Marketing Code of Practice

Developing country perspective on code compliance – Industry perspective

Laurenne James
Aspen Pharmacare

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Acts controlling Health Behaviours

- Pharmacy Act
- Medicines Act
- Health Professions Act
- Corruption Act
- Consumer Protection Act

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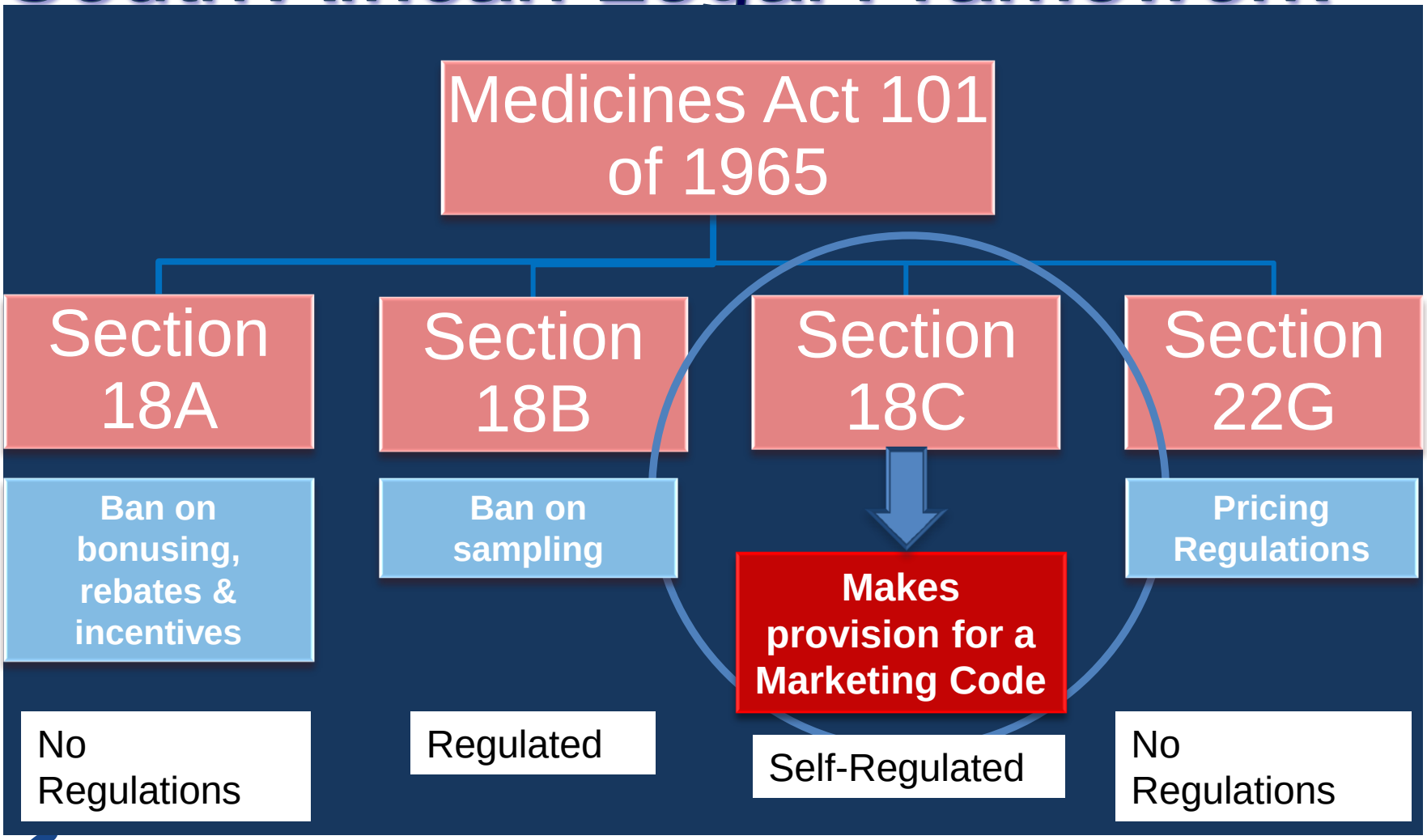
South African Legal Framework



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Marketing Code is provided for:

- Whilst the **Marketing Code of Practice** (the **Marketing Code**) is yet to be promulgated, all industry bodies have agreed to abide by it

- But … **The Medicines Act (Act 101 of 1965) is already law**

- **Section 18C of the Medicines Act 101 of 1965** makes provision for the **Marketing Code**

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How the code fits in

‘Section 18C of the Medicines Act 101 of 1965 (‘the Act”) empowers the Minister, after consultation with the pharmaceutical industry and other stake holders, to make regulations relating to the marketing of medicines, including an enforceable

Code of Practice’

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Main Objectives of the Code

- Self-regulation of marketing practice in the Industry in order to ensure patients' rights to quality, safety and efficacy in medicine supply are upheld

- Instil consumer confidence in the products they receive

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Why Self-Regulate?

- Industry need to display goodwill and credentials
- Instil Consumer confidence
- Regulatory Administrative Burden
- Priority list of DOH (price benchmarking, log fee capping)
- Can always default to regulator if needed

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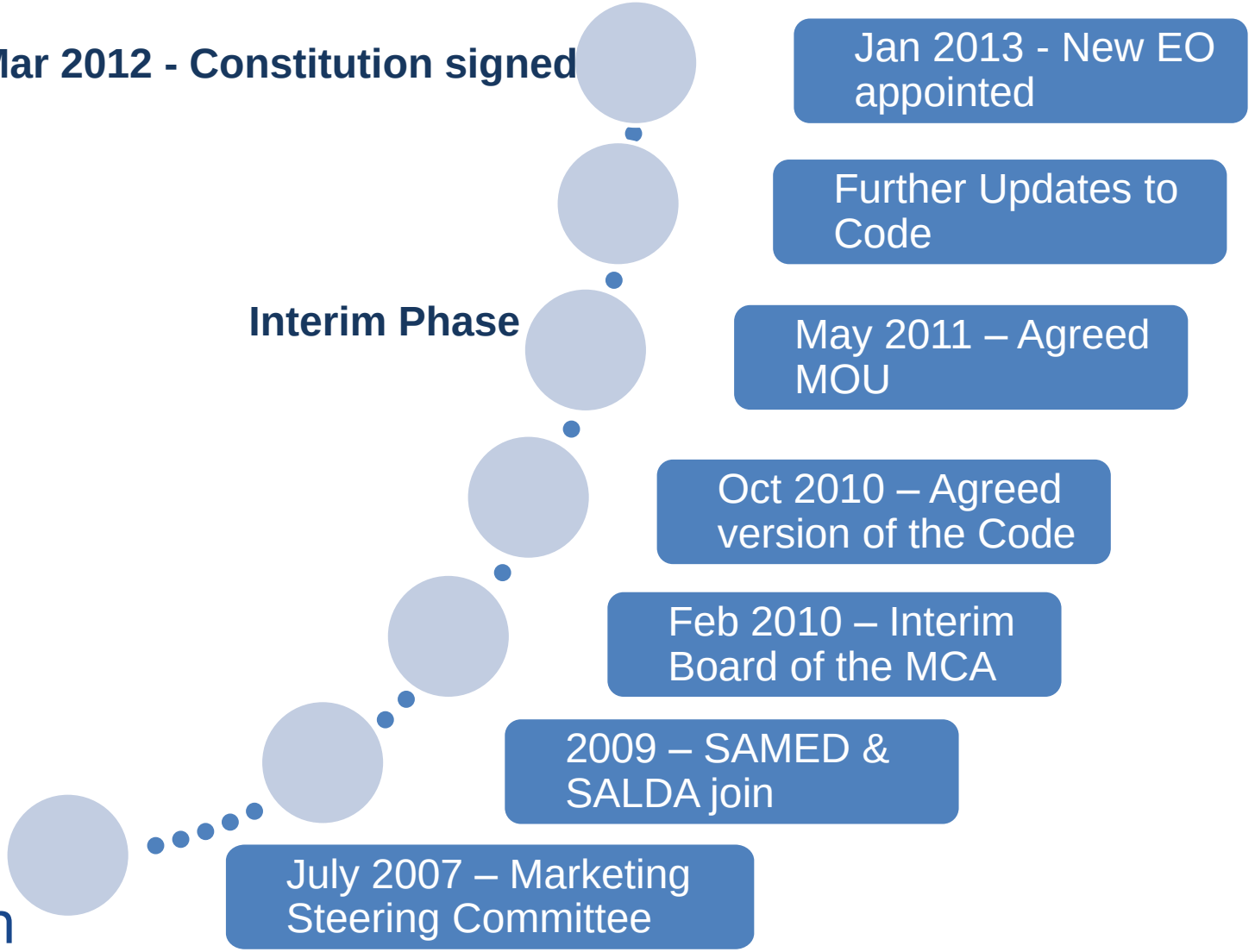
Code Development



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Representation

- SAMED (South African Medical Device Industry Association)
- PIASA (Pharmaceutical Industry Association of South Africa)
- NAPM (National Association of Pharmaceutical Manufacturers)
- SAAHA (South African Animal Health Association)
- IMSA (Innovative Medicines South Africa)
- SMASA (Self Medication Manufacturers of South Africa)
- PHARMISA (Pharmaceuticals Made in South Africa)
- SALDA (South African Laboratory and Diagnostics Association)

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Structure

1. A - To Healthcare Professionals / Other Sellers of Health Products
2. B - To General Public
3. C - Medical devices
4. D - Enforcement of the Code

(All based on Section 18C of Act 101)

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Controls:

- All registered medicines licence holders, their agents, contractors, third party distributors / marketers
- Companies that circumvent the code by engaging or using other companies or agents or dispensing system software vendors or ordering systems will be infringing the Code
- All advertising and/or promotion and promotional activities and communication directed at influencing any member of the medical, dental, pharmacy, nursing or allied health professions who in the course of his or her professional activities may prescribe, purchase, supply, administer a medicine or recommend the use of a medicine

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Advertising / Promotion

- All advertising and/or promotional material, which is directed to members of the public to inform the general public about the medicines available for self medication

- All advertising and/or promotion and all activities directly or indirectly related to marketing which may reflect on the marketing practices of the pharmaceutical industry, including but not limited to sponsorships, patient information-sharing, meetings and entertainment

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Interpretation of the Code

- The provisions should be interpreted in light of both the letter and spirit of the Code.

- Guidance notes, issued from time to time by the MCA will provide companies with an indication as to how the Code should be applied and adhered to

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Limitations

- Confusion around jurisdiction and purview of Code (vs. Section 18A)

- Perspective of interventions regulating behaviour

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Consequences of Contravention

Company

- Reprimand; caution or warning
- Prosecution and/or fines
- Loss of business
- Damage to Company
  - good name/reputation
  - trade & customer relations
  - loss of business opportunities
- Making headlines for the wrong reasons

Employees

- Prosecution/fines/Imprisonment (Section 42 of Act 101)

- Termination of employment
- Loss of incentives & annual increases
- Other disciplinary action as determined by the Company
- Damage to personal reputation

Patients & Public

- Compromised product safety
- Risking patient's lives

Investors

- Loss of confidence in company
- Loss of investment value

Customers

- Loss of good faith in their dealings with company

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Aspen Pharmacare

An emerging market experience of Marketing Code development

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Aspen Group Overview

- Aspen's legacy stretches over 160 years, dating back to **1850** with Lennon Limited.
- Aspen has been ranked as the ninth largest generic company in the world by EvaluatePharma (June 2012).
- Aspen is a supplier of branded and generic pharmaceuticals in more than 150 countries across the globe and of consumer and nutritional products in selected territories.
- Aspen has businesses in **South Africa**, **Mexico, Venezuela, Brazil**, Ireland, Germany, **Kenya**, **Uganda**, **Tanzania**, **Nigeria**, United Arab Emirates, **Mauritius**, Hong Kong, **Philippines** and Australia.
- Aspen is listed on the JSE Ltd and is included in its Top 40 Index.
- Aspen is a leading generics manufacturer in the Southern Hemisphere and is Africa's largest pharmaceutical manufacturer.
- Aspen is also the market leader in Australia.

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Aspen Group Overview cont.

- Aspen's global manufacturing capability is nearly 20 billion tablets.
- Aspen is the leading supplier of generic medicines to both the private and public sectors in South Africa.
- One in four scripts dispensed in South Africa, and one in seven scripts written in Australia are for an Aspen distributed product.
- Aspen is South Africa's number one generic brand.
- Aspen has 17 manufacturing facilities at 12 pharmaceutical manufacturing sites on six continents. Four of the sites are located in South Africa, three in Australia, and one in Kenya, Tanzania, Brazil, Mexico and Germany.
- Aspen has an outstanding generic pipeline. These products are developed under the direction of highly skilled scientists employed by Aspen and in collaboration with other global pharmaceutical companies and research facilities.
- Aspen products are renowned for their quality, efficacy and affordability.

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How Aspen did it

- Participation in all stakeholder meetings in terms of development of the Code
- Signing of the MOU
- Concurrently internal processes and procedures put in place (early 2010)
- Correlation with International Partners' codes of conduct
- Training and retraining of staff at all steps in the process (almost 500 sales and marketing and other relevant employees required training)
- Assessments
- Code of Ethics tied in to behaviours (2012)
- Ongoing training and assessment of compliance
- Internal audits of adherence to internal processes

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Critical Factors

- Leadership commitment
- Understanding the importance of compliance

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Code of ethics

- Corporate Values linked to ethical marketing of medicines
- Set up March 2012
- Formalised by board meeting in June 2012
- Close correlation with Code of Marketing

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Aspen's Corporate Values

Vision and Mission

To deliver value to all stakeholders as a responsible corporate citizen that provides quality, affordable medicines and products globally

Values

- Integrity
- Innovation
- Excellence
- Commitment
- Teamwork

- "Zero Tolerance" approach to unethical conduct
- Commitment to upholding Aspen's reputation
- Ethics management programme implemented throughout Group
- Endorses the ethical marketing of medicines

Ethical Foundation – Aspen Employees

Confirming Aspen's ethical foundation – statements, policies and procedures constituting the ethics frame of reference for the Aspen employees:

- Aspen's Values-statement
- Code of Conduct
- Conflict of Interest Policy
- Gifts and benefits Policy
- Whistleblowers' Standard Operating Procedure
- Applicable marketing codes for sales representatives / marketing employees

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Ethical Foundation – Code of Conduct

Covers:

- Acting in accordance with Aspen's values – being an Aspen ambassador
- Business integrity – avoiding and declaring conflicts of interest
- Gifts, entertainment and bribery
- Integrity of qualitative and quantitative information – misstatement, misrepresentations and/omissions
- Protection and use of property
- Ensuring an effective system of business controls – approvals framework ("act within your authority") and comply with policies and procedures
- Confidentiality and insider trading provisions
- SHE & employment practices
- Compliance with legal requirements (including competition law)

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Additional Regulatory Controls

Medicines Pricing

Consumer Protection Act

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Medicines Pricing Background in Regulatory terms

The medicines regulations dictate a number of interventions that have a logical sequence:

1. Elimination of perverse incentives;	DONE
2. The introduction of a SEP;	DONE
3. Regulation of price increases	DONE
4. Setting of a dispensing fee	DONE
5. Capping of the logistics fee and;	Draft
6. International benchmarking of prices	Draft

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Consumer Protection Act

- The Consumer Protection Act ("**CPA**") was effective 24 October 2010
- May not **mislead** consumers or alter trademarks or descriptions
- Retailer cannot display or supply goods which he suspects may mislead consumer or that the trademark or description may have been altered
- The CPA also extends liability to any **producer, importer, distributor, retailer or service provider** which markets in a manner that is reasonably likely to imply a false or misleading representation concerning those goods or services; or in a manner that is misleading, fraudulent or deceptive in any way.
- Stringent liability on the **producer or importer, distributor or retailer** of any goods, who will be held liable for any harm (death, injury or economic loss) caused by the supply of unsafe goods, a product failure, defect or hazard in any goods or inadequate instructions or warnings provided to the consumer irrespective of whether the harm resulted from negligence by any other party in the supply chain.
- **Limited defences**: for example, the alleged unsafe product failure, defect or hazard did not exist in the goods at the time it was supplied, or, unreasonable to expect the distributor or retailer to discover the unsafe product characteristic, failure, defect or hazard
- In terms of the CPA, any notice to consumers that tries to limit the risk or liability of the supplier, or indemnifies the supplier, has to be drawn to the attention of the consumer and in a manner likely to attract the attention of an ordinarily alert consumer, prior to the conclusion of the sale.

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Exemption from CPA

- The MCC will apply to the relevant Minister for an industry-wide exemption from certain provisions of the CPA
  - particularly the provisions dealing with labelling and trade description restrictions and;
  - provisions dealing with the restrictions on the marketing of goods,
- on grounds that those provisions overlap or duplicate certain provisions of the regulations published in terms of the Medicines Act.
- The Minister may grant the exemption, subject to any limits or conditions necessary to ensure the achievement of the purposes of the CPA.
- If an exemption is not granted, and an inconsistency arises between any provision of the CPA and a provision of any other legislation, the provisions of both Acts would apply concurrently, to the extent possible. To the extent this would not be possible, the provision that extends the greater protection to a consumer prevails over the alternative provision.

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Future Developments

- Training (or facilitation thereof) and Certification by the Marketing Code Authority
- Results of engagement regarding exemption from CPA
- National Certificate: Pharmaceutical Sales Representation qualification – accreditation?
- Regulations pertaining to log fees and price benchmarking

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