



Scientific Committee on Emerging and Newly Identified Health Risks

SCENIHR

4th Meeting of the Working Group on Surgical Meshes

Venue: HITEC building, Rue Eugène Ruppert 11, L- 2453 Luxembourg

Meeting room: HTC 02/280

Meeting date: Monday, 30 June 2014, starting at 9:00

Minutes

1. Welcome and apologies

C2 Head of Unit and the DHoU welcomed the participants. 7 members attended the meeting and 3 apologies received. The representative of SANCO B2 joined the meeting by audio.

2. Adoption of the agenda

The agenda was adopted as presented.

3. Declaration of interests on matters on the agenda

One external expert invited declared an interest which was considered in conflict with the Scientific Committees' Rules of Procedures. His role in this meeting was '*ad hoc*' expert. This means an expert whose role is limited to testify and give specialist advice on a specific issue by providing information and replying to any questions only.

Another external expert declared he may reconsider his future participation, even if his DOI was considered in compliance with the Scientific Committees' Rules of Procedures due to the sensitivity of the subject of this opinion.

4. Rules of procedure of the Scientific Committees and Working Groups

a. The confidentiality/ commitment and DOI forms

It was mentioned that the Committees perform their tasks in compliance with the principles of excellence, independence, transparency and confidentiality. It was mentioned that members of the WG have a permanent duty to declare any interest linked to the subject of the mandate (i.e. surgical meshes). The aim is to have the best scientific advice which cannot be challenged by the failure to fulfil in a timely and complete manner the obligation of declaring the current and past activities of members. It was specified that having an interest does not necessarily mean having a

conflict of interest and the assessment of whether there is a potential conflict of interest is performed by peers (the Chair and the other members of the WG) and the Commission.

b. The statute of external expert (non-voting) and what is the role of external experts within the group

It was mentioned that WG-members are selected based on their expertise. They do not vote. Their roles are:

- To prepare the scientific background for the opinion based on their specific expertise
- To prepare draft report to be finalised and adopted by Scientific Committee
- To strive to reach consensus on the scientific evidence base

Having in mind the duty to deliver an opinion of a good scientific quality and the sensitivity of the topic, in addition to the difficulty to find good experts meeting the independence rules of the Scientific Committees, it was proposed to work with a small WG and to increase the hearing of '*ad hoc*' external experts.

5. Additional External experts

The Chair pointed out that there is a risk to be unable to fulfil the task requested due to the absence of external experts in conformity with SCs rules of independence. The Secretariat stated that, 31 applications were received following an open call for expression of interest. 2 of them were rejected due to non-experience, 1 because was incomplete; out of 28 eligible 21 were excluded because not meeting the Scientific Committees' rules of procedures for independence. Out of the remaining 7, 3 are retired scientists.

It is of outmost importance, to strike the best balance between the best expertise vs. conflicts of interests, between independence and other core values as the delivery of opinions of good quality.

It has been decided to invite 4 experts from the list of applicants and data base of experts to provide the Secretariat with their DOI. Based on the positive assessment of their DOI they can be part of the WG.

6. Discussion on the mandate

The representative of SANCO B2 provided the experts with additional information regarding the mandate and answered to their specific questions.

7. Literature search/review: defining key terms

The approach of literature search was discussed and it was agreed to elaborate a list with key terms in 2-3 weeks' time.

It was proposed to consult the available registries. The Secretariat will try to find a way for collaborating with the Swedish Registry. It was proposed to consult the ones from: Finland, Netherlands, Norway and Austria.

8. Draft Opinion: table of contents, contributions received, distribution of tasks

The group discussed technical matters and produced the structure of the opinion. Different tasks have been distributed among the WG members. The tasks are listed in the updated table of contents (ToC). All contributions have to be submitted to Secretariat by the end of July.

9. Timeline

Timeline was discussed, potential causes of delay and the alternatives along with concrete proposals on how to deal with this.

10. Any Other Business

- Next physical meeting: 15/09/2014.
- The rapporteur of the WG will be elected in September
- The Chair of the WG will attend the AMS Workshop on pelvic surgery, on 03*/07, in Paris