People's Health Movement Background and Commentary on Items coming before EB140

Final edition 17 Jan 2017

7.1	Health emergencies	1
7.2	Global action plan on antimicrobial resistance (and sepsis)	. 10
7.3	Polio	. 14
7.4	Implementation of the IHRs (2005)	. 15
7.5	Review of PIP framework	. 18
8.1	Human resources for health and implementation of the outcomes of the UN High-Level Commission on Health Employment and Economic Growth	20
8.2	Principles for global consensus on the donation and management of blood, blood components and medical products of human origin	. 25
8.3	Addressing the global shortage of medicines and vaccines	. 27
8.4	Evaluation and review of Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA)	30
8.5	Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination	33
8.6	Member States mechanism on substandard/spurious/falsely-labelled/falsified/ counterfeit medical products	
8.7	Promoting the health of migrants	. 38
9.1	Global vaccine action plan	. 41
9.2	Global vector control response	. 44
10.	1 Preparation for the third high level meeting (HLM) of the UN General Assembly (UN GA) on NCDs in 2018	
10.	2 Draft global action plan on public health response to dementia	. 52
10.	3 Public health dimension of the world drug problem	. 53
10.	4 Ending childhood obesity: implementation plan	. 58
10.	5 Cancer prevention and control in the context of an integrated approach	. 60
11.	1 Progress in the implementation of the 2030 Agenda for Sustainable Development	. 61
11.	The role of the health sector in the Strategic Approach to International Chemicals Management towards the 2020 goal and beyond	. 64
11.	3 Global Strategy for Women's, Children's and Adolescents' Health (2016–2030)	. 68
12.	1 Implementation and financing of Programme budget 2016–2017: update	. 74
14.	1 Overview of WHO reform implementation	. 77

14.2 Governance reform: follow-up to decision WHA69(8)	80
14.3 Framework of engagement with non-State actors	83
15.3 Human resources: update	86

7.1 Health emergencies

In focus

Clause 5 of A69(9) requests the Director-General to report to the Seventieth World Health Assembly, through the Executive Board, on progress made and experience gained in establishing and operationalizing the Health Emergencies Programme.

The provisional agenda has structured this item in terms of four sub-items:

- WHO response in severe, large-scale emergencies
 - <u>EB140/7</u> provides information on public health emergencies involving WHO during 2016;
- Independent Oversight and Advisory Committee for the WHO Emergencies Program:
 - EB140/8 conveys the report of the Chair of the IOAC providing observations and recommendations on the implementation of the WHE Programme and its performance in current emergencies and outbreaks;
- Research and development for potentially epidemic diseases:
 - <u>EB140/9</u> provides an update on the blueprint for research and development preparedness and rapid research response; and
- Health workforce coordination in emergencies with health consequences
 - <u>EB140/10</u> describes the work that WHO is undertaking at global, regional and country levels to improve coordination of the response to emergencies with health consequences.

These are important (see below) but the Health Emergencies Program extends beyond these issues (see below). In particular the need for adequate funding of WHO, generally and the Emergency Program in particular, must be discussed.

The <u>Update on WHO's Health Emergencies Program (WHE)</u> prepared for the 2016 funding dialogue provides a very useful summary of the elements of the Program and how it works. it also lays bare the financial crisis the WHE is facing.

Background

These background notes deal with:

- the prehistory of WHO's Health Emergencies Program,
- WHO response in severe, large-scale emergencies,
- the Independent Oversight and Advisory Committee for the WHO Emergencies Program,
- Research and development for potentially epidemic diseases,
- Health workforce coordination in emergencies with health consequences

The Prehistory of WHO's Health Emergencies Program

Strengthening WHO's work in outbreaks and other health emergencies and on the health side of humanitarian emergencies was added to the broader reform program in the aftermath of the West African Ebola outbreak of 2014. As it emerged, the reform of WHO's emergency preparedness comprised three main components: the contingency fund, provisions for a more

systematic approach to deploying an emergency workforce, and a new health emergencies program within WHO.

The Ebola epidemic commenced in late 2013. The first diagnosed cases were in late March in Guinea. By 23 June 2014 MSF had around 300 international and national staff working in Guinea, Sierra Leone, and Liberia and had sent more than 40 tons of equipment and supplies to the region to help fight the epidemic.

WHO was slow to build its response to the Ebola outbreak. The shortfalls in WHO's management of the Ebola outbreak pointed to specific problems in the implementation of the International Health Regulations (IHRs) and WHO's emergency management capability. However, the shortfalls in the management of Ebola also reflected the funding crisis, weaknesses in budgeting, evaluation and accountability, dysfunctional relationships between levels, and deficiencies in human resources management.

In WHA68/26 the secretariat noted:

When Ebola virus disease was first confirmed in West Africa, WHO's only sources of financing for an early, rapid response were regular budget lines and the modest bridge financing already in place for emergency responses. WHO issued its first appeal to underwrite its Ebola response on 27 March 2014, and a second on 10 April 2014. In response, donors contributed US\$ 7 006 230, although processing requirements meant that funds were available on 5 June 2014. Additionally concerning is that most of the funds were highly specified, which inhibited the ability to match funding to need as the crisis evolved.

In August 2014 the DG declared a public health emergency of international concern (PHEIC) under the IHRs and appointed an emergency committee and WHO released its 'Ebola response roadmap'.

The first substantive consideration of the EVD outbreak by the governing bodies was in a special session of the EB held in early January 2015 (EBSS3). The purpose of the special session was to ensure the international Ebola response, including that of WHO, was on track and second, to identify the lessons and reforms needed to do better next time. The agenda of the special session included a range of issues specific to Ebola including the fast tracking of preventive, diagnostic and therapeutic products, building resilient health systems in Ebola affected countries, and planning for 'getting to zero'. The Board's consideration of the implications of Ebola outbreak for WHO's work in health emergencies was informed by two main documents:

<u>EBSS/3/INF./4</u> provided a brief overview of the development of the IHRs and their application in the context of the Ebola outbreak. The paper includes some particularly sharp comments on three areas:

- the need to ensure all countries had established national preparedness capabilities as prescribed by the IHRs;
- the need to ensure the timely sharing of information in such emergencies (something which had not happened in this case), and
- concern regarding 'additional measures', referring to the 40 states parties who had imposed restrictive measures on traffic and trade beyond those prescribed by the emergency committee (in contravention of the IHRs).

<u>EBSS/3/3</u> considered how to ensure WHO's capacity to prepare for, and respond to, future large-scale and sustained outbreaks and emergencies. The paper was structured around five proposals:

- 1. affirming WHO's mandate and role in outbreak, humanitarian and emergency response and preparedness;
- 2. reforming WHO's crisis management mechanisms:
 - 17. As a first step, the outbreak and humanitarian/emergency response activities will be merged. Such a unified all hazards, global emergency response entity would maximize efficiencies and effectiveness, facilitate appropriate accountability and position the Organization to take on the leadership role for which it is poised.
 - 18. To genuinely leverage WHO's expertise, strengths and resources, the emergency response programme would be merged across all three levels of the Organization, with departments or units in each WHO office. The structure would be headed by a lead, or incident command during a response, with substantial delegated authority, giving the programme both singular leadership and direct reporting lines.
- 3. expanding WHO capacities, networks and partnerships, including an adequate standing cadre of emergency staff plus a surge capacity;
- 4. establishing funding mechanisms for the emergency response, including a special fund for emergencies; and
- 5. improving performance management and accountability.

The <u>debate</u> around these documents was fairly general with several delegates denouncing the failures of some states parties (largely the poorest countries in the world) to ensure full implementation of the capacity standards of the IHRs.

One of two standouts in the debate was the intervention of Ms Matsoso of South Africa who commented that "Member States should create an enabling environment that allowed the Organization to respond swiftly in times of crisis, rather than adopting resolutions that tied its hands". It is not clear what resolutions she was referring to.

A second standout was the intervention of Mr Oberreit (for MSF International) who described the work that MSF had been doing and warned the Board that although the number of cases of Ebola virus disease had decreased substantially, the epidemic was not under control. He went on:

"Major gaps remained: there was almost no sharing of information for cross-border contact tracing, surveillance teams lacked basic resources for active case finding, and safe access to health care for non-Ebola cases remained largely neglected. It was necessary to accelerate the development of vaccines, treatments and diagnostic tools and establish an implementation plan. Cases might keep emerging, and health systems therefore had to learn to cope with Ebola. Public health engagement and strong leadership were needed. Thousands had died because of international negligence and because there was no functioning global mechanism to deal with a potential pandemic in countries with fragile health systems. A clear gap remained between commitments made and actions taken."

The Board adopted an omnibus resolution (<u>EBSS3.R1</u>) which included commitments in a range of areas, including health systems (and IHR capabilities), emergency preparedness globally, information flows and funding for emergencies.

These commitments were further advanced in May 2015 at WHA68 which considered discussion papers on a contingency fund for emergencies (A68/26) and provisions for an emergency workforce (A68/27). The proposal for a \$100m contingency fund for emergencies arose first in the report of the review committee on the functioning of the IHRs in the H1N1 2009 outbreak (A64/10) but was not supported by the governing bodies. The proposal resurfaced in 2012 (in EB130/5 Add.6) as part of the DG's early reform proposals but again was not taken forward by the member states.

A68/26 explored the options for a contingency fund in the light of the Ebola outbreak; including size, scope, sustainability, operations, sources of financing and accountability mechanisms. In decision WHA68(10) the assembly endorsed the proposed fund, and:

- 2. Decided to create a specific, replenishable contingency fund to rapidly scale up WHO's initial response to outbreaks and emergencies with health consequences, that merges the existing two WHO funds, with a target capitalization of US\$ 100 million fully funded by voluntary contributions, flexible within the fund's scope;
- 3. Agreed that the contingency fund will reliably and transparently, including with regard to financial reporting and accountability, provide financing, for a period of up to three months, emphasizing predictability, timeliness, and country ownership; humanitarian principles of neutrality, humanity, impartiality, and independence; and practices of good humanitarian donorship;
- 4. Decided that the contingency fund would be under the authority of the Director-General, with disbursement at his or her discretion;
- 9. Requested the Director-General to prioritize in-field operations in affected countries when using the contingency fund.

A68/27 reviewed the kind of workforce likely to be needed for future health emergencies and explored the systems involved in scaling up (and deploying and decommissioning) a global emergency workforce. The first responders would be national. WHO would have both a standing and a surge capacity from existing staff. In addition the paper reviewed the international sources on which further surge capacity would be based. The paper reviewed the resources and systems already operating within the UN and how WHO might work more efficiently with those resources. The paper described how the emergency workforce would function and outlines governance and financing arrangements. In decision WHA68(10) the assembly endorsed the broad framework outlined in A68/27 and looked forward to further details in future governing body meetings.

The third element of the health emergencies reform was introduced in EB138 (in Jan 2016) with EB138/55 which outlined plans for a new WHO health emergencies program. (The design of this proposed new program was informed by the <u>first</u> and <u>second reports</u> of an advisory group on emergency reform.)

A more advanced version of the proposed new health emergencies program was submitted to the WHA69 in May 2016 in A69/30. The key elements of the new program include:

 a single programme, with a common structure across headquarters and all regional offices;

- functions of the programme to include:
 - infectious hazards management (including high threat pathogens, expert networks, etc);
 - country health emergency preparedness and the IHRs, including monitoring and evaluation of national preparedness, planning and capacity building for critical capacities:
 - health emergency information and risk assessments, including event detection and verification, health emergency operations monitoring, and data management and analytics; and
 - emergency operations, including incident management, operational partnerships and readiness, and operations support and logistics.
- a single executive director would be responsible for technical oversight and standards, all strategic and operational planning, risk and performance monitoring, budget and staff planning, and interagency and partner relations;
- the executive director would be supported by regional emergency directors, who will have delegated authority for emergency activities in their regions, and will form part of the global management team of the new programme;
- day-to-day oversight and management of major outbreaks and health emergencies will be delegated to the executive director who will have direct executive control over regional and country office involvement;
- a revised WHO emergency preparedness framework
- a new emergencies oversight and advisory committee to advise the DG and the governing bodies.

In WHA69(9) WHA69 decided:

- (1) to welcome the progress made in the development of the new Health Emergencies Programme [..] and the establishment of the Emergencies Oversight and Advisory Committee;
- (2) to encourage ongoing collaboration with the United Nations Office for the Coordination of Humanitarian Affairs to enhance humanitarian system-wide coordination of the response to large-scale infectious hazards in the future;
- (3) to note that the overall budget for the Health Emergencies Programme and its new operational capacities will be US\$ 494 million for the biennium 2016–2017, representing a US\$ 160 million increase over the current budget for WHO's primarily normative and technical work in health emergency management;
- (4) to approve an increase of US\$ 160 million for the Programme budget 2016–2017 to initiate the implementation plan for the new Health Emergencies Programme, and to authorize the Director-General to mobilize additional voluntary contributions to meet this financial need for the biennium 2016–2017.

WHO response in severe, large scale emergencies

EB140/7 provides information on public health emergencies involving WHO during 2016

A similar report, A68/23, was considered at WHA68 (May 2015). This paper provided a general descriptive overview of six Grade 3 emergencies and the nine protracted crises that WHO was currently responding to. It described the phases of WHO's response and the impact of continuing funding limitations. The Assembly noted the report (see discussion here). PHM comment here. A further report on WHO's emergency response engagement, EB138/23, was considered again at EB138 in Jan 2016. This elaborated on the material covered in A68/23 with a strong emphasis on the impact of funding limitations. It was noted by the Board. PHM comment here. A similar report, A69/26, was discussed again at WHA69 (May 2016) and was noted. PHM comment here.

Emergencies Oversight and Advisory Committee

The Assembly was advised of the establishment of the EOAC in A69/30 (paras 14,15). This built on the reports of the Ebola Interim Assessment Panel (A68/25, A69/25, final report) Advisory Group on the reform of WHO's work in outbreaks and emergencies (see First report of Adv Grp and Second report).

The establishment of this new committee was welcomed by the Assembly in <u>WHA69(9)</u>. See discussion at A4 and A5.

The report conveyed in <u>EB140/8</u> is the first report from the Committee and covers only the first four months of WHO's Health Emergencies Programme (WHE). It provides useful comments on the implementation of the WHE, underlining the risks to the programme consequent upon the shortfall in funding.

R&D for potentially epidemic diseases

<u>EB140/9</u> provides information on the progress made to improve research and development for potentially epidemic diseases. The report describes activities undertaken through the WHO research and development blueprint mechanism in order to reduce the time between the declaration of a public health emergency of international concern and the availability of effective tests, vaccines and medicines that can be used to save lives and avert a large-scale crisis.

The lack of vaccines, therapies and diagnostics in the context of the 2014 Ebola epidemic was a major limitation on the response. A significant effort was put into escalating the development of such products during and after the epidemic. The Interim Ebola Assessment panel in its <u>final</u> report commented on this shortfall (see paras 62-66) and recommended:

16. WHO should play a central convening role in research and development efforts in future emergencies, including the acceleration of the development of appropriate diagnostics, vaccines, therapeutics and medical and information technology.

EBSS3 (Jan 2015) had before it <u>EBSS/3/INF./1</u> on 'Fast-tracking the development and prospective roll-out of vaccines, therapies and diagnostics in response to Ebola virus disease'. In its omnibus resolution <u>EBSS3.R1</u> the Board:

33. RECOGNIZES the good progress made to date, under the leadership of WHO in the process of developing Ebola vaccines, and requests the Director-General to ensure the sustainability of the working groups on therapeutic medicines and vaccine clinical trial designs while they are needed, to ensure continued progress in the development of

quality, safe, effective and affordable vaccines and treatments, while emphasizing the importance of completing WHO's work on emergency regulatory mechanisms and procedures ensuring patient safety, committing results of this work to the most affected countries in West Africa as a first priority, with an accompanying distribution and financing plan, to be communicated to Member States as soon as it is ready;

34. REQUESTS the Director-General to evaluate the current status of the epidemic and to disseminate information on the most critical research studies to complete; and requests the Director-General in consultation with technical experts and Member States' regulatory agencies to develop guidance on the value and limitations of the data obtained from the clinical trials, giving particular attention to ethics, quality, efficacy and safety;

EB138 reviewed Secretariat report <u>EB138/28</u> which was entitled: 'Options for strengthening information-sharing on diagnostic, preventive and therapeutic products and for enhancing WHO's capacity to facilitate access to these products, including the establishment of a global database, starting with haemorrhagic fevers'.

EB138/28 discussed the design criteria for an information platform for information sharing and recommended assigning this function to the Global Observatory on Health Research and Development (established through WHA66.22 in 2013).

EB138/28 then discussed the development of a blueprint for research and development preparedness and rapid research response during future public health emergencies due to highly infectious pathogens. The five workstreams which constitute the blueprint are:

- prioritisation of pathogens and development of an operational plan;
- research and development preparedness: gap analysis and identification of research priorities;
- organization, coordination of stakeholders and strengthening of capacities:
- assessment of research and development preparedness levels and the impact of interventions; and
- funding options for research and development preparedness and emergency response. A revised version of EB138/28 was considered by WHA69 as A6929 and was noted (A7).

<u>EB140/9</u>, circulated for discussion during EB140, reports on subsequent progress on the R&D Blueprint, including planning for the development of R&D roadmaps for 11 priority pathogens. The draft R&D roadmaps have been published for <u>MERS-CoV</u> and for <u>Zika</u>.

EB140/9 also reports on a call for proposals for technology sharing; 35 proposals received; 6 judged to be most promising (three vaccine platforms, one for diagnostics, one for immunotherapy and one covering all product streams).

Other workstreams reported on include:

- revision of pathogen prioritisation;
- stakeholder coordination;
- sharing of data and samples; and
- regulatory capacity.

Health workforce coordination in emergencies with health consequences

<u>EB140/10</u>, submitted at the request of a Member State, describes the work WHO is undertaking at international, regional and country levels to improve coordination during health emergencies. It also provides information on priorities and resource implications for WHO's Health Emergencies Programme.

This item was not included in the original agenda for EB140. The Officers of the Board agreed to accept for addition on the provisional agenda of the 140th session of the Executive Board an item entitled "Coordination of humanitarian emergencies of international concern" with the proviso that the Secretariat's report should give due consideration to funding and staffing – both current and future – at each level of the Organization.

PHM comment

The need for emergency preparedness, response and recovery is huge. The humanitarian crises described in EB147 are dreadful.

The Health Emergencies reform was well conceived and appears to be have been implemented well.

The outstanding weakness in the Health Emergencies Program is the abysmal shortfall in funding.

<u>EB140/7</u> describes WHO's involvement in current and recent crises. In all cases the relatively modest funding needs have not been met.

The shortfall in Iraq is \$40m, equivalent to the capital and annual operating costs of four US army drones. The shortfall in Nigeria is around \$20m, equivalent to .5% of Royal Dutch Shell's annual profit for 2016. WHO and the wider UN Health Cluster are facing similar shortfalls in South Sudan, Syria and Yemen.

The IOAC report (EB140/8 paras 42-47) provides an overview of the financing shortfalls:

- 44. The WHE Programme is funded in three parts: core budget, appeals and the WHO Contingency Fund for Emergencies (CFE). The IOAC was apprised that US\$ 485 million is required for the biennium 2016–2017 for implementation of WHO's core activities in health emergency management and that 56% of the total requirement had been received as of December 2016.
- 45. Since the CFE was established in May 2015 with a target capitalization rate of US\$ 100 million, it has received only US\$ 33.68 million (33% of target) from 10 donors, of which US\$ 18.16 million has already been spent on covering the immediate operational costs for 11 distinct emergencies. The IOAC recognizes that the CFE is critical to WHO's early response to health emergencies and that robust early response can be highly cost-effective in preventing the further spread of outbreaks. The IOAC notes two main challenges: obtaining full funding for the CFE as originally foreseen, and replenishing the CFE to full capitalization.

46. Appeals linked to humanitarian response plans currently have a funding gap of 66% of the total requirement of US\$ 656 million. These funds have mainly been directed towards Grade 3 emergencies. The funds have been slow to materialize for disease outbreaks such as those for Zika virus disease and yellow fever, forcing WHO to use the fast-depleting CFE. The IOAC observes that there is very little staffing capacity at regional and country levels to fundraise, and relatively limited capacity at HQ compared to other international agencies. The IOAC encourages WRs to engage effectively with incountry donor representatives who manage country-level programme funding.

This bleak assessment is reiterated in EB140/10 paras 38-39:

- 38. To implement the core activities of the new Programme, WHO must raise US\$ 485 million in 2016–2017; a gap of 44% remains. Appeals linked to humanitarian response plans have a funding gap of 66% (the total requirement for funding from appeals is US\$ 656 million).
- 39. The WHO Contingency Fund for Emergencies has raised US\$ 31.5 million of its US\$ 100 million target capitalization. Allocations to date total US\$ 18.16 million in support of WHO activities in response to humanitarian crises, disease outbreaks and the impact of natural disasters.

The same story is repeated in the **Update** prepared for the funding dialogue.

PHM urges professional and civil society organisations to voice their support for full funding of the contingency fund and for full (untied) funding the core and operational costs of the Health Emergencies Programme.

7.2 Global action plan on antimicrobial resistance (and sepsis)

Contents

- Antimicrobial resistance
- Sepsis

Antimicrobial resistance

In focus

As requested by Member States during the Sixty-ninth World Health Assembly, this report (EB140/11) will outline the process to further elaborate options for a global development and stewardship framework on antimicrobial resistance. It will also contain updates on progress made in implementing the global action plan on antimicrobial resistance, adopted by the Health Assembly in resolution WHA68.7 (2015), and on the high-level meeting of the General Assembly on antimicrobial resistance.

Background

The current stream of discussion on AMR commenced with a side event at WHA66 which led to formal discussion at EB134 in Jan 2014 informed by <u>EB134/37</u>. In May 2014 the Assembly adopted WHA67.25. See PHM comment at the time. In May 2015, in WHA68.7, the Assembly adopted the Global Action Plan on AMR. See PHM Comment on the draft GAP at WHA68. In Jan 2016 (EB138) the Board considered a Secretariat report (EB138/24) on options for a high level UNGA meeting. This meeting took place in Sept 2016 and adopted Resolution 71/3 and is reported on in the current document (<u>EB140/11</u>).

EB140/11 reports on a number of streams of work relating to AMR:

- the implementation of the Global Action Plan, adopted in <u>WHA68.7</u> (including in particular, the promotion of national action plans);
- the development of a Global Development and Stewardship Framework;
- the creation of an ad hoc interagency coordination group to address AMR;
- action within the Secretariat on drug resistance in HIV, TB and malaria.

Progress with respect to the development of national action plans is reported in <u>EB140/11</u>. See also the Manual for developing NAPs.

The Global Development and Stewardship Framework was endorsed in WHA68.7 recommended in the GAP (para 46), explored in A69/24 Add.1, reiterated in 71/3 (see also PHM Comment in May 2016), but appears to be progressing quite slowly.

For further background across a wider range of related issues see the WHO <u>AMR page</u> and the <u>ARC Newsletter</u>.

PHM comment on AMR

PHM congratulates the DG for negotiating the High Level Meeting in NY in September 2016. This was a constructive event (A71/3 here). PHM also appreciates the work of regional offices in holding workshops for country officials.

PHM is concerned by the patchy progress in developing national action plans. PHM notes that the FAO, OIE, WHO <u>manual</u> for developing national plans is largely about process with little policy content. For this reason it will be essential for the Global Action Plan itself to be kept in the forefront to ensure that the the core of the Plan is widely understood.

PHM has been critical of some aspects of the global action plan and looks forward to future opportunities to strengthen it. See PHM's comments at WHA69 here.

PHM is particularly concerned about the lack of progress on the global development and stewardship framework. Unfortunately EB140/11 provides no information about the barriers to progress.

In many respects the conclusion of the global stewardship framework is a precondition for the completion of national action plans.

Objective 2 calls for surveillance and research. However, as noted in para 33:

... there are no internationally agreed standards for collection of data and reporting on antibacterial resistance in human health, and no harmonizing standards across medical, veterinary and agricultural sectors. In addition, there is no global forum for the rapid sharing of information on antimicrobial resistance.

Leadership with respect to research must involve WHO, OIE and FAO. Research should be supported in national plans but developing the broad research agenda is a global project and presumably this is one of the functions of the proposed development and stewardship framework.

Objective 3 refers to sanitation, hygiene and the wider use of vaccines. In broad terms these can be included in national plans but in some areas there remains a need for globally produced guidelines (eg 'sustainable husbandry practices').

Objective 4 aims to optimise the use of antimicrobials in human and animal health. In part this depends on better information regarding the use of antibiotics in animal and human health. It will be hard for national authorities to fully address this need without agreed standards for data collection. The development of such standards is presumably awaiting the global stewardship framework.

Objective 4 also points to the need for better regulation of the marketing, promotion, prescription, sale and use of antimicrobials. Such regulatory strengthening will be greatly assisted by globally agreed principles and models; progress here appears to be dependent on progress with the global stewardship framework.

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

cannot be included in national action plans.

Objective 5 deals with investment in new medicines, diagnostics, vaccines and other interventions. This objective will be largely progressed at the global level, presumably through the development and stewardship framework.

Sepsis

In focus

The Officers of the Executive Board agreed to merge a proposed item on "Sepsis" with the existing item on the Global action plan on antimicrobial resistance. There is no indication of which member states requested the discussion of sepsis nor the logic of this request.

According to the German minister (here) Germany, Austria, Liechtenstein, Luxembourg, and Switzerland are "lobbying for next year's World Health Assembly to adopt a resolution on sepsis. This resolution would, for instance, call for data to be collected globally on this frequently fatal disease. Other goals on our list are: vaccinations of risk groups against infectious diseases, greater compliance with sanitary measures, the early diagnosis and treatment of sepsis, as well as the reduction of antimicrobial resistance by promoting the appropriate use of antibiotics."

Background

In <u>EB140/12</u> the Secretariat reports on epidemiology and causation, recent initiatives in the field and WHO's work in relation to sepsis.

PHM comment on Sepsis

Sepsis is devastating for patients and their families. The global disease burden and cost are clearly significant. Reducing the incidence of sepsis will involve preventing the infections in which it can occur and better managing those conditions to prevent sepsis supervening. Improving the outcomes of sepsis will involve improvements in clinical practice including diagnosis and treatment.

<u>EB140/12</u> refers to a recent Lancet publication on sepsis (<u>Cohen et al, 2016</u>), largely focused on the need for new treatments. The paper highlights the promise of 'personalised medicine' and biological therapeutics (see Tables 4-7 in particular) and reviews what it refers to as the failures of clinical trials in relation to sepsis.

The Secretariat report demonstrates that several of WHO's programs touch upon causes, public health considerations and clinical practices associated with sepsis. These intersections include Essential medicines, Water and sanitation, Antimicrobial resistance, Integrated health care, Maternal and perinatal care, Infection control, management of outbreaks and antibiotic research and development.

Notwithstanding the clinical, epidemiological and financial importance of sepsis, PHM asks three questions about the appearance of this item on the EB agenda.

- Should this item have been accepted onto the EB agenda?
- Were the risks of a perception of a conflict of interest fully considered?

• Is it possible that WHO's financial crisis influenced the consideration of this agenda item?

Should this item have been accepted onto the EB agenda?

PHM is sceptical as to whether this item would have appeared on the agenda of EB140 if the criteria and weightings presented in EB140/40 Add.1 had been applied. It would also have been useful if the suggestion included in para 13 of EB140/39 "...requiring that proposals for the direct inclusion of items on the provisional agenda of the Health Assembly should be accompanied by an explanatory memorandum ..." had been applied to this item (assuming that the memorandum and its authorship were to be published). Presumably it would argue that focusing the attention of the EB and presumably the Assembly on sepsis *per se* will either open up a new program of work for WHO or add value to the work currently being undertaken by WHO as outlined in paras 13-21 of EB140/12.

Were the risks of a perception of a conflict of interest fully considered?

PHM notes that this item appears on the EB agenda just months after the adoption, by the Assembly, of the <u>Framework for Engagement with Non State Actors</u>, including exhausting discussions regarding the management of conflict of interest. The FENSA lists a number of principles and cautions that could have been considered in the acceptance of this item onto the EB agenda. PHM questions the reference in para 10 to the Global Sepsis Alliance, a non-profit entity which is supported by a range of pharmaceutical and diagnostic manufacturers (see listing of supporters for <u>World Sepsis Day</u> and <u>the 2016 conference</u>). Given the extensive range of therapeutic drugs and biologicals currently in use in the management of sepsis and under development (see Tables 4-7 in <u>Cohen et al., 2016</u>) some consideration of risk management would have been appropriate.

Is it possible that WHO's financial crisis influenced the consideration of this agenda item?

PHM notes the strong support for the Global Sepsis Alliance from the German Minister for Health (here) (and apparently also Luxemburg, Lichtenstein, Austria and Switzerland) and asks whether the prospect of donor funding under the sepsis banner could have influenced the development of this item for inclusion on the Board's agenda.

PHM notes the similarities between this item and the item on Psoriasis which appeared on the EB133 agenda in May 2013 and then at WHA67. PHM raised concerns about the Psoriasis item at the time (see PHM comment at WHA67) which were ignored, even though the FENSA was under close consideration at that time.

7.3 Polio

In focus

The report (<u>EB140/13</u>) will provide summary information on the following: the impact of national emergency action plans to interrupt circulation of endemic poliovirus transmission; measures to limit international spread of polio under the auspices of the Public Health Emergency of International Concern; the phased removal of oral polio vaccines and global containment activities; processes to ensure the transition planning of the Global Polio Eradication Initiative; and the financial implications of the effort.

Background

Useful report from the Secretariat covers most issues.

PHM comment

Support the call from the Secretariat to encourage member states to ensure full implementation of WHA68.3.

7.4 Implementation of the IHRs (2005)

Draft global implementation plan

In focus

In line with decision <u>WHA69(14)</u> (May 2016), <u>EB140/14</u> conveys the draft global implementation plan for the recommendations of the <u>Review Committee on the Role of the IHRs in the Ebola Outbreak.</u>

Background

The IHRs have been around in some form for more than a century, setting forth the obligations of national authorities in the event of infectious disease epidemics with international implications. The <u>revised IHRs</u> (adopted in 2005 following the SARS epidemic; see <u>Fidler 2005</u>) was based on a radically revised strategy for regulating global health security and imposed new obligations on states parties in terms of putting in place the 'core capacity' needed for full implementation (see <u>WHO 2013</u> for the core capacity monitoring framework).

The IHRs (<u>Article 50</u>) provide for a review committee to be appointed by the DG to make recommendations regarding the functioning of the IHRs. There have been two such review committees appointed, the first following the H1N1 pandemic in 2009 (<u>H1N1 report 2011</u>) and the second following the West African Ebola outbreak in 2014 (<u>Ebola report 2016</u>).

The 2011 report was critical of the failure of many member states to establish the required core capacities and a series of deadlines were set (and passed) for full implementation by all countries. The 2016 report reiterated this criticism and, in addition, was critical of the disregard by over 40 member states of their IHR obligations not to impose excessive restrictions on trade and travel.

WHA69 decided in <u>WHA69(14)</u> to develop a global implementation plan for the recommendations of the 2016 Review Committee report. <u>EB140/14</u> conveys the draft global implementation plan for the EB's consideration. The draft global implementation plan identifies six areas of action.

The annex to EB140/14 provides a useful summary of the proposed plan.

PHM comment

The draft implementation plan is sensible and practical. The extended time frame for implementation and the emphasis on the need to mobilise financial support for vulnerable countries are particularly appreciated. However it raises some sensitive and in some respects complex issues.

The opportunity costs of investing in core capacities are very different for poor countries, compared with rich countries, particularly for those with fragile health systems. In many countries the marginal dollar might go much further if, for instance it was directed to reducing maternal mortality rather than strengthening port of entry monitoring. IHR capacities are global

public goods; there is no guarantee that the benefits of such investments will flow to the people of the country making such investments.

These considerations underpin the logic of external funds mobilisation for vulnerable countries. However, the proposed external evaluations of core capacities will raise concerns in developing countries. WHO does not have a strong tradition of member state accountability and independent monitoring so the introduction of such mechanisms, in relation to an issue where implementation shortfalls have been particularly common in developing countries, could appear selective.

The proposed initiatives around 'additional health measures' are appreciated, particularly the publication of countries not complying with emergency recommendations. However, these may raise concerns for some countries.

The proposed 'conceptual framework' on the links between IHR capacity building and health system strengthening will be very useful. Whilst the synergies between these two fields is self-evident in general terms, a more detailed analysis of how health system strengthening might contribute to IHR core capacity development will be helpful.

The sixth action area on the rapid sharing of scientific information overlaps with the consideration of the Nagoya Protocol (discussed below) and will need to be developed in accordance with the principles of fair and equitable benefit sharing.

Public health implications of the implementation of the Nagoya Protocol

In focus

The Nagoya Protocol was adopted in 2010 by the Conference of the Parties to the Convention on Biological Diversity at its tenth meeting (Nagoya, Japan, 18–29 October 2010). The Protocol has as its objective the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including biological materials and genetic sequences relating to human pathogens. The Secretariat's report (EB140/15) provides a summary of its review of the public health implications of the Protocol (see advance copy of full report here).

Background

The <u>Nagoya Protocol</u> adopted under the aegis of the Convention on Biological Diversity seeks to reconcile access to genetic resources and equitable benefit sharing. Users (often big corporations in the rich world) want access to such resources for agriculture or pharmaceutical development. Providers (often developing countries) want fair and equitable benefit sharing.

The Nagoya Protocol envisages 'prior informed consent' (provider countries have the right to give or withhold consent prior to transfer) and 'mutually agreed terms' (the terms of any transfer shall be mutually agreed). The details regarding the implementation of these principles need to be specified in national policy or legislation and countries have considerable leeway in terms of such details. Since the Protocol only entered into force in 2014 many countries have not formalised such policy or legislation.

The provisions of the Nagoya Protocol have significant implications for various international health functions including the Pandemic Influenza Preparedness (PIP) Framework and the rapid production of diagnostics, vaccines and medications in the context of unforeseen epidemics.

The report of the <u>Ebola Interim Assessment Panel</u> highlighted the importance of rapid R&D in the context of an emergency such as Ebola. The report of the <u>Review Committee on the role of the IHRs in the Ebola outbreak</u> highlighted the significance of the Nagoya protocol in policy formulation around emergency response. In his (Jan 2016) <u>briefing of EB138</u> regarding the Review Committee's report the chair of the review committee highlighted the importance of ensuring coherence across the PIP Framework, the IHRs and the Nagoya Protocol. In the subsequent debate (<u>PSR2</u>) several member states emphasised the significance of the Nagoya Protocol and it was agreed that the Secretariat would commission a study (<u>TOR here</u>), the report of which (<u>advance copy</u>) is listed for consideration at EB140.

The Nagoya Protocol was fiercely negotiated. See the Nijar 2011 report prepared for the South Centre. See also Oberthür, S. and G. K. Rosendal, Eds. (2014). Global Governance of Genetic Resources: Access and Benefit Sharing After the Nagoya Protocol. In opposite corners are the big corporations (with their host country backers) and the developing countries concerned about biopiracy as well as benefit sharing. In the debate over the review committee's report at WHA69 (PSR A4) India expressed reservations about the committee's recommendations and underlined the importance of conforming to the requirements of the Nagoya protocol.

PHM comment

The goal in policy terms will be to find the best compromise between biocultural sovereignty, access to genetic resources for public goods purposes, and speed of decision and action in the context of emergencies. Nagoya principles have the authority of an international treaty and must be respected. However, they were not developed for speed of decision making which will be the chief consideration in the next epidemic of international public health concern.

The political context in which this compromise is sought includes *protagonists* (largely the governments and corporations), *interest group organisations* (big pharma, small farming, indigenous groups, public health, etc), and the *wider constituencies* who will in the end benefit from the outcomes and/or pay the price. The outcomes will be determined by popular concern and interest group advocacy in addition to the textual sparring in the negotiating rooms.

The devil will be in the detail. The detail will be determined in word for word combat in closed venues. It will be critical that L&MIC delegates in the negotiating rooms are well informed and are working closely with sympathetic experts and supportive civil society organisations.

The priority now is to raise awareness of the issues and build the dialogue around possible resolutions.

7.5 Review of PIP framework

In focus

The provisions of the Pandemic Influenza Preparedness Framework (PIPF) required that the Framework be reviewed by 2016. The Review Group was appointed in December 2015 and in <u>EB140/16</u> it reports on achievements and effectiveness, and recommends initiatives for advancing the goals of the Framework.

Background

What is the Pandemic Influenza Preparedness Framework (PIPF)? See description on pp 10-11 of Review Committee report, EB140/16.

Key issues arising from Review Committee report include:

- the PIPF is generally working as planned; facilitating both virus sharing and benefit sharing and supporting pandemic influenza preparedness; should be continued;
- need to consider expanding the scope of PIPF to seasonal as well as influenza of pandemic potential;
- the principles of the PIPF could be applied to other pathogens, but by emulation rather than inclusion:
- the recent decline in virus sharing is a worry (see <u>paras 56-60 of minutes</u> of Advisory Group of April 2016 for possible reasons); Review Group provides some suggestions; subject of a separate study by Secretariat due to be released shortly;
- need for closer collaboration between global influenza surveillance and response system (GISRS) and animal laboratories to enhance surveillance and risk assessment of influenza viruses at the animal human interface;
- the traceability mechanism is not working as well as it should; Review Group provides some suggestions;
- amendments to the Framework are needed to properly facilitate the sharing of genetic sequence data (GSD), as well as, not instead of, biological materials;
- there has been some reluctance among manufacturers to sign standard material transfer agreement 2 (SMTA2); Review Group provides some suggestions;
- some criticism from certain stakeholders regarding partnership contributions (PC);
- good work is being done in all five areas of work supported by PCs (laboratory and surveillance, burden of disease, regulatory capacity building, planning for deployment, and risk communications);
- closer links between PIPF implementation and IHR capacity building and regulatory strengthening would yield synergies and efficiencies;
- need to strengthen arrangements for technology transfer as part of PIPF implementation (learning from Global Action Plan for Influenza Vaccines);
- the PIPF should be recognised as a 'specialised international instrument' under the Nagoya Protocol;
- the GISRS should be more formally organised to contribute more to policy making and deliberation:

- funding cuts and travel restrictions across GISRS are a concern; some entities have had to reduce staff, some struggle with rapid staff turnover and experience difficulties in recruiting suitable individuals into senior positions;
- need for more continuity in the membership of the Advisory Group.

PHM comment

PHM welcomes the Review Group report, appreciates the findings, and broadly supports the recommendations.

The report is extensive and complex and it is likely that the EB will decide to ask the Secretariat for an implementation plan.

8.1 Human resources for health and implementation of the outcomes of the UN High-Level Commission on Health Employment and Economic Growth

In focus

The Board will also have before it the outcomes of the high-level ministerial meeting to be held in Geneva on 14 and 15 December 2016 to propose actions and launch a consultative process that can take these recommendations forward.

It is likely that a decision and/or a draft resolution for forwarding to the Assembly will be considered by the Board.

Brief overview

The first substantive chapter of the Commission's report sets out the reasons why L&MICs countries should invest in their health systems:

- good health contributes to labour supply and labour productivity;
- the health system provides jobs and increases demand from other parts of the economy;
- more jobs will contribute to gender equity, social protection and social cohesion;
- technological needs of health services contributes to technological transfer and innovation more broadly; and
- strong health systems reduce the risk of emergencies, promote health security and therefore promote trade and traffic.

The second main part discusses health system development and health workforce education policies including support for:

- government funding to support health workforce education and expansion;
- recognition and fulfilment of health workers' rights including decent work;
- promoting gender equality and rights in the health workforce;
- undertaking health workforce education reforms:
- reforming health service delivery, financing, organisation and regulation;
- investing in cost effective health technologies;
- building emergency preparedness (IHRs) and humanitarian capabilities.

The third main part talks about policies which will enable the above changes:

- increasing domestic funding efficient, equitable, and pooled including through action on tax avoidance;
- reframing health care expenditure as investment rather than purely as consumption expenditure;
- 'aligning incentives, policies and reforms to attract and amplify co-investments by the private for-profit, private not-for-profit and the social enterprise sectors';
- mobilising supplementary external financing, including private and philanthropic financing, for the poorest countries;

- promoting intersectoral policy cooperation across the finance, education, health, social welfare, labour and foreign affairs; and multi-stakeholder partnerships including the public and private sectors, civil society, trade unions, health worker associations, and nongovernmental organizations;
- strengthening the global code on health worker recruitment to maximise 'mutuality of benefit' including providing for resource transfers to support health worker education in source countries:
- improving data collection and information availability about health workforce education and labour markets.

Finally the Commission lists five immediate implementation actions:

- secure commitments, foster intersectoral engagement and develop an implementation plan (the purpose of the December 2016 meeting);
- galvanise accountability, commitment and advocacy (along the lines of the commission on information and accountability for women's and children's health);
- improve health labour market data, analysis and tracking in all countries;
- accelerate investment in transformative education, skills and job creation; and
- develop an international platform on health worker mobility.

Background and interpretation

The reports, of both the Expert Group and the Commission, and also the outcomes of the December 2016 meeting, need to be read at several levels with attention to origins, audience and purposes.

This Commission was first suggested in a UNGA resolution (70/183) adopted in December 2015 which was focused largely on 'strengthening the management of international health crises'; clearly influenced by the Ebola emergency and the degree to which weak health systems exacerbated the crisis. However, the Commission's terms of reference took a broader perspective with reference to UHC, the SDGs, health worker mobility, health worker education and financing.

The rhetoric accompanying the Commission's report places it in the sequence of WHO initiatives in relation to the global health workforce: the Global Strategy on Human Resources for Health: Workforce 2030 (A69.19), the WHO Global Code of Practice on the International Recruitment of Health Personnel (A63.16) and Transforming health workforce education in support of universal health coverage (A66.23). It also emphasises the gender equity implications of scaling up the health care workforce.

This report also echoes some of the arguments of the 1993 WDR 'Investing in health' and the 2001 Commission on Macroeconomics and Health with its strong emphasis on the contribution of improved population health to economic development.

Further insight into the background of this report can be gleaned from the report of a meeting convened by WHO's Dept of Health Systems and Financing in Montreux in December 2014 entitled <u>'Fiscal space, public finance and health financing'</u>. The meeting brought together health financing experts from a range of international organisations with selected representatives from ministries of health and ministries of finance.

Extensive presentations and discussions were held on a range of topics, including the scope for both collaboration and misunderstanding between ministries of finance and ministries of health. Two central issues were fiscal space and health service development, and how public finance management norms can work better for health.

It is particularly significant that the first slide in the <u>first presentation</u> (by Joe Kutzin, the coordinator for health financing policy in WHO) explicated, as the key message of the presentation (and perhaps of the workshop), that 'the next frontier of the health financing reform agenda is the need for effective engagement between health and finance authorities on both the level of budget funding and rules governing their use'. This emphasis is repeated in the 'detailed collaborative agenda' coming out of the meeting. (See full suite of presentations <u>here</u>.)

The 2014 Montreux meeting came as the latest in a stream of international discussion regarding 'fiscal space for health'. The focus of this discussion has been to challenge the assumption that L&MICs 'cannot afford' to direct public monies to health system development. While the IMF and World Bank were the original proponents of this view it appears that many ministries of finance have taken this on as a core assumption of public finance; to such a degree that officials from both the IMF (eg Heller) and the WB (eg Tandon and Cashin) are now arguing for a more sophisticated understanding.

In this context it is significant that <u>WHA69.19</u> (in which the WHA adopted the 'Global Strategy on Human Resources for Health: Workforce 2030') includes, in OP3(3), an invitation to the IMF and the WB 'to adapt their macroeconomic policies and investment criteria in the light of mounting evidence that investments in health workforce planning, and the training, development, recruitment and retention of health workers are conducive to economic and social development and achievement of the Sustainable Development Goals'.

It is useful at this point to return to the <u>policy briefs</u> which were prepared for the UN SG's Commission on health employment and economic growth, in particular, the brief prepared by Chris James of the OECD entitled, '<u>Health and Inclusive Growth: Changing the Dialogue</u>' which is structured around 'three key messages':

- Health systems around the world not only treat the sick and prevent future illness, they
 are also central to the effective functioning of a country's economy. Adults in good health
 are more productive; children in good health do better at school. This strengthens
 economic performance, and also makes economic growth more sustainable and
 inclusive.
- 2. The healthcare sector is also an important source of employment, and is likely to provide more jobs in the future. On average, health and social work activities constituted around 11% of total employment for OECD countries in 2014. Moreover, the percentage of workers employed in health and social work has steadily risen across much of the OECD over time. This growth is likely to continue in the future.
- 3. Healthcare should therefore not be viewed solely as a cost driver, but also as an investment that can offer valuable returns to society. This does not mean more spending on health is automatically worthwhile. Rather, it requires critically assessing the investment case for different types of health spending, so that employment in the health sector achieves better health outcomes and increases the overall productivity of the healthcare sector.

It seems that one of the principal audiences for the current report is the national ministry of finance (or planning or economic development). The Commission's report is offered to the ministry of health as a resource in negotiations with the ministry of finance.

According to this analysis, the <u>recommendations of the report</u> need to be evaluated as a resource, in the hands of ministries of health, in their negotiation with their ministries of finance, with the following messages:

- improved health contributes to economic growth;
- improved health sector employment contributes to gender equity, social protection, social cohesion:
- the health sector is a driver of technological transfer and development;
- improving the health workforce is part of building resilience against prospective humanitarian disasters and emergencies.

Reading this report against the earlier Montreux report suggests that the general references in the Commission's report (to 'broad based health financing reform') might align with more explicit recommendations from Montreux which would urge ministries of finance to rethink the norms of public finance management to allow for more innovative forms of health care financing, including: compulsory funds mobilisation and pooling, single payer financing, and moving away from line item budgeting of public sector health agencies towards various forms of activity based funding.

PHM comment

In evaluating the Commission's report it is useful to keep in mind the conclusions of the 2014 Montreux meeting, one of which was a clear consensus that the achievement of universal health cover will depend on compulsory funds raising and pooling (not 'community financing', not 'voluntary health insurance', and not 'social business').

Within this perspective we may discount some of the more perplexing findings of the Commission and its Expert Group as sops to certain high profile participants. These include

- the glowing endorsement of 'social business' models [which we are told] are emerging as a private-sector, socially oriented solution to serve the unserved;
- the glowing appraisal of 'foreign investments [which] can expand services and stimulate job creation and technology transfer in areas of growing demand' (the example offered is a the establishment of a geriatric training course for nurses and a private residential nursing home by a German company in the Philippines); and
- the breathless anticipation of the report of the Global Commission on Business & Sustainable Development 'and its recommendations on where investments in the health and social sectors can add further value'.

Along the same lines, the extended quotes from the <u>Lancet's 2010 Commission on Health Professional Education</u> in the report of the Expert Group (chaired by the Editor of the Lancet) were inappropriate and disproportionate; not least because that commission restricted its focus to doctors, nurses, midwives and public health professionals.

There is merit in arguing against the austerity agenda and in pointing out the positive social and economic flow-ons from an expanding (and adequately paid) health workforce and there are other useful conclusions developed in the Commission's report.

However, there are also misrepresentations, omissions and risks in this report which need to be highlighted. These include:

- the complete failure to acknowledge the global macroeconomic barriers to economic
 development (eg, unfair trade agreements, neoliberal policies imposed through the WB
 and the IMF) and public revenue generation facing many L&MICs (eg tax
 competition/extortion, global protection of tax havens, the impact of global 'market
 disciplines', etc);
- the highly debatable inference that investing in health care services (including 'prevention') would be a sufficient strategy to reduce the burden of disease in L&MICs without any reference to the non-health investments needed to properly address the social determinants of population health (housing, urban infrastructure, support for small farmers, education, etc);
- the failure to acknowledge the role of foreign private investment in driving the social determinants of disease (eg junk food, agricultural dumping, dumping of toxic wastes, land grabbing, environmental degradation) and the role of big power bullying and investor protection provisions in trade and investment agreements in preventing government regulation of such activities;
- the discounting of the policy challenges involved in regulating private sector health insurance and private health care delivery (since the rich countries have not solved these challenges it is particularly irresponsible to offer private sector investment as a strategy for equitable, efficient, effective health care delivery);
- the failure to engage with the fragmenting impacts on health systems of vertical diseasefocused foreign aid; and
- the complete failure to mention the systematic underproduction of health care workers in the health worker migration destination countries.

It is likely that a draft resolution will be generated through the December meeting and will be considered by the Executive Board. It will be important to keep in mind these misrepresentations, omissions and risks in the Commission's report in negotiating such a resolution.

8.2 Principles for global consensus on the donation and management of blood, blood components and medical products of human origin

In focus

<u>EB140/18</u> sets out ten guiding principles for the donation and management of medical products of human origin.

Background

WHA63 (May 2010) adopted resolutions on the availability, safety and quality of blood products (<u>WHA63.12</u>) and human organ and tissue transplantation (<u>WHA63.22</u>).

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

<u>EB136/32</u> was prepared by the Secretariat in response to this request and considered at EB136 (Jan 2015). EB136/32 set out the main policy issues and sketched directions for further development. The debate at EB136 (<u>10th meeting</u>) focused on a draft decision sponsored by Italy, Lithuania, Malta, Slovenia and Spain and adopted as amended as <u>EB136(2)</u>.

The Secretariat's Jan 2015 report (<u>EB136/32</u>) canvassed a range of issues regarding the collection and use of medical products of human origin including:

- governance for safe donation and use;
- promoting access to life-saving products of human origin in the context of universal health coverage;
- strengthening regulatory oversight including reducing the need for (and inappropriate use of) blood and tissue products;
- a global monitoring system encompassing traceability, surveillance, vigilance, and rapid alert and the reporting and sharing of data on clinical outcomes and adverse events/reactions.

The decision adopted by EB136 (<u>EB136(2)</u>) requested the DG to undertake consultations with a view to developing:

- ethical principles for the donation and management of medical products of human origin;
- good governance mechanisms; and
- common tools to ensure quality, safety and traceability, as well as equitable access and availability.

PHM comment

The report before the EB140 (<u>EB140/18</u>) is largely focused on ethical principles governing the donation and management of medical products of human origin. These principles are sensible.

However, there is very little in EB140/18 on strengthening regulatory oversight or the establishment of a global monitoring system encompassing traceability, surveillance, vigilance, and rapid alert and the reporting and sharing of data on clinical outcomes and adverse events/reactions. There are no practical suggestions dealing with access and availability.

PHM urges the Board to request the Secretariat to further develop this report including attention to these matters.

8.3 Addressing the global shortage of medicines and vaccines

In focus

As requested in resolution <u>WHA69.25</u> (2016) the report (<u>EB140/19</u>) sets out proposed technical definitions for medicines and vaccines shortages and stock outs "taking due account of access and affordability". This focus on definitions reflects a dramatic constriction of the range of issues affecting the shortages problem and identified in <u>EB138/41</u> (considered by the EB in Jan 2016). See below.

Also in focus under this item may be the report of the <u>UN SG's High Level Panel on Access to Medicines</u>. <u>EB140/1 (annotated)</u> advises that the officers of the Board refused a MS request to schedule a debate around the HLP report as a separate item. This will be controversial. It has been reported that the WHO secretariat expects it to be discussed under this item. See below.

Background

This item commenced life with a report (<u>EB138/41</u>) to the EB in Jan 2016, prepared "in response to requests from Member States" on global shortages of medicines suggesting a global approach to deal with supply side failure and market shaping. The inclusion of children's medicines in the title picked up a somewhat different stream of work previously carried under the rubric of the UN Commission on Life-Saving Commodities for Women and Children (see resolution <u>A66.7</u> from May 2013).

At the Board meeting, a draft resolution (from China, Italy, Pakistan and Thailand) was tabled (11th meeting) on children's medicines recommending, inter alia, an essential medicines list for children and affirming, inter alia, the need to fully utilise TRIPS flexibilities. Consensus was not reached in the Board and it was agreed to continue intersessional negotiations (see 12th meeting).

The issues of children's medicines and global shortages were reviewed by the Assembly in May 2016 informed by A69/42 (a revised version of EB138/41). Two draft resolutions were tabled: first a revised version of the earlier draft resolution on medicines for children (but now sponsored by China, Malaysia, Pakistan and Thailand; Italy had withdrawn at this stage) and a new resolution on the shortages problem (from Kenya, South Africa and the USA) (see 5th meeting of Cttee B for both drafts and initial discussion; the debate continued in the 7th meeting of Cttee B). Both resolutions were adopted as amended: A69.20 on children's medicines and A69.25 on addressing the shortages problem.

A69.25 included a request to the Secretariat:

"to develop technical definitions, as needed, for medicines and vaccines shortages and stock outs, taking due account of access and affordability in consultation with Member State experts in keeping with WHO-established processes, and to submit a report on the definitions to the Seventieth World Health Assembly, through the Executive Board".

EB140/19 responds to this request. Interestingly there is nothing in EB140/19 which responds to OP 3(2) of A69.25 which asks the DG "to develop an assessment of the magnitude and nature of the problem of shortages of medicines and vaccines".

The Board's consideration of this item may be complicated by debate around the report of the <u>UN SG's High Level Panel on Access to Medicines</u>. <u>EB140/1 (annotated)</u> advises that the officers of the Board refused a MS request to schedule a debate around the HLP report as a separate item. This will be controversial (see <u>Appeal from Asian Civil Society</u>). Instead, it is expected that the HLP report will be debated under one of a number of related agenda items. It has been reported that the WHO secretariat expects it to be discussed under this item (8.3). It is reported that the member states who requested an agenda item on the HLP will request that it be considered under agenda item 8.4 (Evaluation of the GSPOA) or 8.5 (CEWG follow up) rather than 8.3.

PHM comment

<u>EB138/41</u> discusses shortages of essential largely in terms of malfunctions in the supply chain (see paras 1 & 2).

"The common denominator for these shortages is that medicines likely to be in short supply are products that are mostly old, off-patent or difficult to formulate and that have a tightly-defined shelf life and few or a sole manufacturer."

"Inadequate management practices in procurement and the supply chain, combined with large tender contracts that do not sufficiently define quality standards but whose sole emphasis is on obtaining the lowest prices; and too small profit margins for manufacturers — all these factors may lead to shortages."

This definition implicitly excludes innovation failure, strategic choices by manufacturers to discontinue the production of less profitable drugs, market distortions consequent upon aggressive marketing of expensive patented drugs (sidelining generics) and price barriers to procurement. Price barriers may reflect extreme IP provisions, unreasonably stringent regulatory standards and lack of competition.

This focus on malfunctions in the supply chain is echoed in <u>EB140/19</u> which proposes definitions of shortages cast in terms of supply side and demand side dysfunctions in the supply chain.

<u>EB138/41</u> highlighted the need for a global shortages notification system; work on this track has been mandated in OP3(3) of A69.25 and EB140/19 reports that the Secretariat "will work further on strategic efforts to develop a medicine and vaccine shortage notification system for medicines and vaccines at risk of shortage".

However, a narrow approach to the problem of shortages would mitigate against a full analysis of how all of these different factors (regulatory standards, monopoly, IP protection, market size and demand, rational use, ethical promotion, rational use, and existing price setting mechanisms, eg through regulation, insurance or subsidy).

The wide angle view is illustrated by the report of the SG HLP on Access to Medicines which had some sharp words on prices and TRIPS flexibilities.

On prices the HLP recommended that:

Governments should require manufacturers and distributors of health technologies to disclose to drug regulatory and procurement authorities information pertaining to: (1) the costs of R&D, production, marketing and distribution of health technology being procured

or given marketing approval with each expense category separated; and (2) any public funding received in the development of the health technology including tax credits, subsidies and grants.

WHO should establish and maintain an accessible international database of prices of patented and generic medicines and biosimilars in the private and public sectors of all countries where they are registered.

On TRIPS flexibilities the HLP recommended that countries should make full use of the TRIPS flexibilities as confirmed by the Doha Declaration and make full use of the policy space available in Article 27 of the TRIPS Agreement by adopting and applying rigorous definitions of invention and patentability. The HLP has further and far reaching recommendations on the role of IP in maintaining high prices.

It is regrettable that there is nothing in EB140/19 which responds to OP3(2) of A69.25 which asks the DG "to develop an assessment of the magnitude and nature of the problem of shortages of medicines and vaccines".

PHM urges member states to remind the Secretariat of this commitment and to seek assurances that such a report will be prepared in time for WHA70 in May and further to insist that this report (responding to OP 3(2) of A69.25) takes the wide angle view of cause including price etc, rather than focus solely on supply chain malfunctions.

8.4 Evaluation and review of Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA)

In focus

In May 2015, the Sixty-eighth World Health Assembly adopted resolution <u>WHA68.18</u>, deciding, inter alia, to undertake separately, and in a staggered manner, first, a comprehensive evaluation of the global strategy and plan of action on public health, innovation and intellectual property (GSPOA), and second, a more forward looking overall program review.

The Secretariat's report (EB140/20):

- conveys the Executive Summary of the comprehensive evaluation of the GSPOA, in <u>Annex 1</u>, (full report <u>here</u>);
- outlines the proposed membership arrangements for the Expert Panel for the Overall Program Review and outlines the proposed method of work of the Program Review Panel (including timelines); and
- sets out the proposed terms of reference for the overall programme review.

The focus of the Board's deliberations will be:

- the comprehensive evaluation: initial appraisal of the report and advice to WHA70 about how to handle it; and
- the overall program review: approval, with amendment as determined, of the arrangements for the overall program review.

Background

Pre-history of the GSPOA

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.)

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) 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 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: which endorsed "the global strategy and the agreed parts of the plan of action on public health, innovation and intellectual property...".

The GSPOA was considered again at WHA62 (May 2009) and after much debate an agreed GSPOA was adopted (in Resolution WHA62.16); see integrated version of finally agreed GSPOA. The core elements are:

- Element 1. Prioritizing research and development needs
- Element 2. Promoting research and development
- Element 3. Building and improving innovative capacity
- Element 4. Transfer of technology
- Element 5. Application and management of intellectual property to contribute to innovation and promote public health
- Element 6. Improving delivery and access
- Element 7. Promoting sustainable financing mechanisms
- Element 8. Establishing monitoring and reporting systems

The report of the comprehensive evaluation of the GSPOA, currently before the EB (in EB140/20 Annex 1), provides a brief introduction to each of these elements.

Comprehensive evaluation and programme review

Key to understanding the current discussion around the evaluation and programme review is the separation of the 'evaluation' from the 'programme review'.

<u>Para 41</u> of the GSPOA scheduled a **comprehensive evaluation of the strategy** to be undertaken after four years. However, <u>Clause 6 of Resolution 62.16</u> (through which the Assembly adopted the GSPOA) requested an **overall programme review** of the global strategy and plan of action in 2014, including recommendations on the way forward.

The evaluation of the GSPOA was discussed at EB133 (May 2013) informed by <u>EB133/7</u>. See official summary record of discussion (<u>M4</u>). At EB136 (Jan 2015) the Secretariat proposed (in <u>EB136/31</u>) a set of timelines for the evaluation and the EB adopted decision <u>EB136(17)</u>, in which it decided, inter alia, to recommend to the Sixty-eighth World Health Assembly to extend the deadline for the overall programme review to 2018.

WHA68 (May 2015) reviewed this stream of discussion, informed by <u>A68/35</u>. A68/35 outlined a number of options for undertaking both the evaluation and the program review. The Assembly adopted <u>WHA68.18</u> which committed to a staggered process with the evaluation preceding the program review.

In line with resolution <u>WHA68.18</u>, the Secretariat submitted to EB138 (Jan 2016) <u>EB138/38</u> which provided an update on progress made in relation to the evaluation. An additional report

(EB138/38 Add.1) reviewed the key points from the evaluator's inception report and comments from the ad hoc evaluation management group. Report of debate at EB138 here.

The materials before EB140 include the final report of the comprehensive evaluation and plans for approval for the program review.

PHM comment

Comprehensive Evaluation

A major finding of the evaluation report is the widepread lack of awareness of the GSPOA, presumably due to relatively weak promotion of the GSPOA by the Secretariat. If so this is a reflection of WHO's funding crisis and the highly inflexible funding associated with tightly earmarked voluntary contributions. Clearly the donors have not been willing to properly fund the implementation of the GSPOA.

There is no mention in the Evaluation Report of the barriers to the full use of TRIPS flexibilities in many bilateral and regional trade and investment agreements, nor to the coercive negotiation tactics involved in including such provisions in those agreements. The closest the evaluation report comes to these issues is talk of 'stakeholders' resistance' in relation to Element Five. Note that resolution WHA56.27 (2003) requested the DG inter alia to monitor and analyse trade agreements. It is unfortunate that this provision was not included in the GSPOA.

It is unfortunate that the evaluator does not identify the need for mandatory registration of clinical trials.

Programme Review

PHM urges the Board to include in the terms of reference for the programme review a request to review the UN SG HLP on Access to Medicines and advise how a revised GSPOA can also carry these recommendations forward.

PHM urges the Board to include in the terms of reference for the programme review a reconsideration of the elements of 2003 resolution WHA56.27 (which requested the DG inter alia to monitor and analyse trade agreements). Likewise we urge that the programme review reconsider the May 2008 report of the IGWG (in A61/9) on which agreement was not achieved. In particular, we urge that the programme review reconsider the debate over element 5.2(b) in para 36 of A61/9 which deals with the inclusion of TRIPS plus measures in trade agreements and national legislation.

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

In focus

The Secretariat report, <u>EB140/21</u>, prepared in response to requests made by the Health Assembly in resolution <u>WHA69.23</u> (2016), proposes:

- terms of reference and a costed workplan of the Global Observatory on Health Research and Development (Annex 1 in EB140/21); and
- goals and an operational plan for a voluntary pooled fund to support research and development (Annex 2 in <u>EB140/21</u>; see also <u>TDR report</u>).

Responding to further requests in A69.23, EB140/21 also

- reviews the six demonstration projects and their funding status (in paras 9-10);
- sketches out the roles and inter-relationships of the Global Observatory, the Expert Committee and the Scientific Working Group (in paras 11-14);
- reviews the funding so far secured for the demonstration projects and the global observatory (facing a \$US73m shortfall); and
- (in para 19) acknowledges the need for policy coherence across the principles agreed to regarding R&D under the follow up of the CEWG; the Research and Development Blueprint to foster research and development preparedness for infectious diseases with epidemic potential, and the Global Antibiotic Research and Development Partnership, a joint venture by WHO and the Drugs for Neglected Diseases initiative.

The second report produced in fulfilment of A69.23 is EB140/22 which proposes terms of reference for a WHO Expert Committee on Health Research and Development.

The elephant in the room during this debate will be the June 2016 report of the UNSG's High Level Panel on Access to Medicines (here). There were requests for the report to be included on the agenda for EB140 but the officers of the Board determined otherwise.

In several important respects the HLP has reopened a number of contentious issues which had been closed off in the WHA's deliberations to this point. These include:

- the need for a binding agreement to delink the costs of R&D from prices;
- the need for governments to be free to use to the full the flexibilities available under the TRIPS agreement (including sanctions against countries which pressure other countries to forego the use of such flexibilities);
- the need for transparency regarding the costs of R&D (including the degree to which R&D underpinning privately owned IP has been publicly funded); and
- for WHO to establish and maintain an open database of the prices of patented, generic and biosimilars in the public and private sectors of all countries where they are registered.

Background

The prehistory of the CEWG discussion is described <u>here</u>. The critical documents are the report of the <u>Commission on PHIIP</u> (Jan 2006), the <u>finally agreed GSPOA</u> (May 2009), the final report of the <u>CEWG</u> (May 2012), and <u>WHA66.22</u> and <u>WHA66(12)</u> (both May 2013) which adopted the

CEWG report and authorised a number of parallel but interlocking initiatives including the observatory, the pooled fund to support R&D and the demonstration projects.

The <u>High Level Panel on Access to Medicines</u> was established by the UN SG in November 2015 as an outcome of the <u>Global Commission on HIV and the Law</u> which was convened by UNDP on behalf of UNAIDS in 2010. See the coverage by <u>IP-Watch</u> for comments on the HLP report.

PHM comment

The proposals advanced in <u>EB140/21</u> and <u>EB140/22</u> are reasonable in the light of the decisions which have preceded them in the Assembly and the Board.

The big shadow looming over all of them is the funding (see paras 15-18 of EB140/21):

- a minimum of \$100m is required for the voluntary pooled fund;
- a funding gap of \$2-3m per year for the global observatory;
- insufficient funds for the 5th and 6th demonstration projects.

Para 18 of EB140/21 advises that the Secretariat will be holding a 'high level event' in the first half of 2017 to promote increased investment into R&D in areas where the current investment levels are insufficient to meet global public health needs.

However, the report of the HLP reopens important issues regarding delinking R&D costs from monopoly pricing and places new issues on this agenda.

It seems likely that the report of the HLP will be considered further within the UN system, outside the WHO. While the structures currently being developed under the CEWG process could probably be adapted to whatever comes out of the HLP process, undoubtedly the HLP report will have ramifications within WHO's governing bodies.

PHM urges public interest NGOs, social movements and progressive governments to promote the recommendations of the HLP (see above) and to advance their implementation.

8.6 Member States mechanism on substandard/spurious/falsely-labelled/falsified/ counterfeit medical products

In focus

The fifth meeting of the Member State mechanism on SSFFC medical products was held in Geneva, Switzerland in November 2016, and a range of activities for the period 2016–2017 were discussed. <u>EB140/23</u> conveys the report of the fifth meeting of the MSM (see <u>documents</u> <u>page</u> for this meeting).

The reports on 'activities' in EB140/23 (A-H, paras 3-13) need to be read against the list of prioritised activities in Annex 3 of A/MSM/3/3 (Oct 2014).

In addition to the activities reports the MSM discussed:

- WHO's participation in the Global Steering Committee for Quality Assurance of Health Products (A/MSM/5/3); the Global Fund to be asked to brief the MSM;
- Update on WHO's activities for regulatory systems strengthening, and on the application
 of WHO's global benchmarking tool; further discussion scheduled; Secretariat asked to
 produce a guidance manual on the tool;
- Review of the Member State mechanism on substandard/spurious/falsely-labelled/ falsified/counterfeit medical products (see <u>A/MSM/5/4</u>), scheduled for early 2017.

The appendices to the MSM's report are particularly significant:

- Appendix 1 provides detailed guidance for member states in dealing with SFC medical products; agreed by MSM; no request for EB approval;
- Appendix 2 is a detailed report on authentication technologies; agreed by MSM; no request for EB approval;
- Appendix 3 is the report of a working group appointed by the MSM to consider the
 appropriate terminology to be used in relation to SFC MPs (Activity H); the WG
 recommends that the MSM use the term "substandard and falsified medical products"
 instead of "substandard/spurious/falsely-labelled/falsified/counterfeit medical products";
 in para 13 of the MSM report the MSM recommends that the WHO governing bodies
 adopt this term.

Background

The bottom line

At the heart of this item are two issues which in theory are quite unrelated: first, the quality of medicines in the marketplace (including spurious and substandard medicines); and second, the assertion and protection of intellectual property rights associated with particular medicines. These two issues might have remained separate except for the adoption, by WHO in 1992, of the term 'counterfeit' (which legally refers to trademark violations), to refer to spurious and substandard medicines. The continuing use of the term counterfeit conflates the public health problem of spurious and substandard medicines with the tort (civil wrong) of breaches of intellectual property rights (IPRs), including patent rights as well as trademark rights, and thus links spurious and substandard regarding quality with generic status.

Advocates for generic competition, as a means to reduce the prices of drugs, including the full use of TRIPS flexibilities (including compulsory licensing and parallel importation), have been concerned that propaganda, largely emanating from big pharma, which conflates quality with IP status through the use of the term 'counterfeit', has been directed to encouraging countries to adopt medicines laws which are TRIPS + in the sense that they preclude the use of TRIPS flexibilities.

These issues were ignited with the IMPACT scandal from 2008. The details of the controversy over IMPACT were reviewed in PHM's comment on Item 17.3 (SFC) at WHA68. See also Shashikant (2010) for more detailed documentation.

The term SSFFCMP (or SFC) has been used pending agreement on an alternative definition regarding spurious medical products. The Member State Mechanism (MSM) was established within WHO to drive action on quality of medicines whilst not creating new barriers to the entry of generics.

SFC/MSM timelines

IMPACT was established in 2006. Two years later a report regarding IMPACT (A61/16) plus resolution were tabled at WHA61 (2008). These had not been previously considered by the EB. See draft resolution plus debate in A10(p113). There was strong support for IMPACT from the African region. Significant concern from other regions. Referred to EB124 (2009).

Issues reviewed in EB124 (Jan 2009), informed by $\underline{\text{EB124/14}}$ (corrected in EB124/14 Corr.1). Long debate ($\underline{\text{M9}}$).

Scheduled for further consideration at WHA62 but deferred because of H1N1 pandemic.

Reviewed at WH63 (2011). Informed by <u>A63/23</u> (about counterfeit products) and <u>A63/INF.3</u>. Long debate <u>A6, A8, A9, A9(ii), A11, A12</u>. Decision <u>A63(10)</u> establishes WG on SFCs.

Working Group of SSFFCMPs established by WHA63(10); final report in WHA65/23.

WHA65 (2012) reviews the report of the WG on SSFFCMPs (conveyed in <u>WHA65/23</u>). Long debate B4(255), B5(261). MSM established by WHA65.19.

MSM reports to WHA66 (2013) in $\underline{A66/22}$ (chairmanship in dispute; partially agreed work plan). Debate $\underline{B4}$. Decision $\underline{A66(10)}$ resolves the chairmanship (by rotation) and waits for agreement on the workplan.

WHA67 (2014) receives a report of the second meeting from the MSM (<u>A67/29</u>) including definition of activities and behaviours which lead to SFCs; an agreed workplan; and budget estimates. Report noted (<u>B4</u>).

WHA68 reviews A68/33, report of 3rd meeting of MSM. One year deferral of review of MSM requested and (in WHA68(12)) agreed.

WHA69 (May 2016) reviews A69/41 report of 4th meeting. Noted.

PHM comment

The MSM(SFC) saga reflects well on WHO member states. A serious threat to WHO's integrity was averted. A significant division of opinion among member states has been largely reconciled. A major public health problem has been addressed in a logical and evidence based way.

However, the fundamental political tensions will continue to be expressed in WHO debate and decision making: first, the tension between the corporate interest and the public health interest over how the problem of substandard and falsified medicines should be addressed; and second, the tension between member states who host large pharmaceutical companies and member states who are primarily concerned about the quality and price of medicines.

PHM urges member states at EB140 to support the newly proposed terminology: substandard and falsified medicines (in Appendix 3).

PHM urges MSs to endorse the guidance for member states (in <u>Appendix 1</u>) and the report on authentication technologies (in <u>Appendix 2</u>) by noting the report carried in <u>EB140/23</u>.

8.7 Promoting the health of migrants

In focus

Secretariat report <u>EB140/24</u> summarizes the current global context and the health challenges associated with migrants and refugees. It also describes the Secretariat's actions at the global and regional levels to meet these challenges, and outlines priority actions for the future.

The agenda papers state that this item appears on the EB agenda at the request of unnamed member states. However there is a note at the bottom of page 15 of the <u>Grand Bargain</u> (the Declaration of World Humanitarian Summit in May 2016 to the effect that WHO *will lead* a discussion on the <u>Grand Bargain</u> commitments with its Member States.

The Secretariat cites resolution <u>WHA61.17</u> (2008) as the authority for WHO's work for migrants and refugees. However, it appears that the EB discussion is more likely to focus on the commitments from the <u>Grand Bargain</u> (May 2016) and in the 'New York Declaration for Refugees and Migrants' (<u>UNGA A/RES/71/1</u> (October 2016); see particularly the annexes to the Declaration committing to 'compacts' on refugee response and safe, orderly and regular migration).

There is no draft resolution published at this stage but it is expected. The resolution will make general references to root causes and will include gestures towards the commitments listed below. The tension will be around how tightly such gestures are specified and how accountable the main players. The defence posture will involve extensive use of terms such as 'voluntary' and 'as appropriate'.

Background

<u>EB140/24</u> provides a very useful overview of refugee movements and migration at this time and refers to the <u>New York Declaration</u> and the <u>SDGs</u> as key landmarks in this policy space. It lists some of the key health problems associated with migration and asylum seeking and then reviews WHO Secretariat action in recent times, both from headquarters and at the regional level.

It then lists (in para 23) ten priorities for 'member states, partners and other stakeholders in addressing the health needs of migrants and refugees':

- I. to develop a coherent and comprehensive global migration and health strategy to address the health needs of migrants and refugees;
- II. to support the development of the <u>global compact on refugees</u> and the <u>global compact</u> <u>for safe, orderly and regular migration</u> in order to ensure that health is adequately addressed in the compacts;
- III. to support the development and implementation of migrant-sensitive health policies that incorporate a public health approach and universal and equitable access to quality health services as well as financial protection for migrants and refugees, regardless of status and appropriate to the national context, priorities and institutional and legal frameworks:
- IV. to promote the changes in law and policy needed to ensure that migrants and refugees are included in national and local health planning;

- V. to strengthen and build resilient health systems with the fundamental goals of achieving universal health coverage and universal access to quality essential health services for all (Sustainable Development Goal 3.8), regardless of legal status;
- VI. to increase advocacy and promote the mobilization of resources to address the health needs of migrants and refugees, including innovative and predictable multiyear funding;
- VII. to promote a humanitarian development nexus by bridging short-term humanitarian assistance with long-term health system strengthening;
- VIII. in the most difficult circumstances, to continue to mobilize and coordinate partners in support of Member States in order to provide life-saving health care for those in need;
 - IX. to strengthen intersectoral, intercountry and interagency coordination and collaboration mechanisms to achieve synergies and efficiency, including within the United Nations system, and with UNHCR and the International Organization for Migration in particular, and with other stakeholders working towards improving the health of migrants and refugees in countries of origin, transit and destination; and
 - X. to identify, collate and facilitate the exchange of experiences and lessons learned among Member States, and generate a repository of information on relevant experiences in the affected countries.

In some degree the commitments from the <u>Grand Bargain</u> are encompassed by these ten priorities. However, it is useful to list them here:

- 1. Greater transparency of agencies involved in humanitarian action including funding;
- 2. More support and funding tools for local and national responders;
- Increase the use and coordination of cash-based programming (in contrast to in-kind assistance); note para 12 of <u>EB140/24</u> which reports on WHO's lead role in relation to cash-based programming;
- 4. Reduce duplication and management costs with periodic functional reviews;
- 5. Improve joint and impartial needs assessments;
- 6. Include people receiving aid in making the decisions which affect their lives;
- 7. Increase collaborative humanitarian multi-year planning and funding;
- 8. Reduce the earmarking of donor contributions; see annex on 'earmarking modalities';
- 9. Harmonise and simplify reporting requirements; and
- 10. Enhance engagement between humanitarian and development actors.

The WHO web pages on <u>Humanitarian Health Action</u> provide further references and resources; see particularly migrant health; also refugee and migrant health.

PHM comment

The main focus of the documents before the Board is on strengthening the policies and systems which regulate migration and support refugees. The initiatives proposed are generally sensible although in many respects (eg ceasing the earmarking of grants, greater use of cash programming instead of in-kind programming, respect for human rights) they are quite unrealistic.

Tight earmarking of aid clearly adds to the costs of coordination and is a barrier to effective and efficient service delivery. However, from the point of view of the donors, tight earmarking is a necessary part of maintaining control of intergovernmental organisations like the UN and WHO. The dysfunctions associated with in-kind assistance are also well known but the political gains from subsidising powerful stakeholders (like Big Ag in the US) have to this point taken

precedence over more effective and efficient cash programming. The hypocrisy of certain governments which endorse statements about human rights even while most grievously breaching the rights of asylum seekers justifies some scepticism about their good faith in this domain.

There are a few references in these papers to the root causes of forced migration and asylum seeking and to the forces of racism and xenophobia which, in many settings, impact on the migrant and refugee experience. See in particular the reference to root causes in para 12 of the New York Declaration; the reference to human rights in para 13; and the references to racism and xenophobia in paras 14 and 39. However, these references are all quite general and are not matched by any proposed actions.

PHM calls for honesty and plain speaking about root causes. What are the drivers of economic migration? What are the drivers of refuge seeking? What is the genesis of xenophobia?

Chief among the drivers of economic migration are poverty and economic inequality - across regions, countries, ethnicities and class.

Chief among the drivers of refuge seeking are war (such as the Bush invasion of Iraq), oppression and insurgency (including resistance to oppressive and corrupt regimes as well as religious extremists).

The genesis of xenophobia reflects inequality and insecurity (including precarious employment) and divisive, adversarial, side-show politics.

Looming behind the inequality, conflict and insecurity are the failures of global capitalism, linked to the trashing of national sovereignty, the autonomy and impunity of transnational corporations and the ascendancy of the transnational capitalist class (the 1%).

The failures of capitalism are moral and political as well as economic. The celebration of greed and material possessions reflects a moral bankruptcy which contributes to the rise of religious fundamentalism. The corruption of democratic politics, associated with corporate domination and 'small government', is particularly evident in relation to global warming; itself a driver of migration.

The institutions of global governance are creatures of this system and the politicians and diplomats are its spokespersons. They may propose initiatives to deal with migration and asylum seeking but they will not act to address the root causes.

The hope for change lies not with the politicians, bureaucrats, philanthropists and INGO entrepreneurs who have been empowered by a corrupt system. For PHM, the hope for change lies in the convergence of social and political movements responding to local realities and shared aspirations, working across difference, sharing understandings and building solidarity.

Any resolutions emerging from the discussion of this item will be akin to 'moving deck chairs on the Titanic' unless they are matched by a real mobilisation from below.

9.1 Global vaccine action plan

In focus

The Executive Board will consider (in <u>EB140/25</u>) the Executive Summary of the report of the Strategic Advisory Group of Experts (SAGE) on immunization (full report <u>here</u>), which provides an assessment of progress made towards achieving the goals of the <u>global vaccine action plan</u>. The present report is of particular significance as it falls at the mid-term of the action plan (2010–2020). The report offers recommendations under nine headings:

- 1. Demonstrate stronger leadership and governance of national immunization systems
- 2. Prioritize immunization system strengthening
- 3. Secure necessary investments to sustain immunization during polio and Gavi transitions
- 4. Improve surveillance capacity and data quality and use
- 5. Enhance accountability mechanisms to monitor implementation of Global and Regional Vaccine Action Plans
- 6. Achieve elimination targets for maternal and neonatal tetanus, measles, rubella and congenital rubella syndrome
- 7. Resolve barriers to timely supply of affordable vaccines in humanitarian crisis situations
- 8. Support vaccine R&D capacity in low- and middle-income countries
- 9. Accelerate the development and introduction of new vaccines and technologies

Background

The Global Vaccine Action Plan (GVAP) was adopted by the WHA in A65/17 in May 2012.

A65/17 requested annual update reports. In A66/19 the Secretariat proposed a draft framework for monitoring, evaluation and accountability for GVAP which was endorsed by the Assembly (in May 2013). PHM comment here.

The first update report on the implementation of GVAP was considered by the Assembly in May 2014 in $\frac{A67/12}{1}$. The debate is at $\frac{A3}{1}$ and $\frac{A4}{1}$. The SAGE report ($\frac{A67/12}{1}$) focused on:

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

PHM was critical of the SAGE report <u>here</u> because of it failed to address important elements of the GVAP nor did it comment on the proposed goals, objectives and indicators of the framework for monitoring, evaluation and accountability adopted in WHA66.

A further report was considered by WHA68 in 2014 in A68/30 and after a long debate (A2, A5, A11 and A12) the Assembly adopted a further resolution A68.6 which strengthened the GVAP in certain respects including requesting the Secretariat to collect and present data on vaccine pricing.

PHM posted a detailed commentary (here) on implementation of the GVAP highlighting:

• the limitations of vertical funding programs as compared with investing in health systems strengthening based on comprehensive primary health care;

- the significance of the continuing underfunding of WHO in relation to immunisation and the need for real WHO reform:
- the need for WHO action on pricing, affordability and procurement;
- the need for more critical attention to the opportunity costs associated with the introduction of expensive new vaccines;
- the need for all of WHO's regional and country offices to work with ministries of health to
 encourage the full implementation of the GVAP and regional and national plans and to
 provide technical support especially in relation to information systems and national policy
 making.

In May 2016 the Assembly considered A69/34 which included a report on GVAP generally and specifically on the implementation of A68.6 which was noted by the Assembly (see debate at B7). PHM posted a detailed commentary (here) broadly appreciating the SAGE report.

PHM comment

The positive features of the SAGE report include:

- the insistence on accountability, naming names, including indicting regional committees for their failure to follow up immunisation progress;
- the recognition of the need to integrate immunisation program development with general health system development and for donors to give greater priority to integrated health system development;
- the emphasis on geographic equity in access to immunisation and the need for fine grained district and community data to monitor equity;
- highlighting the 'transition challenges': including countries transitioning out of GAVI eligibility and those facing the threat of losing part of their immunisation workforce post polio:
- promising reports of progress in the development of vaccines for TB, malaria, dengue and others; and
- its strongly worded recommendations.

However, there are several notable omissions and issues which are underplayed:

- there is very little here on the development of NITAGs (national or regional immunisation technical advisory groups) and their policy capability; the indicator proposed in <u>A66/19</u> was the 'presence of an independent technical advisory group that *meets defined* criteria':
- nothing on monitoring community confidence (explicitly included in <u>A66/19</u>) or adverse
 event monitoring (PHM is aware of controversy regarding WHO's causality assessment
 guidelines (see comments following <u>Tozzi et al 2013</u>) and the weaknesses in postmarketing surveillance in many countries (<u>Tafuri et al 2015</u>); rigorous post-marketing
 surveillance is a precondition for community confidence);
- nothing on supply, pricing and procurement (see footnote 2 on page 8 of A66/19; see also paras 7-9 of A69/34 which deal with supply, pricing and procurement but comment that WHO is dependent on donor whim to progress these issues);
- nothing on the tracking of resources (see paras 14-15 of A66/19);
- no recognition of the policy complexity of introducing new and 'under-used' vaccines to national immunisation schedules and the need for nationally specific opportunity cost estimations (discussed in more detail in PHM commentary on Item 16.4 of WHA68), in particular in the context of the Gavi 'graduation trap' (implementation of new and

expensive vaccines under GAVI support followed by the need for full funding upon GAVI graduation).

PHM is concerned that there is a contradiction between the 'elimination' targets for both rubella and congenital rubella syndrome. Rubella is a mild infection that nearly harmless to all except the fetus. Endemic rubella ensures that most adolescents are immune prior to pregnancy. Those who escape infection are best immunized in the preadolescent age.

In developing countries vaccination coverage is often less than optimal and it is here that we can leverage the immunity achieved through the harmless spread of the virus among children. If countries with suboptimal vaccination coverage start immunising against rubella in infancy there is a serious risk that adolescents will face increased exposure to the virus with catastrophic consequences.

The first priority should be universal access to immunisation and only when that has been achieved, to then aim to eliminate rubella. In the meantime priority should be given to reducing the incidence of congenital rubella through universal coverage of adolescents.

PHM urges MSs to request the Secretariat to prepare a supplementary report for submission to WHA70 which addresses the shortfalls in the SAGE report noted above.

9.2 Global vector control response

In focus

Significant recent upsurges in vector-borne diseases, against the background of a persistent global malaria burden, highlight the challenges facing vector control implementation. There is a critical need to build capacity in order to improve impact and mitigate potential challenges, including those posed by insecticide resistance, climate change, rapid urbanization and increased global travel and trade.

The draft global vector control response (summarised in <u>EB140/26</u>, full document <u>here</u>) aims to provide comprehensive technical and strategic guidance for establishing sustainable vector control systems. The response comprises four pillars, aligned with the principles of integrated vector management:

- 1. Strengthen inter- and intra-sectoral action and collaboration;
- 2. Enhance entomological surveillance and monitoring and evaluation of interventions;
- 3. Scale up and integrate tools and approaches; and
- 4. Engage and mobilize communities.

The four pillars rest on two foundations:

- 1. enhanced vector control capacity and capability; and
- 2. increased basic and applied research and innovation.

Three determining factors are identified as necessary to implement the response:

- 1. country leadership;
- 2. advocacy, resource mobilization and partner coordination; and
- 3. regulatory, policy and normative support.

Background

The full revised draft GVC Response <u>here</u> incorporates advice received during the consultation undertaken from June 2016.

See also:

- the work of the <u>Vector Control Advisory Group</u>, jointly established by the Departments of malaria and NTDs;
- <u>note on vector control</u> and other publications on <u>insecticide resistance</u> from the malaria department:
- advice regarding <u>vector control for dengue</u> and also <u>here</u>;
- advice regarding <u>vector control for human African trypanosomiasis</u>;
- conclusions and recommendations of the WHO Vector Control Advisory Group (VCAG)
 <u>meeting on 14–15 March 2016</u> to review potential and existing vector control tools for
 use in the context of the response to the Zika virus outbreak; and the
- page describing the work of the <u>WHO prequalification team in relation to vector control</u> products.

PHM comment

This is a very constructive initiative. Nevertheless there are a few issues where PHM urges closer attention or stronger emphasis.

Primary health care

PHM appreciates the emphasis on community engagement as one of four pillars on which this Response rests and the several references to community health workers as key agents in supporting such community engagement. However, the conditions in which community health workers operate depend on health system policies and in particular the degree to which health system development follows the principles of comprehensive primary health care. What is missing from this Response is a recognition that putting in place the programs and structures needed to implement PHC principles would be a major contribution to the success of this Vector Control Response.

Climate change

PHM appreciates the several references to climate change as one of the environmental influences on the changing ecologies of insect vectors. Nevertheless it is surprising that there are no references to the work of the International Panel on Climate Change in the draft Response. The publications of the IPCC (see Ch 11 (WG2) of AR5) add a certain authority to the logic of the draft response and the methods used for regional projections (eg Europe, North America and Small islands) are key resources to be drawn on in building national capacity for vector control in a changing environment.

Urban development

PHM appreciates the emphasis on reticulated water supply in urban areas, effective drainage and decent housing. However, mobilising the necessary funds to upgrade the informal settlements of the megacities of many developing countries is a major challenge. The draft Response correctly makes the link to SDGs 6 & 11 in this context. However, it is also necessary to recognise the barriers to such infrastructure development which are embedded in the prevailing regime of neoliberal global capitalism. One illustration of this can be found in the pervasive pressures of tax competition, the continued support for tax avoidance, and the protections afforded to corruption by the international financial system.

Agriculture, irrigation and dams

PHM appreciates the references to agriculture and irrigation systems including dams in shaping the conditions for vector prevalence and the recommendation regarding the mandatory need for health impact assessment of large development projects. However, it would be difficult to overstate the challenges which are commonly faced in commissioning, undertaking and acting on such impact assessments. Critical to the outcomes of such debates will be community awareness and the mobilisation of those communities who are most at risk. National and international public interest civil society organisations can play a strategic role in building such awareness and supporting such community mobilisation. This role should not be neglected in the Global Vector Control Response.

Technology transfer, industrial development and vector control products

The draft Response recognises 'country leadership' as one of the key enabling factors. It would facilitate such leadership if the positive spin offs associated with national vector control programs could be highlighted, including the industrial development spin offs associated with the domestic manufacture of insecticides, vaccines and other vector control products. PHM urges WHO to commission further investigations directed at identifying strategies to support such industrial development.

10.1 Preparation for the third high level meeting (HLM) of the UN General Assembly (UN GA) on NCDs in 2018

In focus

The Secretariat report <u>EB140/27</u> starts with an update regarding the lack of implementation of previous commitments regarding NCDs ("In 2015, 138 Member States had shown very poor or no progress towards implementing the four time-bound national commitments for 2015 and 2016 set out in the Outcome document." para 3 of EB140/27). The report lists some of the ways the Secretariat is trying to assist member states to overcome the obstacles to implementation. The draft resolution (para 20) urges member states to 'continue to implement' the various resolutions.

In <u>EB140/27</u> the Secretariat also reports to the Board on the status of its work on two outstanding assignments given by the Health Assembly and the UNGA in preparation for the third High-level Meeting of the General Assembly on the Prevention and Control of NCDs, namely:

- (i) a draft updated Appendix 3 of WHO's global action plan for the prevention and control of noncommunicable diseases 2013–2020 (revising the list of interventions in the light of recent research; see Annex 1 of EB140/27); and
- (ii) development of a draft approach (see <u>Annex 2</u> of EB140/27) that can be used to register and publish contributions of the private sector, philanthropic entities, civil society and academic institutions to the achievement of the nine voluntary targets for the prevention and control of noncommunicable diseases (as mandated in <u>para 37 of UNGA68/300</u>).

The Secretariat also submits for Board consideration a proposed workplan 2018–2019 (Annex 3 of EB140/27) for the global coordination mechanism (of which more below).

The Board is invited to adopt the draft resolution at para 20 of EB140/27 which would endorse the updated Appendix 3 and note the workplan.

The Board is also invited to provide guidance on how the Secretariat may complete its work on the development of an approach to registering and publishing contributions as per Annex 2.

Background

WHO's Global Strategy for the Prevention and Control of NCDs was first presented in <u>A53/14</u> in May 2000 and was endorsed in resolution <u>A53.17</u>.

In May 2008 the Assembly (in A61.14) endorsed the Action Plan for the Global Strategy (for 2008 - 2013). Progress in implementation was reported to WHA63 in 2010 in A63/12.

The first UN HLM on NCDs was held in September 2011 and adopted the <u>Political Declaration</u> on NCDs. This declaration called upon WHO to develop a comprehensive global monitoring framework and a set of voluntary global targets.

In <u>A66.10</u> (May 2013) the Assembly endorsed the <u>global action plan</u> on NCDs (for 2013 - 2020) and adopted the global monitoring framework and the nine voluntary global targets. A66.10 also requested the Secretariat to develop terms of reference for a global coordinating mechanism and to propose an update of <u>Appendix 3</u> of the global action plan. See <u>PHM-MMI</u> intervention in the discussion of this item.

In May 2014 the Assembly considered Secretariat reports (in A67/14) on:

- the action plan for the global strategy for the prevention and control of noncommunicable diseases 2008–2013; and
- 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 (also <u>A67/14</u> Add.2);

and approved:

- the terms of reference for the global coordination mechanism on the prevention and control of noncommunicable diseases (see para 8 of the Annex to <u>A67/14 Add.1</u>) and the proposed work plan for the Global coordination mechanism (at para 5 of <u>A67/14</u> Add.3 Rev.1);
- the proposed terms of reference for the United Nations Interagency Task Force on the Prevention and Control of Non-communicable Diseases (para 17 of A67/14); and the
- limited set of action plan indicators for the WHO global action plan for the prevention and control of noncommunicable diseases 2013–2020 (Annex 4 to A67/14).

See PHM's comment on this item at WHA67.

A second HLM of the UN General Assembly was held in July 2014 to review progress on the 2011 Political Declaration (see 2014 outcome document).

The DG reported to WHA68 in May 2015 ($\underline{A68/11}$) on the discussion at the HLM and the follow up tasks to be carried by WHO. See record of discussion in Ctee B ($\underline{7th}$ and $\underline{8th}$ meetings). The committee noted the report.

PHM's comment on this item at WHA68 focused on:

- the underfunding of WHO's work on NCDs;
- the absence of any reference to trade in the proposed workplan for the Global Coordination Mechanism;
- the failure to address conflict of interest around NCD policy making in WHO and at the UN.
- the need for a legally binding instrument to regulate TNCs as part of any strategy to address NCDs;
- the need for tax reform and to protect L&MICs from corporate extortion (promises and threats around foreign investment) as conditions for sufficient public revenue for health system strengthening;
- the need to address the drivers of increasing drug prices in relation to NCDs, such as cancer.

The focus of discussion at WHA69 was on the preparation for the third HLM of the UNGA on NCDs in 2018. The Assembly considered <u>A69/10</u> and adopted <u>A69.6</u>. See discussion in Committee A, 11th meeting.

PHM's comment on this agenda item at WHA69 highlighted:

- the continued underfunding of WHO's work on NCDs under the 'financing dialogue';
- the need to include tools such as health impact assessment regarding proposed trade agreements in view of the importance of trade relations in shaping the NCD environment;
- the proposal to register and publicise the 'contributions' of private sector entities, philanthropies and civil society organisations to the achievement of the nine global targets; the need to include provision for independent nomination of entities to be registered and for negative contributions to be publicised;
- some of the issues being considered by working groups established under the GCM;
- the need the Inter-Agency Taskforce to progress the proposal for a binding agreement on TNCs.

More about the global coordination mechanism for NCDs (GCM/NCDs)

The GCM was announced 2013 in <u>A66/9</u> (from para 14). In May 2014 WHA67 considered the proposed terms of reference for the GCM (annex to <u>A67/14 Add.1</u>) and the proposed workplan for 2014-15 (<u>A67/14 Add.3</u>) and the <u>7th meeting of Committee A</u> endorsed both. The workplan for 2016-17 was presented to WHA68 in May 2015 in Annex 3 to <u>A68/11</u>. The proposed work plan for 2018-19 is presented in Annex 3 of EB140/27.

It appears that there have been no overview reports of the work of the GCM although there is a report on the 2014-15 workplan in Annex 5 of A69/10 and a range of tools, activities, working groups etc can be accessed from the GCM home page. The GCM is coordinated from within the NCDs unit in the Secretariat and reports to the DG. An evaluation is scheduled for 2017-18.

PHM comment

Current situation and technical assistance

The data about shortfalls in implementation in relation to NCDs come from the $\underline{2015 \text{ NCDs}}$ $\underline{\text{Monitor}}$. A summary of these data was reported to the Assembly in $\underline{\text{A69/10}}$, paras 16-18.

The analysis of obstacles to implementation in para 4 of EB140/27 warrants attention with references to the need for policy and technical expertise, lack of funding (including barriers to instituting domestic taxes on health harming products), and industry interference.

Para 5 of EB140/27 refers to a number of 'technical assistance' projects sponsored by WHO including a Bloomberg supported <u>data platform</u>, two updated systematic reviews (on <u>saturated fat</u>, and on <u>transfats</u>), a technical package on <u>cardiovascular risk management</u> in primary care, and a report on <u>fiscal policies</u> for diet and NCDs. These initiatives, worthy as they are, do not respond to the diagnosed obstacles to implementation referred to in the previous para. Further, there is no reference here to the role of country or regional offices in providing technical assistance.

More significant, there is no reference to the continued underfunding, under the Financing Dialogue, of WHO's NCDs work. See <u>page 48 et seq of A69/45</u>. It is apparent that notwithstanding their rhetoric about the importance of NCDs the big bilateral donors do not want to see progress in this area.

Appendix 3 (A suite of strategies and resources for the prevention and control of NCDSs)

The redrafted Appendix 3 is will be appreciated. WHO has assembled a suite of strategies and resources that national planners will be able to incorporate into their NCD programs.

The report notes that cost effectiveness assessment 'has limitations and should not be used as the sole basis for decision making'. It is unfortunate that WHO has not explored more thoroughly other approaches to priority setting which are better suited to evaluating possible strategies in the context of local realities (see PHM paper on priority setting).

It is unfortunate that there are no 'tools' dealing with (i) the need to ensure the full utilisation of TRIPS flexibilities to promote more affordable medications for NCDs; or (ii) capacity building in relation to the negotiation of trade agreements, including the use of health impact assessment. The dissemination of such tools, both of these are authorised under A59.26, is sorely needed.

The private sector contributions to the <u>consultation</u> around the updating of Appendix 3 provide useful insights into the corporate perspective (for example, the claim by the <u>Distilled Spirits</u> <u>Council of the US</u>, that price increases and restrictions on alcohol availability and promotions do not impact on the misuse of alcohol).

Register and publish the contributions of non state actors

Para 37 of UNGA <u>68/300</u> (July 2014) calls upon WHO to put in place a register which can be used to publicise the 'contributions' of private sector entities, philanthropies and civil society organisations to the achievement of the nine global NCD targets.

This bizarre proposal is part of a wider push to reframe WHO programs and reconceptualise global governance in terms of 'multi-stakeholder partnerships' with the corporate sector recognised as a key player in such partnerships. (For a substantive critique of this drive see <u>Legge (2016)</u>, in particular, from page 18 onwards.)

The Secretariat report in Annex 2 of EB140/27 takes a cautious approach to the proposed 'register'; highlighting the need for detailed guidelines, 'quality criteria' and 'quantifiable output indicators'. The Secretariat also seeks the guidance of member states regarding 'the level of ambition that is required from the Secretariat' regarding the self reporting tool (regarding 'contributions') and the internet platform (for publishing such 'contributions').

PHM urges that the concept of 'contribution' be recognised as having *negative* as well as positive significance and that there should be scope for independent registrations of the negative contributions by private sector entities to the nine global targets.

If a register the 'contributions' of private sector entities (PSEs) were to make a contribution to public policy it would need to have some representative quality (in the sense of being a valid reflection of the field as a whole) to enable useful analysis rather than simply the wish of particular PSEs to be registered.

There may be some merit in registering the contributions of philanthropies if this is undertaken in a comprehensive and independent way. Such registration could help to hold philanthropies to

account for the approach adopted, could encourage more effective strategies, and could support more effective coordination of different funding agencies.

PHM sees no purpose in registering 'contributions' of civil society organisations. Rather PHM urges that public interest CSOs take up this opportunity to register the contributions, positive and negative, of PSEs and philanthropies.

PHM urges member states to assign a very low priority to progressing this project.

Workplan for the GCM-NCD for 2018-19

The Global Coordination Mechanism for NCDs (GCM/NCD) is a fairground of consultative sideshows most of which are quite small scale and not particularly strategic. The main tunes being played are about intersectoral and multi-stakeholder coordination. In part it is an experiment in 'innovative financing', in particular from the private sector a notion that PHM rejects.

Reviewing the <u>proposed workplan for 2018-19</u> it is hard not to be sceptical about the strategic direction, purposes and cost-effectiveness of this global coordination mechanism, particularly given the consistent underfunding of NCDs work through the financing dialogue.

There is nothing in any of the GCM workplans which would direct consideration to the inclusion of investor state dispute settlement provisions in new trade agreements, such as 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.

There have been no references to coordination with the Human Rights Council regarding the proposed binding agreement on transnational corporations as a strategy for curtailing health damaging corporate practice. PHM urges member states to include such collaboration in the GCM workplan for 2018-19.

There are no provisions in the GCM workplan to address the prevalence and risk of improper influence of big pharma, big food and big beverage on policy making around NCDs, including within the GCM. PHM urges that an additional function to be assigned to the GCM to monitor conflicts of interest in the policy processes associated with the Global Action Plan and to advise the DG where conflicts of interest may lead to improper influence in such policy processes.

There has been virtually nothing in the secretariat materials regarding the GCM which speaks about how the GCM program is articulating with the work of country offices. PHM urges member states to ask the Secretariat to include a more active engagement with country and regional offices in the GCM workplan.

It is unfortunate that the secretariat is taking such a leisurely approach to the evaluation of the GCM. PHM urges member states to require more frequent and more comprehensive reports about the work of the GCM to the governing bodies.

10.2 Draft global action plan on public health response to dementia

In focus

<u>EB140/28</u> conveys to the Board a draft global action plan on the public health response to dementia. A draft decision for the Assembly is included.

Background

The focused consideration of dementia by WHO's governing bodies follows a number of international meetings and declarations including the G8 Dementia Summit (2013) and the (WHO organised) first ministerial conference on global action against dementia (2015).

Dementia was listed for discussion at EB138 (Jan 2016) 'at the request of Member States' but was deferred to EB139 (May 2016) at which the Secretariat paper $\underline{\text{EB139/3}}$ was considered (debate at $\underline{\text{M1}}$ and $\underline{\text{M2}}$) and decision $\underline{\text{EB139(1)}}$, authorising the development of a global action plan on dementia, was adopted.

Both EB139/3 and EB140/28 refer to WHO's proposed Global Dementia Observatory which was first <u>announced</u> in May 2015 and <u>'launched'</u> in Jan 2016 but still not publicly accessible on the WHO website.

PHM comment

The burden on individuals, families and communities of dementia is huge. The strategies proposed in EB140/28 all make sense.

However, questions about the funding of the plan are in order, given the fact that there is no paper listed on the financial and administrative implications of the proposed decision (as required by Regulation XV). The delay in unveiling the Global Dementia Observatory suggests that the Secretariat is working on limited resources in this area and is perhaps expecting earmarked donor funds to support the implementation of the proposed plan.

10.3 Public health dimension of the world drug problem

In focus

In April 2016 a special session of the UN General Assembly (UNGASS) adopted an <u>outcomes</u> <u>statement</u> on the world drug problem which included several references to the public health dimensions of this problem.

In May 2016 WHA69 considered a <u>draft resolution</u> proposing that WHO should develop a comprehensive strategy and action plan on the public health dimensions of the world drug problem. The Assembly was not able to come to a consensus on this draft resolution but decided (in <u>WHA69(15)</u>) to review the issue at EB140 in Jan 2017.

The Secretariat report (<u>EB140/29</u>) provides an overview of the policies which inform WHO's current work on the public health dimensions of the world drug problem.

The challenge before the Board will be to agree on a draft resolution for the Assembly in May (WHA70) which will provide WHO with a clear mandate to continue and develop this work.

Background

The public health dimension of the world drug problem appeared on the agenda for EB138 (Jan 2016) because of the forthcoming UNGASS in April 2016. Discussion at EB138 was informed by <u>EB138/11</u> which was noted; see report of debate in the <u>13th meeting</u>. PHM's comment is here.

The UNGASS was held in April, 2016. The <u>outcome document</u> is structured around a series of 'operational recommendations':

- on demand reduction and related measures, including prevention and treatment, as well as other health-related issues;
- on ensuring the availability of and access to controlled substances exclusively for medical and scientific purposes, while preventing their diversion;
- on supply reduction and related measures; effective law enforcement; responses to drug-related crime; and countering money-laundering and promoting judicial cooperation;
- on cross-cutting issues: drugs and human rights, youth, children, women and communities;
- on cross-cutting issues in addressing and countering the world drug problem: evolving reality, trends and existing circumstances, emerging and persistent challenges and threats, including new psychoactive substances, in conformity with the three international drug control conventions and other relevant international instruments;
- on strengthening international cooperation based on the principle of common and shared responsibility; and
- on alternative development; regional, interregional and international cooperation on development-oriented balanced drug control policy; addressing socioeconomic issues.

(There are repeated references to 'supply reduction' and 'demand reduction' in the Outcomes Statement but no references to 'harm reduction'. See also official records of discussion here.)

The outcomes of the special session were reviewed at WHA69, informed by A69/12.

A <u>draft decision</u> (sponsored by Argentina, Australia, Colombia, Guatemala, Mexico, Netherlands, Norway, Panama, South Africa, Sweden, Switzerland, United States of America, Uruguay and Zambia) was circulated and discussed in a drafting group. The draft decision proposed to request the DG to develop a comprehensive strategy and action plan to strengthen action on the public health dimension of the world drug problem. However the drafting group could not find consensus and the Assembly decided <u>A69(15)</u> to schedule the outcomes document for further discussion at EB140.

The report of the debate in the <u>13th meeting of Cttee A</u> suggests that the core issues in contention in the drafting group centred around whether WHO should take a more active role in relation to the public health aspects of the problem (and in particular the set of public health policies generally understood as 'harm reduction').

After the sponsoring member states spoke, generally regretting the lack of consensus on the draft decision, Peru spoke criticising the Secretariat's report including its support for harm reduction strategies and argued that health 'was only one aspect of the world drug problem'. Peru was supported by Cuba. China's contribution was non-committal but at the EB in January China had suggested that references to 'harm reduction' were 'demeaning' and could encourage legalization of drugs.

PHM's comment on A69/12 is here.

<u>EB140/29</u> outlines existing WHO policies and programs regarding the public health dimension of the world drug problem (and their mandate within the wider global context of SDGs and the UNGASS outcomes statement). Essentially EB140/29 suggests the broad shape that 'a comprehensive strategy and action plan' would take if the Board were able to find consensus in January around a recommendation to WHA70.

PHM comment

<u>EB140/29</u> provides a comprehensive overview of the public health dimensions of the world drug problem and would form the basis for a comprehensive strategy and action plan to address the public health dimensions.

However, PHM does not accept that a public health approach to drug misuse can (or should) be seen as somehow separate from the wider context of causes and effects of drug use and drug policy.

Let it be clear: PHM deplores the suffering, illness and violence at all levels (individual, family, community and society) which is associated with drug misuse *and* with the criminalisation of the use of (certain) drugs.

PHM recognises that there is a strong case for the wider use of 'harm reduction' strategies including decriminalisation, needle and syringe exchange and safe injection facilities. Harm reduction is not an alternative to supply reduction and interdiction; it is one set of strategies which needs to be included in a comprehensive and balanced response to drug misuse.

However, the 'criminalisation' versus 'harm reduction' frame is too narrow for policy development at the national level or for analysing the wider policy context of the 'world drug problem'. These choices need to be understood in a much wider frame which takes a critical

approach to the causes of drug misuse. Policy making needs to include a critical analysis of the harm which flows from drug policing as opposed to drug use. It also needs to recognise the political role of criminalisation in diverting attention from the social and political drivers of drug misuse and from the ways in which criminal syndicates benefit from global economic integration, corporate impunity, and state sponsored arms trade. Finally policy making needs to address the contradictions between licit and illicit drug regimes; between the freedom of the alcohol and tobacco industries to promote the misuse and use of those drugs in contrast to the criminal status of syndicates promoting the use of illicit drugs (which are generally responsible for much lower levels of morbidity and mortality).

This is not the place for a definitive analysis of these issues which, in any case, should be undertaken in relation to specific local circumstances. However, the wider framing of the 'world drug problem' is of such importance that a broad sketch of such analyses is needed.

The causes of drug misuse can be usefully categorised in terms of different levels from the biochemical to the geopolitical.

Biochemical causes

Most misused drugs provide a positive psychic experience at least for some users.
 However, once dependence is established the positive experience may be largely associated with the relief of dependent craving.

Socioeconomic causes

- Individuals and communities living in existential pain are particularly vulnerable to the numbing effects of psychoactive drugs. Alienation, marginalisation and exclusion are common social causes of existential pain. Social, political and economic inequalities set the circumstances for widespread alienation and exclusion and thus for the use of psychoactive drugs.
- In many countries the legacies of colonisation and slavery perpetuate inequality and social division (eg USA, Brazil, South Africa). Such legacies contribute to drug use and help to shape contemporary responses to drug use.
- The contemporary world faces a rolling global economic crisis arising from a growing imbalance between productive capacity and effective consumption. The neoliberal response to this imbalance has been to drive (in part through so-called 'free' 'trade' agreements) a process of global economic integration with a view to protecting the interests of powerful transnational corporations (and the global elite) even though it contributes to a further widening of inequality and increases the numbers of excluded and marginalised people at risk of addiction.
- The individualisation and criminalisation of drug use serves to divert attention away from the legacies of colonialism and from the widening inequalities associated with neoliberal globalisation.

Criminal and corporate causes

- There is no doubt that the prospects of profit drive both criminal syndicates as well as the corporate promoters of legal drug use, in particular, alcohol and tobacco.
- Criminal syndicates, like the alcohol and tobacco companies, benefit from global financial integration and deregulation (enabling both money laundering and tax avoidance). State sponsored arms companies sell arms to both the criminals and the police and military.
- There is no doubt that criminal behaviour (from minor crime to pay for individual procurement to narco terrorism) contributes to the individual and social damage

- associated with drug misuse. However, in many respects crime related harm is exacerbated by policing, militarisation and incarceration strategies; in other words by criminalisation.
- In most countries there is a consensus around the legal status of alcohol and tobacco and the management of associated harm through regulation and education. Their implementation has been limited but clearly there is scope for greater effectiveness.

Geopolitical strategy and insurgencies as causes

- The role of the imperial powers forcing opium onto the Chinese in the 19th century is
 perhaps the most notorious example of imperial adventures in creating the conditions for
 drug trafficking and promoting drug markets. However, it is not a unique case, nor is the
 practice of purely historical interest. There is a long history of narco-imperialism in
 Afghanistan and Central America which has, in many ways, created the conditions for
 illicit drug cultivation and trafficking.
- The use of illicit drug revenue to fund various insurgencies (both popular insurgencies and covert imperial interventions) has also contributed to the 'world drug problem'. FARC in Colombia and Shining Path in Peru exemplify.

An exclusionary and unfair trade regime in agricultural products, designed to support Northern agribusiness, contributes to driving some farmers in unstable and conflict zones to consider growing illegal crops. Since the 1980s the IMF and the World Bank have been urging developing countries to invest in growing coffee. More recently the US policy of 'eradication' in the Andes and replacement of coca with coffee has contributed to the glut and to falling prices. The main beneficiary of such policies has been transnational coffee merchants like Nestle.

Global policy making needs to include a critical analysis of the harm which flows from drug policing as opposed to drug use. Black incarceration in the USA, impacting on individuals, families and communities, is an outstanding example; likewise the impact of eradication policies on the welfare of indigenous communities in Peru.

The individualisation and criminalisation of drug use serves to divert attention from the social and political drivers of drug misuse. In the US example, the discourse of 'scourge' and 'war on drugs' serves to divert attention from unemployment, alienation and marginalisation as causes of drug use and from policing / incarceration as the medium of harm. In the Peru example the discourse of 'criminal syndicates' serves to divert attention from the expropriation and marginalisation of indigenous communities from the contemporary global economy.

Finally it is critical to recognise and name the corporate and bureaucratic structures invested in the criminalisation project, starting with the UN Office of Drugs and Crime but extending down to the police forces and armies who are employed in the War on Drugs. In 2015 the <u>US gave</u> \$60m to Peru to support 'law enforcement' and coca eradication.

There is one reference in EB140/19 to the social and environmental determinants of drug use but no elaboration of what this might mean. There is no reference to alienation, unemployment and marginalisation nor to the causes of widening inequalities and intergenerational unemployment which contribute to communities who are predisposed to deploy mind altering substances to reframe their realities.

The Agenda for Sustainable Development provides a beautiful vision of a better world, a world in which the attractions of psychoactive drugs would be weaker, but is silent on the political

economy which reproduces contemporary inequities, exclusions and injustices and is lacking in plausible drivers.

There is an urgent need for a strong WHA resolution to reaffirm the mandate of WHO to address the public health dimensions of the world drug problem. <u>EB140/29</u> provides the basis for such a resolution. However, there is also an urgent need to recognise:

- the harm which flows from drug policing rather than drug use:
- the ways in which alienation, exclusion and marginalisation contribute to drug use;
- the ways in which neoliberal globalisation cultivates exclusion, marginalisation and alienation;
- the ways in which the deregulation of global finance facilitates the work of drug criminals;
- the contradictions between licit and illicit drug regimes and the need for an integrated regime which takes a balanced approach to both criminalisation and to education and regulation of legally available drugs;
- the political role of individualisation and criminalisation in diverting attention from the social and political drivers of drug misuse; and
- the corporate and bureaucratic investment in the criminalisation paradigm and accordingly the 'bureaupolitical' resistance to change.

These issues will not be resolved within the governing bodies of WHO but it would add a sense of reality to the debate to include some recognition of the wider context.

10.4 Ending childhood obesity: implementation plan

In focus

The high-level Commission, 'Ending Childhood Obesity' (ECHO), was established by the Director-General in 2014 in order to create awareness and build momentum for action. Its final report (A69/8) was considered by A69 (debate A11) which adopted WHA69(12).

In accordance with <u>WHA69(12)</u>, <u>EB140/30</u> conveys a draft implementation plan to guide further action on the recommendations included in the ECHO report.

The Board is invited to endorse the implementation plan before it is considered by WHA70.

Background

The WHO website has useful references on its <u>obesity page</u> including a description of the Commission, its work program and the commissioners (<u>here</u>).

For further background see the special issue of <u>Obesity Reviews (October 2013)</u> which reviews a wide range of policy options regarding the regulation of the food environment.

PHM comment

This draft Implementation Plan is an excellent follow up to the outstanding ECHO Report. PHM urges the Board to endorse it, in its entirety, in their recommendation to the Assembly.

However, the international food and beverage industry will be already lobbying its favoured delegates to water down the recommendations, in particular those dealing with the sugar tax, the regulation of marketing, and nutrient profiling and food labelling.

The International Food and Beverage Alliance (IF&BA), in its comments on the draft Implementation Plan, <u>argues</u> that:

Regarding recommendation 1.2 to tax sugar-sweetened beverages - as mentioned in our earlier submissions, we would recommend that this action be approached with caution. An analysis by the McKinsey Global Institute of 74 interventions to address obesity that are being discussed or piloted around the world found that the highest-impact intervention areas are portion control and product reformulation. In our view, further work is still needed to assess the impact of fiscal measures on diet and health outcomes before specific actions in this area are recommended.

We have concerns about recommendations 1.4 on nutrient profiles and 1.6 on a standardized global nutrient labelling system, as we do not believe that a single unified standard can be defined to identify "unhealthy foods" at a global level, regardless of their role in the overall diet and without taking due account of local dietary and cultural specificities.

While the US supported <u>WHA69(12)</u>, their delegate <u>argued</u> that "private sector could play an important role in enhancing access to healthier food and promoting physical activity". The

representative of Japan <u>noted</u> that " ... the issue of labelling, addressed in the Commission's recommendations 1.6 and 1.7, was a sensitive one".

The CEO of Unilever is <u>reported</u> as advising the UK government that a sugar tax is 'too simple' and that 'there was little evidence that introducing a levy on food and drink with a high sugar content would help tackle obesity'. Unilever's contribution to tackling obesity has been to cut the size of its ice-creams.

Meanwhile IBFAN <u>reports</u> that Nestlé has recently announced a four-year deal with Barcelona Football Club to promote Milo processed food (which is nearly 50% sugar).

While the junk food industry will be lobbying against the Implementation Plan their main focus will be at the national level to prevent member states implementing the plan.

The aggregate profit of the 11 members of the IF&BA is between 10 and 20 times the total budget of the WHO.

PHM urges professional and public interest civil society organisations to commit to vigorous education and advocacy at the local, provincial, national and global levels to build support for implementation of the ECHO recommendations.

It is unfortunate that the reference in para 36 of the ECHO Report to the health and equity impacts of national and international economic agreements and policies has not made it to the Implementation Plan. In particular, the spread of investor state dispute settlement provisions (ISDS) which can penalise small countries for considering public health policies and can chill such consideration by other countries.

The Implementation Plan refers to the "significance of agriculture and trade policies and the globalization of the food system" in para 8(c) and to the need for cross portfolio policy coherence including trade in Table 1. PHM urges the inclusion of a more explicit recommendations in the Implementation Plan advising member states to avoid ISDS provisions which might prevent effective public health regulation.

10.5 Cancer prevention and control in the context of an integrated approach

In focus

[Meeting in September 2016, the Officers of the Board agreed to include an item on cancer on the provisional agenda for EB140, with the proviso that it be entitled "Cancer prevention and control in the context of an integrated approach".]

At the request of a Member State, the Secretariat has developed a report (EB140/31) outlining the disease burden and trends in relation to cancer; national cancer strategies undertaken as part of national multisectoral efforts to address noncommunicable diseases that are proving to be effective; and WHO's activities, and other international efforts, to meet the global challenge posed by cancer. The Board is invited to note the report and to consider the draft resolution contained therein.

Background

The preambulatory paragraphs of the draft resolution list the numerous previous resolutions and declarations on cancer and NCDs (including cancer). The main new initiative carried forward in the draft resolution is the proposed world report on cancer.

PHM comment

In view of the burden of disease attributable to cancer and the inequities in terms of exposures, incidence, treatment access and outcomes, it is useful to reiterate the principles expressed in the draft resolution. However, the paper steers clear of some important issues which might be less attractive to potential donors.

There is no substantive discussion of the reference in the title of the paper to 'integrated care'. There are no references to the institutional challenges of fostering networks of excellence in cancer prevention, diagnosis and care which are integrated within generic health systems including strong bidirectional referral pathways between primary health care services and more specialist services. There are no references to the challenges of monitoring standards of practice in relation to cancer prevention, diagnosis and care in such integrated health systems and in particular no reference to the regulatory challenges of quality assurance in relation to cancer care in private practice.

There is no reference in the draft resolution, to WHO having a role in addressing the international prices of various tools (vaccines, drugs, biologicals, equipment) for prevention, diagnosis and treatment of cancer as provided for in relation to member states in OP(1)(8). OP(1)(8) mentions 'patent barriers, quality assurance mechanisms, more effective supply systems and measures to reduce prices' in relation to member state actions. The Secretariat should also be mandated to supporting such actions through technical assistance, the development of tools, support for collaborative procurement, and international policy research, publication and advocacy.

11.1 Progress in the implementation of the 2030 Agenda for Sustainable Development

In focus

In <u>EB140/32</u> the Secretariat reports to the Board on progress made in translating the broad Agenda for Sustainable Development into strategic and practical approaches for health. The report also provides an opportunity to discuss specific actions that WHO can take to implement the health-related Sustainable Development Goals.

Background

A summary of the processes through which the SDGs were developed, with relevant links, can be found in PHM's comment on this item at EB136 (Jan 2015).

PHM comment

EB140/32 is disappointing.

Healthism is a barrier to policy coherence

Speaking about the "centrality of health in the 2030 Agenda" (para 1) is not the best way of building collaboration with policy officials and advocates in other sectors. 'Health in all policies' is a slogan which can inspire public health officials to engage with other sectors, but as a way of speaking *to* other sectors it privileges health objectives over those of other sectors and is a barrier to deepening dialogue.

Health officials have an institutional obligation to give special attention to health and health professionals may have a personal commitment to public health. However, institutional responsibility and professional expertise do not justify claims that health objectives should be privileged over other policy objectives.

It is true that "good health is a precondition for, and an outcome and indicator of, sustainable development" (para 4). However, it is neither the only precondition, nor the only outcome or the only indicator, and is certainly not more 'central' than others.

Need for a gap analysis

WHO has a rich suite of resolutions, plans and strategies that are clearly relevant to many of the non-health SDGs. However, WHO needs to go beyond simply identifying those areas where WHO does have relevant resolutions, plans and strategies and also identify those SDGs where WHO does not have such resolutions, plans and strategies and to explore possible synergies (between health and other objectives) which might flow from adopting specific health oriented policies in those areas.

PHM urges WHO to take stock of its resolutions, plans and strategies to identify: first, where policies and programs are in place which are contributing to the commitments under each of the SDGs; and second, to identify gaps in WHO's policies and programs; where other individual

SDGs point to institutional, political and cultural change which would contribute to Health for All but which have not been given appropriate priority up until now.

PHM calls on the Board to commission a plan for presentation to WHA70 on the gaps so identified and how WHO might address them.

Equitable sustainable development is a challenge for rich as well as low and middle income countries

EB140/32 correctly notes that the MDGs were overly focused on a small number of important diseases and neglected health systems development and neglected equity. It is also important to note that the MDGs were largely focused on mobilising external financial assistance to help to address those diseases in low and middle income countries.

However, one of the key differences between the MDGs and the SDGs is that the sustainable development agenda presents 'development' challenges to rich as well as low and middle income countries, including in relation to equity, human rights, ecological sustainability and the regulation of transnational corporations. These are challenges which are not just about mobilising more funds.

EB140/32 proposes that WHO's action in relation to the SDGs will be driven primarily by its country offices (para 22). However, WHO's country cooperation strategies (CCS) are almost entirely with low and middle income countries. Of 35 countries in the OECD, WHO has CCSs with only four, one of which is its host country, Switzerland. It appears that the Secretariat sees no role for WHO in the pursuit of SDGs in rich countries. By implication issues such as equity, human rights, ecological sustainability and the regulation of transnational corporations have no implications for global health.

The politics of sustainable development at the global level

The language of EB140/32 evokes a parallel universe in which everything is about win win outcomes and where rational policy debate trumps insecurity, fear and greed. In such a universe, wealthy people willingly undertake to pay more tax to support social protection and UHC and citizens of rich countries welcome asylum seekers. In such a universe, food companies care about healthy diets; pharmaceutical companies care about affordable access to essential medicines and the rational use of drugs; and energy companies care about moving to low carbon emissions.

There is nothing in this paper which speaks about the social and political processes through which the SDGs might be achieved. These include moving towards cultures of inclusion and human security to reduce xenophobia and strengthen solidarity. They include meaningful democratic deliberation and decision, including democratic control of the parameters within which private enterprise operates, rather than strengthening corporate power over governments. They include addressing the skewed balance of political power; equity with respect to voice as well as around access to material resources.

EB140/32 does not address the tensions (across differing interests and perspectives) between people, countries and corporations and only superficially addresses the tensions between policy

sectors, eg between health and trade, or between health and large scale intensive pork and poultry farming.

The role of social and political movements in achieving the SDGs

The language of 'partnerships' in EB140/32 focuses attention on the various institutional 'stakeholders', as in para 28:

WHO is engaging more strategically with a variety of stakeholders to achieve the Sustainable Development Goals, for instance, with global health partnerships, philanthropic foundations, the private sector, nongovernmental organizations, international professional associations, financial agencies, research institutes and academia, the media, and civil society.

However, this listing of different kinds of non-state actors obscures the political divisions and the alliances which cut across these institutional categories. It also obscures the processes of political contestation through which the prevailing regime might be changed ('developed').

PHM is particularly concerned about the lack of any reference to the social and political movements through which the marginalised and excluded, the alienated and disillusioned, are working for change and how WHO might work with such political and social movements for equitable sustainable development, including better health outcomes.

The closest EB140/32 comes to recognising such distinct constituencies is the timid statement in para 13:

The approach to equity favoured by WHO is "progressive universalism", where the disadvantaged, whoever they may be, benefit at the least as much as those who are more fortunate.

WHO's financial disabilities exemplify the barriers to achieving the SDGs

EB140/32 makes no reference to the constraints on WHO's capacity as a consequence of its inadequate and inflexible funding.

This is not surprising since the corporate and political forces which maintain the donor chokehold over WHO (in particular the freeze on assessed contributions and the refusal of member state donors to untie their voluntary contributions) are deeply involved in maintaining a regime of global governance which has been demonstrably unable to move the global community towards equitable sustainable development.

Under such circumstances it may seem unfair to criticise the officers of the Secretariat for the twists and gaps in EB140/32. However, such criticism may be unavoidable if the distortions and omissions associated with institutional position are to be named.

11.2 The role of the health sector in the Strategic Approach to International Chemicals Management towards the 2020 goal and beyond

In focus

Resolution <u>WHA69.4</u> (2016) requested the Director-General, *inter alia*, to develop a road map for developing the health sector's role in the management of chemicals at the national, regional and international levels. The report (<u>EB140/33</u>) will present the proposed road map for consideration by the Executive Board.

The focus of discussion at the EB will be the draft road map. The development of the road map and an overview description is included in <u>EB140/33</u>. The road map itself is <u>here</u>.

Background

About the development of the Strategic Approach to International Chemicals Management (SAICM)

PHM's commentary on Item 13.6 at WHA69 (here) provides an overview of the historical background of international chemicals management and the Strategic Approach including the discussion at the Assembly in 2010 regarding the role of the health sector in implementing the Strategic Approach.

See A69/19 for an overview of the SAICM and WHO's involvement.

For more material on the SAICM see the <u>report</u> of ICCM4 (Sept 2015). The progress and challenges report prepared by the secretariat of the SAICM for the 4th session of the ICCM (<u>SAICM/ICCM.4/3</u>) provides a useful overview of the objectives of the SAICM and the continuing issues. The evaluation process described in this report is completely inadequate.

Emergence of the road map

The emergence of the road map at EB140 (and for subsequent consideration at WHA70) reflects several pressures and deadlines.

A63/21, considered by the Assembly in May 2010, reviews the importance of the sound management of chemicals for the protection of human health; reviews the background of the Strategic Approach; and reports on the continuing pressure for greater health sector involvement in chemicals safety from the second session of the International Conference on Chemicals Safety.

In May 2014, in the context of informing the WHA67 discussion of the Minamata Convention the WHO Secretariat document ($\underline{A67/24}$) pointed out that the chemicals safety agenda was not restricted to mercury and suggested a consultation with MSs on priority actions for the health sector in relation to chemicals management. The outcomes of the consultation are here and the list of updated health sector priorities here.

Meanwhile the 2030 agenda for sustainable development adopted in September 2015 includes several references to chemicals safety, discussed further in para 4 of EB138/18.

Finally the post 2020 framework for international chemicals management is presently being discussed (as the term of the Strategic Approach mandate finishes in 2020). The health sector needs to be involved in these discussions.

A draft resolution providing a mandate for WHO's continuing involvement in international chemicals management was launched at EB138 (see discussion at M6, M7, and M14) but consensus could not be achieved. Further negotiations continued in the lead up to WHA69 and a consensus resolution was presented there and adopted (WHA69.4). This resolution provides the mandate for the development of the road map which has been further developed following an online consultation with MSs in September 2016.

PHM comment

Accountability

The proposed road map includes no provisions for holding member states accountable for implementing the proposed actions. PHM urges member states to put in place an independent information and accountability commission to collect and publish meaningful indicators of progress across all of the action areas and priority concerns.

Canada has one of the most rigorous chemicals safety regimes in the rich world but a 2011 government memo revealed that the government had not evaluated most of the hundreds of chemicals used in fracking; not only this, but they did not have the power to force miners to identify the chemicals used. See case study below.

Need for overarching framework convention

The 'problem by problem' approach (Montreal, Minamata, Basel, Rotterdam, and Stockholm) to the regulation of chemicals management fragments the institutional systems required to drive chemicals safety.

Peiry (2014) has called for a framework convention which would mandate the institutional systems and support the necessary capacity building across the full range of chemicals and wastes with separate protocols for particular specific needs.

The continued use of lead paint and the continued illegal transboundary traffic in waste and chemicals illustrate the failures of voluntarism including codes of conduct and best practice guidelines; such voluntarist instruments provide insufficient drive for chemicals safety.

PHM calls for a binding obligation for the production of defined toxicity data to be provided by manufacturers before introducing new chemicals into the environment (work, farm or consumer market).

PHM calls for mandatory labelling in accordance with a mandated classification scheme.

The rise of investor state dispute settlement provisions in 'free trade' agreements underlines the need for comprehensive and binding overarching principles to provide a watertight defence against foreign investor challenges to nation state regulation

Illegal transboundary movement

The road map completely ignores fifth objective of the Strategic Approach: illegal transboundary movement of waste and toxics. It is not credible that WHO's member states believe that there are no health implications associated with illegal transboundary movement of waste and chemicals.

The IHRs are structured around the transboundary movement of disease risk and the capacity building required to give effect to the goals of the IHRs could contribute to effective management of illegal transboundary traffic.

PHM calls upon MSs to request the Secretariat to undertake a comprehensive study of potential uses of WHO's regulation and convention making powers in the interests of international chemicals safety.

Financing

A major challenge is how to approach North South disparities in relation to institutional regulatory capacity and whether industry should be forced to contribute to the costs of capacity building in developing countries.

On the question of financing van der Kolk and Agarwal (2011) argue that any long term financing mechanism for chemical safety can only be achieved if it is internalised as part of the product life cycle and such costs are included as part of the product cost. They point out that the chemical industry has sales of more than \$US1.5 trillion (including pharmaceuticals) per year, and accounted for an estimated 7% of global income and 9% of international trade in 2006. They point out that only a tiny fraction of these amounts would be be sufficient to support effective chemical safety globally. A financing instrument along these lines and managed by one of the new South based development banks would be a practicable approach. However, Hogue (2005) reports chemical industry spokespersons in the US as being fiercely opposed to a 'chemicals tax' and fearful that it might be included within the Strategic Approach.

Technology transfer

Appropriate provisions for North South technology transfer is an important part of capacity building. In approaching technology transfer intellectual property should be handled in accordance with TRIPS flexibilities rather than being tied to private sector investment.

Fracking in Canada: case study

Some quotes from the Boothe memo of 2011 cited below:

In November 2010, the Institut national de santé publique du Québec published a report entitled État des connaissances sur la relation entre les activités liées au gaz de schiste et la santé publique. The intent of the report was to assess the health risks posed by shale gas development to the residents of Québec. The report, however, was not able to perform the assessment because of information gaps regarding technologies used, substances used, and the amount of pollutants emitted.

Fracturing fluid consists mainly of water and sand with a small amount (between 0.5% and 2%) of chemicals. An average well may require between 55,000 and 220,000 L of chemicals. Little information is available on the composition of these chemicals. I am not aware of any jurisdiction in Canada that requires the disclosure of chemicals used for hydraulic fracturing; however, the B.C. Oil and Gas Commission has announced that it may require companies to disclose chemicals used for hydraulic fracturing in the future.

EC staff has reviewed the list of chemicals used in hydraulic fracturing in Québec and the United States. Preliminary results reveal that only 13 of the 265 substances have already been assessed under CEPA 1999. Seven of these, including benzene and naphthalene, were found to be toxic.

References

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11.3 Global Strategy for Women's, Children's and Adolescents' Health (2016–2030)

In focus

<u>EB140/34</u> is submitted in line with resolution <u>WHA69.2</u> (2016), in which the Health Assembly requested regular reports on progress towards women's, children's and adolescents' health. This report has a special focus on adolescent health. The report also highlights progress made in monitoring and accountability.

Background

The field of global action for women's, children's and adolescents' health is complicated by a complex mix of different bureaucracies, different stakeholders, different commitments and different goals, targets and indicators. In this background note an introduction is provided to:

- health status: the present situation,
- the Global Strategy itself,
- the development of the Global Strategy,
- finance,
- human rights,
- the multi-stakeholder partnership.

Health status: the present situation

The present health situation for women, children and adolescents globally is summarised in <u>EB140/34</u>. More detail is provided in the <u>first report (2016) of the Independent Accountability Panel</u>. This is summarised in more dramatic form in the <u>IAP online report</u>.

The Global Strategy (2016-2030)

The <u>Global Strategy for Women's Children's and Adolescents' Health (2016-2030)</u> identifies nine action areas (from page 46):

- 1. Country leadership
- 2. Financing for health
- 3. Health system resilience
- 4. Individual potential
- 5. Community engagement
- 6. Multisector action
- 7. Humanitarian and fragile settings
- 8. Research and innovation
- 9. Accountability for results, resources and rights

The logic of the Strategy links the action, in each of the nine *action areas*, to the implementation of a suite of *evidence based health interventions* set out in Annex 2 from <u>page 88</u> of the global strategy. Interventions are listed separately for women, children and adolescents.

The technical interventions are in turn linked to *health system policies and structures* needed to ensure their implementation. These are summarised in Annex 3 from <u>page 92</u>. Annex 4 from <u>page 95</u> lists the *other sector policies and interventions* which would also be needed.

Chapter 6, which deals with implementation, speaks of three interconnected pillars which will underpin the delivery of the Global Strategy:

- 1. Country planning and implementation,
- 2. Financing for country plans and implementation, and
- 3. Engagement and alignment of global stakeholders.

The chapter highlights the concrete explicit commitments which are expected of different stakeholder groups. See 'Committing to Action' from page 80 of the Global Strategy.

The development of the Global Strategy

In seeking to understand the processes and bureaucracies associated with the Global Strategy it is necessary to review some history. The infographic in Annex 1 of the Global Strategy (from page 88) traces out some of this history.

The first Global Strategy (for Women's and Children's Health) was launched by the UN Secretary-General in September 2010. This was in large part a response to the lack of progress in MDGs 4 & 5 on child and maternal health. The strategy was developed under the auspices of the United Nations Secretary-General with the support and facilitation of the Partnership for Maternal, Newborn & Child Health, based in WHO. An overview of the history and role of the PMNCH is here.

As part of this first global strategy WHO was asked to coordinate a process to determine the most effective arrangements for global reporting, oversight and accountability on women's and children's health. In response, the Director-General established the Commission on Information and Accountability for Women's and Children's Health which reported in 2011 (Keeping promises, measuring results).

The ten recommendations from the UN Commission on Information and Accountability for Women's and Children's Health (as revised in 2016) are set out in Annex 5 of the Global Strategy from page 97 and deal with:

- better information for better results,
- better tracking of resources for women's, children's and adolescents' health,
- better oversight of results and resources: nationally and globally.

One of the recommendations of the Commission was the establishment of an <u>independent Expert Review Group</u> to hold stakeholders accountable for their commitments to the Global Strategy. The IERG reported annually on implementation from 2012 to 2015 (and the conclusion of the MDGs process).

With the transition from MDGs to SDGs, in September 2015, a revised global strategy was developed (this time including adolescents and scheduled for 2016-2030), again under the auspices of the UN SG and the Every Woman Every Child 'movement', and with the support of the PMNCH. The UN SG also appointed a High Level Advisory Group to guide the strategic direction of Every Woman Every Child and the implementation of the new strategy.

With the launch of the revised Global Strategy the UN SG appointed an <u>Independent</u> Accountability Panel (IAP) to be hosted and supported by the PMNCH. The IAP will produce

an annual 'State of the World's Women's, Children's and Adolescents' Health' report and in so doing identify areas to increase progress and accelerate action.

As part of strengthening accountability relations WHO has developed the <u>indicator and monitoring framework</u> (described in EB140/34) and WHO and partners have adopted the <u>Unified Accountability Framework</u>.

As described in the UAF there are three pillars to the implementation plan for the Global Strategy: accountability (the Framework itself, the IAP, the indicators etc), technical support and financing.

Technical support is to be provided by the 'H6' (UNAIDS, UNFPA, UNICEF, UN Women, WHO, and the World Bank Group) and finance is centred on the Global Financing Facility (GFF) hosted by the World Bank.

Finance

As explained in A69/16 the bulk of the funding required for the implementation of the Global Strategy is expected to be raised domestically. However, financial assistance will be made available for 62 low and lower middle income countries through the new Global Financing Facility sponsored by the World Bank. According to A69/16 (para 19):

The newly established Global Financing Facility in support of Every Woman Every Child aims to accelerate efforts towards the implementation of the Global Strategy by coordinating and harmonizing external funding flows in support of national plans, assisting governments in identifying strategies to increase domestic resources for health progressively, and reducing inefficiency in health spending over time. The Facility will provide an opportunity for 62 low- and lower middle-income countries to access substantial new funding for women's, children's and adolescents' health, including through the World Bank's Global Financing Facility Trust Fund. Currently 12 countries have the option of support from the Global Financing Facility Trust Fund linked to International Development Association loans.

The GFF was launched in July 2015, out of the World Bank's Health Results Innovation Trust Fund and with funding from World Bank Group and governments of Canada, Norway, and the United States. According to its director, <u>Mariam Claeson</u>, the GFF was launched in 2015 as "the new approach to smart, scaled and sustained financing across reproductive, maternal, newborn, child and adolescent health". <u>More on the GFF here</u>.

Human rights approach

EB140/34 recalls the 2014 recommendation of the independent Expert Review Group for the establishment of a global commission, on the health and human rights of women and children, to propose ways to protect, augment and sustain their health and well-being. By way of following this up WHO and OHCHR have convened a High Level Working Group for the Health and Human Rights of Women, Children and Adolescents which will recommend ways in which human rights can be integrated into health programming.

The 'multi-stakeholder partnership' model

The fourth pillar of the Global Strategy is the 'multi-stakeholder partnership'. Both the Partnership for Maternal, Neonatal and Child Health and the Every Woman Every Child are multi-stakeholder partnerships. The PMNCH undertakes project work; the EWEC styles itself more as a movement. Likewise the H6 is a partnership within the UN system (plus the WB).

A69/16 explains (in para 15(d)) that the Global Strategy aims to "Harness the power of partnership, reinforce multisectoral and multistakeholder commitments and collaboration, and use governance mechanisms that have the ability to effectively facilitate cross-sector collaboration and action; recognize the importance of informed community engagement in planning, supporting and monitoring services so as to reach everyone."

PHM comment

The Global Strategy

The Global Strategy, as a document, is admirable. The action areas are sensible. The list of evidence based interventions is very useful and the descriptions of the enabling environments which will need to be created also make sense. The targets and the commitment to information and accountability are admirable.

However, the bureaucratic superstructure which has been erected around the implementation of the Strategy is bewildering in its complexity.

It seems that a number of considerations associated with this Global Strategy have combined in contributing to this complexity. These include:

- the legitimation imperative: the need to be seen to be doing something about needs which are widely seen as insufferable and which reflect poorly on the contemporary regime of global governance;
- the leadership imperative: the assumption that assembling as many political celebrities as possible will help to drive implementation;
- the multi-stakeholder partnership requirement: a paradigm of program design based on the assumption that the authority of inter-governmental organisations is insufficient to drive implementation without the blessing of various private sector entities, including the large philanthropies;
- the donor chokehold: the dependence of WHO, and the UN system generally, on voluntary and earmarked donations from philanthropies and rich member states;
- the outcomes measurement fetish: faith in the power of quantitative outcomes feedback on the political drive for implementation;
- the social movement imperative: a recognition that change requires social mobilisation and an assumption that a social movement can be constructed from the top, constrained within particular institutional boundaries and led by the global elite; and
- neglect of the inequities generated through the prevailing global economic regime: an
 assumption that the failures of MDGs 4 & 5 were due to a lack of political will on the part
 of governments rather than an unsustainable and inequitable global economy which
 reproduces poverty and marginalisation and crimps the public revenues needed for
 decent health care and the 'enabling environments' identified in the Strategy.

Financing

The Global Strategy states that expanding the funding flows to women's, children's and adolescents' health should draw largely on domestic financing but concludes that there will still be a huge need for development assistance financing in low and some middle income countries.

The design of the <u>Global Financing Facility</u> reflects in part a recognition that the funding structures established to support the MDGs contributed to health system fragmentation, administrative overload and internal brain drain. However, there is no guarantee that the new GFF will reduce the problems associated with multiple channels of donor assistance. The development of integrated comprehensive health systems is critical for women's, children's and adolescents' health but there is no guarantee under the GFF that funds which are earmarked for women's, children's and adolescents' health will not distort health system development in the same ways as the vertical funding of infectious disease programmes has done.

However, there are no indicators in the <u>indicator and monitoring framework</u> which would signal health system fragmentation consequent upon GFF disbursements. Indeed there are no indicators which might help to evaluate the targeting of GFF disbursements generally.

PHM notes the enthusiasm of the World Bank to promote the role of the private sector in reproductive, maternal, newborn, child and adolescent health:

The majority of resources mobilized from the private sector for RMNCAH will come from private sources at the country level. In addition, the GFF is developing innovative financing mechanisms to bring international sources of private capital to the effort to improve RMNCAH results (page 19 of Business Plan).

This is quite worrying as it is clearly ideological (faith based) rather than evidence based.

Use of process indicators to follow implementation

There is a sharp focus on targets and indicators in the Global Strategy and the <u>indicator and monitoring framework</u> but this is largely restricted to 'outcome' indicators including those specified through the SDGs process.

In fact the Global Strategy is quite innovative in listing, in Annexes 2-4, a series of 'interventions' and a series of 'enabling environments' which are seen as preconditions for delivering those interventions. However, there are no references in either the Strategy or the <u>indicator and monitoring framework</u> to the monitoring of progress with respect to such interventions and enabling environments. Clearly the creation of quantitative indicators in these respects would be difficult but there would be scope for more qualitative methods of review, evaluation and adjustment.

Recognising the macroeconomic determinants of poverty, inequality and undernutrition

There are several references in the Global Strategy to the role of poverty, marginalisation and discrimination in contributing to death and disease. However, there are no references to the unsustainable and inequitable nature of the global economy which contributes to reproducing poverty, marginalisation and exclusion.

While the rich capitalist countries are rallying around this Strategy and promising contributions to the Global Financing Facility (GFF) they are at the same time implementing economic policies globally which reproduce the poverty and inequality in the heavy burden countries.

PHM affirms the importance of addressing the immediate health needs of women, newborns, children and adolescents, including through the interventions and enabling environments mentioned in the Global Strategy. However PHM calls for an approach to global health which also maintains a focus on the macroeconomic and geopolitical dynamics which contribute to reproducing those health needs.

PHM calls for stakeholders in the reproductive, women, newborn, child and adolescent health field to direct more attention to the macroeconomic and geopolitical dynamics which shape health outcomes in this field and to promoting policies which, while addressing the immediate needs of women, children and adolescents, also lead toward a more equal, sustainable and inclusive global society.

12.1 Implementation and financing of Programme budget 2016–2017: update

In focus

<u>EB140/35</u> provides an overview of WHO's financial situation in relation to the Programme Budget 2016-17. In a nutshell:

- WHO faces increased expenses, decreased contributions and increased earmarking (reduced flexibility);
- A significant financial risk is looming associated with commitments to polio staff as that program winds down;
- After a year of fund-raising the Health Emergencies Contingency Fund is almost completely unfunded;
- The Secretariat is redoubling its efforts to recruit new donors and encourage existing donors;
- The DG proposes a US\$93 million increase (10%) in assessed contributions as recommended by the UN High-level Panel on the Global Response to Health Crises;
- Without this increase WHO's work in health emergency management is at risk and other existing programs will need to be scaled back.

Background

WHO's most basic disability, the lack of predictable, flexible and adequate funding has not been effectively addressed in the current reform program. Tightly earmarked voluntary contributions comprised close to 80% of WHO's revenues in the last biennium (EBSS/2/INF.DOC./2). Only a few member state representatives have spoken publicly about the need to increase assessed contributions and most donor states have shown no intention to untie their voluntary contributions. Norway is a signal exception.

The donor chokehold is the single biggest cause of 'inefficiencies' (through competitive fundraising, conflicted accountability, long term staff but short term, unpredictable project funding, transaction costs of 'funding dialogue'). The 'efficiency case' for reform is bogus.

The DG has attempted to curtail competition for funds between clusters, departments and regions through the establishment in the DG's office of a coordinator of funds mobilisation. However, the DG is also committed to developing 'a tailored engagement approach for each key contributor'.

The funding dialogue is represented by the Secretariat as protecting member state sovereignty in that the budget is adopted before the funding dialogue commences. However, the Secretariat is very aware of the predispositions of the donors and to suggest that the budget as submitted to the Assembly pays no attention to the donor wishes would be fanciful.

The funding dialogue is extremely expensive in terms of the time of senior officials. It may have addressed in small degree the problems of rigid and unpredictable donor funding. The move to centralised coordination of funds mobilisation may help to reduce the problems of internal competition for donor attention. However, the power of the donor veto over WHO's work plan is as tight as ever.

The DG has called for financing which is predictable, flexible and adequate. WHO's annual budget is now around \$2,200 million. This is around 30% of the annual budget of US CDC; 4% of Pfizer's turnover; and 3% of Unilever's turnover in 2015; and around 10% of Big Pharma's annual advertising in the US. It is simply not enough for WHO to properly fulfil its responsibilities in global health.

PHM comment

The current WHO Reform program was initiated as a result of an earlier funding crisis. To address the crisis a deal was struck: if the Secretariat could improve its efficiency, effectiveness and accountability the donors would lift the level of assessed contributions (ACs) and untie their voluntary contributions. This was the origin of the current WHO Reform program. The Secretariat has kept its side of the bargain; the member states and other donors now need to make good.

PHM calls on all member states to support the DG's proposed 10% increase in ACs and calls on donor states to untie their voluntary contributions.

PHM calls on public health organisations and other civil society organisations to urgently write to their ministers for health and ministers of finance emphasising the critical need for increased ACs

PHM also calls on public health organisations and other civil society organisations in the major donor states to urgently advocate for the increase in ACs, increased VCs and reduced earmarking of VCs.

12.2 Proposed programme budget 2018–2019

In focus

EB140/36 outlines the proposed budget for 2018-19. It is supported by the budget portal.

Background

WHO budgets on a two year biennial cycle within a six year 'global program of work'. The current GPW12 (2014-19) was adopted in WHA66.1.

This is a budget *space* document, not a conventional expenditure budget. Full funding of the budget space outlined will depend on the DG's success in the 'funding dialogue' scheduled for the latter half of 2017. There is no guarantee that the approved budget will be financed.

PHM Comment

PB18-19 provides a useful perspective on global health (in particular the narrative sections) and the role of WHO in global health (in particular the sections on 'deliverables'). Unfortunately many of the indicators (including a few of the 'outcome indicators' and most of the 'output indicators'), are absurd both in terms of meaningful measurement and an indicative relationship to the programme objectives.

The Secretariat presents a strong case for a significant increase in assessed contributions, see <u>paras 44-50</u>. PHM urges member states to approve this increase.

Notwithstanding WHO's resolutions in relation to social determinants of health, the budget narrative is largely disease focused and ignores the broader geopolitics, macroeconomics and skewed power relations which reproduce much of the global disease burden. These fundamental barriers to global health are also reflected in the forces which maintain the gross underfunding of WHO and the donor chokehold over WHO's budget.

The weakness of community engagement in WHO's programme implementation, in particular at the country level, is evident in this budget narrative. This is in part a consequence of provision in the WHO Constitution which requires the approval of the national government for country offices to work with local NGOs. Under these circumstances there is a need for WHO to work more strategically with international civil society organisations such as PHM in order to strengthen the accountability of health ministries for fulfilling their commitments under WHO resolutions.

The absence of a physical presence of WHO in most HICs and many UMICs (in the sense of not having a country office) is unfortunate, given the development challenges these countries face, in terms of human rights, social determination of health, and the SDGs. Clearly it would be unaffordable under present circumstances.

14.1 Overview of WHO reform implementation

In focus

The Secretariat report (EB140/38) provides:

- an overview of the current status of reform;
- a review of progress made in the three broad reform workstreams; and
- a reference to the indicators that have been established to measure achievement of the reform objectives.

Background

Programmatic reform

The main elements of this stream of reform are: (i) predictable, flexible, adequate funding for WHO (see <u>EB137/3</u>); and (ii) priority setting, planning, budgeting, evaluation and accountability reforms.

Governance reform

The main elements in this stream of reform are: (i) methods of work of governing bodies (including agenda control (see ltem 14.2); and (iii) the 'alignment and harmonisation' agenda (see ltem 14.2); and (iii) the 'alignment and harmonisation' agenda (see ltem 14.3);

Management reform

Within this stream of reform there are a range of reforms in: (i) human resource management, (ii) improved accountability and transparency; (iii) evaluation, (iv) information management, and (v) corporate communication.

Origins and development of reform program

The role, powers, and structures of WHO have been subject to debate since before it was established (World Health Organization 1958, Farley 2008). Criticism and debate continued after 1948 and there have been several rounds of structural reform before the present one, notably under Dr Halfdan Mahler (<u>Joint Inspection Unit 1993</u>, para 22, <u>Litsios 2002</u>) and under Dr Gro Harlem Bruntland (Lerer and Matzopoulos 2001).

The present round of reform dates back to the deficit reported in WHO's financial reports for the biennium 2008/09. The Programme Budget and Administration Committee (PBAC, a committee of the Executive Board) reported to the World Health Assembly (WHA) in May 2010 that the deficit had been in part funded by reducing the carry forward from 2008/09 to 2010/11, in essence borrowing from the future to pay current bills (WHA63/REC3, p219).

The operating deficit was largely the consequence of WHO's dependence on unpredictable earmarked voluntary contributions (VCs) and the associated uncertainties of revenue budgeting, particularly in the aftermath of the global financial crisis. For the 2008/09 biennium only 19% of WHO's expenditure was met through assessed (or mandatory) contributions (ACs) (see

A63/29). The bulk of the VCs were tightly earmarked to specific purposes (A63/ID4). The background to this high degree of donor dependency is discussed in more detail below.

The Director-General (DG), Dr Margaret Chan, commissioned an informal consultation in January 2010 (WHO DGO 2010.1) to consider options for more predictable and flexible funding, and in January 2011 the Executive Board (EB) considered an item labelled 'The future of financing for WHO' (record of discussion here). The ideas outlined in this discussion eventually evolved into a far-reaching program of reform. The reform program took a clearer shape in November 2011 with a special meeting of the EB, focused solely on WHO reform and yielding a series of decisions dealing variously with priority setting, governance and management.

The freeze on WHO's assessed contributions, the tight earmarking of voluntary donations, and the periodic withholding of US assessed contributions (Bond 2003), are designed to discourage WHO from adopting or implementing policy positions in relation to global health governance issues, which run contrary to the interests of the US and the other big donors (including nation states, intergovernmental organisations and philanthropies).

The current round of reform commencing with the DG's informal consultation in January 2010 (WHO_DGO_2010.1) has been shaped by periodic discussions in governing body meetings but its reach was broadly settled in the special session of the Executive Board held in November 2011 (EBSS/2/2011/REC/1) which adopted three decisions (dealing respectively with priority setting, governance and managerial reform) which have largely guided the reform from that time.

A major new element of the reform program, focusing on WHO's capacity to prepare for and respond to outbreaks and emergencies, was added following the special session of the EB held in Jan 2015 to review the lessons from the 2014 Ebola epidemic. The decision adopted in that meeting (EBSS3.R1) addresses a range of issues concerning funding, human resources and product development as well as the need for a major reform of WHO arrangements for dealing with emergencies (discussed below).

The reform program has been steered from within the DG's office, subject to reports and decisions taken in the governing bodies (official reform website). An evaluation framework has been put in place to monitor the implementation of the various governing body decisions (here). A chronology of reform can be found here.

PHM comment

Many of the reform initiatives reported in <u>EB140/38</u> were necessary, have been carried out professionally and appear to be yielding organisational benefit. However, there remain some major shortfalls.

The funding crisis has not been solved by the 'financing dialogue'. The donors have refused to untie their voluntary donations. Large gaps remain between planned expenditures and revenue targets, particularly in policy areas which are not supported by the donors, including action on the social determinants of health, non-communicable diseases, emergency preparedness, and research and development for medical products.

The 'financing dialogue' is based on the proposition that the Assembly adopts a budget based on robust planning and costing and then the DG goes to the donors to fill up the 'budget space'. This is largely spin. The Secretariat knows what the donors will and won't support and the Programme Budget reflects this. The donor chokehold remains a real constraint on the effectiveness of WHO.

A major feature of the human resource reforms has been to adapt the staffing structure of the Secretariat to the unpredictable nature of WHO's finances (dependence on short term donor commitments and fluctuating donor priorities). This has involved discounting the value of corporate memory and core expertise in the interests of corporate agility in the face of short term unpredictable financing (see further comment on the HR reforms in Legge (2016) from page 39).

Progress with respect to the 'alignment and harmonisation' agenda has been slow and unimpressive. The member states remain conflicted about curbing the autonomy of the regional offices. The work of country offices is a critical determinant of WHO's effectiveness but the functioning of regional offices is critical in terms of support to country offices. The failure to fully address 'alignment and harmonisation' is a major shortfall in the reform program.

While the member states have agonised over the Secretariat's relationships with 'non-state actors' (and related conflict of interest issues) the accountability of member states for their implementation of WHO policies remains tenuous.

WHO's role in global health governance, which was a prominent feature of the original discussion papers, has completely dropped off the agenda. This reflects the determination of the US and like-minded states and the global corporate elite to curb the influence of WHO. It also reflects a level of disillusionment regarding regarding WHO's long term prospects among leading developing country delegates.

The corporate alternative to effective intergovernmental organisations is the 'multi-stakeholder partnership' model epitomised by the World Economic Forum's <u>Global [governance] Redesign Initiative</u>.

Real reform of WHO, to empower it to realise the vision of its Constitution, will require a global mobilization directed to empowering WHO as part of democratising GHG more generally. This will include closer civil society engagement with WHO at local, national, regional and global levels, directed to making national governments more accountable for the various roles they play in global health governance and specifically in WHO decision making and the implementation of WHO resolutions. Closer civil society engagement with WHO will find and create opportunities to develop a broader community understanding of the links between local health problems and global decision making and to build practical people-to-people solidarity around global public health issues.

For a detailed review and full critique of WHO's reform program see Legge (2016).

14.2 Governance reform: follow-up to decision WHA69(8)

In focus

The reports and information papers (EB140/39 is the overview report) provide an update on the implementation of decision WHA69(8) based on the agreed recommendations of the Openended Intergovernmental Meeting on Governance Reform (A69/5), dealing largely with the methods of work of the governing bodies and improved alignment of governance across the three levels of the Organization.

The decisions in <u>WHA69(8)</u> included the following measures (with reported actions listed beside each):

- developing a forward looking schedule for the agenda of the EB and WHA (addressed in EB140/INF./3);
- tighter agenda management for the EB and WHA (review of criteria for inclusion of items addressed in <u>EB140/40</u> and <u>EB140/40 Add. 1</u>);
- proposals for closer correspondence between hours available and number of agenda items (see Annex to <u>EB140/39</u>);
- tightening the rules for additional, supplementary and urgent items (work in progress, para 5);
- better use of information technology to support governing body meetings (work is underway, para 6);
- senior management coordination (recognition of Global Policy Group; strengthened senior management coordination for organisational coherence; para 7);
- publication of delegations of authority and letters of representation (done, para 8);
- consideration by RCs of procedures for nomination of regional directors, in accordance with <u>WHA65(9)</u>, 2012 (action in SEARO and EMRO noted);
- improved transparency of process for selection of ADGs (not mentioned);
- strengthened planning mechanisms (eg category networks and the results chain para 10);
- enhancing alignment between RCs and EB as provided in para 4 of WHA65(9);
- strengthening oversight functions at the RC level (initiatives in WPRO and EMRO reported in para 12);
- strengthening WHO cooperation with countries (improved reporting from regional and country offices to RCs; a biennial WHO country presence report (<u>EB140/INF./2</u>).

Background

This item brings together two separate streams of discussion: (i) 'methods of work of governing bodies'; and (ii) 'alignment and harmonisation'.

'Methods of work' has been largely about agenda management but includes issues regarding member state reporting and the use of modern IT and information management (see PBAC25/3). Legge (2016) from page 17 provides a brief history of how this set of issues has evolved.

The 'alignment and harmonisation' stream has centred around the high degree of autonomy exercised by regional directors and a perception that regional committees and regional directors

have not always been sufficiently accountable. This stream of discussion has been highly contentious and <u>WHA69(8)</u> only addresses the issues on which consensus was achieved. Legge (2016) from page 29 provides a brief history of this stream of debate.

Much of the present debate was prefigured by the 1993 report of the UN Joint Inspection Unit (JIU) which concluded "that because WHO's decentralized structure is currently handicapped by many problems identified in this report, it is not functioning as efficiently and effectively in the nineties as it did in the early decades of its existence". The inspectors offered a suite of structural reforms including: "The Director-General should be empowered to select and nominate RDs for confirmation by the Executive Board, following consultations and in agreement with the Regional Committees concerned or their Bureaux, as appropriate". The JIU returned to these issues in 2012(6) and 2012(7) and was again critical of the role of regional offices and regional committees.

The 'harmonisation and alignment' issues bounced along for several years until after a critical report by WHO's Independent Expert Oversight Advisory Committee (IEOAC) in Jan 2015 (EBPBAC21/2) which led to the member state consultative process on governance reform (MSCPGR). This involved a working group and a number of intergovernmental meetings. The second report of the working group (EB/OMSMGR/2/2) sketched an ambitious agenda for reform which is worth returning to. However, the member states were not able to agree on these recommendations. Decision WHA69(8) adopted by the Assembly in May 2016 addresses only the agreed recommendations.

The recommendations of the WG were quite prescriptive and many of them are encompassed by the Decision albeit at a higher level of generality. Thus the WG produced a detailed appendix setting out principles of best practice in governance. This was not considered by the Open-ended Intergovernmental Meeting (A69/5) but is referred to in general terms in para 14 of WHA69(8).

The recommendations of the WG regarding the nomination of regional directors (Rec 2(3)) proposed that candidates for RD positions be shortlisted by the DG 'in consultation with the RC' and then a single candidate would be selected by the RC from the shortlist. The closest this came to being included in WHA69(8) is para (9) which invites the RCs to consider measures to improve the nominations process.

The WG was quite pointed in citing the <u>JIU (2012)</u> criticisms of the functioning of the regional committees and the criticisms of the <u>Stage 2 Evaluation</u> regarding the lack of implementation of the JIU recommendations. The closest this got to WHA69(8) was an invitation to the RCs to consider reviewing their current practices ... where applicable (para (13))..

PHM comment

Much of the material in these papers is sensible and strategic and should be adopted.

- The forward-looking planning schedule of expected agenda items (<u>EB140/INF./3</u>) will be very useful both for people who are following particular items that are on the schedule and for those seeking to get new items onto the schedule.
- The proposed criteria, factors and weightings for the inclusion of items on the provisional agenda of the EB (EB140/40 / EB140/40 Add.1) may help in the management of the

- agenda. It would have been useful to look more closely at the dynamics driving member states to propose new items for the agenda.
- The proposals for closer correspondence between hours available and number of agenda items (annex to <u>EB140/39</u>) are very sensible.
- Better use of IT (as recommended by the WG Rec 1(8)) is urgently needed.

It is regrettable (although inevitable) that the blunt speaking of the <u>JIU</u>, the <u>Stage II Evaluation</u> and the <u>WG on Governance Reform</u> has been smudged by the diplomatese of WHA69(8); see above for example regarding the smudging of the earlier recommendations on the nomination of regional directors. To maintain focus it will be necessary to keep going back to those more explicit recommendations.

In particular, continuing attention to the nomination of regional directors is needed. PHM urges member states to give close consideration to the criticisms of JIU(2012) and the Stage II Evaluation report and to seriously consider the recommendation 2(3) of the Working Group (EB/OMSMGR/2/2):

- (3) To recommend that regional committees work towards standardizing the process of nomination of regional directors, such that:
 - the position would be publicly advertised. This would raise the profile of the position and the Organization and potentially attract a broader field of candidates. It would not remove the requirement for any candidate's home Member State to support the candidacy. This could be addressed by requiring candidates to seek the support of their health ministries as part of the application process, or by the Director-General providing an opportunity for the home Member States of each applicant to comment on/object to the candidacy;
 - candidates would be assessed against the selection criteria and shortlisted by the Director-General in consultation with the relevant regional committee; and
 - the regional committees would continue to interview shortlisted candidates and propose a single candidate to the Board for appointment.

The report on WHO presence in countries, territories and areas in 2015 (<u>EB140/INF./2</u>) provides a useful account of WHO's work with countries. However,

- There is nothing here about WHO's country cooperation with rich countries. The
 Sustainable Development Agenda points very clearly to development goals which are
 applicable to rich as well as poor countries, respect for the human right to health, for
 example. This aspect of WHO's work should not be ignored.
- There are no references in this paper to any contact that Country Office staff might have with sub-national governments (eg provincial and local government), public health professional groups or with public interest civil society organisations. Many WHO resolutions pay (what might be) lip service to the importance of professional advocacy and social mobilisation in driving the implementation of WHA resolutions at country level. The provisions in the WHO Constitution which require WHO personnel to obtain government consent to work with national non-government organisations appear to be holding back the work of WHO country offices in this respect. PHM urges the Secretariat to explore the scope for using FENSA to bypass this unfortunate restriction.

14.3 Framework of engagement with non-State actors

In focus

Following the passing of the FENSA resolution <u>WHA69.10</u> (in May 2016), this will be a standing item on the Board's January agenda; coming to the Board through the Programme Budget and Administration Committee.

<u>EB140/41</u> introduces the Framework and reports on implementation, including the establishment of the <u>Pilot register</u>.

<u>EB140/42</u> outlines the revised PBAC/Board procedures for admitting organisations into official relations, and reviewing the status of organisations in official relations. It proposes five new NSAs for admission into official relations; it proposes continuation for 58 NSAs currently in official relations; it proposes, for various reasons, to defer consideration of a further set of organisations currently in official relations; and it proposes to discontinue official relations with a further five organisations.

<u>WHA69.10</u> also asked the DG to propose criteria and principles governing secondments from nongovernmental organizations, philanthropic foundations and academic institutions. These proposed criteria and principles are outlined in document <u>EB140/47</u>. This item is listed for consideration separately under Item 15.3 on Human Resources update (see PHM comment on this item here).

This item comes to the Board through the PBAC so there will also be a separate report from the PBAC reporting on its consideration of these issues.

Background

The finalised FENSA is a long and complex document which traverses some highly contested territory and it should be no surprise that it required three EB debates, three Assembly debates, three separate open ended intergovernmental (OEIG) meetings and extended closed negotiating sessions to be finalised. Some of the sharpest debates dealt with:

- the precise wording regarding 'conflict of interest', 'due diligence', and 'risk management' and whether distinctions should be made between different kinds of non-state actors in relation to these issues:
- whether to include an explicit prohibition of secondments to the Secretariat from private sector entities (included in final version, see Clause 47);
- provisions regarding pooled funding mechanisms through which private sector entities (PSEs) could contribute financially to the work of the Secretariat (included, but in quite restrictive terms in the final version).

The provisions regarding conflict of interest were the subject of vigorous lobbying from civil society groups from both the access to medicines and nutrition areas who had experience with corporate entities in those fields. One of the early debates was whether the framework should set out different provisions for different types of stakeholders. For example, in the debate at EB130 (Jan 2012) the highly influential Dr Silberschmidt (Switzerland) 'commented that increased stakeholder engagement was also welcome, but given the specific characteristics, roles and interests of non-governmental, private-sector and other organizations, WHO should

avoid differentiating between categories of stakeholders.' Along the same lines and in the same debate Dr Daulaire (US) 'urged caution about differentiating between the various types of nongovernmental and civil society organizations, given the danger of excluding certain stakeholders or not appropriately acknowledging their specific spheres of interest or activities as part of a transparent consultative process'. The view that conflict of interest (COI) provisions regarding NGOs might be the same as for PSEs was not supported in subsequent discussion.

The proposal for 'a mechanism to pool funds from the private sector' had been part of the Secretariat reform agenda since May 2011 (in <u>A64/INF.DOC./5</u>). Some forewarning of opposition to this proposal was provided by Brazil in the <u>debate</u> over this item at WHA64 (May 2011).

One of the issues which attracted much criticism from civil society but remained in the final version was the provision for PSEs (typically business associations) to be accepted as in 'official relations' with WHO. Part of the arrangement is that organisations in 'official relations' with WHO are required to negotiate explicit 'programs of cooperation' with WHO. It is unclear what kind of programs of cooperation the various business associations will undertake.

The finalised FENSA is long and complex and it remains to be seen how it will work in practice (indeed whether it can be fully operationalised in practical terms). The finalised text represents something of a truce between the proponents and opponents of the private sector having a 'seat at the table' of global health governance.

One of the biggest weaknesses of the finalised FENSA is that it is solely about the Secretariat and leaves member states free to advance the interests of private sector entities through the governing bodies and the financing dialogue with no provisions for public accountability (recalling IMPACT, sugar, psoriasis and, on this agenda, sepsis).

The FENSA discussion started with a focus on WHO playing a more proactive role in global health governance, and in particular, helping to coordinate the anarchy of multiple 'global health initiatives' providing 'development assistance for health'. This vision has been completely lost as the focus of debate narrowed to the Secretariat's relationship with private sector entities.

PHM comment

The main issues regarding FENSA which are in focus at this EB will be:

- the structure and procedures associated with the register (EB140/41);
- the review of NSAs in Official Relations with WHO (EB140/42); and
- the provisions regarding secondments (<u>EB140/47</u>, listed for discussion under <u>ltem 15.3</u>).

The <u>pilot register</u> is a positive development and will improve transparency. We note that there is no provision in the pilot register to display the programs of cooperation which are key to the idea of Official Relations.

The decisions proposed in EB140/42 are consistent with the finalised FENSA.

There may be some discussion of the arrangements for 'pooled funding from the private sector' which was controversial during the negotiation of FENSA but which is not mentioned in EB140/41.

The biggest flaw in the FENSA arrangements is that they only deal with the Secretariat's engagement with non-state actors. Member states remain free to advance the interests of private sector entities through the governing bodies, through the financing dialogue and behind closed doors, with no provisions for public accountability.

As noted above the FENSA discussion emerged from a discussion about WHO playing a more proactive role in global health governance, and in particular, helping to coordinate the anarchy of multiple 'global health initiatives' providing 'development assistance for health'. It is unfortunate that this element of the WHO reform project has been so completely extinguished.

15.3 Human resources: update

In focus

Three separate issues will be addressed under this item:

- implementation of the Organisation's human resources strategy;
- evolution of staffing structures with the winding down of the polio program; and
- criteria and principles to apply to secondments into the Secretariat as provided for under the Framework for Engagement with Non State Actors (FENSA) resolution (<u>WHA69.10</u>, 2016).

HR Strategy

<u>EB140/46</u> provides links to: an update on the implementation of the Organization-wide human resources strategy (<u>here</u>), an update on workforce data (<u>here</u>), and also refers to the relevant section of the <u>WHO Reform Dashboard</u> for metrics of progress on implementation of the HR strategy. See also the statement by the staff associations to the EB (<u>EB140/INF./4</u>).

Polio staff

The annex to <u>EB140/46</u> reports on the evolution of staffing in the polio programme and associated issues for the coming years.

Secondments from NSAs

Responding to resolution <u>WHA69.10</u> (2016), <u>EB140/47</u> sets out proposed criteria and principles to be used in evaluating the suitability of secondments to the Secretariat from nongovernmental organizations, philanthropic foundations and academic institutions.

Background

Human resources strategy

The <u>revised HR strategy</u> was presented and adopted at EB134 (and summarised in EB134/INF./2).

Staffing of polio program

The Annex to <u>EB140/46</u> canvasses a range of issues associated with the downscaling of the Global Polio Eradication Initiative.

Criteria and principles for secondments

The acceptance of secondments from private sector entities was one of the most contentious issues in the debate over the FENSA. <u>WHA69.10</u> finally resolved that WHO will not accept such secondments. The resolution also requested the present report on criteria and principles for

accepting secondments from other non-state actors (NGOs, academic centres and philanthropies).

PHM comment

Human resources strategy

There is much to appreciate in the revised HR strategy adopted in 2014 and clearly progress has been made in its implementation.

However, PHM has concerns about several aspects of this strategy.

First we are concerned that the new short term employment modalities and the introduction of mandatory mobility are in large part strategies for adapting to the short term and unpredictable funding situation created by the freeze on assessed contributions and the refusal of donors to untie their voluntary contributions. The risks to office functioning and program outcomes where corporate memory is lost and where specialist capability is replaced by generic skill sets have not been acknowledged and it appears are not being monitored. There is nothing in the (very limited) HR metrics (here) which measures the possible risks of excessive staffing flexibility and staff mobility.

Second, we are concerned about the standard which ties appropriate level of national representation in Secretariat staffing to the level of national financial contribution and as a consequence determines that the US is under-represented among the Secretariat staff. Delegates should recall that the formula for determining that a country has an appropriate number of professional staff (Resolution A56.35) gives great weight to the financial contribution of the country. Thus in 2016 the USA which provides just under 10% of the total number of professional staff in the Secretariat is nonetheless recorded as being 'under-represented' (here). Note that this appears to not include US citizens employed in PAHO.

Third, we note the gross imbalance in favour of the developed countries among interns within the Secretariat. Table 16 shows that over 80% of interns within the Secretariat offices (excluding PAHO) are from developed countries. A period within WHO can make an invaluable contribution to the career of a young public health practitioner. It is unfortunate that such a position is more accessible for young people from the developed countries in contrast to those from developing countries. Interns comprise just under 25% of the total of professional and higher category staff (excluding PAHO).

Finally, we note the absence of HR data regarding the staffing of the office of the Region of the Americas. This highlights the dysfunctions associated with excessive regional autonomy and makes a mockery of the slogan of 'One WHO'.

Staffing of polio program

The report contained in EB140/46 provides a useful review of the HR issues to be managed as part of the downscaling of the Global Polio Eradication Initiative.

Para 4 notes the establishment of the WHO-wide Post-Polio Transition Planning Steering Committee one of the functions of which is 'to consider the potential integration of functions and

resources of polio eradication work into other programmes (for example, emergencies, immunization and health systems/universal health coverage). This is an important element of post polio planning but this is the only reference to it in the present report. PHM urges the Secretariat to provide a more substantial account of such redeployment strategies in future updates.

Criteria and principles for secondments

<u>EB140/47</u> provides a useful text to work on. However, PHM would counsel against endorsing these guidelines in the absence of any information about the current sources, purposes and practices of secondments. It is to be noted that secondments are explicitly excluded from consideration in both the report on the implementation of the revised HR strategy and in the HR data tables.

EB140/47 sets out proposed criteria and principles but says nothing about the circumstances within which secondments are suggested or considered.

- We speculate that the possibility of secondments from philanthropic organisations arise in the context of the financing dialogue. is this true? If so do such secondments represent a threat to member state sovereignty; an extension of donor influence over the operations of the Organisation.
- We speculate that the possibility of secondments from academic centres arise in the context of expert committees and study groups. Is this so? If so does it provide a privileged modality of influence over WHO's normative functions for academic centres from rich countries?
- We speculate that the possibility of secondments from NGOs might arise in the context of programmatic cooperation in particular fields. Is this so? How often does this occur? Do such secondments come from organisations in official relations with WHO or from other organisations?
- Finally, are there other organisations from which secondments come, such as intergovernmental bodies or member state governments? If so how often and from whence?

In the absence of any public information about current secondment practices, neither quantitative or qualitative, it would seem premature to endorse the proposed criteria and principles at this stage.