People's Health Movement Background and Commentary on Items coming before WHA70, May 2017

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11.1 Overview of financial situation: Programme Budget 2016-17

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In focus

WHO faces a funding shortfall in the present biennium, around US\$400m. PB16-17 is funded to around 90% of budgeted expenditure (A70/6).

The options in the short term include:

- increasingly urgent appeals to member states and other donors;
- cutting back on expenditure in the remaining months of the biennium;
- borrowing against contributions in future years.

The IEOAC (<u>PBAC25/2</u>) urged the Secretariat to undertake scenario planning to explore the impact on programmes of the projected funding shortfall. How many staff would need to be retrenched (in the remaining six months) to ensure WHO did not have an operational debt at the end of the biennium?

The options in the longer term, in particular PB18-19 (see Item 11.2 on this agenda) include:

- increasing assessed contributions (a figure of 10% is being talked about);
- budget cutbacks;
- increases in voluntary contributions and contributors (hopefully increasing flexible core contributions).

A70/6 provides a useful overview; see also the PB web portal.

Background

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

See <u>A68/7</u> for the proposed PB16-17 and Resolution <u>WHA68.1</u> which endorsed it. See PHM comment on PB16-17 at <u>WHA68</u> and <u>WHA69</u>.

See <u>A68/INF/7</u> for more info on budget process. For further information about the financing dialogue see: ttp://www.who.int/about/finances-accountability/funding/financing-dialogue/en/. See <u>A69/47</u> for detail regarding 'budget space allocation'. See also PHM 2016 comment on strategic budget space allocation.

It is useful to review the discussion of PB16-17 at EB140 in Jan 2017 in (EB140/PSR8):

• The UK delegate advised that "While her Government remained committed to the principle of zero budget growth across the entire United Nations system, it would

support the proposed increase in assessed contributions on the understanding that such an increase neither represented a change in policy nor set a precedent" and "she urged other Member States to agree to the proposed increase in assessed contributions";

- The US was less positive: "Expectations of funding levels must be more realistic. Budgeting should not be aspirational. The Secretariat and Member States must consider whether programmes that were chronically underfinanced were being budgeted for, and funded, in a sustainable manner" (in other words, if the donors will not support certain programs don't include them in the budget!);
- Thailand reiterated its support for a 10% increase in assessed contributions;
- Bhutan and Brazil noted that a 10% increase in ACs would be 'difficult';
- Several MSs supported the call by the IEOAC for scenario planning;
- Several MSs called for increased VCs and in some cases for less earmarking;

PHM comment

WHO's total budget is ridiculously small in comparison with the needs it faces and its outcomes potential.

With the freeze on assessed contributions comes donor dependence and tight earmarking. As the US delegate implied during the EB140 debate (see above) WHO is being forced to shape its budget in accordance with donor preferences.

Donor dependence and frantic 'resource mobilisation' also create major organisational dysfunctions: first, the divisive competition for donor attention across programs and regions and second, the loss of organisational coherence as the accountability of middle managers is directed to their donors rather than the organisational leadership.

PHM urges: lift the freeze, and increase and until the VCs.

11.2 Proposed Programme Budget: 2018-19

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In focus

A70/7 conveys the Secretariat's revised proposed Programme Budget for 2018-19 incorporating the advice of the PBAC25 and EB140 in January 2017.

Once this budget is adopted by the Assembly (possibly with amendments) the Secretariat will proceed with planning for the Financing Dialogue in the latter part of 2017, seeking to persuade the donors to contribute as required.

The proposed PB18-19 envisages a 3% increase in assessed contributions (ACs) which would fund around 22% of the proposed expenditure (up from 20% in 2016-17). Thus donor funding will be required for the remaining 78%. The case for the 3% increase is presented in A70/INF./2.

<u>A70/INF./5</u> deals with the financing of WHO's indirect administrative and management costs, identified as Category 6, 'Corporate services/enabling functions'. Since assessed contributions are not enough to cover these costs and the donors largely tie their contributions to programs, it is necessary to employ 'cost recovery' arrangements to identify funds for Category 6. Three specific arrangements are used: programme support costs, post occupancy charges and the hosted partnership charge. <u>A70/INF./5</u> describes recent policy development around these arrangements. These issues were originally discussed in <u>EB134/11</u> in Jan 2014.

The final paper published for this item is <u>A70/INF./6</u>. This document foreshadows a new 'value for money' strategy within the Secretariat. The paper starts with a riff on value for money as a concept and how WHO's results structure enables a systematic focus on value for money. The paper foreshadows a process including the PBAC, an informal meeting of member states after WHA70 and the Independent Expert Oversight Advisory Committee, and incorporating ideas from the third stage evaluation of WHO reform (see <u>A70/50 Add.1</u>). The 'value for money' strategy is a response to the financial crisis associated with the ACs freeze and the declining flow of donor funding. The initial focus will be on driving efficiency and finding cost savings in WHO's programmes.

Late in the week before the Assembly a draft resolution was published (A70/7 Add.1) and then a revised draft resolution (A70/7 Add.1 Rev.1). Both versions provide for the same budget space allocations for PB18-19, incorporating the 3% increase in ACs but the revised version, as well as including new preambulatory paragraphs also includes two new subclauses committing the DG to programmatic funding cuts.

The Assembly's consideration of all of these papers will be informed through the advice of the PBAC26 meeting before the Assembly.

Background

WHO is in a funding crisis

The shortfall of over \$500m in the PB16-17 sets the backdrop to the discussions of PB18-19. See <u>PB Web Portal</u>. The cuts which are foreshadowed in the revised draft resolution and dressed up in the 'value for money' slogan will have to start this year, if WHO is not to take a huge debt into the next biennium.

Proposed increase in assessed contributions

Assessed contributions (ACs) supports 20% of the PB16-17 (<u>Budget Portal</u>). Para 46 of <u>A70/7</u> notes that the DG is proposing a 3% increase in ACs for 2018-19. The case for the 3% increase is presented in <u>A70/INF./2</u>. It is considerably less than the 10% increase the DG suggested to EB140 in Jan 2017 (see EB140/36 para 50; see also EB140/INF./5).

The PBAC report to EB140 (EB140/5) advised:

39. Several Member States voiced strong support for the proposed increase in assessed contributions. Others stressed that they were not in a position to support it and encouraged the Secretariat to cover the additional resources required from efficiency savings, improvements to internal control systems and a more stringent prioritization process. One Member State noted that it could not support a 10% increase in assessed contributions, but that circumstances merited further discussions about whether a possible increase in assessed contributions, at a lower rate, would be viable.

Among those speaking to this item at EB140 (see <u>PSR8</u>) the US, the Czech Republic (on behalf of Austria, Bulgaria, the Czech Republic, Hungary, Latvia, Mexico, Poland, the Russian Federation, Slovakia and Spain), Lithuania, Spain and Brazil opposed the increase while Philippines, Canada, Netherlands, Liberia on behalf of the African Region, Sweden, Turkey, Switzerland, Norway, Germany and Finland supported the 10% increase.

About the importance of assessed contributions

Paras 43-45 of A70/7 underline the importance of assessed contributions to WHO funding:

- assessed contributions provide the type of funding that is necessary for an
 organization with mission-critical functions that rely on long-term, predictable
 financing and that could be seriously compromised by dependence on voluntary
 funding;
- assessed contributions provide the highest-quality funding for WHO, as they are uniquely – fully flexible, and can be allocated to any type of work;
- while the financing dialogues have contributed to a significant increase in the predictability of voluntary contributions, but there has not yet been any improvement in the alignment of such funds.

The case for the 3% increase is elaborated in A70/INF./2.

'Value for money'

The value for money slogan provides cover for a new round of cost cutting. While <u>A70/INF./6</u> provides cover the reality is reflected in two additional subclauses added to the draft resolution adopting the Programme Budget 18-19:

11. REQUESTS the Director-General: ...

- (3) to provide additional information on the prioritization process and a plan, including details of the programmes and activities that should be discontinued, in preparation for the Thirteenth General Programme of Work, 2020–2025, through the Executive Board and its Programme Budget and Administration Committee, to the Seventy-first World Health Assembly;
- (4) to control costs and seek efficiencies, and to submit regular reports with detailed information on savings and efficiencies as well as an estimation of savings achieved.

A note on budget structure and methodology

The Programme Budget is structured with Categories and Programmes. However, confusion may arise from the references to Segments as distinct from Categories and Programmes. The reference to Segments concerns the budget space allocation methodology rather than the budget structure.

The concept of budget *space* allocation (as distinct from budget allocation) arose following adoption of the principle that a comprehensive budget proposal would be adopted before engaging the donors in the Financing Dialogue and that assessed contribution (AC) resources would be allocated after the donors had indicated what they were willing to support.

In a document prepared for EB134 in Jan 2014 (<u>EB134/10</u>) the Secretariat identified four budget 'segments' each of which would call for different methodologies for estimating appropriate expenditures. These segments were: country-level technical cooperation; provision of global and regional goods; management and administration; and response to emergency events, such as outbreak and crisis response.

A Working Group on Strategic Budget Space Allocation was established and in its Jan 2015 report (EB136/35) the WG endorsed prevailing methodologies for budget space allocation for Segments 2, 3 & 4 and focused on moving to a more equitable and efficient methodology for Segment 1, country level technical cooperation. The WG identified several options. After further work (EB137/6) the WG recommended a preferred option which was endorsed in May 2015 (EB137(7)) and considered further at WHA69 in May 2016 (in A69/47). In its report to WHA69 the WG provided further detail regarding the preferred methodology for budget space allocation for Segment 1. This methodology was adopted in WHA69(16) and has been applied in A70/7 (see Table 3). There were some grumbles about the impact of

the new formula, in particular in the SEARO region. Bhutan, Nepal and Thailand complained about the allocation to SEARO during the discussion at EB140 (see PSR8).

PHM comment

The absolute inadequacy of WHO's funding

A70/7 envisages an annual budget of around \$2,200 million. This is around 30% of the annual budget of US CDC; 4% of Pfizer's turnover; 3% of Unilever's turnover; 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.

In this commentary PHM does not engage regarding the relative allocations to particular categories and programmes. They are virtually all grossly inadequate. Highlighting the underfunding of TB (\$62m pa) or NCDs (\$24m pa) might be taken to imply that some budget lines are relatively over-funded which is clearly not the case.

Donor control of the WHO budget

In <u>WHA66(8)</u> in May 2013 the Assembly endorsed the principle of approving WHO's entire Programme Budget without regard to revenue sources and then undertaking consultation with donors through the Financing Dialogue (see A66/4 and A66/48).

The myth upon which these arrangements are based is that Member States adopt a budget based on agreed priorities and strategies and then the donors are invited to contribute and thus member state sovereignty is preserved. This myth is repeated in A70/7, para 38:

- 38. The new financing model of the Organization aims to achieve a fully funded programme budget that is realistic and driven by the priorities and expected outputs agreed by Member States. The approval of the programme budget in its entirety by the Health Assembly facilitates the matching of funding, regardless of whether it is from assessed or voluntary contributions.
- 39. The programme budget also serves as the central instrument for a structured and transparent financing dialogue. The financing dialogue, which is held before the start of each biennium, is designed to ensure a match between WHO's results and deliverables as agreed, and the programme budget in its entirety. It aims to achieve full funding of the programme budget.

However, para 33 of the same document gives the lie to this myth:

33. A budget reduction is proposed in the programme areas of noncommunicable diseases, violence and injuries, and food safety. Based on the experience of past bienniums, on average only 60% of the budget for these programme areas in category 2 is funded in each biennium. More than half that funding comes from flexible resources (core voluntary contributions and assessed contributions).

Put simply, most donors insist on tight earmarking and few donors are willing to support action on NCDs, violence, injuries and food safety. The donor chokehold over WHO's budget and priority setting is a major disability.

"Value for money" means cuts in expenditure

WHO is presently facing a shortfall of over \$500m in revenue for PB16-17. While there may be more donor funding forthcoming, the Trump Administration has foreshadowed cuts to US contributions to the UN system. If WHO is not to take a huge debt into the next biennium the expenditure cuts will have to start this year. This is the meaning of the Value for Money paper and the revised draft resolution.

In view of the crisis the need for continuing attention to priority setting and efficiency is inevitable.

However, there are grounds for scepticism regarding the proposal in A70/INF./6) (see 15(g)) that somehow a more strategic use of key performance indicators will help to achieve improved efficiency and effectiveness. In principle it is probably true but the outcome and output indicators in the programme budget are generally lacking in validity and reliability and do not support formative evaluation (the 'learning organisation'). Many of the outcome and output indicators take the form 'number of countries [who have achieved a particular standard]'. The 'deliverables', while not easily measured, make much more sense.

PHM is sceptical also about relying on the recommendations of the Third Stage Evaluation for improving efficiency and effectiveness. Instead of highlighting the inefficiencies and brakes on effectiveness consequent upon the pressure to mobilise funds the evaluators call for increased professionalisation in funds mobilisation. Even while commenting on WHO's fragmentation the evaluators call for outsourcing of 'technical functions'. The recommendation to 'sell the WHO story' is clearly getting in the way of honest reflection, formative evaluation, and creating a learning organisation; the Financial Report in A70/40 is clearly structured around 'selling' the WHO story to the donors in the forthcoming funding dialogue.

There are significant risks associated with continuing stream of reforms directed to adapting to the dysfunctions associated with donor control. These risks arise in the increased use of short term and non-staff contracts, the mandatory mobility policy, and now a new focus on 'efficiency' and cost cutting. The Third Stage Evaluation reports a sharp deterioration in staff perceptions regarding the effectiveness of the Organisation and its impact on health outcomes and national health systems (A70/50 Add.1, p6) in the years since the Second Stage Evaluation.

The emphasis on the role of member states in achieving the outcomes and outputs identified in the PB is welcome (see fig 2 in A70/INF./6). However, the lack of accountability of member states for their contribution to WHO and their implementation of agreed resolutions is one of the major disabilities facing WHO and one which has been largely neglected in the 'reform' programme.

12.1 Health emergencies

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In focus

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

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.

The provisional agenda for WHA70 has structured this item in terms of four sub-items:

- The second report of the Independent Oversight and Advisory Committee for the WHO Health Emergencies Programme (A70/8);
- The Secretariat report on WHO's response in severe, large-scale emergencies during 2016 (A70/9);
- Research and development for potentially epidemic diseases (A70/10); and
- Health workforce coordination in emergencies with health consequences (A70/11).

A70/8 conveys the second report of the Independent Oversight and Advisory Committee commenting on the implementation of the WHE Programme and its performance in current emergencies and outbreaks. The first report of the Committee was submitted to EB140 as EB140/8. The Committee concludes:

48. WHO is making efforts at all levels to transform itself into an operational organization in emergencies. Since the launch of the WHE Programme, progress has been noticed in emergency response at country level, with consistently positive feedback on WHO's expanded role in humanitarian crises. WHO is demonstrating that it can be a reliable and competent partner to governments, organizations in the United Nations system, health cluster partners, implementing nongovernmental organizations and the donor community. However, progress is fragile. WHO's administrative systems and business processes are not effectively supporting its operations, and the WHE Programme is struggling with a funding shortage. Cultural constraints on the emergency response throughout the Organization remain the main challenge for adopting a "no regrets" policy in practice. The Organization must ensure that the WHE Programme can fulfil its potential. Ensuring this success is ultimately a shared responsibility between Member States, WHO's partners and the Secretariat

<u>A70/9</u> provides information on public health emergencies involving WHO during 2016. The number, magnitude and complexity of the various emergencies with which WHO is required to deal is articulated clearly in this report.

A70/10 provides an update on the blueprint for research and development preparedness and rapid research response and the various 'road maps' being developed for particular diseases. The MERS-CoV and Zika road maps appear to be most developed. The document also reports on the call for proposals for production 'platforms' for WHO's priority list of pathogens. It provides a brief overview of several coordination initiatives (including the Blueprint Global Coordination Mechanism (more here); the Coalition for Epidemic Preparedness Innovations (CEPI, more <a href=here); and the Global Research Collaboration for Infectious Disease Preparedness (GloPID-R). The document also reports on progress with respect to the sharing of data and samples and equitable access to products. It also deals with regulatory capacity development in relation to clinical trials.

<u>A70/11</u> describes the work that WHO is undertaking at global, regional and country levels to improve health workforce coordination in responding to emergencies with health consequences. The report notes that:

- WHO needs to raise US\$ 485 million to implement the core activities of the WHE Programme in 2016–2017; a gap of 44% remains;
- appeals linked to specific humanitarian crises have a funding gap of 66% (the total requirement for funding from appeals is US\$ 656 million); and
- the WHO Contingency Fund for Emergencies has raised US\$ 31.5 million of its US\$
 100 million target capitalization.

The need for adequate funding of WHO, generally and the Emergency Program in particular, must be discussed. The WHE website provides a <u>summary of receipts and expenditures</u> through the Contingency Fund for Emergencies. including donor states. Note the removal of "Review of the scope and criteria of the contingency fund for responding to outbreaks and emergencies" (listed as Item 13.2 for WHA70 in <u>EB140/44</u>) from the WHA70 agenda.

PHM's coverage of this item at EB140 is here.

Background

These background notes focus respectively on:

- the prehistory of WHO's Health Emergencies Program,
- 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. (Ms Matsoso is now the Chairperson of the Independent Oversight and Advisory Committee for the WHO Health Emergencies Programme.)

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.

<u>A68/26</u> 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 <u>WHA68(10)</u> 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 <u>EB138/55</u> 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.

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 <u>First</u> report of Adv Grp and <u>Second report</u>).

The establishment of this new committee was welcomed by the Assembly in $\underline{WHA69(9)}$. See discussion at $\underline{A4}$ and $\underline{A5}$.

R&D for potentially epidemic diseases

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 final 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 A69/29 and was noted (A7).

For a close analysis of the implications of the Pandemic Influenza Preparedness Framework (PIP) for benefit sharing in the Emergency Context view TWN Info: "WHO R&D Blueprint: Where's the benefit sharing?"

Health workforce coordination in emergencies with health consequences

'Health workforce coordination' appeared on the agenda of EB140 (informed by EB140/10), 'at the request of a Member State'.

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 A70/9 are dreadful.

The Health Emergencies reform was well conceived and appears to be have been implemented well. However, the IOAC has pointed to key vulnerabilities:

- the abysmal shortfall in funding for all three channels: core, appeals and for the Contingency Fund;
- hundreds of unfilled positions;
- need for greater flexibility and responsiveness in a range of administrative functions.

PHM appreciates the progress with respect to R&D for potentially epidemic diseases. It will be critical to ensure continuing attention to the needs of LMICs especially as regards affordable prices for all health products, benefit sharing and technological development.

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.

12.2 Antimicrobial resistance (and sepsis)

Contents

- Antimicrobial resistance
- Sepsis

Antimicrobial resistance

In focus

This report (A70/12) provides updates on progress made in implementing the global action plan on antimicrobial resistance, adopted by the Health Assembly in resolution WHA68.7 (2015), and in the Political Declaration adopted in UNGA resolution 71/3 during the high-level meeting of the General Assembly on antimicrobial resistance.

The main streams of work reported on are:

- various initiatives undertaken by the Secretariat, in association with FAO and OIE, towards the implementation of the <u>Global Action Plan</u> on AMR;
- the development and implementation of national action plans in accordance with the <u>Global Action Plan</u> on AMR;
- the finalisation of a global development and stewardship framework on antimicrobial medicines and resistance; and
- the establishment of an ad hoc interagency coordination group to provide practical advice on approaches to ensure effective action to address antimicrobial resistance.

An earlier version of this report (<u>EB140/11</u>) was discussed at EB140 in Jan 2017. See <u>PSR4</u> and <u>PSR7</u>.

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 <u>WHA67.25</u>. See <u>PHM comment</u> at the time.

In May 2015, in <u>WHA68.7</u>, the Assembly adopted the <u>Global Action Plan</u> on AMR. See <u>PHM</u> <u>Comment</u> on the draft GAP at WHA68.

In Jan 2016 (EB138) the Board considered a Secretariat report (<u>EB138/24</u>) on options for a high level UNGA meeting. This meeting took place in Sept 2016 and adopted Resolution 71/3 which is reported on in the current document (<u>A70/12</u>).

A70/12 mentions a number of initiatives undertaken by the Secretariat including:

- the <u>manual and tools</u> to support the development of national action plans and new provisions for monitoring progress;
- awareness raising regarding AMR;
- continued development of the Global Antimicrobial Surveillance System including training for national participants in monitoring antibiotic consumption;
- the revision of the Critically Important Antimicrobials list;

- new guidelines on infection prevention and control and on antibiotic use;
- monitoring drug resistance in relation to HIV, TB and malaria; and
- prioritisation of R&D for particular diseases/infections including TB, malaria, gonorrhoea and neonatal sepsis.

Progress with respect to the development of national action plans is reported in <u>A70/12</u>. The report is quite upbeat about progress in this respect.

The report also notes that the ad hoc interagency coordination group has been formed and was due to meet shortly and that an update will be provided to WHA70.

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 slowly.

Despite multiple requests during EB140 for explanations of the delays in progressing the Framework (see PSR4 and PSR7), A70/12 does not explain the delay.

Para 18 of A70/12 indicates that:

The Secretariat will make available a draft road map on how to work towards the finalization of the global development and stewardship framework, including Member States, FAO, OIE and all other relevant stakeholders, on the WHO website, in order to inform the discussion at the Seventieth World Health Assembly.

As of 3 May the draft road map does not appear to have been posted. We note that while the <u>Feb 2016 Consultation</u> on the Framework was sponsored by the Public Health Innovation, IP and Trade department, the <u>presentation on the Framework</u> to the <u>March 2017 meeting</u> of the Expert Committee on Essential Medicines was presented by Dr Beyer of the Essential Medicines department.

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

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 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 <u>A70/12</u> 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 comprehensive 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 accept a proposed item on "Sepsis" on the condition that it be considered conjointly 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."

In A70/13 the Secretariat reports on epidemiology and causation, recent initiatives in the field and provides an overview of WHO's work in relation to sepsis.

The Assembly is invited to adopt the draft resolution included in <u>EB140.R5</u> ('Improving the prevention, diagnosis and management of sepsis').

This item was considered at EB140. See PSR4 and PSR7.

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.

A70/13 refers to a recent Lancet publication on sepsis (Cohen et al, 2016), 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?

PHM is sceptical as to whether this item would have appeared on the agenda of EB140 if the guidelines being discussed to control the workflow of the governing bodies had been applied.

The draft resolution which was presented to the EB140 and now to WHA70 places heavy emphasis on the need for promote 'public awareness' of sepsis. There is no evidence presented in $\frac{A70/13}{1}$ to the effect that a lack of public awareness of sepsis is in some respects a rate limiting step in reducing incidence and improving outcomes.

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 11 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.

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.

12.3 Polio

Contents

- In focus
- Background
- PHM comment

In focus

The papers prepared for this Item respond to the requests of the Secretariat included in EB140(4) (Jan 2017) which in turn refers to WHA68.3 (May 2015)

A70/14 provides an overview of the current status of polio epidemiology and immunisation challenges and strategies. It provides an overview of transition planning and in the Annex provides an update regarding WHO's human resources (over 1000 workers) funded through the Global Polio Eradication Initiative (GPEI), many of whom are contributing to public health work beyond polio eradication.

In the debate at WHA70 there will be close consideration of the challenges and strategies involved in the End Game of the GPEI as surveyed in A70/14. One of the key challenges has been vaccine supply shortages affecting inactivated type 2 vaccine.

<u>A70/14 Add.1 (Polio transition planning)</u> provides a very useful survey of risks, opportunities and mitigation strategies associated with the wind down of the Global Polio Eradication Initiative. In programmatic terms it touches upon risks and opportunities in relation to immunisation, global health security, NTDs and nutritional supplementation, maternal and child health services and health systems. In organisational terms it touches upon risks and mitigation in relation to human resources, revenues and reputation.

The Annex sets out proposed Secretariat actions for the rest of 2017. These include working on a strategic action plan for submission to EB142 in Jan 2018.

Much of the debate at WHA70 will focus on transition planning including the provisions of the proposed strategic action plan.

<u>WHA68.3</u> includes urgings for member states as well as requests to the DG and <u>EB140(4)</u> explicitly encourages member states to ensure its full implementation. This is likely to be a further theme of discussion at WHA70.

Background

While the GPEI is facing significant operational challenges, the global burden of polio is progressively being reduced. It is anticipated/hoped that total eradication will be achieved by the end of 2019. While there will still be a need for significant expenditure to maintain surveillance and control, the voluntary contributions upon which the GPEI depends (entirely) will wind down.

In 2016 WHO expenditure on the GPEI (\$US589) comprised 24% of total WHO expenditure (\$2,470) (A70/40). Of this total expenditure staff costs comprise 17% and 'activity costs'

(which include non-staff personnel) comprise 83%. Many of these workers are contributing to other public health programs as well as polio eradication.

The principal concern driving polio transition planning is WHO's indemnity exposure to contracted personnel in the event of funding drying up faster than attrition or transfer.

However, it becomes very clear from <u>A70/14 Add.1</u> that the risks to public health programs and to health systems of losing the personnel and systems currently funded through the GPEI, would be disastrous. This does not necessarily mean that they should continue to be employed through WHO or continue to be funded through donor funding in the same degree.

Steering a path through the wind down of the GPEI, the indemnity risk to WHO and the health system risk (from lost personnel and dismantled systems) is the job of the various transition plans, in particular the country transition plans, the donor transition plans and the WHO's transition plan.

Further insights into the challenges and achievements of the GPEI can be found in previous reports from 2012 onwards linked from here.

PHM comment

In the short term

Too much has been invested in the GPEI to allow it to fail now. PHM appreciates the strategic and operational challenges facing the GPEI, as outlined in A70/14; commends the technical experts, the managers and the practitioners for their dedication; encourages the governments of the 26 at risk countries; and urges the donors to continue to fund the Initiative up to eradication and beyond.

PHM appreciates the concerns regarding WHO's exposure to indemnity risk in the event that the funding dries up faster than the workforce shrinks.

However, PHM is much apprehensive of the damage to health systems and public health that would occur of the personnel and systems currently deployed through the GPEI were simply discharged and dismantled. PHM urges WHO, the affected countries, and the donors to give the highest priority, in transition planning, to the repurposing of these people and systems as indicated in A70/14 Add.1.

In particular, we urge a focus on merging GPEI staff and systems into general primary health care systems as the platform from which they can continue to support immunisation, epidemiological surveillance, food system interventions and maternal and child health.

This repurposing is likely to involve transferring many to domestic employment and while there may be increasing support from domestic revenues there will still be a need for international assistance.

Longer range issues

There are a number of longer range issues to be noted as insights into global health governance and lessons for global health policy making. These include: the vaccine as a

magic bullet; the opportunity costs of eradication in contrast to control; trophy achievements; and legitimation risk.

In some degree these issues are tied up with the role of the Bill and Melinda Gates Foundation (B&MGF) in funding the GPEI and their relationship with WHO. (See recent commentary on Bill Gates's relationship with WHO in The world's most powerful doctor: Bill Gates). Total funding for the GPEI since 1985 has been \$US14 billion, including \$US2.9 billion from the B&MGF and \$US1.5 billion from Rotary International (GPEI). In 2016 the BMGF contributed 29% of the funding for WHO expenditure on the GPEI. 62% of BMGF contribution to WHO went to polio in that year. (Data from A70/INF./4.)

The vaccine as a magic bullet. Polio is spread through faecal contamination of food. Some of that \$US14 billion could have contributed to more effective sanitation, sewerage and clean water.

However, investing in rural and urban infrastructure is largely a function of more broadly based social and economic development and this depends on how different countries fit into the global economy, on depth and norms of public financing, and on a commitment to equity as well as health. These in turn are determined by neoliberal globalisation; by tax competition and tax avoidance; and by the neoliberal ideology of small government and privatisation.

The opportunity costs of *eradication* in contrast to *control*. The last mile is the most expensive. A less ambitious polio control program could, in theory, have released funds for more efficient applications (measured, for illustration's sake, in terms of DALYs averted per \$ spent).

Historians of public health will compare the policy drivers and technical strategies of polio eradication with those of malaria (a failure) and smallpox (success) and measles (yet to be achieved).

Trophy achievements. Bill Gates's technical orientation, his commitment to polio eradication and his wealth have undoubtedly helped to drive the vaccine focus and the eradication goal. Whether one person's enthusiasm ought to have such an influence on global priority setting is open to debate.

Legitimation. But it is not just one person's enthusiasm; since 1985 the Gates Foundation has contributed only 21% of the total cost of the GPEI. The Initiative has drawn on the concern of millions of good people through the commitment of Rotary International; good people who have also been persuaded by the magic bullet approach and the satisfaction of eradication.

A global regime which allows children to incur preventable disability risks delegitimation. In some degree the \$14b has helped to shore up the perceived legitimacy of an unfair and unsustainable regime.

12.4 Implementation of the International Health Regulations (2005)

Contents

- In focus
- Background
- PHM comment

In focus

<u>A70/15</u> conveys the annual report on the implementation of the IHRs. It reports on the 'public health emergencies of international concern', the work of emergency committees, the Review Committee on the role of the IHRs in the Ebola outbreak and progress in the implementation of the IHRs.

In line with decision <u>WHA69(14)</u> (May 2016), <u>A70/16</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>. The draft Global Implementation Plan comprises six action areas based on the recommendations of the Review Committee. A useful summary of the draft Global Implementation Plan is provided in Annex 1.

One of the recommendations of the Review Committee was for the development of a five-year Global Strategic Plan to Improve Public Health Preparedness and Response. In Annex 2 the guiding principles proposed for the Global Strategic Plan are outlined. Further detail regarding the Global Strategic Plan and its development are provided in para 8 and 9 of A70/16.

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 revised IHRs (adopted in 2005 following the SARS epidemic; see Fidler 2005) 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 WHO 2013 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>). There was also a review committee established on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation which reported in 2014 (<u>A68/22 Add.1</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. The control of 'additional measures' is addressed in Action Area 5 of the draft implementation plan.

The review committee on second extensions (2014) was critical of the exclusive use of self-assessment for reporting progress in implementing core capacities and recommended that the Secretariat "move from exclusive self-evaluation (see Checklist and indicators) to approaches that combine self-evaluation, peer review and voluntary external evaluations involving a combination of domestic and independent experts" (A68/22 Add.1) and in response a new Monitoring and Evaluation Framework was considered and approved by WHA69 in A69/20 Annex. This provides for continued self-reporting plus voluntary joint external evaluations, after-action reviews and simulation exercises. These are included in Action Area 3 of the draft Implementation Plan. See Strategic Partnership Portal for more detail.

WHA69 decided in <u>WHA69(14)</u> to develop the global implementation plan for the recommendations of the 2016 Review Committee report. <u>A70/16</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 <u>A70/16</u> provides a useful summary of the proposed plan.

The draft Global Implementation Plan was discussed at EB140; see PSR3 and PSR4.

Links to previous discussions of IHRs at EB and WHA here.

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 appreciated. However the plan raises some difficult issues.

The opportunity costs of investing in core capacities are very different for poor countries, particularly for those with fragile health systems, compared with rich countries. 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 external evaluations of core capacities raise concerns for 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 is clearly selective.

The proposed initiatives around 'additional health measures' are appreciated, particularly the publication of countries not complying with emergency recommendations.

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 <u>Nagoya Protocol</u> and will need to be developed in accordance with the principles of fair and equitable benefit sharing (more about the Nagoya Protocol <u>here</u>).

The refusal of the big donor states to fully fund WHO's Health Emergencies Program stands in contrast to the pressures being applied to LMICs to develop their core capacities. WHO's capacity is so highly compromised by the ACs freeze and earmarking of insufficient donor funds.

12.5 Review of Pandemic Influenza Preparedness Framework

Contents

- In focus
- Background
- PHM comment

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>A70/17</u> it reports on achievements and effectiveness, and recommends initiatives for advancing the goals of the Framework. The Assembly is invited to note the report.

The report was considered at EB140 informed by $\underline{\mathsf{EB140/16}}$ with a separate report on the Nagoya Protocol ($\underline{\mathsf{EB140/15}}$). See $\underline{\mathsf{PSR10}}$ for report of debate. The EB140 decided, in $\underline{\mathsf{EB140(5)}}$, to:

- continue the current split of partnership contributions (70% preparedness support and 30% response contingency fund) until February 2018;
- request the DG to advise on a new allocation formula for consideration at EB142;
- request the DG to report to WHA70 on the outcome of discussions with the Secretariat of the <u>Convention on Biological Diversity</u> regarding access to pathogens and sharing of benefits and the relationships between Nagoya and the PIP framework.

<u>A70/57</u> 'Collaboration with the Secretariat of the Convention on Biological Diversity and other relevant international organizations' responds to this last request. <u>A70/57</u> reports on consultations with the CBD Secretariat, and with FAO and OIE, and with the Coalition for Epidemic Preparedness.

It is likely that the debate at WHA70 will explore all aspects of the Review Group's report as listed below and next steps regarding the intersections between PIP and Nagoya. .

Background

What is the Pandemic Influenza Preparedness Framework (PIPF)? See description on pp 10-11 of Review Committee report, A70/17.

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, either by inclusion or emulation;
- 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;
- the use of genetic sequence data (GSD) should trigger fair and equitable benefit sharing; the definition of PIP biological material in the PIP Framework should be amended to explicitly include genetic sequence data (GSD);
- there has been some reluctance among manufacturers to sign standard material transfer agreement 2 (SMTA2); Review Group provides some suggestions;
- it is estimated that the cost of the GSIRS now stand at US\$122 million; the partnership contribution should be updated:
- 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);
- the parties to the Nagoya Protocol should consider recognizing PIPF as a 'specialised international instrument' under the Nagoya Protocol (see <u>EB140/15</u>);
- 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.

Some of the highlights of the debate at EB140 (PSR10, from page 13):

- the request for a report on discussions regarding the relationship with the Nagoya Protocol was inserted in the draft decision by Malta speaking on behalf of the EU;
- several MSs argued that the PIP Framework should be recognised as a specialized international access and benefit-sharing instrument under the Nagoya Protocol (New Zealand, Canada, Thailand, Finland, Monaco, Australia and Indonesia; several other MSs emphasised the need to examine this closely; the US and Japan were not enthusiastic about recognition of PIP under the Nagoya Protocol;
- Brazil pointed out that establishing the PIP Framework as a specialized access and benefit sharing instrument of the Nagoya Protocol, must be led by the members of the CBD, referring to a decision taken in December 2016, by Parties to the Nagoya Protocol requesting the CBD Secretariat (that is also secretariat to the Protocol) to "conduct a study into criteria that could be used to identify what constitutes a specialized international access and benefit-sharing instrument, and what could be a possible process for recognizing such an instrument, and to refer the study for further consideration by the Subsidiary Body on Implementation before consideration by the Conference of the Parties serving as the meeting of the Parties at its third meeting" in 2018;
- Canada, Brazil, Australia, Indonesia argued for the inclusion of genetic sequence data within the PIP Framework; the USA opposed including genetic sequence data within PIP;
- Thailand highlighted that vaccines secured under benefit sharing was far below what would be needed in the event of a pandemic;
- Russia, UK, USA, Germany argued for great caution in considering the inclusion of seasonal influenza within the PIP Framework;

 Norway argued against incorporating other pathogens within the scope of the PIP Framework.

The CBD Secretariat is planning

- to share with WHO information from Parties regarding implementation of Article 4(4) of the Nagoya Protocol dealing with health emergencies;
- a study into the criteria for defining a mechanism such as PIP as a specialised instrument under Nagoya;
- undertaking further work on the sharing of genetic sequence data under Nagoya.

PHM comment

Genetic sequence data should be treated in the same way as the viral isolate under the PIP Framework. Access to and use of genetic sequence data should trigger benefit sharing.

Databases that wished to host sequence data should implement a standard user agreement that applied the Framework's benefit-sharing obligations to users accessing sequence data and allowed such users to be tracked.

The Convention on Biological Diversity is the appropriate forum to determine PIP Framework as a specialised instrument. On 16th December 2016, Parties of the CBD/Nagoya Protocol adopted a decision (CBD/NP/MOP/DEC/2/5) requesting the CBD secretariat to "conduct a study into criteria that could be used to identify what constitutes a specialized international access and benefit- sharing instrument, and what could be a possible process for recognizing such an instrument, and to refer the study for further consideration by the Subsidiary Body on Implementation before consideration by the Conference of the Parties serving as the meeting of the Parties at its third meeting" in 2018. (See paragraph 3 of CBD/NP/MOP/DEC/2/5.)

Given this decision it would be appropriate for WHO member states to wait and be guided by the abovementioned CBD study and its consideration by the parties in July 2018.

The partnership contribution paid by manufacturers should be updated, given that the current running costs of the Global Influenza Surveillance and Response System is estimated to be US\$122 million.

Member States should ensure that access to seasonal influenza viruses is balanced by fair and equitable benefit sharing. Preferably this is achieved by creating a new instrument to govern the sharing of seasonal influenza virus, rather than taking action that might undermine the PIP Framework.

PIP principles of virus sharing and benefit sharing should be applied to other pathogens accessed by WHO during times of emergencies but how this might be operationalised requires further study and discussion.

13.1 Human resources for health and implementation of the outcomes of the United Nations' High-Level Commission on Health Employment and Economic Growth

Contents

- In focus
- Background
- PHM comment
- WHA70 debate
- Action arising

In focus

<u>A70/18</u> describes the background to the Commission on Health Employment and Economic Growth and summarises the Commission's recommendations.

In para 10, A70/18 reviews the <u>UNGA Resolution 71/159</u> which welcomes the Commission's report and urges its implementation.

The Annex to A70/18 contains the draft five year action plan which the Secretariat was asked to prepare, in consultation with member states and with the ILO and OECD (EB140(3)). The focus of the draft action plan is on how WHO, ILO and OECD can support member states in "Transformation and scale up of education, skills and decent job creation towards a sustainable health workforce".

It seems that the focus of discussion at WHA70 will be on the draft five year action plan. It is likely that a draft resolution will be considered.

Background

PHM's comment on this item at EB140 provides a brief overview of the Commission's report.

PHM's comment at EB140 also reviews the background to the report and provides an analysis of the recommendations against that analysis. This <u>background and interpretation</u> remains relevant.

In particular, we highlighted the report of the December 2014 Montreux meeting 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.

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 here.)

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.

PHM comment

There is much to appreciate in both the Commission's report and the draft five year action plan. Important positives include:

- the emphasis on the social and economic flow-ons from an expanding (and adequately paid) health workforce;
- the focus on a gender transformative approach (see footnote on page 17 of A70/18);
- the commitment to concerted tripartite collaboration and in particular the production of more and more useful data about workforce and mobility;
- the emphasis on decent work;
- and much else beside.

However, there are some areas of weakness and PHM urges member states to consider strengthening the action plan with further attention to the following issues.

Prevention

There are several references to prevention including gearing the health workforce "towards the social determinants of health, health promotion, disease prevention, ...". However, there is no indication of what this might mean in terms of workforce disposition, roles and relationships.

In particular there is no reference to comprehensive primary health care as a model for health system configuration which deliberately harnesses the expertise and commitment of primary health care practitioners in working with their communities to identify and address both the structural and behavioural determinants of health.

If this action plan initiative is to capture the imagination of finance ministries it needs to demonstrate that the national productivity spin-offs arise from more effective prevention as well as better health care. There is a need for greater recognition of the reforms which will be needed to properly address the social determinants of population health (housing, urban infrastructure, support for small farmers, education, gender equity, etc) and the contribution that comprehensive primary health care can make to driving these objectives.

It would also be important to show how this workforce strategy can contribute to wider understanding of 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.

Role of private sector in health financing and health care delivery

The repeated references to 'universal health coverage' in the draft action plan are not matched by any guidance regarding the principles of health care financing which need to be observed in ensuring financial protection and access to efficient, high quality health care.

One of the clear conclusions of the 2014 Montreux meeting, referred to above, was 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').

We appreciate the recognition of the need to regulate the private sector (see Fig 2 on page 15 of A70/18) but the action plan needs to be clear eyed about the policy challenges involved in regulating private sector health insurance and private health care delivery for quality, equity and efficiency. Since the rich countries have not solved these challenges it would be particularly irresponsible to offer private sector investment as a strategy for equitable, efficient, effective health care delivery.

If health ministries are to persuade finance ministries of the need for single payer financing and for constraining the role of private providers they will need clearer analyses of the dividends in terms of quality and efficiency that will be achieved through single payer financing and predominant public sector service delivery.

Public finance reforms

There is nothing in the action plan which recognises the ways in which the norms and traditions of public finance can constitute barriers to innovative and efficient health care financing. This was a major conclusion of the <u>Montreux meeting</u> referred to above. The action plan should be amended to address this.

The action plan reproduces the mantra of 'domestic and international financing' repeatedly. However, it would be useful to acknowledge the global macroeconomic barriers to economic development (eg, unfair trade agreements, neoliberal policies imposed through the WB and the IMF, corporate extortion) and the constraints on public revenue generation facing many L&MICs including tax competition, global protection of tax havens, and the impact of global 'market disciplines'. There is nothing in the action plan to assist countries to address these challenges.

Development assistance for workforce development

In terms of international assistance for workforce development we note Deliverable 1.5 (page 17) which is "Alignment of domestic resources and official development assistance with national health workforce strategies and investments facilitated" with WHO the lead agent.

This is not a small deliverable and not one where WHO has had huge success in the past. The fragmentation and rigidities associated with vertical, disease-focused foreign aid are widely recognised and appear to persist despite the recurring statements and declarations of intent.

PHM urges member states to assign priority to further analysis of exactly how WHO is going to approach this deliverable.

Workforce mobility / brain drain

PHM appreciates Recommendation 9 - "Advance international recognition of health workers' qualifications to optimize skills use, increase the benefits from and reduce the negative effects of health worker migration, and safeguard migrants' rights" although the proposed deliverables (page 20) are not very clear.

PHM urges that external revenue raising for workforce development, from destination member states, should be constructed in some degree as compensation for expropriation rather than as charitable assistance.

PHM urges that the data collection referred to in the action plan should document the systematic underproduction of health care workers in the health worker migration destination countries.

13.2 Principles on the donation and management of blood, blood components and other medical products of human origin

Contents

- In focus
- Background
- PHM comment

In focus

The document before the Assembly (A70/19) sets forth ten ethical principles which should guide the collection, processing and medical use of human derived products. There will be some debate about the values expressed in the principles but the bigger challenge concerns the operationalisation of these principles in terms of institutions, capacity building and regulatory arrangements.

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.

Pursuant to this request the Secretariat assembled a set of principles and governance models regarding the use of medical products of human origin and undertook an extensive consultation around those principles and models.

The document now before the Assembly (A70/19) presents ten principles and some observations about implementation.

An earlier draft (<u>EB140/18</u>) was considered by EB140 (<u>PSR9</u>). There was general support for the principles as principles although some concern was expressed regarding paid versus voluntarily donated blood / tissues (Principle 5) and over the balance between transparency and confidentiality (Principle 10).

Several MSs commented on the work remaining to be done in terms of operationalising these principles in terms of institutions, standards, regulation, accountability, etc.

Several delegates from smaller and low and middle income countries emphasised the absolute shortage of medical products of human origin and the need for technology transfer to build capacity as well as the challenge of putting in place appropriate regulatory arrangements.

PHM comment

The report before the WHA70 (A70/19) is largely focused on ethical principles governing the donation and management of medical products of human origin. These principles are sensible.

However, the report deals with the institutional, technological and regulatory issues at a very general level and stops short of articulating design principles which might guide the establishment of the necessary structures and capabilities.

The report appears to assume that regulatory arrangements will be largely implemented at the national level. However, in view of the globalisation of supply chains, including the illegal trade in organs, a case can be made for enshrining the required design principles in an authoritative international instrument such as a code or a set of regulations.

Beyond the ethical principles which should be expressed in the medical use of products of human origin there is clearly a major capacity building challenge in many low and middle income countries. PHM urges WHO to set targets and appropriate the resources needed to guide and support for such capacity building.

PHM urges the Board to request the Secretariat to further develop this report including attention to design principles to guide implementation including identifying those principles which should be authorised at the global as well as the national level.

13.3 Addressing the global shortage of, and access to, medicines and vaccines

Contents

- In focus
- Background
- PHM comment

In focus

Two separate issues are canvassed in the Secretariat report prepared for this item (A70/20); dealing respectively with Access to medicines and Shortages and stockouts.

Access to medicines and vaccines

The inclusion of *Access to medicines* (and the revised item name) arose from discussions at EB140 over the report of the <u>UN SG's High Level Panel on Access to Medicines</u> (HLP A2M). Initially the officers of the Board had recommended not to schedule this item for discussion (see p9 of <u>EB140/1 (annotated)</u>) but during consideration of the agenda (<u>PSR1</u>) it was agreed to discuss it under Item 8.5 ('Follow up of CEWG'). Listing the HLP Report for the WHA70 agenda was discussed in the 18th session (<u>PSR18</u>) and it was agreed to add 'Access to medicines' to the foreshadowed item on 'Shortages of medicines and vaccines'.

The discussion of access to medicines in A70/20:

- reviews a number of previous resolutions on various aspects of medicines policy;
- describes WHO's involvement in the HLP process and the parallels between the HLP's recommendations and those of previous WHO inquiries; and
- reviews a wide range of workstreams currently under way within the Secretariat.

During the debate at EB140 (PSR11) a range of opinions were expressed. The US, Switzerland and Japan criticised the HLP's report; Thailand, Brazil, Iran, South Africa and Venezuela argued there was much of value in it and MSs should pick up the recommendations which were acceptable and develop a five year action plan to implement them. India argued that "the Executive Board should recommend that the Seventieth World Health Assembly convene an open-ended meeting of Member States to discuss the High-Level Panel's recommendations and other relevant recommendations emanating from the Consultative Expert Working Group".

Shortages and stockouts

The second issue to be addressed under this item arises from the request in OP3(1) of resolution <u>WHA69.25</u> (2016) for the Secretariat to develop a set of definitions regarding shortages and stockouts. The Secretariat hosted an informal consultation in October 2016 (report <u>here</u>) in association with a quarterly meeting of the Inter-Agency Supply Chain Group. The report now under consideration (<u>A70/20</u>) sets out proposed technical definitions for medicines and vaccines shortages and stockouts. An earlier version of this (part of the) report was discussed at EB140 (<u>PSR9</u>).

Background

Access to medicines (and the role of intellectual property protection)

The pre-history of WHO's consideration of access to medicines and the role of IP is summarised here. See also GHW3 (D4) on the pharmaceutical industry (2011).

The issues have moved through a number of different forums over the last several decades:

- UNGA 1974 and the New International Economic Order (see <u>Drahos, 2002</u>);
- International Anticounterfeiting Coalition, formed in 1979 (by TNCs led by Pfizer), seeks to shift discussion of IP regulation from WIPO to trade negotiations;
- WTO 1994 and the TRIPS agreement;
- WHA resolutions <u>WHA49.14</u> in 1996 and <u>WHA52.19</u> in 1999 regarding TRIPS and medicines;
- 1997-2001 the Treatment Action Campaign in South Africa (and beyond);
- WTO 2001 and the Doha Statement on Public Health
- WHO (<u>WHA56.27</u>) and the Commission into Intellectual Property Rights, Innovation and Public Health, appointed 2004 reported in 2006; (more here)
- the IGWG, EWG and CEWG reports (more <u>here</u>);
- the UNDP sponsored Global Commission on HIV and the Law (2010-2012);
- the Secretary General's High Level Panel on Access to Medicines (2015-16); and
- the Human Rights Council Resolution on Access to Medicines (A/HRC/32/L.23/Rev.1), 30 June 2016.

The report of the SG <u>HLP on Access to Medicines</u> provides a broad sweep of recommendations (see Executive Summary):

- TRIPS flexibilities and TRIPS-plus provisions;
- publicly funded research;
- new incentives for research:
- stronger accountability of governments;
- a stronger role for the UN SG and UNGA;
- greater disclosure and transparency by corporations;
- complete transparency regarding clinical trials;
- publicly accessible databases regarding patents and related data regarding medicines and vaccines.

Global shortage of medicines and vaccines

This item commenced life with a report (EB138/41) 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 A66.7 from May 2013).

At the Board meeting, a draft resolution (from China, Italy, Pakistan and Thailand) was tabled (11.11 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".

<u>A70/20</u> sets out proposed technical definitions for medicines and vaccines shortages and stockouts. An earlier version of this (part of the) report was discussed at EB140 (<u>PSR9</u>). For more detail see the report of the informal consultation in October 2016 (report <u>here</u>) organised in association with a quarterly meeting of the <u>Inter-Agency Supply Chain Group</u>.

PHM comment

Access to medicines

The current monopoly-driven R&D system fails to prioritise public health needs and contributes to the current imbalance in R&D priorities which leaves many people without treatment.

Several years of discussions at the WHO on Innovation, IP and Public Health have not resolved the current innovation and access crisis. We see an opposite trend with continued pressure to extend and enforce monopoly protection in trade negotiations. Increasingly compromised access to medicines due to high prices no longer affects only developing countries, but increasingly patients in high income countries too.

The public sector across many countries already invests huge sums in pharmaceutical R&D. Yet without sufficient public health safeguards, the outcomes of such R&D are often largely garnered by the private sector.

Member States have sufficient resources and capacity to implement novel R&D incentives and regulations. For example, granting end prizes to innovators (instead of patent monopolies) would enable generic production of medicines from the moment of discovery, and would therefore de-link the price of medicines from the cost of R&D.

WHO member states have put enormous efforts into the follow up of the recommendations of the CEWG (see Item 13.5 on this agenda) including the global observatory, the

demonstration projects, the expert committee, the scientific working group and planning for the 'voluntary pooled fund to support research and development'.

However, the 85% funding gap in relation to the 'voluntary pooled fund' does not bode well.

The <u>UN High Level Panel on Access to Medicines</u> arises from the increasing engagement of other UN agencies in this issue (in particular the UNDP and the Human Rights Council) and argues for a much stronger role for the UN Secretary General and the UN General Assembly.

The report of the HLP is an excellent opportunity for the WHO to reinvigorate and renew its work in this area but also to engage more intensively other UN agencies. We urge the WHO and Member States to endorse the HLP Report and work for implementation of its recommendations.

Shortages and stockouts

OP3(2) of A69.25 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 underline this commitment and to seek assurances that such the progress report scheduled for WHA71 will take the wide angle view of cause including price, 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.

A narrow approach to the problem of shortages would mitigate against a full analysis of how all of these different factors interact (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).

<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 <u>A70/20</u> reports that "strategic efforts will be continued to develop a notification system for medicines and vaccines at risk of shortage".

13.4 Evaluation and review of the global strategy and plan of action on public health, innovation and intellectual property

Contents

- In focus
- Background
- PHM comment

In focus

The Assembly will consider A70/21 which conveys the executive summary of the comprehensive evaluation of the GSPOA. The full report is here.

Background

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

Current movements

The Executive Board in Jan 2017:

 reviewed the findings and recommendations of the comprehensive evaluation of the GSPOA;

- noted the Secretariat's proposals for the membership of the Expert Panel for the Overall Program Review and the proposed method of work of the Program Review Panel (including timelines); and
- in <u>EB140(8)</u> approved the proposed terms of reference for the overall programme review and requested the Secretariat to estimate the funding requirements and possible sources of funds for implementation of the Program Review Panel recommendations.

See record of debate at EB140 in PSR11, PSR12 & PSR17. (Highlights include the intervention by India, to the effect that the terms of reference for the Review should include operationalising the recommendations of the High Level Panel on Access to Medicines (not adopted); and by Brazil which was very critical of the capacity, conduct and report of the Evaluation. New Zealand doubted the need to continue the GSPOA which elicited a sharp ripost from South Africa.)

For WHA70 this agenda item is solely about the findings and recommendations of the Evaluation (see executive summary in Annex 1 of A70/21; the full report is here).

The Program Review is not on the agenda of WHA70; it is scheduled to return to the Assembly in May 2018 with the recommendations of the Expert Review Panel and the Secretariat's financing estimates.

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) and 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 <u>A61/9</u>. 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 <u>WHA61.21</u>: 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 <u>WHA62.16</u>); see <u>integrated version of finally agreed</u> 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 Assembly (in A70/21 Annex 1), provides a brief introduction to each of these elements.

PHM comment

PHM regards the GSPoA as critical in ensuring innovation and access to treatments.

The report of the Evaluation does not bring provide novel or useful insights, but instead reiterates issues that have been reaffirmed several times in the past.

A major finding of the evaluation report is the widespread lack of awareness of the GSPOA, due to relatively weak promotion of the GSPOA by the Secretariat.

This is a reflection of WHO's funding crisis and the highly inflexible funding associated with tightly earmarked voluntary contributions. A breakdown of WHO expenditure on the implementation of the GSPOA is not publicly available on the Programme Budget Web
Portal. However, for 'Access to medicines, etc' generally (Programme 4.3) the very limited budget allocation (for 2016-17) country office work (\$US39m for the biennium) has been grossly under-funded; only 45% of a very small budget leaving \$8.5m per year to fund policy support and capacity building in the production and use of medicines and regulatory strengthening as well as implementation of the GSPOA. The budget for regional office work, \$27m for the biennium, is only 66% subscribed. Clearly the big donors have not been willing to properly fund the implementation of the GSPOA (nor work on the use of medicines and regulatory strengthening). This is recognised, albeit indirectly in the Evaluation report recommendation that 'Member States, through the overall programme review, to further review resources expended and financing available for the implementation of GSPOA in order to identify best practices and constraints'. However, WHO's financial crisis does not appear as a barrier to implementation on the evaluator's 'theory of change'.

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 <a href="https://www.wha.edu.org/wha.edu.or

The Evaluation does not clearly identify as an issue, the undue pressure put by some powerful countries and pharmaceutical companies on developing countries, in order to prevent them from making full use of the TRIPs flexibilities.

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

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

Contents

- In focus
- Background
- PHM comment

In focus

The Secretariat report (A70/22), prepared in response to requests made by the Health Assembly in resolution WHA69.23 (2016), proposes:

- terms of reference and a costed workplan of the Global Observatory on Health Research and Development (Annex 1 in A70/22); and
- goals and an operational plan for a voluntary pooled fund to support research and development (Annex 2 in A70/22; see also TDR report).

Responding to further requests in A69.23, A70/22 also

- reports on the approval by EB140 of the terms of reference for the Expert Committee on Health Research and Development (as set out in <u>EB140/22</u>);
- provides an update on the development of the <u>Global Observatory on Health</u> <u>Research and Development;</u>
- reviews the six demonstration projects and their funding status (in paras 10-11);
- sketches out the roles and inter-relationships of the Global Observatory, the Expert Committee and the Scientific Working Group (in paras 12-15);
- reviews the funding so far secured for the demonstration projects and the global observatory (facing a \$US71m 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.

Clause 2(12) of A69.23 also proposes that the DG requests WHA70 to 'consider convening another open-ended meeting of Member States in order to assess progress and continue discussions on the remaining issues in relation to monitoring, coordination and financing for health research and development, taking into account relevant analyses and reports'. Clearly the Secretary General's High Level Panel on Access to Medicines is a relevant analysis and report. This may be why the request in OP2(12) of A69.23 is not mentioned in A70/22. However, it may be raised in debate.

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.

An earlier version of A70/22 was discussed at EB140 (<u>EB140/21</u>) along with <u>EB140/22</u> which proposed terms of reference for the expert committee on health research and development.

In the debate at EB140 (<u>PSR11</u>) several countries regretted the funding shortfall. Both India and Brazil urged reconsideration of a binding research and development instrument.

(The proposal for a binding R&D treaty was examined by the Commission on IPRs, Innovation and Public Health in 2006 (from page 103); encouraged by the GSPOA under Element 2 (page 15); and endorsed by the CEWG. Amid fierce controversy in 2012-13 (see IP chronology) the matter was resolved - for the time being - through resolution WHA66.22 and decision WHA66(12) which do not commit to a binding instrument).

PHM comment

The proposals advanced in A70/22 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 16-19 of A70/22):

- a funding gap of \$2-3m per year for the global observatory (Annex 1);
- a minimum of \$100m is required for the voluntary pooled fund (Annex 2).

The 85% funding gap to support this work is a signal that a voluntary pooled fund is inadequate.

Resolution <u>WHA69.23</u> requested the DG to promote policy coherence. The CEWG Principles, and the notion that R&D should be needs-driven and grounded in de-linkage, should therefore be treated as a normative foundation for health R&D initiatives. These principles should be included in all WHO R&D initiatives (including AMR Stewardship framework). WHO, in its mandate to protect public health, should advocate their inclusion in initiatives outside the WHO too: especially AMR initiatives which may receive public funding.

Para 19 of A70/22 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.

Resolution 69.23 proposes an Open Ended Meeting in 2017. We urge the WHA70 to convene this meeting, to continue unfinished discussions on the CEWG follow-up, including negotiating an R&D Agreement. The scope and discussion that is needed today to address needs-driven innovation and access to medicines is different to what it was 15 years ago. These issues affect all countries, not only developing countries. They will not be solved by increasing investment into some projects. New R&D incentives and regulations are needed, delinking the price of medicines from the cost of R&D, to meet those needs that the current patent-driven system has not met.

The UNHLP report brings expertise and recommendations that can strengthen and renovate the work of the WHO in this area.

13.6 Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products

Contents

- In focus
- Background
- PHM comment

In focus

The Assembly will consider A70/23 which:

- reports on the fifth meeting of the Member State Mechanism;
- sets out a draft decision which would establish 'substandard and falsified medical products' as the standard descriptor, replacing substandard/spurious/falselylabelled/falsified/counterfeit medical products (in accordance with Appendix 3);
- includes a guidance document for member states on developing a national plan for preventing, detecting and responding to actions, activities and behaviours that result in substandard and falsified medical products (in <u>Appendix 1</u>);
- includes report on authentication technologies (in Appendix 2) of A70/23.

The working group on definitions identified three possible circumstances which may bring medical products to the attention of regulatory agencies: substandard, unauthorised and falsified (see Figure on p34). The new term refers explicitly to substandard and falsified products but does not explicitly refer to unauthorised medical products. This is because in some countries and regions the marketing or distribution of medical products without registration/license is permitted. In such circumstances unauthorised is not a breach. In those jurisdictions where medical products are required to be registered or licensed, unauthorised marketing or distribution would constitute a breach.

It appears that the work reported in Appendices 1 and 2 is largely concluded but the 5th report refers to a number of activities where work is still underway.

According to A/MSM/5/4, circulated for the 5th meeting of the MSM, the review of the MSM was scheduled to be undertaken after the 5th meeting in Nov 2016 and to be reported to WHA70. There is no reference to the report of the review in the list of documents circulated for WHA70 nor in A70/23.

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 substandard and falsified 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 substandard and falsified medicines. The continuing use of the term counterfeit conflates the public health problem of substandard and falsified medicines with the civil wrong of breaches of intellectual property rights (IPRs), including patent rights as well as trademark rights, and thus links substandard and falsified 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 a draft resolution supporting WHO's participation 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 <u>EB124/14</u> (corrected in EB124/14 Corr.1). Long debate (<u>M9</u>).

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</u>, <u>A8</u>, <u>A9</u>, <u>A9(ii)</u>, <u>A11</u>, <u>A12</u>. Working Group of SSFFCMPs established by WHA63(10)

Final report of WG in <u>WHA65/23</u> considered by WHA65 (2012). Long debate <u>B4(255)</u>, <u>B5(261)</u>. MSM established by <u>WHA65.19</u>.

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 <u>A68/33</u>, 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.

EB140 (Jan 2017) considers report of 5th meeting plus appendices and advises the Assembly to adopt the new terminology.

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.

These new definitions put an end to the mistaken endeavour of conflating quality of medicines with alleged IP violations. This conflation has been systematically used to promote IP enforcement standards instead of pursuing a public health strategy to address the issue of medicines with compromised quality. We urge that, as per the new decision, WHO stops using the term counterfeit to refer to medicines of compromised quality and communicate the new definitions to other international organisations such as INTERPOL, WCO, UNODC etc. to stop conflating IP related issues with quality of medicines.

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 WHA70 to support the newly proposed terminology: substandard and falsified medicines, as outlined in <u>Appendix 3</u> and set out in the draft decision presented in <u>A70/23</u> (page 1).

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>A70/23</u>.

13.7 Promoting the health of refugees and migrants

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In focus

Secretariat report A70/24 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 presents a draft framework of priorities and guiding principles to promote the health of migrants and refugees (in the Annex to A70/24) as requested in EB140(9).

The main focus of attention in the WHA70 debate will be the proposed framework presented in the Annex to A70/24 and the proposed situation analysis and global action plan requested in EB140(9).

WHO also appears to have committed to leading a discussion on the Grand Bargain commitments with its Member States (page 15 of <u>Grand Bargain</u>).

Background

It appears that this round of discussion of the problems of migration has been initiated in response to the 'New York Declaration for Refugees and Migrants' (<u>UNGA A/RES/71/1</u>) (October 2016); see particularly Annex 2 to the Declaration which commits to developing a global compact for safe, orderly and regular migration). Annex 1 to the NY Declaration sets out a comprehensive refugee response framework.

The NY Declaration was followed up by the Modalities resolution (<u>A/RES/71/280</u>) on 6 April 2017 which outlines the key elements and timelines of the process of developing the Global Compact. These modalities include a series of consultations

- (a) At the United Nations Office at Geneva:
 - (i) Human rights of all migrants, social inclusion, cohesion and all forms of discrimination, including racism, xenophobia and intolerance (April/May 2017);
 - (ii) Irregular migration and regular pathways, including decent work, labour mobility, recognition of skills and qualifications and other relevant measures (October 2017);
 - (iii) International cooperation and governance of migration in all its dimensions, including at borders, on transit, entry, return, readmission, integration and reintegration (June 2017);
- (b) At United Nations Headquarters in New York:
 - (i) Contributions of migrants and diasporas to all dimensions of sustainable development, including remittances and portability of earned benefits (July 2017);

- (ii) Addressing drivers of migration, including adverse effects of climate change, natural disasters and human-made crises, through protection and assistance, sustainable development, poverty eradication, conflict prevention and resolution (May 2017);
- (c) At the United Nations Office at Vienna: smuggling of migrants, trafficking in persons and contemporary forms of slavery, including appropriate identification, protection and assistance to migrants and trafficking victims (September 2017);

Para 24 of A70/24 expresses disappointment that a special session on health had not been scheduled but commits to participating actively in all of the above.

The purpose of the draft framework presented in the Annex to A70/24 is described as:

- (a) to inform discussions around the development of the global compact for safe, orderly and regular migration to ensure that the health aspects are adequately addressed:
- (b) to serve as a foundation for the development of a draft global plan of action on the health of refugees and migrants, to be submitted to WHA72 in 2019;
- (c) to provide a resource for consideration by Member States in addressing the health needs of refugees and migrants, in alignment with the Sustainable Development Goals as appropriate to each country's context and priorities.

Para 36 of A70/24 refers to the framework in the Annex as the 'final draft framework'. However, EB140(9) includes a request to the DG "to conduct a situation analysis by identifying and collecting experiences and lessons learned on the health of refugees and migrants in each region, in order to provide inputs for the development of the framework of priorities and guiding principles to promote the health of refugees and migrants, and to report thereon to the Seventy-first World Health Assembly" which suggests that the draft framework will not be finalised at WHA70.

Para 25 of A70/24 describes the development of the <u>Grand Bargain</u> (May 2016) regarding humanitarian assistance; reports that WHO continues to participate actively in its work; and comments that the commitments in the Grand Bargain are relevant, although not exclusively, to the problems of migration. The commitments in the <u>Grand Bargain</u> include:

- 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 25 of A70/24 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.

Further materials are linked from PHM's <u>comment on Item 14.7</u> (Promoting the health of migrants) at WHA69 in May 2016.

PHM comment

The principles and commitments set out in the Grand Bargain, NY Declaration, and the Annex to A70/24 are admirable although the hypocrisy of governments which endorse statements about human rights even while most grievously breaching the rights of asylum seekers justifies some scepticism about their good faith.

The initiatives proposed in the Grand Bargain 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 principles and priorities set out in the NY Declaration and the draft framework are all admirable and will help to strengthen the pressures on governments to promote protect and respect the rights of asylum seekers, refugees and migrants.

However, there are only weak references in the papers before the Assembly 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. These references are all quite general and are not matched by any proposed actions.

PHM calls for honesty and plain speaking about root causes: the drivers of economic migration; the drivers of refuge seeking; 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 Allied 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, 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 disillusion with respect to the promises of democracy. 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.

14.1 Global vaccine action plan

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In focus

The Assembly will consider (in <u>A70/25</u>) the Executive Summary of the Midterm GVAP (2010–2020) review by 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 global vaccine action plan.

The Midterm GVAP Review was considered by EB140 (<u>EB140/25</u>) and a draft resolution sponsored by Australia, Brazil and Colombia (<u>EB140/CONF./2</u>) was tabled. However, there were amendments proposed and the Board agreed to "postpone the adoption of the draft resolution to allow for further consultations among Member States during the intersessional period before the Seventieth World Health Assembly in order to reach consensus".

It is not clear from the debate (<u>EB140 PSR12</u>) what the issues in contention were. Presumably a compromise resolution will be tabled for consideration by the Assembly.

Background

The Global Vaccine Action Plan (GVAP) was adopted by the WHA in <u>WHA65.17</u> in May 2012.

<u>WHA65.17</u> requested annual update reports. In <u>A66/19</u> the Secretariat proposed a draft framework for monitoring, evaluation and accountability for GVAP which was endorsed by the Assembly (in May 2013). PHM comment at the time is <u>here</u>.

The first update report on the implementation of GVAP was considered by the Assembly in May 2014 in A67/12. The debate is at A3 and A4. The SAGE report (A67/12) 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 use the framework for monitoring, evaluation and accountability which had been adopted in WHA66.

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

In May 2015 (prior to WHA68) PHM posted a detailed commentary <u>detailed commentary</u> on the 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 <u>A69/34</u> which included a report on GVAP generally and specifically on the implementation of <u>WHA68.6</u> which was noted by the Assembly (see debate at <u>B7</u>). PHM posted a detailed commentary (<u>here</u>) broadly appreciating the SAGE report.

The SAGE's <u>Midterm GVAP Review</u> was finalised in late 2016 and considered at the EB140 in Jan 2017. Highlights of the debate at EB140 (PSR12) included:

- Gambia, on behalf of the African region highlighted the current shortage of some vaccines and urged Member States to consider the recommendations of the <u>UN HLP</u> on Access to Medicines (see <u>Item 13.3</u> on this agenda);
- Many delegates expressed concern about the slow progress towards achieving the goals of GVAP;
- Turkey referred to 'anti-vaccine groups' (see our comment below about the failure of the SAGE to address the community confidence goals of GVAP);
- Thailand highlighted the unaffordable cost of vaccines and called for 'innovative mechanisms' to support timely access to affordable vaccines;
- Algeria also highlighted availability and cost of vaccines;
- Colombia "called for the development of information systems to enable accurate vaccine price comparisons and mechanisms to ensure supply":
- Cuba advised that 8 out of 11 vaccines used in its national immunization schedule were produced nationally and a pneumococcal vaccine was under development;
- MSF expressed concern that WHO had recently closed its Middle-Income Countries Task Force, particularly as those countries still faced severe challenges in accessing new and more expensive vaccines; MSF argued that a group, led by WHO, should be reconvened, focusing on pooled procurement, price transparency and competition in order to increase affordability; Pneumococcal conjugate candidate vaccines from developing country manufacturers should be prioritized by the Secretariat for technical and regulatory support, and resources from the GAVI Alliance should be forthcoming to bring such vaccines to market; governments should make use of the WHO Vaccine Product, Price and Procurement database, which had helped to improve transparency on vaccine prices.

PHM comment

The positive features of the Midterm Review 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 key 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*'; the SAGE report makes no reference to these 'defined criteria' nor to the priorities for strengthening NITAGs;
- there is nothing on monitoring community confidence (explicitly included in <u>A66/19</u>) or to 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 post-marketing surveillance in many countries (<u>Tafuri et al 2015</u>); rigorous post-marketing surveillance is a precondition for community confidence);
- there is 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); see also the MSF contribution to debate at EB140, noted above;
- 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).

The SAGE report is very critical of the slow improvement in immunisation performance and many member states speaking at EB140 were likewise critical. However, immunisation performance is dependent on whole of health system performance. In fact immunisation coverage is a valid and reliable indicator of health system capacity generally. The paradox is that attempts to boost immunisation coverage through vertical stand alone programs risk weakening health systems and the implementation of comprehensive primary health care and thus constitute a limit on immunisation performance. WHO and member states need to continue to focus attention on health system strengthening.

PHM urges MSs to give close attention to the challenges of technology transfer with respect to manufacturing capacity as recommended by Thailand during the EB140 debate and illustrated by Cuba's strength in domestic manufacturing.

PHM notes the number of MSs highlighting vaccine prices as a barrier to full coverage. In this context we highlight the call from Gambia, on behalf of the Afro Region, to address the recommendations of the <u>UN HLP on Access to Medicines</u> and the need for new ways of funding vaccine development and production.

PHM emphasises that the decision to introduce new vaccines must be based on country specific epidemiology, health system capability, and financing. For this reason the capacity of NITAGs to undertake these analyses is of critical importance to the implementation of GVAP. For a more detailed commentary on the introduction of new vaccines see PHM commentary from WHA68 in 2015.

In many countries there is a contradiction between the 'elimination' targets for both rubella and congenital rubella syndrome. Rubella is a mild infection that practically 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 who missed out in infancy 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.

14.2 Global vector control response

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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>A70/26</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. Engage and mobilize communities.
- 3. Enhance vector surveillance and monitoring and evaluation of interventions:
- 4. Scale up and integrate tools and approaches; and

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.

The Executive Board discussed this issue in Jan 2017 (EB140) and requested the Secretariat to prepare a draft resolution for consideration by the Seventieth World Health Assembly. This text has not yet been published.

Background

The full revised draft GVC Response is here.

Highlights from the debate at EB140 (EB140 PSR12) include:

- Most speakers supported the draft response and supported the need for a resolution at WHA70;
- Netherlands, however, argued that the draft response was too ambitious and WHO should focus on treatments and vaccines instead of infrastructure and capacity building; there was no support for the Netherlands position from other speakers;
- Thailand supported the draft response but emphasised the importance of tackling climate change;

- Several speakers emphasised the human resource and institutional capacity building which is needed (Jamaica, Philippines, Thailand, US);
- Jamaica emphasised the need to invest in adapting broad principles to specific country circumstances;
- France and Mexico mentioned the importance of community engagement and community ownership;
- Panama highlighted the prevailing inequities in the distribution of the burden of vector-borne diseases.

Other resources include:

- 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 vector control for human African trypanosomiasis;
- conclusions and recommendations of the WHO Vector Control Advisory Group
 (VCAG) meeting on 14–15 March 2016 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 products</u>.

PHM comment

This is a very constructive initiative. In particular, PHM appreciates the emphasis on infrastructure development (drainage, water supply, housing) which has the capacity to reduce the habitats of the vectors of a range of diseases, in comparison with the more disease specific control mechanisms. PHM also appreciates the emphasis on human resource and institutional capacity building to support local adaptation and implementation of the broad strokes of the Draft Response.

There are a few issues where PHM urges closer attention or stronger emphasis.

Primary health care provides a framework for strengthening community engagement and community ownership

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. PHM regrets that there is no reference to comprehensive primary health care in the Draft Response.

Climate change and the importance of locking in the commitments in the Paris Agreement

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, Central and South America and small islands) are key resources to be drawn on in building national capacity for vector control in a changing environment.

PHM urges MSs to highlight the importance of ratifying and implementing the <u>Paris</u> Agreement.

Infrastructure needs of informal urban settlements reflect the inequities in power and wealth which are driven by the prevailing regime of neoliberal globalisation

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 (which impacts on public expenditure), the continued support for tax avoidance, and the protections afforded to corruption by the international financial system.

Agriculture, irrigation and dams; the need to strengthen the regulation of transnational corporations to ensure that impacts are assessed and action can be taken

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.

It is also important to acknowledge the role of transnational corporations in driving such 'developments' and the need to strengthen the regulation of TNCs (as is under consideration in the <u>open-ended intergovernmental working group</u> on transnational corporations and other business enterprises with respect to human rights);

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.

15.1 Preparation for the third High-level Meeting of the General Assembly on the Prevention and Control of Noncommunicable Diseases, to be held in 2018

Contents

- In focus
- Background
- PHM comment

In focus

The Secretariat report A70/27 starts with an update on the global disease burden attributable to NCDs; regrets the lack of implementation by member states of previous commitments regarding NCDs (para 6 of A70/27); and lists some of the ways the Secretariat is trying to assist member states to overcome the obstacles to implementation. The draft resolution (EB140.R7) urges member states to 'continue to implement' the various resolutions.

In <u>A70/27</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) to update 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 <u>Annex 1</u> of A70/27); and
- (ii) development of a draft approach (see <u>Annex 2</u> of A70/27) 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 A70/27) for the Global Coordination Mechanism (of which more below).

A70/27 also notes work which is underway on: the mid term evaluation of progress under the global action plan for the prevention and control of noncommunicable diseases 2013–2020 (WHA66.10) and a preliminary evaluation of the Global Coordination Mechanism (A68/11)

Finally, <u>A70/27</u> reports on (i) preparation of a report to the UNGA on progress made on the commitments coming out of high level meetings of the General Assembly in 2011 and 2014, by way of preparing for a third high level meeting in 2018 (report foreshadowed in <u>A69/10</u>); and (ii) preparation for a WHO Global Conference on NCDs in Uruguay in Oct 2017.

The Assembly is invited to adopt the draft resolution in <u>EB140(7)</u> which would endorse the updated Appendix 3 in Annex 1; note the proposed workplan (Annex 3); and urge member

states to 'continue to implement' various resolutions. MSs and Secretariat are urged and requested to continue to work towards the third high level meeting of the UNGA on NCDs.

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

Background

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

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</u> <u>Declaration on NCDs</u>. 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 intervention</u> 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> <u>Add.2</u>);

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 Noncommunicable Diseases (para 17 of <u>A67/14</u>); 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 (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 (7th and 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 for 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 the Global Action Plan 2013-2020 in the Annex to $\underline{A66/9}$. The main aim of the GCM will be (from para 14 of the Annex):

"... to engage with Member States, United Nations funds, programmes and agencies, international partners including academia and relevant nongovernmental organizations and selected private sector entities that are committed to implementing the action plan, while safeguarding WHO from any real, perceived or potential Annex A66/9 9 conflicts of interest; the engagement with non-State actors will follow the relevant rules currently being negotiated as part of WHO reform."

In May 2014 WHA67 considered the proposed terms of reference for the GCM (annex to A67/14 Add.1) and the proposed workplan for 2014-15 (A67/14 Add.3) and the 7th meeting of Committee A endorsed both. The workplan for 2016-17 was presented to WHA68 in May 2015 in Annex 3 to A68/11. The proposed work plan for 2018-19 is presented in Annex 3 of A70/27.

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 <u>GCM home page</u>. The GCM is coordinated from within the NCDs unit in the Secretariat and reports to the DG. An evaluation is scheduled for 2017-18 (see para 21 in A70/27).

Links to previous WHA discussions of NCDs here.

PHM comment

Current situation and technical assistance

The data about shortfalls in implementation in relation to NCDs come from the <u>2015 NCDs</u> Monitor. A summary of these data was reported to the Assembly in A69/10, paras 16-18.

The analysis of obstacles to implementation in para 7 of A70/27 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 8 of A70/27 refers to a number of 'technical assistance' projects sponsored by WHO including a Bloomberg supported data platform, two updated systematic reviews (on saturated fat, and on transfats), a technical package on cardiovascular risk management in primary care, and a report on fiscal policies 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 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 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 A70/27 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 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.

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

Workplan for the GCM-NCD for 2018-19

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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.

15.2 Draft global action plan on the public health response to dementia

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- PHM comment

In focus

The Assembly will consider the draft global action plan ($\underline{A70/28}$) and is likely to decide, in accordance with $\underline{EB140(7)}$, to endorse and commit to implementing the plan.

Background

The focused consideration of dementia by WHO's governing bodies follows the <u>2012</u> <u>Dementia as a public health priority</u> and 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 <u>EB139/3</u> was considered (debate at <u>M1</u> and <u>M2</u>) and decision <u>EB139(1)</u>, authorising the development of a global action plan on dementia, was adopted.

The draft global action plan was discussed further at EB140 (Jan 2017). See <u>PSR13</u> and <u>PSR14</u>. The discussion was broadly supportive; the only substantive issues raised concerned the financial challenges facing low and middle income countries and the importance of cultural traditions being taken into account.

PHM comment

The burden on individuals, families and communities of dementia is huge. The strategies proposed in the draft plan all make sense.

However, questions about the funding of the plan are in order, given the reduction in funding projected for non-communicable disease programs and the continued financial crisis. The delay in unveiling the fully operative Global Dementia Observatory suggests that the Secretariat is working on limited resources in this area.

15.3 Public health dimension of the world drug problem

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- PHM comment

In focus

A70/29 sets out the public health challenges associated with the 'world drug problem' and invites the WHA70 'to provide further guidance on the implementation of the operational recommendations related to health of the special session on the world drug problem' [in the Outcome Document of the 2016 UNGASS debate].

Background

Recent history of this debate

In Jan 2016 the EB138 noted the forthcoming UN General Assembly (UNGASS) discussion on 'the World Drug Problem'. The EB discussion was informed by <u>EB138/11</u> which canvassed a number of public health issues relevant to the World Drug Problem. In the discussion (here) several countries spoke about the importance of WHO bringing a public health perspective to the UNGASS discussion. China, on the other hand, questioned the use of the term 'harm reduction' in the Secretariat document.

The UNGASS discussion took place in April 2016 and adopted the Outcome Document. While this document does not use the term 'harm reduction', it does recognise (para 1(o)) effective measures aimed at minimizing the adverse public health and social consequences of drug abuse, including appropriate medication-assisted therapy programmes, injecting equipment programmes, as well as antiretroviral therapy and other relevant interventions that prevent the transmission of HIV, viral hepatitis and other blood-borne diseases associated with drug use

This is clearly an advance on the <u>2009 Political Declaration and Plan of Action</u> which doesn't recognise the public health consequences of an exclusive focus on supply and demand reduction.

In May 2016 the WHA69 considered a Secretariat report on the UNGASS discussion (A69/12) and a draft decision (in A69/A/CONF./4) sponsored by the delegations of Argentina, Australia, Colombia, Guatemala, Mexico, Netherlands, Norway, Panama, South Africa, Sweden, Switzerland, United States of America, Uruguay and Zambia. The proposed decision would mandate the Secretariat to develop 'a comprehensive strategy and action plan to strengthen action on the public health dimension of the world drug problem'. WHA69 was not able to achieve consensus on this draft decision. The opposition was led by Peru, Cuba, and China. Instead of adopting the decision, the Assembly (in WHA69(15)) committed to further deliberation at EB140 in Jan 2017.

The discussion at EB140 was informed by <u>EB140/29</u> which contextualised the discussion in relation to the UNGASS debate and the SDGs and provided an overview of WHO's current range of actions of relevance to the World Drug Problem. Most speakers endorsed the directions outlined in EB140/29. <u>Peru</u> again sought to apply the brake and <u>Cuba</u> interpreted the Secretariat document as potentially undermining the current international drug control framework.

The issue returns to the Assembly at WHA70 with A70/29 which provides a direct challenge to those countries who are arguing against harm reduction strategies: "If public health measures are not adequately prioritized and urgent action is not taken, drug-related mortality, morbidity, disability and impact on well-being will continue to pose a significant global public health problem" (para 5). The report provides a positive account of WHO's work in this field although with the funding of WHO's NCDs work slashed the resources available are slight. Essentially A70/29 suggests the broad shape that 'a comprehensive strategy and action plan' would take if the Assembly were able to achieve consensus at WHA70.

Issues in contention

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.

While there is no reference to 'harm reduction' para 1(o) refers positively to a range of harm reduction strategies.

It seems that the main issue in contention among WHO member states is the principle of 'harm reduction' (alongside 'demand reduction' and 'supply reduction'). Harm reduction encompasses strategies which accept that drug use is taking place and seek to mitigate the risks including overdose and infection. The Secretariat report emphasises the contribution of injecting drug use to the HIV pandemic and to the spread of hepatitis C and B and the burden of disease which could be averted if such spread could be interrupted. The UN

Office on Drugs and Crime (UNODC) has traditionally steered clear of harm reduction on the assumption that it would compromise demand reduction objectives. It appears that those WHO member states opposing the draft decision at WHA69 share this fear.

See <u>Sabin (2016)</u> for the opposing argument. As expressed in A70/29 (para 5): 'If public health measures are not adequately prioritized and urgent action is not taken, drug-related mortality, morbidity, disability and impact on well-being will continue to pose a significant global public health problem'.

The debate is not simply about harm reduction. A70/29 lists seven main areas of collaboration between WHO and the UNODC:

- (a) prevention of drug use;
- (b) prevention and treatment of drug use disorders;
- (c) access to medicines under international control;
- (d) new psychoactive substances;
- (e) prevention, diagnosis, treatment, care and support for HIV, viral hepatitis and tuberculosis among people who use drugs and among people who are in prisons;
- (f) prevention of violence and violence-related deaths; and
- (g) monitoring drug use and its health and social consequences.

A70/29 elaborates on these.

A70/29 emphasises collaboration between WHO and UNODC, presumably in the hope that the sceptic member states (Peru, China and Cuba in particular) will be persuaded that a commitment to harm reduction need not compromise the demand reduction and supply reduction objectives.

PHM comment

PHM urges member states to mandate the Secretariat to develop 'a comprehensive strategy and action plan to strengthen action on the public health dimension of the world drug problem' as provided for in A69/A/CONF./4.

However, optimism about outcomes would need to be tempered given the continuing freeze on assessed contributions and the refusal of donors to contribute to WHO's non-communicable disease programmes.

15.4 Outcome of the Second International Conference on Nutrition

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In focus

<u>A70/30</u> describes progress (and lack of progress) in the implementation of the Second International Conference on Nutrition (ICN2) under three headings: (i) action at the international level; (ii) action at the country level; and (iii) action within and across the UN system.

At the international level the focus of the report is on the Decade of Action on Nutrition and the action areas which comprise the <u>work program</u> of the Decade of Action. The action areas are described at a high level of generality and there are no indications regarding their impact.

At the country level, the report reviews progress in the implementation of the commitments of the Rome Declaration and implementation of the actions recommended in the Framework for Action. The data presented (largely based on self-reporting by countries) suggest that progress has been slow or non-existent.

In relation to action across the UN system the report describes very briefly the work of WHO, FAO, UNICEF, the World Food Program (WFP) and the International Fund for Agriculture and Development (IFAD). There is no reference to UNDP.

The conclusion (in para 21) is gloomy. "In general, implementation needs to be expanded, investments have to be increased and greater policy coherence must be created."

It is surprising that there are no references to the current famine in South Sudan and the looming disasters in Nigeria, Somalia and Yemen (WFP, UNDP).

Background

ICN₂

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

Outcomes document and Framework for Action

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

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

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

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

Civil society and social movement statements

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

The <u>Public Interest CSOs and Social Movements Vision Statement</u> adopted at the Public Interest CSOs and Social Movements Pre ICN Conference. It goes into more detail than the Statement above. Social movements attending the pre-conference issued their own <u>Social Movements Statement</u>.

The food crisis

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

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

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

PHM comment

The food, nutrition and agricultural circumstances are very different across the world but worrisome everywhere. Action on food and nutrition must therefore be planned and

implemented at the national and local levels. However, the political and economic context within which such national planning takes place is strongly shaped by economic globalisation, the increasing power of transnational corporations and the drive to regulate the global economy in the interests of the TNCs through trade and investment agreements.

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

First, acknowledge the current ongoing food crises in South Sudan, North-eastern Nigeria, Somalia and Yemen

It is not right that a report on the implementation of the outcomes of ICN2 (2014) should not mention the ongoing food crises in South Sudan, North-eastern Nigeria, Somalia and Yemen. These are to some degree measures of the success (or otherwise) of ICN2.

Clearly there is an urgent need for food aid, particularly in South Sudan and Yemen.

However, it is also important to acknowledge the structural factors underlying conflict and drought including global warming, a global economic regime which drives widening economic inequalities, and the impact of free trade in industrialised agricultural commodities on small scale farming.

National action

National nutrition plans are central to the implementation of the ICN2 commitments. However, without a strong domestic constituency demanding action on the structural causes of malnutrition national nutrition plans will remain toothless.

PHM calls on organisations in the UN system and member states to give priority to building the domestic constituency needed to drive implementation of nutrition reform. See PICS&SM statement.

International action

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

In this context we urge staunch opposition to the use of ISDS to prevent effective regulatory strategies at the national level. We urge a return to multilateral negotiations around trade in agricultural commodities to ensure the elimination of dumping and of protection and subsidies to corporate agriculture. WHO has a mandate (through WHA59.26, page 37) to take the lead in this work. The ICN2 follow up needs to fully address these issues. UN SCN has committed to a policy document on trade and nutrition.

There are deep conflicts between the assumptions underlying the food sovereignty movement, which envisages food and agricultural systems based on agroecological principles (see PICS&SM <u>statement</u>), in contrast to the globalised corporate industrial model

of corporate agriculture and corporate dominated food systems. PHM calls for a new Commission to be jointly sponsored by WHO and FAO to investigate and report on the role of food sovereignty in addressing the challenges of food security.

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

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

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

15.5 Report of the Commission on Ending Childhood Obesity: implementation plan

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In focus

The high-level Commission on '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 in 2016 (debate A11) which adopted WHA69(12).

In accordance with <u>WHA69(12)</u>, a draft implementation plan (<u>A70/31</u>) has been prepared to guide further action on the recommendations included in the ECHO report.

The Assembly is invited to endorse the implementation plan.

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 ECHO Report. PHM urges the Assembly to endorse it, in its entirety.

Build on the PAHO nutrient profiling guidelines

PHM urges WHO regional committees to consider adopting the PAHO nutrient profiling guidelines because they focus on highly processed and ultra processed foods (drawing on the Brazilian guidelines) and are designed to support a broad set of interventions, not just the regulation of marketing.

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

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

supportive of local economic development. The food sovereignty paradigm also promises less energy dense foods.

Regulatory strategies needs treaty status to protect them from corporate challenge

Nutrient profiling, food labelling, the sugar tax and other regulatory strategies all need to be given treaty status globally to protect them from corporate challenge under trade agreements.

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

The rising significance of free trade agreements in shaping global food systems points towards the importance of robust standards which can constrain what is provided for in trade agreements and jurisprudence of dispute settlement. Provisions for investor state dispute settlement have been widely recognised as a threat to policy space in terms of regulating the food environment. Robust standards in a binding agreement would go a long way to protecting such policy space.

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.

PHM urges member states to commit to the negotiation of a framework convention on nutrition under Article 19 of the WHO Constitution and for such a treaty to be negotiated within WHO. If it is referred to the Codex it is likely to be stalled, watered down or simply not enacted.

Rising opposition from Junk Food industry

The international food and beverage industry is already lobbying its favoured delegates to water down the recommendations of the draft Plan, 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, argued 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 is lobbying globally 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.

PHM urges regional and country offices to reach out to civil society organisations locally, nationally and regionally to hold governments accountable for implementing the Plan.

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

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In focus

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

The Secretariat report (A70/32) outlining the disease burden and trends in relation to cancer; reviewing the current situation regarding national cancer control plans; reviewing the main elements comprising cancer control (from prevention to palliative care) and and summarising WHO's activities, and other international efforts, to meet the global challenge posed by cancer. The paper lists a range of recommended actions for member states at the country level and actions for the Secretariat.

The Secretariat report provided to EB140 (<u>EB140/31</u>) included a draft resolution which urged member states to progress a wide range of national cancer control policy issues and urged the DG to provide appropriate support including publishing a world report on cancer.

There were several amendments proposed to the draft resolution at the EB but member states at EB140 were not able to finalise an agreed text. See record of debates PSR15 and PSR18.

IP Watch has published the draft resolution as it was at 31 Jan plus a comment.

The parts of the draft resolution still in contention on 31 January include:

- OP1.6 urging MSs to promote the highest possible coverage of vaccination against cancer:
- OP1.14 urging MSs to promote the affordability of medicines and vaccines with provisions regarding generics, appropriate financing arrangements and TRIPS flexibilities.

There were several proposed amendments which had not been fully discussed.

It was agreed to continue discussion during the intersessional period and if this has achieved a consensus this will be submitted to the WHA70.

Background

The preambulatory paragraphs of the draft resolution list the numerous previous resolutions and declarations on cancer and other NCDs.

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 was no reference in the original 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. We urge MS to support the Indian proposed amendment OP2.5ter which requested the DG to undertake a "feasibility study of creating a multi-country push and pull fund for cancer R&D as an alternative to incentives-based intellectual property rights and/or regulatory monopolies and to progressively delink cancer R&D from product prices".

The currently market driven system of R&D, relying on IP-protected monopolies as the main incentive for R&D, is driving the prices of treatments for NCDs, including cancer, to prohibitive levels and even HICs are adversely affected.

Noting the interference of the tobacco industry in public health policy, accelerating the implementation of FCTC is critical for the success of reducing cancer risk factors.

We urge WHO to form a commission for a comprehensive and systematic report to address the issue, creating a clear, integrated action plan as done by ECHO on ending childhood obesity.

15.7 Strengthening synergies between the World Health Assembly and the Conference of the Parties to the WHO Framework Convention on Tobacco Control

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In focus

In May 2016 a document appeared before the WHA (A69/11) proposing that the outcome of the Conference of the Parties to the FCTC would appear as a stand-alone item on the provisional agenda of the session of the Health Assembly immediately following the Conference of the Parties (held every two years).

According to A69/11 the fact that tobacco has recently been considered by the Assembly under the heading of 'noncommunicable diseases' "may have created the impression that implementation of the Convention is not accorded the attention it deserves by the Health Assembly".

A69/11 reviewed Assembly and regional committee consideration of the Convention; references to the Convention in various international decisions and declaration; and cooperation between the two secretariats. There is no reference to the role of WHO country offices in supporting implementation.

WHA69 adopted decision <u>WHA69(13)</u> which invites the Conference of the Parties to the WHO FCTC to provide a report to the WHA on the outcomes of the Conference of the Parties.

Following this decision, the seventh session of the Conference of the Parties (COP7) adopted decision FCTC/COP7(18) on strengthening synergy between the Conference of the Parties and the Health Assembly. In that decision, the Conference of the Parties requests the President to report on the outcomes of COP7 to the Seventieth World Health Assembly.

The COP7 decision also invites the World Health Assembly to request the WHO Director-General to continue to provide regular reports to the Conference of the Parties on resolutions and decisions of the Health Assembly relevant to the implementation of the WHO FCTC.

<u>A70/33</u> conveys the report of the President of COP7 to the WHA. The report refers to 31 decisions made by the COP7 dealing variously with treaty instruments and technical matters; implementation assistance and international cooperation; budgetary and institutional matters; the proceedings of the COP; and finally the Delhi Declaration.

Background

The text of the Convention and the Protocol on Illicit Trade are linked from here. The full set of documents associated with COP7 is here. The Final Report of the COP (here) provides a more detailed overview of the issues at stake in the various decisions summarised in the President's report to the Assembly.

Some of the highlights from the Final Report include:

- continuing concern that the tobacco industry is still exercising influence on public policy in a significant number of jurisdictions, contrary to Article 5.3; including through the inclusion of tobacco industry personnel in their delegations to the COP;
- the uneven implementation of the Convention; the Head of the Convention
 Secretariat reports (para 22 of Final Report) that "one quarter of reporting Parties had
 not yet confirmed implementation of time-bound measures under Article 8 (Protection
 from exposure to tobacco smoke) and 40% of reporting Parties lacked a
 comprehensive advertising ban":
- the control and prevention of globally emerging products (waterpipes, e-cigarettes, etc); see Decision FCTC/COP7(9);
- the importance of addressing the need for alternative livelihoods; see Decision FCTC/COP7(10)
- debates over implementation of Article 19 'Liability' which refers to the need to
 ensure that the tobacco industry is held accountable through civil or criminal law for
 the burden of disease it creates; only 34% of Parties report having implemented
 Article 19; see Decision FCTC/COP7(11);
- addressing gender-specific risks in developing tobacco control strategies; see Decision <u>FCTC/COP7(12)</u>;
- debates over the accountability of Parties for implementation of the Convention; debates focusing on a proposal for an 'implementation review committee';
- the interactions between tobacco control and trade law, including the management of disputes between Parties arising from such interactions; see Decision FCTC/COP7(21);
- the parlous financial state of the Convention Secretariat with a freeze on 'voluntary assessed contributions' and many parties in arrears, some of whom have never contributed.

The final resolution of the COP, the 'Delhi Declaration' (<u>FCTC/COP7(29)</u>) provides a useful overview of the issues addressed and directions agreed at the Conference.

PHM comment

It is apparent that the negotiation of the FCTC was a major achievement and that progress in tobacco control is being achieved. The Impact Assessment by the Expert Group (FCTC/COP/7/6) demonstrates that implementation of the provisions of the FCTC in the key demand reduction domains is associated with a decline in smoking prevalence.

The WHO DG, in her message to the COP (Annex 4 of the Final Report) states that, "The tide of tobacco use is beginning to turn. After decades of Big Tobacco targeting low- and middle-income countries and years of steadily increasing profits, tobacco sales are beginning to decline".

However, the Expert Group also demonstrates that fewer than 50% of Parties report having implemented Articles 9 (regulation of the contents of tobacco products), 13 (Tobacco advertising, promotion and sponsorship), 18 (Protection of the environment and the health of persons), 22(Cooperation in the scientific, technical and legal fields and provision of related expertise), 19 (Liability) and 17 (Provision of support for economically viable alternative activities). The lack of implementation of Article 19 on Liability is particularly disappointing.

The <u>Expert Group</u> reviews the obstacles to full implementation and concludes that the biggest single obstacle to implementation is 'Aggressive action by the global tobacco industry to oppose tobacco control measures and to undermine Article 5.3'.

The Head of the Secretariat comments (in Annex 6 to the Final Report) that:

We are also watched by sugar and alcohol products manufacturers, who see the tobacco control movement as a precursor to threats they now face from public health campaigns. These industries fear a united international community acting on behalf of consumers. In the coming days, I hope their fears will be fully justified as we take further steps to end the tobacco epidemic.

However, it is apparent that the capacity of the FCTC Secretariat to drive implementation is weakened by the freeze on assessed contributions and divisions among the Parties to the FCTC.

It is perplexing that there are no specific references in <u>A69/11</u> or <u>A70/33</u> to the role of WHO Country Offices in supporting governments in FCTC implementation and in working with public health oriented civil society to progress the purposes of the FCTC;

PHM calls upon MS in the World Health Assembly to:

- recommit to the full implementation of the FCTC, recognising that despite progress global smoking deaths are predicted to rise from the current 6 million p.a. to 8 million p.a. by 2030;
- urge the COP to develop and implement stronger mechanisms to hold Parties to account for their implementation of the Convention; including in particular Article 5.3;
- request the Secretariat to report to the next Assembly on the implementation of WHA59.26 on International Trade and Health, with particular attention to the challenges facing tobacco control;
- request the Secretariat to report to the next WHA on the contribution of country offices to the full implementation of the FCTC;
- engage proactively with the <u>Open-ended Intergovernmental Working Group</u>
 established by the UN Human Rights Council on transnational corporations and other
 business enterprises with respect to human rights to ensure that the right to health is
 fully addressed and protected in the recommendations of that working group; and
- commit to adequately funding the FCTC Secretariat.

15.8 Prevention of deafness and hearing loss

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- PHM comment

In focus

The Secretariat report (A70/34) surveys the prevalence and consequences of hearing loss; reviews the importance of prevention and intervention; recalls previous resolutions and WHO initiatives touching upon hearing loss; and lists a range of actions needed at country level and by the Secretariat

This item was considered at EB139 in May 2016 and the Board adopted a draft resolution, <u>EB139.R1</u>, for the Assembly to consider.

Background

Highlights from the debate when this matter was discussed at the EB139 (see EB139 M2) included:

- Many delegates commented on the problem of noise induced hearing loss including occupational exposure and the emerging problem of entertainment venues and personal devices;
- The UK emphasised the need to include consideration of employment outcomes as well as education in national plans; this doesn't seem to have been incorporated into the draft resolution:
- Germany emphasised the human rights dimension of deafness, citing the Convention on the Rights of Persons with Disabilities;
- India emphasised the need for technology transfer to support local manufacture of assistive technologies;
- Saudi Arabia the need for integration of ear care into the primary health care system;
 and
- Algeria raised the issue of vaccine shortages and the need of some countries for technological assistance.

PHM comment

The issue is important. The Secretariat report is useful. The resolution is constructive.

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

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In focus

This item appears as a consequence of a follow up request in Resolution <u>WHA69.11</u> ('Health in the 2030 Agenda for Sustainable Development ') adopted in May 2016.

The Secretariat report published for this item (A70/35) has two sections: first, a global level report on countries' progress towards the 'health-related' SDGs and targets, drawing on data presented in World Health Statistics 2016; and second, a review of Secretariat action, of particular relevance to the SDGs, structured loosely around the 'requests to the DG' in OP2 of WHA69.11.

When this item was discussed at the EB140 in Jan 2015 (<u>PSR15</u>) the Secretariat proposed (in <u>EB140/32</u>) a framework for relating pre-existing health priorities and programs to the Agenda for Sustainable Development. This framework comprises six 'instruments of change and enabling factors', referred to in A70/35 as 'six main lines of action. These are:

- intersectoral action by multiple stakeholders;
- health systems strengthening for universal health coverage;
- respect for equity and human rights;
- sustainable financing;
- scientific research and innovation; and
- monitoring and evaluation

It is not clear whether there is a draft resolution being prepared.

Background

Key sites for following the 2030 Agenda for Sustainable Development include:

- <u>UN Sustainable Development Knowledge Platform</u>
- High Level Political Forum
- Inter-Agency and Expert Group on Sustainable Development Goal Indicators
- SDG Indicators website

PHM comment

The SDGs are a great improvement over the MDGs. PHM appreciates that progress is being achieved in relation to some of the SDG indicators and appreciates also the emphasis that the Secretariat places on intersectoral collaboration and health systems development in the 'six main lines of action'.

However...

Neglecting the politics of sustainable development

Much of the discourse around the SDGs evokes a parallel universe in which everything is about win win outcomes and 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 rich countries willingly negotiate non-reciprocal trade and investment agreements which enable low and middle income countries to achieve (sustainable) economic development. 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.

The reality is very different.

There is nothing in A70/35 which speaks about the social and political processes through which the SDGs might be achieved. These 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. They include moving towards cultures of inclusion and human security to reduce xenophobia and strengthen solidarity.

The language of 'multi-stakeholder partnerships', as in SDG17.16 and 17.17, projects universal beneficence and completely ignores the Trojan horse functions of many such 'partnerships'.

- SDG17.16: "Enhance the Global Partnership for Sustainable Development,
 complemented by multi-stakeholder partnerships that mobilize and share knowledge,
 expertise, technology and financial resources, to support the achievement of the
 Sustainable Development Goals in all countries, in particular developing countries";
 the proposed indicator for this target is the "number of countries reporting progress in
 multi-stakeholder development effectiveness monitoring frameworks that support the
 achievement of the sustainable development goals";
- SDG17.17: "Encourage and promote effective public, public-private and civil society partnerships, building on the experience and resourcing strategies of partnerships"; the proposed indicator for this target is "Amount of United States dollars committed to public-private and civil society partnerships".

In similar vein para 28 of <u>EB140/32</u> focuses attention on various categories of 'stakeholders': 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.

This commitment to 'engage more strategically' assumes an analysis of the political forces and dynamics which sustain an unfair and unsustainable global economy. Strategic engagement informed by such an analysis would involve different kinds of relationships ('partnerships') with these different stakeholders. However, no such analysis is presented.

In the Secretariat's 'six lines of action' and in the review of WHO action around the SDGs in A70/35 there is no consideration of how WHO might work more constructively with the social and political movements (local, national, regional and global) which are already working towards a more equitable and sustainable world.

Limited selection of 'health-related' goals and targets

The description of progress by member states towards the 'health-related' SDGs in <u>A70/35</u> is based on <u>World Health Statistics Report 2016</u> which purports to "bring together the most recent data on the proposed health and "*selected* health-related SDG indicators" – to assess the current situation and describe crucial data gaps". (Page v.)

However the goals and targets reported on represent a very arbitrary definition of 'health-related' goals and targets.

There is no reference in this report to many other 'non-health' SDGs which have profound implications for health equity:

- SDG4.5: "By 2030, eliminate gender disparities in education and ensure equal access to all levels of education and vocational training for the vulnerable, including persons with disabilities, indigenous peoples and children in vulnerable situations";
- SDG5.2: "Eliminate all forms of violence against all women and girls in the public and private spheres, including trafficking and sexual and other types of exploitation;
- SDG5.3: "Eliminate all harmful practices, such as child, early and forced marriage and female genital mutilation";
- SDG5.6: "Ensure universal access to sexual and reproductive health and reproductive rights":
- SDG8.5: "By 2030, achieve full and productive employment and decent work for all women and men, including for young people and persons with disabilities, and equal pay for work of equal value";
- SDG9.1: "Develop quality, reliable, sustainable and resilient infrastructure, including regional and trans-border infrastructure, to support economic development and human well-being, with a focus on affordable and equitable access for all" (Proposed indicator 9.1.1: "Proportion of the rural population who live within 2 km of an all-season road" is directly relevant to maternal mortality);
- SDG10.7: "Facilitate orderly, safe, regular and responsible migration and mobility of people, including through the implementation of planned and well-managed migration policies";
- SDG11.1: "By 2030, ensure access for all to adequate, safe and affordable housing and basic services and upgrade slums";
- SDG12.4 "By 2020, achieve the environmentally sound management of chemicals and all wastes throughout their life cycle, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil in order to minimize their adverse impacts on human health and the environment;
- SDG14.4: "By 2020, effectively regulate harvesting and end overfishing, illegal, unreported and unregulated fishing and destructive fishing practices and implement science-based management plans, in order to restore fish stocks in the shortest time feasible, at least to levels that can produce maximum sustainable yield as

- determined by their biological characteristics" (critical for employment, trade and nutrition in small island nations);
- SDG15.2: "By 2020, promote the implementation of sustainable management of all types of forests, halt deforestation, restore degraded forests and substantially increase afforestation and reforestation globally" (directly relevant to the Ebola epidemic);
- SDG17.1: "Strengthen domestic resource mobilization, including through international support to developing countries, to improve domestic capacity for tax and other revenue collection":
- SDG17.6: "Enhance North-South, South-South and triangular regional and international cooperation on and access to science, technology and innovation and enhance knowledge-sharing on mutually agreed terms, including through improved coordination among existing mechanisms, in particular at the United Nations level, and through a global technology facilitation mechanism; (such as, perhaps, an R&D Treaty on R&D for medicines and vaccines).

The Secretariat appears to have a very narrow understanding of 'health-related' SDGs.

Need for a gap analysis

WHO has a rich suite of resolutions, plans, strategies and programmes 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 within WHO up until now.

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

A70/35 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.

Action

PHM calls on WHO to develop a strategy for civil society engagement around working towards and building a global constituency for health equity as part of the Agenda for Sustainable Development.

PHM urges the WHO Secretariat to review more carefully the implications of all of the 'non-health but health-related' SDGs for population health and to ensure that WHO programming is fully aligned with the principle of an integrated indivisible Agenda for Sustainable Development.

PHM urges member states to bring forward a resolution commissioning the Secretariat to report annually on the health dimensions of each of the 17 SDGs. This annual report would include:

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

PHM calls on the Assembly to commission a gap analysis to ensure that WHO has policies and programs in place for addressing all of the non-health SDGs insofar as they have implications for health equity.

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

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- PHM comment

In focus

Resolution <u>WHA69.4</u> (2016) requested the Director-General, *inter alia*, to develop a roadmap, for consideration by WHA70, for developing the health sector's role in the management of chemicals at the national, regional and international levels.

A draft road map was considered by the EB140 in Jan 2017 and with minor additions was approved and is submitted for consideration by the Assembly in A70/36 (also available in colour here).

<u>A70/36</u> explains that the roadmap is based on four actions which "are closely aligned with the objectives set out in the Strategic Approach's <u>Overarching Policy Strategy</u>". In fact the Overarching Policy Strategy includes a fifth objective which concerns the illegal transboundary movement of toxic waste which is not addressed substantively in the roadmap; certainly not as a 'action area'.

It is not clear why the illegal transboundary movement of toxic waste was not included in the roadmap. What we do know is that the drafting group at EB138 in Jan 2016 was not able to find consensus around the draft resolution; and that references to Stockholm, Rotterdam and Basel in OP1.8 of the early draft (EB138/CONF./7) does not appear in WHA69.4 adopted in May.

<u>WHA69.4</u> does include a request in OP2(2) asking the DG "to build on and enhance implementation of actions pursuant to resolution <u>WHA63.25</u> on improvement of health through safe and environmentally sound waste management, and to develop a report on the impacts of waste on health, the current work of WHO in this area, and possible further actions that the health sector, including WHO, could take to protect health".

However, the report on waste which was requested in <u>WHA69.4</u> and which the Director Public Health, Environmental and Social Determinants advised EB140 that the Secretariat "would be pleased to prepare" see <u>EB140/PSR15</u> has not emerged. Instead there is a one paragraph note (para 18 of <u>A70/36</u>) explaining that the job is broader than expected and that the "Secretariat is in the process of identifying the additional resources needed to broaden the data collection for the report".

The Assembly will consider the roadmap and adopt the decision at para 19 of A70/36. There may be some further questions about the exclusion of illegal transboundary movement of waste from the roadmap and about the report on waste which has not emerged.

It seems possible that Russia's continuing opposition to the listing of chrysotile asbestos in Annex III of the Rotterdam Convention may have influenced the exclusion of illegal transboundary movement from WHO's draft roadmap and may have also influenced the decision of the Secretariat not to present the promised report on waste. See more background below.

Background

The management of chemicals and waste is of critical public health importance. With increasing economic integration the sound management of chemicals and waste must be approached at both national and international levels.

In a report prepared for WHA69 in May 2016 (A69/19) the WHO secretariat summarises:

The OECD estimates that annual global sales of products from the chemicals sector doubled between 2000 and 2009 and will increase six-fold between 2010 and 2050, with a continued shift of production from OECD countries to other countries.

About 25% of the global burden of disease in humans is thought to be linked to environmental factors, including exposures to chemicals. Worldwide, lead exposure, for example, is estimated to account for 143 000 deaths per year, with the highest burden in developing regions. Childhood exposure to lead is estimated to contribute to about 600 000 new cases of children developing intellectual disabilities every year. Some 9% of the global disease burden due to lung cancer is attributed to occupational exposure to chemicals.

Many countries still lack the necessary regulatory and policy frameworks and institutional capacities to assess and prevent the negative health impacts of chemicals. For example, despite lead in paint being a significant cause of childhood poisoning, only 59 countries are known to have regulated lead-based paint.

The chemicals and related industries are very powerful and consistently oppose regulatory strategies that might entail costs or restrict their autonomy. The interests of the chemicals and related industries are generally protected and advanced by certain countries both within the WHO and in other international fora.

Responsibility for the management of chemicals at the international level is distributed across WHO, UNEP, ILO and multilateral environmental conventions. Likewise, social movement monitoring and advocacy tends to be divided across environmental and labour as well as health oriented social movements.

While the inclusion of environmental clauses in trade and investment agreements has been controversial, the principle of minimal necessary regulation in trade law with the disciplines of various dispute settlement provisions is a significant constraint on regulation.

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 4th session of the International Conference on Chemicals Management (ICCM4) in 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.

It was decided at ICCM4 (resolution IV/4) to initiate an intersessional process to prepare recommendations regarding the Strategic Approach and the sound management of chemicals and waste beyond 2020. The first meeting of the intersessional process took place in February 2017.

WHO's roadmap process is running alongside the intersessional process but will clearly contribute to it.

Emergence of the road map

The emergence of the road map at WHA70 reflects several pressures and deadlines.

A63/21, considered by the Assembly in May 2010, reviewed the importance of the sound management of chemicals for the protection of human health; reviewed the background of the Strategic Approach; and reported 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 (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 under discussion (as the term of the Strategic Approach mandate finishes in 2020); clearly 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. The issues in contention have not been made public.

There are significant policy issues at play in shaping future frameworks for international chemicals management. PHM's comment on Item 13.6 at WHA69, here canvasses a range of issues under the headings of:

regulatory strategies;

- how to approach North South disparities in relation to institutional regulatory capacity;
- links between sound chemicals management and the challenges of sustainable development including the role of trade and investment agreements.

Further negotiations continued in the lead up to WHA69 and a consensus resolution was presented there and adopted (<u>WHA69.4</u>). 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 and following discussion in EB140 (see <u>EB140/33</u> and <u>EB140 PSR15</u>)

We have commented above on the fact that references to Stockholm, Rotterdam and Basle in OP1.8 of the early draft (<u>EB138/CONF./7</u>) in Jan 2016 do not appear in <u>WHA69.4</u> adopted in May 2016. This may have been one of the sticking points.

Some of the highlights of the debate at EB140 were:

- the need for capacity building (Gambia for Afro, China, Ghana); delegates referred variously to human resources, technical, regulatory and institutional capacity including capacity for effective intersectoral collaboration
- the need for international financing (Philippines, Angola)
- the need for funding and promotion of clean and safe technology transfer (China, Ghana)
- the importance of legally binding agreements on chemicals and waste (Philippines)
- the absence of reference in the roadmap to illegal international trade in chemical waste and toxins (Ghana, Angola)

Transboundary traffic in toxic waste

The <u>Basel Convention</u> on the Control of Transboundary Movements of Hazardous Wastes and their Disposal was adopted in 1989 in Basel, Switzerland, in response to a public outcry following the discovery, in the 1980s, in Africa and other parts of the developing world of deposits of toxic wastes imported from abroad.

Basel includes a range of regulatory provisions including the mechanism of 'prior informed consent' which means that '... before an export may take place, the authorities of the State of export notify the authorities of the prospective States of import and transit, providing them with detailed information on the intended movement. The movement may only proceed if and when all States concerned have given their written consent (articles 6 and 7)'.

The <u>Rotterdam Convention</u>, adopted in 1998 by in Rotterdam, the Netherlands, created legally binding obligations for the implementation of the Prior Informed Consent (PIC) procedure. PIC applies to substances which are listed in Annex III of the Convention. Substances which are nominated for listing are assessed by an expert committee but the decision to list them is by consensus at the conference of the parties (COP).

Chrysotile asbestos has been recommended for listing for 10 years but objections from a small number of countries has prevented its being listed.

On the health risks of asbestos see <u>WHO Fact Sheet</u>. In the context of the 2013 controversy (see below) the <u>IARC</u> declared that, "For chrysotile, the only asbestos fibre type being mined today, a small mesothelioma burden should not be interpreted as a small total cancer

burden. The future chrysotile-related cancer burden will predominantly consist of lung cancer".

The international trade union movement is campaigning for chrysotile to be listed. See Global Asbestos Action Alliance.

2008. Bali Declaration

See <u>Bali Declaration</u> on Waste Management for Human Health and Livelihood (June 2008), adopted on the occasion of Basel COP.9 invites:

the World Health Assembly to consider a resolution related to the improvement of health through safe and environmentally sound waste management.

2010. WHO expresses support for Rotterdam and Basel and is explicit about the dangers of asbestos

EB126/20 (Jan 2010), in para 4 & 5 comments:

- 4. Despite what has been known for many years about the public health risks posed by chemicals such as mercury, lead and asbestos, these problems have not been fully recognized. They persist particularly in developing countries, which typically have fewer resources for chemicals risk management. The projected growth in production and use of chemicals in the developing world is likely to result in greater negative effects on health if sound chemicals management is not put in place.
- 5. To counter the negative health impacts arising from exposure to hazardous chemicals, in addition to health-sector action, substantial health gains could result from cooperation with other sectors such as environment, transport and agriculture. The health impacts of chemicals are dealt with in multilateral environment agreements, including the Stockholm Convention on Persistent Organic Pollutants and the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade.

Note reference in the preamble to EB126.R12:

Having also considered the letter of President of the ninth meeting of the Conference of the Parties to the Basel Convention on the Control of Transboundary Movement of Hazardous Wastes and their Disposal to the Director-General of WHO, [presumably conveying the 'invitation' from Bali, above]

And in the preamble to WHA63.25 (May 2010)

Welcoming the Bali Declaration on Waste Management for Human Health and Livelihood adopted at the ninth meeting of the Conference of the Parties to the Basel Convention on the Control of Transboundary Movement of Hazardous Wastes and their Disposal in 2008,

And OP2(1) of <u>WHA63.25</u> which requests the Director-General "to support the implementation of the actions set out in the Bali Declaration on Waste Management for Human Health and Livelihood, within WHO's mandate and available resources".

2013. Controversy over IARC and chrysotile asbestos

WHA66 (May 2013). Item 18, Progress Reports (Documents <u>A66/27</u>). J. Workers' health: global plan of action (Resolution WHA60.26) Report of discussion in Committee B, <u>Session</u> 6 and <u>Session 7</u> - focus of debate (see <u>extracts of debate at B6 and B7</u>) was the inclusion of chrysotile asbestos in Annex III of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. See <u>GHW note</u> about asbestos (2013) .

2017. COP.8 - no consensus on chrysotile asbestos

UNEP/FAO/RC/COP.8/11 (and Add.1) (linked from here): recommendation of the Chemical Review Committee to the effect that chrysotile asbestos should be listed on Annex III

See comment from the Global Asbestos Action Alliance in advance of the COP.8

<u>Synergies Press Release (May 4)</u> "No agreement was reached, however, on [the listing of] chrysotile asbestos [in Annex III]".

PHM comment

The roadmap as presented to WHA70 sets out a huge agenda for action but is cast at a very general level. PHM urges member states to support the draft decision in <u>para 19 of A70/36</u>. However, the effectiveness of the proposed actions in enhancing health sector engagement towards meeting the 2020 goal and contributing to the SDG targets, will depend on the specific commitments might might arise from the roadmap.

The roadmap is comprehensive, in that it mentions a wide range of possible 'actions'. However, it does not project a vision; it doesn't project any kind of big picture regarding the international regulation of chemicals and waste.

PHM urges member states to consider the need for :

- stronger accountability mechanisms to hold member states accountable for implementing agreed actions;
- a binding international agreement along the lines suggested by Peiry (2014);
- a financing instrument along the lines suggested by van der Kolk and Agarwal (2011); to be managed by one of the new South based development banks;
- further deliberation and discussion regarding more specific regulatory strategies with a view to achieving, at the very least:
 - mandatory obligation for the production of defined toxicity data to be provided by manufacturers introducing new chemicals to market;
 - o mandatory labelling in accordance with a mandated classification scheme;

Accountability

The proposed road map includes no provisions for holding member states accountable for implementing the proposed actions or for holding transnational corporations accountable.

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 cited in PHM comment on WHA69 13.6.

The main intergovernmental forum which is addressing the accountability of transnational corporations is the <u>Open-ended Intergovernmental Working Group</u> established by the UN Human Rights Council on transnational corporations and other business enterprises with respect to human rights. It seems that there has been no collaboration between WHO and the HRC in these matters.

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.

Information and labelling

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.

Illegal transboundary movement

The road map ignores fifth objective of the Strategic Approach: controlling the illegal transboundary movement of waste and toxics. In this context the failure to schedule chrysotile in Annex III of the Rotterdam Convention (discussed above) illustrates the failure of the consensus approach to the regulation of individual chemicals and the need for further development of the Basel Rotterdam system.

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 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.

Trade

PHM notes that there is no reference to trade and investment agreements in the roadmap. This is unfortunate in view of the increasingly common inclusion of investor state dispute settlement provisions in new trade and investment agreements. Such provisions can greatly constrain national level regulation but authoritative international agreements can provide significant defence in the face of such challenges.

References

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van der Kolk, J. and R. Agarwal (2011). Future outlook and challenges. Chemicals, Environment, Health A Global Management Perspective. P. Wexler, J. v. d. Kolk, A. Mohapatra and R. Agarwal. Boca Raton, Hoboken: Taylor and Francis: 761-771.

16.3 Global Strategy for Women's, Children's and Adolescents' Health (2016–2030): adolescents' health

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- Background
- PHM comment

In focus

<u>A70/37</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. The report highlights progress made in 16 key indicators which are held to reflect the key objectives of the Global Strategy: survive, thrive, transform. The report also has a special feature on adolescent health.

The report also conveys the recommendations of the High-level Working Group on Health and Human Rights announced (<u>here</u>) by WHO and the Office of the High Commissioner for Human Rights at the time of the WHA69 in May 2016.

The Assembly is invited to note the report.

There may be some discussion during the Assembly of the likely impact on maternal mortality of the US President's decision to reimpose the 'global gag rule'.

Background

The US decision to reimpose the global gag rule overshadows the recital of statistics in A70/37. Undoubtedly it will contribute to a rise in maternal mortality. See comment from Marie Stopes.

Health status: the present situation

The present health situation for women, children and adolescents globally is summarised 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>.

Further data are presented in the Global Health Observatory.

The Global Strategy (2016-2030)

The Global Strategy for Women's Children's and Adolescents' Health (2016-2030) (launched by the UN SG in Sept 2015) 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. Multisectoral 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 page 88 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</u> <u>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 <u>High Level Advisory Group</u> 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 Accountability Panel (IAP)</u> 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 <u>A70/37</u>) 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, Mariam Claeson, the GFF was launched in 2015 as "the new approach to smart, scaled and sustained financing across reproductive, maternal, newborn, child and adolescent health". More on the GFF here.

Human rights approach

Following 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, WHO and OHCHR convened in 2016 a High Level Working Group for the Health and Human Rights of Women, Children and Adolescents to recommend ways in which human rights can be integrated into health programming.

Recommendations from the Working Group are conveyed in the Annex to A70/37.

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

A detailed commentary on the Global Strategy was included in the PHM comment on this item at EB140 (here).

However, the over-riding policy issue in question at this Assembly is the reimposition of the Global Gag Rule.

Women's health is determined by their timely access to a full range of reproductive health services. This is a basic human right. PHM supports freely and publicly available sexual and reproductive health services in all countries. We condemn the re-introduction of the Global Gag Rule, and discourage member states from assuming that private donors will fill in the gaps left behind by the withdrawal of funding for reproductive health services by member states.

We urge member states to request the DG to prepare estimates of the anticipated morbidity and mortality burden consequent upon the reintroduction of the Global Gag Rule and to report to WHA71 regarding the observed impact of this policy".

17. Progress reports

Contents

A70/38

Noncommunicable diseases

- A. WHO global disability action plan 2014–2021: better health for all people with disability (resolution WHA67.7 (2014))
- B. Addressing the challenges of the United Nations Decade of Action for Road Safety (2011–2020): outcome of the second Global High-level Conference on Road Safety Time for Results (resolution WHA69.7 (2016))
- C. Towards universal eye health: a global action plan 2014–2019 (resolution WHA66.4 (2013))

Communicable diseases

- D. Eradication of dracunculiasis (resolution WHA64.16 (2011))
- E. Global strategy and targets for tuberculosis prevention, care and control after 2015 (resolution WHA67.1 (2014), Global Strategy)
- F. Global technical strategy and targets for malaria 2016–2030 (resolution <u>WHA68.2</u> (2015), <u>Global technical strategy</u>)

Promoting health through the life course

- G. Public health impacts of exposure to mercury and mercury compounds: the role of WHO and ministries of public health in the implementation of the Minamata Convention (resolution <u>WHA67.11</u> (2014))
- H. Strategy for integrating gender analysis and actions into the work of WHO (resolution <u>WHA60.25</u> (2007))

Health systems

- I. Progress in the rational use of medicines (resolution WHA60.16 (2007))
- J. Regulatory system strengthening for medical products (resolution <u>WHA67.20</u> (2014))
- K. Strengthening emergency and essential surgical care and anaesthesia as a component of universal health coverage (resolution WHA68.15 (2015))

Preparedness, surveillance and response

- L. Smallpox eradication: destruction of variola virus stocks (resolution <u>WHA60.1</u> (2007))
- M. Enhancement of laboratory biosafety (resolution WHA58.29 (2005))

20.1 WHO mid-term programmatic and financial report for 2016–2017, including audited financial statements for 2016

Contents

- In focus
- Background
- PHM comment

In focus

A70/40 includes:

- a preliminary section from the internal auditor demonstrating the rigor and transparency of the Organisation's stewardship;
- a series of chapters on the Programme Budget categories; providing in each case an overview of achievements, challenges and lessons learned, priorities for 2017 and key statistics;
- a statement of internal control;
- mid term financial reports;
- an overview of the financial situation (Annex 1); and
- output ratings and financial information by programme (Annex 2).

A70/40 presents important financial, audit and programmatic information. However, it is also designed with an eye to the donors and the financing dialogue for PB18-19.

In a nutshell, half way through the present 16-17 biennium:

- 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 still seriously underfunded;
- The Secretariat is redoubling its efforts to recruit new donors and encourage existing donors:
- The DG is proposing a 3% increase in assessed contributions (cut down from the 10% recommended by the <u>UN High-level Panel on the Global Response to Health</u> Crises);
- Without a significant increase in funding WHO's work in health emergency management is at risk and other existing programs will need to be scaled back significantly over the next seven months.

More data is available from the WHO Programme Budget Web Portal

Details of voluntary contributions by fund and by contributor, 2016 in document A70/INF./4.

Documents from recent WHAs linked here.

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 proposed increase in ACs and calls on donor states to until 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.

21.1 Report of the External Auditor

Contents

- In focus
- Background
- PHM comment

In focus

<u>A70/43</u> conveys the External Auditor's report. The auditor finds WHO's accounts and transactions in order.

The auditor takes a focused look at a number of management processes and country offices and offers a number of recommendations (from page 10).

Background

The auditor's report will be considered by <u>PBAC26</u>, meeting before the Assembly, and will receive a report from the PBAC. The report from PBAC24 to WHA69 is conveyed in <u>A69/64 WHA69.15</u>

PHM comment

The auditor notes the dramatic improvement in compliance with regard to direct financial cooperation (DFC), funding transfers from country office to national government.

In relation to information systems, the auditor recommends that WHO:

- develop 'a concrete and formal Information Technology (IT) Strategic Plan';
- establish an IT Board to oversight IT projects and ensure that the IT strategy is aligned with the strategic goals of the Organization;
- establish an IT Performance Management Framework; and
- upgrade the role of Chief Information Security Officer.

21.2 Report of the Internal Auditor

Contents

- In focus
- Background
- PHM comment

In focus

The role of the Internal Auditor is to evaluated and improve risk management, control and governance. It undertakes 'integrated audits' of selected country offices or departments at regional or head offices; 'operational audits' of cross cutting functions and various offices and departments. The office also undertakes investigations into causes for concern.

A70/44 provides summary reports regarding integrated audits of:

- the Department of Health Systems Governance and Financing;
- WHO in the United Republic of Tanzania;
- Communicable Diseases Cluster at the Regional Office for Africa; and
- Maternal, Newborn, Child and Adolescent Health Department at headquarters.

It reports on 'operational audits' of:

- Global Management System user provisioning;
- Oracle workflow and project approval application controls; and
- WHO Staff Health Insurance:
- the regional offices for South-East Asia and the Eastern Mediterranean;
- country offices in Syria, South Sudan, Russia, Lebanon, Maldives, Rwanda,
 Comoros and Ghana; and
- the Polio Eradication Initiative at the country offices in Afghanistan and Pakistan.

The Office is also responsible for conducting investigations of alleged wrongdoing. <u>A70/44</u> provides summary reports regarding such investigations.

The reports of audits and investigations provide useful insights into the work of the Secretariat.

The Internal Auditor also reports on the status of previous audit recommendations and evaluates organisational risk. Annex 5 (from page 30) is particularly useful.

Background

Previous reports from the Internal Auditor are linked from here.

PHM comment

The report describes a range of operational shortfalls in its various audit reports. The Internal Auditor (in Annex 5) rates as severe the following risk areas:

- financing of the programme budget 2016/17;
- WHO's health emergency program;
- the polio transition.

These risks are in large part a consequence of the freeze on assessed contributions and the inadequacy and inflexibility of earmarked voluntary contributions.

22.1 Human resources: annual report

Contents

- In focus
- Background
- PHM comment

In focus

The human resources annual report is conveyed in <u>A70/45</u>, supplemented by data available online in the HR Tables 2016.

Background

Highlights from the 2016 report and the data tables include:

- the increasing proportion of staff in country offices and slight decrease in regional office staff:
- increasing use of temporary appointments and of non-staff contracts (as part of making the Organisation more 'flexible' and 'agile';
- the male skewed gender balance in the staff profiles of Afro and EMRO;
- the relative youthfulness of professional and senior staff in WPRO, EMRO and Euro and the relatively older staff profile in Afro and SEARO;
- the reliance on interns, just under one intern for every two professional staff;
- the relatively high number of interns in headquarters, Euro and WPRO compared with Afro, EMRO and SEARO;
- the low proportion of interns from developing countries, especially in Headquarters and in WPRO (the top four 'donors' of interns (the US, Australia, the UK and Canada) contribute 42% of all interns).

The report describes the implementation of the human resources strategy including:

- performance management,
- geographic mobility,
- internal justice,
- occasional teleworking,
- emergency response, and
- · whistle-blowing.

Highlights from the data tables include:

Documents and commentary regarding this item in previous WHAs are linked from here.

PHM comment

Increasing use of temporary appointments and non-staff contracts

Para 3 of the <u>HR Strategy</u> comments that

The main objectives are to ensure that the revised HR strategy supports WHO's strategic direction and priorities and responds to HR needs at all three levels of the

Organization, taking into account WHO's financing model. To achieve these objectives, WHO needs a workforce that is more flexible, more mobile, highly performing, and fully trained and ready to take on new professional challenges.

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

Commenting on the abolition of continuing appointments the staff associations' report to EB135 in May 2014 (EB135/INF./1) highlighted the need to balance managerial flexibility with technical depth and institutional memory. There is nothing in the Strategy or this annual report which shows how the Secretariat proposes to manage this balance.

PHM calls upon the member states to lift the freeze on assessed contributions; increase and untie voluntary donations and, in the words of the WHO Reform Stage 2 Evaluation (2013), to fulfill "their duty of care for the Organization, notably through adequate financing" (EB134/39, p11).

Global mobility

The move to mandatory rotation (in the context of the move away from permanent appointment) will need to be carefully evaluated for unintended adverse consequences.

The principle of declaring certain positions non-rotatory makes sense although in many organisations it is the person rather than the position who is of unique value in particular settings.

Geographical balance

A70/45 reports that 32% of MS are 'under represented in the international professional staff category. See also Table 3 of the HR Tables which lists the MS identified as under- and over-represented as of Dec 2016. The use US with 154 professional staff in the Secretariat is recorded as being under-represented.

The formula for determining that a country has the right number of professional staff (Resolution <u>WHA56.35</u>) gives great weight to the financial contribution of the country. This is inappropriate. The bias should be towards countries with needs for human resource development and high public health needs.

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

Interns constitute around 16% of the human resources upon which WHO depends. Both interns and junior professional officers represent very promising pathways towards recruitment to formal employment. For interns see Tables 16 to 18 in the
HR Tables 2016">HR Tables 2016.

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

23.1 Overview of WHO reform implementation

Contents

- In focus
- Background
- PHM comment

In focus

<u>A70/50</u> reviews progress in WHO reform since the report to the WHA69 (<u>A69/4</u>). The report deals with programmatic reform, governance reform and management reform.

<u>A70/50 Add.1</u>, conveys the executive summary of the report of the 'third stage evaluation of WHO reform' prepared by an independent external evaluation team. It appears that the full report has not been published.

In <u>A70/50 Add.2</u> the Secretariat reports on WHO's performance and results at country level throughout the era of the MDGs and into that of the SDGs in three domains: (1) WHO's leadership and convening role, (2) WHO's technical cooperation and operational role in health emergencies, and (3) WHO country offices' administration and management to ensure accountability for resources and results.

The biennial report on country presence (A70/INF./3) reports on: (i) who we are as an organization; (ii) what we do to support countries, territories and areas; (iii) how we do our work at country level; and (iv) with whom we work. It is based on an online survey, access to administrative data, and some external sources. The full report (here) also describes a range of illustrative 'success stories' and includes a series of descriptive and statistical annexes.

Background

An overview history of the WHO reform program is provided in the PHM comment on this item at EB140 (<u>here</u>). For a more detailed review and full critique of WHO's reform program see <u>Legge (2016)</u>.

PHM comment

Specific comments on the present documents

Under governance reform there is no reference in <u>A70/50</u> to WHO's role in global health governance, or to the challenges of 'alignment and harmonisation' across regions and levels. The report notes the continuing constraints in relation to adequate, predictable, flexible funding.

<u>A70/50 Add.1</u> is a useless evaluation which constructs WHO's financial crisis largely as a consequence of its management and governance failures and makes no reference to the real politik of deliberately imposed donor dependence, directed to maintaining donor control

over WHO's effective agenda. Indeed the recommendations under priority 1.2 'Link financing to value delivery' would appear designed to further entrench donor control. It appears that the full report has not yet been published.

<u>A70/50 Add.2</u> appears to be a hastily put together report, with comments on staff development and performance evaluation mixed with selected anecdotes of country office activities. It is quite surprising that a report on country office performance is not structured around the 'country office deliverables' which are set out clearly in the programme budget (see PB16/17 in <u>A68/7</u>) nor is there any analysis of performance against country cooperation strategies.

The biennial report on country presence (A70/INF./3) advises that a total of 109 country offices (out of 148) reported the existence of, or undertaking work on, country cooperation strategies. Of these 109, 63 reported having a valid country cooperation strategy. This is less than half.

The document is not structured in any degree around either the country cooperation strategies nor the country office 'deliverables' set out in PB16/17. The 'output indicators' in the programme budget are quite mechanistic, lacking in validity and reliability, and purely summative and as such offer no scope for learning. In contrast this report is an unfortunate compromise between a resource to describe and explain WHO's work at the country level and a sharing and learning platform. The aspirations expressed in many of the Reform papers for WHO to become a 'learning organisation' do not appear to have yet been realised.

More general comments on the WHO reform program generally

Many of the reform initiatives reviewed in <u>A70/50</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) trom 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 Global [governance] Redesign Initiative.

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.

23.2 Governance reform: follow-up to decision WHA69(8) (2016)

Contents

- In focus
- Background
- PHM comment

In focus

At present the EB is required to include on the provisional agenda of the Health Assembly 'any item proposed by a Member or Associate Member'.

As part of streamlining the WHA agenda, <u>A70/51</u> proposes rule changes which would give the Board the authority to defer or to not include on the provisional agenda items proposed by member states.

This is likely to be quite controversial with some MSs opposing any restriction on their right to propose and have accepted additional items for the Health Assembly.

Background

The origins of WHA69(8)

Governance reform was adopted as one of the three main poles of the WHO Reform program in Decision <u>EBSS2(2)</u> adopted at the Second Special Session of the EB (EBSS2) in November 2011.

Governance reform included 'methods of work of the governing bodies' and 'the alignment of governance across global and regional governing bodies'. Not much progress was made until Jan 2015 when in <u>EB136(16)</u> the EB established the Member State Consultative Process on Governance Reform.

In Jan 2016 (through <u>EB138(1)</u>) this morphed into an Open-ended Intergovernmental Meeting on Governance Reform. The work of the Meeting commenced with a working group (report here) and then two member state meetings.

The member states were able to agree on very few of the recommendations of the working group and in A69/5 reported to WHA69 (May 2016) on what was agreed (or not).

The Assembly adopted decision $\underline{WHA69(8)}$ which sought to progress the agreed recommendations of the Open-ended Intergovernmental Meeting ($\underline{A69/5}$).

The decisions in WHA69(8) included:

- developing a forward looking schedule for the agenda of the EB and WHA;
- tighter agenda management for the EB and WHA;
- proposals for closer correspondence between hours available and number of agenda items;

- tightening the rules for additional, supplementary and urgent items;
- better use of information technology to support governing body meetings;
- improved senior management coordination;
- publication of delegations of authority and letters of representation;
- consideration by RCs of procedures for nomination of regional directors, in accordance with WHA65(9), 2012;
- improved transparency of process for selection of ADGs;
- strengthened planning mechanisms (eg category networks and the results chain);
- 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 noted);
- strengthening WHO cooperation with countries (improved reporting from regional and country offices to RCs; a biennial WHO country presence report (EB140/INF./2).

A range of these issues were considered by the EB140 in Jan 2017 with a range of Secretariat reports and proposals (linked here) and extended discussion (PSR16).

The paper presently before the Assembly (<u>A70/51</u>) is focused mainly on the rules for Executive Board consideration of items for inclusion on the provisional agenda for the Health Assembly. Two different possible revisions of Rule 5 are presented.

PHM comment

Authority to defer, not to exclude

PHM urges MS to adopt the proposed rule change in Table 2 (authority to defer) rather than Table 1 (authority to exclude).

Governance reform an unfinished agenda

Two broad sets of issues have been considered under 'governance reform': 'methods of work' and 'alignment of governance across regional and global governing bodies'.

While some progress has been made in relation to the former, member states have been reluctant to address the alignment dysfunctions. See PHM commentary prepared for WHA69 on regional autonomy versus alignment of governance.

The report of the 2015 Working Group on Governance Reform (<u>EB/OMSMGR/2/2</u>) sets out a substantive agenda for governance reform including 'alignment' which remains relevant. The provisions of <u>WHA69(8)</u>, based on the 'agreed recommendations' of the Open-Ended Intergovernmental Meeting is much more tentative.

PHM urges MS to reconsider the WG recommendations.

23.3 Engagement with non-State actors

Contents

- In focus
- Background
- PHM comment

In focus

In <u>A70/52</u> the Secretariat reviews the history of the adoption of the Framework of Engagement with Non-state Actors(FENSA), through <u>WHA69.10</u> in May 2016; provides a brief description of the provisions of the Framework, and reports on its implementation, including regional adoption and creation of the <u>register</u>. See also <u>EB140/42</u> on Official Relations and Decision <u>EB140(10)</u>.

One of the most vexed questions during the FENSA debates concerned secondments, including from private sector entities, into the WHO Secretariat. WHA69.10 finally resolved that WHO will not accept such secondments. WHA69.10 also asked the DG to prepare a set of criteria and principles for secondments from nongovernmental organizations, philanthropic foundations and academic institutions. They are set out in document A70/53.

Background

A useful overview of the debates around the development of the FENSA is provided in PHM's commentary on Item 14.3 at EB140.

Links to all of the meetings where FENSA has been discussed are here.

PHM comment

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 (recalling MPACT, Sugar, Descriptions of public accountability (recalling MPACT, Sugar, Descriptions of public accountability (recalling MPACT, Sugar, Descriptions of public accountability (recalling MPACT, Sugar, Descriptions of public accountability (recalling MPACT, Sugar, Descriptions of public accountability (recalling MPACT, Sugar, Descriptions of public accountability (recalling MPACT, Sugar, Descriptions (recalling Descriptions (recalling MPACT, Sugar, Descriptions (recalling MPACT, Descriptions (recalling <a href="MPACT"

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.

Criteria and principles for secondments

<u>A70/53</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.

<u>A70/53</u> 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
 might 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.