

Scientific Committee on Health, Environmental and Emerging Risks

(SCHEER)

9th Meeting of the Working Group on Guidelines on benefit - risk assessment of Phthalates in Medical Devices

- 18 & 19 February 2019 -

Minutes

1. Welcome and apologies

The Chair welcomed all the participants who attended the meeting. One participant apologised and six participated via audio both days. The Chair welcomed the mandating DG GROW both days, as well as DG JRC during the second day. Both Commission services are observers.

2. Adoption of the agenda

The agenda was adopted.

3. Adoption of the minutes of the 8th meeting held on 8 January 2019

The minutes were adopted on 24 January 2019. They will be published on the web: <u>https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_miwg_118.pdf</u>

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

The revised draft document based on comments received from SCHEER members during their plenary meeting on 7 February, as well as from WG members, was discussed and modified, chapter by chapter. Annexes will be further commented by writing process.

6. Distribution of tasks

Comments from the WG members will continue to be collected and will be addressed during the next days as the WG is planning a last WG meeting on 5 March to finalise both documents: the Guidelines and the Annexes. The SCHEER written adoption is foreseen from 8 to 15 March and the public consultation from 18 March to 29 April.

7. Any Other Business

A public hearing will be on 4 April 2019 in Brussels. Details were published beginning of February.Registrationismandatoryby6March2019:https://ec.europa.eu/health/scientific committees/events/ev20190404 en