

## **Implementation of the Framework of engagement with non-State actors (FENSA)**

**Respondents: Regional offices, Country offices and Headquarter clusters assessing its implications**

### **Introduction:**

1. The 138<sup>th</sup> Executive requested the Secretariat to provide a balanced and objective report of the implications of the implementation of the Framework of engagement with non-State actors (FENSA) well in advance of the resumed session of the Open-ended intergovernmental meeting of 25-27 April.
2. To this end, all WHO Regional Offices and Clusters in Headquarters and a selection of Country Offices are invited to provide their inputs through this questionnaire. In addition a more detailed matrix of analysis will be sent for comments to FENSA focal points in regions and clusters.
3. In order to assure that we can present a balanced and objective report to Member States, the External Auditor has kindly agreed to validate and comment this questionnaire, the more detailed analysis matrix and write the final report.
4. The adoption and implementation of FENSA will modify the way WHO manages its engagement with non-State actors (NGO's, private sector entities, philanthropic foundations and academic institutions). The main changes concern the following points
  - a. FENSA is covering all engagements within with all non-State actors, while the current policies covered engagement with private sector entities and NGOs in official relations only
  - b. Transparency will be increased through the Register of non-State actors (including information on objectives, governance and funding of non-State actors and description of engagements)
  - c. FENSA calls for a consistent implementation at all 3 levels of the Organization and all regions and hosted partnerships through an electronic workflow, due diligence by central unit for, a guide for staff, clear decision making
  - d. FENSA will increase accountability towards Members States by strengthened oversight of the Executive Board
  - e. The Director General will report annually on engagement with non-State actors
5. Some of the proposals made during the negotiation process have not been included in the text and are no longer under consideration. They should therefore also be excluded from the analysis of implications of FENSA implementation. Such issues include in particular:
  - a. FENSA applies only to engagement with non-State actors as institutions and not to engagements with individual experts.
  - b. There will not be a defined ceiling for contributions received from non-State actors
  - c. Due diligence and risk assessment is a process conducted by the Secretariat with no direct involvement of Member States

- d. Free services provided by non-State actors are an in-kind contribution, but not covered by the not yet agreed provisions on secondments.
6. Several current policies are confirmed by the draft Framework and often made more explicit:
- a. WHO does not engage with the tobacco and arms industries
  - b. Official relations (while currently all entities are called NGO's, non-State actors in official relations will in the future be distinguished in NGOs, International Business Associations and Philanthropic foundations)
  - c. Several specific paragraphs on private sector engagement (such as clinical trials) are transposed from the current guidelines into the private sector policy.
  - d. The CPSC (Committee on Private Sector Cooperation) will be replaced by an engagement coordination group ECG
7. For information here are the elements which would likely be covered in the report on implications of implementation of FENSA:
- a. Changes to the work of WHO governing bodies
  - b. Costs of implementation
    - i. Direct financial costs of implementation
    - ii. Direct human resource costs
    - iii. Indirect human resource costs
    - iv. Startup costs
      - GEM build up to provide the IT tool for the Register of non-State actors
      - Training costs
      - Additional burden of filling the register with first time entries
  - c. Potential efficiency savings through implementation of FENSA
    - i. Information gathering
    - ii. Clarity on actors, process and earlier decisions
  - d. Added value of FENSA
    - i. Stronger protection from undue influences
    - ii. Coherence in engagement across WHO and across different engagements
    - iii. Clarity on engagement
    - iv. Transparency

- v. Better information, documentation, intelligence and lessons learnt on non-State actors and engagements
- vi. Clear process of senior management decision making
- e. Risks of FENSA
  - i. Potentially cumbersome process
  - ii. High number of engagement
  - iii. Lack of flexibility
  - iv. Potential bottle-neck in due diligence and risk assessment process
- f. Changes to the engagement opportunities and risks
  - i. Policy changes in engagement
  - ii. Incentive changes for engagement

## QUESTIONS:

8. Please provide a rough estimate of the numbers of engagements per year (e.g. in 2015) and by type of engagement in the following table. (please note that this refers to formalized engagement as defined in the paragraphs 15-21 of the draft FENSA and not to informal interactions, for engagements covering more than one type count them only once for the most relevant type)

At Cluster level (excluding country office engagements)

### Number of engagements per year – HIS cluster, WHO/HQ

		Participation	Resources	Evidence	Advocacy	Technical collaboration
<b>NGOs</b>	<b>EMP</b>	750	250	250	150	500
	<b>HGF</b>	300	40	100	50	83
	<b>HSR</b>	15	71	71	71	71
	<b>HWF&amp;HWA</b>	66		3	12	42
	<b>IER</b>	50	30	90	50	60
	<b>SDS</b>	65	15	40	30	40
	<b>WKC</b>	100	10	5	0	15
<b>Private sector entities</b>	<b>EMP</b>	1200	150	350	100	800
	<b>HGF</b>	155	20	46	30	62
	<b>HSR</b>	10	43	43	43	43
	<b>HWF&amp;HWA</b>	11	0	0	90	0
	<b>IER</b>	50	40	30	90	40
	<b>SDS</b>	35	0	0	0	180
	<b>WKC</b>	20	0	0	0	0

		Participation	Resources	Evidence	Advocacy	Technical collaboration
Philanthropic foundations	EMP	50	200	0	30	20
	HGF	30	0	10	10	15
	HSR	3	0	3	3	3
	HWF&HWA	0	0	0	0	10
	IER	50	40	50	40	70
	SDS	20	15	18	0	0
	WKC	0	0	0	0	0
Academic institutions	EMP	240	0	600	120	240
	HGF	103	0	50	50	0
	HSR	48	170	170	170	170
	HWF&HWA	60	0	0	4	300
	IER	50	30	50	50	70
	SDS	45	0	35	0	155
	WKC	40	0	40	40	30
TOTALS		3566	1124	2054	1233	3019
TOTAL		10996				

**Number of non-State actors we engaged with in 2015 – HIS cluster, WHO/HQ**

		Participation	Resources	Evidence	Advocacy	Technical collaboration
NGOs	EMP	70	30	10	10	40
	HGF	60	5	5	20	30
	HSR	7	14	16	16	9
	HWF&HWA	11	0	3	130	7
	IER	40	50	20	60	20
	SDS	25	5	10	10	15
	WKC	30	0	20	0	10
Private sector entities	EMP	100	30	5	15	80
	HGF	60	0	20	40	35
	HSR	8	9	9	9	9
	HWF&HWA	7	0	0	54	70
	IER	10	10	5	5	5
	SDS	10	0	0	0	30
	WKC	40	0	0	0	0
Philanthropic foundations	EMP	7	8	0	5	2
	HGF	3	0	2	0	2
	HSR	2	0	2	2	2
	HWF&HWA	0	0	0	13	0
	IER	5	5	5	0	10
	SDS	5	2	3	0	0
	WKC	2	3	2	0	0

		Participation	Resources	Evidence	Advocacy	Technical collaboration
Academic institutions	EMP	30	0	20	10	10
	HGF	15	0	5	9	0
	HSR	32	44	44	44	44
	HWF&HWA	6	0	0	100	43
	IER	62	55	90	5	95
	SDS	15	0	7	0	40
	WKC	100	0	30	0	20
TOTALS		762	270	333	557	628
TOTAL		2550				

Comments on the methodology used and its difficulties of this estimation,

Figures reported in the table above are realistic estimates, although they cannot be considered as accurate numbers due to the large number of interactions that the Cluster of Health Systems and Innovation has every day with NSAs, and to lack of precise definition on what constitutes an “interaction”. The high numbers of interactions in EMP<sup>[1]</sup> are largely due to the work on Prequalification of medical products.

9. Please describe the main opportunities you see for the work of your region / cluster through the adoption and implementation of FENSA

For the HIS cluster, we see the opportunity to link in a transparent way with key collaborators sharing common goals to strengthen health systems and pursue the goal of UHC.

10. Please describe the main risks you see for the work of your region / cluster through the adoption and implementation of FENSA. This question does not refer to the risks of individual engagements as defined in FENSA but rather to the overall risks and challenges of implementing FENSA as a new policy.

We take it that agreement has been reached that schemes such as the one proposed for financing Prequalification partially through a fee/cost recovery approach would not be impacted by the new framework related to NSA.

A significant risk is that some NSA with whom HIS has very productive relationships in the area of health systems and innovation might terminate their relations with WHO because of the burden of reporting. In addition, we see a serious risk for our staff who will only be able to comply with the requested reporting processes at the expense of technical work.

<sup>[1]</sup> the important number of interactions with private sector entities is explained by the volume of activities through the Prequalification Programme and the interaction with the industry in the domain of inspection, evaluation of dossier, assessment of products applications.

A significant risk is the potential delay of our technical work, including our advisory functions as the current administrative process with 11 individual clearing steps will certainly cause delays in the approval.

11. Please describe the specific resources (staff and activity costs) currently working on engagement with non-State actors within your region / cluster.

We currently have the following due diligence processes in place: For every expert committee, proposed candidates need to fill in DOIs. For the process of assigning WHO /CC's, an in-depth analysis of COI is undertaken. We also fully follow CRE processes for individual experts. For the Cluster, we estimate the work load to be the equivalent of 1.75 FTE.

12. Please describe the specific incremental resources (staff and activity costs) that you would expect to be necessary to implement FENSA :

1) One off resources/costs:

This highly depends on the administrative process that is going to be applied. Resources are difficult to measure as standard times to come to an agreement to engage with an NSA have not yet been set. However, from our experience, and if the current flow chart containing 11 clearing steps is maintained, the following average time requirements are as follows:

Enter a basic profile in a centralised data base: 45 minutes for a G-staff

Enter engagement proposal: 30 minutes to 1 hour for a P-Staff

Submit profile for NSA to complete (including a telephone call explaining the process) 30 minutes for a P-Staff

Check if profile and engagement proposal complete: 10-30 minutes of a G-Staff, depending on the nature of the engagement

Review NSA profile and engagement proposal: 30-60 minutes for a P-Staff ,depending on the nature of the engagement

If clarification is needed: 60 minutes for the cluster focal point, 60 minutes for the technical unit, 15 minutes for G-staff to organise

Review NSA profile and engagement proposal and copy focal points, including active verification of the information being provided by the NSA: 2 hours (in 10% of all cases)

Approve engagement and write to the NSA: 30 minutes for a G-staff.

Thus, we estimate:

Depending on the nature of involvement for each NSA:

1.5 hours for a G-staff, 4 hours for a P Staff on average for 1 NSA

For G-Staff: 3460 hours for 2306 NSAs = 2 FTE G-Staff and

5.5 FTE P-Staff

2) Recurring or On-going resources/costs:

We have been informed that each NSA will then be reviewed every year. The administrative process has not been defined. If the same process applies, the above time and costs would apply. In addition, the numbers of engagements per year need to be following the NSA process as well. If the administrative process will be the same as above (which we have been advised), the following applies:

10.265 engagements per year times 1.5 hours for a G-Staff = 15.397 hours equals approximately **9 FTE for G-Staff and 24.5 FTE for P-Staff**. (The estimates are done on the usual basis of an 8 hour day/221 days/year)

**Draft matrix of analysis of implications of implementation of FENSA**

Issue	Current policy and practice	FENSA policy and practice	Change	Importance / volumes	Opportunities	Risks	Comments
Applicable policies	Constitution, NGO principles, private sector guidelines	Constitution, FENSA	One framework covering all engagements with non-State actors	n/a	Create clarity of policy	Possible “over-regulation” Only little benefit for a significantly increased level of work	Up to now, we had not encountered difficulties in differentiating between NGOs and the private sector, so added value is questionable.
Scope of application	Private sector guidelines do not provide tools to assess levels of implementation	FENSA is explicitly applicable to all 3 levels of the organization				Possible “over-regulation”	The risk of over-regulation is high. FENSA looks at individual engagements on a case by case basis. The high number of administrative processes in the electronic workflow might lead to the risk that a lot of time is spent to deal with non-problematic engagement, diluting attention to more ambiguous situations.
Overall engagement principles	No explicit guiding principles other than the constitutional principles	Explicit definition of principles, benefits and risks of engagement	Explicit codification of current practice	n/a	Increases clarity for staff and non-State actors	None, since it reflects established practice. Risk of decreasing appetite for engagements which could be very beneficial for WHO mission	The change would be more than simple “Explicit codification of current practice”
Definitions and distinction of actors	NGO’s defined in a broad sense in the NGO principles (1987), private sector; Commercial enterprises and not-at arm’s length entities defined in the Private sector guidelines (2001)	Definition of 4 groups of non-State actors	Clear and public attribution of each non-State actors to one of the 4 groups. International business associations are no longer attributed to NGOs but as a subgroup of private sector entities	n/a	Clarity for all staff and other stakeholders on which entity is subject to which policy	Some non-State actors might disagree with their attribution by WHO to one of the groups	Many Universities are private or funding from private sources. Does this make them private sector?
Participation in governing bodies	Open to NGOs in official relations, modalities regulates by NGO principles and rules of procedures	Open to non-State actors in official relations, modalities regulates by FENSA and rules of procedures	No major change (Mostly the same entities can qualify but will be called differently). Currently only some operative foundations are in official relations, philanthropic foundations would clearly qualify under FENSA. Private sector entities not considered as international business associations would no longer qualify.	Currently 206 NGOs are in official relations, no important changes are expected	Member States will know better which non-State actor in governing bodies has which background	Some entities will disagree if the EB excludes them from official relations	An additional accreditation system would imply more changes and possibly an increase of numbers



Participation in other meetings	Based on practice and mostly decided by the technical units. Co-sponsoring regulated in the e-manual and reviewed by LEG in consultation with PNA	Clear distinction of consultations, hearings and other meetings	FENSA makes participation in meetings subject to due diligence and risk assessment	(xx high numbers)	More clarity affiliations and background of entities participating in meetings	High volumes could create delays, centralization and bottlenecks	High volumes of engagements will necessarily create delays. The preparation of WHO meetings involving NSAs and the participation of WHO staff in NSA meetings would become very complex. The risk is high that WHO meetings with big numbers of NSAs will no longer be carried out. For instance, a World Conference on a seminal public health topic to which WHO in the past has invited approximately 700 NSAs, would simply be impossible to organise under the planned FENSA process. This might decrease our convening function and our role laid out in WHO's constitution to engage with all relevant stakeholders and actors. Also, with due diligence procedures that need to be followed if NSAs invite WHO staff to their meetings, they might no longer invite WHO. Given that global health governance becomes increasingly complex, this might have serious impacts on our role of being <u>the</u> coordinating agency of global health.
Receiving resources	Financing rules and regulations; private sector guidelines	Financing rules and regulations; FENSA	For private sector no policy changes, for other non-State actors more clarity on policy with no major changes, transparency already exists through the PB web-portal	(xx add from financial report)		Decreased capacity of the secretariat to conduct technical work mandated by MS	Cost recovery/fees schemes with as financing of PQ should NOT be impacted by FENSA
Providing resources	Financing rules and regulations, procurement policy	Financing rules and regulations, procurement policy, FENSA for implementing partners	Procurement remains unchanged and not covered by FENSA; collaboration with NGOs and academic institutions as implementing partners will follow FENSA procedures	(do we have any data on numbers of implementing partners?)			
Evidence	Regulations for Study and Scientific Groups, Collaborating Institutions and other Mechanisms of Collaboration	Regulations for Study and Scientific Groups, Collaborating Institutions and other Mechanisms of Collaboration + FENSA	For provision of evidence there is more clarity on policy with no major change				Although individual experts do not fall under FENSA, there is a risk that we will be restricted in the diversity of experts that can be consulted.
Advocacy	No specific policies	FENSA	More clarity of policy, no major change in				

			content				
Technical collaboration	private sector guidelines	+ FENSA	More clarity of policy, no major change in content	Xx			
Management of institutional conflicts of interest	Private sector guidelines	FENSA					
Management of individual conflicts of interest			No change due to FENSA, system has been strengthened separately		Use of synergies between institutional and individual COI management through common IT tool	Risk of confusion between institutional and individual COI	Management of individual conflicts of interest is not regulated by FENSA
Due diligence and risk assessment procedures	Private sector guidelines	FENSA	Will become more systematic and more efficient through IT tool GEM. More engagements will be subject to due diligence	Currently 620/ year, in future much more	More systematic due diligence; clear SOPs and electronic workflow, synergies of merger with other clearance processes (RM, LEG, management)	High volumes, bottleneck with delays	See above Very cumbersome process, which will need regular “refresh”
Risk management	Delegation of authority, advised by due diligence. Private sector guidelines with Committee on Private Sector Collaboration (CPSC)	Delegation of authority, advised by due diligence and FENSA with Engagement Coordination Group ECG	Due diligence advice cannot be ignored, but escalated for senior management decision making	The CPSC was hardly used in recent years, the ECG should initially decide on key questions of interpretation, but afterwards be used for a low number of cases	Better coherence of decision making and clear documentation of jurisprudence	Centralization of decision making for “jurisprudence cases”	
Transparency	No overarching transparency rules	FENSA provided a high degree of transparency	Register of non-State actors will provide transparency and accountability non-State actors engages with and what engagements have happened		Transparency improves accountability. WHO can less be criticized for having hidden an engagement .	Transparency can expose inconsistencies publicly, lead to attacks on individual decisions and might expose non-State actors in some situations	We totally agree with the risk mentioned here.
Register of non-State actors	Only a pilot exists since 2015	FENSA		Currently 200 entities in the pilot, several thousand entities are expected to be registered	The register could become a central database of all main global health actors and thereby strengthen WHO’s coordinating role in global health. Internally the register should provide better intelligence on actors and thereby create synergies and efficiency gains in engagements	Non-state actors might challenge the fact that their information is published and some might chose not to engage fearing this transparency.	We have ample experience: many NSAs increasingly decline our invitations to serve on WHO’s expert committees due to their perceived risk of being exposed publicly.  Maintaining/updating the database will be a significant administrative burden.
Non-engagements	Private sector guidelines	FENSA	No change to policy of non-engagement with tobacco and arms industry. Transparency will force WHO into more consistency in the interpretation of these				

			rules				
Particular caution	Private sector guidelines	FENSA	No policy change				
Association with WHO's name and emblem	Private sector guidelines	FENSA	No policy change		Synergies by using GEM for the procedure of clearance on co-sponsorship and the use of name and emblem.		
Secondments	Staff rules and regulations + Established practice of a small number of secondments and none from private sector entities.	Staff rules and regulations + FENSA	Depending on outcome of FENSA negotiations				
Official relations	NGO principles	FENSA	No major changes (details see participation), but clearer designation of the nature of entities in official relations. Review of proposals by PBAC instead of NGO Standing Committee.		MS will be better documented on engagements through the register and can thereby take better informed decisions.		
Oversight of engagement	No overall oversight other than generic organizational rules	FENSA defines governing body oversight	DG will report annually to EB on engagement through the PBAC; MS can see all engagement through register		Stronger oversight can strengthen trust in the Secretariat	Micromanagement	Micromanagement is the result of mistrust and will generate more mistrust
Non-compliance	Ad hoc procedures	FENSA defines non-compliance	Clearer basis for the Secretariat to react to non-compliance by non-State actors				
Applicability to emergencies	Private sector guidelines	FENSA	To be defined how much flexibility the Director General will have to avoid delaying emergency responses.		None	Increase in the risk of failure	Any kind of administrative bottleneck is unacceptable for emergencies