CONCLUSIONS

Actions are highlighted in yellow

1. **Welcome and introduction**
   a. **Confidentiality & Competition Law.** Participants were reminded on their obligation to comply with confidentiality and Competition Law rules.
   b. **Tour de table.** The list of participants is available in Annex 1.
   c. **Approval of the minutes of the last cc 13 Dec 2011.** The minutes were approved.
      i. Follow-up of agreed actions: All actions have been done or are on-going and addressed today:
         - **Action 1.** Evonik confirmed not having any useful data to provide to PMC.
         - **Actions 2. and 3.** Member companies involved in pharmaceutical applications of Au compounds were contacted but indicated not having any additional information; it was agreed that contacting non-Member companies to obtain access to studies on Au (1+) compounds would probably be administratively very burdensome and expensive, without having any certainty on the relevance of their data to fulfil REACH purposes (often formulations containing Au rather than Au-alone are tested). Cf. item 2.c below.
         - **Actions 4., 6., 10. and 11.** Ecotox dose-range finding study results were used as a checkpoint to determine potential pH issues; none were identified. Mammalian toxicity testing programme will consider outcome of discussions on pH-related issues with D. Kirkland and bio-elution test results.
         - **Action 5.** Sample provider of Au provided a sample fulfilling the conditions of the bio-elution testing protocol.
         - **Actions 7. 12., and 13.** On-going.
         - **Action 8.** The tests were finalised before PMC could decide whether to stop these.
         - **Action 9.** Potassium dicyanoargentate was finally received and the test programme was finalised.
   d. **Approval of the Agenda.** The Agenda (Annex 1) was approved. The slides which were presented at the conference call as available in Annex 2.

2. **Au project**
   a. **Test status/progress:**
      i. **PSD and N-BET.** Done by Member company on sample equivalent to the one used for bio-elution testing. Action finalised.
      ii. **Bio-elution.** Starting at CIMM w/c 28 April 2012; update expected by end May 2012, just before CIMM dissolves and/or loses its known experts.
      iii. **Genotoxicity.** Ames test starting end Apr-mid-May, micronucleus test scheduled to take place in Jun, and HPRT gene mutation/MLA study starting end Aug 2012 if Ames and micronucleus were negative. **Post-meeting note:** *cf. Annex 3.*
      iv. **Ecotox (Algae, Daphnia, ASRIT).** All tests finalised, reports available for comment, no change in ecotoxic profile of TCA (Aq Chronic 3 remains).
   b. **PBT assessment of Gold balsams.** Conducting a biodegradation test for this substance would be very challenging due to the low solubility and lack of compositional data. Hence, WCA proposed to estimate the partition co-efficient of balsams on the basis of water solubility data (based on Au and Total Organic Content), which results in a value which is several orders of magnitude below the threshold for Bioaccumulation (log KOW 4,5). It is hence extremely unlikely that the substance is bioaccumulative, and it should therefore not be classified as PBT (cf. Annex 4). The REACH Annex III assessment of balsams can now be finalised.
   c. **Literature search on Au 1+ and Au 3+ and proposed way forward.** The literature search performed by WCA (Annex 5) indicated there is likely to be insufficient data in the published literature to fill the required endpoints for TCA under REACH (**Post-meeting note:** *S. Verberckmoes confirmed that no additional information was found in Umicore's database*

either). The first option to contact potential data holders from the pharmaceutical industry was deemed too burdensome and uncertain (cf. item 1.c.i above) compared to the second option to actually perform an OECD 422 test rather than reading across from another test item. Before the OECD 422 test can be conducted however, a number of issues need to be addressed, namely pH and how to proceed with the proper neutralisation of TCA before administration. Read-across from TCA to the other Au compounds will be confirmed/refined in due course.

3. **PM CN- project**
   a. **Contact with CuCN registrants: ECHA Helpdesk, SIEF, Cu compounds Consortium.** All attempts to contact the (Lead) Registrant of Cu cyanide has failed so far. Having looked at the ECHA Dissemination Portal for CuCN though, it does not seem as the registrants of this substance have developed a specific testing or assessment approach and instead, that they have read-across from existing HCN *et al*. data. A direct approach to the Cu Consortium has been tried as a last resort.
   b. **Test status/progress:**
      i. **Dustiness.** Finalised, inhalation is not a relevant exposure route and inhalation testing can hence be waived under REACH.
      ii. **Ecotox (Daphnia, ASRIT).** All tests finalised, reports available for comment, no change in ecotoxic profile.
   c. **Update (-d report) on modelling of PM CN- toxicity (if available).** Modelling of toxicity was validated by eco-toxicity testing for Ag cyanide compounds but not for Au ones, where the speciation remains unclear and hence actual testing is recommended instead (**Post-meeting note:** cf. Annex 6). The group agreed to proceed with testing.
   d. **Analysis of free cyanide (Intertek proposal & quotation dd 16 & 27 March 2012).** Based on the outcome of the above modelling exercise, as regards the mammalian toxicity testing programme, instead of engaging into a full testing programme directly, it is recommended to validate an approach to measure free cyanide first. The approach proposed by Intertek was discussed; the proposed colorimetric reagent (which has a high affinity with CN) may cause an overestimation of the free CN concentration and it was proposed to use another reagent or ion-selective electrode method instead. **Post-meeting note:** *Heraeus experts held a conference call with Intertek representatives on 9 May 2012 (Annex 7.1) and agreed obtain stability constants to be used to calculate the amount of free cyanide that is likely to be released, which could be subsequently validated using analytical measurement. Preliminary calculations were shared by Heraeus with Intertek on 18 Jun 2012 (Annex 7.2).*

4. **ITS reports: way forward for updates and addenda.** Rather than preparing regular updates of the ITS reports, it was agreed to prepare individual reports for each on-going discussion item, which could be attached as an addendum to the ITS. Once the REACH registration process is finalised, the individual addenda could be integrated at once in a unique ITS summary report.

5. **AOB, next cc/mtg and closing remarks.** It was agreed to hold the next cc after Intertek has reverted with an alternative suggestion to analyse free cyanide.

Annexes:
1. Agenda and list of participants
2. Slides presented at the conference call
3. Conclusions of conference call on genotoxicity testing programme on TCA
4. WCA's report on PBT assessment of Balsams
5. WCA's report on literature search on TCA-related salts
6. WCA's report on modelling of PM CN mixture toxicity assessment
7. Conclusions of WCA+Intertek+Heraeus cc on analysis of free cyanide