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11.1 Overview of Reform Implementation

In focus

The Secretariat has published a report (A69/4) providing the following:

- an overview of the current status of reform;
- a review of progress made in the three broad reform workstreams (programmatic, governance, and management reform); and
- reports on indicators that have been established to measure achievement of the reform objectives.

Advice of the PBAC regarding A69/4 will be published as EB139/2 (NYP).

Advice of the PBAC regarding previous version of this report ($\underline{\mathsf{EB}138/5}$) is in $\underline{\mathsf{EB}138/3}$. Notes of discussion of $\underline{\mathsf{EB}138/5}$ at $\underline{\mathsf{EB}138}$ is at $\underline{\mathsf{PSR3}(12)}$.

Other aspects of WHO Reform on this WHA69 agenda include:

11.2 Member state consultative process on governance reform

PHM Comment

11.3 Framework of engagement with non-State actors

PHM Comment

14.9 Reform of WHO's work in health emergency management

PHM Comment

20.2 Financing of Programme budget 2016–2017

PHM Comment

Background

See the WHO Reform page for further background on WHO Reform.

There is a reference in A69/4 to WHO joining the International Aid and Transparency Initiative (IATI). More about IATI from IATI itself here; from Wikipedia here; and from UNDP here.

PHM comment

WHO suffers from weaknesses (governance, programmatic and managerial) and much of the work going into the present reform program is very worthwhile.

Donor dependence and the freeze on assessed contributions

However, the dysfunctions associated with donor dependence consequent upon the freeze on assessed contributions is the most fundamental disability and it is being ignored by most of the member states. WHO's dependence on donor financing has led to donor capture of WHO's operational agenda; with gross misalignments between priorities identified in the Assembly and expenditures underwritten by donors. Equally destructive has been the competition for donor funds between clusters, departments and regions. Departments are forced to compete for

opportunities for visibility, including workshops, publications, projects and governing body resolutions. Not surprisingly collaboration suffers when colleagues are seen as competitors.

The establishment of a Department for Coordinated Resource Mobilization within the Director-General's Office is appreciated but it remains to be seen how effectively it can overcome the fragmenting dynamic of competition for funds.

Beyond donor capture and the fragmenting effect of internal competition, is the fact that WHO's budget is in absolute terms quite inadequate. <u>Kickbusch (2013)</u> notes that the annual budget of WHO is comparable to that of the Geneva Cantonal Hospital and she compares the miniscule WHO budget to the global cost of SARS, the increased funding which China has allocated to rebuilding rural medical care and the huge budgets of the Global Fund and the Gates Foundation.

Indicators

A69/4 reports that some progress is being made in these three areas and reports on the attempts being made to measure progress in reform. The validity and reliability of some of these metrics are very problematic. In other cases the metrics have yet to be developed.

International Aid and Transparency Initiative

PHM applauds WHO joining the IATI. While WHO is not a large donor the documentation and acquittal of direct financing transfers has been poor and presumably this will be included in the IATI data set. Annex 4B in A69/51 suggests that internal controls over direct financing transfers were ineffective in 48% of cases in 2015 (which is an improvement on 2014 when the comparable figure was 70%). See Annex 4A in A69/51.

However, more important than applying the IATI to WHO is the use of the IATI dataset to strengthen the accountability of the major health development donors. See for example Open UNDP.

11.2 Member State consultative process on governance reform

In focus

A69/5 conveys the report of the Open Ended Intergovernmental Meeting on Governance Reform (OEIGM) as mandated by EB decision EB138(1).

A69/5:

- 1. reports that it did not have time to discuss the Draft Guidelines of Best Practice on Governance Reform (Appendix III to EB138/6);
- 2. reports that there was no consensus on a way forward (without specifying where the conflict was); and
- 3. proffers a draft decision for the Assembly to consider.

The draft decision deals with the management of governing body agendas; senior management structures and practices; and cooperation with countries.

Background

The original mandate for this process covered:

- 1. working methods of the governing bodies; and
- 2. concrete ways to improve the alignment of the governance of all three levels of the Organization (Decision EB136(16) (2015)).

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

There are also some sensitive structural issues under 'alignment of governance', the most sensitive of which concerns the election / nomination of regional directors. This issue simmered below the surface during the EBSS/3 on Ebola and during EB136. At the end of the debate on WHO reform at the EB (here) the DG berated MS who had implied that there might be a problem regarding the accountability of regional directors (perhaps she protested too much). Nevertheless the mandate given to the MSCP, regarding 'the alignment of governance' across the three levels of the Organisation, implicitly includes consideration of the split accountability of the regional directors to both the DG (and through her to the EB and Assembly) and separately to the regional committees and member states. See report of EB/OMSMGR/1/2 for a list of the issues identified regarding alignment of governance.

The report to the EB in Jan 2016 (<u>EB138/6</u>) provided details on the outcome of the Second Open Member States Meeting on Governance Reform, held in Geneva on 10 and 11 December 2015. See <u>OMSMGR</u> page.

The December OMSMGR had before it the recommendations of the Working Group on Governance Reform in <u>EB/OMSMGR/2/2</u> (30 November 2015) which was included as Appendix I in EB138/6.

The Dec 2015 meeting of the OMSMGR was able to agree on very few of the recommendations of the WG. See the bracketted onscreen text version of the recommendations included at <a href="https://doi.org/10.1007/nc.100

The PBAC had considered the outcomes of the Dec 2015 meeting prior to EB138 and recommended to the Board that a drafting group be established during the Board meeting to consider next steps.

The EB debated the issues and appointed a small working group to advise on next steps. This group reported back at the eighth meeting with a draft decision which was adopted as EB138(1) (PSR8)

See PSR4 for official record of discussion.

To access more of the documents of relevance to this process see:

- the <u>online platform</u> established to support the member state consultative process (MSCP)
- the 'homepage' for the OMSMGR.

See also JIU reports:

- Review of Management, Administration and Decentralization in the World HealthOrganization (WHO) - 2012 Part II
- Review of Management, Administration and Decentralization in the World HealthOrganization (WHO) - 2012 Part I
- Review of management and administration in the World Health Organization(WHO) - 2001

PHM comment

The recommendations of the <u>WG</u> were constructive and practicable. The opposition to those recommendations, as reflected in the brackets in <u>Appendix II</u> and the report from the OEMSMGR in A69/5 is unfortunate.

However, the issues run deep.

Regional autonomy versus alignment of governing bodies

It appears that most of the opposition was to WG recommendations which might have been seen to reduce the autonomy of regional committees and regional directors.

Regional dysfunction consequent in part on the arrangements under which regional directors are appointed is a major disability for WHO. This was brought out particularly clearly in the report of the Ebola Interim Assessment Panel which was critical of the communication and judgement of the Secretariat including both regional and headquarters units. The Panel was also critical of the lack of compliance of member states with the requirements of the IHRs incliuding both capacity development and breaches of the regulations through the imposition of illegal travel restrictions.

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

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

The findings of the most recent report of the Joint Inspection Unit (<u>JIU2012</u>) are worth reviewing:

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

The powers vested by the Constitution in the Regional Directors as elected officials weaken the authority of the Director-General as chief technical and administrative head of the Organization, compared to other United Nations system organizations, and have been a source of tension in their relationship in the past....

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

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

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

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

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

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

A recent review conducted by Chatham House in the UK (Clift 2014) commented that ... numerous external reports going back more than 20 years have identified key problems arising from the WHO's unique configuration of six regional offices, with directors elected by

member states, and its extensive network of about 150 country offices. While these reports have recommended sometimes radical reforms, there has been hardly any response from the WHO and its member states. This is because the governance structures in the WHO mean that there is a very strong interest in maintaining the status quo.

Clift quotes Chow (2010) as commenting that 'Regional leadership posts are pursued as political prizes'. Chow comments further

With competition between branches and body, the assignments of WHO country representatives often involve extensive negotiations between the power in Geneva and the power in the region. Key appointments have many a time been blocked not by qualifications of the individuals but for political reasons.

Clift refers to the 1993 JIU report which:

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

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

The JIU report of 2012 commented that:

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

The reluctance of MS to reform the central regional relationships in the context of the OMSMGR process points towards continuing dysfunction.

Lack of member state accountability

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

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

In the context of the Ebola crisis the disregard of their obligations regarding 'additional measures' under the IHRs by certain MSs illustrates. However, the disregard by member states of their obligations under a wide variety of resolutions, strategies and plans. Of course MS have the right not to implement such but they should be asked to account for what they have or have not done.

The repeated emphasis on the voluntary nature of MS obligations within WHO stands in sharp contrast to the binding commitments with serious sanctions being implemented through plurilateral trade agreements. Notwithstanding the Doha Declaration of 2001 it appears that the trade interests of powerful countries overrides the health goals arising from the WHO Constitution.

There has been an extended discussion over recent years of the importance of protecting the integrity of the WHO from conflicts of interest arising from experts who provide advice or the institutions with whom WHO collaborates. However, there have been some quite high profile instances where lack of accountability on the part of MS has significantly undermined the integrity of WHO. See our WHA68 commentary under NSAs (here regarding a number of such cases.

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

Ultimately the constituency, to which MS officials are presumed to be accountable, is the domestic electorate and there are precedents (NCDs, tobacco control, breastfeeding) which illustrate the possible roles which could be played by professional constituencies and community based organisations in mediating more firmly such accountability. However, to fully recognise the power of domestic civil society in health development might make ministers uncomfortable.

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

The suspicion, disregard or neglect with which member states treat WHO is nowhere more evident than in relation to the freeze on assessed contributions and the refusal of donors to untie their donations.

This has had direct impact on the coherence of WHO's programmes.

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

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

Beyond donor capture and the fragmenting effect of internal competition, is the fact that WHO's budget is in absolute terms quite inadequate. <u>Kickbusch (2013)</u> notes that the annual budget of WHO is comparable to that of the Geneva Cantonal Hospital and she compares the miniscule WHO budget to the global cost of SARS, the increased funding which China has allocated to

rebuilding rural medical care and the huge budgets of the Global Fund and the Gates Foundation. It is clear that WHO's response to the Ebola crisis was severely restrained by the continuing freeze on assessed contributions (<u>Gostin and Friedman 2014</u>).

WHO's role in the wider structures of global health governance and global governance for health

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

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

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

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

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

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

11.3 Framework of Engagement with NSAs

In focus

A69/6 conveys the outcomes of the OEIGM convened in late April 2016 in accordance with EB138(3).

A69/6 comprises (i) the draft framework including square brackets (attachment from page 7); (ii) a draft resolution including brackets (appendix from page 4); and (iii) the chair's report including chair's text for certain contested paragraphs, some of which has been agreed.

It appears that agreement has been reached in all respects except certain issues regarding private sector entities. The chair suggests further consultations regarding the draft resolution during the period of the Assembly and further discussion in the Assembly of the chair's proposed paragraphs regarding PSEs and certain (agreed) paragraphs of the draft framework with reference to implementation.

It appears that A69/INF./2 (NYP) will be the Secretariat document required by EB138(3), "an objective and balanced report on the implications for WHO of the implementation of the framework".

PBAC24 considered this item prior to the Assembly and recommended (A69/60) that: that item 11.3 of its provisional agenda be opened early in Committee A in order to establish a drafting group to finalize the draft framework of engagement with non-State actors and the related draft resolution, and expressed the expectation that this work could be concluded in, and the framework adopted by, the Sixty-ninth World Health Assembly.

Background

<u>Legge (2015)</u> in Third World Resurgence (July 2015) provides a broad overview of the ongoing struggle for the control of WHO: member states or donors or corporations.

The pre-history of the FENSA debate incorporates a range of dynamics:

- the freeze on assessed contributions, increased dependence on tied donations, and the budget ceiling;
- the increasing pressure on WHO to construct all of its programs in terms of 'multistakeholder partnerships', incorporating transnational corporations who are subject to sharp conflicts of interest, as 'partners';
- previous initiatives directed to providing formal structures for the engagement of transnational corporations in WHO deliberations (the so-called Committee C proposal, and the proposed World Health Forum).

The PHM commentary prior to <u>WHA68</u> provides a detailed overview of FENSA related issues since 2013.

WHA68 considered A68/5 which presented the current state of agreement and disagreement regarding the draft FENSA. The debate over FENSA at WHA68 is reported in the provisional

summary records of WHA68: <u>PSR1(6)</u> (one para), <u>PSR14(2)</u> (one para); <u>PSR15(3)</u> bracketted text; 44-51.

See also Resolution A68.9 (which requests the DG to convene an open-ended intergovernmental meeting to continue working towards a consensus around the FENSA).

EB138 considered <u>EB138/7</u> which conveyed the outcome of the open-ended intergovernmental meeting regarding FENSA which was convened in line with resolution <u>WHA68.9</u> (2015).

Provisional summary records of FENSA discussion at EB138: <u>PSR4</u>, <u>PSR5</u>, <u>PSR13</u>. EB138 decided (<u>EB138(3)</u>) to extend the mandate of the OEIGM to include a meeting in late April the result of which will be reported to WHA69.

Further resources can be located on the Secretariat <u>resources page</u> and the Medicus Mundi International WHO Reform repository.

There have been significant differences of opinion among the various critics of the current FENSA draft:

- is the emerging FENSA too complex to be operationalisable? (this will be addressed, from the Secretariat perspective, in A69/INF./2; PHM has argued this case for sometime);
- to what extent can protocols and procedural safeguards contain the influence of the corporate sector when the big donors are driving a programming model (the 'multistakeholder partnership') which incorporates a privileged role for the corporate sector?
 On the practicability of the FENSA, see:
 - the October 2015 <u>non-paper</u> produced by the Secretariat (which was criticised by some observers as being too pessimistic); and
 - the March 2016 report of the <u>external auditor</u> on the organisational implications of FENSA.

PHM comment

The debate over FENSA has highlighted the deep and fundamental conflicts of interest confronting private sector 'partners' in WHO programs. While the focus of the FENSA discussions have been on protecting Secretariat deliberations and actions from covert distortions, the overt pressures of the donors are driving policies and program models which privilege the corporate interest, in particular 'multi-stakeholder' 'partnerships'.

The multi-stakeholder partnership guarantees the private sector a 'seat at the table' and hence a privileged position to prevent effective regulatory strategies.

In many respects the debate over FENSA is a side show. The fundamental issues are:

- donor capture of the WHO agenda and the undermining of member state sovereignty;
- neoliberal globalisation, including the ascendancy of transnational capital, and the weakening of WHO's capacity to recognise the associated threats to health, far less take action on them;
- the lack of accountability of member states (to their peers and their publics) for their custody of WHO as a global institution, their defence of WHO's integrity and for the implementation of WHO norms.

12.1 Maternal, infant and young child nutrition

In focus

Several different issues will be considered under this item:

- progress made in the implementation of the Comprehensive implementation plan on maternal, infant and young child nutrition (A69/7 paras 3-25);
- progress in the implementation of the <u>International Code of Marketing of Breast-milk</u> <u>Substitutes</u> (A69/7 paras 26-30);
- management of conflict of interest in nutrition programmes (A69/7 paras 31-33);
- draft guidance regarding inappropriate promotion (A69/7 and A69/7 Add.1); and
- Rolling out the UN Decade of Action on Nutrition (<u>A69/7 Add.2</u>).

Progress in the implementation of the Comprehensive implementation plan on maternal, infant and young child nutrition

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

WHA68 (in 2015) adopted decision A68(14) which adopted an expanded set of indicators for monitoring the CIP.

Progress towards the global targets is reported in A69/7.

See some of the background to this item summarised in PHM's commentary on Item 13.2 from WHA68.

This item also overlaps with the SDGs, specifically SDG2.

Implementing the Code of Marketing of Breast-Milk Substitutes Is reported in paras 26-30 of A69/7.

COI in Nutrition

The Secretariat also reported on the outcome of the consultation on identifying and managing conflict of interest in relation to nutrition issues. See the <u>report of the COI consultation</u>. The consultation appears to have been quite successful in delineating key issues and suggesting tools for risk assessment and management. There are no formal recommendations for carrying forward the issues identified through the consultation, either in the report of the consultation or in A69/7.

See PHM commentary from WHA67 regarding: COI in Nutrition, and GAIN and ISDI.

Guidance on inappropriate promotion

The most contentious paper will be the draft *guidance on ending the inappropriate promotion of foods for infants and young children* (current draft not yet available). The main decision focus

will be on the draft resolution on the *inappropriate promotion of foods for infants and young children* which is still subject to intersessional discussion (and not yet available).

A69/7 also reports on the findings of a Scientific and Technical Advisory Group (STAG) on inappropriate promotion of foods for infants and young children. The STAG proposed a set of recommendations on approaches to limit the inappropriate promotion of foods for infants and young children and a draft resolution for EB consideration.

The debate at EB138 is recorded in <u>PSR12</u>. There were comments touching on many of the different issues raised in the Secretariat report. At the conclusion of the debate:

The CHAIRMAN took it that the Board wished to request the Secretariat to revise the Guidance on ending the inappropriate promotion of foods for infants and young children taking into account the comments made during the discussion and any further comments made up to the end of February 2016. She also took it that the Board wished to request the Secretariat to hold intersessional consultations in order to review the draft resolution prior to the Sixty-ninth World Health Assembly. It was so agreed.

<u>A69/7</u> is a revised version of <u>EB138/8</u> taking into account comments made during the discussion at EB138 and during the following four weeks as well as the outcome of an informal consultation (in Geneva, 8 April 2016). <u>A69/7</u> advises that both the Guidance and the draft Resolution are still subject to intersessional consultation (<u>A69/7 Add.1</u> provides a revised draft of the Guidance; the draft resolution is not yet available).

UN Decade of Action

A69/7 Add.2 reports on work underway to roll out the UN Decade of Action on Nutrition (2016-2025) as authorised in <u>UNGA 70/259</u>. The first step will be a 'commitment conference' to be held in association with the UNGA in September 2016. This will lead to a work programme and biennial reporting.

See PHM commentary on Item 13.1 (ICN2) at WHA68.

Background

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 crisis has complex determinants including:

- the realities of hegemonic global production, distribution, marketing and consumption 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.

Progress in implementing the Comprehensive Implementation Plan

The degree of 'progress' in relation to the five targets (stunting, anaemia, low birth weight, overweight and breastfeeding) has been very slow and in some cases going backwards.

At a general level the Actions identified for the CIP are sensible but they are largely cast in general terms and do not appear to have progressed very far.

It appears that progress in developing and implementing national plans has been particularly slow. The national plan must deal with major intersectoral issues and such whole-of-government policy work is always hard. However there are also powerful industries watching very closely and ready to intervene to protect their interests.

PHM is very concerned about WHO's reliance of SUN for providing support to countries. SUN includes corporations and business organisations which are deeply invested in national food systems. Indeed one of the functions of SUN's Business Network is to recruit more business organisations to the SUN network. It is unfortunate that SUN was not considered as a case study in the Technical Consultation on COI in Nutrition.

PHM urges WHO at global, regional and country level to invest more in working with civil society networks to strengthen the political demand for effective national plans and for full implementation.

The work of the CFS in following up the recommendations of ICN2 is appreciated. However, these recommendations were disappointing in many respects. See PHM Comment on ICN2 at WHA68.

The barriers to food security and food sovereignty in current trade and investment agreements need to be clearly addressed. **PHM urges staunch opposition to the use of ISDS to prevent effective regulatory strategies.** We urge a return to multilateral negotiations around trade in agricultural commodities to ensure the elimination of dumping and of protection and subsidies to corporate agriculture. WHO has a mandate (through <u>WHA59.26</u>, page 37) to take the lead in this work. 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 open negotiations with UNCTAD and HRC with a view to exploring in more detail possible strategies for regulating TNCs** (see PICS&SM statement).

Access to decent food, consistent with cultural traditions, is a basic human right (see OHCHR); the human rights perspective must permeate all policies and actions in this field. **PHM urges WHO to work with the Special Rapporteurs on the Right to Food and the Right to Health**

in preparing an information product on the human rights dimension of food and nutrition policies, and particularly the Outcomes commitments of the ICN2, designed to inform national nutrition planning.

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

Progress in implementing the Code

We regret the slow rate of progress in the implementation of the Code. Only 47 countries have adopted legal measures; only 27 countries are monitoring outcomes; political commitment is weak.

The lack of accountability of member states for implementing WHO resolutions is one of the core weaknesses of WHO, unfortunately not being addressed in the current reform programme.

Conflict of interest regarding nutrition programmes

The report of the Technical Consultation is rich with insights and suggestions.

Unfortunately there is no recommendation directed to giving authoritative status to the findings of the consultation and putting in place appropriate programs and regulatory structures.

Ending inappropriate promotion of foods for infants and young children The STAG reports that inappropriate promotion is happening widely.

The draft guidance document (<u>A69/7 Add.1</u>) includes some very useful ideas. In the version submitted to the EB the guidance was supported by a draft resolution requesting implementation action from governments, manufacturers and distributors, health care professionals, media and creative industries, civil society, and the Director General.

PHM urges MS to consider strengthening the draft resolution through including references to the bolded passages above.

Roll out of UN Decade of Action

The lead up to the Commitments Conference in September 2016 provides some opportunity for advocacy around ambition, equity, and sustainable development in relation to nutrition. See bolded passages above.

12.2 Report of the Commission on Ending Childhood Obesity

In focus

Document A69/8 conveys the final report of the WHO Commission, 'Ending Childhood Obesity' which was established in 2014. The report includes specific recommendations. It is likely that a resolution and plan of action will emerge.

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.

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

PHM Comment

We appreciate the report of the Commission and the comprehensive approach taken.

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.

PHM strongly supports the recommendations regarding the Sugar Tax and food labelling.

The Commission's recommendations are largely cast in terms of unhealthy foods which will elicit howls of protest from big food and big beverage regarding unhealthy rather than unhealthy foods. In this context Rec 1.4 'Develop nutrient-profiles to identify unhealthy foods and beverages' will be critical and if it is referred to the Codex it is likely to be stalled, watered down or simply not enacted.

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

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

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

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

12.3 Draft global plan of action on violence

In focus

The focus of discussion will be the Global Plan of Action on Violence, conveyed to the Assembly in $\underline{A69/9}$ and the draft resolution adopting the Plan of Action as recommended by the EB in EB138.R3.

The Secretariat report (A69/9):

- summarises the consultation processes which have been undertaken around the proposed Global Plan of Action;
- presents the report of the Nov 2015 meeting of member states convened in Nov 2015 to consider further the draft Global Plan of Action;
- presents the most recent draft of the proposed Global Plan of Action including various appendices.

This GPA is organized as follows:

- Section 1 introduces and describes the scope of the plan.
- Section 2 sets out the vision, goals, objectives, strategic directions and guiding principles of the plan.
- Section 3 outlines the actions to be taken by Member States, national and international partners, and WHO: This section is further subdivided into three sections:
 - Section 3.A focuses on violence against women and girls;
 - Section 3.B focuses on violence against children;
 - Section 3.C focuses on all forms of interpersonal violence: cross-cutting actions;
- Section 4 describes the monitoring and accountability framework, including mechanisms for reporting and suggestions for global-level indicators and targets.
- Appendices include a glossary of terms, links to relevant resolutions and consensus documents, and details of the Secretariat's work.

The four strategic directions are key to the structure of the Plan:

- Strengthen health system leadership and governance;
- Strengthen health service delivery and health workers'/providers' capacity to respond;
- Strengthen programming to prevent interpersonal violence;
- Improve information and evidence.

In <u>EB138.R3</u> the EB recommends that the Assembly adopts the plan of action. The EB debate is recorded in <u>PSR12</u>.

Background

WHO produced the World report on violence and health in 2002 and its recommendations endorsed in A56.24.

See WHO topic page on Violence.

Violence appeared on the EB134 agenda (Jan 2014) 'at the request of a member state'. (Work on the Global Status Report was underway at this time.) See:

- PHM commentary
- Secretariat report (EB134/21)

- Record of debate (13th meeting)
- Decision EB134(6)

Some of the key issues in contention during this discussion include: marital rape, female genital mutilation, dowry violence, rape, sexual abuse and references to the human rights and freedoms of women and girls.

It returned to WHA67 (May 2014) as Item 14.3. See:

- PHM commentary
- Secretariat report (<u>A67/22</u>)
- Record of debate
 - Committee A, First Meeting
 - o Committee A, Twelfth Meeting
- WHA67.15

After long and difficult negotiations WHA67.15 was adopted. One of the sticking points before adoption was the reference to '*intimate* partner violence'. Several delegations urged that *intimate* partner violence be removed.

The <u>Global status report on violence prevention 2014</u> was jointly published (December 2014) by WHO, UNDP and UNODC (office on drugs and crime).

Violence returned to EB136 (Jan 2015) as Item 6.5. See:

- PHM commentary
- Secretariat reports: (EB136/12, EB136/12 Corr.1)
- Record of debate

The Secretariat report introduced the Global Status Report and proposed the development of a global plan of action. There was appreciation of the Global Status Report and the proposed process and timelines were agreed to.

PHM comment

In many respects this is an excellent Global Plan of Action. It is comprehensive, evidence-based and strongly informed by humanistic principles. However, there are some weaknesses.

Invisibility of LGBTI people

A major flaw in the Plan is the invisibility of sexual orientation. While there is reference to 'vulnerable groups' in the introduction and the glossary there are no references in the substance of the plan to violence against gays, lesbians, bisexuals and transsexuals; such violence is common in many countries, including against children and young people.

A critical consequence of the exclusion of sexual orientation from the purview of this Plan is that there is no suggestion, in relation to monitoring, that data collection should include reference to sexual orientation. This perpetuates the invisibility of LGBT people in relation to violence and in doing so avoids action on homophobic violence.

Monitoring and data collection

Strategic direction 4: 'Improve information and evidence' references disaggregation by age, ethnicity, socioeconomic status and education, among other factors. It should include reference to LGBTI and to caste.

The SDGs commit to disaggregate data by a broader range of groups: income, sex, age, race, ethnicity, migration status, disability and geographic location and other characteristics relevant in national contexts (para 74g Agenda 2030).

Cultural barriers to access to services and information

There is no recognition of cultural barriers to accessing services, other that an acknowledgement of the disproportionate vulnerability of 'certain populations' (para 23). This is despite the fact that para 32 notes 'Few women and children access services in case of violence'.

For many marginalised women and children – indigenous people and other cultural and ethnic minorities, for example - the health sector remains inaccessible due to numerous social and cultural barriers. Without action to address these, the plan of action will not be applicable to some of the most marginalised people. The plan needs to acknowledge and introduce specific recommendations to address the cultural barriers that many women face in accessing health and other services. 'Culturally appropriate' should be included as an additional guiding principle in this Plan.

In Strategic direction 2: 'Strengthen health service delivery and health workers'/providers' capacity to respond', actions for member states should include explicit references for the need for care to be culturally appropriate and actions to address the cultural barriers such as language and discrimination which prevent women and children from culturally marginalised groups accessing care. These include training for health workers, community actors and therapists and religious leaders, the provision of materials in local languages and the participation of marginalised groups in decision making processes.

The principle of cultural appropriateness also extends to health information and education. Therefore Strategic direction 3: 'Strengthen programming to prevent interpersonal violence' should emphasize the need for education and messages to be culturally appropriate.

Post-discharge services

In some instances women may be discharged from hospital and have no option but to return home - which in cases of interpersonal violence may put them in direct access of the perpetrator. There should be a reference to immediate safety management – i.e. ensuring the patient is not discharged from medical care without access to a safe place of refuge.

Sexual violence as a weapon of war.

The action plan is weak in relation to sexual violence as a weapon of war.

In line with <u>UN Resolution 1325</u> on Women, Peace and Security, and <u>Resolutions 1820</u> and <u>1888</u> on sexual violence in conflict the Secretary General has called on UN Member States to

implement the <u>Women, Peace and Security Resolutions</u> through National Action Plans. Currently only a small number of countries have such plans associated with Resolution 1325.

12.4 Prevention and control of NCDs: responses to specific assignments in preparation for the third High-level Meeting of the UNGA on the Prevention and Control of NCDs in 2018

In focus

Documents:

Secretariat report A69/10
Record of EB138 debate PSR12,
Resolution EB138.R4

A69/10 notes the importance of the <u>SDGs</u> and the <u>Addis Ababa Action Agenda</u> (financing for development) for the prevention and control of NCDs;

Reports progress on specific global assignments arising out of WHA66.10 (2013), UNGA 68/300 and United Nations ECOSO 2014/10; specifically:

- describes progress made between 2013 and 2015 in implementing the WHO Global
 <u>Action Plan</u> for the prevention and control of noncommunicable diseases 2013–2020
 (Annex 1);
- proposes a process for updating <u>Appendix 3</u> of the GAP which sets out policy options and tools for achieving the nine global targets (<u>Annex 2</u>); the annex also proposes an addendum to Appendix 3 dealing with methodological and implementation issues;
- describes progress made in 2015 towards attainment of the nine global targets (<u>Annex</u> 3);
- describes the proposed development of an approach to register and publish the contributions of NSAs (PSEs, philanthropies, CSOs) towards the achievement of the nine global targets (Annex 4);
- reports on progress in implementing the <u>workplan of the Global Coordinating Mechanism</u> in 2014/15 (<u>Annex 5</u>);
- reports on progress achieved by <u>Inter-Agency Taskforce</u> (in <u>Annex 6</u>);
- set out the contours of a report to the UNGA in late 2017 on implementation of the 2011 Political Declaration (<u>UNGA66/2</u>) and the 2014 Outcomes Document (UNGA <u>68/300</u>) (in <u>Annex 7</u>);
- describes the 'NCD-related' SDG indicators developed by the UN Inter-Agency and Expert Group on SDG indicators and identifies WHO's role collecting and publishing data on these indicators as part of the global accountability framework (Annex 8);
- reports options for a purpose code to track ODA for NCDs (Annex 9).

The report also:

- reviews (<u>from para 15</u>) the four time-bound commitments to which Ministers are committed (through the 2011 Political Declaration (<u>UNGA66/2</u>) and the 2014 Outcomes Document (<u>UNGA68/300</u>));
- refers to the <u>WHO NCDs Progress Monitor 2015</u> through which national progress regarding the four time bound commitments is being measured and reported;

• presents a diagram which seeks to integrate the various policies, strategies, commitments and targets adopted at the national and global levels (Fig 2).

Finally, the report notes the draft resolution (<u>EB138.R4</u>) recommended by the EB for the consideration of WHA69. The proposed resolution endorses and enacts the proposals and exhortations presented elsewhere in the report and summarised above. The proposed resolution also requests the DG:

- to update <u>Appendix 3</u> of the Global Action Plan, dealing with policy options, in accordance with recently available evidence (as described in Annex 2);
- to submit an approach that can be used to register and publish contributions of non-State actors as provided for in Annex 4 of the report.

The mandate for the Secretariat's work on these various projects is given by:

- the Health Assembly (in WHA66.10, 2013);
- the Political Declaration of 2011 (United Nations General Assembly resolution 68/300, see Annex 1 of A68/11); and
- United Nations Economic and Social Council resolution <u>2014/10</u> regarding the Inter-Agency Task Force.

The mandate also includes <u>SDG3</u> ("Ensure healthy lives and promote well-being at all ages)" including the 13 health targets for 2030. WHO has <u>argued</u> that there are health implications arising from many of the other 16 goals.

The debate at EB138 (<u>PSR12</u>) canvassed a wide range of issues linked to the various initiatives summarised above.

Background

Global policy and decision making around NCDs has become very complicated with multiple overlapping mandates and forums of discussion/decision. The fundamental issues are at real risk of getting lost amidst the forest of documents, resolutions, objectives, commitments and indicators.

Nevertheless the politics of (non) decision making around NCDs is reflected in the history of this forest.

References to previous documents, and some analytical commentary can be found in the:

- PHM comment on Item 7 (Sugar Guidelines) at EB137 (May 2015);
- PHM comment on Item 13.4 (NCDs omnibus) at WHA68 in May 2015;
- PHM comment on EB136 (Jan 2015): Items 6.1 (ICN2), 6.2 (Maternal and Young Child Nutrition), 6.3 (Ending Childhood Obesity), and 6.4 (Follow up of 2014 HLM on NCDs); and
- the PHM comment on Item 13.1 (NCDs omnibus) at WHA67 (May 2014).

A range of useful resources can be accessed WHO's NCDs topics page and the NCDs & Mental Health programmes page.

PHM comment

PHM comments on specific Secretariat documents included in A69/10)

Annex 1. Implementation of Global Action Plan

This annex reports on progress at the National level; progress made by International Partners (development assistance donors) and civil society; and progress made by the Secretariat under each of the six objectives of the GAP.

The indicators purporting to measure progress in national capacity are highly questionable. It is not clear that the questions in the questionnaire are being interpreted in a uniform way by national respondents. It is not clear that the institutions and programs reported by respondents in response to specific questions have comparable levels of effectiveness in practice.

The culture of self-reporting by member states in WHO reflects a deep flaw with respect to MS accountability and constitutes a barrier to WHO effectiveness. It is a serious weakness of the WHO Reform Program that there has been no move to a more independent and more discerning reporting and review system such as operates in OECD, IMF, WTO and HRC, all of which deploy peer review systems.

In reporting Secretariat action there is no reference to the 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.

Likewise there is no reference to trade, tax, or the regulation of TNCs (other than tobacco). We appreciate the reference to capacity building in accordance with <u>WHA59.26</u> in para 11 but this appears to apply only to tobacco.

Annex 2. Process for updating Appendix 3 of the GAP

<u>Appendix 3</u> of the GAP comprises a list of evidence based policy options and interventions to support the achievement of the six objectives of the Plan. It was intended that this appendix would be reviewed periodically to ensure it remains abreast of contemporary evidence.

PHM urges the Secretariat to consider closely the need for trade and health policy coherence and the development of trade and health policy capacity in the revision of this appendix. We urge the inclusion of guidelines for health impact assessment of trade agreement provisions.

By way of illustration we refer to the secret TTIP negotiations currently underway threatening significant weakening of consumer safety standards. The introduction of investor dispute settlement provisions threaten to limit the power and responsibility of national parliaments.

Annex 3. Progress in attaining the nine voluntary global targets

Annex 3 presents global data for 18 indicators designed to measure progress towards the nine voluntary global targets. Some data for 2010 and 2014 are presented.

Many of the putative indicators have no data available but there is no discussion of the barriers to collection. Is this lack of funding? It is because the global targets are 'voluntary'? Perhaps

the collection of data is also 'voluntary'. Because of burden of disease in question the voluntariness of data collection needs to be urgently reframed in international health legislation.

There is no reference to methods for statistical evaluation of the differences between 2010 and 2014 for those targets for which data are available.

Annex 4. Contributions of NSAs to the nine global targets

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 targets.

This appears to be a very silly commitment. There is no discussion in <u>68/300</u> of the purpose of this provision. There is no argument presented along the lines of strengthening accountability or improving coordination and proposed procedures do not appear to offer any such benefits.

The main motivation for private sector entities to seek registration would appear to be the public relations benefits to be gained therefrom. The transaction costs of handling this publicity platform will be burdensome for WHO and not consistent with the emerging FENSA principles.

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

If a register of PSE 'contributions' were to make a contribution to public policy it would need to have some representational 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 CSOs. Rather PHM urges that CSOs take up this opportunity to register the contributions, positive and negative, of PSEs and philanthropies.

PHM urges the WHO Secretariat to assign a very low priority to progressing this project.

<u>Annex 5</u>. Progress in implementing the workplan of the global coordination mechanism (<u>GCM</u>)

Annex 5 presents a very brief summary of Secretariat action on eight action areas from the workplan of the GCM.

Three of these deal with the interface between development assistance and action around NCDs. Two dialogues and a web-based platform are reported. An initiative to disseminate best practice in intersectoral collaboration is reported. A series of webinars 'to support the coordinating role of WHO' is reported. A community of practice has been established (within the Secretariat).

Two working groups and their interim reports are reported on, dealing respectively with:

- Action 3.1: How to encourage the private sector to strengthen its contribution to NCD prevention and control (para 44 of 2011 Political Declaration); an interim report is published (WG3.1) and responses; a final report is due to the DG by end 2015;
- Action 5.1: How to realise the commitment in <u>para 45(d) of the Political Declaration</u> to 'explore the provision of adequate, predictable and sustained resources, through domestic, bilateral, regional and multilateral channels, including traditional and voluntary innovative financing mechanism'; an interim report is published (<u>WG5.1</u>) and <u>responses</u> and a final report is due with the DG by end 2015.

Action 5.1 concerns resource mobilisation for NCD responses. The Interim Report (i) acknowledges that such responses will have to rely primarily on domestic public resources; (ii) calls for more effective and scaled up ODA for NCDs action; (iii) recommends promoting investment by PSEs in areas critical to NCD control; and (iv) urges more philanthropy in this area.

Rec (v) is a useful reminder of the importance of addressing the coherence and consistency of financial, investment, trade, development and public health policy as a condition for mobilising sufficient funds for action on NCDs. The WG refers to para-30(a)(vi) of UN 68/300 and recommends consideration of:

- Strengthening safeguards in investment treaties to protect public health;
- Strengthening policy coherence between development, health, finance and trade sectors; and
- Promoting better alignment between existing multi-stakeholder partnerships, such as
 The Global Fund and GAVI, with a view to encourage them to improve their contribution
 to health system strengthening and universal health coverage in way that would also
 ensure better health outcomes for NCDs.

Currently, there is no procedure in place to ensure that recommendations of the Working Groups are reported to the governing bodies of WHO. PHM calls upon MS to request that a formal process is put in place to ensure that WG recommendations be reported to the governing bodies.

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

WHO has a mandate (through <u>WHA59.26</u>) to take the lead in this work, and not just in relation to tobacco or pharmaceuticals.

Conflict of interest

PHM notes the lack of any commitments in the GCM workplan to address the influence of big pharma, big food and big beverage on WHO and UN policy making around NCDs and points to the importance of managing effectively the risk of improper influence in relation to NCDs policy making.

During the recent GCMNCD dialogue meeting on international cooperation, that took place on 30 November and 1 December, participating civil society organisations have alerted the GCMNCD secretariat to the risks regarding conflicts of interest, the lack of transparency in the modalities for participation, and the failure to identify who is who in the meeting. Similarly, it was

highlighted that the selection process for Working Group members is not transparent and should be opened up for inputs from civil society. For future dialogues and on-line platforms and communities of practice, a coherent and transparent system of constituencies and related rules and procedures ought to be in place.

Transparency is only a first step though, and PHM urges that an additional function to be assigned to the GCM to monitor potential 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.

Annex 6. Progress of the Inter-Agency Taskforce

Annex 6 reports:

- joint country programming missions involving 'interested organisations' of the UN system;
- development of three joint global programs;
- the development of the 2016/17 workplan; and
- concern about collaborative and funding relationships between certain members of the Taskforce and the tobacco industry.

Regulation of TNCs

PHM calls on WHO to open discussions with the Human Rights Council regarding the proposed internationally legally binding instrument on TNCs and other business enterprises (A/HRC/26/L.22/Rev.1) with a view to developing a global joint program on the regulation of TNCs within the IATF, focusing on the regulation of foods and beverages in the first instance.

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.

Pharmaceutical innovation

PHM calls upon WHO to open discussions with appropriate members of the IATF (UNAIDS, UNICEF, IARC, etc) regarding a global joint programme on alternatives to market driven R&D and IP protected monopoly pricing as drivers of pharmaceutical research and innovation. This model is driving the prices of treatments for NCDs, such as cancer and autoimmune diseases, to absurd levels; to the point where public procurement or reimbursement programs, even in rich countries, are unable to offer such treatments.

Annex 8. Data collections and reports for global accountability framework

Annex 8 seeks to make sense of the maelstrom of targets and indicators proposed and adopted for tracking action around NCDs.

PHM notes that the focus of Table 1 (page 39) is restricted to the so-called Health SDG and discusses indicators related to NCDs from this point of view.

It is unfortunate that there is no mention in this annex of WHO's interest in following progress with respect to all of the other SDGs which have implications for NCDs.

PHM urges member states to request the DG to add a report to the list in Table 2 which provides an overview of progress in 'the other SDGs' - beyond health - which have implications for NCDs. See <u>table on page 5 from the WHO note</u> on a monitoring framework with targets and indicators for the health goals of the post-2015 Sustainable Development Goals.

Proposed amendments to the draft resolution

PHM proposes the following amendments to the draft resolution included in EB138.R4:

- OP1: NOTES the process to update, in 2016, Appendix 3 of the global action plan for the prevention and control of noncommunicable diseases 2013–2020;
- OP2: ENDORSES the process to further develop, in 2016, an approach that can be
 used to register and publish contributions of non-State actors to the achievement of the
 nine voluntary global targets for noncommunicable diseases; including provision for
 independent nomination and provision for negative contributions to be nominated;
- New OP2 (bis): <u>DECIDES to add to the TOR of the GCM a mandate to monitor potential conflicts of interest arising in the implementation of the Global Action Plan and to advise the DG where conflicts of interest may lead to improper influence on policies and programmes;</u>
- New OP3 (bis): <u>URGES donors to WHO (especially donor MS) to until their donations to WHO so that action on NCDs can be properly funded;</u>
- OP4. REQUESTS the Director-General:
 - OP4.1: to submit an updated Appendix 3 of the global action plan for the
 prevention and control of noncommunicable diseases 2013–2020, through the
 Executive Board, to the Health Assembly in 2017, in accordance with the
 timelines contained in Annex 2 of the report; and to give close attention to trade
 and health policy coherence and the development of trade and health policy
 capacity including the development of guidelines for health impact assessment of
 trade agreement provisions in the revision of Appendix 3;
 - OP4.2 to submit an approach that can be used to register and publish contributions of non-State actors, through the Executive Board, to the Health Assembly in 2017, in accordance with the timelines contained in Annex 4 of the report providing for independent nominations and providing that negative contributions can also be nominated.
 - New OP4.3 'to submit to EB139 proposals to progress recommendation 5 of WG5.1 (as reported in Annex 5) viz:
 - Strengthening safeguards in investment treaties to protect public health;
 - Strengthening policy coherence between development, health, finance (including taxation) and trade sectors; and
 - Promoting better alignment between existing multi-stakeholder partnerships, such as The Global Fund and GAVI, with a view to encourage them to improve their contribution to health system strengthening and universal health coverage in way that would also ensure better health outcomes for NCDs.
 - New OP4.4: to ensure that recommendations made by the Working Groups under the GCM be reported to the WHO governing bodies;
 - New OP4.5: <u>'to open discussions with the Human Rights Council regarding the</u> proposed internationally legally binding instrument on TNCs and other business enterprises (A/HRC/26/L.22/Rev.1) with a view to developing a global joint

- program on the regulation of TNCs within the IATF, focusing on the regulation of foods and beverages in the first instance;
- New OP4.6: <u>'to open discussions with appropriate members of the IATF</u> (UNAIDS, UNICEF, IARC, etc) regarding a global joint programme on alternatives to market driven R&D and IP protected monopoly pricing, as codrivers of pharmaceutical research and innovation.
- New OP4.7: to submit an annual report to the Assembly on progress towards
 NCD-related SDGs beyond those listed under SDG3.

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

In focus

In <u>A69/11</u> a resolution is proposed that would have the effect of including the outcome of the Conference of the Parties 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).

Background

It appears that people or organisations associated with the COP of the FCTC feel that the WHA has not been paying the COP "the attention it deserves" (see para 9 and 18).

PHM comment

No evidence is provided in A69/11 of any negative consequences for tobacco control arising from the reduced attention it has received (as a stand alone item) in recent years.

WHO member states have been going through agonising debates over the last four years around, amongst other things, control of the agenda of the Board and the Assembly. Under Item 11.2 of this agenda the Assembly will consider 'working methods' as part of 'governance reform'. 'Agenda management' is Included under working methods. See report of EB/OMSMGR/1/2 for a full list of identified issues concerning the working methods of the governing bodies.

PHM urges the Bureau of the Assembly to remove this item from the agenda of the Assembly.

12.6 Public health dimension of the world drug problem including the Special Session of the UNGA, to be held in 2016

In focus

The Assembly will consider A69/12 which conveys the outcomes (in A/RES/S-30/1) of the Special Session of the United Nations General Assembly on the World Drug Problem (19-21 April 2016) including recommendations which require action by WHO.

A69/12 also reviews key issues for public health consideration as part of 'the world drug problem' including:

- prevention of drug use and reduction of vulnerability and risks
- treatment and care of people with drug use disorders
- prevention and management of the harms associated with drug use
- access to controlled medicines
- · monitoring and evaluation
- WHO's role in the follow up of the special session of the UNGA on the World Drug Problem:

The Assembly is invited to note the report and provide further guidance regarding WHO's response to the public health dimension of the World Drug Problem. This sounds like a resolution is in the wings. See in particular paras 25-30 of A69/12.

The record of the EB debate is in <u>PSR13</u>. Many speakers highlighted the importance of harm reduction policies such as needle and syringe exchange programs (Thailand) although others were opposed. China suggested that references to 'harm reduction' were 'demeaning' and could encourage legalization of drugs. Several speakers regretted the shortages of therapeutically valuable drugs, especially opioid analgesics, as a consequence of tight restrictions on access.

Many speakers called for a full consideration of the outcomes of the UNGASS at the WHA in May and perhaps a new global action plan addressing the public health aspects of the world drug problem.

The UNGASS was held from 19-21 April (see the outcomes document in A/RES/S-30/1).

While the outcomes document does not mention 'harm', para 1(o) does endorse

'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, as well as consider ensuring access to such interventions, including in treatment and outreach services, prisons and other custodial settings, and promoting in that regard the use, as appropriate, of the technical guide for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users...'.

Background

See the <u>documentation prepared for the SS of UNGA</u>. See also the <u>Political Declaration and Plan of Action on International Cooperation towards an Integrated and Balanced Strategy to Counter the World Drug Problem (2009) will be reviewed at the April UNGASS.</u>

See WHO Management of Substance Abuse website.

PHM comment

This is an excellent report and should form the basis for a strong resolution and perhaps a global action plan.

Nevertheless, the analysis needs to be strengthened in certain areas.

There is a reference in para 11 of A69/12 to the need for action on the social determinants of drug use including unemployment and marginalisation but not much which reflects on causes of widening inequalities, intergenerational unemployment and deep alienation which contribute to communities who are predisposed to deploy mind altering substances to reframe their realities.

It is interesting to return to the Statement by the United Nations Under-Secretary-General and Executive Director of the United Nations Office on Drugs and Crime, Mr. Antonio Maria Costa which introduces the 2009 Political Declaration.

... the largest share of the world's drug trade and abuse can be traced to a few blocks, in a few neighbourhoods of a few big cities. The key to regaining control of these areas is for law enforcement, combined with social reintegration, to create viable alternatives for young people who are lost to addiction, or who have become urban child soldiers of crime syndicates. In a rapidly urbanizing world, drug control will be won, or lost, in the cities.

The world faces a rolling global economic crisis including a growing imbalance between productive capacity and effective consumption. The neoliberal response to this imbalance is to drive (through so-called 'free' 'trade' agreements) a process of global economic integration with a view to protecting the interests of powerful transnational corporations even though it contributes to a further widening of inequality and increases the numbers of excluded and marginalised. Talk about 'reintegration of marginalised people into their communities' in this context belongs to a parallel fantasy world.

The drug cartels use the same covert channels and havens for moving money globally as the big corporations use to avoid paying tax. However, the leading capitalist powers continue to stall on a multilateral agreement on taxation.

Another quote from Mr Antonio Maria Costa directs our attention to the role of imperial destabilisation and overt warfare in creating the conditions for drug trafficking.

While ghettos burn, West Africa is under attack, drug cartels threaten Central America, and drug money penetrates bankrupt financial institutions,

The role of the imperial powers forcing opium onto the Chinese is perhaps the most notorious example of imperial adventures in creating the conditions for drug trafficking or even promoting drug markets. However, it is not a unique case, nor is the practice of purely historical interest.

There is a long history of imperial interference in Central America and in the Eastern Mediterranean which has in many ways created the conditions for illicit drug cultivation and trafficking.

An exclusionary and unfair trade regime in agricultural products, designed to support Northern agribusiness, contributes to driving some farmers in unstable and conflict zones to consider growing illegal crops.

There is an urgent need for a strong resolution to give authority to the public health perspective in the UNGASS outcomes document. A69/12 provides the basis for such a resolution and plan of action. It would add a sense of reality to such a resolution to include some recognition of the additional issues referred to above.

12.7 Addressing the challenges of the UN Decade of Action for Road Safety (2011–2020): outcome of the Second Global High-level Conference on Road Safety – Time for Results

In focus

The Assembly will consider <u>A69/13</u> which includes information:

- on the progress made in attaining the objectives of the <u>Decade of Action for Road Safety</u> 2011–2020;
- about road traffic injury in the SDGs (<u>SDG Goal 3, Target 6</u>: "By 2020, halve the number of global deaths and injuries from road traffic accidents");
- on the <u>outcomes</u> of the Second Global High Level Conference on Road Safety: Time for Results, held in Brasília on 18 and 19 November 2015; and
- on the <u>UNGA resolution 70/260</u> on global road safety adopted in April 2016.

The EB debate, reported in <u>PSR13</u>, was structured loosely around a draft resolution tabled by Brazil and the Dominican Republic and directed to implementing the Brasilia Outcomes Statement. However, the draft resolution still had three paras still in square brackets and it was agreed to continue intersessional consultations in preparation for WHA69.

The outstanding issues still in debate appear to relate to:

- the reference to 'multi-stakeholder collaboration' (too often code for public private partnerships);
- references to a process for developing national and global road safety indicators and targets to reduce road traffic injuries and fatalities in accordance with the road safety targets of the SDGs and whether the national targets should should be voluntary or not;
- (and more subterranean) the role of WHO in relation to the two SDG targets dealing with road trauma. From para 14 of A69/13: "Target 3.6 calls for reducing by 50% road traffic deaths and injuries by 2020 and Target 11.2 calls for providing by 2030 access to safe, affordable, accessible and sustainable transport systems for all, improving road safety, notably by expanding public transport, with special attention to the needs of those in vulnerable situations, women, children, persons with disabilities, and older persons".

Background

World report on road traffic injury prevention, produced in 2004 and co-sponsored by WHO and WB.

More reports here.

PHM comment

The title of this agenda item refers to road safety, not road trauma, and certainly not the burden of disease attributable to personal motorised transportation. The body of the report speaks about road trauma but makes no reference to physical inactivity or air pollution.

A discursive shift has taken place in WHO's language practices since the 2004 World report on road traffic injury prevention. Since then road safety appears to have moved to centre stage. This shift from road trauma to road safety has the effect of excluding transport planning and land use planning from consideration and diverting attention from the wider links between motorisation and the burden of disease, including that associated with physical inactivity and air pollution.

The 2004 World report on road traffic injury prevention focused on a range of factors which contribute to death and injury on the roads. In a section headed 'factors influencing exposure to risk' it discusses 'motorisation', transport, land use and road planning (p74). Clearly the number of people exposed is a major determinant of the number of people killed or injured.

The discourse shifted significantly after WHO was appointed as coordinator for the <u>UN Road Safety Collaboration</u> in 2004; the <u>Decade of Action for Road Safety</u> 2011-2020 was launched; two global ministerial conferences on *road safety* were held: <u>2009 in Moscow</u>, and <u>2015 in Brasilia</u>; and a series of global status reports on *road safety* were produced by WHO in <u>2009</u> and 2013 and 2015.

WHO's <u>Global Status Report on Road Safety 2015</u> is almost entirely about driver and rider behaviour, with short sections on safe vehicles and safe roads but nothing about public transport, urban planning or pollution control.

In many countries the political power of the automobile industry and urban developers has shaped urban planning around roads with the neglect of public and active transport infrastructure.

It appears that the UN and WHO are exposed to similar pressures.

In April 2015 the UN announced that Jean Todt, the president of the Fédération Internationale de L'Automobile (FIA), had been appointed as the <u>UN Secretary General's Special Envoy on Road Safety</u> (bio here).

The FIA is the governing body for world motor sport and the federation of the world's motoring organisations, both of which are heavily supported by the automobile industry.

WHO partners with the FIA Foundation in managing the <u>Road Safety Fund</u> and partners with FIA and the FIA Foundation (and the WB and a group of countries) in the <u>'Friends of the Decade of Action on Road Safety'</u>.

The UN Road Safety Collaboration, which WHO coordinates, is a typical <u>global public private</u> <u>partnership</u> with intergovernmental bodies, governments, NGOs and private sector entities. Among the latter are a tyre manufacturer, a steel manufacturer and the international Motorcycle Manufacturers Association, as well as the FIA.

PHM notes (para 10) that United Nations Road Safety Collaboration only attracts around 80 partner organisations to its twice yearly gatherings. In fact there are only 14 Member States participating in the Collaboration and several of these are sub-national.

From a public health point of view there is considerable scope for linking the objectives of cutting greenhouse gas emissions, controlling NCDs and reducing road trauma. Greenhouse

gas emissions, air pollution and physical exercise are all mentioned but only once each in the 2015 global status report.

There are frequent references in both the policy declarations and various reports to the need for an intersectoral approach to road safety. However in this context intersectoral appears to mean the engagement of health with police, auto design standards and road planning. The slogan of 'One WHO' suggests there might be scope for synergies with respect to the advocacy and mobilisation around road trauma, NCDs prevention, air pollution control, greenhouse gas reduction and urban / transport planning.

WHO and the UN are working closely in the field of road trauma / road safety with private sector entities with secondary interests in the policy outcomes. The WHO is producing documents which take a very narrow approach to road trauma policy, neglecting both the urban planning side and the synergies with air pollution and physical activity. The conjunction of these relationships and policy positions raise questions about conflict of interest and improper influence over WHO's activities.

Government investment in urban development and public transport has been under increasing pressure through decades of 'structural adjustment' and 'austerity' (and neoliberalism more generally) which have weakened governments' capacity and willingness to undertake the necessary urban planning and infrastructure development. According to the neoliberal doctrine money transferred from households to auto manufacturers is good but money transferred through taxation to building decent transport and decent cities is somehow wasted.

In this context PHM notes the interest of FIA, and Jean Todt personally, in promoting road investment through their involvement in national 'road assessment programs' and iRAP (the International Road Assessment Program). At the heart of 'road assessment' is a standardised five star rating system, protocols for risk mapping and guidelines for lobbying for public investment in roads. Jean Todt speaking as the Secretary General's Special Envoy celebrated the star rating system as a guest speaker at <u>EuroRAP meeting in Sept 2015</u> in London (<u>speech here</u>)

The iRAP is also in a partnership with the UN under the <u>2030 Agenda for Sustainable</u> <u>Development</u>. Under the <u>Agenda</u> there are two SDGs dealing with road trauma and road safety:

- 3.6: By 2020, halve the number of global deaths and injuries from road traffic accidents;
- 11.2: By 2030, provide access to safe, affordable, accessible and sustainable transport systems for all, improving road safety, notably by expanding public transport, with special attention to the needs of those in vulnerable situations, women, children, persons with disabilities and older persons.

The iRAP / SDG partnership appears to have 'generous support' from the World Bank, the FIA Foundation and the Road Safety Fund (jointly managed by WHO and FIA Foundation). It also has funding agreements in place with other development banks. It boasts total funding of USD50m. Safer roads clearly has a place in achieving SDG3.6 although containing motorisation could well be more effective in reducing road trauma as well as addressing global warming. The contribution of iRAP to SDG11.2 would have to be marginal.

PHM is in favour of safer roads but there are opportunity costs of investing disproportionately in lobbying for safe roads (and in the road construction which follows from such lobbying). The efficiency question is whether investing comparable resources in lobbying for better urban

planning and public transport could deliver a greater yield in terms of burden of disease (including road trauma, physical activity and air pollution) as well as reducing greenhouse gases.

It appears that this is not a question that WHO has asked. Is this because of its close relations with organisations which have secondary interests in the policy outcomes?

This item should provide a useful case study for exploring the application of the emerging FENSA principles, the rules governing WHO partnerships, and risk management in the face of conflict of interest.

13.1 Monitoring of the achievement of the healthrelated Millennium Development Goals

In focus

The Assembly will consider A69/14 which is a revised version of EB138/13 which was considered by the EB in January. (See EB138 discussion at PSR5.)

The report reviews efforts made to achieve the health-related Millennium Development Goals with a focus on global and regional progress, success factors and the unfinished agenda.

In January items 13.1 (MDGs) and 13.2 (SDGs) were considered conjointly. Most of the discussion was focused on the SDGs and possible lessons from the MDGs.

Background

See PHM Commentary on the MDGs in relation to Item 14.1 at WHA68.

PHM comment

The Secretariat report provides a thoughtful commentary on levels of achievement of MDG targets and review of the role of WHO strategies, plans and programmes in this achievement.

The review celebrates the achievements of vertical programs as in HIV and malaria but progress in terms of nutrition, health systems and environmental hygiene has been much slower. These are system problems which inhere more deeply in the political and economic structures and which also impose real limits on the potential achievement of the more narrow targets.

13.2 Health in the 2030 Agenda for Sustainable Development

In focus

The Assembly will consider A69/15 which is a revised version of EB138/14 which was considered by the EB in January. (See EB138 discussion at PSR5, PSR12 and PSR13.)

The 2030 Agenda for Sustainable Development, adopted by the United Nations General Assembly in September 2015, builds on the Millennium Development Goals but has a much broader agenda for all countries. The Secretariat report (<u>EB138/14</u>) analyses the implications for health, including the role of the Health Assembly in implementing the 2030 Agenda.

In January the items regarding MDGs and SDGs were considered conjointly.

The Board also considered a draft resolution entitled 'Health in the 2030 Agenda for Sustainable Development', proposed by Japan, Panama, South Africa, Thailand, United States of America, Zambia and Zimbabwe. After drafting negotiations a revised and re-named resolution 'Strengthening essential public health functions in support of the achievement of universal health coverage' was adopted as Resolution EB138.R5.

During the EB there was mention of another draft resolution under consideration.

Background

The Secretariat paper provides some useful background on the SDGs and their implications for health and for WHO. More about the SDGs can be found here.

<u>UN Resolution A/RES/70/1</u> carries the 2030 Agenda for Sustainable Development, the Declaration and the Goals and Targets.

The Addis Ababa Action Agenda on Financing for Development (<u>A/RES/69/313</u>) is referenced in the 2030 SD Agenda as the blueprint for mobilising the funds needed to implement the agenda in low and middle income countries.

PHM comment

In this comment PHM:

- <u>first</u>, reviews the leadership potential of the 2030 Agenda on Sustainable Development emphasising the need to go beyond inspiring rhetoric;
- <u>second</u>, reviews the implications for WHO of the SDGs, going beyond the analysis provided in A69/15;
- third, highlights the fact that the draft resolution contained in <u>EB138.R5</u> represents a
 dramatic shrinkage of ambition from the scenario suggested in A69/15; and
- <u>finally</u>, suggests possible amendments for consideration by member states, directed to widening the ambit of the draft resolution in <u>EB138.R5</u>.

The 2030 Agenda for Sustainable Development: the need to go beyond inspiring rhetoric

There is much to appreciate in the <u>2030 Agenda for Sustainable Development</u>. Para 3 illustrates the inspiring rhetoric:

We resolve, between now and 2030, to end poverty and hunger everywhere; to combat inequalities within and among countries; to build peaceful, just and inclusive societies; to protect human rights and promote gender equality and the empowerment of women and girls; and to ensure the lasting protection of the planet and its natural resources. We resolve also to create conditions for sustainable, inclusive and sustained economic growth, shared prosperity and decent work for all, taking into account different levels of national development and capacities.

The 17 goals and 169 targets are comprehensive and visionary; an inspiring vision can mobilise people to work together for change. However, false promises lead to disillusion and withdrawal or worse.

The Agenda promises action on inequality, human rights, gender equity and protection of the planet. There are repeated references to sustainable production and consumption, as in Para 28:

28. We commit to making fundamental changes in the way that our societies produce and consume goods and services. Governments, international organizations, the business sector and other non-State actors and individuals must contribute to changing unsustainable consumption and production patterns ...

Goal 12 elaborates a series of targets which might contribute to changing unsustainable consumption and production patterns but the Agenda lacks drivers which could make Governments, international organizations, the business sector and other non-State actors and individuals contribute to changing unsustainable consumption and production patterns.

In fact the Agenda proposes to rely on economic growth (Goal 8), of at least 7% in the LDCs, and free trade (Goal 17, targets 17.10 - 17.12) to fund the necessary transformations. This assumption ignores the contradictions between economic growth and ecological sustainability.

Jason Hickel ('<u>The UN's new SDGs aim to save the world without transforming it'</u>) applauds the ecological goals but points out that the SDG program for development and poverty reduction relies precisely on the old model of industrial growth — ever-increasing levels of extraction, production, and consumption.

Woodward (2015) has estimated that eradicating poverty (using a \$5 per day benchmark) through economic growth would take 200 years and would only be achieved when per capita GDP exceeds \$1m. Woodward points out that carbon constraints are likely to severely limit such 'growth'. Certainly economic growth does not necessarily require greenhouse gas emissions but it is hard to see the projected economic growth as consistent with the control of global warming.

In terms of de-carbonising economic growth the SDGs are very weak. The following from Goals 12(c) illustrates just how weak:

12.c Rationalize inefficient fossil-fuel subsidies that encourage wasteful consumption by removing market distortions, in accordance with national circumstances, including by restructuring taxation and phasing out those harmful subsidies, where they exist, to reflect their environmental impacts, taking fully into account the specific needs and conditions of developing countries and minimizing the possible adverse impacts on their development in a manner that protects the poor and the affected communities

The other targets under Goal 12 are equally weak. Consider for example, 12.6:

Encourage companies, especially large and transnational companies, to adopt sustainable practices and to integrate sustainability information into their reporting cycle.

The promises of the SDGs need to be viewed alongside the drive for plurilateral trade agreements, in particular, the TPP and the TTIP, which run counter in major respects to the promises of the SDGs. A recent report by the World Bank concludes that the TPP will seriously prejudice the export prospects of Thailand and other countries who are not included in the agreement. In large degree the benefits accruing to Vietnam are achieved at the cost of Thailand through trade diversion.

Ending poverty (Goal 1) and ending hunger (Goal 2) are unlikely to be achieved through economic growth; it seems even less likely that they will be achieved through financial transfers.

The SDGs make gestures but do not provide any credible strategy for addressing:

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

The contradictions and weaknesses embedded in the SDGs should not take away from the inspiring vision that they project. However, they do underline that the SDGs are not enough; that there remains an urgent need for more fundamental reforms in the structures and flows of the global economy and the power relations which maintain those structures and flows.

Implications of the SDGs for WHO

A69/15 provides a thoughtful exploration of the implications for WHO of the emergence of the SDGs. It hints at some of the contradictions embedded in the SDGs, for example:

... only if the governments of developed countries do more to tackle inequality and insecurity at home, as part of their contribution to the Sustainable Development Goals, will they have the political space to pursue the idea of global solidarity that underpins the new Agenda (para 17)

A69/15 has been significantly revised from EB138/14 which was the corresponding document circulated for the EB in January. The revisions are restricted largely to the section on

Implications for the work of WHO. Perhaps the most significant revision is the complete elimination from A69/15 of paragraph 49 in EB13814 which comments that

While the new Agenda attaches greater weight to issues such as noncommunicable diseases than was the case in the past, there is no guarantee, given the continued reliance on voluntary funds from official development assistance and development cooperation agencies, that funding to WHO will follow suit.

This may be a reference to the underfunding of NCDs, health systems and action on the SDH as reflected in Fig 1 of WHA68/6 (May 2015). It appears that powerful stakeholders (perhaps large donors) were alarmed at the possibility that the SDGs might add to the pressures for the adequate funding of WHO so that it can contribute effectively to the full sweep of the SDGs.

If WHO is to effectively engage in the intersectoral collaboration suggested by the new goals an early step would be a fuller review of the implications for health of each of the other SDGs and the implications for WHO priorities and programmes.

WHO needs to respond to the SDGs in ways which gain leverage from the inspiring rhetoric but which also raise awareness of the need for more fundamental reforms in the structures and flows of the global economy and the power relations which maintain those structures and flows.

The draft resolution contained in EB138.R5 represents a dramatic shrinkage of ambition from the scenario suggested in A69/15

The draft resolution contained in EB138.R5:

- elevates Target 3.8 'universal health coverage' to pre-eminent status among the health related SDGs thereby discounting the other 12 targets (see Annex 2 in A69/15);
- fails to address the policy coherence challenges arising from the health dimensions of all of the 'non-health' SDGs;
- makes no reference to the challenge of negotiating policy coherence across trade and health which is of particular significance in view of the shrinking policy space (regarding both health care and action on the social determinants of health) arising from contemporary trends in trade agreements; and
- makes no reference to the constraints on WHO's capacity as a consequence of inadequate and inflexible funding.

Suggested amendments to the draft resolution in <u>EB138.R5</u> for consideration by member states

In view of the constraints on WHO's work implied in the draft resolution recommended through the EB PHM has developed a number of proposed amendments to the draft resolution for consideration by delegates to the Assembly. See PHM proposed amendments below.

Health in the 2030 Agenda for Sustainable Development

PHM urges member states to amend the draft resolution proposed by the EB in <u>EB138.R5</u> as outlined below. (See more extended analysis of WHA69 Item 13.2 'Health in the 2030 Agenda for Sustainable Development' <u>here</u>)

Strengthening essential public health functions in support of the achievement of universal health coverage Health in the 2030 Agenda for Sustainable Development

The Sixty-ninth World Health Assembly,

Noting the importance of public health functions as the most cost-effective, comprehensive and sustainable ways to enhance the health of populations and individuals and to reduce the burden of disease;

Recognizing also the need to strengthen public health governance, institutional and technical capacities in countries in order to contribute effectively to population health and protect people from the social and economic consequences of ill-health in a globalized world;

Acknowledging that Goal 3 of the 2030 Agenda for Sustainable Development (Ensure healthy lives and promote well-being for all at all ages) with its 13 health targets, together with the multiple other health-related targets and goals in the 2030 Agenda, will require strong intersectoral action in order to be fully implemented;

Recalling the 2010 Adelaide Statement on Health in all Policies and recognizing that all of the goals of the 2030 Agenda for Sustainable Development have important implications for creating the conditions for healthy populations and that the full participation of WHO at all levels in the planning, implementation and evaluation of actions directed at the "non-health" goals will be essential to fully yield the potential benefits to health inherent in those goals;

Reaffirming the commitment made in United Nations General Assembly resolution 70/1 of 25
September 2015, entitled "Transforming Our World: the 2030 Agenda for Sustainable
Development", especially target 3.8 (Achieve universal health coverage, including financial risk protection, access to quality essential health care services, and access to safe, effective, quality, and affordable essential medicines and vaccines for all) which will contribute to ending poverty and fighting inequality and injustice;

Recalling United Nations General Assembly resolution 67/81 (2012) on global health and foreign policy, acknowledging that universal health coverage implies that all people have access, without discrimination, to nationally determined sets of the needed promotive, preventive, curative and rehabilitative basic health services and essential, safe, affordable, effective and quality medicines, while ensuring that the use of these services does not expose the users to financial hardship, with a special emphasis on the poorest and marginalized segments of populations in accordance with the principle of social inclusion, in order to enhance their ability to realize their right to the enjoyment of the highest attainable standard of physical and mental health;

Recalling resolution WHA59.26 (2006) on international trade and health which recognizes the demand for information on the possible implications of international trade and trade agreements for health and health policy at national, regional and global levels amd affirms the need for all relevant ministries, including those of health, trade, commerce, finance and foreign affairs, to work together constructively in order to ensure that the interests of trade and health are appropriately balanced and coordinated;

Further recalling that United Nations General Assembly resolution 67/81 (2012) also recognizes that effective and financially sustainable implementation of universal health coverage is based

on a resilient and responsive health system that provides comprehensive primary health care services, with extensive geographical coverage, including in remote and rural areas, and with a special emphasis on access to populations most in need, and that has an adequate skilled, well-trained and motivated workforce, as well as capacities for broad public health measures, health protection and addressing determinants of health through policies across sectors, including promoting the health literacy of the population;

Recalling also resolution WHA62.12 (2009) on primary health care, including health system strengthening, which urges Member States to put people at the centre of health care by adopting, as appropriate, delivery models focused on local and district levels that provide comprehensive primary health care services including health promotion, disease prevention, curative and palliative care, and noting the importance of equitable and affordable access to services;

Further recalling resolution WHA64.9 (2011) on sustainable health financing structures and universal coverage, which recognizes that effective health systems delivering comprehensive health services, including preventive services, are of utmost importance for health, economic development and well-being and that these systems need to be based on equitable and sustainable financing;

Recalling also United Nations General Assembly resolution 68/300 (2013), the outcome document of the high-level meeting of the General Assembly on the comprehensive review and assessment of the progress achieved in the prevention and control of noncommunicable diseases, which recognizes, inter alia, that insufficient progress in the prevention and control of noncommunicable diseases undermines social and economic development throughout the world, and which commits to the implementation of effective multisectoral public policies to promote health, and to strengthen and orient health systems to address prevention and control of noncommunicable diseases and underlying social determinants through people-centred primary health care and universal health coverage throughout the life cycle;

Recalling resolution WHA62.14 on reducing inequities through action on the social determinants of health which confirmed the importance of addressing the wider determinants of health, and resolution WHA60.24 on health promotion which affirms that the promotion of health is central to the global development agenda and is a core responsibility of all governments; and WHA65.8 on the outcomes of the World Conference on Social Determinants of Health which reiterated member states determination to take action on the social determinants of health and reaffirmed member states will to make health equity a national, regional and global goal and to address current challenges – such as eradicating hunger and poverty; ensuring food and nutritional security, access to affordable, safe, efficacious and quality medicines as well as to safe drinking-water and sanitation, employment and decent work and social protection; protecting environments and delivering equitable economic growth;

Recalling regional resolutions EUR/RC61/R2 (2011) on strengthening public health capacities and services in Europe: a framework for action, CD42.R14 (2000) on essential public health functions and CD53.R14 on Strategy for Universal access to Health and Universal Health Coverage, WPR/RC53.R7 on essential public health functions, as well as the briefing to the sixty-second session of the WHO Regional Committee for the Eastern Mediterranean on assessing essential public health functions in the Eastern Mediterranean Region, encouraging Member States to strengthen essential public health functions as a basis for improving public

health practice and as a means of achieving resilient health systems moving towards universal health coverage;

Recognizing that essential public health functions are the responsibility of Member States and support the achievement of the objectives of universal health coverage, facilitate the financial feasibility thereof by reducing health risks and threats, the burden of noncommunicable and communicable diseases and contribute to the achievement of other health related sustainable development goals and targets;

Noting that essential public health functions that span across multiple non-health sectors and address, among other things, economic, environmental and social determinants of health, benefit the health of the entire population and could be undersupplied without government intervention;

Recognizing that successful implementation of essential public health functions requires strengthening of governance and public health capacities, which may include, inter alia, building the knowledge and evidence base for policy options and strategies; ensuring sustainable and adequate resources, agency support and skilled and dedicated staff; assessing health and health-related gender impacts of different policy options; understanding the political agendas of other sectors and creating intersectoral platforms for dialogue and addressing challenges, including with social participation; evaluating the effectiveness of intersectoral work and integrated policy-making and working with other sectors of government to advance health and well-being;

Recalling resolution WHA58.3 (2005), encouraging Member States to strengthen and maintain public health capacities to detect, report, assess and respond to public health emergencies and public health risks, as part of countries' obligations to fully implement the International Health Regulations (IHR 2005); and resolution EBSS3.R1 (2015) of the Special Session of the Executive Board on Ebola, which recognized the importance of addressing long term systemic gaps in capacity to prevent and detect health threats and to respond to them effectively with the aim to improve health security at national, regional and global levels, and noting that this equally requires intersectoral action;

Underscoring the integrated, cross-cutting nature of the Sustainable Development Goals, which call for multisectoral action and provide new legitimacy for addressing wider determinants of health.

Recognizing that realising the vision projected by the SDGs will require a profound transformation of the structures, stocks and flows of the global economy and of the power relations which presently sustain those structures, stocks and flows;

Reconizing the limitations imposed on WHO as a consequence of inadequate and inflexible funding because of the freeze on assessed contributions and the refusal of donors to until their donations;

1. URGES Member States:

(1) to show leadership and ownership in establishing establish effective health governance by national and subnational health authorities including cross-sectoral health policies and integrated strategies aiming to improve population health to achieve the Sustainable

Development Goal target 3.8 on universal health coverage and other health related Sustainable Development Goals, in accordance with nationally set priorities, accelerating their achievement, as appropriate, through establishing and enhancing monitoring, evaluation and accountability mechanisms and capacities;

- (2) to enhance international cooperation to achieve universal health coverage, including financial risk protection, access to quality essential health care services and access to safe, effective, quality and affordable essential medicines and vaccines for all;
- (3) to invest adequate sustainable resources for health system strengthening towards universal health coverage, including needs-based allocation among socioeconomic groups in favour of the most vulnerable and deprived populations within national contexts in order to reduce burden of disease, financial risks, inequality and injustice;
- (4) to enhance institutional and operational capacity and infrastructure for public health, including scientific and operational competence of public health institutions, as appropriate to national circumstances, as well as a cross-sectoral infrastructure for delivering essential public health functions, including the capacity to address existing and emerging health threats and risks:
- (5) to invest into the education, recruitment and retention of a fit-for-purpose and responsive public health workforce that is effectively and equitably deployed to contribute to effective and efficient delivery of essential public health functions, based on population needs;
- (6) to ensure coordination, collaboration, communication and synergies across sectors, programmes and, as appropriate, other relevant stakeholders, with a view to improving health, protecting people from the financial risk of ill-health, and promoting a comprehensive approach to public health in support of the achievement of universal health coverage throughout the life cycle;
- (7) to foster approaches that systematically tackle social, environmental and economic determinants of health and health inequity, taking into account gender impacts;
- (8) to monitor, evaluate, analyse and improve health outcomes, including through the establishment of comprehensive and effective civil registration and vital statistics systems and effective delivery of essential public health functions, equitable access to quality health care services, and the level of financial risk protection;

(9) to lift the freeze on assessed contributions and the budget ceiling and to untie their donations to WHO

2. REQUESTS the Director-General:

- (1) to develop and disseminate technical guidance on the application of essential public health functions, taking into account WHO regional definitions, in the strengthening of health systems and for the achievement of universal health coverage;
- (2) to facilitate international cooperation and to continue and enhance support to Member States upon request in their efforts to build the necessary institutional administrative and scientific capacity, providing technical support in relation to essential public health functions, for health systems strengthening, including to prevent, detect, assess and respond to public health events,

and integrated and multisectoral approaches towards universal health coverage; and to develop facilitating tools in this regard;

(2 bis) to undertake a review of each of the non-health SDGs to identify issues with significant health implications and to suggest how, in the spirit of intersectoral collaboration and recognising the integrated and indivisible nature of the SDGs, WHO might ensure that the health dimensions are appropriately considered at global, regional and national levels;

- (3) to take the leading role, facilitate international cooperation and foster coordination in global health at all levels, particularly in relation to health system strengthening, including essential public health functions, supportive to the achievement of the health related sustainable development goals and targets;
- (4) to report to the Health Assembly on the implementation of this resolution as a contribution to the achievement of the health-related targets in the 2030 Agenda for Sustainable Development.

13.3 Operational plan to take forward the Global Strategy on Women's, Children's and Adolescents' Health

In focus

The Assembly will consider Secretariat report <u>A69/16</u> (a revision of <u>EB138/15</u> which was considered in January by the EB).

<u>A69/16</u> reviews the development of the new Global Strategy on Women's, Children's and Adolescents' Health and highlights the challenges involved in implementation. These included country plans, mobilising funds, commitments, measurement, and accountability.

The record of the EB debate is in PSR5 and PSR6.

There was some talk during the EB discussions of a possible draft resolution but such is not flagged in the papers currently available.

The new Global Strategy

The new (updated) <u>Global Strategy on Women's, Children's and Adolescents' Health</u> was launched by the United Nations Secretary General in September 2015. The new Strategy includes:

- Chapter 4: Vision, Principles, Objectives (Survive, Thrive, Transform) and Targets (drawn from the SDGs).
- Chapter 5: Nine Action Areas, and
- Chapter 6: Implementation.

Chapter 6 indicates that an Operational Framework is being developed. It 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.

WHO Operational Plan

The Secretariat report (A69/16) outlines the main components of the proposed Operational Plan for WHO to help drive the implementation of the Global Strategy.

The report highlighted a series of key activities (para 15) which should be included in country plans. It highlighted the need for coordination, referred to the foreshadowed Operational Framework, referred to technical resources, and introduced the Global Financing Facility.

The report underlined the need for concrete commitments (para 20), referring to the list of commitments from page 80 in the Global Strategy, and calling for MS to make specific commitments.

Finally the report reviewed the provision for indicators (drawn from the SDGs) and accountability, in particular the role of the Independent Accountability Panel.

In Annex 2 the Secretariat proposed a set of milestones for the implementation.

If a resolution is being developed, it will presumably follow the lines of the Secretariat's recommendations for country action, specific commitments, coordination, technical support, financing, measurement and accountability.

Background

The Global Strategy for Women's Children's and Adolescents' Health 2016-2030 can be downloaded here: Every Woman Every Child.

The Strategy foreshadows a five year operational framework which will be developed in 2016 and which, presumably, would frame the operational plan foreshadowed in <u>A69/16</u>.

There is some obscurity about the relationship between the UN process foreshadowed in the Global Strategy for the development of an 'operational framework' in early 2016 and the WHO Secretariat proposal for an 'operational plan'. Presumably the WHO staff are expecting to take the lead in the development of the 'operational framework' and are getting started by asking the EB to mandate this work on an 'operational plan' through the WHO.

See the May issue of the Bulletin of WHO (here) for a series of articles of relevance to this item.

The record of the EB debate is in PSR5 and PSR6.

See also suite of articles in May issue of WHO Bulletin:

- The Global strategy for women's, children's and adolescents' health (2016–2030): a roadmap based on evidence and country experience. Kuruvilla, Bustreo et al. http://dx.doi.org/10.2471/BLT.16.170431
- Knowledge for effective action to improve the health of women, children and adolescents in the sustainable development era. Bustreo, Gorna & Nabarro. http://dx.doi.org/10.2471/BLT.16.174243
- Sexual and reproductive health and rights in emergencies. Askew, Khosla, et al. http://dx.doi.org/10.2471/BLT.16.173567
- Young people's contribution to the Global strategy for women's, children's and adolescents' health (2016–2030). Mabaso, Erogbogbo & Toure. http://dx.doi.org/10.2471/BLT.16.174714
- Political leadership for women's, children's and adolescents' health. Moeloek & Admasu. http://dx.doi.org/10.2471/BLT.16.174367

PHM comment

The Global Strategy

The Global Strategy has been extensively consulted upon. The principles which are elaborated and which imbue the text will resonate with advocates for women's, children's and adolescents' health in many countries and at all levels. The targets are admirable. The list of evidence based

interventions and the descriptions of the enabling environments which will need to be created to enable those interventions to be implemented are useful. The Action Areas identified are also appropriate.

This is an excellent strategy and needs to be strongly supported. However we highlight some reservations and cautions.

Financing

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

The World Bank has established a <u>Global Financing Facility</u> to provide a common platform for bilateral and multilateral donations for women's, children's and adolescents' health in L&MICs. Hopefully the new Global Financing Facility (GFF) will reduce the problem of multiple channels of donor assistance to women's, children's and adolescents' health. However, it is not clear that it will not reproduce the health systems fragmentation of the old vertical funding streams.

The development of integrated comprehensive health systems is critical for women's, children's and adolescents' health but there is no guarantee under the GFF that funds which are earmarked for women's, children's and adolescents' health will not distort health system development in the same ways as the vertical funding of infectious disease programmes has done.

We note the enthusiasm of the World Bank to promote the role of the private sector in reproductive, maternal, newborn, child and adolescent health (<u>page 19 of Business Plan</u>). This is quite worrying as it is clearly faith based rather than evidence based.

In view of the importance of the country specific 'investment case' in framing disbursements through the GFF WHO should give priority in its Operational Plan to offering technical assistance to countries in the preparation of their investment cases and in capacity building for this function.

Critical monitoring of the operations of the GFF should also be a key function of WHO's operational plan.

Use of process indicators to follow implementation

There is a sharp focus on targets and indicators in both the Global Strategy and EB138/15 but this is largely restricted to the 17 outcome indicators specified through the SDGs process.

In fact this Strategy is quite innovative in listing, in Annexes 2-4, a series of 'interventions' and a series of 'enabling environments' which are seen as preconditions for delivering those interventions. However, there are no references in either the Strategy or <u>A69/16</u> to the monitoring of progress with respect to interventions and enabling environments.

This must be a major focus on the proposed Operational Plan.

Recognising the macroeconomic determinants of poverty, inequality and undernutrition

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

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

This is a good strategy but one which may be motivated in some degree by the objective of legitimising the prevailing global economic order, through being seen to address the needs of women, children and adolescents.

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

PHM calls for stakeholders in the reproductive, women, newborn, child and adolescent health field to commit to focusing attention on the macroeconomic and geopolitical dynamics which shape health outcomes in this field and to promoting policies which lead towards a more equal, sustainable and inclusive global society.

The operational plan

It seems that the Secretariat is foreshadowing the development of an 'operational plan' which might in due course merge with the 'operational framework' foreshadowed in the Global Strategy.

A69/16 highlights a number of important issues which should be incorporated into such a Plan.

PHM urges the inclusion amongst such issues:

- priority to providing technical support for the development of the investment cases for countries eligible for and proposing to approach the GFF;
- monitoring the priorities approved by the GFF in the funding of investment cases and reporting thereon to the Assembly;
- monitoring the impact on health system coordination and coherence of the special purpose funds disbursed through the GFF;
- monitoring the implementation of the Global Strategy in terms of the deployment of the interventions listed in the Global Strategy and the enabling environments identified;
- to include among the commitments which are urged upon different stakeholder groups continuing attention to the macroeconomic and geopolitical dynamics which shape health outcomes in this field and the need for policies which would lead towards a more equal, just, sustainable and inclusive global society.

13.4 Multisectoral action for a life course approach to healthy ageing: draft global strategy and plan of action on ageing and health

In focus

Under this item the Assembly will consider A69/17 which introduces the draft global strategy and plan of action (GS&POA). It was agreed at EB138 that the Secretariat would prepare a draft resolution endorsing the draft global strategy and plan of action but it is not included in A60/17.

Populations are ageing rapidly, with some of the most significant changes occurring in low- and middle-income countries. The draft global strategy and plan of action on ageing and health responds to a request in decision <u>WHA67(13)</u> (2014) and is intended to frame a comprehensive response designed to foster healthy ageing, and one that is relevant to all countries.

A69/17 outlines the extensive consultation process involved in the development of the draft global strategy and plan of action and conveys the full strategy in the Annex.

The strategy proposes five years of work on evidence building and awareness raising (2015-20) before launching a Decade of Healthy Ageing from 2020 to 2030.

Five strategic objectives are proposed:

- Commitment to action on Healthy Ageing in every country;
- Developing age-friendly environments
- Aligning health systems to the needs of older populations
- Developing systems for providing long-term care (home, communities, institutions)
- Improving measurement, monitoring and research on Healthy Ageing

Activities are proposed under each of these objectives for Member States, the Secretariat (including WHO and other UN bodies), and 'national and international partners'.

The draft global strategy and plan of action (GS&POA) on ageing and health should be read in association with the recently released <u>World Report on Ageing and Health</u>.

The development of the World Report (and presumably the development of the draft strategy) was supported by grants from the governments of Japan and the Netherlands and through core voluntary contributions.

The EB debate is recorded in PSR6.

Background

The proportion of older people in the population is increasing in almost every country. See Chapter One of the recently released <u>World Report on Ageing and Health</u>. By 2050 most countries will have >30% of their population aged 60+; for many countries well before this.

WHO has been doing good works on Active Ageing for many years; it released the <u>2002 Active Ageing Policy Framework</u> and the <u>Madrid Plan of Action</u> was published in 2002 also.

In May 2014 the Assembly considered A67/23 and adopted Decision WHA67(13) which requested the Director-General to develop, in consultation with Member States and other stakeholders and in coordination with the regional offices, and within existing resources, a comprehensive global strategy and plan of action on ageing and health, for consideration by the Executive Board in January 2016 and by the Sixty-ninth World Health Assembly in May 2016.

PHM comment

The World Report is a very useful document and the draft GS&POA will also be very useful..

The designers of the draft GS&POA are to be particularly commended for the activities proposed to support SOs 3 & 4 which deal with health systems and long term care systems respectively. The corresponding chapters in the World Report are also well presented.

Funding

Several speakers at the EB in January mentioned the need for adequate resourcing to implement this GS&POA. It remains to be seen whether the big donors will accept healthy ageing as deserving of their largesse.

Neglect of the SDGs

It is unfortunate that both the Report and the GS&PA have been prepared without regard to the emerging Sustainable Development Goals. At this same Assembly member states will consider a report from the Secretariat which points out that there are health implications in most of the 'non-health' SDGs and argues that WHO should take a pro-active stance in developing intersectoral collaboration around these goals.

<u>Chapter 6</u> of the Report is structured around five domains of functional ability which are essential for older people to:

- meet their basic needs;
- learn, grow and make decisions;
- be mobile:
- build and maintain relationships;
- contribute.

The social and economic norms which facilitate or obstruct these abilities are determined across many of the 'non-health' <u>SDGs</u>. However, under the relevant strategic objective in the draft GS&PA (<u>SO2</u> Developing age-friendly environments) there is no consideration of how intersectoral collaboration across the SDGs might provide leverage to support these abilities. (Despite the lack of any reference to the SDGs in the World Report, its Chapter Six provides a more coherent account of these five abilities than SO2.)

The neglect of the SDGs is a particular problem in relation to indicators and metrics generally. However, the action plan foreshadowed envisages continuing work on indicators.

The brutality of neoliberal transnational capitalism

It would be too much to expect the WHO to comment on the degree to which the barriers to healthy ageing are embedded in the norms of neoliberal globalising capitalism and its cultivation of inequality and insecurity; its continuing pressure on public revenues (through 'tax competition' and structured tax evasion); and its disregard for full employment, decent work and adequate pensions as part of equitable social protection.

Para 17 of A69/15 is directly relevant to creating the conditions for healthy ageing:

... only if the governments of developed countries do more to tackle inequality and insecurity at home, as part of their contribution to the Sustainable Development Goals, will they have the political space to pursue the idea of global solidarity that underpins the new Agenda.

The closest that the World Report comes to these links is in its discussion of the 'economic imperative' from page 16. These relationships are completely absent from the draft GS&POA.

The false promises of the UHC rhetoric

Strategic objectives 3 & 4 deal with health care and long-term care respectively. Financial provision for these is reduced to single slogans in the GS&POA but the discussions of institutional relations and financing arrangements in the corresponding chapters of the World Report are more insightful; see page 113 and page 144.

In order to preserve its collaboration with the World Bank under the flag of "UHC" WHO has backpedalled in terms of providing guidance regarding institutional configurations for decent health care. However chapters 4 & 5 of the World Report include useful discussions of the kinds of service systems required for decent health care and long-term care for older folk. These service relationships and patterns of service delivery are not compatible with the privatized marketized stratified health care systems advocated by the World Bank under the shared rubric of UHC.

While the full draft global strategy mentions the SDGs in para 2 it is astonishing that Goal 3, which in the <u>UN Resolution 70/1</u> (adopted 25 September) reads "Ensure healthy lives and promote well-being for all at all ages", has been amended in para 2 of the draft global strategy (November 2015) to read, "Ensure healthy lives and promote well-being for all at all ages through universal health coverage including financial risk protection". PHM urges member states to request the Secretariat to quote Goal 3 correctly and not by exclusion discount the other elements of Goal 3. See page 16 of 70/1.

Neglect of the PHC model

The PHC model envisages PHC agencies and practitioners working with their communities to identify and address the barriers to better health and better health care, including healthy ageing. This model recognises the need for good policy models *and* for a constituency which will push for such models to be introduced. By contrast the current discourse of patient centred care refers to the models of care but fails to consider the constituency-building challenge.

This applies to both health systems development, the development of long-term care, and to the social determinants of healthy ageing, including social protection.

Proposed resolution on Healthy Ageing

The Secretariat is preparing a draft resolution for the consideration of WHA69.

PHM urges member states to ensure that the resolution adopted includes support for the following provisions:

- explicit recognition that the system relationships and standards of performance implied in Objectives 3 & 4 and described in chapters 4 & 5 of the Report require single payer funding and strong publicly accountable stewardship and are not compatible with private marketised funds mobilisation and competitive private sector markets in the delivery of services;
- explicit rejection of the neoliberal doctrines of small government, low tax, minimal social protection and inaction on widening inequality as absolute barriers to achieving the vision of the global strategy;
- stronger endorsement of the comprehensive PHC model including active partnerships between PHC agencies and practitioners and the communities they are serving directed to achieving action in service development and action around the social determinants of healthy ageing;
- stronger appreciation of the strategic benefits of linking Objective 2 (Developing agefriendly environments) more explicitly to the range of relevant non-health SDGs and action to address the social determinants of health;
- close attention to the metrics being developed for the SDGs in the development of indicators for this global strategy and plan of action;
- call for lifting of the freeze and untying of donations to WHO so that the priorities adopted in WHO's governing bodies can be pursued by the Secretariat without depending on the largesse or otherwise of particular donors.

13.5 Health and the environment: draft roadmap for an enhanced global response to the adverse health effects of air pollution

In focus

The Assembly will consider A69/18 which includes a revised version of the *draft road map for an enhanced global response to the adverse health effects of air pollution* (considered by the EB in January) and (presumably) a draft resolution.

This report presented is a response to resolution <u>WHA68.8</u> (2015) on air pollution and health which requested the Director-General to propose to the Sixty-ninth World Health Assembly a "roadmap for an enhanced global response to the adverse health effects of air pollution and to report on progress made and challenges faced in mitigating these effects."

Background

This issue has been fiercely contested in recent governing body meetings. However the issues at stake have not been articulated very clearly.

A report on addressing the health impact of air pollution (<u>EB135/4</u>) was considered by the Executive Board at its 135th session. In light of comments made during the discussions, the Board decided to include the issue of the health impact of air pollution on the provisional agenda of its 136th session. The Secretariat report provided for EB136 (<u>EB136/15</u>) outlined a number of strategies for the prevention, control and mitigation of the adverse effects of air pollution on health.

See PHM comments in advance of the discussion at EB135 here. These issues remain of concern.

The discussion of air pollution was sharply contested at EB136 in Jan 2015. See PSRs of

- 8th meeting (<u>here</u>) draft resolution presented; discussion deferred because informal consultations were underway;
- 2. 15th meeting (<u>here</u>) revised resolution tabled; consensus not achieved; Decision EB136(14) adopted:

The Executive Board, having considered the report on addressing the health impact of air pollution [EB136/15], noted the ongoing discussions on the draft resolution ... contained in document EB136/CONF./9 Rev.1, and encouraged Member States to finalize this work, in order for the draft resolution to be duly considered by the Sixty-eighth World Health Assembly. (Fifteenth meeting, 3 February 2015)

The discussion continued at WHA68. Again sharply contested. See PSRs of:

- 1. 6th meeting (here) highly contested [lots of square brackets] draft resolution tabled; formal discussion deferred because informal consultations underway;
- 2. 14th meeting (here) considered new draft resolution, broad support;

3. 15th meeting (here) and WHA68.8 adopted.

Resolution <u>WHA68.8</u> (May 2015) requested the Director-General to propose to the Sixty-ninth World Health Assembly a roadmap for an enhanced global response to the adverse health effects of air pollution.

What were the issues in contention? A preliminary analysis of the various texts of the draft resolution identifies some of the key issues which were contentious. These included

- naming diesel and coal (opposed by Saudi Arabia);
- linking control of air pollution to the control of greenhouse gas emissions (opposed by Saudi Arabia);
- exploration of the use of TRIPS flexibilities in deploying new technologies in developing countries (proposed by India and Egypt; opposed by USA, EU, Norway, Switzerland and Monaco); and
- various references to technology transfer and the funding of technology transfer.

China, sometimes with the USA, proposed including 'on a voluntary basis' in many of the operative paragraphs.

The proposed roadmap (as outlined in A69/18) seeks to address the fundamental issues associated with air pollution through:

- (a) Expanding the knowledge base,
- (b) Monitoring and reporting,
- (c) Global leadership and coordination, and
- (d) Institutional capacity strengthening.

However, the roadmap also steers a careful path through the member state sensitivities as revealed in the debates leading to WHA68.8 in May 2015.

The debate at EB138 is recorded in PSR6.

PHM comment

PHM congratulates the Secretariat on the very constructive report (A69/18).

However, the roadmap has, of necessity, skirted around some of the issues which were contentious in the earlier governing body debates, in particular, regarding the ground rules for intersectoral collaboration and the synergies between controlling air pollution and reducing greenhouse gas emissions. (See for example the 2013 Health and Environment Alliance report on the disease burden in Europe associated with coal fired power.)

PHM urges Member States to recognise that:

- Ambient air pollution is closely associated with greenhouse gas emissions from fossil fuel powered industries, in particular, power generation and motorised transport;
- In the large informal settlements of the megacities of the developing world, ambient air pollution and indoor air pollution reflect the lack of clean, efficient and affordable energy supplies;
- A focus on small scale clean energy technologies for domestic cooking, in homes without access to electricity, should not detract from the urgency of efficient and affordable energy infrastructure in both urban and rural settings;

- Technical innovation and the introduction of clean technologies, in power generation and transport, call for massive investment and reframed policy environments (regulation, incentives, subsidies, etc);
- In the present regime of neoliberal economic globalisation, transnational corporations
 with global reach control in large degree the flow of funds to R&D and productive
 enterprise; the global policy environment which shapes such investment flows is a major
 determinant of action on clean energy;
- Fossil fuel corporations (and their shareholders and the politicians who represent them) have actively sought to prevent investment in clean energy and clean transport and to prevent the reform of policy environments (which shape investment);
- Low standard / high protection patent regimes, linked with tight investor protection provisions, both of which are being aggressively driven through plurilateral economic integration agreements, constitute together a major barrier to the governments of poorer countries deploying advanced clean energy and transport technologies;
- Access, by governments of poor countries, to advanced clean energy technologies can be facilitated by international funds mobilisation ('multi-stakeholder partnerships') or by lowering the IP barriers; the latter is more sustainable and less exposed to distortion by vested interests.

The roadmap provides scope for addressing many of these issues albeit in fairly general terms.

PHM urges member states to insist on a more strategic and more focused approach to the fundamental determinants of air pollution. This should include:

- Collaboration with UNCTAD to define the policy environments shaping investment in clean energy and transport and recommend how these might be reformed; such collaboration should include case studies of particular industries, corporations and countries;
- Collaboration with WIPO and WTO to define the ways in which economic integration agreements (in particular IP and ISDS provisions) shape the access to clean energy technologies of developing country governments and what provisions in such agreements would be required to overcome such barriers;
- Partnerships with civil society organisations, such as Corporate Accountability
 International, in exposing the role of disinformation, corruption and intimidation in the
 defensive strategies of the fossil fuel industry.

13.6 Role of the health sector in the sound management of chemicals

In focus

The Assembly will consider A69/19 which is a revised version of EB138/18 which was considered by the Board in January. It will also return to the draft resolution (B138/CONF./7) which was discussed in January but not agreed upon.

The document provides information on the importance of sound management of chemicals for the protection of human health, and on the role of the health sector in chemicals management.

The key paragraph in the Secretariat report is para 12 which notes that the 'Strategic Approach' to international chemicals management is currently under review and discussions are underway towards the design of a new framework for chemicals management after 2020.

In this context there are several references in A69/19 which need to be underlined; these include:

- a strong emphasis on the global burden of disease associated with human exposure to chemicals in the environment;
- widespread shortfalls in regulatory capacity (as illustrated by the lack of regulatory control of lead in paint); and hints about the need for stronger regulation and more sustainable financing, as well as capacity building;
- the wide range of challenges facing health ministries in relation to chemicals management (para 7 para 11); (including money and regulations);
- collection and sharing of data including toxicity data and risk assessment;
- Industry participation and defined responsibility across the life cycle, including costrecovery policies and systems.

A draft resolution was tabled at the EB138 (<u>B138/CONF./7</u>) but was not able to garner consensus. It was agreed to hold further intersessional discussions with a view to developing a resolution that would attract consensus. The EB debate is recorded in <u>PSR6</u>, <u>PSR7</u> and <u>PSR14</u> but the underlying policy issues are not explicitly identified.

It appears that some of the references in A69/19, in the context of a new framework from 2020, may have raised red flags for some stakeholders. The debate over the resolution appears to be a debate as to whether to empower or constrain the WHO Secretariat in its participation in the planning for a new chemicals management regime after 2020.

To appreciate the politics of these issues it is necessary to explore the history of negotiation and action around international chemicals management.

Background

History

<u>Buccini (2004)</u> provides a useful introduction to international cooperation to promote the sound management of chemicals in the environment (up to 2004). Key landmarks constituting relevant background to this Item include:

- 1921 ILO adopts convention to address the risks associated with white lead in paints;
- 1945 formation of UN and various specialised agencies (FAO, ILO, UNECE, UNEP,
- WHO, etc) dealing with different aspects of chemicals management;
- 1962 Silent Spring by Rachel Carson;
- 1971 ILO Convention on protection from hazards associated with benzene;
- 1973 IMO Convention on the prevention of pollution by ships
- 1974 ILO Convention on control of carcinogens;
- 1980 International Program on Chemical Safety (ILO, UNIEP and WHO);
- 1985 <u>Vienna Convention</u> and (1987) <u>Montreal Protocol</u> to restrict the use of ozone-destroying chemicals;
- 1985 FAO code of conduct on the use of pesticides;
- 1986 ILO convention on the safe use of asbestos;
- 1989 <u>London guidelines</u> for the exchange of information on chemicals in international trade;
- 1990- ILO convention on safe use of chemicals at work;
- 1992 UNEP convention on biological diversity;
- 1992 UN Conference on Environment and Development (UNCED) in Rio produced Agenda 21 (Ch 19 deals with 'Environmentally sound management of toxic chemicals, including prevention of illegal international traffic in toxic and dangerous products'; Ch 20 deals with the management of hazardous wastes; Ch 37 with capacity building in developing countries);
- 1993 Intergovernmental Forum on Chemical Safety (IFCS);
- 1995 Inter Organisation Program for the Sound Management of Chemicals (<u>IOMC</u>), includes FAO, ILO, OECD, UNEP, UNIDO, UNITAR & WHO;
- 1989 Basel Convention on control of transboundary movement of hazardous wastes;
- 1998 Rotterdam Convention on 'prior informed consent' (before accepting toxic wastes)
- 2000 (IFCS sponsored) <u>Bahai Declaration</u> on chemical safety and <u>Priorities for action</u> beyond 2000;
- 2001 IMO Convention on the control of harmful anti-fouling systems on ships;
- 2001 Stockholm Convention on POPs,
- 2002 UNEP identifies the need for a **Strategic Approach to International Chemicals Management (SAICM)** and requests WSSD to endorse this, based on the IFCS documents (including Bahai Declaration and Priorities for Action);
- **2002 World Summit on Sustainable Development (Johannesburg)** recognises need for a more strategic approach to international chemicals management
- 2003 WHA endorses development of SAICM (WHA56.22)
- 2006 (first) International Conference on Chemicals Management (ICCM) in Dubai adopts the SAICM;
- 2006 WHA endorsed SAICM in WHA59.15;

2012 - United Nations Conference on Sustainable Development (Rio de Janeiro, Brazil, 20–22 June 2012) adopts "The future we want", in particular paras 213-223 2012 - Third session of ICCM (Nairobi) adopts a <u>strategy for strengthening the engagement of the health sector</u> in the implementation of the SAICM and; 2013 - (UNEP sponsored) <u>Minamata Convention</u> on mercury exposure adopted; 2014 - WHA endorsed Minamata convention in <u>WHA67.11</u> (in doing so authorises Secretariat to undertake consultation on health sector priorities more generally as proposed in <u>A67/24</u>)

2015 - 2030 Agenda for Sustainable Development adopted by UN

The evolution of the Strategic Approach

Prior to 1992 international action around the management of chemicals was largely focused on quite specific issues (lead, pesticides, asbestos, waste, etc). Notwithstanding this *ad hoc* approach there was a great deal of progress in documenting risk, classification and labelling, guidelines for safe handling and capacity building; largely in the rich countries.

The systematic approach to the sound international management of chemicals starts with UNCED in 1992. Priority program areas identified in <u>Ch 19 of Agenda 21</u> include:

- 1. Expanding and accelerating international assessment of chemical risks,
- 2. Harmonization of classification and labelling of chemicals,
- 3. Information exchange on toxic chemicals and chemical risks,
- 4. Establishment of risk reduction programs
- 5. Strengthening of national capabilities and capacities for managing chemicals,
- 6. Prevention of illegal international traffic in toxic and dangerous products.

The Intergovernmental Forum on Chemical Safety (IFCS) was established in 1993. In 2000 the (IFCS sponsored) Bahai conference reviewed progress with respect to Chapter 19 and adopted the <u>Bahai Declaration</u> on Chemical Safety and <u>Priorities for Action</u> (regarding the above six program areas) beyond 2000 which again underlined the need for a systematic approach to international chemicals management.

In 2002 the UNEP governing body recognised the need for a Strategic Approach to International Chemicals Management (SAICM) and requested the World Summit on Social Development to endorse this, based on the IFCS documents (including <u>Bahai Declaration</u> and <u>Priorities for Action</u>), which it did.

Four years later in 2006 the (first) International Conference on Chemicals Management (ICCM) in Dubai adopted the <u>Strategic Approach to International Chemicals Management</u> with its overall objective to achieve "the sound management of chemicals throughout their life cycle so that, by 2020, chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment".

The Overarching Policy Strategy of the Strategic Approach identified chemicals that might be prioritized for assessment and related studies as including: persistent, bioaccumulative and toxic substances (PBTs); very persistent and very bioaccumulative substances; chemicals that are carcinogens or mutagens or that adversely affect, inter alia, the reproductive, endocrine, immune, or nervous systems; persistent organic pollutants (POPs), mercury and other chemicals of global concern; chemicals produced or used in high volumes; those subject to wide dispersive uses; and other chemicals of concern at the national level.

WHO's IPCS web site also includes a list of 10 chemicals of public health concern including Air pollution, Arsenic, Asbestos, Benzene, Cadmium, Dioxin and dioxin-like substances, Inadequate or excess fluoride, Lead, Mercury, and Highly hazardous pesticides. Further information is available through WHO's 'concise international chemical assessment documents (CICADs)' here.

In May 2006 the WHA endorsed the SAICM and in resolution <u>WHA59.15</u> urged Member States to take full account of the health aspects of chemical safety in national implementation of the Strategic Approach and to participate in national, regional and international efforts to that end, including the <u>International Conference on Chemicals Management</u>.

Over the next six years, however, it appears that officials associated with the SAICM judged that the health sector was not engaging as fully as it might in the implementation of the SAICM and the third session of the ICCM (in 2012) adopted a <u>strategy to strengthen the engagement of the health sector in the SAICM</u>. This strategy had six specific objectives:

- (a) To foster a deeper interest in and awareness of sound chemicals management among stakeholders in the health sector and to build their capacity to undertake preventive actions, especially by increasing the amount, quality and relevance of information disseminated to the sector on the human health aspects of chemicals management;
- (b) To actively involve the health sector in increasing the amount and improving the quality and relevance of information available on the impacts of chemicals on human health, including through risk assessment;
- (c) To strengthen the capacity of the health sector to fulfil its roles and responsibilities in chemicals management;
- (d) To improve consultation, communication and coordination with other sectors and increase the number of joint actions at the national, regional and international levels:
- (e) To ensure the effective use of existing resources, including organizations and funds, and to leverage additional resources where needed;
- (f) To strengthen coordination, leadership and coherent action by international agencies, including United Nations agencies, relevant convention secretariats, multilateral funding agencies and regional development banks, with regard to the implementation by the health sector of the Strategic Approach.

(It maybe that the initiative for a special strategy directed at the health sector originated within UNEP and the IFCS but it may have been initiated from within the WHO Secretariat, concerned about the lack of attention to chemicals safety issues from the governing bodies of WHO.)

Two years later (2014), in the context of reporting to the WHA on the implementation of the Minamata Convention the Secretariat (in document A67/24) canvassed a wider range of issues associated with chemicals safety (see paras 18-22) including the SAICM.

18. Mercury is only one of a number of chemicals of major public health concern. Preventable exposure to lead, carcinogens, highly hazardous pesticides and other hazardous chemicals continues to occur. These exposures result in significant disease burden and demands on health systems. In the outcome document of the United Nations Conference on Sustainable Development (Rio de Janeiro, Brazil, 20–22 June 2012) "The future we want", deep concern was expressed that many countries lack the

capacity for sound management of chemicals, and called for additional efforts to enhance work towards strengthening capacities, including through partnerships, technical assistance and improved governance structures. Governments reaffirmed their aim to achieve by 2020 sound management of chemicals throughout their life cycle and of hazardous waste in ways that lead to minimization of significant adverse effects on human health and the environment, as set out in the Johannesburg Plan of Implementation.

19. Member States have numerous opportunities to reduce or eliminate exposures to hazardous chemicals, including implementation of the Strategic Approach to International Chemicals Management. In resolution WHA59.15 on that matter, the Health Assembly urged Member States to take full account of the health aspects of chemical safety in national implementation of the Strategic Approach and to participate in national, regional and international efforts to that end, including the International Conference on Chemicals Management. The strategy for strengthening the engagement of the health sector in the implementation of the strategic approach, adopted by the International Conference on Chemicals Management at its third session (Nairobi, 17–21 September 2012), sets out various actions.

22. In order to guide the work of the Secretariat and Member States towards the achievement of the 2020 goal for the sound management of chemicals, the Secretariat proposes to consult Member States on identifying a set of core priority actions for the health sector.

The secretariat's proposed consultation regarding health sector priorities (responding to the call from ICCM3 to strengthen the engagement of the health sector) was undertaken during 2015 here and produced an updated listing of health sector priorities in this field here. In summary the updated priorities are:

- Devising better and standardized methods to determine impacts of chemicals on health;
- Formulating strategies aimed at prevention of ill-health and disease caused throughout the life course by chemicals;
- Building capabilities of countries to deal with poisonings and chemical incidents and emergencies;
- Promoting alternatives to highly toxic and persistent chemicals;
- Filling of gaps in scientific knowledge;
- Elaborating globally harmonized methods for chemical risk assessment; and
- Actions to improve ability to access, interpret and apply scientific knowledge.

The outcomes of the consultation and the updated list of priorities were reported to the 4th session of the ICCM in 2015 along with a summary <u>report</u> which outlines the wide range of WHO (Secretariat) engagements in international chemicals safety. A number of WHA resolutions dealing with various aspects of chemicals safety have been adopted (<u>here</u>).

In 2015 the UN finalised the 2030 Agenda for Sustainable Development including 17 goals and 169 targets (here). There are several references to chemicals safety:

 Para 34 of the Agenda: "We will reduce the negative impacts of urban activities and of chemicals which are hazardous for human health and the environment, including through the environmentally sound management and safe use of chemicals, the reduction and recycling of waste and more efficient use of water and energy";

- Target 3.9: "By 2030, substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water and soil pollution and contamination;
- Target 6.3: "By 2030, improve water quality by reducing pollution, eliminating dumping and minimizing release of hazardous chemicals and materials, halving the proportion of untreated wastewater and substantially increasing recycling and safe reuse globally";
- Target 12.4: "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".

A69/19 (para 12) notes that

The Strategic Approach concludes in 2020, with the fifth session of the International Conference. The International Conference at its fourth session decided to initiate an intersessional process to prepare recommendations on the Strategic Approach and the sound management of chemicals and waste beyond 2020. The health sector contributes significantly to the sound management of chemicals, but its level of participation in the processes of the Strategic Approach, for example, the International Conference, has been low in comparison to that of the environment sector. Health ministries are urged to participate in the intersessional process in order to ensure that the recommendations for the future meet their needs.

More detail about the SAICM after 2020 is here.

So, what are the issues in contention?

The EB138 debate (at <u>PSR6</u>, <u>PSR7</u> and <u>PSR14</u>) was not able to find consensus around the <u>draft resolution</u>.

The underlying issues in contention are nowhere spelled out and discussed in the papers before the Assembly. However, some of the long standing debates in this field (see for example, Quick and Brouder, 2010) include differences over:

- regulatory strategies:
 - the need for binding international agreements versus 'co-regulation' (codes of conduct, including ICCA sponsored <u>Responsible Care program</u>);
 - broadly inclusive agreements versus highly specific instruments (such as Montreal, Minamata, Basel, Rotterdam, and Stockholm); what Peiry (2014) calls the 'problem by problem' approach;
 - whether the IHRs should be developed so as to contribute more to international chemicals management, in particular to capacity building;
 - specific agreements versus the framework convention plus protocols model (as in the FCTC, Vienna plus Montreal);
 - giving leverage to chemicals management policies through linkage to trade agreements; including so-called 'environmental clauses' in trade and investment agreements;
 - modalities of regulation: mandatory information provision (especially toxicity information), mandatory substitution (of safer in place of hazardous chemicals), consumer awareness, risk assessment / management, etc; in particular, differences between the European and North American models;

- how to approach North South disparities in relation to institutional regulatory capacity:
 - whether industry should be forced to contribute to the costs of capacity building in developing countries (user pays regulation; a 'chemicals tax');
 - North South funding to support effective regulation;
 - ways in which intellectual property is handled in approaching technology transfer (eg private sector investment versus the use of TRIPS flexibilities)
- links between sound chemicals management and the challenges of sustainable development including trade and investment agreements

Peiry (2014) is critical of the problem by problem approach and argues for the development of an overarching binding agreement using the convention plus protocols approach. She comments on the move to closer cooperation between the Basel, Rotterdam and Stockholm conventions and argues that they could be brought within the umbrella of such an instrument. She outlines proposed substantive provisions. The Strategic Approach is non binding. It is likely that if there are moves towards a binding treaty approach it would be strongly opposed by the industry and the USA.

On the question of financing van der Kolk and Agarwal (2011) argue that any long term financing mechanism for chemical safety can only be achieved if it is internalised as part of the product life cycle and such costs are included as part of the product cost. They point out that the chemical industry has sales of more than \$US1.5 trillion (including pharmaceuticals) per year, and accounted for an estimated 7% of global income and 9% of international trade in 2006. They point out that only a tiny fraction of these amounts would be be sufficient to support effective chemical safety globally. 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.

Substitution is a controversial issue. Lissner and Romano (2011) describe the European approach to mandatory substitution and the wider arrangements known as REACH. Hogue reports the opposition of chemicals industry spokespeople to entry controls to the chemicals market being linked to toxicity data ('no data; no market').

The role of environmental clauses in trade / investment agreements is controversial. However, whether or not there are specific references to environmental issues in such agreements the increasing salience of investor protection provisions has far-reaching implications for environmental protection and the need for binding regulation. The field of international chemicals management is awash with non-binding guidelines such as the Strategic Approach. In the context of litigation under ISDS provisions non-binding guidelines provide much weaker protection for national environmental regulation than formal multilateral agreements.

These debates are not referred to directly in either A69/19 or in the draft resolution. Rather there are debates over inserting or deleting 'as appropriate' or 'voluntary' or underlining or downplaying the seriousness of the chemicals threat to health or inserting or removing references to funds mobilisation or technology transfer or alternatives; generally to limit and weaken or to strengthen and broaden the reach of the resolution.

Institutions, stakeholders and development

The disease burden associated with chemicals in the human environment is substantial (lead, asbestos, benzene, dioxins etc) and there is a global movement towards implementing the

goals of the Strategic Approach, simply to improve the environment. (For burden of disease estimates see Prüss-Ustün, Annette, Carolyn Vickers, Pascal Haefliger, and Roberto Bertollini. "Knowns and Unknowns on Burden of Disease Due to Chemicals: A Systematic Review." Environmental Health 10, no. 9 (2011). http://dx.doi.org/10.1186/1476-069X-10-9.)

However, there are institutions and stakeholders with other purposes beyond cleaning up the environment who also play an influential role in developing and implementing (or not) environmental policies.

The chemicals industry comprises a wide range of different interest groups. Industry leaders who have evolved in the highly regulated environments of North America and Europe, are ambivalent about further global regulation. On the one hand they are cautious about policies which might add to their costs or jeopardise their monopoly position. On the other hand uniform global regulation based on rich country standards would help to reduce competition from less advanced corporations often based in developing countries.

The unions exercise significant leverage within ILO and have driven the adoption of some important conventions. However, ILO plays a limited role in the intergovernmental politics of chemicals management.

The environmental movement through organisations such as Consumers International, the Pesticide Action Network, Friends of the Earth are active in policy making but not particularly strong. There are many forums and many issues to keep abreast of and the science is complex.

There are many official bodies involved, at the national, regional and global level all of whom have their own preferred regulatory strategies, models and tools (and jealousies).

Behind the institutional conflicts of interest the geopolitical and macroeconomic polarities loom, in particular, between the rich developed nations (and their chemical industries) and the developing countries who carry a disproportionate burden of disease associated with environmental chemicals (see Bhopal), who have much weaker environmental regulatory capacity, but who are also looking to develop and grow their own indigenous chemical industrial capacity.

Glyphosate controversy

The controversy between the International Agency for Research on Cancer (IARC) and the European Food Safety Authority (EFSA) over the carcinogenic potential of glyphosate (<u>Portier</u>, <u>2016</u>) provides a useful case study of the interplay of science and politics in chemicals regulation.

See the <u>April 2016 comment by Ruff</u> describing the attacks on the IARC by scientists associated with the chemicals industry.

PHM calls on member states to reject industry associated attacks on the IARC and to put in place robust protections against industry perversion of global chemicals governance.

References

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Lissner, L. and D. Romano (2011). "Substitution for Hazardous Chemicals on an International Level—The Approach of the European Project "Subsport"." NEW SOLUTIONS: A Journal of Environmental and Occupational Health Policy 21(3): 477-497.

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Quick, R. and A. Brouder (2010). Strategic Approach to International Chemicals Management Handbook of Transnational Economic Governance Regimes. C. Tietje and A. Brouder. Leiden & Boston, Martinus Nijhoff Publishers 1071-1081.

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PHM comment

PHM urges member states to engage in the debate over the proposed resolution with a view to mandating the WHO Secretariat to participate actively in the discussions regarding the post 2020 Strategic Approach with a view to achieving:

- 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;
 - mandatory labelling in accordance with a mandated classification scheme;

14.1 Implementation of the International Health Regulations (2005)

In focus

In the first part of this item the Assembly will consider A69/20, the annual report on the implementation of the IHRs (2005). This includes updates on Ebola, MERS, polio, Zika, and avian influenza. It also reports on discussions in a number of venues directed to supporting capacity building for IHR implementation.

When the EB considered the IHRs item in January the Secretariat was asked to prepare a note analysing how the <u>Nagoya Protocol</u> might affect the sharing of pathogen genetic material.

Under this item the Assembly will be asked to approve the proposed monitoring and evaluation framework described in the July 2015 <u>concept note</u>, subsequently discussed by regional committees and by the EB, and included in the <u>annex to A69/20</u>. The provision for external independent evaluations may be controversial.

The Assembly will also consider A69/21 which is the final report of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response. The progress report (in EB138/20) was considered by the Board in Jan. See in particular the recommendations from para 12.

Background

Lots of background references are available from the WHO IHR (topics) page

IHRs discussed at PSR1, PSR2

Review Committee on the Role of the IHRs in Ebola Outbreak and Response: home page.

See also the <u>final report of the Ebola Interim Assessment Panel</u> (and presentation to the Review Committee by the erstwhile chair of the Interim Assessment Panel at <u>Appendix 3 of EB138/20</u>).

The 13 themes reported from the Review Committee's discussions (Para15 of <u>EB138/20</u>) are also very useful. These included:

- a poor awareness and/or incomplete understanding of the International Health Regulations (2005) at many levels, inter alia ministries of health, political and decision-making levels, health-care workers and community;
- the need to develop an alert system that is not limited to the declaration of a PHEIC, that
 is a graded mechanism of risk assessment that would allow for an intermediate level of
 alert;
- the importance of strengthening core capacities, including wide support for the Ebola Interim Assessment Panel's recommendation for WHO and the World Bank to develop a prioritized, costed plan to strengthen core capacities;
- the inadequacy of self-assessment and the need for better monitoring of capacitybuilding, and the importance of this for pandemic influenza preparedness;

- the importance of strengthening health systems concurrently with strengthening core capacities, while acknowledging that implementation of the International Health Regulations (2005) is possible in countries with poor health systems;
- the need to ensure effective implementation of the International Health Regulations (2005) at all points of entry, underscoring the importance of migration across borders and linkages with disease spread;
- the development of effective incentives and disincentives in compliance and notification, and the importance of regional collaboration and knowledge-sharing;
- an understanding of WHO's specific role in emergencies and its integration with normative functions, and the need for organizational change;
- the critical need for community engagement and, more importantly, ownership in managing disease outbreaks, including collaborating with civil society organizations in fostering this ownership;
- the positioning of health within global health security, and how this can be reflected in the International Health Regulations (2005);
- the urgent need for better synergy between humanitarian and health sectors, such that each sector understands the priorities of the other;
- the complexities of implementing the International Health Regulations in conflict zones, which are often at high risk of infectious disease outbreaks; and
- the importance of refraining from taking unnecessary traffic and trade restrictions.

PHM comment

Many member states have not established in full the core capacities required of all member states by the IHRs.

Many of these MSs will need financial and technical assistance to do so. Global health security is a global public good and low income countries facing local priorities in public health and health care are entitled to financial transfers to enable them to contribute to global health security.

The self-assessment method for monitoring capacity development is inadequate. The WHO Secretariat is developing a revised approach to monitoring and assessment including an external evaluation component (see annex to A69/20). The EB discussed the idea of peer evaluation and while there were reservations there was a general acceptance.

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

In focus

The Assembly will consider:

- A69/22, a biennial report on the status of, and progress in implementing, the <u>Pandemic Influenza Preparedness Framework</u> in line with the relevant obligations under <u>section 7.4.1</u> of the Framework:
 - in Para 11 the Secretariat comments that the <u>Global Action Plan for Influenza</u> <u>Vaccines</u> terminates in 2016 and that the Review of the Framework might recommend that some activities from the Global Action Plan continue under the PIP Framework;
 - Para 15 comments on challenges facing the development of <u>standard material</u> transfer agreements with manufacturers;
 - Paras 21-23 report on work under way regarding how the PIP Framework should be operationalised in relation to genetic sequence data; this was also discussed at the AG meeting (more here);
- <u>A69/22 Add.1</u> reports on the outcomes of the Special Session of the Pandemic Influenza Preparedness Framework <u>Advisory Group</u>, which was held in Geneva on 13 and 14 October 2015 to discuss the review of the Framework and its annexes.
 - Paras 5-8 summarise the issues raised by industry representatives and other stakeholders during the consultation stage of the Advisory Group meeting;
 - Paras 14-19 set out the recommendations of the Advisory Group to the DG regarding the scope and terms of reference of the Review of the Framework.

These documents were considered by the EB in January. The record of discussion is at PSR7.

Background

See WHO PIP Page

See Background Notes in PHM's Commentary on Item 16.2 at WHA67 on PIP

PHM comment

The focus of the Assembly in this item will be procedural, in particular regarding Review.

We note that there is no reference, in either document prepared for this discussion, to the (strict or less strict) application of the definition under PIP of biological materials and whether the strict application might lead to the exclusion of significant animal viruses. This was discussed at EB134 and WHA67 (see here).

14.3 Smallpox eradication: destruction of variola virus stocks

In focus

The Assembly will consider A69/23 which

- summarizes the conclusions of the <u>Independent Advisory Group on Public Health</u>
 <u>Implications of Synthetic Biology Technology Related to Smallpox</u>, which met in Geneva at the end of June 2015;
- reports on the WHO's biosafety inspections of the two variola virus repositories in 2014– 2015;
- summarizes the work being carried out on the operational framework for access to WHO's smallpox vaccine stockpile; and
- reports on the conclusions of the <u>WHO Advisory Committee on Variola Virus Research</u> (Geneva, 12 and 13 January 2016).

The Advisory Group concluded "that the risk of the re-emergence of smallpox has changed and that there is a need to update preparedness efforts and to adapt research frameworks". This will be quite controversial as there is a widely held view, including among many experts, that the remaining stocks should be destroyed.

The record of EB discussion of this item is at PSR7.

Background

The proposed destruction of remaining variola virus stocks is a recurring item on the WHA agenda. For a summary of this history see PHM comment prepared for WHA67 here.

This item was considered at EB134, informed by <u>EB134/34</u> (Jan 2014) and again at WHA67 (May 2014), informed by <u>A67/37</u> (a revision of <u>EB134/34</u> following the debate within the Board). The focus of discussion was again whether to set a timetable for the destruction of remaining variola stocks. <u>A67/37</u> provides a summary of previous discussions and decisions regarding the variola stockpile.

There was some concern expressed at the Board in Jan 2014 (EB134) regarding modern biosynthetic technologies and the possibility of synthesising the virus from the known genome sequence and the DG indicated that she proposed to convene an expert group to advise on this possibility. See official record of discussion at WHA67: WHA67/2014/REC/3.

The Independent Advisory Group mein June 2015; their deliberations were informed by the findings of a Scientific Working Group, convened by the Secretariat in April 2015. The key conclusions and observations of the IAG include:

- 1. the risk of smallpox re-emergence has increased with the low cost and widespread availability of technology to synthesize genomes;
- 2. the WHO recommendations concerning synthesis and use of variola virus DNA fragments should be revised urgently (see page 12 for more detail);

- MS should amend national public health laws so as to provide legal backing for WHO's
 recommendations concerning the distribution, handling and synthesis of variola virus
 DNA:
- 4. if the last stocks of the variola virus had been destroyed in 1996 as originally mandated the risk of synthesis would not arise because the virus had not been sequenced at that time:
- 5. if there is a refusal to destroy the variola virus, it is unlikely that any dangerous pathogens would be destroyed following eradication in the future;
- 6. in the event of an outbreak in a remote location "it would be beneficial to have a reference standard against which to measure a circulating virus" to reduce the risk associated with a delay in diagnosis; (see discussion page 9); and
- 7. consideration should be given to expanding the number of research sites and developing further expertise at the global level (no consensus on these two issues).

A69/23 advises that WHO biosafety inspection teams visited and inspected the containment facilities at the two WHO collaborating centres (Koltsovo, Novosibirsk Region, Russian Federation) and the Centers for Disease Control and Prevention (Atlanta, Georgia, United States of America), in December 2014 and May 2015 respectively. The reports of these biosafety inspections are under preparation, currently pending the submission of self-assessment reports and supplementary information by the repositories to WHO. Once finalized, they will be made available on the WHO website (but NYP).

PHM comment

The reports of the SWG and the IAG are useful.

It is apparent that the risk of smallpox re-emergence has increased with the low cost and widespread availability of technology to synthesize genomes. (It is ironic that if the last stocks of the variola virus had been destroyed in 1996 as originally mandated the risk of synthesis would not arise because the virus had not been sequenced at that time.)

The recommendations regarding the revision of the guidelines under the IHRs appear sensible as does the enforcement of these guidelines through national public health laws.

It appears that there was a view in the IAG to the effect that destruction of remaining stocks could lead to a delay in diagnosis in the event of an outbreak in a remote area. One corollary of this view was that the number of research sites (with variola stocks) should be expanded so that reference materials for confirmation of the diagnosis could be made available more rapidly. This position appears to argue for increasing the risk (more sites) in order to decrease the risk (more rapid diagnosis).

PHM's position has been that WHO should proceed to the final destruction of the remaining stocks of variola virus. The only argument for not proceeding turns on the need for reference material for more rapid diagnosis. This argument needs to be tested more robustly in both technical and policy terms.

14.4 Global action plan on antimicrobial resistance

In focus

The Assembly will consider A69/24 which reviews progress in the implementation of the global action plan on antimicrobial resistance (adopted in resolution WHA68.7 in May 2015), and document A69/24 Add.1 which reports on options for a global development and stewardship framework related to antimicrobial medicines.

See also DG speech to high level dialogue with UN member states (18 April, 2016).

Background

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

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

WHA68 (May 2015) considered <u>A68/19</u> which provided a summary report on progress made in implementing resolution <u>WHA67.25</u> on antimicrobial resistance.

One of the commitments in <u>WHA67.25</u> was to produce a global action plan on antimicrobial resistance. A draft global action plan was considered by WHA68 (<u>A68/20</u>) and after a long debate was adopted (<u>WHA68.7</u>). Through this resolution the Assembly adopted the Global Action Plan (GAP); urged MSs to implement the Plan, including developing national action plans; and requested the DG to undertake a range of actions. (See <u>PHM Comment</u> from May 2015 on the provisions of the GAP.)

PHM comment

It seems that the focus of debate will be on <u>A69/24 Add.1</u> and options for a global development and stewardship framework.

Objectives? Proposed objectives in para 4 are good. However, the objectives should include explicit reference to monitoring and data collection. Close monitoring of antimicrobial usage should be a core element of this framework (contrary to para 6). This will require specification of the data collections needed from various end users, including meaningful data about purpose of use. Ensuring such data collections will require binding regulation.

What kind of framework? PHM urges the adoption of a binding convention such as the FCTC (although OIE and FAO should be co-sponsors of any such convention). Antibiotic stewardship

is a global public good. Over many years authoritative guidelines on responsible use (in both humans and animals) and on ethical promotion have been widely flouted. The urgency of the issue and its international character call for a binding international agreement.

Which medical products? PHM urges inclusion of all antimicrobials but for antibiotics to be given priority initially.

Appropriate use? Paras 12-18 review some of the complexities in developing strategies to encourage appropriate use and ethical promotion. These complexities should not obscure the need for binding regulation to ensure such strategies are implemented as is discussed in paras 20-21.

Development of new products? PHM strongly supports the principle of delinking of the cost of investment in research and development from price and sales volume. PHM urges that a stewardship convention should include a financing mechanism as has been suggested through the CEWG.

Access? PHM strongly supports WHO playing a more active role in encouraging countries to use TRIPS Flexibilities in ensuring access to antimicrobials.

14.5 Polio

In focus

In 2015, wild poliovirus transmission is at its lowest level in history. Resolution <u>WHA68.3</u> (May 2015) recognized that progress has been made and urged Member States to fully implement and finance the <u>Polio Eradication and Endgame Strategic Plan 2013–2018</u>.

The report before the Assembly (A69/25) summarizes the impact of national emergency action plans in the remaining countries affected and of the temporary recommendations under the International Health Regulations (2005) in connection with the public health emergency of international concern. (See WHO Statement for the original statement declaring the emergency.)

The report also confirms April 2016 as the date for the globally coordinated switch from the trivalent formulation of oral polio vaccine to the bivalent formulation (see SAGE discussion from p6 of <u>WER 89(01)</u>), and outlines a revised timeline for global certification of poliomyelitis eradication and associated budget implications.

The Assembly is invited to note the report and to urge Member States to ensure full implementation of resolution WHA68.3.

Background

This report traverses a range of somewhat different issues:

- the interruption of wild poliovirus transmission
 - wild poliovirus type 2 declared eradicated globally:
 - Afghanistan and Pakistan only remaining endemic countries with falling incidence of new cases of wild type polio; Nigeria no longer recognised as endemic;
 - o international spread of wild virus continues (from both Afghanistan and Pakistan);
- circulating vaccine-derived type 1 (Madagscar & Lao) and type 2 (Nigeria, South Sudan);
 - importance of stopping outbreaks of circulating vaccine derived poliovirus type 2 (cVDPV2) before removal of type 2 from oral PV;
 - vaccine derived polio reflects low level of immunisation coverage;
- withdrawal of type 2 component of oral PV;
 - transfer to bivalent oral vaccine scheduled for late April 2016;
 - priority to ensuring inactivated vaccine available before switch, especially in high risk countries;
 - stockpiles of inactivated and oral type 2 vaccines in case of outbreaks of VD polio 2;
- need to strengthen routine immunisation;
- containment of PV2
 - o need inventory of facilities where PV2 (wild and Sabin) is held;
 - destruction of PV2 materials (wild and Sabin)
 - biorisk provisions where olding PV2 is regarded as 'essential';
- legacy planning; WHO guidelines but national leadership critical;

• funding shortfall (of \$2 b) owing to delay in estimated date of achieving interruption of wild PV transmission.

Some of these issues are quite technical. <u>WER 89(01)</u> is a useful resource. Further information can be found under <u>topics</u> and <u>GPEI</u>.

Record of EB debate at PSR8

PHM comment

Polio is a disease of war, displacement, poverty and fragile health systems. These are the essential conditions which have so far prevented eradication.

The work of WHO and its partners and the field staff in polio eradication is admirable but it would be good if the experience of WHO in polio could find a place in the continuing development of the SDGs, in particular the non-health goals such as:

- 1. No poverty
- 6. Clean water and sanitation
- 10. Reduced inequalities
- 16. Peace, justice and strong institutions.

The polio experience also underlines the importance of strong health systems structured around the PHC model and with strong district health system structures. A clear and valued role for CHWs is crucial in this.

14.6 WHO response in severe, large-scale emergencies

In focus

In accordance with para 57 of resolution EBSS3.R1 (see below) the Secretariat has produced A69/26, (a revised version of EB138/23 which was considered by the Board in January). A69/26 provides an overview of the progress made by the Organization in responding to Grade 3 emergencies during 2015. It describes the scope and scale of all emergencies to which WHO has responded during the year, and includes a summary of WHO's activities in each of the six Grade 3 emergencies (namely, those in Central African Republic, Iraq, Nepal, South Sudan and Syrian Arab Republic, together with the Ebola virus disease outbreak in West Africa). See also earlier corresponding report A68/23.

A69/26 is structured in two parts. In the first part an overview is provided of the outbreaks and emergencies that WHO was involved in during 2015. Very prominent are the emergencies associated with conflict. The structures, policies and procedures are outlined briefly. The big shortfalls in funding are noted.

In the second part the report provides an overview of WHO involvement in Grade 3 emergencies in 2015: Central African Republic, Ebola virus disease outbreak, West Africa; Nepal; South Sudan; Syrian Arab Republic; Yemen. The magnitude of the challenges being faced in all these area is huge and in all cases the funding has been far less than is needed.

In January 2016 this item was considered conjointly with 'Update on 2014 Ebola virus disease outbreak and Secretariat response to other issues raised' which is item 14.8 on this agenda (PHM Comment here) and is informed by document A69/28 (NYP, a revised version of document EB138/27 considered by the EB in January).

See record of EB debate at PSR2(9) and PSR3(2).

Background

Para 57 of resolution EBSS3.R1 (Jan 2015)

FURTHER REQUESTS the Director-General to report to the Sixty-eighth World Health Assembly on all Grade 3 and United Nations Inter-Agency Standing Committee Level 3 emergencies where WHO has taken action since the Sixty-seventh World Health Assembly and calls for annual reports on WHO's actions in health emergency response

PHM comment

The funding shortfalls are the most worrying aspects of this report. Para 8 reports that WHO was funded at around 55% of what it needed to fulfill its obligations in relation to humanitarian needs in 2015. "Iraq is the first Grade 3 emergency where funding shortages have obliged WHO and partners to shut down health care services, affecting almost 3 million people."

Funding for the six Grade 3 emergencies facing WHO in 2015 was well below needs in all cases:

	Funding of WHO as % of funds needed
Central African Republic	28%
Ebola crisis in West Africa	
Iraq	72%
Nepal	44%
South Sudan	51%
Syria	56%
Yeman	55%

14.7 Promoting the health of migrants

In focus

The current global refugee and migrant crisis underlines the need to have a coordinated and strategic response to the public health and health-system implications of large-scale population movements, and the right to health care of the populations concerned.

The Secretariat report (A69/27) provides an update on implementation of resolution WHA61.17 (2008) on the health of migrants; information on key public health issues facing refugees and migrants; and considers the way forward with regard to strengthening the capacity of Member States' health systems to provide refugees and migrants with the essential and necessary health support at the initial stages of population movements and thereafter.

Useful links

International Organisation for Migration

UN High Commission for Refugees

Special Rapporteur on the Human Rights of Migrants

<u>Human rights of migrants (August 2014)</u>. Report of Special Rapporteur on the Human Rights of Migrants (to UNGA)

Outcomes of high level meeting in Rome 23-4 Nov 2015 on Refugee and Migrant Health

Record of discussion at EB138 PSR8(9)

PHM comment

The Secretariat report (A69/27) provides a useful overview of current migration and refugee trends and some of the health problems migrants and refugees face. It lists some of the actions undertaken by the Secretariat as mandated through WHA61.17 (2008). The report concludes by articulating eight priorities for member states, partners and 'other stakeholders':

- to support the development and implementation of migrant-sensitive health policies that incorporate a public health approach and equitable access to health services (health promotion, disease prevention and clinical care) for migrants and refugees, regardless of status and without discrimination or stigmatization;
- 2. to ensure that health services are culturally, linguistically and epidemiologically appropriate, and increase the capacities among the health workforce to understand and address the health issues associated with population displacement;
- to promote coherence among policies of various sectors that may affect migrants' and refugees' abilities to access health services, as well as among countries involved in the migration process, to guarantee continuation and effective surveillance;
- 4. to develop or strengthen bilateral and multilateral social protection agreements between source and destination countries to include portable health care benefits;

- 5. to explore the role of relevant sectors, including employers and private partners, in health security schemes;
- 6. to raise awareness among migrants and refugees of their entitlements and obligations;
- 7. to involve migrants and refugees in decisions relating to the delivery of health care and social services so as to enhance integration and self-reliance and improve public health; and
- 8. in the most difficult circumstances, to continue to mobilize and coordinate partners in support of Member States to provide life-saving health care in countries of origin and host communities alike.

However, the report is weak in relation to human rights and the challenges of intersectoral collaboration in this space and is mute in relation to the social and political determination of health in relation to migration, displacement and refugees. All three principles are identified as cross cutting priorities in WHO's GPW 2014-19 and the importance of human rights to health is enshrined in the WHO Constitution (see Box 1 of GPW14-19).

There are major barriers to access to health care for migrants, refugees and undocumented people in many countries who have signed up to 'UHC'. See Chan (2015) on the denial of UHC for undocumented migrants in Southeast Asia.

Action on the social determination of health is recognised in the (GPW14-19) as a cross cutting priority:

The concept of social determinants of health constitutes an approach and a way of thinking about health that requires explicit recognition of the wide range of social, economic and other determinants associated with ill health, as well as with inequitable health outcomes. Its purpose is to improve health outcomes and increase healthy life expectancy. The wider application of this approach – in line with the title of the Twelfth General Programme of Work and in a range of different domains across the whole of WHO – is therefore a leadership priority for the next six years in its own right.

Implicit in the concept of the social determinants approach to health, as articulated in the Rio Political Declaration, is the need for better governance of health, both within national governments, and in relation to the growing number of actors in the health sector. This is generally referred to as health governance. Equally, the social determinants approach promotes governance in other sectors in ways that positively impact on human health, referred to as governance for health. This latter perspective is well illustrated by the whole-of-society approach to noncommunicable diseases, as well as in a statement made in 2010 by the foreign ministers of the seven participating countries in the Foreign Policy and Global Health Initiative: "Foreign policy areas such as security and peace building, humanitarian response, social and economic development, human rights and trade have a strong bearing on health outcomes".

Against this background A69/27 is lacking any useful discussion of:

- the inhumane treatment of refugees (including the denial of basic health care) as a strategy for deterring other asylum seekers (see for example the repeated findings by the Human Rights Council that Australia's treatment of refugees constitutes a violation of international law);
- the role of economic insecurity, promoted by neoliberal economic policies, in driving racism and xenophobia;

- the role of imperialism (through war, sanctions and political support for brutal and oppressive regimes) in mass displacements;
- the increasing role of climate change in driving population movements with related health consequences:
- the role of agricultural dumping in creating food insecurity and urbanisation (internal displacement);
- a global economy which treats over a billion people as surplus to requirements other than as a reserve army to threaten those who do have jobs with lower wage competition.

These factors all lie outside the technical domain of disease causation, prevention and treatment. However, the GPW14-19 was subtitled 'Not merely the absence of disease' recognising that WHO has a responsibility to contribute to 'whole-of-society' approaches to the problems of migrants and refugees.

A useful first step would be to approach those intergovernmental organisations whose mandate is more centred on these issues with proposals for cooperation, for example, in terms of meetings or status reports.

14.8A Update on 2014 Ebola outbreak and Secretariat response to issues raised

In focus

In response to the relevant requests in decision <u>WHA68(10)</u> (2015), the Secretariat will submit a report to the Assembly (A69/28 (NYP), a revised version of <u>EB138/27</u> considered by the Board in January) reviewing the status of WHO's work on developing a new programme for outbreaks and emergencies with health and humanitarian consequences, as catalysed by recent crises, including the Ebola virus disease outbreak in West Africa.

The reform of WHO's emergency work is informed by the report of the <u>Ebola Interim</u> <u>Assessment Panel</u> and the advice of the Advisory Group on WHO's work in outbreaks and emergencies (<u>about</u>, <u>first report</u>, <u>second report</u>). A69/28 provides a further update on progress made in the areas of work listed by the Director-General in May 2015 in her address (<u>A68/3</u>) to the Sixty-eighth World Health Assembly.

Also relevant is A69/21 (NYP) which is the final report of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response (to be considered under Item 14.1 of this agenda. The progress report (in <u>EB138/20</u>) from the Review Committee was considered by the EB in January.

In January 2016 the Board considered this item conjointly with 'WHO response in severe, large-scale emergencies' which is item 14.6 on this agenda (PHM Comment here) and is informed by document A69/26 (NYP, a revised version of document EB138/23 considered by the EB in January).

See record of EB debate at PSR2(9) and PSR3(2).

Background

The key document for this discussion is (A69/28 (NYP, a revised version of <u>EB138/27</u> considered by the Board in January) which reviews progress in developing a new WHO programme for outbreaks and emergencies.

The mandate for this work is decision <u>WHA68(10)</u> on the 2014 Ebola virus disease outbreak and follow-up to the <u>Special Session of the Executive Board on Ebola</u>

The framework for reform of WHO's outbreak and emergency capability is set by:

- the report of Interim Assessment Panel; and
- the <u>first</u> and <u>second</u> reports of the Advisory Group on WHO's work in outbreaks and emergencies;
- the final report of the Review Committee on the Role of the IHRs in the Ebola Outbreak and Response is also relevant (for discussion under Item 14.1 of this agenda; see PHM Comment on this item).

See also Heymann et al (2015) for further comment

The Advisory Group's final recommendations are grouped under:

- a. Overarching principles for WHO's work in outbreaks and emergencies;
- b. Structure and functions of the Programme;
- c. Lines of authority in incident management systems;
- d. WHO's strategic collaborations;
- e. Business processes for human resources and financial management;
- f. Resources needed for a viable Programme;
- g. Resource mobilization and political strategies;
- h. Independent oversight of WHO's work in outbreaks and emergencies;
- i. Timeframe for the roll-out of the new Programme.

14.8B 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

In focus

The Board will consider A69/29 (a revised version of EB138/28) which;

- recommends that the proposed database regarding diagnostic, preventive and therapeutic products (starting with haemorrhagic fevers) be vested in the proposed Global Observatory on Health Research and Development; and
- outlines five work streams directed to enhancing WHO's capacity to facilitate access to diagnostic, preventive and therapeutic products for infectious diseases that may cause public health emergencies (the 'blueprint for R&D preparedness').

It is likely that the Assembly will consider a decision or a resolution regarding the first of these issues. The second is just a progress report and is likely to be just noted.

Background

Resolution <u>EBSS3.R1</u>, adopted in January 2015 by the Executive Board at its <u>special session</u> <u>on the Ebola emergency</u>, is an omnibus resolution addressing a wide range of issues emerging from the Ebola crisis.

In OP32 the Director-General was requested to provide to the Executive Board at its 138th session options for strengthening information sharing and for enhancing WHO's capacity to facilitate access to diagnostic, preventive and therapeutic products, including the establishment of a global database, starting with haemorrhagic fevers.

The Secretariat report (A69/29) responds to this request.

The Secretariat report addresses separately:

- options for strengthening information sharing on diagnostic, preventive and therapeutic products, including the establishment of a global database, starting with haemorrhagic fevers; and
- 2. enhancing WHO's capacity to facilitate access to diagnostic, preventive and therapeutic products for infectious diseases that may cause public health emergencies

In relation to the first task the Secretariat suggests that the mandate of the proposed Global Observatory on Health Research and Development (<u>WHA66.22</u>, 2013) be extended to include the proposed database.

In relation to the second task A69/29 reports on the development of a 'blueprint' for R&D preparedness and rapid research response. Developing this blueprint involves five different workstreams:

- 1. Prioritization of pathogens and development of an operational plan (with separate modules for each of the prioritised pathogens);
- 2. Research and development preparedness: gap analysis and identification of research priorities (for the prioritised pathogens);
- 3. Organization, coordination of stakeholders (in the research effort) and strengthening of capacities (includes guidelines, protocols, etc);
- 4. Assessment of research and development preparedness levels and the impact of interventions (conceptualising R&D preparedness and developing a checklist); and
- 5. Funding options for research and development preparedness and emergency response. For further background on the ebola crisis see:
 - 1. The Ebola section on the WHO website,
 - 2. The report of the Ebola Interim Assessment Panel,
 - 3. Documents prepared for the EB Special Session on the Ebola crisis (EBSS3),
 - 4. Resolution EBSS3.R1,
 - 5. Summary records of EBSS3.

Provisional records of the discussion at the EB in <u>PSR3(7)</u>. Some highlights from this discussion:

The representative of ARGENTINA noted that the review of existing WHO databases had pointed to the value of the Global Observatory in fulfilling the objectives set out in the document. It was hoped that the Observatory would have the capacity to store all research and development data in one place. New, good-quality evidence bases should be identified, and the Observatory should manage and promote the use of information for the generation of new data, taking into account the problems identified and possible alternative solutions. WHO had a role to play in facilitating access to diagnostic and therapeutic tools. While the Ebola outbreak had shown that research and development efforts could be accelerated during an epidemic, epidemics should not be the driving force behind such activities on neglected diseases. Instead, the limited incentives to conduct research and development on such diseases had to be expanded, so that more rapid and effective action could be taken in the future. However, an emergency should not be used to justify violations of patients' rights during trials, and a health system disrupted by an emergency was not the best place to monitor a controlled clinical trial. The research and development system had to be strengthened, by reaffirming the relevance of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property and implementing the recommendations of the Consultative Expert Working Group on Research and Development: Financing and Coordination. Finally, innovative solutions were needed to ensure sustainable funding options.

The representative of COLOMBIA endorsed the establishment of the Global Observatory, which should initially prioritize haemorrhagic fevers. [...] The work of the Observatory should be linked to the implementation of the recommendations of the Consultative Expert Working Group, and should constitute the initial phase of a strategy to correct the current research and development model for diagnostic and therapeutic products. [...] Resources should be pooled in order to ensure the greatest possible impact for the population and avoid fragmented research processes. Transparency and

accountability had to be guaranteed at all levels, and the research priorities and criteria for the investment of available resources should be determined by Member States.

The representative of INDIA [commented that the] five work streams of the blueprint related directly to the discussions of the Consultative Expert Working Group. The principles of that Group on open access, de-linkage, affordability and equity should be fully integrated into the blueprint. WHO should look at how the provisions of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, would help ensure that the benefits of research and development efforts were shared equitably. The Secretariat should consider those linkages when it submitted the report requested under item 8.1 of the Agenda. He noted that the distribution and financing plan on Ebola drugs and vaccines requested under resolution EBSS3.R1 was still outstanding. Open data and transparency were important; and those principles should apply to the cycle of innovation and development and include a clear access policy

PHM comment

PHM strongly supports the proposal to vest responsibility for the proposed data base with the Global Observatory on Research and Development.

That this item is under WHO consideration is a reflection of the kind of market failure which the Commission on Public Health Innovation and Intellectual Property identified and which the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property and the Consultative Expert Working Group on Research and Development: Financing and Coordination were intended to address.

The 5-10 priority pathogens which, it is mooted, will be the initial focus of the WHO capacity building ('research preparedness') have all been neglected because they do not promise ongoing profits for the pharmaceutical corporations and perhaps because national research funding agencies have likewise neglected them as 'not relevant'.

PHM urges that MSs consider this item in close conjunction with the ongoing debate about the follow up to the CEWG recommendations (Item 16.2 on this Agenda). The proposed Treaty on the financing of R&D envisages a new mechanism for funding R&D which would bypass the market failures which are at the heart of this item.

PHM insists that epidemic preparedness is more than vaccines, diagnostics and chemotherapies but includes strong and resilient health systems and other components of social and economic infrastructure (literacy, communications, transport, etc). WHO should be participating actively in the implementation of the SDGs; emphasising in intersectoral communications the significance of the SDGs for epidemic preparedness.

14.9 Reform of WHO's work in health emergency management

In focus

The Secretariat report A69/30 provides an overview of the progress made by the Organization in reform of WHO's work in health emergency management: design, oversight, implementation, and finance.

See also A69/30 Add.1 (NYP)

Some of the key features of the new Health Emergencies Programme include:

- The new Executive Director reporting directly to the DG with direct operational responsibility for emergency preparedness and response;
- A similar organisational structure (protocols, rules, etc) in the regional offices and in headquarters to facilitate communication and collaboration;
- An Emergencies Oversight and Advisory Committee;
- Implementation plan;
- Financing (increased resource mobilisation and lifting the budget ceiling).

The centralisation of control of emergencies will be controversial; there may be resistance to raising the budget ceiling.

A69/30 includes a draft decision for the Assembly which welcomes progress made in establishing the Health Emergencies Program, notes the increased costs incurred, and authorises the DG to increase the Program Budget 16-17 by \$160m and to mobilise the required funds.

A69/30 was considered by PBAC24 prior to WHA69 (see its report at A69/61). Concern was expressed regarding the unfilled budget for WHO's work in emergencies:

The budget for the Organization's work on emergencies in the Programme budget 2016–2017 is a combination of the core budget and activities budgeted under outbreak and crisis response. Only 42% and 13% respectively of those budgets had been funded as at April 2016.

Some Member States proposed that the Director-General should request an increase in assessed contributions, a step that would be crucial to the long-term operation of WHO, and using voluntary contributions to supplement those funds.

The PBAC recommended that the Health Assembly note the report by the Director-General in document A69/30. It also recommended the Health Assembly to continue the discussions started in the Committee and to consider the proposed draft decision contained in paragraph 24 of document A69/30, taking into account the need to ensure full and sustainable financing for the Health Emergencies Programme.

Background

In the wake of the failures in WHO's initial response to the Ebola crisis a special session of the Executive Board (EBSS3) was convened to focus on addressing immediate issues and putting in place such investigations and reforms as might be needed to prevent such failures in future.

The outcome of the SS3 was the omnibus resolution <u>EBSS3.R1</u> which provided for a range of reforms in WHO's health emergency management. The Secretariat's reform of emergency management has also been informed by reports from:

- the Ebola Interim Assessment Panel,
- the <u>Director-General's Advisory Group</u> on Reform of WHO's Work in Outbreaks and Emergencies with Health and Humanitarian Consequences,
- and the <u>Review Committee on the Role of the International Health Regulations</u> (2005) in the Ebola Outbreak and Response.

The Health Emergencies Programme to be considered under this Item at the Assembly is one of the several work streams which comprise the Secretariat's <u>Road Map for Action</u> in health emergency management (see Secretariat <u>Emergency Reform Page</u>). Other work streams include:

- a global health emergency workforce;
- <u>priority core capacities under the International Health Regulations</u> (2005) developed as part of resilient health systems;
- <u>improved functioning, transparency, effectiveness and efficiency of the International Health Regulations</u> (2005);
- a framework for research and development preparedness and for enabling research and development during epidemics or health emergencies (the R&D Blueprint, Item 14.8 on this agenda, PHM comment here);
- adequate international financing for pandemics and other health emergencies, including the <u>WHO Contingency Fund for Emergencies</u> and a pandemic emergency financing facility as proposed by the World Bank;
- risk communication and community engagement.

The discussion at the EB in Jan is recorded in <u>PSR2(9)</u>, and <u>PSR3(2)</u>. Certain sensitivities regarding regional and national sovereignty were expressed.

PHM comment

The flaws in WHO's response to the Ebola crisis reflected in large part the distortions arising from the AC freeze, the budget ceiling and the tight earmarking of donations. The fact that these constraints continue means that WHO and global health remain vulnerable.

Although the crisis had highlighted the importance of strong and resilient health systems and core capacities under the International Health Regulations (2005), due priority and resources had not been given to strengthening those areas.

PHM applauds the new Health Emergencies Program with a single line of authority and accountability. However, the need to bypass incompetence and lack of accountability in certain regional offices in relation to emergencies only underlines the importance of strengthening regional and country office administration across the full range of WHO programmes.

The crisis revealed a failure to drive innovation for global health, rather than corporate profit, and underlined the need for a binding treaty to mobilize funding for research and development, in response to identified needs.

During the Ebola crisis certain Member States imposed restrictive measures beyond those mandated by the International Health Regulations Emergency Committee. PHM urges Member States to request a report to the World Health Assembly listing the countries and the measures.

Nation state contributions to the global emergency workforce should be guaranteed.

15.1 Draft global health sector strategies

In focus

Draft global strategies 2016-2021 for HIV ($\underline{A69/31}$), viral hepatitis ($\underline{A69/32}$), and sexually transmitted infections (A69/33) have been prepared using a common universal health coverage framework.

These three strategies were considered conjointly by the EB in Jan 2016; the record is PSR9(2).

The Board mandated the Secretariat to finalise the three strategies in accordance with the discussion at the Board and to prepare a draft resolution endorsing all three global health sector strategies for consideration by the Assembly

HIV

The <u>global health sector strategy on HIV/AIDS</u>, <u>2011–2015</u> ended in December 2015. In May 2014 the Sixty-seventh World Health Assembly discussed progress made in implementing the strategy (<u>A67/40A</u>) and the Secretariat was requested to draft a global health sector strategy on HIV for the post-2015 period.

A draft strategy has been developed (in the Annex to <u>A69/31</u>) to define the health sector contribution towards the 2030 Agenda for Sustainable Development target of eliminating the AIDS epidemic by 2030. This draft health sector strategy has been developed in parallel with the UNDAIDS 2016-21 Strategy (<u>here</u>).

Viral hepatitis

Resolution <u>WHA67.6</u> (2014), inter alia, urged Member States to develop and implement coordinated multisectoral national strategies for preventing, diagnosing, and treating viral hepatitis based on the local epidemiological context, and requested the Director-General to examine the feasibility of, and strategies needed for, the elimination of hepatitis B and hepatitis C with a view to potentially setting global targets.

The Board is invited to consider the draft global health sector strategy on viral hepatitis 2016–2021, presented in the Annex to A69/32.

STIs

In 2006, the Health Assembly adopted resolution WHA59.19 in which it endorsed the Global Strategy for the Prevention and Control of Sexually Transmitted Infections, covering the period 2006–2015 (here). The final progress report on implementation of the Global Strategy (in full here and in document A68/36(G)) was considered by the Sixty-eighth World Health Assembly in 2015, with speakers emphasizing the need for a new strategy to be developed (APSR12 and 13).

The Global Strategy has therefore been updated and is presented to the Executive Board for its consideration (in A69/33). The draft strategy which is aligned with the other global health sector strategies, includes innovative solutions and interventions towards eliminating sexually

transmitted infections, and is linked to the broader objectives of the 2030 Agenda for Sustainable Development.

PHM comment

Health systems design and financing: need for more than slogans about UHC

The decision to structure these three draft strategies around the three dimensions of the UHC cube has the effect of downplaying the issues of health systems configuration although it is clearly recognised. For example, in para 62 from the hepatitis strategy:

"An effective hepatitis response requires robust and flexible health systems that can sustainably deliver people-centred care across the full continuum of services to those populations, locations and settings in greatest need. The hallmarks of such health systems are: a strong health information system; efficient service delivery models; appropriately trained and distributed workforce in adequate numbers and with an appropriate skills mix; reliable access to essential medical products and technologies; adequate health financing; and strong leadership and governance." (A69/32, p30)

Delivering effective and comprehensive disease programs which are integrated within the broad structures of health care is not just about UHC, important though this is. Critically it is also about the configuration and governance of the health systems through which healthcare is delivered.

Strategic directions 2 & 3 in the HIV Strategy deal respectively with interventions and service delivery. These sections are cast in quite general terms and there is no discussion of broad questions of health system design questions such as: (i) single payer versus competitive health insurance markets; (ii) tax based health care funding versus social (and other forms of insurance); (iii) mixed service delivery versus public sector service delivery.

These variables make a huge difference to integration of services, information systems, procurement systems, quality assurance and workforce development. The challenge of ensuring equity in the context of stratified health care funding arrangements are well known. The challenges of achieving high standards of care and prevention in the context of fragmented service delivery are well known. WHO should be providing guidance in both of these areas. The continued repetition of UHC is not sufficient.

The frequent references in all three communicable diseases strategies to including interventions in 'national benefit packages' appears to assume health insurance as the principal service delivery framework and disregards other dimensions of health service delivery including PHC as an approach to service delivery; links between treatment services and health promotion and outreach / community engagement programs; the relation between specialist programs and PHC and other more generic services; the concept of district health systems and the overarching issue of clinical governance. References to "core packages" provide no guidance at all about delivery systems.

Clearly the authors of the strategies are very aware of the service delivery dimensions as is evident in the reference (in the STI strategy) to a public health approach on p10, 'strengthening health systems' from p34, and 'optimise service delivery' under research.

HIV

Strengths

The strengths of the draft HIV strategy include:

- the ambitious but achievable vision, goal and 2020 targets,
- the discussion of national accountability.
- the discussion of the role of civil society in the AIDS response, including in demanding accountability (see <u>Fig 10</u> of UNAIDS Strategy),
- the focus on measurement, evidence and innovation.

There are some other areas where both strategies are somewhat thin.

Funding

Both the WHO draft strategy and the UNAIDS Strategy emphasise the need to 'fast track' the upscaling of the AIDS response. See <u>Fig 8 from draft strategy</u>. Both emphasise that significant new money will be needed.

In some degree this new money will have to be mobilised from domestic sources, in particular, various forms of taxation. Both strategies are silent on the question of tax avoidance and tax competition and the need for a multilateral agreement on tax avoidance. This is a serious weakness.

There are references to equity throughout both strategies but no references to the conditions for solidarity in the response to AIDS, including a willingness to contribute to tax funded service programs.

There will also be a need for additional funds through 'development assistance'. In this context the 'name and shame' Fig 15 from the UNAIDS Strategy is relevant. Japan, Germany, France, Italy, Canada and Australia all appear to be shirking their responsibilities with respect to contributing to HIV funding.

Multiple competing vertical funding agencies

The challenges presented by a multiplicity of vertical funding agencies are notorious. They include: (i) barriers to coordinated person centred care from the fragmentation of service programs; (ii) the opportunity costs borne by government seeking to liaise and coordinate with various different funders; and (iii) domestic brain drain from public employment to better paid foreign funded programs.

The only reference to these problems is in a very limited discussion in the UNAIDS Strategy here). It is good news if these problems have all been solved; if not they should have been addressed.

In view of the emphasis on measurement and national accountability the lack of any recommendations for monitoring donor incoordination is surprising.

Unique national identifier

There is a reference to the value of a unique national identifier to ensure data linkage for data systems and follow up (page 31 of draft health strategy). This is mentioned with specific reference to HIV/TB co-morbidity; not discussed elsewhere in the draft strategy and not at all in the UNAIDS Strategy. Clearly there are privacy and data security issues associated with this kind of facility but it is also clear that data linkage could be used in tracking the epidemic and ensuring quality and integration of services. It is surprising that there is no discussion of this.

Viral hepatitis

The global situation described in this draft strategy reflects a gross shortfall in terms of delivery against needs. Hepatitis, especially B & C, is responsible for a very high burden of disease. The absolute number of deaths exceeds TB, HIV or malaria (see Fig 2, p4). Vaccines, treatments and preventive strategies are available but not adequately deployed.

Some of the main causes for the shortfall, against potential achievement, in relation to hepatitis include:

- Cost of constructing clean water and sanitation infrastructure in low resource and emergency settings
- Ideological opposition to harm reduction strategies,
- Low levels of achievement of birth dose HBV vaccine,
- Cost of diagnostics and drugs for treating HBV and HCV,
- Unsafe &/or unnecessary use of injections in health care settings.

Unmet but meetable need offers huge opportunity. But the draft strategy does not offer a plausible scenario for overcoming the barriers.

The draft strategy is otherwise comprehensive and sensible.

The cost of the proposed strategy is significant (see <u>Fig 8</u>). While middle and upper income countries might expect to fund it out of domestic sources the situation for low and low-middle income countries is not promising, given the lack of donor funding for hepatitis hitherto.

WHO needs to add its weight to the demands for real action on corporate tax avoidance and the pressures on countries to reduce tax revenues (through 'tax competition'). There is an urgent need for a multilateral tax agreement which addresses both of these issues.

STIs

The new draft strategy is to be welcomed. While the presentation of the strategy may be criticised the principles and strategies are comprehensive and sensible.

The metrics implied in the Vision, the Goal and the Global Targets are quite mixed. The vision is expressed in terms of the concept of 'zero STI-related complications and deaths' (which corresponds to Box 3 (para 10) summarising the burden of disease associated with STIs). The goal is expressed in terms of STI as no longer a 'major public health concern'. The Global Targets are cast in terms of incidence rates, and service coverage.

The third milestone for 2020 is listed (para 39) as "70% of key populations have access to a full range of services relevant to sexually transmitted infection and HIV, including condoms". This milestone does not appear in Figure 7 (para 40).

Drafting one strategy for a group of diseases which share a mode of transmission but have different clinical and epidemiological features is not easy, particularly when it is forced into the UHC box (services, populations and funding). Likewise the references to 'key populations' raises questions about the degree to which 'key populations' can be addressed as a generic group and to what extent are they different and require specific policies and strategies?

The decision to force all three communicable disease strategies into the UHC box tends to obscure some of the critical issues the strategy should be clarifying.

Clearly the technical content of preventive and treatment strategies needs to be considered separately from health service delivery issues including the relations between specialist programmes and generalist PHC or between programmes in the community and those in particular settings (prisons etc) or between health promotion programs and clinical programs. However, structuring the strategy within the UHC box privilege the technical 'interventions' and ignores to some extent the service and program delivery questions; most notably the lack of reference to workforce development as a key dimension of the strategy.

The delivery of prevention and treatment for STIs takes place at the conjunction of three different kinds of strategy:

- technical strategies focused on particular diseases;
- service and program delivery strategies (different kinds of service, different settings);
 and
- strategies to assist public health practitioners to engage with various 'key populations'. The challenge for the policy makers and programme managers at the national and subnational levels is to ensure that the technical strategies and engagement strategies are most effectively and efficiently realised through the service delivery strategies. It is not clear that structuring these WHO strategies within the UHC box is the best way to assist those policy makers and programme managers, particularly in such a heterogeneous field as STIs.

The section on implementation and accountability from para 113 is promising although there is no mention of how the various groups affected ('key populations') might be engaged in the implementation process and accountability relations. There is a reference in the Guiding Principles (para 46-7) to "Meaningful engagement and empowerment of people living with sexually transmitted infections, key populations and affected communities" but it is not clear where this is enacted within the strategies.

The reference to benchmarking is appreciated but this needs to include rich descriptions of service and programme delivery, not just country questionnaires.

The treatment of HPV vaccination is a bit limited. There are opportunity costs associated with adding HPV to the immunisation schedule and these costs vary with the prevailing epidemiology and service delivery capacity. There are also financial risks associated with HPV immunisation arising from graduation from Gavi eligibility. The need for functioning national immunisation technical advisory groups (NITAGs) as discussed in the SAGE GVAP Assessment Report could have been underlined here.

There are repeated references to the need for further research, including various applications of operations research into service delivery.

There is also a need for new diagnostics, vaccines and antibiotics. The strategy does not include any assessment of the global pipelines for this research and the current investment effort. This may be something that the R&D Observatory could answer. It may be time to delink research into the prevention and control of STIs from its dependence on the profit incentives associated with monopoly pricing. (See PHM commentary on Item 10.3 on CEWG here.)

15.2 Global vaccine action plan

In focus

The Assembly will consider the third report of the Strategic Advisory Group of Experts (SAGE) on immunization on implementation of the Global Vaccine Action Plan (GVAP). The Secretariat report (A69/34) reproduces the summary of the SAGE Assessment Report and provides a report on Secretariat activities to address vaccine supply issues (Annex 2).

WHA66 in 2013 endorsed the Secretariat's proposed <u>Framework for Monitoring</u>, <u>Evaluation and Accountability for the GVAP</u>.

Delegates need to read the original <u>SAGE Assessment Report for 2015</u> because the extract included in <u>A69/34</u> includes only the SAGE Recommendations. In particular, delegates should be aware of the overall SAGE conclusions:

In recommending what needs to change, this report focuses on two major problems that are holding back progress in the Decade of Vaccines:

- The elimination strategies for maternal and neonatal tetanus, and for measles and rubella, and their implementation, are in urgent need of change and adequate resourcing;
- The monitoring and accountability framework for the Global Vaccine Action Plan has gaps in its mechanisms for accountability, undermining the translation of the plan's goals into reality.

These conclusions are backed up by the evidence presented in the main report.

The SAGE Assessment Report is sharply critical of shortfalls in GVAP implementation and provides practical recommendations. The criticisms and recommendations were largely confirmed during the EB debate.

One of the key shortfall areas concerns vaccine supply issues including pricing, competition, local manufacture and the GAVI cut off. Responding to these concerns the Secretariat has provided in Annex 2 a summary of activities currently underway to address the various issues involved.

It is likely that a draft resolution mandating action on these recommendations will appear before the Assembly.

Background

See GVAP home page for the <u>GVAP</u> and SAGE assessment reports from <u>2013</u> and <u>2014</u> including for <u>2015</u> (en) and <u>monitoring framework</u>.

Record of EB138 discussion is at PSR9(12) and PSR10(2)

PHM comment

The SAGE report for 2015 is a very useful report. It sets out clearly the current shortfalls against the GVAP and offers practical suggestions to address these. Its blunt speaking is

appreciated. The focus of the SAGE report is on the shortfalls in maternal and neonatal tetanus, the shortfalls in measles and rubella, and the shortfalls in monitoring, planning and accountability.

The report:

- reviews basic immunisation coverage (based on national DTP3) and identifies the countries where because of weak health systems or conflict and disruption coverage is low:
- reviews specific diseases and highlights maternal and neonatal tetanus and measles and rubella as being well behind the GVAP targets;
 - SAGE comments that "The funding gap to rid the world of maternal and neonatal tetanus is estimated at \$130 million, which is miniscule compared with the \$1.1 billion spent in 2014 by Gavi, the Vaccine Alliance on its new and underused vaccine programmes."
- comments on the speed with which new vaccines against Ebola were developed;
- comments on the introduction of new and 'under-used' vaccines, noting the vulnerability
 of GAVI 'graduates'; (PHM has previously commented (here) on the importance of
 countries having robust capacity to evaluate the need for new vaccines in relation to
 their specific circumstances; this requires a functioning NITAG);
 - The SAGE report for 2015 comments: "Progress towards outcomes set out in plans should be reviewed annually by an independent body with technical expertise such as the country's national immunization technical advisory group (NITAG) and a body with management expertise such as an inter-agency coordinating committee (ICC). In 2014, 123 countries reported having a NITAG, and only 25 of these were Gavi-eligible countries. Only 81 countries had a NITAG that met WHO criteria for functionality, and only 15 of these were Gavi-eligible countries." This is clearly something that both WHO regional offices and global partners should be supporting!
- improved data on vaccine pricing
- success factors
 - data quality
 - community ownership
 - vaccine supply (and "moribund procurement systems")
- leadership (in country) and accountability (country, region, global partners)
 - need for national immunisation plans and national immunisation technical advisory groups (NITAGs)
 - importance of functioning health systems and effective equitable health care delivery
 - SEARO singled out for being behind in its planning
 - global partners "...should align their efforts and contributions to achieving the GVAP's goals going forward, both in relation to specific disease targets and to the broader immunization agenda. They can best do this by supporting countries towards better healthcare systems and improved accountability." (presumably they are not doing so at this time).

Many but not all of the shortfalls against the targets set in the GVAP are due to poverty, conflict and displacement. Weak health systems, funding anomalies and accountability failures also need to be attended to.

Annex 2 in A69/34 provides a useful overview of activities being undertaken by the Secretariat to help to address the vaccine supply issues. There are some intriguing references in this report which need to be followed up:

- clear application of conflict of interest guidelines in the various collaborations and forums involving regulatory agencies and manufacturers (para 12);
- need for evaluation of the Developing Country Vaccine Regulators' Network and what
 can be done to strengthen it (see para 12; see also <u>DCVRN members</u> and <u>assessment</u>
 of NRAs in vaccine producing countries);
- explanation of why member states in the EMR are 'lacking in interest' in pooled procurement (para 14);
- Explanation as to why over 70 member states have not shared information on vaccine prices (para 16):
- Need for further progress on vaccine shortages (paras 17&18)

See earlier PHM comment from <u>WHA68 (Item 16.4)</u> on the 2nd GVAP Assessment Report (here) including commentary on vaccination and:

- health systems
- fragmenting impact of vertical funding programs
- WHO reform
- pricing, affordability, procurement and logistics
- introduction of new vaccines
- data quality and use
- clinical trial data reporting
- rubella

See also PHM commentary on the first GVAP Assessment Report (here) at WHA67

15.3 Mycetoma

In focus

The Assembly will consider Resolution <u>EB138.R1</u>, Strengthening Control of Mycetoma Disease, and the Secretariat's updated report <u>A69/35</u>.

Background

A proposal for an additional item (<u>WHA68/1 Add.1</u>) to be added to the WHA agenda in May 2015 (with accompanying resolution) was submitted by Sudan (and co-sponsored by India, Nigeria, Somalia and Mexico).

Basically the draft resolution called for increased attention to mycetoma, including research and for mycetoma to be added to the list of neglected tropical diseases (NTDs).

The item was bounced to EB137 where a revised resolution (EB137/CONF./1 – Strengthening Control of Mycetoma Disease, proposed by Egypt, Jordan & Sudan) was considered supported by EB137/11, a report by the Secretariat on Mycetoma. At EB137 there was considerable support for the issue and the resolution to be considered at WHA69 but Sweden, UK and Belgium proposed deferring further consideration to EB138 on the grounds of expense and seeking further advice from regional offices. There was also some debate as to whether mycetoma is a disease or a condition. It was decided to review the issue in EB138 after further discussion in the regional committees. Official provisional summary notes of discussion at EB137 PSR1(8) and PSR2(9).

The Secretariat report to EB138, <u>EB138_33</u>, provided a descriptive overview of mycetoma (clinical features, aetiology, epidemiology) and summarised WHO's broad strategy for NTDs and proposed initiatives in relation to mycetoma (including soliciting further funds from donors and partners). Record of EB discussion at <u>PSR10(3)</u>

PHM comment

A69/35 explains that mycetoma infection "is thought to be acquired by traumatic inoculation of fungi or bacteria into the subcutaneous tissue following minor trauma or a penetrating injury, commonly thorn pricks. People of low socioeconomic status who walk barefoot and manual workers, such as agricultural labourers and herdsmen, are those worst affected. ... The disease occurs in tropical and subtropical environments characterized by short rainy seasons and prolonged dry seasons that favour the growth of thorny bushes".

The global burden of disease attributable to mycetoma is not huge but it is a major problem in particular localities. It appears that it is under-diagnosed and under-reported.

There is clearly a case for further investment in developing preventive strategies, improved diagnosis and effective treatment. It is regrettable that WHO will need to seek donor funding for such increased investment.

Clearly there is also a need for health system development in affected localities, including action around the social and economic factors which contribute to the prevalence of this condition.

PHM urges the Assembly to adopt the resolution.

Is mycetoma a 'neglected tropical disease'?

This item has faced a number of barriers in getting to its present stage.

It first surfaced at WHA67 in May 2014 in an awareness-raising side-event co-sponsored by the Secretariat, several governments, the University of Khartoum (recently designated as the WHO Collaborating Centre on Mycetoma) and the Drugs for Neglected Diseases initiative.

The draft resolution was submitted for inclusion on the agenda for WHA68 in May 2015 but was bounced to EB137 (immediately following WHA68). At EB137 Sweden and Belgium expressed reservations about the budgetary implications of the draft resolution and both argued that it should be revisited at the next EB in Jan 2016. Both the UK and Japan suggested that the issue should be reviewed in the regional committees in late 2015 before returning to the EB.

At the EB in Jan 2016 there were many speakers in favour of the resolution. The US made several interventions protesting at adding mycetoma to the list of neglected tropical diseases "on the basis of political, rather than technical, considerations". The US sought to have the Board note rather than endorse the resolution; sought to have the Strategic and Technical Advisory Group for NTDs to consider the inclusion of mycetoma in the list of neglected tropical diseases, at its scheduled meeting in April 2016; and sought to add to the draft resolution a request to the STAG NTDs to define a 'systematic, technically-driven process for evaluation and potential inclusion of additional diseases among the "neglected tropical diseases.""

The representative of SUDAN, invited to take the floor by the CHAIRMAN at the request of the representative of THAILAND, said that the proper legal processes had been followed in the preparation of the draft resolution and at no stage had any mention had been made of the Strategic and Technical Advisory Group for Neglected Tropical Diseases. Fundamentally, the Secretariat had performed all of the tasks assigned to it by the Executive Board at its 137th session and had presented the relevant documentation over 15 days in advance of the current session. No issue had ever been raised, however, until the previous day, which was frankly astounding, especially when there were already precedents of other diseases with less impact being included on the list of neglected tropical diseases. He therefore appealed to the Board to adopt the draft resolution for submission to the forthcoming Health Assembly. Procedural rules were always desirable but they must be followed in the proper manner.

The representative of MALTA observed that there seemed to be consensus for the adoption of the draft resolution with the addition of the subparagraph as proposed by the representatives of the United States of America and the United Kingdom of Great Britain and Northern Ireland.

The representative of INDIA pointed out that the Strategic and Technical Advisory Group for Neglected Tropical Diseases already had its own terms of reference, and that the inclusion of the new subparagraph served only to duplicate them.

The US position may have been motivated by geopolitical friction between Sudan and the US; and/or a determination to maintain WHO's budget ceiling. The accusation that the draft resolution was based on political rather than technical considerations is a bit rich coming from the US.

16.1 Health workforce and services

This is an omnibus item with several different issues up for consideration:

- progress reports on three resolutions (<u>A69/36</u>);
- report on the second round of national reporting on the WHO Global Code of Practice on International Recruitment of Health Personnel (A69/37 and A67/37 Add.1);
- the draft strategy on human resources for health: Workforce 2030 (A69/38);
- Framework for Integrated, People-centred health services (<u>A69/39</u> and draft resolution in <u>EB138.R2</u>).

Three resolutions

In focus

The Secretariat report on Health workforce (A69/36) describes progress made in implementing three health workforce resolutions:

- WHA64.6 (2011) on health workforce strengthening
- WHA64.7 (2011) on strengthening nursing and midwifery, and
- WHA66.23 (2013) on transforming health workforce education in support of universal health coverage.

Background

A69/36 provides all necessary background to these various resolutions.

PHM Comment

A69/36 reports on meetings, analyses, publications and tools which have been organised by the Secretariat by way of implementing the three resolutions.

The new global strategy on human resources for health will carry forward in a more comprehensive and strategic manner the initiatives commenced under these three resolutions.

Second round of reporting under the Code

In focus

In <u>A69/37</u> (in accordance with <u>WHA63.16</u> (2010) and <u>WHA68(11)</u> (2015)) the Secretariat presents aggregate findings across WHO regions, as derived from the second round of national reporting. <u>A69/37</u> reports on (i) support provided to member states; (ii) results from national reporting; (iii) the way forward.

A67/37 Add.1 provides additional analyses from the second round reporting dealing with (i) the national instrument; (ii) foreign trained doctors and nurses; (iii) role of non-state actors in supporting implementation; and (iv) a report on the 'Brain drain to brain gain' project.

Further information on the WHO migration page.

Background

The WHO Global Code of Practice on the International Recruitment of Health Personnel was adopted by the Assembly in resolution WHA63.16 in 2010.

In May 2013 the Assembly reviewed the results of the first round of reporting on the implementation of the code (in $\frac{A66}{25}$).

In May 2015 the Assembly reviewed the report of the Expert Advisory Group on the Relevance and Effectiveness of the code (in <u>A68/32 Add.1</u>). The provisional summary record of the debate is <u>here</u> and the decision <u>WHA68(11)</u> was adopted.

There were some comments on the Code in the EB debate in January 2016 (PSR10(12))

PHM Comment

The increased number of countries who have identified a 'national authority' for the purposes of the Code is good. The number of national authorities who did not submit a national report to the Secretariat by the due date is surprising. However most of the major destination countries appear to have reported. The Secretariat report does not provide a useful analysis of the data collected through the national reports.

It appears that progress with respect to substantive implementation of the Code has been slow, including:

- mandating the provisions of the Code in legislation
- including the provisions of the Code in bilateral agreements
- putting in place comprehensive data collections regarding HRH generally and migration data specifically

<u>Decision A68(11)</u> remains important. Further implementation of the Code will be facilitated by the adoption and implementation of the proposed Global Strategy (<u>here</u>).

The new global strategy for HRH: Workforce 2030

In focus

In resolution <u>WHA67.24</u> in May 2014, the Assembly requested the Director-General to develop and submit a new global strategy on human resources for health for consideration by the Sixtyninth World Health Assembly. A summary of the draft strategy is provided in document <u>A69/38</u>. The full strategy is <u>here</u>. Note that the summary provided in A69/38 does not include the range of suggested policy options for member state consideration. For these see the full draft strategy.

A draft resolution supporting the Draft Strategy was considered at EB138 (see <u>PSR10(12)</u>) but was deferred for further intersessional informal discussion.

- Brazil was critical of the way the needs of different countries had been categorised in the draft Strategy. Brazil was supported by Argentina, Cuba and Colombia in this criticism.
- Russia was concerned about reporting burden provided for in the draft resolution.
- The US felt that the objectives on capacity building for data collection and analysis and evidence-based planning should be strengthened and that the language in which the

- guiding principles were expressed should be more consistent with the goal of promoting the right to enjoyment of the highest attainable standard of physical and mental health.
- The UK asked the Secretariat to clarify how the strategy's metrics would be finalized and monitored and also supported the issue raised by Brazil.
- NZ asked the Secretariat to amend the draft global strategy to place greater pressure on Member States to increase funding for the education of nurses and other health care workers and for the introduction of professional regulation and oversight.
- Namibia, speaking for the Afro Region said that the draft global strategy should refer more clearly to occupational health and safety and programmes for employee wellbeing, in order to create an enabling environment and better working conditions and argued that the private sector should be given greater responsibility for training health workers
- Canada was critical of a reference to 25% as a target for the proportion of health sector development assistance that goes to HRH [this reference is removed from the current version].
- Cuba highlighted a range of areas in the draft strategy which should be strengthened.
- India urged that the strategy should mention the continuing medical education required to update and enhance the capacity and capability of health care professionals and workers and also the use of modern information and communication technology for teaching and updating skills and knowledge.

A revised resolution will be presented to the Assembly but has not yet been published.

Background

The GHWA <u>synthesis paper</u> lists some of the landmarks in HRH policy making in the recent past:

- the Joint Learning Initiative,
- the WHO World health report 2006,
- the convening of three global forums on HRH (in 2008, 2011 and 2013), and
- the adoption in 2010 by the World Health Assembly of the <u>WHO Global Code of Practice</u> on the International Recruitment of Health Personnel.

PHM Comment

The issues identified and policy reforms summarised in A69/38 and set out in full in the draft strategy are of the highest importance. Health systems are constituted by people. The deployment and production of the health care workforce are central to health system strengthening.

The draft global strategy has been produced through a highly consultative process which is described in A69/38 and in the full strategy document.

The background section of the draft strategy canvasses the importance of addressing health workforce issues and lists four sets of policy levers to address health workforce issues. These include:

- Policies on production
 - on infrastructure and material
 - on enrolment
 - on selecting students

- o n teaching staff
- Policies to address inflows and outflows
 - o to address migration and emigration
 - o to attract unemployed health workers
 - o to bring health workers back into the health care sector
- Policies to address maldistribution and inefficiencies
 - to improve productivity and performance
 - o to improve skill mix composition
 - o to retain health workers in underserved areas
- Policies to regulate the private sector
 - o to manage dual practice
 - to improve quality of training
 - o to enhance service delivery

The <u>draft</u> proposes a sensible goal; articulates a series of important principles; and proposes four objectives:

- optimising the deployment of the workforce;
- improved workforce planning;
- institutional capacity building; and
- improved data for planning and accountability.

In relation to each of these objectives the draft lists policy reforms which countries should consider; lists activities for the Secretariat (assuming the final strategy gets funded); and offers recommendations to 'other stakeholders and partners'. The content of these reforms, activities and recommendations overlap greatly across the four objectives.

A repeated theme throughout the strategy concerns the macroeconomic arguments for investing in a strong health workforce. (This is clearly a reference to the UN Secretary-General's appointment of the Commission on Health Employment and Economic Growth in March 2016. See UNSG media release and WHO Comm HEEG page.)

From the PHM perspective there are some policy issues which could have been better developed but in general the policy directions identified are sensible.

However, the strategy lacks a convincing implementation dynamic. The implementation drive appears to depend on advocacy and evidence (to achieve 'political will') and on the WHO Secretariat providing data, tools and advice. The strategy is full of 'shoulds' and 'needs' including many good ideas (some of which have been in circulation for many years) but it is not clear why bringing these good ideas together into this strategy will make them easier to implement.

The weak implementation drive evident in this draft strategy reflects the lack of peer accountability among the member states of the WHO. It is a fundamental weakness of the WHO (completely neglected in the current round of 'WHO Reform'). The culture of WHO is characterised by an undue respect for member state sovereignty and the avoidance of peer accountability.

This respect for MS sovereignty regarding health policies stands in sharp contrast to the pressures for economic integration and regulatory harmonisation in relation to trade. The IMF, WTO and OECD all sponsor rigorous assessments of national policies and performance in relation to finance and trade.

National health workforce policies and performance should be subject to similar international scrutiny and publicly available evaluation. This would put pressure on political leaders, not least because it would support professional and community advocacy at the national and subnational levels.

This is not a call for uniformity. The processes of peer accountability would necessarily have regard to national circumstances. However, the application of the principles which inform this draft strategy to those national circumstances would be critically evaluated.

The <u>draft strategy</u> includes a very useful annex setting out global and regional workforce estimates and projections. The annex introduces an innovative methodology for estimating workforce needs based on workload rather than arbitrary ratios.

A framework for integrated, people centred health services

In focus

In accordance with resolution <u>WHA62.12</u> (2009), the Secretariat has produced a framework on integrated, people-centred health services (<u>A69/39</u>). This is accompanied by a draft resolution for the consideration of the Assembly suggested by the EB138 in <u>EB138.R2</u>.

Background

In accordance with resolution <u>WHA62.12</u> ("Primary health care, including health system strengthening", 2009), the Secretariat is developing a framework on integrated, people-centred health services (summarised in <u>A69/39</u>), which is designed as a roadmap for countries to foster and guide reforms to reorient health services in a shift away from fragmented, vertical, supply-oriented models, towards models that put individuals, families, carers and communities at their centre

The framework proposes five interdependent strategic goals and related policy options for national action to make health services more integrated and people-centred:

- 1. empowering and engaging people;
- 2. strengthening governance and accountability;
- 3. reorienting the model of care;
- 4. coordinating services within and across sectors; and
- 5. creating an enabling environment.

Chapter Two of the Framework (here) locates the proposed framework in relation to:

- the UHC campaign (and the need to consider models of service delivery as well as financing);
- the Alma-Ata Primary Health Care movement;
- the rising pressures associated with NCDs;
- the increased awareness of inequities in health and the need to address the social determination of health;
- the continuing threats of epidemic and disaster and the need to strengthen emergency capabilities and health system resilience.

A69/39 also emphasises the inter-relations between this framework and the draft global strategy on health workforce (which includes the reform of service delivery as one of its policy strategies).

Record of discussion at EB138 at <u>PSR10(12)</u>. Most comments were supportive. Critical comments included:

- Namibia on behalf of the Afro Region said that the draft framework should be revised to emphasize that the provision of health services should be based on need and the public interest, and not on individual preference, as implied in the current draft. [Maybe a reference to Strategic Approach 3.1 in the Strategy or OP(2)(2) in the Resolution]
- Namibia also urged that the framework be more explicit about the considerable efforts needed at the country level to manage change, reorganize front line service provision and improve the patient experience which would require more work on process reengineering, skills development and the establishment of multidisciplinary teams.
- Liberia on behalf of the African Region, said that the words "preferences and expectations" should be deleted from paragraph 2 of the draft resolution on strengthening integrated, people-centred health services. [Urges MS ...to make health care systems more responsive to people's needs, preferences and expectations, while recognizing their rights and responsibilities with regard to their own health]

PHM comment

This is a very good framework. PHM urges that the Assembly endorse this framework in substance.

Nevertheless, there are some areas where PHM would wish to see revision. We note the repeated use of the term 'primary care' among the policy options listed despite the explicit wording of WHA62.12 which is cited as the principal mandate for this framework. One of the critical ideas which is lost in replacing PHC with primary care is the Alma-Ata vision of PHC practitioners and agencies working with their communities to address health care issues and to address the social determinants of health. While there are references to community empowerment and to action on the SDH, the concept of PHC practitioners working with their communities for health development has been seriously discounted. This is perplexing given the repeated claims by WHO that UHC includes action on the social determinants of health.

By way of comparison see the <u>Ougadougou declaration on PHC from 2008</u> which reaffirms the importance of PHC but not acknowledged in the IPCHS document.

However, the principal weakness of this framework (like the draft Global Workforce Strategy) lies in the lack of implementation drive. The framework is full of excellent policy suggestions, many of which have been circulating for many years. The implementation drivers envisaged in this framework include: political commitment, leadership (distributed leadership across various 'stakeholders'), empowerment (especially of disadvantaged populations), data and evidence, and (through the Secretariat) advocacy and technical cooperation.

This set of drivers could be sufficient to achieve real change but it is not very obvious that it would be sufficient. See our comments above in relation to the Health Workforce strategy and weak implementation drive.

Stronger peer accountability among the member states of WHO would give this excellent framework a much better chance of successful implementation.

16.2 Follow-up to the report of the CEWG on R&D: Financing and Coordination – Report of the openended meeting of Member States

In focus

In resolution <u>WHA66.22</u> (2013), as part of the follow up of the <u>report</u> of the Consultative Expert Working Group (see <u>pre-history</u> below), the Director-General was requested, inter alia, to convene an open-ended meeting of Member States prior to the Sixty-ninth World Health Assembly in order to assess progress and continue discussions on the remaining issues in relation to monitoring, coordination and financing for health research and development.

A69/40 reports on the outcomes of the open ended meeting in Geneva from 2-4 May. A69/40 includes:

- a report from the secretariat summarising progress in relation to the various elements of the CEWG workstream (Appendix 2); and
- a richly conflicted draft [decision / resolution] on the follow up to the report of the CEWG.

The Secretariat's Progress Report (A/RDMCF/2) reviews the elements of the CEWG workstream and summarises progress with respect to:

- the global health research and development observatory;
- the health research and development demonstration projects;
- the budget line for demonstration projects and the global health R&D observatory;
- exploration of financing mechanisms for contributions to health R&D;
- · coordination of health research and development; and
- two new emerging areas of R&D requiring funding and coordination:
 - o research and development blueprint for action to prevent epidemics; and
 - research and development for new antibiotics as part of WHO's global action plan on antimicrobial resistance.

During the EB138 discussion of this item (at <u>PSR11(4)</u>) there were expressions of support for the various elements of the program but regret at how far behind the financial commitments were against the estimated needs.

See <u>WHO preparatory page</u> for the OE Meeting including reports, background documents and presentations.

Appendix 3 to A69/40 constitutes a draft [decision / resolution] which remains highly contested. From the pattern of brackets it seems that the main areas of disagreement include:

- Strong or weak in relation to member states support for R&D for diseases that primarily affect developing countries;
- Strong or weak in reaffirming the right to use TRIPS flexibilities;
- Whether or not to agree that IP protection is important for the development of new medicines (which would be problematic recognsing that the focus of this whole project is on diseases that primarily affect developing countries and where market failure has been significant);
- Emphasis on poverty as a barrier to access to medicines;

- Welcoming or noting the establishment of the HLP on A2M;
- Whether the responsibility of member states is 'shared' or 'common';
- Level of support for the Global Observatory and specificity of funding obligations;
- Importance of funding the Global Observatory through assessed contributions and unearmarked voluntary contributions;
- Conflict over advisory structures in relation to the coordination and funding of R&D for Types I, II and III diseases; and/or where market failure exists;
- Funding sources
- Delinkage
- Policy coherence between WHO decision making and the outcomes of the HLP on A2M.

See also <u>Lancet assessment</u> (7 May) that delinkage models are gaining ground while 'countries mull over incentives for developing antibiotics'.

It seems likely that there will be a drafting group appointed on Day 1 and it may come up with a consensus resolution by the end of the Assembly.

Background

While the focus of the Assembly will be on the conflicted draft resolution it is worth reviewing the background to the whole engagement and the more specific components.

CEWG Pre-history

See CEWG pre-history up to and including EB136 in Jan 2015.

WHA68 (May 2015) reviewed two reports: <u>A68/34</u> dealing with the proposed funding mechanism; and <u>A68/34 Add.1</u> which reported on progress made in implementing the selected health research and development demonstration projects.

Document A68/34 proposed the Special Programme for Research and Training in Tropical Diseases (TDR) to host a pooled fund towards research and development. The report described how such a fund might be established and managed, as well as its relationship with the R&D Observatory and the future coordination mechanism.

The Secretariat's report was noted (Fifth meeting).

The observatory

In resolution <u>WHA66.22</u> the Assembly requested the Director-General to establish a global R&D observatory and to review existing mechanisms which could be used to coordinate R&D under the CEWG process.

The Assembly (May 2014) considered the report A67/27 which *inter alia* reported on the work done to date in relation to the Observatory. It reported that the Secretariat has started the process of establishing the Global Health Research and Development Observatory. It proposed the establishment of a global research and development advisory body and the institutionalization of an annual research and development stakeholder conference.

The objectives of the Global Observatory are described in document A67/27. Further information is available at http://www.who.int/phi/implementation/phi_rd_observatory/en/.

Document A68/34 discusses how the relations between the Funding Mechanism, the Observatory, the Coordination Group and TDR are seen by the Secretariat.

At the end of the debate at WHA68 the Secretariat noted that the Observatory was expected to be launched in Jan 2016. See <u>call for publications</u>.

See <u>presentation</u> on progress on the global observatory presented at OE MSM in May 2016

The demo projects

The emergence of the demonstration projects is documented <u>here</u>, from the original adoption of the Global Strategy and Plan of Action to the discussions at EB136.

<u>A68/34 Add.1</u> refers to this history but focuses on the more recent re-evaluation of one merged project and three resubmitted projects.

See presentation on demo projects prepared for OE MSM.

More in A/RDMCF/2.

Funding mobilisation, hosting and coordination

Resolution <u>A66.22</u> commissioned further exploration of pooled funding and funding coordination.

A67/27 discussed 'Managed coordination' of R&D activities and their funding. It argued that the creation of any new funding mechanism would introduce strong, managed coordination of the research that a new fund would support. The priorities supported under such a financing mechanism would be those identified through the global advisory committee and could be endorsed at the annual stakeholder conference.

In Decision $\underline{A67(15)}$ the Assembly asked the Secretariat to explore this proposal in more detail and to report, through EB136 to WHA68 in May 2015 on the outcomes of this exploration.

A range of possible hosts for the pooled funding had been considered in <u>EB134/26</u> (Jan 2014) and the EB was advised that TDR had rated highly on most criteria. In early May 2014 WHO hosted a meeting of the proponents of the four projects selected in the initial round of demonstration projects (<u>A67/28 Add.1</u>). At this meeting TDR tabled a proposal (<u>9 May 2014</u>) outlining how it might take on the role of manager of the pooled funds (see also <u>TDR news release 9 May</u>). While the TDR proposal was not included in the papers published by the Secretariat for WHA67 it was clearly under consideration with several speakers referring to it in debate and its endorsement in <u>A67(15)</u> above.

The Joint Coordination Board (JCB), the top governing body of the Special Programme for Research and Training in Tropical Diseases (TDR) held its annual meeting in Geneva from 23 June 2014 to 25 June 2014. In its media note (<u>26 June, 2014</u>), TDR recorded the support of the JCB for taking on this role.

The TDR option was further discussed at EB136 (<u>report of debate</u>) and there was general support plus some specific suggestions which were incorporated into <u>A68/34</u> which was noted.

More in A/RDMCF/2.

See presentations prepared for the OEMSM in May 2016 on: financing and coordination.

UN High Level Panel on Access to Medicines

<u>Secretary-General Appoints Two Former Presidents, 14 Others as Members of High-Level</u> Panel on Access to Medicines (19 Nov 2015)

See UNAIDS comment on the appointment of the HLP

The recently appointed United Nations High-Level Panel on Access to Medicines is meeting for the first time on 11 and 12 December in New York, United States of America, to explore innovative approaches of ensuring access to medicines for people most in need. The panel was set up as part of efforts to achieve Sustainable Development Goal 3: ensuring healthy lives and promoting the well-being of people of all ages.

The UN Secretary-General established the panel based on the findings and recommendations of the <u>Global Commission on HIV and the Law</u> convened by UNDP on behalf of UNAIDS. Its aim is to ensure that everyone can access quality, affordable treatment while incentivizing innovations and new health technologies. The newly established High-Level Panel will review and assess proposals and recommend solutions to policy incoherencies between the rights of inventors, international human rights law, trade rules and public health in the context of access to health technologies.

See report of discussion at EB138 at PSR11(4).

PHM comment

Overview

The scope of the proposed fund would be to finance R&D projects to address priority research gaps as identified by the Global Observatory and the future coordination mechanism (currently being explored by WHO).

The fund will be managed by the Special Programme, while the Global Observatory and the coordination mechanism will be managed by the WHO Secretariat.

The focus of the fund would be the development of effective and affordable health technologies related to type III and type II diseases and the specific research and development needs of developing countries in relation to type I diseases, taking into account the principles formulated by the Consultative Expert Working Group on Research and Development: Financing and Coordination, namely delinkage of the delivery price from research and development costs, the use of open knowledge innovation, and licensing for access.

The contractual arrangements for the funding of projects will ensure that any future health technologies financed through the fund will be accessible to those in need. Arrangements could include clauses on at-cost or preferential pricing, non-exclusive licensing agreements or licences to WHO or the Special Programme.

The priorities of the fund would be informed by the analysis of the research landscape provided by the Global Observatory.

The Health Assembly, on the recommendation of the Programme, Budget and Administration Committee of the Executive Board, would decide on the allocation of the research and development fund to be apportioned to support research and development projects and to support the Global Observatory and the coordination mechanism

A new scientific review group would be established within the Special Programme under the governance of its Joint Coordinating Board. The Joint Coordinating Board would approve the final selection of projects as submitted by the scientific review group.

There are weaknesses in the current proposals but they do represent a step towards public funding of R&D and delinking.

Funds mobilisation

PHM believes that voluntary funding of the system will prove to be unsustainable and that WHO will in due course need to return to a treaty with mandatory contributions.

Broader scope of R&D

In the <u>KEI statement</u> to the 2014 Assembly, HAI and KEI argued that the purposes to be addressed by this CEWG initiative should be widened to include the development of new antibiotic drugs, better low cost diagnostics, basic research in areas of particular interest to all member states, and the funding of independent clinical trials to evaluate the efficacy of pharmaceutical drugs.

Other items on the WHA69 agenda (see especially antimicrobial resistance and STIs) illustrate the need to broaden the range of medical products to be included under this mechanism.

Trade agreements

In the <u>KEI statement</u> to the 2014 Assembly, HAI and KEI argued for: need to confront more directly the barriers to access to treatment which arise from trade agreements. TRIP plus provisions are standard in contemporary plurilateral trade agreements.

Proceeding with the new system does not preclude WHO taking a more active stand in relation to the full use of TRIPS flexibilities and a moratorium on trade agreements which raise new barriers to affordability.

See note above about the new UN HLP on access.

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

In focus

The Assembly will consider A69/41 which conveys the report of the fourth meeting of the Member State mechanism on substandard/spurious/falsely labelled/falsified/counterfeit medical products, which met in Geneva on 19 and 20 November 2015. See SFC MSM page for more context.

The Executive Board at its 138th session considered and noted this report. See report of EB discussion at PSR11(8).

The papers prepared for the Steering Committee of the MSM in March 2016 (see yellow highlight below) do not appear to have been published.

Background

The bottom line

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

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

The term SSFFCMP (or SFC) has come into use because agreement on an alternative definition regarding spurious medical products has not been achieved. The Member State Mechanism (MSM) is the latest structure established within WHO to drive action on quality of medicines whilst not creating new barriers to the entry of generics.

The MSM is governed by a set of Objectives (in <u>Annex 2</u> to WHA6.19), an Agreed Workplan (<u>Annex 2</u> to A/MSM/2/6, Nov 2013), and a list of prioritised activities (<u>Annex 3</u> of A/MSM/3/3).

[The following summary of the issues up for consideration at WHA69 should be read as a continuation of the previous sequence, summarised under time lines below.]

Papers from the fourth meeting of the MSM

The fourth meeting of the MSM for SFC medical products was held in Geneva, Switzerland on 19 and 20 November 2015. The Mechanism discussed the range of prioritised activities (here) from the agreed workplan, including:

- Activity A. Recommendations for Health Authorities engaged in the detection of SSFFC medical products (draft discussed (Annex 1 to <u>A68/33</u> appears to be the most recent public version), training resources sought, one year extension decided);
- Activity B. Focal point network for the exchange of information among Member States and ongoing virtual exchange forum (draft TOR discussed and <u>adopted (Appx1)</u> as amended);
- Activity C. A working group to survey "track and trace" models (survey of existing models adopted as amended (see Appx2), one year extension agreed to allow time for further sharing of experiences around authentication and detection);
- Activity D. WHO work on access to quality, safe, efficacious and affordable medical products (review <u>presented (A/MSM/4/4)</u>, <u>concept note requested</u> before SC meeting in March 2016 regarding element 8(c):
 - Increase the knowledge and understanding about the links between the lack of accessibility/affordability and its impact on the emergence of SSFFC medical products and recommend strategies to minimize that impact;
- Activity E. Communication and awareness raising materials (see UK <u>submission</u> (A/MSM/4/5)) info on WG to be posted before SC in March 2016;
- Activity F. Economic impact of falsified and substandard medicines (<u>report (A/MSM/4/6)</u> discussed, cost estimates controversial see <u>TWN</u>); <u>second draft to be circulated</u> for March SC meeting;
- Activity G. Budget and prioritised activities for MSM5
 - Secretariat to provide budget update for March SC;
 - Expert working group on definitions; see <u>TWN</u>; Expert Group on definitions to be set up; <u>Secretariat to report on modalities and progress to SC in March</u>;
 - Activities which fall outside the SFC mandate (existing contested <u>document</u> (Appx3) reviewed); to be resumed 'at a future point in time';
 - The issue of **transit** to be considered by Steering Committee of the MSM for discussion at MSM5 (see WHO Watch review here; also Abbott (2009), Seuba (2009), <a href="Baker (2012), Saez (2013), Chee (2014));
- Other issues:
 - WHO participation in global steering committee for quality assurance of health products (A/MSM/4/8); Secretariat to provide more details about GSC;
 - Update provided on WHO work on regulatory system strengthening;
 - Methodology for review of MSM (<u>A/MSM/4/9</u>); further report due for SC in March
 - o Terms of office (and rotations) of Chair and Vice-Chairs decided;
 - Next meeting (MSM5) scheduled for Oct or Nov 2016; unresolved debate about scheduling a panel discussion of national regulatory authorities - deferred to a future meeting of the SC.

The record of EB138 discussion of this report is in <u>PSR11(8)</u>. MS comment on various aspects of the MSM process.

Useful links

Previous PHM commentaries on SFC discussions

- WHA68 (May 2015) <u>here</u> (includes report of 3rd meeting of MSM & postponement of review of MSM)
- EB136 (Jan 2015) here (considered report of 3rd meeting of MSM)
- WHA67 (May 2014) here (considered report of 2nd meeting of MSM)
- EB134 (Jan 2014) here (considered report of 2nd meeting of MSM)

WHO web pages

- WHO GB SFC page; includes links to
 - WG of MS on SFC (2011)
 - OEWG on activities, actions and behaviours (July 2013)
 - meetings 1-4 of MSM on SFC (including papers circulated for each meeting)
- WHO SFC home page, includes links to
 - MSM page
 - WHO surveillance and monitoring for SFC products (here)

TWN reports (thanks to KEIOnLine)

- 26 Nov 2015 Expert working group on SSFFC definitions established (here)
- 20 Nov 2015 Socio-economic impact study of SSFFC medicines is "propaganda", says South (here)
- 6 June 2014 Governmental pushback on industry role in medical product regulation (here)
- 30 July 2013 Members agree to list of behaviors linked to compromised medical products (here)
- 24 July 2013 Slow progress in WHO Open Ended Working Group on SSFFC medical products (here)
- 30 July 2013 Members agree to list of behaviors linked to compromised medical products (here)
- 6 June 2013 South to introduce resolution on access to medicines (here)
- 26 Jan 2012 New compromised medicines mechanism agreed, some concerns remain (here)
- 10 Nov 2011 'Member State' mechanism on comprised medical products (here)
- 9 March 2011 QSE Working Group divided, IMPACT Secretariat moves to Italy (here)
- 8 Mar 2011 Members meet to shape role in QSE, examine IMPACT (here)

TWN documentation of IMPACT saga

• Sangeeta Shashikant (2010)

The pre-history of the SFC saga

The pre-history of the SFC saga (from WHA68)

Time lines

IMPACT was established in 2006 with WHO Secretariat support and participation.

A report regarding WHO's role in IMPACT appeared on the EB agenda in Jan 2009 (EB124/14) with a draft resolution endorsing WHO's involvement in IMPACT.

Two further reports were submitted to the WHA62 (May 2009), <u>A62/13</u> on 'counterfeit medical products', and <u>A62/14</u> on IMPACT, but these were not discussed owing to the H1N1 epidemic.

The issue returned to WHA63 in May 2010 with Documents A63/23 and A63/INF.DOC./3.

OE IG WG

WHA63 adopted <u>WHA63(10)</u> which called for an open ended intergovernmental working group (OE IG WG) on SSFFCMPs. The OE WG of MS on SFC met from 28 Feb-2 Mar, 2011 (see <u>web page</u>) but in its report to WHA64 (<u>WHA64/16</u>) it sought an extension of time for a further meeting which was approved.

The second meeting of the OE WG of MS on SFC met in Geneva from 25-28 October 2011 (see) and reported to EB130 (Jan 2012) in Document EB130/22). The WG proposed (in EB130/22) a draft resolution for the EB to recommend to the Assembly which would mandate a new Member State Mechanism (MSM) for "international collaboration among Member States, from a public health perspective, excluding trade and intellectual property considerations, regarding "substandard/spurious/falsely-labelled/falsified/counterfeit medical products" in accordance with the goals, objectives and terms of reference annexed to the present resolution". The draft resolution was adopted as amended (EB130.R13) and forwarded to WHA65 in May 2012.

WHA65 (May 2012) reviewed the resolution as proposed in A65/23 and after a long and vigorous discussion the draft resolution, establishing a Member State mechanism (MSM) on substandard/spurious/falsely-labelled/falsified/counterfeit medical products (SSFFC), was approved (as WHA65.19).

1st meeting of MSM

The MSM on SFC was <u>launched</u> in Buenos Aires 19-21 Nov 2012 and the report of its first meeting (<u>EB132/20</u>) was considered by EB132 (Jan 2013). Important points from the report of the first meeting:

- There was agreement on how the MSM would operate; but
- There are a lot of square brackets in the draft Work Plan;
- The meeting had not been able to establish a Steering Committee (waiting on nominations from each region of two vice-chairpersons) and did not have a Chairperson (which was emerging as a critical issue);
- The meeting decided to establish an open-ended working group to identify the actions, activities and behaviours that result in SSFFC medical products;
- The meeting decided to progress work on those activities under areas 1, 2, and 3 of the workplan that were agreed.

SFC returned to WHA66 (May 2013) supported by <u>A66/22</u> which records that the MSM had met in Buenos Aires in Nov 2012; that the work plan was not fully agreed upon but that there was a commitment to an OE MS WG on Actions, Activities and Behaviours which drive SFC. A Steering Committee was established but there was no agreement on the chairperson.

A66/22 was noted and the Assembly decided in <u>A66(10)</u> to recommend that the chairmanship of the Steering Committee of the Member State Mechanism should operate on the basis of rotation, on an interim basis, without prejudice to the existing terms of reference of the mechanism.

2nd meeting of MSM

The Assembly in May 2014 considered A67/29, (which forwarded EB134/25 from the EB to the Assembly) conveying the report of the second meeting of the MSM, held in late November 2013.

The MSM had:

- considered and adopted the report of the OEWG on actions, activities and behaviours (Appendix 1 of EB134/25);
- reviewed the Secretariat's global surveillance and monitoring project (<u>here</u>);
- approved continuing discussion on strategies for regulating actions, activities and behaviours;
- adopted the revised work plan (Appendix 2);
- noted the budget shortfall (Appendix 3) and asked for a full report to the WHA67;
- authorised an EWG, to be led by Argentina, "to continue the work of the Open-ended working group on actions, activities and behaviours that result in SSFFC medical products" (here);
- authorised an EWG, to be led by India, to focus on element 5(b) of the work plan on the identification of activities and behaviours that fall outside the mandate of the Mechanism (See Appendix 2 of WHA67/29);
- agreed that next interim Chair would be Argentina;
- agreed to hold "an informal technical meeting, open to all Member States, to finalize the
 outcomes of the electronic consultations would be held before the third meeting of the
 Member State mechanism"; and
- agreed that the third meeting of MSM would be in the week of 27 October 2014, to be preceded by a meeting of the Steering Committee and continue the system of chairing through the rotation of vice chairs;

Issues discussed at 3rd meeting of MSM

The 68th Assembly reviewed A68/33 which had been considered by the EB in January, and also Decision EB136(1), in which the Board recommended to the Assembly, in accordance with the request of the Member State Mechanism (MSM), that the review of the Mechanism be postponed by one year to 2017.

A68/33 includes the report of the third meeting of the Member State Mechanism for SSFFCMPs, which was held in Geneva, Switzerland 29 October to 31 October 2014.

The third meeting of the MSM reviewed (and apparently approved) the outcome of the informal technical meeting on recommendations for health authorities to detect and deal with actions, activities and behaviours that *result in SSFFC*, reviewed the outcome of the informal technical meeting on element 5(b) of the work plan on the identification of activities and behaviours that *fall outside the mandate* of the mechanism, and reviewed a proposal by the Steering Committee on proposals and priorities for implementation of the work plan.

Annex 1 (to <u>A68/33</u>) is the outcome document from an informal technical meeting designed to provide advice to national and regional regulatory authorities regarding actions, activities and behaviours which result in SSFFCMPs. It is a revision of an earlier document shared with the EB in Appendix 1 of EB134/25. The revised document covers monitoring, detection,

assessment, investigation and prevention. It appears to have been adopted by the MSM and will inform further activities in the workplan of the MSM, in particular Activity A (Annex 3).

Annex 2 (to A68/33) is a report to the MSM from an informal technical meeting tasked with revising the list of actions, activities and behaviours that fall outside the mandate of the mechanism. The informal technical group did not reach consensus on the title, a paragraph in the introductory section nor clauses 3 and 7 of the document.

The debate over the introductory paragraph appears to involve words suggesting that actions, activities and behaviours which fall outside the mandate of the Mechanism "will not face unjustified regulatory actions, in order not to hamper access to quality, safe and efficacious medical products".

The debate over Clause 3 appears to focus on whether deviations from GMP "which do not compromise the quality or which do not pose a health risk" should lie within or beyond the mandate.

The debate over Clause 7 is about the seizure of medical products in transit. It appears that the critics of the EU seizures (see below) want to declare the seizure "of medical products in transit, which are in compliance with the regulatory requirements of the country of export and the country of final destination" as outside the mandate and therefore not justified on the grounds of SSFFC.

The MSM requested the Steering Committee to undertake further consultations on the document with a view to proposing language for the remaining issues in the paper for submission to the fourth meeting of the Member State Mechanism on SSFFC.

The mechanism revised and agreed the list of prioritized activities for 2014–2015 (<u>Annex 3</u>). This annex needs to be read in conjunction with paragraph 7 of the main MSM report which indicates which countries or the Secretariat will lead the various activities. It also refers to the agreed workplan previously shared with the EB in <u>EB134/25 Appendix 2</u>.

The report notes that the MSM 'expressed concern over the unfunded activities in the budget'.

[Now return to in focus to pick up the threads under discussion at this Assembly.]

Record of EB138 debate at PSR11(8)

PHM comment

The bottom line

The SFC struggle is critical with respect to affordable access to quality, safe and efficacious (QSE) medicines.

The big pharma strategy is:

- first, to conflate the issue of QSE-compromised medicines (SSFFCMPs in WHO speak)
 with asserted breaches of IPRs:
- second to create a global panic around the fear of 'counterfeit medicines' based on the (real) problem of QSE compromised medicines; and

 third, encourage countries to adopt laws and treaties which have the effect of reducing and restricting access to cheap (quality, safe and efficacious) generic medicines (eg through in transit seizure, patent linkage, and domestic laws which preclude the use of TRIPS flexibilities).

Big pharma is supported in this campaign by the governments of the rich countries, in part because they are IP exporters, but in part because of their commitment to corporate globalisation.

The countries, NGOs and social movements working towards access to affordable safe and efficacious medicines are seeking to:

- achieve a practical definition of SFC medicines which clearly distinguishes between QSE risk and IP status;
- establish technologies and regulatory structures which prevent QSE compromised medicines from accessing medicines markets.

While the fundamental issues are simple the policy development and political maneuvering is taking place around the 'prioritised activities' (activities A-G, here) referred to above, within an almost impenetrable snowstorm of processes, bodies, acronyms and documents.

While the WHO processes grind slowly, big pharma, and its various supporters and cheerleaders, are pursuing their extreme IP agenda through trade agreements (including the TTP and TTIP) and national / regional regulations (notably the EU regulations directed to seizure of medicines in transit on suspicion of their breaching IPRs in the countries of transit).

PHM urges MS representatives to keep the fundamental issues (summarised above) uppermost in mind in evaluating the report from the MSM and participating in the debate and keep in mind also SDG Goal 3 (Ensure healthy lives and promote well-being for all at all ages) including Target 3.8: 'achieve universal health coverage (UHC), including financial risk protection, access to quality essential health care services, and access to safe, effective, quality, and affordable essential medicines and vaccines for all.

Critical issues which may be highlighted in the debate at WHA69 include:

- where is the Concept Note on the links between accessibility and affordability and the emergence of SFC products?
- in transit seizure (links above) and whether it falls outside the mandate of the MSM (Appx3);
- membership, procedures and funding of the EWG on definitions (para 15(ii) of EB138/40);
- recommendations for regulatory authorities (Annex 1 to A68/33);
- 'track and trace' technologies (Appx2); links to in transit seizure; integrity and security of data systems;
- communications and awareness raising (<u>Activity E</u>); what progress has been made with regard to the Working Group?
- 'socio economic impact' (<u>Activity F</u>); where is the current draft of this report?
- update on global steering committee for quality assurance of medical products?
- continued funding of the MSM process;
- methodology for the scheduled review of the MSM process.

PHM urges NGOs and community organisations and networks to disseminate, publicise and advocate around the issues at stake in this SFC struggle and in particular to hold MS representatives accountable for the policy positions advanced in the governing bodies of WHO.

PHM urges NGOs and community organisations following the SFC struggle within the WHO to strengthen the links with those activists who are mobilising against the extreme IP agenda in the context of trade agreements and EU regulations.

16.4 Addressing the global shortages of medicines, and the safety and accessibility of children's medication

In focus

This item brings together two somewhat different although overlapping issues: (i) shortages of medicines; and (ii) the development, safety and accessibility of medicines for children.

The general issues of shortages appears to have been initiated by the Secretariat, responding in part to publications in the research literature (see <u>below</u>) and the program on shortages run by the <u>US FDA</u>. The WHO Secretariat organised an expert meeting on shortages in December 2015 and the conclusions from that meeting have been included in <u>A69/42</u>. A resolution on shortages, sponsored by South Africa and other countries, is being prepared for WHA69.

Issues relating to the development, safety and accessibility of medicines for children appears to have come to the Assembly agenda through a draft resolution sponsored by China, Italy, Pakistan and Thailand. This draft resolution is in a sense a follow up to Resolution A60.20 from 2007. The Secretariat report prepared for that discussion, A60/25, remains useful and paras 14-20 of A69/42 provides an update on work in this area since 2007. However, as the ADG (HSI) confirmed in the EB debate: "Action taken under resolution WHA60.22 (2007) notwithstanding, many essential children's medicines were still not manufactured or registered, or were expensive. Further comprehensive action was clearly required in order to increase access to medicine for children and address shortages."

There was extended 'drafting group' discussion of the China, Pakistan, Italy and Thailand resolution on children's medicines during the EB but consensus was not achieved and it was agreed that further intersessional consultations would proceed with a view to recommending a resolution to the Assembly.

The proposed resolution on shortages more generally was not tabled but will be submitted for the WHA69. Presumably it will correspond more closely to the discussion of shortages developed in <u>A69/42</u>.

Background

Document A69/42 provides a useful although incomplete overview of the shortages problem.

A60/25 (2007) provides an overview of access to children's medicines with more recent programmes summarised in paras 14-20 of A69/42.

The record of EB discussion is at: PSR11(11) & PSR12(2)

PHM comment

Shortages

The South Africa et al resolution is not yet publicly available. However, PHM urges that the main thrust of any resolution on the shortages problem should be to commission further examination of particular aspects of causation and particular policy strategies.

Drug shortages constitute a serious problem and there is a strong case for WHO to pay closer attention to causes and solutions. However, it is not clear that the evidence is sufficient to initiate policy action immediately. It would be appropriate for the Assembly to list the kinds of research and policy studies that will be needed to properly address the shortages problem.

A69/42 is a useful first step in the analysis of the problem, the causes and possible solutions. However, possible causes which are not explicitly mentioned in A69/42 include:

- unreasonably stringent regulatory standards in some jurisdictions which have the effect
 of raising the cost of production beyond profitable for export into those markets (and the
 role of big pharma in promoting such standards);
- the oligopoly structure of the medicines and vaccines industries with mergers and acquisitions reducing competition in particular markets (in addition to the anti-competitive consequences of softer, longer patents with more aggressive policing arising from modern trade agreements);
- intensive promotion of expensive patented drugs and neglect of older out of patent drugs (often of comparable or greater efficacy).

PHM also has reservations about the reference to 'market shaping' in para 22(c) of A69/42 in the absence of any systematic examination of the interplay of regulatory standards, monopoly, market size and demand, rational use, ethical promotion, and existing price setting mechanisms (eg through insurance or subsidy).

There may be a role for advance market commitments and price volume agreements but there is a prior need for clear evidence based guidelines regarding principles, criteria and risk management to ensure that such mechanisms are used appropriately.

Children's medicines

PHM urges member states to support the China, Pakistan, Italy and Thailand resolution.

It appears likely that the reason why the China, Pakistan, Italy, Thailand resolution did not achieve consensus at the EB would have been the clauses urging accelerated implementation of the actions laid out in Resolution <u>A60.20</u>. The provisions of A60.20 include:

- OP1(8) which urges member states: to use all necessary administrative and legislative means including, where appropriate, the provisions contained in international agreements, including the agreement on Trade-Related Aspects of Intellectual Property Rights, in order to promote access to essential medicines for children; and
- OP2(5) which requests the DG: to collaborate with governments, other organizations of the United Nations system, including WTO and WIPO, donor agencies, nongovernmental organizations and the pharmaceutical industry in order to encourage fair trade in safe and effective medicines for children and adequate financing for securing better access to medicines for children.

Both of these provisions from A60.20 are carried forward in the China et al resolution in OP1(7) and OP2(5).

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17. Progress reports (and PHM comment)

- A. Eradication of dracunculiasis (resolution WHA64.16)
- B. Sustaining the elimination of iodine deficiency disorders (resolution WHA60.21)
- <u>C.</u> Strengthening of palliative care as a component of comprehensive care throughout the life course (resolution <u>WHA67.19</u>)
- <u>D.</u> Contributing to social and economic development: sustainable action across sectors to improve health and health equity [follow-up of the 8th Global Conference on Health Promotion] (resolution <u>WHA67.12</u>)
- E. Reproductive health: strategy to accelerate progress towards the attainment of international development goals and targets (resolution WHA57.12)
- F. Health intervention and technology assessment in support of universal health coverage (resolution WHA67.23)
- G. Access to essential medicines (resolution WHA67.22)
- <u>H.</u> Access to biotherapeutic products, including similar biotherapeutic products, and ensuring their quality, safety and efficacy (resolution <u>WHA67.21</u>)
- I. WHO strategy on research for health (resolution WHA63.21)
- J. Multilingualism: implementation of action plan (resolution WHA61.12)

A. Eradication of dracunculiasis (resolution WHA64.16)

What is being followed up?

A64/20, the report provided to the Assembly in 2011 when this resolution was adopted, highlights the importance of (1) provision of adequate and safe supplies of drinking-water in the remaining diseaseendemic communities; (2) implementation of intensified case-containment measures including detection of all cases within 24 hours of worm emergence in all remaining areas where the disease is endemic as well as in the dracunculiasis-free areas, should a case be imported; (3) raising community awareness nationwide about dracunculiasis and the reward system for reporting dracunculiasis cases through appropriate channels of communication; (4) continued certification activities in countries that meet the eradication criteria.

The resolution <u>WHA64.16</u> endorses the strategy of intensified surveillance, case containment, use of cloth and pipe filters, vector control, access to safe drinking-water, health education and community mobilization. The main thrust of the resolution is call for political commitment and funds to continue the path to eradication of the disease.

Secretariat report

<u>A69/43</u> reports that indigenous transmission is now restricted to only four countries, Chad, Mali, Ethiopia and South Sudan. The report describes the main agencies involved and the main elements of the eradication programme.

The sting is in para 12 which notes a \$US214m funding gap for the programme for the years 2016-2020.

PHM Comment

This is a disease of unclean drinking water and lack of public health infrastructure. The fundamental need is for economic development which in turn calls for peace and a sustainable and equitable global economic regime.

In the short term \$214m is needed in the next four years. As A69/43 says, this funding gap 'must be closed to achieve the goals of eradication and its certification'.

B. Sustaining the elimination of iodine deficiency disorders (resolution WHA60.21)

What is being followed up?

The more substantive resolution is A58.24. Resolution A60.21simply calls for a redoubling of efforts in the implementation of A58.24, in particular monitoring and reporting on the state of iodine nutrition every three years .

Secretariat report

A69/43 reports good progress in reducing the number of people who are at risks of iodine deficiency. It reiterates the established control strategy is iodised salt although it notes possible risks associated with excessive iodine intakes.

The report discusses iodine supplementation before during and after pregnancy and the Secretariat has commissioned a systematic review on this.

A separate review has been commissioned on the use of biomarkers in monitoring population wide iodine status.

PHM Comment

Strong public health infrastructure is critical for maintaining attention, undertaking monitoring, identifying strategies for iodine supplementation and working with legislators to implement.

C. Strengthening of palliative care as a component of comprehensive care throughout the life course (resolution WHA67.19)

What is being followed up?

The debate in which WHA67.19 was adopted was informed by A67/31 which highlighted

- 1. (a) health system policies to ensure the integration of palliative care services into the structure and financing of national health care systems at all levels of care;
- 2. (b) policies for strengthening and expanding human resources, including education and training of health care professionals, in order to ensure adequate responses to palliative care needs, together with training of volunteers and education of the public;

- 3. (c) a medicines policy in order to ensure the availability of essential medicines for the management of symptoms, including pain and psychological distress, and, in particular, opioid analgesics for relief of pain and respiratory distress; and
- 4. (d) a policy for research into assessing the needs for palliative care and identifying standards and models of service that work, particularly in limited resource settings.

Secretariat report

A69/43 describes work undertaken by the Secretariat in these areas, through work in:

- Strengthening palliative care policies, services and funding;
- Guidance and tools;
- Training;
- Access to essential medicines;
- Integrating palliative care into global disease control and health system plans;
- Building the evidence base and monitoring progress.

The issue of access to opioids is also considered in this agenda under Item 12.6 "Public health dimension of the world drug problem including in the context of the Special Session of the United Nations General Assembly on the World Drug Problem, to be held in 2016".

PHM Comment

PHM urges MS to give priority to the reform of international drug regulation so that people are not denied access to proper pain relief.

D. Contributing to social and economic development: sustainable action across sectors to improve health and health equity [follow-up of the 8th Global Conference on Health Promotion] (resolution WHA67.12)

What is being followed up?

The 8th Global Conference on Health Promotion was held in Helsinki, in June 2013. This was the latest in the series which commenced with the Ottawa Conference in 1986. The Helsinki Conference statement was entitled 'Health in all policies'.

Resolution <u>WHA67.12</u> was adopted in May 2014. It appreciated the Helskinki Conference as reported in <u>A67/25</u> and urged member states to take action on health equity including collaborating with other sectors. It asked the DG to prepare a framework for country action and to work with other intergovernmental organisations to ensure they take health into account in their work.

The <u>Framework for Country Action</u> was presented to the Assembly in <u>A68/17</u> and was duly noted.

Secretariat report

In <u>A69/43</u> the Secretariat lists the actions it has taken in fulfillment of <u>WHA67.12</u>. These include:

- building capacity to promote action across sectors and Health in All Policies through education and training;
- scaling up country action through Health in All Policies projects;
- facilitating country action and advancing the science base on how to promote action across sectors and develop tools for Health in All Policies;
- securing country commitment through regional plans, statements and dialogues.

It has also taken steps to strengthen WHO's role, capacities and knowledge resources to give guidance and technical assistance, and to ensure coherence and collaboration across programmes and initiatives within WHO and is promoting HiAP in various intergovernmental collaborations.

PHM Comment

The logic of HiAP is clear and has been repeated in many forms since the Alma-Ata Declaration defined PHC as involving, "in addition to the health sector, all related sectors and aspects of national and community development, in particular agriculture, animal husbandry, food, industry, education, housing, public works, communications and other sectors; and demands the coordinated efforts of all those sectors".

The Helsinki Statement and the Framework for Country Action focus largely on intersectoral collaboration at the policy level; there is no recognition in either of the importance of intersectoral collaboration at the local level and the role of primary health care agencies in promoting this.

E. Reproductive health: strategy to accelerate progress towards the attainment of international development goals and targets (resolution WHA57.12 - NB yields a '404')

What is being followed up?

Resolution WHA55.19 (2002) requested WHO to develop a strategy for accelerating progress towards attainment of international development goals and targets related to reproductive health. The Reproductive Health Strategy was adopted in 2004 through WHA57.12 (which does not appear to be accessible at this time).

Secretariat report

A69/43

See also Progress Report 2010

F. Health intervention and technology assessment in support of universal health coverage (resolution WHA67.23)

What is being followed up?

The Secretariat paper on HTA which was considered at the WHA67 is <u>A67/33</u>. This paper describes HTA and why it is important; surveys how it is being used by member states; and reports on how it is being used by the WHO Secretariat (in particular, in relation to essential medicines).

Following discussion of that paper the Assembly adopted <u>WHA67.23</u> which urges MSs and the Secretariat to develop the skills, institutions, policy and management frameworks to develop and use HTA.

Secretariat report

A69/43 reports that a survey of the status of HTA across MSs has been carried out and the results published here. It is a very interesting report.

The Secretariat is developing a training programme and technical resources to support the development and application of HTA.

PHM Comment

HTA can be extremely useful. It is an essential capability.

However, some caution is needed in the application of HTA in relation to 'benefit packages' and health insurance. Effectiveness varies according to epidemiological, infrastructure and clinical context. WHO recognises a range of purposes for HTA (clinical practice guidelines, planning and budgeting, pricing of health products, indicators of quality of care, reimbursement/benefit packages and certificate of need). However for those, like the WB, who choose to define UHC in terms of health insurance there is a tendency to privilege benefit package decisions in speaking about the purposes of HTA. Blanket inclusions or exclusions in 'benefit packages' on the basis of tightly specified HTA modelling can be lead to arbitrary and inequitable outcomes.

G. Access to essential medicines (resolution WHA67.22)

What is being followed up?

The Secretariat paper which led to the adoption of this resolution (A67/30) notes that "WHO's strategy to improve access to essential medicines is based on the principles of evidence-based selection of a limited range of medicines, efficient procurement, affordable prices, effective distribution systems, and the rational use of medicines". However availability and affordability remain problematic and the paper explores some of the causes of this and strategies to address those barriers.

The report summarises key areas of policy action as including:

- Supporting universal health coverage.
- Monitoring and the use of information.

- Access to medicines for noncommunicable diseases.
- Rational use of medicines.
- Antimicrobial resistance.
- Access to medicines for HIV/AIDS, tuberculosis and malaria, reproductive and maternal and child health.
- Innovation and the local production of medicines.

The resolution (WHA67.22) urges MSs to build capacity and put in place the policy settings needed to support access to essential medicines and address the barriers and urges the Secretariat to support MSs in these processes.

The most controversial elements of this resolution are OP1(11) and OP2(8) which encourage the full use of TRIPS flexibilities as part of curbing the costs of essential medicines.

Secretariat report

A69/43 refers to the work of the Secretariat in supporting access to essential medicines but underlines some of the challenges. These include: high prices for branded drugs for hepatitis C and generic medicines to prevent cardiovascular disease; regulatory restrictions on access to opioids for pain relief; poor prescribing practices (eg for epilepsy drugs); and global supply problems.

PHM Comment

Many of the issues highlighted in the Secretariat report (A69/43) are the subject of continuing discussion including on the agenda of this Assembly. However, there is no mention in the report of initiatives to support local manufacturing (or the barriers to such initiatives) or the increasing IP barriers associated with preferential trade deals such as TPP, TTIP and RCEP.

H. Access to biotherapeutic products, including similar biotherapeutic products, and ensuring their quality, safety and efficacy (resolution WHA67.21)

What is being followed up?

The Secretariat report (A67/32) informing the discussion out of which this resolution arose addressed 'regulatory system strengthening'. Two resolutions emerged out of the discussion of this paper, one of which (WHA67.20) was directly focused on regulatory system strengthening for medical products (for review at WHA70 and WHA72) and the other (WHA67.21) addressed some of the challenges specific to biotherapeutic products.

In fact A67/32 does not deal with the specific issues associated with biotherapeutic products. However these issues were explored in the lead up to the 16th International Conference of Drug Regulatory Agencies (ICDRA) in August 2014 and clearly the preliminary discussions leading to ICDRA informed the preparation of the draft which became WHA67.21.

<u>WHA67.21</u> addresses the challenges of regulating similar biotherapeutic products ('biosimilars'). The essential problem is that the regulatory approach to generic small molecule drugs in relation to previously authorised patented (identical) small molecule drugs does not map easily

into biotherapeutics because biosimilars may not be identical. The research based pharmaceutical corporations argue that the manufacturers of biosimilars should be required to undertake all of the clinical trials required of the first, patented drug and applicants for marketing approval for biosimilars should not be able to draw upon safety and efficacy results submitted by the original innovator.

An important element of the debate around the regulation of biosimilars turns upon the norms for their official naming through the International Non-proprietary Names system (INN).

WHA67.21 does not in fact offer any solutions. Rather it urges MSs and WHO to get to work on the problem and to report to WHA69.

The ICDRA16 meeting some months after WHA67 produced recommendations (here) for MSs and for WHO which took the debate a bit further than WHA 67.21.

Secretariat report

A69/43 refers to the ICDRA16 and its recommendations regarding biosimilars, and reports on a range of more specific initiatives:

- that the WHO Expert Committee on Biological Standardization has been able to finalize and adopt new WHO guidelines on regulatory assessment of approved rDNA-derived biotherapeutics (to be reported to EB140 in Jan 2017);
- that work is underway on the regulatory evaluation of monoclonal antibodies developed as similar biotherapeutic products;
- on a workshop in Ghana in Sept 2015 which strongly endorsed the 2009 WHO quidelines on the evaluation of SBPs;
- that WHO's Expert Committee on Biological Standardization has recommended that WHO enhance communication on the appropriate use of reference standards (as part of the regulatory framework) and advocate for the continued provision by manufacturers of source materials as a public good for the development of WHO standards as public reference materials;
- that a voluntary scheme has been proposed for the addition of biological qualifiers to International Nonproprietary Names; this is currently subject to an impact assessment study;
- on planning for further work.

PHM Comment

The WHO Expert Committee on Biological Standardization guidelines of 2009 [here] require 'head to head' comparisons between the SBP and the RBP for purposes of marketing approval as a biosimilar. The research based pharmaceuticals industry argues for "a solid, scientifically-based process for reviewing, approving, and monitoring reference biotherapeutic products before embarking on the evaluation of a proposed biosimilar".

This would present a very high barrier to the approval of biosimilars (and therefore competition and lower prices), especially in countries where the originator company has not sought approval.

Access to biologics is compromised in LMICs because of the very high cost of these products, thus denying treatment to a very large number of patients in these countries. National regulations are necessary to ensure the quality, safety and efficacy of biologics and biosimilars. At the same time, the regulatory framework should promote accelerated access to low cost biosimilars and not act as a barrier to their introduction. There is, as yet, no perfect regulatory system for these products. LMICs will be well served if they do not blindly follow the systems in place in the EU and the US, and instead develop systems best suited to national situations.

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

I. WHO strategy on research for health (resolution WHA63.21)

What is being followed up?

A63.22, considered by the WHA63, set out a draft strategy for research on health.

- 22. Five interrelated goals have been defined in order to enable WHO to realize the draft strategy's vision of the application of research-based evidence to inform decisions and actions in support of health and health equity.
- 23. The **organization goal** involves the strengthening of the research culture across WHO; the **priorities goal** concerns the reinforcement of research that responds to priority health needs; the **capacity goal** relates to the provision of support to the strengthening of national health research systems; the **standards goal** concerns the promotion of good practice in research, drawing on WHO's core function of setting norms and standards; and the **translation goal** involves the strengthening of links between the policy, practice and products of research.

The Strategy outlines a range of actions which will be taken to achieve each of these goals.

Resolution <u>WHA63.21</u> endorsed the strategy; urges MSs to undertake various actions in their own countries; invites MSs and various other stakeholders to provide support to WHO in the implementation of the Strategy; and requests the DG to take a range of appropriate actions.

Secretariat report

A69/43 describes a range of initiatives directed to generating better data about research for health including methods (data mining), convergence regarding data systems among international donors, supporting countries' in research data collection, the proposed global observatory on research and development, and support for research-related work within WHO.

The only reference to content or direction of research is a brief mention of the harmonisation of the implementation of the WHO strategy on research for health with that of the global strategy and plan of action on public health, innovation and intellectual property.

J. Multilingualism: implementation of action plan (resolution WHA61.12)

What is being followed up?

<u>EB121/6</u> proposed a Multilingualism Plan of Action which was endorsed in <u>WHA61.12</u> which also asked for a strategy, a timetable, a database of language skills within the Secretariat and promotion of language training for Secretariat staff.

Secretariat report

A69/43 reports on progress in producing WHO resources in official (and non-official) languages and on the take up of language training by WHO staff.

20.1 Unified programmatic and financial report for the year ended 31 December 2015

In focus

The Assembly will consider A69/45 which brings together the programmatic and financial reports. A69/45 should be read in association with the original Programme Budget 14-15 and the Programme Budget Portal. More financial docs here.

PBAC24 considered this item before the Assembly and reported in <u>A69/62</u>. The Committee recommended that the Assembly accept the WHO programmatic and financial report for 2014–2015, including audited financial statements for 2015.

PHM Comment

This report reflects well on the Secretariat. Despite the challenges WHO is doing excellent work. It evident that the WHO Reform program has helped to tighten up the management of the Secretariat.

Overview

The report commences with an overview which surveys changing environments, leadership priorities and governance, financing and management for the biennium 2014-15.

One of the highlights of this narrative is the blunt speaking about resources: inadequate in total and shackled by the earmarking of voluntary contributions. The disingenuity of the member states who have blocked an increase in assessed contributions is stark. First, they claimed that WHO needed to demonstrate that it was efficient and accountable as a condition for increased funding. Now after five years of programmatic and management reform which has been demonstrably successful they continue to block adequate and flexible funding. The real politic is that the donors are determined to maintain control over WHO's operational priorities through the donor chokehold.

The most obvious disappointment, from PHM's perspective, is the continued repitition of the UHC slogan and the willful agnosticism regarding the implications of different funding and service delivery configurations for efficiency, quality and equity.

It is also worrying that the narrative suggests that there may be no need for programmatic units focused on equity, gender, human rights and social determinants on the grounds that they are now embedded in all of the operational programme units. This is certainly not evident in the narrative report regarding Category 1: Communicable disease.

Category and programme review

Following the overview the report reviews achievements and financial results on a programme by programme basis across all six 'categories' of the Programme Budget 14-15.

Each programme area is introduced with a narrative account of achievement in a selected area under this programme. This is followed by an output evaluation for the programme area generally and an overview of expenditure by major office on this programme area.

This approach to accountability needs to be understood against the structure of the PB14-15; its hierarchy of outcomes, outputs and deliverables; and its performance assessment methodology. Outcomes are improvements in the conditions for health improvement; outputs refer to what WHO is trying to do to help achieve those outcomes; deliverables is what different offices and levels are expected to contribute to the achievement of those outputs.

In A69/45 achievements with respect to outputs are graded (under the relevant 'outcome' heading) according to a three step standard: fully delivered, partially delivered, not delivered (or not applicable). Both A69/45 and the PB Portal are opaque in terms of how these grades are determined. Annex 1 to A69/45 purports to provide a description of the performance assessment methodology but it is not very clear.

Notwithstanding the selected anecdotes representing the work of each programme and the opaque methods for judging 'achievement' it appears that the Secretariat is doing a fine job.

From a financial point of view the report demonstrates that the Secretariat has spent its money in accordance with the budget priorities adopted for the PB14-15. For an overall breakdown in budgeted expenditure across the categories see <u>Table 2 in A66/7</u>.

What is also clear is that there has been a continuing shortfall in funding subscribed for agreed and budgeted priorities. Most donors continue to earmark their contributions, notwithstanding the earnest entreaties of the DG through the financing dialogue.

Funding

The tables in the last part of the document provide details of revenue and expenditures but for most observers the financing overview (from page 20 will be more useful). While voluntary contributions increased by 11% over the previous biennium, most of the increase was in specified contributions, particularly for Ebola. Flexible voluntary contributions fell by 7% from the previous biennium.

20.2 Financing the Programme Budget 2016-17

In focus

Financing dialogue

A69/46 reports on the outcomes to date of the financing dialogue and the status of the financing of the Programme budget 2016–2017. It includes a report on progress in the financing of WHO which addresses transparency (improving), predictability (slight improvement), flexibility (very restricted), alignment (highly problematic) and broadening of the contributory base (slow).

This report needs to be considered with a view also to the new "unified programmatic and financial report" scheduled for discussion as Item 20.1, supported by A69/45 (NYP). See also PHM Comment on Item 20.1.

See the Portal for more detailed financial information.

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 PB16-17 and Resolution <u>WHA68.1</u> which endorsed it. See PHM commentary on the review of PB14-15 at WHA68 and PHM comment on PB16-17 at WHA68.

See A68/INF/7 for more info on budget process.

For further information about the financing dialogue see: http://www.who.int/about/finances-accountability/funding/financing-dialogue/en/

See report of discussion at EB138 at PSR14(2)

Strategic budget space allocation

The Assembly will consider A69/47 which conveys the report of the Working Group on Strategic Budget Space Allocation and presents for the Assembly's consideration the draft decision EB137(7) recommended from EB137.

An earlier report from the WG was considered at EB136. The WG report was conveyed in <u>EB136/35</u> and the discussion was also informed by the report of the PBAC (in <u>EB136/3</u>) which included comment on Strategic Budget Space Allocation.

In EB136/35 the WG recommended the Secretariat budget be considered in terms of four separate 'segments' (1. country level technical cooperation; 2. provision of global and regional 'goods'; 3. management and administration; and 4. emergency preparedness and response) with different algorithms for budgeting in each 'segment'.

There was general support in EB136 for the methodologies advanced for Segments 2-4. However, MS from SEARO mounted a strong case for a review of the proposed methodology for Segment 1 (sceptical about DALYs, inadequate consideration of poverty) and also of the

proposed broader allocation of only 23% to Segment 1. Several of the EMRO MSs argued that there should be a stronger emphasis on humanitarian emergencies such as in Iraq, Syria and Afghanistan.

In decision <u>EB136(5)</u>, the Executive Board adopted the methodologies suggested for segments 2-4 but requested the Working Group to further develop operational segment 1 (technical cooperation at country level) taking into consideration the issues raised during the 136th session of the Executive Board regarding methodology, indicators and data availability. In addition Member States were invited to submit written comments to the Secretariat by 28 February 2015.

The WG report considered at EB137 is circulated for consideration by WHA69 in the Annex to A69/47. This report includes two appendices; one deals with a new set of terms of reference for the WG; the second presents the detailed calculations regarding Segment 1 and the basis for recommending Model C.

The revised report was considered at EB137 (see record of discussion at <u>PSR3(2)</u> and <u>PSR3(13)</u>) and draft decision EB137(7) was adopted.

Background

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

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

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

A Working Group was established under the PBAC which submitted an interim report, <u>A67/9</u>, which was considered by the PBAC and the WHA and a further iteration was produced taking into account PBAC comments. This version was distributed to RCs for their consideration (see <u>EUR/RC64/20</u>).

The revised model, presented to EB136 in EB136/35, involved

- four 'segments' which operationally distinct and therefore need different algorithms for budgeting:
 - 1. country level technical cooperation (currently around 23% of total budget space, all at country level);
 - 2. provision of global and regional 'goods' (currently 33% of total: 20% HQ, 13% regional):
 - o 3. management and administration (22% across all levels); and
 - 4. emergency preparedness and response (22% largely at country level);

- a series of six overarching principles;
 - o based on needs and evidence,
 - results-based management,
 - o fairness and equity,
 - o accountability and transparency,
 - clear roles and functions,
 - performance improvement.
- separation of activity costs and staffing costs in each segment;
- incremental movement from current budget space allocation (within each segment) to new more explicit procedures;
- the WG does not seem to have proposed a methodology for allocating budget space between segments.

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

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

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

The WG recognised that full implementation of its recommendations need to be aligned with the continuing implementation of WHO Reform more broadly, including reform of outbreak and emergency capability.

PHM comment

The financing dialogue

The underfunding of WHO and the donor chokehold over the Secretariat's work program are shameful acts of global health vandalism. It has led to:

- critical limitations on Secretariat capacity to carry out its job;
- substantial distortions of the mandate of the governing bodies by the donors who choose
 what they will or will not fund and, because of the freeze on ACs, have almost total
 power over the budget; and
- exacerbation of silo behaviour and organizational fragmentation as units, clusters and regions compete for donor visibility and funding.

The % of the PB16-17 with assured funding is estimated to be 80%. Better than previously but seriously unstable. 70% of the budget is funded by VCs, 63% of which are tightly earmarked. In view of the budget lines which have to be funded through ACs, this leaves the governing bodies with very little flexibility.

The alignment of the expenditure budget to global health priorities is skewed by the knowledge of what the donors will and will not fund. However, the actual funds mobilised for agreed budget lines is also very unbalanced. See Fig 1 from WHA68/6 (regarding PB14-15) which depicts the serious under-funding of social determinants, NCDs and 'integrated people-centred health services'.

PHM appreciates the establishment of the Department for Coordinated Resource Mobilization within the Director General's Office, and the 'end to end resource mobilization process' attempting to coordinate resource mobilization focal points from each region and cluster. It is a shame that it wasn't done before.

Member state delegates are urged to lift the freeze on the budget ceiling and lift the freeze on assessed contribution. Donors are urged to untie their donations.

Strategic budget space allocation

The WG's <u>EB136/35</u> report was clearly a step forward from non-transparent and historically based allocation practices. However, there remain some significant issues which still need to be resolved.

The formula suggested for Segment 1 depended on some very rubbery data (in particular, PPP exchange rates, DALYs, and deliveries in the presence of skilled birth attendants). This provided grounds for debates about fairness. Unfortunately PPP and DALY calculations are irremediably subjective and rubbery. It is not clear whether the country specific allocations for Seg 1 will be determined within the regional office or will involve HQ. PHM urges firm involvement of HQ.

The revised methodology for Segment 1 (in A69/47) appears more robust.

The WG sees Segment 2 in terms of the priorities identified in the GPW, the resolutions adopted by the governing bodies and the roles and functions of the three levels of the Organisation. The WG picks up on the emphasis in the report of the Independent Evaluation Team in 2013 (EB134/39) on stronger project management. One reading of the WG's report is that budget space in this segment will be the aggregation of expenditure needs of a series of projects, based largely on governing body resolutions. However, these projects also have an organisational reality; they are carried by the clusters, departments, units and regions. Ultimately budgeting is about funding organisational entities. There is nothing in the WG's report about how 'program budgeting' based on 'the project management approach' will mesh with the funding of organisational units in HQ and regions.

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

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

The WG provides no guidance regarding methods for budget space allocation between segments, other than historical. This is an important missing component. There was no discussion of how 'segments' map onto the 'categories' which form the basis of the <u>GPW12</u>.

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

WHO does not have enough money!

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

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

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

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

20.7 Scale of assessments

In focus

The Assembly will be invited (in <u>A69/49</u> and <u>EB138.R6</u>) to adopt the revised scale of assessments, based upon the new United Nations scale, for implementation with effect from the second year of the biennium 2016–2017.

Background

See WHO PB web portal.

PHM comment

Unfreeze the ACs!

Untie the VCs!

Lift the donor chokehold over WHO!

21.1 Report of external auditor

In focus

The report of the External Auditor is contained in <u>A69/50</u>. Also relevant is <u>EBPBAC24/3</u>, the report provided by secretariat to PBAC24 on external and internal audit recomm progress and implementation.

The Assembly will also receive (in A69/64) the advice of the PBAC on:

- A69/51 (the report of the Internal Auditor);
- A69/50 (the report of the External Auditor),
- <u>EBPBAC24/3</u> (the Secretariat report on progress on the implementation of external and internal audit recommendations),
- EBPBAC24/2 (the report of the Independent Expert Oversight Advisory Committee)

The PBAC recommends that the Assembly accepts the report of the External Auditor and notes the report of the Internal Auditor.

Background

Record of discussion of previous report from External Auditor at WHA68

21.2 Report of the internal auditor

In focus

The Assembly will review the report of the internal auditor (A69/51).

The Assembly will also hear (in A69/64) the advice of the PBAC on:

- A69/51 (the report of the Internal Auditor);
- A69/50 (the report of the External Auditor),
- <u>EBPBAC24/3</u> (the Secretariat report on progress on the implementation of external and internal audit recommendations),
- <u>EBPBAC24/2</u> (the report of the Independent Expert Oversight Advisory Committee)

The PBAC recommends that the Assembly accepts the report of the External Auditor and notes the report of the Internal Auditor.

Background

The official record of the discussion of this item at WHA68 (2015) is here.

WHO deploys the 'three lines of defence' model in assuring compliance with guidelines, rules and regulations. The first line is operational management, the second includes functions providing advice on control issues (the role of the Office of Compliance, Risk Management and Ethics), and the third is internal audit (the role of the Office of Internal Oversight Services).

PHM Comment

The Office of Internal Oversight Services (internal auditor) reports a large number of breaches, not all of which reflect fundamental weaknesses in the Organisation.

However, some are more noteworthy.

Paras 17 & 18 report on a performance audit carried out by the Office on WHO's support to operational services to contain the 2014 Ebola outbreak. The findings add to the available information regarding WHO's response to Ebola.

Audit 12/884 was a review of declarations of interest. 15 recommendations remain 'in progress' but the Office has not heard from the auditee for almost four years. In view of the current debate over FENSA it would be of interest to know what the 'in progress' recommendations are and why the auditee (Director/CRE) has failed to report progress more recently.

Audit 12/906 was a review of the Department of Governing Bodies and External Relations. The Office has not heard from the Dept of Governing Bodies over the outstanding recommendations for almost three years. Perhaps there was some debate over the level of importance of these recommendations. Since this refers to the work of the governing bodies it would be interesting to know what were the outstanding recommendations.

Annex 4A graphs trends in the operational effectiveness of internal controls in country offices. The high rate of ineffective controls in relation to direct financial cooperation (funds transfers to countries) is worrying although it is improving.

The report of the Independent Expert Oversight Advisory Committe to the PBAC23 (EBPBAC23/3) in January 2016 includes comment on the African Region Accountability and Internal Control Strengthening Project. It appears that good progress is being made. It is intriguing that one of the measures being taken as part of this project is the translation of critical guidelines, SOPs, policy notes and manual provisions into French.

22.1 HR Annual Report

In focus

<u>A69/52</u> provides an update on the implementation of the Organization-wide human resources strategy, in particular:

- the global mobility scheme (involving professional staff and a distinction between rotational and non-rotational positions);
- gender balance;
- geographic balance;
- staff costs:
- amendments to staff rules (see).

A69/52 should be read in conjunction with Workforce Data at 31 Dec 2015.

Note that the PBAC24 will consider this item and will provide their advice to the Assembly in a document yet to be named and posted.

<u>EB138/51 Add.1</u> considered by the EB in January reported on a review and proposed reform of the system for the nomination, selection and training of WHO country representatives.

Note that PBAC23 considered a Secretariat report (<u>EBPBAC23/2</u>) on WHO's internship programme. The PBAC conclusions were reported to the EB138 in the PBAC report (<u>EB138/3</u>).

See also the WHO staff associations' advice to the EB139 in EB139/INF./1.

A69/52 was reviewed by the PBAC24 before the Assembly (see A69/65) and it recommended that the Assembly note the report contained in A69/52.

Background

The <u>revised HR Strategy</u> was noted by the EB134 in Jan 2014. Revision was necessary in order to align HR policies with the requirements of the WHO Reform.

Notable features of the new strategy, as reported in <u>EB136/45</u>, included the abolition of continuing appointments, greater encouragement for staff mobility and the move to more uniform HR policies and practices across the Organisation.

Record of discussion of HR item at WHA68 in 5th meeting, and 6th meeting.

PHM comment

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

Para 8 of A69/52 states that 33% of MS are under represented in the international professional staff category. See also Table 3 of WHA69 HR 2015 which lists the MS identified as under and over represented as of Dec 2015.

Delegates should recall that the formula for determining that a country has the right number of professional staff (Resolution A56.35) gives great weight to the financial contribution of the country. Thus as of Dec 2015 the USA had more of its citizens in professional and higher categories than any other country but were still recorded as being under represented.

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 15 and 16 and for JPOs see Table 17 in WHA69_HR_2015.

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

The Secretariat report to PBAC23 (<u>PBAC23/2</u>) acknowledged the problem with respect to interns but simply referring candidates to lists of scholarships is inadequate.

22.2 Report of International Civil Service Commission

In focus

A69/53 contains details of the deliberations and recommendations of the International Civil Service Commission for the year 2015, including those relating to the comprehensive review of the common system compensation package. The report provides a link to the <u>forty-first annual report</u> of the International Civil Service Commission.

22.3 Amendments to the Staff Regulations and Staff Rules

In focus

The Secretariat document, <u>A69/54</u> and accompanying resolutions <u>EB138.R10</u> (Amendments to the Staff Regulations and Staff Rules: remuneration of staff in ungraded posts and of the Director-General) and <u>EB138.R13</u>

seeks confirmation by the Board of amendments to the Staff Rules and Regulations made by the DG:

- amendments necessary because of salary decisions applying across the UN system;
- amendment dealing with financial responsibility, classification review, and recruitment;
- amendments necessary for the WHO internal justice policy reforms.

Background

See Annex 1.

23.1 Real estate: update on the Geneva buildings renovation strategy

In focus

<u>EB138/45</u> reports on preliminary studies of the selected design and provides the Board with more information upon which to base a recommendation to the Sixty-ninth World Health Assembly about proceeding with the construction of the annex building as an integral part of the comprehensive renovation strategy.

A draft resolution (here) is recommended.

Background

Renovation was discussed in May 2013. The report (A66/42) was noted by the Assembly in May 2013. Several delegates (including the Swiss delegate) spoke in favour of Option 1.

The project was reviewed at WHA67 (May 2014) in A67/52 and the Assembly adopted decision WHA67(12) authorising the DG to proceed with the planning.

In May 2015, WHA68 noted the Secretariat report (A68/49) on the Geneva buildings renovation strategy, which was submitted prior to the submission of a more comprehensive technical and financial report to the Executive Board at its 138th session.

23.2 Process for election of DG

In focus

In the document published for this item reference is made to previous reports (<u>EB134/43</u> and A67/51) and a previous resolution WHA66.18 (2013) regarding the election of DGs.

The purpose of EB138/46 is to raise further procedural and managerial issues including:

- the leave status of internal candidates,
- the candidates' forum,
- the electronic voting system,
- support for nominated candidates, and
- opportunity for nominated candidates to address the Health Assembly before the vote.

The elaboration of these issues in EB138/46 is clear.

Background

Necessary background is provided in EB134/43 and A67/51.

Richard Horton (Dec 16) form guide (per Twitter)

- WHO DG criteria: 1) Diplomate 2) Manager 3) Inspiring 4) Consider UN-in, but WHO-Outsider 5) < 50 years 6) Female 7) Africa
- At dinner tonight Peter Piot states for the record that he is not standing for WHO Director-General.
- Here are the candidates so far (as reported to me second hand).
- France: Philippe Douste Blazy.
- Iraq: Ala Alwan.
- Mali: Michel Sidibe.
- Nigeria: Babatunde Osotimehin or Muhammad Pate. The government will have to decide which to support, of course.
- Botswana: Tshidi Moeti, current RD of AFRO.

PHM comment

Not an easy job.