



**Scientific Committee on Health, Environmental and Emerging Risks
(SCHEER)**

**8th Meeting of the Working Group on
Guidelines on benefit - risk assessment of Phthalates in Medical Devices
- 8 January 2019 -
Minutes**

1. Welcome and apologies

The Chair welcomed all the participants who attended the meeting. Two participants apologised and 7 participated via audio.

2. Adoption of the agenda

The agenda was adopted.

3. Adoption of the minutes of the 7th meeting held on 28 November 2018

The minutes were adopted and published on 12 December 2018:

https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_miwg_104.pdf

4. Declaration of interests on matters on the agenda

The Chair invited participants to declare any interest regarding matters on the agenda. None of the participants declared any interest conflicting with the matters on the agenda.

5. Literature search

Some papers on risk-benefit analysis were checked and ISO documents were reviewed.

6. Guidelines on benefit - risk assessment of Phthalates in Medical Devices

The revised draft document based on comments received from the WG members has been discussed again, chapter by chapter. Annexes have also been discussed and commented.

8. Distribution of tasks

Comments from the WG members and SCHEER plenary members will continue to be collected and will be addressed during the next meeting of the WG on 18 and 19 February, in order to be prepared for the SCHEER written adoption and publication around mid-March.

9. Any Other Business

A public hearing is planned on 4 April 2019 in Brussels. Details will be published in due time, beginning of February: https://ec.europa.eu/health/scientific_committees/open_consultation_en