

**THE INFLUENCE OF THE CONSUMER PROTECTION ACT 68  
OF 2008 AND THE PLAIN LANGUAGE REQUIREMENT OF  
PHARMACEUTICAL PRODUCT LABELLING**

by

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## ABSTRACT

The dissertation deals with the influence of the plain language requirement provided for in section 22 of the Consumer Protection Act 68 of 2008 (CPA) on the current practice of pharmaceutical product labelling.

The introduction in Chapter 1 sets the scene by providing an overview of the dissertation: It includes a brief description and layout of the chapters; a discussion of the research problem and aims; a demarcation of the methodology used; and an explanation of the scope, limitations and delineations of the study.

The focus in chapter 2 is on prescription medication and the legislation applicable thereto. The focus is on the Medicines and Related Substances Act 101 of 1965, specifically regulations 8 to 10 promulgated in terms thereof. Furthermore, the relevant provisions of both the abovementioned Acts are critically discussed and analysed. An overview of the appropriate supply chain in this specific context is provided with reference to medical practitioners, pharmacists and suppliers. Section 61 of the CPA concerning damaged goods is also examined.

The development, meaning and importance of plain language as well as the application and definition of an 'educated consumer' are discussed in chapter 3. As this study concerns product labelling, section 24 of the CPA as well as the terms 'product labelling' and 'package inserts' are examined in chapter 4. At the same time, section 22 and the meaning of 'document', 'notice' and 'visual representation' are kept in mind.

The dissertation is concluded in chapter 5. Here the final part of the golden thread is completed – the aims described in chapter 1 are confirmed through a brief summation of the information provided and investigated in chapters 2 to 4.

## TABLE OF CONTENTS

CHAPTER 1: INTRODUCTION .....	1
1.1 Background .....	1
1.1.1 The Consumer Protection Act .....	2
1.2 Research problem and aims.....	3
1.2.1 Research problem .....	3
1.2.2 Research aim .....	4
1.3 Methodology.....	4
1.4 Chapter breakdown.....	5
1.4.1 Chapter 2: Legislation applicable to pharmaceutical product labelling .....	5
1.4.2 Chapter 3: The CPA and the importance of plain language.....	5
1.4.3 Chapter 4: Product labelling .....	6
1.4.4 Chapter 5: Conclusion .....	6
1.5 Limitations and delineations on the scope .....	6
1.6 Chapter conclusion .....	7
CHAPTER 2: LEGISLATION APPLICABLE TO PHARMACEUTICAL PRODUCT LABELLING.....	8
2.1 Introduction.....	8
2.2 The CPA .....	9
2.2.1 Interpretation, purpose and application .....	9
2.2.2 Fundamental consumer rights .....	15
2.2.7 Other applicable provisions .....	19
2.2.8 Conclusion .....	26
2.3 The Medicines Act.....	26
2.3.1 Regulation 8: Labelling .....	26
2.3.2 Regulation 9: Package inserts .....	28
2.3.3 Regulation 10: Patient information leaflet (PIL) .....	29
2.3.4 Conclusion .....	31
2.4 Chapter conclusion .....	32
CHAPTER 3: THE CPA AND THE IMPORTANCE OF PLAIN LANGUAGE.....	33
3.1 Introduction.....	33
3.2 The plain language movement.....	34
3.3 Section 22 of the CPA.....	35
3.3.1 What is plain language?.....	36
3.4 Pharmaceutical product labelling and plain language .....	39

3.4.1 Consumer knowledge .....	39
3.4.2 Overcoming the barrier.....	41
3.5 Chapter conclusion .....	43
CHAPTER 4: PRODUCT LABELLING .....	45
4.1 Introduction.....	45
4.2 Section 24: Product labelling .....	45
4.3 Package labelling versus package inserts .....	48
4.4 Chapter conclusion .....	49
CHAPTER 5: CONCLUSION .....	50
6 BIBLIOGRAPHY .....	52

## CHAPTER 1: INTRODUCTION

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### SUMMARY

- 1.1 Background
  - 1.2 Research problem and aim
  - 1.3 Methodology
  - 1.4 Chapter breakdown
  - 1.5 Limitations and delineations on the scope
  - 1.6 Chapter conclusion
- 

### 1.1 Background

Pharmaceutical products are the ultimate instruments utilised for the prevention and relief of illnesses in the world.<sup>1</sup> These products can be extremely effective, and could be of high quality with the potential to impact the public health system extensively – but without proper instructions on the manner in which to use these products the benefits are not attainable.<sup>2</sup>

The development of pharmaceutical products in the modern world has been exposed to fluctuating phases, resulting in the innovation and stagnation of pharmacological advancements.<sup>3</sup> The unqualified principle that patients should not be harmed by pharmaceutical products taken for the purpose of treatment is common knowledge in the healthcare sector.<sup>4</sup> The majority of pharmaceutical products have undesirable side effects that require formal methods of regulation to ensure that maximal benefit is extended to all consumers.<sup>5</sup> The objective of regulation is to ensure that proportionality

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<sup>1</sup> Abbott & Dukes (2009) 116. Due to the wide meaning of “pharmaceutical products” and the variety of products it encompasses the dissertation focuses only on prescription medication. See Du Toit *et al* 2015 724. The authors define a prescription as “a doctor’s written instruction authorising a patient to be issued with a medicine or treatment”.

<sup>2</sup> Abbott & Dukes (2009) 126. Without appropriate usage of pharmaceutical products, the risk of introducing new problems increases, endangering the health of consumers tenfold.

<sup>3</sup> *Idem* 3.

<sup>4</sup> *Idem* 7.

<sup>5</sup> *Ibid*.

exists between the benefit offered by the medicine and the harm suffered by the patient.<sup>6</sup> To ensure the safety and effectiveness of medicines the rules governing them should be enforced.<sup>7</sup>

There is no point in denying the pivotal role and duty of healthcare professionals (medical doctors and pharmacists) firstly to complete a comprehensive inquiry into patients' medical history in order to prevent possible contraindications and, secondly, to inform patients of possible side-effects that they might experience during the course of the treatment.<sup>8</sup> However, healthcare professionals might not always live up to the high standard expected of them, resulting in the patient being placed in a vulnerable position.<sup>9</sup> Patients are ultimately exposed to decisions regarding pharmaceutical products which could lead to dire consequences if they are uneducated and uninformed as consumers.<sup>10</sup> Van Eeden<sup>11</sup> refers to the importance of consumer awareness regarding the availability and possibility of alternative products as well as all the possible effects that may be caused by the use thereof.

### **1.1.1 The Consumer Protection Act<sup>12</sup>**

The CPA came into effect on 1 April 2011 and has had an extensive impact on numerous industries including the pharmaceutical industry.<sup>13</sup> It applies to all services offered in pharmacies and to the products supplied or sold by them.<sup>14</sup> The implementation of the CPA and the established pharmaceutical product labelling

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<sup>6</sup> *Ibid.*

<sup>7</sup> *Idem* 10.

<sup>8</sup> *Idem* 167-168. The heavily burdened medical practitioner may find too little time extensively to discuss with the patient the correct way in which a medicine should be used, the adverse effects that may occur and required precautions in taking it. Further when dealing with the pharmacist's duty to inform, a patient may be more hesitant to seek advice when standing before a sales counter than when seated in the privacy of the doctor's office.

<sup>9</sup> *Idem* 126. Professional medical staff are in short supply and commonly overburdened especially where public education is still constrained by the limited availability of applicable resources.

<sup>10</sup> Rowe & Moodley 2013 3-6. Due to an extremely high patient burden, the majority of physicians are unable to devote sufficient time to ensure that uneducated patients are satisfactorily informed in order to make their own decisions.

<sup>11</sup> (2013) 5.

<sup>12</sup> 68 of 2008 [hereinafter "CPA" or "the Act"].

<sup>13</sup> Du Toit & Van Eeden 2014 738; Nöthling-Slabbert *et al*/ 2014 171. The definition of "goods" in s 1 of the CPA (goods are very broadly defined and include anything marketed for human consumption) includes not only medication, but also devices and consumables.

<sup>14</sup> *Ibid.*



industry requires a critical analysis to comprehend the extent of the influence of the relevant provisions on existing laws, regulations and practices.

The fundamental reason why the law needs to protect the individual where medicines are concerned, is that patients are usually not equipped with the required knowledge regarding the quality and safety of the medicines and are unable to judge for themselves in this regard.<sup>15</sup> In most instances, patients as consumers of pharmaceutical products depend on knowledgeable and educated healthcare professionals to 'act' on their behalf.<sup>16</sup>

In order to operate effectively and safely as independent functionaries, consumers should be placed in a position to know what products and ingredients are ingested as well as the concomitant consequences and risks. To achieve this, the importance of pharmaceutical product labelling cannot be overlooked. The labels will have to meet a series of requirements in order to effectively inform and educate consumers on the specific medication, resulting in the fulfilment of the purpose to promote and advance the social and economic welfare of consumers as provided for in section 3 of the CPA.<sup>17</sup> After all, the CPA is primarily aimed at the protection of consumers, which is evident from its title, preamble and purposes.<sup>18</sup>

## **1.2 Research problem and aims**

### **1.2.1 Research problem**

The CPA's application and influence on the pharmaceutical industry pose serious practical challenges and create uncertainties.<sup>19</sup> The purpose of this study is to establish how the plain language requirement in section 22 of the CPA affects pharmaceutical product labelling, more specifically prescription medication. The impact of section 22 and all the related provisions concerning prescription medication

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<sup>15</sup> Lifestyle reporter. Package inserts are mostly technically written and the majority of people would not be able to understand it. Consumers are entitled to clear and useful information; thus, pharmaceutical product labelling should communicate the information to consumers in plain language.

<sup>16</sup> Abbott & Dukes (2009) 86.

<sup>17</sup> Rowe & Moodley 2013 8. "The importance of clear instructions and warnings to patients as well as drawing the patient's attention to any unusual or serious risks...cannot be over-emphasised..." S 3 is discussed in more detail in chapters 2 and 3.

<sup>18</sup> Barnard 2014 3. The CPA has an imperative purpose, namely, to promote and advance the social and economic welfare of consumers in South Africa.

<sup>19</sup> Nöthling-Slabbert *et al* 2014 169.

labelling cannot be interpreted on a mere superficial reading but requires a thorough investigation.

However, an analysis of only section 22 does not suffice for purposes of this study. The impact of section 24 dealing with product labelling as well as section 58 concerning warnings of the fact and nature of risks are investigated in order to ensure a proper understanding of the applicable provisions of the CPA.

### **1.2.2 Research aim**

The extent of the influence of section 22 on pharmaceutical product labelling is examined while keeping in mind other sources of law and applicable practices.<sup>20</sup> In this regard, section 24 of the CPA is an important provision to explore and harmonise with the plain language requirement.

Apart from the CPA, the applicable provisions of the Medicines and Related Substances Control Act<sup>21</sup> as pre-existing legislation are interpreted. An analysis is done by reading, interpreting and applying both Acts, while bearing in mind the purposes of the CPA. Whenever a provision in one Act is in conflict with a provision in the other, the Act offering the most protection to the consumer will apply.<sup>22</sup>

Certain key factors are addressed, including:

- (a) The impact and influence of sections 22 and 24 of the CPA on prescription medication labelling;
- (b) the term ‘plain language’ (history, development and in the context of section 22);
- (c) the impact of the Medicines Act, specifically regulations 8 to 10; and
- (d) the current practice regarding prescription medication labelling (in terms of the manufacturer, service provider and consumer relationships as provided for in the CPA).

### **1.3 Methodology**

A critical approach – including a discussion of not only primary sources (legislation, case law and common law) relevant to this dissertation but also secondary sources

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<sup>20</sup> Klink E. In this article Klink discusses pharmaceutical label information and package inserts. She states that regulation 10 of the Medicines and Related Substances Control Act 101 of 1965 could be amended in order to harmonise it with s 22 of the CPA.

<sup>21</sup> Act 101 of 1965 [hereinafter “Medicines Act”], specifically, regulations 8 to 10 promulgated in terms thereof.

<sup>22</sup> S 4(4) CPA.

(journal articles and textbooks) – is followed in order to achieve the research aims of the dissertation. The author's own arguments combined with the influence of the diverse material researched and analysed are used in the argument formulation process. Furthermore, as can be seen in the Bibliography, a simplified mode of citation is used as referencing method in the dissertation.

## **1.4 Chapter breakdown**

The abovementioned research problem and objectives are addressed in the following chapters:

### ***1.4.1 Chapter 2: Legislation applicable to pharmaceutical product labelling***

This chapter starts with the relevant provisions of the CPA and the most important definitions contained in the Act, with emphasis on sections 22, 24 and 58. Other sections impacting the CPA are also investigated (sections 2 and 3).<sup>23</sup> It should be noted that a thorough investigation of section 22 follows in chapter 3 where 'plain language' is dealt with.

This is followed by a discussion of the applicable provisions of the Medicines Act, commencing with an outline of the selected definitions and ultimately resulting in an analysis of regulations 8 to 10. Other provisions that may be applicable are mentioned for the sake of completeness but this does not necessarily entail an in-depth analysis.

Furthermore, both pieces of legislation are considered in the context of section 2 of the CPA to establish whether they are co-existing or in conflict with one another. It is emphasised that no matter what the ambiguous nature of the provisions might be, the one certain and key element should always be to ensure that the consumer is provided with maximum protection.

### ***1.4.2 Chapter 3: The CPA and the importance of plain language***

In order to reach a clear understanding of the origin and nature of the plain language requirement provided for in section 22, the development of plain language and the plain language movement are traced and discussed.

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<sup>23</sup> Specifically, s 2(9)(a) of the CPA provides for the situation when there is an inconsistency between the CPA and any other Act.

The plain language requirement is analysed in view of the implications that this section has on the present pharmaceutical product labelling industry.

The application of section 22, viewed in theory versus in practice, is discussed and criticised. The importance of educating and informing consumers regarding prescription medication is emphasised throughout the chapter.

#### **1.4.3 Chapter 4: Product labelling**

This chapter contains an investigation and interpretation of the meaning of product labelling in terms of section 24 of the CPA and other relevant sources. The meaning of package inserts and leaflets is also considered and product labelling and the plain language requirements of section 22 are dealt with. Finally, section 58 of the CPA (regarding warnings of the fact and nature of risks) is discussed in as far as it relates to product labelling.

#### **1.4.4 Chapter 5: Conclusion**

The aim of this chapter is to indicate how and whether the research aims outlined in chapter 1 were achieved. A further objective is to provide a clear, structured and brief summary of the influence of the relevant provisions of the CPA on prescription medication labelling.

### **1.5 Limitations and delineations on the scope**

As a limitation is imposed on the length of the dissertation, only the most relevant issues relating to the topic are dealt with. An overview of the duties and liability of the manufacturer, medical practitioner and pharmacist in terms of section 61 of the CPA is provided but an in-depth investigation and analysis of this topic is not possible. The major part of the dissertation is devoted to investigating section 22 as well as the impact of section 24 on pharmaceutical product labelling as far as the CPA is concerned. Due to the wide meaning of pharmaceutical products, the dissertation focuses on prescription medication. Section 58 of the CPA, and as far as necessary for the interpretation thereof, section 49, are dealt with briefly to ensure that a comprehensive overview and analysis is reached in the available space.

Explicitly excluded from the scope of the dissertation are sections 51 to 57, the consequences of non-compliance as laid down in chapter 3 of the CPA (sections 68 to 78) and section 60 concerning safety monitoring and recall. Only regulations 8 to

10 of the Medicines Act and related provisions are discussed; however, a discussion of all the possible related and relevant provisions cannot be achieved in this study. Only the most important provisions or parts of the provisions as identified by the author (until 29 October 2016, the final date research was done) are dealt with.

In the interest of gender-neutral language, the following should be noted: The exclusive use of masculine forms of expression (he, his and him) in the dissertation includes reference to all other genders.

## 1.6 Chapter conclusion

The CPA was enacted with the aim of providing a unified mechanism to ensure that marketplace fairness is achieved on all levels of consumer and supplier interaction.<sup>24</sup> Each and every transaction concluded in South Africa, unless specifically excluded, is subject to the CPA.<sup>25</sup> There is no doubt that the CPA does influence the current practice of pharmaceutical product labelling. The question, however, is to what extent and how adherence to the relevant provisions can be achieved. The main objective is to ensure that consumers are protected and placed in the best position possible in order to make informed decisions that impact them as individuals.

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<sup>24</sup> Stoop 2015, 1091.

<sup>25</sup> *Idem* 1092. S 5 of the CPA deals with the exclusions.

## CHAPTER 2: LEGISLATION APPLICABLE TO PHARMACEUTICAL PRODUCT LABELLING

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### SUMMARY

- 2.1 Introduction**
  - 2.2 The CPA**
  - 2.3 The Medicines Act**
  - 2.4 Chapter conclusion**
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### 2.1 Introduction

Due to the inherent hazardous nature of medicine it is crucial to ensure that it is properly regulated, ultimately ensuring its safe and effective use by consumers. Nöthling-Slabbert and Pepper correctly state that even though medicines differ from ordinary commodities and are not regarded as trade merchandise, all medicines are subject to the provisions of the CPA.<sup>26</sup> There are two main pieces of legislation applicable to pharmaceutical product labelling, namely, the CPA and the Medicines Act.

In this chapter, the most important provisions governing product labelling are discussed in detail. It should be noted that chapter 3 contains a detailed discussion of section 22 of the CPA regarding the application of plain language and it is only referred to in this chapter where necessary. Chapter 4 contains an investigation and interpretation of section 24 regarding product labelling as well as a discussion of labelling and package leaflets or inserts.

This chapter also mentions the supplier and his responsibilities. As far as pharmaceutical product labelling and the specific parties involved in the supply chain responsible for supplying medication are concerned, it is necessary to determine who will be held responsible if medication is not properly labelled. However, due to the endless number of people who may possibly be involved, only manufacturers, medical

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<sup>26</sup> Nöthling-Slabbert & Pepper 2011 801. All medicines mean prescription as well as over-the-counter medicines.

practitioners and pharmacists are discussed as parties who are likely to be held responsible in case of inadequate labelling.<sup>27</sup>

## 2.2 The CPA

The CPA is divided into 7 chapters and is further subdivided into alphabetically-numbered parts. The dissertation focuses on chapters 1 and 2. Chapter 1 contains the interpretation, purposes and application of the Act, and chapter 2 deals with fundamental consumer rights. It is necessary to quote extensively from the CPA to appreciate the scope of application of the relevant provisions.

### 2.2.1 Interpretation, purpose and application

#### 2.2.1.1 Section 1: Definitions

A number of definitions contained in section 1 of the CPA are important for the interpretation of the relevant sections and for the discussion of concepts and provisions below.<sup>28</sup>

#### Consumer

The term ‘consumer’ is derived from Latin, meaning “to take up completely”. It is defined as “someone who...eats or uses something”.<sup>29</sup>

In terms of section 1 of the CPA, ‘consumer’ is defined as “a person to whom the particular goods or services are marketed in the ordinary course of the supplier’s business” and “a person who has entered into a transaction with a supplier in the ordinary course of the supplier’s business, unless the transaction is exempt from the application of this Act by section 5(2) or in terms of section 5(3)”. Du Toit and Van Eeden correctly state that a consumer is regarded as both a natural and a juristic person (with certain exceptions).<sup>30</sup> De Stadler submits that both ‘consumer’ and ‘supplier’ are key terms included in the majority of the sections of the CPA.<sup>31</sup>

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<sup>27</sup> S 61 CPA dealing with the liability for damage caused by goods is discussed below in this chapter.

<sup>28</sup> De Stadler ‘Section 1’ (2014) para 1. Unlike in the majority of Acts, the definitions in the CPA fulfil a valuable interpretational function.

<sup>29</sup> Rowe & Moodley 2013 2.

<sup>30</sup> Du Toit & Van Eeden 2014 738.

<sup>31</sup> De Stadler ‘Section 1’ (2014) para 1.



According to Rowe and Moodley,<sup>32</sup> patients are viewed as consumers from a legal perspective and this has numerous implications for health care providers and the doctor-patient relationship. They also state that the decision to use ‘patient’ and ‘consumer’ interchangeably is highly significant from a sociological perspective.<sup>33</sup> Nöthling-Slabbert and Pepper correctly state that, depending on the specific context, patients will be included under the statutory definition of consumers and that they are beneficiaries of services.<sup>34</sup>

### Section 5(2) and (3)

Section 5(2) of the CPA contains certain exclusions from its ambit. They do not have any direct or meaningful bearing on the pharmaceutical labelling issue but should be mentioned.<sup>35</sup>

The exclusions include transactions concluded with the State as a consumer, when a juristic person is a consumer with an annual turnover of R2 million or more, when dealing with a credit agreement under the National Credit Act,<sup>36</sup> when services are provided in terms of employment agreements, and so forth.<sup>37</sup>

Section 5(3) further provides that on application to the Minister of Trade and Industry, a regulatory authority may be granted industry-wide exemption from one or more of the Act’s provisions. However, the grounds will be scrutinised and the body seeking exemption should indicate that the provisions of an existing regulatory Act are duplicated in the CPA. Subsection 3 finds no application to this study as the Minister has not excluded the pharmaceutical industry or a related manufacturing component from the ambit of the CPA’s application. Until such an exclusion is granted the CPA will be applicable to all medication provided to consumers.<sup>38</sup>

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<sup>32</sup> Rowe & Moodley 2013 1.

<sup>33</sup> *Idem* 2.

<sup>34</sup> Nöthling-Slabbert & Pepper 2011 801.

<sup>35</sup> De Stadler ‘Section 5’ (2014) para 1. S 5(5) provides that ss 60 and 61 will apply even if s 5(2) to (4) is applicable.

<sup>36</sup> Act 34 of 2005. This Act and the provisions are not discussed here as they find no application to the issue at hand.

<sup>37</sup> R2 million is the latest amount proclaimed by the Minister in *Government Gazette* No 34181 of 1 April 2011.

<sup>38</sup> De Stadler ‘Section 5’ (2014) para 1. Like all sections of the CPA, s 5 should always be interpreted with s 3 (the purposes) in mind.



In terms of this definition it is clear that a purchaser of prescription medication at a pharmacy falls under the umbrella term of ‘consumer’ for purposes of the CPA.

### Consumer Agreement

‘Consumer agreement’ is defined as an “agreement between a supplier and a consumer other than a franchise agreement” and ‘facility’ as “any premises, space or equipment set up to fulfil a particular function, or at, in, or on which a particular service is available”.<sup>39</sup> Gouws<sup>40</sup> discusses the meaning of ‘agreement’ and states that ‘agreement’ can be defined as an arrangement or understanding concluded to establish a legal relationship between two or more parties.

‘Goods’ include “anything marketed for human consumption”. Nöthling-Slabbert and Pepper correctly state that the meaning of ‘goods’ includes medicine, devices and consumables.<sup>41</sup> De Stadler correctly states that the term ‘goods’ is a key concept included in the CPA, featuring in the majority of its provisions.<sup>42</sup> Gouws further submits that the term ‘goods’ includes any literature, music, photograph, motion picture, information, data and any object marketed for human consumption.<sup>43</sup> The definition of medicines as contained in the Medicines Act states that it is a substance used or suitable for use to diagnose and treat physical or mental disease symptoms in people.<sup>44</sup>

Pharmaceutical products – more specifically prescription medication – is manufactured for human consumption and will thus be classified as goods for purposes of the CPA.<sup>45</sup>

### Supplier

‘Supplier’ is defined as “a person who markets any goods or services” and ‘supply’ when used as a verb with regard to goods “includes sell...in the ordinary course of business for consideration”. Rowe and Moodley submit that ‘health care’ can be

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<sup>39</sup> De Stadler ‘Section 1’ (2014) para 1. Mention is made that ‘consumer agreement’ is specifically referred to in ss 14(2), (3) & (4); 15(1); 47(1)(b); 49(1); 50.

<sup>40</sup> Gouws 2010 84.

<sup>41</sup> Nöthling-Slabbert & Pepper 2011 801.

<sup>42</sup> De Stadler ‘Section 1’ (2014) para 1.

<sup>43</sup> Gouws 2010 84.

<sup>44</sup> See 2.2 for a discussion of the Medicines Act.

<sup>45</sup> Consumption is related to the verb consume, which means to eat, use, or buy. Gouws 2010 84.

defined in itself as a product or goods supplied by the medical practitioner for purposes of the CPA.<sup>46</sup> Nöthling-Slabbert and Pepper<sup>47</sup> state that medical practitioners (including pharmacists) will be included as part of the supply chain in terms of ‘suppliers’ or ‘retailers’. They further submit that the consumer in terms of the CPA is in a position to sue anyone in the supply chain. This burdens the practitioner and places him in a challenging position as he is the most easily and often only distinguishable and identifiable person in the supply chain.<sup>48</sup>

With reference to the term ‘supplier’ when dealing with prescription medication, pharmacies will be classified as suppliers; furthermore, the manufacturers of the medications will also be regarded as such. The main problem when dealing with suppliers is the question of who will be held responsible for noncompliance with the provisions of the CPA. Nöthling-Slabbert and Pepper correctly state that the consumer (claimant) may identify anyone in the supply chain and hold him liable. All the health professionals who delivered the care (often medical doctors) are easily identifiable and can be held strictly liable for the cost of the damages.<sup>49</sup> This situation requires further investigation. However, due to the nature of the dissertation, the main focus is not on the responsible parties but on the influence of the Act on pharmaceutical labelling.<sup>50</sup>

In view of the above definitions, a consumer for purposes of the CPA is a person buying goods; with further interpretation, it is clear that the terms ‘consumer’ and ‘patient’ can be used interchangeably and medications are considered to be goods in terms of section 1 of the CPA.

### 2.2.1.1 Section 2: Interpretation

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<sup>46</sup> Rowe & Moodley 2013 1.

<sup>47</sup> Nöthling-Slabbert & Pepper 2011 800-201.

<sup>48</sup> *Ibid.* The writers argue that this situation is unsatisfactory as it places an onerous burden on health care providers.

<sup>49</sup> *Idem* 803. The specific harm covered includes death, injury, illness or pure economic loss.

<sup>50</sup> ‘Market’ as a verb “means to promote or supply any goods or services” and ‘service’ “includes any work or undertaking performed by one person for the direct or indirect benefit of another”.

Section 2 of the CPA provides for the interpretation of the Act. Statutory interpretation is not only important when ordinarily dealing with the Act but even more so when two or more pieces of legislation find concurrent application.<sup>51</sup>

Du Toit and Van Eeden<sup>52</sup> confirm the following interpretation of this provision: When dealing with the applicable provisions of the CPA and the Medicines Act, both Acts will apply in as far as it is necessary; in the event of any inconsistencies between the two, the one offering more protection to consumers will prevail.<sup>53</sup> As stated by De Stadler, the CPA unfortunately contains quite a number of ambiguities and uncertainties and thus a purposive method to legislative interpretation will often be used when the substantive provisions of the CPA are interpreted.<sup>54</sup> The writer quotes Du Plessis<sup>55</sup> who describes the purposive method, which approach can be outlined as follows: Determine the purpose of the legislative provision; while continuously keeping the context of the instrument of which it forms part in mind; and then attribute meaning to that specific part within that specific context.<sup>56</sup> De Stadler further submits that this approach is only necessary when the legislative provision is unclear, as is frequently the case with the CPA.<sup>57</sup>

Due to the constitutional structure of South Africa as well as the nature of the Act, the purposes of the CPA are extremely important in any interpretation.<sup>58</sup> De Stadler states that section 2 should be read with the purpose and policy of the Act as contained in section 3.<sup>59</sup> A consumer's wellbeing and protection should always be the main concerns whenever any section or part of the CPA is to be interpreted. The CPA sets out the minimum requirements for consumer protection in South Africa and is a crucial

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<sup>51</sup> S 2(9) of the Act is applicable and provides that "if there is an inconsistency between any provision of this Act and a provision of any Act...the provisions of both Acts apply concurrently, to the extent that it is possible to apply and comply with one of the inconsistent provisions without contravening the second..." and if the above is not applicable "the provision that extends the greater protection to a consumer prevails over the alternative provision".

<sup>52</sup> Du Toit & Van Eeden 2014 739.

<sup>53</sup> S 2(9) CPA. Neither s 2(8) nor any query relating to hazardous chemical products is applicable in this situation.

<sup>54</sup> De Stadler 'Section 2' (2014) para 1.

<sup>55</sup> Du Plessis (2015) 96.

<sup>56</sup> De Stadler 'Section 2' (2014) para 2.

<sup>57</sup> *Ibid.*

<sup>58</sup> S 2(1) CPA is applicable when interpreting the Act. It should be done in a manner that gives effect to the purposes of the Act as laid down in s 3.

<sup>59</sup> De Stadler 'Section 2' (2014) para 1.

piece of legislation which intends to ensure that proper regulatory functions exist between individual consumers and businesses.

### 2.2.1.2 Section 3: Purposes of the CPA

The purposes of the CPA as contained in section 3 are, amongst others, “to promote and advance the social and economic welfare of consumers in South Africa by reducing and ameliorating any disadvantages experienced in accessing any supply of goods or services by consumers whose ability to read and comprehend any advertisement, agreement, mark, instruction, label, warning, notice or other visual representation is limited by reason of low literacy, vision impairment or limited fluency in the language in which the representation is produced, published or presented...improving consumer awareness and information and encouraging responsible and informed consumer choice and behaviour”. De Stadler states that irrespective of section 3 it is possible for additional purposes to be inferred from the ambit of the CPA.<sup>60</sup>

The CPA ensures the existence of an extensive framework for the objective of protecting, developing and enhancing individual consumer rights.<sup>61</sup> When interpreting the abovementioned purposes, a number of observations can be made regarding the application of the CPA to pharmaceutical product labelling:

By reading section 3(1)(b)(iv) it is clear that the CPA aims to protect consumers who have limited understanding (due to a number of reasons) regarding certain products/goods. Interlinking this with pharmaceutical product labelling, it should be kept in mind that the purpose of the CPA is to protect consumers with limited understanding regarding certain specific goods – in this instance medicine. It is submitted that this section inherently requires relevant laws to be brought in line with the CPA to ensure that this purpose materialises. As is discussed in chapter 3, plain language is extremely crucial when dealing with consumers and their ability to comprehend. Further, section 3(1)(e) is concerned with consumer awareness and knowledge, providing for the situation and circumstances in which consumers are

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<sup>60</sup> *Idem* ‘Section 3’ para 2. The preamble to and the long title of the CPA are also included.

<sup>61</sup> Jacobs *et al* (2010) 303-305.

placed in a position where they are informed to make individual decisions on their own, which will be to their benefit.

Through proper instructions on the use of pharmaceuticals, one of the aims of the CPA, namely, the prevention of exploitation or harm to consumers will be achieved.<sup>62</sup> Packaging and labelling must not mislead or deceive consumers, or make any representation about a supplier or any goods or services unless there are reasonable grounds for believing the representation to be true.<sup>63</sup>

It is clear that the purposes of the CPA are very important when dealing with the interpretation of any section of the Act and should be kept in mind at all times.

## **2.2.2 Fundamental consumer rights**

### *2.2.2.1 Section 22: Right to information in plain and understandable language<sup>64</sup>*

This provision is contained in part D of the CPA concerning the right to disclosure and information. In terms of this section any notice, document or visual representation (referred to as a 'document') presented to a consumer should be produced, provided or displayed in terms of any required prescribed form or if no such form exists it should be in plain language.<sup>65</sup> Numerous authors have commented on this section, amongst them Burt and Gordon who analysed and applauded it.<sup>66</sup> Gouws correctly submits that section 22 seeks to ensure that consumers understand the terms and conditions of the transactions or agreements they enter into and that they are afforded the opportunity to make informed choices about the products they consume.<sup>67</sup> The writer further argues that this section goes beyond requiring plain language to be used and raises this requirement to a fundamental right, a view which is confirmed and further discussed by Stoop.<sup>68</sup>

Such a document should be written or laid out in such a way that it can be easily construed so that an ordinary consumer, with average literacy skills, minimal experience in the applicable consumer field and for whom the document is intended,

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<sup>62</sup> Brushwood (1986) 100.

<sup>63</sup> Prem M.

<sup>64</sup> See chapter 3 for more detail regarding plain language.

<sup>65</sup> S 22(1)(a) and (b) CPA.

<sup>66</sup> Gordon & Burt (2010) 59-60.

<sup>67</sup> Gouws 2010 85.

<sup>68</sup> *Ibid.* See Stoop 'Section 22' (2014) para 1.

would understand the “content, significance and import” of the document “without undue effort”; or, as Stoop states, the information should be ‘transparent’ especially when dealing with procedural fairness.<sup>69</sup> To make sense of the provisions of section 22 it is necessary first to deconstruct a number of key words.

Barnard discusses the concept of an ‘ordinary consumer’. She states that due to South Africa’s demographics a substantive number of consumers are regarded as ‘vulnerable’ and that a realistic answer to the question who falls under ‘ordinary consumer’ will not be achieved easily.<sup>70</sup> Gouws submits that regard should be had to the CPA’s preamble (which acknowledges the variations among consumers due to inequalities in their education and finances) and that an ‘ordinary consumer’ will be defined by determining the type of consumer dealt with.<sup>71</sup> Stoop and Churr suggest that ‘average literacy skills’ as contained in section 22 require that the document should cater for average South African consumers of the class for whom it was intended.<sup>72</sup> Furthermore, when drafting a document the focus should not be on the average consumer but rather on the consumer with the least experience.<sup>73</sup> Gouws argues that the starting point for a test in this regard is to determine the average literacy skills of the consumer at hand.<sup>74</sup>

Van Eck<sup>75</sup> submits that a document will be in plain language if the reader understands it the very first time it is read; and that it will satisfy the requirement if it the most effective method for writing the information used. Van Eck furthermore states that the requirements contained in section 22 come across as subjective and that there are no objective legislative methods available to determine whether the document fulfils the ‘plain language’ requirement.<sup>76</sup> The key to determine whether it is in plain language is ultimately whether the reader understands it or not.<sup>77</sup> The starting point of drafting a document should be to bear in mind its intended audience.<sup>78</sup>

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<sup>69</sup> Stoop ‘Section 22’ (2014) para 1.

<sup>70</sup> Barnard 2014 3.

<sup>71</sup> Gouws 2010 87.

<sup>72</sup> Stoop & Churr 2013 533; Stoop ‘Section 22’ (2014) para 3.

<sup>73</sup> *Ibid.*

<sup>74</sup> Gouws 2010 87.

<sup>75</sup> Van Eck 2012 21.

<sup>76</sup> *Ibid.*

<sup>77</sup> *Ibid.*

<sup>78</sup> *Ibid.*

Van Eck lists certain objective factors regarding the average intended reader that might assist in the drafting style, namely, the consumer's age, education, literacy level and language.<sup>79</sup> Stoop and Churr correctly argue that the sentence “for whom a notice, document or visual representation is intended” emphasises the fact that suppliers will have to draft documents in order to cater for the specific situation and consumer at hand.<sup>80</sup> This requires suppliers to draft more than one document in advance for the same situation to ensure that it is suited to the target audience for which it is intended.<sup>81</sup>

They further correctly argue that this section only applies to notices as required by legislation, visual representations and written agreements and that oral agreements are excluded.<sup>82</sup> It is submitted that a product label or package insert will fall under one of the above categories and thus will have to comply with the plain language requirement contained in section 22.<sup>83</sup>

#### *2.2.2.2 Section 58: Warning concerning fact and nature of risks*

Section 58(2) provides that the person who packages (this could be a pharmacist, supplier or manufacturer, depending on the situation) any hazardous or unsafe goods (which include, it is submitted, prescription medication) “must display on or within that packaging a notice that fulfils the plain language requirements of section 22, and any other applicable standards, providing the consumer with adequate instructions for the safe handling and use of those goods”.<sup>84</sup> Naudé states that section 58, amongst others, requires certain instructions to be applied to the packaging of hazardous or unsafe products.<sup>85</sup>

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<sup>79</sup> *Ibid.*

<sup>80</sup> Stoop & Churr 2013 533.

<sup>81</sup> *Ibid.*

<sup>82</sup> *Idem* 531.

<sup>83</sup> See chapter 4 for a discussion of product labelling and an analysis of s 24. It should also be noted that as medicines are required by law to have labels as well as package inserts (see 2.3 for a discussion of the Medicines Act), s 22 will be applicable as it applies to documents required by law.

<sup>84</sup> S 58(1) CPA provides that the supplier of any activity or facility must ensure that a consumer is specifically made aware (according to the standards set out in s 49 above) of any activity or facility when “subject to any risk of an unusual character or nature” or a risk “which a consumer could not reasonably be expected to be aware of or which an ordinarily alert consumer could not reasonably be expected to contemplate in the circumstances” or a “risk that could result in serious injury or death”. As S 58 (1) relates to activities and facilities, the impact thereof on the issue at hand is not explored as it will require the interpretation of ‘activity’ and ‘facility’ relating to medication use which is beyond the scope of this study.

<sup>85</sup> Naudé ‘Contract’ (2014) para 7.



Section 58(4) applies to the installation of any hazardous goods as contemplated in subsection 2. The word ‘install’ can further be interpreted and if this section is viewed strictly by looking at the meaning of the words, section 58 does not apply to pharmaceutical products for purposes of this study. However, if the word ‘install’ is only mentioned in section 58(4) for other purposes and section 58 does not intend merely to regulate physical goods and not consumables, this section will extend further and have an impact on the current practice of pharmaceutical product labelling.

In light of the information provided by Van Zyl<sup>86</sup> it is unlikely that section 58 will be applicable with regard to medication as dealt with in this study. However, this section and the ambit thereof is open to further examination in order to determine the application thereof on the pharmaceutical product labelling industry.

#### Section 49: Notice required for certain terms and conditions

The CPA is quite an extensive piece of consumer legislation and therefore numerous sections thereof may be applicable to and influence the way in which the Act is applied to product labelling. It is, however, impossible to deal with all relevant sections in depth. It should also be noted that section 49 which deals with the notice required for certain terms and conditions might also have an influence on pharmaceutical product labelling. Moreover, section 58 refers the reader to section 49 in that the supplier of any activity subject to any unusual risk, or a risk the consumer could not possibly have been aware of, or an activity that could result in injury or death, must “specifically draw the fact, nature and potential effect of that risk to the attention of consumers in a form and manner that meets the standards set out in section 49”.<sup>87</sup>

Section 49 could possibly apply to pharmaceutical product labelling but since the focus of this provision is on dangerous activities or facilities and not on goods it is not discussed in detail. It is submitted that there is doubt as to whether this section (even though it is concerned with notices and plain language) applies to product labelling.

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<sup>86</sup> Van Zyl ‘Section 58’ (2014).

<sup>87</sup> S 58(1)(a), (b) and (c) CPA. However, seeing that s 58(1) relates to any activity or facility, it is doubted that this will have a noteworthy influence on product labelling and plain language. Thus, s 49 CPA does not require an in-depth discussion in this specific context.



## 2.2.7 Other applicable provisions

Eiselen states that chapter 2 “lies at the heart of the Act”.<sup>88</sup> All the provisions discussed below are part of Chapter 2 of the CPA.

### 2.2.7.1 Section 8: Protection against discriminatory marketing

Section 8 deals with protection against discriminatory marketing. Although it is not directly related to product labelling, this section provides that a supplier should not unfairly “exclude any person or category of persons from accessing any goods or services offered by the supplier”. At first glance this provision might not seem to be of importance, but it could be argued that by not providing clear and understandable instructions on medicine (by labelling it effectively in order for uneducated consumers to be placed in a position to understand and use the product safely and effectively), suppliers are excluding them from accessing the goods as they will not be in a position to make informed and educated decisions.<sup>89</sup> Barnard and Kok state that this section is important to achieve equality in South Africa.<sup>90</sup> They refer to Jacobs *et al*<sup>91</sup> who discuss this provision with regard to the new constitutional dispensation.<sup>92</sup> However, there is no conclusive investigation of this aspect as this provision is mentioned only because of its possible application to the issue at hand.<sup>93</sup>

### 2.2.7.2 Section 18: Consumer’s right to choose or examine goods

Section 18 provides that “despite any statement or notice to the contrary, a consumer is not responsible for any loss or damage to any goods displayed by a supplier, unless the loss or damage results from action by the consumer amounting to gross negligence or recklessness, malicious behaviour or criminal conduct”. It is submitted that this section may possibly be interpreted to the extent that a consumer may hold a

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<sup>88</sup> Eiselen ‘Section 8’ (2014) para 1.

<sup>89</sup> See Eiselen ‘Section 8’ (2014) para 3.

<sup>90</sup> Barnard & Kok 2015 1-5.

<sup>91</sup> Jacobs *et al* 2010 5.

<sup>92</sup> Barnard & Kok 2015 5.

<sup>93</sup> S 8(2) CPA could provide a further point to argue and interpret as it provides that a supplier should not indirectly or directly treat any person differently (and in a manner that could constitute unfair discrimination in terms of s 9 of the Constitution or in terms of s 2 of the Promotion of Equality and Prevention of Unfair Discrimination Act) when “selecting, preparing, packaging or delivering any goods for or to the consumer, or providing any services to the consumer”. Once again this is mentioned not for discussion but to make the reader aware of possible argument(s) that could be raised.

supplier liable for any harm suffered by him due to the use of medicine, especially in the absence of an appropriate explanation that would have placed him in a position to use the medication safely and effectively. This is of course subject to the consumer using the medication responsibly and with proper care.<sup>94</sup>

#### *2.2.7.3 Section 29: General standards for marketing of goods or services*

This section protects consumers from producers, importers, distributors, retailers and service providers who make a false or misleading representation regarding the goods or services marketed. These representations may relate to the nature, advantages or use of the goods as well as “any other material aspect of the goods or services”.<sup>95</sup> The importance of clear and understandable instructions on medication cannot be over-emphasised. Even though a supplier may not intentionally mislead a consumer, it is submitted that providing only minimal clarity and guidance as to the proper use of medicine may be construed as a misleading and/or false representation.<sup>96</sup>

#### *2.2.7.4 Section 40: Unconscionable conduct*

Section 40 deals with unconscionable conduct. Section 40(2) provides that ‘unconscionable conduct’ is “for a supplier knowingly to take advantage of the fact that a consumer was substantially unable to protect the consumer’s own interest because of physical or mental disability, illiteracy, ignorance, inability to understand the language of an agreement, or any other similar factor”. This section uses the word ‘knowingly’ which is indicative of intent.<sup>97</sup> It is submitted that if intent is provided for in section 40, section 29 might include situations and circumstances where the supplier does not live up to the standard expected of him and unknowingly misleads and creates a false impression to a vulnerable consumer.

#### *2.2.7.5 Section 61*

Before dealing with liability for damage caused by goods, an outline and overview of section 61 are provided. For purposes of this study, the discussion of the parties who may be held liable is limited to the supplier, medical practitioner and pharmacist. The

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<sup>94</sup> As already mentioned this study does not attempt to determine the consequences of non-compliance with s 8, but mentioning it is necessary to ensure the reader is placed in a position to fully comprehend the possible impact non-adherence might have as well as to mention all the likely applicable provisions.

<sup>95</sup> Reference is also made to s 41 of the CPA concerning false, misleading or deceptive representations.

<sup>96</sup> Van Zyl ‘Section 29’ (2014) para 4.

<sup>97</sup> Du Plessis J ‘Section 40’ (2014) para 3; Stoop ‘Section 24’ (2014) para 3.

reasons for this are the word count imposed on this study and the topic of prescription medication, which requires certain specific people to be involved in the supply chain. Rowe and Moodley correctly argue that the CPA enforces strict liability for harm caused by goods and that everyone in the supply chain, including the doctor, can be held jointly and severally liable.<sup>98</sup>

Nöthling-Slabbert and Pepper state that this section as well as other provisions of the CPA (including section 54) are applicable to health care and extend to all transactions ranging from medical treatment to the dispensing of medicine.<sup>99</sup> They further submit that insufficient instructions or warnings provided to the consumer regarding any hazard arising and associated with the use of goods, irrespective whether the harm caused might be due to the negligence of any party, will cause the producer, importer, distributor, supplier or retailer to be accountable to the consumer.<sup>100</sup> Loubser & Reid note the distinction between ‘instructions’ and ‘warnings’.<sup>101</sup> According to them, warnings are used to inform consumers of possible risks whereas instructions direct consumers on how products should be used in order to avoid the risks.<sup>102</sup>

#### Liability of the parties in the supply chain

Section 61 of the CPA provides for liability for damage caused by goods used. This section sets out the liability of the producer, importer, distributor and retailer of any goods and provides that they will be liable for any harm that the consumer may incur through the use of the unsafe goods supplied. The words ‘any goods’ and ‘any unsafe goods’ used in the section make it clear that medicine as goods will also fall under this section.

The provision that “the producer or importer, distributor or retailer of any goods is liable for any harm...caused wholly or partly as consequence of...inadequate instructions or warnings provided to the consumer pertaining to any hazard arising from or associated with the use of any goods, irrespective of whether the harm resulted from any negligence on the part of the producer, importer, distributor or retailer, as the case

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<sup>98</sup> Rowe & Moodley 2013 1.

<sup>99</sup> Nöthling-Slabbert & Pepper 2011 801.

<sup>100</sup> *Ibid.*

<sup>101</sup> Loubser & Reid ‘Section 61’ (2014) para 1.

<sup>102</sup> *Ibid.*

may be” further indicates that pharmaceutical products should contain clear instructions, whether on the label or package insert, to ensure that the relevant parties will not be in contravention of section 61.<sup>103</sup>

Medicine is inherently unsafe and when supplied to the consumer without proper indications, warnings and instructions it will be even more hazardous<sup>104</sup> and section 61 will thus be applicable to pharmaceutical products. As stated earlier the focus of the dissertation is not on the liability of the parties, but for completeness sake the parties to be discussed are the medical practitioner, pharmacist and pharmaceutical product supplier. According to Nöthling-Slabbert and Pepper medical practitioners will be regarded as ‘suppliers’ or ‘retailers’ in the supply chain, and may be held liable in terms of the CPA for harm and loss suffered by the consumer.<sup>105</sup>

This section also defines ‘supplier’ and provides that “a supplier of services who, in conjunction with the performance of those services, applies, supplies, installs or provides access to any goods, must be regarded as a supplier of those goods to the consumer”.<sup>106</sup> If more than one person is liable, for instance the pharmacist and the supplier, their liability will be joint and several.<sup>107</sup> The parties mentioned above will not be held liable if the harm was “wholly attributable to compliance by that person with instructions provided by the person who supplied the goods to that person”.<sup>108</sup>

A party may be held liable for different types of harm including “the death of, or injury to, any natural person; an illness of any natural person...any economic loss that results from harm”.<sup>109</sup> This further indicates that if medicine is not correctly administered and no proper instructions are provided it may lead to the supplier, medical practitioner or pharmacist being held liable. Loubser & Reid correctly state that when dealing with a claim based on section 61(5)(a) the ‘injury’ will also include harm to organs caused by a defective pharmaceutical product.<sup>110</sup> This section is important as plain language used on product labelling and inserts is for the benefit, protection and in the interest of

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<sup>103</sup> S 61(1)(C) CPA.

<sup>104</sup> Nelson *et al* 2014 165-172.

<sup>105</sup> Nöthling-Slabbert & Pepper 2011 800.

<sup>106</sup> S 61(2) CPA.

<sup>107</sup> S 61(3) CPA.

<sup>108</sup> S 61(4)(b)(ii) CPA.

<sup>109</sup> S 61(5) CPA.

<sup>110</sup> Loubser & Reid ‘Section 61’ (2014) para 5.

consumers as well as for the protection of suppliers, medical practitioners and pharmacists.

### Medical practitioner

The duties of the doctor are not discussed in detail as this requires a separate investigation but it should be noted that the doctor has a duty to inquire into the patient's medical history before prescribing medication.<sup>111</sup>

The medical practitioner is generally the first party to be involved in the supply chain as he is the one consulting, diagnosing and prescribing medication to the consumer (patient). A consumer (especially a vulnerable one as referred to in section 3 of the CPA) cannot be expected to have the required knowledge to provide all the necessary information to the doctor regarding his medical history.<sup>112</sup> The practitioner should ensure that the patient is informed of all the relevant information regarding his diagnosis as well as the medication prescribed.<sup>113</sup>

The medical practitioner has a duty to ensure that the medication prescribed will accord with the patient and be in his best interest. Breach of this duty may lead to the medical practitioner being held liable in terms of section 61 and in terms of any other applicable provision. According to Rowe and Moodley the doctor is an expert who usually makes decisions on behalf of patients.<sup>114</sup> They are, however, in favour of a mutual relationship model to encourage individual consumers to refrain from being passive followers but rather to become self-determining free agents.<sup>115</sup>

### Pharmacist

After the consultation with a medical practitioner, the most logical next step for a consumer is to approach a pharmacist.<sup>116</sup> The recently diagnosed consumer will be in possession of a prescription containing the medication necessary for the appropriate treatment.<sup>117</sup>

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<sup>111</sup> Nelson *et al* 2014 170.

<sup>112</sup> *Idem* 170-172.

<sup>113</sup> *Ibid.*

<sup>114</sup> Rowe & Moodley 2013 4.

<sup>115</sup> *Idem* 3.

<sup>116</sup> Gilbert 1998 83.

<sup>117</sup> *Ibid.*

A pharmacist can be regarded as an intermediary of the supplier and the consumer, and of the doctor and the consumer.<sup>118</sup> A pharmacist is a specialist in pharmacology and is required to have excellent knowledge of all the medication to be dispensed to consumers, and of the side-effects, contraindications and complications that the medication may cause.<sup>119</sup>

It will be dangerous and negligent for a pharmacist blatantly to accept that a medical practitioner has ensured that the medication to be prescribed is the best and safest remedy for the consumer, especially since medical practitioners are pressured for time and are only human beings.<sup>120</sup>

The same applies to a medical practitioner who assumes that a pharmacist (who supposedly knows pharmaceutical products by the tip of his fingers) will educate a consumer on the prescription medication to be taken as prescribed by the medical practitioner, and will conduct an investigation to ensure that the medication is in the best interest of the consumer.<sup>121</sup>

The pharmacist has a duty to ensure that the consumer is knowledgeable about the use of the medicine as well as all the risks associated by using it, and ultimately has to ensure that the consumer is placed in a position in which he is informed and able to make the best decisions regarding his own health and medication usage.<sup>122</sup>

To inquire, investigate and inform a consumer of the intended medication, dosage and risks will ensure that a pharmacist is not held accountable in terms of the CPA. The pharmacist should also keep in mind that merely speaking to a consumer, who might already be devastated by his diagnosis or who might not be paying attention when the pharmacist consults with him, will not provide protection; a pharmacist should add all of the required information in plain language on the medication provided.<sup>123</sup> Due to the nature of medication this will not be an easy task, but it should be one that is complied with as far as possible to ensure that a vulnerable consumer is protected.<sup>124</sup> Whether

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<sup>118</sup> *Idem* 83-90; Abduelkarem 2014 866, 868-869 & 872.

<sup>119</sup> Schwartz & Woloshin 2011 1463-1468.

<sup>120</sup> *Ibid.*

<sup>121</sup> Gilbert 1998 83-86.

<sup>122</sup> *Ibid*; Jeetu & Girish 2010 107-111.

<sup>123</sup> Abduelkarem 2014 870.

<sup>124</sup> *Idem* 872.

this information will be provided by a label or a product insert does not matter; what does matter and should take preference is the information contained therein.<sup>125</sup>

### Supplier

Lastly to be discussed regarding liability is the responsibility of the supplier of pharmaceutical goods to provide clear packaging in compliance with section 22 of the CPA.

The problem with packaging can be linked to pharmacies, where even though the medication's original packaging might adhere to the provisions (as provided by the supplier), prescription medication is often removed from the original packaging to provide the consumer with the specific amount prescribed by a medical practitioner.<sup>126</sup>

In these instances the package will usually have a label bearing minimum information attached to it.<sup>127</sup>

It is submitted that the above practice followed by pharmacists is not adequate to adhere to the provisions of the CPA and that a proactive approach to this system is required in order to ensure that consumers are informed and protected by the CPA. The supplier should ensure that the original packaging complies with the CPA, but the pharmacist's duty relates to placing medication in smaller packages when providing the consumer with the prescribed amount. Merely giving the information orally will not suffice because of the inherent risk and harm connected to the use of prescription medication.<sup>128</sup> If, however, the original packaging does not comply with section 22, the supplier of the pharmaceutical products will be liable in terms of any harm that might be caused as envisaged in section 61 of the Act.

Section 61 also provides for the situation where more than one person failed to adhere to the provisions of the Act, in which case they will be jointly and severally liable.<sup>129</sup> This may, for example, be where a pharmacist as well as the medical practitioner or supplier are the responsible parties.<sup>130</sup>

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<sup>125</sup> Jeetu & Girish 2010 107-111.

<sup>126</sup> Shrank *et al* 2007 1760-1765.

<sup>127</sup> *Ibid.*

<sup>128</sup> Jeetu & Girish 2010 107-111.

<sup>129</sup> Loubser & Reid 'Section 61' (2014) para 3.

<sup>130</sup> S 61(3) CPA: "If in a particular case, more than one person is liable in terms of this section, their liability is joint and several."



## **2.2.8 Conclusion**

The provisions of the CPA identified as important for discussion were outlined above and where applicable, critically analysed. However, even though the CPA's provisions are the main focus of this study another Act applies to the specific issue of pharmaceutical product labelling, namely, the Medicines Act which is examined below.

## **2.3 The Medicines Act**

The Medicines Act and specifically regulations 8 to 10 promulgated in terms thereof are analysed below. It is necessary to quote extensively from the Medicines Act in order to appreciate the extent of the relevant provisions.

### **2.3.1 Regulation 8: Labelling**

Regulation 8 requires the package or container of all medicine sold and intended for human consumption to have a label on it that is (a) in English and one other official language; and (b) printed with clear and legible permanent letters thereon.<sup>131</sup>

The Act also requires that when dealing with scheduled medicine (which is relevant to this study regarding prescription medication), the schedule of the medicine should be provided in a "prominent type size and face"; it should also be "surrounded by a square border" and this should immediately precede the proprietary name of the medicine.<sup>132</sup> Moreover, the label should contain the name, registration number, medicine dosage, approved name of the active ingredients and anti-oxidant contained in the medicine and approved indications for administering it.<sup>133</sup> Regulation 8(3) provides for any other

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<sup>131</sup> Reg 8(1) Medicines Act.

<sup>132</sup> Reg 8(1)(a) Medicines Act.

<sup>133</sup> Reg 8(1)(b) to (e), (g) & (j) Medicines Act. In terms of the regulation, the following information is to be provided on the label: The name and percentage of any bacteriostatic or bactericidal agent which has been added to the medicine as a preservative; in the case of a medicine for oral or parenteral administration, the quantity of sugar contained in the medicine; or ethyl alcohol contained in the medicine, expressed as a percentage of the total volume of the medicine, if such quantity exceeds two per cent by volume; the content of the medicine package expressed in the appropriate unit or volume of the medicine; where applicable, the instruction 'Shake the bottle before use'; in the case of a medicine intended for injection by a particular route of administration only, that route of administration by means of suitable words or abbreviations; the lot number of the medicine; the expiry date of the medicine; the name of the holder of certificate of registration of the said medicine; the requirements regarding the manner in which the medicine shall be stored with specific reference to the applicable storage temperature and other precautions required for the preservation of the medicine; where applicable, the statement: 'For external use only'; the warning: 'Keep out of reach of children; in the case of a medicine which contains aspirin or paracetamol the warning: 'Do not use continuously for more than 10 days without consulting your doctor; in the case of a medicine for oral administration which contains fluorides, the warning: "Contains fluoride; in the case of a medicine for oral administration which contains an



special information to be included as authorised by the Medicines Control Council, even if it is not required by this Act.

Regulation 8(4)(c) provides that the abovementioned regulation will not apply to any medication sold by a pharmacist (or a person authorised to dispense it) if the medication is dispensed in a hospital or with a prescription issued by a medical practitioner. In such a case, the packaging should contain the following minimum information: “(i) the proprietary name, approved name, or the name of each active ingredient of the medicine, where applicable, or constituent medicine; (ii) the name of the person for whose treatment such medicine is sold; (iii) *the directions in regard to the manner in which such medicine should be used*;<sup>134</sup> (iv) the name and business address of the person authorised to sell such a medicine; (v) date of dispensing; and (vi) reference number.”

#### 2.3.1.1 Regulation 8(4)(c)(iii)

This provision provides a clear exception to all the required and compulsory information in terms of regulation 8. As it still (as a minimum) requires the directions of use to be stated, it is submitted that these instructions should be done in plain language and with the background of the consumer in mind; it can thus be harmonised and interpreted with the provisions of the CPA discussed above in mind.<sup>135</sup>

#### 2.3.1.2 Conclusion

It is possible to interpret regulation 8 to ensure that the applicable provisions of the CPA (section 22 and so forth) are complied with. Although the Medicines Act mentions certain minimum information to be placed on medicine labels, it is submitted that this bare minimum information will not be sufficient to satisfy the requirement of plain language as envisaged by the CPA. However, the discussion below of two other regulations may assist in a clearer and more thorough application and understanding of the required and relevant pharmaceutical product labelling information.

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antihistamine, the warnings: ‘This medicine may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol or other central nervous system depressant agents’; in the case of eye drops or artificial tear solutions in respect of which evidence concerning the self-sterilising ability of the medicine has not been approved by the Council, the warning ‘Do not use more than 30 days after opening’; in the case of a medicine that contains TARTRAZINE, the warning: ‘Contains TARTRAZINE.’

<sup>134</sup> Own emphasis.

<sup>135</sup> “[T]he directions in regard to the manner in which such medicine should be used.”

### **2.3.2 Regulation 9: Package inserts**

This regulation provides that every package of medicine must contain (“be accompanied” by) a minimum legibly printed package insert in English and one other official language “either as a separate entity or as an integral part of the package”. This package insert must contain the following information: The scheduling status; proprietary name and dosage; composition which includes the approved name of each active ingredient and quantity thereof, the approved name and quantity of any bactericidal or bacteriostatic agent included as a preservative and expressed as a percentage; the amount of ethyl alcohol included; whether the product contains tartrazine; a warning if the medication contains sugar; pharmacological classification; indications; contra-indications; the pharmacological action, “i.e. a description of the pharmacological action of the medicine, and where applicable, under a sub-heading: Pharmacokinetics, pharmacodynamics; summary of clinical studies”; warnings and special precautions; interactions; pregnancy and lactation; dosage and directions for use; side effects; known symptoms of over dosage and particulars of its treatments; identification; presentation; storage instructions practically formulated and storage temperatures; the registration number; name and business address of the holder of the certificate of registration; and date of package insert’s publication.<sup>136</sup> Regulation 9(3) provides that the above shall not apply to, amongst others, “any medicine compounded and/or sold by a medical practitioner, dentist, pharmacist or any other person who is authorised to dispense medicines in the course of his or her professional activities for the treatment of a particular patient or any medicine sold by a pharmacist or by a hospital pharmacy in accordance with a prescription issued by a medical practitioner or dentist for the treatment of a particular patient”.<sup>137</sup>

Thus, there is no requirement that pharmacists or suppliers must ensure that all the relevant information is contained on or in the package in terms of this Act. Without a legal obligation resting on health care providers to provide such written information, the plain language provision cannot find application unless one takes into account the

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<sup>136</sup> Reg 9(1)(s)(ii) Medicines Act. “The Council may on application authorise the deviation from the format and content of a package insert prescribed as a condition of registration of a medicine”. (iii) “The Council may on application authorise the inclusion on a package insert of any specified information not required by this regulation to be so included.”

<sup>137</sup> Reg 9(4) Medicines Act further provides that “nothing contained in sub-reg (2) and (3) shall be construed as prohibiting the inclusion of a package insert in the medicine”.

other provisions of the CPA concerning the nature and risk of hazardous and harmful products. With this inference, it can be stated that due to the nature of medication, consumers are entitled to plain language information provided on their medication, irrespective of whether the pharmacist (and other medical practitioners) fulfil their duties by providing them with a clear and comprehensive explanation regarding its use.

### **2.3.3 Regulation 10: Patient information leaflet (PIL)**

#### *2.3.3.1 What is a patient information leaflet?*

According to Mwingira and Dowse<sup>138</sup> the PIL as provided for in regulation 10 of the Medicines Act plays a key role in informing and educating patients on the use and contents of their medicines. They correctly argue that consumers need appropriate information in order to use prescription medication safely and effectively.<sup>139</sup> They further state that this ‘appropriate information’ should be provided verbally or by means written or multimedia.<sup>140</sup> They also submit that verbal information is not adequate when dealing with medicine, as a study showed that over half of the consumers (patients) forgot what their medical practitioner told them within five minutes of leaving the consultation room.<sup>141</sup>

#### *2.3.3.2 Regulation 10*

As regards the patient information leaflet as provided for in the Medicines Act it is stated that each package must contain a patient information leaflet with certain information provided thereon in English and one other official language: The scheduling status; proprietary name and dosage form; the composition of the medicine; the approved indications and use; instructions before taking the medicine, which include contra-indications, precautions and warnings, warnings, for example, concerning sedative properties of the medicine or risks involved with sudden withdrawal of the medicine, interactions, and the following general statement: “Always tell your health care professional if you are taking any other medicine” and “If you are pregnant or breast feeding your baby please consult your doctor, pharmacist or other health care professional for advice before taking this medicine”; instructions on how to

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<sup>138</sup> Mwingira & Dowse 2006 49.

<sup>139</sup> *Ibid.*

<sup>140</sup> *Ibid.*

<sup>141</sup> *Idem* 50-52.

take the medicine, including the following statements: “Do not share medicines prescribed for you with any other person.” “In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre”; and side effects, including the following general statement: Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice; storage and disposal information, including the following general statement: “Store all medicines out of reach of children.”<sup>142</sup>

Regulation 10(3) contains the following very important statement: “[A] person dispensing or administering a medicine must ensure that a patient information leaflet is made available at the point of such dispensing or administration.” It is submitted that the above wording is of such a nature that it could be interpreted to mean that there is a duty on pharmacists to ensure that patient information leaflets accompany all medication (including prescription medication) at all times.<sup>143</sup>

As regulation 10 contains no exception similar to those provided for in regulations 8 and 9, this also increases the likelihood that this regulation is of a compulsory nature.<sup>144</sup> Further in regulation 10(4) it is stated that on application and in respect of certain medication the Council may determine any additional information to be furnished under a particular heading.

### *2.3.3.3 Consumers should understand the content of the PIL*

Mwingira and Dowse submit that consumer knowledge and education is an important subject that has been a topic of discussion and development throughout the world; of all the written consumer documents, the PIL is the most popular and effective method of conveying important health and medicine information to consumers.<sup>145</sup> Moreover, the writers correctly refer to Harvey and Plumridge who state that the benefits of PILs include the improvement of patient understanding and knowledge regarding their

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<sup>142</sup> Reg 10(2) Medicines Act provides that the Council, as provided for the Act, may authorise a deviation from ss 1 as discussed.

<sup>143</sup> Fage-Butler 2013 142-143.

<sup>144</sup> It is submitted that in the contemporary pharmaceutical environment, pharmacists clearly dispense with their duty of providing the required compulsory information more often than is deemed acceptable.

<sup>145</sup> Mwingira & Dowse 2006 50-52.

medicines; also, appropriate instructions can be recalled with much more ease, while the end result is the reduction of medication administration errors as well as consumer anxiety.<sup>146</sup> The final result is a reduction in the information gap between consumers and medical practitioners.<sup>147</sup>

They further submit that the form and quality of the information to be provided on the PIL should be in line with consumers' literacy level and should take into account their culture, beliefs, attitudes and expectations.<sup>148</sup> It is submitted that this statement by Mwingira and Dowse is in line with the requirements regarding plain language outlined in section 22 of the CPA. Thus it can be deduced from the compulsory nature of this regulation that section 22 of the CPA should be complied with and that the information contained on the PIL should be provided in plain language.

### **2.3.4 Conclusion**

It is clear that regulation 10 of the Medicines Act should be brought in line to ensure that section 22 of the CPA is complied with. Although the title of this dissertation concerns 'product labelling' it is submitted that a PIL should comply with the same plain language requirements.<sup>149</sup>

The provisions of the Medicines Act do regulate the issue at hand to a certain extent. However, the required information seems to be intended more for the sake of completeness and for interpretation by educated consumers. It is submitted that the current practice and the information required by the Medicines Act are not adequate. Although its provisions are extremely important they are inadequate for purposes of complying with section 22 of the CPA. The consumer should be placed in a position to make informed decisions regarding his health. By merely complying with the current practice of pharmaceutical product labelling in terms of the Medicines Act, the purposes of the CPA are not fulfilled in any way or form. Consumers should be given preference in all situations, especially when their health and inherent dangerous products are involved.<sup>150</sup>

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<sup>146</sup> *Ibid.*

<sup>147</sup> *Ibid.*

<sup>148</sup> *Idem* 50.

<sup>149</sup> See chapter 3 for a comprehensive discussion of plain language as well as certain guidelines to ensure that documents are brought in line with the Act.

<sup>150</sup> Du Toit & Van Eeden 2014 738.

## 2.4 Chapter conclusion

When interpreting the CPA, especially when another Act is also applicable, section 2 of the CPA will apply, in terms of which “this Act must be interpreted in a manner that gives effect to the purposes set out in section 3”. It further provides that when interpreting or applying the CPA and “there is an inconsistency between any provision of this Act and a provision of any Act...the provisions of both Acts apply concurrently, to the extent that it is possible to apply and comply with one of the inconsistent provisions without contravening the second”; and to the extent that this cannot apply “the provision that extends the greater protection to a consumer prevails over the alternative provision”.<sup>151</sup>

It is thus clear when dealing with the CPA and the Medicines Act, or any other Act that might apply, that according to section 2 they will apply simultaneously as far as it is possible. If it is not possible the consumer’s best interest should be the main priority and at all times the provision(s) affording greater protection should prevail. All the provisions mentioned and discussed in this chapter (including those not specifically mentioned) will be applicable depending on the situation at hand, and should be interpreted and applied in order to ensure that the consumer is protected and that the purposes of the CPA as stated in section 3 are achieved.

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<sup>151</sup> S 2(9)(a) and (b) of the CPA.

## CHAPTER 3: THE CPA AND THE IMPORTANCE OF PLAIN LANGUAGE

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### SUMMARY

- 3.1 Introduction**
  - 3.2 The plain language movement**
  - 3.3 Section 22 of the CPA**
  - 3.4 Pharmaceutical product labelling and plain language**
  - 3.5 Chapter conclusion**
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“I didn’t have time to write a short letter, so I wrote a long one instead.”<sup>152</sup>

### 3.1 Introduction

The provisions, especially the plain language requirement, outlined in chapter 2 are critically discussed as part of this chapter. The plain language phenomenon is not a modern concept introduced by the CPA but it is in fact a movement that has developed over the centuries in the international environment.

In a General Household Survey done by Statistics South Africa in 2014, 16% of the adults (persons over 20 years) of 31 486 sampled households visited were illiterate (with less than Grade 7 as their highest level of education).<sup>153</sup> Stoop refers to statistics indicating the importance of plain language as 11% of adult South Africans are illiterate.<sup>154</sup> Thus, there are still pharmaceutical product consumers who will not be in a position to comprehend product labelling information – even if it is written in clearer terms – due to their lower level of understanding.<sup>155</sup> Exactly what plain language in

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<sup>152</sup> French mathematician, physicist, inventor, writer and Christian philosopher: Blaise Pascal (1623-1662). This indicates that using plain language is a skill and not an easy task, it is much easier to write a lot of words than being concise; perhaps the reason why there is a lot of criticism and commentary against the use of plain language.

<sup>153</sup> General Survey 2014 5.

<sup>154</sup> Stoop ‘Section 22’ (2014) para 3.

<sup>155</sup> S 22(2) CPA: “For the purposes of this Act, a notice, document or visual representation is in plain language if it is reasonable to conclude that an ordinary consumer of the class of persons for whom the notice, document or visual representation is intended, with average literacy skills and minimal experience as a consumer of the relevant goods or services, could be expected to understand the content, significance and import of the notice, document or visual representation without undue effort.” For a comprehensive discussion of s 22 see 3.3 below.



terms of product labelling entails, including the core elements thereof, is a factual question in need of evaluation.

The practical implementation of plain language, especially in terms of pharmaceutical product labelling, requires an improved systematic approach as well as a competent operational structure. In the long run this will benefit consumers and ensure that the underlying objectives of the CPA and ultimately the values and rights provided by the Constitution are attained.<sup>156</sup>

In this chapter, section 22 of the CPA is discussed with reference to plain language development, the importance of plain language on pharmaceutical product labelling as well as different views on the interpretation of the meaning of plain language.

### 3.2 The plain language movement

Throughout the centuries, many objections were raised against the inconspicuousness of legal jargon.<sup>157</sup> During the consumer movement in the 1970s, the 'Plain English Movement' of which the United Kingdom was the frontrunner became more dominant.<sup>158</sup> This increased the demand for plain language in consumer agreements as well and continued to do so throughout the world.<sup>159</sup>

The foundation of the plain language movement rests on providing clear and understandable terminology (especially when dealing with legal documents) to ensure that the average person is able to comprehend adequately all relevant information pertaining to their dealings.<sup>160</sup> This movement includes a variety of people not limited to practitioners and campaigners and in the modern era, law is only one of the aspects covered by it.<sup>161</sup> Various plain language institutions have been established over the last 30 years, including the international organisations Clarity and the Plain Language Association InterNational (PLAIN).<sup>162</sup>

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<sup>156</sup> S 3 CPA and the Constitution ss 1, 6, 9, 11, 27 & 30.

<sup>157</sup> Tiersma P 1-2.

<sup>158</sup> Stoop & Churr 2013 518.

<sup>159</sup> *Ibid.*

<sup>160</sup> Tiersma P 1.

<sup>161</sup> Adler (2016) 70.

<sup>162</sup> *Idem* 71. In 1983 a British local government solicitor established an organisation – namely Clarity – to ensure that lawyers realise the importance of simplifying legal English Today it is the largest international plain language organisation with more than 650 members from 50 countries. PLAIN is an international non-profit



There is no generally accepted definition of plain language and mostly the definition of what it is, is left to the plain language community to determine.<sup>163</sup> It can be stated with certainty that not only in South Africa but throughout the world the importance of plain language has been emphasised as is evident from the advantages below. Numerous advantages for the use of plain language have been identified, namely, that it (a) is more precise and sophisticated;<sup>164</sup> (b) prevents unnecessary confusion;<sup>165</sup> (c) is clearer and promotes better comprehension;<sup>166</sup> (d) is quicker and reduces costs;<sup>167</sup> (e) is more persuasive;<sup>168</sup> and (f) is accessible to the public.<sup>169</sup>

When taking all the above factors into account, it is clear that section 22 was not inserted in the CPA without just cause. The critique regarding this ‘phenomenon’ might be abundant in respect of the effect and difference in application thereof in theory and on paper, but when it comes to pharmaceutical products precision, clarity and comprehension are crucial.<sup>170</sup>

### 3.3 Section 22 of the CPA<sup>171</sup>

Section 22 is an extensive provision, comprising of requirements, recommendations and a stated standard. As with all interpretations regarding legal terminology and

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company based in Canada run on a volunteering basis, with members from over 20 countries. Its objective is mainly to promote clear communication in any language around the world.

<sup>163</sup> *Ibid.*

<sup>164</sup> Kimble 1994-1995 53-54: “It is much harder to simplify than to complicate. Anybody can take the sludge from textbooks, thicken it with a few more provisions, and leave it at that. Only the best minds and best writers can cut through.”

<sup>165</sup> *Idem* 78.

<sup>166</sup> *Idem* 62, 72, 75.

<sup>167</sup> Adler (2016) 72.

<sup>168</sup> *Ibid.*

<sup>169</sup> *Ibid.* One of the purposes of the CPA contained in s 3(1)(a) is to promote and advance social and economic welfare of consumers in South Africa to achieve a consumer market that is fair and accessible for the benefit of consumers generally.

<sup>170</sup> Srivastava *et al* 2010 228-230.

<sup>171</sup> S 22 CPA provides as follows: “The producer of a notice, document or visual representation that is required, in terms of this Act or any other law, to be produced, provided or displayed to a consumer must produce, provide or display that notice, document or visual representation in the form prescribed in terms of this Act or any other legislation, if any, for that notice, document or visual representation; or in plain language, if no form has been prescribed for that notice, document or visual representation. For the purposes of this Act, a notice, document or visual representation is in plain language if it is reasonable to conclude that an ordinary consumer of the class of persons for whom the notice, document or visual representation is intended, with average literacy skills and minimal experience as a consumer of the relevant goods or services could be expected to understand the content, significance and import of the notice, document or visual representation without undue effort, having regard to – the context, comprehensiveness and consistency of the notice, document or visual representation; the organisation, form and style of the notice, document or visual representation; the

definitions, the meaning and application of plain language in terms of the CPA are no exceptions.

### **3.3.1 What is plain language?**

There are numerous opinions and legal arguments as to what exactly constitutes plain language in terms of section 22. However, ultimately there is general consensus on the component that consumers should comprehend the application as well as the effect of the contents of the relevant document.<sup>172</sup> Gouws submits that information is in plain language when it is understood the first time the intended audience reads it.<sup>173</sup>

There is no obligation in terms of the CPA to use a specific official language when dealing with written documents and the plain language requirement.<sup>174</sup> It is difficult to appreciate how the requirements of plain language can ever be complied with if consumers do not understand the language used in information supplied to them.<sup>175</sup> Stoop,<sup>176</sup> however, correctly states that “an official language requirement would have placed an enormous burden on suppliers in South Africa”.<sup>177</sup> Due to the complex nature of some information (as might be the case when dealing with medical terminology) plain language does not automatically mean the language must be simple; it does, however, imply that it should be in understandable terms.<sup>178</sup>

What is understandable language? What is important is that it is not the information conveyed that should be simplified but the language used.<sup>179</sup> The content and significance (the express and implied meaning) of the intended information should be entirely, without undue effort, comprehensible to the consumer.<sup>180</sup> One of the main objectives of this section is that consumers should be educated and have the required knowledge available to them to ensure that they make informed decisions.<sup>181</sup>

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vocabulary, usage and sentence structure of the notice, document or visual representation; and the use of any illustrations, examples, headings or other aids to reading and understanding.”

<sup>172</sup> Barnard 2014 4.

<sup>173</sup> Gouws 2010 81.

<sup>174</sup> De Stadler (2013) 112.

<sup>175</sup> Stoop & Churr 2013 536; Stoop ‘Chapter 22’ (2014) para 4.

<sup>176</sup> Stoop ‘Chapter 22’ (2014) para 4.

<sup>177</sup> *Ibid.*

<sup>178</sup> De Stadler (2013) 105.

<sup>179</sup> *Ibid.*

<sup>180</sup> *Idem* 105-106. ‘Undue’ will depend on the circumstances of each case.

<sup>181</sup> Barnard 2014 4.

### 3.3.1.1 Guidelines to assist in plain language drafting

The broadness of the definition of plain language contained in section 22 fails to provide drafters of documents with much direction as to what is required of them.<sup>182</sup> This in turn requires drafters to seek outside guidelines to assist when drafting in order to ensure that the section is complied with.<sup>183</sup>

Suggestions made by Van Eck include using shorter sentences and paragraphs; inserting headlines tables, diagrams, illustrations and tables; using bullet points and lists; removing monotonous writing and technical terms; and using active voice as guidelines to ensure documents are drafted in plain language.<sup>184</sup>

Stoop and Churr provide three measures to be applied in order to assist in assessing whether a document complies with plain language requirements, namely, informal assessments, formal assessments and using assessment software.<sup>185</sup> The informal assessment (even though difficult to regulate) is a valuable internal method and includes internal style guides and assessment procedures.<sup>186</sup> A formal and objective guide provides substance to the provisions and serves as a material and valuable test mechanism and guide to drafters.<sup>187</sup>

Furthermore they refer to guidelines adopted in the United States of America and suggest these as a possible solution to provide meaning and effect to the requirements of section 22.<sup>188</sup> The guidelines include the following: use short words, paragraphs and sentences; avoid legal jargon and technical language; refrain from using Latin and foreign words; and do not use cross-references unless they are clear and brief.<sup>189</sup> They also state that drafters should take note of the size of the letters used, line length, column and margin width, spacing between lines and paragraphs, using bold headings, and using ink that is in sharp contrast to the paper.<sup>190</sup> All of this should be

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<sup>182</sup> Stoop & Churr 2013 533.

<sup>183</sup> Stoop 'Chapter 22' (2014) para 5.

<sup>184</sup> Van Eck 2012 22-23.

<sup>185</sup> Stoop & Churr 2013 537.

<sup>186</sup> *Ibid.*

<sup>187</sup> *Idem* 538.

<sup>188</sup> *Idem* 539.

<sup>189</sup> *Ibid.* Some of these guidelines are in line with Van Eck's suggestions stated above.

<sup>190</sup> *Ibid.*

done in such a way as to ensure that consumers are able to read the document with much more ease.<sup>191</sup>

When dealing with an objective test as mentioned above, the following requirements, amongst others should be complied with:

- (a) Use less than 22 words per average sentence.
- (b) The maximum number of words per sentence in a single document must be 50.
- (c) The average number of words per paragraph must be less than 75.
- (d) The maximum amount of words per paragraph in a document must be 150.
- (e) The average number of syllables per word must be fewer than 1.55.
- (f) No typeface of less than eight points may be used.<sup>192</sup>

Implementing the above requirements does have advantages as they can be tested by computers using certain calculations and are easy to apply.<sup>193</sup> Gouws submits that a document will be in plain language if it is semantically clear, coherent and legible.<sup>194</sup> The writer further defines each of the elements mentioned above. Semantic clarity requires a comprehensibility test which in turn will ensure due regard to the intended audience.<sup>195</sup> With regard to legibility the writer states that it is all about the ease with which the document can be read.<sup>196</sup> The writer provides the following plain language drafting techniques: avoid clichés; use the singular where possible; use symbols and abbreviations that the reader will understand; adopt a verbal style; avoid difficult synonyms if a generic term exists; express cardinal and ordinal numbers in numbers and not in words; use you and we; increase the amount of white space on a page without causing unnatural breaks in the text; use titles and headings; avoid using fine print; avoid drafting in a manner intent on misleading the consumer; define terms sparingly; define a term near to where it is first used; use footnotes to set out the meaning of terms on a page; avoid artificial concepts; and use examples to explain the meaning of the terms.<sup>197</sup>

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<sup>191</sup> *Ibid.*

<sup>192</sup> *Idem* 540.

<sup>193</sup> *Idem* 542.

<sup>194</sup> Gouws 2010 87.

<sup>195</sup> *Ibid.*

<sup>196</sup> *Idem* 89.

<sup>197</sup> *Idem* 91-93.

Plain language drafting is a skill that requires the use of numerous techniques in order to determine the grammar, style and language to be used, especially with regard to pharmaceutical product labelling.

### 3.4 Pharmaceutical product labelling and plain language

#### 3.4.1 Consumer knowledge

Medicines are regarded as ‘prescription’ medicines if professional participation is required to diagnose the condition and to safeguard safe usage.<sup>198</sup> Subject to the schedule of the medicine prescribed, health professionals’ regulation or intervention in different degrees will be required.<sup>199</sup> A consumer is usually completely incapable to judge for himself the quality and safety of the medicine offered, and in reality, is not adequately equipped to determine of his own accord whether it is in fact effective.<sup>200</sup> Du Toit and Van Eeden correctly state that medicines are inherently unsafe and emphasise the importance of instructions and warnings.<sup>201</sup>

Without proper understandable labelling in place the consumer will remain reliant on health professionals who are in effect acting on his behalf.<sup>202</sup> Even though the consumer will ultimately use the medicine, his control is mostly limited; this establishes the fundamental reason why the law needs to protect consumers with regard to pharmaceutical product labelling.<sup>203</sup> Consumers should be placed in a position where they are not mere passive followers but self-determining free agents.<sup>204</sup>

The manner in which pharmaceutical products are used determines the ability of the medicine to satisfy consumers in terms of its efficiency, quality and safety – inappropriate usage can endanger the health of consumers through the introduction of new problems as well as the failure to address existing ones.<sup>205</sup> Medical

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<sup>198</sup> Hassim *et al* (2007) 422. Furthermore, s 5 of the Medicines Act states that Schedule 2, 3, 4, 5 or 6 substances may only be sold by a pharmacist, pharmacist intern or a pharmacist assistant acting under the supervision of a pharmacist, who may sell only Schedule 2 substances without a prescription.

<sup>199</sup> *Ibid.*

<sup>200</sup> Abbott & Dukes 86. See Hassim *et al* (2007) 415: the decision to purchase medicine is mostly made when a person is ill.

<sup>201</sup> Du Toit & Van Eeden 2014 740.

<sup>202</sup> *Idem* 86-87.

<sup>203</sup> Hassim *et al* (2007) 414-415 who also confirm the difficulty to assess the quality of medicine except by trained pharmacists and further state that the information on medicines can be unbalanced.

<sup>204</sup> Rowe & Moodley 2013 3,5.

<sup>205</sup> Abbott & Dukes 126.

practitioners and pharmacists are overburdened in practice – and the number of consumers capable to comprehend medical terms is limited.<sup>206</sup> This leads to an expectation error that the total responsibility for the rational usage<sup>207</sup> of medicine should be placed on medical practitioners, pharmacists and the common sense of consumers.<sup>208</sup>

Corina and D' Angelo argue correctly that a consumer's comprehension ability has less to do with literacy and more with his emotional state.<sup>209</sup> Most of the time medication will be prescribed to a patient because of an existing ailment. Even if the health care practitioner were to comply with his duty to convey all the required information on the prescribed medication, the patient might not be in a mental state to comprehend or even listen to what the practitioner is telling him (due to the patient's deteriorating physical condition or the information received about his diagnosis).<sup>210</sup> The consumer will then be in a vulnerable position and may use the medication incorrectly if the instructions on the labelling or packaging insert are not in comprehensible terms.<sup>211</sup> The CPA in section 3(1)(b)(iii) explicitly sets out the purpose of the Act, which amongst others is to protect the vulnerable; it is submitted that any patient diagnosed with an illness should fall under the CPA's definition of vulnerable.<sup>212</sup>

The circumstances of each patient will differ. It could be that medication was prescribed to a patient by a medical practitioner, but due to circumstances he is now taken care of by a family member.<sup>213</sup> The person who is now responsible for the care of the patient should be in a position to understand the medication even though he did not personally consult with the practitioner. This places even further emphasis on the importance of using plain language on pharmaceutical product labelling.<sup>214</sup> Without

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<sup>206</sup> *Ibid.* See also Rowe & Moodley 2013 6.

<sup>207</sup> WHO 15: Rational use of medicines implies that "patients receive the right medicines at the right time, use them appropriately, and benefit from them".

<sup>208</sup> Abbott & Dukes 126.

<sup>209</sup> Corina I & D' Angelo L 6.

<sup>210</sup> Mansoor L & Dowse R 38.

<sup>211</sup> Rowe & Moodley 2013 5.

<sup>212</sup> *Ibid.*

<sup>213</sup> Corina I & D' Angelo L 7.

<sup>214</sup> Stoop & Churr 2013 533. The targeted consumer should be catered for.

the correct knowledge, the caregiver may unwittingly cause the patient more harm than good.<sup>215</sup>

A 2012 World Health Organization (WHO) report stated that approximately 50% of all patients take their medication incorrectly.<sup>216</sup> Consumer involvement in decision making regarding treatments and adherence to the correct administration thereof is a challenge that needs to be encouraged.<sup>217</sup> This challenge should firstly be addressed through the established plain language requirements of section 22. Medicines with labelling and leaflets written in the simplest manner possible for them to be understood and considered by consumers as understandable, will be a step in the right direction towards consumer education and responsible involvement.<sup>218</sup>

### **3.4.2 Overcoming the barrier**

Perilous health information should be communicated to consumers on medicine labels and package inserts in clear and useful terms in order to satisfy both consumer safety and the plain language requirement.<sup>219</sup>

#### *3.4.2.1 World Health Organization*

In 2002 the WHO formulated guidelines regarding pharmaceutical product labelling and package inserts for consumers (patient information leaflets).<sup>220</sup> They require all medicine labelling to comply with the relevant national legislation<sup>221</sup> and the minimum information to be contained on a label is as follows: the name of the medicine; a list of its active ingredients; the batch number assigned by the manufacturer; the expiry date; special storage conditions or handling precautions; directions, warnings and precautions in terms of the use of the medicine; and the name and address of the manufacturer or the details of the person responsible for placing the medicine on the market.<sup>222</sup>

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<sup>215</sup> Rowe & Moodley 7.

<sup>216</sup> WHO 15.

<sup>217</sup> Morris 2015 2.

<sup>218</sup> Mansoor L & Dowse R 38: "Overcoming this barrier requires both knowledge of the reading skills of the targeted population and the development and use of medicine information resources written at that skill level."

<sup>219</sup> Lifestyle reporter. This was stated by Dr Sarah Slabbert of the Plain Language Institute (a member of PLAIN). The institute drafts documents in order to meet the requirements of s 22 of the CPA.

<sup>220</sup> WHO Technical Report 131.

<sup>221</sup> See Chapter 2.

<sup>222</sup> WHO Technical Report 122-123.



Paragraph 1.3.3 of the report states that product information must be of assistance to all users (including patients) to *understand* the medication.<sup>223</sup> Furthermore the objective of the package insert and label is to provide the consumer with crucial information regarding the medicine.<sup>224</sup> This includes the appropriate use of the medication, possible adverse reactions and interactions, storage conditions as well as the expiry date.<sup>225</sup> Paragraph 4.1 provides that the packaging and label information should be of such a degree to in fact assist the health care practitioner by reinforcing the instructions given and in turn improving consumer compliance.<sup>226</sup>

The word ‘understand’ in paragraph 1.3.3 indicates the importance of section 22’s plain language requirement on pharmaceutical product labelling.<sup>227</sup> The current practice of prescription medication labelling and package inserts fails to comply with the requirement of ‘understanding’. Whether there will ever be a mutual understanding as well as compliance is a question which will only be answered through the test of time.<sup>228</sup> It is submitted that even though true compliance in terms of ‘understandable medical terminology’ would be difficult to achieve, an effort to accommodate the majority of the literate population of South Africa would make a substantial difference.

#### 3.4.2.2 Medicines Control Council (MCC)

Regulation 43(1) promulgated under the Medicines Act provides that “[e]very medicine shall comply with the standards and specifications which were furnished to the Council on the form prescribed by regulation 22 and which have been accepted by the Council with regard to such medicine”.

In a presentation by Professor Peter Eagles, who was appointed as the chairperson of the MCC until 2015, he referred to the main obligations of the MCC.<sup>229</sup> Amongst

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<sup>223</sup> *Idem* 131.

<sup>224</sup> *Ibid.*

<sup>225</sup> *Ibid.*

<sup>226</sup> *Ibid.*

<sup>227</sup> Stoop & Churr 2013 534. The meaning of ‘without undue effort’ in s 22 of the CPA indicates that in the instance where consumers first have to consult a dictionary (the internet) or an advisor (e.g. medical practitioner) to understand the terms, this would result in undue effort and the document would not be in plain language. In the majority of prescription medication labelling or the package inserts, this would be the case.

<sup>228</sup> Lifestyle reporter.

<sup>229</sup> Eagles P.



them were ensuring public safety, public protection and minimising of harm and maximising of benefit.<sup>230</sup>

#### 3.4.2.3 Methods & guidelines

Awareness of the specialised needs of vulnerable consumers (such as the less literate and disabled) has caused an increase in the use of pictograms in pharmacy.<sup>231</sup> In order for this to be an effective method to comply with the CPA it should be clear and unambiguous when communicating an important medical word or phrase through a pictorial symbol.<sup>232</sup> Research has proven that providing the patient with a picture as a reminder instead of placing reliance on the recalling of information that was verbally communicated to him, has improved the recall rates of patients.<sup>233</sup>

When dealing with any type of written information, including pharmaceutical product labelling, two questions should be posed: (1) What is the purpose of the written information? (2) Who is the intended audience?<sup>234</sup> With specific regard to medicine labelling, the answers may be summarised as follows: (1) To ensure proper usage of the medication by providing comprehensible instructions as well as clear information on all aspects relating thereto. (2) The consumer, who will in most instances be the patient (who will either have low literacy skills, have limited time available, or will be subjected to illness and/or stress).<sup>235</sup> It will be necessary to use words that are familiar to the consumer, while shorter sentences, active voice and minimal Latin terms should also be taken into account when drafting the labelling and package inserts for medications.<sup>236</sup>

### 3.5 Chapter conclusion

It is clear from section 22 of the CPA that plain language is an important requirement regarding any consumer information. When dealing with pharmaceutical products, consumer comprehension is even more important due to the risk factor that essentially

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<sup>230</sup> *Ibid.*

<sup>231</sup> Mansoor L & Dowse R 38.

<sup>232</sup> *Ibid.*

<sup>233</sup> *Ibid.*

<sup>234</sup> Stableford S & Riffenburgh A 57.

<sup>235</sup> *Ibid.*

<sup>236</sup> *Idem* 93.

forms part of the very nature of medicines.<sup>237</sup> Consumer education is necessary in order to equip patients to make well-informed decisions and to take responsibility for their own health without complete reliance on third parties.<sup>238</sup>

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<sup>237</sup> Du Toit & Van Eeden 2014 738-740.

<sup>238</sup> *Ibid.*

## CHAPTER 4: PRODUCT LABELLING

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### SUMMARY

- 4.1 Introduction
  - 4.2 Section 24: Product labelling
  - 4.3 Package labelling versus package inserts
  - 4.4 Chapter conclusion
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#### 4.1 Introduction

As the dissertation deals with the plain language requirement and product labelling as main factors, a discussion of product labelling is of utmost importance. Du Toit and Van Eeden correctly submit that information in notices, documents, promotional offers including medication labelling and inserts should be in plain and understandable language.<sup>239</sup> It is crucial to investigate section 24 of the CPA to ensure that a comprehensive picture is painted regarding product labelling, package inserts and product information leaflets. This will ultimately lead to an appreciation of the influence of section 22 of the CPA on these labels and documents.

#### 4.2 Section 24: Product labelling

In terms of section 24 of the CPA a trade description is applied to goods “if it is (a) *applied* to the goods, or to any covering, label or reel in or on which the goods are packaged, or *attached* to the goods; (b) *displayed together with*, or in proximity to, the goods in a manner that is likely to lead to the belief that the goods are designated or described by that description;<sup>240</sup> or (c) is contained in any sign, advertisement, catalogue, brochure, circular, wine list, invoice, business letter, business paper or other commercial communication on the basis of which a consumer may request or

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<sup>239</sup> Du Toit & Van Eeden 2014 739.

<sup>240</sup> Own emphasis, footnote supplied.

order the goods”.<sup>241</sup> Stoop submits that section 24(2) creates certain duties regarding trade descriptions to ensure that consumers are protected.<sup>242</sup>

#### 4.2.2.1 *Applied, attached or displayed together*

The words ‘applied’, ‘attached’ or ‘displayed together’ indicate that a wider interpretation and meaning should be afforded to the concept of product labelling. The ordinary meaning of the word ‘label’ can be understood as merely referring to the label applied to the outside of the package. However, when talking about a document attached or displayed together, the meaning is extended beyond such narrow interpretation.

It is submitted that the above words may be construed to extend also to package inserts or package information leaflets as discussed in chapter 2. If such application and extension are effected, ignoring the requirements of section 22 cannot be justified or brushed away; all the parties involved in the supply chain will need to bring their part to ensure that the relevant requirements are met (regardless of whether the information provided is on or in the medication package).

Section 24(3) further provides that retailers “must not offer to supply, display or supply any particular goods if the retailer knows, reasonably could determine or has reason to suspect that a trade description applied to those goods is likely to mislead the consumer as to any matter implied or expressed in that trade description”. Stoop states that section 24(3) only applies to retailers who are under a duty to refrain from supplying goods if it is possible that the trade description could mislead consumers.<sup>243</sup> He further states that this section places a positive duty on retailers by obliging them to take reasonable steps to ensure that consumers are not misled.<sup>244</sup>

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<sup>241</sup> Footnote supplied. S 1 of the CPA defines ‘trade description’ as “any description, statement or other direct or indirect indication, other than a trade mark, as to the number, quantity, measure, weight or gauge of any goods; the name of the producer or producer of any goods; the ingredients of which any goods consist, or material of which any goods are made; the place or country of origin of any goods; the mode of manufacturing or producing any goods; or any goods being the subject of any patent, privilege or copyright; or any figure, work or mark, other than a trade mark, that, according to the custom of the trade”.

<sup>242</sup> Stoop ‘Section 24’ (2014) para 3.

<sup>243</sup> *Ibid.* ‘Retailer’ in s 1 “means a person who, in the ordinary course of business, supplies those goods to a consumer”.

<sup>244</sup> *Ibid.*

Section 24(6) provides that “any person who produces, supplies, imports or packages any prescribed goods must display on, or in association with the packaging of those goods, a notice in the prescribed manner and form that discloses the presence of any genetically modified ingredients or components of those goods in accordance with applicable regulations”.<sup>245</sup>

#### 4.2.2.2 Trade descriptions

Prescription medications are given a trade description on the package in which the medicine is provided to the consumer.<sup>246</sup> Moreover, no trade description may knowingly be applied to pharmaceutical products if there is a likelihood that the consumer may implicitly or explicitly be misled by that description.<sup>247</sup>

The word ‘misleading’ is an adjective used when a false or confusing impression is created; as antonym, the word ‘straightforward’ can be used.<sup>248</sup> Synonyms for the word ‘misleading’ include confusing, false, ambiguous, deceptive, spurious, evasive, disingenuous, tricky, casuistically and so forth.<sup>249</sup>

The words ‘ambiguous’ and ‘confusing’ are important for purposes of section 22 regarding the right to information in plain and understandable language: Section 22 provides as follows: “(1) The producer of a notice, document or visual representation that is required, in terms of this Act or any other law, to be produced, provided or displayed to a consumer must produce, provide or display that notice, document or visual representation, (a) in the form prescribed in terms of this Act or any other legislation, if any, for that notice, document or visual representation; or (b) in plain language, if no form has been prescribed for that notice, document or visual representation. (2) For the purposes of this Act, a notice, document or visual representation is in plain language if it is reasonable to conclude that an ordinary consumer of the class of persons for whom the notice, document or visual representation is intended, with average literacy skills and minimal experience as a consumer of the relevant goods or services could be expected to understand the

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<sup>245</sup> The information regarding the trade description to be displayed is contained in s 1 of the definitions.

<sup>246</sup> S 24(1) CPA is thus applicable when dealing with pharmaceutical product labelling. Regs 8 and 9 of the Medicines Act are applicable when dealing with what information is compulsory to be provided on the package.

<sup>247</sup> S 24(2)(a)(b) CPA.

<sup>248</sup> Collins Thesaurus (2010) 436 and Collins Dictionary (2010) 518.

<sup>249</sup> *Ibid.*

content, significance and import of the notice, document or visual representation without undue effort.”

#### *4.2.2.3 Notice, document or visual representation*

Due to the lack of a definition or clarification in the CPA itself on what the meanings of the words ‘notice’ and ‘document’ in terms of the Act are, they should be interpreted with the aid of external sources.<sup>250</sup>

‘Document’ can be defined as “a piece of written, printed, or electronic matter that provides information or evidence or that serves as an official record” and the word ‘notice’ as a displayed sheet or placard providing news or information, and further as a notification or warning.<sup>251</sup>

The trade description on the package – which is a piece of written information – can be defined as either a notice or a document. By reason of the above, section 22 will apply and influence section 24. For true adherence to the provisions of the CPA, trade descriptions should be in plain language.

The word ‘or’ is located between section 22(1)(a) and (b). If there is in fact a prescribed form for the trade description (namely, the trade description of a specific medicine on the packaging), there is no requirement that it should be in plain language. However, when dealing with pharmaceutical products and the Medicines Act, certain information must be displayed on the packaging, but no prescribed form for this exists. Thus, section 22(1)(b) will be applicable and the trade description on package labelling should be in plain language.<sup>252</sup>

### **4.3 Package labelling versus package inserts**

The CPA prohibits misleading trade descriptions, which include any statement made in an advertisement, label or packaging, or any display of a supplier which describes the number, quantity, measure, weight or gauge of the goods advertised and/or referred to on the labels or packaging.<sup>253</sup> For example, a supplier must not knowingly use a trade description that is likely to mislead the consumer as to any matter implied

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<sup>250</sup> Stoop ‘Section 22’ (2014) para 4.

<sup>251</sup> Frohmann 2009 291-293.

<sup>252</sup> See chapter 3 for a comprehensive discussion of the plain language requirement.

<sup>253</sup> S 24(2)(a) CPA.

or expressed in that trade description, for instance ‘slimming’.<sup>254</sup> The packaging and labelling must furthermore be in clear and plain language.<sup>255</sup>

Packages containing any hazardous or unsafe goods must have sufficient information advising the consumer of the risk of such goods.<sup>256</sup> Should a consumer suffer harm due to unsafe goods, the supplier may be held liable without the need to prove negligence on his part.<sup>257</sup> The type of harm suffered may include death, injury, illness, loss of or damage to property or any economic loss that results from any of the types of harm listed above.<sup>258</sup>

#### **4.4 Chapter conclusion**

It is concluded that section 24 regarding product labelling can also apply to instances mentioned in regulation 10 of the Medicines Act concerning PILs. The narrow interpretation of the word ‘labelling’ will not in itself suffice to include PILs but due to the wide meaning attributed to this, it is submitted that section 22 will be applicable to prescription medication product labelling. All the information required by regulation 10 of the Medicines Act should be provided to the consumer in plain language as discussed in chapter 3 above.

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<sup>254</sup> S 24(3)(b) CPA.

<sup>255</sup> S 22 read with s 24(1)(a) and (c) CPA.

<sup>256</sup> S 58(2) CPA.

<sup>257</sup> S 61(1)(a)(b) and (c) CPA.

<sup>258</sup> S 61(5) CPA.

## CHAPTER 5: CONCLUSION

The nature and extent of the CPA necessitated a discussion of numerous applicable provisions, some discussed in more depth than others. The requirements and influence of regulations 8 to 10 promulgated in terms of the older Medicines Act were also dealt with.

In this study, no existing conflict was discovered between the two pieces of legislation investigated and it was not necessary to apply section 2 (the interpretational provision of the CPA). Section 22 dealing with the plain language requirements is applicable to medicine product labelling, more specifically prescription medication. Regulations 8 to 10 of the Medicines Act deal with the provisions relating to pharmaceutical product labelling as well as the package inserts which after a careful analysis was found to comply with the terms 'document' and 'notice' as required by section 22. Thus, it was found that the provisions of the Medicine Act obligating certain information to be contained on medication labels and on package inserts can be and should be aligned with the plain language requirements of section 22.

Although section 24 of the CPA relates to package labelling, the Medicines Act and section 22 of the CPA suffice in terms of compelling the pharmaceutical industry to comply with the plain language requirements.

Plain language is a two-word concept with a more or less equal number of admirers and haters. Even though the CPA is not the most useful source to ensure that section 22 is complied with as there are requirements in place without the necessary guidelines, the fact that section 2 provides that one may use foreign law when interpreting is a move in the right direction. Furthermore, there are abundant external sources developed by bodies, foreign governments and even well thought-through methods suggested by numerous respected writers and academics which could assist in the drafting process.

The very inherent hazardous nature of pharmaceutical products requires consumer protection to regulate the packaging thereof in order to ensure that the purposes of the CPA as outlined in section 3 and mentioned throughout the Act are attained. To protect vulnerable South African citizens is only one of the purposes but a very important one; to protect them they need to be placed in a position where they are able to protect



themselves. Providing consumers with clearer and understandable instructions on how to use medication will not only educate them but protect them – the very essence of the CPA.

When supplying, retailing and providing consumers with pharmaceutical advice and products there are three major role-players involved, namely, (a) the medical practitioner or doctor; (b) the pharmacist; and (c) the manufacturer or medicine supplier.

They all form part of the supply chain and have certain duties imposed on them not only by the CPA but also inherently by their professional and industry regulations. When inadequate information is provided to consumers (for instance no label/insert or a technical label/insert) it is clear from the CPA (especially when evaluating the impact of section 61) that these parties could and would be held responsible for any harm incurred by consumers through use of the medication.

Consumers should be placed in a position to make self-informed decisions regarding the medication they consume. The current practice of pharmaceutical product labelling and package inserts is in need of development and refinement to comply with the plain language requirement. By utilising plain language drafting guidelines and referring to foreign law (as provided for in section 2 of the CPA when interpreting the Act) adherence to the provisions and purposes as defined in section 3 of the CPA can be achieved.

By using the regulations of the Medicines Act and applying section 22 of the CPA, a possible solution to the current uninformed and uneducated consumer's vulnerable position can be achieved. This in turn will result in suppliers being protected from legal action taken against them if the consumer suffers any harm.

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