



MINUTES

PMCN Work Group Meeting

Chair: Steven Verberckmoes

21 March 2017, 10:30 – 11:00

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 Precious Metal Cyanides ("PMCN") 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 October 16, 2016 are approved.

1.4. Status of actions

The status of actions that were agreed at the last PMCN meeting(s) are presented on slides 7 of the meeting's slide deck (Annex 2). All actions were completed.

2. Phase III: Testing programme

2.1. Progress testing programme $KAg(CN)_2$

As for the combined repeated dose toxicity study (OECD 422) no toxicity was observed at the highest dose level of 10 mg/kg bw/day, even though this dose is already quite close to the LD50 of 21 mg/kg bw, additional analytics of blood plasma and urine samples are ongoing to confirm exposure. As the OECD 422 study was performed as planned, the additional analytics should not influence the outcome of the study. The final results of these analytics are expected in June '17 and have an impact the registration timing.

The testing proposal for the *in vitro* gene mutation endpoint has been drafted and commented by the WG.

3. Phase IV: Testing programme

Only for the inhalation route for long-term systemic effects a DNEL and quantitative risk characterisation was drafted. For the other exposure routes a qualitative risk characterisation was performed, due to the



corrosive properties of $\text{KAg}(\text{CN})_2$. The Occupational Exposure Scenarios are currently under review by the WG.

4. Phase V: Dossier finalisation

Due to the additional analytics of blood and plasma samples for the OECD 422 with $\text{KAg}(\text{CN})_2$, the dossier can only be completed in June '17. Therefore it is agreed that the review of the dossier by the WG will start without the final OECD 422 study report attached and approval of the WG will follow immediately after the final study report is incorporated. Although finalisation is later foreseen at previously predicted, registration of $\text{KAg}(\text{CN})_2$ in Q3 2017 is still on schedule.

5. Budget

The final accounts of 2016 were presented on slide 17 (Annex 2). Project reserves are healthy and contain about €80,000 more than minimum reserve needed. The WG approved that this additional amount is kept in the reserves for now and to be used to finance the additional analytics for $\text{KAg}(\text{CN})_2$ (\pm €30,000) and the rest to be spent in the coming years.

A draft budget for 2018 was proposed, reserving some budget for the ad hoc updates of the submitted dossiers and anticipating on the conduction of the proposed *in vivo* gene mutation study with $\text{KAu}(\text{CN})_2$. It is requested by the WG to give further guidance on the future tasks by the WG.

6. AOB

For the upcoming WG meetings in October, a discussion is planned on the future work by the PMCN working group.

7. List of Annexes

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