RULES OF PROCEDURE

Expert Panel on Effective Ways of Investing in Health

The Expert Panel on Effective Ways of Investing in Health,

Having regard to Commission Decision 2012/C 198/06¹ (hereinafter the "Decision") to set up a multi-sectoral and independent Expert Panel (hereinafter the "Panel") to provide advice on effective ways of investing in health,

Having regard to the standard rules of procedure of expert groups²,

HAS ADOPTED THE FOLLOWING RULES OF PROCEDURE:

Point 1

Operation of the Panel - Principles

- 1. The Panel shall act at the request of the Commission.
- 2. The Panel should perform its tasks in compliance with the principles of excellence, independence, multi-sectoral approach, transparency and confidentiality.
- 3. Excellence the advice (hereinafter referred to as the "opinion") delivered must represent and be based on the best information (best data, scientific knowledge and methodology available at the time of preparation of an opinion).
- 4. Independence the opinion delivered by the Panel must not be influenced by any consideration other than the evaluation of elements relating to the request for advice (hereinafter referred to as the "mandate"). This principle implies in particular the independence from any external economic or political interests. Members of the Panel and external experts shall undertake to act independently of any external influence. For this purpose, they shall make in writing a declaration of interest at the beginning of their term of office and should proactively highlight any potential conflict of interest depending on the issues discussed in the Panel. See also point 14 below.
- 5. Transparency the meaning of the opinion and its purpose, the way conclusions were drawn, the limits of their validity and the relevant uncertainties must be clear and understandable for users, relevant stakeholders and the public. Equally, the organisation and process leading to the opinion, as well as their rationale, must be presented in a clear and understandable manner. Dialogue and collaboration with third parties should also be transparent. See also Point 16 below.
- 6. Confidentiality (Professional Secrecy) the Panel members are to respect the confidentiality during the preparation of the opinion. The obligation not to disclose confidential information shall continue to apply even after the end of the term of office.

¹ Commission Decision 2012/C 198/06 of 5 July 2012 on setting up a multi-sectoral and independent expert panel to provide advice on effective ways of investing in health, OJ C198 06.07.2012 p.7

² C (2016) 3301 (Annex 3).

For this purpose, they shall make in writing a declaration of confidentiality at the beginning of their term of office.

7. Multi-sectoral approach - the opinions delivered by the Panel should be the result of a collegiate, multi-disciplinary approach integrating interlinked competences in the areas of expertise mentioned in Annex I to the Commission Decision 2012/C 198/06³ (e.g.: health planning and budget prioritisation, health services research, hospital and healthcare management, healthcare provision and health education and promotion).

Point 2

Opinions

- 1. The Panel shall prepare and issue opinion at the request of the Commission.
- 2. The opinion shall be confined to issues relevant to the fields of expertise of the Panel (as set out in Annex I of Commission Decision 2012/C 198/06).
- 3. The mandate requesting an opinion shall consist of background/rationale, the specific questions to the Panel and timing for finalizing the opinion.
- 4. The Secretariat of the Panel, provided by Directorate-General for Health and Food Safety, will be responsible for organising the appropriate dialogue between the Panel and the Commission services at various stages, including feedback from the Commission services on the draft opinions.
- 5. The Panel may ask the Secretariat to clarify the mandate and/or to supply additional information. For each mandate, the Secretariat will give a contact person from the Commission services responsible for providing the Panel members with the relevant background information and support its work.
- 6. The Panel may bring to the attention of the Secretariat any new, emerging or important issues in the area covered by the Panel, which they think, would need to be addressed by the Panel in the form of an opinion and may suggest possible mandates.
- 7. The Panel shall take all the necessary measures to ensure that the deadlines for finalizing the opinions are respected.
- 8. The members of the Panel are responsible for the drafting process of the opinions as well as for carrying out some substantial work themselves including background work on which the opinion will be based.
- 9. The opinion, depending on its type, comprises of:
 - a) an abstract (where appropriate),
 - b) an executive summary (where appropriate),
 - c) the mandate by the Commission with specific question(s),
 - d) the background information,
 - e) the considerations used by the Panel to reach its conclusions (rationale),
 - f) the conclusion, setting out the response to the question(s) posed by the Commission.
 - g) a bibliography,
 - h) a list of abbreviations (where appropriate),
 - i) a glossary (where appropriate),

³ Decision 2012/C 198/06 of 5 July 2012 (and amended by Decision C(2015) 6719 of 30 September 2015).

- j) any minority opinions,
- k) composition of the drafting group (including the names of the Chair and Rapporteur/s of the Drafting Group.)
- 10. The Panel shall adopt opinions at any of its valid plenary meetings and it may also adopt an opinion, previously discussed in a Panel plenary meeting, using the written procedure.
- 11. As far as possible, the Panel should strive to adopt its opinions by consensus. If there are diverging views, the opinion will be deemed adopted if it is supported by an absolute majority of the Panel members (half of the total experts appointed as members plus one).
- 12. The members that have voted against or abstained shall have the right to have a document summarising the reasons for their position annexed to the opinion.

The Chair

- 1. The Panel shall elect a Chair and a Vice-Chair from among its members.
- 2. The terms of office of the Chair and the Vice-Chair shall be for the whole term of office of the Panel (3 years).
- 3. The Chair shall be elected by secret ballot and in writing. The election procedure shall be chaired by a Commission official and it will take place at the beginning of the first statutory valid plenary meeting of the new term of the Panel.
- 4. Members may present themselves as candidates or be proposed by another member. The candidates must, prior to the vote, declare that they are aware of the responsibilities of the Chair, be prepared to accept the post of Chair of the Panel and be prepared to assist the Secretariat on matters related to the co-ordination of Panel's work.
- 5. Candidates may withdraw their candidature at any time during the procedure.
- 6. The candidate receiving the majority of the votes of the members of the Panel present in the meeting shall be elected as Chair.
- 7. If none of the candidates receives a majority in the first ballot round, a second ballot shall be held between the two candidates with the highest individual totals of votes in the first ballot. The procedure shall be repeated until one candidate obtains the majority of the votes of the members of the Panel present in the meeting.
- 8. Where there is or remains a single candidate, that candidate shall be elected provided that he/she receives the majority of votes cast.
- 9. The same steps described in point 3-8 above under this point should be followed for the election of the Vice-Chair.
- 10. A specific record shall be kept of the election procedure.
- 11. The name of the Chair and the Vice-Chair of the Panel shall be made public.
- 12. The Chair will be responsible for:
 - a) Planning the work of the Panel in agreement with the Secretariat,
 - b) Chairing, steering and moderating the discussions at meetings and drawing conclusions,
 - c) Appointing the Chair of the Drafting Groups and Rapporteur(s) for each mandate.

- 13. If the Chair is not in a position to fulfil his/her function, the Vice-Chair, failing that, another member chosen in agreement with the members and the Secretariat, will fulfil the tasks.
- 14. In case of conflict of interest (as defined in point 14 of these Rules of procedure) of the Chair with an item on the agenda, he/she shall be replaced by the Vice-Chair or another member chosen in agreement with the members and the Secretariat.

Meetings

- 1. As a general rule, meetings of the Panel shall be held on Commission premises.
- 2. The Secretariat shall establish with the Panel a schedule for Panel's plenary meetings and Drafting Groups meetings for the forthcoming calendar year.
- 3. Meetings of the Panel and its Drafting Groups shall not be open to the public. Individual views, whether expressed orally or in writing by members during deliberations within the Panel plenary meetings or Drafting Group meetings shall be confidential.
- 4. Commission officials with responsibilities related to the mandates submitted to the Panel shall participate and support the work of the Panel.
- 5. The Secretariat shall draw up the agenda of meetings of the Panel and its Drafting Groups in agreement with the Chair.
- 6. The agenda shall be adopted by the members of the Panel present at the start of each meeting, considering any agreed amendments.

Point 5

Documentation to be sent to Panel members

- 1. The Secretariat shall send the invitation to the meeting no later than 30 days and the draft agenda no later than 10 calendar days before the date of the meeting.
- 2. Wherever possible, documents including draft opinions prepared by a Rapporteur shall be made available to the Secretariat for distribution to the members, one week before the meeting where they will be discussed. Rapporteurs and members entrusted with the drafting of opinions shall ensure that this requirement is complied with.

Point 6

Drafting-groups

- 1. The Panel may set up temporary Drafting Groups for the purpose of drafting specific opinions.
- 2. Drafting Groups will only undertake tasks which are clearly defined and directly linked to the given mandate.
- 3. Drafting Groups shall comprise of at least 1/3 of the members of the Panel and shall be chaired by a member of the Panel.
- 4. Rapporteur(s) and members of a Drafting Group shall be designated by the Chair of the Expert Panel from among the members of the Panel.

- 5. Rapporteur(s) shall be responsible for assembling information, editing and revising draft opinions and for respecting deadlines.
- 6. There might be several Rapporteurs who can work jointly on one opinion, under the guidance of the Chair of the Drafting Group.
- 7. The work of a Drafting Group is concluded when the Panel publishes the opinion.

Invited experts

The Secretariat may invite, at the request of the Panel members, experts with specific knowledge with respect to a subject matter discussed at a Panel plenary meeting or in a Drafting Group, to take part in the work on an ad hoc and temporary basis. Similarly, experts might be invited to input into the work process through written contributions.

Point 8

Minutes of the meetings

- 1. Minutes of plenary and Drafting Groups meetings shall be meaningful and complete. Minutes shall be drafted by the Secretariat under the responsibility of the Chair and shall contain at least:
 - a) the list of participants and apologies for absence,
 - b) declaration of interests by participants concerning their independence including the relevant details, the action taken and its rationale,
 - c) a summary of discussions,
 - d) a record of decisions taken and opinions adopted.
- 2. The draft minutes shall be circulated to members of the Panel for comments. They should be adopted no later than in the next meeting.
- 3. After their adoption, the text of the minutes shall be published on the Panel's website.

Point 9

Participation Criteria

- 1. In each calendar year, it is expected that members will attend at least 70% of the meetings of the Panel and Drafting Groups to which they have been invited, whether in person or through video/teleconference.
- 2. Members are expected to contribute actively to the discussion and deliberations during meetings of the Panel and its Drafting Groups and/or through written contributions.
- 3. The extent to which members have participated in the work of the Panel will be assessed by the Secretariat on a yearly basis using the participation criteria mentioned in paragraph 1 and 2 of this point. If this assessment would conclude that one or several members would not have complied with these criteria, the Secretariat will examine, after consultation with the Chair, the situation with the member(s) in question.

Secretariat

- 1. Directorate-General for Health and Food Safety shall provide secretarial support to the Panel and its Drafting Groups.
- 2. The Secretariat shall be responsible for :
 - a) providing administrative support necessary to facilitate the efficient functioning of the Panel,
 - b) monitoring compliance with the rules of procedure,
 - c) ensuring communication on the Panel's activities and publication of the opinions,
 - d) any other actions deemed necessary for ensuring the efficient work of the Panel.

Point 11

Public hearing on a draft opinion

- 1. The Secretariat shall organise hearings, i.e. public information/consultation meetings to discuss with any interested parties the draft opinion being prepared by the Panel members and gather specific comments on the draft opinion.
- 2. The Panel will decide who will represent them at the hearings. The members of the Panel shall not take any decisions during hearings.
- 3. The organisational aspects of such hearings shall be decided upon and managed by the Secretariat.
- 4. Hearing proceedings report will be drafted after each public hearing. These reports shall contain a detailed record of the interventions of the participants/stakeholders and a summary text recording the main issues raised described thematically rather than by interventions and capturing the overall feedback on the draft opinion.
- 5. The hearing proceedings will be published on Panel's website.

Point 12

Dissemination of finalised opinion

- 1. The Secretariat shall be responsible for determining the appropriate level of publicity to be given to an opinion and may request the assistance of the Chair, Rapporteurs or other members to ensure the validity of communication materials.
- 2. Suitable dissemination actions will be undertaken for each published opinion, clearly indicating the potential target audience and the best and most efficient ways of reaching them. This might include circulation of the opinions and lay-language summaries after the publication, as well as preparation of communication materials and events including targeted workshops and conferences.
- 3. The opinions may also be presented to the Council Working Party on Public Health on a regular basis, if the Presidency agrees.

Point 13

External representation

- 1. The Secretariat may invite the Chair to represent the Panel in external events, contacts, missions etc. as appropriate. Chairs of Drafting Groups, Rapporteurs and any other members may be designated by the Secretariat to present an opinion and/or to attend events or meetings where they represent the Panel.
- 2. When contacted by third parties, or when requested by the press or a media, to present opinions or represent the Panel or its views, the Panel members should first inform the Secretariat and the Chair and wait for their agreement before confirming their participation in this activity.
- 3. When representing the Panel in an event or a meeting with third parties, or when requested by the press or a media for the same purpose, the Panel members shall ensure that they convey the views of the Panel, without expressing personal views or interpreting adopted opinions in a way that goes beyond the established position of the Panel. Moreover, they should use the formats, templates and logos provided by the Secretariat in order to make visible the attribution of their presentations to the Panel.
- 4. Panel members shall not speak on behalf of the Commission unless officially requested by the Secretariat to do so.

Conflicts of interest⁴

- 1. Panel members are obliged to submit to the Secretariat a declaration of interest in writing in the beginning of the term of office. These declarations are published in the Register of Commission Expert groups. They must be completed or updated timely with any relevant additional or new information.
- 2. The Chair shall, at the first meeting of each calendar year, remind all members of their obligation to promptly inform the Secretariat of any relevant change in the information previously provided, including as regards upcoming activities, in which case they must immediately submit a newly completed declaration of interests describing the change, in order to enable the Secretariat to assess it in due course, in compliance with the horizontal rules on the creation and operation of Commission expert groups⁵.
- 3. At the beginning of each meeting, the Panel members will be invited by the Chair to report any activity, situation, circumstance or other fact potentially involving a direct or indirect

⁴ A conflict of interest occurs when an <u>individual</u> or <u>organization</u> is involved in multiple interests, one of which could possibly <u>corrupt</u> the motivation for an act in another. The presence of a conflict of interest is independent from the execution of impropriety. Therefore, a conflict of interest can be discovered and voluntarily defused before any <u>corruption</u> occurs. A widely used definition is: "A conflict of interest is a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest."^[1] Primary interest refers to the principal goals of the profession or activity, such as the protection of clients, the health of patients, the integrity of research, and the duties of public office. Secondary interest includes not only financial gain but also such motives as the desire for professional advancement and the wish to do favors for family and friends. The secondary interests are not treated as wrong in themselves, but become objectionable when they are believed to have greater weight than the primary interests. The conflict in a conflict of interest exists whether or not a particular individual is actually influenced by the secondary interest. It exists if the circumstances are reasonably believed (on the basis of past experience and objective evidence) to create a risk that decisions may be unduly influenced by secondary interests.

⁽¹⁾Lo and Field (2009). The definition originally appeared in Thompson (1993).

⁵ COMMISSION DECISION of 30.5.2016 establishing horizontal rules on the creation and operation of Commission expert groups.

interest with issues on the agenda of the meeting in question. This will be noted in the minutes of the meetings.

4. Should a conflict of interest in relation to a member arise, the Secretariat shall put it in writing in the minutes of the meeting and take all appropriate measures, in compliance with the horizontal rules⁶. Any member who, in accordance with his/her declaration or in the opinion of the Panel, or the Secretariat, may not be able to act independently, shall be excluded from the activities considered or may only be allowed to participate to the extent and in a way compatible with the objective to preserve the process from any undue influence. In such a case, the extent of the concerned individual's participation in the Panel's work shall be decided by the Chair in agreement with the Secretariat. Measures may include the physical withdrawal from the meeting for the point under discussion, or participation limited to the provision of factual information.

Point 15

Correspondence

- 1. Correspondence relating to the Panel shall be addressed to the Secretariat.
- 2. Correspondence for Panel members shall be sent to the e-mail address which they provide for that purpose.

Point 16

Transparency

- 1. The Panel shall be registered on the Register of the Commission expert groups.
- 2. As concerns the Panel composition, the following data shall be published on the Register of expert groups:
 - The name of individuals appointed in a personal capacity⁷;
 - Declarations of interest
- 3. Availability of preparatory and draft documents shall be restricted, on a need-to-know basis, to Panel members, invited experts (as described in point 7 above), the Secretariat and other Commission staff.
- 4. They shall not be available to third parties unless for the purpose of the hearings on the draft opinions as explained in point 11 above or unless a different decision is taken in specific cases by the Secretariat, at the suggestion of Panel members.
- 5. The following documents related to the work of the Panel are published on the Panel's website (with a weblink introduced into the Register of the Commission expert groups). Access to dedicated websites shall not be submitted to user registration or any other restriction. Exceptions to publication shall only be foreseen where it is deemed that disclosure of a document would undermine the protection of a public or private interest as defined in Article 4 of Regulation (EC) N° 1049/2001⁸.

⁶ C(2016) 3301, Article 11.

⁷ Individuals who do not wish to have their names disclosed may submit a request to the responsible DG for a derogation from this rule. A derogation shall be granted where justified on compelling legitimate grounds in relation to the specific situation of the individual, in particular where disclosure of the experts' name could endanger their security or integrity.

⁸ These exceptions are intended to protect public security, military affairs, international relations, financial, monetary or economic policy, privacy and integrity of the individual, commercial interests,

- a) The names of the members of the Panel together with their brief biography
- b) Agendas of plenary meetings of the Panel
- c) Minutes of plenary meetings and of Drafting Groups
- d) Mandates
- e) Invitation to hearings and draft opinions to be discussed in hearings
- f) Final opinions
- g) Rules of procedures.
- 6. For any other document, the Secretariat shall decide about the publication case by case.

Access to documents

Applications for access to documents held by the Panel shall be handled in accordance with Regulation (EC) No 1049/2001⁹.

Point 18

Intellectual Property Rights

Final opinions shall be subject to reuse in accordance with Decision 2011/833/EU and distributed under the Creative Commons Attribution 4.0 International licence (https://creativecommons.org/licenses/by/4.0/legalcode).

court proceedings and legal advice, inspections/investigations/audits and the institution's decision-making process.

⁹ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).