SUMMARY OF THE INDUSTRY TASK GROUP MEETING HELD AT 09:00
ON 17 MARCH 2015 AT THE CIVITAS BUILDING

Present

**MRA/DoH**
Alice Sigobodhla (ASi)  Estelle Taute (ET)  Ndimuhulu Dowelani (ND)
Shyamli Munbodh (SM)  Jerry Molokwane (JM)  Khamusi Mutoti (KM)
Hellen Moropanye (HM)  Themba Nukeri (TN)  Momeena Omarjee (MO)
Dorah Diale (DD)  Davis Mahlatji (DaM)  Enos Motshitela (EM)
Griffith Molewa (GM)

**Industry**
Judy Coates (JC)  Nicole Edelstein (NE)  Nerine du Plessis (NdP)
Anita Smal (ASm)  Vivian Frittelli (VF)  Ernest Schay (ES)
Hayley Eager (HE)  Robyn Daniel (RD)  Tebogo Sebata (TS)
Avanthi Bester (AB)  Salma Ismail (SI)  Rhoda Kruger (RK)
Deepa Maharaj (DeM)

1. **WELCOME AND APOLOGIES**

ASi chaired the meeting and welcomed everybody to the meeting.

Apologies were received from: Joey Gouws, Portia Nkambule, Silverani Padayachee, Kaizer Thembo, Celecia Pleass, Abeda Williams, Sanjay Lakha, Merle Scher, Trevor Phillips, Muhammad Bodhania, Stavros Nicolaou, Miranda Viljoen, Lynette Terblanche, Leigh Howes, Bulelwa Maponya, Tanya Vogt, Corinne Pillai and Allison Vienings.

ASi gave general feedback:
- JM is acting as Director: Inspectorate and Law Enforcement.
- The previous Medicines Control Council (MCC) was dissolved on 31 January 2015. The new MCC has been appointed by the Minister of Health. Prof Helen Rees is the new Chair and Dr Edith Madela-Mntla the Vice-Chair. The first meeting of the new Council will take place on 23-24 March 2015.
- Expert Committees are carrying on as usual ensuring a smooth process.
- 52 positions were advertised and more will be advertised in due course to fill vacancies and gear up for SAHPRA.

NE expressed ITG’s appreciation for the opportunity to meet and announced that Robyn Daniel is the new vice-chair of ITG.

ASi asked for suggestions to make ITG meetings more fruitful and meaningful for everybody.

There is still a perception that messages from ITG meetings are not filtered down as the same questions are being asked. ASi again asked ITG to ensure that the messages are filtered down. NE suggested that the ITG minutes should perhaps also be published on the MCC website to improve communication of the messages. ET asked that this proposal be sent to the Registrar.

**Action item:**
- ITG to send a proposal to the Registrar that ITG minutes should be published on the MCC website in future.

2. **APPROVAL OF THE MINUTES OF THE MEETING HELD ON 13 NOVEMBER 2014**

One correction requested under “Present”: Alice Sigobodhla and not Alice Sighobodhla.

The minutes of the meeting held on 13 November 2014 were accepted as an accurate reflection of the meeting.

NE proposed
ET seconded
3. MATTERS ARISING AND FEEDBACK

3.1. Medicines Evaluation & Research

3.1.1. Pre-registration unit
Applicants must ensure that three copies of P&A responses are submitted. One copy is sent to Ops & Admin, one is used for evaluation and one is used to prepare P&A Committee documents.
The revised Biostudies and Dissolution guidelines are due to be tabled at the next Council meeting for finalisation and implementation.
Action item:
- Revised Biostudies and Dissolution guidelines to be finalised and published for implementation.

3.1.2. Post-registration unit
The unit is still busy evaluating amendments from Nov/Dec 2013. The backlog is mainly due to the large number of urgent amendment requests jumping the queue, particularly for API source changes for priority and tender products. Industry was requested to submit more than one API source where possible to reduce the number of post-registration amendments.
Council approved a pilot project for five APIs, where the API manufacturers will submit the restricted or closed part of the DMF directly to the MCC to reduce the necessity to review the same DMF in multiple dossiers. If successful, it will be rolled out to other molecules. The unit will meet with Ops & Admin to map out a process to prevent bottlenecks.
The unit is still experiencing problems with companies resubmitting applications without prior approval from the unit. Applicants need to ensure that they obtain a resubmission number from the unit beforehand.
Guidelines under review:
- The Post-importation testing guideline will be tabled at Council and published for comment. A workshop with interested parties on this revised guideline may be considered if deemed necessary.
- The revision of the Amendments guideline is still work in progress. The requirements for Section 3.2.S in the P&A guideline must first be revised as this would have an influence on the Amendments guideline.
- The Labelling of medicines containing sugars guideline should also be ready to be tabled at the next Council meeting.
Action items:
- The revised Post-importation testing guideline to be finalised and published for comment.
- The revised Labelling of medicines containing sugars guidelines to be finalised and published for implementation.

3.1.3. Biological medicines
KM reported that the documents regarding pre-IND type meetings were finalised and published on the website for implementation.

3.1.4. CAMs
The unit is busy working through the submissions and comments received on the amended draft Regulations and proposed QSE guidelines for Health Supplements. The possibility of hearings will be considered to avoid queries and questions once the documents are finalised.
Reference numbers will not be issued for CAM products previously issued with a Registry number and Registry numbers should not be used on the labelling or PIs and PILs of these products. It is important to ensure that these products comply with the definition for CAMs.
NE queried the current status and labelling requirements for Health Supplements. ASi undertook to get clarity on the issue and issue a written communication to industry to provide clarity.
Action item:
- Written communication to provide clarity on the current status and labelling requirements for Health Supplements to be provided to ITG.
3.1.5. **Veterinary Medicines**

Veterinary antimastitis medicines guideline – the VCC will revise parts of the guideline. The revised guideline will be tabled at the April Council meeting.

Phenylbutazone was declared an undesirable/banned substance. A submission has been made that it should be included in Schedule 6 for equine use only, which will be tabled at Council.

ASI reported that they attended the VICH meeting as observers and are looking at the various guidelines to determine which guidelines can be adopted. A workshop will be held with SAAHA in this regard.

3.2. **Clinical evaluation & trials**

3.2.1. **Clinical trials**

DD reported that the dedicated central e-mail process is being finalised and due to be implemented beginning April.

The Risk-based monitoring guideline is to be tabled at the next Council meeting and will then be published for comment. The Committee is still busy with the review of the CTF1 form. The list of FAQ’s compiled by SACRA is still being discussed. The dispensing by healthcare professionals during clinical trials policy is still being discussed and will be tabled at the April Council meeting.

ASI reported that a guideline for clinical trials for veterinary medicines has been drafted and is being discussed at Committee level. Once finalised, it will be published for comment.

The Committee has raised concerns regarding the quality of submissions. Some are substandard, not properly bound, insurance certificates are missing and there are inconsistencies, grammar and spelling errors. Frustrations faced when reviewing applications will be communicated in writing to industry. It was clarified that the Committee insists on insurance certificates before approval is given to ensure that patients are covered before the trial commences.

It was clarified that recommendations regarding patient reimbursement are aligned with NHREC’s guidelines. An increase may be recommended for children as a caregiver must accompany the child.

**Action items:**
- Dedicated central e-mail addresses and processes to be followed to be published.
- Risk-based monitoring guideline to be published for comment.
- Dispensing by healthcare professionals during clinical trials policy to be tabled at Council

3.2.2. **Pre-registration clinical evaluation**

Nothing to report.

3.2.3. **Post-registration clinical evaluation**

HM appealed to industry to include clear cross references in cover letters where a package insert amendment is submitted post-registration, and the same package insert is included in a line extension submission pre-registration, to ensure that the submissions are sent to the same evaluator.

The process for the implementation of the amended Regulations 9 and 10 was published in December. The concern regarding the unrealistic timeline for implementation was raised again following ITG’s letter in January. Leniency in this regard was requested based on the volume of PIs and PILs affected. Applicants should do their best to comply and have a plan in place to show how they are going about achieving this. There is no need to recall and repack products in this regard.

Applicants should ensure that when submitting new PI/PIL amendments, changes made to comply with Regulations 9 & 10 should also be annotated on the same document so they can be reviewed simultaneously.

SAPRAA will be extending an invitation to the Clinical Unit via the Registrar’s office to present at their June meeting to clarify a number of expectations from MCC with regard to PIs and PILs (both from Clinical and P&A side).
With regard to the discrepancy in headings in the PIL between Regulation 10(1)(b) to Act 101/1965 that states ‘Proprietary name and dosage form’ and the PIL guideline, 2.14_PIL_Dec13_v4, pg 6 that states ‘Proprietary Name, Strength and Pharmaceutical Form’, HM advised that the meaning remains the same even though the wording may differ. Applicants are therefore advised to use the PIL heading as it appears in the guideline rather than the one in Regulation 10. It was noted that this advice was contrary to that given and minuted at the previous meeting. A formal response will be issued to ITG.

ITG submitted a letter to express concern regarding the strict implementation of the SR-PINs guideline which will only allow a small portion of safety updates to be processed as a notification. HM replied that a formal response has been drafted and will be sent to ITG.

**Action item:**
- Response will be sent to ITG regarding the headings in the PIL and concerns expressed in terms of the implementation of the SR-PINs guideline.

### 3.2.4. Pharmacovigilance

ND confirmed that Mukesh Dheda is no longer with the unit. Any queries should be addressed to ND or the person indicated on the letter from the unit.

The Post-marketing ADR guideline is being amended and should be ready to table at the April Council meeting after which it will be published for comment. In the meantime the current guideline should be followed.

Risk Management Plans (RMPs) will be tabled at the PV Committee for the development of a guideline.

DHCPs – clarity was requested regarding the letter received from the PV Committee which requested that “the distribution of DHCP letters should be a dual process encompassing both email and surface mail.” The response was that the preferred method is still postal delivery but that distribution by both methods for a period of time would serve as a pilot study to ascertain the relative effectiveness of each. It was advised that ITG request further clarity in writing in this regard directly from the PV Committee.

**Action items:**
- Post-marketing ADR guideline to be published for comment.
- ITG to request clarity in writing from the PV Committee regarding the distribution of DHCPs.

### 3.2.5. Section 21

SM reported that the Section 21 guideline will be tabled at the April Council meeting.

When emergency authorisation for named patients is required over a weekend, the documentation must be submitted in writing and telephonic approval will be given.

**Action items:**
- Section 21 guideline to be published for comment.

### 3.3. Inspectorate & Law Enforcement

#### 3.3.1. Inspectorate unit

The Guideline for Wholesalers to Export Medicines has been published for comment which is due by 20 May 2015. Of particular importance is that the wholesaler cannot export on its own without the relevant company’s knowledge. This is to ensure transparency and avoid round-tripping.

It was advised that a hard copy of SMFs must be submitted, together with an electronic copy on CD-ROM. It was confirmed that SMF numbers will not be published on the website due to confidentiality reasons.

Guidelines are being drafted on how Inspection Reports should be responded to as well as on requirements for bonded stores.

There is currently a 99% rejection rate for requests for once-off approvals as most are not warranted and are not once-off occurrences. Valid reasons for these requests are necessary.
For type C amendments requiring Inspectorate approval, once P&A approval is received, applicants should confirm the status of the application with the Inspectorate prior to following up with Ops & Admin.

3.3.2. Licensing unit
NE confirmed that consensus could not be reached within ITG regarding the 2D barcode pilot study and it was agreed to remove the topic from the ITG agenda. Individual associations can take the matter forward should they wish to do so.
ITG is still very interested to take the proposal regarding a central repository for PIs forward and to replace the PI in the pack with the PIL. RD asked if a joint working group between ITG and MCC can be established to find a solution. JM requested that a proposal be sent to the Names & Scheduling committee.

Action item:
- ITG to send proposal to N&S Committee regarding the PI repository.

3.3.3. Law Enforcement
ES mentioned that SAAHA submitted a formal complaint to the Registrar regarding autogenous vaccines and a response was still awaited. ASi replied that the Registrars of Medicines, the Veterinary Council and Fertilizers, Farm Feeds and Agricultural Remedies are meeting to discuss issues and present a united front.

3.4. Operations & Administration
Retention fees are due by 30 June every year. Companies are requested to pay asap and not wait until the last minute as payment even a few days late becomes an audit finding.
Routine post-screening submissions submitted January to March 2012 are currently being allocated for evaluation. The fast-track submissions and submissions for priority diseases are taken out of the routine queue and allocated for review depending on availability of the relevant expert evaluators.

**NB: Industry is again requested not to follow-up on products submitted (post-screening) after January to March 2012, unless these were approved for fast-track evaluation.**

Screening outcome letters are being sent for products up to June 2014. If screening outcomes have not been received for products submitted prior to June 2014, applicants can follow-up on these with Santhani Chetty. Acknowledgement letters that applications have been received will be sent to applicants.

Progress is being made in terms of the process that will be followed for multiple submissions of the same application with different proprietary names.
Requests have been received to submit Modules 4 & 5 electronically. These must be submitted to Ops & Admin and are reviewed case by case. The electronic copy will be kept as file copy and the format will be specified by Ops & Admin. Paper copies are still required for evaluators until eCTD is rolled out. Submissions must still comply with requirements and raw data should be removed from paper copies.
Applicants are reminded to apply for fast track review and get the approval letter before submission of the screening copy. A copy of the fast track approval letter must be included in the screening copy.
Two products have been registered via the eCTD pilot, one NCE and one generic. The rollout of the eCTD has been negatively impacted by the lack of IT support. The planned go-live date of June 2015 will depend on the IT infrastructure. The same problems are still being experienced with the responses being submitted for the submissions in the eCTD pilot project. A workshop will be held with Industry to highlight problems picked up during the pilot project.
Requests for meetings with the Chairs of Committees must be channelled through the Registrar's office.
Queries regarding the status of submissions must be made on the applicant's letterhead and must be logged in. Queries sent via e-mail only are not logged in and therefore not recorded.
3.5. **General**

ES mentioned that the VICH guideline on the electronic format for veterinary submissions has been finalised. ASi advised that a request should be sent to the Registrar’s office that this format be considered and adopted.

4. **ANY OTHER BUSINESS**

4.1. **Institute of Regulatory Science (IRS)**

A project manager has been appointed. The IRS will cater for the Regulator and Industry and will be a virtual campus with input from various universities.

4.2. **Medical devices**

Comments on the draft Regulations and guidelines were received. A Unit and Committee are being established and comments will then be reviewed.

5. **NEXT MEETING DATES**

To be arranged once the Council meeting dates for 2015 are confirmed.

*Post meeting note: meeting dates for the rest of 2015 were confirmed as 23 June, 18 August and 10 November.*

6. **CLOSURE**

ASi thanked everybody for their attendance and contributions.

The meeting closed at 11:20.