CAMS: UPDATE & PRACTICAL EXPERIENCES

Henriette Vienings
Friday, 25 November 2016

SAPRAA Meeting

Bytes Conference Centre
Midrand, Gauteng, South Africa

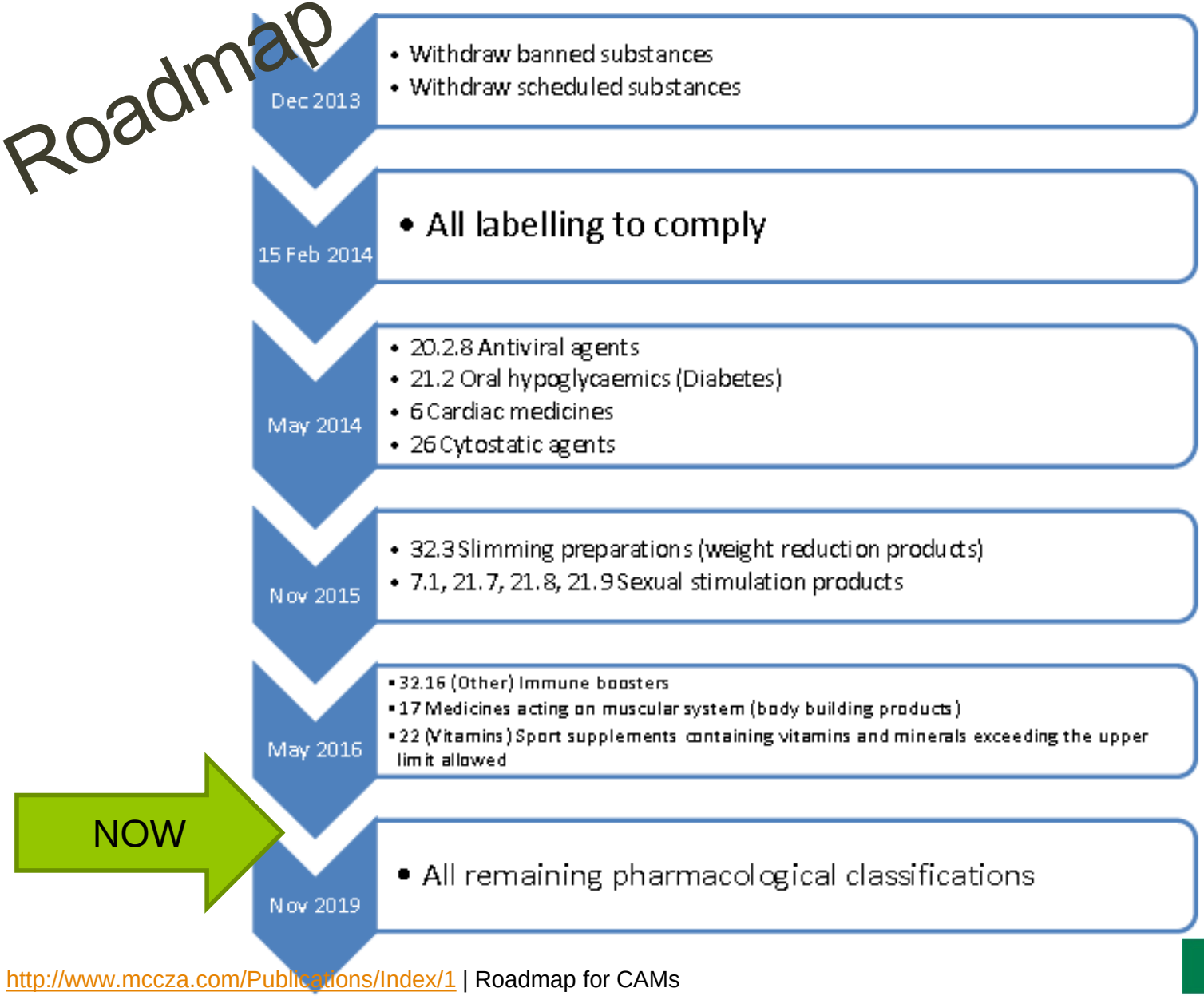
MRA REGULATORY CONSULTANTS

Overview of Presentation

- 2016
  - The Implementation Plan – Where are we?
  - Guideline Updates – CAMs | DS & HS
  - ITG Feedback
  - Experiences from the Registration Process
- 2017
  - Looking ahead

MRA REGULATORY CONSULTANTS

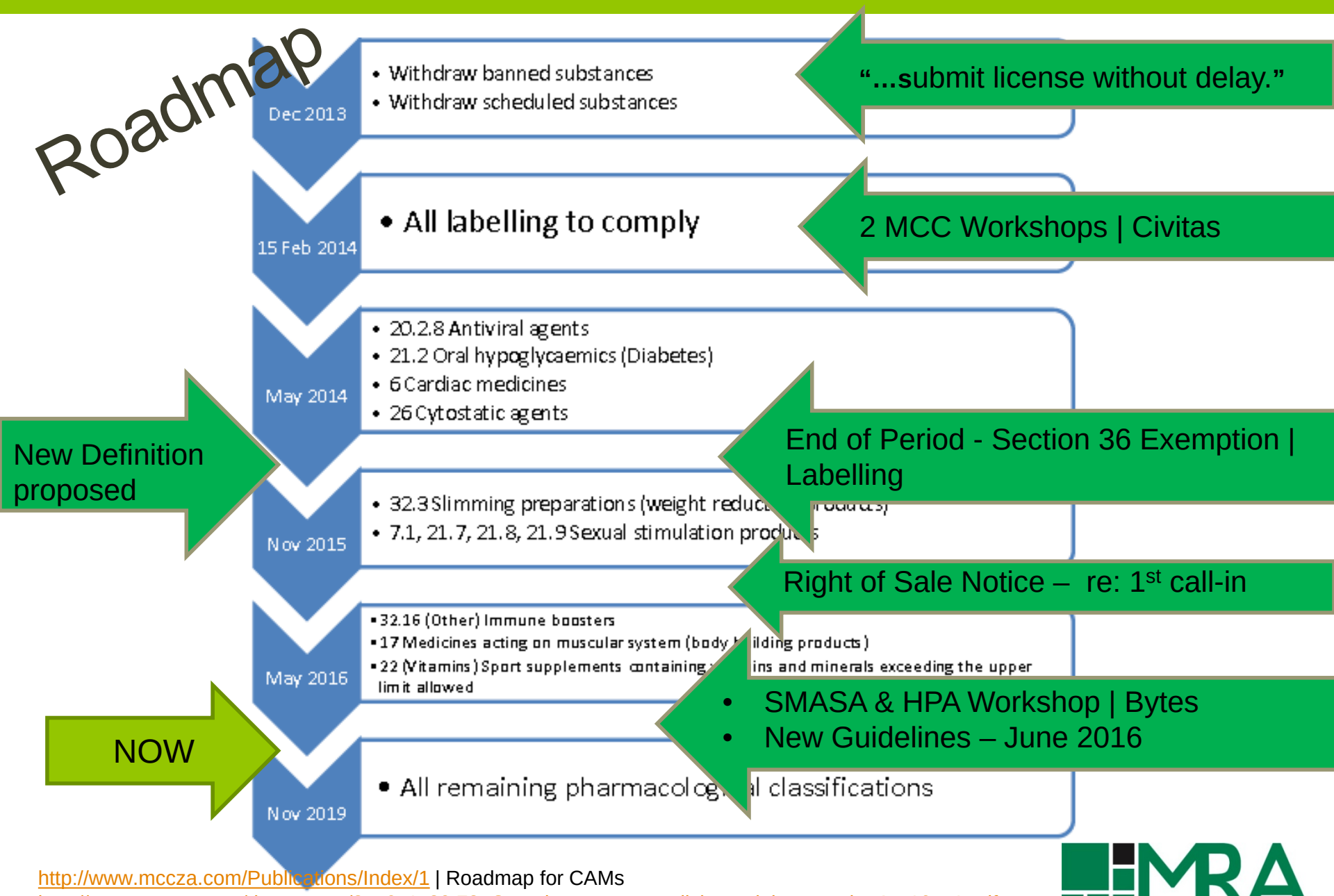
Roadmap



http://www.mccza.com/Publications/Index/1 | Roadmap for CAMs

MRA REGULATORY CONSULTANTS

Roadmap

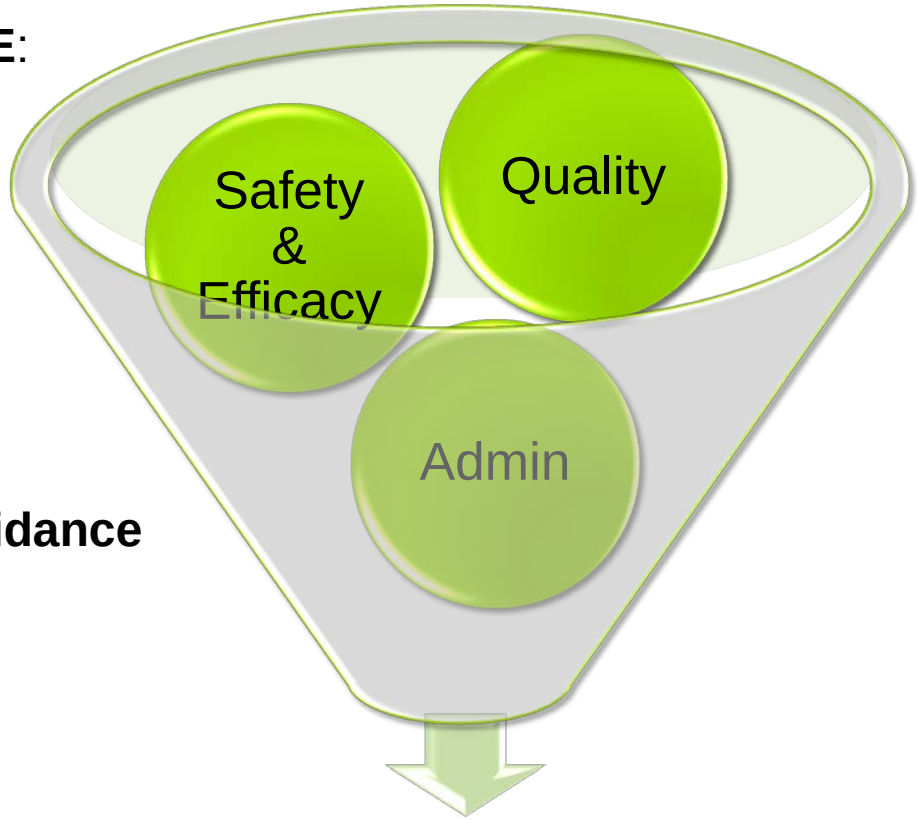


http://www.mccza.com/Publications/Index/1 | Roadmap for CAMs
http://www.mccza.com/documents/2ca6c1c29.72_Complementary_medicines_right_to_sale_Apr16_v1.pdf

MRA REGULATORY CONSULTANTS

CAMs Specific Guidelines | June 2016

2 Guidelines on S&E:
- 7.04 SE HS
- 7.01 CMs SE DS



7.05 CMs Quality
– Applicable to:
- Discipline Specific (DS) CMs, and
- Health Supplements (HS)

Administrative Guidance
7.03 CAMs ZA CTD

Registration Dossier

MRA REGULATORY CONSULTANTS

CAMs | June 2016 - Highlights

- ZA CTD
  - Additional guidance to further references and guidelines
  - Removal of Module 3 information which was consolidated into the Quality guideline

- Quality
  - Expanded explanations for data requirements with extensive guidance and cross referencing to guidelines and other references, as well as the interrelationships of documents within the dossier.
  - Annexure for Stability Testing included

CAMs | June 2016 - Highlights

- Safety & Efficacy | CMs – Discipline Specific
  - Decision Making Tree - useful for classifications & data requirements – Annexure A

- Safety & Efficacy | Health Supplements
  - Decision Making Tree - useful for classifications & data requirements – Annexure A
  - Process for Motivation for Inclusion of Substance as a HS – Annexure B
  - It is necessary to first include the substance in the HS list before submitting a product for registration with the ingredient

MRA REGULATORY CONSULTANTS

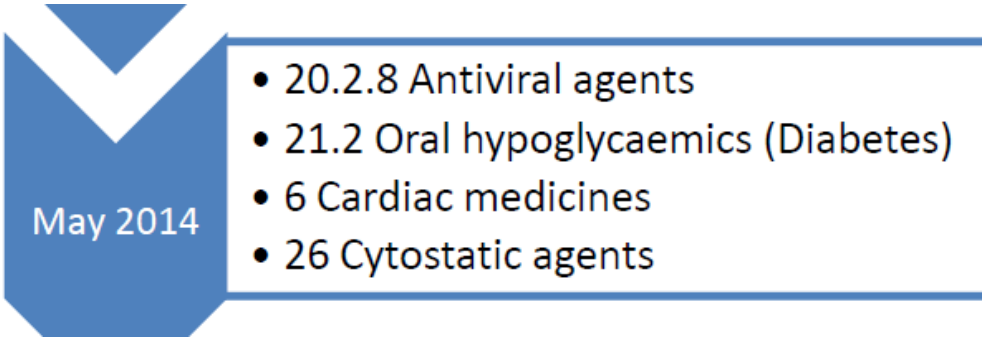
ITG Feedback | CM - Focussed

- From the Minutes of the ITG Meeting on 22 August 2016:
  - Act 72 of 2008 and Act 14 of 2015 await the regulations to be promulgated. Consolidated regulations to amend the General Regulations to the Medicines Act should be published before end of 2016.
  - The Inspectorate is concerned that not all companies selling CMs have applied for licenses
  - Comment period on the amended CM regulations closed on 25 August 2016
  - A Specialist CAMs working group has been established to discuss challenges and find solutions

MRA REGULATORY CONSULTANTS

Experiences from Industry

- Limited experience from evaluation process to share
- Products submitted in May 2014 – High Risk Claims:



- Many products were not accepted into review due to incorrect classifications – they were not CMs
- The products for which evaluation continued have already progressed to recommendation response phase by P&A and Clinical evaluators
- Unfamiliarity with administrative processes are causing misdirects and delays in responses being traced by the CMC

MRA REGULATORY CONSULTANTS

Experiences from Industry

- Data constraints are a critical problem
  - API sources used by many manufacturers do not provide / have no information on the quality of their products, including stability data
  - Many suppliers of ingredients manufacture in accordance with food quality standards and are not willing / able to provide data that is suitable for use in a dossier
  - Methods for testing have either not been developed, or they aren't reproducible and validated
  - Without validated methods, stability programmes and finished product testing produce unreliable results
  - Product Formulations often need to be changed to ensure that the product can qualify as a CM. In the process the previous data or a large portion thereof becomes unsuitable for use in a dossier. Data generating in essence starts at the beginning again.

MRA REGULATORY CONSULTANTS

Experiences from Industry

- Constraints in Regulatory Expertise
  - Very few companies have regulatory experience related to the writing of ZA CTD dossiers from manufacturing documents
  - Many companies have too few staff members to manage the demands of project managing the data generating activities, reviewing and monitoring results and actioning activities needed thereafter.
  - Multi-multi-multi-ingredient formulations are considered to be the most desired by marketing. They are by far the biggest challenge to manage from a scientific rationale – quality and regulatory perspective.

MRA REGULATORY CONSULTANTS

Experiences from Industry

- Constraints in Management awareness
  - Contracts with suppliers are mainly dealing with the business-related matters and rarely are there agreements in place that address technical/quality concerns. The responsibility to pay for the generation of regulatory information is then passed on the ZA Applicant – who often has to do this through a third party.
  - The institutional awareness and company culture is most often founded in marketing and sales with limited awareness of regulatory, quality, Good Practice requirements and risk management. Decisions to retain and invest into products are made from the market-value perspective, not considering the most likely products to be able to progress through the registration process and the data generating challenges.

Experiences from Industry

- HR and Finance Constraints
  - Very few companies were able to submit for licensing as they do not have the necessary expertise and experience in-house to strategically drive the change management process in the company.
  - Responsible Pharmacists are in short supply.
  - The development of Quality Management Systems and related master documentation can consume much needed HR attention and the opportunity costs to develop regulatory information whilst developing plans and related quality system components are detrimental.
  - Many labels, leaflets and packaging components on products on the shelves in supermarkets and other suppliers still do not comply with the labelling requirements.

What does 2017 hold ?

- New regulations – SAHPRA, CAMs & Medical Devices
- SAHPRA | April 2017
- First CAMs product registrations
- Health supplements may be called-up but there will be no roadmap like there was for the DS CAMs
- Port Health seizures will most likely intensify as we progress through the year
- Licensing will come under scrutiny – three years have passed since the 15 November 2013 changes to the regulations
- More workshops have been promised
- Closer co-operation between the MCC and the industry through the ITG to further develop the HS lists and define the critically needed data sets for registration.

MRA REGULATORY CONSULTANTS

What does 2017 hold ?

More knowledge and experience than we have today.

MRA REGULATORY CONSULTANTS

References & Acknowledgements

- **References:**

MCC Website: http://www.mccza.com/

1. http://www.mccza.com/NewsEvents | ITG Meeting Summaries
2. http://www.mccza.com/Publications/Index/1 | 7.02 Roadmap for CAMs | December 2013 | v1
3. http://www.mccza.com/Publications/Index/1 | 7.01 CMs SE DS| June 2016 | v3
4. http://www.mccza.com/Publications/Index/1 | 7.03 CAMs ZA CTD | June 2016 | v3
5. http://www.mccza.com/Publications/Index/1 | 7.04 SE Health Supplements | June 2016 | v2
6. http://www.mccza.com/Publications/Index/1 | 7.05 CMs Quality | June 2016 | v1
7. http://www.mccza.com/Publications/Index/1 | 9.72 CMs Right to Sale | April 2016 | v1

ITG Minutes | Summary of Industry Task Group Meeting – 22 August 2016

- **Acknowledgements:**

- Gratitude to the MRA consulting team for the knowledge and experience shared.
- The Industry Task Group (ITG) for valuable work done in sharing information and experiences with industry.

MRA REGULATORY CONSULTANTS

Thank you for your attention!

Any Questions?

henriette@mra-regulatory.com | 083 435-4453

012 803-6223 |-5955 |-1039

MRA
REGULATORY CONSULTANTS

Intellectual Property Notice

MRA
REGULATORY CONSULTANTS