the arrangements for the 'mainstreaming' of gender, equity and human rights, including accountability arrangements?
- how effectively is WHO engaging with other sectoral interests (trade, migration, security, IP, etc) in promoting health and health equity?
- how effectively is WHO addressing the six leadership priorities (Para 60, Box 2 of [A66/6](#)), in particular addressing the social, economic and environmental determinants of health?
- how effective has WHO been in projecting global leadership in global health governance?
- how effective has WHO been in positioning health in relation to global governance issues listed in paras 119 to 123 of [GPW12](#)?
- are the post occupancy charges being paid?
- what is the cost of the financing dialogue (no data provided).

The weaknesses in WHO's evaluation practices (see [PHM comment](#) on Item 8.2 at EB137 on Evaluation) mean that MSs are not able to make judgements regarding important questions about how well the limited resources are being used.

However, the more basic issue is the inadequacy in absolute terms of the Programme Budget. The freeze on assessed contributions and the continuing donor dependence are profound disabilities in relation to WHO's operations, both regarding priorities, effectiveness and efficiency.

The serious underfunding of the budget space for SDH, NCDs and health systems reflects the fact that despite repeated urgings donors are refusing to untie their 'specified' voluntary contributions.

According to the [Portal](#), projected revenues for PB14-15 for Core Voluntary was \$250m whereas Specified Voluntary was \$3.2b.

Clearly the freeze continues and continues to serve its purpose which is to prevent WHO from implementing Assembly resolutions which the big donors don't like. The Funding Dialogue is a fig leaf, not a lasting solution.

## 12.2 Proposed programme budget 2016–2017

### In focus

The Assembly will consider [A68/7](#) which conveys the proposed Programme Budget for 2016-17 and will discuss and adopt draft resolution [A68/7 Add.1](#) as amended. The draft resolution as submitted to the Assembly commits to the category and programme expenditures set out in A68/7 but leaves open the projected amounts from ACs and VCs.

The PB16-17 was considered at the regional committee meetings in late 2014 and at EB136. See [notes of EB136 discussion](#).

PB16-17 is framed by GPW12, 2014–2019, which was set out in [A66/6](#) and approved through [WHA66.1](#). GPW12 uses six broad categories of work' (para 144) and 30 'programme areas' within categories (see annex).

Note that the WG on Budget Space (EB137, Item 8.1, [PHM comment](#)) is proposing a further split into 'segments' with a view to using different approaches to budget (space) building in each segment.

Note that PB16-17 involves the allocation of budget space. Given the freeze on assessed contributions, filling this 'space' with real money depends on the success of the Financing Dialogue (for discussion as Item 5 at EB137, see [PHM comment](#)).

Note that, in her introduction to the Budget, the DG proposes a 5% increase in assessed contributions:

*In order to ensure the programme budget is adequately and securely financed, I am proposing a 5% increase of assessed contributions, which will contribute an additional US\$ 47 million over the biennium, as part of the overall 8% increase. Without this, the proportion of the programme budget financed from assessed contributions would fall to levels that could compromise our ability to manage the work of WHO strategically across all programme areas and offices. That said, I want to thank the growing number of Member States that provide flexible voluntary contributions, which are not earmarked for a specific activity or area of work.*

### Background

See WHO [Budget webpage](#).

### PHM Comment

#### The proposed increase in assessed contributions

The call for a 5% increase in ACs is a bold move for which the DG should be congratulated and strongly supported. However the increase should be a great deal larger.

## Evaluating the budget shifts

It is hard to evaluate the shifts by program, region and level summarised in the introduction to A68/7. As the PBAC has previously commented, the budget space allocation practices of the Secretariat are not very transparent.

Clearly the gross underfunding of WHO is a more serious constraint on WHO's ability to fulfill its mandate than arguable misallocations of an inadequate total across programmes, regions and levels.

## Policy coherence: trade and health

The lack of any explicit reference to policy coherence across trade and health under Outcome 3.4 (from page 60) is disappointing. New trade agreements with serious implications for public health policy are being introduced at a rapid pace. Investor state dispute provisions threaten to seriously curtail the capacity of countries to regulate for public health, including in relation to NCDs. [Resolution WHA59.26](#) gives the Secretariat a clear mandate to engage robustly in intersectoral dialogue at all levels around these issues

The deliverables promised under Outcome 3.4 do not suggest an appropriate level of urgency.

## Monitoring and evaluation

The Secretariat's results chain (see para 148 of GPW12 in [A66/6](#)) proceeds thus:

Inputs → Activities → Outputs → Outcomes → Impact.

PB16-17 does not discuss Impacts (ultimate health outcomes). These are seen as being followed across the whole period of the GPW12. See page 43 of A66/6 for the 8 Impact goals indicators and targets for GPW12.

The Activities through which the Secretariat will produce its Outputs are described in the PB16-17 in terms of 'deliverables'.

The draft PB16-17 includes proposed Outcome indicators ('increased access to health services and/or reduction in risk factors') and Output indicators ('delivery of products and services' by the Secretariat).

The indicators proposed for Outcomes and Outputs are in many cases loosely defined and present huge challenges (and costs) in terms of valid and reliable measurement. It does not appear that provision is made for following the extraneous influences which interact with WHO's Activities and Outputs in generating Outcomes. It does not appear that robust means will be available for drawing conclusions about the contribution that Activities and Outputs have made to Outcomes. It does not appear that the data being collected will enable programme and office leaders to evaluate the strategic assumptions underpinning the distribution of Inputs (money and staff) across programmes and offices.

## 13.1 Outcome of the Second International Conference on Nutrition (ICN2)

### In focus

The Assembly will consider the report on the outcomes of ICN2 contained in [A68/8](#) including the implementation actions proposed for the Secretariat and the draft resolution forwarded from the EB136 (as adopted in [Decision EB136\(4\)](#), see report of debate [here](#)).

[A68/8](#) includes:

- an overview of the two outcome documents from ICN2, the Rome Declaration, and the Framework for Action (both of which are attached as annexes);
- an overview of the Secretariat's plans with respect to implementing its obligations arising out of the Declaration and Framework; including:
  - technical assistance to member states;
  - supporting the engagement of sectors other than health in country nutrition plans;
  - participating in joint UN mechanisms;
  - facilitation and enhancement of coordination of activities, multi-stakeholder engagement and action across sectors;
  - mobilization of financial resources for the implementation of nutrition policies and programmes;
  - development of an accountability framework;
  - reporting progress on implementation of the outcomes of the Conference;
  - supporting wider endorsement of the ICN2 outcome documents;
  - identifying how nutrition actions should be encompassed under the 17 proposed sustainable development goals;
- a draft resolution
  - endorsing the outcome documents;
  - calling on MSs to implement the commitments of the Declaration in accordance with the Framework; and
  - requesting the DG to report biennially to the Assembly on progress with respect to implementation.

It is likely that the debate at the Assembly will include;

- endorsements of the Declaration and the Framework and congratulations to WHO and FAO on the Rome Conference;
- broad support for the Secretariat's work plan and the draft resolution;
- discussion of some of the analyses and options which were *not* included in the outcome documents and are *not* mentioned in A68/8.

# Background

## ICN2

Preparation for ICN2 (19-21 November, 2014) was considered by WHA67 in relation to maternal, infant and young child nutrition. An earlier version of A68/8 was considered at EB136. More about ICN2 according to [FAO](#), [WHO](#) and [UNSCN](#).

## Outcomes document and Framework for Action

The two main (official) outcomes of ICN2 were the political declaration and the framework for action.

The final [Outcomes Document: Rome Declaration on Nutrition](#) recognises that eliminating malnutrition will require cross sectoral collaboration, including in agriculture and trade. However, there is no reference to dumping of agricultural commodities, to TNC control of food systems, or of food sovereignty. The document includes a raft of 'needs' and 'shoulds' but little in the way of firm direction.

The [Framework for Action](#) provides a list of 60 recommendations, all of them non-binding. Several member states from the North sought to prevent the FFA being endorsed by the ICN2 Plenary. Some of the recommendations are weak, critically, the human rights perspective on food and nutrition, but they provide a menu for WHO to work on.

Neither documents were open for discussion during the ICN2 plenary. They were approved by acclamation in literally 15 seconds in the opening plenary despite the fact that, in the search of consensus, the MS of the South had to concede attenuating language.

## Civil society and social movement statements

The [Consensus Statement](#) of 170 social movements and public interest civil society organisations ([English](#), [Spanish](#)) was read in the closing plenary receiving wide acclamation. French and Portuguese versions are now available. The statement was critical of both the official documents and provides an alternative framework for action including actions in health.

The [Public Interest CSOs and Social Movements Vision Statement](#) adopted at the Public Interest CSOs and Social Movements Pre ICN Conference. It goes into more detail than the Statement above. Social movements attending the pre-conference issued their own [Social Movements Statement](#).

## The food crisis

The food crisis has complex determinants. It is necessary to consider its different aspects separately:

- the material realities of hegemonic global production, distribution, marketing and consumption of system that neglects small producers;
- the political economy of a vertically integrated global food production and supply system;
- governance structures which constrain the development of a small farmer based and ecologically sustainable global food production and supply system;
- a lack of integration of nutrition considerations in food security approaches;



- the policy and strategic implications of the above.

Global Health Watch is a good starting place for further analysis. Every issue of GHW since 2005 has commented on the food and nutrition crisis (see [GHW3](#), [GHW2](#), [GHW1](#) and [GHW4](#)). See also [Food First](#), [FIAN](#), [IATP](#), [Via Campesina](#).

## PHM Comment

The food, nutrition and agricultural circumstances are very different across the world. Action on food and nutrition must therefore be planned and implemented at the national and local levels. However, the political and economic context within which such national planning takes place is strongly shaped by economic globalisation, the increasing power of transnational corporations and the drive to regulate the global economy in the interests of the TNCs through trade and investment agreements.

The nutrition future for the hundreds of millions of hungry people depends on action at the national and international levels.

### Draft resolution

PHM urges the Assembly to adopt the draft resolution ([here](#)) based on the Civil Society Vision Statement.

### National action

Member states should develop national nutrition plans as per Rec 2 of the FFA. Such plans should consider the applicability of FFA Recs 1-16, 19-57. They should also express the core principles outlined in the [PICS&SM](#) statement.

There is a need for strong commitment by MS and other partners to building the domestic constituency needed to shape such plans and to drive implementation. See [PICS&SM](#) statement.

### International action

The barriers to food security and food sovereignty in current trade and investment agreements need to be clearly articulated, indicating the provisions which should be included in such agreements to guarantee food security and food sovereignty (see FFA Recs 17 & 18).

**In this context we urge staunch opposition to the use of ISDS to prevent effective regulatory strategies. We urge a return to multilateral negotiations around trade in agricultural commodities to ensure the elimination of dumping and of protection and subsidies to corporate agriculture.** WHO has a mandate (through [WHA59.26](#)) to take the lead in this work.

There are deep conflicts between the assumptions underlying the food sovereignty movement, which envisages food and agricultural systems based on agroecological principles (see [PICS&SM statement](#)), in contrast to the globalised corporate industrial model of corporate agriculture and corporate dominated food systems. **PHM calls for a new Commission to be jointly sponsored by WHO and FAO to investigate and report on the role of food sovereignty in addressing the challenges of food security.**

The increasing power of transnational corporations vis a vis the democratic expression of the public interest is widely recognised. **There is an urgent need for new international instruments to regulate the TNCs in areas where their profit objectives run counter to public policy objectives such as food sovereignty and environmental sustainability.** PHM calls on WHO to open negotiations with UNCTAD with a view to exploring in more detail possible strategies for regulating TNCs (see PICS&SM statement).

The Outcomes Statement and the FFA are both weak in acknowledging that access to decent food, consistent with cultural traditions, is a basic human right (see [OHCHR](#)); the human rights perspective must permeate all policies and actions in this field. PHM urges WHO to work with the Special Rapporteurs on the Right to Food and the Right to Health in preparing an information product on the human rights dimension of food and nutrition policies, and particularly the Outcomes commitments of the ICN2, designed to inform national nutrition planning.

It is self-evident that governments by themselves are not able (and in some cases not willing) to put in place the necessary national and international reforms needed to guarantee the right to food (as articulated by the Special Rapporteur on the Right to Food). Civil society and social movements have a critical role to play at both the national level and international level. PHM calls for member states (both individually and through WHO) to recognise the powerful role that CSOs play in defending the RTF and decent nutrition and advancing the principles of food security through food sovereignty and to explore ways of working productively to this end at both the national and global levels.

## UN Committee on World Food Security

MS are requested to oppose any attempt to create yet another bureaucracy to oversee food and nutrition issues in the form of what UNICEF and WFP have termed ‘United Nations Nutrition’ (UNN). PHM sees no advantage whatsoever in such a move. **Instead PHM urges MS and WHO to quickly join the Committee on Food Security (CFS) secretariat** so as to fill the current gap in the same to consider health and nutrition implications of food security. In this context, the responsibilities of the SCN – currently under the umbrella of WHO - can be moved to the CFS.

## Monitoring and accountability

PHM endorses Recommendations 58-60 of the FFA on monitoring and accountability

However, **we urge MS to recognise the importance of accountability structures and channels which give a clear voice to women, small farmers, agricultural and plantation workers and the myriad of other civil society organisations in the food sovereignty movement.**

PHM points out that despite the scientific evidence supporting exclusive breast feeding for the first six months the Code has been fully expressed in domestic legislation [in only 37 countries](#) and this is largely due to the unceasing advocacy and mobilisation of civil society networks.

PHM points out that there is no reference, under monitoring and accountability, to FFA Recommendations 17-18 (regarding trade and investment agreements). **PHM urges WHO, FAO, the UNHCHR and UNCTAD to create a commission to report on the implications of trade and**

**investment agreements for the right to food** in accordance with para 25 of UNGA resolution [A/RES/68/177](#).

## Foxes and chickens

PHM endorses Recommendation 3 of the FFA on the need for robust safeguards against abuse and conflicts of interest.

This need is elaborated in the [PICS&SM](#) Statement which notes a range of issues where the goals articulated in the outcomes statement may run counter to corporate interests, including land and water grabbing; soil, food, water and human contamination with agrochemicals; the commodification of seeds and livestock breeds; the marketing of breastmilk substitutes; and the production and marketing of ultra-processed and junk food in particular though not exclusively to children.

The PICS&SM Statement referred to the establishment, through the UN HRC, of an Open-Ended Intergovernmental Working Group on a legally binding instrument on transnational corporations and other business enterprises with respect to human rights ([A/HRC/26/L.22/Rev.1](#), see also [GPF commentary](#)).

PHM urges a high level of caution in relation to ‘multi-stakeholder platforms’ such as SUN. Where such platforms include, or even depend upon, private sector participation, the consensus dynamic can prevent proper consideration of regulatory or fiscal strategies which might run counter to the corporate interest.

Managing such conflicts of interest require: transparency, structural separation and accountability. It requires a high level of probity and judgement by intergovernmental officials. These are not easy to maintain in the era of money politics, revolving doors, and the power of TNCs to threaten nation states.

## Draft resolution

PHM urges the Assembly to adopt the draft resolution ([here](#)) based on the Civil Society Vision Statement.

## 13.2 Maternal, infant and young child nutrition: development of the core set of indicators

### In focus

The Assembly will consider A68/9 which will refer to the report of the working group ([EB136/9](#)) set up to finalise a core set of indicators to monitor the implementation of the Comprehensive Implementation Plan in Maternal, Infant and Young Child Nutrition and report on the Member State Consultation held 16-17 April.

### Background

The Comprehensive Implementation Plan (CIP) in Maternal, Infant and Young Child Nutrition was presented to the Assembly in [A65/11](#) in 2012 and endorsed in resolution [WHA65.6](#).

Included in the Comprehensive Implementation Plan were a simple set of proposed indicators regarding inputs (3), outputs/outcomes (8) and impacts (10) (Table 3 in [A65/11](#)). A more complex draft set of indicators ([indicators](#)) had previously been discussed in the EB. These were structured around biological outcomes (15), implementation of nutrition programs (12), food security (6), and policy environment (5).

Further consultations were requested by Member States and a revised set of indicators was developed ([here](#)) and discussed in informal consultations on 30 September and 1 October 2013. This set had primary outcome indicators (6), intermediate outcome indicators (16), and process indicators (18). An online consultation, held from 7 September to 10 October 2013, indicated that consensus could only be reached on the *primary outcome* indicators (it appears that there was disagreement regarding *process* and *intermediate outcome* indicators).

Maternal, infant and young child nutrition was considered by the EB in January 2014 which adopted decision [EB134\(2\)](#). Paras 2(a) and 2(b) of Decision [EB134\(2\)](#) both deal with the global monitoring framework for the comprehensive implementation plan.

- Para 2(a) asks the WHA to endorse seven indicators for global monitoring of MIYCN (as listed in Annex 1 of [A67/15](#)) which would form part of a 'core set' of indicators.
- Para 2(b) asks the WHA to ask the DG to establish a working group to further develop the core set of indicators, including indicators of policy and program implementation, as well as an 'extended set' of indicators which would be more country specific.

WHA67 considered document [A67/15](#). Annex 1 to [A67/15](#) summarized the discussion to date on the global monitoring framework, introduced the concept of core and extended indicators and proposed a first agreed set of seven core indicators for use at global level.

There was not much comment on the specific issue of indicators at the Assembly. Among the exceptions were Canada who spoke in favour of fewer rather than more and Burkina Faso who spoke about the importance of monitoring process as well as outcomes. See PHM comment at WHA67 and report on the debate [here](#).

In [Decision A67\(9\)](#) the Assembly:

*(1) endorsed the seven indicators to monitor progress towards the achievement of the global targets as part of the core set of indicators of the global monitoring framework on maternal, infant and young child nutrition;*

*(2) requested the Director-General to establish a working group composed of representatives and experts appointed by Member States and United Nations bodies in order to complete the work, before the end of 2014, on the development of the core set of indicators to monitor the comprehensive implementation plan on maternal, infant and young child nutrition, building on “tracer” indicators for policy and programme implementation in health and other sectors that are relevant to the achievement of the global nutrition targets, as well as developing an extended set of indicators in order to track processes that have an impact on the global targets in specific country settings, for consideration by Member States at the Sixty-eighth World Health Assembly;*

Document [EB136/9](#) transmitted the recommendations of the Working Group regarding the additional core indicators. Disaggregation by gender, geographical and socioeconomic variables (such as urban and rural residence) and by age is proposed. The document refers to the WHO website ([here](#)) for a fuller report which also includes the proposed extended set of optional indicators and a range of other indicators, some of which may justify further work.

In January EB136 noted the report (see report [here](#)) and agreed to recommend that WHA68 approve the global monitoring framework on maternal, infant and young child nutrition, and to provide further guidance on the frequency of periodic revisions of that framework.

In wrapping up the discussion the ADG mooted the possibility of a web consultation or informal consultation to take the process further and it appears (A68/9) that this was arranged for 16-17 April.

See report of EB discussion [here](#).

## PHM Comment

The CIP has five Actions:

1. Create a supportive environment for the implementation of comprehensive food and nutrition policies;
2. Include all required effective health interventions with an impact on nutrition in national nutrition plans;
3. Stimulate development policies and programmes outside the health sector that recognise and include nutrition;
4. Provide sufficient human and financial resources for the implementation of nutrition interventions;
5. Monitor and evaluate the implementation of policies and programs.

Under each of these actions, activities are proposed for Member States, for the Secretariat and for international partners. However, many of these proposed activities are expressed in very general terms.

The first round of indicators were exhaustive (and accordingly costly). It makes sense to restrict the core indicators, to be monitored in all countries, to relatively few and to develop a panel of further indicators which can be used to follow the specific circumstances of different countries. We also appreciate the proposed disaggregation of indicators by socioeconomic group, sex and ethnicity in order to identify and address inequalities.

We appreciate the inclusion of nutrition governance in the extended set of optional indicators and note the regulation of marketing and level of soft drink consumption among the newly suggested indicators in the 2013 consultation.

The global determinants of food security, food sovereignty and healthy nutrition are undeniable including the supply chains linking agriculture, trade, retail and marketing which are themselves shaped by the processes of globalization and international trade agreements. However, since the CIP was silent regarding the political economy of food sovereignty, there is a lack of policy and program indicators which might follow progress in reforming the structures and dynamics of global food supply. In PHM's view, the global monitoring framework should capture the multisectoral nature of nutrition and include indicators relating to the structural causes of malnutrition and able to cut across different sectors (e.g. health, trade, environment)

The food sovereignty of many LMICs continues to be undermined by "land grabbing", the contentious issue of land acquisitions mainly by transnational companies. Meanwhile the diversion of land from food to biofuels is contributing to jeopardising food security and nutrition. As a consequence, an increasing number of countries are now net food importers and therefore increasingly food insecure and dependent on imported (often obesogenic) food. Nutrition needs therefore to be understood in the context of food security (and insecurity). We are not asking WHO to address the issues of trade alone but to take a pro-active stance in working with other competent intergovernmental bodies.

## 13.3 Update on the WHO Commission on Ending Childhood Obesity

### In focus

The high-level Commission, 'Ending Childhood Obesity', established by the Director-General in order to create awareness and build momentum for action met first in July 2014 in Geneva and is required to report in 2016. The Commission is supported by two working groups; one on science and evidence, addressing the epidemiological burden, the drivers of childhood obesity, the economic burden, and the scientific evidence for effective interventions; and a second addressing implementation, monitoring and accountability. (See WHO [obesity page](#) and a description of the Commission, its work program and the commissioners [here](#)).

The WHA will have before it [A68/10](#) which provides an update on the work of the Commission. In January the EB reviewed [EB136/10](#) which provided an earlier update on the work of the Commission. See notes of the debate at EB136 [here](#).

The interim report of the Commission was released on 16 March 2015 ([here](#)) and a program of regional consultations has commenced.

### Background

The WHO website has useful references on its [obesity page](#) and a description of the proposed Commission, its work program and the commissioners ([here](#)).

The Commission held two one day consultations in October, one for private sector entities and one for NGOs. See [here](#) for summary of issues emerging. Further consultations in the WHO regions are proposed for 2015.

The report of the first meeting (in June 2014) of the Ad Hoc Working Group on Science and Evidence is summarised [here](#) with link to a [detailed report of the meeting](#). The report sketches a comprehensive conversation ranging from epigenetics to strategies to regulate the marketing of processed foods. The report notes but does not address trade agreements as determinants of food supply and constraints upon public interest regulation. However, it does consider the possibility of a framework convention on nutrition and mandatory standards governing product formulation, pricing and marketing.

The Commission has planned a series of regional consultations around the Commission's Interim Report (released March 2015, [here](#)), the first of which was held in Manila (for the Western Pacific region) on March 24-25. The next dates and places are May 10-11 in Amman (for EMRO) and Oct 29-30 in Malta (for Europe). Dates and locations for PAHO, SEARO, and Africa have not yet been set. International online consultations will be conducted in Nov and Dec 2015 before the final report will be given to the DG by the end of 2015. This will be presented to the EB in Jan 2016 and the WHA in May 2016.

For further background see the special issue of [Obesity Reviews \(October 2013\)](#) which reviews a wide range of policy options regarding the regulation of the food environment.

[Swinburn, et al \(2013\)](#) (in Obesity Reviews 14: 24-37) introduce a tool, Food-EPI (Government Healthy Food Environment Policy Index) for monitoring and benchmarking government policies and actions to improve the healthiness of food environments. An evaluation of the New Zealand food policy environment in 2014, using this tool, is reported [here](#).

## PHM Comment

PHM appreciates the initiative of the DG in setting up the Commission and was encouraged by the report of the first meeting of the Working Group on Evidence.

However, in our draft submission ([here](#)) to the Commission's Interim Report ([here](#)), developed for the Manila Consultation, PHM was sharply critical of the lack of attention to poverty; the failure to consider the role of trade agreements in affecting price; and the unseemly relationship between the Commission and the corporate sector. PHM pointed out that small farmers and fisherfolk are also private sector but the Commission does not appear to have engaged with them as part of its consultations with 'the private sector'.

PHM would strongly support the proposal for a framework convention on nutrition and mandatory standards as flagged in the report of the Working Group meeting. The experience of the voluntary Code on the Marketing of Breastmilk Substitutes ([Forsyth 2013](#)) as compared with the FCTC or the IHRs underlines clearly the importance of mandatory standards.

From a PHM point of view putting the regulation of TNCs on the global agenda is a key objective. [WHO's Article 19](#) is an available legislative mechanism and the framework convention is a model which has currency. The framework convention model proposed allows for a general framework convention out of which a suite of protocols is negotiated. These could include marked restrictions in the marketing of ultra-processed foods, a mandated set of regulations on the marketing of breastmilk substitutes, a set of guidelines based on the new Brazilian dietary guidelines, etc.

An alternative to Article 19 would be an independently negotiated treaty around the regulation of TNCs generally. The UN Human Rights Council has established a Working Group to consider this possibility (overview [here](#)). The [Treaty Alliance](#), formed to push for such a treaty, already has 1000 members, including important social movements. This would be a broader treaty and hence more strategic. For example, an agreement struck under the power of WHO's Article 19 would be unlikely to binding commitments around food sovereignty which is a critical element in this field.

The rising significance of free trade agreements in shaping global food systems points towards the importance of robust standards which can constrain what is provided for in trade agreements and jurisprudence of dispute settlement. See, for example, the Grain report on 'Free trade and Mexico's junk food epidemic' ([here](#)). Provisions for investor state dispute settlement have been widely recognised as a threat to policy space in terms of regulating the food environment ([Kelsey & Wallach 2012](#)). Robust standards in a binding agreement would go a some way to protecting such policy space.

The increasing control by transnational food companies of global food systems has been accompanied by increasing presence of ultra-processed and energy dense foods which contribute to increasingly obesogenic environments.



The economic logic of ultra-processed foods is partly based on the opportunities for employment and profit from value adding along the supply chain and partly on shelf life, transport costs and market reach. However, the contrary paradigm of food sovereignty and relative self-sufficiency also promises employment and commerce although more distributed and more local and more supportive of local economic development. The food sovereignty paradigm also promises less energy dense foods.

## 13.4 Follow-up to the 2014 high-level meeting of the United Nations General Assembly to undertake a comprehensive review and assessment of the progress achieved in the prevention and control of noncommunicable diseases

### In focus

The Assembly will consider [A68/11](#) in which the DG:

- reports on the high level meeting (HLM) of the UN General Assembly (UNGA) in July 2014, called to follow up on the UN Political Declaration on NCDs from September 2011; reporting that meeting had ‘noted’ a series of national ‘commitments’ (heavily qualified by ‘consider’ and ‘as appropriate’); and summarising various international commitments endorsed by or initiated by the HLM;
- notes that the HLM had failed to agree on ‘process indicators’ to assess progress in implementation of the Political Declaration at the country level; and
- provides an overview of 11 separate actions on the Secretariat’s NCDs agenda which arise from or were endorsed by the HLM.

These actions include:

- Para 16. Technical assistance to be provided by the Secretariat to Member States (policy briefs, an e-learning platform, and a donor-funded work plan for aligning activities across the three levels of the Secretariat);
- Para 17. Technical assistance provided through the Inter-Agency Task Force ([here](#)) on the Prevention and Control of Noncommunicable Diseases to member states (proposing a guidance note to support the embedding of NCDs in the [UN Development Assistance Framework](#), also planning intersectoral technical assistance missions and joint programs with other UN agencies);
- Para 18. Facilitation and enhancement of coordination of activities, multi-stakeholder engagement and action across sectors; refers to work of the Global Coordination Mechanism (GCM/NCD) and includes working groups, dialogues, communities of practice, and internet platforms; see also Annex 3 of A68/11 which presents the proposed workplan for the global coordination mechanism;
- Para 19. Development of an approach that can be used to register and publish contributions of non-State actors to the achievement of the nine voluntary global targets for the prevention and control of noncommunicable diseases; follows from para 37 of the [Outcomes Document](#) regarding lack of action by non-state actors - read corporations - in relation to the [2011 Political Declaration](#); expect discussion paper in late 2015.
- Para 20. Development of a Framework for Country Action to engage sectors beyond health; currently open to [consultation](#) - see Discussion Paper [here](#); draft framework to be presented to WHA68;
- Para 21. Updating the menu of policy options and cost-effective interventions for the prevention and control of noncommunicable diseases to assist Member States in implementing actions to

achieve the nine voluntary global targets (see Appendix 3 of [Global Action Plan](#); will include systematic reviews);

- Para 22. Updating the WHO global status reports on noncommunicable diseases - trends, programs, suggestions, including country-specific data - modelled on [Global Status Report 2010](#);
- Para 23. Reporting progress to the Health Assembly including evaluation of the Global Action Plan and reports on the 9 voluntary global targets (see [A66/9](#));
- Para 24. Reporting progress to the United Nations Economic and Social Council regarding the establishment and work of the IATF on NCDs (see EcoSoc Resolution [E/RES/2013/12](#); see also [IATF Secretariat page](#));
- Para 25. Reporting progress to the United Nations General Assembly on progress with the [2011 Political Declaration](#) and the 2014 HLM Outcomes Document (Annex 1 of [A68/11](#)); scheduled to report in 2017; preparing a 'technical note' (as requested in [EB136\(13\)](#)) on how the DG will report in 2017 to the UNGA on the national commitments included in the 2014 outcome document (Annex 1 to [A68/11](#)) and 2011 Political Declaration ([Resolution 66/2](#)) "using existing survey tools and taking into account existing indicators at the global and regional levels" (technical note will be published on WHO NCDs website ([www.who.int/ncd](http://www.who.int/ncd)));
- Para 26. Preparatory process for the third high-level meeting of the United Nations General Assembly on the prevention and control of noncommunicable diseases - scheduled for 2018 - and perhaps a second Ministerial meeting (following [Moscow 2011](#)), perhaps in 2016.

EB136 debate [here](#)

The Assembly is invited to note the report ([A68/11](#)) including the work plan for the global coordination mechanism as set out in Annex 3 (which includes the modalities for the General Meeting (Appendix 1 of Annex 3) and the modalities for the preliminary evaluation (Appendix 2).

## Background

### Follow up of July 2014 HLM

The UN Political Declaration on NCDs ([Resolution 66/2](#)) of 16 September, 2011, in para 65, commissioned the UNSG to present to the 68th session of the UNGA "a report on progress in realising the commitments in the Declaration", "in preparation for a comprehensive review and assessment in 2014 of the progress achieved in the prevention and control of non-communicable diseases".

In [A/68/650](#) (10 Dec 2013) the UNSG transmitted to the UNGA a report from the DG of WHO on progress in realising the commitments made in the Political Declaration.

In UNGA Resolution [A/RES/68/271](#) (13 May 2014) the UNGA decided to review progress in a high level event to be held on the 10 & 11 July 2014 and sets forth the broad structure of the event. See documentation prepared for the HLM [here](#).

The Outcome Document from the HLM in July 2014 (68/300) is included as Annex 1 of [A68/11](#). See also the NCD Alliance report of HLM [here](#).

## Global Coordination Mechanism

The global coordination mechanism on the prevention and control of noncommunicable diseases (GCM/NCD) was required by paras 3.2 and 3.3 of [WHA66.10](#) and referred to in paras 14-15 of the new Action Plan in [A66/9](#).

The workplan for the GCM/NCD (in Annex 3 of [A68/11](#)) is structured around the five objectives of the GCM and includes a number of actions under each objective (11 in total).

Annex 3 of A68/11 also includes a note on the proposed General Meeting of the GCM (Appendix 1) and a preliminary evaluation of the value added of the GCM (Appendix 2).

See PHM comment on the GCM at EB136 [here](#).

### Proposed work plan for 2016-17

#### “Process indicators”

There was intense debate in the lead up to the 2014 HLM and at the WHO Executive Board in Jan 2015 over whether WHO should develop a series of ‘process indicators’ to monitor member state implementation of the commitments of the [2011 Political Declaration](#) which in Para 61:

*Call[ed] upon the World Health Organization, with the full participation of Member States, informed by their national situations, through its existing structures, and in collaboration with United Nations agencies, funds and programmes and other relevant regional and international organizations, as appropriate, building on continuing efforts to develop, before the end of 2012, a comprehensive global monitoring framework, including a set of indicators, capable of application across regional and country settings, including through multisectoral approaches, to monitor trends and to assess progress made in the implementation of national strategies and plans on non-communicable diseases;*

Paragraphs 12-15 of [A68/11](#) reports on the debate in the lead up to the July 2014 HLM over whether such ‘process’ indicators are needed. The report refers to the process indicators adopted by EMRO in 2012 in EM/RC59/R.2.

During the debate at EB136 ([here](#)) several countries from EMR spoke in favour of process indicators and were supported by the US. However, there was reluctance to adopt more indicators from other regions; arguing that the 9 plus 25 from the GAP would be sufficient.

Annex 4 of [A67/14](#) outlines a set of 9 indicators for the WHO global action plan for the prevention and control of noncommunicable diseases 2013–2020 proposed from the Nov 2013 consultation with Member States. These indicators are mandated by para 3.4 of [WHA66.10](#); they apply the global objectives and targets from the Global Monitoring Framework ([A66/8](#)) to the country level. EB134 endorsed the nine action plan indicators in [EB134\(1\)](#).

Appendix 2 of [Annex 4](#), from page 28 (referred to in Resolution [A66.10](#) of 2013) sets out the 25 indicators and the nine voluntary global targets

## Global Action Plan on NCDs 2013-2020

Global Action Plan 2009-2013 (see [A61/8](#)) was adopted through [WHA61.14](#) (2008) 'Prevention and control of noncommunicable diseases: implementation of the global strategy'.

Global Action Plan 2013–2020 is set out in [A66/9](#) (as corrected in [A66/9 Corr.1](#)) and endorsed in [WHA66.10](#).

See PHM Comment on GAP from WHA67 [here](#).

### Recent documents

- [Global Status Report on NCDs \(2014\)](#)
- [Global status report on alcohol \(2014\)](#)
- [Preventing suicide \(2014\)](#)
- [Global status report on violence prevention 2014](#)
- [Global Nutrition Report 2014](#)

For reference to a range of earlier documents see [PHM comment on Item 13.1 at WHA67](#).

## PHM Comment

### Neglect of NCDs in the implementation of PB14-15

The Secretariat's report on the implementation of PB14-15 in [A68/6](#) notes (para24) that:

*The multisectoral nature of noncommunicable disease prevention and control remains a major challenge and requires investment in policies that go beyond the health sector. The resourcing of noncommunicable disease surveillance and monitoring work at country level remains unreliable. Only 50% of countries in 2013 had operational national policies and plans for tackling noncommunicable diseases. Despite commitments made by world leaders to increasing and prioritizing budget allocations, the provision of resources through domestic channels remains limited, even though the potential to increase taxation on tobacco and alcohol exists in many countries; even a small portion of those proceeds, if allocated to health, could greatly enhance prevention and access to services.*

In the same report, Fig 1 (page 15) demonstrates that action on NCDs and on the SDH are grossly underfunded; the big donors do not want to support WHO in working on these commitments.

### Absence of trade from workplan for the Global Coordination Mechanism

The proposed workplan for the GCM is set out in Annex 3 of [A68/11](#). There are some useful activities foreshadowed in this work plan.

However, there is no mention of trade in the proposed work plan. Objective 3 of the GCM aims to "identify barriers and share innovative solutions and actions for the implementation of the global action plan ... and to promote sustained actions across sectors". To address this objective the GCM proposes working groups on AIDS, development assistance, and health education. But no mention of trade or

strategies to regulate transnational corporations which promote ultra-processed foods?

Of particular concern is the inclusion of investor state dispute settlement provisions in new trade agreements such as the Trans Pacific Partnership (TPP) and presumably also the Trans-Atlantic Trade and Investment Partnership (TTIP). These provisions provide a powerful weapon in the hands of transnational corporations to intimidate governments, in particular the governments of smaller L&MICs.

WHO has a mandate (through [WHA59.26](#)) to take the lead in this work. However, despite very general references to policy coherence across trade and health in the [GPW12](#) (see for eg para 106) there is nothing in the [draft PB16-17](#) due for consideration at this EB. PHM urges the EB to revisit WHA59.26 and ensure that action on this resolution is included in the PB for 2016-17.

PHM urges WHO and member states to give more priority to policy coherence across sectors with special attention to trade and investment. This could be progressed in the first instance through establishing a working group on this topic in the GCM/NCDs; perhaps leading to a high level meeting under the aegis of the UN.

PHM urges that a WG be established to explore strategies for promoting policy coherence across sectors such as trade/investment and health and protecting policy space for NCD prevention/regulation in the face of the expanding application of ISDS provisions in bilateral and plurilateral trade and investment agreements.

Despite the lack of any references to trade in the workplan WHO proposes to involve WTO in organising the general meeting of the GCM (see Appendix 1 of Annex 3 of [A68/11](#)).

### **Conflict of interest regarding NCDs**

PHM notes the lack of any reference to conflict of interest in the NCDs space and urges an additional function to be assigned to the GCM to monitor potential conflicts of interest in the policy processes associated with the Action Plan and to advise the DG where conflicts of interest may lead to improper influence in such policy processes.

Widespread concern regarding the influence of big pharma, big food and big beverage on WHO and UN policy making around NCDs points to the importance of ongoing attention to conflict of interest and managing the risk of improper influence in relation to NCDs policy making.

PHM urges MS to expand the proposed Work Plan for the GCM/NCDs to include monitoring for potential conflicts of interest in the policy processes associated with the Action Plan and advising the DG where conflicts of interest may lead to improper influence in such policy processes.

### **Binding regulation of transnational corporations**

The increasing power of transnational corporations vis a vis the democratic expression of the public interest is widely recognised. There is an urgent need for new international instruments to regulate the TNCs in areas where their profit objectives run counter to public policy objectives such as food sovereignty and environmental sustainability.

PHM calls on WHO to open discussions with the Human Rights Council (perhaps in association with the IATF) with a view to exploring how the proposed internationally legally binding instrument on TNCs and other business enterprises ([A/HRC/26/L.22/Rev.1](#)) might provide a framework for regulating TNCs in relation to foods and beverages in particular.

## **Health system strengthening, public finance and tax reform**

PHM urges continuing attention to the crucial importance of strong health systems based on comprehensive PHC for the treatment and control of NCDs

This must include international attention to tax avoidance and the corporate driven race to the bottom with respect to public finance.

## **IP reform**

PHM urges continuing attention to the reform of market driven R&D and IP protected monopoly pricing that are driving the prices of treatments for NCDs, such as cancer and autoimmune diseases, to absurd levels; to the point where public procurement programs in rich countries are unable to offer such treatments.

## **Neglect of the prevention and control of Type 1 diseases**

Increasing attention to the prevention and control of NCDs should not obscure the continuing high rates of Type 1 diseases (communicable disease, undernutrition, maternal and infant mortality, etc).

The shortfalls with respect to the MDGs regarding nutrition, maternal and infant health, sanitation and water supply all underline the need for continuing priority for Type 1 diseases.

## 13.5 Global burden of epilepsy and the need for coordinated action at the country level to address its health, social and public knowledge implications

### In focus at WHA68

WHA68 will have before it [A68/12](#) which includes [EB136/13](#) which was considered by the Executive Board in January and the draft resolution adopted by the Board for the consideration of the Assembly.

[EB136.R8](#) recommends a draft resolution to the Assembly with exhortations to MS; invitations to partners inside the health sector and beyond; and requests for technical recommendations and support from the Secretariat.

Notes of the debate in the Board are [here](#).

### Background

As well as the current Secretariat report (in [A68/12](#)) see also:

- WHO's [Fact Sheet \(Oct 2012\)](#)
- [WHO Programme on Reducing the Epilepsy Treatment Gap](#)
- [ILAE/IBE/WHO Global Campaign Against Epilepsy](#)

### PHM Comment

The disability, exclusion and death associated with untreated epilepsy is huge. Most cases can be treated in primary health care settings.

The main challenges are:

- access to medicines (price and supply chain),
- weak PHC systems, including lack of specialist support,
- stigma, and
- leadership and accountability.

Leading players in global health policy have, for almost 40 years, opposed the realisation of the Alma-Ata Declaration: through 'selective primary health care' in the 1980s; through WB mandated stratified health systems in the 1990s; and through vertical disease focused silos in the 2000s.

The epilepsy treatment gap demands a renewed commitment to the full implementation of comprehensive primary health care including procurement and supply chains systems and strong referral and support relations between primary care and secondary and tertiary services. Treatment coverage for epilepsy would be an excellent indicator of successful implementation of such a commitment.

The continued price barriers to epilepsy treatment reflects the failure of the user pays model for health care financing. The total cost is small; the barriers to treatment for poor people are huge.



## **Health systems**

Health systems need to be strengthened to ensure that people with epilepsy can be managed within a comprehensive primary health care environment, with access to neurologists when required. This requires developing the primary health care workforce to improve knowledge and management of the disease and promote awareness to reduce stigma and discrimination. Inter-sectoral policies need to be developed to reduce structural barriers to health, education, transport, employment and social participation.

During the debate in the Executive Board both Argentina and Brazil, supported by Thailand, questioned the fixation on 'universal health coverage' (UHC) rather than universal access to health care in the draft resolution. Australia and the US, supported by China, opposed inserting 'universal access to health'. The result was some seriously tangled language in OP1(3).

## **Stigma and discrimination**

Inter-sectoral engagement is required to reduce discrimination, and misconceptions of the disease. These need to target health, education and employment to ensure human rights and full engagement in civil society.

## **Evaluation / indicators**

Indicators specific to epilepsy need to be identified including measures of access to medicines particularly within middle and low-income countries. The impact of trade negotiations and the impact of trade agreements on access to newer drugs through intellectual property restrictions should be included as part of any indicator/evaluation.

## 14.1 Monitoring of the achievement of the health-related Millennium Development Goals

### In focus

The Assembly will have before it [A68/13](#) which is a revised version of [EB136/14](#) which was considered by the Board in January.

This report summarizes progress towards achievement of the health-related Millennium Development Goals and specific targets. It also described progress made towards reducing child mortality through: the prevention and treatment of pneumonia; reducing perinatal and neonatal mortality; prevention and management of birth defects; and achieving universal coverage of maternal, newborn and child health care.

During the debate at the EB (see notes [here](#)) it was noted that the deadline for achieving the MDGs is fast approaching but many of the goals have not been achieved.

### PHM Comment

The picture revealed in [A68/13](#) is that of a global health crisis. Evaluating health trends against unambitious targets does not provide grounds for complacency; the glass is not half full.

The MDGs were adopted at a time when, in the words of the Macroeconomics and Health report,

*“Yet globalization is under trial, partly because these benefits are not yet reaching hundreds of millions of the world’s poor, and partly because globalization introduces new kinds of international challenges...”*

The MDG response was based on the charity model with new vertical disease programs seeking to apply technical solutions to palliate the effects of an unfair global dispensation rather than progressing the necessary structural reforms.

Technical solutions are necessary but they must be accompanied by structural changes directed to reforming:

- an unfair trading regime (which sanctions the dumping of subsidised agricultural products driving small farmers off their lands and into huge informal settlements in the cities;
- an unstable financial regime (in which policy priority is given to banks which are too big to fail rather than the communities who suffer as a consequence of greed and lack of effective regulation);
- a global tax regime which drives tax competition and facilitates capital flight and tax avoidance;
- an IP regime which is a major barrier to urgently needed technology transfer;
- an investment regime which privileges the interests of transnational corporations at the cost of reducing the regulatory and policy space of sovereign governments (as in ISDS provisions in contemporary trade agreements);
- a global regime which because of greed and competition is unable to deal effectively with global warming.

With the charity model comes the minimum benefit package approach, epitomised by the Macroeconomics and Health estimate of \$34 per person per year for health care. It is unfortunate that

WHO has joined the World Bank in including minimum benefit packages and privatised health care in its definition of UHC.

PHM calls for an approach to development cooperation based on human rights and human solidarity rather than charity. PHM calls for WHO base its health system recommendations on comprehensive primary health care supported by integrated district health systems and effective action on the social determination of health.

## Post 2015 processes

All of the (proposed) SDGs are highly relevant to health, either through access to decent health care or through action on social, political, environmental determinants of health.

As of mid April there is no Secretariat report dealing with the Post-2015 process which now appears to be firmly based on the 17 SDGs, nor is there a resolution foreshadowed, nor are the SDGs listed for discussion at EB137.

The MDGs were focused in large part on the problems of L&MICs and development assistance and they played a role in guiding priorities for donor funding, including for the bilaterals, the multilaterals and the philanthropies. This led to a dramatic increase from 2000 onwards in donor funding for health in L&MICs. A small amount of this funding flowed through WHO.

The new SDGs, in contrast, are more policy focused and offer a vision for humanity generally; one which is as much a challenge for the rich world as for the poor world. Donor funding will still have a role but deeper issues which call for cultural and institutional change and the redistribution of power and resources have been brought more explicitly onto the policy agenda. The report of the Open Working Group ([A/68/970](#)) displays the magnitude of the challenge which has been articulated.

If the new SDGs are to provide inspiration and guidance in terms of popular mobilisation and policy advocacy their roots in basic human rights principles will need to be continually reaffirmed.

WHO has a rich suite of resolutions, plans and strategies which are relevant to most of the SDGs including those that deal explicitly with health care as well as those addressing the determination of health.

PHM urges WHO to undertake a stocktake of its resolutions, plans and strategies to identify: first, where policies and programs are in place which are contributing to the commitments under each of the SDGs; and second, to identify gaps in WHO's policies and programs; where individual SDGs point to institutional and cultural changes and redistributions which would contribute to Health for All but which have not been given appropriate priority up until now.

PHM calls for the Assembly to commission a consolidated plan for presentation to WHA69 (in 2016) on how WHO will might the gaps identified, and monitor progress towards the health outcomes which could potentially be achieved through each of the SDGs.

## 14.2 Health in the post-2015 development agenda

### In focus

The Assembly will have before it [A/68/14](#) which provides some background to the emergence of the 17 SDGs and 169 associated targets and notes the process underway:

- to finalise the SDGs and targets;
- to ensure funding of the SDGs; and
- to devise a manageable set of indicators.

### Background

There have been two broad streams of discussion taking place within the aegis of the UN. The first of these arose from the UN Conference on Sustainable Development ('Rio+20') in 2012 ([here](#)) in the form of the post Rio+20 sustainable development goals (SDGs). The second stream was focused on the post-MDGs , post-2015 'development agenda' and was driven largely by the Secretary General.

More detail on both of these streams of discussion was included in PHM's commentary on Item 7.1 on the EB136 agenda ([here](#)). See also UNDESA's [summary page](#) on the UN Secretariat process and the UN Sustainable Development [knowledge platform](#).

In September 2014 the UNGA adopted [A/RES/68/309](#) through which it decided:

that the proposal of the Open Working Group on Sustainable Development Goals contained in the report [A/68/970](#) shall be the main basis for integrating sustainable development goals into the post-2015 development agenda, while recognizing that other inputs will also be considered, in the intergovernmental negotiation process at the sixty-ninth session of the General Assembly.

In accordance with this resolution the UN Secretary General presented his [Synthesis Report](#) on 4 Dec 2014 which recognised the adoption of the OWG report as the basis for the new SDGs. This provides for 17 SDGs:

Goal 1. End poverty in all its forms everywhere

Goal 2. End hunger, achieve food security and improved nutrition and promote sustainable agriculture

Goal 3. Ensure healthy lives and promote well-being for all at all ages

Goal 4. Ensure inclusive and equitable quality education and promote lifelong learning opportunities for all

Goal 5. Achieve gender equality and empower all women and girls

Goal 6. Ensure availability and sustainable management of water and sanitation for all

Goal 7. Ensure access to affordable, reliable, sustainable and modern energy for all

Goal 8. Promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all

Goal 9. Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation

Goal 10. Reduce inequality within and among countries

Goal 11. Make cities and human settlements inclusive, safe, resilient and sustainable

Goal 12. Ensure sustainable consumption and production patterns

Goal 13. Take urgent action to combat climate change and its impacts

Goal 14. Conserve and sustainably use the oceans, seas and marine resources for sustainable development

Goal 15. Protect, restore and promote sustainable use of terrestrial ecosystems, sustainably manage forests, combat desertification, and halt and reverse land degradation and halt biodiversity loss

Goal 16. Promote peaceful and inclusive societies for sustainable development, provide access to justice for all and build effective, accountable and inclusive institutions at all levels

Goal 17. Strengthen the means of implementation and revitalize the global partnership for sustainable development

In his report he also elaborated a set of six 'essential elements' for delivering on the SDGs: people, dignity, prosperity, justice, partnership, and planet. The SG's Synthesis Report also deals with financing for the SDGs and measurement.

It appears that the main work to be done before the new SDGs are formally adopted in September 2015 will be to agree on funding (see [Third International Conference on Financing for Development](#)) and measurement (see [Technical Report of UN Stats Commission](#) of March 2015).

The challenge now for WHO is to decide how to position itself in relation to the 17 SDGs.

## PHM Comment

All of the (proposed) SDGs are highly relevant to health, either through access to decent health care or through action on social, political, environmental determinants of health.

The MDGs were focused in large part on the problems of L&MICs and development assistance and they played a role in guiding priorities for donor funding, including for the bilaterals, the multilaterals and the philanthropies. This led to a dramatic increase from 2000 onwards in donor funding for health in L&MICs.

The new SDGs, in contrast, are more policy focused and offer a vision for humanity generally; one which is as much a challenge for the rich world as for the poor world. Donor funding will still have a role but deeper issues which call for cultural and institutional change and the redistribution of power and resources have been brought more explicitly onto the policy agenda.

If the new SDGs are to provide inspiration and guidance in terms of popular mobilisation and policy advocacy their roots in basic human rights principles will need to be continually reaffirmed.

WHO has a rich suite of resolutions, plans and strategies which are relevant to most of the SDGs including those that deal explicitly with health care as well as those addressing the determination of health.

PHM urges WHO to undertake a stocktake of its resolutions, plans and strategies to identify: first, where policies and programs are in place which are contributing to the commitments under each of the SDGs; and second, to identify gaps in WHO's policies and programs; where individual SDGs point to institutional and cultural changes and redistributions which would contribute to Health for All but which have not been given appropriate priority up until now.

PHM calls for the Assembly to commission a consolidated plan for presentation to WHA69 (in 2016) on how WHO might address the gaps identified, and monitor progress towards the health outcomes which could potentially be achieved through each of the SDGs.

## 14.3 Adolescent health

### In focus

The Assembly will have before it [A68/15](#) in which the Secretariat propose elements of a comprehensive plan on adolescent health, together with a process for consultation with countries and stakeholders. This is a revised version of [EB136/17](#) which was noted by the Board in January (notes of the debate [here](#)).

### Background

In May 2011 the Assembly considered [A64/25](#) on youth and health risks and adopted Resolution [A64.28](#). One of the flow-ons from this resolution was the multi-media report on 'Health for the world's adolescents' released in early May 2014 ([full experience here](#); summary [here](#); media release [here](#)). See also WHO's adolescent health topics [here](#).

The main thrust of [A68/15](#) is to propose the development of a formal framework for action on adolescent health. A broad sketch of the proposed framework is provided.

The framework would address five domains: health services, diet and nutrition, safe and supportive environments, physical activity and safe sex. The framework will focus particularly on the role of the health sector and the role of families and communities as well as young people. The report envisages a framework which will encourage young people to play an active part in its development and its implementation.

The report speaks of the need to 'scale up' effective and promising interventions in relation to all five of the domains identified. (There is an extended discussion of interventions in the 'Health for the world's adolescents' report ([see Fig 4, page 9](#)).

### PHM Comment

[Health for the world's adolescents](#) refers to the macro as well as immediate determinants of adolescent health but [A68/15](#) is focused largely on the more immediate risks.

There is no mention of jobs or employment but for millions of young people living in cities or regions of high unemployment the experience of marginalisation and exclusion are powerful determinants of current and future well being. [Health for the world's adolescents](#) notes that heading the causes of avoidable mortality are violence for boys and maternal mortality for girls both of which speak to upstream social determinants.

Para 12 states that the proposed 'framework would aim to build on and reinforce existing global and regional strategies and action plans that are relevant for the health of adolescents'. The report lists a range of previously adopted strategies and plans dealing variously with violence, women's health, sexual and reproductive health, nutrition, etc. It is not clear how this new strategy will contribute to the implementation of these earlier commitments. Para 12 of [A68/15](#) promises that the proposed framework will "spur the development of tools for young people to monitor health determinants in their

communities and the implementation of national action plans". It is to be hoped that these tools will address the macro determinants of adolescent health (marginalisation, exclusion, patriarchy) as well as immediate behavioural and health care access issues.

While the term 'primary health care' does not appear in the report it is to be hoped that the proposed tools will provide resources and encouragement for primary health care practitioners and agencies to work more actively with young people to explore and act upon both the proximal and distal determinants of adolescent health.



## 14.4 Women and health: 20 years of the Beijing Declaration and Platform for Action

### In focus at WHA68

*In January the Board considered report ([EB136/18](#)) which highlights progress made in relation to women and health since the Beijing Declaration and Platform of Action (1995). It also reviews the unfinished business of women and health in the context of the Millennium Development Goals, together with challenges and emerging priorities in respect of the twentieth anniversary of the Beijing Declaration.*

*In the debate at EB136 ([here](#)) the ADG indicated that a longer paper was being developed and would be shared with the MS, presumably at the Assembly. The ADG also spoke about developing a new strategy?*

### Background

The Fourth World Conference on Women was held in Beijing in September 1995 (see UN Women [here](#) for reference to previous conferences). The report of the Conference ([here](#)) includes the Beijing Declaration and Platform for Action. The Platform for Action includes twelve major action areas including [health](#).

[EB136/18](#) reviews: the unfinished agenda (poor sexual and reproductive outcomes, maternal mortality, HIV, sexual violence, genital mutilation); the emerging priorities (adolescent pregnancy, noncommunicable disease, vulnerability in older age); and health system responses (addressing structural determinants of women's health, addressing inequities in access, quality of care, and monitoring and accountability). The EB is invited to provide further guidance.

Several pages on the WHO website provide further information. The [Women's Health topic page](#) highlights some of the 'sociocultural factors that prevent women and girls to benefit from quality health services and attaining the best possible level of health' including:

- unequal power relationships between men and women;
- social norms that decrease education and paid employment opportunities;
- an exclusive focus on women's reproductive roles; and
- potential or actual experience of physical, sexual and emotional violence.

The page comments that while poverty is an important barrier to positive health outcomes for both men and women, poverty tends to yield a higher burden on women and girls' health due to, for example, feeding practices (malnutrition) and use of unsafe cooking fuels (COPD).

Two streams of parallel activity should be noted; first, the UN Secretary General's Global Strategy for Women's and Children's Health, and second, WHO's gender mainstreaming strategy.

The United Nations Secretary-General's [Global Strategy for Women's and Children's Health](#) was launched in September 2010 in order to accelerate progress on Millennium Development Goals 4

(Reduce child mortality) and 5 (Improve maternal health). See [Every Woman Every Child](#). WHO was involved in design and implementation but particularly in the Commission on Information and Accountability for Women's and Children's Health ([2012 report here](#)).

In May 2007, the WHA approved resolution [WHA60.25](#) (from page 92) on the Strategy for integrating gender analysis and actions into the work of WHO. The strategy builds on the WHO gender policy adopted by the Secretariat in 2002, and involved four strategic directions (SD):

- SD1: Building WHO capacity for gender analysis and actions
- SD2: Bringing gender into the mainstream of WHO's management
- SD3: Promoting use of sex-disaggregated data and gender analysis
- SD4: Establishing accountability

The [mid term review of the Strategy in 2011](#) concluded that from 2008 to 2010 there had been little progress in implementing these directions.

## Human rights

Two key documents underpinning the Beijing Platform are the Convention on the Elimination of All Forms of Discrimination against Women ([CEDAW](#)) adopted in 1979, and Article 12 (The right to the highest attainable standard of health) of the [International Covenant on Economic, Social and Cultural Rights](#) (1976), as elaborated in [General Comment No. 14](#) (from page 128) adopted by the UN Committee on Economic, Social and Cultural Rights in May 2000. For more detail see [WHO/OHCHR \(2007\)](#).

These declarations and statements carry strong moral authority but limited legal sanctions. Their realisation depends on refusal of governments, backed by social and political movements, to tolerate breaches of these standards. The documents provide authority, inspiration and political leverage but without social and political pressure they lack enforcement. This principle is of critical importance in driving towards fulfillment of the Beijing Platform.

## PHM Comment

### The unfinished agenda

There has been some progress over the last 20 years but comparing the Beijing Platform of 1995 with the situation sketched in [EB136/18](#) it is apparent that such progress has been limited.

### Diversity and discrimination

The lack of any reference to transsexual or lesbian women reproduces heteronormativity and elides the health challenges associated with discrimination (for example in access to health care) and homophobia (which can be fatal in many countries).

Health policy needs to recognise the full breadth of diversity and accommodate the needs and voices of marginalized and excluded groups such as indigenous, transgender, sex workers, migrant, HIV +, adolescents, elderly, differently abled, persons with mental health issues. It is necessary to address all

forms of discrimination and include, equity, participation, inclusive partnership, accountability and human rights.

## Disaster and conflict

All necessary support to integrate medical care, provision of security and legal investigation, grievance redressal towards justice and rehabilitation must be assured in all conflict situations and war zones and in situations of mass violence that have serious implications for the health of girls and women

## Health systems

The underfunding of public health care impacts particularly heavily on women in many countries, including such conditions as falciparum malaria, tuberculosis and other communicable diseases and noncommunicable diseases such as cancers (breast, cervical, diabetes, heart disease etc).

A strong primary health care base is essential in ensuring universal access, equity and quality of care. It is also essential in addressing the social determinants of health and in strengthening women's participation in health decisions.

Quality mental health services, support, counselling and rehabilitation are required for women suffering from mental health problems. Urgent steps need to be taken towards a health system response to violence against girls and women.

The private sector is unable to deliver comprehensive primary health care or to address the social determinants of health. It is extremely hard to regulate quality and rational resource use in the private sector. Where universal access to health care is interpreted as public funding to support private practice, the scope for comprehensive PHC, for action on the SDH and for effective public policy guidance in health care development is sacrificed.

## Lack of regulation of the private sector: an epidemic of intervention

A stark example of the challenge of regulating the private sector and its profit focus is the epidemic of deliveries by Caesarean section, despite the lack of evidence base in most cases. In Brazil the rate of unnecessary interventions during delivery is alarming: in 2008, the proportion of Caesareans was 48%, comparing with 15% in the 1970s (Victora, Lancet, 377, p.1863-1876, 2011).

A more recent 2014 [study](#) has identified that in 2014, 52% of deliveries in Brazil are Caesarean, reaching 88% in the private health sector. These numbers are highly abusive, considering WHO recommendation of 15% of expected Caesarean deliveries. Women's rights are being denied due to unequal power relations that are putting money and convenience above scientific evidence and women's right to decide.

## Access to safe quality abortion services without discrimination

The high number of unsafe abortions is mentioned in EB136/18 and its contribution to high maternal mortality rates including in adolescents. However, the document does not make the point that unsafe abortions are largely a consequence of illegality or cost barriers to care in the private sector. [WHO \(2012\)](#) estimates that 47,000 women die and 5 million women suffer complications or impairment as a

consequence of unsafe abortion. These may be underestimates because of its illegality in most low and middle-income countries. The restrictions regarding access to safe abortions is one of the reasons why progress has been limited in terms of maternal mortality.

The role of institutionalised patriarchy in denying women access to safe and affordable contraception and safe and quality abortion services illustrates one of the major on-going barriers to women's health.

## Underlying causes

Despite the promises of the Gender Mainstreaming Strategy (SD1 in particular), document [EB136/18](#) is weak in explaining why progress has been so patchy and in pointing towards useful strategies.

Three groups of conditions contribute to the avoidable disease burden carried by women:

- conditions which are directly attributable to patriarchy: including gender based violence (including the post-traumatic consequences of such violence); denial of education; differential access to food; additional exposure to indoor pollution; household delays in access to health care; denial of access to contraception and other forms of reproductive health care;
- conditions which reflect more general social determinants of health but, because of gender inequality bear more heavily on women: including poverty, marginalisation and exclusion associated with neoliberal globalisation; displacement through land grabs, mining, and the dumping of agricultural commodities; under nutrition; institutional racism;
- conditions which reflect more general failures of health and social care but which, because of gender inequality, bear more heavily on women: including cost barriers to accessing health care; weaknesses in health care delivery; poverty and neglect in old age.

Patriarchy and gender inequality are sustained and reproduced through:

- embedded cultural traditions within families and communities;
- the intensification of patriarchal oppression in communities suffering from poverty, exclusion, displacement and racism;
- vested interests of patriarchal institutions, in particular, religious and military institutions;
- government policies (of omission and commission) which reflect prevailing power relations in society including patriarchal power relations.

Understanding the avoidable disease burden carried by women requires understanding the interaction of gender inequality with the political, cultural and economic conditions which sustain and reproduce poverty, exclusion, marginalisation, environmental degradation (including neoliberal globalisation) and which sustain and reproduce weak health systems (including selective interventionism, stratified health care financing, disease focused funding programs, race to the bottom in tax rates, tax avoidance, corporate supported corruption).

The increasing investment by Big Tobacco in marketing tobacco use to women in low and middle income countries illustrates these kinds of interactions. WHO ([here](#)) has highlighted increasing tobacco use among women as one of 'most ominous developments in the tobacco epidemic'.

The interplay of institutionalised patriarchy and access to health care is illustrated in the political factors that impede the registration and distribution of drugs for emergency contraception or abortion such as misoprostol and mifepristone.

Action on gender relations will involve empowering women and reframing gender relations, creating new pathways to access to knowledge, richer conversations to share new ways of seeing things, realising women's rights including access to resources, and opportunities for new alliances and new organisational relationships. Action on social determinants will include action in many sectors and at many levels but it must include explicit support for women to engage in such action as part of reframing the gender dimensions. Action on health systems strengthening will include many elements of health care reform but must include support for women to engage in such action as part of reframing the gender dimensions.

The implications for WHO are several:

- encourage new partnerships with women's organisations at all three levels of WHO's work, including in the governing bodies;
- strengthen the effectiveness and accountability of WHO's member states (including the Holy See) for action on the innumerable declarations, statements and policies which have accumulated around women's health, in particular, the Platform for Action from 1995;
- return to the PHC model in addressing the social determinants of health and in health system strengthening; enrolling PHC practitioners to work with their communities (in particular the women of their communities) on the factors which shape their health and access to health care, but in ways which also help to reframe gender relations;
- re-invigorate WHO's gender mainstreaming strategy including implementing the recommendations of the 2011 mid-term review ([here](#), from page 19);
- ensure accountability for implementing a human rights based approach in all of WHO's work.

Ultimately the capacity of WHO to contribute to women's health is limited by the same factors which limit all of its work: the donor chokehold, regional dysfunction, and the lack of accountability of member states. These underlie the need for real reform of the Organisation.

## 14.5 Contributing to social and economic development: sustainable action across sectors to improve health and health equity

### In focus at WHA68

Resolution [WHA67.12](#), adopted by the Assembly in May 2014, requests the DG, among other things (which see):

*to prepare, for the consideration of the Sixty-eighth World Health Assembly, in consultation with Member States, 1 United Nations organizations and other relevant stakeholders as appropriate, and within existing resources, a Framework for Country Action, for adaptation to different contexts, taking into account the Helsinki Statement on Health in All Policies, aimed at supporting national efforts to improve health, ensure health protection, health equity and health systems functioning, including through action across sectors on determinants of health and risk factors of non-communicable diseases, based on best available knowledge and evidence;*

Presumably this Framework for Country Action will be the main issue under consideration at WHA68 in May 2015.

### Background

The [8th Global Conference on Health Promotion](#) was held in Helsinki in June 2013 and focused on 'Health in all Policies'. At the 134th Session of the EB in Jan 2014 Finland requested inclusion of this item on the EB agenda in document [EB134/1 Add.1](#). Finland proposed that WHO should provide more guidance to member states:

1. which structures, strategies and processes are necessary for the evaluation of the impact of societal policies on health and health equity outcomes,
2. how to prioritize and seek multisectoral solutions at the different levels of governance,
3. how the health sector can engage with other sectors as a broker and as an advisor.

The Board considered this issue in January 2014 (notes of EB134 debate [here](#)) and adopted [EB134.R8](#) which recommended a draft resolution for the consideration of the Assembly.

WHA67 considered [EB134.R8](#) with the Secretariat document [A67/25](#) (notes of WHA67 debate [here](#)) and adopted [WHA67.12](#).

For other background information see PHM [Call to Action](#) at the 8<sup>th</sup> Global Conference on Health Promotion and also the [Alternative Civil Society Declaration](#) at the Rio Conference on Social Determinants of Health.

### PHM comment

We endorse the recognition of 'different levels of governance' but we suggest clearer differentiation between intersectoral collaboration at the domestic level and effective action around global governance issues which affect health across regions and globally.

In relation to the former, WHO has an important role in providing guidance regarding institutions, procedures and evidence. In relation to the international dimension WHO has responsibilities for actively engaging stakeholders in other sectors and driving policy development and implementation. In this respect the reference to 'guidance to member states' in the Finnish proposal may be taken as referring to member states in their role as decision makers in the governing bodies of the WHO.

We note that the idea of intersectoral collaboration is not new for WHO, indeed many of the items on the agenda for the current EB require an intersectoral approach. What is new about the Finnish proposal is the call for a more systematic approach to sustainable social and economic development as a necessary step towards population health and equity.

In line with this proposal, PHM proposes that for WHO to adopt a more systematic approach to multisectoral action for sustainable development will involve: first, identification of the key development issues which are limiting population health and health equity; and second, the cultivation of a deeper understanding of development issues beyond health so that health experts, domestically as well as in the governing bodies, can approach the immediate health issues in ways that also contribute to sustainable multisectoral action.

At the same time, as mentioned by the document but not further elaborated, it is crucial the translation of the increased understanding of the broad determination of health into guidance for concrete actions.

Accordingly PHM proposes a program of research and analysis to develop resources to support member states in the following critical issues which profoundly affect health and equity:

- global finance sector regulation including the shadow banking system and over the counter derivatives; arguments for financial transaction taxes; closing of offshore financial centres;
- policy issues regarding extractive industries especially in developing countries, including scope for increasing the royalties, reducing tax holidays for FDI, closing off capital flight (through enforced withholding taxes);
- transparent and equitable taxation systems, especially in Sub-Saharan Africa, adding 'aid for progressive tax reform' to the current 'aid for trade' agenda and thereby reducing the dependencies of developing countries on rich nations and TNCs;
- (in the context of the post-2015 agenda) pathways to reducing socioeconomic inequities, and not simply poverty (witness the achievement of MDG 1 in the midst of egregiously huge income/wealth inequalities);
- food sovereignty and health; local, community, regional and at the very least, national control over food production and distribution;
- full recognition of WHO standards in any future trade and investment treaties (enforceable treaty language, not just pre-ambular or chapeau language) requiring that dispute settlements that involve any form of public health regulation to take full account of WHO law (e.g. FCTC) and WHA approved action plans (e.g. on NCDs);
- ensuring that the GATT and GATS health exceptions under the WTO treaties be incorporated in all future trade and investment treaties (since WTO dispute panels are actually now beginning to use these in ways that could protect public health);
- continuing engagement with intellectual property issues including ensuring that no trade or investment treaty should initiate intellectual property rights that go beyond those articulated

under the multilateral TRIPS agreement, and that the specific wording of the 2001 Doha Declaration on the right to issue compulsory licences be written into all future trade and investment treaties; this should also include that the WHO provide technical support to member states to benefit from the flexibilities embedded in the TRIPs agreement and related declarations;

- review of investor-state dispute settlement chapters to assess their impact on social and economic regulation and health equity.

These are some of the critical content issues in building the capacity of the health sector to engage effectively in multi-sectoral collaboration.

WHO also needs to develop guidance resources regarding structures, processes and evidence. In this context we urge close attention to:

- capacity building within the health sector, at all levels, with a view to building health sector understanding of the broader social and economic development issues which frame pathways towards health for all;
- structures which engage public health academics and professionals and public interest civil society organisations and networks in the formulation and implementation of multisectoral collaboration;
- programs which build public understanding of the issues and create a constituency for moving towards sustainable development and health equity.



## 14.6 Health and the environment: Addressing the health impact of air pollution

### In focus at WHA68

The Assembly will have before it a report from the Secretariat on air pollution ([A68/18](#)) and a draft resolution (A68/18 Add.1, not yet published).

In January the EB considered [EB136/15](#) which outlined a number of strategies for the prevention, control and mitigation of the adverse effects of air pollution on health.

The Board also had before it a draft resolution proposed by the delegations of Chile, Colombia, France, Monaco, Norway, Panama, Ukraine, United States of America, Uruguay and Zambia ([EB136/CONF./9](#)).

Consensus on this resolution was not achieved and in Decision [EB136\(14\)](#) the EB requested MS to continue working towards a draft resolution for the Assembly. It appears from the notes of the debate at the Board in January ([here](#)) that the main tension may have been between the USA and India.

See below for further exploration of the failure to achieve consensus.

### Background

This item was introduced at EB135 in May 2014 with the following note:

*At the request of Member States, recognizing that addressing the social, economic and environmental determinants of health is a leadership priority in the Twelfth General Programme of Work 2014–2019 and that air pollution is a major global health issue requiring urgent response by all countries, the Board is invited to consider [EB135/4](#) and give further guidance.*

During the discussion it emerged that the MSs requesting this discussion were Panama, Bangladesh and France.

The secretariat paper ([EB135/4](#)) explored briefly:

- health impacts of exposure to indoor and outdoor pollution;
- the broader context and opportunities for action;
- the role of the health sector and priorities for action; and
- the existing work program of WHO (including the commitment to action around the social and environmental determinants of health).

See also [WHO topic page on air pollution](#).

At EB135 28 MSs endorsed the importance of air pollution and spoke in support of WHO taking the issue further. See PHM comment and report from EB135 [here](#).

It was agreed to review it further at EB136, presumably with a view to a new resolution and perhaps a global strategy and action plan.

The revised paper ([EB136/15](#)):

- summarised the effects of air pollution on human health;
- reviewed strategies for reducing the health impacts of air pollution;
  - intersectoral policies (power generation, transport, urban planning, etc)
  - addressing equity issues through the health in all policies approach;
  - air quality guidelines, monitoring process as well as outcomes;
  - city focused policies;
  - clean energy technologies and corresponding market environments;
- reviewed ways in which ministries for health can contribute
  - epidemiological study and research
  - policy development and communication
  - intersectoral (and across level) engagement
- listed some of the ways the Secretariat can help
  - sharing evidence
  - monitoring and reporting global trends
  - capacity building and technical support
  - leadership in global efforts
  - evidence based guidelines

At EB136 a draft resolution was tabled ([EB136/CONF./9](#)) and initially the discussion within the Board was commendatory regarding the Secretariat report and the draft resolution. (See notes of EB debate [here](#).) However, when the drafting committee came to report it became clear that consensus had not been achieved in the drafting group. Accordingly it was decided ([EB136\(14\)](#)) that MS would continue to work on the draft in the lead up to the Assembly anticipating a clean draft (A68/18 Add.1) would be available for the Assembly.

## Why could consensus not be achieved?

The deliberations within the drafting group are not made public. However, it is interesting to compare the first version of the Air Pollution draft resolution ([EB136/CONF./9](#)) and the second version which came out of the conflicted drafting group ([EB136/CONF./9 Rev1](#)) and to note the paragraphs which are bracketed (indicating that agreement could not be reached).

For example four new paragraphs were proposed (but also opposed) to follow PP9:

- [(PP9 bis) Cognizant that there are also other air pollutants, not resulting from human activity which cause significant health threats, radon in particular, and that exposure to indoor radon is an important cause of lung cancers in the general population and that this exposure can be substantially reduced by awareness raising programmes aimed at the general public and in particular property owners, as well as by prevention and remediation measures in buildings];
- [(PP9 ter) Underscoring that the root causes of air pollution and its adverse health impacts are socioeconomic in nature, and recognizing that rapid and uncontrolled urbanization is a major driver for air pollution, especially in developing countries];
- (PP9 quart) [Reaffirming that poverty eradication is the greatest global challenge facing the world today, and is an indispensable requirement for sustainable development, including finding sustainable solutions for air pollution];

- (PP9 cinc) [Recognizing that ensuring open channels for technology transfer and providing support for innovation is essential for addressing indoor and outdoor air pollution];

Other interesting but conflicted changes include that PP14&15 be replaced by PP15 bis and the brackets in OP1-3-(10).

India's contribution to the debate at the Board proper included: "...Controlling air pollution is not entirely within the health sector, need for intersectoral actions and coordination. This is easier said than done. Health sector can facilitate the adoption of interventions and contribution of dissemination of initiatives. SDH are linked to air pollution and health of vulnerable people. There is a disparity between countries and a need to transfer technology and mobilise resources. Tackling air pollution is distinct from climate change: but action on AP should not take from action on climate change. WHO work on AP should not be used to reduce focus on climate change action."

It appears that India believes that air pollution has been promoted as a strategy for reducing the focus on climate change, perhaps because of the DG's action in convening the WHO Conference on Health and Climate. Does India have evidence that AP was brought forward in some way as a response to the DG's Conference?

The references to technology transfer and mobilising resources suggest that India's intervention was drafted by the officials who are engaged in the UNFCCC negotiations in the lead up to Paris this year.

It appears that India was the country being criticised by UK and Monaco for 'trying to politicise the resolution'. It is interesting that in speaking to the Climate Change item Monaco went out of her way to specifically welcome "activities to cut down morbidity from air pollution impacts".

Can we speculate that the WHO Conf on Climate Change may have been initially suggested by the UN climate negotiators as part of a 'One UN' approach to Paris. This might be supported by the interventions by France and Norway in the Climate Change debate who both commended WHO for working with other UN organisations.

And what was the US going on about with the reference to the Obama Plan ([see](#))? Was it the commitment to 'Negotiate global free trade in environmental goods and services' in the Obama Plan' (initiative launched in July 2014)? Is there a contradiction between 'technology transfer' and a 'free trade' solution? Is this what was motivating the Indian opposition to the AP initiative?

The US contribution to the debate over climate change referred to the [Climate and Clean Air Coalition](#) (CCAC) to reduce short-lived climate pollutants (SLCPs). The CCAC to remove SLCPs brings together the UN Environment Program with 46 countries (not including India or China) and a range of intergovernmental, non-governmental, and private sector entities and appears to focus on replacing kerosene lamps, reducing motor vehicle emissions and cleaner cooking stoves.

It seems that the debate in EB136 may be part of the manoeuvring between US (and other rich countries) and India (and other developing countries) in the lead up to the [COP21](#) in November-December 2015 in Paris. More complex because the DG's Conference on Climate Change was not commissioned by the governing bodies of WHO but prompted by solidarity between UN agencies in the lead up to the COP.

Some of the finger pointing in this debate appears to include:

- Blaming poor countries for having kerosene lamps, polluting stoves and polluting buses;
- Blaming rich countries for refusing to support technology transfer and financial transfers to support mitigation and adaptation and instead focusing on village housepersons and bus drivers; and
- Rich countries arguing for a free trade solution to technology transfer, within the context of increasing intellectual property protection, including TRIPS plus measures in 'free trade agreements'.

At the WHO Conference on Climate Change the [Global Climate and Health Alliance](#) is reported ([here](#)) as calling for 'a shift away from fossil fuels to tackle climate change and non-communicable diseases, and supported declaring climate change a global public health emergency'. (Interestingly the US delegate highlighted 'reducing air pollution as a key priority that provides for win-win solutions and stressed that WHO can play an important role by, inter alia, conducting quantification of air pollution health effects'.)

## PHM Comment

PHM recognises the serious burden of disease associated with air pollution urges WHO to strengthen the health sector's engagement around clean air policy and practice.

PHM highlights swelling urbanisation as an important driver of air pollution and refers the Secretariat to the work of the [Urban Settings Knowledge Network](#) of the Commission on the Social Determinants of Health. We urge a focus on strategies such as rural electrification, investment in rural education and support for small farmers as strategies for restraining urbanisation.

We also urge attention to the geographic distribution of pollution within global production chains. It is too easy for transnational corporations to displace polluting production to L&MICs.

PHM endorses the package of strategic actions listed in [EB136/15](#) but notes that the document does not address the political challenge of effecting change in this field. Retooling the household, urban and industrial infrastructure which generates air pollution will involve costs, will necessarily cut across vested interests and will thus confront opposition and conflict. Committing WHO (and MS MOHs) to this project should be based on a systematic mapping of the stakeholders and power relations involved; a structured exploration of various strategies and scenarios; and a clear set of strategies for building the constituencies which will drive for change.

There are already massive inequities with respect to the exposure of different populations to indoor and outdoor air pollution. Urban populations in developing country megacities and women cooking with open polluting fuels compare sharply with the conditions in the rich strata of rich countries. There is a risk that effective action on air pollution could further improve the air quality of the latter without significant change for the former. Thus any set of strategies for change need to demonstrate a capacity to redress the causes of such inequalities.

In this context the leading principle must be to work closely with those who have most to gain from effective, equitable and sustainable action. This includes the communities most at risk. It also includes the industries which offer reduced pollution in the kitchens, on the roads and in the workplaces.

PHM urges that in the conception and development of this strategy serious attention is paid to the development of meaningful partnerships with civil society organisations and networks, in particular those community based organisations who work with the communities who have most to gain. This includes workers who are exposed to air pollution in unsafe mines and workplaces.

The operationalisation of these principles will be very different in different countries and regions which points towards the need for extended capability building at the regional and country level and strengthening of the different constituencies for change in those settings. We urge full consideration of the principles of PHC in this context, in particular, the idea of PHC practitioners working in partnership with their communities to build a constituency which can demand healthy living conditions.

There are significant international dimensions to this project which will need attention as it develops. Ensuring open channels for technology transfer and providing support for innovation will be critical. The continuing pressure from the US, Japan and Europe for higher levels of IP protection and TRIPS+ conditions runs counter to the objective of open technology transfer.

PHM emphasises the need for strong international norms regarding air quality to protect national policy makers from the threat of corporate intimidation under investor state dispute settlement provisions in trade and investment agreements.

We urge full consideration to the role of binding international instruments to achieve change, as opposed to voluntary codes of conduct.

## 15.1 Antimicrobial resistance

### In focus

The Assembly will have before it [A68/19](#) which provides a summary report on progress made in implementing resolution [WHA67.25](#) on antimicrobial resistance. One of the commitments in [WHA67.25](#) was to produce a global action plan on antimicrobial resistance and in a separate document ([A68/20](#)) the revised draft global action plan is presented.

There was a long and constructive discussion at EB136 ([here](#)) following which the ADG requested MS to provide their suggested amendments and inclusions in writing please. Member states were advised that the final meeting of the [Strategic Advisory Group \(STAG\) on antimicrobial resistance](#) was due to meet on 24/25 Feb and that the revised document would then be forwarded to the WHA.

### Background

Increasing prevalence of antimicrobial resistance (combined with the slowdown in the development of new antimicrobials) has been recognised as a major threat within public health for some years.

In 2001 WHO published the global strategy for containment of antimicrobial resistance, and the Health Assembly has adopted several resolutions on the subject including [WHA60.16](#) concerning the rational use of medicine and [WHA62.15](#) on prevention and control of multidrug-resistant tuberculosis and extensively drug-resistant tuberculosis and [WHA67.25](#) (in May 2014). Various initiatives have been launched, including in 2011 a call for action on [World Health Day](#), with a policy package for stakeholders.

There was a well attended side event on anti-microbial resistance at WHA66 (May 2013) and the first meeting of the newly convened Strategic and Technical Advisory Group on Antimicrobial Resistance (STAG-AMR), was held in Geneva in September 2013.

In May 2014 WHO released the [report of the global surveillance of antimicrobial resistance](#).

### Draft global action plan

[WHA67.25](#) requested the DG to develop a draft global action plan to combat antimicrobial resistance. This is presented for WHA consideration in [A68/20](#) and the Assembly is asked to endorse the plan.

The draft global action plan envisages separate plans at each of three levels: individual member states, the WHO Secretariat, and international and national partners. The plan articulates five principles and five objectives which are to be expressed in all of these plans.

The five principles are:

1. Whole-of-society engagement including a one-health approach,
2. Prevention first,
3. Access [equitable access to, and appropriate use of, existing and new antimicrobial medicines],
4. Sustainability, and

5. Incremental targets for implementation.

The five objectives are:

1. Improve awareness and understanding of antimicrobial resistance through effective communication, education and training;
2. Strengthen the knowledge and evidence base through surveillance and research;
3. Reduce the incidence of infection through effective sanitation, hygiene and infection prevention measures;
4. Optimize the use of antimicrobial medicines in human and animal health;
5. Develop the economic case for sustainable investment that takes account of the needs of all countries, and increase investment in new medicines, diagnostic tools, vaccines and other interventions

The plan includes a table which identifies actions at each level under each objective.

## Implementation of the rest of [WHA67.25](#)

[WHA67.25](#) requests the DG to ensure that all relevant parts of the Organization, at headquarters, regional and country levels, are actively engaged and coordinated in promoting work on containing antimicrobial resistance, including through the tracking of resource flows for research and development on antimicrobial resistance in the new global health research and development observatory. [A68/19](#) reports on the work of the WHO Global Task Force on Antimicrobial Resistance and on a project linked to the proposed global health R&D observatory.

[WHA67.25](#) requests the DG to ensure that adequate resources are available to support WHO's work on AMR. [A68/19](#) reports that adequate provision will be made in the PB16-17.

[WHA67.25](#) requests the DG to strengthen the tripartite collaboration between FAO, OIE and WHO for combating antimicrobial resistance in the spirit of the "One Health" approach. [A68/19](#) reports that focal points from OIE and FAO have participated in the development of the draft action plan and are working with the WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance.

[WHA67.25](#) requests the DG to explore with the United Nations Secretary-General options for a high-level initiative, including a high-level meeting, to increase political awareness, engagement and leadership on antimicrobial resistance; [A68/19](#) reports that progress is being made.

## PHM Comment on draft global action plan

In the following notes the analysis and strategic directions in the draft global action plan are reviewed against the [Declaration](#) of the Antibiotic Resistance Coalition which is a federation of civil society networks (including PHM) concerned about antimicrobial resistance.

### Animal husbandry

Under **Objective 3**: MSs are invited to promote vaccination as a method of reducing infection in food animals and OIE is invited to update its codes and manuals to take account of new developments in vaccines. There is no recognition under the MS action column that intensive industrial food production is a driver of illness and hence the need for antibiotics. The draft suggests that "FAO should continue to

engage and support producers and stakeholders in the food and agriculture sectors in adopting good practices in animal husbandry”. This is weak.

The [ARC Declaration](#) states that “antibiotic use for mass disease prevention must not substitute for good animal husbandry and welfare. Farm practices such as overcrowding, unhygienic conditions, inappropriate diets, and early weaning requiring routine antibiotic administration, must be prohibited.”

Consumers International has commented that: “[over 70% of cattle on larger United States feedlots](#) receive the critically important antibiotic tylosin for most of the feeding period (160 days) primarily as prophylaxis/prevention for liver abscesses. Liver abscesses occur in feedlot cattle [due to diets that are too high in starch](#) so in essence tylosin use occurs at extremely high levels because its use is cheaper than providing adequate diets”.

Under **Objective 4** the actions scheduled for member states should also include a recommendation that government institutions and healthcare facilities demonstrate leadership in the control of AMR by procuring meat and fish products from suppliers which are certified as not using antibiotics as growth promoters. Will require a certification and labelling scheme to be set up. Will require involvement of OIE and FAO and Codex.

Under **Objective 5** the draft plan proposes that “FAO, OIE and other partners should support appropriate analyses to establish the case for investment and to inform the selection of interventions to improve animal husbandry, management, health, hygiene and biosecurity practices aimed at reducing antimicrobial use (and antimicrobial resistance) in different production settings.” This includes a very indirect recognition of the role of intensive industrial food production and is much too weak.

MSs are urged to include the “phasing out of use of antibiotics for animal growth promotion and crop protection, and reduction in nontherapeutic use of antimicrobial medicines in animal health”. Need to mention explicitly that industrial food production causes illnesses which require treatment and justify prophylaxis.

The [ARC Declaration](#) states that “Food produced without routine use of antibiotics and without antibiotic residues should be labelled through reliable, certified schemes to facilitate consumer choice. Food produced with routine use of antibiotics must be clearly labelled, until effective prohibition of such antibiotic use can be introduced.”

## Collecting data about antimicrobial usage

Under **Objective 2**, MS are urged to ‘collect and report data on use of antimicrobial agents in human and animal health and agriculture so that trends can be monitored and the impact of action plans assessed. Under **Objective 4**, MS are urged to include in their action plans on AMR the “collection and reporting of data on use of antimicrobial agents in human and animal health and agriculture so that trends can be monitored and the impact of action plans assessed”.

Clause 14 of the [ARC Declaration](#) urges that “The public sector in every country needs to build a robust national system for monitoring antibiotic use and resistance trends in humans and animals, as well as contributing to the development of an effective global monitoring system. Essential inputs to a global surveillance system include data on prices, availability, affordability, sales and use of antibiotics, by



drug and by indication, as well as drug resistance patterns and changes in antibiotic efficacy. These data for both human and non-human uses must be gathered and publicly disclosed in sufficient detail to enable effective action by stakeholders such as civil society, medical professionals and governments.”

We urge the explicit inclusion in the plan of the need to collect data on prices, availability, affordability, sales and use of antibiotics, by drug and by indication as well as drug resistance patterns and changes in antibiotic efficacy.

## Regulation of marketing and promotion

MSs are urged to include, in their action plans on AMR, the “regulation and control of promotional practices by industry”. Need to say explicitly what principles need to be met in this respect.

Under **Objective 4** the Secretariat will “Provide leadership to strengthen medicines regulatory systems at national and regional levels, so that appropriate practices for optimizing use of antimicrobial medicines are supported by appropriate and enforceable regulation, and that promotional practices can be adequately regulated”. This is good.

The Secretariat will “Consult with Member States and pharmaceutical industry associations on innovative regulatory mechanisms for new antimicrobial medicines, for example considering them as a class of medicine that will require a different set of regulatory controls, and on new approaches to product labelling that focus on public health needs rather than marketing claims...”. Why only new medicines?

Under **Objective 4** “Professional bodies and associations, including industry associations, health insurance providers and other payers, should develop a code of conduct for appropriate training in, education about, and marketing, purchasing, reimbursement and use of antimicrobial agents. This code should include commitment to comply with national and international regulations and standards, and to eliminate dependence on the pharmaceutical industry for information and education on medicines and, in some cases, income.”

The [ARC Declaration](#) states that “ Promotion and advertising of antibiotics, including marketing for inappropriate uses or incentivising medical and veterinary personnel to overuse or inappropriately prescribe antibiotics, is harmful to health and should be prohibited.”

The references to a ‘code’ in Objective 4, presumably a voluntary code, is weak. The need is for mandatory binding regulations.

Under **Objective 4** there are no references to Investor State Dispute Settlement provisions in trade agreements which have the potential to greatly limit the capacity of governments to regulate for antimicrobial stewardship.

The [ARC Declaration](#) notes that “ New trade and investment regimes threaten to place commercial interests above public health and consumer protection, thereby undercutting effective control of antibiotic use and resistance.”

In the context of contemporary trade regulation there is a danger that Codex and other standards,

which are designed as minimum standards become de facto maximum standards. This is because of the principle of 'least trade restrictive' in the arbitration of trade disputes. Tribunals tend to treat regulations of a higher standard than intergovernmentally authorised standards as being beyond the 'least trade restrictive' requirement.

## Environmental standards

Under **Objective 4** the WHO Secretariat undertakes to “develop standards (within the tripartite collaboration with FAO and OIE), based on best available evidence of harm, for the presence of antimicrobial agents and their residues in the environment, especially in water, wastewater and food (including aquatic and terrestrial animal feed)”.

This objective should mention explicitly monitoring waste from health care facilities and should be linked with a recommendation under **Objective 2** for MSs to undertake monitoring and research in relation to the risks associated with microbial mixing in health care sewage.

Hot spots for horizontal resistance gene transfer such as in wastewater treatment facilities need to be controlled. Health ministers should work with their colleagues in infrastructure and local government to ensure a clean water supply. ... The pollution of the environment via sewage, waste disposal of hospitals as well as industrial meat processing needs to be monitored. The pollution of the environment via livestock waste, sewage, industrial meat processing waste, and hospital disposal needs to be monitored and controlled.

## Alternatives to antibiotics

More emphasis could be placed in the Global Action Plan on exploring alternatives to antibiotic drugs, diagnostics and vaccines--from approaches building on an understanding of the human microbiome, like probiotics and fecal transplants, to more holistic solutions such as healthy building design and reengineering medical instruments to improve infection control.

## Further resources

See also [Outcomes Statement](#) from Ministerial Meeting at The Hague 25-26 June 2014. See the WHO [antimicrobial resistance webpage](#) provides links to a range of very useful references. See also the Joint Programming Initiative on Antimicrobial Resistance ([here](#)); and [ReAct](#). PHM is also a member of the Civil Society Antibiotic Resistance Coalition ([www.abrdeclaration.org](http://www.abrdeclaration.org)).

## 15.2 Poliomyelitis

### In focus

The Assembly will consider [A68/21](#) which is a revised version of the report considered by the EB in January.

#### [A68/21](#):

- describes the emergency measures implemented over the last 12 months and the most recent advice of the Emergency Committee;
- reports on the current situation in Pakistan, Africa and the Eastern Mediterranean;
- reviews progress on the withdrawal of type-2 oral polio vaccine globally;
- reviews progress in relation to Polio Legacy Planning;
- notes the funding shortfall and other risks to the Polio Eradication and Endgame [Strategic Plan 2013–2018](#) (summarised in [A67/38](#)) ; and
- invites the Assembly to consider the draft resolution recommended by the Board at its January 2015 meeting (A68/21 Add.1).

The focus of discussion at WHA68 will be on the emergency measures put in place during 2014; the conditions for the final withdrawal of type-2 OPV (bivalent OPV plus at least one doses of IPV); legacy planning; and risk mitigation.

### Background

The report, [A67/38](#) ('Poliomyelitis: intensification of the global eradication initiative') provided a useful summary of the status of each of the four objectives of the Polio Eradication and Endgame [Strategic Plan 2013–2018](#), including the impediments to achieving the milestones, the current financing situation, and the priorities for 2014.

The discussion at WHA67 ([here](#)) ranged over Endgame issues (moving to IPV (see SAGE discussion from p6 of [WER 89\(01\)](#)), legacy planning, staffing and budget implications of 'end game') and emergency issues (security situation in Pakistan and the Horn of Africa, the killing of health workers, border controls, migration vaccination requirements, etc).

Six weeks after [A67/38](#) was circulated, the DG declared a Public Health Emergency of International Concern and issued temporary recommendations to deal with the growing risk of further spread. These recommendations were extended in August and then again in November 2014. See WHO "WHO statement on the meeting of the International Health Regulations Emergency Committee concerning the international spread of wild poliovirus" See [WHO Statement](#).

### PHM Comment

PHM appreciates the creativity, persistence and dedication of practitioners at all levels in confronting the technical, logistic and resource barriers to polio eradication. The sacrifice of the vaccinators (and their support teams) who have been murdered is a terrible part of the cost of eradicating polio.

The struggle for Health for All is not just a technical or institutional struggle but includes also action around the determinants of inequality, poverty and war.

PHM appreciates the logic of the policies and initiatives which define the endgame and the emergency.

In the short term the main uncertainties are simply whether the instructions of the Emergency Committee and DG are feasible in circumstances of conflict and whether they will be implemented. In particular, the states 'currently exporting wild virus' (only Pakistan according to A68/21) are required to:

- *ensure that all residents and long-term visitors (i.e. > 4 weeks) receive a dose of OPV or inactivated poliovirus vaccine (IPV) between 4 weeks and 12 months prior to international travel;*
- *ensure that those undertaking urgent travel (i.e. within 4 weeks), who have not received a dose of OPV or IPV in the previous 4 weeks to 12 months, receive a dose of polio vaccine at least by the time of departure as this will still provide benefit, particularly for frequent travellers.*

States which are infected but not currently exporting (Afghanistan, Equatorial Guinea, Ethiopia, Iraq, Israel, Somalia and Nigeria) are required to:

- *encourage residents and long-term visitors to receive a dose of OPV or IPV 4 weeks to 12 months prior to international travel; those undertaking urgent travel (i.e. within 4 weeks) should be encouraged to receive a dose at least by the time of departure.*

The logistics assumed by these requirements are significant.

There are also continuing uncertainties about the medium to long term strategy. We draw upon two different policy debates in thinking through these uncertainties: first, the eradication, elimination, control debate; and second, the vertical program versus comprehensive PHC debate.

In a useful note in the Bulletin of WHO [Heymann](#) reviews the definitions and implications of eradication, elimination and control. Quoting:

*Whereas the proposed definition of eradication emphasizes that routine intervention measures are no longer needed once interruption of transmission has been certified worldwide, inherent in the definitions of control and elimination is the need for continued intervention measures to prevent re-emergence and re-establishment of transmission. It is this need for continued intervention after reaching control or elimination targets that has been the source of confusion among public health workers, health policy-makers and the politicians who provide resources for infectious disease control. At times, misunderstanding has led to neglect or complete cessation of intervention activities, with concurrent decrease in financial resources, and thus to re-emergence of the target disease.*

Smallpox eradication has been used as example of eradication but there is continuing uncertainty about how feasible and cost-effective the eradication of poliovirus might be in the circumstances of the Middle East, northern Nigeria, central Africa and Pakistan.

In these circumstances it is inevitable that polio eradication will face escalating costs during the so called "endgame" of polio eradication, as is illustrated by what is presently happening in Pakistan. In part the high costs of the endgame are a consequence of the continuing reliance on vertical

programming. In situations of conflict and disruption embedding vaccination and surveillance in comprehensive primary health care is impossible while continuing to implement vertical vaccination campaigns, including military support, is difficult and expensive but not impossible.

Notwithstanding the example of smallpox (which has a very different ecology from polio) a strong case can be made for reducing programmatic ambition to 'elimination' or 'control' until the social conditions for integrated universal health systems based on PHC are established. These are the necessary conditions for polio eradication.

## 15.3 Implementation of the International Health Regulations (2005)

### In focus

The Assembly will have before it:

- A68/22 (not posted as of 0511) which provides a report on the operations of the IHRs in 2014;
- [A68/22 Add.1](#), conveying the report of the Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation;
- a draft resolution, [EB136.R6](#) giving effect to the recommendations of the Review Committee;
- a report on yellow fever vaccination with a draft resolution [EB136.R5](#).

In Jan 2015 the EB considered a Secretariat report on the operations of the IHRs in 2014 ([EB136/22](#)) and the report of the IHR Review Committee on Second Extensions (conveyed to the Assembly in [A68/22 Add.1](#)) and adopted a draft resolution on such extensions for consideration by the Assembly ([EB136.R6](#)).

Argentina also tabled a draft resolution on yellow fever (as covered in the IHRs) regarding the challenge of identifying and recognising people who had been vaccinated, given the resolution of the Assembly in [WHA67.13](#) which amended the IHRs to give effect to the advice of the SAGE ([WER.2013;88\(20\):201](#)) to the effect that one dose of yellow fever vaccine should be taken as conferring lifelong immunity. This had been discussed at PAHO in Sept 2014 ([CD53/14](#)) where the challenge facing border officials of knowing whether people had in fact been vaccinated was discussed.

The EB adopted two resolutions;

- [EB136.R5](#) Yellow fever risk mapping and recommended vaccination for travellers (arising from the Argentine intervention) and
- [EB136.R6](#) The recommendations of the review committee on second extensions for establishing national public health capacities and on IHR implementation.

See notes of discussion at EB136 [here](#).

### Background

#### Public health capabilities

The IHR 2005, which entered into force on 15 June 2007, require countries to report certain disease outbreaks and public health events to WHO. The Regulations aim to provide 'a legal framework for the prevention, detection and containment of public health risks at source, before they spread across borders, through the collaborative actions of States Parties and WHO. Notification is required under IHR for all "events that may constitute a public health emergency of international concern" (WHO).

A68/22 (when posted will):

- give an account of key public health emergencies during 2014 (Ebola, Mers-CoV, polio and avian influenza A(H5N1) and A(H7N9);
- report on progress in the implementation of the IHR(2005), in particular the establishment of the

- required public health capabilities; and
- report on the establishment of the Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR (2005) Implementation.

States parties were given until 2012 to develop the required surveillance and control capabilities. The EB reviewed the Implementation of the IHRs in Jan 2012. They were advised that most states parties were far from having fully acquired the required capabilities. The shortfalls in the development of capacity were worst in Africa and South East Asia. Globally the capacities relating to 'points of entry' and chemical events were least well developed. By January 2014 it was clear that many states parties would need a further extension of time to fully put in place the required capabilities.

Following WHA67 (May 2014) the DG appointed a new review committee (1) to advise the Director-General on requests from States Parties on second extensions (2014 – 2016) for establishing the core capacities; and (2) to advise the Director-General on how to better strengthen and assess IHR core capacities in the short- and long-term.

[A68/22 Add.1](#) conveys the report of the IHR Review Committee on Second Extensions, including conclusions and recommendations and associated papers. The Assembly is invited to adopt draft resolution [EB136.R6](#) to give effect to the recommendations of the review committee.

## Yellow fever

The WHO Strategic Advisory Group of Experts on Immunization recommended in 2013 that a single dose of yellow fever vaccine is sufficient to confer sustained immunity and lifelong protection against yellow fever disease and that a booster dose of the vaccine is not needed ([Weekly epidemiological record. 2013;88\(20\):201](#)). This recommendation was endorsed by the Sixty-seventh World Health Assembly and led to the approval in May 2014 of Resolution [WHA67.13](#), "Implementation of the International Health Regulations (2005)," on the amendment of Annex 7 of the IHR.

The implementation of this resolution was discussed by PAHO in Sept-Oct 2014 (see para 132 of [CD53/FR](#)). Issues discussed included adoption of guidelines for certification of points of entry and coordination across different inter-governmental bodies in this respect, and the revision of the map of yellow fever risk areas in the Americas.

Following this discussion Argentina proposed a draft resolution (in [EB136/CONF./10](#)) which after discussion was adopted as [EB136.R5](#) and forwarded for the consideration of the Assembly.

## PHM Comment

### Commitment to the IHRs

It is evident that many MSs are lukewarm regarding their commitment to the IHRs. Many countries have not responded to inquiries from the Secretariat regarding the status of implementation; not all of these are L&MICs. Many countries of disregarded the obligation not to implement 'additional measures' in relation to declared events. Many of these are HICs.

These are different problems. Many L&MICs appear to see the high standards required by the IHRs as serving a 'global health security' agenda which may be a higher priority for the rich countries than for the poorer ones. An appropriate response to this concern would be the transfer of additional resources from the rich donor countries to the countries of the South to enable full implementation.

The disregard of the IHRs evident in the 'additional measures' problem appears to reflect a disregard for WHO's authority generally, perhaps influenced by the lack of sanctions attached to IHR implementation. These countries should be publicly challenged to defend their additional measures.

### **Continuous capacity improvement**

The Review Committee has recommended that implementation of the Regulations, and capacity strengthening in particular, should be seen as a continuous process, as opposed to one that comes to an end at any particular date, including in 2016.

While the term is not used PHM would argue for the concept of continuous capacity improvement to guide the progressive installation and improvement of the capacities specified by IHRs.

### **Antimicrobial resistance**

PHM regards the emerging crisis of antibiotic resistance and antimicrobial resistance more generally as a public health emergency of international concern and urges the EB to commission a study of the feasibility of using the IHRs to gain increasing control over AMR including requiring appropriate surveillance.

### **Adequate funding for WHO**

Installation of required capacities is a global public health good. WHO should be funded at a level from which it could provide the necessary support for implementation in low income countries. The continued freeze on assessed contributions is contributing directly to the death toll associated with outbreaks and emergencies.



## 15.4 WHO Response in large-scale emergencies

In focus

Awaiting A68/23

Background

PHM Comment

Notes of discussion

## 16.1 2014 Ebola virus disease outbreak

### In focus at WHA68

In January the EB called for an interim assessment, by a panel of outside independent experts, on all aspects of WHO's response in the Ebola outbreak. The first report of this Panel is provided to the Assembly as [A68/25](#).

This report is quite blunt in dealing with WHO's capacity and the role of Member States. It recommends firmly that WHO's emergency response capacity be developed and that the Assembly be asked to authorise this, and appropriate financing.

The report argues for a formal costing of countries' IHR capability strengthening and fund raising for this purpose.

In addition to this report the Assembly will consider:

- A68/24 (NYP), presumably a revised version of [EBSS3/2](#) which reviewed the challenges posed by the outbreak of Ebola virus disease in West Africa and described the global response;
- A68/26 (NYP) regarding the contingency fund
- A68/27 (NYP) on the global health emergency workforce

### Background

#### EBSS3 on the EVD Outbreak

- [EBSS3/3](#) which included proposals for ensuring WHO's capacity to prepare for and respond to future large-scale and sustained outbreaks and emergencies.
- [EBSS3/INF./1](#): Fast-tracking the development and prospective roll-out of vaccines, therapies and diagnostics in response to Ebola virus disease
- [EBSS3/INF./2](#): Building resilient health systems in Ebola-affected countries
- [EBSS3/INF./3](#): Highlight of efforts made to date towards preparing non-affected countries and regions to respond to potential importation of EVD
- [EBSS3/INF./4](#): IHR and Ebola
- [EBSS3/INF./5](#): Ebola at end-2014: 'Getting to Zero'

The Ebola epidemic was subject to an extended discussion during the Special Session of the Executive Board (EBSS3) on 25 Jan, 2015. The Board adopted Resolution [EBSS3.R1](#) which deals with:

- current context and challenges,
- leadership and coordination,
- health systems,
- medical assistance,
- information,
- preparedness,
- drugs and vaccines,
- WHO's emergency response capacity

- WHO's structure and human resources,
- research and development
- resources,
- communication, and
- evaluation and next steps.

Notes of discussion at EBSS3 [here](#)

## The epidemic

[EBSS3/2](#) (?A68/24, NYP) reviewed the context of the Ebola epidemic in West Africa and described the scaling up of the international response from June 2014 including:

- the Ebola Response Roadmap ([here](#)) from late August;
- the Declaration of the epidemic as a public health emergency of international concern under the IHRs (8 August);
- the UN Mission for Emergency Ebola Response ([UNMEER](#)) from 18 September;
- preparedness in non-affected countries ([EBSS/3/INF./3](#));
- current status regarding research and development towards vaccines, treatments and diagnostics ([EBSS/3/INF./1](#)); and
- health systems development in the affected countries ([EBSS/3/INF./2](#));

EBSS3/2 referred also to the latest [Ebola Situation Report](#) on the [GAR \(Ebola\)](#) website.

## WHO capability

A68/25 provides a systematic assessment of WHO's capability as revealed in the EVD outbreak. The Panel emphasises that WHO here includes MS as well as the Secretariat and comments on the erosion of WHO capacities associated with the continued freeze on ACs. It also notes that more than 40 countries adopted 'additional measures' (travel restrictions beyond those recommended by the Emergency Committee), most of whom failed to inform WHO and failed to justify the measures (despite the IHRs).

## PHM Comment

### About the epidemic

PHM salutes the heroism of the local practitioner and volunteers and the foreign experts and practitioners (from WHO, NGOs such as MSF, and other MSs). PHM affirms the dedication and professionalism of the WHO Secretariat once the response commenced.

### Delay in WHO response

The first diagnosed cases in this epidemic were in late March in Guinea. By 23 June 2014 [MSF](#) had around 300 international and national staff working in Guinea, Sierra Leone, and Liberia and had sent more than 40 tons of equipment and supplies to the region to help fight the epidemic. The WHO response does not appear to have commenced until June.

It is reported that the DG was critical of this delay. [Gostin and Friedman 2014](#) have argued that WHO's budget crisis contributed to the delay in response.

[AFR/RC64/9](#) provides much useful information but does not offer further insights into the causes of the delay.

## Historical and economic determinants of Ebola and to weaknesses in the local response

The Secretariat notes that:

*All three countries were suffering economically, following years of civil war and unrest, and in spite of determined efforts, their health systems remained weak, including with regard to surveillance and laboratory capacity. Populations of interconnected families and communities living close to porous borders moved easily and regularly between countries. Timber harvesting and mining over the previous decades had changed the ecology of densely forested areas. Fruit bats, which are thought to be the natural reservoir of the virus, moved closer to human settlements. Collectively, this presented a favourable context for a virus like Ebola to spread.*

This is a useful summary (see also [People's Health Movement 2014](#)). It would also be useful to recognise the role of the global tax regime, designed to support transnational tax evasion (see [Health Poverty Action](#)), in constraining the availability of public finance to develop health systems, and the role of IMF austerity programs imposed on the countries of West Africa ([Rick Rowden](#)) in limiting their responses to the outbreak

It would also be appropriate to note how the profit driven model of pharmaceutical R&D contributed to [the neglect of Ebola](#) vaccine development.

## Research and development

[EBSS/3/INF./1](#) describes the impressive progress that has been made during 2014 in relation to the development and roll out of vaccines, blood therapies, drugs and diagnostics.

Unstated is the indictment of the profit driven model for research and development regarding vaccines, drugs and diagnostics, which has neglected Ebola since the isolation of the virus in 1976. [AFR/RC64/9](#) notes that:

*Past outbreaks of EVD have occurred primarily in remote villages in Central and West Africa, near tropical rainforests, specifically in the Republic of Congo (2001-2002, 2003, 2005), Cote d'Ivoire (1994), Democratic Republic of Congo (1976, 1977, 1995, 2007, 2008-2009, and 2012), Gabon (1994, 1996-1997 2001-2002), Sudan (1976, 1979, and 2004) and Uganda (2000-2001, 2007- 2008, 2011, and 2012). Almost 3000 cases of EVD with over 1900 deaths have been documented since the Ebola virus was first discovered. During outbreaks, people at highest risk of infection are health workers, family members of victims and people in close contact with EVD victims, dead or alive. EVD outbreaks can wreak havoc on families and communities. However, infection can be prevented or controlled through adherence to recommended protective measures in health care settings, in communities especially at gatherings, or in homes. No*

*specific medicines or vaccines are available for use by people or animals. Patients who are severely ill require intensive supportive care.*

This outbreak underlines the importance of delinking R&D funding from the market opportunities associated with monopoly pricing.

## Health systems

[EBSS/3/INF./2](#) outlines the devastating impact the Ebola outbreak has had on the health systems and the economies of the affected countries but highlights the opportunities for a stronger and more coherent approach to health system development.

*Ebola became epidemic in Guinea, Liberia, and Sierra Leone in large part because of their weak health systems.*

*Despite the acknowledged health systems challenges pre-existing in the affected countries, their pre-EVD performance on many indicators mirrors many other countries in the subregion and this raises both the opportunity and the need for a broader cross-country and regional approaches to building robust and resilient health systems.*

The key principles (para 9) adopted in the December 2014 meeting of various national and intergovernmental bodies are of critical importance. In particular:

*Instead of creating yet another vertical programme for a specific health condition or to respond to a crisis, investments should be used to build systems that are grounded in primary health care and universal health coverage principles and capable of responding to diverse and unexpected challenges that might arise in the future.*

This conclusion runs counter to the policies adopted over the last 15 years (and longer) by some of WHO's most influential donors, including MSs, philanthropies and global PPPs. The challenge will be to build a global movement to reframe what has been the dominant paradigm in development assistance for health.

## Preparedness of non-affected countries

[EBSS/3/INF./3](#) highlight the efforts to date in preparing non-affected countries and regions to respond to potential importation of EVD.

The full implementation of the IHRs is an important part of this effort. The paper highlights the weaknesses of IHR core capacities at points of entry across the 14 African countries which were assessed.

The paper describes the technical assistance provided by all three levels of the WHO Secretariat towards meeting the specific requirements of preparedness for EVD.

This exercise highlights ongoing uncertainties regarding the functionality of WHO's regional arrangements (see PHM comment in relation to Item 5.3 on WHO Reform, [here](#)).

## IHRs and Ebola

[EBSS/3/INF./4](#) reviews the history of the IHRs and highlights several issues of concern arising from the Ebola experience: (i) continuing gaps in core capacity; (ii) delays in publication of important information owing to country sensitivities; (iii) disregard by some states parties of the obligations regarding 'additional measures' beyond those recommended by the Emergency Committee.

The paper notes that:

*Very few countries informed WHO that they were implementing additional measures significantly interfering with international traffic and when requested to justify their measures, few did so. The IHR provide the secretariat with little leverage in relation to the implementation of the temporary recommendations or the justification of the implementation of additional measures, such as closing borders, with a high potential to disrupt travel or trade, or the introduction of measures which may be discriminatory towards individuals travelling from affected and neighbouring countries. This situation is putting the entire IHR at risk.*

While the paper does not name these countries it is well known that they include several of the richer countries and in one case, Australia, a government that was reluctant to contribute personnel to the crisis in West Africa.

The paper suggests that

*regional meetings could be held in 2015 under the coordination of the WHO Regional Offices and the global IHR Secretariat as part of a global process, including the IHR Review Committee, to further identify issues and to formulate potential solutions for consideration at the 2016 Executive Board and the World Health Assembly.*

PHM urges MS support for this suggestion.

## About WHO capabilities

### Mandate

PHM urges MSs to support the arguments developed in paras 7 & 8 regarding the need for WHO to expand its emergency risk management mandate, and in particular its operational role in emergency response. PHM urges MS to also recognise a parallel need to re-affirm WHO's mandate in relation to the social and political determination of population health and of effective health care

The paper notes that "WHO's institutional identity has traditionally been driven by its normative and highly technical work". This is only part of the story.

Several of WHO's rich MSs (and donors) have repeatedly argued for WHO to be restricted in its role to technical and normative issues. The continued freeze on assessed contributions has been justified as a strategy for forcing WHO to stay away from the social and political determinants of health and of effective health systems.

The Ebola outbreak illustrates the need for WHO's mandate to be reaffirmed, both in relation to emergency response preparedness and in relation to the the social and political determinants of health and of health systems (see [above](#)).

### Reforming WHO's crisis management systems and structures

The recommendations under Proposal 2 are quite radical. They propose that

*the emergency response programme would be merged across all three levels of the Organization, with departments or units in each WHO office. The structure would be headed by a lead, or incident command during a response, with substantial delegated authority, giving the programme both singular leadership and direct reporting lines.*

It would be unfortunate if this proposal were opposed by regional offices and the advocates for regional autonomy on regional committees.

Longstanding dysfunctions associated with WHO's regional structures have been revealed by the Ebola crisis. Creating an integrated emergency response capacity across the three levels would be a positive step but PHM urges MSs to look at the more fundamental need for restructuring the relationships between the centre and the regions (see PHM comment in relation to Item 5.3 on WHO Reform, [here](#)).

### Expanding WHO's capacities, networks and partnerships

The recommendations under this heading make sense. Whether anthropology should be explicitly listed as a core component of emergency staffing ahead of other important disciplines may be debated.

### Funding mechanism

EB136/49 argues that

*Funding should be appropriately allocated to support the day-to-day functioning of WHO's emergency risk management and response programme, with a reserve budget available to immediately support a rapid scale up once an emergency is validated and a response required.*

In her posting on the Ebola response on Global Health Check [Debbie Hiller](#) comments that the World Bank has also suggested a contingency fund for health crises.

It is depressing to note that WHO Afro has set up an African Public Health Emergency Fund which remains virtually unfunded (see [AFR/RC64/7](#)) and which the African Development Bank has refused to support. (See PHM comment on Afro RC debate [here](#).)

It is clear that WHO's response to the Ebola crisis was severely constrained by the continuing freeze on assessed contributions ([Gostin and Friedman 2014](#)). Putting aside adequate funding for emergency preparedness is important but it is also critical that the freeze be lifted, the donations be untied and the donor chokehold is lifted. See PHM comment on WHO Reform under EB136 Item 5.3 ([here](#)).

## Performance management and accountability

PHM urges MSs to support the suggestions proposed under this heading. However, we note that the references to accountability appear to apply only to the Secretariat. The MSs are part of WHO and should be accountable for their contribution to the organisation and their implementation of agreed provisions and principles.

In the context of the Ebola crisis the disregard by certain MSs of their obligations under the IHRs to restrict and report 'additional measures' as is described in [EBSS/3/INF./4](#) illustrates the lack of MS accountability. It is a weakness of WHO, as it presently operates, that MS are not fully accountable for their custody of the Organisation.



## 16.2 Malaria: draft global technical strategy: post 2015

### In focus

The Assembly will consider [A68/28](#) and will be asked to consider adopting the draft resolution forwarded from the EB in January 2015: [EB136.R1](#) “Global technical strategy and targets for malaria 2016–2030”.

The draft resolution

- ADOPTS the global technical strategy for malaria 2016–2030;
- URGES Member States to undertake a range of initiatives in accordance with the Strategy
- INVITES various partners to support the implementation of the Strategy, in particular the partners involved in Roll Back Malaria
- CALLS UPON WHO’s international partners to support Member States in the implementation of the Strategy; and
- REQUESTS the Director-General to provide such support as is needed.

The draft global technical strategy (GTS) has been put together by WHO’s Global Malaria Program (GMP) under the guidance of the GTS Steering Committee incorporating feedback from consultations held during 2014.

There may be some discussion of the relationship between the GTS and the new ‘Second Generation Global Malaria Action Plan’ (GMAP2) under development by the Roll Back Malaria Partnership Board ([here](#)).

### Background

In response to a request by the [Malaria Policy Advisory Committee](#) (MPAC) in 2012, and an expression of support by member states at the 2013 World Health Assembly, WHO’s Global Malaria Programme (GMP) has coordinated the development of a Global Technical Strategy for Malaria (GTS) for the 2016-2025 period. The GTS articulates the goal and global targets for malaria over the next decade. It is envisaged as a unifying document that synthesizes current policy recommendations and comprehensive, evidence-based and cost-effective strategies for WHO Member States to use in developing their own strategies. (See [Concept Note GTS Malaria 2016-25](#), March 2014.)

In parallel with the development by GMP/WHO of the GTS, the RBM Partnership is developing the new global malaria action plan (GMAP2). See [Concept Note GMAP2](#). GMAP2 will build upon the current [GMAP \(2008-2015\)](#). GMAP2 is envisaged as a mobilisation document and complementary to the GTS.

A [briefing note](#) prepared by WHO’s Global Malaria Program for the Malaria Policy Advisory Committee (March 2013) summarises the background to the two new documents including links to:

- [WHO \(1993\) A Global strategy for malaria control](#) and
- [WHO \(1993\) Implementation of the global malaria control strategy: report of a WHO Study Group on the Implementation of the Global Plan of Action for Malaria Control 1993-2000](#).

In relation to the first Global Malaria Action Plan produced in 2008 through the RBM partnership, the briefing note comments:

*This document, while quite technically detailed in nature, was not a new technical strategy. Rather, it was a “call to arms” for the many partners working on malaria control to focus on the same goals and objectives, and follow similar strategies.*

For more background see:

- [Global Technical Strategy for Malaria 2016-2025](#) on WHO website,
- [World Malaria Report 2013](#),
- [Policies and strategies for malaria control 2012](#).

See also notes of debate at EB136 [here](#).

## PHM Comment

At the global level malaria policy and programming is largely shared between WHO's Global Malaria Program (around \$50m per year) and Roll Back Malaria (around \$2b per year). Both are funded by the same general mix of donors: GFATM, WB, G7, Gates and UNDP. WHO's GMP is governed by the MS through the WHA. RBM is governed by a complex mix of 'constituencies' including the corporate sector operating through the Partnership Board.

Both programs operate largely through disease-focused vertical programming: bed nets, indoor residual spraying and in part through improved diagnostics and treatments delivered through general health services.

Significant progress has been achieved in malaria control since 2000 although the rate of progress has slowed and continuing progress is threatened by weak health systems, increasing resistance (of parasite and vector) and lack of funding. In some countries incidence and mortality rates are increasing. The World Malaria Report 2013 points towards a serious funding shortfall for malaria control.

What is missing from this package are health system strengthening, in particular, PHC development and community involvement, including in integrated vector management; effective regulation of the private sector; action on the social determination of health; and integrating malaria control within meaningful social and economic development.

It is self-evident that effective primary health care services with strong community involvement are critical in diagnosis, treatment and local action for vector control but vertical programs such as RBM are not well placed to support the development of comprehensive PHC. In fact vertical disease focused programs jeopardise PHC development by fragmenting management and competing for human resources. Stand-alone vertical programs also weaken disaster preparedness.

The draft technical strategy also identifies lack of regulation of the private health sector which allows the continued use of ineffective antimalarial medicines or vector control tools.

It is well established that malaria disproportionately affects the poor and rural communities but the scope for integrating broadly based development strategies into malaria control programs is quite restricted given the vertical structure of the RBM program. The concept of addressing the social determination of malaria morbidity and mortality does not figure in the policy documents of either the GMP or the RBM.

The links between vector control and land use planning, housing development, urban infrastructure and rural development are also well known although the specific relationships vary with local context. It appears that integrated vector management which might address land use planning, housing, urban infrastructure and rural development does not play a very prominent role in either WHO's GMP or the RBM.

However, vector control without social, economic and infrastructure development risks creating ecological space for alternative infective agents or vectors. The magnitude of this risk is not clear but neither is it clear that it is being properly explored in the context of malaria control.

The vertical orientation of both GMP and RBM is a direct consequence of the involvement of the G7 donors, US philanthropy, and the neoliberal technocrats of the WB and other development banks who are reluctant to invest in strong health systems based on PHC principles and capable of driving action around the social determination of health, equity and development. In this respect the freeze on assessed contributions and the marginalisation of WHO in malaria control (in funding terms) are necessary as part of defending the contemporary regime of globalisation, growing inequality and the development of under-development.

While development assistance funding has stalled, low and middle income countries lose revenue through tax avoidance and reduced tariff revenues due to the continuing pressure of 'free trade agreements.

For more on Global Public Private Partnerships see [GHW\(2008\) 'The global health landscape'](#)

Data on malaria funding through WHO see the [WHO Program Budget Portal](#).

More on Integrated Vector Control, see [WHO \(2012\) Handbook for IVM](#); Lindsay & Birley. 2004. Rural Development and Malaria Control in Sub-Saharan Africa. *EcoHealth*, 1, 129-137; [Mukabana et al. 2006. Ecologists can enable communities to implement malaria vector control in Africa. \*Malaria Journal\*, 5, 9.](#)

## 16.3 Dengue: prevention and control

### In focus

The Assembly will consider [A68/29](#) which is a revised version of [EB136/24](#) which was noted by the Board in January. The report provides an overview of the Prevention and Control of Dengue.

*The escalation of dengue fever worldwide poses a serious public health problem. At the Sixty-seventh World Health Assembly in May 2014, several Member States referred to the public health and economic burdens of dengue in the plenary discussion on the link between climate and health. This report outlines the global threat to public health posed by dengue, the elements of the global strategy to prevent and control the disease, and essential steps to be taken.*

The report ([A68/29](#)) notes the sharp increase in reported cases in recent years but cautions that this is partly explained by improved surveillance. The report notes the spread of the principal vectors of dengue, facilitated by increased trade.

The report discusses the five technical elements of the 2012 [Global Strategy](#):

- diagnosis and case management,
- integrated surveillance and outbreak preparedness,
- sustainable vector control,
- vaccine development,
- basic, operational and implementation research.

See notes of discussion at EB136 [here](#).

### Background

#### General information

- WHO Topics: [Dengue](#)
- Global Alert and Response [home](#)

#### Incidence estimates

Serious disease burden and both spreading and increasing:

- See [Global Strategy for dengue prevention and control 2012-2020](#) (2012) see page 2 for cases reported to WHO.
- See also [Dengue: guidelines for diagnosis, treatment, prevention and control](#) (2009), Chapter 1, Epidemiology.
- See [Bhatt et al \(2013\)](#) (The global distribution and burden of dengue. Nature, **496**, 504-507) for global and country predictive estimates, on average three times greater than WHO estimates; in some cases much more (see below).
- See also [ProMED-Mail](#) search and map application.

## Control strategies

### [Global strategy for dengue prevention and control 2012-2020](#) (2012)

*Dengue mortality can be reduced by implementing early case detection and referral systems for patients; managing severe cases with appropriate treatment; reorienting health services to cope with dengue outbreaks; and training health personnel at all levels of the health system.*

*Dengue morbidity can be reduced by implementing improved outbreak prediction and detection through coordinated epidemiological and entomological surveillance; promoting the principles of integrated vector management; deploying locally-adapted vector control measures, including effective urban and household water management; and through communication to achieve behavioural outcomes in prevention programmes.*

### [Dengue: guidelines for diagnosis, treatment, prevention and control](#) (2009)

See also (under NTDs):

- [Global plan to combat neglected tropical diseases 2008–2015](#), (2007) and
- Accelerating work to overcome the global impact of neglected tropical diseases – A roadmap for implementation (2012): [Summary](#), [Full version](#)

## Resolutions

### WHA

- [WHA66.12](#) (2013) Neglected Tropical Diseases
- [WHA55.17](#) (2002) Prevention and control of dengue fever and dengue haemorrhagic fever
- [WHA58.3](#): Revision of the International Health Regulations (2005)

### Regional committees

- [CE142/17 Dengue: Progress Report; 2008](#)
- [CSP27.R15 Dengue Prevention and Control in the Americas; 2007](#)
- [CE140/17 Dengue Prevention and Control in the Americas: Integrated Approach and Lessons Learned; 2007](#)
- [WPR/RC59.R6](#) of the Regional Committee for the Western Pacific (2008)
- [SEA/RC61/R5](#) of the Regional Committee for South-East Asia (2008).
- [EM/RC/58.R4](#) EMR (2011)

## Climate change

In Section 11.5.1.2, 'Dengue Fever', in [Chap 11 \('Human health', 2013\)](#) of WG2 contribution ('Impacts, Adaptation, and Vulnerability') to IPCC 5th Assessment Report, the IPCC comments that:

*The principal vectors for dengue, *Aedes aegypti* and *Ae. albopictus*, are climate-sensitive. Over the last two decades, climate conditions have become more suitable for *albopictus* in some areas (e.g. over central northwestern Europe) but less suitable elsewhere (e.g. over southern Spain).*

## PHM Comment

Dengue causes significant mortality and morbidity. The incidence is increasing and its prevalence is spreading.

The global strategy identifies five 'technical elements':

- diagnosis and case management
- integrated surveillance and outbreak preparedness
- sustainable vector control
- future vaccine implementation
- basic operational and implementation research

A strong primary health care sector, well supported by more specialist dengue control and surveillance and communications capabilities constitute the critical infrastructure for dengue control.

It is evident that some countries are doing better than others in dengue control. There may be value in encouraging more learning and sharing of experience.

The increasing incidence of dengue reflects in part the fragmenting effect of proliferating vertical disease control programs on primary health care and public health. It is not a solution to dengue or the other neglected tropical diseases to create new vertical disease specific programs.

The Secretariat's advocacy of 'universal health coverage', widely understood to mean mixed (public/private) service delivery with provider reimbursement based on a minimal package of defined benefits, will do little to create the local capacity needed to ensure early diagnosis, effective treatment, local monitoring, and community support for integrated vector management.

The importance of integrated surveillance and preparedness is underlined by the warnings of the IPCC re the implications of climate change.

The core capacity requirements for surveillance and response set out in Annex 1A of the [IHRs](#) are particularly relevant to dengue control. A strong case can be made for international support for those countries who are lagging with respect to putting in place the required capacity.

Likewise the increasing geographical spread of dengue is in some degree a reflection of increased travel and trade as part of globalisation. This underlines the importance of international cooperation as provided for through the IHRs.

There may be a case for assembling an emergency committee as provided for in the IHRs to advise the DG (and highlight the epidemic).

In a side event associated with the West Pacific Regional Committee in 2014 a number of possible interventions for dengue were reviewed, including natural bacteria spread through mosquito populations, genetically modified mosquitos and vaccines. Clinical trial data was shown on new vaccines which demonstrated that many vaccines under development are not effective for some serotypes. At the WPRC itself, Malaysia was critical of dengue vaccine data and called on WHO to use an evidence based approach to new vaccines, including for dengue.

## Learning from Cuba

The publication by [Bhatt and colleagues](#), cited above, raises questions about the surveillance and reporting of dengue. The predictive estimates of Bhatt and colleagues (for 2010) are generally well above WHO estimates (see pages 68-74 of the [supplementary document](#) from the Nature website). However, for some countries, and Cuba is an outstanding case (also Hong Kong), the gap between the predictive estimates and the WHO estimates is quite huge. These wide gaps can either be explained by under-reporting or very efficient prevention programs.

Cuba has an efficient primary health care system with a strong emphasis on community involvement and public health. [Fitz \(Feb 2012\)](#) describes the mobilisation of medical students to look for dengue cases and identify collections of still water where *Aedes aegypti* may be breeding. Solidarity as a core value in public health and primary health care has an important role to play in dengue control and preparedness.

There is a strong case for closer attention to the Cuban model of UHC, budget funded and public sector delivery, as opposed to the insurance model, based on the 'purchasing' of defined benefit packages and currently being promoted by the WHO Secretariat.

## 16.4 Global vaccine action plan

### In focus at EB136

The Assembly will have before it [A68/30](#) which was considered and noted by the EB in January. In line with resolution [WHA65.17](#), the report describes the progress made towards the achievement of the global immunization targets, using the monitoring and accountability framework approved by the Sixty-sixth World Health Assembly, and conveys also the assessment report of the GVAP by the Strategic Advisory Group of Experts on immunization (SAGE), which met in October 2014.

The Assembly will be invited to take note of the report and to consider the recommendations (of the SAGE) for actions to be taken by the various stakeholders of the [global vaccine action plan \(GVAP\)](#) (adopted in May 2012) in particular by Member States.

There may be a resolution committing to the SAGE recommendations.

### Background

[A68/30](#) provides a summary report of the [2014 Assessment Report by the Strategic Advisory Group of Experts \(SAGE\) on immunization](#) which itself was based on the [GAVI Secretariat 2014 Draft Report](#). [A68/30](#) is a very summarised version of the [SAGE report](#) which is much more hard hitting and useful.

The SAGE report finds that progress, with respect to the implementation of the GVAP is 'far off track'. Five of the six goals set by the [GVAP](#) with deadlines at the end of 2014 or 2015 still require substantial progress to get the goals on track (poliovirus transmission interruption, maternal and neonatal tetanus, measles and rubella elimination, and DTP3 coverage targets). Most have seen very little progress. Some have been missed multiple times before.

The SAGE report recommends that action focus particularly on addressing five priority problems:

1. Weak implementation,
2. Poor quality and use of data,
3. Vaccine affordability and supply,
4. Failures of basic integration, and
5. Situations disrupting immunisation.

Specific recommendations under each of these headings are briefly summarised in [A68/30](#) and but are elaborated more fully in the [SAGE report](#).

See notes of the discussion of this item at EB136 [here](#).

### PHM Comment

The SAGE report is unequivocal: 'stagnant vaccine coverage' and 'eradication and elimination goals repeatedly missed'.

In the following commentary PHM highlights:



- the limitations of vertical funding programs as compared with investing in health systems strengthening based on comprehensive primary health care;
- the significance of the continuing underfunding of WHO in relation to immunisation and the need for real WHO reform;
- the need for WHO action on pricing, affordability and procurement;
- the need for all of WHO's regional and country offices to work with ministries of health to encourage the full implementation of the GVAP and regional and national plans and to provide technical support especially in relation to information systems and national policy making.

## Health systems strengthening and primary health care

Under the heading, 'failures of basic integration', the SAGE report regrets the lost opportunities to immunise where primary health care providers are not sufficiently conscious of the importance of immunisation. The report comments, "This is how programmatic silos at global and national level can unfortunately affect what happens in health care facilities."

Elsewhere in the report the SAGE comments on the failure to progress maternal and neonatal tetanus elimination. The report speaks of "gross underfunding" and notes that tens of thousands of babies die each year with 20 or more countries still affected.

Elimination of maternal and neonatal tetanus depends on real health system strengthening with comprehensive primary health care provision and strong referral and support relationships to secondary and tertiary facilities.

Surprisingly there is no reference in this report to comprehensive primary health care as a model which highlights the whole of population responsibility of primary health care providers and which explicitly promotes integration of services.

The [2013 SAGE meeting](#) noted "the importance of improved coordination and integration of immunisation initiatives with other critical public health interventions such as clean water and sanitation programs to ensure universal health coverage. Social determinants of health should be taken into consideration when integrating routine immunisation into primary health care...". This insight is lacking from the 2014 evaluation report.

It is surprising that the (2014) SAGE report recommends giving civil society organisations (CSOs) 'substantially more formal involvement in the delivery and improvement of vaccination services'. This is the route for further disintegration of primary health care systems. The priority should be for the development of strong public health systems based on the comprehensive primary health care model, not out-sourcing to NGOs.

PHM notes also the ambivalence of GAVI in relation to the need for health systems strengthening (HSS). On the one hand GAVI's CSO HSS Platform promotes the role of CSOs in advocacy for HSS but the direction of such HSS is largely focused on strengthening health system capacity to delivery immunisation.

## **‘Programmatic silos’**

PHM appreciates the recognition by the SAGE of the fragmenting impact of vertical programmatic silos. Clearly the continued domination of vaccination assistance by GAVI illustrates, reflects and perpetuates the fragmentation which the report criticises.

The gross underfunding of WHO, which does promote a coherent integrated approach to health care and public health, is part of the cause of the stagnation of the ‘Decade of Vaccines’.

In this context it is not clear why the SAGE recommends that the GVAP secretariat agencies (Bill & Melinda Gates Foundation, GAVI Alliance secretariat, UNICEF, US National Institute of Allergy and Infectious Diseases and WHO) approach World Economic Forum to seek help in the implementation of the Decade of Vaccines. It may be that such an approach will yield more funding for GVAP (although DAH funding generally appears to be declining) but it is also likely to further entrench the vertical programmatic silo approach to global health priorities.

## **WHO Reform**

The SAGE report aims some legitimate criticism at WHO’s regional offices and regional committees for failing to establish regional and national verification committees regarding measles, rubella and CRS elimination and for delays in adopting regional vaccine action plans.

The report doesn’t repeat the criticism in [EB134/13](#) that, “many countries are still lagging behind in the establishment of [National Immunisation Technical Advisory Groups], particularly in the African and Western Pacific regions”. This issue was underlined also in the [Action Plan](#) where Para 34 urged the establishment of national TAGs “that can guide country policies and strategies based on local epidemiology and cost effectiveness”.

PHM appreciates the recommendation that DG asks ministries of health of countries with less than 80% DTP3 coverage to report on challenges, plans and timelines to improve coverage.

PHM calls for meaningful action on WHO Reform: lift the freeze on assessed contributions; reform the regions; and strengthen the accountability of individual member states to the full membership.

## **Pricing, affordability, procurement and logistics**

The SAGE is critical of the lack of public information regarding vaccine prices. It notes particular concern regarding the affordability of newer vaccines for middle income countries who are not eligible for GAVI support. The clear implication is that there may be price gouging by some vaccine manufacturers and that the availability of more comprehensive price information could strengthen market pressures for more reasonable pricing. PHM supports the urgent need for transparent pricing of vaccines and clearer documentation of price barriers to the introduction of priority vaccines. We note the support expressed at several of the regional committee meetings for this initiative. (At the WPRC Korea asked the committee to guarantee transparency in vaccine costs in each country).

See also recently released MSF report on vaccine pricing ([here](#)). The report shows that between 2001 to 2014, the introduction of new vaccines – including those against pneumococcal and diarrhoeal

diseases, and cervical cancer – has pushed the cost of a full vaccines package up by 68-fold in the poorest countries, with the pneumococcal vaccine accounting for 45% of the total cost.

PHM urges the EB to act on this set of recommendations from the SAGE but to include an assessment of the scope for further support for technology transfer, local production and pooled regional procurement.

The SAGE was shocked to find that, “In 2013, more than 40% of low and middle-income countries suffered a national level stockout of at least one vaccine that lasted at least one month. ... If anything, 40% may be an under-estimate.” Even worse, it appears that the extent and root causes of the problem are not clearly known. This is an issue for the EB to take immediate action to assess “(i) the extent to which the reported national-level stockouts are affecting local vaccine supply and delivery, and (ii) the root causes of these stockouts”.

## Introduction of new vaccines

The GVAP recognises that national strategies for vaccination should respond to priorities and needs of local populations and the efficacy and cost effectiveness of vaccines and immunization campaigns have to be evaluated case by case in the specific country context. This is particularly important as new and increasingly sophisticated vaccines have become available in the last decade. As recognised in the [Action Plan](#) (p20), “New and more complex vaccines will bring new funding requirements and countries will be confronted with difficult decisions in dealing with competing health priorities. Resources will need to be allocated more efficiently, with the relevant decisions guided by national priorities, capacity, clear information on the costs and benefits of choices, and improved financial management. Expenditures must be linked to outputs and impacts, showing a clear investment case for immunization.”

The opportunity costs of introducing new vaccines, measured in terms of cash and health outcomes forgone, can only be assessed in the specific context of local epidemiology, local health care expenditure and vaccine delivery capacity. Even powerful vaccines have opportunity costs: other ways of spending the same monies which might also contribute to health outcomes. Cost effectiveness comparisons of this sort require consideration of vaccine, disease, health systems and current health expenditure patterns. In health care systems which cannot deliver DTP3 to more than 50% of infants it might make sense to allocate additional resources to primary health care, including basic vaccination and effective treatment of diarrhoea.

Effectiveness depends on absolute risk reduction (ARR) which depends on the burden of disease in each country. The low incidence of invasive Hib disease in Asia is an example. We need country-specific ARR to calculate numbers needed to treat (NNT = 1/ARR) and find cost per case avoided. The inclusion of vaccines like Hib in the immunization schedules of countries with low disease burdens is associated with high opportunity costs.

Many new vaccines target only specific strains of the causative pathogen and their use is limited by the ability of pathogens to mutate and take up the space ceded by strains that are sensitive to vaccines. The country-specific evaluation of cost-effectiveness of new vaccines is essential and has to be conducted through a transparent process that avoids conflicts of interests.

PHM calls upon WHO regional offices and country offices to provide the necessary support for fully informed decisions by countries on this issue, including guidance on the opportunity costs of expensive vaccines for low incidence conditions. This also requires that countries, which have not done so, proceed to establish and strengthen their National Immunisation Technical Advisory Groups.

We are aware that many MSs are also concerned to strengthen the capacity of MSs to undertake broadly based assessments of new vaccines before deciding to add them to the national immunisation schedule. (At the WPRC both China and Malaysia spoke firmly about the need for broadly based national assessments of new vaccines.)

WHO should be concerned about the introduction of new vaccines in the absence of surveillance and information systems covering epidemiology, delivery, and evidence of safety and efficacy. The introduction of HPV vaccination in the absence of properly functioning country-wide cancer registries illustrates the point.

## **Data quality and use**

The SAGE report argues strongly for action to improve the quality of information systems and the use of data to guide immunisation programs.

The lack of data about vaccine prices and the causes and effects of national stockouts illustrate the need; likewise the data systems needed to support decisions regarding new vaccines - see below.

There is no comment in the report on data regarding adverse events following immunisation (AEFI) but clearly this is another area where information and decision systems need to be strengthened.

We note the controversy over the safety of pentavalent vaccines which in essence is an example of the broader problem of post marketing surveillance. PHM urges WHO to give increased priority to the development of rigorous post-marketing surveillance systems including adverse events following immunisation.

## **Clinical trial data reporting**

The recent WHO statement on clinical trial data reporting ([here](#)) and the subsequent commentary in PLOS ([here](#)) not only re-affirms the ethical imperative of clinical trial results reporting, it also defines reporting timeframes, calls for results-reporting of older but still unpublished trials, and outlines steps to improve linkages between clinical trial registry entries and their published results. It states that 'it is unethical to conduct human research without publication and dissemination of the results of that research. In particular, withholding results may subject future volunteers to unnecessary risk'.

Open reporting should extend to post marketing surveillance of vaccines and the confidential disclosure of manufacturers data to the regulator must be deprecated.

## **Rubella and congenital rubella syndrome (CRS)**

The SAGE report notes that progress on the elimination of rubella and rubella/congenital rubella syndrome (CRS) lags far behind targets.

Unfortunately there is no discussion of the risks of low coverage infant rubella immunisation, in particular the risk that partial population immunity will push the age profile of new cases into the child-bearing years. In such circumstances a strong case can be made for focusing on adolescent immunisation rather than young child. If countries are unable to deliver high coverage in both infancy and adolescence the focus should be on adolescence.

Rubella by itself is a mild disease and it will help reduce chances of CRS if rubella is allowed to spread in the community. The priority must be to eliminate congenital rubella. Further reduction of CRS can be achieved by adolescent rubella vaccination. In countries with uncertain coverage of infant immunisation there is a risk that the WHO strategy of eliminating rubella in childhood by immunization in the 2nd year of life will actually increase the incidence of CRS.

## 17.1 Strengthening emergency and essential surgical care and anaesthesia as a component of universal health coverage

### In focus

*Strengthening capacity to deliver basic surgical and anaesthetic services at first referral facilities can contribute to reducing death and disability from both communicable and noncommunicable diseases and support progress towards universal health coverage.*

The Assembly will have before it [A68/31](#) and a draft resolution ([EB136.R7](#)) forwarded from the EB in January.

### Background

The Secretariat report, [A68/31](#), reviews the global burden of surgical conditions, the importance and cost effectiveness of surgery and reviews some significant gaps in surgical and anaesthetic services globally. The report surveys a number of areas for action at the country level and current action at the Secretariat level.

Highlighted in the section on country level action were: awareness raising, access to and quality and safety of emergency and essential surgical services, strengthening the surgical workforce better data on surgery for policy making, monitoring and evaluation, and global collaboration and partnerships.

Actions by the Secretariat which are highlighted include: the Integrated Management for Emergency and Essential Surgical Care (IMEESC) [toolkit](#); the [WHO-CHOICE project](#) on cost-effectiveness of interventions; and the [WHO Global Initiative for Emergency and Essential Surgical Care](#). The Secretariat will work with MS to ensure that “surgical services at district and subdistrict levels of care are assessed and monitored”.

There was an extended discussion on this issue at EB135 and EB136 where there was widespread support for progressing this issue. The case for strengthening essential and emergency surgical and anaesthetic services was not contentious although many of the challenges were canvassed. See reports of discussion at EB135 ([here](#)) and EB136 ([here](#)).

### PHM Comment

This is an important area and it is good that WHO is moving to adopt a formal integrated strategy and plan of action.

The issues canvassed in the Secretariat paper ([A68/31](#)) are important. The following issues are of particular importance to PHM:

- models of service organisation and service delivery,
- workforce development: quality of training, numbers trained, conditions for retention,
- surgical and anaesthetic task distribution within the health workforce,
- affordable access to medicines (including ketamine and other anaesthetics) and equipment,

- efficacy and effectiveness: evidence, clinical guidelines, clinical audit,
- safety and quality, clinical governance and clinical accountability,
- professional accountability and public policy control over training, regulatory frameworks and financing,
- the role of informed public and community involvement in policy, planning, management and institutional accountability.

It will be important to explore and evaluate the options with respect to service organisation and service delivery in different settings as part of planning this initiative. This will involve surveying existing models and developing criteria for assessing options for service development.

Ensuring a high return on investment with respect to any expansion of surgical services will depend on: focusing surgery for conditions where surgical treatment has demonstrated efficacy; ensuring high quality and safety with respect to environments and practice; sustainable financing and payment arrangements; and appropriate workforce policies.

There are many lessons from the experience of surgery in rich countries including what to avoid: unreasonable reimbursement, exploitation of professional monopoly power, inappropriate and unsafe practices. Likewise there are valuable models from resource poor settings (eg the [Aravind Eye Care System](#)).

One of the key issues for L&MICs is ensuring appropriate workforce profiles. Surgery in rich countries is highly specialised, relatively autonomous both in clinical decision making and entry control (associated with long training programs), and generously remunerated. However, many surgical (and anaesthetic) procedures can be performed by personnel with more limited training and less generous remuneration. The use of such practitioners in a supportive organisational context can ensure greater cost-effectiveness, reach and access. Carefully designed training programs for these practitioners, including rich continuing in-service training, is critical.

Developing models of service delivery will involve identifying in broad terms the types of surgery which might be carried out in local (often quite isolated) hospitals, those which might be restricted to the referral centres, and the more complex but less urgent surgery which can be scheduled for visiting teams. In many L&MICs properly equipped mobile surgical teams play a critical role in facilitating access. Mobile teams can also play an important role in providing in-service training. Surgery should be integrated within existing PHC programs; it should not be constructed as a new vertical program. Provision should be made for adequate supplies, maintenance and technical support to ensure that surgical facilities in isolated areas and for mobile teams are safe for both patients and staff. It may be necessary to include security for mobile teams in some settings.

PHM urges a return to the district health system model. The roles assigned to the district hospital are critical. These include both the provision of first level hospital services, including basic surgery and anaesthetics, but also a range of functions that would strengthen and support primary health care and other district-level services.

PHM shares the concern of the World Federation of Societies of Anaesthesiologists that policies directed to controlling the recreational use of ketamine should not create barriers to its use in PHC and district hospital settings in L&MICs where it is often the sole, safest, and most appropriate anaesthetic.

Organisational policies and information systems to ensure that surgical services provided are efficacious and effective are critical. This will require systems for reviewing and synthesising evidence and the availability and observance of clinical guidelines. Safety and quality are critical. This will require clinical governance arrangements which ensure professional accountability - to peers, to management, to communities and to families and patients. Excessive professional autonomy of the surgical and anaesthetic professions is to be avoided. This requires that arrangements are in place for effective public policy control over training, regulatory frameworks and financing (including remuneration).

The process of expanding access to surgery in low resource settings will be fraught with risks and challenges. One of the prerequisites for success will be to ensure that policy making, service planning and operational management are all embedded within an environment of public and community accountability.

There will be no 'one size fits all' model for expanding surgical services. While general principles and strategies can be elaborated, institutional arrangements and operational details will need to respond to local and national context. Adapting general principles to local context will require developing local capacity for operations research before, during and after the roll out.

The development of any future strategy and action plan for WHO will need to break away from the prevailing culture of prolonged training, high specialisation, high clinical autonomy, private practice and high remuneration. We urge that whatever expert committees are assembled for this exercise they include people with experience in delivering surgery in low resource settings and that the process includes careful documentation and analysis of existing models of service delivery.



## 17.2 WHO Global Code of Practice on the International Recruitment of Health Personnel

### In focus

The Assembly will consider [A68/32](#) which:

- reports on progress in undertaking the first review of the relevance and effectiveness of the Code (to be reported to WHA68 in A68/32 Add.1);
- reviews the results of the first round of periodic reporting by Member States on the implementation of the Code (reported to WHA66 in [A66/25](#));
- describes arrangements for the second round of reporting;
- reports on a collaborative WHO/OECD statistical survey (see [Joint Action Plan, 2012](#)) which is currently underway with first round results available in June 2015.

The WHA resolution which authorised the [Global Code of Practice \(WHA63.16\)](#) scheduled a review of the relevance and effectiveness of the Code at WHA68 (May 2015). It also invited the DG to make proposals as appropriate, based on periodic reporting, for strengthening the Code.

In Jan 2015 the Executive Board considered (in [EB136/28](#)) the process that had been established to facilitate the first review, and the progress made to date. [EB136/28](#) outlined the proposed membership and terms of reference of a proposed Expert Advisory Group to undertake the review of relevance and effectiveness between February and May 2015. See the [Call for Submissions](#) from March 2015.

At the EB136 (see notes of debate [here](#)) Liberia, on behalf of the Afro region proposed that the expert advisory group should, in the first instance, consider only the relevance of the code on the grounds that it would be premature to consider effectiveness based on the first round. This appears to be a reference to the very low level of returns of completed NRIs in the first round of reporting from source countries. Liberia argued that the proposed expert adv group should continue to Aug 2015 to be adequately informed on the effectiveness of the code (in light that prelim results won't be available until June). In concluding the discussion at EB136 the Chair of the Board stated that "the African proposal can be discussed at the WHA".

### Background

#### Global code on recruitment

Some background to the development of the [Code](#) was provided [A63/8](#) which was considered by the Assembly in May 2010 when the Code was adopted. Further background is provided in the [User's Guide](#). See also [WHA66/25](#) (submitted to WHA in May 2013) which includes an overview of the current situation regarding (reported) implementation of the Code and a summary of challenges for the future (better data, political will, regional HRH observatories, a global strategy regarding the production of health workers).

The most recent data on the implementation of the Code appears to be in the [Siyam&DalPoz\(2014\)](#) paper on health worker migration. This document is described in the introduction as a 'progress report'

on the implementation of the code recognising that only 56 countries (mainly in Europe) had reported to WHO in the first round of reporting (to end May 2012) using the [National Reporting Instrument](#).

It appears that the implementation of the Code has been partial and patchy and the reporting to WHO on implementation even more so. In particular, the required information systems remain under-developed.

## A new global strategy on HRH

Resolution [WHA63.16](#) in 2010 also requested the Director-General to make proposals, if necessary, for the revision of the text of the Code in line with the first review, and for measures needed for its effective application.

It seems likely that the DG will address this request in the context of resolution [WHA67.24](#) (May 2014) which requests the DG to develop a new global strategy on HRH for consideration at WHA69 (2016). It would make sense to address the migration and recruitment issue within this strategy (see below and [Sidibé/Campbell 2015](#)).

Resolution [WHA67.24](#) arose from the follow up of the Recife Forum which was pushed onto the agenda of EB134 (in Jan 2014) by Brazil despite the reluctance of the Bureau to include it on the provisional agenda. Once it was secured on the agenda the Secretariat paper [EB134/55](#) was circulated. The Board noted [EB134/55](#) and recommended a draft resolution ([EB134.R15](#)) for the consideration of the Assembly (WHA67). EB134/55 was re-issued as [WHA67/34](#) for the Assembly.

The Assembly adopted [Resolution WHA67.24](#) on the Follow up of the Recife Declaration on HRH which calls for MS to implement the commitments of Recife, calls upon the DG to take Recife into consideration and requests a new global strategy on HRH for consideration at WHA69 (2016). This last request was added in debate by Japan which, in the same intervention, promised 'full support'. (See [PHM notes from WHA67 which includes report of WHA debate](#)).

## More resources

Resources developed for or from the [Third Global Forum](#) on Human Resources for Health (10-13 November 2013 in Recife, Brazil) include:

- [Aid in reverse: the UK's responsibility to address the health workforce crisis](#), produced in October 2013 by *Healthworkers4all*.
- [GHWA&WHO\(2014\)](#) 'A universal truth: no health without a workforce', prepared for the Third Global Forum on Human Resources for Health.
- Outcome document: "[The Recife Political Declaration on Human Resources for Health: renewed commitments towards universal health coverage](#)".
- [Alternative Civil Society Declaration: No progress to universal health without health workers: a civil society commitment](#).

Previous WHO resolutions on health workforce development [here](#).

WHO Health Workforce page [here](#). Note in particular the [Resources](#) page (many useful links).

[Kampala Declaration and Agenda for Global Action \(2008\)](#)

[WHO \(2010\)](#). International migration of health workers: improving international cooperation to address the global health workforce crisis.

MMI HRH page [here](#). Report of [CS Side Event on Code 2013](#).

## PHM Comment

We welcome the review and look forward to discussing its results at the WHA. We comment on the following issues:

- apparent lack of commitment on the part of most regional offices and member states,
- membership of EAG,
- terms of reference,
- process of EAG; need to engage ROs and MSs,
- relevance,
- effectiveness, and
- new directions.

### Regional and country commitment

We are worried about the apparent lack of commitment of member states to the WHO Global Code of Practice on the International Recruitment of Health Personnel. The fact that most of the first round reports on the implementation of the Code came from the European region suggests that the implementation of the Code has not been prioritised in the other regions. Certainly implementation of the Code was not on the agenda of any of the regional committee meetings in 2014.

[Dambisya and colleagues \(2014\)](#) suggest that the weaknesses of the Code, in particular the lack of attention to compensation (see below), may have contributed to its loss of traction in Sub-Saharan Africa.

We note that Australia which is one of the four main destination countries had not designated a national authority nor submitted a first round report by the due date (31 May 2012).

We urge the Expert Advisory Group to give consideration to whether the regional and country offices of WHO could do more to promote the implementation of the Code including in investing in developing the necessary capacity in African and Asian member states to undertake the necessary actions regarding the code. It may be that the attention given to the Code in Europe reflects the activity of civil society advocates as much as regional office priority.

### Membership

We note the proposed membership structure. We urge the inclusion of civil society organisations from amongst those that issued the [Alternative Recife Declaration](#).

### Terms of reference

The DG has proposed terms of reference which highlight relevance and effectiveness. Some of the

questions which PHM believes need to be considered include:

- Why have the source countries and source regions ignored (at least in the first round) the reporting requirements of the Code?
- Has the funding crisis facing WHO impacted upon its ability to drive implementation of the Code?
- What needs to be done to improve the information situation and the establishment and effectiveness of national and regional observatories?
- Consider whether the NRI reports should be made publicly available; we believe that transparent release of National Reports contents is an essential requirement to create, maintain and increase both the accountability of the Member States and the commitment of civil society at the national level.
- Consider whether there may be scope for increasing the civil society drive for implementation in regions other than Europe.
- Explore strategies for implementing the demand for compensation to source countries as proposed by the Afro Regional Committee.

## Process

We note that the report of the EAG is scheduled for distribution prior to the WHA from 18-26 May 2015 and that it is unlikely to meet before March.

The narrow timelines will make it difficult to fully discharge its terms of reference, particularly since it will be relying in large part on the series of papers being prepared for publication in HRH Journal which are not scheduled for publication until April 2015.

We recommend MS consider rescheduling the commitment to report to WHA69 (2016). This would allow more time available for a proper process, including full consideration of the information gathered through the second round of national reporting (due in 2015) and would align more closely the processes of Code review and the development of the global HRH strategy.

We urge that the EAG involve the regional offices and seek input from MSs and CS at the regional level. Special attention is due to the four main destination countries.

## Relevance

The HRH crisis continues to be a major barrier to the full enjoyment of the right to health in L&MICs. Unethical recruitment and inadequate investment in domestic self-sufficiency in the rich countries are critical contributors to this crisis, underlying the continuing relevance of the Code.

## Effectiveness

We believe that the Code has potential to address the problems of unethical recruitment and the willingness of the destination countries to continue to staff their health care facilities at the cost of depleting urgently needed human resources from the Global South.

However, it appears that the information needed to confirm effectiveness or even implementation is not available.

One of the questions for the EAG is whether the HRH crisis can be effectively addressed without a more comprehensive set of strategies, as envisaged in the proposed HRH strategy scheduled for consideration in WHA69.

One of the questions the EAG should consider is whether the voluntary nature of the Code detracts from its effectiveness and whether WHO should move to the negotiation of a binding instrument to address recruitment and migration issues in the context of a more broadly based HRH strategy.

## Compensation

The Code is weak in relation to the need for 'compensation', for an appropriate transfer of resources to assist in health development in source countries by way of compensation for the transfer of value associated with health professional migration.

In 2009 the African Regional Committee adopted [RC59/R6](#) which inter alia urges Member States:

*(c) to foster bilateral and multilateral agreements aimed to better manage migration and reduce the negative effects **and develop mechanisms for facilitating fair compensation of source countries by destination countries;***

Mills et al (*The financial cost of doctors emigrating from sub-Saharan Africa: human capital analysis*. BMJ. 2011 Nov 23;343:d7031) found that:

*The overall estimated loss of returns from investment for all doctors currently working in the destination countries was \$2.17bn (95% confidence interval 2.13bn to 2.21bn), with costs for each country ranging from \$2.16m (1.55m to 2.78m) for Malawi to \$1.41bn (1.38bn to 1.44bn) for South Africa.*

Clause 3.3 of the Code suggests that "developed countries should, to the extent possible, provide technical and financial assistance to developing countries and countries with economies in transition aimed at strengthening health systems, including health personnel development".

The need for fair compensation needs to be put back on the agenda.

The EAG should give consideration to the economics of health professional migration including the net resource transfers and including consideration of remittances. Given the support of international financial institutions for the policy driven export of health practitioners for remittance purposes the EAG should explore the implications for domestic health worker education of producing for export. The benefits of the remittance strategy, in terms of sustaining the exchange rate, accrue mainly to those who spend heavily on imports, whereas the costs are borne by the domestic health system which must adapt to this deliberately constructed brain drain. Remittances do not compensate the health system for lost resources.

## New directions

Resolution [WHA63.16](#) in 2010 requested the Director-General to make proposals, if necessary, for the revision of the text of the Code and for new measures needed for its effective application. We urge that this request be addressed in the context of responding to resolution [WHA67.24](#) (May 2014) which requests the DG to develop a new global strategy on HRH for consideration at WHA69 (2016).

## WHO reform

It appears that the lack of resources at WHO headquarters and regional and country offices has seriously delayed the effective implementation of the Code. See the [CS Side Event on the Code](#) and the [MMI statement](#) at WHA66 (2013).

Five years after the adoption of the Code, the HRH capacity of the WHO Headquarters is reduced due to financial austerity, while the regional offices appear have insufficient resources to even adequately liaise with Member States on the issue. This appears to have had an impact on both monitoring and reporting on Code implementation.

The implementation of the Code and necessary monitoring involved demands commitment, leadership and a spirit of ownership for the Code at all levels. The spirit needs to be further developed, as the Code is one of only few regulatory instruments developed and adopted by WHO over the last years. The success or failure of its implementation will be seen as a case study for the capacity of WHO – and its members – in the field of global standard setting and regulation. This links the technical issue of Code implementation with the overall issue of WHO reform and the role of WHO in global health governance.

PHM calls for real WHO reform: lift the freeze, reform the regions, and hold the MSs accountable.

## 17.3 Substandard/spurious/falsely labelled/falsified/counterfeit medical products

### In focus

The Assembly will consider [A68/33](#) which includes [EB136/29](#), which had been considered by the EB in January, and also Decision [EB136\(1\)](#), in which the Board recommends 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 substandard/spurious/falsely-labelled/falsified/counterfeit medical products (SSFFCMPs), which was held in Geneva, Switzerland 29 October to 31 October 2014.

See notes of discussion at EB136 [here](#).

### Issues discussed at MSM

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.

#### Actions that result in SSFFC

Annex 1 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).

#### Actions that do not result in SSFFC

Annex 2 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 core of the debate over the title is not clear. It may be over whether the title should affirm that the actions, activities and behaviours listed do not result in a public health risk.

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.

## Work Plan

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.

Activity A (develop recommendations for the Health Authorities engaged in the detection of SSFFC medical products and establish a strengthening and tool-generating programme to contribute to Member States’ training) will be led by Brazil and will be carried by an MSM working group comprised of experts from member states.

Activity B (create a focal point network for the exchange of information and consultation at large among member states and establish an ongoing virtual exchange forum) will be undertaken by the Secretariat supported by Switzerland and UK.

Activity C (establish a working group to survey the technologies, methodologies and “track and trace” models in place and to be developed to analyse their advantages and disadvantages and to survey the available authentication and detection technologies and methodologies and analyse their advantages and disadvantages) will be led by Argentina.

Activity D (identify WHO areas working on the issue of access to quality, safe, efficacious and affordable medical products and request a report on the current state of affairs) will be led by the Secretariat.

Activity E (create a working group to develop and leverage existing recommendations for effective risk communication and recommendations for awareness campaigns on SSFFC medical products and related actions, activities and behaviours) does not appear to have been assigned to a responsible party. Presumably the Steering Committee will arrange.

Activity F (a proposal for a study on the public health and socioeconomic impact of SSFFC medical products) will be led by the Secretariat and will involve an expert group of health economists.

## Funding

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



## Background

### The bottom line

At the heart of this issue 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 trade mark 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 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 pre-history

The WHO website describes the pre-history of this debate ([here](#)) in the following terms

*From the early 1980s, World Health Organization Member States reported cases on counterfeit, spurious, substandard and presumably falsified medicines entering their markets.*

*In response to reports of Member States on such medicines the World Health Assembly, in its Resolution WHO 41.16, requested WHO to initiate programmes for the prevention and detection of spurious, counterfeited and substandard pharmaceutical preparations in May 1988. The first international meeting on "counterfeit drugs" was organized by WHO in 1992. One of the outcomes of this meeting was the first WHO definition of "counterfeit drug". In May 1994 Resolution WHA 47.13 requested WHO to assist Member States in their efforts in combating the use of counterfeit drugs. In answer to this request WHO initiated the Project on Counterfeit Drugs.*

*In addition, several International Conferences of Drug Regulatory Authorities (ICDRAs) dealt with this issue. The ICDRA held in 2004 in Madrid, Spain, recommended WHO to initiate an international convention on counterfeit medicines. This recommendation was converted into the establishment of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) at a meeting in July 2006 in Rome.*

It is worth noting that the emergence of 'counterfeit' on the WHO agenda came at a time when Pfizer was leading a campaign for new global rules to provide easier establishment of IP, greater privileges associated with IPRs and stricter enforcement. These rules became the TRIPS agreement.

It should be noted also that the above account of the pre-history of SSFFC states that the 1992 meeting, which determined to use the term counterfeit to apply to substandard medicines, was organised by WHO. According to the report of the meeting ([WHO/DMP/CFD/92](#)) it was a joint WHO and IFPMA (Int Fed of Pharm Mfrs and Assns) workshop. From the report of the meeting it is clear that the conflation of IPRs and the quality of medicines was uncritically accepted.

WHO was one of the original partners in IMPACT from 2006 and the host but it also included a very strong presence of the pharmaceutical industry, customs agencies and regulatory agencies from Northern countries. Subsequently, through a process seen as non-transparent by many developing countries, the WHO commenced hosting the IMPACT secretariat, without ratification by either the EB or the WHA. This was objected to by many states (led by Brazil, India, Thailand and others) given the close association between IMPACT and the pharma industry. There were also reservations that the pharma industry, through IMPACT, was deliberately confusing the issue of 'counterfeit' – a trademark issue – with the issue of quality and safety, especially as regards generic drugs.

WHO has subsequently stopped functioning as the secretariat of IMPACT and the member state mechanism on SSFFC was set up to clearly define different terms related to quality of medicines and demarcate these from issues of IP/trademark infringements. There, however, still continues to be divergent perceptions among member states as regards concrete ways to deal with the issue. This is apparent from the clumsy nomenclature of "substandard, spurious, false labelled, falsified, counterfeit medicines'.

IMPACT's aim to fight 'counterfeiting' represented a long-held strategy of international pharmaceutical companies and some country governments that are home to large pharma TNCs to conflate generic medicines produced in developing countries with the very real health issue of unsafe and poor quality medicines. By conflating intellectual property issues with the issue of poor quality medicines, international pharmaceutical companies, aim to maintain their market monopolies by delegitimising generic medicines and persuading countries to include TRIPS plus provisions (such as patent linkage) in domestic legislation.

This has been a highly contested debate, in part because of the continuing efforts of some member states and big pharma to conflate the issue of substandard or fake medicines with generic medicines which are not licensed by companies who have IP rights regarding those medicines within particular jurisdictions.

The MSM is the outcome of a process arising out of the IMPACT saga and is directed to distinguishing clearly between medicines which are subject to claims of IP infringement and medical products which are substandard with respect to quality, safety or efficacy and reinforcing WHO's mandate to promote effective regulation of medical products with respect to quality, safety and efficacy.

## 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](#).

WHA63 adopted [WHA63\(10\), see p67](#), 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 page 5](#)) 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, page23](#)) 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 from page 28](#)).

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 [Doc 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.

Doc 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.

The meeting of the EB in January 2014 considered the report of the Second Meeting of the Member State mechanism on SSFFCMPs which met in Geneva on 28 and 29 November 2013. The report of the meeting was transmitted to the Board as Document [EB134/25](#).

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;
- approved continuing discussion on strategies for regulating actions, activities and behaviours;
- adopted the revised work plan (Appendix 2);
- noted the budget shortfall (see 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.ue the system of chairing through the rotation of vice chairs;

See WHO Watch report of discussion at A67 [here](#).

For more detailed background information see WHO Watch Report: IP and affordability, quality, safety and efficacy: a chronology of WHO debates from 2003-2013 ([here](#)).

## PHM Comment

The attempt by the MSM to put in place a rules based and transparent mechanism to control the very real public health problem posed by medicines of poor quality is a step forward. The mechanism is member state driven and has disengaged itself from collaboration with pharma led bodies, such as IMPACT.

However, after six years of negotiations the processes are still confused, politicized and without clear guidance from WHO Secretariat. The definitions are still ambiguous and some MSs continue to conflate 'counterfeit' with issues of quality, safety and efficacy (QS&E). Big pharma has been promoting this ambiguity and confusion since the early 1990s.

## Issues arising from Report of MSM Third Meeting

### Budget shortfall

The continuing budget shortfall in relation to the implementation of the MSM workplan is a major concern. The pledged contributions for implementation of the report are in the form of voluntary contributions from a few countries. This is not probably the best approach; the budget for implementation should be drawn from WHO's core budget and not from voluntary contributions. This is especially important as, given divergences in perceptions regarding SSFFCs, reliance on voluntary contributions could lead to distortions in implementation, linked with the preferences of donor countries.

### Need to adopt new terminology to describe junk, spurious and dangerous medical products

The continuing presence of the term 'counterfeit' in the term 'SSFFC' continues to sow confusion and provides leverage for Big Pharma and its supporters to sow confusion.

This issue of terminology came to a head in WHA63 (2010) when there were three draft resolutions submitted and consensus was not achieved. The UNASUR draft spoke of 'falsified medical products'. The Africa draft affirmed the use of the term 'counterfeit' to describe false medical products. The Indian-Thai draft spoke about falsely labelled, substandard medical products and quality, safety and efficacy (QSE) compromised medical products.

In the end WHA63 adopted [WHA63\(10\), see p67](#). which called for an open ended intergovernmental working group (OE IG WG) on SSFFCMPs "from a public health perspective, excluding trade and intellectual property considerations". The OE WG of MS on SSFFCMPs report was forwarded to the Assembly in [A65/23](#) which included a draft resolution which was adopted establishing a Member State mechanism (MSM) on substandard/spurious/falsely-labelled/falsified/counterfeit medical products (SSFFC) as [WHA65.19 from page 28](#).

The use of the term SSFFC, linked to the repeated qualification "from a public health perspective, excluding trade and intellectual property considerations", has established a *de facto* definition of SSFFC meaning quality, safety and efficacy compromised medical products. However the confusion and the conflation remain.

PHM urges the adoption of a more unambiguous term such as 'QSE compromised' and leaving the term 'counterfeit' to the trademark lawyers.

### In transit seizures

The lack of agreement on item 7 in Annex 2 appears to reflect a continuing defense of in-transit seizures of generic medicines notwithstanding that they are "in compliance with the regulatory requirements of the country of export and the country of final destination".

This is a blatant attack on generic competition by Big Pharma and it is completely wrong that it should be in any way linked to the medicines regulatory status in the country of transit.

The MSM should make it clear that in transit seizures of generic medicines that are “in compliance with the regulatory requirements of the country of export and the country of final destination” belong clearly on the list of actions, activities and behaviours which lie outside the mandate of the MSM.

WHO should advocate through the World Customs Union and the World Intellectual Property Organisation against such practices on the grounds that they are an attack on access to legitimate generic medicines and treatment affordability and that they have no justification in terms of standards of quality, safety and efficacy.

### Cease collaboration between national and regional regulatory agencies and IMPACT

PHM urges member states to discontinue existing collaborations between IMPACT and their regulatory agencies and customs authorities. Such collaborations can seriously jeopardize access to affordable generic medicines of proven quality, safety and efficacy.

### Trade agreements and ‘TRIPS plus’ provisions regarding intellectual property

While WHO debates SFC a raft of new trade agreements are being negotiated and signed which explicitly seek to harness the status and authority of national and regional medicines regulatory agencies in the policing of intellectual property claims.

The recent [UNITAID Report \(2014\)](#) compares the proposals of the USA in the context of the TPP negotiations with the existing provisions under the TRIPS agreement. The analysis is technical but the implications for public health are significant:

- the US is seeking a form of words in the TPP which requires countries to presume the validity of IP claimed by complainants; would increase the difficulty in challenging patents and increase the likelihood of poor-quality patents remaining in force;
- the US proposals would limit the ability of government to balance intellectual property enforcement with public interest and development priorities;
- the US proposals would have a chilling effect on generic producers and create new risks for governments and treatment providers;
- the proposed border measures on trademarks are likely to hamper import and export of generic medicines and increase the risk of seizure of generic medicines in transit.

See the [Moir et al \(2014\)](#) assessment of the impact of different patent arrangements on the cost of health care and HIV treatment in Vietnam.

### Advocacy priorities

PHM calls for:

- full funding of the MSM from core budget;
- adequate funding for WHO’s work with national and regional regulatory agencies; lift the freeze!
- remove ‘counterfeit’ from the terminology used to refer to QSE compromised medical products;
- campaigning against in-transit seizures;
- capacity building including resourcing for national and regional regulatory authorities;
- encouraging patent legislation which provides for the full use of the flexibilities provided for in

the TRIPS Agreement;

- campaigning against trade agreements which impose TRIPS plus provisions including patent linkage, in transit seizure, presumption of validity, excessive penalties;
- addressing the role of high prices in driving SFC products; delinking R&D from patent protection.

## 17.3 Substandard/spurious/falsely labelled/falsified/counterfeit medical products

### In focus

The Assembly will consider [A68/33](#) which includes [EB136/29](#), which had been considered by the EB in January, and also Decision [EB136\(1\)](#), in which the Board recommends 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 substandard/spurious/falsely-labelled/falsified/counterfeit medical products (SSFFCMPs), which was held in Geneva, Switzerland 29 October to 31 October 2014.

See notes of discussion at EB136 [here](#).

### Issues discussed at MSM

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.

#### Actions that result in SSFFC

Annex 1 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).

#### Actions that do not result in SSFFC

Annex 2 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 core of the debate over the title is not clear. It may be over whether the title should affirm that the actions, activities and behaviours listed do not result in a public health risk.

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.

## Work Plan

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.

Activity A (develop recommendations for the Health Authorities engaged in the detection of SSFFC medical products and establish a strengthening and tool-generating programme to contribute to Member States’ training) will be led by Brazil and will be carried by an MSM working group comprised of experts from member states.

Activity B (create a focal point network for the exchange of information and consultation at large among member states and establish an ongoing virtual exchange forum) will be undertaken by the Secretariat supported by Switzerland and UK.

Activity C (establish a working group to survey the technologies, methodologies and “track and trace” models in place and to be developed to analyse their advantages and disadvantages and to survey the available authentication and detection technologies and methodologies and analyse their advantages and disadvantages) will be led by Argentina.

Activity D (identify WHO areas working on the issue of access to quality, safe, efficacious and affordable medical products and request a report on the current state of affairs) will be led by the Secretariat.

Activity E (create a working group to develop and leverage existing recommendations for effective risk communication and recommendations for awareness campaigns on SSFFC medical products and related actions, activities and behaviours) does not appear to have been assigned to a responsible party. Presumably the Steering Committee will arrange.

Activity F (a proposal for a study on the public health and socioeconomic impact of SSFFC medical products) will be led by the Secretariat and will involve an expert group of health economists.

## Funding

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

## Background

### The bottom line

At the heart of this issue 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 trade mark 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 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 pre-history

The WHO website describes the pre-history of this debate ([here](#)) in the following terms

*From the early 1980s, World Health Organization Member States reported cases on counterfeit, spurious, substandard and presumably falsified medicines entering their markets.*

*In response to reports of Member States on such medicines the World Health Assembly, in its Resolution WHO 41.16, requested WHO to initiate programmes for the prevention and detection of spurious, counterfeited and substandard pharmaceutical preparations in May 1988. The first international meeting on "counterfeit drugs" was organized by WHO in 1992. One of the outcomes of this meeting was the first WHO definition of "counterfeit drug". In May 1994 Resolution WHA 47.13 requested WHO to assist Member States in their efforts in combating the use of counterfeit drugs. In answer to this request WHO initiated the Project on Counterfeit Drugs.*

*In addition, several International Conferences of Drug Regulatory Authorities (ICDRAs) dealt with this issue. The ICDRA held in 2004 in Madrid, Spain, recommended WHO to initiate an international convention on counterfeit medicines. This recommendation was converted into the establishment of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) at a meeting in July 2006 in Rome.*

It is worth noting that the emergence of 'counterfeit' on the WHO agenda came at a time when Pfizer was leading a campaign for new global rules to provide easier establishment of IP, greater privileges associated with IPRs and stricter enforcement. These rules became the TRIPS agreement.

It should be noted also that the above account of the pre-history of SSFFC states that the 1992 meeting, which determined to use the term counterfeit to apply to substandard medicines, was organised by WHO. According to the report of the meeting ([WHO/DMP/CFD/92](#)) it was a joint WHO and IFPMA (Int Fed of Pharm Mfrs and Assns) workshop. From the report of the meeting it is clear that the conflation of IPRs and the quality of medicines was uncritically accepted.

WHO was one of the original partners in IMPACT from 2006 and the host but it also included a very strong presence of the pharmaceutical industry, customs agencies and regulatory agencies from Northern countries. Subsequently, through a process seen as non-transparent by many developing countries, the WHO commenced hosting the IMPACT secretariat, without ratification by either the EB or the WHA. This was objected to by many states (led by Brazil, India, Thailand and others) given the close association between IMPACT and the pharma industry. There were also reservations that the pharma industry, through IMPACT, was deliberately confusing the issue of 'counterfeit' – a trademark issue – with the issue of quality and safety, especially as regards generic drugs.

WHO has subsequently stopped functioning as the secretariat of IMPACT and the member state mechanism on SSFFC was set up to clearly define different terms related to quality of medicines and demarcate these from issues of IP/trademark infringements. There, however, still continues to be divergent perceptions among member states as regards concrete ways to deal with the issue. This is apparent from the clumsy nomenclature of "substandard, spurious, false labelled, falsified, counterfeit medicines'.

IMPACT's aim to fight 'counterfeiting' represented a long-held strategy of international pharmaceutical companies and some country governments that are home to large pharma TNCs to conflate generic medicines produced in developing countries with the very real health issue of unsafe and poor quality medicines. By conflating intellectual property issues with the issue of poor quality medicines, international pharmaceutical companies, aim to maintain their market monopolies by delegitimising generic medicines and persuading countries to include TRIPS plus provisions (such as patent linkage) in domestic legislation.

This has been a highly contested debate, in part because of the continuing efforts of some member states and big pharma to conflate the issue of substandard or fake medicines with generic medicines which are not licensed by companies who have IP rights regarding those medicines within particular jurisdictions.

The MSM is the outcome of a process arising out of the IMPACT saga and is directed to distinguishing clearly between medicines which are subject to claims of IP infringement and medical products which are substandard with respect to quality, safety or efficacy and reinforcing WHO's mandate to promote effective regulation of medical products with respect to quality, safety and efficacy.

## 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](#).

WHA63 adopted [WHA63\(10\), see p67](#), 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 page 5](#)) 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, page23](#)) 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 from page 28](#)).

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 [Doc 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.

Doc 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.

The meeting of the EB in January 2014 considered the report of the Second Meeting of the Member State mechanism on SSFFCMPs which met in Geneva on 28 and 29 November 2013. The report of the meeting was transmitted to the Board as Document [EB134/25](#).

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;
- approved continuing discussion on strategies for regulating actions, activities and behaviours;
- adopted the revised work plan (Appendix 2);
- noted the budget shortfall (see 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.ue the system of chairing through the rotation of vice chairs;

See WHO Watch report of discussion at A67 [here](#).

For more detailed background information see WHO Watch Report: IP and affordability, quality, safety and efficacy: a chronology of WHO debates from 2003-2013 ([here](#)).

## PHM Comment

The attempt by the MSM to put in place a rules based and transparent mechanism to control the very real public health problem posed by medicines of poor quality is a step forward. The mechanism is member state driven and has disengaged itself from collaboration with pharma led bodies, such as IMPACT.

However, after six years of negotiations the processes are still confused, politicized and without clear guidance from WHO Secretariat. The definitions are still ambiguous and some MSs continue to conflate 'counterfeit' with issues of quality, safety and efficacy (QS&E). Big pharma has been promoting this ambiguity and confusion since the early 1990s.

## Issues arising from Report of MSM Third Meeting

### Budget shortfall

The continuing budget shortfall in relation to the implementation of the MSM workplan is a major concern. The pledged contributions for implementation of the report are in the form of voluntary contributions from a few countries. This is not probably the best approach; the budget for implementation should be drawn from WHO's core budget and not from voluntary contributions. This is especially important as, given divergences in perceptions regarding SSFFCs, reliance on voluntary contributions could lead to distortions in implementation, linked with the preferences of donor countries.

### Need to adopt new terminology to describe junk, spurious and dangerous medical products

The continuing presence of the term 'counterfeit' in the term 'SSFFC' continues to sow confusion and provides leverage for Big Pharma and its supporters to sow confusion.

This issue of terminology came to a head in WHA63 (2010) when there were three draft resolutions submitted and consensus was not achieved. The UNASUR draft spoke of 'falsified medical products'. The Africa draft affirmed the use of the term 'counterfeit' to describe false medical products. The Indian-Thai draft spoke about falsely labelled, substandard medical products and quality, safety and efficacy (QSE) compromised medical products.

In the end WHA63 adopted [WHA63\(10\), see p67](#). which called for an open ended intergovernmental working group (OE IG WG) on SSFFCMPs "from a public health perspective, excluding trade and intellectual property considerations". The OE WG of MS on SSFFCMPs report was forwarded to the Assembly in [A65/23](#) which included a draft resolution which was adopted establishing a Member State mechanism (MSM) on substandard/spurious/falsely-labelled/falsified/counterfeit medical products (SSFFC) as [WHA65.19 from page 28](#).

The use of the term SSFFC, linked to the repeated qualification "from a public health perspective, excluding trade and intellectual property considerations", has established a *de facto* definition of SSFFC meaning quality, safety and efficacy compromised medical products. However the confusion and the conflation remain.

PHM urges the adoption of a more unambiguous term such as 'QSE compromised' and leaving the term 'counterfeit' to the trademark lawyers.

### In transit seizures

The lack of agreement on item 7 in Annex 2 appears to reflect a continuing defense of in-transit seizures of generic medicines notwithstanding that they are "in compliance with the regulatory requirements of the country of export and the country of final destination".

This is a blatant attack on generic competition by Big Pharma and it is completely wrong that it should be in any way linked to the medicines regulatory status in the country of transit.

The MSM should make it clear that in transit seizures of generic medicines that are “in compliance with the regulatory requirements of the country of export and the country of final destination” belong clearly on the list of actions, activities and behaviours which lie outside the mandate of the MSM.

WHO should advocate through the World Customs Union and the World Intellectual Property Organisation against such practices on the grounds that they are an attack on access to legitimate generic medicines and treatment affordability and that they have no justification in terms of standards of quality, safety and efficacy.

### Cease collaboration between national and regional regulatory agencies and IMPACT

PHM urges member states to discontinue existing collaborations between IMPACT and their regulatory agencies and customs authorities. Such collaborations can seriously jeopardize access to affordable generic medicines of proven quality, safety and efficacy.

### Trade agreements and ‘TRIPS plus’ provisions regarding intellectual property

While WHO debates SFC a raft of new trade agreements are being negotiated and signed which explicitly seek to harness the status and authority of national and regional medicines regulatory agencies in the policing of intellectual property claims.

The recent [UNITAID Report \(2014\)](#) compares the proposals of the USA in the context of the TPP negotiations with the existing provisions under the TRIPS agreement. The analysis is technical but the implications for public health are significant:

- the US is seeking a form of words in the TPP which requires countries to presume the validity of IP claimed by complainants; would increase the difficulty in challenging patents and increase the likelihood of poor-quality patents remaining in force;
- the US proposals would limit the ability of government to balance intellectual property enforcement with public interest and development priorities;
- the US proposals would have a chilling effect on generic producers and create new risks for governments and treatment providers;
- the proposed border measures on trademarks are likely to hamper import and export of generic medicines and increase the risk of seizure of generic medicines in transit.

See the [Moir et al \(2014\)](#) assessment of the impact of different patent arrangements on the cost of health care and HIV treatment in Vietnam.

### Advocacy priorities

PHM calls for:

- full funding of the MSM from core budget;
- adequate funding for WHO’s work with national and regional regulatory agencies; lift the freeze!
- remove ‘counterfeit’ from the terminology used to refer to QSE compromised medical products;
- campaigning against in-transit seizures;
- capacity building including resourcing for national and regional regulatory authorities;
- encouraging patent legislation which provides for the full use of the flexibilities provided for in

the TRIPS Agreement;

- campaigning against trade agreements which impose TRIPS plus provisions including patent linkage, in transit seizure, presumption of validity, excessive penalties;
- addressing the role of high prices in driving SFC products; delinking R&D from patent protection.



## 17.4 Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination

### In focus

The Assembly will consider two reports:

- Document [A68/34](#) deals with the proposed funding mechanism to fund de-linked R&D;
- Document [A68/34 Add.1](#) reports on progress made in implementing the selected health research and development demonstration projects.

At its meeting in January the Board noted earlier versions of both reports. See notes of discussion at the EB [here](#).

### Proposed pooled funding mechanism and involvement of TDR

Document [A68/34](#) proposes using the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR) to host a pooled fund towards research and development. The report describes the establishment of such a fund, under the management of the Special Programme, as well as its relationship with the Global Health Research and Development Observatory and the future coordination mechanism.

The Assembly is invited to note the report *“and to consider the establishment of a pooled fund for voluntary contributions towards research and development for type III and type II diseases and the specific research and development needs of developing countries in relation to type I diseases to be hosted by the Special Programme for Research and Training in Tropical Diseases”*.

### Review of demonstration projects

In line with resolution [WHA66.22](#) and decision [WHA67\(15\)](#), the Assembly will consider a second report ([A68/34 Add.1](#)) detailing progress made in implementing the selected health research and development demonstration projects.

### Background

See below, under ‘The pre-history of the CEWG’ for the earlier background, leading up to [WHA66.22](#) and [WHA66\(12\)](#).

### Funding coordination and hosting and resource mobilisation

Resolution [A66.22](#) commissioned further exploration of pooled funding and funding coordination.

[A67/27](#) discussed ‘Managed coordination’ of R&D activities and their funding. It argued that the creation of any new funding mechanism would introduce strong, managed coordination of the research that a new fund would support. The priorities supported under such a financing mechanism would be those identified through the global advisory committee and could be endorsed at the annual stakeholder conference.

In Decision [A67\(15\)](#) the Assembly asked the Secretariat to explore this proposal in more detail and to report, through EB136 to WHA68 in May 2015 on the outcomes of this exploration.

A range of possible hosts for the pooled funding had been considered in [EB134/26](#) (Jan 2014) and the EB was advised that TDR had rated highly on most criteria. In early May 2014 WHO hosted a meeting of the proponents of the four projects selected in the initial round of demonstration projects ([A67/28 Add.1](#)). At this meeting TDR tabled a proposal ([9 May 2014](#)) outlining how it might take on the role of manager of the pooled funds (see also [TDR news release 9 May](#)). While the TDR proposal was not included in the papers published by the Secretariat for WHA67 it was clearly under consideration with several speakers referring to it in debate and its endorsement in [A67\(15\)](#) above.

The Joint Coordination Board (JCB), the top governing body of the Special Programme for Research and Training in Tropical Diseases (TDR) held its annual meeting in Geneva from 23 June 2014 to 25 June 2014. In its media note ([26 June, 2014](#)), TDR recorded the support of the JCB for taking on this role.

The TDR option was further discussed at EB136 and there was general support plus some specific suggestions which have been incorporated into A68/34.

## Implementation of demonstration projects

The emergence of the demonstration projects is documented [here](#), from the original adoption of the Global Strategy and Plan of Action to the discussions at EB136.

[A68/34 Add.1](#) refers to this history but focuses on the more recent re-evaluation of on merged project and three resubmitted projects.

## Observatory

In resolution [WHA66.22](#) the Assembly requested the Director-General to establish a global R&D observatory and to review existing mechanisms which could be used to coordinate R&D under the CEWG process.

The Assembly (May 2014) considered the report [A67/27](#) which *inter alia* reported on the work done to date in relation to the Observatory. It reported that the Secretariat has started the process of establishing the Global Health Research and Development Observatory. It proposed the establishment of a global research and development advisory body and the institutionalization of an annual research and development stakeholder conference.

The objectives of the Global Observatory are described in document A67/27. Further information is available at [http://www.who.int/phi/implementation/phi\\_rd\\_observatory/en/](http://www.who.int/phi/implementation/phi_rd_observatory/en/).

Document [A68/34](#) discusses how the the relations between the Funding Mechanism, the Observatory, the Coordination Group and TDR are seen by the Secretariat.

## Pre-history of the CEWG

Since the TRIPS Agreement in 1994 the role of intellectual property (IP) protection in maintaining higher prices and constituting a barrier to access has been controversial within WHO. Particularly after the Treatment Action Campaign (1997-2001) in South Africa and the Doha Declaration on Public Health and Trade there were repeated debates about whether countries were (or should be) using the full range of flexibilities included in the TRIPS Agreement to promote access to medicines. (References and more detail [here](#).)

In June 2001 one of the Working Groups of the WHO Commission on Macroeconomics and Health published a paper ([Scherer and Watal](#), 2001) exploring the use of compulsory licenses, parallel imports, and price controls, for ensuring affordable access to patented medicines in developing countries. It also reviewed the role of corporate charity (drug donations by research-based pharmaceutical companies) and the role of aid through intergovernmental and nongovernmental organizations.

The debate over access and pricing found its way onto the WHA56 Agenda (May 2003) with Secretariat report, [A56/17](#). The WHA56 adopted resolution [WHA56.27](#) which urged member states (MSs) inter alia to: adapt national legislation to enable the full use of TRIPS flexibilities, and requested the DG inter alia to: promote technology transfer; establish an expert inquiry into IPRs, Innovation and Public Health; and monitor and analyse trade agreements.

The Commission into IPRs, Innovation and Public Health was established 2004, at the end of Dr Brundtland's period as DG, and reported at the Assembly in 2006 which was the year Dr Lee died and so the Commission's report was inherited by Dr Chan. The terms of reference of the Commission were focused on how to reconcile the claims of the manufacturers that monopoly pricing was necessary to fund innovation and the claims of developing countries that high prices were an unconscionable barrier to access.

The final [Report of the Commission](#) was submitted to EB117 (in Jan 2006); was considered by WHA59 (in May 2006) which (in [Resolution A59.24, p32](#)) appointed an intergovernmental working group (IGWG) "to draw up a global strategy and plan of action in order to provide a framework based on the Commission's recommendations, with a focus on research and development relevant to diseases that disproportionately affect developing countries."

The final report of the IGWG was presented to the WHA61 in May 2008, see [Document A61/9](#). A drafting committee was appointed to finalise the proposed global strategy and plan of action but it was not able to resolve all of the disagreements over the draft GSPA. In the end the Assembly adopted [WHA61.21 \(p31\)](#): which endorsed "the global strategy and the agreed parts of the plan of action on public health, innovation and intellectual property...". These 'agreed parts' included a commitment "to establish urgently a results-oriented and time-limited *expert working group* to examine current financing and coordination of research and development".

The GSPA was considered again at WHA62 (May 2009) and after much debate an agreed GSPA was adopted (in Resolution [WHA62.16](#)); see [integrated version of finally agreed GSPA](#).

Meanwhile the EWG was discussing financing and coordination of research and development as well as proposals for new and innovative sources of funding for R&D. A summary of the EWG report was

considered by the EB126 (Jan 2010) but the full report had not been translated into all official languages. A member state consultation to consider the full report was arranged (for May 13, 2010).

Later in May 2010 WHA63 considered the EWG report ([A63/6 Add.1](#)) plus the Chair's summary of the member state consultation on 13 May, 2010 ([A63/6 Add.2](#)). The EWG report was poorly received, partly because it had not followed its terms of reference and partly because of allegations of poorly managed conflicts of interest (more [here](#)). In Resolution [WHA63.28](#) the Assembly established a new *Consultative Expert Working Group* to take forward the work of the EWG.

The final report of the CEWG ([Doc A65/24](#) and [A65/24 Corr.1](#)) was presented to WHA65 in May 2012 (see [report, from p51](#)). The CEWG report set the scene, reviewed all of the proposals which had been considered by the EWG, reviewed options for funds mobilisation and coordination, and ended up proposing a binding instrument for health research and development. The Assembly had before it four resolutions. An informal drafting group was set up which produced a draft resolution (mandating an open ended MS meeting) was presented which was adopted ([WHA65.22](#)).

The open ended Member State meeting to follow up the report of the CEWG was held 26-28 Nov, 2012 and reported to EB132 (Jan 2013) as [EB132/21](#) which comprised a brief report plus a draft resolution for submission to the WHA. The report and draft resolution were duly reported to the WHA66 (May 2013) as [A66/23](#).

Dr Viroj Tangcharoensathien from Thailand who had chaired the OEMS meeting explained the substance of the proposed resolution:

*“The outcome of the meeting held in November 2012 – the draft resolution contained in the Appendix to document A66/23 – provided for a complex, stepwise process of implementation and reporting thereon. Two reports would be drafted in time for the Sixty-seventh World Health Assembly, one on the review of existing coordination mechanisms, as proposed in subparagraph 4(5) of the draft resolution, and the other on the evaluation of existing mechanisms for contributions to health R&D, as proposed in subparagraph 4(6). A further report would be prepared for the Sixty-eighth World Health Assembly on the implementation of health research and development demonstration projects, as proposed in subparagraph 4(4). Another open-ended meeting of Member States would be held prior to the Sixty-ninth World Health Assembly and would report to that Health Assembly on its findings.”*

There was a long debate. In the [Sixth Meeting](#) of Committee B the Draft Resolution in [A66/23](#) was approved (as [WHA66.22](#)) and the draft decision (based on the US draft as amended, see pp2-3 of [record of 6th meeting](#)) was adopted as [WHA66\(12\)](#).

See the [Secretariat Background page](#) for more references and more recent developments.

# PHM Comment

## Overview

The scope of the proposed fund would be to finance R&D projects to address priority research gaps as identified by the Global Observatory and the future coordination mechanism (currently being explored by WHO).

The fund will be managed by the Special Programme, while the Global Observatory and the coordination mechanism will be managed by the WHO Secretariat.

The focus of the fund would be the development of effective and affordable health technologies related to type III and type II diseases and the specific research and development needs of developing countries in relation to type I diseases, taking into account the principles formulated by the Consultative Expert Working Group on Research and Development: Financing and Coordination, namely delinkage of the delivery price from research and development costs, the use of open knowledge innovation, and licensing for access.

The contractual arrangements for the funding of projects will ensure that any future health technologies financed through the fund will be accessible to those in need. Arrangements could include clauses on at-cost or preferential pricing, non-exclusive licensing agreements or licences to WHO or the Special Programme.

The priorities of the fund would be informed by the analysis of the research landscape provided by the Global Observatory.

The Health Assembly, on the recommendation of the Programme, Budget and Administration Committee of the Executive Board, would decide on the allocation of the research and development fund to be apportioned to support research and development projects and to support the Global Observatory and the coordination mechanism

A new scientific review group would be established within the Special Programme under the governance of its Joint Coordinating Board. The Joint Coordinating Board would approve the final selection of projects as submitted by the scientific review group.

There are weaknesses in the current proposals but they do represent a step towards public funding of R&D and delinking.

## Funds mobilisation

PHM believes that voluntary funding of the system will prove to be unsustainable and that WHO will in due course need to return to a treaty with mandatory contributions.

## Broader scope of R&D

In the [KEI statement](#) to the 2014 Assembly, HAI and KEI argued that the purposes to be addressed by this CEWG initiative should be widened to include the development of new antibiotic drugs, better low

cost diagnostics, basic research in areas of particular interest to all member states, and the funding of independent clinical trials to evaluate the efficacy of pharmaceutical drugs.

## Trade agreements

In the [KEI statement](#) to the 2014 Assembly, HAI and KEI argued for: need to confront more directly the barriers to access to treatment which arise from trade agreements. TRIP plus provisions are standard in the raft of secret trade agreements currently being negotiated.

Proceeding with the new system does not preclude WHO taking a more active stand in relation to the full use of TRIPS flexibilities and a moratorium on trade agreements which raise new barriers to affordability.

## 17.5 Global strategy and plan of action on public health, innovation and intellectual property

### In focus

In January the EB considered the timelines and methodology of the evaluation of the GSPOA and the proposed extension of the finalisation of the GSPOA. The Board's consideration was informed by ([EB136/31](#)).

See notes of Board discussion [here](#).

The Board adopted Decision [EB137\(17\)](#) as follows:

*The Executive Board, having considered the report by the Secretariat on evaluation of the global strategy and plan of action on public health, innovation and intellectual property,*

*(1) decided to recommend to the Sixty-eighth World Health Assembly to extend the deadline of the overall programme review of the global strategy and plan of action on public health, innovation and intellectual property on its achievements, remaining challenges and recommendations on the way forward to 2018, recognizing it was not presented in 2015, as requested by resolution WHA62.16;*

*(2) decided also to recommend to the Sixty-eighth World Health Assembly to extend the time frame of the plan of action on public health, innovation and intellectual property until 2022;*

*(3) requested the Director-General to provide a report for the Sixty-eighth World Health Assembly on options, in consultation with Member States, for the conduct of the comprehensive evaluation and the overall programme review of the global strategy and plan of action on public health, innovation and intellectual property, on its achievements, remaining challenges and recommendations on the way forward, including whether to combine the two instruments, sequencing, terms of reference, timing and options for establishing an evaluation management group with the goal of completing this exercise by 2018.*

Resolution [WHA62.16](#) in May 2009 (through which the GSPOA was adopted) includes the following request to the DG:

*6. FURTHER REQUESTS the Director-General, in addition to continued monitoring, to conduct an overall programme review of the global strategy and plan of action in 2014 on its achievements, remaining challenges and recommendations on the way forward to the Health Assembly in 2015 through the Executive Board.*

Two starting points for this review are

- the Plan of Action itself ([here](#)) with its eight elements (below) and the proposed indicators associated with each element, linked to the actions foreshadowed under each element;

- [EB126/6](#), from 2009, which outlines the actions being implemented by WHO and other stakeholders, and which is supported by more detailed papers linked [here](#).

## Background

Since the TRIPS Agreement in 1994 the role of intellectual property (IP) protection in maintaining higher prices and constituting a barrier to access has been controversial within WHO. Particularly after the Treatment Action Campaign (1997-2001) in South Africa and the Doha Declaration on Public Health and Trade there were repeated debates about whether countries were (or should be) using the full range of flexibilities included in the TRIPS Agreement to promote access to medicines. (References and more detail [here](#).)

In June 2001 one of the Working Groups of the WHO Commission on Macroeconomics and Health published a paper ([Scherer and Watal](#), 2001) exploring the use of compulsory licenses, parallel imports, and price controls, for ensuring affordable access to patented medicines in developing countries. It also reviewed the role of corporate charity (drug donations by research-based pharmaceutical companies) and the role of aid through intergovernmental and nongovernmental organizations.

The debate over access and pricing found its way onto the WHA56 Agenda (May 2003) with Secretariat report, [A56/17](#). The WHA56 adopted resolution [WHA56.27](#) which urged member states (MSs) inter alia to: adapt national legislation to enable the full use of TRIPS flexibilities, and requested the DG inter alia to: promote technology transfer; establish an expert inquiry into IPRs, Innovation and Public Health; and monitor and analyse trade agreements.

The Commission into IPRs, Innovation and Public Health was established 2004, at the end of Dr Brundtland's period as DG, and reported at the Assembly in 2006 which was the year Dr Lee died and so the Commission's report was inherited by Dr Chan. The terms of reference of the Commission were focused on how to reconcile the claims of the manufacturers that monopoly pricing was necessary to fund innovation and the claims of developing countries that high prices were an unconscionable barrier to access.

The final [Report of the Commission](#) was submitted to EB117 (in Jan 2006); was considered by WHA59 (in May 2006) which (in [Resolution A59.24, p32](#)) appointed an intergovernmental working group (IGWG) "to draw up a global strategy and plan of action in order to provide a framework based on the Commission's recommendations, with a focus on research and development relevant to diseases that disproportionately affect developing countries."

The final report of the IGWG was presented to the WHA61 in May 2008, see [Document A61/9](#). A drafting committee was appointed to finalise the proposed global strategy and plan of action but it was not able to resolve all of the disagreements over the draft GSPA. In the end the Assembly adopted [WHA61.21 \(p31\)](#): which endorsed "the global strategy and the agreed parts of the plan of action on public health, innovation and intellectual property...". These 'agreed parts' included a commitment "to establish urgently a results-oriented and time-limited expert working group to examine current financing and coordination of research and development" which led to the stream of work designated as follow up of the CEWG report. .



The GSPA was considered again at WHA62 (May 2009) and after much debate an agreed GSPA was adopted (in Resolution [WHA62.16](#), page 29, see also Annex 4 from page 58); see [integrated version of finally agreed GSPA](#).

- Element 1. Prioritizing research and development needs
- Element 2. Promoting research and development
- Element 3. Building and improving innovative capacity
- Element 4. Transfer of technology
- Element 5. Application and management of intellectual property to contribute to innovation and promote public health
- Element 6. Improving delivery and access
- Element 7. Promoting sustainable financing mechanisms
- Element 8. Establishing monitoring and reporting systems

Note that supplementary information was provided to WHA62 in the form of [A62/16 Add.1](#) (Time frames and funding), [Add.2](#) (Proposed progress indicators), and [Add.3](#) (Open paragraphs on stakeholders).

The evaluation of the GSPOA was discussed at EB133 (May 2013). See [EB133/7](#), see official summary record of discussion ([here, from page 78](#)). See PHM report ([here from page 43](#)).

The Secretariat proposes ([EB136/31](#)) the following timeline for the evaluation:

- January 2015: establish evaluation management group.
- March 2015: Finalize and approve the terms of reference for the evaluation, and request proposals for potential members of the evaluation team.
- June 2015: Select the members of the evaluation team and finalize the contracts
- August 2015: Issue an inception report, which presents the plan of action, the timeline and the terms of reference.
- September 2015 to September 2016: Facilitate the evaluation exercise and monitor the outputs.
- January 2016 and May 2016: Report to the Executive Board and the World Health Assembly on the progress of the evaluation.
- October 2016: Review and finalize the evaluation report.
- January 2017 and May 2017: Submit the report to the Executive Board and the World Health Assembly.

## PHM Comment

This is a critical item in terms of access to treatment.

The Secretariat paper (EB131/31) is inadequate but the evaluation is urgent. PHM urges EB members to put together a decision for adoption by the 136th EB which spells out in more detail the purposes of the evaluation and the kind of expertise that will be needed.

There will have to be some ongoing structure to carry forward the work of the GSPOA and a properly carried out evaluation would provide critical input to the development of GSPOA MkII.

The Secretariat paper provides no framework regarding either purpose or process or personnel for the evaluation but the timelines proposed provide no opportunity for the EB to contribute to this thinking.

The EB needs to negotiate a Decision on these matters before and during the EB session.

## Need for interim extension of the mandate of the GSPOA

The timelines adopted as part of the GSPOA (see [A62/16 Add.1](#)) are clear that the mandate for all of the actions extends only to 2015.

It is also self-evident that the objectives of the GSPOA have not been achieved. There will be a continuing need for a GSPOA after 2015.

It would make sense for a revised and relaunched GSPOA to be informed by the results of the evaluation. However, the timelines for the evaluation proposed by the Secretariat do not envisage a final report coming to the Assembly before May 2017.

In the absence of some kind of interim extension of the GSPOA (and its funding) the Plan ceases in December 2015 while the result of the evaluation is not available before May 2017.

## Terms of Reference and Evaluation Methodology

One option would be to simply evaluate whether the GSPOA had achieved the indicators set out in [A62/16 Add.2](#) and the magnitude of any shortfall. This would be quite insufficient. Many of the indicators are quite superficial and further exploration will be needed to explore the context and implications of such indicators. Where there are significant shortfalls in meaningful indicators, WHO needs to know why and needs evaluators who can point to useful lessons for the future.

The timelines suggested for the evaluation in EB136/31 do not provide any opportunity for the EB to approve of the terms of reference before these are shared with published as part of the request for proposals.

It appears that the Secretariat envisages the PBAC providing such guidance as is needed by the Evaluation Management Group in accordance with the Evaluation Policy (set out in [EB131/3](#) and approved in [EB131\(1\)](#) and as provided for in EB131.R2 regarding the terms of reference of the PBAC.) In this context we note (from EB131/3) that an evaluation management group 'may comprise external experts and/or WHO staff'.

However, in the discussion of the evaluation in May 2013 ([from page 78](#)) the DG suggested that the Evaluation Monitoring (sic) Group comprise the officers of the EB. There was some discussion of other members of the EB being coopted to the Group.

In the same discussion of the evaluation of the GSPOA in May 2013 Dr Kieny commented that:

*The Secretariat was planning to review five to seven countries in detail, element by element, since the allocated resources were not sufficient for a detailed case study of all countries. Efforts would be made to build on the PAHO Regional Platform on Access and Innovation for Health Technologies and other platforms in different regions; the Secretariat was also building a global platform. Although the global health research and development observatory that the Director-General had been requested to establish in*

*resolution WHA66.22 would be useful for the purposes of reporting, it would not be fully operational by the 2015 deadline.*

*The evaluation was complex and in order to ensure independence and the use of appropriate methodology, the Secretariat would prefer to use a consultancy firm with appropriate knowledge and experience. The details of the evaluation and all the results would be provided to Member States.*

It is not clear what the Secretariat understands to be ‘appropriate knowledge and experience’.

In large degree the shortfalls in achievement are a consequence of the contested nature of some of the central issues and achieving progress on these has been like walking through treacle. Useful comment on these processes may call for diplomatic expertise and insight into the engagement of various stakeholders in the process, rather than management consulting.

In some degree the shortfalls reflect the funding crisis that WHO is in and the reluctance of some donors to support the kind of work required by the GSPOA. Useful comment here would require some insight into the politics of funds mobilisation for the GSPOA.

In view of ongoing concerns about the relationships between WHO’s regional and country offices and headquarters it would be useful to explore how the directions in the GSPOA have been progressed in the different regions, for example, support for the development of NRRAs.

The proposed focus on five to seven countries will not throw useful light on the diplomatic processes or lobbying nor the impact of WHO’s financial crisis nor the dysfunctions in the region central relationships. It maybe that a commercial management consulting company may not be the best place to look for the expertise and experience needed to usefully explore the experience of the Commission on PH, I and IP and the GSPOA with a view to shaping the next iteration.

## 18. Progress reports (PHM comment)

Secretariat follow up reports: [A68/36](#)

### Original resolutions

#### Noncommunicable diseases

- A. Comprehensive mental health action plan 2013–2020 (resolution [WHA66.8](#), see also [A66/10 Rev.1](#))
- B. Comprehensive and coordinated efforts for the management of autism spectrum disorders (resolution [WHA67.8](#), see also [A67/17](#))
- C. Disabling hearing loss (resolution [WHA48.9](#))

#### Communicable diseases

- D. Eradication of dracunculiasis (resolution [WHA64.16](#))
- E. Elimination of schistosomiasis (resolution [WHA65.21](#))
- F. Neglected tropical diseases (resolution [WHA66.12](#))
- G. Prevention and control of sexually transmitted infections: global strategy (resolution [WHA59.19](#))

#### Promoting health through the life course

- H. Newborn health (resolution [WHA67.10](#))
- I. Working towards universal coverage of maternal, newborn and child health interventions (resolution [WHA58.31](#))
- J. Implementation of the recommendations of the United Nations Commission on Life-Saving Commodities for Women and Children (resolution [WHA66.7](#))

#### Health systems

- K. Social determinants of health (resolution [WHA65.8](#))
- L. Sustainable health financing structures and universal coverage (resolution [WHA64.9](#))
- M. Strategy for integrating gender analysis and actions into the work of WHO (resolution [WHA60.25](#))
- N. Progress in the rational use of medicines (resolution [WHA60.16](#))

#### Preparedness, surveillance and response

- O. Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits (resolution [WHA64.5](#))
- P. Smallpox eradication: destruction of variola virus stocks (resolution [WHA60.1](#))

## PHM Commentary (below)

### Noncommunicable diseases

#### A. Comprehensive mental health action plan 2013-2020 (resolution [WHA66.8](#))

##### What is being followed up?

In May 2013 the World Health Assembly passed resolution [WHA66.8](#) which adopted the Comprehensive Mental Health Action Plan 2013-2020 ([CMHP13-20](#)) and, under four objectives, listed actions for Member States, the Secretariat and 'national and international partners'.

See PHM's WHO Watch commentary in 2013 ([here](#), from page 12).

The WHO Secretariat has now provided its first update report on implementation of the Plan ([here](#), from page 3).

##### PHM Comment

The global burden of treatable and preventable mental and emotional health problems is huge and, apart from the individual and family disability and suffering, has a wide ranging ramifications in the lives of communities. The inclusion of mental health in the right to health has been emphasised in various authoritative statements on the right to health (see [General Comment 14 \(2000\)](#) on the Right to Health).

Recent issues of [Global Health Watch](#) have thrown a critical light on key mental health issues. See [Mental health and inequality](#) in GHW3 and [Mental health: culture, language and power](#) in GHW2.

The resolution which the Secretariat is supposed to be reporting on ([WHA66.8](#)) is simple. It adopts the [CMHP13-20](#) which is structured around four objectives:

1. to strengthen effective leadership and governance for mental health;
2. to provide comprehensive, integrated and responsive mental health and social care services in community-based settings;
3. to implement strategies for promotion and prevention in mental health; and
4. to strengthen information systems, evidence and research for mental health.

Under each of these four objectives the Plan lists tasks for: Member States, the Secretariat, and national and international partners.

In addition the Plan identifies one or two 'indicators' under each of the four objectives.

The report focuses on work done by the Secretariat to develop the indicators and has surveyed Member States through the pre-existing [Atlas questionnaire](#). The questions correspond loosely to the indicators; they are answered by MS and allow considerable discretion in interpretation. Among the questions, respondents were asked to report:

- whether their country has an officially approved, dedicated mental health policy and if so, the year of its latest review year of its latest revision;

- whether their country has an officially approved mental health plan and if so, the year of its latest revision;
- whether their country has dedicated mental health legislation and if so, the year of its latest revision;
- total mental health spending and spending on mental hospitals in local currency; and
- about regulations and procedures, mental health training, and resources in PHC settings.

A summary of the Plan and in particular the indicators is [here](#).

The follow up report (in [A68/36](#)) also lists a number of mental health plans adopted by regional committees and reports on a number of projects being undertaken by the Secretariat.

**The report does not attempt to review whether or not the MS or the ‘national and international partners’ have taken any action at all in relation to the specific actions recommended in the Plan. Some of the Secretariat actions reported on in A68/36 correspond to tasks assigned to the Secretariat in the Plan but in a quite unsystematic and arbitrary way.**

This report reflects a profound weakness of WHO; namely the lack of accountability of Member States and the weakness of the Organization in holding MS to account. The lack of MS accountability (for implementing agreed global norms) is striking; all the more so because it has been completely ignored by the current WHO Reform Program.

The self-report procedure adopted in the Atlas is very different from the IMF assessments of countries’ economies; the OECD’s assessments of economic policy; the WTO’s trade policy reviews; or the Human Rights Council’s reviews of countries’ human rights performance.

## **B. Comprehensive and coordinated efforts for the management of autism spectrum disorders (resolution [WHA67.8](#))**

What is being followed up?

Background

PHM Comment

## **C. Disabling hearing loss (resolution [WHA48.9](#))**

What is being followed up?

Background

PHM Comment

## Communicable diseases

### D. Eradication of dracunculiasis (resolution [WHA64.16](#))

What is being followed up?

Background

PHM Comment

### E. Elimination of schistosomiasis (resolution [WHA65.21](#))

What is being followed up?

Background

PHM Comment

### F. Neglected tropical diseases (resolution [WHA66.12](#))

What is being followed up?

Background

## PHM Comment

The document cites WIPO's research consortium, in which 'pharmaceutical companies have opened their libraries of compounds to outside researchers, improving prospects for the development of new medicines' - WIPO has nothing to do with WHO and WIPO's 'consortium' is a forum shifting strategy of big pharma in the threat of models like DNDi (they retain IP in this model).

## G. Prevention and control of sexually transmitted infections: global strategy (resolution [WHA59.19](#))

What is being followed up?

### Background

## PHM Comment

## Promoting health through the life course

### H. Newborn health (resolution [WHA67.10](#))

What is being followed up?

### Background

## PHM Comment

### I. Working towards universal coverage of maternal, newborn and child health interventions (resolution [WHA58.31](#))

What is being followed up?



## Background

### PHM Comment

## J. Implementation of the recommendations of the United Nations Commission on Life-Saving Commodities for Women and Children (resolution [WHA66.7](#))

What is being followed up?

## Background

### PHM Comment

## Health systems

## K. Social determinants of health (resolution [WHA65.8](#))

What is being followed up?

WHA65.8 includes recommendations for:

- member states,
- 'the international community' (includes UN agencies, aid agencies & multilateral donors),
- developed countries regarding levels of official development assistance, and
- the Secretariat.

NB This is the last report on the implementation of this resolution as mandated in WHA65.8.

## Background

SDH was put on the policy agenda by Dr Lee in 2006 who with the support of UK (and others) established the Commission on SDH which [reported](#) in 2008.

"In 2009, the Health Assembly adopted resolution [WHA62.14](#) on reducing health inequities through action on the social determinants of health. It requested the Director-General to provide support to Member States in measures that included convening a global event, with the assistance of Member States, before the Sixty-fifth World Health Assembly in order to discuss renewed plans for redressing the alarming trends of health inequities through actions on the social determinants of health" (From para 2 of [A65/16](#))

The Rio Conference on SDH took place 19-21 October 2011. The Conference adopted the Political Declaration (reported in [EB130.R11, Annex](#)). See the report to the Assembly in May 2012 ([A65/16](#)).

The Assembly considered the report ([A65/16](#)) and adopted [A65.8](#) which is the resolution being reported on in [A68/36](#) and considered here.

PHM has contributed to the on-going discussions regarding the social determinants (and the social determination) of health. Key documents include:

- the [Civil Society Report](#) (2007) to the Commission (to which PHM contributed)
- [Chapter D1.2](#) in GHW2 (2008) on the WHO & CSDH
- the [Declaration by Public Interest Civil Society Organisations](#) at the Rio Conference in 2011 (to which PHM contributed)
- [Statement by social movements](#) at Rio Conference in 2011 (to which PHM also contributed)
- [PHM commentary on Item 13.6](#) (Outcomes of Rio Conference) at WHA65 in May 2012

#### PHM Comment

Seems to be mainly about what the Secretariat has done. Not much here about MSs, 'international community' or bilateral donors.

### L. Sustainable health financing structures and universal coverage (resolution [WHA64.9](#))

What is being followed up?

#### Background

#### PHM Comment

### M. Strategy for integrating gender analysis and actions into the work of WHO (resolution [WHA60.25](#))

What is being followed up?

#### Background

## PHM Comment

### N. Progress in the rational use of medicines (resolution [WHA60.16](#))

#### What is being followed up?

Resolution [WHA60.16](#) was adopted in May 2007, prompted in part by increasing concern about anti-microbial resistance. The Secretariat document accompanying the draft resolution, Document [A60/24](#), provides further background to the issue.

Resolution [WHA60.16](#) commissioned biennial reviews without end. Follow up reports were submitted to the Assembly in [2009](#), [2011](#), and [2013](#).

#### Background

WHO's [Medicines Strategy \(Countries at the Core - 2004 - 2007\)](#) is referred to in the Secretariat report [A60/24](#). The current Secretariat policies are contained in [EMP/MAR/2012.3](#) (The Pursuit of Responsible Use of Medicines) and are summarised on the [RUM page](#). The RUM page identifies 12 key policy principles to promote rational use:

- Establishment of a multidisciplinary national body to coordinate policies on medicine use
- Use of clinical guidelines
- Development and use of national essential medicines list
- Establishment of drug and therapeutics committees in districts and hospitals
- Inclusion of problem-based pharmacotherapy training in undergraduate curricula
- Continuing in-service medical education as a licensure requirement
- Supervision, audit and feedback
- Use of independent information on medicines
- Public education about medicines
- Avoidance of perverse financial incentives
- Use of appropriate and enforced regulation
- Sufficient government expenditure to ensure availability of medicines and staff.

WHO's 1988 statement on [Ethical Criteria for Medicinal Drug Promotion](#) is also a key reference.

## PHM Comment

The resolution identifies tasks for Member States and tasks for the Secretariat.

Both the 2011 and 2013 reports comment that most Member States are not doing very much:

*2011: the majority of countries have yet to tackle rational use of medicines in their national plans and commit resources as recommended in the resolution*

*2013 the national efforts that Member States were urged to make in resolution WHA60.16 remain limited*

The 2015 report is a bit more detailed, listing countries in the various regions who are doing something. Only the SEARO region has a systematic Situation Analysis survey in place and a schedule of country (and state) surveys. It appears that the above list of 12 key principles has informed the survey methodology.

Operative para 1(5) in WHA60.16 urged member states: 'to enact new or enforce existing legislation to ban inaccurate, misleading or unethical promotion of medicines, to monitor promotion of medicines and to develop and implement programmes that will provide independent, non-promotional information about medicines'. None of the progress reports since 2007 have mentioned any progress on this front.

The biennial reports are much more detailed when it comes to reporting on what the Secretariat has been doing and it is apparent that the Secretariat, both in Geneva and the regions, has been very active in this area. However, there are gaps; the reports are strangely silent on the issue of 'ethical criteria for medicinal drug promotion'.

The progress reports since 2007 seems to be drifting away from some of the main points raised the (WHA60.16) agenda item 12.17 on the Progress in the Rational Use of Medicines. As well as some of the previous resolutions mentioned in the preamble clauses; namely WHA47.16 on ethical criteria for medicinal drug promotion and WHA51.9 on cross border advertising, promotion and sale of medical products using the internet.

Operative para 2(6) of WHA60.16 requested from the Director General to report 'on progress achieved, problems encountered and further actions proposed in the implementation of WHO's programmes to promote rational use of medicines'. Nonetheless, there was rarely any mention of the problems encountered, nor suggesting a way to solve those problems encountered by the member states.

If the Member states are failing to act in accordance with the resolution ('enforcing existing legislation and banning inaccurate, misleading or unethical promotion of medicines'), it is the role of the Director General to highlight those challenges, and suggest a way to overcome them.

It would also be useful if the DG were to provide detailed figures on the costs of Secretariat work on rational use of medicines and the donors involved.

There is a strong focus in all of the progress reports since 2009 on action around anti-microbial resistance. While AMR is of critical importance it should not be allowed to overshadow other important aspects regarding the rational use of medicines.

It appears that big donor sensitivity has discouraged a focus on operative para 1(5) ('legislation to ban inaccurate, misleading or unethical promotion of medicines') although the Bulletin has carried a [strong commentary on direct to consumer advertising](#) in 2009.

The position of the US pharma industry and the US government on DTCA was clearly expressed in its proposals for the so-called '[transparency annex](#)' for the TPP, leaked in 2011. This bizarrely named annex proposes that:

*Each Party shall permit a pharmaceutical product manufacturer to disseminate to health professionals and consumers through the manufacturer's Internet site registered in the territory of the Party, and on other Internet sites registered in the territory of the Party linked to that site, information that is truthful and not misleading regarding its pharmaceutical products that are approved for sale in the Party's territory, provided that the information includes a balance of risks and benefits and is limited to indications for which the Party's competent regulatory authorities have approved the marketing of the pharmaceutical products.*

Because the TPP is being negotiated in secret it is not clear whether this provision remains in the current text of the draft agreement.

Clearly this is an issue regarding which WHO's Trade and Health resolution ([WHA59.26](#)) would require action if 59.26 were ever to be properly funded.

The structure of the biennial reports, 2015 included, is not very systematic. It comprises reports from headquarters and the regions on the various projects in which they have been involved. It certainly does not report systematically on progress with respect to the 12 key principles listed above or perhaps the seven strategic recommendations provided in [EMP/MAR/2012.3](#):

- 1. Develop and mandate a List of Essential Medicines at the national level to inform reimbursement decisions and ensure access to essential medicines.*
- 2. Invest to ensure national medicines procurement and supply systems are efficient and reliable to support the responsible use of medicines.*
- 3. Promote a shift in focus to early screening and accurate diagnosis to guide/inform medicines prescription and avoid overuse, underuse and misuse of medicines.*
- 4. Facilitate the implementation of evidence-based treatment guidelines; where they exist, remove regulatory or administrative barriers and directly target all key stakeholders: prescribers, dispensers and patients.*
- 5. Promote initiatives that put patients at the centre of treatment in order to maximize adherence to therapy.*
- 6. Monitor medicine use, from purchase to health outcome, to evaluate the real-world efficacy of treatment and guide evidence-based policy-making.*
- 7. Ensure sustained, top-down commitment of national authorities and promote active, bottom-up engagement of prescribers, patients and dispensers to the principles and policies fostering the responsible use of medicines.*

## Preparedness, surveillance and response

### O. Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits (resolution [WHA64.5](#))

#### What is being followed up?

In resolution WHA64.5, the World Health Assembly adopted the Pandemic Influenza Preparedness Framework (the “PIP Framework”), which seeks to improve and strengthen the sharing of influenza viruses with human pandemic potential through a WHO-coordinated network of laboratories, known as the Global Influenza Surveillance and Response System, and to promote fair and equitable access to the benefits arising from such sharing, by developing countries.

Section 7.4.1 of the Framework states that the Director-General shall on a biennial basis, inform the World Health Assembly on the status of and progress on the Framework’s implementation.<sup>2</sup> The present document describes progress since the biennial report to the Sixty-sixth World Health Assembly in May 2013.

#### Background

#### PHM Comment

**R**eport notes money received from pharma since 2013 - 15 million total? a bit unclear - but very low! Report says actions began in second half of 2014 re building capacity - very light on what has actually be done so far.

### P. Smallpox eradication: destruction of variola virus stocks (resolution [WHA60.1](#))

#### What is being followed up?

#### Background

#### PHM Comment