16B. Framework of engagement with non-State actors

Contents

In focus at WPR RC65

At the Executive Board in January 2014, the Secretariat issued a report on a draft framework of engagement with non-State actors (NSAs) (EB134/8). A further iteration (here) was circulated at the March 27-8 Consultation of member states. TWN issued a report on the meeting in April report.

At the World Health Assembly in May 2014, member states considered the draft framework for engagement with non-State actors A67/6. Member states raised concerns over the draft framework of engagement, in particular over the need to strengthen conflict of interest with respect to the private sector. MS agreed to further discussions and to submit questions to the Secretariat (by July), in which the DG would issue a report on the questions with responses from the Secretariat and a revised framework for discussion at the regional committees.

In accordance with decision WHA67(14) 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. See Annex 5 (from page 41) of WPR/RC65/11 which 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 WHA67(14) a report integrating RC feedback and a new draft policy based on this will be considered at EB136.

Background

WHA67 considered the Secretariat's report on the draft framework for engagement with NSAs (A67/6). The Assembly adopted decision WHA67(14). Annex 5 (from page 41) of WPR/RC65/11 includes a summary of Member State comments and Secretariat responses during and after the Assembly.

Draft framework (A67/6)

The draft framework 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.

The draft framework identifies **four boundaries**:

- decision making in the governing bodies the exclusive prerogative of MSs;
- protect WHO's role in setting norms and standards;
- WHO does not engage with industries making products which are harmful to health;
- protect WHO's integrity, independence, credibility and reputation.

The draft framework 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 commercial 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 draft framework defines **five types** of interaction:

- participation: attendance of non-state 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 information and managing knowledge and research;
- advocacy: increase awareness, foster collaboration;
- technical collaboration: product development, capacity-building, support to policy making, operational collaboration in emergencies, contributing to implementation.

The draft framework emphasises a risk management approach and identifies the **main risks** to the WHO as:

- undue or improper influence (real or perceived) on WHO's work,
- negative impact on WHO reputation and credibility,

- non-state actors could use WHO collaboration to their own benefits including competitive advantage.

The framework provides further details regarding due diligence, risk assessment and risk management, transparency, regulation and management of engagement, including details regarding the terms of reference of the Committee on NSAs of the EB and details of the policy on Official Relations.

It then elaborates four separate policies for each of four **types of NSA**; each policy is structured around the five **types of interaction** and sets out detailed policies and operational procedures regarding each NSA/type of interaction combination.

Debate at WHA67

A range of issues were raised by Member States during the discussion at WHA67 in May 2014. See PHM report on WHA67 debate.

The key issues raised by member states (as reported in WPR/RC65/11, from p41):

- defining conflict of interest
- risk management provisions
- due diligence processes and transparency of such processes
- defining and managing the risks to WHO integrity associated with earmarked donations
- defining and managing the risks associated with secondments to the Secretariat
- protocols in dealing with non-profit entities which are not 'at arm's length' from private sector entities
- expanding the range of entities 'with which WHO should not engage'
- provisions of existing 'official relations' policy
- involvement of Member States in management of engagement with NSAs
- definitions of non-state actors and boundaries to its application
- competitive neutrality
- management of donated medicines

Member States asked a number of questions seeking further information (see para 22-24).

Member States asked for clarification of a number of issues (paras 26-34):

- what is new in the draft framework
- what information will be recorded in the register
- possible role of an accreditation procedure for NSAs
- consequences for non-compliance by NSAs
- contractual relations between WHO and NSAs
- distinctions between 'scientific initiator' and logistics manager in relation to conferences WHO is co-sponsoring
- meaning of product development collaboration

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 WPR/RC65/11 Annex 5. 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; agri-chemical industries whose products have been implicated in diseases like cancers, and industries involved in labour law violations and environmental damage.

Notes on discussion at WPR RC65