



Scientific Committee on Emerging and Newly Identified Health Risks

SCENIHR

1st meeting of the Working Group on Reprocessed Single-use Medical Devices

15 October 2009

Minutes

1. WELCOME AND APOLOGIES

The Chair of the working group (WG) welcomed the participants and communicated the single apology received.

2. ADOPTION OF THE AGENDA (ANNEX I)

The draft agenda was adopted as proposed.

3. DECLARATION OF INTEREST ON MATTERS ON THE AGENDA

No declarations of interest were made.

4. DISCUSSION ON THE DRAFT OPINION

4.1. Terms of Reference (ToR)

The WG discussed the ToR and suggested one modification of the ToR to enhance the clarity of the mandate. DG Enterprise and Industry (ENTR) agreed with the proposal.

The final mandate is available at the following webpage:

http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_q_021.pdf

4.2. Documentation

The WG decided that additional, specific information would be relevant for producing an opinion. In agreement with the Commission they proposed to publish a Call for information focusing on documented evidence for cases where the use of reprocessed medical devices intended for single use has either caused physical injury to patients or has transmitted infections/cross contamination. The call would be published at the following webpage:

4.3. External experts

The WG decided that it would need additional expertise in the fields of sterilization, hygiene, biomaterials, cardiology, surgery, and, possibly, ophthalmology. Suitable scientists were identified through a combined search in the Pool, the Database, and in the scientific literature. They would be invited to participate in the Working Group starting from the next meeting.

4.4. Structure of the opinion

The WG decided on a provisional structure of the opinion.

4.5. Distribution of tasks

A preliminary distribution of tasks to current members of the WG was done.

4.6. Time schedule

Contributions would be sent to the Secretariat in due time for preparing a revised draft to be discussed at the next WG meeting.

The Secretariat informed members that due to the deadline of the mandate, no public consultation on the preliminary opinion would be carried out.

The WG decided on future meeting dates. These will be confirmed by the Secretariat via an official invitation in due time.

4.7. Practical issues

Relevant background material would be collected at a CIRCA-webpage to which members would have access.

5. ANY OTHER BUSINESS

None.

ANNEX I

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Agenda

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- 4. DISCUSSION ON THE DRAFT OPINION**
 - 4.1. Terms of Reference (ToR)**
 - 4.2. Documentation**
 - 4.3. External experts**
 - 4.4. Structure of the opinion**
 - 4.5. Distribution of tasks**
 - 4.6. Time schedule**
 - 4.7. Practical issues**
- 5. ANY OTHER BUSINESS**