

The Consumer Protection Act Pharmaceutical Industry - Update

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The Consumer Protection Act

- The Consumer Protection Act was signed by the President on 24 April 2009 and came into effect on 1 April 2011

Aims

- The CPA, which aims to promote and advance the social and economic welfare of consumers in South Africa, will place extensive obligations on businesses in general in South Africa, and will have far-reaching consequences, particularly for the pharmaceutical industry

Of interest: National Consumer Commission launching investigations into 3 major consumer driven industries, including healthcare

- Samples of health complaints received:
 - Medical schemes not paying for pensioners' life-saving medication
 - Medical scheme funds running out within three months of the year
 - Application of discriminatory rules (e.g. denying HIV patients care)

CPA Working Group Formed

- INNOVATIVE MEDICINES SA (IMSA)
- NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS (NAPM)
- PHARMACEUTICALS MADE IN SA (PHARMISA)
- PHARMACEUTICAL INDUSTRY ASSOCIATION OF SA (PIASA)
- SELF-MEDICATION MANUFACTURERS ASSOCIATION OF SA (SMASA)
- THE SOUTH AFRICAN ANIMAL HEALTH ASSOCIATION (SAAHA)
- SOUTH AFRICAN MEDICAL DEVICE INDUSTRY ASSOCIATION (SAMED)
- SOUTHERN AFRICAN LABORATORY DIAGNOSTICS ASSOCIATION (SALDA)
- PHARMACEUTICAL WHOLESALERS AND DISTRIBUTORS (PLASA)
- PHARMACEUTICAL SOCIETY OF SOUTHERN AFRICA (PSSA)

Exemptions

- A regulatory authority may apply for an industry-wide exemption from one or more provisions of this Act on the grounds that those provisions overlap or duplicate provisions of any other national legislation administered by that regulatory authority
- The MCC and HPCSA would be regarded as a regulatory authorities for purposes of the Consumer Protection Act

An Exemption Process

- MoH has applied to the National Consumer Commission for an industry-wide exemption
 - From certain provisions of the CPA
 - Particularly in relation to the provisions dealing with labelling and trade description restrictions, as well as the provisions dealing with the restrictions on the marketing of goods
 - On the grounds that those provisions overlap or duplicate certain provisions of the regulations published in terms of the Medicines and Related Substances Act.

An Exemption Process

- The Commission may grant the exemption, subject to any limits or conditions / or a MoU
- 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

An Exemption Process

- To the extent this would not be possible; the provision that extends the greater protection to a consumer prevails over the alternative provision

An Exemption Process

- It is understood that the Minister of Health is confident of getting an exemption
- An exemption has however not as yet been granted

An Exemption Process

- The Commissioner of The National Consumer Commission has requested a meeting with The CPA Pharmaceutical Steering Committee
- To discuss ‘consumer protection issues within the pharmaceutical industry’
- This meeting is scheduled for 14 June 2011

Work to Date

- Dossier compiled/ comment submitted
- Met with Commissioner (seen dossier)
- Met with Registrar
- Provided dossier to MCC (adapted)
- To meet with Commissioner

Dossier

Provisions as Found in the CPA	Applicable Provisions in Medicines Act, Pharmacy Act and other Health Legislation	Comment in Relation to Possible Exemption from the CPA

Purpose

- To show the general scope of regulation currently in place for consumers of medicine (patients), for the supply chain (from manufacturer/importer to dispenser/retailer) and for the personnel or staff involved in sales activities (i.e. healthcare professionals such as doctors, pharmacists / pharmacies and nurses)



And...

- How this scope protects consumers in relation to the goods (medicines) they buy, as well as protect them through comprehensive regulation of the total supply chain

Note

- Complementary medicines and traditional medicines, are not (yet) regulated, and that this submission only pertains to medicines subject to the medicine-specific legal frameworks outlined below or medicine recognised as being registered (so-called “old” medicines)

Example

PROVISIONS AS FOUND IN THE CONSUMER PROTECTION ACT (CPA)

(3) A consumer may rescind a transaction resulting from any direct marketing without reason or penalty, by notice to the supplier in writing, or another recorded manner and form, within five business days after the later of the date on which—

- (a) the transaction or agreement was concluded; or*
- (b) the goods that were the subject of the transaction were delivered to the consumer.*

APPLICABLE PROVISIONS IN MEDICINES ACT, PHARMACY ACT AND OTHER HEALTH LEGISLATION

There are specific provisions in relation to medicines that prohibit the return of medicines

COMMENT IN RELATION TO POSSIBLE EXEMPTION FROM THE CPA

Hence **exemption would be required** from s16 of the CPA in order to prevent consumers demanding to return products based on them having rescinded the agreement

Thank You

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