Chairman: *Dave Boyd* (Johnson Matthey)

16th November 2011, 10:00 – 11:00 CET

List of participants

Angela Alderman	Johnson Matthey	United Kingdom
Bodo Berkner	Ferro	Germany
Dave Boyd	Johnson Matthey	United Kingdom
Roland Brasch	Heraeus	Germany
Natalie Dom	Umicore	Belgium
Manfred Probst	C. Hafner	Germany
Mark Raffray	Johnson Matthey	United Kingdom
Klaus Rothenbacher	EPMF	Belgium
Mike Shepherd	Vale	United Kingdom
Hege Stubberud	Xstrata	Norway
Rüdiger Thiele	Heraeus	Germany
Steven Verberckmoes	Umicore	Belgium
Roland Winde	Umicore	Germany

Minutes

1. **Welcome and introduction (DB)**
   The agenda and the minutes of the last meeting have been approved.
   The participants were reminded on their obligation to comply with confidentiality and Competition Law.

2. **PGM project scope**
   - **2.1.** Recent changes in scope
     PMC informed the PGM WG about the following changes in scope
     - RhCl3 and RuCl3: only available/covered in their hydrated form
     - Diamminedichloropalladium: more details on the composition are available
     - PtCl2: removed from scope
     - IrCl4: added to scope
     - PdO2: substance not available for testing

     There were no objections/ questions to these changes.
   - **2.2.** Blacks/ nano-materials
     The WG agreed with the proposed way forward:
     - Confirm member interest in the metal blacks
     - Check if blacks meet the new EU definition for nanomaterials (PSD, surface area)
     - Evaluate above data along with results from dustiness tests before deciding on further tests

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2.3. Registration of substances in 100-1000 tpa band (2013 deadline)
Three substances will require registration in 2013:

	Highest tonnage	Deadline	Dossier
Diammonium hexachloropalladate *(Intermediate)*	• SCC: 100-1000 tpa • Non-SCC: 10-100 tpa	• 2013 • 2018	• Available info. • Full dossier
Diammonium hexachloroplatinate *(Intermediate)*	• SCC: 100-1000 tpa • Non-SCC: 10-100 tpa	• 2013 • 2018	• Available info. • Full dossier
Diammine dichloropalladium *(Substance)*	• 100-1000 tpa	• **2013**	• **Full dossier**

Diamminedichloropalladium: it was agreed to subject the substance to a "fast track" testing approach (option 1 in the slides) and attempt to develop a complete dossier by 2013.
PMC has proposed a corresponding "Fast track test plan" (circulated on 15 November) detailing how practically this could be achieved. There were no objections to the proposed plan.
Action: Members to review the fast track plan and raise potential comments/ questions by 25th November 2011

Due to time limitations, it will not be possible to request multiple quotes, compare them, and then discuss which lab we would prefer to work with. PMC therefore proposed for this particular case to work with a limited set of CROs that we worked with previously for PGMs and for other projects (e.g. Re). This was agreed. The final choice of CRO will depend on their confirmed price and availability.
The task of validating dose formulations (stability, homogeneity, etc) was identified as a major bottleneck. This will be given highest priority as soon as decision for CRO has been made.
Action:- PMC to initiate discussions with CROs, get definitive quotes and reserve lab space.
- **If no objections by 25th November, PMC to commission the testing.**

Timing: it was appreciated that the timing for the fast-track programme is very ambitious, however it has just become more achievable since it is likely that no acute inhalation test will be necessary (s. agenda point 3.2.4). In case, due to unforeseen circumstances, the testing will not be fully completed by the deadline, a tentative DNEL will have to be developed, which will then be used in the risk characterization. The PGM WG agreed with this approach.

PMC reminded the members that the success of the fast track programme will depend on the ready availability of the test material. If the material has not been received by the CRO at the foreseen time, the tests obviously cannot be conducted in time (see also discussion under agenda point 5.2). The PGM WG recommended to develop an improved sample tracking sheet that can summarize the different sample requests per company.
Action: PMC to develop company specific sample tracking sheet

For the two intermediates (Diammonium hexachloropalladate and diammonium hexachloroplatinate) it was decided to progress these along with the main body of PGM test work ("normal track") and thereby report all available information generated by the time the 2013 dossier is submitted (option 1 in the slides). This may necessitate update of these dossiers at a later stage.

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2.4. Karstedt concentrate

The PGM WG agreed with the proposed way forward on the Karstedt concentrate

Action: PMC to formalise collaboration with Reconsile consortium

Once a formal collaboration is established: PMC to meet with WCA and Reconsile consultants (PFA) to discuss way forward

3. ITS Reports – update on progress

3.1. Recap of recent developments

The initial ITS reports had been slightly delayed: reports were received end August/ early September instead of June. Following a PEG commenting round in September, the draft final reports have now been received by PMC.

Action: PMC to circulate draft final ITS reports

These ITS reports will need to be updated once the results of the enabling tests are available. This is foreseen for Q1 2012.

Data base: PMC informed the PGM WG that they are working on a data base. PMC are also reviewing their current IT tools (ReachSuite) since this has not been user friendly and that they are considering moving to a better system.

Action: PMC to establish data base of available information

3.2. Enabling- /phys.-chem. tests

3.2.1. Oxidising properties

The tests are ongoing. The tests were slightly delayed due to the fact that one sample (Ruthenium IV oxide) arrived late. The tests should be completed in November.

3.2.2. Water solubility testing

Some additional tests on water solubility are ongoing. The presented strategy, a combination of standard shake-flask tests, non-standard shake-flask tests and TD tests had been agreed previously with the PEG. There were no objections.

3.2.3. Bio-elution testing

A contract is currently being drawn up with the testing lab (CIMM).The project scope was briefly reviewed: an open question was whether or not to include the metal blacks in the scope. PMC recommended to ask the lab to put in placeholders for the 4 blacks ("optional substances") and finalise the contract on that basis. The final scope can then be reviewed once the assessment discussed above (point 2.2) is completed. This approach was agreed by the PGM WG.

Action: PMC to finalise contract with CIMM and start bio-elution tests

3.2.4. Dustiness testing

The tests on 9 materials at DMT have been completed and test reports were circulated. WCA is currently manipulating the data and carrying out lung deposition modelling (MPPD). It was noted that the metal blacks are included in this testing scope. These results will further inform the assessment discussed under point 2.2.

Initial data for dustiness and MPPD were presented for the fast track substance Diamminedichloropalladium. The full data (report by WCA) were circulated in advance of the call on 15th November. The WCA report used 2 different models (symmetrical model and 5-lobar model) and then used 2 different breathing modes (oronasal and oral only) for each model. This was done to demonstrate that these different methods all lead to similar conclusions. PMC recommended for future work to focus on one setting for further MPPD evaluations and use this report as a rationale for this. For consistency, it was proposed to use the same settings as were used for our silver dossiers. This was agreed.

The MPPD results for Diamminedichloropalladium demonstrated that there is very little potential for inhalation exposure (< 1%). PMC therefore recommended to waive testing of the acute inhalation route. This will also save time and allow the dossier to be completed on time. This was agreed.

3.2.5. In-vitro irritation testing

Tests are currently ongoing at CiToxLAB (EPISKIN/ ICE tests) and at Harlan (EPISKIN/ BCOP). No further discussion was required.

3.3. Ecotox testing

The testing plan for ecotox testing was presented. There were no objections by the group.

3.4. Mammalian tox testing

3.4.1. Genotoxicity

Initial testing recommendations have been developed, however an expert assessment is required on 2 issues

- Impact of extreme pH on genotoxicity study results
- (Apparently) conflicting study results on Rh (III) substances

PMC is currently consulting on these issues with independent genotoxicity expert (David Kirkland).

3.4.2. Sensitisation

Similar to the genotoxiciy tests, initial testing recommendations have been developed. The final scope will depend on the outcome of the (ongoing) irritation tests

3.4.3. Irritation

This point was already discussed under point 3.2.5. No further discussion was required.

3.4.4. Acute tox (oral/dermal/inhal)

The testing strategy was presented. Reach requires testing a second route of exposure in acute toxicity testing for substances > 10 tpa (Annex VIII). In order to be able to decide on the second route of exposure, the data generated by the enabling tests are needed:

- Data on dustiness (is inhalation relevant at all?)
- Bio-elution (what is the predicted bioavailability characteristic in artificial respiration fluid?)
- Irritation
- Practicalities (can stable testing atmosphere be created?)

A final decision will be made once the data from the enabling tests are available. This will be documented in an updated ITS report.

4. CLP

PMC is preparing an update of the PGM classifications for Q1 2012. This is due to the fact that some classification changes are required due to new data (see discussion 6th April 2011 PGM WG call) and that further changes may be possible as new test data are generated. Moreover, the 2nd ATP to CLP has come into force and will need to be implemented by Dec. 2012. The 2nd ATP includes changes on sensitization (skin/ resp.) and environment classification (chronic effects, new M factors, etc). PMC is currently reviewing the classifications to make sure that they comply with the 2nd ATP.

Action: PMC to provide CLP update report in Q1 2012

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5. Next Steps

5.1. Review overall timeline

5.2. "Fast-track" timeline

Sample provision: this has become the bottleneck in the PGM testing programme, in particular for the fast-track testing, where time is of the essence. In order to facilitate this process, the following approach was proposed

- PMC to estimate the total amount of substance needed for the testing programme
- PMC to select CRO that can ship sub-samples to other test houses
- Companies to ship the total sample amount to the above CRO, which then handles further shipping of sub-samples
- Since companies can now invoice the full sample cost to PMC upfront, they will not incur any increased net costs.

This approach was agreed by all participants of the call.

Action: PMC to confirm the above approach with companies not represented at this call

6. AOB, next meeting and closing remarks

6.1. Agreed actions/timeline

The next conference call will be scheduled after the enabling tests have been completed and a draft revised ITS is available. This is planned for Q1 2012 but the exact timing remains to be confirmed.

Action: PMC to propose date for next PGM WG call in January/February 2012

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