



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

**7th Meeting of the Working Group on
Guidelines on benefit - risk assessment of Phthalates in Medical Devices
- 28 November 2018 -
Minutes**

1. Welcome and apologies

The Chair welcomed all the participants who attended the meeting. Five participants followed via audio.

2. Adoption of the agenda

The agenda was adopted.

3. Adoption of the minutes of the 6th meeting held on 17 September 2018

The minutes were adopted on 24 September and published on 30 October 2018:

https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_miwg_103.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

The MEDDEV 2.7/1 revision 4 - Clinical evaluation: a guide for manufacturers and notified bodies under directives 93/42 and 90/385 was checked.

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, chapter by chapter.

Annexes, including detailed information, will be discussed at the next WG meeting.

8. Distribution of tasks

Comments from the WG members will continue to be collected and addressed before Christmas holidays so that a revised version can be prepared for the WG members for further discussion next year.

9. Any Other Business

A public hearing is planned early April 2019. Details will be confirmed next year and a publication will be advertised in due time.