International Agency for Research on Cancer

World Health Organization

Governing Council **GC/60/17**
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RECOMMENDATIONS FROM THE GOVERNING COUNCIL WORKING GROUP ON THE IMPLEMENTATION OF THE FRAMEWORK OF ENGAGEMENT WITH NON-STATE ACTORS (FENSA)

1. The IARC Governing Council (GC) adopted Resolution GC/59/R5, at its Fifty-ninth session in May 2017, deciding "to establish a Working Group, to explore ways for IARC to implement the Framework of Engagement with Non-State Actors (FENSA) in the context of IARC's work and research programme, including acceptance of funds from private sector sources" and requested the Working Group "to report back to the Governing Council on its recommendations at the 60th session of the Governing Council in May 2018".

2. The Working Group was composed of GC Representatives from France, India, Italy, Morocco and The Netherlands and four members of the Secretariat (the Director, the Director of Administration and Finance and two senior scientists). WHO participated as an observer in the Working Group meetings.

3. The Working Group held discussions three times since the last GC to explore, inter alia, ways to adapt the FENSA resolution and the WHO's guide for staff on engagement with non-State Actors (NSAs) to IARC's day to day operations. WHO has been consulted throughout the process.

4. During the period of the Working Group's activities the discussion within WHO on how to implement FENSA has evolved, removing existing barriers and alleviating a number of areas of concern for the IARC Secretariat. Most notably, the role of technical units in conducting an initial risk assessment has been expanded, and the procedural requirements for a low-risk simplified procedure have been eased.

5. The Working Group discussions resulted in the document "IARC-specific guide on engagement with non-State Actors", provided as an Appendix to this document. WHO and IARC are aligned in their intention to create two levels of due diligence and risk assessment, as foreseen by FENSA, by distinguishing between a standard and a low-risk simplified procedure.

6. In summary, FENSA is an opportunity to further expand IARC's engagement with NSAs. FENSA is expected to result in increased transparency and accountability of engagement with NSAs; in open access to information on potential donors, experts and potential partners; and in an enhanced oversight role of IARC Participating States.

CONCLUSION

7. The Governing Council is requested to note the "IARC-specific guide on engagement with non-State Actors" (see Appendix). The guide will be used by IARC to implement the FENSA, while recognizing that this is a living document which will be updated regularly. The Secretariat will report to the Governing Council each year on its engagement under FENSA as described in the Appendix.

Appendix
IARC-specific guide on engagement with non-State Actors

March 2018

A. Background

The "Framework of Engagement with Non-State Actors (FENSA)", adopted by the World Health Assembly through Resolution WHA69.10 in 2016 is applicable to all "entities established under WHO" (Footnote 1 of Annex to Resolution WHA69.10, refers), therefore including IARC.

FENSA recognizes four groups of non-State Actors (NSA): (i) nongovernmental organizations; (ii) private sector entities; (iii) philanthropic foundations; and (iv) academic institutions. In addition to the overarching framework of engagement with NSAs, for each group of NSAs a specific policy and operational procedure are defined in the document.

The FENSA Resolution defined the timelines and mandates for the implementation of FENSA. Specifically, the World Health Assembly requested the WHO Director-General to:

(a) immediately start implementation;

(b) report annually to the Executive Board through the Programme, Budget and Administration Committee;

(c) fully establish the register of NSAs by the Seventieth World Health Assembly;

(d) fully operationalize implementation of FENSA within a two-year timeframe;

(e) conduct an initial evaluation of the implementation of FENSA in 2019.

The WHO Independent Expert Oversight Advisory Committee (IEOAC) reviews the implementation of FENSA, and reports to the WHO Executive Board (EB) through the Programme, Budget, and Administration Committee (PBAC) at each of its January sessions. At the 2017 January EB session, the IEOAC cautioned against being too restrictive, and called for a balanced approach, carefully weighing benefits against risks. It was considered important to set up from the beginning a system across the Organization that would allow the application of rules and risk identification and management in a consistent and harmonized manner. Furthermore, the IEOAC strongly advised the Organization to create two levels of due diligence and risk assessment as foreseen by FENSA, by distinguishing between a regular and a low-risk simplified procedure.

The IARC Governing Council (GC) adopted Resolution GC/59/R5, at its Fifty-ninth session in May 2017, deciding "to establish a Working Group, to explore ways for IARC to implement the FENSA in the context of IARC's work and research programme, including acceptance of funds from private sector sources". The WHO Office for Partnership and Non-State Actors (PNA) has been consulted throughout the process.

During the period of the Working Group's activities the discussion on how to implement FENSA has continued within WHO with the arrival of the new senior leadership team. The implementation approach WHO is taking has alleviated a number of areas of concern for the IARC Secretariat, e.g., the role of technical units in conducting an initial risk assessment has been expanded, and the procedural requirements for a low risk simplified procedure have been alleviated.

In summary, FENSA is expected to result in increased transparency and accountability of NSAs; in open access to information on potential donors, experts and potential partners; and in an enhanced oversight role of WHO Member States and IARC Participating States.

B. Challenges and Opportunities

The implementation of FENSA at IARC is complex and requires careful assessment over the above-mentioned two-year timeframe.

Under FENSA, all instances where IARC works with a NSA in any of the five areas mentioned in the resolution (i.e. participation, resources, evidence, advocacy, and technical collaboration) would be subject to due diligence and risk assessment, including new activities with previous partners. The scope of FENSA includes partnerships and collaborations even in the absence of exchange of funds.

Concurrently, FENSA offers an opportunity for IARC to further clarify the procedures on how to engage with NSAs, and how to engage IARC's limited resources most effectively to promote new collaborations, partnerships and resource mobilization opportunities.

The initial phase of implementation of FENSA at IARC has presented a number of challenges, not in relation to private sector entities, which remain limited in number and have always been subject to a comprehensive due diligence and risk assessment process, but in relation to:

a) timing for conducting due diligence and risk assessment prior to submitting competitive grant applications, which frequently involve large numbers of collaborators and where IARC is often not the principal investigator; and

b) frequent (almost daily) engagements with academic institutions, non-governmental organizations, and philanthropies (through research collaborations, often including material and data transfers).

WHO engages differently with NSAs in a number of ways compared to IARC. WHO's work is not primarily scientific, but more operational or normative. IARC's engagement also appears to differ in scale. IARC estimates that the number of NSA engagements annually, taking account of research collaborations, participation in consortia, participation in grant applications, exchanges of biological samples and data, and other forms of collaborative work would necessitate more than 1000 assessments each year. If IARC would be required to submit all these through the WHO PNA, it would run the risk of significantly extending the time required for clearance of grant submissions. If all partnerships and collaborations in the absence of exchange of funds were to be added, IARC's ability "to promote international collaboration in cancer research", in line with its Statute requirement, would risk being compromised in the absence of major new investment.

IARC's challenge is how to manage the reputational risk of NSA engagements, while retaining scientific flexibility, and formally complying with FENSA with the limited human resources currently available. The strong advice of the IEOAC, to create two levels of due diligence and risk assessment as mandated by FENSA, offers the potential for a pragmatic approach to complying

with the implementation of FENSA at IARC, distinguishing between a standard and a low-risk simplified procedure. The former would be referred to the WHO PNA, whereas the latter could be locally processed and independently evaluated by IARC.

C. IARC's Due Diligence and Risk Assessment Process

When engaging with NSAs, IARC and/or WHO can be faced with a combination of converging and conflicting interests. An institutional conflict of interest is a situation in which IARC's interests may be unduly influenced by the conflicting interest of a NSA in a way that affects, or may reasonably be perceived to affect, the independence and objectivity of IARC's work. In actively managing institutional conflict of interest, IARC aims to avoid allowing the conflicting interests of a NSA to exert, or be reasonably perceived to exert, undue influence over the Agency's decision-making process or to prevail over its interests. Figure 1 explains the IARC's clearance process for engagement with NSAs adopted by IARC (adapted from WHO's Guide for Staff on engagement with NSAs dated 2018).

IARC needs to know the NSAs that it engages with. Therefore relevant information about each NSA and its activities is reviewed by IARC following necessary due diligence processes. IARC conducts a risk assessment in order to identify the specific risks of engagement associated with each engagement with a NSA. Risk management concerns the process leading to a management decision whereby the IARC Secretariat decides explicitly and justifiably on entry into engagement, continuation of engagement, engagement with measures to mitigate risks, non-engagement or disengagement from an existing or planned engagement with NSAs. It is a management decision taken by the IARC Director based on a recommendation of the specialized team at IARC responsible for performing due diligence and risk assessment. Complex or high risk cases are sent for due diligence and risk assessment to the WHO PNA.

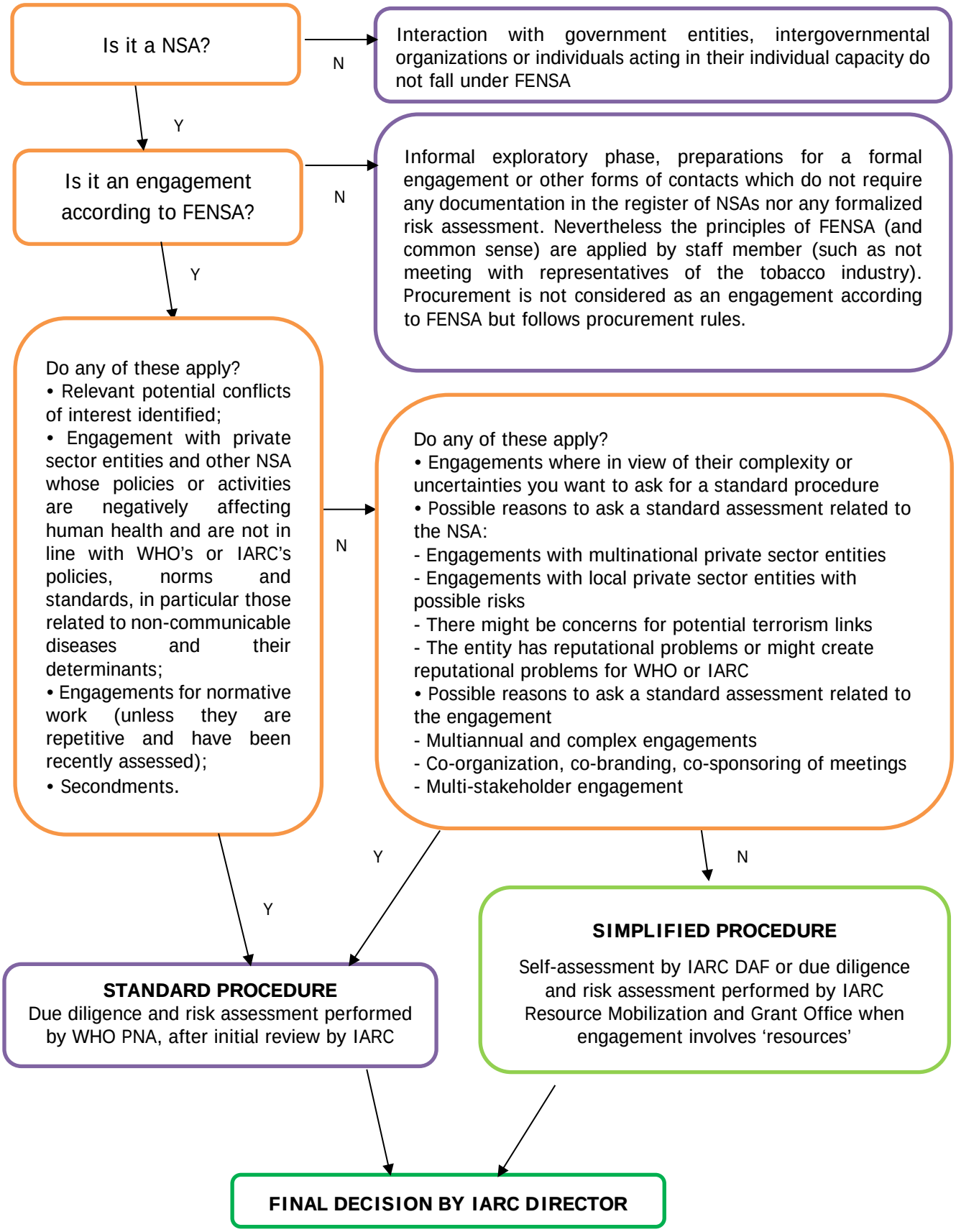

Figure 1 – IARC's Clearance Process for NSA Engagements
(adapted from WHO's Guide for Staff on engagement with NSAs dated 2018)

Figure 2 describes IARC's decision matrix, including the criteria applied by IARC to derive the level of associated risk for all type of engagements with NSAs, whereby 'RA' stands for due diligence and risk assessment.

		Data project	Pre-result project (methods development)	Project producing results	Working group meetings
	For profit organisation – Private companies	**Moderate** *RA by PNA after consultation with DIR/DAF*	**High** *RA by PNA after consultation with DIR/DAF*	**High** *RA by PNA after consultation with DIR/DAF*	**High** *RA by PNA after consultation with DIR/DAF*
Academic institutions, Foundations, NGOs, Hospitals, etc.	**Not for profit organisation with some private funding and with some private sector involvement in its governance**	**Low risk** *Preliminary RA by IGO and validated by DIR*	**Low risk** *Preliminary RA by IGO and validated by DIR*	**Moderate** *RA by PNA after consultation with DIR/DAF (depends on the source of funding)*	**High** *RA by PNA after consultation with DIR/DAF*
	Not for profit organisation with some private funding but no private sector involvement in its governance	**Low risk** *Preliminary RA by IGO and validated by DIR*	**Low risk** *Preliminary RA by IGO and validated by DIR*	**Low risk** *Preliminary RA by IGO and validated by DIR*	**High** *RA by PNA after consultation with DIR/DAF*
	Not for profit organisation with no involvement of private sector in its governance	**Low risk** *Preliminary RA by IGO and validated by DIR*	**Low risk** *Preliminary RA by IGO and validated by DIR*	**Low risk** *Preliminary RA by IGO and validated by DIR*	**Moderate** *RA by PNA after consultation with DIR/DAF*

Figure 2– IARC's Decision Matrix

Abbreviations:
DAF = Director of Administration and Finance
DIR = Director
IGO = Resource Mobilization and Grant Office
PNA = WHO Office for Partnership and Non-State Actors

D. Registering NSAs at IARC

FENSA identifies the registration of the NSA entity in the 'NSA Register' as an important step in the process, prior to the conduct of due diligence and risk assessment. According to the FENSA Guide for Staff published by WHO in early 2018, completing the register is imposed on the NSA itself.

IARC has numerous institutional donors providing small competitive grants for its research projects. In these cases, IARC has virtually no negotiation power, as it is one amongst many to compete for research funds. In this context, it is difficult to expect that IARC's existing and potential new donors would be willing to spend time filling in the 'NSA Register', and consequently the Agency would risk losing important resource mobilization opportunities.

Another challenge is that numerous scientific projects are conducted in partnership with large academic consortia, within which IARC is only one of the scientific partners; there is insufficient motivation for such academic partners to complete an NSA register when IARC is the beneficiary. Registering and clearing them all through the 'NSA Register' would be unmanageable. IARC will continue to closely liaise with WHO, following further developments of their IT system, which should take into consideration IARC's requirements.

Concurrently, IARC maintains its own database of funders and scientific collaboration institutes within the consortia, which is regularly updated.

E. Five Type of Engagements with NSAs

FENSA regulates the following five areas of engagement with NSAs:

1. Resources (financial or in-kind)

IARC assesses 'resources' engagements, by classifying them according to their assessed risk from low to moderate to high.

- At IARC when submitting grant applications with short deadlines, speed is often of essence. An internal IARC pre-clearance mechanism for such cases is required.
- 96% of IARC's engagements with NSAs in 2017 fell in the low risk category. The Resource Mobilization and Grant Office (IGO) conducts a preliminary due diligence and risk assessment, which is validated by the Director prior to submission of a grant application or funding proposal.
- For all high risk engagements, IARC further consults WHO PNA in order to obtain their recommendation in the form of a due diligence and risk assessment, following 'standard procedure'.
- The final decision of engaging with a NSA remains with IARC Director.
- Declaration of no conflict of interest, including any involvement with the tobacco or arms industries, are duly completed by the respective NSA and uploaded in IARC's own database.

2. Technical Collaboration

For the purpose of FENSA, technical collaboration refers to collaboration with NSAs in activities that fall within IARC's mandate in support of research for cancer prevention.

- Collaborative Research Agreements (CRA) at IARC are one of the most widely used contractual modalities to engage the services and establish collaboration with academic and scientific institutions around the globe.
- CRAs can involve financial resources or can be in-kind, including donation of equipment, scientific supplies, material, or data.
- The IARC DAF reviews all types of collaborations with external parties by conducting a self-assessment of the involved NSAs, applying the principles of FENSA.
- Engagements assessed as high-risk are subject to consultation with WHO PNA.
- IARC developed an electronic workflow for the clearance of CRAs, where the Principal Investigator (i.e., Project Manager) uploads the WHO declaration of interest form, including mention of any involvement with the tobacco or arms industries, duly completed by the respective NSA. The IARC DAF (supported by IARC's Bioethics and Compliance Officer) formally reviews all submissions and clears them, before they are submitted to the IARC Director for final approval and signature.
- Data and material transfer agreements can also be concluded without an underlying CRA. These are also cleared by the IARC DAF, who is always an integral part of the workflow, ensuring that all NSAs are self-assessed.

3. Participation

NSAs may attend various types of meetings organized by IARC. The nature of their participation depends on the type of meeting concerned. The format, modalities, and the participation of NSAs in scientific working groups, scientific conferences and other meetings is decided on a case-by-case basis by the IARC governing bodies or by the IARC Secretariat.

- Meetings of the governing bodies involves sessions of the Scientific Council and the Governing Council. NSAs' participation is determined by the governing bodies' respective rules of procedure, policies and practices as well as the section of FENSA that deals with official relations.
- Scientific working groups include any physical or virtual meeting, other than governing body sessions, organized for the purpose of exchanging information and views. Inputs received from NSAs shall be made publicly available, wherever possible. These include meetings organized for the IARC Monographs or WHO Classification of Tumours (Blue Books) Programmes, following strict protocol and rules of procedure.

- Other meetings include information meetings, briefings, scientific conferences, and platforms for coordination of actors or IARC's involvement in meetings organized wholly or partly by an NSA. In these cases the IARC DAF and/or Director are consulted, prior to any formal engagement with an NSA. Following a self-assessment of the risk of engagement by the Principal Investigator, the Director's approval is required to proceed with the invitation.

4. Evidence

For the purposes of FENSA, evidence refers to inputs based on up-to-date information, knowledge on technical issues, and consideration of scientific facts, independently analysed by IARC. Evidence generation by IARC includes information gathering, analysis, generation of information and the management of knowledge and research.

- NSAs may provide their up-to-date information and knowledge on technical issues, and share their experience with IARC, as appropriate, subject to applicable WHO and IARC rules, policies and procedures. Such contribution, including scientific evidence, should be made publicly available, as appropriate, wherever possible.
- Given IARC's scientific focus as a research institution, this category overlaps with the category 'technical collaboration', as described above. Similarly, self-assessment of risks in engaging with a particular NSA is carried out by the IARC DAF.

5. Advocacy

Advocacy is action to increase awareness of health issues, including issues that receive insufficient attention; to change behaviours in the interest of public health; and to foster collaboration and greater coherence between NSAs where joint action is required.

- IARC very seldom engages in advocacy, and when it does so, it usually involves WHO and/or other public organizations.
- The applicable WHO and IARC rules and procedure, including the use of name and emblem are always respected.
- The responsible manager self-assesses the risk of engaging with the respective NSA, and if judged low risk, seeks the IARC Director's approval. Engagements self-assessed as high risk would not be pursued further.

F. Reporting to the IARC Governing Council

The WHA FENSA resolution specifies reporting through the EB/PBAC and refers to WHO Member States. From IARC's perspective, reporting to a body which does not exert management responsibility appears problematic and indeed insufficient in terms of accountability, hence IARC would be reporting to the IARC Governing Council annually instead, as part of the Director's Report.

G. Concluding Remarks and Way Forward

This IARC-specific guide on engagement with NSAs (based on the WHO Guide for Staff on engagement with NSAs dated 2018), noted by the GC Working Group, provides guidance to IARC personnel on the implementation modalities of the FENSA at IARC. The guide will be used by IARC to implement the FENSA, recognizing that this is a living document which will be updated regularly.

IARC's engagement with NSAs is guided by the following overarching principles: (a) demonstrate a clear benefit to public health; (b) conform with IARC's Statute, mandate and medium-term strategy; (c) respect the intergovernmental nature of IARC and the decision-making authority of Participating States as set out in the IARC's Statute; (d) support and enhance, without compromising, the scientific and evidence-based approach that underpins WHO's work; (e) protect IARC from any undue influence; (f) not compromise WHO's integrity, independence, credibility and reputation; (g) be effectively managed, including by, where possible avoiding conflict of interest and other forms of risks to IARC; (h) be conducted on the basis of transparency, openness, inclusiveness, accountability, integrity and mutual respect.

WHO's position has evolved over 2017, removing existing barriers and alleviating a number of areas of concern for the IARC Secretariat. Most notably, the role of technical units in conducting an initial risk self-assessment has been expanded, and the procedural requirements for low-risk simplified procedure have been alleviated.

IARC, in close coordination with WHO, will continue to explore ways to further align its FENSA implementation modalities, with special reference to WHO's electronic 'Global Engagement Management' system, currently under development, and will be reporting annually to the Governing Council on the implementation of FENSA at IARC as part of the Director's Report.