



## PHM Commentary on the Agenda of the 136th Session of the WHO Executive Board

Geneva: 22 Jan 2015

The comments set out below have been prepared by the People's Health Movement as a contribution to Member State deliberation during the 136<sup>th</sup> Session of the WHO Executive Board.

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 EB136 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 EB136 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/eb136](http://www.ghwatch.org/who-watch/eb136). 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 EB meeting and will be pleased to discuss with you the issues explored below.

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## EBSS3 Special Session on Ebola Emergency

### In focus at EBSS3

The DG, in consultation with the Chair of the EB, has convened this Special Session and proposed for the agenda (see [EBSS/3/1 \(annotated\)](#)), two main items:

- [Item 1](#). Current context and challenges; stopping the epidemic; and preparedness in non-affected countries and regions (in the morning session; see [EBSS3/2](#) aka [EB136/26](#)); and
- [Item 2](#). Ensuring WHO's capacity to prepare for and respond to future large-scale and sustained outbreaks and emergencies (in the afternoon session; see [EBSS3/3](#) aka [EB136/49](#)); a resolution will be considered under this item.

See also:

- [EBSS/3/INF./1](#) (aka EB136/INF./4): Fast-tracking the development and prospective roll-out of vaccines, therapies and diagnostics in response to Ebola virus disease
- [EBSS/3/INF./2](#) (aka EB136/INF./5): Building resilient health systems in Ebola-affected countries
- [EBSS/3/INF./3](#) (aka EB136/INF./6): Highlight of efforts made to date towards preparing non-affected countries and regions to respond to potential importation of EVD
- [EBSS/3/INF./4](#) (aka EB136/INF./7): IHR and Ebola

Note that Ebola remains on the EB136 agenda at:

5.3 Overview of reform implementation (and Ebola response) ([EB136/7](#), [EB136/49](#))

9.4 2014 Ebola virus disease outbreak ([EB136/26](#))

Document [EBSS/3/DIV./1](#) which sets out the formalities associated with the special session notes that the special session:

... will not in any way preclude discussion on Ebola during the 136th session of the Executive Board, particularly under agenda item 9.4 (2014 Ebola virus disease outbreak), as well as under other related items, including item 10 (Health systems), item 8.3 (Implementation of the International Health Regulations (2005)) and item 11.2 (Proposed programme budget 2016–2017).

### Item 1. Current context and challenges; stopping the epidemic; and preparedness in non-affected countries and regions

#### In focus

*[EBSS3/2](#) (aka EB136/26) contextualizes the outbreak, providing a summary of the virus' spread, the country-level and global response, work on preparedness, research and development and building resilient health systems in the affected countries. The document concludes with an overview of the strategy for bringing the outbreak to an end.*

*The Secretariat appears to have planned this item as an opportunity to review the crisis and consider how best to manage it from here. Clearly there will also be lessons to be learned from this review which are of relevance to the afternoon item on 'Ensuring WHO's capacity'.*

Consideration of this item will be supported also by :

- [EBSS/3/INF./1](#) (aka EB136/INF./4): Fast-tracking the development and prospective roll-out of vaccines, therapies and diagnostics in response to Ebola virus disease
- [EBSS/3/INF./2](#) (aka EB136/INF./5): Building resilient health systems in Ebola-affected countries
- [EBSS/3/INF./3](#) (aka EB136/INF./6): Highlight of efforts made to date towards preparing non-affected countries and regions to respond to potential importation of EVD
- [AFR/RC64/9](#): "Ebola virus outbreak in West Africa: Update and lessons learnt – Report of the Secretariat" (1 August 2014) for further region-specific lessons learnt and proposed actions. See also [PHM comment on this paper](#) prepared for the Afro RC.

## Background

[EBSS3/2](#) (aka [EB136/26](#)) reviews the context of the Ebola epidemic in West Africa and describes 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 refers also to the latest [Ebola Situation Report](#) on the [GAR \(Ebola\)](#) website.

## PHM Comment

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 but there is no explanation of it in the papers before the Board. [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 the 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.

## Item 2. Ensuring WHO's capacity to prepare for and respond to future large-scale and sustained outbreaks and emergencies

### In focus

[EBSS3/3](#) is quite radical. It suggests that WHO's focus on technical support and normative guidance has contributed to a neglect of its operational capacity in relation to outbreaks and emergencies.

*Though WHO has often been called on to support Member States as they respond to crises, the unprecedented complexity and scale of the current Ebola outbreak demonstrates that the Organization's capacities, methods and approaches are not necessarily scalable or adaptable to novel or larger challenges. Further, WHO's focus on technical support and normative guidance has left a gap in institutional capacity for and appreciation of the importance of operations.*

[EB136/7](#) notes:

*"the unprecedented complexity and scale of the outbreak has placed enormous strain on WHO's managerial structures and systems. Challenges in mobilizing human resources,*



*organizational efficiency, alignment and effectiveness across the three levels of the Organization, as well as financing – all of which are targets of the reform agenda – are crucial elements of the response that have been exposed as persisting weaknesses”.*

[EBSS3/3](#) declares that “*WHO must substantially strengthen and modernize its emergency management capacity*”; sets out five proposals for modernising and reforming; and urges the EB to adopt a resolution along these lines. The five proposals involve:

1. recognition and clear delineation of WHO’s mandate and role in emergency response;
2. effective crisis management mechanisms to enable WHO to fulfil that role;
3. adequate capacities exist to predictably apply these crisis management mechanisms;
4. appropriate and dedicated funding is in place; and
5. a robust performance management and accountability framework.

## PHM Comment

### 1. 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](#)).

### 2. 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](#)).

### 3. 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.

### 4. Funding mechanism

EBSS3/3 (aka 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](#)).

### 5. 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.

See further comment under the heading Member State Accountability in the PHM commentary on WHO Reform under EB Item 5.3 ([here](#)).

## 5.1 Framework of engagement with non-State actors

### In focus at EB136

The Board will consider [EB136/5](#) in which the Secretariat:

- provides 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](#))
- summarises the issues raised during regional committee debates ([EB136/INF./2](#));
- sets out the Secretariat's responses to the issues raised; and
- provides a revised draft framework for engagement with NSAs in the Annex to [EB136/5](#).

### 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 ([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. See notes from EB134 debate [here](#).

At the Executive Board in January 2014, the Secretariat tabled a draft framework to govern WHO's engagement with non-State actors ([EB134/8](#)). A further iteration ([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 are summarised in [EB136/INF./2](#) and the Secretariat's response and revised framework are presented in [EB136/5](#).

## PHM comment

The paper presented to the EB ([EB136/5](#)) is quite comprehensive in terms of providing official policy to govern the Secretariat's relations with NSAs.

## Operational practicability

However, the proposed procedures are also very complex (in part because of their comprehensiveness). 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.

## Learning from the past: the role of judgement and culture as opposed to bureaucratic protocols

There have been several incidents of real or perceived improper influence in recent years, including for example: the International Medicines Product Anti-Counterfeiting Taskforce (IMPACT) debate (see [Third World Network report here](#)), Paul Herrling and the Expert Working Group on Financing and Coordination (see [PHM report](#) and [KEI](#)), virus sharing in the context of PIP (See debate at WHA60 [WHA60-REC3/A60\\_REC3-en](#) from page 12; see especially the Indonesian contribution), the management of the H1N1 outbreak ([see A64/10](#)) and the case of psoriasis at EB133 (see [WHO Watch report here](#)). Retrospective analysis of instances of real or perceived improper influence and publication of such analyses in order to learn from them. The [Fineberg Report](#) is a fine example. See [below](#) for a more detailed review of these cases.

These episodes provide real life cases for testing the comprehensiveness and practicability of the Secretariat's proposed policy package. It is hard to see the complex bureaucratic protocols envisaged in the present draft protecting WHO from the risks arising from any of these episodes. In all of these cases the risks to WHO were self-evident. What was missing was the culture of integrity and the assurance of organisational support for officials who might resist the pressures to place the Organisation at risk.

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.

## Oversight

The new draft policy provides for the PBAC to oversee WHO's engagement with NSAs on behalf of the EB (clause 65) with an 'engagement coordination group' (clause 35) within the Secretariat with representatives from regions and clusters. It is not clear where the proposed register of non-State actors will be based.

The summary of regional committee debates refers ([EB136/INF./2](#), Clause 15) to a proposal introduced during the WPR debate (by the USA) for a 'dedicated office [in the Secretariat] to oversee implementation that would not only exercise a watchdog function but also play a facilitating role in promoting engagement and actively support WHO programmes in their efforts to reach out to non-State actors, including the private sector'.

PHM sees this as a 'Trojan horse' strategy which would reduce transparency and weaken the proposed framework. The proposal does not appear in the EB revised framework and PHM urges MSs to resist any further attempt to introduce such a mechanism.

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

The modalities of influence of non-state actors are still not addressed in the risk assessment. 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 practice of due diligence

Para 28 & 29 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. The draft framework 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 revised framework does not make it clear how WHO will determine whether an NGO is independent or influenced by private sector funding sources.

## 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 (CI 30) 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 (CI 48(a)).

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 issue of COI is on the EB agenda in a recommendation by SAGE on the global vaccine action plan ([item 9.3 page 3](#)) that WHO (as part of GVAP Sec alongside Gates Foundation) attend Davos World Economic Forum and solicit assistance from private sector entities - how will this process ensure no COI and ensure due diligence?

## Harmonisation

Another issue is harmonisation of rules between the WHO governing bodies. For example, WPRC requires that non-state actors in official relations submit statements two weeks prior to the meeting, which are vetted. The regions should now be consistent with WHO EB/WHA rules that statements can be submitted by 8am on the day of the agenda item to be discussed, and should not require statements to be vetted.

## Footnote: Learning from previous episodes

There have been several incidents of real or perceived improper influence in recent years, including for example: the IMPACT debate, Paul Herrling and the EWG, virus sharing in the context of PIP, the management of the H1N1 outbreak, and the case of psoriasis at EB133.

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

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.

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.

Either way it is hard to believe that the complex and convoluted policy package put forward by the Secretariat would have prevented this. Against this episode it seems that it was a more general issue of cultural awareness (lack of) and lack of sensitivity.

Management of H1N1 (see [A64/10](#)). During the H1N1 pandemic there were some decisions taken which were controversial at the time (in particular the size of the vaccine order and inconsistent/changing definitions of 'pandemic'). The Fineberg inquiry did not accept that the size of the vaccine order reflected improper influence (nor the changing definitions of 'pandemic'). However, there was reputational damage and the Professor Fineberg made some useful recommendations which might have avoided such damage. These are largely about awareness, sensitivity and judgement.

Psoriasis (see WHO Watch report [here](#)). 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.

Retrospective analysis of instances of real or perceived improper influence and publication of such analyses in order to learn from them. The [Fineberg Report](#) is a fine example.



## 5.2 Method of work of the governing bodies

### In focus at EB136

*In response to a request by the Executive Board at its 135th session, the Secretariat's report ([EB136/6](#)) provides recommendations for improving the work of the governing bodies, with a view to promoting manageable agendas, reforming reporting requirements, encouraging early discussion of draft resolutions, and ensuring timely distribution of documentation. In addition, options for saving time and better focusing on the strategic work of the governing bodies will be presented.*

The 'request by the Executive Board' referred to above was not formalised as a decision or a resolution. Rather it was a loose consensus evident in the discussion of the outcomes of the WHA67 (see [WHO Watch report](#)).

[EB136/6](#) reviews previous decisions aimed at managing governing body meetings including agenda setting, submission of draft resolutions/decisions, management of the session, and capacity building. The paper further proposes reducing future reporting requirements in resolutions, enabling early discussion of resolutions, establishing a temporary web page for MS statements which are too long to be read at the session, scheduling an extra day before Assembly meetings to provide for the increasing number of side events.

### Background

WHA67 was very difficult with several sessions going well into the night. EB135 reviewed the experience of the Assembly ([here](#)) and identified that the problem was not so much 'agenda control' nor the use of 'traffic lights' to restrict speakers but poorly prepared, irrelevant and undisciplined contributions by many MS and lax chairing. (See [Kickbusch and Monk](#) comment in BMJ following the Assembly).

It seems that many delegates come prepared with authorised statements from their governments, prepared without a clear understanding of the purpose and focus of the agenda item. In such cases it is common to provide 'national reports' describing national programs and structures of variable relevance to the agenda item. One option mentioned during the EB135 discussion would be to establish an electronic portal for posting such reports without taking up the time of the Assembly. This is further advanced in [EB136/6](#).

### PHM comment

There are serious challenges facing WHO with respect to 'methods of work' of governing bodies.

There is nothing in EB136/6 to address poorly prepared, irrelevant and undisciplined contributions by MS delegates.

One of the burdens of the Assembly, particularly for countries with small delegations are the numerous working groups negotiating text around the most contentious issues. This is not addressed in EB136/6.

Another common problem is when amendments are proposed during the session with no hard copy or e-copy and often in one language only. Greater use of e-documents or real time video streaming of such documents, particularly if they could be translated quickly might help. This latter possibility does not seem to have been considered.

PHM supports the proposal for early exposure of draft resolutions, in particular, for the posting of draft resolutions as conf papers on the documentation page as soon as they have been formally submitted.

PHM appreciates the commitment to more timely distribution of documents. From an NGO perspective this needs to be linked to the harmonisation across governing bodies of the requirement for early submission of NGO statements. The full week requirement stands in sharp contrast with the 24 hour requirement in Geneva. At the 2014 WPRC session NGOs were required to submit draft statements a week before the session commenced which was particularly difficult when the publication of the Secretariat statements was late.

## 5.3 Overview of reform implementation

### In focus

*The Secretariat will report to the Board ([EB136/7](#)) on the status of WHO's reform process, and describe how reform has helped the Organization in responding to the outbreak of Ebola virus disease. The report will also give details of the areas for further improvement that have been identified during the Ebola response.*

### Background

The WHO Reform program is a sprawling multifaceted exercise reaching into many aspects of WHO's work.

[EB136/7](#) summarises progress since WHA67 including programmatic reform and priority setting, governance reform, and management reform.

Also relevant, in terms of an overview of the reform project generally, is the report of the Independent Evaluation Team considered by EB134 as [EB134.39](#).

One of the most contentious issues, which has not systematically addressed in the reform program to date, is 'WHO's role in the wider structures of global health governance'.

### Ebola

The Secretariat notes

*the unprecedented complexity and scale of the outbreak has placed enormous strain on WHO's managerial structures and systems. Challenges in mobilizing human resources, organizational efficiency, alignment and effectiveness across the three levels of the Organization, as well as financing – all of which are targets of the reform agenda – are crucial elements of the response that have been exposed as persisting weaknesses.*

See further PHM commentary on the Ebola crisis under the EBSS3 discussion ([here](#)).

### PHM Comment

PHM recognises that WHO suffers from many weaknesses and that much of the work going into the present reform program is very worthwhile. However, there are three fundamental issues highlighted by the Ebola outbreak but not being properly addressed in the reform program; these are: the freeze on assessed contributions; the dysfunctional arrangements under which regional directors are appointed; and the lack of accountability of MSs for their contribution to and implementation of agreed provisions and principles.

## Donor dependence and the freeze on assessed contributions

Donor dependence consequent upon the freeze on assessed contributions is one of the overshadowing fundamental disabilities. Regional dysfunction is a longstanding disability which has been virtually ignored in the current reform program. Linked to both of these is the lack of accountability on the part of member states for (what the Independent Evaluation Team called) their “duty of care” to the Organisation.

These structural disabilities cannot be considered separately from the wider structures and dynamics of global economic and political governance, articulated clearly in the People’s Charter for Health.

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](#)).

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. The continued opposition from Big Pharma and its advocates in WHO to delinking pharma R&D from revenues based on IP monopoly illustrates this clearly. 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.

## Regional dysfunction

A draft internal document obtained by Associated Press 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 cause 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.*  
...

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

## **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 Breast Milk 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.

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 OECD 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.

## 6.1 Outcome of the Second International Conference on Nutrition

### In focus

*In decision [EB134\(2\)](#) the Executive Board requested the Director-General, inter alia, to report to the Sixty-eighth World Health Assembly, through the Executive Board at its 136th session, on the outcome of the Second International Conference on Nutrition. This report ([EB136/8](#)) describes the outcomes of the Conference and WHO's role in its follow-up.*

It is likely that a resolution is being drafted for forwarding to the Assembly.

**A draft resolution**, based on the Civil Society Vision Statement presented to the conference, has been prepared for the consideration of the EB. It is [here](#).

### Background

#### WHO consideration

Preparation for ICN2 (19-21 November, 2014) was considered by WHA67 in relation to maternal, infant and young child nutrition (see PHM notes [here](#)). More about ICN2 according to [FAO](#), [WHO](#) and [UNSCN](#).

Assembly consideration was informed by report [A67/15](#) and structured around Decision [EB134\(2\)](#) from January 2014. Para 3 of Decision [EB134\(2\)](#) deals with WHO's involvement in ICN2 (and taking into account WHO's rules for dealing with NSAs). Paras 3(a) - 3(e) deal with the arrangements for producing the draft outcomes document for ICN2 by the end of September. Paras 3(f) and 3(g) request the DG to report on progress towards the ICN2 to WHA67 and on the outcomes of ICN2 to WHA68.

The Assembly was invited to note [A67/15](#) and consider the draft decision recommended in decision [EB134\(2\)](#), in particular providing further guidance on a Member State-driven process to develop an outcome document for the Second International Conference on Nutrition. The Assembly adopted [Decision A67\(9\)](#).

See PHM comment at WHA67 and report on debate [here](#).

#### 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](#).

[A draft resolution based on the Civil Society Vision Statement \(here\)](#) has been prepared for the consideration of the EB.

## 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 carries a further updated analysis. 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 EB 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.

Need strong commitment to building the domestic constituency needed to shape such plans and to drive implementation. See [PICS&SM](#) statement.

## International action

Need to clearly articulate the barriers to food security and food sovereignty in current trade and investment agreements and to point towards 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 World 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 EB to adopt the draft resolution ([here](#)) based on the Civil Society Vision Statement.

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

### In focus

*The Board will consider the report of a 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.*

### 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](#) transmits 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.

## 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. 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 appreciate the proposed disaggregation of indicators by socioeconomic group, sex and ethnicity. This is important 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.

We appreciate the inclusion of full implementation of the Voluntary Code on Marketing of Breastmilk Substitutes as a core policy and capacity indicator. Nevertheless, the time has come to strengthen the Code and render it mandatory rather than voluntary.

The global determinants of food security, food sovereignty and healthy nutrition are undeniable including the supply chains linking in agriculture, trade, retail and marketing which are themselves shaped by the processes of globalization, international trade agreements. However, since the CIP was silent regarding the political economy of food sovereignty the demand is not there for policy and program indicators which might follow progress in reforming the structures and dynamics of global food supply.

The food sovereignty of many LMICs continues to be undermined by 'land grabs, the speculation by traders on food futures and an increasing number of countries are now net food importers and therefore increasingly food insecure and dependent on imported (often obesogenic) food.

## 6.3 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. Its work 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. The EB will review [EB136/10](#) which provides an update on the work of the Commission to date. The Board is invited to note the report.*

The Commission will be represented at the EB to both brief the Board but also to listen to the comments of the MSs. EB136/10 notes that the Commission plans to issue preliminary recommendations in early 2015 dealing with the consequences, the importance of a life-course approach and preventive actions.

### 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.

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

We appreciate the work done until now by the high-level commission and the comprehensive approach used.



PHM would strongly support the proposal for a framework convention on nutrition and mandatory standards as flagged in the report of the Commission's first meeting. The experience of the voluntary Code on the Marketing of Breast Milk Substitutes as compared with the FCTC or the IHRs underlines clearly the importance of mandatory standards.

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. Provisions for investor state dispute settlement have been widely recognised as a threat to policy space in terms of regulating the food environment. Robust standards in a binding agreement would go a long way to protecting such policy space.

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

The economic logic of highly 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 wetter less energy dense foods.

WHO must find ways of engaging more effectively with the rising significance of trade and investment agreements in global health governance. This commission could lead the way.

## 6.4 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 Board is invited to note the Outcome Document (see Annex 1 of [EB136/11](#)) from the High Level Meeting of the UNGA on NCDs in July 2014. In her report on the meeting ([EB136/11](#)) the DG notes that the HLM could not achieve consensus on the need for process indicators, as opposed to outcome indicators, and suggests the Board might like to provide further advice on the need for such indicators in view of WHO's obligation to report to the UNGA in 2017 on the implementation of the [2011 Political Declaration](#).

[EB136/11](#) also provides an overview of 11 separate actions on the Secretariat's NCDs agenda which arise from or were endorsed by the HLM. These include:

- Para 15. 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 16. 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 17. 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 discussion of [EB136/11 Add.1](#) below;
- Para 18. 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 19. 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 20. 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 21. Updating the WHO global status reports on noncommunicable diseases - trends, programs, suggestions, including country-specific data - modelled on [Global Status Report 2010](#);

- *Para 22. 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 23. 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 24. Reporting progress to the United Nations General Assembly on progress with the [2011 Political Declaration](#) and the 2014 Outcomes Document (see Annex 1 of [EB136/11](#)); scheduled to report in 2017;*
- *Para 25. 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.*

*In a second document, ([EB136/11 Add.1](#)) the Director-General submits the proposed work plan for the Global Coordination Mechanism on NCDs (with a secretariat within the office of the ADG for NCDs) covering the period 2016–2017 to the Board for its consideration.*

## Background

### 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](#).

### Moscow Declaration

[Moscow Declaration](#) (2011) came out of the first global ministerial conference on healthy lifestyles and NCDs April 2011.

### Follow up of July 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 [EB136/11](#). 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 [EB136/11 Add.1](#)) is structured around the five objectives of the GCM and includes a number of actions under each objective (11 in total).

[EB136/11 Add.1](#) also includes a note on the proposed General Meeting of the GCM and a preliminary evaluation of the value added of the GCM.

The Board is invited to comment on the work plan, the modalities for the General Meeting (Annex 1 of [EB136/11 Add.1](#)) and the modalities for the preliminary evaluation (Annex 2).

## PHM Comment

PHM's comment on Agenda Item 13.1 at WHA67 on NCDs ([here](#)) surveys the broader field of global policy action around NCDs.

## A note on the Global Action Plan for Prevention and Control of NCDs ([WHA 66/9](#))

The goal, principles and objectives are good. None of the global targets, however, address social determinants of health or reducing inequity in the distribution of risk factors. Thus, need clearer SDH targets (including those related to trade and investment treaties affecting unhealthy products) and commitments to reducing inequities in distribution and not just in absolute percentages.

Although the GAP acknowledges SDH and a host of other related issues, it argues that one action plan addressing all would be unwieldy. This may be justifiable. However, clearer direction to MSs (member states) should be given on their need to develop an HIAP approach to NCDs (in which actions on SDH, intersectoralism, trade and investment, social protection, regulation of the marketing of foods and beverages, etc. are brought into policy and program development at the national and sub-national levels).

Appendix 1 lists a number of related risk factors to the four behavioural ones highlighted throughout the GAP; but the Appendix contains no mention of either health equity in terms of risk factor reduction, or of SDH. Para 18 elaborating the principles is strong, but there is no implementation guidance (apart from passing reference to HIAP) or reporting advice on these. Trade and industry, one of the key determinants of the globalization of NCDs, appears buried in a shopping list of every possible sector. Para 21 (policy options for member states) identifies numerous useful areas for advocacy (though no reference to trade or industry) but excludes any reference to SDH. Para 22 (actions for secretariat) similarly is silent on SDH and trade but does refer to management of conflicts of interest (code for reducing industry influence). Same comments apply to para 23 on private sector actions.

Importantly para 30(f) emphasizes strengthened multisectoral action on SDH of NCDs, some examples of which are in Appendix 5 (p.50). This needs more emphasis and accountability for how MSs are responding. Para 34 repeats the importance of multisectoral action including regulation, fiscal

measures etc. But there is no reference to trade/industry, or to trade and investment treaties, and how these might undermine regulatory efforts. This applies particularly to several of the recommended healthy diet options proposed for MSs (para 39). For example, the cases mentioned in footnotes 4, 5 and 6 (p.21) could be challenged under provisions in the leaked text of the proposed TPP Agreement. Some of the strategies for alcohol (para 43a) could similarly be challenged under new generation trade and investment treaties. Emphasis on the use of trade-related IPR flexibilities (para 50) is good, but could be strengthened by importing specific reference to the Doha Declaration, e.g.: that every country “has the right to grant compulsory licences, the freedom to determine the grounds upon which such licences are granted” and “the right to determine what constitutes a national emergency or other circumstances of extreme urgency.”

The monitoring framework (para 59) excludes reference to SDH or determinants of NCDs, a point already raised during the 2013 WHA by Thailand, Iran, and the UK.

Finally, Appendix 4 (p.48 of [A66/9](#)) references the role of the WTO to support trade ministries with respect to ‘address the interface between trade policies and public health issues in the area of NCDs’ – but is this happening, and what is the relevant relationship between WHO and WTO in this regard?

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\(1\)](#).

PHM notes that the sole indicator (Indicator 1) which might indicate how countries are addressing the social determinants of NCDs is quite weak: “Number of countries with at least one operational multisectoral national policy, strategy or action plan that integrates several noncommunicable diseases and shared risk factors in conformity with the global/regional noncommunicable disease action plans 2013–2020.”

## **Global Coordination Mechanism on the Prevention and Control of Noncommunicable Diseases**

The Global Coordination Mechanism was mandated in the [GAP for NCDs 2014-20](#) (see para 14 et seq).

The terms of reference for the GCM were adopted at WHA67 (May 2014) (para 8 of, and Appendix to Annex to [A67/14Add.1](#)).

The Workplan for the GCM was adopted in para 5 of [A67/14 Add.3Rev1](#) and the terms of reference for WGs for GCM (in the annex to [A67/14 Add.3Rev1](#)).

In para 15 of [A67/14Add.1](#) the Assembly requested the Secretariat to submit draft WP(2016-17) for GCM to WHA68. The draft work plan is included in [EB136/11 Add.1](#).

PHM appreciates the inclusion among the proposed functions of the GCM/NCD “Advancing multisectoral action: Advance multisectoral action by identifying and promoting sustained actions

across sectors that can contribute to and support the implementation of the WHO Global NCD Action Plan 2013–2020”. PHM urges that this be elaborated to include promoting policy coherence across sectors such as trade/investment and health and protecting policy space for NCD prevention/regulation.

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 be alert for instances where conflicts of interest may lead to improper influence in such policy processes.

## UN Inter Agency TF

The UN EcoSoc resolution ([E/RES/2013/12](#)) calls on the UN Secretary General to create a UN Inter-Agency Task Force on the Prevention and Control of NCDs, to be headed by WHO. This has potential to strengthen global policy coherence on NCDs and deal with SDH and trade/investment related issues.

The terms of reference for IATF (as set out in the DG’s report to the SG in [E/2010/55](#)) were adopted by EcoSoc in July 2014 in [E/RES/2014/10](#).

However the terms of reference contain nothing about action on the social determinants of health, the regulatory challenges of regulating TNCs in a liberalizing environment or on the role of trade and investment agreements in limiting action on NCDs.

The TOR speak of ‘harmonization of activities across the UN system’ but not of the need to reduce policy incoherence implicit in the mandates of several of the inter-governmental agencies. The WTO is mentioned twice in an accompanying table, but only as a source of information to MSs on its trade treaties with respect to NCDs (which is weaker than the reference to the WTO made in WHA66/9 GAP). There is no mention of the need to improve public health policy space for NCDs within bilateral and plurilateral trade treaty texts (WTO agreements have been eclipsed by bilateral and plurilateral ones, where the real trade-related problems are arising).

## PHM advocacy priorities

### Conflict of interest

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.

### Addressing the disparities in the burden of NCDs (and risk factors) and action on the social determination of health

Despite the extensive coverage by the [Commission on Social Determinants](#) the Global Action Plan is particularly weak in relation to the socioeconomic disparities in the burden of NCDs and NCD risk factors. The knowledge networks on employment, social exclusion and urbanisation traced in detail how social exclusion and economic inequality reproduce a disproportionate disease burden on the marginalised and excluded.

A plan of action which focuses principally on specific risk factors inevitably neglects the 'causes of the causes'. These inequities will not be addressed while WHO, including its member states, refuse to confront the ideology of neoliberalism which drives and seeks to justify widening economic inequality, social exclusion and the weakening of social solidarity.

PHM urges the IATF and the GCM to address explicitly the ideological forces which seek to normalise widening economic inequality, social exclusion and the weakening of social solidarity.

### 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.

### Trade and health policy coherence

PHM appreciates the inclusion among the proposed functions of the GCM/NCD "Advancing multisectoral action: Advance multisectoral action by identifying and promoting sustained actions across sectors that can contribute to and support the implementation of the WHO Global NCD Action Plan 2013–2020". PHM urges that this be elaborated to include promoting policy coherence across sectors such as trade/investment and health and protecting policy space for NCD prevention/regulation.

The proposed terms of reference for the IATF contain nothing about action on the social determinants of health, the regulatory challenges of regulating TNCs in a liberalizing environment or on the role of trade and investment agreements in limiting action on NCDs.

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.

The IATF should prepare guidance to MSs on trade and investment rules. This would include advice on trade agreements negotiation that could weaken public health regulatory policy space for NCDs and public health more broadly (such as the TPP and the TTIP) and also the type of language in such treaty articles that should be incorporated to protect that policy space.

The Work Plan 2016/2017 of the GCM/NCDs includes a dialogue in 2017 on how governments can promote policy coherence between different spheres of policy making but trade and investment are not mentioned as particular areas of concern. However, there is increasing evidence that innovative policy measures taken by governments to protect health and nutrition – for example in the area of food

labeling – are being frustrated (blocked, delayed, diluted) in trade disputes or in the WTO committee on technical barriers to trade.

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.

### 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 Type1 diseases (communicable disease, under nutrition, 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.



## 6.5 Global status report on violence and health

### In focus

The Secretariat report ([EB136/12](#), [EB136/12 Corr.1](#)) describes progress made in implementing resolution [WHA67.15](#) (see page 19), in line with a request contained in that resolution. The resolution WHA67.15 was entitled, *Strengthening the role of the health system in addressing violence, in particular against women and girls, and against children*.

It identifies nine areas where MSs can adopt policies towards this objective, mostly cast in quite general terms.

The resolution requests the DG to:

- to continue to strengthen WHO's efforts to develop the scientific evidence on violence and violence prevention and on best practices in order to develop effective national health systems prevention and response;
- to continue to support Member States by providing technical assistance for strengthening the role of the health system in relation to violence;
- to report on both the finalization of the global status report on violence and health and
- to develop a draft global plan of action 'to strengthen the role of the health system within a national multisectoral response to address interpersonal violence in particular against women and girls and against children'.

[EB136/12](#) (as corrected) :

- *provides detail regarding the Secretariat's continuing work to develop the scientific evidence and to provide technical assistance;*
- *introduces the [Global status report on violence prevention](#) which "represents the progress countries have made in implementing the recommendations of the 2002 World report on violence and health" as endorsed in [A56.24](#) in 2003; and*
- *sets out the proposed timelines for the development of the draft global plan of action.*

### Background

The first [World report on violence and health](#) was published in 2002 and its recommendations were endorsed in [A56.24](#).

The 2014 [Global status report on violence prevention](#) provides useful descriptive statistics and summarises self-reports from countries regarding government plans, policies and programs.

At the national level, the report's key recommendations are:

- to improve data collection in order to reveal the true extent of the problem
- to draw up comprehensive and data-driven national action plans
- to integrate primary and secondary violence prevention into other health platforms
- to strengthen mechanisms for leadership and coordination

- to ensure prevention programmes are comprehensive, integrated and based on evidence
- to ensure that services for victims are comprehensive and informed by evidence
- to strengthen support for outcome evaluation studies
- to enforce existing laws and review their quality
- to implement and enact policies and laws relevant to multiple types of violence
- to build capacity for violence prevention.

At the regional and global levels, the report's key recommendations are:

- to strengthen the global violence prevention agenda
- to increase support for comprehensive and integrated violence prevention programming
- to strengthen efforts of regional and subregional organizations to work with national offices to coordinate data collection and disseminate data gathered
- to increase collaboration between international organizations and donor agencies
- to set baselines and targets, and track progress.

See also the WHO [webpages on Violence and Injury Prevention](#).

The global challenge of violence, in particular against women and girls was discussed as WHA67 Item 14.3 and resolution [WHA67.15](#) (from page 19) was adopted (see PHM's comment and report on the [debate at WHA67](#)).

## PHM Comment

Violence is a huge problem both in terms of mortality burden and the damage consequent on non fatal violence.

It is a very heterogeneous problem which comprises a variety of different challenges, for example:

- intimate partner violence and the norms of gender relations,
- gun control,
- the role of alcohol in releasing and amplifying anger and desperation, and
- cultural milieu and norms which predispose to aggressive and violent responses to uncertainty and difference.

## The Global Status Report

The Global Status Report is focused largely on the proximal causes of violence and its consequences. Responses are conceived largely in terms of government policies and programs. The discussion of the wider political economy and geography of violence is very inadequate.

The incidence of homicide varies from 2.1/100,000 in the Western Pacific to 28.5 in Latin America (Table 1, p8). Deaths from violence in high income countries have reduced in the high income countries over the last decade but not in the low and middle income countries (Fig 4, p12).

These variations reflect the complex interplay of income, living conditions, access to education, and access to safe, rewarding and fulfilling work as well as cultural norms, guns and alcohol. These are issues of social and economic development and the global conditions which enable or prevent such development which are virtually ignored in this report.

The report completely neglects the potential role of primary health care agencies and practitioners in engaging with communities at the local level to challenge accepted norms and to work together for the social conditions which provide security against violence.

## **Draft global plan of action**

Para 20 of EB136/12 sets out the following timelines:

- early 2015: regional and global consultations based on a draft plan
- later 2015: consideration by regional committees of a revised draft
- January 2016: consideration of a final draft by EB138
- May 2016: adoption by WHA69.

## 6.6 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 EB136

*At the request of a Member State, the Secretariat is providing information ([EB136/13](#)) on the global burden of epilepsy and the need to raise the priority accorded to coordinated action at country levels in order to mitigate its health and socioeconomic consequences. The Board is invited to note the report and provide further guidance.*

### Background

See WHO's [Fact Sheet 999 \(Oct 2012\)](#)

See [WHO Programme on Reducing the Epilepsy Treatment Gap](#)

See [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.

The crooks who determine global health policy have, for almost 40 years, struggled to prevent the realisation of the vision of Alma-Ata: 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.

## **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.

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

### In focus

*In response to requests made in resolutions [WHA58.31](#), [WHA63.15](#), [WHA63.17](#), [WHA63.24](#), [WHA64.13](#) and [WHA65.7](#), this report ([EB136/14](#)) summarizes progress towards achievement of the health-related Millennium Development Goals and specific targets. In line with the relevant additional requests in those resolutions, it also describes 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.*

### Background

#### MDGs

See [EB134/17](#) which appears to have covered similar grounds in Jan 2014.

#### Post 2015

While there is no reference to the Post 2015 processes in [EB136/14](#) these have previously been linked with items dealing with the MDGs and may be discussed.

There are two broad streams of discussion, now largely taking place within the aegis of the UN, first, regarding the post Rio+20 sustainable development goals (SDGs) and, second, the post-MDGs development agenda.

Landmarks in the consideration of the post-MDGs development agenda include:

- the [High Level Plenary Meeting of the UNGA on the MDGs](#) (NY, 20-22 September 2010)
- the *Special Event* on progress towards the MDGs (NY, 25 September 2013, [outcome document](#))
- the [report of the High-level Panel of Eminent Persons on the Post-2015 Development Agenda](#) (2013) which drew upon:
  - [Realising the Future We want](#) (report of the UN Task Team, 2012) prepared as an input to HLP EPs
    - [Thematic paper on health](#) (May 2012), prepared by UNAIDS, UNICEF, UNFPA, WHO as input to UN Task Team
  - the 'Global Conversation' (national and thematic) sponsored by the UN Development Group (UNDG), which was also structured as an input to HLP EPs. See final Integrated Report: [A million voices: the world we want](#) (2013) which was informed by
    - the [Health Thematic Consultation](#), see the [Health Thematic Consultation Report](#) (April 2013)

Running in parallel to this 'post MDGs' process has been the 'sustainable development' process. The landmarks in this sequence include:

- the [UN Conference on Sustainable Development, Rio+20](#) (Rio, 20-22 June, 2012)
  - UNGA resolution 66/288 '[The future we want](#)' (July 2012, endorsing Rio+20 outcomes)
  - High Level Political Forum on Sustainable Development here ([1st meeting](#), 24 Sept, 2013; [2nd meeting](#): 30 June -9 July, 2014) following up Rio+20
  - [Open Working Group \(OWG\) on SDGs](#) (undertaking detailed follow up work in the SDG sequence, from March 2013 onwards)
- the Sustainable Development Solutions Network which led to the [UN Secretary General's Action Agenda for Sustainable Development](#) (June 2013, updated May 2014).

The UNGA in September 2014, will consider

- the final report/s of the OWG on SDGs,
- a further review of progress towards MDGs
- the HLPEPs report on the post-MDG agenda
- the Review of the Political Declaration of 2011 on NCDs

The UN Secretary General will then integrate these different streams of work into a single framework of goals and targets, integrating both the SDGs and the post-MDGs process, which will be the first step in a final program of work during 2015 which will culminate in a summit of Heads of State/Government at the UNGA in September 2015 at which the post-2015 UN Development Agenda will be adopted.

The WHA67 considered document [A67/20](#) which described the process of intergovernmental negotiations towards a post-2015 development agenda and urged WHA delegates to advocate for 'health' at the national level to ensure that 'health' is well placed in the UN deliberations. See debate at WHA67 on Health in the post-2015 development agenda [here](#). See also Resolution [WHA67.14](#).

Update (2 July) from UN DESA [here](#).

## PHM Comment

### MDGs

The picture revealed in this report 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.

## Post 2015 processes

See [Legge \(2014\) Health in the post-2015 development agenda](#) for a PHM perspective on the MDGs and the maneuvering around the post-2015 development agenda.

There is space for considerable scepticism regarding the suffocating policy rhetoric within which the post 2015 development agenda is being discussed.



## 7.2A Health and the environment: Addressing the health impact of air pollution

### In focus at EB136

*A report on addressing the health impact of air pollution ([EB135/4](#)) was considered by the Executive Board at its 135th session. In light of comments made during the discussions, the Board decided to include the issue of the health impact of air pollution on the provisional agenda of its 136th session. Among other things, the [revised] report ([EB136/15](#)) outlines a number of strategies for the prevention, control and mitigation of the adverse effects of air pollution on health.*

A draft resolution for consideration by the Assembly in May 2015 may be presented. Such a draft resolution would likely suggest a global strategy and plan of action on air pollution.

### 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](#)):

- summarises the effects of air pollution on human health;
- reviews 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;
- reviews ways in which ministries for health can contribute
  - epidemiological study and research
  - policy development and communication
  - intersectoral (and across level) engagement
- lists 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

## 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. We need 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.

## 7.2B Climate and health: outcome of the WHO Conference on Health and Climate

### In focus

The WHO Conference on Health and Climate (Geneva, 27–29 August 2014) marked a major step in responding to the requests made to the Director-General by the Health Assembly in resolution [WHA61.19](#). The present report ([EB136/16](#)) summarizes the proceedings and conclusions of the Conference and presents a revised workplan for WHO in relation to climate change and health.

There may be an accompanying resolution as well.

### Background

The WHO organized global conference on health and climate was held at WHO headquarters in Geneva from 27 to 29 August 2014. See [background to conference](#). See IISD [report](#) of conference. More from WHO on [climate change and health](#).

See also IPCC [Fifth Assessment Report](#) and [WGII Report](#) and [WHO summary](#).

See also the [Civil Society Call to Action](#) issued at the WHO Conference.

[EB136/16](#) describes the context of the conference and provides a brief summary of the evidence presented and conclusions (and a link to the full [report](#) of the conference).

[EB136/16](#) refers to previous resolutions [EB124.R5](#) and [WHA61.19](#) and presents a revised version of the WHO Work Plan on Climate Change and Health. The revised work plan has four main objectives and a number of actions under each objective. The objectives are:

1. Strengthen partnerships to support health and climate within and outside the United Nations system
2. Awareness raising
3. Promote and guide the generation of scientific evidence
4. Provide policy and technical support to the implementation of the public health response to climate change

### PHM Comment

The revised work plan provides a useful framework to guide the Secretariat and member states in addressing global warming. However, there are several areas we would like to see strengthened.

#### Member state accountability

Action 3.4 foreshadows country-specific profiles regarding climate related hazards, impacts and potential interventions. We propose that this also include a critical assessment of the policies currently being implemented. Governments (and ministries of health) should be held accountable for their

commitment to reducing greenhouse gas pollution and mitigating the effects of global warming. We note Action 4.6 which speaks of a voluntary system for MS reporting. We propose that a peer review system be developed so that a panel of MS (from different regions) can assess and comment on these country reports.

### **Action on awareness raising**

PHM strongly supports Actions 2.1 and 2.2 aimed at increasing public and political awareness of the serious consequences of climate change for human health. PHM believes that greater awareness of the health consequences could be a strong additional motivator towards action to combat climate change.

### **Action on global warming as part of the primary health care challenge**

Action 2.2 commits the Secretariat to disseminating information 'to the wider community of health professionals'. Vulnerabilities arise from various levels, and there is particular need for support to local level adaptation needs and plans. Climate change provides a canvas for addressing various facets of poverty and thereby strengthening resilience. We would like to see a stronger and more explicit reference to WHO promoting the role of primary health care practitioners in working with their communities to understand, assess and respond to the threat of climate change (as described in Para VII of the Alma-Ata Declaration).

Action 4.4 commits the Secretariat to encouraging health care facilities to adopt institutional policies and practices in the areas of energy, water, sanitation, waste which will reduce and mitigate. We urge that health care facilities should also be encouraged to publicise across their communities why they are adopting such policies and to exercise a leadership role in relation to understanding and action on climate change.

### **Action on greenhouse gas emissions**

PHM notes the reference in paragraph 7 to the evidence presented concerning the principal role played by the burning of fossil fuels in changing global climate systems. PHM is also aware of the evidence that the international and national policy changes required to reduce and then eliminate fossil fuel consumption must be made in the next 5-10 years if we are to avoid catastrophic global warming by 2100. PHM urges WHO to take a strong leadership role in pressing international organisations and national governments to set targets and implement policies over the next 5 years to achieve a rapid and dramatic reduction in fossil fuel use, leading to elimination by mid-century.

### **Action on short lived climate pollutants**

PHM congratulates WHO on linking air pollution with action on global warming. PHM urges continuing attention to ozone, methane and HFCs as well as soot. Effective action on these short lived pollutants can yield much needed space for systemic action on carbon pollution.

## Conflicts and displacements

Elsewhere on the agenda at this EB are a number of items concerning WHO's role in relation to disasters, outbreaks and humanitarian emergencies. PHM urges WHO to give due weight to the likelihood of conflicts and displacement associated with climate change impacts in its efforts towards disaster prevention, preparedness and response.

## Meat and climate change

PHM urges WHO to focus more attention on the links between a high meat diet, global warming and climate change adaptation.

Methane production by cattle is part of this story. However, significant resources (land and energy) go into the production of food stocks for industrial farming of cattle, pigs, chicken and fish and the opportunity costs of *not* producing plant based food products for human consumption is huge.

It is time for WHO's dietary guidelines to take global warming seriously and incorporate limits on meat intake for reasons of climate stability as well as NCDs.

## Funding

PHM endorses the commitment in the new plan for a focus on country specific vulnerabilities, projected impacts, priorities and actions; eg food security, extreme weather risks. Providing this sort of advice has cost implications but, as noted in paragraph 33 of EB136/16, WHO's capacity to contribute to global action on global warming is sharply constrained by the continuing 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.

PHM calls upon MSs to lift the freeze on ACs and to cease the practice of ear-marking donations to the WHO budget.

## 7.3 Adolescent health

### In focus

A comprehensive plan on adolescent health, based on current evidence and existing global commitments and action plans, and with measurable outcomes, may be needed in order to support countries to implement interventions and strategies for adolescents' health, taking into consideration their national contexts. In the report ([EB136/17](#)), therefore, the Secretariat is proposing elements of a plan together with a process for consultation with countries and stakeholders. The Executive Board is invited to provide guidance thereon.

It is likely that the Board will also see a draft resolution proposing the development of a framework for action as foreshadowed in [EB136/17](#).

### 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 [EB136/17](#) 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 notes the crucial 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. (We note that there is an extended discussion of interventions in the 'Health for the world's adolescents' report ([see Fig 4, page 9](#)), some of which may be challenged on cultural/religious grounds during the EB debate.)

### PHM Comment

[Health for the world's adolescents](#) refers to the distal or macro determinants of adolescent health but [EB136/17](#) appears to focus largely on more immediate or proximal 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 11 of EB136/17 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.



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

### In focus at EB136

*The report ([EB136/18](#)) 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.*

### 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.

## 8.1 Antimicrobial resistance

### In focus

In response to resolution [WHA67.25](#), the Secretariat presents ([EB136/20](#)) a draft global action plan to combat antimicrobial resistance, to be submitted to the Sixty-eighth World Health Assembly through the Executive Board. In a separate report ([EB136/19](#)), details are provided of progress made in implementing the other aspects of resolution [WHA67.25](#).

There may be an accompanying draft resolution.

### 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 afterwards 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](#).

The Secretariat report to WHA67 ([A67/39](#)) dealt with the current response to antimicrobial resistance, the call for a global action and the next steps to be undertaken. [A67/39](#) was well received in the WHA67 debate ([here](#)) and after some minor amendments Resolution [WHA67.25](#) was adopted. See PHM [report](#) of discussion of Item 16.5 at WHA67.

### Draft global action plan

[WHA67.25](#) requests the DG to develop a draft global action plan to combat antimicrobial resistance. This is provided in [EB136/20](#).

### 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. [EB136/19](#) 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. [EB136/19](#) 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. [EB136/19](#) 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; [EB136/19](#) reports that progress is being made.

### Some member state comments from WPRC

France argued for greater collaboration between the agricultural, environmental and health sectors.

China urged the secretariat to provide a standard definition and discussion on "what is rational use?"

Viet Nam asked the Secretariat to provide technical guidance on relations between human and animal drugs.

The Secretariat reiterated the importance of multi-sectoral cooperation and participation and importance of R&D. The Secretariat acknowledged that they have not fully addressed the issue of animal health and AMR due to its complexity.

## PHM Comment on draft global action plan

### 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 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.”

Under **Objective 4** the actions scheduled for ‘others’ 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.

## Collecting data about antimicrobial usage

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”.

We urge the explicit inclusion of the need to include the indications for which antimicrobials are being used as core elements of the data collections.

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.”

## 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; why consult with Pharma?

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.”

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.”

## 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)).

## 8.2 Poliomyelitis

### In focus

In May 2014 the Director-General declared the spread of wild poliovirus a “public health emergency of international concern” and issued temporary recommendations to deal with the growing risk of further spread. These recommendations (summarised in [WHO Statement](#)) were extended in August and then again in November 2014.

The report ([EB136/21](#)):

- describes the impact of emergency measures to interrupt circulation of both endemic and imported wild polioviruses, together with the new measures to stop international spread;
- proposes a firm timeline for the withdrawal of type-2 oral polio vaccine globally in April 2016, which requires urgent action by Member States to ensure the interruption of any persistent circulating vaccine-derived type-2 poliovirus and full implementation of readiness criteria such as the introduction of inactivated polio vaccine;
- 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
- suggests a decision for the Board to consider.

### Background

The report, [A67/38](#) ('Poliomyelitis: intensification of the global eradication initiative') summarizes 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.

Six weeks after [A67/38](#) was circulated, the DG declared a Public Health Emergency of International Concern on 5 May. See WHO “WHO statement on the meeting of the International Health Regulations Emergency Committee concerning the international spread of wild poliovirus” [here](#). The Emergency Committee which recommended the declaration identified specific initiatives and policy measures that active polio states are expected to implement. See [WHO Statement](#).

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).

The focus of discussion at EB136 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.

## 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' (Pakistan, Cameroon, Syria) 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.

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

### In focus

In line with the reporting mechanism established under resolution WHA61.2, [EB136/22](#) provides a report on the operations of the IHRs in 2014. The report reviews

- reviews the event and emergencies that were reported, assessed and declared;
- reviews the experience of WHO, focusing on the IHRs, in relation to EVD, MERS-CoV, polio, avian influenza A(H5N1) and A(H7N9);
- summarises progress in implementation of the IHRs and in particular, the installation of national capacity requirements;
- reports that extension requests for 2014-16 were granted in accordance with the advice of the Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR (2005) Implementation (this leaves 48 states parties who have not communicated their status nor sought extension);
- provides, in the Annex, a country by country summary of capacity scores for 2014.

The second document [EB136/22 Add.1](#):

- conveys the report of the IHR Review Committee on Second Extensions and associated papers;
- a draft resolution for the consideration of the EB for forwarding to the Assembly directed to driving the recommendations of the Review Committee.

The Review Committee report

- provides an overview of progress and challenges in the implementation and operation of the IHRs;
- reviews the requests for second extensions;
- discusses ways of accelerating IHR implementation;
- explores strategies for shorter and longer term development of IHR capacities and emphasises the need to move beyond checklists regarding implementation to a continuous improvement model;
- highlights the resource requirements associated with IHR capacity development;
- conveys the draft resolution referred to above.

The Review Committee report includes a number of conclusions and recommendations which will be discussed under this item.

### Background

The IHR, 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).

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 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.

The second document [EB136/22 Add.1](#) conveys the report of the IHR Review Committee on Second Extensions, including conclusions and recommendations and associated papers.

## 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 public 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.



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

### In focus

*At the Sixty-sixth World Health Assembly, Member States expressed support for the proposal that the Secretariat draft a global technical strategy for malaria for the post-2015 period. The Board is invited to consider the draft WHO global technical strategy for malaria 2016–2030 ([EB136/23](#)), and to recommend its submission to the Sixty-eighth World Health Assembly.*

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.

The Board will also have before it, for information, the most recent draft of the new 'Second Generation Global Malaria Action Plan' (GMAP2) under development by the Roll Back Malaria Partnership Board.

### 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) is coordinating the development of a Global Technical Strategy for Malaria (GTS) for the 2016-2025 period. The GTS will articulate the goal and global targets for malaria over the next decade. It will be 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. (From [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.](#)

## 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 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; this may be relevant to the current ebola outbreak in Central and West Africa.

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.](#)

## 9.2 Dengue: prevention and control

### Contents

- [In focus](#)
- [Background](#)
- [PHM Comment](#)
- [Notes of discussion at EB136](#)

### In focus

The EB will consider [EB136/24](#) which 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 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.

It is not clear where the focus of attention in the EB discussion will be; potentially:

- vaccine development,
- resource mobilisation,
- implications of global warming,
- implementation of recommended control strategies,
- surveillance and reporting,
- use of IHRs to encourage full implementation of recommended control strategies (see references below).

There may be a resolution under development.

### 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', interpreted 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.

While it is unlikely that dengue would be identified as a 'public health emergency of international concern' 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.

## 9.3 Global vaccine action plan

### In focus at EB136

In line with resolution [WHA65.17](#), a summary report is provided ([EB136/25](#)) on 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 including the recommendations of the Strategic Advisory Group of Experts on immunization, which met in October 2014.

The Executive Board is invited to take note of the report and to consider the recommendations for actions to be taken by the various stakeholders of the [global vaccine action plan \(GVAP\)](#), in particular by Member States.

It is likely that this item will take some time and may generate some debate. The issues are complex and important and represent a significant challenge for WHO.

### Background

[EB136/25](#) is a summary report of the [2014 Assessment Report by the Strategic Advisory Group of Experts \(SAGE\) on immunization](#) which itself is based on the [GAVI Secretariat 2014 Draft Report](#). [EB136/25](#) 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 [EB136/25](#) and but are elaborated more fully in the [SAGE report](#).

### 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 EB 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.

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. 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.

## **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.

## 9.4 2014 Ebola virus disease outbreak

### In focus at EB136

*The Secretariat's report ([EB136/26](#)) notes the challenges posed by the outbreak of Ebola virus disease in West Africa and describes the global response. The current epidemiological situation is reviewed, along with the response by WHO, the United Nations system as a whole and other international partners. Updates are given on: research and development in the areas of therapeutics, vaccines and clinical trials; logistics and operational issues; resource mobilization; and preparedness, including capacities required by the International Health Regulations (2005).*

*A further report ([EB136/49](#)) was added late to the papers for the EBSS and the EB. This paper includes five proposals for ensuring WHO's capacity to prepare for and respond to future large-scale and sustained outbreaks and emergencies.*

### PHM Comment

See PHM commentary on the Ebola issues at the [EBSS3](#), under

- Item 1. Current context and challenges (PHM comment [here](#)); and
- Item 2. Ensuring WHO's capacity (PHM comment [here](#)).

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

### In focus

*The Executive Board at its 135th session agreed to include strengthening emergency and essential surgical care and anaesthesia as a component of universal health coverage on the provisional agenda of its 136th session and that a new version of the report that it had noted would be prepared. 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. On that basis, the Board is invited to consider (in [EB136/27](#)) specific country-level and Secretariat actions for supporting improved service delivery in this area.*

EB136 will be asked to consider a draft resolution on surgery for recommending onwards to the WHA68 (sponsored by the US, Australia and Zambia amongst other countries). The focus of the resolution will be on strengthening surgical programs in low resource settings, including the mobilisation of financial and technical support. A road map for such developments will be needed including country-specific health services research and planning.

This topic may have been considered at the regional committees in the lead up to EB136.

### Background

[EB136/27](#) is a revised version of [EB135/3](#) (considered by EB135 in May 2014). The paper 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 “surgical services at district and subdistrict levels of care are assessed and monitored”.

There was an extended discussion on this issue at EB135 ([here](#)) where there was widespread support for progressing this issue. The case for strengthening essential and emergency surgical and anaesthetic services was not contentious.

The US spoke of rational and cost-effective service provision and spoke of task shifting. Cuba, South Africa, Maldives emphasised the need to consider different levels of service delivery and the referral and support relationships between levels. Namibia emphasised the need to locate service

development within a comprehensive PHC framework. This was supported by Korea and Argentina. The UK supported by Australia emphasised rational use of antibiotics in surgical practice. DRC emphasised the need for a stocktake before adopting general strategies and plans. Nepal endorsed the inclusion of anaesthetic services but pointed out that human resources were a big constraint.

It seems that a resolution (apparently led by the US) is being developed for WHA68 which will call for a strategy and plan of action. This resolution will provide the focus of discussion at EB136.

## 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 ([EB136/27](#)) are important. The following issues are of particular importance to PHM:

- models of service organisation and service delivery,
- surgical and anaesthetic task distribution within the health workforce,
- 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.

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.

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.



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

### In focus

*In resolution [WHA63.16](#), the Health Assembly decided that the first review of the relevance and effectiveness of the Code should be made by the Sixty-eighth World Health Assembly. The Executive Board is invited to consider (in [EB136/28](#)) the process that has been established to facilitate the first review, and the progress made to date.*

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

[EB136/28](#) outlines the proposed membership and terms of reference of a proposed Expert Advisory Group to undertake the review between February and May 2015. EB136/28 also provides an overview of the appointment of national designated authorities and of the first round national reports through the National Reporting Instrument ([NRI](#)); the deadline for submitting reports was 31 May 2012. The paper also reports on an HRH data collection initiative being jointly developed and implemented through WHO and the OECD.

### 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 *Healthworkers 4all*.
- [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 appears to have 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.

## 10.3 Substandard/spurious/falsely labelled/falsified/counterfeit medical products

### In focus at EB136

*This item is a report ([EB136/29](#)) 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.*

It is not clear whether the substantive issues concerning SSFFC will be discussed at the EB. The one issue which the EB will need to consider is the request of the Member State Mechanism (MSM) that the World Health Assembly postpone the review of the Mechanism by one year to 2017.

There may be discussion of the budgetary implications of the MSM's work plan, including its request to defer the scheduled review. The report notes that the MSM 'expressed concern over the unfunded activities in the budget'.

### 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.



## 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/false-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.

## 10.4 Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination

### In focus at EB136

There are two main issues under consideration under this agenda item:

#### Proposed pooled funding mechanism and involvement of TDR

EB136 will consider report [EB136/30](#) on the possibility of 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. This 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 Board 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 Board will consider a second report (EB136/30 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.

The report detailed an assessment of 15 existing mechanisms (such as the Global Fund, DNDI, GAVI, RMB, etc.) based on a number of criteria. It argued that if any existing mechanism were to be selected to host a new funding mechanism, some adaptation would be required.

In the meantime TDR had prepared a proposal for WHA consideration ([9 May 2014](#)) indicating the conditions under which it might take on this role.



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.

See [KEI report 22 Dec 2014](#)

Decision [A67\(15\)](#) *inter alia*

*(4) noted, without prejudice to future discussions in the context of recommendations of the Consultative Expert Working Group on Research and Development Financing and Coordination and actions on other sustainable mechanisms for financing health research and development, the assessment made by the Secretariat and the possibility of using an existing mechanism to host a pooled fund for voluntary contributions towards research and development for type III and II diseases and the specific research and development needs of developing countries in relation to type I diseases;*

*(5) requested the Director-General to further explore this option with the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases recognizing the following:*

*– that the scope of the diseases should not be limited to type III diseases but should be in line with the mandate of the global strategy and plan of action on public health, innovation and intellectual property;*

*– the need for a sustainable financial mechanism for health research and development;*

*– the role of Member States in the governance of the coordination mechanism;*

*(6) requested the Director-General to report to the Sixty-eighth World Health Assembly through the 136th session of the Executive Board with reference to this decision.*

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 the Assembly 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 stated the following outcome from the JCB,

*The World Health Organization’s financing and coordination mechanism from the Consultative Expert Working Group on Research and Development (CEWG) was also discussed. TDR has been identified as the best option for managing this by utilizing its technical expertise and extensive R&D networks. Four demonstration projects have already been identified through the WHO-led process. Overall governance of such a scheme would be through the Joint Coordinating Board of TDR. See earlier news on this here. The board strongly supported the concept and the continuation of discussions with WHO through its established sub-committee.*

See KEI update of 18 Aug 2014 on [thiru'sblog](#).

## Implementation of demonstration projects

Decision [WHA66\(12\)](#) requested the DG to convene a technical meeting to assist in the identification of demonstration projects. This meeting was held in Dec 3-5, 2013.

A further meeting to examine additional information received was held on 10 March 2014. The former Chair and Vice-Chair of the CEWG, facilitated by the Secretariat and observed by Member States, assessed the 7+1 identified projects based on the 6 additional questions posed to proponents. The purpose of this assessment was to determine which of the 8 proposals were ready enough to move forward with stakeholder meetings before the World Health Assembly and which required more work.

Based on this assessment, it was determined that the Secretariat will move forward with convening stakeholder meetings for the following four proposals:

- The Visceral Leishmaniasis (VL) Global R&D & Access Initiative - Drugs for Neglected Diseases initiative (DNDi), submitted via AFRO and EMRO.
- Exploiting the Pathogen Box: an international open source collaboration to accelerate drug development in addressing diseases of poverty - Medicines for Malaria Venture (MMV), submitted via EURO.
- Development of Class D Cpg Odn (D35) as an Adjunct to Chemotherapy for Cutaneous Leishmaniasis and Post Kala-Azar Dermal Leishmaniasis (Pkdl) - United States Food and Drug Administration (US FDA), et al., submitted via AMRO.
- Development for Easy to Use and Affordable Biomarkers as Diagnostics for Types II and III Diseases - African Network for Drugs and Diagnostics Innovation (ANDI), et al., submitted via AFRO.

Noting the significant public health impact and scientific and technical merit of the remaining 4 projects, it was agreed that although these projects are not ready enough to move forward to the implementation stage, the Secretariat will assist the proponents of these proposals in improving the innovative aspects of their projects (if they so desire):

- Multiplexed Point-of-Care test for acute febrile illness - Translational Health Science and Technology Institute (THSTI), India, et al., submitted via SEARO.
- Demonstration of the potential of a single dose malaria cure of artemether-lumefantrine through reformulation in a nano-based drug delivery system - Council for Industrial and Scientific Research, South Africa, et al., submitted via AFRO.
- Development of a Vaccine Against Schistosomiasis Based on the Recombinant Sm14 A Member of the Fatty Acid Binding Protein: Controlling Transmission of a Disease of Poverty - Oswaldo Cruz Foundation (Fiocruz), et al., submitted via AMRO.
- (Dengue vaccine development - Health Systems Research Institute (HSRI), Thailand, et al., submitted via SEARO, now withdrawn.)

Resolution [A66.22](#) (from May 2013) had requested the DG to report on the implementation of the health research and development demonstration projects to the Sixty-eighth World Health Assembly, through the Executive Board at its 136th session.

Document [A67/28](#), considered by the Assembly in May 2014, reported on progress to that date and was supplemented by [A67/28 Add.1](#) which reported on a meeting of the proponents of the first four demonstration projects which was hosted by WHO in early May 2014.

Document [A67/28](#) also explored indicators to measure the success of demonstration projects and an approach to evaluation.

In Decision [WHA67\(15\)](#) the Assembly:

(2) recognized the indicators to measure success in implementing the health research and development demonstration projects, and requested the addition of an analysis of the extent of innovative components being implemented by the projects, including financing, the use of open access models, multisectoral research platforms, and delinkage, among other criteria;

(3) requested the Director-General to expedite the process of the remaining four projects, in addition to the four already agreed, and to report on progress to the 136th session of the Executive Board;

The report on the intermediate evaluation of the demonstration projects is contained in document EB136/30 Add.1.

## Observatory

In resolution [WHA66.22](#) the Assembly requested the Director-General, *inter alia* to:

*(1) establish a global health research and development observatory to monitor and analyse relevant information on health research and development;*

*(2) review existing mechanisms in order to assess their suitability to perform the coordination function of health research and development; and*

*(3) explore and evaluate existing mechanisms for financial contributions to health research and development and, if there is no suitable mechanism, to develop a proposal for effective mechanisms, and a plan to monitor their effectiveness independently.*

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/).

## Open source pharma

A subsequent meeting at Bellagio in early August 2014 explored some of the pathways towards delinking research and innovation from IPRs and proposed ten operating principles. See [Open Source](#)

[Pharma](#) (5 Aug 2014) and [www.opensourcepharma.net](http://www.opensourcepharma.net). The outcomes of this meeting may find their way to EB136.

## 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\(12\)](#).

## PHM Comment

### Overview of [EB136/30](#)

In [EB136/30](#), the Secretariat makes the case that the ‘demonstration projects, together with their budget line established by TDR, as well as the Global Observatory, could provide the nucleus for the development of the pooled funding mechanism’.

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.

### Proceed as foreshadowed

There are weaknesses in the current proposals but they do represent a step towards public funding of R&D and delinking. Let not the perfect be an enemy of the good. Proceed!

## Issues for continuing attention and periodic review

### Funds mobilisation

PHM has previously argued that voluntary funding of the system will be unsustainable and unreliable and that we need to return to a treaty with mandatory contributions.

### Demo projects

PHM has previously expressed concerns regarding the process of selection of the eight and then the four demonstration projects. PHM also agrees with HAI and KEI who, in the [KEI statement](#) to the 2014 Assembly, argued for return to the original purpose of the demonstration projects, namely to create and demonstrate innovative funding mechanisms.

Presently awaiting 136/30 Add. 1 regarding the evaluation of the demo projects.

### Scope of R&D to be supported

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.

## 10.5 Global strategy and plan of action on public health, innovation and intellectual property

### In focus at EB136

*In response to a request by the Executive Board at its 133rd session, the Secretariat has prepared the present report ([EB136/31](#)) that provides a proposed timeline for the evaluation of the GSPOA.*

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 from Jan 2016 to at least May 2018**

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.

## 10.6 Blood and other medical products of human origin

### In focus at EB136

*In response to proposals from Member States to call for a Health Assembly resolution on self-sufficiency in blood and blood products based on voluntary non-remunerated donations, and the call at the Sixty-seventh World Health Assembly for the WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation to be applied to medical products of human origin, the Secretariat has produced this report ([EB136/32](#)) which covers both blood and other medical products of human origin.*

### Background

WHA63 (May 2010) had before it Secretariat reports on Availability, safety and quality of blood products ([A63/20](#)) and Human organ and tissue transplantation ([A63/24](#)). Two corresponding resolutions were adopted: [WHA63.12 \(page 19\)](#) on blood products and [WHA63.22 \(page45\)](#). Both of these resolutions commissioned progress reports, at least every four years.

Progress reports were submitted to WHA67 in May 2014 in [A67/40](#) and in the Assembly debate ([A67/A/PSR/12, page 48](#)) both Spain and Argentina spoke commenting on the broad area of medical products of human origin emphasising the non-commercial nature of the supply systems. Spain welcomed the Secretariat's special initiative on medical products of human origin and asked that it continue to be developed.

[EB136/32](#) has been prepared by the Secretariat in response to this request. EB136/32 sets out the main policy issues and sketches the directions for further development. The EB is requested to advise on further action.

There are two broad policy objectives involved:

- access according to need to blood and tissue products and services; and
- reducing the need for (and inappropriate use of) blood and tissue products.

Access according to need to medical products of human origin involve:

- funded and functional public health systems; health system strengthening,
- technologies for processing (capacity building, technology transfer, institutional development),
- institutional systems for collection, processing, distribution and regulation:
  - health services capacity building: prompt and efficient harvesting, sensitive conversations,
  - capacity building, development cooperation,
- community understanding (importance of donation, willingness to donate without remuneration, advance permission),
- quality and safety of blood and tissue products:
  - national regulatory authorities and institutional systems,
  - international policy frameworks (self sufficiency, guiding principles, regulatory norms, limits on price gouging),

- international biological standards and reference materials,
- monitoring, surveillance, responding (national and international; eg policing organ trade, responding to new risks),
- quality and safety regarding the use of blood and tissue products:
  - clinical standards and guidelines,
  - institutional systems for monitoring usage including adverse event monitoring, and
- investing, evaluating, adapting, regulating new technologies.

Reducing the need for medical products of human origin involves:

- injury and NCDs prevention,
- containing overuse and inappropriate use, and
- development and use of alternative products.

## PHM Comment

The report before the EB ([EB136/32](#)) argues for voluntary, non-remunerated, non-coerced donation of blood and tissues/organs on the basis of the principle of 'human dignity'. In fact the ethical analysis underlying this argument is not well presented. For example, it is not clear why donation of human tissues should be non-coerced in comparison to seat belt laws or drink driving laws.

The Report is confused and confusing regarding incentives for donation. On the one hand it insists (for instance in paras 2, 5 and 7) on 'donation' (free of remuneration, incentive and inducement but potentially including reimbursement for genuine loss of income and out of pocket expenses) but then also discusses 'undue inducement' and 'disproportionate incentives' (para 3), both of which are open to interpretation and exploitation. In paras 3 and 4 there is explicit acceptance of the use of incentives: 'The use of incentives to improve the rate of donation should be avoided when this becomes an undue inducement or coercion' and '... donation incentives should not adversely affect the availability and safety of the final products'. Any material incentive or inducement (other than genuine reimbursement) that causes someone to do something that they would not otherwise do negates the idea of donation. Further work is needed to develop a more useful and ethical position on the use of medical products of human origin, including for research as well as clinical use.

In para 10 the Report notes the need to ensure evidence based use of medical products of human origin and to avoid inappropriate or overuse. The emerging evidence of widespread inappropriate blood transfusion with considerable morbidity and mortality is of deep concern. (See for instance the worrying video about blood transfusions at: <https://www.youtube.com/watch?v=gV4Nmjg29p0> and Goodnough & Murphy in the BMJ in Nov 2014 at <http://www.bmj.com/content/349/bmj.g6897>). In revising this Report for the Assembly the issue of inappropriate and harmful use of blood products needs to be elaborated much more clearly.

It is not clear from the current nor previous reports:

- what progress is being made in terms of redressing the current inequities with regard to access to needed medical products of human origin?
- what are the principal barriers to addressing these inequities as fast and efficiently as possible?

- what progress is being made in curbing inappropriate use of medical products of human origin?
- whether all levels of the Secretariat working in the most strategic and coherent ways to overcome the access barriers and to curb inappropriate use?
- if not, what new directions may be required?

The directions suggested under the heading 'The way forward' are quite general. PHM recommends that the Board consider the development of a standardised protocol for health impact assessment regarding both the costs and benefits of the use of medical products of human origin and the costs and benefits of various methods of increasing availability.

PHM urges the Board to request a more comprehensive report regarding availability and use with quantitative indicators reflecting on progress, trends, barriers, and Secretariat activities at all three levels. A health impact protocol as suggested above could provide the basis for comparative indicators.

The availability and use of medical products of human origin is an important issue for health systems around the world. It is not clear that the resources necessary to properly address these issues are currently available to the WHO Secretariat. PHM calls for Real Reform: lift the freeze, reform the regions, hold the MSs accountable.

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

### In focus at EB136

The EB is invited to review progress with respect to implementation and financing of PB14-15 as reported in [EB136/33](#). Likely foci of debate are:

- funding of emergency programs such as Ebola,
- underfunding of key programme areas (vaccine-preventable diseases, integrated people-centred health services, noncommunicable diseases, alert and response capacities and health and the environment),
- cost implications of certain resolutions and decisions adopted by EB133rd and EB134, (see Annex to EB136/33),
- cost of the financing dialogue (no data provided).

### 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 is framed by six broad categories of work' (para 144) and 30 'programme areas' within categories (see annex). 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 is set out in [A66/7](#) and approved in [WHA66.2](#) and reviewed in [EB136/33](#). 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'. Relevant recent documents 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](#)).

See webpage on [Resources and Planning](#)

### PHM Comment

[EB136/33](#) provides some useful information on the implementation of the PB14-15 but there are many important questions which it does not answer, including:



- 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), in particular addressing the social, economic and environmental determinants of health?
- 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 [our comments under Item 13.1](#)) 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 Funding Dialogue is a fig leaf, not a lasting solution.

## 11.2 Proposed programme budget 2016–2017

### In focus at EB136

*A revised draft of the Proposed programme budget 2016–2017 has been prepared, following review and discussion by the regional committees, for consideration by the Board ([EB136/34](#)).*

PB16-17 needs to be adopted at WHA68 (May 2015) which means the document approved by EB136 needs to be final or near final.

A draft version of the PB16-17 was considered by the regional committees, see for example, [EUR/RC64/23](#).

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 ([EB136/35](#)) is proposing a further split into 'segments' with a view to using different approaches to budget (space) building in each segment.)

PB16-17 will also be strongly influenced by the outcomes of PB14-15 (see [Item 11.1](#) of this agenda; EB136/33 posted and then withdrawn).

### Background

#### Scenarios

The Secretariat has presented three scenarios for the EB to consider (paras 20-22; tables 1-3). Scenario 1 applies the budget cap as previously agreed notwithstanding increasing staff costs over which the Secretariat has no control. Scenario 2 makes allowances for increased staff costs (+\$91m). Scenario 3 also makes allowance for decisions taken by the Assembly after the commencement of the quinquennium.

#### Programmatic shifts

The Secretariat is proposing some reductions and some increases against the approved PB14-15. Working from Scenario 2, reported in Table 2 (which is a \$90.8m increase over Scenario 1), the shifts in absolute terms against PB14-15 are:

1. Communicable diseases (-\$52.9m), largely coming from TB (-\$10.5m) and vaccine preventable diseases (-\$64.9m; note that VPD were significantly under funded in PB14-15). Increases are suggested for in Malaria (+\$9.2m) and NTDs (\$12.7m). HIV/AIDS is unchanged.
2. NCDs sees a significant increase (+\$28m) which is distributed across all programme areas.
3. Promoting health through the life course sees a modest increase (+\$25.2m), half of which goes to Reproductive, maternal, neonatal, child and adolescent health, and the rest is spread among the other programmes.
4. Health systems sees a significant increase (+\$45.7 or 9%) most of which goes to medicines and health information.
5. Preparedness, surveillance and response sees a significant increase (+\$48.5m).

- a. Emergencies (budgeted separately) sees an increased provision of \$194m for polio and a drop of \$23m for crisis response. These are indicative figures.
6. Corporate services sees an increase of \$19.2m.

## Shifts by region

EB136/34 provides a breakdown of budget space by region and country offices, based on Scenario 1. Comparing this with the PB14-15 (from [A66/7](#)) shows:

1. Africa: \$1,099m, a decrease of \$21m
2. Americas: \$174m, decrease of \$2m
3. SEA: \$347m, increase of \$7m
4. Europe: \$228m, increase of \$3m
5. EMR: \$586m, increase of \$26m
6. WPR: \$271m, increase of \$1m
7. HQ: \$1,466m, increase of \$180m

## Shifts by level

Comparing PB14-15 (from [A66/7](#)) with the proposed PB16-17 (Scenario 1):

1. Country offices: decrease of \$78
  - a. 14/15: \$1,890
  - b. 16/17: \$1,812
2. Regional offices: increase of \$92m
  - a. 14/15: \$801
  - b. 16/17: \$893
3. HQ: increase of \$180m
  - a. 14/15: \$1,286
  - b. 16/17: \$1,466

See also webpage on [Resources and Planning](#)

## PHM Comment

### Budget scenarios

PHM urges MSs to support scenario 3 rather than 2 or 1. WHO is grossly under-funded the proposed increase is modest.

### Evaluating the budget shifts

It is hard to evaluate the shifts by program, region and level summarised above. 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 56) 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.

The movement of oversight of the Secretariat's Evaluation function from the Office of Internal Oversight to the DG's Office (described in [EB136/38](#)) is step forward. Hopefully the new unit will allocate increased attention to measurement across the results chain.

## 11.3 Strategic budget space allocation

### In focus at EB136

[EB136/35](#) conveys the report of the Working Group in which a revised version of the strategic budget space allocation methodology is outlined, incorporating input from regional committees, further work by the Secretariat, the outcomes of a further face to face meeting of the Working Group and the advice of the PBAC.

### Background

One of the key elements which has been raised repeatedly in the discussions of WHO Reform has been the seeming irrationality of expenditure patterns in relation to needs, priorities and achievable outcomes. It has been recognised that this is in part a consequence of the competition between clusters, departments and regions for donor funding.

Part of responding to this has been the decision to adopt a programme budget and then seek to fund it through the Financing Dialogue with the expectation that budgeted line items will not be exceeded, even if donors wish to give in total more than the budget projection. However, this does not guarantee that budget projections will be funded.

A further element of the reform program is the development of a more rigorous approach to resource allocation planning in the context of developing the expenditure budget. In view of the fact that full funding of all line items cannot be guaranteed, the PBAC has suggested that this be referred to as strategic budget space allocation. This accommodates the reality that in some degree programmes and regions will be allocated empty budget space.

A Working Group was established under the PBAC which submitted an interim report, [A67/9](#), which was considered by the PBAC and the WHA and a further iteration was produced taking into account PBAC comments. This version was distributed to RCs for their consideration (see [EUR/RC64/20](#)). In [A67/9](#) the WG set out a roadmap for developing the new methodology for strategic budget space allocation:

- present the revised paper to Regional Committees for input and further guidance – September–October 2014;
- in parallel, the Secretariat develops different models by applying the principles and criteria – June 2014 onwards;
- hold a face-to-face meeting of the Working Group to review the models developed and provide guidance to the Secretariat – following the Regional Committee sessions;
- provide update on the draft proposal to Member States – mid-December;
- the Secretariat presents a draft proposal on the new strategic budget space allocation to the Programme, Budget and Administration Committee – January 2015.

The revised model, as presented in [EB136/35](#), now involves

- four 'segments' which operationally distinct and therefore need different algorithms for budgeting:

- 1. country level technical cooperation (currently around 23% of total budget space, all at country level);
- 2. provision of global and regional 'goods' (currently 33% of total: 20% HQ, 13% regional);
- 3. management and administration (22% across all levels); and
- 4. emergency preparedness and response (22% largely at country level);
- a series of six overarching principles;
  - based on needs and evidence,
  - results-based management,
  - fairness and equity,
  - accountability and transparency,
  - clear roles and functions,
  - performance improvement.
- separation of activity costs and staffing costs in each segment;
- incremental movement from current budget space allocation (within each segment) to new more explicit procedures;
- the WG does not seem to have proposed a methodology for allocating budget space between segments.

The Working Group proposes a formula approach to Segment 1, based on countries, aggregated to the region but then distributed flexibly within the region in accordance with a set of broader considerations.

The WG proposes that Segment 2 and Segment 3 budget space allocation broadly follow current practice with some tweaking.

Under Segment 4, the WG includes polio eradication and diverse emergencies and humanitarian crises. Methodology for polio would remain as is. The WG proposes a global revolving fund and regional emergency funds for the remaining component of Segment 4.

The WG recognises that full implementation of its recommendations need to be aligned with the continuing implementation of WHO Reform more broadly.

## PHM Comment

The WG's report is clearly a step forward from non-transparent and historically based allocation practices. However, there are some significant issues which still need to be resolved.

The formula suggested for Segment 1 depends on some very rubbery data (in particular, PPP exchange rates, DALYs, and deliveries in the presence of skilled birth attendants). This may provide the grounds for debates about fairness. Unfortunately PPP and DALY calculations are irremediably subjective and rubbery.

It is not clear whether the country specific allocations for Seg 1 will be determined within the regional office or will involve HQ. PHM urges firm involvement of HQ.

The WG sees Segment 2 in terms of the priorities identified in the GPW, the resolutions adopted by the governing bodies and the roles and functions of the three levels of the Organisation. The WG picks up

on the emphasis in the report of the Independent Evaluation Team in 2013 ([EB134/39](#)) on stronger project management. One reading of the WG's report is that budget space in this segment will be the aggregation of expenditure needs of a series of projects, based largely on governing body resolutions. However, these projects also have an organisational reality; they are carried by the clusters, departments, units and regions. Ultimately budgeting is about funding organisational entities. There is nothing in the WG's report about how 'program budgeting' based on 'the project management approach' will mesh with the funding of organisational units in HQ and regions.

It is not clear how the WG conceives the management of the global revolving fund and of the regional emergency funds, given that Table 1 'allocates' almost all of the emergency money to the country level. Table 1 establishes the foundation for the new methodology in terms of 'planned costs' in which case it makes sense that most of the money will be spent at the country level. However, 'allocation' does imply something about who will be holding the funds.

The idea of regional emergency funds will need further attention in view of the fact that the Afro fund has been completely unfunded and the African Development Bank appears to have refused to assist in its management (see [AFR/RC64/7](#)).

The WG provides no guidance regarding budget space allocation between segments. This is an important missing component. There was no discussion of how 'segments' map onto the 'categories' which form the basis of the [GPW12](#).

The report does not touch upon the relationships between regions and directorates and how these will work together in developing and evaluating expenditure proposals.

## **WHO does not have enough money!**

In view of the gross underfunding of WHO it is hard not to see the 'strategic budget space allocation' debate as a side show. The elephant in the room is the ridiculously small budget in aggregate which is a consequence of the freeze on assessed contributions.

With the freeze on assessed contributions comes donor dependence and with donor funding comes competition between clusters, departments and regions for donor attention. The funding dialogue, the new budget space allocation methodology and the strategy of the treating line items in the budget as a fixed ceiling regardless of donor willingness will not solve the divisive effects of competition for donors since clusters and regions still face the possibility of line items being under funded.

This situation is in turn used by donors to insert and push their own agendas into the WHO, further distorting its priorities.

The dependence of the WHO on (tied) donors' contributions remains the central issue. Despite the freeze on assessed contributions MSs should increase their voluntary contributions, but these should be untied.

## 12.1 Draft financial strategy for WHO

### In focus at EB136

*In its report on financing of administrative and management costs ([A67/7](#)), which was noted by the Sixty-seventh World Health Assembly, the Secretariat proposed to present a report ([EB136/36](#)) linking the various reform initiatives in the financing domain and mapping out the broad strategic directions for the financing of WHO.*

[EB136/36](#) explains that the draft financial strategy comprises five components (programming and budgeting; mobilizing resources; managing and tracking resources; reporting; and accountability and risks) and surveys the arrangements being put in place in relation to each of these components.

This item will be considered by the PBAC before the EB and the debate over EB136/36 will be informed by the PBAC report (Item 3)

### Background

See webpage on [Resources and Planning](#).

See notes of discussion at [WHA67](#) (from page 4).

### PHM Comment

#### Broadening the contributor base

The discussion of resource mobilisation highlights the need to broadening the contributor base by encouraging more MSs to contribute.

PHM would applaud an increased flow of donations from the 'emerging economies'. However, it needs to be recognised that while WHO is seen to be the pliant captive of the big donors there is going to be some ambivalence in Southern capitals about increasing their voluntary contributions.

#### Competition for visibility and funding

The Independent External Oversight Advisory Committee (see comments of IEOAC at para 28 in [PBAC21/2](#)) comments on silo behaviours in the following terms:

*28. IEOAC observed that one of the biggest barriers to WHO reform is “silo style functioning within WHO”. The Committee is concerned at the lack of alignment in priorities at the three levels of the Organization. The organizational barriers are inhibiting integrated and coordinated efforts to tackle issues related to compliance, risk, asset tracking, human resources and information technology.*

The competition between clusters, departments and regions for donor attention is one of the most damaging consequences of donor dependence.



Under the heading mobilising resources EB136/36 refers to the role of the new Coordinated Resource Mobilization Unit in the office of the DG in ‘coordinating resource mobilization efforts across WHO’.

It will be very challenging to achieve cooperation across organisational departments and across levels if this means sacrificing parochial advantage. This applies, not just to the mobilising of funds but to programmatic cooperation more generally.

### **Lift the freeze**

The paper mentions but passes over the need to lift the freeze on assessed contributions.

Under ‘Reporting’ (para 16) the Secretariat states that “Contributors will only provide funds to WHO if they have the confidence that the resources will be used according to the intended initiatives”. This is not the whole story. It is also the case that many contributors will only contribute if they are assured that their funds will go to purposes of which they approve. It is also the case that powerful member states continue to oppose increased assessed contributions because that would give the Secretariat the power to implement policies adopted through the Assembly which those donors oppose.

This situation deeply undermines WHO’s integrity and credibility.

### **Untie voluntary contributions**

EB136/36 avoids any discussion of the need for donors to untie their voluntary donations. Presumably this is a discussion which has been attempted unsuccessfully in the context of the ‘funding dialogue’.

PHM urges that the metrics referred to in para 24 include reporting on the proportion of donor funds which are tightly, loosely or not tied.

### **Transaction costs**

Under ‘reporting’ the Secretariat notes again the transaction costs associated with different donors requiring different reporting and acquittal forms.

However, the transaction costs associated with the funding dialogue and the management of empty budget space would far exceed these bureaucratic irritations.

PHM urges that the metrics referred to in para 24 include reporting on the costs of resource mobilisation, including the funding dialogue and the management of budget space.

## 12.2 Scale of assessments for 2016–2017

### In focus

Report on scale of assessments 2016-17 ([EB136/37](#))

### Background

See webpage on [resources and planning](#)

### PHM Comment

The freeze on assessed contributions and the dependence of WHO on tied donor funding are doing serious damage to the Organisation:

- The total resources available to WHO are completely inadequate for it to properly do its job. Consider the Ebola crisis (see [PHM comment on EBSS3](#)).
- The dependence on donor funding has created a competition for visibility and donor attention that is completely inimical to organisational coherence and collaboration. See the comments of the Independent Expert Oversight Advisory Committee (see [PBAC21/2](#), and the corresponding [PHM note](#)).
- Third, the preferences of the donors, *not to fund certain functions*, means that certain decisions and policies adopted by the Assembly are not funded. Furthermore the implicit threat from the donors, that funding is contingent on approved behaviour, distorts the decision making of the governing bodies.
- Fourth, the transaction costs associated with the funding dialogue and funds mobilisation are huge and detract from the real purposes of WHO.

## 13.1 Evaluation

### In focus

The report ([EB136/38](#)) provides an update on progress made in implementing the Organization's evaluation policy ([here](#), from page 13).

There may also be reference to the Organisation-wide evaluation work plan which was approved at EB135 (see [EB135/5](#)).

This item will be considered by PBAC in advance of the EB meeting so the discussion of Item 13.1 will be informed by the PBAC comments.

### Background

Concern has been expressed about WHO evaluation practice and capability throughout the WHO reform period.

EB130 (Jan 2012) discussed evaluation as part of WHO Reform. See:

[EB130/5 Add.8: Draft WHO Evaluation policy](#) ([see WW comment](#))

[EB130/5 Add.9: Managerial reform: evaluation](#) ([see WW comment](#))

EB131 (May 2012) adopted the Evaluation Policy as revised in [EB131/3](#)

The Independent Evaluation Team (IET) commissioned to evaluate the implementation of the Reform program, was quite critical of WHO's 'results chain, theory of change and monitoring framework'. Reporting in Jan 2014 (see [EB134/39](#)) the IET commented:

*The robustness of the reform results-chain, theory of change and monitoring framework needs to be strengthened. Most notably outcome indicators are weak. This limits the ability of the Secretariat to first, direct efforts to areas that are most closely linked to the achievement of reform outcomes and second, report on the benefit realisation of the reform. Further outputs and deliverables are mostly of an 'Assess and Strategise' and 'Design' nature (33% and 51% respectively) and with only 3 out of 151 deliverables relating to training. Since the status of implementation and institutionalisation of deliverables is not tracked, the reporting on the completion of outputs can give a false sense of comfort that reform is more advanced than it actually is.*

[EB136/38](#) advises (para 3) that in August 2014 oversight of the evaluation function has been moved from the Office of Internal Oversight Services (largely internal audit) to a separate unit within the DG's office and that the DG has appointed a Representative for Evaluation and Organizational Learning. This shift of responsibility is long overdue.

## PHM comment

PHM has been critical of the treatment of evaluation by the Secretariat for several years. Programmatic evaluation has been weak or non-existent. Organisational evaluation has been weak with meaningless indicators proffered to demonstrate organisational effectiveness. The evaluation policy has been overly influenced by the audit perspective and the accountability function and has neglected formative evaluation, 'learning whilst doing'. The disciplines of plausible attribution have been generally ignored. Validity and reliability are expensive but indicators which are not valid or reliable can be very misleading.

There has been talk of developing an evaluation culture and creating a learning organisation but these objectives require the Organisation to move beyond the audit and accountability paradigm. (See discussion of WHO evaluation policy and practices under [Item 6.1 at EB135.](#))

[EB136/38](#) makes no reference to the 'results chain' and 'theory of change' issues identified by the IET (above).

The weaknesses in the monitoring of the 'results chain' is reflected in the draft 2016-17 programme budget ([EB136/34](#)). Many of the indicators, through which implementation of the PB16/17 is supposed to be monitored, are far from valid and reliable. The indicators will not identify how WHO has contributed to the changes which are reported.

PHM applauds the move of evaluation oversight to the DG's office. We hope that this leads to more substantive progress towards WHO as a learning organisation. However, it might be time for the EB to consider the possibility of following the World Bank precedent of creating an independent evaluation unit which reports directly to the EB.

The World Bank's [Independent Evaluation Group](#) is charged with evaluating the activities of all of the organisations within the World Bank Group and the Director-General of IEG reports directly to the World Bank Group's Board of Directors. The IEG's evaluation reports are sometimes quite robust.

*IEG conducts not only project-level evaluations, based on the review of self-evaluation reports prepared by Bank Group staff and supplemented by independent assessments, but also reviews of literature, analytical work, and project documentation; portfolio reviews; country case studies; structured interviews and surveys of staff and stakeholders; and impact evaluations.*

*IEG use a variety of evaluation approaches. These approaches include assessing outcomes against stated objectives, benchmarks, standards, and expectations, or assessing what might have happened in the absence of the project, program, or policy (counterfactual analysis).*

## 13.3A Reports of committees of the Executive Board: Standing Committee on Nongovernmental Organizations

In focus at EB136

*During its session the Board will receive the report (EB136/40) of the Standing Committee on Nongovernmental Organizations, which contains, inter alia, the Committee's recommendations on requests from organizations for admission into official relations with WHO, and the review of collaboration between WHO and one third of the organizations in official relations during the period 2012–2014.*

Background

PHM Comment

See [PHM note on Engagement with NSAs \(Item 5.1\)](#)

## 14.4 Human resources: update

### In focus

*The report ([EB136/45](#)) provides an update on the implementation of the Organization-wide human resources strategy.*

### Background

The [revised HR Strategy](#) was noted by the EB134 in Jan 2014. Revision was necessary in order to align HR policies with the requirements of the WHO Reform.

Notable features of the new strategy, as reported in EB136/45, include the abolition of continuing appointments (see [below](#)), greater encouragement for staff mobility (see [below](#)) and the move to more uniform HR policies and practices across the Organisation (although PAHO remains governed by separate rules and regulations).

Polio legacy planning to deal with HR implications of eventual successful eradication of polio is also a key feature. See also Annex to [A67/47](#).

The revised HR strategy and EB136/45 include a range of HR management tools which promise much and, if effectively implemented, could achieve useful objectives. These tools include a skills inventory, the corporate framework for learning and development, the global learning and management system; and the enhanced WHO global competency model.

The report notes a range of possible obstacles and dependencies (para 35 & 36) which will determine whether these promises can be delivered. The report promises that performance indicators are being developed which will monitor implementation and the achievement of the promised outcomes (see comment below).

This report should be reviewed in conjunction with [A67/47](#), the Annual Report on HR (plus additional tables [here](#)) which was presented to WHA67.

See also [Staff Regulations and Rules](#) and the [Resources and Planning](#) page.

### PHM Comment

#### Meaningful performance indicators will be critical

The Secretariat faces significant challenges on the HR front and is taking a systematic approach to dealing with these challenges. This is to be applauded and supported. However, the potential obstacles to implementation are significant and close monitoring, adjustment and reinforcement will be critical. In this context the validity and reliability of the proposed performance indicators will be critical.

We have [commented](#) under Item 13.1 Evaluation on inadequacies in WHO's selection of performance measures in relation to the achievement of organisational goals. The comments of the Independent

Evaluation Team (see [EB134/39](#) from Jan 2014) regarding having a theory of change and following the results chain remain relevant.

## **Working across silos**

There is nothing in the Strategy or this report about dissolving the walls of the silos, most recently highlighted in the report of the Independent External Oversight Advisory Committee (PBAC21/2):

*28. IEOAC observed that one of the biggest barriers to WHO reform is “silo style functioning within WHO”. The Committee is concerned at the lack of alignment in priorities at the three levels of the Organization. The organizational barriers are inhibiting integrated and coordinated efforts to tackle issues related to compliance, risk, asset tracking, human resources and information technology.*

There is nothing in the Strategy or the report which might project and instill an inspiring vision which might help to overcome barriers and give the Organisation coherence in times of flux and uncertainty.

The EB will be discussing the management of conflict of interest under Item 5.1. PHM believes that WHO's vulnerabilities in dealing with COI reflect in part the imperative of gaining donor attention which, in the midst of a financial crisis, overrides commitment to the vision of the Constitution. This is centrally a question of organisational culture; creating resilience in face of risk (such as risk of COI).

## **Interns and junior professional officers: exclusion of young people from L&MICs**

Neither the Strategy nor the report mentions interns who constitute around 16% of the human resources upon which WHO depends nor junior professional officers ([here](#)). Both of these categories represent very promising pathways towards recruitment to formal employment.

However, in both cases, these pathways effectively exclude young people from low and middle income countries. Access to internships requires independent funding. Access to JPO opportunities appears to be completely restricted to Europeans. Given the commitment to 'diversity' in the Strategy this exclusion is not appropriate. PHM urges the inclusion in the HR Strategy provision for scholarships to support young people from L&MICs to access intern and JPO opportunities.

## **Risks associated with secondments from governments, universities and corporations**

There is no reference in either the Strategy or the report to the issue of secondments to the staff of WHO from governments, universities and corporations. Given the importance that this issue has attracted in relation to the Framework for Engagement with Non-State Actors it is surprising that the HR report is silent on the issue.

## **Fixed term appointments: the need to balance managerial flexibility with technical depth and institutional memory**

Commenting on the abolition of continuing appointments the staff associations' report to EB135 in May 2014 ([EB135/INF.1](#)) highlighted the need to balance managerial flexibility with technical depth and

institutional memory. There is nothing in the Strategy or EB136/45 which shows how the Secretariat proposes to manage this balance.

### **Staff mobility: the need to balance building cohesion and multi-skilling versus building and maintaining technical depth**

In commenting on the emphasis on staff mobility in the revised Strategy, the staff associations report to EB135 ([EB135/INF./1](#)) commented on the need to find an appropriate balance between building cohesion and multi-skilling versus building and maintaining technical depth. There is nothing in the Strategy or EB136/45 which shows how the Secretariat proposes to manage this balance.

### **Adapting to financial crisis through questionable personnel policies**

Para 3 of the [HR Strategy](#) comments that

*The main objectives are to ensure that the revised HR strategy supports WHO's strategic direction and priorities and responds to HR needs at all three levels of the Organization, taking into account WHO's financing model. To achieve these objectives, WHO needs a workforce that is more flexible, more mobile, highly performing, and fully trained and ready to take on new professional challenges.*

In other words the abolition of continuing appointments and the increasing pressures on staff to be more mobile are necessary strategies for adapting to the financial crisis and the uncertainties of donor dependence. The arguments which are offered in the Strategy for these provisions are clearly predicated upon the need to adapt to the financial crisis. The warnings of the staff associations may foreshadow a new set of organisational failings for which the member states must take responsibility.

PHM calls upon the member states to lift the freeze on assessed contributions; increase and untie voluntary donations and, in the words of the IET (2014), "fulfilling their duty of care for the Organization, notably through adequate financing" ([EB134/39](#)).



## 15.1 Reports of advisory bodies

### In focus

[EB136/48](#) conveys reports from:

- Expert Committee on Drug Dependence (report of meeting in June 2014);
- FAO WHO Expert Committee on Food Additives
  - on certain veterinary drug residues in food (report of meeting Sept 2013);
  - on certain food additives and contaminants (June 2014)
- WHO Study Group on Tobacco Product Regulation (Dec 2013)

[EB136/48 Add.1](#) reports:

- that no new panels have established in 2014 nor old ones disestablished;
- on memberships of expert advisory panels including gender and regional distribution;
- that there are a total of 47 advisory panels of which four met during 2014

### PHM Comment

Watch this space.