



MINUTES

Gold Work Group Meeting

Chair: Steven Verberckmoes

6 October 2016, 11:30 – 12:00

Metals Conference Centre
Rue du Duc 100, Brussels (Belgium)



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.

The minutes of the WG meeting on April 19, 2016 are approved.

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). All actions were completed and can be summarised as follows:

A reimbursement of the OECD 422 and 474 studies was agreed and signed by Covance and PMC. At this moment we are awaiting the payment and are urging Covance get this in order. This reimbursement will be kept on an account in pounds, to cope with the recent devaluation of the pounds.

LPT, Germany, was chosen to start the retest of the dose range finding and OECD 422 with TCA.

2. Phase I

2.1. Inventory and latest classifications

No changes to the classification were made.

3. Phase II: Data gap analysis & ITS

For the flammability endpoint of TCA an expert judgment waiver will be used, based on the oxidation state of gold in TCA. This is also in accordance to statements made in other dossiers. WCA will be asked to include this waiver in the dossier. **[A38]**



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

4.1. Physicochemical Analyses, TCA

The remaining physicochemical endpoints, water solubility and particle size distribution, were completed for TCA.

4.2. Mammalian Toxicity Analyses, TCA

Currently the OECD 422 is ongoing and a draft report is expected by April 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.

5. Phase V: Dossier finalisation

The dossiers for gold (CAS n° 7440-57-5), Balsams (CAS n° 68990-27-2) and Aurio(1+) 2,6,6-trimethylbicyclo[3.1.1]heptanethiolate (CAS n° 68365-87-7) have been finalized and submitted by the LR.

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

6. 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.

7. 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*.

8. List of actions and decisions

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

[A]	WHAT	WHO	WHEN
38	Waiver statement, expert judgement on flammability of TCA based on the oxidation state of the compound	EPMF/WCA	Dec '16
39	Completion of the gene mutation endpoint by a weight of evidence approach.	EPMF/WCA	Jun '17

9. Annexes

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