SAPRAA FORUM

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Declaration and Disclaimer

I declare that I am a member of the Medicine Pricing Committee.

This presentation is a personal commentary and does not reflect the views of the Department of Health nor the Pricing Committee or any of its Task Teams.

SAHPRA & THE LATEST PUBLISHED PROPOSED REGULATIONS

NASCITURUS FICTION v WRONGFUL LIFE

- Unborn foetus has no rights - rights only realised when born
- Never being born at all is a better alternative to a disabled life

AGENDA

1. SAHPRA – what is it and how does it differ from the MCC
2. SAHPRA’s current status
3. The proposed transitioning
4. The published regulations and what they mean for SAHPRA

REGULATORY AUTHORITIES (IN GENERAL)

- Public authority or government agency
- Executive functionary
- Empowered by statute (birth right)
- Legal areas:
  - administrative law,
  - regulatory law,
  - secondary legislation, and rulemaking (codifying and enforcing rules and regulations and imposing supervision or oversight for the benefit of the public at large)

MCC v SAHPRA

	MCC	SAHPRA
Products	Medicines (and CAMS) and related substances	Medicines, Medical Devices, IVDs
Other products	Certain other products and hybrid products	cosmetics, foodstuffs and certain substances currently regulated as Group III and Group IV by the Hazardous Substances Act No. 15 of 1973 – only regulatory oversight not registration
Resources (expert reviewers)	Expert Committees Approximately 100 FTE (part of MRA) + PTE	Approximately 200 Mainly FTE with ++ capacity
Statutory	Department within the NDoH	Section 3A Public Entity (Public Management Finance Act) Outside Public Service, but still in Public Sector
Funding	Mainly from fiscus	Fiscus but ultimately 70% fees

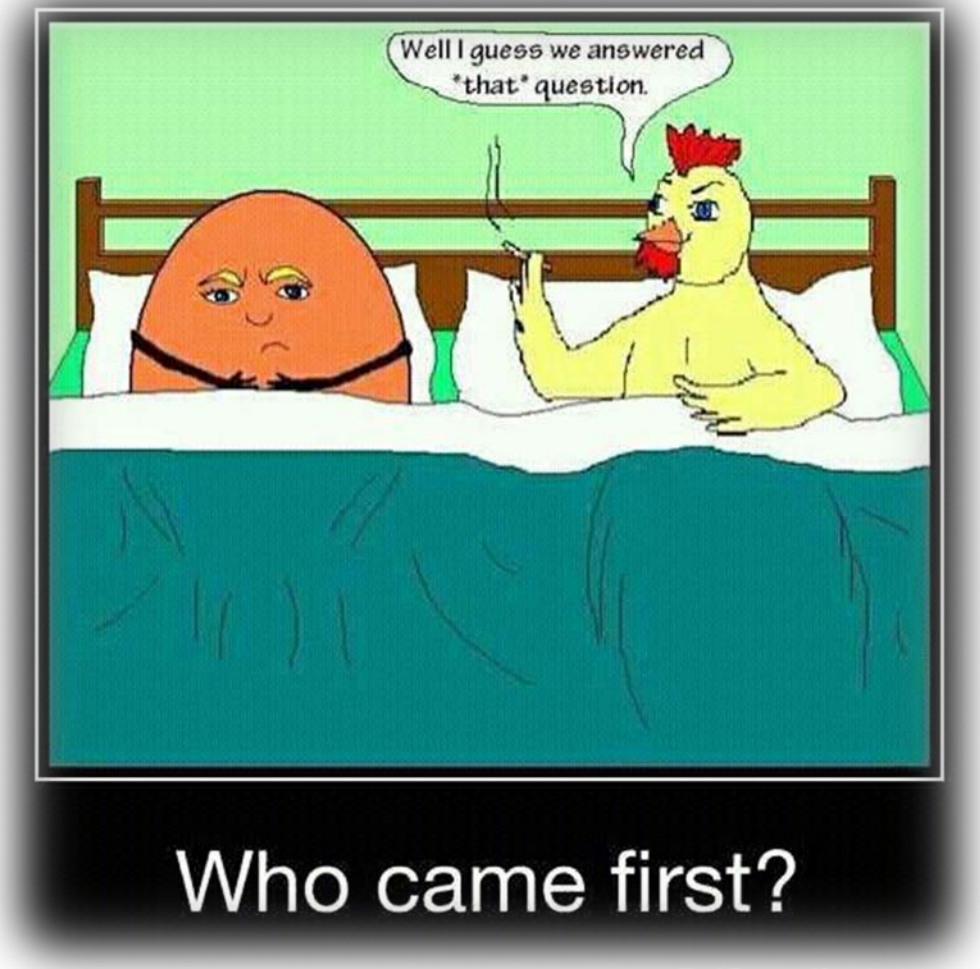
MCC v SAHPRA

	MCC	SAHPRA
Purpose	quality, safety and efficacy of medicines	(Clause 2A) for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, clinical trials and medical devices and related matters in the public interest
Structure	Registrar and Deputy Registrar No other staff Staff “seconded” by DoH	Board (appointed by the Minister ito 2D). The SAHPRA Board will consist of between 10 and 15 members Chairperson and Vice-Chairperson (appointed by the Minister ito 2E)
Registers	Not publicly available	Clause 13 medicines, IVDs and medical devices , scheduled substances, registered entities (and clinical trials?)

CURRENT STATUS OF SAHPRA

- On 24 December 2015 the *Medicines and Related Substances Amendment Act, 14 of 2015* (The Medicines and Related Substances Amendment Bill [B6 – 2014]) was passed into law - 'the 2015 Amendment'.
- The 2015 Amendment adds to the changes in the *Medicines and Related Substances Amendment Act, 72 of 2008* ('the 2008 Amendment').
- The 2015 and 2008 Amendments are in abeyance
- Regulations (gazetted for comment by the Department of Health on the 27th of January) will have to be passed to allow SAHPRA to become effective

Chicken and egg situation



TRANSITION FROM MCC TO SAHPRA

- Clause 25 of the Bill deals with various transitional provisions so as to ensure consistency between the acts of the MCC and that of SAHPRA including, in terms of clause 25(4), pending registration applications and pending appeals in terms of section 24 of the Medicines Act
- Preparatory work required before the launch of SAHPRA
  - Appointment of its board
  - Appointment of Chair and Vice-Chair
  - Appointment of the CEO.
- **Treasury** to formally approve SAHPRA as a section 3A public entity so that it can retain revenue
- Staff transitioning
- Product Transitioning

TRANSITIONING (continued)

- The transitional provisions in the 2015 Amendment state that the MCC continues to perform the functions, but ceases to exist on the day immediately before the date of the first SAHPRA board meeting. The date of this meeting will be determined by the Minister of Health.
- The Minister is also required to designate all relevant employees of the Department to SAHPRA at least 30 days before the commencement date of the Amendment Acts.

Executive Committee (ExCo)

Meeting: Executive Committee (ExCo)

Date: 17 February 2017

Time: 10:00

Venue: PSCBC Boardroom, Centurion

Agenda:

Agreement on the transfer and placement of the medicines regulation affairs function in the National Department of Health to the South African Health Products Regulatory Authority (SAHPRA)

IS SAHPRA THE SILVER BULLET?

- New applications number between 1,200 and 1,600 a year
- The MCC has an estimated backlog of 1,200 novel medicines (new chemical entities), 2,900 generic medicines, 9,500 grandfathered medicines which have never been assessed for their safety or effectiveness
- additional 120,000 complementary medicines and health supplements requiring registration applications
- That's potentially 133,000 products
- Only 13,000 medicines were fully assessed and registered by the MCC in the past 50 years

DRAFT REGULATIONS – 27 JANUARY (IN BRIEF)

- Create the legal mechanism to launch the new South African Health Products Regulatory Authority (SAHPRA)
- Definitions worth noting:
  - The definition of a complementary medicine has changed (once again)
  - Definition of Health Supplement included
- 4 – Compounding
- 5 – Timeframes for application to authority
- 21A – Internal appeal committee
- 23A – Transfer of information from medicine to other registers (between?)
- 35 - Skills of the staff of SAHPRA
- 49- Repeal of old regulations
- Comments due on 26 April 2017

THANKS