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Rules of Procedure 08.05.2014

The Expert Panel on Effective Ways of Investing in Health

Rules of Procedure

RULES OF PROCEDURE

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1. INTRODUCTION AND BACKGROUND

Commission Decision 2012/C 198/06¹ (hereinafter "the Decision") set up an multi-sectorial and independent Expert Panel (hereinafter "the Panel") to provide advice on effective ways of investing in health.

Sound and timely scientific advice is an essential requirement for the Commission's provision of information and knowledge relating to sustainability of health care systems. The mission of the Panel is to provide the Commission with independent and sound advice on effective ways of investing in health. The output of the Panel may take the form of opinions or ad hoc advice.

According to the Decision, Rules of Procedure are adopted by the Panel on proposal by and in agreement with the Commission.

These Rules of Procedure will be regularly reviewed by the Commission in order to introduce the appropriate adaptations in light of experience through the same procedure applied for their adoption.

2. OBJECTIVES OF THE RULES OF PROCEDURE

The rules of procedure shall ensure that the Panel performs its tasks in compliance with the principles of excellence, independence, multi-sectoral approach, transparency and confidentiality.

The Rules of Procedure provide guidance aimed at ensuring the effective functioning of the Panel according to the above-mentioned principles by defining the appropriate modalities for the operation of the Panel.

In order to achieve these objectives and given the experience with the functioning of other Commission advisory structures in the past, these Rules of Procedure regulate the functioning of the Panel, its Working Groups, the role of Panel Members and of the external experts, the various activities mentioned in the Decision, and the role and responsibilities of the Secretariat of the Panel (hereinafter "the Secretariat").

3. PRINCIPLES

According to the Decision, the Panel should perform its tasks in compliance with the principles of excellence, independence, multi-sectoral approach, transparency, and confidentiality. Articles 2 and 4 of the Decision provide guidance on the mission and operating principles of the Panel.

3.1. Excellence

The scientific advice delivered must represent the best information and

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

guidance that science can provide at the time of adoption of the opinion under the conditions and deadlines imposed. It shall be based on the best data, scientific knowledge and methodology available at the time of preparation of an opinion.

The principle of excellence refers to the performance and outcome of the entire process. It refers in particular to the intrinsic scientific quality of the opinion, its adequacy in relation to the aims of the consultation, its clarity, completeness and transparency. It also refers to the effective communication of the contents and conclusions of the opinions and the actual and perceived credibility of the process.

3.2. Independence

The scientific advice delivered by the Panel must not be influenced by any consideration other than the evaluation of scientific elements relating to the question.

This principle implies in particular the independence from any external economic or political interests, but also from bias related to political, economic, social, philosophical, ethical or any other non-scientific considerations.

The principle of independence refers to the organisation and results of the process, including in particular the independence criteria and conditions and arrangements for the participation of members, advisors and experts.

3.3. Transparency

The meaning of the scientific advice, 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 scientific advice, as well as their rationale, must be presented in a clear and understandable manner. Openness, dialogue and collaboration with other bodies and third parties should also contribute to transparency.

3.4. Confidentiality (Professional Secrecy)

The scientific advice delivered by the Panel is sometimes based on confidential information. The members of the Panel and the external experts are expected to respect the principle of confidentiality and exercise due diligence in not divulging confidential information acquired as a result of the work of the Panel, thematic workshops, working groups or other activities related to the application of this Decision. All participants and observers of the work of the Panel are to respect the confidentiality during the preparation of the opinion.

3.5. Multi-sectoral Approach

The scientific advice delivered by the Panel should be the result of a collegiate, multi-sectorial, integrated approach integrating complementing and interlinked competences in the areas of health planning and budget prioritisation, health services research, hospital and healthcare management, healthcare provision and health education and promotion.

4. RULES AND PROCEDURES RELATED TO INDEPENDENCE

- 4.1** 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 commitment (see Annex I) at the beginning of their mandate. They shall ensure that they do not directly or indirectly delegate their responsibilities to any other person or allow themselves to be influenced in any way in the execution of their duties.
- 4.2** Members of the Panel shall also make in writing an annual declaration of interests (see Annex II).

External experts shall make in writing a specific declaration of interest when accepting to participate in any of the activities of the Panel (see Annex II).

Members and external experts shall be in a position to show beyond question that they can act independently. They are under a continuing duty to declare before undertaking any activity, situation, circumstance or other fact potentially involving a direct or indirect interest, as indicated in the explanatory notes included in the Annex in question, in order to allow the Panel and/or the Commission to identify those interests which might be considered prejudicial to the independence of the member, advisor or external expert.

These declarations of interest shall be made in writing and published in the Panel's website. They must be completed or updated timely with any relevant additional or new information.

- 4.3** Members and external experts participating in meetings of the Panel or in a Working Group or in any other activity on behalf of the Panel shall declare at the beginning of each meeting or event any activity, situation, circumstance or other fact potentially involving a direct or indirect interest, as indicated in the explanatory notes included in the relevant Annex in order to allow the Panel and/or the Commission to identify those interests which might be considered prejudicial to their independence in relation to the items on the agenda for that meeting or event. This declaration shall be made in writing or verbally, following a request of the Chair or the Commission and should be noted in the minutes of the meetings.
- 4.4** The Secretariat, the Chairs and the Panel shall ensure that the principles of independence of members and experts are complied with at all times. Members shall draw the Panel's and the Secretariat's attention through its Chair to any factual matter that could undermine external credibility of the Panel's work. The Panel's discussions of the matter shall be recorded.

In particular, the Secretariat shall draw the Commission's attention to all cases where it appears that a member or expert might have ceased to fulfil the requirement to act independently from any external influence and address the measures to be taken, included as appropriate, the revocation of his/her appointment.

- 4.5** Any member or external expert who, in accordance with his/her declaration or in the opinion of the Panel, the Working Group or the Commission, 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 member, advisor or expert may not act as Rapporteur or as Chair in relation to the specific matter and may not participate in decision-making. The extent of the concerned individual's participation in the Panel's work shall be decided by the Chair in consultation with the Panel or Working Group members and in agreement with the Commission within the framework of these Rules of Procedure. Measures may include the physical withdrawal from the meeting for the point under discussion, or participation limited to the provision of factual information.
- 4.6** Conclusions and decisions taken in relation to the declarations of interest, as well as their rationale, shall be recorded. In the case of declarations presented during meetings, such records will be part of the minutes
- 4.7** Members or external experts who receive documents or information of relevance for the Panel's or the Working Group's activities from third parties shall ensure that the information is made available promptly to the Secretariat.
- 4.8** Members or external experts contacted by third parties in connection with their participation on a specific question in Panel meetings, a Working Group or any other activity of the Advisory Structure shall inform the Secretariat and refer the third party to the Secretariat.
- 4.9** Members and external experts shall inform the Secretariat of relevant contacts they might have with petitioners, special interest groups, other stakeholders or other Community or international bodies engaged in overlapping activities. The Secretariat shall advise on the action to be taken in consultation with the Panel as necessary.
- 4.10** When invited to represent the Panel, members or external experts 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. In such cases, they should inform and consult with the Secretariat in advance. 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.
- 4.11** They shall not speak on behalf of the Commission unless officially requested by the Commission itself to do so.

5. RULES AND PROCEDURES RELATED TO TRANSPARENCY

- 5.1** The Panel shall operate in accordance with the need for a high level of transparency as set out in Decision (2012/C 198/06), without prejudice to legitimate requests for confidentiality or the need to safeguard the freedom and scientific integrity of the scientific debate and the independence of members and external experts vis-à-vis external influence.
- 5.2** Requests for access to documents will be handled in accordance with the provisions of Regulation n° 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, p.43). When considering the exceptions listed in Art. 4 of 1049/2001 account shall be taken of the need to preserve the integrity and the independence of the scientific advice which supports the decision making process of the Community.
- 5.3** The following documents of the Panel are published on the Panel's website (link introduced into the Register of the Commission expert groups and other similar entities and in the Health and Consumers Directorate General Public Health site), subject to respect of confidentiality requirements as well as protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data:
- 5.3.1** Draft agendas of plenary meetings of the Panel.
 - 5.3.2** Minutes of plenary meetings and of working groups.
 - 5.3.3** Requests for opinions (mandates).
 - 5.3.4** Final opinions and pre-consultation opinions published for public consultation.
 - 5.3.5** Declarations by members and external experts participating in on-going work of their commitment to act independently of any external influence.
 - 5.3.6** Annual declarations of interest made by members of the Panel and specific declarations of interests made by external experts who participated in working groups.
 - 5.3.7** Declarations of interest made in relation to items on the agendas of plenary meetings and Working Groups will be published as part of meeting minutes.
 - 5.3.8** The names of the members of the Panel together with their brief CVs.
 - 5.3.9** Panel reports clarifying contentious issues as a result of a substantive divergence over scientific issues with other Community or international bodies
 - 5.3.10** Rules of procedures.
 - 5.3.11** Stakeholder dialogue activities (mandate consultations, calls for

information, calls for experts, calls for hearings, public consultations on pre-consultation opinions etc.)

- 5.4** Names of Members and external experts appointed to Working Groups, as well as their declarations of interest, shall be published.
- 5.5** Availability of preparatory and draft working documents shall be restricted, on a need-to-know basis, to members, external experts, the Commission's secretariat, and representatives of the Commission's services with competence for a specific question. They shall not be given to third parties unless a different decision is taken in specific cases by the Panel in agreement with the Commission, in view of a specific need to involve or inform urgently a third party as part of the process to complete the relevant work.
- 5.6** The Commission shall be responsible for determining the appropriate level of publicity to be given to a scientific opinion and may request the assistance of the chair, rapporteurs or other members to ensure the scientific validity of its press releases or related communication actions.
- 5.7** In the case of requests to the Panel for ad hoc advice, the rules and procedures related to transparency in sections 5.1 to 5.6 will be applicable in line with the provisions of Article 4 and Article 5 of Regulation n° 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, p.43).

6. RULES AND PROCEDURES RELATED TO CONFIDENTIALITY (PROFESSIONAL SECRECY)

- 6.1** Members and external experts shall make a written declaration of confidentiality (see Annex III). They shall not divulge confidential information acquired as result of their work in the Panel, or one of the Working Groups. This will include in particular, documents provided by third parties concerning sensitive industrial and commercial matters, and/or for which confidentiality has been requested and agreed by the Commission in accordance to the applicable provisions.
- 6.2** The obligation not to disclose confidential information shall continue to apply even after the participation of members and external experts in the work of the Panel has ceased.
- 6.3** With the exception of minority opinions, individual views, whether expressed orally or in writing by members and external experts during deliberations within the Panel or a Working Group, shall be confidential.

7. RELATIONS WITH THE COMMISSION

- 7.1** The Panel may bring to the attention of the Commission any new, emerging or important issues in the area covered by the Panel which may need to be addressed by the Panel in the form of an opinion, statement or position paper.
- 7.2** The Panel may also bring to the attention of the Commission events (e.g. conferences, symposia) organised by other EU bodies, Member States, or international organisations which may necessitate the involvement or participation of members of the Panel on behalf of the Panel or the Commission.
- 7.3** The Commission will, in all instances, examine the matter brought to its attention by the Panel and decides on an appropriate course of action. It will inform the Panel of its decision.

8. RELATIONS AND DIALOGUE WITH STAKEHOLDERS AND THE PUBLIC

- 8.1** The Panel may require additional information from stakeholders for the completion of a scientific opinion. This may involve in particular invited face to face meetings, consultations, hearings, request for the submission of information etc. To this end, targeted calls for information may be organized by the Secretariat in agreement with the Panel. A deadline for the submission of required information shall be given in agreement with the Commission. If the required information has not been submitted within the deadline, the Panel may adopt the opinion on the basis of the available information. This procedure and its actual application may not be invoked as a reason to delay the adoption of, modify or reconsider a scientific opinion.
- 8.2** A stakeholder dialogue procedure is established in Annex IV of these Rules. This procedure applies to the activities of the Panel. The aim of such procedure is to enhance the quality of the scientific opinions. The procedure will be applied in agreement and co-operation between the Panel and the Secretariat.
- 8.3** The stakeholder dialogue procedure shall apply when and as compatible with the fundamental requirement to ensure the full independence and autonomy of the Panel in elaborating, determining and deciding the contents and conclusions of its opinions and to preserve the integrity of the process for the establishment of scientific advice. The Secretariat shall suspend the application of the procedure in a particular case if there is any risk to the independence and integrity of the process and shall alert the Commission of the nature and extent of such risk. No aspect of the stakeholder procedure and its actual application may be invoked as a reason to delay the adoption of, modify or reconsider a scientific opinion.

9. FUNCTIONING OF THE PANEL

9.1. Election of Chair and Vice-Chair of the Panel

- 9.1.1** The Panel shall elect from among its members a Chair and a Vice-Chair.
- 9.1.2** The terms of office of the Chair and Vice-Chair shall be three years, renewable.
- 9.1.3** A separate record shall be kept of the election procedure. The names of the Chair and the Vice-Chair of the Panel shall be made public.
- 9.1.4** The Chair and Vice Chair shall be elected by secret ballot and in writing.
- 9.1.5** The election procedure shall be chaired by the Commission.
- 9.1.6** The procedure shall be as follows:
- The election of the Chair and of the Vice Chair can be held in a valid meeting session if the absolute majority of the total members (one half of the total experts appointed as members plus one) agree to do so. Failing this, the election of the Chair and the Vice Chair shall be conducted via written procedure.
 - A meeting is considered valid when the absolute majority (half of the total number of members plus one) of the experts who have been appointed by the Commission as members of the panel are present.
 - The election of the Chair and the Vice Chair shall be held separately.
 - The names of those wishing to stand as candidates shall be notified to the Secretariat before the meeting or be announced at the meeting. Members may present themselves as candidates or be proposed by another member.
 - The candidates must, prior to the vote, declare that they are prepared to accept the post of Chair (or Vice Chair) of the Panel and be prepared to assist the Commission on matters relating to the co-ordination of the Panel's work, including if necessary participating in co-ordination meetings organised and chaired by the Commission.
 - The candidate receiving the majority of the votes of the members of the Panel shall be elected.
 - Meetings are considered valid when the majority (one half of members plus one) of the experts who have been appointed by the Commission as members of the Panel are present.
 - Members who have resigned or whose membership has been terminated shall not be taken into account for the calculation of the majority required.
 - If none of the candidates receives an absolute majority, 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.

- Candidates may withdraw their candidature at any time during the procedure.
- Where there is or remains a single candidate, that candidate shall be elected provided that he/she receives the absolute majority of votes cast.

9.1.7 In the case of a written procedure, the process of election of the Chair and Vice Chair set out in section 9.1.6 will be followed and will be conducted by a member of the Secretariat. The records of the vote will only be known to that member of the Secretariat and will be kept in confidence and security.

9.1.8. In the event of a tied vote between the candidates, the election of the Chair and Vice Chair will be conducted via a drawing.

9.2. Role and replacement of Chair and Vice-Chair of the Panel

9.2.1 The Chair, in collaboration with the Secretariat will be responsible for:

- Planning the work of the Panel in agreement with the Secretariat.
- Chairing, steering and moderating the discussions at meetings and drawing conclusions.
- Examining the declarations of interest, deciding, in consultation with the Panel and in agreement with the Commission the relevant conclusions and action in order to ensure the effective application of the independence requirements
- In collaboration with the Secretariat, monitoring the conformity of the activities of the Panel with all the relevant procedural methodological and substantive requirements, principles and standards established or deriving from the Commission Decision 2012/C 198/06, and these Rules of Procedure, and taking, or requesting the Commission to take as appropriate, the necessary measures
- Representing the Panel
- Appoints the Rapporteur(s) for each mandate (question)

9.2.2 If the Chair is not in a position to fulfil his/her function, he/she shall be replaced by the Vice-Chair or, failing that, another member chosen in common accord by the members.

- 9.2.3** In case of conflict of interest² of the Chair with an item on the agenda, he/she shall be replaced by the Vice-Chair or failing that another member chosen in common accord by the members.

The Vice-Chairs will support the Chair in fulfilling his or her responsibilities. The Chair will consult the Vice-Chair on a regular basis and as appropriate on emerging issues requiring urgent decisions that could not be postponed for discussion at plenary meetings.

9.3. Requests for Opinions, or ad hoc advice (mandates)

- 9.3.1** Requests for scientific opinions or ad hoc advice shall be submitted by the Secretariat to the Panel. The request shall consist of the terms of reference, the Community interest and the scientific background. The mandate shall be presented to the Panel by a representative of the requesting service, assisted by the Secretariat, or by the Secretariat on behalf of the requesting service.
- 9.3.2** The terms of reference of the mandate 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.
- 9.3.3** All mandates will be reviewed by the Secretariat in advance to submission to the Panel for conformity with the applicable template, clarity and completeness, pertinence in relation to the fields of competence of the Panel, and appropriateness of the terminology.
- 9.3.4** Mandates may be submitted to public consultation according to the procedures set out in Annex IV of these Rules. The mandate may or may not be modified on the basis of the public consultation. In either case a proper justification should be provided in the opinion so as to ensure and document the transparency of the process.
- 9.3.5** Questions submitted to the Panel, shall be subject to the transparency rules and procedures set out in section 5 of this document/Rules of

² A **conflict of interest** occurs when an individual or organization is involved in multiple interests, one of which could possibly corrupt 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 corruption 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).

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- 9.3.6** Where necessary, the Commission may require the Panel to adopt a scientific opinion within a specified deadline. The Panel shall take the necessary measures to ensure that the deadline is respected.
- 9.3.7** The Panel may ask the Commission to clarify a question and/or to supply additional information.
- 9.3.8** The Commission may specify in the request for an opinion the consultations, hearings, or collaboration with other scientific bodies it deems necessary for the preparation of the opinion.

The Panel, in agreement with the Commission, may decide to hold a hearing and/or a consultation if considered necessary for completing an opinion. The practical aspects of such hearings and consultations shall be decided upon and managed by the Secretariat.

- 9.3.9** The Commission may request the Panel to provide ad hoc advice to support the Commission with information in case of a need to react to specific concerns or requests from other institutions. When requesting an ad hoc consultation, the Secretariat will contact the Chair to identify the relevant expertise in the Panel, sources of information, scoping and formulation of the issue in question, and to agree on appropriate procedures and format for advice.

9.4. Designation and role of Rapporteurs

- 9.4.1** The Chair of the Panel (or the Vice Chair when replacing the Chair) designates Rapporteurs from among Panel members.

The designation may be revoked.

- 9.4.2** Rapporteurs shall be responsible for assembling information, editing and revising draft opinions and ensuring that draft reports and scientific opinions are prepared within a set time period, where appropriate. The Rapporteur should also ensure that draft opinions are well structured, written in clear and simple language and are coherent. The Rapporteur shall work in close co-operation with the Secretariat.
- 9.4.3** The work of a Rapporteur is concluded when the Panel publishes the opinion.

9.5. Establishment and role of Working Groups

- 9.5.1** The Panel may establish Working Groups to undertake tasks which are clearly defined and directly linked to the question submitted by the Commission. In particular, the Working Group may be asked to undertake all necessary preparatory tasks in relation to a draft opinion. The Panel can require that these tasks be completed within a set period.
- 9.5.2** Working Groups shall comprise at least one member of the Panel and

may include external experts, as well as experts from other Community bodies. Working Groups shall be chaired by a member of the Panel.

- 9.5.3** Members and external experts of a Working Group shall be designated by its Chair in agreement with the Chair of the Panel and in collaboration with the Secretariat in accordance with the procedure described in paragraph 9.6 below. They shall be invited to meetings by the Secretariat. If an expert is invited but not available, the Secretariat may, in agreement with the Chair, invite another suitable expert.
- 9.5.4** A Working Group shall endeavour to reach a consensus. In the absence of a consensus, the position of the Working Group shall be that approved by a simple majority of its members. Nevertheless, the Chair of the Working Group and the Rapporteur shall inform the Panel of all the positions expressed.
- 9.5.5** The Working Group shall report to the Panel to whose work it contributes, providing it with such reports or draft opinions as the Committee has requested.
- 9.5.6** The names of participants in the Working Groups shall be included in the opinion to which they have contributed

9.6. Selection of external experts to participate in Working Groups

External experts designated to participate in Working Groups may be identified and selected from (to be followed sequentially or simultaneously) 1) the Database of experts; 2) by conducting a specific Call for Experts; 3) or through another systematic method as appropriate and 4) by suggestions from Panel members. The selection process set out should be recorded.

A short list of suitable candidates will be established by the Secretariat on the basis of the required fields of expertise defined by the Panel.

The Chair of the Panel and the Working Group Chair in collaboration with the Working Group members as appropriate will select the appropriate candidates from the short list. The selection process should be properly recorded in order to document the transparency of the process.

9.7. Meetings (Notice, Agendas, Deadlines, Minutes, Access)

- 9.7.1** The Secretariat shall establish with the Panel a schedule for the Panel's plenary meetings for the forthcoming calendar year.
- 9.7.2** As a general rule, the Secretariat will confirm meetings of the Panel and Working Groups at the earliest possible date but no later than ten working days before the date of the meeting and shall give notification of cancellation not less than two working days before the date of the meeting.

- 9.7.3** Meetings of the Panel and Working Groups may be called at short notice according to the urgency of the matters.
- 9.7.4** The Secretariat shall prepare the draft agenda of meetings of the Panel and the Working Group and circulate it to members as far as possible no later than two weeks before the date of the meeting. The draft agenda of plenary meetings shall be published on the Panel's website before the meeting takes place.
- 9.7.5** The draft agenda shall include new mandates submitted by the Commission and shall be accompanied by all appropriate and available supplementary information of relevance to the new mandates submitted. The Secretariat shall provide any additional information as soon as possible to the members.
- 9.7.6** The agenda shall be adopted at the beginning of the meeting taking account of any agreed amendments.
- 9.7.7** Wherever possible, documents including reports and draft opinions prepared by a Rapporteur or external expert shall be made available to the secretariat for distribution to the members, associated members and external experts one week before the meeting where they will be discussed. Rapporteurs and members entrusted with the drafting of documents, reports or draft opinions shall ensure that this requirement is complied with.
- 9.7.8** Meetings of the Panel and its Working Groups shall not be open to the public.
- 9.7.9** Commission services with responsibilities relating to the topics on the agenda shall be entitled to be present in the meeting. They may assist for the purposes of clarification or provision of information but shall not seek to influence the outcome of discussions.
- 9.7.10** The Secretariat of the Panel shall prepare draft minutes of plenary meetings which shall contain at least:
- the list of participants and apologies for absence,
 - declaration of interests by participants concerning their independence including the relevant details, the action taken and its rationale,
 - the adopted agenda
 - a summary of discussions, including important minority stand points and agreed actions,
 - a record of decisions taken and opinions adopted,
 - any abstentions during voting.
- 9.7.11** The draft minutes shall be circulated to members of the Panel for comments. They should be adopted not later than the next meeting.
- 9.7.12** Without prejudice to the provisions of paragraph 6.4 above, minutes

shall be published on the Panel' website as soon as possible after their adoption.

9.7.13 Legitimate requests for commercial confidentiality shall be respected.

9.8. Format and content of Opinions

9.8.1 The scientific opinion, depending on its type, comprises of:

- an abstract (where appropriate)
- an executive summary (where appropriate),
- the background (Community interests and scientific background),
- the terms of reference giving the specific question(s),
- the considerations used by the Panel to reach its conclusions (scientific rationale),
- the conclusion (opinion), setting out the response to the question(s) posed by the Commission. For complex opinions, the conclusions shall be accompanied by a summary in non-specialised language,
- a bibliography,
- a list of abbreviations (where appropriate)
- a glossary (where appropriate)
- any minority opinions,
- composition of the working group.

9.8.2 The Panel shall adopt its scientific opinions at its plenary meetings.

9.8.3 The Panel may adopt an opinion, previously discussed in a Panel meeting, using the written procedure.

9.8.4 In case of urgency, opinions may be adopted by accelerated procedures.

9.8.5 Adoption of an opinion at the plenary meeting, by written procedure or by accelerated procedure will be done by a majority vote of those physically present or those who have responded (in the case of written or accelerated procedures) provided a quorum is attained. A plenary meeting is considered to have attained a quorum when at least half plus one of the members (at least 7 members) are either being physically present at the meeting or are participating in the meeting via teleconferencing. In the cases of adoption by written procedure or by accelerated procedure, quorum is considered to be attained when half plus one (at least 7 members) respond in writing to the request for adoption.

9.8.6 Legitimate requests for commercial confidentiality are to be respected.

9.9. Minority opinions

The Panel should strive to reach common conclusions. However, when it is

not possible to reach such common conclusions, transparency should be ensured and the opinions of the Panel shall include any minority opinions together with supporting argumentation. Minority opinions can only be expressed by members and shall be attributed accordingly.

9.10. Rapid advice and Accelerated Procedure

In case of urgent needs, the Commission may request the Panel to provide rapid advice. The rapid advice is intended to support the Commission with scientific information in case of urgent need to react to public concerns or requests from other institutions. This procedure is not intended to produce full-fledged scientific reports. Normally it will apply in cases where the advice is needed within at the latest a few days.

When requesting rapid advice, the Secretariat will contact by the fastest means the Chair and, if necessary, the Vice-Chair for identifying the relevant expertise in the Panel, the appropriate sources of information on the subject matter, and the scoping and formulation of the issue in question. On the basis of the indications obtained, the Secretariat will collect from the appropriate members and experts the information needed and will summarize it in collaboration with the Chair and Vice-Chair as appropriate.

The rapid advice may take either the form of informative "Rapid Advice Notes on Specific Issues" issued by the Secretariat in the most urgent cases prepared in accordance to the procedure mentioned above, or an opinion adopted by the Panel through an accelerated procedure launched by the Secretariat in agreement with the Chair.

In the latter case the Secretariat shall request, whenever possible in agreement with the Chair of the Panel, an external expert or a Working Group to draw up a draft opinion and submit it to the Secretariat within a set deadline.

If the Chair and Secretariat consider that the nature and urgency of the matter require an emergency meeting, the Secretariat shall endeavour to organise a meeting at short notice. The Secretariat shall put the draft opinion on the agenda of the next meeting of the Panel.

In the event that the circumstances do not require or allow holding a meeting, a draft opinion may be adopted by written procedure. In this case, the Secretariat shall send the draft opinion to the members of the Panel with a request for approval by a set deadline. The draft shall be adopted if the majority of the members of the Panel have expressed their approval before the deadline. If a majority is not reached, the draft opinion must be put on the agenda of the following meeting of the Panel or, if the urgency of the matter so requires, of an ad hoc meeting to be convened at the earliest date at which the quorum can be assured.

9.11. Voting Rules

9.11.1 The Panel shall adopt its opinions, ad hoc advice, rapid advice

documents, memoranda and /or position statements in a valid meeting session by an absolute majority vote (one half of the total experts appointed as members plus one). If an absolute majority is not obtained, the opinion, rapid advice, memoranda and/or position statement shall be adopted via written procedure.

9.11.2 Meetings are considered valid when the absolute majority (one half of plus one) of the experts who have been appointed by the Commission as members of the Panel are present.

9.11.3 Members who have resigned or whose membership has been terminated shall not be taken into account for the calculation of the majority required.

9.12. Information to the Secretariat

Members and external experts should inform the Secretariat on all issues concerning their activities related to the Panel work, for example:

9.12.1 Communication with members/experts regarding the work of the Panel

9.12.2 Relations with the media (interviews, articles, letters etc.)

9.12.3 Presentations/speeches regarding the work of the Panel

9.13. Co-operation with other Scientific Bodies

9.13.1 Diverging opinions

The Panel shall assist the Commission and contribute in identifying, resolving or clarifying at an early stage potential or actual divergence between their scientific opinions and the scientific opinions of Community, National and International bodies carrying out similar tasks. Similarly, they will assist and contribute in identifying needs and possibilities for co-ordination of work and collaboration, in particular the need for a joint opinion and/or a joint working group or exchange of experts as members of a working group.

When a substantive divergence is identified with a Community body, the Panel concerned shall, on the request of the Commission, cooperate with the body concerned. To this end the Commission may convene a meeting between the Panel and the scientific organs of the bodies concerned. The Panel shall designate a Rapporteur.

When it is not possible to resolve divergent opinions, a joint document clarifying the contentious scientific issues and identifying the relevant uncertainties in the data shall be submitted to the Commission. This document shall be made public.

9.13.2 Co-operation with other EU, national, international and non-EU bodies

– The Panel shall assist the Commission in establishing and maintaining collaboration relationships with other relevant

Community, National or International bodies.

In particular, the Panel shall assist the Commission on scientific technical matters requiring co-ordination and co-operation with other Community bodies, notably with the Economic Policy Committee and the Social Protection Committee.

10. ROLE OF THE SECRETARIAT

In addition to the specific tasks referred to in these Rules of Procedure, the Secretariat shall be responsible for providing scientific and administrative support necessary to facilitate the efficient functioning of the Panel, to monitor compliance with the rules of procedure, particularly in relation to the requirements for excellence, independence, transparency, multi-sectorial approach and confidentiality, to ensure communication on the Panel's activities and the appropriate stakeholder dialogue, including in particular organisation of hearings, and publication of the opinions and other public documents. Moreover, the Secretariat shall provide support to the Panel and organise and apply quality control of the opinions as far as completeness, consistency, clarity, correspondence with requests and with editorial standards are concerned. Specific duties shall include in particular:

- 10.1** Ensuring best use of resources and the planning to meet priorities and time limits.
- 10.2** Ensuring that requests for opinions comply with the requirements on mandates.
- 10.3** Identifying, in collaboration with the requesting service, and including in the mandates the requirements concerning scientific meetings, hearings, consultations, collaboration with other bodies.
- 10.4** Avoidance of overlapping or inconsistent opinions.
- 10.5** Preparing the work of the Panel and its Working Groups, in consultation with the Chair.
- 10.6** Provide information on the legislative/policy aspects of the questions with the help of the relevant and interested Commission services.
- 10.7** Ensuring that relevant background information is made available to the Panel and its Working Groups.
- 10.8** Assisting in identifying the appropriate advisors and experts to be invited in working groups.
- 10.9** Organising the appropriate dialogue between the Panel and the requesting services at the various stages, including feedback from the services on the adopted opinions. The Secretariat will agree with the requesting services procedures for ensuring that the dialogue with the

Panel takes place on a systematic basis. It shall inform the Panel of the arrangements made and systematically monitor their application.

- 10.10** Assisting the Chair of the Panel and its Working Groups in the preparation of the draft opinions in particular by monitoring, assessing and reporting to the Committees, before adoption, the quality of draft opinions, in particular in relation to correspondence with the mandate, completeness, clarity and coherence, editorial standards, as well as conformity to the principles of excellence, independence, multi-sectorial approach and transparency and the other relevant principles and standards referred to in these rules of procedure.
- 10.11** Assuring the scientific and technical co-ordination of the activities of the panel in relation to the activities of other Community and international bodies with similar fields of competence.
- 10.12** Deciding, in agreement with the interested Commission Services, about the publication of memoranda, position statements, documents resulting from scientific meetings and thematic workshops.
- 10.13** Monitoring compliance of members with participation criteria and informing the Commission as appropriate.

11. EXTERNAL EXPERTS

External experts possessing particular and relevant scientific knowledge may be invited to contribute to the work of the Panel or its Working Groups. This will include in particular the preparation, compilation and presentation of the scientific evidence base which serves as a basis for the opinion of the Panel.

To that end, the Secretariat will make use as far as possible of the data base in which experts may register in view of their possible involvement in Working Groups.

12. PUBLICATION OF THE OPINIONS AND OTHER DOCUMENTS

- 12.1** All documents mentioned under paragraph 5(3) and in particular the adopted Scientific Opinions shall be published on the Panel's website without undue delay by the Secretariat.
- 12.2** For any other document, the Secretariat, in agreement with the interested services shall decide about the publication and dissemination case by case.

13. REPRESENTATION OF THE SCIENTIFIC ADVISORY STRUCTURE

The Secretariat may invite the Chair and the Vice-Chair to represent the Panel in external events, contacts, missions etc. as appropriate. Chairs of Working Groups

and Rapporteurs may be designated by the Secretariat to make presentations of the opinions to which they have contributed. Other members and experts may be invited by the Secretariat to attend events, meetings etc. in relation to the work of the Panel's activities, but shall not speak on behalf of the Panel, unless explicitly requested to do so on specific issues by the Secretariat.

14. PARTICIPATION CRITERIA AND TERMINATION OF MEMBERSHIP

The minimum participation criteria are fixed as follows:

- 14.1** In each calendar year, it is expected that members will be in a position to attend at least 70% of the meetings of the Panel and Working Groups in which they have been invited
- 14.2** Members are expected to be in a position to contribute actively to the discussion and deliberations on subjects within their field of competence during meetings of the Panel and its working groups and, when requested, with written comments

The extent to which members have been in a position to participate in the work of the Panel will be assessed by the Secretariat on a yearly basis. After consultation with the Chair, the Secretariat shall examine the situation with the members who have not been in a position to comply with the participation criteria and inform the Commission in view of possible decisions in accordance with Article 3(5) of the Commission Decision 2012/C 198/06.

15. THEMATIC WORKSHOPS, SCIENTIFIC MEETINGS, NETWORKS

Thematic workshops shall be organised by the Secretariat:

- 15.1** At the request of the Commission itself, or
- 15.2** At the own initiative of the Panel, in agreement with the Commission.

The objective of such workshops may be to review data and scientific knowledge on particular risks or broad health issues. These workshops may involve members, external experts, including experts from Community, national or international bodies carrying out similar tasks.

Workshops at the initiative of the Panel will be organised by the Secretariat subject to consultation of the interested Commission services, availability of funds and adequate planning.

16. MISSION EXPENSES AND INDEMNITIES OF MEMBERS AND EXTERNAL EXPERTS

- 16.1** Travel and subsistence expenses incurred by members, advisors and external experts in connection with Panel meetings and activities are reimbursed in accordance with Commission's rules.
- 16.2** Members of the Panel and external experts are entitled to a special indemnity for the attendance and the preparation to meetings as set out in Annex II of Commission Decision 2012/C 198/06.
- 16.3** Indemnity payments for attendance are directly linked to presence as documented by the attendance list which is signed by participants in the meetings of Committees and Working Groups or agreed external meetings and certified as correct by the meeting secretary. Participation through audio or video link will be authorised by the Secretariat.
- 16.5** Rapporteurs shall be entitled to an indemnity for attendance and for preparation as set out in Annex II of Commission Decision 2012/C 198/EC. A written agreement between the Rapporteur and Commission services will be established when the Rapporteur is nominated. Payment of the indemnity will be made after adoption of the specific opinion by the Panel.

Duration: The validity of the present Declaration is limited to one mandate of the Panel from the date of signature, unless I inform the Panel's Secretariat on the termination of my activities in the Panel.

2- Personal data processing & respect of privacy

- Regulation (EC) N° 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data applies to Scientific Committees' activities. The present Declaration constitutes a legal act in the sense of Article 23 of the aforementioned Regulation and the undersigned is considered to be a processor of personal data on behalf of Scientific Committees in the sense of Article 2(e) of the Regulation. As a processor of personal data, the undersigned is subject to the following obligations:
- To process the data received in the context of the assignment with the Panel solely for the purpose for which it was transmitted ;
- To act only on instruction of the Panel's Secretariat, in its capacity of controller with regard to any personal data processing in the context of the assignment with the Panel;
- To ensure the confidentiality and security of personal data processing in the sense of Articles 21 and 22 of the Regulation, without prejudice to the obligations regarding confidentiality and security laid down in the national data protection legislation of the EU Member State, in which the undersigned is having her/his residence;
- To follow specific instructions of the Panel's Secretariat in the case of transfer of personal data to any third party, therefore observing appropriate security safeguards to avoid unauthorised processing and disclosure.

3- Copyrights and library working tools provided by the Panel

In case I am involved in the preparation of scientific outputs, I may receive from the Panel Secretariat scientific publications and journals protected by copyrights as hand outs or via e-mail.

I shall be allowed to make limited use of journals and scientific publications, but shall not:

- Distribute copies of articles and journals to third parties;
- Use articles or journals for commercial purposes;
- Use the materials for other purposes than the Scientific Committees' assignment

Done at

Date

Signature :

ANNEX II

GUIDANCE TO DECLARATION OF INTERESTS

INTRODUCTION

1. This guidance relates to the implementation of the provisions on independence and transparency of Commission Decision 2012/C 198/06
2. It aims at giving clear indications on how to declare any interest that could affect the ability of the expert to act in the public interest.
3. According to Decision 2012/C 198/06, the responsibility for declaring all relevant interests is placed on the individuals completing their declaration.
4. Experts are nominated to the Expert panel on effective ways of investing in Health of the European Commission as independent experts, strictly in their personal capacity and not as representatives of public or private bodies, organizations or states.
5. An "interest" declared is not automatically considered to create a conflict of interest. It is well understood that, in general, individuals who are involved in a particular process have an inherent professional interest in the subject and in being involved in the process as such. In particular, interests of an intellectual nature are considered as essential to safeguard the quality and overall objectivity of the scientific work.
6. These rules of procedure cover the Declaration of Interest to be filled in by the Members before the start of their mandate, the Annual Declaration of Interests (ADoI), required from all members of the Panel and the Specific Declaration of Interests (SDoI), required from all experts participating in Working Groups (including the relevant Panel members).
7. The ADoI is a written declaration which has a broad scope and describes all the interests that could conceivably give rise to a conflict in the general operation of the Panel. This declaration has to be done on an annual basis, at the beginning of the year.
8. The SDoI is linked to a specific subject matter and enables to assess whether a conflict of interest exists in the context of the specific activity. It is to be filled in before the start of the work of every Working Group. It should be completed by all members of the WG. It should be updated whenever a new relevant interest occurs which is not yet specified in the actual SDoI or ADoI. In addition, ad hoc SDoIs may be requested from Working Group experts who are not Panel members when they are asked to participate to special events on behalf of the Panel (e.g. hearings at the EP, meetings with stakeholders, etc).
9. Declarations of Interest are declared by an expert as an indication of where conflicts of interest could arise and do not require from the author to assess

whether there is actually a conflict. The assessment of whether there is a potential conflict is performed by the peers (i.e. the Chair and the other members of the Panel) and by the Secretariat.

WHAT TO DECLARE?

Members of the Panel and external experts shall declare current and past activities (as specified under "other definitions" below) in the ADoI and SDoI (same form). The Commission recognizes that high quality and up-to-date scientific expertise is by nature based on prior experience, connection to the scientific world and involvement in current research. Therefore, having an interest does not necessarily mean having a conflict of interest.

1. Ownership of shares or other investments.

Any financial interests in a company or other entity operating in a business that can be affected directly by the opinions of the Panel. This includes holding of any form of equity, bonds, partnership interests³ in the capital of a company. The holding of financial interests connected with a pension scheme or other complex investment funds would not be considered a financial interest, provided that the individual has no influence on its financial management.

2. Membership in a Management Body or equivalent structure.

Any participation in the internal decision-making of a company, trade association or other private entity such as a non-profit organisation dealing with issues related to the scope of work of the Panel (e.g. board membership, directorship).

3. Membership in another Scientific Advisory Body

The person concerned is participating or has participated in the works of a Scientific Advisory Body with a right to vote on the outputs of that entity.

4. Employment

All forms of employment, part-time and full-time, either paid or unpaid, in any organisation having activities falling within the scope of the work of the Panel.

5. Consultancy/Advice

Any paid or unpaid, past, present or future activity in which the expert or his depended collaborators provides technical or scientific advice or services in domains of relevance for the work of the Panel.

6. Research

³ When declaring financial interests e.g. stock and shares, only the kind, company name need to be stated.

Any current or future influence on the definition of research priorities, the drafting of research programmes or the selection of research projects and current funding of research in relation to matter or work financed by a private or public entity, including grants, rents, sponsorships and fellowships.

7. Intellectual property rights (IPR)

Rights granted to creators and owners of works that are the result of human intellectual creativity that bring personal financial benefit to the expert. Only the IPR falling within the remit of the work of the Panel need be taken into account. These can be copyrights, patents, trademarks et cetera.

8. Other membership or affiliation

Any membership or affiliation other than the above which can be perceived as an interest in the field of activity of a Committee.

9. Interests of close family members

Known interests as described under points 1 to 8 held by family members and relatives (spouse, parents, children, brothers and sisters) or other persons under the care of the members of the household of the expert. In order to maintain privacy, their names do not need to be declared. The relationship (e.g. wife) need not be specified.

10. Other

Any interest other than the above which can be perceived as a potential source of conflict in an activity included in a Committee's remit.

Other definitions

Current means ongoing activities.

Past period means activities that are no longer ongoing and which have been completed in the preceding five years.

Name of entity or organization means name, location and nature of all organisations (private, public, etc.) that relate to the Panel's remit. Thus, for the purpose of the declarations of interests the involvement in public bodies needs to be included as well.

Subject matter is to be interpreted as means the domain in which the activity was or is carried out. Any data collection and any other interest stemming from prior experience or affiliation of the individual with private or public institutions should equally be declared.

CONSEQUENCES OF NOT DECLARING an Interest

Failure to fulfil in a timely and complete manner any of the obligations detailed above will be considered as a prima facie breach of trust towards the

Commission. As a consequence, the Commission will take any actions deemed necessary, including the dismissal of the concerned persons from the Panel.

PUBLICATION

The ADols and SDoIs will be made public in accordance with the provisions on transparency foreseen by Decision 2012/C 198/06. They will be posted on the website of the Panel: http://ec.europa.eu/health/expert_panel/index_en.htm.

COMPLIANCE WITH PROVISIONS ON PERSONAL DATA PROTECTION

The Commission shall process Dols pursuant to Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.

DECLARATION OF INTERESTS

Expert Panel on Effective ways of Investing in Health

(Please note that high quality of scientific expertise is by nature based on prior experience and that therefore having an interest does not necessarily mean having a conflict of interest)

Name:

Position: Member of the Panel

Title:

Profession:

[please copy rows as needed for subsequent or parallel activities of the same nature]

Nature of Activities	Period	Organisation	Subject matter
I. Ownership or other investments, including shares	MM/YYYY – MM/YYYY	Companies or organisations in which the financial interest is placed	[Relevant field of activity]
II. Member of a Managing Body or equivalent structure	MM/YYYY – MM/YYYY	-Name, Place -Type: public, private, ...	Function of expert: Function of institution: [Describe e.g. role of yourself and of the institution] Link to website of institution:

Nature of Activities	Period	Organisation	Subject matter
III. Member of a Scientific Advisory Body	MM/YYYY – MM/YYYY	-Name, Place -Type: public, private, ...	Member of Scientific Committee, sub-committees, working group on ... Function of expert: Function of body: Link to website of body:
IV. Employment	MM/YYYY – MM/YYYY	-Name, Place -Type: public, private, ...	[Describe professional activities in relation to activities of the SCs]
V. Consultancy/Advisory	MM/YYYY – MM/YYYY	-Name, Place -Type: public, private, ...	[Describe role]
VI. Research funding	MM/YYYY – MM/YYYY	-Name, Place -Type: public, private, ...	[Describe research]
VII. Intellectual property	MM/YYYY – MM/YYYY		
VIII. Other membership or affiliation	MM/YYYY – MM/YYYY	-Name, Place -Type: public, private, ...	[Describe activity, function, website]
IX. Other	MM/YYYY – MM/YYYY	-Name, Place -Type: public, private, ...	[Describe activity, function, website]

Nature of Activities	Period	Organisation	Subject matter
X. Interests of close family members	MM/YYYY – MM/YYYY		[Describe activity, function]

I hereby declare that I have read both the Guidance Document on Declarations of Interests and the Rules and Procedure related to Independence (section V of the Rules of Procedure) and that the above Declaration of Interests is complete.

Done atDate:

Signature:

Done at

Date

Signature:

ANNEX IV

STAKEHOLDER DIALOGUE PROCEDURES

<p style="text-align: center;">COMMISSION Expert Panel on Effective Ways of Investing in Health</p>
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1. Introduction

These procedures are intended to enable structured, balanced, ordered and manageable engagement with stakeholders in the process of elaboration of scientific opinions by the Panel, whilst ensuring the effectiveness of the process and compliance with the principle of independency.

These procedures will be implemented as part of the Rules of Procedure of the Panel. It needs to be emphasised that the procedures described are not intended to be used for each opinion and will be applied taking into account the expected added value in each specific case and the need for sound management of the limited resources available.

Stakeholder interaction will particularly be encouraged on issues that are:

- relevant to several Member States;
- of potentially high importance for health care and health care systems;
- not closely related to a particular product of company;
- not previously addressed by the Panel.

While these procedures contribute to the implementation of the principle of transparency and are part of the Commission's efforts to engage with stakeholders in a spirit of openness and accountability, it should be clear that the work of the Commission Expert Panel on effective ways of investing in Health is, and must remain, independent of any influence. These procedures must therefore, not be seen as, and must not be used to interfere with the internal work of the Panel, claiming a right or trying to be involved in such work or exerting pressure on the Panel's members. The overall aim of these procedures is to contribute to ensure the highest quality of the scientific opinions adopted by the Panel. In case of any evidence of significant risks for the independence of the committees due to the application of these procedures, the Commission will discontinue their application in part or in total as appropriate.

The procedures apply to the following stages:

- suggestions for new topics which the Commission may consider to submit to the Panel
- finalisation of new mandates
- calls for data and information
- scientific input during the preparation of the opinion
- public Consultations on a pre-consultation opinion
- scientific comments on existing opinions

Only submissions sent to the appropriate functional mail box (published on the website of the Commission: and complying with all the other conditions mentioned below will be considered. In all other cases, the Commission will not be in a position to consider the submission.

2. Suggestions to the Commission for new topics for the Panel

The Panel been established to advise the Commission. According to its legal basis, they develop and adopt opinions upon Commission's request. DG Health and Consumers is in charge of managing the Panel.

In order to maximise the potential of the panel, the Commission will welcome motivated and documented suggestions for new topics for the Panel, provided the suggested topics do not fall under the competence of other European agencies like in particular, EMA or ECDC. The suggestions will therefore be considered under the following conditions:

- the issue is related to competences of the EU in the healthcare and health systems;
- the issue falls under the competence of the Panel, both in terms of nature and specific content;
- the background, interest, importance for the EU and the Commission in particular are demonstrated with solid arguments;
- the issue is clearly and completely defined. In particular the questions for the Panel are clearly formulated;
- the issue and the questions are formulated in neutral terms, without explicitly or implicitly suggesting a particular answer or asking for the endorsement of a predefined thesis or hypothesis;
- the suggestion does not aim at obtaining reconsideration of a recent opinion on which consultations have been closed (unless important published scientific results and the urgency of the matter require such reconsideration);
- adequate data and scientific knowledge (published literature etc) exist and are provided, enabling the Panel to develop an opinion.

If the above conditions are met, DG Health and Consumers, in collaboration with the other interested Commission services, will examine the suggestion in view of a decision on the possible follow-up, taking into account the degree of relevance, importance and priority of the issue (in general and in relation to

Commission priorities and policy orientations), as well as any practical limitation in light of possible difficulties and other priorities.

If the Commission services decide to take the proposal on board, the suggested questions might be revised and/or amended by the interested services.

The proponent will be informed of the decision and its motivations.

This procedure does not create any right for stakeholders to have the proposed issues accepted by the Commission and examined by the Panel.

3. Finalisation of new mandates

All new mandates are published at the following Internet address: http://ec.europa.eu/health/expert_panel/index_en.htm.

For issues of broader significance or wider public interest, DG Health and Consumers, when so agreed by the requesting Commission service, will submit 'working' mandates to public consultation. In selecting mandates for a public consultation, the Commission services will take into account the expected added value of such consultation for the completeness and clarity of the questions as well as the need to ensure sound management of the limited resources available. The working mandates could still be refined in light of the comments received. In such a case, a final version of the mandate will replace the "working" one.

The Commission will welcome comments on the 'working mandates' submitted in general within 20 working days from the date of publication, unless a shorter period is fixed due to the urgency of the matter. After such a period, in general, the Commission shall not be in a position to ensure consideration or follow up further comments.

Stakeholders may subscribe to an alert system which will enable them to receive an alert each time a new mandate is published and a consultation is launched.

The comments and proposals will be considered provided that they meet the following conditions:

- they are expressed in a clear way, related to the questions in the mandate and the relevant scientific matters;
- in case additional issues and questions are proposed, see the conditions mentioned in the paragraph "Suggestions for new topics" above
- any modification requested must be motivated by documented scientific considerations and must be related to the aims, background and subject matter of the mandate;
- any modification must be presented in a neutral way;
- the reasons, relevance and importance of the issues raised must be clearly explained;
- in case the comments involve an extension of the scope of the mandate, adequate data and scientific knowledge exist and is provided to enable the Panel to advise on the suggestion and the Commission to decide.

If the above conditions are met, the Commission services concerned will examine the comments in view of a decision on the possible follow up, taking into account the degree of relevance, importance and priority of the matter (in general and in relation to Commission priorities and policy orientations), and the practical implications on the Commission and on the Panel priorities and resources.

If the Commission service requesting the opinion decides in agreement with DG Health and Consumers to take the proposal on board, questions might be revised and/or amended

The Commission services may decide on a case- by- case basis to meet with the proponents in order to discuss the comments presented if they are of particular interest.

The results of the consultation will be summarized on the web site of DG Health and Consumers mentioned above.

This procedure does not entail any right for stakeholders to have their proposals accepted.

This procedure will not apply in case of urgent matters and accelerated consultation procedure.

4. Call for Information

The objective of a Call for information is to ensure that all relevant scientific information as specified in the Call is available to the Panel for its assessment.

In general, only submissions directly related to the Call and complying with its specifications will be considered. Any document referred to shall be attached to the e-mail in an appropriate electronic form. All relevant material specified in the scope of the Call should be attached to the submission of the contribution.

No research of referenced documents or websites will be carried out. The name, title, organization, postal address, telephone number and e-mail address of the sender should appear in the text of the e-mail.

It should be noted that a submission shall not under any circumstances be considered if:

- it is submitted after the deadline set out in the call;
- it does not correspond to the scope and format specified in the call and in these guidelines.

An automatic system to acknowledge receipt is foreseen but no further individual reply will be made.

Confidential data:

- the submission of confidential data should be accompanied by appropriate documentation to justify the confidentiality requirement.
- a statement confirming/permitting that the data may be considered in the risk assessment carried out by the scientific committee and that at least a summary of the data provided may be presented in the opinion.

5. Scientific input during the preparation of the opinion

5.1. Organisation of hearings

Technical hearings with individuals, petitioners or other stakeholder representatives may be organised:

- at the initiative of the Panel, if they consider it necessary for the completion of a scientific opinion;
- upon request of a stakeholder who makes a valid 'prima facie' case. A relevant element is the ability to offer relevant scientific data and analysis not otherwise available to the Panel. Requests shall be accompanied by a clear scientific justification for the hearings and be supported by credible scientific documentation. The Commission services will assess the request in collaboration with the Panel and decide upon the action to be taken. The precise organisation of the hearing will be decided on a case-by-case basis. The requesting party will be informed of the conclusions.
- at the initiative of the Commission services in agreement with the Panel.

The Panel will decide who will represent the Panel at the hearing. As a general rule, only members of the Panel will be involved in such hearings.

The persons attending the hearings should be scientists with appropriate expertise in the field who can present and understand the scientific arguments.

The Secretariat and the Chair shall ensure that, when invited to such hearings, individuals, petitioners or other stakeholders limit their presentations to scientific matters related to the subject (for example, to provide additional scientific evidence, discuss interpretation of data or clarify data). Invitees shall under no circumstances engage in public relations or lobbying activities.

The members of the Panel shall not take any decisions during hearings.

In conformity with the generally applicable obligation to respect confidentiality in all the aspects of the work of the Panel, Members, external experts shall exercise care during hearings to avoid giving information to competitors or other interested parties regarding specific products where this information is not public

On occasion, open public hearings might be organised at the initiative of the Panel or the Commission (with the agreement of the Panel). The objectives of such hearings will be to gather specific comments, suggestions, explanations or contributions on the scientific basis of a particular opinion. Open hearings can be organised as stand-alone independent events or in conjunction or with the other data/information gathering activities of the

Panel (call for information, public consultation on pre-consultation opinion)

In those cases, the following procedures will be followed:

- DG Health and Consumers will publish the intention to organise a public hearing on behalf of the Panel on a particular subject, the specific items on which the Panel would wish to receive contributions and an invitation to interested parties to register;
- registration will be open for a period of 30 days;
- when registering, potential participants will be asked to provide full professional details, to specify the subject they wish to address in the hearing and to submit a 1-2 page technical justification for their request.
- approval for participation to the hearing will be decided on the basis of the following criteria:
 - interested participants should be scientists or technical experts with appropriate expertise in the field who are able to present and understand the scientific arguments;
 - interested participants have clearly identified the subject matter they would wish to contribute to and have provided sufficient technical justification;
- all registered participants will be informed at least two weeks before the hearing;
- DG Health and Consumers will publish the final programme of the hearing together with the participants' names;
- during the hearing, the Secretariat and the Chair shall ensure that participants limit their presentations to scientific matters related to the specific matters indicated in their registration;
- invitees shall under no circumstances engage in public relations or lobbying activities;
- the members of the Panel shall not take any decisions during hearings;
- during hearings, members, associated members and external experts shall avoid giving information to competitors or other interested parties regarding specific products if this information is not public.

5.2. Public Consultation on pre-consultation opinions

The Panel may decide to submit a pre-consultation opinion to a public consultation in case the Panel and the Commission consider that it would enhance the quality of the work.

The objective of public consultations is to gather specific comments and suggestions on the scientific basis of the opinion, as well as any other relevant scientific information regarding the questions addressed, in order to allow the Panel to focus on issues which need to be further analysed.

This consultation process shall not deal with policy needs and measures. In addition, this particular consultation procedure should not be confused with other consultations launched by the Commission regarding policy or regulatory matters, for which a different scope, as well as rules and

procedures apply.

In general, only submissions directly referring to the content of the pre-consultation opinion and relating to the issues that the report addresses will be considered. Furthermore, only studies and data which are published or accepted for publication in scientific reports or journals will be taken into consideration.

Any document referred to shall be attached as indicated in the template in an appropriate electronic form. All relevant material should be attached to the contribution. No researching of referenced documents or websites will be carried out.

It should be noted that a submission will not under any circumstances be considered if:

- it is submitted after the deadline set out in the call;
- it is presented in any other form than the template provided;
- it exceeds the maximum length indicated for each section, or contains comments which do not correspond to the indicated title of that particular section;
- it contains information on individual cases or any other material not included in published reports;
- it contains complaints against institutions, personal accusations, irrelevant or offensive statements or material. Complaints should be made according to the existing procedures;
- it is related to policy or risk management aspects.

Follow up to submissions

An automatic system to acknowledge receipt is foreseen and no further individual reply will be made.

The Commission services may decide, on a case- by- case basis, to publish the submissions corresponding to the criteria of the consultation, unless the author has explicitly opposed publication of his or her contribution.

The Panel will consider all the relevant submissions related to the scope of the public consultation and will decide if and in how each of the contributions should be taken into account in the formulation of the final opinion.

Depending on the results of the consultation, the Panel shall include a section on the results of the consultation, summarising in general terms the main issues arising from the consultation and how they are addressed in the opinion as well as an Annex to the opinion listing the contributions received.

It is not intended to provide any separate document on the consultation, the participation in it or a summary of the submission received.

5.3. Revision of existing opinions

As a rule, the opinions of the Panel on a particular subject will be considered closed and not subject to revision for a period of 3 years.

After that period and in order to keep the Panel opinions up-to-date with new scientific knowledge, the panel may, at its own initiative, at the request of the Commission services or at the request of stakeholders, consider it appropriate to revise an existing opinion in light of new evidence.

The revision of an existing opinion will be initiated on the basis of new evidence meeting one or more of the following criteria:

- New data or information is provided in response to the explicit needs expressed by the Panel in the existing opinion;
- substantial new evidence was made available in the public domain that, in the view of the Panel or the Commission or of stakeholders, is worth evaluating with a view to update an existing opinion.
- stakeholders, international organisations, third countries, submit adequate new data;

6. Functional mailboxes and practical guidance

Two types of functional mail boxes will serve the communication needs of the Panel: a permanent mail box and specific mail boxes of limited duration.

The permanent mail box will serve as a general communication tool for the Panel allowing stakeholders and interested parties to communicate with the Panel secretariat on a number of items identified in the present document such as suggestions for new topics, comments on the mandates, inquiries on status of work in progress, general information on conferences and scientific events of potential interest to the Panel or organised by the Panel, general comments, etc.

The temporary specific mail boxes will be of limited duration (start and end dates) and will serve a specific purpose such as data/information collection, public consultations, open public hearings etc.