People's Health Movement

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Open Letter to the Distinguished Delegates of the 64th Session of the African Regional Committee of the World Health Organization

Distinguished delegates,

The People's Health Movement (PHM) of the African Region submits the following comments and suggestions on four of the items appearing on the agenda of the 64th Session of the Regional Committee of WHO for the African Region:

- Item 10: Ebola virus disease outbreak in West Africa: update and lessons learned (here)
- 11. African Public Health Emergency Fund: Accelerating the process of implementation (here)
- 16. Strategic budget space allocation (here)
- 17. Framework for engagement with non-State actors (here).

The following commentary was developed, through a consultative process involving PHM circles across the region. We hope that you may find time to read and consider these comments before the relevant discussions during the Committee discussions next week. We hope that you find our input useful.

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

This commentary was developed as part of the WHO Watch project which is sponsored by People's Health Movement, Medicus Mundi International, Third World Network and Medico International. More about WHO Watch here.

Yours sincerely

PHM Africa

Item 10. Ebola virus disease outbreak in West Africa: update and lessons learned

In focus at AFRO/RC64

The Committee will consider the Secretariat report on EBV epidemic (AFR/RC64/9). The version posted on the regional office website (as of 21 October) is dated August 1.

Background

See WHO EVD webpages and WHO's Ebola Portal.

See also PHM's Ebola Statement.

PHM Comment

PHM mourns with the families and communities who have been devastated by the current epidemic. We salute the commitment of the health workers at the front line and honour in particular the health workers who have died.

Slowly a comprehensive response is being put in place although under-funded, under-supplied and under-staffed.

Our focus in this comment is on the report prepared by the Secretariat for the Regional Committee (AFR/RC64/9) which is out-of-date, quite unreflexive and somewhat myopic.

It is outdated in that it deals with the response to the epidemic from March to July but does not cover the period from August to October. How useful is a 'situation analysis' which is three months out of date? The PSC, meeting in September, called for an updated document but as of 30 Oct no update had been published.

The report is unreflexive. All of the five issues (and 'lessons learned') deal with the local national responses; there is nothing here about the responses of WHO's country offices, the regional office or of the Headquarters team. In speaking about 'lessons learned' it is regrettable WHO's response is not subject to any critical scrutiny. Were there delays in WHO's response? Could WHO's response have been earlier and more urgent and more effective? Was there a failure to anticipate, prevent and prepare? It needs to be taken note of that while the WHO received its first report about Ebola cases in Guinea on March 22, it took more than three months to convene a meeting of regional health ministers or open a regional coordination centre.

Hard questions also need to be asked about how the financial crisis in the WHO, which we talk about later, impacted on the WHO's ability to mount a quick and effective response. WHO's current budget saw cuts in WHO's outbreak and crisis response of more than 50 percent from the previous budget -- from $469 million in 2012-13 to $228 million for 2014-15

The report is myopic in that it completely ignores the wider, longer term context of the epidemic which has framed the vulnerability of West Africa to EVD and has also framed the inadequate preparedness and response. While the EVD epidemic itself calls for immediate and sustained responses, it is extremely unfortunate that the report restricts itself to just the context of the current epidemic. This means that there is no application of mind being attempted to remedy a situation that has been brought about by an interplay of complex circumstances that relate to the gross inequity in global power relations, that sustains many of the gaps and deficiencies in the health care systems in countries of the region that the report points towards. It also means that the region will continue to be vulnerable to similar public health threats in the future.

We urge members of the Regional Committee to insist on full consideration of the following questions:

- Why are poor countries vulnerable to EVD and limited in their capacity to respond? Why are the three centrally affected countries poor?
- Why do people lack confidence in the public health system?
- Could WHO, globally, regionally and nationally have done more to highlight the risk of EVD in the years since 1976?
- What research has been done since 1976 into vaccine and treatment development and by whom?
- Why has EVD been ignored by both public and private pharmaceutical R&D?
- Who should have been warning and researching about the possible implications, in terms of contact with animal hosts, of mining, palm oil plantations, the displacement of people in West Africa by agribusiness?

Are there lessons to be learned from these questions? These are complex questions and PHM does not claim to know the ultimate answers but we insist that the questions must be asked.

Why are poor countries vulnerable to EVD and limited in their capacity to respond? Why are the three most affected countries poor?

Liberia, Guinea and Sierra Leone number 175, 179 and 183, respectively, on the United Nation's Human Development Index, out of 187 countries. Their poverty is a function of colonialism, structural adjustment and the continued exploitation of the region's natural resources.

Neoliberalism and the Washington Consensus have contributed to the emergence of the epidemic and undermining the countries' capabilities to manage it.

The social conditions for health and the health care of the people of West Africa are sharply constrained by the global economy, geopolitics and the increasing and unaccountable power of transnational corporations.

The WHO Commission on the Social Determinant of Health concluded that:

> *the poor health of the poor, the social gradient in health within countries, and the marked health inequities between countries are caused by the unequal distribution of power, income, goods, and services, globally and nationally.*

> *Deep inequities in the distribution of power and economic arrangements, globally, are of key relevance to health equity.*
>
> *Dramatic differences in the health and life chances of peoples around the world reflect imbalance in the power and prosperity of nations. The undoubted benefits of globalization remain profoundly unequally distributed.*

Has the Regional Committee for Africa fully worked through the implications of these conclusions in relation to health development in the region (and the EVD epidemic in particular)?

Some of the disabilities facing health systems in West Africa are referred to by the Regional Director in his biennial report:

> *A major constraint has been the global financial crisis that has resulted in diminished resources available to WHO and further translated into inability to deliver adequately in some important programme areas. The earmarking of Voluntary Contributions has limited the WHO Secretariat's flexibility in consistently allocating resources to the priorities agreed with Member States, leaving under-funded areas such as health systems strengthening and addressing the risk factors and key determinants of health. While the increase in the number and diversity of actors in health development has helped mobilize additional financial and technical resources, it has in some cases led to fragmentation, poor coordination and duplication of support to countries, thereby increasing transaction costs.*
>
> *Other constraints WHO faced in the Region included identification of more opportunities for resource mobilization including strengthening capacity and timely reporting to donors, as well as fluctuations in transaction costs and the challenges of working with partners who have different mandates and interests. In addition, the operationalization of, and effective contribution of Member States to, the APHEF, which is an innovative way to mobilize resources within the Region, need to be accelerated.*

The rich countries, led by the USA, who have sought to hobble WHO through the freeze on assessed contributions and earmarking of donor funds carry a significant responsibility for the unpreparedness of the Ebola epidemic countries.

The hobbling of WHO is matched by a development assistance regime (sponsored in particular by the OECD countries) which seeks to legitimise an unbalanced, unsustainable and exploitative economic globalisation through vertical, disease-focused aid programs which are small in comparison to the parallel outflows (tax evasion, brain drain, resource extraction) but which fragment health systems and burden national health ministries with heavy transaction costs.

The countries of the African region should take the lead in demanding an appropriate increase in assessed contributions so that WHO is no longer held hostage to the donors.

The commitment of the African region to addressing the underlying social and economic determinants of health points to the importance of bringing economic issues onto the Regional Committee's agenda.

Why do people lack confidence in the public health system?

The failure to contain the epidemic is also a failure of the public health system. But it also needs to be noted that, in large measure, it is this public system that has mounted some form of a response to the epidemic and its consequences. The report lists a number of gaps and deficiencies in the public health system. Yet, it does not discuss the reasons for the state of the public health system, especially the fact that there has been a sustained attempt by multilateral agencies, donor organisations, and donor countries to suggest that public systems are inefficient and governments need to rely increasingly on private sector participation in health care delivery. If people today do not have faith in the system and are suspicious of its objectives, it is not merely a function of ignorance and cultural beliefs. The neglect of public services is the primary reason why people have been less than supportive of its role in the present crisis.

It is imperative that Member States deliberate upon the causes of decline of public health systems in the region (which is a trend found in other regions as well) and also set in place some concrete mechanisms that are designed to strengthen, reorient and rebuild public systems. For too long the WHO (including in its present position on UHC) has chosen to be an 'honest broker' and has chosen to remain neutral in the discussion on whether the public or the private system needs to be the primary provider of healthcare services. We urge Member States to request the Regional Committee to develop a Plan of Action to revive and revitalise public provision of healthcare in the region.

Could WHO (globally, regionally and nationally) have done more to highlight the risk of EVD in the years since 1976?

Was the DG too slow in declaring an emergency under the IHRs? The failure of WHO to foresee, prevent and respond promptly to the epidemic is in part a reflection of the continued freeze on assessed contributions and the control of WHO's agenda by the big donors. See Legge (2012); see Clift (2014); see Briand et al (2014).

The inadequate response of the country and regional offices was allegedly the focus of a confidential memo generated within the Geneva Secretariat in June. The memo has not been released but it has been leaked to journalists; see Gale and Lauerman, (2014). The Secretariat paper (AFR/RC64/9) makes no reference to any weaknesses identified in WHO's operations.

Clearly, WHO should have done more to promote research on EVD over the last 30 years. Does this reflection organisation wide failure to anticipate threats to public health?

What research has been done since 1976 into vaccine and treatment development and by whom? Has EVD been ignored by both public and private pharmaceutical R&D?

The profit funded research and development model has failed to mobilise funds for the development of vaccines or treatments since EBV was first described. WHO's Commission on IP, Innovation and Public Health (and the subsequent Consultative Expert Working Group) argued for delinking pharmaceutical research and development from profits shored up by IP protection. Instead they have called for a binding treaty to mobilise the necessary funds up front so that such vaccines and treatments can be made available at the cost of production. The 10-90 gap -- i.e. the paradox that 10% of research funds are directed at conditions that affect 90% of the people and vice versa -- has been talked about for decades. Yet the WHO continues to drag its feet on the issue and has been singularly reluctant to boldly promote mechanisms for collaborative research and eschew the pernicious influence of high level IP protection on new drug and vaccine research for diseases of the poor.

The WHO at all levels, continues to be captive to the interests of rich donor countries and private foundations. This has prevented it from taking clear and decisive position on the negative impact of a research system that works within the framework of Intellectual Property Rights (IPRs). Even the recent WHA stopped short of mandating a process that would lead to a binding R&D treaty, designed to delink the cost of research from the price of medicines. We urge Member States to ask the WHO to animate its work on alternate models of drug development, which uses mechanisms that promote collaborative rather than competitive research and works on the principles of delinkage.

Who should have been warning and researching about the possible implications of mining, palm oil plantations, the displacement of people in West Africa by agribusiness?

A particular trajectory of 'Development' in the region, promoted by multilateral agencies and donors, is clearly changing the ecology of communicable disease in West Africa. Gross ecological changes have been brought about by the takeover of agricultural land by agribusiness. These changes could well be responsible for hitherto unknown pathogens, which had earlier been confined to the wild, to start infecting humans. There are good reasons to believe that prolonged dry spells in the region, brought about by massive deforestation, as well as the penetration of new roads into previously remote forest areas primarily for extractive operations, have led to easier inter-mixing between the animal population in the forests and to the desperation of humans who have been driven deeper into the forest areas for survival and sustenance.

See Wallace, Robert G, et al "Did Ebola Emerge in West Africa by a Policy-Driven Phase Change in Agroecology?" at http://www.envplan.com/openaccess/a4712com.pdf

The report entirely ignores the possible effects that environmental changes in the region have had in triggering the EVD epidemic. What kinds of health impact studies were done before large swathes of land were leased to logging, palm oil and mining? What is the role of the Regional Office and country offices in providing guidance in relation to such matters? Surely there lessons to be learned here that need to be incorporated in any comprehensive review of the causes of the EVD epidemic. We urge Member States to ask the WHO to commission a study that examines the link between environmental factors and the epidemic.

These questions must be asked

PHM does not claim to have all of the answers to these questions. However they should be seriously addressed and it appears that they are being neglected.

PHM statement on the political economy of the EVD epidemic

Item 11. African Public Health Emergency Fund: Accelerating the process of implementation

In focus at AFRO/RC64

The regional committee will consider the Secretariat report (AFR/RC64/7) on the implementation of the African Public Health Emergency Fund. The report identifies the low level of contributions, the delay in finalising negotiations with the African Development Bank as putative trustee and limited involvement of the private sector as three key challenges.

The PSC report notes that a resolution will be considered but it does not appear to have been published at this time.

Background

The African Public Health Emergency Fund (APHEF) was mandated in 2011 in line with Framework Document (AFR/RC61/4) and through Regional Committee Resolution AFR/RC61/R3.

The fund was established in recognition of the high occurrence of public health emergencies in the African Region and the lack of adequate resources to respond effectively to these emergencies.

PHM Comment

In view of the Ebola crisis in West Africa, the reluctance of (all but 8) member states to contribute to the African Public Health Emergency Fund is a deep disappointment, as is the apparent refusal of the African Development Bank to undertake the role of trustee. The reluctance of MS to honour their commitments is symptomatic of the erosion of trust in the functioning of the WHO and its ability to intervene effectively in crisis situations. It is also engendered by the trend at the global level, of the tendency to starve UN agencies of resources and thereby to effectively prevent them from discharging their functions. This is apparent in the freeze on assessed contributions to UN agencies, since the 1990s, which is instrumental in the financial crisis that the WHO now faces.

The survival of a solidarity based fund of this kind is dependent on both the proclivity of MS to extend solidarity in emergency situations and the perception of MS regarding the role played by the WHO in intervening in emergency situations. While urging MS to honour their commitments to the fund, the WHO should also review its role in intervening in emergency situations and the possible connection this could have with the reluctance of MS to fund the APHEF.

The Secretariat report (AFR/RC64/7) documents the reluctance of MS to contribute to the fund. However, it is not clear from the Secretariat report whether this represents a lack of commitment in ministries of health, or their failure to persuade their ministry of finance colleagues.

The Secretariat sees the solution in terms of engaging the private sector and wealthy individuals as donors. We urge MS to be wary about such a ‘charity’ solution. Emergency preparedness is the paradigm case of government responsibility. Pan-African solidarity (exemplified by the idea of the fund) cannot be replaced by the grace and goodness of rich individuals and corporations. Further, as has been the experience with WHO’s funding in general, funding from the private sector is seldom ‘untied’, and is generally tied to specific budget lines. Given that the APHEF can be used in situations that are politically sensitive, it is particularly dangerous to build a system that could allow the fund to be used by private donors to interfere in political matters, by picking and choosing budget lines that they would want to fund. Similarly problematic is the document’s suggestion that MS can consider funding specific budget lines, instead of making untied contributions. This approach is in total contradiction to the solidarity concept of the fund.

While the Secretariat is happy to countenance seeking charity from the private sector, in its discussion of advocacy for the APHEF (para 16) there is no suggestion of a collaboration with civil society to build a constituency to demand that ministries of finance properly fund emergency preparedness as a mark of African solidarity.

PHM calls on the regional committee to recognise the importance of building collaboration between WHO (and ministries of health) and civil society networks and community based social movements. We also urge MS to honour their commitments to the fund, while at the same time demanding that a special provision be made in the global budget of the WHO to significantly increase contribution to a health emergency fund for Africa.

Item 16. Strategic budget space allocation

In focus at AFRO/RC64

The Committee will consider two documents from Geneva Secretariat: first a general note on Strategic budget space allocation (AFR/RC64/11A) and second, a more specific note on 'Operational segments' (AFR/RC64/11B).

Background

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

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

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

A Working Group was established under the PBAC which submitted an interim report, A67/9, which was considered by the PBAC and the WHA and a further iteration was produced taking into account PBAC comments. This version is now distributed to RCs for their consideration (AFR/RC64/11A and AFR/RC64/11B). The WG has set out a roadmap for developing the new methodology for strategic budget space allocation:

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

It was decided at EB135 to maintain the membership of the WG until it had finished its work, notwithstanding the new membership of the EB and the PBAC (noted here).

The WG proposes six principles to guide strategic budget space allocation. It proposes to

consider budget space allocation in relation to four ‘segments’:

- technical cooperation at the country level
- provision of global and regional goods: mandatory/long term and emerging needs
- administration and management
- emergency response.

See PHM note of the WHA67 discussion of Strategic Resource Allocation, Item 11.5, here.

PHM Comment

The ever changing nomenclature, from core functions, to categories, to segments, does not inspire confidence in the process.

The fundamental problem is the donor dependence associated with the freeze on assessed contributions. With this comes competition between clusters, departments and regions for donor attention. The funding dialogue and the strategy of ttreating 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.

It certainly appears that the expenditure budgeting practices of WHO are somewhat chaotic. Disjunctions between the priorities set by the Assembly and budget allocations have been commented upon by many observers.

This is partly due to the insistence on earmarking by most of the big donors. However, the competition for donor funding has a much more pernicious influence on planning and budgeting. Visibility and achievement are critical in terms of catching the donors’ attention. But the commodification of WHO outputs, for the purposes of competing in the donor auction, is quite antithetical to the kind of collaboration required for generating a coherent program of work where synergies and maximised and functions are located in the most productive location.

PHM calls upon the Regional Committee to reject the charade and to commit to lifting the Assessed Contribution freeze and setting the WHO budget at a level commensurate with its responsibilities.

Item 17. Framework for engagement with non-State actors

In focus at AFRO/RC64

At the Executive Board in January 2014, the Secretariat issued a report on a draft framework of engagement with non-State actors (EB134/8). A further iteration (here) was circulated at the March 27-8 Consultation of member states. This not available but TWN issued a report on the meeting in April report.

Current debate is focused around A67/6 (which is provided to the RC as AFR/RC64/12B). Consensus was not achieved at the Assembly. MSs were asked to advise the Sect of their concerns in time for a new paper to be prepared for regional committee consideration and for the outcomes of that discussion to be reviewed at EB136. A summary of the issues raised in the WHA67 discussion has been prepared by the Secretariat and despatched for the consideration of the Regional Committees (presented to AFR RC64 in AFR/RC64/12A). The basic issue in question is whether the proposed protocols will provide adequate protection from improper influence associated with conflicts of interest (COI).

AFR/RC64/12A contains the summary of member state discussions and questions during and after the World Health Assembly, including Secretariat responses, and the revised draft framework proposed by the Secretariat.

In accordance with WHA Decision A67(14) (see A67/DIV/3), a report integrating RC feedback, and a new draft policy based on this, will be considered at EB136.

Background

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

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

For many years WHO has found it very difficult to formulate a policy regarding the relationships between the Secretariat and various NSAs, including individuals (experts etc) and organisations (including corporations, industry front organizations, public interest civil society organisations,

philanthropies, etc). This challenge has come to the fore again in the context of the current WHO Reform.

The Secretariat provided a detailed paper (EB133/16) to the EB in May 2013. Following an extended discussion of this paper the Director-General was asked to provide a further report to EB134 (which emerged as EB134/8) on the development of a framework of engagement with non-State actors.

Paragraph 28, under Next Steps, proposed four adjustments to current protocols to be implemented immediately: prior screening of NGO statements to be dropped; web pages for the posting of NGO statements to be created; NGOs to nominate a head of delegation; and for documentation submitted to the SC on NGOs to be made public. There was general support for these adjustments. See notes from EB134 debate here.

The discussion in the EB was followed up by a two day MS only consultation in March 27-28, 2014 which considered a new discussion paper from the Secretariat (here). See PHM's comment on this discussion paper (here). According to the TWN report of this meeting (here) the MSs were unable to agree upon key principles regarding NSA relations. Of particular concern were: the proposal on secondment (including secondment of staff from private sector entities into the Secretariat), a lack of effective safeguards to protect WHO from undue influence of private and philanthropic organisations, and the silence of the framework with regard to engagement with philanthropic and academic institutions. TWN reports that the United States and the United Kingdom complained that the draft policy sets a high degree of scrutiny for the private sector compared to other NSAs.

Draft Framework (A67/6)

The draft framework which emerged from this consultation (A67/6) was considered by the Assembly in May 2014. Detailed protocols are set out for managing the risks associated with COI arising in WHO's dealings with NGOs, private sector entities (PSEs), philanthropic foundations and academic institutions. This paper broke new ground by recognising that business associations and NGOs which are largely corporate funded might be better treated as private sector entities rather than lumped in with 'public interest' NGOs.

The draft framework set out in A67/6 contains **five principles** that any engagement of WHO with non-state actors should satisfy:

- demonstrate a clear benefit to public health,
- respect the intergovernmental nature of WHO,
- support and enhance the scientific and evidence-based approach that underpins WHO's work,
- be actively managed so as to reduce and mitigate any form of risk to WHO (including conflicts of interest),
- be conducted on the basis of transparency, openness, inclusiveness, accountability, integrity and mutual respect.

It defines **five types of actors** as non-state actors:

- nongovernmental organisations: not-profit entities, “free from concerns which are primarily of a private, commercial or profit-making nature” which include grassroots community organisations, civil society groups and networks, faith-based organizations, professional groups, disease-specific groups and patient groups.
- private sector entities: commercial enterprises, intended to make a profit, including business associations and partially or fully state-owned commerical enterprises acting like private sector entities.
- international business associations: do not intend to make a profit for themselves but represent members like private enterprises.
- philanthropic foundations: non-profit whose assets provided by donors, income spent on socially useful purposes, must be “clearly independent” from private sector entities in governance and decision-making.
- academic institutions: engaged in pursuit and dissemination of knowledge through research, education and training.

The document defines **five types** of interaction:

- **participation:** attendance of nonstate actors at WHO governing bodies, consultations, hearings, other meetings, and WHO role in meetings organised by non-state actors.
- **resources**: funds, in-kind contributions including donated medicines, pro-bono work.
- **evidence:** gathering informaiton and managing knowledge and research.
- **advocacy**: increase awareness, foster collaboration
- **technical collaboration**: product development, capacity-building, support to policymaking, operational collaboration in emergencies, contributing to implementation.

The draft framework emphasises a risk management approach and identifies the **main risks** the WHO considers: undue or improper influence (real or perceived) on WHO’s work, WHO regulation and credibility could be affected, non-state actors could use WHO collaboration to their own benefits including competitive advantage, creating an excessive burden on WHO, conflict of interest.

Debate over draft framework

Wide differences of opinion were expressed during the debate on this document (see PHM’s report here). Most of the richer countries were quite happy with the document. Many of the L&MICs who spoke expressed misgivings. Suriname (speaking for UNASUR) commented that procedural rules are not always adhered to in practice. IBFAN spoke about the dangers of WHO’s dependence on donor funding and expressed concern about the idea of private sector employees being seconded to work in the Secretariat.

PHM/MMI (here) was sceptical about the effectiveness of complex bureaucratic procedures when the pressures on the Secretariat are so great. PHM/MMI listed a number of recent incidents and suggested that the risks associated with COIs in each case were very clear and would have been evident to the officials involved. PHM/MMI argued it is a cultural rather than procedural issue, “In a situation where managers at every level are competing for visibility and donor attention, it is not surprising that the risks of improper influence are seen as low priority.”

At the end of a long debate (full report of debate here) the DG undertook to prepare another draft of the paper on the basis of MS concerns but asked that MSs with concerns or questions provide them in writing quickly so the Secretariat could get a next draft to the regional committees for further consideration.

The report AFR/RC64/12A provided to the AFR RC64 includes a summary of member state comments and Secretariat responses during and after the Assembly.

PHM Comment

PHM shares the concerns of many Member States expressed or implied in the issues, questions and clarifications referred to above and set out in more detail in AFR/RC64/12A. However, we particularly wish to draw Member States attention to the following issues.

Operational practicability

The proposed procedures are extraordinarily complex. Under the four specific policies included in A67/6 dealing with four specific types of NSA detailed policy provisions concerning each type of interaction for each type of interaction are provided. These are in toto extremely complicated.

Presumably officials at all levels will have to know these details and keep them uppermost in their minds in all their dealings with NSAs. The challenge of monitoring the compliance of WHO staff with the provisions of these policies is even more complex.

The complexity of these procedures has implications for their operational practicability and the transaction costs involved in their implementation.

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

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

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

The IMPACT saga (see TWN report here) involved certain MSs working with certain Secretariat officials and the IFPMA to set up a Taskforce to be hosted by WHO and funded in some degree by WHO without any reference to WHO GBs, certainly no mandate. It was only after two years of operations that the work of IMPACT was drawn to the attention of the GBs. The concern regarding improper influence centres upon the conflation of IP protection and the regulation of QSE through the use of the term 'counterfeiting'. The strategy of big pharma appears to have been to amplify concerns about substandard medical products and use the urgency so created to persuade countries to implement regulatory strategies which had the effect of harnessing the

medicines regulatory agencies in the policing of IP claims. In fact the problematic definition of 'counterfeit' has been traced back to a 1992 meeting between WHO officials and industry representatives. More here. It may be relevant that the establishment of IMPACT coincided in time with the election of a new DG.

Decisions of the GBs since 2008 have made it clear that the original decision to launch IMPACT was ill-considered. Having regard to the widely held concerns regarding the purpose of big pharma in this exercise it appears that there were conflicts of interest at play and that big pharma (and perhaps certain MSs) exerted improper influence.

It is not clear that the procedures outlined in the new policy package would have prevented this episode. What was needed and what was lacking was a high level of awareness of the risks within the Secretariat and a high level of discipline regarding risk control.

The case of Paul Herrling and the EWG (see TWN report here) involved the appointment (to the EWG) of a Novartis employee who was identified with a particular proposal to be considered by the EWG. Despite concerns being expressed by MSs and CSOs, Professor Herrling remained on the EWG but excused himself from the meeting which considered his proposal. Whether EWG deliberations were in fact subject to improper influence remains debatable but clearly there was reputational harm done to WHO.

Clearly Prof Herrling's affiliation with Novartis was known to the Secretariat as was his association with one of the project proposals under consideration. However, we do not know how much pressure was exerted by Switzerland on behalf of the Herrling nomination. Complex bureaucratic policies and procedures seem somewhat irrelevant here. The situation called for judgement and discipline.

Virus sharing (and PIP). See debate at WHA60 (WHA60-REC3/A60_REC3-en from page 12; see especially the Indonesian contribution). Indonesia complained that contrary to agreed protocol virus samples collected in and contributed by Indonesia were being provided to vaccine manufacturers without consultation with Indonesia and were being patented and there was no guarantee that Indonesia would have access to the vaccines. This was the beginning of what became the PIP virus sharing and benefit sharing saga which looks to be a positive outcome but it started badly. The episode may be understood as carelessness by the relevant WHO officials, some disregard for any rights which the source country might claim. It seems not unreasonable to conclude that the officials concerned were closer to the vaccine manufacturers than to the sensitivities of the countries. Whether this is improper influence or a failure of administration is open to argument.

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

Management of H1N1 (see A64/10). During the H1N1 pandemic there were some decisions taken which were controversial at the time (in particular the size of the vaccine order and

inconsistent/changing definitions of ‘pandemic’). The Fineberg inquiry did not accept that the size of the vaccine order reflected improper influence (nor the changing definitions of ‘pandemic’). However, there was reputational damage and the Professor Fineberg made some useful recommendations which might have avoided such damage. These are largely about awareness, sensitivity and judgement.

Psoriasis (see WHO Watch report here). At the EB133 in May 2013 the EB was presented with a proposal that it endorse World Psoriasis Day which is sponsored by and extensively supported by pharmaceutical manufacturers who have much to gain from promoting psoriasis as a treatable disease. The EB members were not alerted to the commercial benefits to the pharmaceutical manufacturers of WHO support for World Psoriasis Day nor were they alerted to the substantial support provided to the patients’ organisations involved. If there was improper influence in getting this item onto the agenda it appears to have involved Member States rather than (or perhaps as well as) Secretariat officials. However, the fact that the EB was not alerted to the commercial dimensions of this resolution appears to be a failure of risk assessment and risk management. The issue of WHO’s engagement with NSAs was actually on the agenda of the same meeting.

It is hard to see the complex bureaucratic protocols envisaged in A67/6 protecting WHO from the risks arising from any of these episodes.

In all of these cases the risks to WHO were self-evident. What was missing was the culture of integrity and the assurance of organisational support for officials who might resist the pressures to place the Organisation at risk.

The accountability of Member States for protecting WHO’s integrity

The proposed protocols say nothing about the accountability of the Member States for protecting WHO’s integrity. However, in several of the above cases particular Member States were involved in putting in train initiatives which created risks for the integrity and decision making of the Organisation.

In a situation where departments and units depend on voluntary donations for their survival and regions and clusters depend on voluntary donations for their effectiveness there are powerful incentives on WHO staff to overlook the risks to the Organisation as a whole arising from particular initiatives, if those initiatives promise much needed resources for those groups.

The elephant in the room is the power of the donors over WHO’s agenda and this stems from the continuing freeze on assessed contributions.

We urge the Regional Committee to explore ways of strengthening the accountability of individual Member States in terms of defending the integrity of WHO.

We urge the Regional Committee to adopt a strong position regarding the need to increase assessed contributions and untie earmarked voluntary donations.

‘Patient groups’ funded by pharmaceutical companies

It is unclear how the Secretariat plans to handle ‘patient groups’ funded by pharmaceutical companies. The draft framework appears to deal with this by stating that NGOs can be considered as private sector entities if the “level and funding are such that the non-state actor can no longer be considered as independent of funding private sector entities”.

Member states asked for explicit process and criteria - the revised framework, however, does not make it clear how WHO will determine an NGO “independent” or unduly influenced by private sector funding sources, nor criteria it will apply, or whether this process of assessment will be transparent.

Entities with which WHO will not deal

Paragraph 13 (p43) should also include: manufacturers of unhealthy foods and beverages, which are increasingly being linked to obesity and NCDs; violators of the International Code of Marketing of Breastmilk Substitutes; agro-chemical industries whose products have been implicated in diseases like cancers, and industries involved in labour law violations and environmental damage.