



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

11th Meeting of the Working Group on Guidelines on benefit - risk assessment of Phthalates in Medical Devices

15-16 May 2019

Minutes

1. Welcome and apologies

The Chair welcomed all the participants who attended the meeting. Five members apologised. EFSA and EMA did not participate.

2. Adoption of the agenda

The agenda was adopted.

3. 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.

4. Adoption of the minutes of the 10th meeting held on 05 March 2019

The minutes were adopted and published on the website on 25 March 2019:
https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_miwg_120.pdf

5. Adoption of the minutes of the Hearing held on 4 April 2019

Minutes of the Hearing held on 4 April were adopted and published:
https://ec.europa.eu/health/scientific_committees/events/ev_20190404_en

6. Feedback from Hearing meeting held on 4 April in Brussels

An expert in blood was required during the Hearing in order to finalise the Guidelines' document while following-up the issue of blood bag system. The most relevant expert has been selected from the EU database, after consultation of the Reserve list, to join the WG.

7. Feedback from the public consultation process

This consultation process ended on 29 April 2019. Commission received 197 entries/comments that have been forwarded to SCHEER for discussion and drafting responses that will be published later.

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

The revised draft documents based on comments received during the public consultation were discussed and modified, page per page. The Guidelines and Annexes have not been finalised yet.

9. Distribution of tasks and timeline

The Rapporteur will circulate the updated version to the group by the end of the month so that members can comment before the foreseen new audio meetings in June.

The SCHEER adoption is foreseen during their plenary meeting o 18-19 June 2019.

10. Any Other Business

The mandating DG informed that a last consistency check will be made from their side during the summer before publication, which is now planned most probably after summer.
