DEPARTMENT OF HEALTH
Republic of South Africa

MEDICINES CONTROL COUNCIL

SAHPRA and relevant legislative update

Outline

- SAHPRA status
- Preparation for SAHPRA implementation
- Legislative update
- Capacity building
- Current Initiatives

SAHPRA

- Amendment Bill in parliament
- Caters for a board appointed by the Minister
- Will cover wider scope of commodities beyond medicines – medical devices, in vitro diagnostics, traditional medicines and cosmetics
- Envisages recognition of work done by other regulators in the statute e.g.

➢ Exchange of information

➢ Sharing reports

➢ Work sharing etc. undr confidentiality agreements

Legislative Framework

- Bill of Rights in the Constitution
- Medicines and Related Substances Act
- Pharmacy Act
- Consumer Protection Act
- Regulations to these statutes

Legislative Update

- Regulations for Complementary and Alternative medicines (CAMS) published
- Risk-based and phased approach followed
- Concerns have been raised on some aspects of the Regulations
  - **Definition of CAMS**
  - **Time –line for complying with labelling requirements**
  - **Vitamin levels & probiotics pathway**
  - **Linkage of a product to a disease and not an indication**
- Amendments of levels of vitamins in the schedules have been gazetted
- Draft Regulations on labelling and advertising foodstuffs to be published for comment soon
  - **Include health claims, food for special medical purposes & prebiotics**
- Draft Regulations for Medical devices and In vitro diagnostics will be published soon for comment

CAMS Roadmap

Dec 2013
- Withdraw banned substances
- Withdraw scheduled substances
- Withdraw medicines not fitting definition of CAMS
- Submit new CAMS

15 Feb 2014
- All labelling to comply

May 2014
- 20.2.8 Antiviral agents
- 21.2 Oral hypoglycaemics (Diabetes)
- 6 Cardiac medicines
- 26 Cytostatic agents

Nov 2015
- 32.3 Slimming preparations (weight reduction products)
- 7.1, 21.7, 21.8, 21.9 Male and Female hormones and Sexual stimulation products

May 2016
- 32.16 (Other) Immune boosters
- 17 Medicines acting on muscular system (body building products)
- 22 (Vitamins) Sport supplements containing vitamins and minerals exceeding the upper limit allowed

Nov 2019
- All remaining pharmacological classifications

CAMS cont.

- Concerns around definition of CAMS being considered and will serve at next MCC meeting
- Labelling time-line reviewed under section 36 and will be extended 15 August for all applicants that requested extension
- Discussions around other concerns ongoing

Capacity Building

- Internal short term capacity building programmes at planning stage
- In partnership with the EU, conducting an option identification longer term project for the establishment of a training centre
- Envisaging a blended learning programme
- Partnerships with training institutions
- Flexibility and responsiveness

Current Initiatives

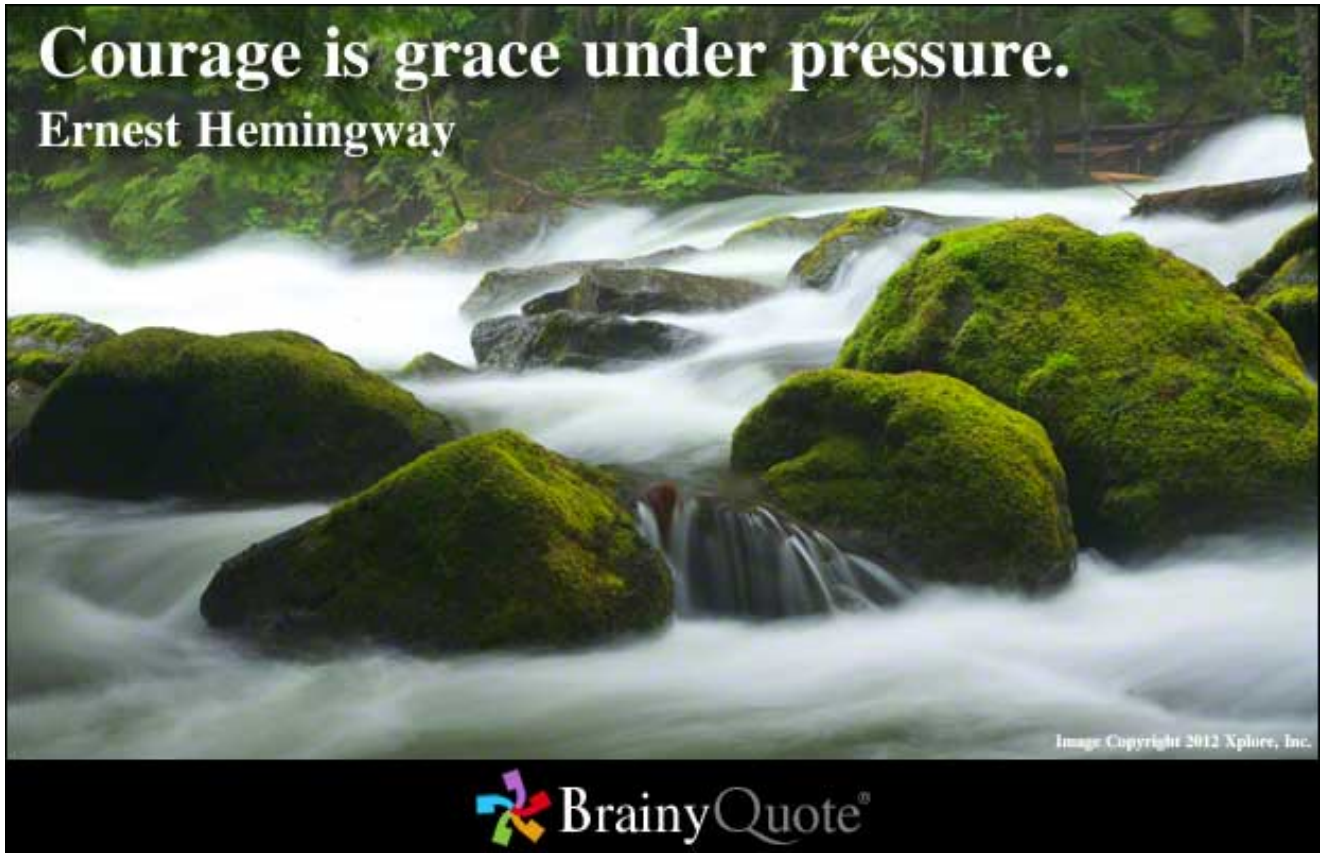
- eCTD pilot – the first reviews to be tabled at the June MCC meeting
- DMF pilot being initiated
- Safety related package insert notification (SR-PINS) guideline finalised and on website
  - ➢ If the application does not comply with the requirements, it must be rejected within 60 working days of receipt at the MCC.
  - ➢ If there is no rejection from MCC after 60 working days, the SR-PIN submission can be regarded as accepted.
  - ➢ The time period for the response starts on the day of receipt at the MCC (not necessarily the date recorded on the cover letter of the applicant)
  - ➢ Cycles are no longer applicable and applicants can now submit SR-PINs routinely
- Budget ring-fenced by the Treasury for the first time

Conclusion

- The area of Complementary and Alternative is complex as there are no common international standards as in orthodox medicines
- The mandate of regulators is to protect citizens in their countries within the framework of existing laws
- Globalisation is a reality and efforts towards harmonisation should be strengthened
- Efficiency through information sharing is desirable.

Knowing is not enough; we must apply. Willing is not enough; we must do.

Johann Wolfgang von Goethe


Courage is grace under pressure.
Ernest Hemingway
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