

People's Health Movement

Commentary on the Agenda of the 67th World Health Assembly

Geneva
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This set of comments, prepared by the People's Health Movement, is presented as a contribution to Member State deliberation during the 67th World Health Assembly.

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

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 WHA67 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.

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

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11.1 Reform implementation plan and report

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In focus at WHA67

The Assembly will consider report [A67/4](#) and [A67/INF./1](#) in support of this item. These documents provide an opportunity to review the whole reform plan and assess progress on all of the various elements of the plan. Several of these elements are the subject of separate agenda items.

For the EB134 meeting the Secretariat listed Evaluation as an agenda item and presented two reports under this item:

- the Secretariat's evaluation update report and its proposed Organization-wide evaluation work plan 2014–2015 (as [EB134/38](#)), and
- the report of the Stage II Evaluation of the WHO Reform Program by the Independent External Evaluation consultant (as [EB134/39](#)).

For the WHA67 the Evaluation was initially listed as a separate agenda item (11.8) but in a subsequent revision of the agenda it disappeared.

Background

The Secretariat report ([A67/4](#)) presents a summary of WHO's efforts and actions towards reform; highlighting some of the key achievements in reform over the past year; noted some of the challenges that will guide the key focus of reform during 2014–2015; and responded to some of the findings and recommendations of the second stage evaluation of reform.

The report reviews progress on: programmatic, governance and managerial reforms.

Under the heading 'Response to the Stage-Two evaluation of WHO Reform' the Secretariat paper overviews briefly its response to the recommendations of the Independent Evaluation Team (transmitted to the EB in [EB134/39](#)) which were directed towards the Secretariat:

- build a simplified reform framework through a stronger theory of change
- realign change and communication activities
- strengthen reform programme management.

The Secretariat report makes no mention of the IET recommendations which were directed towards Member States, in particular, under 'Ownership and accountability' where the IET commented on the responsibilities of Member States.

Discussion at EB134

The Reform program was discussed at EB134 on the basis of [EB134/5](#). This report provides more detail than A67/4. See WW report of EB debate [here](#).

PHM Comment

It is of concern that the Stage II Evaluation report ([EB134/39](#)) has not been brought to the WHA67 for consideration, especially considering its critical tenor.

The IET report speaks about the MSs having a 'duty of care' in relation to the Organisation and makes three sets of important recommendations for actions by MSs about financing. The IET recommends MSs assessed contributions to be brought up to one third of the overall budget by 2016-17 and to 50% in the longer term. It further recommends that MSs redirect earmarked funding to the voluntary core account. Finally, the IET recommends that donors should pay the full program support cost of the programs they are funding. It is worrying that these recommendations do not find mention in the Secretariat Report.

The Assembly should consider closely the critique of the IET and all of its recommendations, including those regarding the financing of the Organisation.

11.2 Options for improved decision-making by the governing bodies

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In focus at WHA67

WHA67 will deliberate upon [A67/5](#) and will be asked to adopt certain draft decisions contained in EB decision [EB134\(3\)](#) which in particular:

(3) recommended that the Sixty-seventh World Health Assembly decide to introduce webcasting for future public meetings of its committees A and B, as well as of its plenary meetings, to all internet users through a link on the WHO website, subject to resolution of any relevant technical issues and to the availability of financial resources;

(6) recommended that the Sixty-seventh World Health Assembly approve the recommendations of the Secretariat, contained in document [EB134/6 Add.1](#), to rent a cost-effective and secure electronic voting system for the nomination and appointment of the Director-General, and to test such a system in advance through mock votes by the governing bodies prior to the election of the next Director-General;

(8) recommended that the Sixty-seventh World Health Assembly amend the Rules of Procedure of the World Health Assembly, with effect from the closure of that session, as follows:

Delete Rule 49 and replace Rule 48 with the following text:

“Formal proposals relating to items of the agenda may be introduced until the first day of a regular session of the Health Assembly and no later than two days prior to the opening of a special session. All such proposals shall be referred to the committee to which the item of the agenda has been allocated, except if the item is considered directly in a plenary meeting.”

(10) recommended that the Sixty-seventh World Health Assembly decide that progress reports shall henceforth be considered only by the Health Assembly and no longer by the Executive Board;

Background

EB134 considered a report from the Secretariat ([EB134/6](#)) on the options for criteria for inclusion, exclusion or deferral of items on the provisional agenda of the Board, as well as the outcome of a study conducted to ensure coherence between the proposed amendments to the Rules of Procedure of the governing bodies and the existing Rules of Procedure.

The report also included information on work undertaken to minimize the use of paper documents by the governing bodies.

An accompanying report ([EB134/6 Add.1](#)) appraised the scope for using an electronic voting system for the appointment of the Director-General. (In resolution [WHA66.18](#), the Sixty-sixth World Health Assembly had requested the Director-General "... to explore options for the use of electronic voting for the appointment of the Director-General, including the financial and electronic security implications thereof, and to report thereon, through the Executive Board, to the Sixty-seventh World Health Assembly".)

Document [EB134/6](#) dealt with requests regarding capacity-building and training, electronic access to governing body meetings, and minimal use of paper documents or "paper-smart" meetings, and with options for managing the number of agenda items, and proposals for amendments to the Rules of Procedure.

EB134 also considered Document [EB134/7](#) which

- reported on progress towards a less burdensome and more coherent approach to collecting health data from MSs including reports on implementation of GB resolutions and health laws and other health system data and
- reported on progress towards a web based platform for communication between the Secretariat and member states.

The report foreshadows a new organisation wide information management strategy and proposes to report on further progress to the EB136

Highlights of discussion at EB134

Improved GB decision making was considered by EB134 on Day 3 (Wed Jan 22). It was considered conjointly with the item on streamlining reporting and communication. The issue of limiting agenda items was revisited on Day 5 (Jan 24) when the debate was structured around the conference paper which eventually became [EB134\(3\)](#).

The debate ranged widely.

See final decision [EB134\(3\)](#).

In addition to the recommendations to the WHA67 listed above, the final decision endorses:

- capacity building for EB members and officers
- webcasting of public sessions of PBAC and EB

- minimising the use of paper by greater use of electronic documentation
- improved methods for communicating between the Secretariat and member states
- rules for the timely circulation of draft decisions and draft resolutions at EB
- timely despatch of papers for EB meetings (at least 6 weeks before)
- explanatory memoranda explaining new agenda items to take into account the criteria in EB121.R1 and identify linkages to the GPW and PB
- supporting statements proposing new late items for the EB agenda explain the urgency and risks of delay
- minutes of meetings of officers of the Board be available to MSs

PHM comment

The proposed new rules are generally sensible.

The use of electronic communication to replace paper depends on the quality of wireless internet in the EB chamber and the Palais. In fact the WHO internet crashed while the above debate was taking place. Web casting will add a further burden to the venue's internet capacity.

While there was a lot of talk about the number of items there was very little talk about the relevance and depth of MS contributions to the debate. It is a minority of MSs who speak precisely and to the point and whose contributions reflect careful thinking about the underlying issues. Too many MSs repeat key phrases from the Secretariat documents; speak in broad generalities regarding the issues in question; but do not say anything new.

One contributing factor to the agenda overload is the competition from within the Secretariat for visibility as a necessary strategy for getting donor funding. Visibility can be achieved through publications, strategies, events, and resolutions. While donor funding dominates the Organisation's culture and procedures this dynamic is likely to continue.

11.3 Framework of engagement with non-State actors

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- [PHM comment on the March Consultation document](#)
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In focus at WHA67

The Assembly will consider Document [A67/6](#). An earlier document ([EB134/8](#)) was discussed at the EB and a further iteration ([here](#)) was circulated for the March 27-8 Consultation.

In her final comments during the debate over EB134/8 at the EB in Jan 2014 the DG said, “Eventually we shall have disaggregation of PINGO and BINGO; give us more time. On the question of one policy for everybody or different policies: give me the time to do some analysis and I will present something at the next opportunity. We must make progress, give me a bit of flexibility.”

Following the EB in Jan the Secretariat published a new discussion paper ([here](#)) and organised a closed meeting of MSs to consider ([here](#)). There has been no official report of this meeting released (as of 140506) but TWN has published a [report](#).

See PHM comment on the discussion paper [here](#) and IBFAN comment [below](#).

Background

WHO's relationship with various non-state actors (NSAs) has been an important and sensitive element of the current WHO reform program.

There has been a number of high profile controversies centred around the perception of undue or inappropriate influence on WHO decision making. WHO's role in IMPACT (International Medical Products Anti-Counterfeiting Taskforce) illustrates. The approach of IMPACT to the problem of counterfeit medical products conflated contentious intellectual property issues with the very real problem of quality, safety and efficacy compromised products and sought to harness the power of national drug regulation in policing intellectual property claims. International pharmaceutical corporations were very prominent in the conception and establishment of IMPACT and WHO's participation from 2006 was never authorised by any governing body resolutions or decisions.

For many years WHO has found it very difficult to formulate a policy regarding the relationships between the Secretariat and various NSAs, including individuals (experts etc) and organisations (including corporations, industry front organizations, public interest civil society organisations, philanthropies, etc). This challenge has come to the fore again in the context of the current WHO Reform.

In response to the request made in decision [EB133\(2\)](#), the Director-General reported to EB134 ([EB134/8](#)) on the development of a framework of engagement with non-State actors.

The Secretariat report was structured around

- objectives, principles and boundaries
- definitions
 - non-state actors,
 - types of interaction (participation, resources, evidence, advocacy, technical cooperation)
- management of engagement
 - due diligence, risk assessment, risk management
 - transparency
- next steps

Paragraph 28, under Next Steps, proposed four adjustments to current protocols to be implemented immediately. It is presumed that these adjustments will be implemented immediately since, in the words of the Chair (see below), 'there was general support for para 28'. The four adjustments concern: 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 documentation submitted to the SC on NGOs to be made public. See notes from EB134 debate [here](#).

The discussion in the EB was followed up by a two day MS only consultation in March 27-28 which considered a new discussion paper from the Secretariat ([here](#)). See PHM's preliminary comment on this discussion paper ([here](#)).

There has been no official report from the MS consultation but a detailed report of the consultation has been published by TWN ([here](#)). According to the TWN report the MSs were unable to agree upon key principles regarding NSA relations. Of particular concern were: the proposal on secondment, 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 high degree of scrutiny for the private sector compared to other NSAs.

PHM comment

The draft policy starts with a broad framework (rationale, principles, boundaries, actors and interaction types). The report articulates clearly that the risks which are to be managed are improper influence and the perception of improper influence. The report acknowledges that the existence of conflicts of interest indicate a risk of improper influence or the perception of such.

The list of 'actors' includes NGOs, private sector entities (PSEs, includes business associations), philanthropies and academics. The inclusion of business associations with PSEs is an important step forward. The report acknowledges that some "NGOs" have close relations with corporations but proposes that potential conflicts of interest arising can be handled on a case by case basis.

The types of interaction include: participation, resources, evidence, advocacy, and technical collaboration.

The draft policy provides detailed policies with respect to WHO relations with all four categories: NGOs, PSEs, philanthropies and academics. It notes other policies which also deal in various ways with the risk of improper influence and conflict of interest.

NGOs and NGO statements

The immediate adjustments proposed in para 28 of [EB134/8](#) and endorsed by the EB are welcome.

Managing the risks

Risk is a function of power as well as purpose: in this respect people who have unlimited resources and the support of large donors represent a greater risk of 'improper influence' than civil society organisations who happen to offer a different perspective on the various issues in contention.

The risk management strategies needed to guard against undue or improper influence need to reflect some appreciation of the power and modalities of influence of various NSAs. Transparency and due diligence are critical in effectively managing these risks.

When civil society organisations which are largely funded by the pharmaceutical industry speak at governing body meetings or work with Member States to bring forth resolutions the governing body should be aware of this relationship.

A further study of the modalities of improper influence (as in the case of IMPACT) would be useful in operationalising the principles of transparency and due diligence. In the EB debate several countries spoke about the need to analyse more closely WHO's experience in dealing with NSAs. None spoke explicitly about modalities of improper influence.

The draft policy does not appear to have considered the modalities of improper influence that may be available to particular NSAs. This is an important aspect of the risk profile of any particular NSA and one which would have direct implications for risk management procedures

The draft does not address the risk to WHO of improper influence being mediated through MS delegates. One obvious way of exercising influence over WHO is to promote issues onto the agenda with accompanying resolutions. However, there is nothing in the Secretariat paper which might ensure transparency with respect to the provenance of agenda items or resolutions, and therefore risk control through collective alertness.

BINGOs and PINGOs

Most NGOs in official relations have been arguing for years for a clear distinction between PINGOs and BINGOs; a clear definitional distinction and different policies and protocols to expose and manage risks.

The main reason that CSOs have been arguing for a clearer separation between PINGOs, business associations and pharma-sponsored 'patient organisations' is that they have identifiably different risk profiles. The risks of improper influence are far greater in the case of business associations and pharma-sponsored 'patient organisations' because their range of purposes and interests diverge from the objectives of WHO to a much greater extent than is the case for the PINGOs and they have access to specific modalities of influence. Due diligence would require that business associations and pharma-sponsored 'patient organisations' are seen by WHO officials as carrying particular risks associated with their commercial interests and sponsorship.

The new draft policy appears to acknowledge this distinction by formally assigning business associations to the category of PSEs rather than NGOs which was proposed in the March 2014 discussion paper. However, pharma sponsored 'patient organisations' remain categorised as NGOs.

Testing the proposed policy package against some historical episodes of real or perceived improper influence (and associated reputational harm)

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.

Conclusions

The paper is highly procedural in the sense that it is based largely on structures, procedures and protocols in contrast to creating a culture of awareness and sensitivity to 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 package does not consider the involvement of member states in generating or managing risks.

PHM policy priorities

Reorient the organisational cultural which presently discounts the risk of improper influence because it is over-shadowed by the need to attract donor attention.

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.

11.4 Financing dialogue

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In focus at WHA67

The financing dialogue (FD) was launched in June 2013.

WHA67 will consider the report from the Secretariat, [A67/7](#), which conveys a slightly revised version of doc [EB134/9](#) which was considered at the EB in Jan 2014.

Among the critical issues which undoubtedly will be discussed:

- the continuing funding gap;
- the risk to WHO's integrity of the continuing power of the donors over WHO's effective budget;
- the transaction costs of the FD;
- the strictures of the Independent Evaluation Team in their Stage II Evaluation regarding the need for MSs to increase ACs and to redirect VC to the 'core account' which is not earmarked

Background

WHO funding and reform have been discussed repeatedly over many years. John Farley ('Brock Chisholm, the World Health Organisation and the Cold War'. Vancouver, UBC Press, 2008) describes a recurring tension between the 'have' nations and the 'have not' nations over the level of 'assessed contributions' from the earliest years of the WHO.

Since the 1980s there has been a freeze on increases in Assessed Contributions (AC), initially in the 1980s a relative freeze but from 1993 (at the insistence of the USA) an absolute freeze (Lee, K. (2009). The World Health Organization (WHO). London and New York, Routledge). Meanwhile, Voluntary Contributions (VC) have increased to a point where the latter contribute almost 80% of total WHO expenditure.

In 1994 a study of WHO revenues was commissioned which confirmed that even at that stage WHO was slipping into a funding crisis. Further [details](#).

The freeze on AC has been mainly driven by the US, in part because of, sequentially, the Code on the Marketing of Breast-milk Substitutes; the Essential Medicines List; the Primary Health Care model; the Framework Convention on Tobacco Control and most recently (2006) the resolution on Trade and Health.

The prevailing discourse from those who support the freeze on AC has been that WHO suffers from administrative inefficiencies and that a tight chokehold is necessary to discipline the Organisation.

In fact, in large degree the inefficiencies of the Organisation are a consequence of having to manage two sources of funds, assessed and untied versus tied voluntary contributions. The former, the smaller tranche, is available to support what the WHA commits to through its resolutions. The latter, vastly overshadowing flexible funds, is available to support what the donors want WHO to do (and to prevent WHO from doing what they, the donors, do not support).

The current reform program was developed in an attempt to find a pathway through this contradiction.

The 'financing dialogue' was conceived as a way of encouraging donors to support the WHA-adopted Program Budget.

At its special session in November 2011 the EB welcomed the Director-General's proposals on management reform and asked (in decision [EBSS2\(3\)](#)) the Director-General to develop a detailed proposal, for mechanisms to increase predictability of financing and flexibility of income, which supports priorities set by Member States.

[A65/5](#) prepared for WHA65 in May 2012 provided the framework for the proposed 'financing dialogue' (see paras 93-95)

WHA65 adopted a comprehensive decision ([WHA65\(9\)](#)) encompassing a range of reform related areas including the funding dialogue. Para 12 of [WHA65\(9\)](#) requested the Director-General, based on guidance received from the Sixty-fifth World Health Assembly, to further develop the proposals to increase the transparency, predictability and flexibility of WHO's financing, for presentation to the Executive Board at its 132nd session.

Immediately following WHA65, [EB131](#) gave further consideration to WHO Reform and decided ([EB131\(10\)](#)) to hold an extraordinary (open to all MS) meeting of the (newly empowered) PBAC from Dec 6-7, 2012 which would consider amongst other things the modalities for the proposed Funding Dialogue. At the special PBAC meeting MSs welcomed the proposed funding dialogue (see paras 7 & 8 of [EB132/3](#)).

In its decision [EB132\(16\)](#) (Jan 2013) the EB recommended that the WHA66 agree to the funding dialogue in accordance with the modalities set out in the annex to EB132(16).

Further details regarding the funding dialogue were included in [WHA66/48](#) which was submitted to the WHA66 in May 2013 and a PBAC report on the Financing of WHO ([A66/50](#)). A66/48 included a draft decision (which was adopted as [WHA66\(8\)](#)) in which the WHA decided to establish a financing dialogue, convened by the Director-General and facilitated by the Chairman of the Programme, Budget and Administration Committee of the Executive Board, on the financing of the programme budget, with the first financing dialogue on the Programme budget 2014–2015 to take place in 2013, in accordance with the modalities described in

document [A66/48](#). (This is the most detailed public description of the funding dialogue.)

The dialogue was launched on 24 June 2013; following the June meeting the dialogue was considered at regional committee meetings (see [EB134/4](#)); was discussed in briefings with Geneva based missions; and was reviewed in bilateral meetings with 19 of WHO's largest donors. The dialogue surfaced again in November with a two day meeting to review progress, identify areas of underfunding and develop strategies to address shortfalls. The agenda, papers, participants and presentations from this meeting are available [here](#).

EB134 (Jan 2014) had before it [EB134/9](#) which summarised the discussion at the November meeting and included commentary on:

- Predictability: WHO is marginally more secure than it was at this time two years ago;
- Alignment and flexibility: there are serious shortfalls in funding the WHA approved Program Budget;
- Transparency: there is appreciation of the new Program Budget web Portal ([PBP](#));
- Vulnerability: WHO depends upon 20 contributors (11 of whom are not member states) for 80% of voluntary contributions;
- Financing of administration and management: proposed re-allocation of the costs of management and administration to the programs;
- Coordination of resource mobilisation: need for continuing funds mobilisation;
- Reporting on results; support for better reporting on results;
- Evaluating the financing dialogue: need for evaluation of the financing dialogue.

Notes from EB134 debate [here](#).

PHM Comment

PHM acknowledges that the financing dialogue has brought about some benefits:

- The [PB portal](#) looks useful (although there are no meaningful financial statistics available for download in spreadsheet format and data provided to WHA are still available as PDFs only);
- There is considerable scope for improvement in the Organisation's evaluation practices and any impetus in this direction is to be welcomed.

However, Member States should be deeply concerned because:

- the transaction costs associated with the financing dialogue and the mix of revenue sources are huge, in terms of senior person time and cash expenditure on dialogue;
- huge swathes of the developing world have been disenfranchised by the progressive restrictions on WHO autonomy; the large donors, including large nation-states, private philanthropies, corporations and IFIs, exercise increasing influence over WHO's program;
- important initiatives commissioned through the WHA are being held up for want

of funding support; these include: medicines regulation, trade and health, action on junk food.

The urgent needs now are to increase assessed contributions and to increase the flow of voluntary contributions to the core account: firstly by increasing the voluntary contributions from the emerging economies (presently very low); and second, by increasing the proportion of voluntary contributions going to core (untied) which is presently very low.

In order to save WHO from the rich donor chokehold, PHM calls upon:

- Member States to agree to increase assessed contributions; this was indeed one of the outcome of the extraordinary PBAC meeting held in December 2012 and it is also one of the recommendations of the report of the second stage evaluation on WHO reform (Doc [EB134/39](#): “An initial step could be to increase AC contributions to a third of the overall budget in 2016-17, with the view to achieve a balanced 50% AC-50% VC in the long-term”);
- developed countries to re-allocate their voluntary contributions from specified purposes to the voluntary core account; and
- emerging economies to consider increasing their voluntary contributions to core funding (see reference in [EB134/9](#) to the BRICS Health Ministers’ communique to BRICS support for the financing dialogue).

If the emerging economies were to increase their voluntary contributions to core funding it would assist the Secretariat in operationalising the governing body resolutions. However, it would be unlikely to be enough to challenge the hegemony currently exercised by the USA and by Gates and other rich donors over the direction of the Organisation.

The External Evaluator ([EB134/39](#)) calls upon Member States to fulfill their ‘duty of care’ to the Organisation and recommends an immediate increase in assessed contributions and the reallocation of earmarked funds to the more flexible voluntary core account. This is an important and timely warning.

Annex. Analysis of A66/29 Add.1 and A66/30

Relatively few countries make any contribution to the voluntary core account

All member states:

· Vol contribs	104
○ >50% of vol to core	8
○ >10%,<50% of vol to core	10
○ >0%,<10% of vol to core	1
○ 0% of vol to core	85
· No vol contr	87

OECD and G20 member states:

- >50% of vol to core 5 (Greece, Belgium, Luxemburg, Denmark, Ireland)
- >10% but <50% 9 (Korea, Sweden, Finland, Australia, Switzerland, Netherlands, Norway, New Zealand, UK)
- 0% vol to core 16 (Israel, Canada, USA, Germany, France, Slovenia, Italy, Japan,

Saudi Arabia, Austria, Russian Fed, Spain, China, Indonesia, India, Brazil)

- No vol contribs 10 (Estonia, Czech, Poland, Slovakia, Hungary, South Africa, Chile, Argentina, Portugal, Mexico)

Of the 21 countries with GDP >\$500 billion:

• Vol contr	19
○ >50% to core	0
○ >10% but <50% core	6
○ >0% but <10%	1
○ 0% core	13
• No vol contr	1 (Mexico)

Of the 149 countries with GDP <\$500 billion

• No vol contr	74
• Vol contr	75
○ >50% to core	8
○ >10% but <50% to core	3
○ Nil to core	64

Total contributed (assessed/received plus voluntary) as a proportion of GDP (per million dollars of GDP, pm GDP) varies very widely

Among the OECD countries (33),

• >\$50 pm	6 (Luxemburg, Norway, Finland, Canada, UK, Sweden)
• >\$10 but <\$50	15 (Australia, Netherlands, Denmark, Belgium, Ireland, New Zealand, Switzerland, USA, Germany, Korea, France, Slovenia, Italy, Japan, Austria)
• >\$5 but <\$10	6 (Mexico, Estonia, Czech, Poland, Slovakia, Turkey)
• <\$5	5 (Hungary, Chile, Greece, Spain, Portugal)
• No GDP data	1 (Israel)

G20 but not OECD (8):

• >\$50 pm	0
• >\$10 pm	1 (Saudi Arabia)
• >\$5 but <\$10 pm	1 (Russian Fed)
• <\$5 pm	6 (South Africa, Argentina, China, Indonesia, India, Brazil)

Not G20 or OECD:

• >\$50	11
• >\$10 but <\$50	12
• >\$5 but <\$10	22
• <\$5	85
• No GDP data	24

References

GDP data taken from WB (<http://data.worldbank.org/indicator/NY.GDP.MKTP.CD>) at current

US\$. For some countries there are no 2012 data.

PHM advocacy priorities

In order to save WHO from the rich donor chokehold, PHM calls upon:

- Developed countries to re-allocate their voluntary contributions from specified purposes to the voluntary core account; and
- Member States to agree to increase assessed contributions; this was indeed one of the outcome of the extraordinary PBAC meeting held in December 2012 and it is also one of the recommendations of the report of the second stage evaluation on WHO reform (Doc [EB134/39](#): *“An initial step could be to increase AC contributions to a third of the overall budget in 2016-17, with the view to achieve a balanced 50% AC-50% VC in the long-term”*).

11.5 Strategic resource allocation

Contents

- [In focus](#)
- [Background](#)
- [PHM comment](#)

In focus at WHA67

The processes through which WHO's expenditure budget is developed were considered at [EB134](#) (based on [EB134/10](#)) and it was decided to set up a working group and also to ask the PBAC to finalise advice to the WHA.

The Assembly will consider [A67/9](#) which is a report from the 20th PBAC meeting 14-16 May 2014 and which includes a report from the Working Group on Strategic Resource Allocation appointed at EB134. The WG met face to face during 23-24 April 2014 and a report arising out of this meeting was submitted to the PBAC20. [A67/9](#) includes the report of the WG plus the advice of the PBAC.

The road map, following the PBAC consideration, looks like this:

- report to the Assembly through the PBAC - May 2014;
- DG to rec to EB135 that the membership of the WG be extended - May 2014;
- revise the paper based on input from the PBAC – June 2014;
- 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;
- face-to-face meeting of the Working Group to review the models developed and provide guidance to the Secretariat – following the Regional Committee sessions;
- briefing to Member States ahead of the Executive Board in January 2015;
- the Secretariat presents a draft proposal on the new strategic resource allocation to the Programme, Budget and Administration Committee – January 2015.

Background

WHO's expenditure budgeting has been widely criticised (most recently by the IET in [EB134/39](#)) for lack of transparency and wide inconsistencies between policy priorities and expenditures.

Decision [WHA66\(9\)](#) requested the Director-General to propose a new strategic resource allocation methodology, starting with the programme budget for 2016–2017, utilizing a

robust, bottom-up planning process, realistic costing of outputs, and based on clear roles and responsibilities across the three levels of WHO. The Secretariat's submitted a paper to the EB in January ([EB134/10](#)) which reported on progress and sought broad guidance for further work by the Secretariat.

The paper circulated for the EB ([EB134/10](#)) reviews the three proposed 'pillars' underpinning strategic resource allocation (SRA): bottom up budgeting, costing of outputs, clarity of responsibilities between levels and then identifies four 'broad operational segments' to be funded (country cooperation, global public goods, administration and management, and emergencies) and explores some considerations specific to resource allocation to these 'segments'.

The PBAC and the EB judged that EB134/10 needed further development before WHA67 and in [EB134\(4\)](#) a working group was mandated to consider SRA further and an extra day was scheduled for the PBAC in May to finalise advice to the Assembly.

[A67/9](#) includes the report of the WG plus the advice of the PBAC.

Notes from EB134 debate [here](#).

PHM Comment

The document [EB134/10](#) did not touch upon the sequence of choices involved in expenditure budgeting; at what levels in which hierarchies the comparative merits of bottom up expenditure proposals are to be determined and aggregated and then transmitted for higher level consideration.

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

The identification of the different 'operational segments' implies that somehow funding will be allocated within segments; the paper did not speak to how allocations across 'segments' might be determined. There was no consideration of how 'segments' map onto 'categories'.

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. The WHO should be deciding of the allocation of financial resources based on priorities defined by the WHA.

The practice allowing donors and MSs alike to choose the programs they are interested to fund, has created unhealthy competition between programs, units, departments and clusters. Competitive fund raising has led to competition for visibility between programs - units, departments and divisions - which distorts resource allocation and acts as a barrier to collaboration and rational resource allocation.

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

11.6 Financing of administrative and management costs

Contents

- [In focus at WHA67](#)
- [Background](#)
- [PHM comment](#)
 - [Priorities](#)

In focus at WHA67

The Assembly will consider [A67/10](#).

At one level this item is about a simple matter of accounting. How will administrative and management and leadership and governance costs be accounted for?

Behind this is the question whether certain donors will continue to get away with donating to program costs but not picking up the associated administrative and infrastructure costs. It is necessary to have this issue dealt with at the Assembly to strengthen the hand of the Secretariat in dealing with these donors and insisting on them paying the PSC (program support cost) and POC (post occupancy charge).

Looming behind both issues is the continued freeze on assessed contributions, the refusal of most voluntary contributors to contribute to the core voluntary account (not earmarked), and the continuing donor chokehold over WHO.

Background

With the freeze on assessed contributions (AC), the proportion of WHO expenditure coming from ACs has fallen to around 23%. ACs as a source of funds has gone increasingly to fund administration, management, infrastructure etc. The total cost of 'Administration and Management' (A&M) and 'Stewardship and Governance' (S&G) in 2012 was in excess of the total revenue from ACs. WHO has sought to raise administration and management funds from voluntary contributions (VCs) through the 13% admin charge on VC funded programs (from 1981); the 'post occupancy charge' (POC), from 2010 which is an admin charge on VC funded staff; and the Real Estate Fund.

However, many donors have been reluctant to pay the admin charge or the POC and, in the past, have negotiated discounts, thereby increasing the burden on AC funds.

If ACs are used solely to cover the admin costs that the donors do not pick up, it means that the governing bodies have absolutely no discretion with respect to implementing programs which have GB support but which do not attract donor support.

In May 2013 Member States considered the findings of the study by an external consultant on the funding, budgeting and monitoring of management and administrative costs at WHO ([EBPBAC18/3](#) and [EB133/2](#)). The report to the Board in Jan 2014 ([EB134/11](#)) described the approach proposed to Member States in relation to the recommendations of the consultant.

The report before the Assembly [A67/10](#):

- defines and delineates the category Administrative and Management (A&M) costs for budgeting and accounting purposes;
- defines and delineates the category Stewardship and Governance (S&G) costs for budgeting and accounting purposes;
- proposes that A&M costs be budgeted and accounted for in the five functional categories of the program budget so that their link to program functions is clear, and so the requirement on donors to fund these costs (in relation to donor supported programs) is clear although they would also be reported separately;
- proposes that S&G costs remain in Category 6 as a separate category;
- reviews possible mechanisms for raising A&M funds;
- recommends a policy approach to be applied from 2016-17:
 - S&G to be funded by ACs so as to be secure from uncertainties with respect to VCs
 - Infrastructure and admin costs to be categorised as direct (identifiably related to a program) and indirect
 - direct infrastructure and admin to be funded as a component of program funding whether AC funded or VC funded
 - indirect infrastructure and admin to be aggregated within a 'programme support cost budget' across all five functional categories and differential charges applied to voluntary contributions depending on complexity and earmarking (non earmarked funds to be exempt from the charge).

Notes from EB134 debate [here](#).

PHM Comment

It is a known strategy to starve an institution for funds and compromise its capacity to work in order to use the institution's inactivity to justify decreasing its funds further and cut its human resources until it is weakened to dysfunctionality. PHM believes that this is the strategy currently used against the WHO.

PHM recognizes that clear accounting categories are necessary. But PHM does not believe that bureaucratic responses will solve the structural roots of the lack of resources to cover core costs. The fixed costs of the organization seem high today due to the choking of the organisation's overall budget. The system proposed in the Secretariat Report is complicated and will carry significant transaction costs. As long as assessed contributions freeze, the refusal of most MSs to contribute to the core untied account and donor dependence are not addressed, other interventions will be cosmetic in nature.

In 2012 although more than half did not make voluntary contributions (104), very few contributed to the core voluntary account (19/104), out of which close to half (8) contributed less than 50% of their total voluntary contribution to the core account. 87 MS made no voluntary contribution at all. (More details [here](#). Revenue data from [A66/29 Add.1](#) and [A66/30](#).)

MSs have a duty of care. However, donors are today getting away with tied contributions which do not cover for administrative costs of programs. Donors are using the existing competition for funding to negotiate such 'preferential' treatment, thereby deepening the tension between fixed costs and programmatic costs.

PHM urges MSs to increase assessed contributions immediately. PHM urges MSs to increase their voluntary contributions and redirect them to core instead of tied purposes. PHM urges MSs to direct the Secretariat to ban the practice of giving 'discounted' program funding options to donors, as a matter of funding policy.

12.1 Global strategy and targets for tuberculosis prevention, care and control after 2015

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- [Background](#)
- [Summary of debate at EB134](#)
- [PHM comment](#)
 - [Priorities](#)

Focus at WHA67

A new global strategy and targets for tuberculosis prevention, care and control after 2015 ([A67/11](#)) will be considered at the May 2014 World Health Assembly.

Background

In 1993 WHO declared tuberculosis (TB) as a global public health emergency. Many actions were implemented (the DOTS strategy; inclusion of tuberculosis-related indicators in the Millennium Development Goals; development and implementation of the Stop TB Strategy that underpins the Global Plan to Stop TB 2006–2015; and adoption in 2009 of resolution [WHA62.15](#) on the prevention and control of multidrug-resistant tuberculosis and extensively drug-resistant tuberculosis) in order to accelerate the global expansion of tuberculosis care and control.

In May 2012, [WHA](#) requested the DG to submit a comprehensive review of the global tuberculosis situation and to present a new strategy for the post-2015 period to the Sixty-seventh World Health Assembly in May 2014, through the Executive Board. The process to prepare this has involved consultation across a wide range of partners.

The draft global strategy submitted for consideration by the WHA67 ([A67/11](#)) differs in minor respects from the version considered by the EB ([EB134/12](#)). These differences are noted in para 2 of A67/11.

Document [A67/11](#) provides an outline of the achievements, challenges and approaches needed in controlling the TB epidemic and a comprehensive description of the draft post-2015 Global TB strategy. Such a strategy, with its vision (a world free of TB), goal and targets (divided into milestones for 2025 and targets for 2035), is articulated around three pillars and their relative components, and four principles. Finally the document gives suggestions on how adapting and implementing the strategy as well as measuring progress and impact through a list of key global indicators, and envisages the role of the WHO Secretariat.

In January 2014, through Resolution [EB134.R4](#), the EB recommended that the WHA67 adopt the Strategy.

See also the [MSF Crisis Alert](#) and [petition](#) launched on 24th March (World Tuberculosis Day). See [MSF India criticisms](#) of poor regulation of TB treatment in India and the consequent increase in drug resistance.

Summary of discussion at EB134

Second meeting, section 1 and fourth meeting, section 1 (document EB134/2014/REC/2).

The majority of the Member States endorsed the new strategy and its multisectoral approach although they recognised that the proposed targets are ambitious and need to be more flexible and tailored to the different country's situations.

MSs appreciated the emphasis in the document on the importance of the social determinants in shaping the epidemics. South Africa stressed the role of the labour market, while others mentioned the role of poverty, environment, lack of education as well as access to basic services. On the same issue, Colombia called for a strong political commitment and the importance of social protection. Also the Universal Health Coverage was envisaged as a tool to improve the disease prevention and control.

The EU, along with others MSs, raised the problem of the vulnerable at-risk groups including migrants, homeless and people with HIV/AIDS. The issue of the HIV coinfection and the challenge of the multidrug resistance were common concerns across the interventions.

Speaking about new drugs and diagnostic tools, many MSs agreed on the need for more investment on R&D while Germany criticised that the document for specifically citing the GeneXpert technology without being more generic or citing other tests.

Among the civil society speakers, the International Pharmaceutical Federation, renewing its commitment, highlighted the role of the pharmacists as front providers and the need to systematically engage them in the fight against TB.

Both MSF and the PHM recalled the importance of developing new medicines and making them available to the poorest in-need populations by decreasing the price and delinking it from the innovation.

The EB considered a draft resolution ([EB134_CONF4Rev1](#)) proposed by Brazil and cosponsored by many MSs. See text of final resolution [EB134.R4](#).

Fuller report of debate [here](#)

PHM comment

PHM recognizes the importance of TB on WHO's agenda. TB remains a significant public health concern and that long-lasting solutions remain elusive.

The Global Strategy, like many before it, is largely focused on diagnosis, treatment and cure: diagnostics, medicines, research and innovation. Yet despite decades of similar programmes, strategies, and chemotherapies, TB persists.

The failure of earlier programs to control TB is rooted in poverty and marginalisation and not merely the lack of access to medication, poor compliance, or insufficient TB surveillance. The persistence of TB is linked to the failure to address social determinants of health.

The draft Global Strategy mentions key social determinants of health, but falls short of creating mechanisms that will promote substantive changes, changes that will tackle the root causes of disease spread, such as urbanisation and marginalisation, migration and detention in refugee camps, unhealthy working and living conditions, and gross health inequities.

PHM appreciates the multi-sectoral approach in the Global Strategy but it will depend on achieving the integration and patient centredness rather than on vertical programmes. Integration means coordinated health systems that simultaneously involve multiple programmes, stakeholders, and initiatives across a continuum of concerns, from health services to socioeconomic factors.

Under the first pillar of the strategy (integrated patient-centred care and prevention), emphasis is given to diagnosis and treatment, but among the illustrative indicators, only one focuses on the treatment success rate and there is no target to be reached.

Inadequate attention is given to health system strengthening, which should be at the core of this strategy. Strengthening health systems is a means of addressing key barriers and mitigating TB: access to drugs and treatment, drug shortages, and treatment interruptions. These, together with good and timely diagnostic tests, are essential where multi-drug resistant TB is prevalent.

PHM further believes that TB programmes (prevention, management, and care) should be fully in the public sector, have a strong primary health care orientation, be integrated with specialised care, and be supported by proper technical backing.

While having a specific pillar on research and innovation is valuable, not enough attention is paid to innovative mechanisms that ensure new and adequate sources of funding and the affordability of products. This can be done through the scaling-up of public investment models that delink innovation from pricing. The document on the Global Strategy fails to mention the ongoing battle to ensure access to diagnostics and medicines that are patented and priced beyond the reach of the most vulnerable populations.

Understandably, the focus of WHO has been on the 22 high-burden countries (22 countries that account for 80% of TB cases in the world). Yet equal attention should be given to countries that may not have a high total number of cases but have a high incidence rate. Of the top ten countries with the highest incidence rates, only three are among the 22 high-burden countries: South Africa, Zimbabwe, and Mozambique. A long-term control strategy reaching beyond the 2035 target of 90% reduction in TB incidence rate requires a strong focus on both the high-incidence rate countries as well as the high-burden countries.

While governments are being called upon to do their part in ending the TB epidemic, a higher level of accountability should be expected of drug industry actors. In this context, the bold policies promised in the second pillar should work towards:

- Opposing unjustified and excessive profits on critically needed tools and medicines;
- Patent law reforms which provide for the full utilisation of TRIPS flexibilities and ensure affordability;
- Opposing corporate practices that trap governments - and public budgets - into expensive long-term contracts (e.g. exorbitant prices for warranty on GeneXpert modules).

As regards implementation, PHM recognises that the timely collection and efficient use of data can still be improved. While waiting for countries to set up their surveillance systems, a few massive surveillance studies should be funded together with other stakeholders and non-State actors in order to get information on the magnitude of epidemics, including information on the real cure rate the programmes are able to achieve.

Most importantly, policies and strategies have to explicitly address the issues of fundamental human rights, ethics, and equity. PHM calls upon WHO to work with the UN Human Rights Council to sponsor public hearings and strengthen the accountability of funders, managers, and service providers.

PHM policy priorities

PHM calls upon the WHO to:

- Ensure that the Global Strategy, its goals, methodologies, and targets, are anchored in health systems strengthening and is premised on integration: coordinated health systems that simultaneously involve multiple programmes, stakeholders, and initiatives in a continuum of concerns, from health services to socioeconomic factors;
- Ensure that the implementation of this new plan is embedded in a Primary Health Care-oriented approach and with inter-sectoral and participatory processes;
- Work with the UN Human Rights Council to explore ways of using human rights instruments to ensure the right to health, including the right to diagnosis, treatment, and care; and to promote new accountability structures that will prevent barriers to access and treatment;
- Encourage and support Member States to uphold the right to health by avoiding TRIPS-plus provisions being advanced through bilateral trade agreements and commercial lobbying; and to implement patent law reforms that promote access to affordable treatments;
- Ensure that the goals, strategies and targets adopted as part of this Global Strategy properly address the social and political context within which vulnerable groups (migrants,

indigenous peoples, and refugees, among others) are exposed to TB and are able to access preventive protections and appropriate treatments; and

- Promote innovative mechanisms for the funding of research and development of diagnostic and therapeutic products that delink research and development funding from patent-based monopoly pricing.

12.2 Global vaccine action plan

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Focus at WHA67

The main focus of discussion is likely to be the report of the SAGE group on the implementation of the Global Vaccine Action Plan. The executive summary of this report is included in [A67/12](#).

The report comments upon and offers recommendations regarding:

- data quality improvement
- improving immunisation coverage
- disease eradication and elimination
- country ownership

Background

In May 2012, the Sixty-fifth World Health Assembly endorsed the global vaccine action plan (presented in [A65/22](#)) in resolution [WHA65.17](#) and requested the Director-General to monitor progress and report annually on progress. In May 2013, the 66th World Health Assembly noted the Secretariat's proposed framework for monitoring, evaluation and accountability (presented in [A66/19](#)) as well as the process for reviewing and reporting progress under the independent oversight of the Strategic Advisory Group of Experts on immunization ([SAGE](#)).

The executive summary of the Global Vaccine Action Plan Assessment report prepared by the SAGE group was provided to the EB in January in Document [EB134/13](#). (See also summary report of [SAGE November 2013 Meeting in WER](#).)

The report included in A67/12 is the same document as was considered by the EB134 in Jan 2014 with minor updates in paras 9, 12 & 15.

Summary of EB debate

This item was considered by the EB in its second meeting, on Monday 20 Jan.

All Member States welcomed the report by the Secretariat and stressed the need for accurate immunization coverage and disease surveillance data as critical tools for making better programmatic decisions. Panama warned that immunisation policy should be based on cost-effective analysis taking into account the long term sustainability and the issue of equity. Myanmar asked for the recommendations elaborated by the Strategic Advisory Group of

Experts on immunization to be seriously taken into account and properly reflected. Iran, on behalf of EMRO, spoke about the importance of strengthening capacity at national level. Cuba and Brazil highlighted the importance of supporting countries in implementing national immunisation programs who are fully self sufficient and where vaccines are produced locally. Maldives highlighted the challenge of the procurement of vaccines in countries who completely depend on imported vaccines, with a particular focus on the problem of costs.

PHM ([here](#)) raised the issue of opportunity costs which should be central in decision making at the national level. MSF asked for vaccine price data openly and publicly available since it is unclear what the majority of countries pay. MSF stated also that “it is critical that the cost of vaccines be monitored, particularly for countries that will lose GAVI support, and the middle income countries that increasingly cannot afford these high costs”.

After the discussion, the EB took note of the report.

More detail of EB debate [here](#).

PHM Comment

Assessment of GVAP

This SAGE report (as included in [EB134/13](#) and slightly amended in [A67/12](#)) does not bear a close relationship to the [Global Vaccine Action Plan](#) (endorsed by WHA65) nor to the [Framework for Monitoring, Evaluation and Accountability](#) (endorsed by WHA66). The comments are useful nonetheless.

The six strategic priorities of the GVAP are:

1. All countries commit to immunization as a priority
2. Individuals and communities understand the value of vaccines and demand immunization as both their right and responsibility
3. The benefits of immunization are equitably extended to all people
4. Strong immunization systems are an integral part of a well-functioning health system
5. Immunization programmes have sustainable access to predictable funding, quality supply and innovative technologies
6. Country, regional and global research and development innovations maximize the benefits of immunization

The Action Plan included, at Annex 2, a listing of Stakeholder Responsibilities (individuals and communities, governments, health professionals, academia, manufacturers, global agencies, development partners, civil society, media and the private sector). This could provide a useful tool for accountability but it seems to have been ignored in the preparation of this report.

The Framework included a summary of proposed indicators as an annex with indicators corresponding to the goals of the Action Plan. The Action Plan also included a set of strategic objective level indicators.

The current report from SAGE (EB134/13 in [A67/12](#)) discusses:

- Data quality improvement
- Improving immunization coverage
- Accelerating efforts to achieve disease eradication or elimination
- Enhancing country ownership of national immunization programmes

It makes no reference to the six strategic priorities, the stakeholder responsibilities, or either set of indicators (of goals and of strategic objectives).

It seems unusual to present an assessment report which bears such an indirect relationship to the Action Plan being assessed. It is surprising that there was no mention of this disconnect in the EB debate.

Data quality and information systems reflect the functioning of health systems generally

The current report focuses on data quality and information systems, emphasising disease surveillance, vaccine coverage (administrative data and sero-surveys) and adverse event monitoring. The report urges countries to improve and technical agencies to provide support in relation to information technologies and surveillance methodologies.

It would be useful to explore in more depth the barriers to effective collection, collation, analysis of information and dissemination of the knowledge emerging. WHR 2000 pointed out that information systems are part of health systems generally. WHO continues to fudge its definition of Universal Health Coverage, allowing for the possibility that private financing and private provision could deliver UHC. The SAGE group discussed the public private fragmentation of health systems as a barrier to consistent delivery and, of course, to the collection and reporting of surveillance data. “SAGE noted that in some places the increasing involvement of the private sector in primary health care is not being coordinated with public sector efforts. In particular, differing vaccination schedules in the private and public sectors is a matter of concern”.

The importance of data quality was widely supported during the EB debate including: the need to explore in more depth the barriers to effective collection, collation, analysis of information and dissemination of the knowledge emerging; need to follow expenditures as well as coverage; and the importance of unpacking sub-national coverage patterns.

Comprehensive disease control also depends on integrated health systems

The SAGE meeting also discussed “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 useful insight does not find its way into the report now before the EB and was lacking also in the proposed “Framework for monitoring, evaluation and accountability” discussed during the last WHA ([A66/19](#)). Indeed, the proposed indicators did not locate the vaccination targets within any wider picture of disease control.

The importance of integrating vaccination within more comprehensive disease prevention was emphasised by Azerbaijan in the EB debate.

Immunisation coverage

The SAGE Report points out that coverage rates in most countries remain below the coverage target for DTP3. The report hints at problems with vaccine supply. Technology transfer with a view to the development of domestic vaccine production is mentioned in the Action Plan, although not in the proposed indicators.

The notes of the SAGE November meeting also suggest that policies to expand the role of the private sector in primary health care delivery may also be contributing to shortfalls in coverage. In many countries, DTP vaccination is free or subsidized, and therefore not attractive for the private health sector. Large-scale progression of privately provided health care leaves large white areas on the public health map and needs to be recognised as a negative factor for public health programs such as vaccination. The GVAP highlights within country inequalities in coverage, in particular the gap between rich and poor and urban and rural coverage.

Prices, procurement and technology transfer

During the debate in the EB134 many countries (Panama, Lebanon, Azerbaijan, Suriname, Albania, Maldives, Colombia, Bangladesh) spoke about the cost of vaccines and in particular the burden on MICs which do not benefit from GAVI support (and the LICs who ‘graduate’ out of GAVI support).

MSF spoke cogently about the need for WHO to track prices and to explore ways of reducing the cost burden.

In the EB debate Cuba, Brazil and Indonesia highlighted the benefits of local production which means closer attention to technology transfer.

The GVAP doesn't consider the lack in manufacture capacity in LMIC that deepens inequalities on access and distribution of vaccines. The effect of this is the most pronounced in the case of new vaccines.

Several MSs including Lebanon and Maldives, spoke about supply chain issues. This also needs systematic attention.

PHM underlines the need for technology transfer and more diffuse production of vaccines worldwide in order to assure equal access.

Disease eradication or elimination

WHO needs to make a clear distinction between “eradication” and “elimination”. Both terms are well defined, but are being used often interchangeably by authors and agencies. Eradication refers to ending the disease condition by eradicating its causative agent (ie smallpox), while elimination refers to control the disease but not necessarily extinguishing the causative agent. It would be useful for the WHO Secretariat to clarify again the criteria on which eradication or control are identified as the policy goal.

PHM highlights the problems caused during the so called “endgame” of polio eradication in Pakistan currently. PHM wants to draw also attention to the enormous cost in the last phases of an eradication campaign, although health benefits are acknowledged. Guinea Worm eradication in South Sudan is another example of increased social cost of eradication, especially in conflicts situations.

The report from SAGE reviews progress in relation to polio, neonatal tetanus, measles and rubella/congenital rubella syndrome (CRS) and urges countries to do better.

It maybe that SAGE needs to reflect upon its own advice in the case of rubella/CRS. In countries (regions and classes) where infant rubella immunisation remains at a low coverage level there is a 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 the 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 there is a risk that the WHO strategy of eliminating rubella in childhood by immunization in the 2nd year of life will actually increase CRS.

Country ownership, local estimates of cost effectiveness and opportunity costs

In EB134/13 the SAGE emphasises the importance of national ownership and country-specific decision making through the establishment of National Immunisation Technical Advisory Groups (NITAGs) but comments in par. 18 that: “many countries are still lagging behind in the establishment of such a body [NITAGs], 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”.

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, including the one against infection with human papillomavirus (HPV). As recognised in para 19 of the [Action Plan \(WHA65\)](#): “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.” This principle is reiterated in Document [A67/33](#) circulated in support consideration of Item 15.7 on health intervention and technology assessment.

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. Notwithstanding WHO continues to offer recommendations such as “Rotavirus vaccines should be included in all national immunisation programmes and considered a priority, particularly in countries with a high RVGE-associated fatality rates, such as in south and south-eastern Asia and sub-Saharan Africa” ([WER, 2013, 88, 49-64](#)). 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 representatives to provide support and dispassionate advice to countries on these issues.

Community confidence

The Action Plan emphasises public trust in relation to so-called ‘vaccine hesitancy’. There is a note in the Action Plan indicating that Strategic Advisory Group of Experts working group on vaccine hesitancy will develop a definition of vaccine hesitancy and recommend specific questions from surveys (either existing or new) to fully formulate this indicator. The proposed indicator does not appear in the Monitoring Framework and is not referred to in this Report.

We note the controversy over the safety of pentavalent vaccines which in essence is an example of the broader challenge of effective post marketing surveillance. Despite the

assurances of SAGE regarding the safety of pentavalent vaccines there is a risk that concern in this respect will continue to grow. PHM urges WHO to give increased priority to the development of rigorous post-marketing surveillance systems including adverse events following immunisation.

Concerns about the safety of pentavalent vaccines in South Asia have not been well handled. The expert group commissioned to review adverse events following immunisation in Sri Lanka in 2008 raised the possibility that immunisation in association with malnutrition could contribute to adverse events that would not be seen in adequately nourished populations. This does not appear to have been followed up.

Community confidence requires more than public relations. It requires regulators to ensure that vaccines are not introduced without systems and research to ensure safety and effectiveness in real life settings. Studies of efficacy require appropriate statistical power at country level using clinically meaningful endpoints (rather than surrogate endpoints with uncertain relations to clinical outcomes). Community confidence requires mandatory systematic post marketing surveillance including phase 4 trials. 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.

PHM advocacy priorities

- Health system strengthening is key to effective vaccine delivery and improve the quality of the health information system.
The action plan should focus on primary health care and a social determinants of health approach instead of focus its attention on data systems quality
- Data quality: the WHO should explore in more depth the barriers to effective collection, collation, analysis of information and dissemination of the knowledge emerging.
- Country ownership and opportunity cost: all countries need to have sovereign control over their immunisation programmes that should respond to priorities and needs of local populations and should not be imposed (especially by marketing strategies). The efficacy and cost effectiveness of vaccines and immunization campaigns have to be evaluated case by case in the specific country context
- The building of disperse manufacture capacity ie technology transfer of vaccine production should be addressed as an important measure for countries to put into practice sovereign control on National Immunization Policy.
- Community confidence and vaccine hesitancy are related to pharmacovigilance

12.3 Hepatitis

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In focus at WHA67

WHA67 will consider the Secretariat report on viral hepatitis ([A67/13](#)) which is a revised version of the document ([EB134/36](#)) considered by the EB in January. The Assembly will also consider a draft resolution ([EB134.R18](#)) which at the conclusion of the EB134 still had some text bracketted.

The draft resolution is quite comprehensive and includes reference to a range of key issues.

The one issue which remains bracketted concerns the nine core interventions listed in the [WHO/UNODC/UNAIDS Technical Guide](#) (and referred to in United Nations General Assembly [UNGA resolution 65/277](#), subparagraph 59(h)) which include: needle and syringe programmes; opioid substitution therapy and other drug dependence treatment; HIV testing and counselling; antiretroviral therapy; prevention and treatment of sexually transmitted infections; condom programmes for injecting drug users and their sexual partners; targeted information, education and communication for injecting drug users and their sexual partners; vaccination, diagnosis and treatment of viral hepatitis; and prevention, diagnosis and treatment of tuberculosis.

Some countries do not want to see these interventions listed or referenced in the Assembly resolution. It seems likely that the debate in the Assembly will canvass the full range of issues of relevance to the prevention and treatment of viral hepatitis but there will be some focus on the above issue.

Since the EB there has been global controversy over the prices that Gilead proposes to charge for its brand of sofosbuvir. This debate will be revisited at the WHA also.

Background

The Health Assembly adopted in 2010 the resolution [WHA63.18](#) urging Member States to support an integrated and cost-effective approach to the prevention, control and management of viral hepatitis; the Secretariat then established the [Global Hepatitis Programme](#) to help implementing such approach. Afterwards, in 2012 the Secretariat issued a [Framework for Global Action on Viral Hepatitis](#).

The Secretariat report submitted to EB134 (Document [EB134/36](#)) outlined the current epidemiological situation of viral hepatitis and the challenges needing to be met in order to fulfil

the objectives of the Framework and improve the health of patients infected with viral hepatitis. This report plus a resolution developed initially by Brazil (and co-sponsored by Egypt, Colombia, Costa Rica, Moldova and other MSs) and provided the focus of the debate at EB134 (Jan 2014).

A drafting group at EB134 worked on a draft resolution for WHA67 for several days but was not able to reach a final agreement (see remaining brackets in [EB134.R18](#)). The sticking point was whether the resolution should make explicit reference to harm reduction interventions needed to prevent spread among people who inject drugs.

Following the EB a controversy exploded over the prices Gilead proposes to charge for sofosbuvir (Sovaldi). Sofosbuvir is a pipeline hepatitis C (HCV) drug that has been recommended for treatment by the US FDA and EMA. HCV is a significant public health issue for low- and middle-income countries, that are home to 90% of the 185 million people who are infected with HCV. Although HCV is curable, high drug prices make treatment inaccessible, leaving people at risk for liver cancer or liver failure. (I-MAK DOT ORG)

See:

- [Politicians add fuel to the firestorm over Gilead's hep C drug pricing \(24 March\)](#)
- [Universal hepatitis C treatment is possible with patent reform and competition \(Antigone Barton March 18\)](#)
- [Grounds for opposing patent applications on sofosbuvir \(I-Mak.Org, 21 March\)](#)
- [New treatments for Hepatitis C, a great hope for people infected with HCV, but accessible for how many? \(MDM, March 17\)](#)
- [Pharma refuses to ensure access to lifesaving Hepatitis C treatment at global meeting \(TAG, Feb 28\)](#)
- [The price of one Sovaldi® pill equals a month of minimum old-age pension \(ACT UP Paris, 25 Feb\)](#)

Report of EB134 debate [here](#).

PHM comment

The draft resolution ([EB134.R18](#)) appears to be comprehensive and includes reference to all of the key issues mentioned in the debate, including:

- national strategies including other sectors
- integrating hepatitis prevention and treatment within comprehensive health system approach
- appropriate preventive strategies for all forms of viral hepatitis including hep A
- surveillance and monitoring
- hep B birth vaccination
- food and drinking water safety
- needs of indigenous groups
- need for technical guidance on cost-effective program strategies

- prevention and care in association with IVDU
- infection control in health care including single use equipment
- safe blood and tissue donation
- promoting access to treatments and diagnostics
- full use of TRIPS flexibilities to overcome access barriers
- call to other international agencies (eg GF, UNITAID, PEPFAR) to include viral hepatitis in their programs

The outstanding issue with respect to the draft resolution is whether the resolution should mention the nine core interventions listed in the [WHO/UNODC/UNAIDS Technical Guide](#) (and referred to in United Nations General Assembly [UNGA resolution 65/277](#), subparagraph 59(h)) and in particular, whether it should note that these are important components for both hepatitis B virus and hepatitis C virus prevention, diagnosis and treatment, and that access to them remain limited or absent in many countries of high hepatitis B virus and hepatitis C virus burden.

The nine core interventions include: needle and syringe programmes; opioid substitution therapy and other drug dependence treatment; HIV testing and counselling; antiretroviral therapy; prevention and treatment of sexually transmitted infections; condom programmes for injecting drug users and their sexual partners; targeted information, education and communication for injecting drug users and their sexual partners; vaccination, diagnosis and treatment of viral hepatitis; and prevention, diagnosis and treatment of tuberculosis.

This is a comprehensive list of harm reduction strategies but it appears that certain countries are uncomfortable about direct references to some of these strategies. In these circumstances it does not seem necessary to include such direct references.

PHM policy priorities

The nine core interventions are well established as harm reduction principles in relation to the health risks of IVDU. Harm reduction saves lives. However, it would be unfortunate if the debate over harm reduction was allowed to prevent the more immediate issue of drug pricing and the importance of the use of the TRIPs flexibilities.

PHM notes that OP2(9) requests the DG to:

“support Member States with technical assistance in the use of trade-related aspects of intellectual property rights (TRIPS) flexibilities when needed, in accordance with the global strategy and plan of action on public health, innovation and intellectual property;”

It would seem possible that certain countries are insisting on the inclusion of unnecessarily direct references to particular harm reduction strategies in order to set up a negotiating scenario in which OP2(9) is removed or heavily qualified as a condition for removing the direct references to those specific harm reduction strategies.

PHM urges MSs to give priority to the issues of drug pricing and access and exercise discretion as to whether there is a need for specific references to all harm reduction measures.

13.1 Follow up Political Declaration of UNGA on NCDs

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In focus at WHA67A

The Assembly will consider [A67/14](#), [A67/14 Add.1](#), and [A67/14 Add.2](#).

[A67/14](#) includes:

- the final report on progress in implementing the action plan for the global strategy for the prevention and control of noncommunicable diseases 2008–2013 ([WHA61.14](#)); see Annex 1 of [A67/14](#), (for noting);
- a report on WHO's role in the preparation, implementation and follow-up to the United Nations General Assembly comprehensive review and assessment in 2014 of the progress achieved in the prevention and control of noncommunicable diseases (as provide for in the Political Declaration ([UNGA A/66/L.1](#)) of 2011); a high level UNGA event is planned for late 2014; consultations with regions, MSs and other stakeholders are in train; a zero draft outcome statement will emerge from these consultations which will be adopted as amended in the UNGA event; see paras 11-15 of [A67/14](#) and also [A67/14 Add.2](#);
- a report on work towards the terms of reference for the global coordination mechanism on the prevention and control of noncommunicable diseases (as 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](#)); see recommended terms of reference in Appendix 1 of [A67/14 Add.1](#);
- proposed terms of reference, divisions of tasks and potential members for the United Nations Inter-Agency Task Force on the Prevention and Control of Non-communicable Diseases (responding to both para 3.5 of [WHA66.10](#) and para 4 of the EcoSoc Resolution [UN EcoSoc E/RES/2013/12](#)); see Annex 2 of [A67/14](#) with appendix, and Annex 3 of [A67/14](#); and
- proposed indicators for the WHO global action plan for the prevention and control of noncommunicable diseases 2013–2020 (as required by para 3.4 of [WHA66.10](#)); this project applies the global objectives and targets from the Global Monitoring Framework ([A66/8](#)) to the country level; the EB endorsed the nine action plan indicators in [EB134\(1\)](#); see Annex 4 of [A67/14](#).

See also Annex 5 of [EB134/14](#) which lists the reports which will have to be produced by the WHO Secretariat over the next several years and proposes a sequencing of these reports (see paras 6-11 of [EB134/14](#)).

Earlier documents

WHO has been receiving reports and adopting resolutions on NCDs for many years. There are a few of these which are still useful and relevant to the present discussion. These plus the more recent UN ones include:

[WHA56.1](#) (2003) WHO Framework Convention on Tobacco Control (convention attached),

[WHA57.17](#) (2004) Global strategy on diet, physical activity and health (strategy attached),

[WHA58.26](#) (2005) Public health problems caused by the harmful use of alcohol (Refers to [A58/18](#) Secretariat report),

[WHA61.14](#) (2008) Prevention and control of noncommunicable diseases: implementation of the global strategy (Refers to [A61/8](#) Action Plan),

[WHA62.1](#) (2009) Global action plan for the prevention of avoidable blindness and visual impairment 2009–2013 (refers to [A62/7](#)), now superseded by WHA66.4 ([see](#)),

[UNGA A/66/L.1](#) (2011) Political declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases,

[WHA66.10](#) (May 2013) Follow-up to the Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases (Refers to

- [A66/8](#): Draft comprehensive global monitoring framework and targets for the prevention and control of noncommunicable diseases; and
- [A66/9](#), & [A66/9 Corr.1](#)) Draft action plan for the prevention and control of noncommunicable diseases 2013–2020 (Replaces A61.14, 2008)

[UN EcoSoc E/RES/2013/12](#) (October 2013) United Nations Inter-Agency Task Force on the Prevention and Control of Non-communicable Diseases.

EB134

Report of EB debate [here](#).

PHM Comment

Our comments on the specific issues canvassed in this report follow below but two general comments apply to the package as a whole.

The package as a whole is weak in relation to social determinants of health and equity and includes virtually nothing on trade/investment. There is very little about the regulatory challenges involved in creating healthy environments.

WHO appears to have placed itself as secretariat to two parallel coordinating mechanisms; one mandated by the ECOSOC resolution, the other by the 2013 WHA resolution A66.10. The terms of reference both are similar. Despite the ECOSOC structure putatively promoting coordination across UN agencies, it is still mostly about sharing information and best practices with member states.

Final report on progress in implementing the action plan for the global strategy for the prevention and control of noncommunicable diseases 2008-2013

Annex 1 of [A67/14](#) provides an overview of achievement against the six objectives in the implementation of the Global Strategy 2008-2013 as authorised in [WHA61.14](#). The report is for noting.

The Secretariat is to be congratulated for the significant achievements reported. In many countries and in many populations NCDs represent a serious disease burden and cause of premature death, illness and disability

PHM remains concerned that the focus on risk factors should not obscure the policy actions needed to 'make healthy choices easy choices', including effective and binding regulations at the global as well as national levels to ensure healthy food environments. While progressing the agenda on NCDs WHO appears to have reduced its commitment to action on the social determinants of health.

PHM is concerned that political support for action on NCDs may have been facilitated by the interest of big pharma in the market possibilities of risk factor control while the lack of effective action on the SDH may have been held up by the opposition of the food and beverage industries to such action.

These influences underline the importance of ongoing attention to conflict of interest and managing the risk of improper influence in relation to NCDs policy making.

WHO's role in the United Nations General Assembly review and assessment in 2014 of the progress achieved in the prevention and control of noncommunicable diseases

Para 65 of [UNGA A/66/L.1](#) of 2011 requests

the Secretary-General, in collaboration with Member States, WHO, and relevant funds, programmes and specialized agencies of the United Nations system to present to the General Assembly at the sixty-eighth session a report on the progress achieved in realizing the commitments made in this Political Declaration, including on the progress of multisectoral action, and the impact on the achievement of the internationally agreed development goals, including the Millennium Development Goals, in preparation for a comprehensive review and assessment in 2014 of the progress achieved in the prevention and control of non-communicable diseases.

Paras 11-15 of [A67/14](#) and [A67/14 Add.2](#) report on preparations for the high level UNGA event planned for late 2014.

A meeting of WHO Member States on 1 May 2014 adopted a draft resolution to be submitted for UNGA consideration regarding the proposed review and assessment.

The draft resolution takes into its purview consultations already in train with regions and MSs and proposes further consultations with civil society and the private sector before June 2014 (!) with a view to developing a zero draft outcome statement which would be considered in the UNGA event.

PHM is concerned that the time lines for this proposed consultation are far too limited. It may be possible for big pharma, big food and big beverage to generate input for the consultation but it will be impossible to achieve significant engagement with the range of civil society organisations with an interest in NCDs control.

Terms of Reference for a Global Coordination Mechanism on the Prevention and Control of Noncommunicable Diseases

Appendix 1 of [A67/14 Add.1](#); conveys the recommended terms of reference for the global coordination mechanism (GCM/NCD) which emerged from the second formal meeting of Member States in Geneva from 23 to 25 April 2014 (pursuant to paragraph 3 of Executive Board decision [EB134\(1\)](#)) and as 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](#).

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.

Terms of Reference for UN Inter Agency TF

Annex 2 of (with appendix) and Annex 3 of [A67/14](#) present the terms of reference, divisions of tasks and potential members for the United Nations Inter-Agency Task Force on the Prevention and Control of Non-communicable Diseases as recommended by the formal meeting of WHO MSs held 13 and 14 November 2013.

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.

However the proposed terms of reference (Annex 3) 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.

Two meetings a year will be scheduled. A Secretariat housed in WHO will be created, but there are no details of staffing and the costs will be borne by WHO (para 19, p.26). Who will pay? What are the opportunity costs? Why are not other UN agencies pooling funds for the Secretariat's staffing? Only two other UN agencies (UNICEF and UNFPA) have committed to lead on certain work areas aligned with the six objectives of the WHA GAP (WHA 66/9).

Para 30 speaks 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).

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.

Guidance on trade and investment rules should be included in the terms of reference for the UN IA Task Force. 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.

Development of a Limited Set of Action Plan Indicators for the WHO Global Action Plan

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.”

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

The goal, principles and objectives are good. The ‘voluntary global targets’ should be included in the post-2015 development goals. None of the global targets, however, address social determinants of health (lifestyle drift) 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 etc. are brought into policy and program development at the national or 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 throughout the GAP, 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?

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.

PHM notes the lack of any reference to conflict of interest in the NCDs space in the GCM/NCD terms of reference 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.

Timelines for consultation on zero draft for UNGA event

The time lines for the proposed consultation around the UNGA event are far too limited. It may be possible for big pharma, big food and big beverage to generate input for the consultation but it will be impossible to achieve significant engagement with the range of civil society organisations with an interest in NCDs control.

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.

Guidance on trade and investment rules should be included in the terms of reference for the UN IA Task Force. 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.

Health system strengthening

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

IP reform

PHM urges continuing attention to the reform of the prevailing IP system that constrains access to treatments for NCDs, such as cancer and autoimmune diseases, to rich country populations.

Neglect of the prevention and control of Type 1 diseases

Increasing attention to the prevention and control of NCDs should not obscure the continuing high rates of Type 1 diseases (communicable disease, 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.

a13.2 Maternal, infant and young child nutrition

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In focus at WHA67

The Assembly will consider document [A67/15](#) and decision [EB134\(2\)](#) from January 2014.

However, the discussion of maternal, infant and young child nutrition (MIYCN) at WHA67 will be largely structured around Decision [EB134\(2\)](#) from January 2014.

Para 1 of the Decision simply records the fact that EB134 noted the reports provided by the Secretariat on:

- progress in implementing the **Comprehensive Implementation Plan** on maternal, infant and young child nutrition (presented in [A65/11](#), and endorsed in 2012 in resolution [WHA65.6](#)); see report in [A67/15](#);
- the global strategy for **infant and young-child feeding**, endorsed in 2002 in [WHA55.25](#) (see report in [EB134/15](#)); and;
- the status of national measures to give effect to the **International Code** of Marketing of Breast-milk Substitutes ([WHA34.22](#) (1981) and subsequent resolutions); see report in [A67/15](#).

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) would have WHA67 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.

(Following the adoption of the Comprehensive Implementation Plan (and global targets) in May 2012 ([A65/11](#)) a draft set of indicators ([indicators 2012](#)) for monitoring implementation and outcomes of programmes was prepared. In response to further consultations requested by Member States, a revised set of indicators was developed ([here](#)) and discussed in informal consultations with Member States and United Nations bodies, civil society and the private sector. An online consultation, held from 7 September to 10 October 2013, indicated that consensus could only be reached on a set of outcome indicators (it appears that there was disagreement regarding *process* and *intermediate outcome* indicators). 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.)

Para 2(c) of Decision [EB134\(2\)](#) would have the WHA67 request the DG to support the development of risk assessment and risk management tools to deal with **COI in global nutrition** policy (as referred to in para 3(3) of [WHA65.6](#)) for WHA69. See para 14 in [A67/15](#) which seeks further guidance from the Assembly “on the work expected from WHO on the management of engagement with the private sector by individual Member States”.

Para 2(d) of the Decision would have the WHA67 note progress on **inappropriate promotion of foods for infants and young children** and request the DG to proceed with this work and develop recommendations for MS national policies in time for WHA69. (Responding to the concern expressed in para 1(4) in [WHA63.23](#) and the request in para 3(1) of [WHA65.6](#) regarding inappropriate promotion of foods for infants and young children, Annex 2 of [A67/15](#) reports on the advice received from a Scientific and Technical Advisory Group ([STAG full report here](#)) convened by the DG. The STAG advice was largely about criteria for defining ‘inappropriate promotion’ rather than what to do about it.)

Para 3 of Decision [EB134\(2\)](#) deals with **WHO’s involvement in the Second International Conference on Nutrition (ICN2)**, cosponsored by WHO and FAO and scheduled for 19-21 November 2014 (and taking into account WHO’s rules for dealing with NSAs). (More about ICN2 in paras 19-21 in [EB134/15](#) and on the [WHO website](#).)

- 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.

More about ICN2 according to [FAO](#), [WHO](#) and [UNSCN](#).

The Assembly is invited to note the report ([A67/15](#)) and consider the draft decision recommended in decision EB134(2), in particular providing further guidance on

- (a) next steps to develop risk assessment and management tools for conflicts of interest in nutrition;
- (b) the global monitoring framework on maternal, infant and young child nutrition;
- (c) next steps to address the inappropriate marketing of complementary foods; and
- (d) a Member State-driven process to develop an outcome document for the Second International Conference on Nutrition.

See report of EB134 debate [here](#).

PHM Comment

Progress with implementation of Comprehensive Implementation Plan

Although it is positive that many global initiatives have been deployed since the comprehensive implementation plan on maternal, infant and young child nutrition (http://www.who.int/nutrition/topics/WHA65.6_annex2_en.pdf) the recent estimates in the Report ([A67/15](#)) are evidence of the slow progress and even stagnation on this issue which is increasingly acknowledged as fundamental to maternal, newborn and child health and development.

In view of the increased role of SUN in the Comprehensive Implementation Plan, appropriate management of conflicts of interest within SUN will be necessary. This includes internal decision making within SUN as well as in the multi-stakeholder platforms in countries.

Progress in breastfeeding (target 5) is not known and is likely to be minimal. The same applies in the case of the prevalence rate of wasting, where no progress has been noted since 1990.

Therefore, in order to accelerate the progress towards adequate nutrition for mothers and children worldwide, several actions should be stressed with greater emphasis and urgency:

Breastfeeding is a major safeguard against early child malnutrition and needs to be protected, promoted and supported as part of comprehensive primary health care. Enabling breastfeeding also requires laws governing workplace practice, statutory paid rest periods at work and an acceptance of breastfeeding including in public. In the latter regard, WHO should assume a stronger advocacy role towards governments and engage purposively with the ILO regarding relevant labour rights.

Regarding the implementation of the International Code of Marketing of Breast-milk Substitutes, we comment on the lack of progress in many countries. With “only 37 (22%) (of countries) passing comprehensive legislation reflecting all the recommendations of the Code” (Para 33), this issue clearly needs to receive greater attention, in order to promote the inclusion of the Code in Member States’ legislation and policies. Given the ongoing challenges of implementing the Code, it is likely that a more robust and regulatory approach to food trade, including retail and marketing will be necessary.

While Para 17, about Action 2 (To include all required effective health interventions with an impact on nutrition in national nutrition plans) mentions that “in China and Viet Nam (the Secretariat) is collaborating in the design of culturally-sensitive ready-to-use therapeutic foods and in agricultural demonstration projects aimed at dietary diversification”, this appears to be restricted to only a few countries and should be widened. We feel that this matter deserves more emphasis and wider discussion. Crucial to making nutritional interventions sustainable in local contexts is to align their implementation with the development of health systems based on primary health care with strong intersectoral links (eg to agriculture) and community participation. Ready-to-use therapeutic foods (RUTF) should be restricted to treating severe acute malnutrition and the use of such preparations designed for ‘moderate’ malnutrition or to ‘prevent’ malnutrition opposed. Local RUTF production should be accelerated, with a focus on sustainability by promoting awareness of their basic ingredients so users may cultivate or purchase them in the future. Therefore, the risk should be underlined of the indiscriminate use of RUTF in undermining breastfeeding and the use of suitable home-prepared and/or local foods be encouraged, as cited among the criteria for inappropriate promotion of foods for infants and young children (Annex 2).

In Action 4 (To provide sufficient human and financial resources for the implementation of nutrition interventions), Para 25, we support the inclusion in high concentration of community health workers to strengthen community and home-based nutritional interventions in the context of primary health care and integrated health systems.

Inappropriate marketing of complementary foods

The Health Assembly (in para 3(1) of [WHA65.6](#)) requests the DG “to provide clarification and guidance on the inappropriate promotion of foods for infants and young children cited in resolution [WHA63.23](#), taking into consideration the ongoing work of the Codex Alimentarius Commission”. However, there is also a need to open up Codex decision making to reduce the dominance of the food corporations.

Annex 2 of [A67/15](#) refers to the position paper prepared by a Scientific and Technical Advisory Group convened by the DG. This paper lists five criteria for judging promotion to be inappropriate. These criteria are elaborated upon in the [STAG Technical Report](#) to WHO. Actually the [full meeting report](#) is a more useful overview of the promotion and marketing of complementary foods for infants and young children.

As recognised in Decision [EB134\(2\)](#) the next step is to identify the steps that MSs can take to regulate the inappropriate marketing of foods for infants and young children in many countries.

PHM urges the DG to seek ‘clarification and guidance’ in this matter from IBFAN.

Implementation of the International Code of Marketing of Breast-milk Substitutes

The implementation of [WHA34.22](#) (1981) and subsequent resolutions is too slow. Industry interference has prevented full implementation in many jurisdictions.

It is time to convert the voluntary code into binding regulations.

The global monitoring framework

It is concerning that the online consultation of September / October 2013 was unable to agree on process or intermediate outcome indicators as proposed in the [Secretariat paper](#) prepared for the September October consultations. Final outcome indicators are important but managing and steering implementation will require meaningful process and intermediate outcome indicators.

Food security and healthy nutrition reflect the outcomes of a complex mix of:

- productive and distributive arrangements in agriculture, trade, retail and marketing which are themselves shaped by the processes of globalization, international trade agreements, and
- local specificities regarding land, climate (including climate change), demography (eg urbanisation) and economic development; all of which take place in the context of
- political and commercial relations of power and interests (including the role of transnational food corporations and big power manoeuvring over trade relations; which are conducted within
- global institutions including the WTO, WEF, G20, OECD, UNCTAD, FAO, WHO, etc.

The extended set of indicators suggested for the Global Monitoring Framework must include indicators of some of the above determinants since it is clear that the long-term achievement of

adequate nutritional status for mothers and children rests on consistent action to tackle its structural determinants.

Concerning the report on Annex 1 of [A67/15](#), we support the disaggregation of indicators by socioeconomic group, sex and ethnicity. This is important to identify and address inequalities.

We note the focus on prevalence measures in Annex 1 and the use of absolute numbers for targets 1 (Para 3) and 4 (Para 6) in the body of the report. Some of these data will also need to be presented as proportions, to allow comparability between regions and over time.

Including the adoption of the concept of food sovereignty will require the adoption of additional indicators.

Conflicts of interest in nutrition

Resolution [WHA65.6](#) (May 2012, adopting the Comprehensive Implementation Plan on Maternal, Infant and Young Child Nutrition) requested the DG “to develop risk assessment, disclosure and management tools to safeguard against possible conflicts of interest in policy development and implementation of nutrition programmes consistent with WHO’s overall policy and practice”.

Para 14 of [A67/15](#) affirms that conflicts of interest “must be managed both by the Secretariat and by Member States”.

(This discussion of COI in WHO’s work runs parallel to a similar discussion taking place in relation to the SUN Movement (Scaling Up Nutrition). SUN is a public private partnership which provides funding support to participating countries for a range of nutrition related initiatives (see about SUN [here](#)). A toolkit for managing COI within the SUN movement was published recently ([here](#)) and a consultation around COI in SUN (funded by the Gates Foundation) is underway ([here](#)). SUN is supported financially by the rich country donors, Gates and the World Bank ([see](#)). It includes in its Business Network all of the biggest transnational food corporations ([see](#)). If corporate control and the globalisation of food supply are contributing to over- and under nutrition globally, then there is a profound conflict between the constitution of SUN and its avowed purposes. This ‘COI’ does not appear to be encompassed by the current COI project.)

Conflicts of interests are ubiquitous. In relation to WHO the risk is that WHO decision making is perverted through the power of certain stakeholders to promote interests and purposes which run counter to the vision and mandate of WHO. Managing this risk requires transparency (that sufficient information about all participants is publicly shared to enable conflicts of interest to be widely known). However, managing the risk also requires accountability procedures which deal directly with the various modalities of influence that different stakeholders are able to exert.

Ongoing consultation processes should be fully transparent through publication on the website of all submissions, and clear identification and disclosure of conflicts of interest, including institutional as well as individual ones. A specific case concerns the representation in certain of WHO’s technical advisory panels of the largest producer of infant formula.

The envisaged industry participation in the development and implementation of the comprehensive implementation plan carries significant risks of perversion of decision making. Industry representatives commonly argue against regulatory strategies and assert that 'voluntary' codes and corporate social responsibility are sufficient. This proposition runs counter to historical experience.

GAIN and ISDI

In resolution [EB134.R20](#) the EB

2. DECIDES to admit into official relations with WHO the [Global Alliance for Improved Nutrition](#) after satisfactory consideration of the information concerning the nature and extent of the links between the Global Alliance for Improved Nutrition and the global food industry, after confirmation of the closure of its Business Alliance, and the position of the Global Alliance for Improved Nutrition with regard to its support and advocacy of WHO's nutritional policies, including those on infant feeding and the marketing of complementary foods;

3. DECIDES to discontinue official relations with [...] [International Special Dietary Foods Industries](#), [...].

The acceptance of GAIN was a controversial decision. See:

IBFAN Press Release 25 Jan 2014 regarding the renewal of IBFAN's status with WHO and the decision not to grant the International Special Dietary Foods Industries (ISDI) official status ([here](#))

IBFAN Press Release from 19th January: GAIN, a wolf in sheep's clothing, will try once again to enter WHO's policy setting process ([here](#))

Times of India article: WHO accepts GAIN as NGO after it ends global food industry alliance ([here](#))

Draft outcomes document for the Second International Conference on Nutrition

The draft outcomes document and the outcomes generally of the ICN2 are of particular importance. It is critical that civil society networks are fully engaged in the development of the final outcomes document.

Food sovereignty and healthy nutrition reflect the outcomes of a complex mix of: commerce and trade, local contingencies, political economy and global institutions. These parameters are poorly represented in the Draft Zero circulated by FAO and WHO. The importance of food sovereignty as distinct from food security must be acknowledged. This has been resisted by FAO in the past. Food security, which could mean total reliance on imported foods, is not the same as food sovereignty which emphasises democratic national control over

food production (including farm policy and industry policy) and food importation including trade agreements and ‘development cooperation’.

Food security **as it is promoted in the United Nations initiative Scaling Up Nutrition – SUN** is a misleading concept as it is concerned with the protection and distribution of existing food systems but does not question the areas of conflict and the social and political determinants leading to socio-economic stratification as major cause for mal/undernutrition. The concept of food security catalyzes investments from the private sector instead of empowering local and traditional food-production on the base of food sovereignty.

Reasons for malnutrition are complex and intersectional originating in the way how power relations in the political and economic sphere shape food production. The private sector is given a key role to play in developing sustainable agriculture and delivering nutrition for all people (<http://www.fao.org/food/nutritional-policies-strategies/icn2/en>). Following the premise “that governments cannot feed people on a sustainable basis”, the alliance urges to deal with “structural conditions which constrain development”. It encourages the private sector to “continue to innovate and invest in the food and agriculture sector”. Although it mentions local business development it underestimates the effects of aggressive marketing policies and the dominance of global companies threatening local food production. Private Public Partnerships as approved in SUN weaken the regulatory role of the state without recognizing the existing unequal power relations in the field of food and nutritional security and tend to follow business and managerial logics oriented towards profit. There is a risk that it is neglected that unregulated markets absent of democratic control fail to provide access to healthy foods especially for poor populations (in both North and South), creating the ‘double burden’ of over/undernutrition. This problem should be on the Agenda of the Second International Conference on nutrition.

ICN2 has the potential to set new directions and reinvigorate the movement for equitable, healthy and ecologically sustainable food systems globally. This potential must be realised. The Conference outcomes should highlight the long-term goals of peace, the right to health, the right to nutrition, food sovereignty, social justice and health equity.

In this context we challenge the WHO/FAO/UNICEF to recognize people’s need for food as a human right, as Human Right to Proper Food and Nutrition (Recine&Beghin_201140306_InternationalNutritionAgenda_En). The alliance should put a rights based account to the center of the nutrition related policy-strategies. That is to say food is more than just a commodity based on the global economy and on liberalized agricultural markets. The Human Right to Proper Food and Nutrition based on the principle of food sovereignty outlines the right of people to define their own food systems and obligates the international community to implement this right.

A promising step towards the right direction is the new FAO Strategy for Partnerships with Civil Society Organizations, which aims to strengthen ties with social movements, member-based organizations and NGOs that share the goal of eradicating hunger, malnutrition and food insecurity.

See excellent comment from Elisabetta Recine and Nathalie Beghin [here](#) for the Brazilian National Council on Food and Nutrition Security. Excellent overview of global food policy initiatives and five key principles which must be realised in the outcomes of ICN2.

PHM advocacy priorities

The International Code of Marketing of Breast-milk Substitutes should be applied by regulation

Global monitoring framework should include indicators of food sovereignty and measures of global food trade related to food security and food sovereignty.

Under COI (Conflict of Interest) in global nutrition, MS will note that the SC on NGOs has not re-accredited ISDI ([International Special Dietary Foods Industries](#)) but has accredited GAIN (Global Alliance for Improved Nutrition)

Encourage opening up of the STAG (Scientific and Technical Advisory Group) process to civil society input including consideration of strategies to control inappropriate promotions of food for infants and young children. Not to rely solely on a code. Need regulation and therefore need legal and trade advice.

Preparation of the draft outcomes statement for ICN2 should include the active participation of CS. Likewise the orgainb

nisation of the conference itself and follow up of its recommendations.

Expose and counter the role of Big Food and Big Beverage in preventing the prevention of NCDs. Argue for binding regulation; voluntary agreements do not work.

Ban the use of antibiotics as growth promoters in animal husbandry and support such industry restructuring as will be needed to adapt to animal production without antibiotics as growth promoters.

Increased scrutiny of decision making within SUN (Scaling Up Nutrition) and in particular, the management of conflict of interest of industry partners.

13.3 Disability

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- [Background](#)
- [PHM comment](#)

In focus at WHA67

The Assembly will consider ([A67/16](#)) and will be asked to endorse the Global Disability Action Plan included in that report.

Background

In resolution [WHA66.9](#) the Director-General was requested, inter alia, to prepare a comprehensive WHO action plan on disability with measurable outcomes.

The draft WHO global disability action plan 2014-2021 was presented to the EB in Jan 2014 as [EB134/16](#). The Board was requested to note the report and provide guidance on the draft action plan, which was to be submitted to the sixty-seventh World Health Assembly. World Health Assembly in May 2014.

Report of debate at EB [here](#).

PHM comment

The draft action plan has been widely discussed and is widely supported. It presents a comprehensive and strategic package.

We hope to see further consideration in research and monitoring of the need to disaggregate by type of impairment. People with intellectual and psychological impairments do worse across a whole range of issues including health, employment and discrimination. There is some recognition of diversity in terms of age and sex but not type of impairment. We underline the importance of rebalancing research expenditure, in particular, towards areas such as reproductive and sexual health which have been relatively neglected.

Certain disabilities constitute rich market opportunities, others less so. Strong leadership and accountability are needed to prioritize people's needs and not those of the big corporations.

In the prevailing globalised culture values and identity are to some extent driven by the productivity of people. This is expressed in cultural norms and attitudes, in income levels and in the design of public policy such as social protection and health care programs.

WHO should make sure that access to health care is guaranteed for disabled people and that health care itself is not a factor of exclusion and/or stigmatization.

WHO should address the cultural discounting of people with disabilities and the material expressions of such attitudes.

13.4 The management of autism spectrum disorders

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- [In focus](#)
- [Background](#)
- [Highlights from EB discussion](#)
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In focus at WHA67

The Assembly will consider a report on autism spectrum disorders ([A67/17](#)) and the draft resolution ([EB133.R1](#)) forwarded from EB133.

The report included in [A67/17](#) differs from the report considered by EB133 ([EB133/4](#)) in one respect only which concerns the alleged relationship between vaccination and autism. Para 6 in the new report is unequivocal: "Available epidemiological data conclusively prove that there is no evidence of a causal association between measles, mumps and rubella vaccine and autism spectrum disorders".

Background

Autism appeared on the EB agenda in May 2013 at the request of a Member State accompanied by document [EB133/4](#) prepared by the WHO Secretariat. A draft resolution was tabled at EB133 and was adopted (as [EB133.R1](#)) for consideration by WHA67 in May 2014.

The Secretariat report commences with an overview of ASD including clinical features, diagnostic criteria and epidemiology. Under the heading 'key challenges and priorities' the report considers: policy leadership and governance (policy, funding, consultation); service development (early detection in PHC services, community based services, holistic approach, inclusion in all sectors of social practice, training staff, reducing disparities in access); prevention (especially against stigmatisation); and information, evidence and research.

The report reviews various considerations of ASD at the international level including:

- UNGA Resolution [A62/139](#) (2008) which designates April 2 as World Autism Awareness Day;
- the [Dhaka Declaration on Autism Spectrum Disorders and Developmental Disabilities](#) which arose out of a meeting in Dhaka in July 2011 which was organised by a number of groups including SEARO of WHO, the Government of Bangladesh (with the personal involvement of Prime Minister, Sheikh Hasina Wazed), academics and Autism Speaks (a US based international advocacy group);
- Resolution [SEA/RC65/R8](#) adopted (Sept 2012) by the SEARO RC of member states in the SEA Region of WHO;
- UNGA Resolution [A67/82](#) (2013) on the socioeconomic needs of individuals, families

and societies affected by autism spectrum disorders, developmental disorders and associated disabilities.

In addition the report refers to discussions in EURO on the care of people with intellectual disability, and EMRO on maternal, child and adolescent mental health.

The draft resolution to be considered by the WHA67 urges member states to recognise ASD, develop appropriate policies, support research and public awareness, increase the capacity of services systems, move away from long stay facilities, provide appropriate support to families and carers and a range of other steps. The draft requests the DG to take a range of useful steps in conjunction with stakeholders and member states; to implement resolution [WHA66.8](#) on the comprehensive mental health action plan 2013–2020, as well as resolution [WHA66.9](#) on disability; and to continue to monitor the situation.

Report of EB debate [here](#).

PHM comment

Autism is a major social challenge globally. Decent service systems (including informal networks of support) can make a big difference to the lives of people who are affected by autism, including families. Community attitudes to autism, intellectual disability and disability generally are very significant determinants of the material and emotional support that families can access. There are deep uncertainties about the causes of autism and the best ways of diagnosing and managing it (in its wide range of manifestations).

The main locus of responsibility for dealing with ASDs lies at the national level although research into causes, prevention and management is international. WHO has a role in providing policy and technical advice and helping to raise the profile of the spectrum for governments, researchers and funders and public.

The Secretariat report which was submitted to the EB133 in May 2013 and forwarded to WHA67 for adoption, provides very broad guidelines for member state governments to consider in developing national and sub-national policies around autism. WHO could play a significant role in providing policy advice for governments and service providers; supporting access to training; supporting public communication; and encouraging research and development.

However, it is not self-evident that a medically dominated body such as WHO is the central repository of expertise in relation to ASDs. The [mhGAP program](#) within the Secretariat (where responsibility for ASD lies) has traditionally had a biomedical psychiatric orientation which clearly has limitations in approaching this group of disabilities. A search for autism on the WHO website produces more references to the alleged association with vaccination than any substantive technical papers on ASDs. WHO's roots in the biomedical paradigm might constitute something of a limitation in its ability to support MSs in relation to ASDs. The lack of budget provision and dependence on donor funding is a further limitation.

It appears that [Autism Speaks](#), a philanthropic civil society advocacy organisation based in the US, has played a significant part in putting autism more firmly on the public agenda, nationally

(in the US) and internationally, since 2005.

13.5 Psoriasis

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- [PHM comment](#)
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In focus at WHA67

The Assembly will consider the Secretariat report dealing with psoriasis ([A67/18](#)) and a draft resolution from EB133 ([EB133.R2](#)) asking MSs to raise awareness of psoriasis and to support “World Psoriasis Day” and asking the DG to include information about psoriasis on the WHO website.

This item should be treated as a test case for the willingness and capacity of the Secretariat and the MSs to apply appropriate risk management protocols in their dealings with Non-State Actors, in this case NSAs which are formally NGOs but in fact have close relations with big pharma.

It is conceivable that the appearance of this item on the EB agenda reflected improper influence and the Secretariat should have alerted the Board members to this possibility and undertaken appropriate due diligence.

More below.

Background

Psoriasis appeared on the agenda for EB 133 (May 2013) without any note as to how it got there.

The Secretariat report (considered by the EB as [B133_5-en.pdf](#) and now forwarded to the WHA as [A67/18](#)) provided an overview of psoriasis, still with no account of how it came to be on the agenda, nor why the Secretariat felt the need to prepare a report.

A draft resolution, entitled 'World Psoriasis Day', appeared and was discussed under this item. This draft resolution appears to have been urgent because it had not been posted in the papers for the EB. The draft resolution, was adopted as [EB133.R2](#) after some discussion. The resolution urges the Assembly (at WHA67) to:

- encourage Member States to engage further to raise awareness of psoriasis, in particular through activities held every year on 29 October; and
- requests the DG: to draw attention to psoriasis, including a global report, and include information about psoriasis on the WHO web site, aiming to raise public awareness of psoriasis.

Report of EB133 debate [here](#).

PHM comment

The handling of this item by the EB and the Secretariat was surprising. During an EB session when 28 member states plus the DG had spoken about the risks inherent in WHO's relationships with 'non-state actors' the Board adopted a resolution which at the very least should have triggered an alert.

Psoriasis is a common and sometimes debilitating disease and in some cases may be associated with discrimination. There may be benefits (to sufferers) of awareness raising activities, including access to information and reduced stigma. There is always a need for more research. However...

It seems that the appearance of this item and resolution on the EB133 agenda was driven at least in part by the International Federation of Psoriasis Associations (IFPA), funded by drug companies, working with the International Association of Patients' Organisations (IAPO), which is also funded by drug companies. The IFPA appears to be the main sponsor of World Psoriasis Day.

World Psoriasis Day is sponsored by the International Federation of Psoriasis Associations which is supported by, among others, Pfizer, Novartis, Lilly, Leo, Celgene and Abbvie. Over half of the 42 member associations with active websites (at 13 June 2013) acknowledged drug company support on their websites (including Abbvie, Leo, Janssen, Pfizer, Abbott, Ducray, La Roche-Posay, Pierre Fabrie Dermatologie, Janssen-Cilag). At least one national association acknowledged receiving drug company support to the value of several million USD per year.

It is reasonable to speculate that the involvement of drug companies in supporting the IFPA (and its member associations) and their support for World Psoriasis Day is in some degree a marketing strategy directed to expanding the global market for psoriasis treatments.

The Psoriasis Association (UK) (whose representative spoke under the IAPO banner) is supported by grants from AbbVie, Dermal Laboratories Ltd, Forest Laboratories Ltd, Galderma (UK) Ltd, LEO Pharma, MSD and T&R Derma. IAPO also receives extensive support from pharmaceutical companies, individually and through the IFPMA.

The amount of funding provided to psoriasis associations and the IFPA is not trivial. The only website which actually indicates the size of the sponsorships is the USA which has one donor of >\$1m and several others providing six figure donations.

It is reasonable to speculate that the involvement of drug companies in supporting the IFPA (and its member associations) and their support for World Psoriasis Day are part of a marketing strategy directed to expanding the global market for their products.

Drugs for treating psoriasis are among the top revenue-earning drugs in the world. Three of these – adalimumab (marketed by AbbVie as Humira), etanercept (marketed by Pfizer as Enbrel), and infliximab (marketed by Janssen as Remicade) – have been identified by Forbes in

2012 as being among the top ten revenue earning drugs ever. The combined sales of just these three products was US\$ 25 billion. These high revenues have, in large measure, been sustained by IP protection and monopoly pricing. All these drugs are extremely expensive and are therefore inaccessible in LMICs; on average, a year's treatment with any of these drugs cost about \$20,000. These drugs are also key to the healthy profit margins of the companies involved; Humira sales accounted for 51.7% of the revenues of AbbVie in the first quarter of 2013.

There was no reference during the EB debate to the possibility that World Psoriasis Day serves two separate functions: first, awareness raising for the benefit of sufferers and second, expanding the market for drug company products. There was no discussion of the criteria which might be involved in evaluating the benefits to psoriasis sufferers of WHO giving its name in support of World Psoriasis Day, weighed against the reputational risks to WHO of supporting a drug company marketing strategy.

It is painfully ironic that this item was on the same agenda as the item about WHO's involvement with non-state actors. In fact several of the countries who spoke about managing conflicts of interest in the debate over WHO's relations with NSAs (including Panama, Argentina and Monaco) actually supported this resolution without reference to any conflict of interest.

PHM believes that WHO's de facto endorsement of an event planned and organised by an organisation such as the IFPA, which is funded and promoted by the pharmaceutical industry, would contravene WHO's stated position regarding engagement with non-state actors.

The WHO has a legitimate role in raising awareness regarding psoriasis, in promoting access to treatment and in harnessing research capacity towards finding better remedies. However, WHO's endorsement of the World Psoriasis Day cannot be seen as an appropriate way to pursue these objectives.

Following the EB, PHM wrote to DG expressing concern about the origins of the resolution and the reputational risks to which the EB was exposing WHO. See [PHM letter \(130712\) to DG](#) here. As of March 2014 no reply had been received.

PHM policy priorities

The Assembly should not agree to endorse World Psoriasis Day.

The Assembly should ask the DG to investigate the provenance of the original agenda item and report to the EB.

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

Two distinct issues will be considered under this heading at the Assembly: monitoring the health related MDGs and health in the post 2015 development agenda. It is not clear how the chair of the session will structure the discussion. They are dealt with separately here.

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

In focus at WHA67

This is largely a reporting item, reporting on the achievements and shortfalls of the MDGs and related goals and targets. The Assembly will be presented with [A67/19](#) which corresponds to the report which was submitted to the EB (as [EB134/17](#)).

Background

At the EB134 an earlier version of Secretariat report [A67/19](#) was considered. This report reviewed progress towards achievement of the health-related Millennium Development Goals 1, 4, 5 and 6 and their specific targets. In addition, the report describes progress towards reducing child mortality through the prevention and treatment of pneumonia and diarrhoea, reducing perinatal and neonatal mortality; prevention and management of birth defects; achieving universal coverage of maternal, newborn and child health care, and progress achieved in the follow-up of the recommendations of the Commission on Information and Accountability for Women's and Children's Health.

[A67/19](#) provides an overview of trends in global health, structured largely around the MDGs but including a review of health trends in relation to a range of previous WHA resolutions.

Report of EB debate [here](#).

PHM Comment

The picture revealed in the report provided to the EB under this heading ([EB134/17](#)) 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.

The technical strategies described in [A67/19](#) are necessary and beneficial. However 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.

PHM policy priorities

The MDGs did not address these structural distortions and injustices which are worse now than they were then. Development has to be more than charity for the poor while the other side of the coin remains untouched.

Development is not a process which only applies to poor countries. The rich countries desperately need to be ‘developed’ if we are to live harmoniously on this fragile blue planet.

14.1B Health in the post-2015 development agenda

In focus at WHA67

This is largely an information item as the centre of action has moved to NY and the UN.

The Assembly will consider [A67/20](#) which is a revised version of document [EB134/18](#) which was presented to the EB in January.

Document [A67/20](#) describes the process of intergovernmental negotiations towards a post-2015 development agenda:

- UNGA [resolution 66/288](#) 'The future we want' (July 2012)
- the report of the [UN system task team](#) (2012)
- the report of the [high level panel of eminent persons](#) (2013)
- the thematic consultation [on health](#)
- the [report](#) of the thematic consultation on health
- the [UN Secretary General's Action Agenda](#) (June 2013)
- the [outcome document](#) from the Special Event on progress towards the MDGs in New York in September 2013

The report to the EB discussed 'the emerging narrative on health' in the post-2015 development agenda including reference to the discussions on health in the post-2015 development agenda by the WHO regional committees in 2013.

While the decision making has moved to the UN, many delegates will wish to take the floor to share their perspectives on the post 2015 agenda. There may be some debate around the argument that UHC ought to be given particular prominence in the post 2015 agenda. The Secretariat may argue that MOHs can still lobby ministers of foreign affairs to ensure 'health is well placed' in the post 2015 development agenda.

Summary of the EB debate

Many countries have recognized the importance to include health in post-2015 agenda, the necessity not to abandon the current MDGs, and the leadership of WHO in the post 2015 agenda. While all the countries agreed under these points of view, the proposed solutions to achieve these goals still show some differences.

The majority of Member States stressed the importance of Universal Health Coverage as the principal means to achieve health development goals and to achieve health equity; there is also a wide acknowledgement of the necessity to tackle social determinants of health, in very general terms, but few practical inputs were taken into consideration.

Interestingly, only the Union of South American Nations (UNASUR) has explicitly underlined the opportunity to consider the post 2015 agenda as a chance to promote a new development

paradigm through new economic, social and environmental policies.

The whole discussion was centred on the future strategies and objectives to be reached, but a very superficial analysis was conducted on the reasons which had led to the failure of the current MDGs.

PHM recalled the importance to pay attention to the need to reform the economic and political architecture in order to eradicate poverty, as proclaimed by the current MDGs. Trying to reform the post 2015 without taking these aspects into consideration, as well as other determinants of health, put the basis for an healthiest approach which refuse the analyze the real distal causes of health and disease mainly driven by neoliberalism.

Another issue of concern was the priority given to Universal Health Coverage as a goal per se; we believe that UHC could diverts the attention from building inclusive and participatory Health Systems, with a strong commitment on SDH, to mere service delivery systems poorly linked to populations needs. Moreover, the issue of UHC could potentially open the way to dangerous public-private partnerships which have been repeatedly associated to a raise in health inequalities.

More detailed report of EB discussion [here](#).

PHM Comments

While we appreciate the process and progress towards developing a health framework for post-2015, we wish to raise the following critical concerns on the subject.

Paragraph 21 in [A67/20](#) states that “the key message of the High-level Panel’s report is to eradicate extreme poverty in the context of sustainable development by 2030.” The five transformative changes proposed by the Panel (“leave no one behind; put sustainable development at the core; transform economies for jobs and inclusive growth; build peace and effective, open and accountable public institutions for all; and forge a new global partnership”) do not seem to tackle the root causes of poverty as they are failing to address the **need to reform the global economic and political architecture**.

While WHO and the UN are trying to develop a development framework for the years following 2015 that is oriented to equality and sustainability, neoliberal economic policies currently being implemented are leading to wider inequalities: provisions being included in trade agreements to further extend patent durations are going to maintain high prices for medicines; the ‘free trade’ agreements now being debated are going to protect the interests of transnational corporations at the cost of reducing the regulatory and policy space of sovereign governments. New economic relations and new forms of regulation are therefore critical pre-requisites for addressing the challenges of today and the post-2015 era.

In paragraph 21, sustainable development is later translated to "inclusive growth". Development must not be construed solely as economic growth and industrialisation; it must include also social, cultural and institutional development. The growth fetish is destroying the human environment.

Regarding paragraph 20, we have concerns about **Universal Health Coverage (UHC)** as a flagship priority for the post-2015 agenda, especially because of the several interpretations and ambiguities of this concept.

Paragraphs 27 and 28 state that “the position of health is so far well established” and that “the prime concern for WHO at this stage is to support an approach that allows a wide variety of interests within the health sector to be accommodated as part of a single framework.” PHM would like to raise its concern on this position which appears to reflect an intersectoral competition for prominence in the post-2015 development agenda. Trying to get health into the post-2015 agenda rather than thinking about structural determinants of health and the challenges of ecological sustainability and taking a more constructive role in the overall process seems to be a somewhat **'healthist' approach**. Clearly, improving the health of world population will depend on achieving important goals in other sectors and intersectoral competition does not facilitate cooperation to this end. The final result risks to be a framework with different goals and indicators reflecting different pressures instead of one coherent set of demands coming out of a deep analysis.

PHM policy priorities

- Keep the attention of MS and civil society on the necessity to address the root causes of health inequities, such as economic and political architecture, as the only possible starting point for the redefinition of the MDGs.
- Draw the attention to the shift occurred from the “Health for all” paradigm to the “Universal health coverage” paradigm, and its implications.
- Promote goals which are directed tackling social determinants of health, with strong accountability systems.
- Reconsider the centrality of a Primary Health Care approach, rather than Universal Health Coverage approach, as the principal mean to reach the new MDGs.

14.2 Newborn health: draft action plan

Contents

- [In focus at WHA67](#)
- [Background](#)
- [PHM comment](#)
 - [Priorities](#)

In focus at WHA67

The latest draft of [Every Newborn: an action plan to end preventable deaths](#) is presented (as [A67/21](#)) to the Assembly for adoption.

Background

In document [EB134/17 Add.1](#), the Board was presented with an earlier draft of [Every Newborn: an action plan to end preventable deaths](#) – a document which it is planned to take forward the United Nations' Secretary General's Global Strategy for Women's and Children's Health by identifying actions for improving survival, health and development.

The draft action plan is based on five principles:

- country leadership
- integration
- equity
- accountability and
- innovation.

It includes three goals dealing respectively with

- Coverage and quality of care at birth
- Coverage and quality of care for newborns at risk
- Home visits and participatory group support for women and newborns

The action plan is structured around five strategic objectives

1. Strengthen and invest in care during labour, childbirth, and the first day and week of life
2. Improve the quality of maternal and newborn care
3. Reach every woman and every newborn to reduce inequities
4. Harness the power of parents, families and communities
5. Count every newborn - measurement, programme tracking and accountability

Notes from the EB debate [here](#)

PHM Comment

The [draft Action Plan](#) to end preventable neonatal deaths is comprehensive and persuasive and the Secretariat is to be congratulated on its development so far. Further work is clearly needed with respect to implementation planning. The EB134 was advised that the Plan would be subject to consultation in early 2014 and would be submitted for approval to WHA67 in May.

UHC

PHM notes the frequent references to ‘universal health coverage’ in the current draft. As commonly used by WHO, UHC is quite ambiguous. It treats mixed public / private health systems and unified public health systems as equally valid ways of delivering health care. In countries with insurance/reimbursement systems UHC treats single payer as an equally valid approaches to health care financing as multiplex stratified private insurance. It claims that UHC includes appropriate institutional support for meaningful action around the SDH.

This ambiguity is the price that WHO pays for the rhetorical support of the WB and other powerful players for the UHC slogan. However, the WB remains committed to mixed health systems and market forces in health insurance.

The evidence summarised in the draft action plan points to the need for an unified integrated health system based on the principles of primary health care. In this degree the continued prosecution of an ambiguous conception of universal health coverage does not support the achievement of the goals of the plan.

The plan notes that a seamless continuum between primary care and referral level facilities saves lives and therefore every maternity service should be able to provide basic life-saving interventions for mothers and their newborns and have uninterrupted access to transport for referral when serious complications arise. However, poor transport and communications infrastructure and inadequate emergency transport reflect countries’ underdevelopment: such problems require fundamental changes in the prevailing global economic pecking order.

The kind of health care towards which Every Newborn points will be much easier to achieve through a publicly funded and publicly delivered system, adequately funded and based on the principles of primary health care. It would be extremely difficult if not impossible to deliver in low and middle income setting through a mixed public private system, particularly with fragmented financing.

The plan asserts that ‘(e)ngaging the private sector through public--private partnerships can bring multiple benefits, including technology transfer to low-income countries, lower costs and increased availability of affordable and quality-certified essential medicines and commodities, improved quality of care and the provision of evidence-based services by private practitioners, stewardship and regulatory function of governments, provision of transport for emergency cases, stronger employer-based health services, and development of innovative technologies’. However, there is substantial evidence that an unregulated private sector can adversely affect access to essential services through user charges/fees, result in over-servicing eg excessive caesarean section rates in private health care, and irrational promotion of formula feeding in many private maternity units. The plan should be more cautious and balanced about ‘public-private partnerships’ in newborn care.

WHO should present a clearer account of the kind of UHC that can best address the global crisis in newborn health as well as the barriers associated with mixed systems and pluralistic funding.

Workforce issues

The plan calls for improved coverage and quality of care at birth. It aims by 2020 that ninety percent of women giving birth and of babies born in facilities will receive effective high-quality and respectful care that includes essential care during pregnancy, labour and following birth, with preventive care and appropriate management of complications for the mother and newborn. It notes that this will require a far larger number of midwives and other health professionals with improved knowledge, competences, motivation and work load, and availability of commodities, especially in sub Saharan Africa. It further notes that staffing levels for each facility providing maternal and newborn care need to be planned in such a way that services can be provided on a continuous basis, 24 hours a day, seven days a week. Yet there is no reference to the key factors underlying the crisis of health human resources, namely inadequate training capacity and limited budgets to employ sufficient health workers, as well as continuing migration of health professionals to rich countries. These will need to be addressed by more fundamental economic and political interventions that will allow countries to expand their health and education budgets, and by measures that are more effective than the WHO Global Code of Practice on the International Recruitment of Health Personnel and limit migration or compensate sending countries.

It is encouraging that the plan promotes '(i)vestment in creating demand for newborn care through participatory community approaches', noting that this is an essential cross-sectoral activity. Emphasis on 'community demand' is welcome and needs to be re-inserted in health policy, which currently favours 'supply-side' approaches such as limiting the definition of health systems to six supply-side 'building blocks'.

PHM policy priorities

Need to go beyond UHC rhetoric and articulate more clearly the pre conditions for the kind of well coordinated health system which this plan calls for.

14.3 Addressing the global challenge of violence, in particular against women and girls

Contents

- [In focus at WHA67](#)
- [Background](#)
- [PHM comment](#)
 - [PHM policy priorities](#)

In focus at WHA67

The assembly will consider the Secretariat report ([A67/22](#)) which is a revised version of the document considered at EB134 ([EB134/21](#)).

The Assembly will be advised of the EB decision, [EB134\(6\)](#), which noted that a draft resolution was being discussed and urged the participants to bring the discussions to a fruitful conclusion. See [B134 CONF10-en](#) for an indication of the sections of the draft which were holding up consensus.

Depending on how successfully the informal negotiations have proceeded, the Assembly may be presented with a draft resolution with no brackets and full, partial or no reference to cultural sensitivities, or with the brackets intact or it may not see a draft resolution. It would be an embarrassment to the WHO if it was unable to address effectively the problem of violence against women and girls.

Background

This item appeared on the EB Agenda, 'at the request of Member States'. The document [EB134/21](#) commences with an overview of the magnitude of the problem and a summary of what is known about settings, causes and consequences. It then underlines the importance of a strong evidence base and emphasises WHO's role in establishing this evidence base.

Under the heading 'policy background and development' the paper summarises the long list of commitments, conventions and declarations which have been formulated. See in particular, the most recent of these, the [agreed conclusions](#) adopted by the Commission on the Status of Women at its 57th Session in March 2013 for transmittal to the Economic and Social Council of the UN. Provides a broad interdisciplinary overview.

The paper then moves to a para on multisectoral action, a summary of the role of the health sector in addressing the problem, and then a review of the work which has been sponsored by or contributed to by WHO in this field.

In Decision [EB134\(6\)](#) the Board took note of the ongoing discussions among member states on a draft resolution towards a global plan of action ([B134 CONF10-en](#)) and encouraged member states to finalize this work, in order for it to be duly considered by the Sixty-seventh World

Health Assembly. (Fourteenth meeting, 25 January 2014)

PHM Comment

It seems that “cultural and religious sensitivities’ prevented the EB members achieving a consensus on this important topic. It seems that some members were not happy with the reference to legal rights either.

Despite the difficulties in opening a debate on these issues, cultural and religious aspects of gender based violence should not be avoided. Not to use religion and culture as an excuse or rationalise or legitimise violence. Emphasise the universal nature of human rights. Urge MS to criminalise forms of violence against women including sexual harassment and genital mutilation...

We urge WHO to adopt a strong human rights based approach that would provide the basis for practical legislative and constitutional processes. Acknowledging the importance of multisectoral action, this work might be done in collaboration with other UN entities such as Unifem and the UN Human Rights Council which can provide the legal framework and support.

Considering the role of the health system, the actions outlined in para 11 need to be strengthened.

Women carry a disproportionate burden of inadequate health systems. They are an extremely vulnerable population that is affected severely through limited access to essential sexual and reproductive health services in poor and rural areas. Lack of access to sexual and reproductive health services can also be considered as a form of violence against women. This is reflected in the high maternal mortality ratios in developing countries. A focus is needed on access to maternal and child health services in rural areas.

Health systems should not just deal with the immediate needs and physical consequences of violence, but also to offer educational and preventive services as well as long lasting supports for the victims of violence. As highlighted in para 10, those services should be integrated and built in collaboration with other social sectors.

Finally, there is no mention of violence against sex workers or transgender women in document [A67/22](#). Any approach implemented by WHO should include these vulnerable groups as well.

PHM policy priorities

It is important that WHO adopts a strong and meaningful resolution about this. We clearly ask WHO for a strong human rights based approach and not to allow religion and culture to be used to excuse or rationalise or legitimise violence.

14.4 Multisectoral action for a life course approach to healthy ageing

Contents

- [In focus](#)
- [Background](#)
- [PHM comment](#)

In focus at WHA67

The Assembly will consider a Secretariat report (in [A67/23](#)) which has been considered in January by EB134 (as [EB134/19](#)).

There may be an accompanying resolution submitted on the initiative of individual member states.

The Secretariat has indicated that it is working towards a comprehensive global strategy on ageing and health, followed by a global ageing and health action plan with measurable outcomes. It is not clear whether any such drafts will be circulated for the Assembly. There may be side meetings arranged as part of the consultation process.

Background

The proportion of older people in the population is increasing in almost every country. WHO has been doing good works on Active Ageing for many years; it released the [2002 Active Ageing Policy Framework](#) and many [WHO publications on Active Ageing](#). In 2002 also the [Madrid Plan of Action](#) was published. WHO is going to release the first global report on ageing and health in 2015.

The report before the Assembly ([A67/23](#)), after presenting the current situation, discusses the implications of population ageing in terms of health care policy, workforce, new social models, gender, knowledge, and leadership. The subheading “New social models” refers to the life course approach (social contribution of elders, intergenerational links and capacity building at all stages) and global trends (migration, changing roles of women, urbanisation and globalisation). Under “leadership” the paper argues that the [2002 Active Ageing Policy Framework](#) and the 2002 [Madrid Plan of Action](#) now need to be updated, rather urgently in certain respects.

Finally, the paper recommends: advocacy, a comprehensive global strategy, support to member states and knowledge generation and management.

The Assembly is invited to note the report and perhaps give guidance for future action. It appears that the authors of the report are hoping for a “comprehensive global strategy on ageing and health, followed by a global ageing and health action plan with measurable outcomes, which is needed to shape future global priorities in this area”. Presumably this will emerge in due course.

Report of EB debate [here](#).

PHM Comment

Ageing is important and all of the generalisations in this paper are supportable. However, it remains unclear how this item came onto the EB agenda lacking any reference to a previous resolution to be followed or a specific request from MSs.

There have been repeated references to the management of governing body agendas in the WHO reform papers, including in the Reform Evaluation Report of Stage II. In this regard see the discussion in [EB134/39](#) under 5.2.3 and 9.1.2; and in Section 2 of [EB134/6](#).

In commenting on the Programme Budget 2014-2015, the Independent Evaluation Team (Stage II of the evaluation process) ([EB134/39](#)) comments that the budget for ageing and health has also jumped by 125% compared to 2012-13. "While this budget, is relatively marginal (9 million USD), the increase is significant and not backed by a supporting rationale."

Health systems

This topic brings an important question, not addressed by the WHO, of how health systems will respond to aging, regarding to the massively increasing cost it entails if health systems will not be organized differently. The end of life care stays often institutionalized, with a massively increasing cost.

A strong primary health care approach utilising community health workers and community volunteers and extension of the home care is necessary. In this way the care of elderly can be affordable and could promote the wellbeing of the frail elderly while sharing the task more broadly.

Workforce

Not only is the workforce not adequately trained (as mentioned in the report), but more important, personnel trained in LMIC are being attracted away to serve the needs of the elderly in developed countries.

Physical deteriorations as market opportunity

Ageing is associated with a variety of bodily deteriorations all of which represent cost control challenges for health system managers and marketing opportunities for corporations.

In OECD countries with advanced health care systems, the over-use of medications for the elderly is widespread, reflecting aggressive pharmaceutical marketing and a 'pill for every ill' approach to medical care. It is unfortunate when this bypasses effective non-pharmaceutical treatments such as physiotherapy but can also have dangerous consequences for patients (as illustrated by the Vioxx and other scandals) as well as adding to the financial burden on Ministries of Health (MoH).

More effective strategies to regulate pharmaceutical promotions and to promote the rational use of medicines are urgently needed. Moves to non pharmacy dispensing and 'direct to consumer' advertising and sales need to be resisted.

Gender issues

The report notes that most elderly people live at home and when they need care rely in the first instance on the family. While some rich countries provide services and some cash benefits to assist families this is out of reach for poor countries. With ageing populations there is a risk that the care of frail elderly will add to the burdens carried by women who are overwhelmingly care-givers in poor countries.

Advocacy

While dealing with advocacy, the document focuses its attention on the social and economic benefits of good health. An approach based on human rights principles and effective social protection, would be more reliable and sustainable, as is proposed in the [rights-based approach to social protection in the Post-2015 Development Agenda](#) proposed by the United Nations Special Rapporteur on Extreme Poverty and Human Rights (Magdalena Sepúlveda Carmona), and the United Nations Special Rapporteur on the Right to Food (Olivier De Schutter).

14.5 Public health impacts of exposure to mercury and mercury compounds: the role of WHO and ministries of public health in the implementation of the Minamata Convention

Contents

- [In focus](#)
- [Background](#)
- [Highlights of EB debate](#)
- [PHM comment](#)

In focus at WHA67

The Assembly will consider the Secretariat report ([A67/24](#)) (previously considered by the EB as [EB134/23](#)). This report provides an overview of mercury as a health hazards and the story of the negotiation and adoption of the Minamata Convention.

The Assembly is also invited to adopt the draft resolution adopted by the Board ([EB134.R5](#)) which welcomes the Convention, urges MSs to ratify and to seek such support as is needed from the Secretariat.

The Secretariat may provide a separate report regarding priority actions for the health sector with respect to chemicals management generally.

Background

The Secretariat paper ([A67/24](#)) commences with a brief overview of sources of mercury exposures and health impacts. It proceeds to recount the negotiation and adoption of the [Minamata Convention on Mercury](#). It then reviews the role of health ministries in the implementation of the Convention and the role of WHO in implementing the Convention. The paper then reviews the management of chemicals more broadly and the need for stronger collaboration between the health and the environment sector.

Finally the paper notes that the Secretariat proposes to consult member states regarding priority actions for the health sector with respect to chemicals management.

The Board adopted [EB134.R5](#) which includes a draft resolution for the Assembly to consider appreciating the signing of the Convention and urging delegates to encourage their governments to ratify. (At the time of the Board meeting only one country had ratified the Convention.)

Notes of EB debate [here](#).

PHM Comment

This is clearly a good treaty from a public health and environmental point of view. However, only one country has so far ratified the Minamata Convention.

PHM strongly calls upon MS to ratify the Convention recognizing that mercury is a chemical of major public health concern.

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

Contents

- [In focus at WHA67](#)
- [Background](#)
- [Debate at EB](#)
- [PHM comment](#)

In focus at WHA67

The Assembly will consider document [A67/25](#) from the Secretariat and draft resolution [EB134.R8](#) recommended from the EB to the WHA.

Background

Following the 8th Global Conference on Health Promotion, held in Helsinki in June 2013 and focusing on 'Health in all Policies', Finland has suggested this additional agenda item, document [EB134/1 Add.1](#). Finland proposes that WHO should provide more guidance to member states:

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

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

Notes of EB134 debate [here](#).

PHM comment

PHM supports the recommended resolution.

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

In relation to the former, WHO has an important role in providing guidance regarding institutions, procedures and evidence. In relation to the international dimension WHO has responsibilities for actively engaging stakeholders in other sectors and driving policy development and

implementation. In this respect the reference to 'guidance to member states' in the Finnish proposal may be taken as referring to member states in their role as decision makers in the governing bodies of the WHO.

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

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

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

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

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

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

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

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

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

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

15.1 Traditional medicine

Contents

- [In focus](#)
- [Background](#)
- [PHM comment](#)
 - [Priorities](#)

In focus at WHA67

The Assembly will be presented with a Secretariat paper, [A67/26](#) (considered by the EB as [EB134/24](#)) which describes and refers to the [revised WHO traditional medicine strategy](#) plus the recommended resolution from the EB, [EB134.R6](#). The resolution simply endorses the strategy and seeks follow up on its implementation.

The discussion at the Assembly will canvass the issues and principles covered in the revised strategy as well as the commitments carried within the draft resolution.

Background

At the EB134 in January 2014 the Secretariat presented, 'for noting', a [revised WHO traditional medicine strategy](#). The authority for this new strategy derives from a 2009 resolution ([A62.13](#)) which requested the Director-General "to update the WHO traditional medicine strategy 2002–2005, based on countries' progress and current new challenges in the field of traditional medicine". There was nothing in the resolution which required any further consideration of the issue by either the EB or the WHA.

The Secretariat paper commences with a review of progress and challenges in the field of traditional and complementary medicine (T&CM). It then proceeds to introduce in summary form the revised strategy, reviewing Objective 1 on the knowledge base, Objective 2 on regulation of T&CM for quality assurance, safety, utilisation and effectiveness, and Objective 3 which aims to integrate T&CM into universal health coverage.

In addition to the Secretariat paper the EB considered a draft resolution proposed by China, Malaysia and the Republic of Korea which was circulated as [EB134/CONF./2](#) which was adopted as [EB134.R6](#). This resolution essentially asks MSs to implement the Strategy and asks the DG to help them to do so.

Notes of EB debate [here](#)

PHM Comment

The new strategy provides useful guidance to member states in relation to knowledge about traditional and complementary healing (T&CM) and the regulation of T&CM.

The new strategy is strongly influenced by the East Asian, South Asian, and 'Western' experience (especially Europe and North America). The vibrant and challenging Indigenous health movement in Latin America is virtually ignored.

The emphasis on formalising and aggregating the knowledge base of T&CM contrasts with the failure to address the differing epistemological assumptions which underpin allopathic and T&CM and the wider philosophical and ecological implications of those differences. The focus on 'evidence' (which appears to mean empiricist and reductionist constructions of evidence) risks losing much of value in the T&CM traditions, and does not address the debate on the different epistemological paradigms.

In many parts of Latin America indigenous healing traditions are associated with powerful challenges to the materialism, consumerism and eco-destruction of Western hegemonies. These associations should not be neglected simply because they do not fit within frameworks derived from the allopathic tradition.

The strategic directions and actions proposed in relation to the integration of T&CM within broader health system frameworks are quite limited. The integration of traditional and western medicines in the context of China in the 1950s meant both that traditional Chinese medicine would be respected *and* that it would also provide the backbone of primary care, public health campaigns, immunisation and family planning.

In contrast, the current strategy (A67/26) is all about integrating T&CM into mainstream health care systems but there is no mention in this paper of the least developed countries, many of whom have very few Western trained physicians, and how they might harness the workforce of T&CM to strengthen the health system as a whole, nor a recognition of the role of traditional practitioners in extending the reach of life saving allopathic interventions and public health strategies. Traditional medicine should be integrated in other WHO's strategies in order to strengthen the health systems, with reference to the paradigm of interculturality of health practices.

The proposed strategy is quite selective in its dealing with traditional medicine, given WHO's rejection of traditional birth attendants for 'trained birth attendants' in the field of birthing. Traditional birth attendants, like many T&CM practitioners face recurrent challenges to their legitimacy, including from WHO. It seems surprising that this 'strategy' was not submitted for the consideration of the governing bodies before it was published as a strategy.

PHM raises awareness that it is important to clarify goals in term of implementation and how the strategy has to be operationalized at the country, regional and hq levels. Also increase integration between regional offices strategies and headquarters – there are weak traditional medicine representations on Regional Offices level as in African Region, PAHO, EURO; hq should support coordination within and across regions.

PHM policy priorities

There are significant epistemological and ontological differences between the T&CM traditions and the allopathic tradition. There is a need for a dialogue between these different paradigms; not for T&CM to be evaluated and classified in accordance with the empiricist tradition.

There are values and benefits in the T&CM traditions which go beyond simple questions of instrumental efficacy. These include different resources for living with pain, grief, disability and anxiety. They include different ways of understanding humans' relationship to our wider environment. There is much which allopathy can learn from these traditions.

WHO should be exploring how T&CM might be integrated into other WHO strategies such as NCD and PHC.

T&CM practitioners are widely trusted in many different societies. As such they can assist in extending the reach of modern public health, where they are treated as collaborators rather than discounted as quacks.

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

Contents

- [In focus](#)
- [Background](#)
- [Summary of debate at EB134](#)
- [PHM comment](#)
 - [Advocacy priorities](#)

In focus at WHA67

The Assembly will consider two Secretariat reports on action underway by way of follow up of the CEWG. [A67/27](#) presents a revised version of [EB134/26](#) dealing with the Observatory, options for coordination of R&D, options for funding and management of funds, and [A67/28](#) (revised version of [EB134/27](#)) will deal with the selection of demonstration projects.

In addition the EB decision [EB134\(5\)](#) deals with the next step in the selection of demonstration projects.

Since the EB the process of selecting demonstration projects has advanced (see WHO page: [Identification of R&D demo projects](#)) and the summary of the evaluation ([here](#)).

Based on this assessment, it was determined that the Secretariat will move forward with convening stakeholder meetings for the following 4 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 four 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.

Background

History

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 action² 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 [Doc 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 touching on many of the issues. 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\(12\)](#).

Consideration at EB134 (Jan 2014)

In resolution [WHA66.22](#) the Assembly had 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 document provided to the EB in Jan 2014, [EB134/26](#), describe the work done to date in response to these requests.

The document 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 document also 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. The report says that, as yet, the Secretariat has not developed a proposal for new mechanisms.

In response to the Health Assembly’s request in resolution [WHA66.22](#) and decision [WHA66\(12\)](#) to facilitate the implementation of a few health research and development projects and to convene a technical consultative meeting over two to three days in order to assist in the identification of these demonstration projects, the WHO hosted a technical consultative meeting of experts that was held in Geneva, 3 to 4 December 2013, followed by a meeting of Member States on December 5, 2013. Document [EB134/27](#), also submitted to EB in Jan 2014, described the outcomes of these two meetings.

Report of discussion at EB134 [here](#).

Meeting to Examine Additional Information Received - 10 March 2014

http://www.who.int/phi/implementation/phi_cewg_meeting/en/

http://www.who.int/phi/implementation/10_March_2014_exam_add_info_results.pdf?ua=1

“The meeting to examine the additional information received in relation to the 7+1 demonstration projects identified by the Global Technical Consultative Meeting took place on 10 March 2014 at WHO headquarters. 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 4 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.
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- *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."

Summary of debate at EB134

After long informal discussions in the previous days, on January 24th the Executive Board considered this issue. Several Member States welcomed the proposal to establish the Global Health R&D Observatory that will analyse data on financing for global health R&D and identify R&D priorities.

Qatar, on behalf of EMRO, said the process lacked regional coordination so far and proposed that one Member State from each region should be included in the next meetings. Panama suggested that the Member States could participate "as observers." The United States supported the draft decision and opposed any amendments that would slow down and unnecessarily politicize the process.

Three NGOs took the floor: PHM ([here](#)) renewed a call for a global R&D treaty funded through mandatory contributions from countries; Health Action International and Médecins Sans Frontières said the selected demonstration projects do not test the more transformative reforms that are needed to scale up access to medicine for all.

The ADG for health systems and innovation, Marie-Paule Kieny, said she was encouraged to see Member State support for this agenda item not faltering after all these years. Margaret Chan asked Member States not to cast any doubt on the process.

At the end of the discussion the Board noted the report and adopted a draft decision, [EB134\(5\)](#), on the way forward on eight demonstration projects listed in Document [EB134/27](#). The draft decision states that further meetings will be held in order to develop the project plan and mobilize the financial resources necessary for implementation of the projects. For transparency purposes, it was decided by the Board that the meetings will include, as observers, one Member State from each of the six WHO regions.

Detailed notes of debate at EB134 [here](#).

Summary and comment from IP-Watch [here](#).

KEI report [here](#)

PHM Comment

Voluntary funding base

PHM recognises that [WHA66.22](#) specifies that the funding pool should be funded voluntarily and this is clearly reflected in the report in EB134.26.

We urge member states to consider that a mechanism based on voluntary funding (including funding from non state entities) is likely to be financially unstable and would face pressures from donors (whether countries or other entities) based on their individual interests in funding such a

mechanism. Instead member states should re-consider a mechanism to put in place a global R&D treaty that is funded through mandatory contributions from countries. Such an R&D treaty, in addition to secure funding through mandatory contributions, should incorporate the two most important principles enunciated in the CEWG report – (i) innovation systems that are based on open sharing of knowledge; and (ii) de-linkage of the costs of R&D from the price of the final product. The report also says that “The mechanism would also have to put in place an appropriate access policy to ensure that any product developed using its funds is made available at an affordable price in countries in need”.(para 18) Unfortunately, this formulation is far removed from the principle of ‘de-linkage’ as described in the CEWG report.

Observatory

Para 4 and 5 explain the role of the Global Health and Research and Development Observatory. The Observatory seems to be structured as a top down process. The document doesn't explain either how the Observatory will engage with the actors (researchers or institutions) at the country level nor how the Observatory will exist in the context of non WHO similar initiatives promoted by diverse organizations (such as the Bill & Melinda Gates Foundation) that may be driven by agendas different from the one of WHO.

Also concerning is the proposal to create an Advisory Committee (para 8-11), particularly given the past TDR experience or more recently with the way how WHO secretariat worked with the committee for the selection of the demonstration projects (see below regarding EB134/27).

The document analyses a group of existing product development partnerships as potential hosts for a pooled financing mechanism for global R&D. As the report itself says, none of the existing mechanisms analysed by the Secretariat are ideal choices, and would require adapting to the specific needs of the proposed mechanism.(para 37) We are also concerned by the emphasis on the role of the public private partnerships as a model to promote R&D, when what the whole exercise is aiming at is building country owned R&D initiatives.

Member states are also urged to consider pressing for a new mechanism for R&D co-ordination and funding, and not continue to explore ways to host a co-ordinating mechanism within an existing mechanism. Ideally, such a mechanism should be hosted within the WHO.

Finally, the report mentions an annual ‘stakeholder’ conference but does not detail who the stakeholders would be. Unless adequate safeguards are put in place there is a possibility that Big Pharma would hijack such a conference and look at the conference as a way to fund their own activities.

Demonstration projects

On the funding of demonstration projects PHM would like to highlight the following key issues.

It is unacceptable that there were so many individuals with declared conflict of interests (see Box in page 3) in the project selection committee. Even if they were excluded from consideration and decision-making regarding proposals in which they were directly involved, it is still possible to wonder how this affected their judgement of other competing projects. It is not

credible that from the global pool of experts, the process could not come up with individuals not directly associated with any of the proposals.

Concerning the fundamental criteria that have driven the whole process (Appendix 2), we are surprised that the Category C criteria (whether the demonstration project would test a new approach to R&D) was not the starting point for the selection but was only examined after projects were selected on the basis of Criteria A and B. It is even more questionable the proposal to request now (after the selection) that the selected projects address the Category C criteria (page 5). The process is therefore failing to achieve the fundamental mandate of this initiative which was to test new models of innovation that could incorporate the principles of open knowledge innovation and the de-linkage of the costs of R&D from the price of the final product;

It is also surprising that among the selected proposals quite a number are not country based/owned, even if the ultimate intention of the whole process was to find innovative means to build country R&D initiatives.

Given these concerns, it is difficult to imagine how the demonstration projects could represent an important contribution to the current failure of global health R&D.

March 2014 decision

The projects selected to move forward in the stakeholder meeting are from: DNDi, MMV (both strongly financed from the North), ANDI (a WHO inside invention) and NIH the only one "Country based" (USA!!!). We wonder what happened to the aim to have projects from (developing) countries?

It is not clear what new "innovation" (apart from the PPP model itself) these organizations offering which will help to delink R&D costs from access. All excluded projects are from developing countries.

This clearly confirms our concerns on the selection process including how well addressed were the existing conflicts of interest.

PHM Advocacy priorities

Member states should consider preparing the reference documents to start negotiations to put in place a global R&D treaty that is funded through mandatory contributions from countries. Such an R&D treaty, in addition to secure funding through mandatory contributions, should incorporate the two most important principles enunciated in the CEWG report – (i) innovation systems that are based on open sharing of knowledge; and (ii) de-linkage of the costs of R&D from the price of the final product.

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

Contents

- [In focus](#)
- [Background](#)
- [PHM comment](#)
 - [Priorities](#)

In focus at WHA67

The Assembly will consider [A67/29](#), (which forwards [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;
- decided to continue the system of chairing through the rotation of vice chairs;

Presumably the Secretariat will provide a further report to the Assembly regarding the budget shortfall.

The discussion at the Assembly may canvas the full range of issues linked to SFC but will focus on the issues raised in the MSM report as above.

Background

The Sixty-fifth World Health Assembly (May 2012) adopted a resolution ([A65.19](#)) establishing a Member State mechanism (MSM) on substandard/spurious/falsely-labelled/falsified/counterfeit medical products (SSFFC).

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 SSFFC issue dates back to a controversy regarding WHO's association with IMPACT (International Medical Products Anti-Counterfeiting Taskforce). IMPACT arose out of a seminar in which the WHO was one of the partners, but which 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 formal ratification by 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 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 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.

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](#)).

Notes of the EB debate [here](#).

PHM Comment

The document (EB134/25) that was considered by the EB contained the report of the second

meeting of the member state mechanism on SSFC held in November 2013.

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 pharmaceutical bodies, such as IMPACT. We welcome the clear statement in the report that “*The Mechanism emphasized that the scope of the Member State Mechanism excludes trade and intellectual property considerations*”. However, after almost 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 QS&E. Big pharma has been promoting this ambiguity and confusion since the early 1990s.

We would like, however, to draw MSs’ attention to possible interpretations of some sections of the report that might link the issue of SSFFCs to IP related issues. For example, in Appendix 1, entitled ‘Action, activities and behaviours that result in SSFFC Medical Products’ (p.4-5) one of the points mentioned is “*manufacturing medical products which replicate registered medical products or their packaging without authorization of the national and/or regional regulatory authority*” (p5). This formulation can be interpreted to include generic medicines, even if of good quality, as generic medicines do replicate existing medicines. This would also need to be understood in the context of the practice of ‘patent linkage’. Under this practice, now part of many bilateral and regional trade agreements (though not the TRIPS requirement), the national medicines regulatory authority is first required to evaluate the patent status of a generic medicine before granting marketing approval. Thus national regulatory authorities end up acting on behalf of international pharmaceutical firms, to protect their patent rights. This is not the designated role of regulatory agencies, as patents are private rights and the safeguard of such rights is not the job of a public regulatory agency.

Another issue identified in the document is: “*failing to comply with good practices of manufacturing, distribution, transportation and storage of medical products, as set out by the national and/or regional regulatory authority*”. This needs to be read in the context of attempts by international pharmaceutical firms to influence national regulatory authorities in developing countries to amend good manufacturing practice and procurement norms in a manner that could prevent the manufacture/procurement of legitimate and safe generic medicines.

The document also identifies as an issue of concern: “*importing, exporting, distributing, including transporting, storing, supplying or selling medical products obtained from an unauthorized or unknown origin*”. This can lend itself to an interpretation similar to that used in 2008 and 2009, when several batches of legitimate good quality generic medicines on route from India to other countries (some procured by UNICEF) were seized in Europe by customs agencies under the guise of suspected counterfeiting. This is especially so as the term ‘*unauthorised*’ is not qualified by an explanation regarding who has the jurisdiction to ‘authorize’ medical products, especially when they are in transit.

The report points to a major budgetary gap in relation to the implementation of its proposals. It also mentions that 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.

We also urge member countries to consider the negative impact of existing collaboration 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.

PHM policy priorities

Strategies for regulating actions, activities and behaviours

Need for full funding of MSM

To prevent counterfeit pricing needs to be addressed

Capacity building for drug regulatory authorities

15.4 Access to essential medicines

Contents

- [Focus of consideration at WHA67](#)
- [Background](#)
- [PHM Comment](#)
 - [PHM advocacy priorities](#)

Focus of consideration at WHA67

The Assembly will consider [A67/30](#) which includes [EB134/31](#) which was considered by the Board under this item. The Assembly will also consider resolution [EB134.R16](#) which is forwarded from the Board to the Assembly.

The draft resolution would provide the Secretariat with a mandate to take action on a range of critical issues (although there is presently a shortfall of \$5.6m in the PB for 14/15 according to [EB134/CONF./14 Add.1](#)).

There are lots of policy conflicts implicit in the discussion, not least the behaviour of Big Pharma in South Africa and the ongoing issue of TRIPS flexibilities. See possible [advocacy priorities](#) below.

One issue not included in the draft resolution concerns the application of the principles in this resolution to vaccines and biologicals. The DG was a bit dismissive when she was asked during the EB debate over vaccines to collect data on the costs of vaccines just as WHO sponsors the collection of such data for medicines. Likewise the issues of technology transfer are also relevant but not fully dealt with.

Background

Immediate issues

This item appeared on the EB agenda in Jan 2014, “At the request of a Member State”. It was accompanied by a Secretariat report (Document [EB134/31](#)) which reviewed access to medicines globally both in relation to the MDGs as well as NCDs. It presented an analysis of challenges faced and lessons learnt by countries in increasing access to essential medicines in support of universal health coverage, and on the ways countries have implemented the essential medicines concept. The paper identifies eight areas of activity to promote access to essential medicines:

- support for universal health coverage,
- health technology assessment and cost-effectiveness pricing,
- monitoring and the use of information,
- medicines for NCDs,
- rational use of medicines,

- action around anti-microbial resistance
- medicines for HIV, TB, malaria, reproductive, maternal and child health,
- innovation, local production and technology transfer.

The Secretariat report describes WHO programs which support access to essential medicines including: the essential medicines model list, the Good Governance for Medicines program, country support in cost-effective procurement and reimbursement, monitoring prices, rational use and support for ethical promotion.

The debate was complicated by (or perhaps illustrated by) the leak regarding ‘Pharmagate’ ([here](#)) in South Africa; see under [Comment](#) below for more.

After some tense debate the Board adopted a resolution ([EB134.R16](#)) for transmittal to the Assembly.

Notes of EB debate [here](#).

History

WHO has had an essential medicines program since 1975. See Laing and colleagues (2003) for a detailed history of the essential medicines program. See also the WHO [programs page on essential medicines](#). The purpose of the essential medicines list (EML) is to provide guidance to government authorities as to the priority drugs based on health needs, efficacy, safety and cost. These are the drugs which should be given priority in government supply chains, in subsidy and reimbursement programs, and in programs to promote rational use. The obverse of an explicit inclusive list is an implicit list of excluded drugs; not necessarily denied marketing rights but facing an additional hurdle in marketing. In particular Big Pharma has been and is worried that the concept of a limited list of priority drugs might migrate to the richer countries.

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

The Director-General, in his reply, stressed the problem of sales pressure from drug manufacturers, especially in developing countries. Without unstinting support from the Executive Board and the Health Assembly, the Secretariat could do very little to stop that. The Health Assembly would have to consider ways of offering protection that was not merely technical but also political and moral. The global social responsibility that certain members had called for could be exercised only if governments were prepared to limit the activities of the pharmaceutical industry. (WHO, [Third ten years](#), 2008)

[Laing and colleagues \(2003\)](#) recall that

In 1987, the International Federation of the Pharmaceutical Manufacturers Associations (IFPMA) called the medical and economic arguments for the EML fallacious and claimed that adopting it “could result in sub-optimal medical care and might reduce health

standards". The pharmaceutical industry was concerned that the EML would become a global concept applicable to public and private sectors in developing and developed countries, and were especially opposed to attempts by developed countries to introduce limited medicines lists. In 1982, a spokesman of the US pharmaceutical manufacturers organisation said "The industry feels strongly that any efforts by the WHO and national governments to implement this action program should not interfere with existing private sector operations".

The USA opposed WHO's Essential Medicines Program during the 1980s and according to Lee (2009) this was one of the reasons for the major donors imposing the zero nominal growth policy on assessed contribution. Lee writes:

By the early 1980s, the rise in EBFs [Extra Budgetary Funds] represented not only a "vote of confidence" in special WHO programs, but also a "vote of non-confidence" for some activities funded by its regular budget, namely campaigns on essential drugs, breast milk substitutes and health for all. In a context of financial austerity, major donors (known as the Geneva Group) introduced a policy of zero real growth (adjusting for inflation) in the 1980s to the RBFs of all UN organizations. In part, this policy was in response to the alleged "politicization" of certain UN organizations, notably UNESCO and the International Labour Organization (ILO). This policy remained in place until 1993, when an even more austere policy of zero nominal growth (not inflation adjusted) was introduced, reducing the WHO's budget in real terms. (Lee, K. (2009). The World Health Organization (WHO). London and New York, Routledge.)

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

The agenda item at the EB was entitled 'Access to essential medicines' but the focus of the report was on the essential medicines concept. However the emergence of Pharmagate in the middle of the debate underlined how the conflicts over intellectual property rights have intersected with concerns regarding access to essential medicines.

One of the key issues here has been the legitimacy of countries utilising to the full the 'flexibilities' embedded in the TRIPS Agreement and endorsed in the 2001 Doha Declaration. (More on TRIPS flexibilities [here](#).)

Notes of debate at EB134 [here](#).

PHM comment

WHO has in place a range of useful programs although in most cases seriously under-funded. In addition to the programs which are in place, the governing bodies are working on critical

issues concerning innovation, pricing, access and regulation, all topics which are on the current Board agenda.

There are further issues highlighted in [A67/30](#) which need more focused attention by the governing bodies. These are:

- the management of shortages and stockouts, particularly in small countries (para 14);
- the need to support technology transfer and local and regional production; and
- the need for a much greater investment in post marketing surveillance of medicines, vaccines, diagnostics and other products.

Resolution [EB134.R16](#), if adopted by the Assembly, would authorise the Secretariat to explore these issues more closely and to bring forward appropriate strategies and proposals.

However, looming behind these policy issues are the constraints arising from WHO's financial crisis, the conflicts around IP, and the politics of regulating Big Pharma. The [Pharmagate](#) controversy and the shadow boxing in the EB around the language to be used in [EB134.R16](#) demonstrates that the struggle over IP and the use of TRIPS flexibilities is alive and well.

Financial crisis

The Independent Evaluation Team for the Stage II Evaluation has referred to Member States' 'duty of care' in referring to WHO's financial crisis and has highlighted WHO's inadequate budget by comparing it to the expenditure of the Geneva University Hospital.

The consequence of the crisis is evident in the failure to properly fund WHO's Rational Use of Medicines Program which is a contributing cause of the crisis of AMR. Resources going into rational use of medicines are trivial compared with Big Pharma's expenditure on marketing (funded from revenues which are maintained by monopoly pricing). Even if all of Big Pharma's marketing conformed to WHO's 'ethics in pharmaceutical marketing', simply the magnitude of Big Pharma's spending would continue to swamp the funding available nationally and globally to promote rational use.

The rational use of medicines is a challenge also in relation to NCDs where SDH play such a huge role. There are significant commercial and political barriers to addressing the social determinants while there is a powerful corporate drive to focus only on risk factors and to address these with medicines.

Compromise language restricts scope of resolution

The proposed resolution includes restrictions on scope imposed in the course of the negotiations at the EB134.

Operative para 2(8) requests the Director-General:

“to provide, as appropriate, upon request, in collaboration with other competent international organizations, technical support, including, where appropriate, to policy processes to Member States that intend to make use of the provisions contained in the TRIPS agreement, including the flexibilities recognized by the Doha Ministerial Declaration on the TRIPS agreement and Public Health and other WTO instruments related to TRIPS agreement, in order to promote access to essential medicines, in accordance with the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property;”

- “as appropriate” / “where appropriate” lay the ground for possible challenges to Secretariat practice in fulfilling the mandate of this clause;
- “upon request” precludes the Secretariat from issuing general advice except where explicitly requested by a MS;
- “in collaboration with other competent international organizations” is intended to force the WHO Secretariat to involve the WTO in the provision of any advice in accordance with this clause.

These weasel words need to be removed.

Comparative cost-effectiveness

It has been standard practice to include the criterion of ‘comparative cost-effectiveness’ while setting national priorities as regards access to essential medicines, including in the development and updation of national Essential Drug Lists (EDL). However cost-effectiveness considerations, using such methodology, keeps out almost all new drugs which are protected by patents. Cost-effectiveness comparisons, need to be seen in the context of the possible use of TRIPS flexibilities (especially liberal use of compulsory licenses) to drastically reduce the actual costs of medicines. This would facilitate the inclusion of a number of new medicines in priority lists of countries, including in National EMLs.

Technology transfer

The draft resolution is weak in relation to technology transfer. It would be good to insert into either or both operative paragraphs provisions which would strengthen cooperation around technology transfer for generic manufacturer, in particular South-to-South cooperation.

Conflict of interest and risk management

WHO faces a continuing risk management challenge in its dealings with the pharmaceutical industry (in all its various manifestations). PHM argues that risk management in this set of relationships requires attention to modalities of influence and power to influence as well as the more obvious conflicting purposes.

It is well to remember that the establishment of the EML was a response to a request for help from L&MICs who were subject to aggressive pharmaceutical marketing and under pressure to stock the most recent and most highly priced drugs. This remains a challenge for WHO.

See also report and comment on EB debate from IP Watch [here](#)

See also TWN report of debate [here](#).

PHM policy priorities

The draft resolution to be presented to the Assembly would provide a useful mandate to the Secretariat to accelerate progress on a range of key issues around A2EMs.

There may be scope for further action around some of these issues such as RUM and AMR.

In contributions to the WHA debate it would be appropriate to emphasise the importance of countries being free to utilise to the full the flexibilities provided for in TRIPS.

The full utilisation of TRIPS flexibilities has been under attack through a variety of strategies:

- big power trade sanctions
- TRIPS plus provisions in bilateral and plurilateral trade agreements (TPP and TTIP)
- ISDS provisions in bilateral and plurilateral trade agreements (TPP and TTIP) and investment agreements
- corporate lobbyists urging countries to adopt TRIPS plus provisions in their domestic legislation
- PR campaigning from behind artificial front organisations as in South Africa.

It might be appropriate to explore WHO's relationships with the pharmaceutical companies which are seeking to prevent South Africa from introducing patent examination.

The leaked email in question was sent to IPASA members on January 10th by Michael Azrak, the Managing Director of Merck Southern and East Africa and Head of IPASA's Intellectual Property Committee. Its recipients include AstraZeneca, Bayer, BMS, Boehringer-Ingelheim, Johnson & Johnson, Lilly, Merck, Novartis, Novo Nordisk, Pfizer, Roche, Sanofi and Takeda.

Roche and Novo Nordisk have publicly distanced themselves from the IPASA exercise but not the others. Merck/MSD has not apologised for its role in the affair.

Unethical promotions: Japan against Novartis, Glaxo in China

15.5 Strengthening of palliative care as a component of integrated treatment throughout the life course

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In focus at WHA67

WHA67 will consider [A67/31](#) (a revised version of [EB134/28](#)) and EB resolution ([EB134.R7](#)).

The report and resolution address palliative care generally but the key issue at stake is improving access to necessary pain relief through achieving a better balance between conventions directed to the control of narcotics and the need for effective pain relief.

Background

The Executive Board in January 2014 considered Document [EB134/28](#) which provided an analysis of palliative care generally, and certain specific measures, in particular, access to pain relief.

The first document produced by the Health Assembly on this topic is the [WHA55.14](#) on “Access to Controlled Medication Programme”, and the first explicit mention to Palliative Care is found in the [WHA58.22](#).

In 2011, WHO published the revised edition of its “Guide for assessing the availability of and access to controlled medications in Member States” ([here](#)). In 2012 the WHO, in collaboration with the Commission on Narcotic Drugs of the United Nations Economic and the Social Council and International Narcotics Control Board, issued a “Guidance on estimating requirements for substances under international control” ([here](#)). Medicines for pain and palliative care are included in WHO model list of Essential Medicines both for [adult](#) and [children](#), and WHO’s [global action plan](#) for the prevention and control of noncommunicable diseases 2013–2020 has included palliative care among the policy options proposed to Member States. The global action plan has been endorsed by the Health Assembly in resolution [WHA 66.10](#) in May 2013.

In addition to EB134/28 the Board also had before it a draft resolution which was adopted as amended as [EB134.R7](#). This resolution which will be submitted to WHA67 offers principles and strategies for promoting effective palliative care generally but also includes provisions designed to overcome barriers to patients accessing controlled substances for pain relief.

Notes of the EB debate [here](#).

PHM comment

The ageing of the population and the continuous increase in chronic conditions are driving the debate on how to strengthen palliative care. Despite sometimes being considered a marginal part of health systems, palliative cares offer support both to the patients and care-givers.

The Report by the Secretariat well describes the main issues related to palliative cares. The following aspects warrant emphasis.

Primary health care approach. The Report urges the need to integrate palliative care inside health systems under a primary health care based approach, carrying out multidisciplinary and multisectoral actions. In this sense, community and home based care should be considered as the gold standard for the implementation of these processes.

Social and cultural barriers related to palliative care and, in particular, opioids use. The International Narcotics Control Board underlines that the three main causes affecting the availability of opioids for medical needs are concerns about addiction, reluctance to prescribe or stock and insufficient training for professionals. All these factors can be prevented with a strong investment on education, both at academic and social level. Investments in research are necessary to better address the causes of the underuse of opioids, and to raise the consciousness regarding their use.

Access to essential medicines. It is critical to implement government policies to facilitate access to essential medicines and, at the same time, avoid irrational use of these substances. This involves monitoring both access to palliative care and the use of opioids at national level, in order to tackle differences and inequalities in the distribution of palliative care services. It also involves reducing the transaction costs associated with compliance with international narcotics regulation.

15.7 Health intervention and technology assessment in support of universal health coverage

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Focus of consideration at WHA67

The Assembly will consider document [A67/33](#) (which conveys a slightly amended version of [EB134/30](#)) and the draft resolution [EB134.R14](#) forwarded from the EB in January.

There have been rising calls for WHO to take a more pro-active, leadership role in encouraging the application of health intervention and technology assessment methods (HTA) into policy and program development.

For WHA67 the Secretariat has disseminated a technical report ([A67/33](#), incorporating a revised [EB134/30](#)) which provides a broad introduction to HTA and its applications, plus a draft resolution ([EB134.R14](#)) recommended by the EB which urges the Secretariat and MSs to promote the wider use of this set of methods.

HTA is technical and requires expertise and data and there will be discussion around issues of capacity building and guidance.

Cost-effectiveness is an important criterion in health decision making but not the only one and there may be some discussion of the interplay of the technical, cultural and political determinants of health planning.

One of the purposes for which HTA can be used is for price setting in medical products procurement and reimbursement programs. The USA and the EU are presently promoting provisions in bilateral and plurilateral trade agreements which are designed to prevent the application of cost-effectiveness criteria in price setting in such programs. Health ministers and finance ministers need to be aware of the potential costs of (their trade colleagues) agreeing to such provisions.

Background

This item appeared on the EB agenda for EB134 in Jan 2014, 'at the request of a member state'. The Secretariat report to the EB (Document [EB134/30](#)) provided an account of the role of health intervention and technology assessment in funding decisions and priority setting in health systems within the broader context of working towards universal health coverage.

EB134/30 commences with a brief introduction to HTA and then surveys its use among Member States and by the Secretariat.

The paper traces how the consideration of HTA in recent conferences and in WHO regional committees laid the ground for its consideration in the EB and WHA.

Notes of discussion at EB134 (Jan 2014) [here](#).

PHM comment

PHM commends the Secretariat report on HTA and the Resolution [EB134.R14](#).

One of the valuable uses of HTA is in price setting for both supply and reimbursement purposes. The WHO Secretariat has an important role in supporting best practice in health technology assessment (HTA) for reimbursement and pricing purposes, as described in paragraph 15 of EB134/30:

15. The Secretariat is working with Member States on identifying best practices for supply, reimbursement and pricing policies for health technologies, and, through the [WHO Guideline on Country Pharmaceutical Pricing Policies](#) (published in 2013), recommends that Member States consider health technology assessment as a tool to support reimbursement decision-making as well as for price setting and negotiation.

In this light EB members should be aware of developments in current trade negotiations that create an urgent threat to Member States' abilities to implement the recommendations of the 2013 WHO Guideline on Country Pharmaceutical Pricing Policies, particularly Recommendation 5.5 (Promotion of the use of generic medicines) and Recommendation 5.6 (Use of health technology assessment).

Twelve Member States of the WHO – Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Singapore, the United States and Vietnam – are currently in the final stages of negotiations for a large regional trade agreement, the Trans Pacific Partnership Agreement (TPP). The aim of the participating countries is for the TPP to form the basis for a larger regional trade bloc. The terms of the TPP will be binding and the agreement is intended to provide a template for future trade agreements.

Leaked documents [[1](#), [2](#)] from the negotiations indicate that provisions have been proposed for this trade agreement that would [[3](#)]:

1. Delay the market entry of generic drugs in the participating countries ; and
2. Constrain the ability of pricing and reimbursement programs to contain costs and ensure affordable access to medicines (including through HTA).

Given the report before the EB on HTA, we focus below on the aspects of the negotiations that may compromise the ability of Member States to effectively employ HTA in the pricing and reimbursement of medicines and medical devices.

In a 2011 proposal for an annex to the Transparency Chapter of the TPPA [2], the US proposed text that would circumscribe the mechanisms national governments can use to set the reimbursement price for medicines and medical devices. Paragraph X.3(d) states that Parties shall:

*ensure that the Party's determination of the reimbursement amount for a pharmaceutical product or medical device has a transparent and verifiable basis consisting of **competitive market-derived prices in the Party's territory, or an alternative transparent and verifiable basis consisting of other benchmarks that appropriately recognize the value of the patented or generic pharmaceutical products or medical devices at issue** (emphasis added)*

This provision would preclude best practice pricing strategies including HTA and internal reference pricing, restricting countries to determining prices based on “competitive market-derived prices” (ie. the price set by the manufacturer) or other mechanisms that value drugs according to whether they are under patent. The provision also appears to preclude other pricing strategies such as international (external) reference pricing [6].

Furthermore, the proposed annex also includes:

- a set of onerous obligations for so-called “transparency” and disclosure, which would facilitate pharmaceutical industry influence over pricing and reimbursement processes,;
- expanded opportunities for manufacturers of pharmaceuticals and medical devices to influence decision making regarding listing, pricing and reimbursement;
- a review/appeals process able to overturn listing and pricing decisions made by health expert bodies;
- establishment of mechanisms for ongoing influence with capacity to influence formulary decision making.

These provisions would further hobble the ability of national pharmaceutical policies and programs to contain costs and ensure value for money and affordable access to medicines.

Likewise the draft EU-Singapore trade agreement, initialled in September 2013, includes an annex on pharmaceutical products and medical devices. See http://trade.ec.europa.eu/doclib/docs/2013/september/tradoc_151731.pdf.

The fact that the EU is incorporating such text into its trade agreements is a strong signal that there will be such an annex in the Trans-Atlantic Trade and Investment Partnership (TTIP) perhaps including text about pricing.

In order to ensure Member States retain the capacity to implement best practice pharmaceutical pricing policies, WHO will need to take action on this issue.

PHM urges the Assembly to adopt a strong statement urging rigorous HTA and cost effectiveness pricing for supply and reimbursement for pharmaceuticals, devices, diagnostics and other medical products. We urge that any such resolution includes explicit mandate for the Secretariat to provide advice to Member States in accordance with the Resolution on Trade and Health ([WHA59.26](#)) regarding the need for coherence between trade and health. Member States should avoid entering into trade agreements which compromise their capacity for HTA and cost effectiveness pricing.

PHM policy priorities

Recognise that resource allocation decisions are cultural and political as well as technical.

Promote health technology assessment through capacity building, guidelines, opportunities for sharing etc.

Recognise the role of HTA in price setting for procurement and reimbursement.

Highlight the risk of new provisions in trade agreements which are directed at preventing the use of cost-effectiveness criteria in pharmaceutical procurement and reimbursement programs

15.6 Regulatory system strengthening

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In focus at WHA67

WHA67 will have before it a Secretariat report ([A67/32](#), developed from [EB134/29](#)) and two draft resolutions: [EB134.R17](#) and [EB134.R19](#) both of which are contested.

[EB134.R17](#) derives from an original proposal from Switzerland, with Australia, Colombia, Mexico, Nigeria, South Africa and the United States of America, ([EB134/CONF./12](#)) and deals broadly with medical products regulation, including self-assessment, capacity building, international collaboration, and networking. The draft resolution before the Assembly contains several clauses upon which consensus could not be achieved at the EB.

[EB134.R19](#) derives from an original proposal from Argentina with Colombia, Costa Rica, Paraguay and Uruguay ([EB134/CONF./3](#)) and deals with biological medicines and is directed to developing frameworks within which 'biosimilars' (products which are biologically similar to comparators which have been licensed for marketing) can be brought to market expeditiously. It also contains bracketed text.

The Secretariat report provided to the EB ([EB134/29](#)) lists the traditional functions of medicines regulation and then reviews contemporary challenges to regulatory systems: expense, risks of 'user pays' revenue models, globalisation and complex supply chains. The paper canvasses some strategies to deliver effective regulation in the face of these challenges: capacity building, international collaboration, and strengthened governance of the pharmaceutical industry.

It maybe that between January and May the informal consultations may come to a consensus and two 'clean' resolutions are put to the Assembly.

If not the focus of discussion at the Assembly will be on the remaining issues of contention in each draft resolution.

Background

History

Statutory medicines regulation is a core principle of medicines policy and WHO has been involved since the early 1950s. (More detail and references [here](#).)

Currently under consideration

EB134/R17

One of the main problems in this report and the draft resolution [EB134.R17](#) is the reference to the “Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use” (ICH). This process has been, and still is, totally funded and driven by the transnational pharmaceutical companies of USA, EU and Japan. Their standards are driven by commercial interest more than public health protection. The reference to ICH in a WHA resolution may legitimize norms and standards not based in health needs but in trade protection putting standards higher than health needs to exclude manufactures from developing countries.

WHO has a long established mandate to work in medicines regulation, including capacity building generally and specific programs in marketing approval, essential medicines; rational use of medicines, regulation of unethical marketing, IP and trade barriers to access, pharmacovigilance and post-marketing surveillance and the regulation of clinical trials. The main factor underlying the present crisis in medicines regulation is that these established functions have been grossly underfunded as part of the donor chokehold on WHO’s budget.

EB134R19

The chief points of conflict in draft resolution [EB134.R19](#) lies in preambular para “noting that...” and bracketed OP1(2).

The preamble states: “[Noting that WHO Expert Committee on Biological Standardization guidelines of 2009 [\[here\]](#) on evaluation of similar biotherapeutic products and that the placing on the market of these types of products is expected to significantly increase;]” and

OP1(2) urges member states to: [...ensure that a solid, scientifically-based regulatory review process for reviewing, approving, and monitoring reference biotherapeutic products has been conducted before embarking on the review and approval of similar biotherapeutic products;]

At issue here is the status of *similar* biotherapeutic products and the evaluation studies, in particular, comparisons with the *reference* biotherapeutic product needed to justify assigning the status of *biosimilar*.

The WHO Expert Committee on Biological Standardization guidelines of 2009 [\[here\]](#) require ‘head to head’ comparisons between the SBP and the RBP for purposes of marketing approval as a biosimilar. The provision in OP1(2) goes beyond this. It would require a solid, scientifically-based process for reviewing, approving, and monitoring reference biotherapeutic products *before* embarking on an evaluation of a proposed biosimilar. This could present a very high barrier to the approval of biosimilars, especially in countries where the originator company has not sought approval.

Report of discussion at EB [here](#).

PHM Comment

The report A67/32 (incorporating EB134/29) speaks at considerable length about what Member States (MS) should be doing but has less regarding what WHO is doing to help MS. Even if it does not propose any resolution, a first priority should be to endorse and properly fund the various support programs through which WHO is seeking to support national and regional medical products regulation:

- setting norms and standards,
- capacity building,
- pre-qualification,
- pharmacovigilance,
- networking and information exchange.

Therefore, MS should also ask the WHO Secretariat to provide details regarding the headings under which it allocates resources, and the quantum thereby, as regards its medicines related programmes.

At present the entire emphasis of WHO's work is on QSE (quality, safety and efficacy). While this is an important area of work as regards regulation of medicines access and use, it cannot be the sole area of work. WHO urgently needs to scale up its work in:

- Essential Drug Programme;
- Rational Use of medicines;
- Regulation of Unethical Marketing;
- IP and Trade Barriers to medicine access;
- Regulation of Clinical Trials.

In the context of the politics of medical products regulation, PHM would urge full consideration of the importance of active civil society engagement in policy formation and program implementation including health professional organisations and community based organisations.

Regarding the regulation of Clinical Trials, the report points to the growing problem of unethical trials taking place in L&MICs. However there is no mention about what the WHO is planning to do to address the need to enhance regulatory capacity in these countries. To this regard WHO needs to significantly scale up resources allocated in these areas and develop programmes that support member states

Other problems pointed to in this paper include the risk of regulatory capture when medical products regulation is funded from fees levied on corporate sponsors and the need to strengthen existing pharmacovigilance programs.

Resolution on Regulatory system strengthening for medical products (EB134.R17)

The resolution has a number of useful suggestions. It also has some unresolved text (in square brackets). One set of unresolved issues in the text deals with the 'International Conference on Harmonisation' which is being promoted by a number of developed countries. Essentially the ICH looks to raise the bar on acceptable quality standards, and to globalise these standards. In

the case of most medicines, ratcheting up quality standards does not add to public health outcomes but adds to costs of manufacturing and also makes generic manufacturing much more difficult in LMICs. It is in the interest of LMICs that they not agree to the proposal to be part of a process that harmonizes quality standards.

The other issue of contention relates to global supply chains that contribute to the production of a finished product. Unlike a few decades earlier, in a majority of cases, pharmaceutical manufacturing is not an integrated process. Most countries (and manufacturers of finished medicines) source Active Pharmaceutical Ingredients (APIs) from manufacturers situated in different countries (r from API manufacturers in the same country). API manufacture is thus global, while drug regulatory agencies are national in their jurisdictional authority. The WHO needs to work together with member states to develop a framework for regulatory oversight of the quality of APIs.

Access to biotherapeutic products and ensuring quality, safety and efficacy (EB 134.R19)

The draft resolution pertains to issues regarding the promotion of biotherapeutic products (also called 'biologics') and biotherapeutic similars (also called 'biosimilars'). The resolution needs to be seen in the context of the fact that a significant number of drugs in the R&D pipeline are biologics (many them for treating different cancers and autoimmune disorders), as are a number of top selling drugs in the market.

The draft resolution's preamble states: "[Noting that WHO Expert Committee on Biological Standardization guidelines of 2009 [\[here\]](#) on evaluation of similar biotherapeutic products and that the placing on the market of these types of products is expected to significantly increase;]"

Further OP1(2) urges member states to: [...ensure that a solid, scientifically-based regulatory review process for reviewing, approving, and monitoring reference biotherapeutic products has been conducted before embarking on the review and approval of similar biotherapeutic products;]"

At issue here is the status of *similar* biotherapeutic products and the evaluation studies, in particular, comparisons with the *reference* biotherapeutic product needed to justify assigning the status of *biosimilar*. The WHO Expert Committee on Biological Standardization guidelines of 2009 [\[here\]](#) require 'head to head' comparisons between the SBP and the RBP for purposes of marketing approval as a biosimilar. The provision in OP1(2) goes beyond this. It would require a solid, scientifically-based process for reviewing, approving, and monitoring reference biotherapeutic products *before* embarking on an evaluation of a proposed biosimilar. This could present a very high barrier to the approval of biosimilars, especially in countries where the originator company has not sought approval.

Access to biologics is compromised in LMICs because of the very high cost of these products, thus denying treatment to a very large number of patients in these countries. National regulations are necessary to ensure the quality, safety and efficacy of biologics and biosimilars. At the same time, the regulatory framework should promote accelerated access to low cost

biosimilars and not act as a barrier to their introduction. There is, as yet, no perfect regulatory system for these products. LMICS will be well served if they do not blindly follow the systems in place in the EU and the US, and instead develop systems best suited to national situations.

The WHO should build its own capacity to provide guidance as regards regulation of biologics and biosimilars. The guidance it provides should also include help in scaling up the use of biotherapeutics in LMICs and in promoting local production of biosimilars in LMICs.

PHM policy priorities

MS should the deletion of all reference to ICH, to keep medicines standards guided and based on public interest. ICH is an industry body and where industry and public interests are in conflict the efforts of ICH will bend towards the interests of the corporations.

MS should also ask the WHO Secretariat to provide details regarding the headings under which it allocates resources across its various programs in medicines regulation, including capacity building generally and specific programs in marketing approval, essential medicines; rational use of medicines, regulation of unethical marketing, IP and trade barriers to access, pharmacovigilance and post-marketing surveillance and the regulation of clinical trials.

WHO urgently needs to scale up its work in all of these areas.

Further work may be required to address the impasse regarding the approval for marketing of biosimilars.

15.8 Follow-up of the Recife Political Declaration on Human Resources for Health

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- [Background](#)
- [PHM comment](#)

In focus at WHA67

The Assembly will consider [A67/34](#) which includes EB134/55 and EB resolution EB134.R15.

In November 2013 Brazil hosted the [Third Global Forum](#) of human resources for health in Recife.

At the EB in Jan 2014 Brazil proposed an additional item to be entitled: "Follow-up of the Recife Political Declaration on Human resources for Health: renewed commitments towards universal health coverage". The proposal ([EB134/1 Add.2](#)) was accompanied by a draft resolution which:

1. Endorses the call to action and the commitments made by Member States in the "Recife Political Declaration on Human Resources for Health: renewed commitments towards universal health coverage" (see [EB134/55](#));
2. Urges Member States: to implement the commitments made in the "Recife Political Declaration on Human Resources for Health: renewed commitments towards universal health coverage";
3. Requests the Director General: to take into consideration the "Recife Political Declaration on Human Resources for Health: renewed commitments towards universal health coverage" in the future work of the WHO.

Once the EB had agreed to consider the item the Secretariat produced [EB134/55](#) and [EB134/55 Add.1](#) (assessing the financial and administrative implications of the resolution proposed by Brazil in [EB134/1 Add.2](#)).

Background

From 10th to 13th of November Brazil hosted in Recife the [Third Global Forum](#) on Human Resources for Health - an initiative of the Global Health Workforce Alliance (GHWA), the World Health Organization, the World Bank and several other institutions, with strong participation and important contributions from civil society. The Forum produced an outcome document-"[The Recife Political Declaration](#) on Human Resources for Health: renewed commitments towards universal health coverage". See also Alternative Civil Society Declaration: [No progress to universal health without health workers: a civil society commitment](#)

Notes from EB134 debate [here](#).

PHM Comment

The issue of HRH in relation to health workforce migration will continue, especially in the light of the persisting needs for health personnel in developed countries. For instance, the Affordable Care Act in the United States will lead to a greater demand for physicians and other health workers. Situations like this will inadvertently undermine efforts to strengthen health systems in developing countries.

PHM recognises the global action to address the issue of HRH, from the World Health report in 2008 to Kampala in 2008 to Recife in 2013. PHM endorses the Brazilian proposal regarding the importance of HRH issues and in reiterating the need for more definite commitments to ensure the continuity of gains made at the Recife Conference.

In this regard, PHM would like to call the attention of Member States to the Alternative Civil Society Declaration entitled: "[No Progress towards Universal Health without Health Workers: A Civil Society Commitment](#)", which also emerged from the Recife Conference. The Alternative Declaration includes a number of key issues that were absent in the Recife Political Declaration, including the needed 'fiscal space' for investing in HRH, the continuing brain drain and the need to compensate source countries, and the need to strengthen national training institutions in the global South.

The Alternative Declaration includes a commitment to:

- Strengthen the advocacy of health workers for improved infrastructure, support, and working conditions;
- Catalyse a strong movement for health workers; and
- Ensure accountable HRH systems at national and global levels

Accordingly, PHM urges Member States to consider amendments to the Brazilian resolution that will strengthen the accountability of donors, governments, and multilateral actors. Specifically, there is a need to:

- Ensure the development of a strong national health workforce, through direct economic governance and fiscal space, as a long-term investment for the wellbeing of the people and the economy of a country. The return on investment of employing a health worker is many times higher than that of bailing out a bank.
- Promote equitable access to health care by investing in health workers at the primary and community levels, through increased health worker retention, and by establishing community structures that facilitate citizens' participation.
- Provide substantive investments in the development of the health workforce, including salaries and social protection, and in national training institutions so as to rapidly increase numbers of HRH.

PHM also urges Member States to implement and strengthen the Global Code of Practice on the International Recruitment of Health Personnel. Advances made by WHO and groups like the Global Health Workforce Alliance must be sustained.

Lastly, in light of the continuing ascendancy of market forces and neoliberal programmes over public interest, more long-term solutions require the elimination of social and economic inequities within and among countries. PHM promotes the creation of stronger mechanisms like enforceable legislation, regulation, and redistribution processes aimed at mitigating and eventually eliminating the international 'brain drain' that exacerbates global health inequalities.

16.1 Implementation of the International Health Regulations (2005)

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- [Focus of consideration at WHA67](#)
- [Background](#)
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In focus at WHA67

The Assembly will consider document [A67/35](#) which canvasses three issues:

- a report of action taken in relation to MERS-CoV (for which an emergency committee has been convened under the IHRs);
- an update on negotiations around extensions of the target dates for meeting the capacity standards set out in the IHRs; and
- consideration of a revision to Annex 7 of the IHRs concerning yellow fever (the Assembly will be asked to adopt the draft resolution ([EB134.R10](#)) accepting life long immunity for yellow fever).

The application of the IHRs to slow burning threats to global health security such as AMR may be discussed.

Background

At the EB134 in Jan 2014 the Board had before it a report ([EB134/32](#)) on the implementation of the IHRs (touching on criteria for extensions of time and providing an overview of implementation). The report also described Secretariat involvement with the MERS-CoV outbreak and included a proposed revision of Annex 7 of the IHRs dealing with yellow fever (with an accompanying resolution regarding the updated Annex 7 on yellow fever which as amended ([EB134.R10](#)) will be transmitted for the consideration of the Assembly).

The IHRs were adopted in 2005 to come into force in 2007. States parties were given until 2012 to develop the required surveillance and control capabilities. There would be a two year (or at the maximum four year) extension for states parties needing extra time to develop the required 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.

The report provided to the EB proposed that the criteria for extensions would remain as in [EB132/15 Add.1](#). The Board noted the report. (The report noted that some regional committees

had discussed modifications to the time lines associated with these criteria.) The report also provides a detailed account of MS shortfalls in the full implementation of the IHRs and describes the efforts of the Secretariat to support those MSs.

The IHRs are particularly significant for the future of the WHO. They are one of two 'treaty making powers' that distinguishes WHO from the other foundations, funds and corporates swimming in the over-crowded sea of 'global actors' in global health governance (the other base for treaty making is the framework convention as used in the Framework Convention on Tobacco Control).

The WHO Watch report of the EB134 debate on this item is [here](#)

PHM comment

PHM is happy to accept the advice of the experts regarding YF and therefore supports the resolution.

PHM is keen to see full implementation of the capacities specified by IHRs with the flexibility that the DG spoke of and with full exploration of sub-regional arrangements as proposed by Suriname.

There may be scope for the wider use of the new Regulations which has yet to be explored. In 2007 Raviglione and Smith (both senior officers inside WHO) flagged the possibility of using the IHRs to address extensively drug resistant tuberculosis. In 2011 Didier Wernli and colleagues called for action more broadly as to apply the IHRs to the global threat of anti-microbial resistance (AMR).

The IHRs mandate surveillance and control in a particular field. There are other fields such as anti-microbial resistance and vaccine coverage which are not currently required by the IHRs but may be of comparable importance to global health security.

Advocacy priorities

- Push ahead with mandated capacity building although flexibly and with full scope for sub-regional capacity building and without undue harassment.
- Adopt the resolution on yellow fever.
- Raise for further exploration the possible use of IHRs (or the regulatory powers of WHO more generally) to control AMR (or at least to maintain appropriate surveillance). See [PHM comment on Item 16.5 \(on AMR\)](#) on the agenda for this Assembly.

16.2 Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits

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Focus at WHA67

PIP is scheduled for consideration by the Assembly in accordance with [WHA64.5](#) of May 2011 which requests the DG “to report, on a biennial basis, to the World Health Assembly through the Executive Board on progress in the implementation of this resolution”.

The Assembly will consider the Secretariat report, [A67/36](#), slightly updated from [EB134/33](#) considered by the Board. Unless there is a resolution in the wings the Assembly will be required simply to note the report.

Member states will very likely canvass many of the same issues discussed in the Board:

- negotiations around SMTA2,
- the handling of genetic sequences within the PIP Framework,
- partnership contributions invoiced (and received) for 2013,
- distribution and use of partnership contributions
- partnership contribution distributions
- virus sharing
- traceability
- exclusion of animal viruses
- SMTA2 negotiations

PHM is also hoping that consideration be given to partnership contributions from recipients outside GISRS who have benefited from their use of GISRS resources but who are not manufacturers. This could include research entities that acquire and benefit from intellectual property arising from research utilizing GISRS influenza materials.

Background

History

The pandemic influenza preparedness framework ([here](#)) was developed because of concern regarding inequities that had through WHO influenza sharing through what was then known as the Global Influenza Surveillance Network (GISN). Countries shared influenza viruses with WHO linked laboratories, which in turn shared candidate vaccine viruses with vaccine manufacturers, but no benefits were returned to WHO or the countries that shared the influenza viruses. In fact countries that shared the influenza viruses often were not able to gain access to the vaccines, either because there were unavailable or because they were unaffordable. Discussions over the inequities peaked in 2007, leading to intensive negotiations and finally a [Framework](#) for virus and benefit sharing in 2011.

Under this Framework recipients of viruses have to share benefits. Benefits are shared through two channels: SMTA agreements and partnership contributions.

Recipients of biological materials are required to enter into an agreement with the WHO known as the Standard Material Transfer Agreements (SMTA) to indicate how the benefits of accessing these materials are to be shared with the WHO. Two different SMTAs are provided for. SMTA1 is for entities within the GISRS receiving materials. SMTA2 is for entities outside the GISRS receiving materials. The benefits shared under SMTAs are largely in kind benefits. (See details of SMTAs in Annex 1 & 2 of the PIP.)

Entities outside the GISRS are also expected to make 'partnership contributions' to WHO to help support the Global Influenza Surveillance and Response System (GISRS). In 2012, WHO received \$US18 million from 6 manufacturers. WHO expects to receive \$US28m for 2013 from 37 companies. The total financial contribution sought through partnership contributions is set at around half of the total cost of running the GISRS (\$56m). Thus the total expectation is up to \$US28 million per year. The distribution of the partnership contribution obligation is determined in accordance with rules (8 May, 2013) [here](#). The use of the partnership contribution is governed by Decision [EB131\(2\)](#) from May 2012: broadly 70% is to be used for preparedness (laboratory and surveillance) and 30% reserved for to support response capability.

An Advisory Group was set up to monitor implementation of the PIP framework. This Group meets twice a year.

More about PIP on WHO website [here](#). See also WHO Watch history [here](#).

Immediate

The Executive Board in Jan 2014 received a report (Document [EB134/33](#)) on the distribution among companies of the partnership contribution obligation for 2013. In addition, the report included a summary of key points discussed by the PIP Advisory Group at its meeting in October 2013 and a synopsis of its second annual report.

The key points discussed by the AG in October 2013 included: negotiations around SMTA2, the handling of genetic sequences within the PIP Framework, partnership contributions invoiced for 2013, partnership contribution distributions.

The key issues covered in the synopsis of the second AR included: virus sharing, traceability, exclusion of animal viruses, SMTA negotiations, partnership contributors, use of partnership contributions.

Notes of debate at EB134 [here](#).

PHM / TWN comment

However a few points/issues should be noted as follows:

Receipt of total partnership contribution

It's unclear from [EB134/33](#), how much of the full partnership contribution expected for the year 2013 (US\$ 28 million) has been received by WHO. How secure is this expectation?

Obligation of research entities to make a partnership contribution

The WHO Secretariat has interpreted Section 6.14.3 of the [Framework](#) as requiring only actual manufacturers (entities producing vaccines, diagnostics, and anti-virals) to make a financial partnership contribution (see [PC Distribution 8 May 2013](#)).

This means that companies, universities, and other research entities that acquire intellectual property on the basis of research utilizing GISRS influenza materials are not currently required by WHO to make a partnership contribution to the WHO system, even though they may financially benefit from it.

This narrow interpretation of the Secretariat is not in line with Section 4.3 of the [Framework](#) which defines "Influenza vaccine, diagnostic and pharmaceutical manufacturers" as "public or private entities including academic institutions, government owned or government subsidized entities, nonprofit organizations or commercial entities that develop and/or produce human influenza vaccines and other products derived from or using H5N1 or other influenza viruses of human pandemic potential."

The Framework references to academic institutions and non-profit organizations and to "other products" clearly indicate that it was the intention for all those that benefit from the GISRS system by receiving the biological materials, to also make financial contribution to the WHO system.

It is important to recall that the PIP Framework was developed to address the shortcomings of the WHO Influenza system, particularly the inequity of entities outside of WHO GISN gaining access to PIP biological materials and profiting from the use of the materials without having to commit to any form of benefit sharing. Thus it is important to ensure that this inequity does not re-emerge in the context of the PIP Framework. Towards this end, it is critical that the Advisory

Group and WHO define appropriate mechanisms to ensure that any entity that uses GISRS and benefits from the use makes a partnership contribution.

Benefit sharing from sequence data

In Annex 1, paragraphs 4-6, it is highlighted that the Secretariat is in the process of initiating a discussion on the best process to handle the use of influenza sequence data under the Framework.

Today it is possible for an equipped and experienced lab to download the sequence of an influenza gene or of an entire virus and create functioning virus from it in only a few days. These sequences of viruses that are in the WHO system have potential commercial application in vaccines, diagnostics, and drug development. Use of influenza viruses that are created in this manner (wholly or partially from sequence data) should also be subject to the Framework's benefit sharing rules, just as if they would be if they were acquired as biological material from the WHO network.

During the discussion it should be stressed that use of such sequence data to create viruses (and parts thereof) must trigger benefit sharing obligations in terms of financial contribution as well as the signing of a SMTA. If this use of WHO system virus sequence data is not subject to the benefit sharing elements in the PIP Framework, the Framework will eventually be undermined by synthesis technology.

Definition of PIP biological materials

In Annex 2 of EB134/33, Section 2.3 on Definition of PIP Biological Materials, it states that the "Advisory Group expressed a view that a strict application of the definition met the intent of Member States during the PIP Framework negotiations and would be least likely to dampen collaboration between human and animal sector laboratories".

This position raises concern that animal viruses sent to WHO will not be subject to the PIP Framework, although in practice they would fall within its scope, which is supposed to cover all influenza viruses with human pandemic potential. The position effectively undermines full implementation of the PIP Framework. If there are certain unaddressed issues with animal sector laboratories that collect and study influenza viruses, these issues should be clearly identified and resolved in an equitable manner.

It is also not clear on what basis the Advisory Group is stating that the strict application of the definition met the intent of the WHO Member States.

PHM policy priorities

How confident is the Secretariat of receiving the \$28m?

Exclusion of animal viruses appears to weaken the reach of GISRS and the PIP Framework. What are the sensitivities? Can this decision be reconsidered?

How to investigate the issue of genetic sequences?

Further consideration to be given to partnership contributions from recipients outside GISRS who have benefited from their use of GISRS resources but who are not manufacturers. This could include research entities that acquire and benefit from intellectual property arising from research utilizing GISRS influenza materials.

16.3 Smallpox eradication: destruction of variola virus stocks

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In focus at WHA67

The WHA67 will consider the Secretariat report, [A67/37](#), a revision of [EB134/34](#) following the debate within the Board. The focus of discussion will again be whether to set a timetable for the destruction of variola stocks. However, there was some concern expressed at the Board regarding modern biosynthetic technologies and the DG proposes to convene an expert group to advise. This will attract some comment as well perhaps.

Background

Immediate

The document considered by the EB in Jan 2014 ([EB134/34](#)) reported on work undertaken by the Secretariat in preparation for the 67th World Health Assembly. It summarized the conclusions of both the Fifteenth meeting of the WHO Advisory Committee on Variola Virus Research (ACVVR) in Geneva, 24 and 25 September 2013, and the second Advisory Group of Independent Experts (AGIES) to review the smallpox research programme (Geneva, 5 and 6 November 2013), and the recommendations of a meeting of the Strategic Advisory Group of Experts on immunization (SAGE) in Geneva, 5–7 November 2013. The latter Group based its conclusions and recommendations on the outcome of an expert consultation on smallpox vaccines and the WHO smallpox vaccine stockpile (Geneva, 18 and 19 September 2013).

History

Destruction of variola (smallpox) virus stocks is one of the oldest standing issues on the World Health Assembly's agenda. Even before smallpox was declared eradicated in 1980, debate began among WHO Member States about how to eventually destroy all remaining laboratory samples of the virus. In the late 1970s and 80s, worldwide collections of these samples were either destroyed or sent to two WHO Repositories for safekeeping. In the midst of the Cold War, these repositories were unsurprisingly located in Russia and the United States.

After the samples were condensed to two locations and Member States confirmed they held no more viruses on their own, in 1990 the United States pledged to destroy the stocks located at

the WHO Repository in Atlanta once a virus sample was genetically sequenced. This sequencing project was done and, in 1996, the World Health Assembly resolved to destroy all remaining stocks by 1999.

Destruction of the virus is possible because smallpox vaccines are manufactured from a related virus called vaccinia. And in the unlikely event that smallpox ever reappeared in the wild, it is vaccinia virus and not variola virus that is needed to make new vaccines.

When 1999 came, as the WHA's date to destroy the remaining virus stocks approached, the United States and Russia both balked, refusing to implement the WHA resolution. Part of their hesitancy related to mutual distrust – each feared the other might use the virus as a weapon (even though it is not especially well suited for such use).

Instead of destroying the viruses deposited by many Member States in the WHO Repositories, Russia and the US kept them, and insisted on performing further research with them, research that is especially risky given transmissibility of the virus between humans, its high fatality rate and often debilitating effects on survivors. Moreover, globally, immunity against infection was on the decline, with the termination of routine vaccination programs in developing countries in the late 1970s and 80s. (Many developed countries stopped vaccinating earlier.)

After the 1999 failure to destroy the viruses, the WHA agreed to allow a time-limited and specific research program with the remaining stocks. This research program was wholly restricted to enumerated purposes deemed essential for public health. These were additional sequencing, new diagnostics, a new generation of vaccines, development of antiviral drugs, and development of an animal model of smallpox infection, using variola virus, in order to support vaccine and antiviral studies.

Some experts, including participants in the successful eradication program, never warmed to the research program, feeling that the risks outweighed the benefits or, as the American who led the WHO Eradication Program quipped, the less that was done with variola virus, the better. Fewer risks, fewer suspicions.

Nevertheless, for more than a decade the US and Russia – but especially the US – have conducted smallpox studies under the theoretical supervision of a WHO committee called the Advisory Committee on Variola Virus Research (ACVVR). This committee has suffered from opaque procedures and geographic imbalance and, by 2005, had caved in to US pressures to the point of approving genetic engineering experiments with smallpox.

This latter research approval prompted a reaction from civil society, including members of the Peoples' Health Movement, and from WHO Member States. There was great concern expressed that initiating genetic engineering experiments with WHO endorsement with the virus was a dangerous idea and precedent.

The WHO Director-General, under pressure, reversed the ACVVR's decision, setting into motion a series of WHA debates on destruction of the virus samples that could culminate in another decision to destroy the virus stocks at the upcoming 67th WHA in 2014. A notable development in this process was a Major Review of the research program, released in 2011 and

discussed by the WHA in 2012. Although the Major Review concluded that the research program was largely complete, the 64th WHA could not agree on a new date for destruction of the virus stocks, postponing the discussion until the upcoming 67th WHA.

(A series of NGO publications track the process of the WHA's debate since 2005, including the major review, in great detail. These papers can be downloaded at www.smallpoxbiosafety.org.)

One important organizational outcome of the Major Review was the establishment of a second WHO committee to assess the variola virus research program. This committee is the Advisory Group of Independent Experts (AGIES) to review the smallpox research program. Whereas the ACVVR has opaque procedures and outsized representation from some countries and institutions with vested interest in continuing variola virus research, the AGIES is composed of public health experts, has a clear structure, and is not beholden to the interests of specific governments and research agencies.

The AGIES met in late 2013 and unequivocally concluded that no essential public health purpose remains for retaining the variola virus stocks, meaning that the WHA should now move to again fix a date for their destruction. Many viruses have been sequenced, many new, rapid, and accurate diagnostics have been developed, several new generation vaccines have been developed, licensed, and in some cases stockpiled, and two new antiviral drugs are in late stages of regulatory review, with the US Food and Drug Administration having stated that no further studies utilizing variola virus will be necessary for their licensure.

Remarkably, the ACVVR, which at its last meeting in 2013 had more voting representatives from the United States than some entire WHO regions, largely agrees with the AGIES public health experts. The ACVVR's only area of disagreement with the AGIES relates to the desirability to keeping variola virus for further antiviral drug studies. But there, the Committee favored retaining the virus by only a bare majority. Thus, if it were not for the outsized representation of the USA (which wielded 4 votes out of 15 attendees), the committee would have voted to recommend destroying the virus samples on every count.

Although the United States and Russia are likely to resist, the 67th WHA could – and should - take a historic decision to fix a new destruction date for the virus. With the WHA authorized research program satisfied in the view of a majority of experts, no technical obstacles to destruction remain. It is simply a matter of WHO Member States' political will.

Notes of EB134 debate [here](#).

TWN comment. Smallpox - WHO Executive Board passes the buck to the World Health Assembly

TWN IP Info, 28 January 2014 (<http://www.twinside.org.sg/title2/health.info/2014/hi140104.htm>)

Dear Friends and Colleagues

Smallpox: WHO Executive Board passes the buck to the World Health Assembly

For the first time since 2011, the World Health Assembly (WHA) will undertake a substantive consideration of destruction of smallpox virus stocks when it meets in May 2014. At the meeting of the World Health Organization's Executive Board on 20-25 January 2014, a preliminary exchange of views revealed significant disagreement among Member States.

This despite a WHO public health expert committee concluding that no public health purpose remains to retain the virus stocks, held at WHO Repositories in the US and Russia. The committee says that sufficient sequences, diagnostics, and vaccines exist, and that anti-viral drug research is sufficiently advanced, so that the stocks can now be destroyed.

Some countries favored fixing a date of destruction of the virus, while others said doing so was premature. Some, particularly the US, appear to favor expansion of the research programme to address "new threats", a move that could indefinitely delay destruction of the stocks if taken on board by the WHA.

There is concern among experts that the US is attempting to raise fears about the "threat" of synthetic biology as a means to try to gain WHA approval to expand the research programme (and thus provide justification for virus retention), and that such an expansion could possibly include genetic engineering experiments, the subject of prior controversy at the WHA.

Please find below a report on the Executive Board's discussion on the issue.

With best wishes

Third World Network

Smallpox: WHO Executive Board passes the buck to the World Health Assembly

Austin, Texas, 28 Jan (Edward Hammond) – For the first time since 2011, the World Health Assembly will undertake a substantive consideration of destruction of smallpox virus stocks when it meets in May 2014.

At the meeting of the World Health Organization's Executive Board on 20-25 January 2014, a preliminary exchange of views revealed significant disagreement among Member States on the issue.

The research program on virus stocks of the eradicated disease, which since the 1980s have been held only at WHO repositories in Russia and the United States, is reaching its conclusion. The research was only authorized for public health purposes, and all Member States of the World Health Assembly have agreed to destroy the stocks once this is completed. According to a WHO's public health expert committee (the Advisory Group of Independent Experts (AGIES) to review the smallpox research program), no public health purpose remains to retain them. The AGIES says that sufficient sequences, diagnostics, and vaccines exist, and that anti-viral drug research is sufficiently advanced, so that the stocks can now be destroyed.

Another WHO oversight committee (the Advisory Committee on Variola Virus Research, ACVVR), which has less transparent operations and heavy representation from smallpox labs, somewhat disagrees. The ACVVR concludes that for most purposes, no need for smallpox virus remains, however, voting by a small majority late last year, it concluded that a narrow scientific rationale exists to retain stocks in order to finalize studies on anti-viral drugs. But in its bare majority ballot on anti-viral drugs, members from the United States cast over 25% of the vote, more than some entire WHO regions, such as Africa.

On the evening of 23 January, the WHO Executive Board took up the issue, and the exchange of views that took place suggests that discussions at the World Health Assembly will be difficult. Some countries favored fixing a date of destruction of the virus, while others said doing so was premature. Some, particularly the United States, appear to favor expansion of the research program to address what it terms "new threats", a move that could indefinitely delay destruction of the stocks if taken on board by the WHA.

China and Iran were clearest in calling for the WHA to set a destruction date for the virus. Iran recalled its statement from the 64th WHA calling for a destruction date and called for a mechanism to oversee destruction to be set up. China said that the research program had come a long way and that it was now time for use of live variola virus to stop and for strict and effective restrictions to be placed on artificial variola. China called for the process of destruction to begin, and for Member States to have equal footing in access to the results of the research program.

Most stridently opposed to destruction were, unsurprisingly, Russia and the United States. Russia noted the results of research conducted at the WHO Repository located within Russia and said these were of use to the international community. Russia said that it was working on antiviral drugs and that virus retention was justified and necessary. Russia did not specifically address the conclusion of the AGIES that the research program no longer has a compelling public health purpose.

The United States said fixing a destruction date is premature, and drew particular attention to what it termed as "new threats" stemming from synthetic biology. The US considered that release of synthetic DNA could have "catastrophic" consequences, and supported the suggestion by Mexico (see below) that the WHO Director General form an expert group to report on variola virus and synthetic biology.

The United States has long held the position that it would agree to destroy the viruses in the WHO Repository in Atlanta once the WHA-authorized research program is completed. The US, observers noted, was now facing greater pressure to do so because of the conclusions of the AGIES that retaining the virus no longer has a public health purpose. Pressure is building on the US also because its outsized representation on the ACVVR appears to be the only reason why that Committee too did not vote to destroy the virus on every count.

Thus, there is concern among experts that the United States is attempting to raise fears about the "threat" of synthetic biology as a means to try to gain WHA approval to expand the research program (and thus provide justification for virus retention), and that such an expansion could possibly include genetic engineering experiments, the subject of prior controversy at the WHA. (This aspect of the Executive Board discussion will be addressed in greater detail in a future TWN article.)

Several other countries said that they could agree to continued retention of stocks, with varying degrees of enthusiasm. Brazil, Panama, Argentina, Australia, Japan, Lithuania, Albania, Saudi Arabia and Malaysia were among these. Most of these countries offered short statements with few details other than to note progress in the research program and the opinion that it is premature to destroy the stocks.

A few of these countries offered perplexing rationales for retention, such as an alleged need for more vaccines, despite the conclusion of both the AGIES and the ACVVR that sufficient vaccines exist. These include less "reactogenic" vaccines suitable for immunologically vulnerable populations and, of course, it was effective vaccines that have existed since the

1960s that led smallpox to be eradicated from the wild in the first place. Smallpox vaccines are not made from variola virus (which causes smallpox), but from Vaccinia, a related virus; hence live variola virus is not needed for vaccine production.

Canada's intervention was a mixed bag. On the one hand, Canada notably stated that no public health purpose remained for retention of the virus stocks. On the other, it said the stocks should be destroyed when "necessary measures" were in place. Among these, Canada mentioned that Member States should certify that they are free of variola virus, a suggestion that first came up at the 64th WHA, where it was proposed by the United States.

Specifics on this proposal are thin. Neither the United States nor Canada have addressed the fact that the WHO has already conducted a certification process. This took place in the 1970s and early 80s when, under WHO supervision, existing variola virus samples (at dozens of labs across the world) were either destroyed or deposited by Member States in WHO Repositories. (Originally five, now reduced to two.) The certification proposed by the US and now Canada thus duplicates work already done by WHO, and no specific rationale for re-certification has been proffered.

South Africa affirmed its commitment to prior WHA decisions that the virus stocks should be destroyed, and noted that variola DNA fragments found a few years ago in a South African lab would shortly be destroyed, in coordination with WHO.

Mexico and several other countries proposed that the WHO Director-General establish an expert group to report on variola virus and synthetic biology. The schedule and parameters of this group are unclear. The Director-General noted that she would try to obtain the resources for such an expert group which, presumably, would make a report to the WHA in May. It is unclear why this task could not be assigned to the existing AGIES committee, if necessary, supplemented by advisors.

Destruction of smallpox virus stocks will next be formally considered as a substantive agenda item at the 67th World Health Assembly, beginning on May 19, 2014 in Geneva.

PHM advocacy priorities

PHM urges the MSs to commit to the final destruction of the remaining stocks of variola virus.

16.4 Poliomyelitis: intensification of the global eradication initiative

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In focus at WHA67

The Assembly will be invited to note the Secretariat report, [A67/38](#), a revised version of [EB134/35](#), which summarises progress and risks in achieving the objectives of the new [Polio Endgame Plan](#), and provides an overview of the programmatic and risk management priorities for 2014.

The issues are quite complex. [A67/37](#) provides an overview. More detail can be found in the SAGE reports (linked below).

During the EB134 debate the US asked the DG to convene a WHO emergency committee under IHR which the DG agreed to do although not immediately. An update on this may be provided.

Background

In May 2012, the World Health Assembly considered the Secretariat's report ([A65/20](#)) and adopted [WHA65.5](#) which declared the completion of polio eradication a programmatic emergency for global public health and requested the Director-General to rapidly finalize a comprehensive eradication and endgame strategy for the period 2013-2018 ([final version here](#)).

The sequence of reports from SAGE provide an overview of progress with respect to the Endgame: [Feb 2012](#), [April 2012](#), [Nov 2012](#), [April 2013](#), [Nov 2013](#), April 2014.

In April 2012 SAGE was alarmed by the funding shortfalls for the Plan at a time when eradication is in sight, with OPV campaigns already cancelled or scaled back in over 25 high risk countries in 2012.

In November [2012, SAGE](#) endorsed the four major objectives and milestones in the new strategic plan. SAGE also recommended that all countries should introduce at least one dose of inactivated polio vaccine (IPV) in their routine immunization program to mitigate the risks and consequences associated with the eventual withdrawal of the type 2 component of OPV (OPV2).

SAGE will continue to review progress on achieving the pre-requisites for OPV2 withdrawal, including the availability of affordable IPV products to ensure the earliest possible date for OPV2

withdrawal with sufficient advance notification to ensure programmatic readiness and vaccine availability.

See WHO's [polio page](#) for an overview of the disease and links to further resources.

See also the Global Polio Eradication Initiative [website](#).

Notes of discussion at EB134 [here](#).

PHM Comment

It will be an historic achievement if polio is eradicated and will reflect success in overcoming a range of barriers, technical, logistic and resourcing. It will reflect creativity, persistence and dedication. The sacrifice of the vaccinators who have died is part of the cost.

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.

Polio eradication has been on the WHO agenda since 1988 and, although much progress has been made, eradication is still an issue not resolved. Smallpox eradication has been used as example of eradication but the debate on how feasible, possible and even cost-effective eradication of poliovirus might be has been taken out of the agenda.

There is no reference to analyses on benefits, costs, risks between the plan of eradicate the virus or control the disease. PHM argues that it is necessary to clarify these distinctions. Both terms are well defined, but are being used often interchangeably by authors and agencies.

It is well known that Polio Eradication Campaign has escalating costs during the so called "endgame" of polio eradication, as what happens in Pakistan currently, along with high costs of social and health systems structuring, specially in concerns to actions taken by foreign organisations through vertical approaches.

16.5 Antimicrobial drug resistance

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- [PHM Comment](#)
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In focus at WHA67

The Assembly will be invited to consider the Secretariat report [A67/39](#) (based on [EB134/37](#)) and a draft resolution recommended by the EB ([EB134.R13](#)).

Background

Immediate

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.

The Secretariat report ([A67/39](#)) deals with the current response to antimicrobial resistance, the call for a global action and the next steps to be undertaken. Under 'need for global action' the paper highlights:

- integration of prevention of antimicrobial resistance into all health systems and practice (both human and animal health)
- reduction of antimicrobial use in all sectors, where appropriate
- emphasis on hygiene and infection prevention and control
- recognition that extending quality healthcare through universal health coverage and awareness are important enabling factors
- technical and service innovation across all aspects of a global action plan.

Under 'next steps' the paper lists:

- Intersectoral engagement
- National plans
- Knowledge and information
- Medicines regulation
- Prevention of infection
- Technology innovation
- Service innovation.

The EB developed a draft resolution for consideration by the Assembly ([EB134.R14](#)). The resolution urges MSs to implement a range of policies and procedures and requests the DG to develop a draft global action plan to combat AMR, among other initiatives.

History

The extensive use, misuse and overuse of antimicrobials in both human and animal health have increasingly raised levels of antimicrobial resistance in a wide range of pathogens (bacteria, viruses, fungi and parasites) in all countries and patients of all age groups.

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

The 2013 Prince Mahidol Awards Conference in January 2013 ([here](#)) focused on 'One Health' including a broad overview of the ways in which agriculture as well as medicine are contributing to AMR ([here](#)).

Summary of discussion at EB134

The antimicrobial resistance (AMR) has been widely recognised as a threat to public health worldwide and some Member States, highlighting the multiple connections between human health and the broader factors, called for a multisectoral approach and a closer collaboration with other sectors and actors including FAO and the World Organisation for Animal Health. To this regard the US reported that they phased out the use of growth promoters in agriculture. *[This is actually not accurate. The FDA has released voluntary guidance, not rules, that may lead to phase outs sometime in the future. The companies have formally agreed through non-binding letters to follow the guidance but have not done so yet for any products that are currently marketed. - PHM]*

The action plan was envisaged as the proper tool to deal with the AMR; some MSs specifically call upon WHO for coordination and support. The EU suggested to integrate the surveillance of the the AMR into the WHO regular epidemiological surveillance while South Africa focused on the need of such a surveillance system for the XDR TB control.

Lebanon pointed out the problem of self medication and OCT especially in developing countries and Myanmar along with Cuba stressed the importance of health professional training in a rational prescription of drugs.

The report by the Secretariat was accompanied by a draft resolution proposed by Sweden and cosponsored by many other MSs. Regarding the resolution, Belgium expressed some concerns about its financial implications and the funds needed for the 2014-15 biennium.

After MSs, 3 NGOs took the floor. Consumers International pointed out that the global action plan should include strong measures to prevent the use of antibiotics as growth promoters and as prophylactics and that global and national plans should promote an improvement in animal husbandry as vital part of infection control. Both PHM and MSF called for innovative mechanism

able to decrease the price of new antibiotics and new diagnostics that are desperately needed; MSF in particular stressed the need for a clearer language on R&D.

The Secretariat stated that the world is in a post-antibiotic era for some pathogens and recalled the importance of a multisectoral and global action being AMR an issue in which the North/South divide is not relevant.

The report was noted and the draft resolution as amended was approved ([EB134.R14](#)).

Detailed report of EB134 debate [here](#).

PHM Comment

The Report by the Secretariat identifies the imminent danger to global health which antimicrobial resistance, in particular, represents but downplays the urgency of the situation and measures needed. In accordance with the next steps list provided by the Secretariat, there is a need of urgent measures that are not mentioned or weakly defined in the document.

Intersectoral engagement

The use of antibiotics as growth promoters in animal husbandry needs to be phased out and tight controls on 'prophylactic' and 'therapeutic' use. Progress on this front will require persistent work in building the intersectoral partnerships and global, national and local levels needed to implement and monitor such an objective. Regulations will be needed to support effective surveillance.

The Report of the Secretariat states the need to "to limit antibiotic use, as well as to stop antibiotic use for non-therapeutic purposes in livestock and agriculture." This should include the restriction of the group medication of animals for disease prevention and the shifting away from livestock production practices known to drive antibiotic use such as early weaning, inadequate sanitation, or inappropriate diets. Intersectoral engagement should prioritize public health and should be part of all other action steps.

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. Such an effort would have further beneficial effects of immediately saving millions of children from diarrheal diseases every year and is long overdue. 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

Knowledge and information

The document calls upon WHO to develop global standards for data collection and reporting and to facilitate the development of national and regional surveillance networks.

Proper global and local surveillance will require significantly upgrading laboratory capacity in L&MICs.

An early warning system to detect outbreaks/events as well as new mechanisms of resistance should be put in place. Such a system would enable the rapid identification and reporting of AMR events of serious public health significance. The use of the IHR (2005) to mandate such a system would be appropriate. Public access to data on antibiotic use and resistance is essential.

In many respects surveillance information (in particular on drug sales) is collected but not available publicly. In important institutional settings decision making is far from transparent and conflicts of interest abound.

Medicine regulation

Medicines regulation including tighter controls over antibiotic prescribing and sales is critical. This needs to be supported by educational programs for both clinicians and for the public.

Commercial promotion of antibiotic use to physicians and veterinarians should be banned. Likewise over the counter sales and direct to consumer advertising should be banned.

Prevention of infection and infection control

The prevention of transmission of infectious disease gains new urgency in the face of resistance to chemotherapy for tuberculosis, HIV and hepatitis.

A revitalised initiative around infection control in healthcare settings is likewise urgent.

The major reasons for the use of antibiotics in food animals should be investigated and alternative practices should be identified and promoted.

Technology innovation

New antibiotics and new diagnostics are needed; likewise new ways of funding research and development. The challenge of AMR adds weight to the proposed R&D Treaty as well as other initiatives such as the proposed Antibiotics Innovation Funding Mechanism (AIMF) which combines the advantages of supporting innovation, eliminating incentives to overuse, and supporting transfer of technologies to insure access to medicines for low income countries (full text at <http://keionline.org/node/1832>).

Use of WHO's treaty making powers

Serious consideration needs to be put into whether, and if so how, WHO's treaty making and regulation making powers could be used to mandate necessary standards governing the use of antibiotics and appropriate surveillance systems.

PHM policy priorities

- Intersectoral partnerships and regulations are needed to support effective surveillance and to phase out the use of antibiotics as growth promoters in animal husbandry and tight controls on 'prophylactic' and 'therapeutic' use;
- Knowledge and information: an early warning system to detect outbreaks/events as well as new mechanisms of resistance should be put in place;
- Medicine regulation, including tighter controls over antibiotic prescribing and sales is critical. This needs to be supported by educational programs for both clinicians and for the public.
- The prevention of transmission of infectious disease gains new urgency in the face of resistance to chemotherapy for tuberculosis, HIV and hepatitis;
- New antibiotics and new diagnostics are needed; likewise new ways of funding research and development. The challenge of AMR adds weight to the proposed R&D Treaty as well as other initiatives such as the proposed Antibiotics Innovation Funding Mechanism (AIMF) which combines the advantages of supporting innovation, eliminating incentives to overuse, and supporting transfer of technologies to insure access to medicines for low income countries;
- Consideration of how WHO's treaty making and regulation making powers could be used to mandate necessary standards governing the use of antibiotics and appropriate surveillance systems.

19. Health conditions in the occupied Palestinian territory, including east Jerusalem, and in the occupied Syrian Golan

Background to agenda item(s)

The secretariat report [A67/41](#) was requested from the Director-General by the resolution [WHA66.5](#) adopted in 2013. The report provides an overview of the health situation in Palestine and highlights the progress in relation to key areas of WHO support in the Palestinian Ministry of Health.

The WHO Secretariat also received and published two information documents from the permanent mission of Israel in Geneva ([A67/INF./2](#)) and the Government of Syria ([A67/INF./2](#)).

PHM Comments

The WHA resolution [WHA66.5](#) requested the Director-General to report on the implementation of the resolution. The Secretariat report [A67/41](#) provided an overview on the health situation in Palestine (West Bank and Gaza) with hints on some of the underlying causes of this situation. In addition, it elaborated about the key areas of the cooperation with the Ministry of Health of Palestine. However, the Secretariat paper did not report on the implementation of what Israel and member states were urged/requested to do by the resolution.

The report recognized the implications of the restricted mobility of Palestinian citizens on accessing health services. It also recognized the obstacles that UNRWA is facing to serve the refugees population. However, in both cases the report does not discuss the causes and responsibilities for these restrictions.

The report failed to link the limitations on mobility and the difficulty in accessing the health facilities to practices of the occupation forces. It failed to recognize the fact of an occupation, the continuous aggression of the occupation forces and the use of collective punishment as major threats to people's lives, physical and mental health, dignity and livelihoods.

The report does not mention the attacks on health personnel, the conditions of political activists in the prisons of the occupying forces. The report does not report the number of deaths and the much larger numbers of handicapped people – consequent upon the conflict arising out of the occupation of the region.

In its report to the Assembly ([A67/INF./3](#)), the Permanent Mission of Syria has described the deterioration of the health situation of the population of occupied Golan without any mention to the situation in Syria which resulted in hundred thousands of deaths, millions of refugees and unprecedented health crisis in Syria and the neighboring countries.

Instead of addressing, defending or even denying the few facts contained in the Secretariat report (out of many others), the report submitted by Israel seeks to divert consideration to whether or not the Assembly is the place for this discussion.

20.1 Programme budget 2012-2013: performance assessment

In focus at WHA67

The Assembly will review [A67/42](#). For details re organisation-wide expected results (OWERs) and indicators for PB12-13 see [A64/7](#). See also report prepared for PBAC [EBPBAC19/2](#).

PHM Comment

Donor control

The power of the donors to determine WHO's effective agenda is clearly reflected in the tables and graphs in [A67/42](#). See in particular Fig 2 and Table 4.

The % of expenditure derived from ACs vs VCs on different strategic objectives varies very widely. VCs account for >95% of expenditure on SO1 (communicable disease) and SO5 (emergencies). These together account for >56% of VCs. The SOs 1 (comm disease), 2 (AIDS, TB and malaria) & 5 (emergencies) account for almost 70% of total VCs.

Seven SOs accounted for <15% of total VCs (7 (SDH, 0.6%), 9 (nutrition, 1.4%), 8 (envt, 1.9%), 6 (risk factors, 2.1%), 3 (NCDs, 2.3%), 12 (leadership, 2%) and 11 (med products, 3.6%) .

Evaluation

Many of the indicators through which implementation of the PB12/13 was supposed to be monitored are silly. The summary tables ('fully', 'partially' and 'not' achieved) are not very meaningful.

The narrative comment on the achievement of the 13 SOs does not seek to clearly identify how WHO has contributed to the changes which are reported.

The evaluation practices of WHO, reflected in the clumsy OWERs and weak attribution, attracted substantive criticism from the Stage II Reform Evaluation consultants ([EB134/39](#)).

22.1 Human resources

In focus at WHA67

The assembly is asked to note [A67/47](#).

PHM comment

The report does not mention interns who constitute around 16% of the human resources upon which WHO depends.

The distribution by region of nationality of staff working at HQ (See Figure 11) demonstrates that a far too greater number of HQ staff are from the European and American regions, constituting 70% of total HQ staff.

The restriction of Junior Professional Officers to Europeans, Australians and Japanese is very surprising. Is this because the Secretariat charges sponsors such high prices?

There remains a disparity between HQ and the regions especially PAHO. Further work on this matter is required.

The report does not discuss the culture of the Organisation. PHM is very concerned that the competition for visibility and funding across units, departments, clusters and regions appears to create a huge barrier to cross organisational collaboration. We are aware of instances of units competing with the unit 'next door' for visibility and funding. How can MSs expect an efficient and coherent organisation when they torture the Organisation thus?