



MINUTES

Gold Work Group Meeting

Chair: Steven Verberckmoes

21 March 2017, 10:00 – 10:30

Teleconference



1. Welcome and Introduction

1.1. Reminder on Confidentiality and Competition Law

Participants are reminded on their obligation to comply with confidentiality and competition laws. All participants to the meeting are acting as moderators in this respect.

1.2. Tour de table and apologies

The list of participants is available in Annex 1.

1.3. Objectives, previous WG meeting minutes' approval, agenda approval

The objectives of the meeting are to update Members of the Gold Work Group ("the WG") on the current status of the different phases of the project, to exchange critical information on the elements necessary to timely progress in the making of the registration dossier, and to agree on the next steps for its finalisation. The slides presented during the meeting are available in Annex 2.

The draft agenda is approved as distributed and is available in Annex 1.

Minor revisions were received on the minutes of the WG meeting on October 16, 2016 and are approved by the WG.

1.4. Status of actions

The status of actions that were agreed at the last Au meeting(s) are presented on slides 7 of the meeting's slide deck (Annex 2). Waiving of the flammability endpoint for TCA [A38] is regarded as an unsuitable approach due to the increased manual screening of waiver statements by ECHA and therefore this action is considered completed.

2. Phase III: Testing programme & Exposure Scenario Data Collection.

2.1. Physicochemical Analyses, TCA

For the flammability endpoint of TCA, care should be taken using waivers for this endpoint. No suitable column II statement can be used and ECHA has increased their manual screening of waiver statements, as has been observed on other dossiers. Proposed is to complete this endpoint using an weight-of-evidence approach. A non-exhaustive list of information that can be taken into consideration:

- No flammable products are formed during the decomposition of TCA (Otto et al., 2014)
- The oxidation state of gold in TCA
- The oxidising properties of TCA
- Presence of chlorine
- Hygroscopic nature of TCA



Johnson Matthey, the LR for TCA, has proposed to take the lead in drafting this weight-of-evidence [A40]. All WG members are invited to share additional information.

2.2. Mammalian Toxicity Analyses, TCA

The in-life phase of the OECD 422 with TCA has ended end of January and a draft report is expected by May 2017.

To complete the gene mutation endpoint it was agreed to use a weight of evidence approach, where the information of the partial OECD 474 study with Covance and additional analytical data on gold exposure upon TCA dosing will be combined. [A39] To confirm exposure of the target organ to TCA in the OECD 474, remaining urine and blood samples from the DRF Covance study were analysed for the presence of gold. Previously, detection of gold in bone marrow slides from the OECD 474 were undertaken by Umicore, but proved to be technically too challenging due to the biological background of the samples. Analyses from the blood and urine samples showed a difference between treated and non-treated samples, although no significant difference was observed between the different TCA doses.

3. Phase V: Dossier finalisation

Finalization of the TCA dossier is foreseen by Q3 2017. As results of the OECD 422 retest are predicted to be available by May 2017, reviewing of this key study and the exposure work should occur by the agreed deadlines.

4. Budget

The bigger part of the 2017 budget is reserved for the OECD 422 retest and the occupational exposure work for TCA. The 'to be invoiced budget' takes also the reimbursement by Covance into account. Additional extra budget is foreseen for rebuilding the reserves of the project.

5. AOB

As we are nearing the 2018 deadline, most of the compounds have already been registered. For the next Gold WG meetings only updates related to the TCA dossier will be discussed and therefore the format of the meeting is up for discussion. Instead of having a face-to-face meeting, the WG meeting can be held by conference call in March to give the most important updates. If urgent matters arise a face-to-face meeting could be scheduled *ad hoc*.



6. List of actions and decisions

Table 1. Actions agreed on at the Au WG meeting of 19 April '16

[A]	WHAT	WHO	WHEN
40	Weight-of-Evidence, flammability endpoint TCA	NR	May '17
41	Weight-of-Evidence, <i>in vivo</i> gene mutation endpoint TCA	WCA/SV	Jun '17

7. Annexes

1. Approved Agenda and List of participants
2. Slides presented during the meeting