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Eleven of the products did not contain direct medicinal claims, as phrases such as “soothes”, “assists” and “supports” were present. However, Products A and B provided conflicting information on the immediate container label and the outer container label, as reflected in Table 4-2. Since the immediate container label did not contain the term “supportive” and merely stated “recommended”, this could be interpreted as a medicinal claim. The immediate container label was deemed non-compliant.

#### 4.4 Labelling Requirements in Terms of Act 101 of 1965

##### 4.4.1 Regulation 8: Information on Immediate and Outer Container Labels

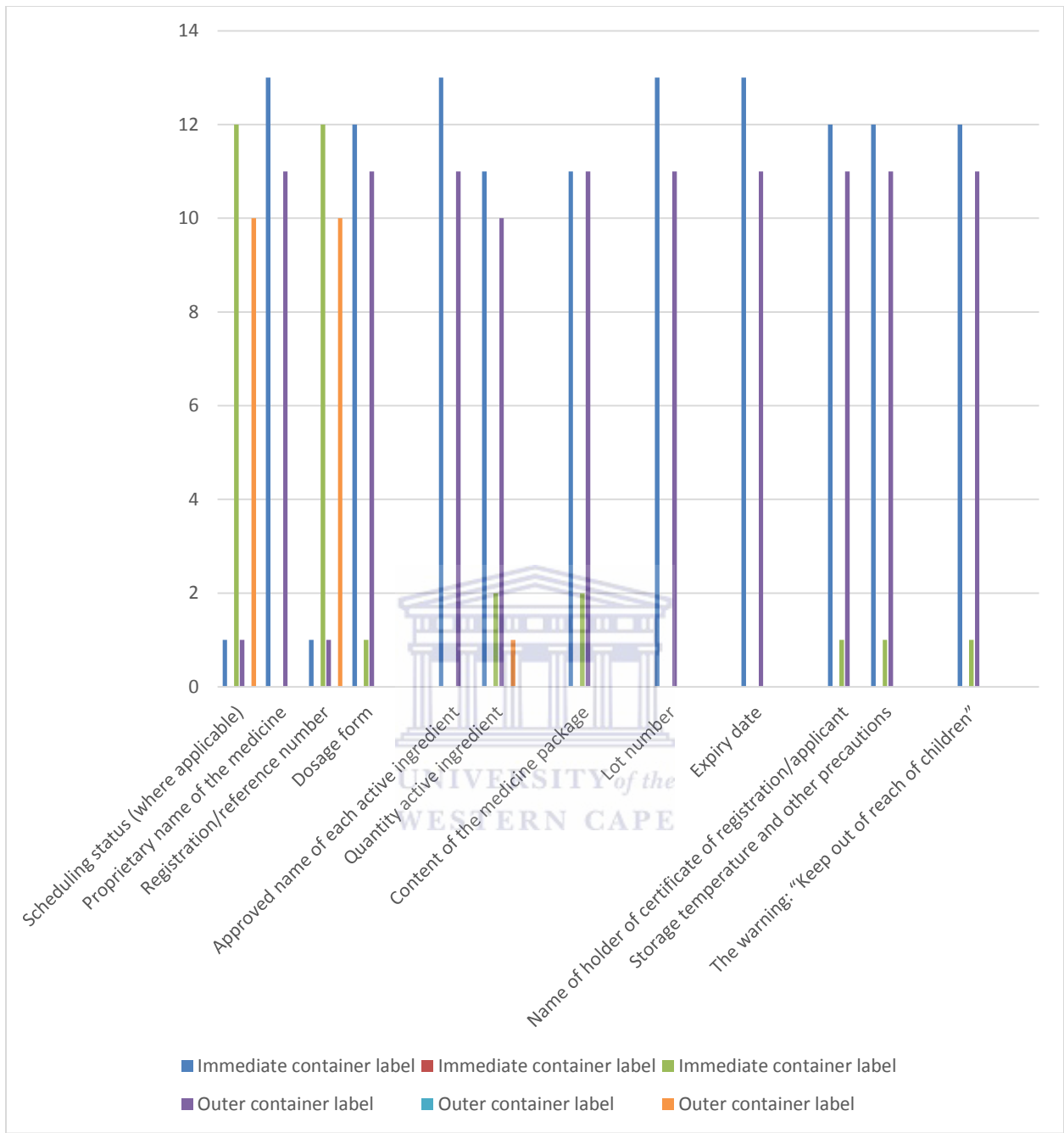
Table 4-7 Information on immediate and outer container labels as required by regulation 8 of Act 101 of 1965.

Immediate label n = 13

Outer label n = 11

Requirements	Immediate container label			Outer container label		
	Number of products compliant	Number of products partially compliant	Number of products non-compliant	Number of products compliant	Number of products partially compliant	Number of products non-compliant
Scheduling status (where applicable)	1	0	12	1	0	10
Proprietary name of the medicine	13	0	0	11	0	0
Registration/reference number	1	0	12	1	0	10

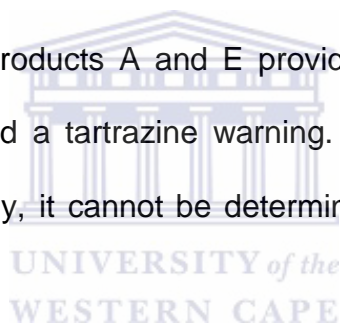
Requirements	Immediate container label			Outer container label		
	Number of products compliant	Number of products partially compliant	Number of products non-compliant	Number of products compliant	Number of products partially compliant	Number of products non-compliant
Dosage form	12	0	1	11	0	0
Approved name of each active ingredient of the medicine	13	0	0	11	0	0
Quantity thereof contained in a dosage unit, or per suitable mass or volume or unit	11	0	2	10	0	1
Content of the medicine package expressed in the appropriate unit or volume of the medicine	11	0	2	11	0	0
Lot number	13	0	0	11	0	0
Expiry date	13	0	0	11	0	0
Name of the holder of certificate of registration (or name of applicant)	12	0	1	11	0	0
Storage temperature and other precautions required for the preservation of the medicine	12	0	1	11	0	0
The warning: "Keep out of reach of children"	12	0	1	11	0	0



**Figure 4-2 Graph illustrating compliance with Information on immediate and outer container labels as required by regulation 8 of Act 101 of 1965.**

All the products contained a label affixed to the immediate container, featuring text in English. Eleven of the products featured an outer container label. Only one product, Product G, contained a scheduling status (S 0). While medicines in this category of CMs are not scheduled, there should still be information in the package insert stating that the product is unscheduled, or S 0.

Only two of the products contained information pertaining to the preservative content. Product I stated that it contained no preservatives, and only the outer container label of Product E stated that alcohol was the preservative. Product E was the only product stating sugar content, and while Product G stated that it contained sugar, it did not provide the quantity thereof. Products A and E provided alcohol content information. None of the products contained a tartrazine warning. Since the product formulations were not evaluated in this study, it cannot be determined if the products required this warning.



The products were assessed to determine whether the indications were provided. The accuracy of the indications has been discussed in 4.2.3 (Therapeutic Indications). Products C and H did not contain any indications on their immediate labels, but both contained the indications on the outer label. Similarly, dosage was only assessed for presence, not accuracy. The immediate labels of products H and I were non-compliant, as the only dosage instruction was to refer to the package insert. However, the outer labels of these two products provided the dosage instructions.

One product contained a "Reg. No." on its immediate and outer container label, while this was deemed compliant in that a number was provided, the terminology "Reg. No."

which was used is not correct. No CMs have yet been evaluated by the MCC, and therefore referring to the number provided as a registration number implies that the product has undergone evaluation and is approved. The more appropriate term is “complementary registry number”, as seen in the package inserts of some of the products. It is most likely that the number referenced is not a registration number, but a registry number, provided by the MCC during the call up in 2002. This is confirmed by the product’s package insert, whereby the “registration number” contained a statement that the registration number was “to be allocated”.

#### **4.4.2 Regulation 9: Information on Package Inserts**

Two of the products did not contain package inserts, and therefore were deemed non-compliant with all the package insert requirements. Subsequent analysis refers only to the products that contained package inserts. For a summary of the information present in the package inserts, refer to Table 4-8.

One product provided a “product information leaflet” containing similar information to that required by the package insert, but the information was not provided in the format of the package insert requirements. All the package inserts were in English, and nine were in Afrikaans as well.

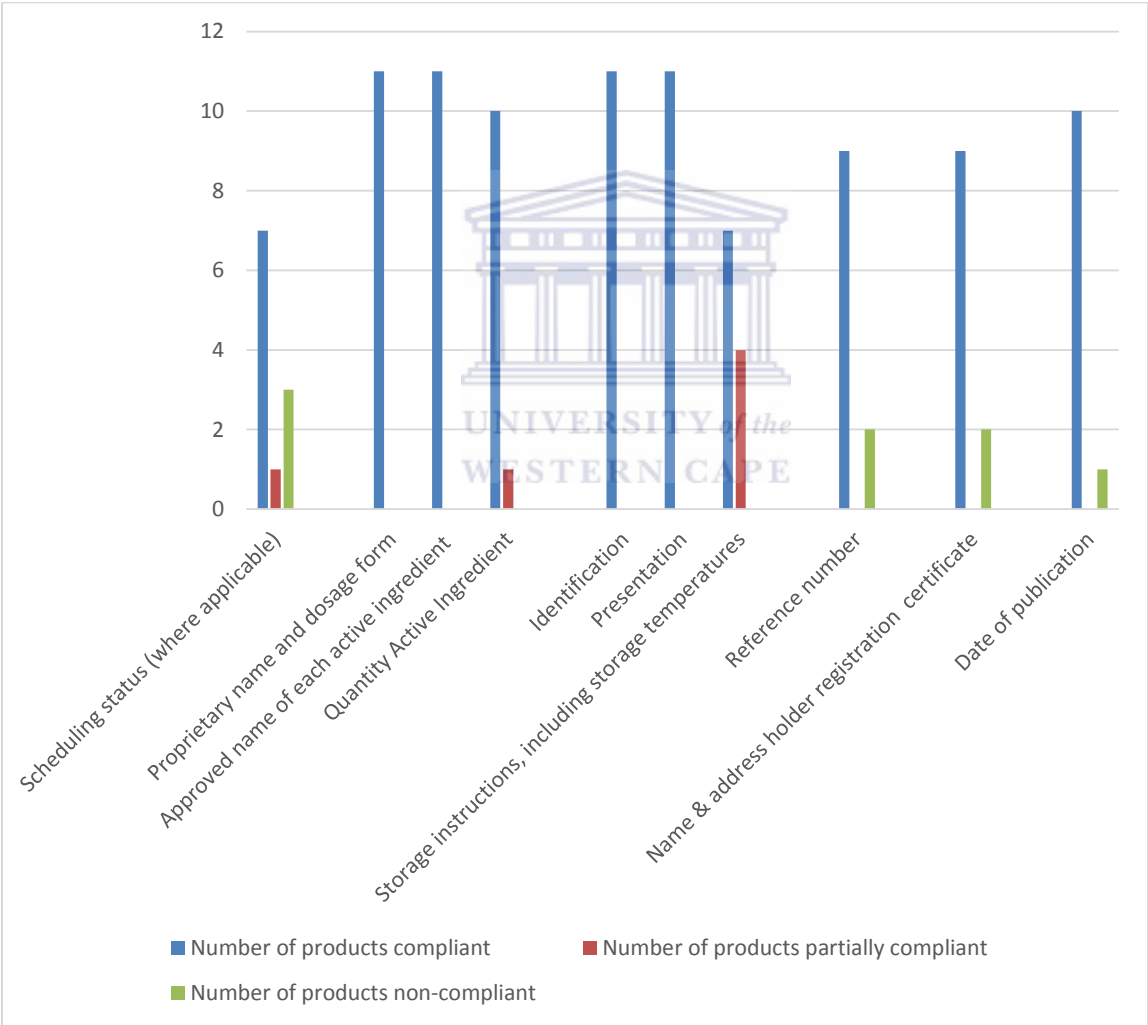
Compliance with the scheduling status requirement was fulfilled if information was listed either as S 0, “not scheduled”, or “not applicable”. One product was deemed partially compliant as it stated “nutritional supplement” under the scheduling status.

Compliance was granted for the reference number requirement if relevant information was provided, such as the number, or the phrases “to be allocated” or “pending”. Two products contained postal address information instead of the physical address, and were deemed non-compliant.

**Table 4-8 Information appearing on the package insert of products (n=11) as compared to the requirements as stipulated in Act 101 of 1965.**

<b>Required information</b>	<b>Number of products compliant</b>	<b>Number of products partially compliant</b>	<b>Number of products non-compliant</b>
Scheduling status (where applicable)	7	1	3
Proprietary name and dosage form	11	0	0
The approved name of each active ingredient	11	0	0
Quantity thereof contained in a dosage unit or per suitable mass or volume or unit of the medicine	10	1	0
Identification	11	0	0
Presentation	11	0	0
Storage instructions, including storage temperatures	7	4	0
Reference number (where applicable) followed by the expression: "Act 101/1965"	9	0	2

Required information	Number of products compliant	Number of products partially compliant	Number of products non-compliant
Name and business address of the holder of the certificate of registration/applicant	9	0	2
Date of publication of the package insert (where applicable)	10	0	1



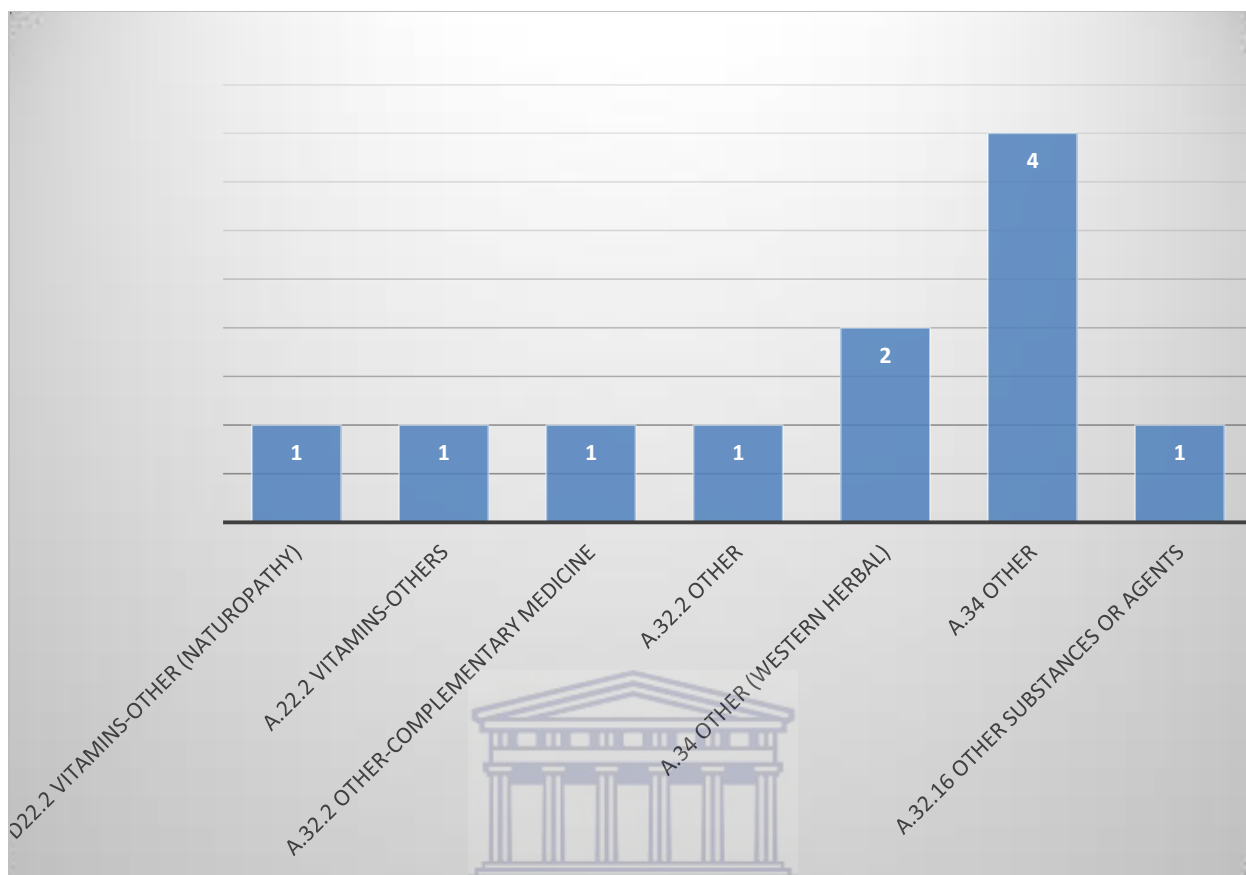
**Figure 4-3 Graph illustrating compliance of information appearing on the package insert of products (n=11) as compared to the requirements as stipulated in Act 101 of 1965.**

Only product E provided information about preservative content. Compliance or non-compliance regarding preservative information could not be determined in the other products, as it was not known if their formulation included preservatives. It is likely that they would contain preservatives, however, in which case they would be non-compliant. Two of the liquid formulations provided information about their alcohol content, and were therefore compliant. Products C, G and M contained information pertaining to sugar.

Nine of the products were deemed compliant for containing a reference number, in that they either contained the statement “to be allocated” or the provided number was preceded by: “complementary registry number”. This demonstrated that the numbers were not medicine registration numbers, and that the products had not been evaluated.

#### *4.4.2.1 Pharmacological Classification and Pharmacological Action*

The MCC has classified immune boosters under: 32.16 (Other) Immune Boosters (MCC, 2013b). Various classifications appeared in the package inserts. The results for this section are depicted in Figure 4-1 (presented overleaf).



**Figure 4-4 Pharmacological classification as per the package insert of the sampled products (n=11).**

Category D.22.2 Vitamins-Other (Naturopathy) is not correct. Even though the product contained vitamins, its Western Herbal discipline is not recognised. Category A.22.2 is likely to be outdated as CMs now fall under Category D. Similarly, Category A 32.2-Other would be outdated, even in the case where the manufacturer has stated that it is a complementary medicine. Four of the products were classified under category A. 34, but this category was not found in the Regulations of Act 101 of 1965. These results demonstrate that there is uncertainty as to which classification should be used. Nine of the products contained information under the pharmacological action heading.

#### 4.4.2.2 Sections Corresponding to the European Medicines Agency Monographs

The sections presented in Table 4-9 were assessed to determine if information was provided under the required headings of Regulation 9 of Act 101 of 1965. Products were deemed compliant if the information was in accordance with the information presented in the monographs. Products were deemed partially compliant if information was provided in the package insert, but was not consistent with the monographs. Products were deemed non-compliant if no information was provided.

**Table 4-9 Compliance with Regulation 9 sections corresponding to European Medicines Agency (EMA) monograph (n=11).**

Heading	Product										
	A	B	C	D	E	F	G	I	J	L	M
<b>Indications</b>	+	+	+	+	+	+	+	+	+	+	+
<b>Contra-indications</b>	=	=	+	+	=	=	+	=	+	=	=
<b>Warnings</b>	=	=	=	=	=	=	+	=	-	=	=
<b>Interactions</b>	=	=	=	=	+	+	=	-	-	-	=
<b>Pregnancy</b>	+	+	+	+	+	+	+	+	-	+	=
<b>Dosage and directions for use</b>	+	+	+	+	+	+	+	+	+	+	+
<b>Side effects and special precautions</b>	+	+	=	=	=	=	=	=	=	+	=
<b>Known symptoms of overdose and particulars</b>	+	+	+	+	+	+	+	+	+	+	+

Heading	Product											
	A	B	C	D	E	F	G	I	J	L	M	
of its treatments												

Key:

+ Complies in that information was provided

= Complies with EMA monograph

- Non-compliant

#### 4.4.3 Regulation 10: Information on Patient Information Leaflets

Only product G contained a patient information leaflet. As there was only one patient information leaflet available for the study, no further analysis was conducted into compliance in this regard.

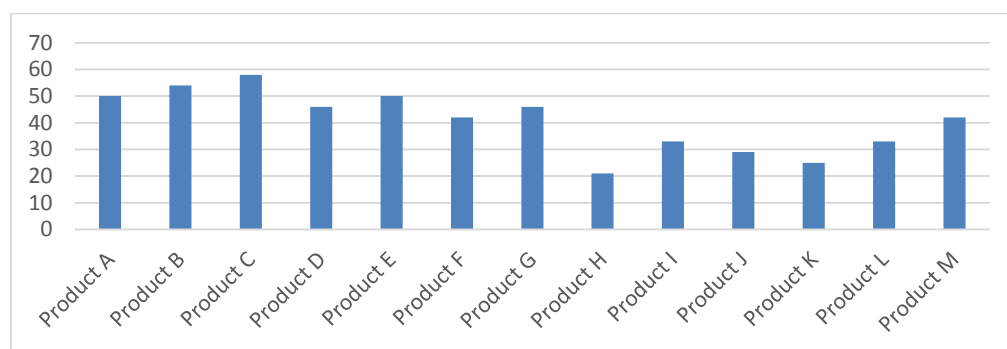
#### 4.5 Limitations of the Study

The majority of the products did not conform to the EMA monographs. A limitation of this study is that only EMA monographs were used to assess compliance, and perhaps the use of other monographs recognised by the MCC would provide additional information surrounding compliance. However, the EMA remains a reputable and MCC-recognised reference source.

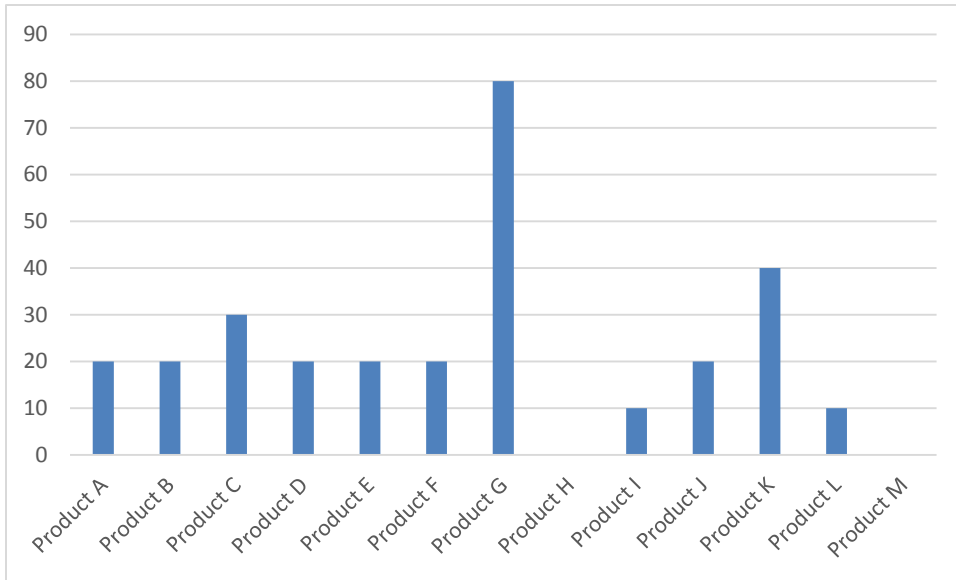
Another limitation is that the labelling of the products in this study may have been superseded with conformant labelling by the time of this writing. CM companies may have revised and updated product labelling in order to comply with the MCC's guidelines, and these new batches of products could now be available on the market.

#### 4.6 Overall Compliance

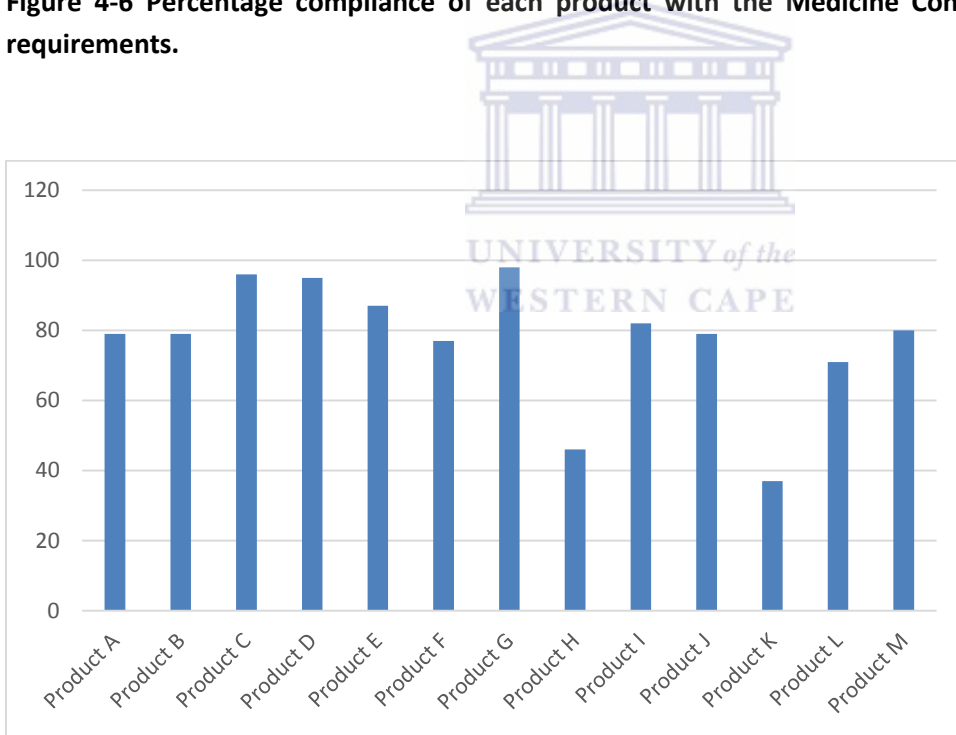
An overall percentage compliance for each product was allocated to each of the three sections of the data collection tool. This was determined by assigning each variable a level of compliance as follows: 0 for non-compliance; 0,5 for partial compliance or where information only complied in that it was provided; and 1 for total compliance. In order to determine the percentage of compliance, the total value was added up and divided by the number of headings. Appendix 3 details the variables included and excluded in the assessment. The overall compliance of each product with each section of the data assessment is demonstrated below, in Figures 4-2 to 4-4.



**Figure 4-5 Percentage compliance of each product with the European Medicines Agency monograph.**



**Figure 4-6 Percentage compliance of each product with the Medicine Control Council's minimum requirements.**



**Figure 4-7 Percentage compliance of each product with Regulations 8 and 9 of Act 101 of 1965.**

## **5 Conclusions**

### **5.1 Quality**

The study of the monographs affirmed the importance of composition, as a specific part of the herbal plant is required to achieve a product's intended therapeutic indications. Furthermore, the results of the literature search demonstrated that plant composition may have a direct impact on efficacy. However, due to a lack of information about the composition of the products in this study, it was difficult to determine quality compliance with the corresponding monograph. Therefore, CM companies applying for registration will need to submit detailed and accurate information about product composition. In turn, regulators will be responsible for verifying this information before approving product registration.



Some of the products presented conflicting data between the package inserts and labels. This demonstrated a poor quality of data presentation, and is not acceptable as inconsistent dosage or composition information will cause patient confusion. It also demonstrates that the applicant has poor control over its internal regulatory processes, which may be due to a lack of Good Manufacturing Practice (GMP). Applicants should ensure that product labelling does not provide conflicting information, and stricter regulatory labelling approval processes will need to be created and followed.

### **5.2 Efficacy**

All the products were non-compliant with regard to indications because they contained therapeutic indications that were not stated in the monographs. While the literature

search provided some support for the flu indication, these studies would not satisfy the MCC's requirements. Applicants are required to conduct an extensive and well-balanced literature search when applying for evidence of efficacy, if efficacy cannot be obtained from a recognised source, such as the Martindale (MCC, 2013a).

Products were non-compliant with regard to posology. Underdosing could lead to a lack of efficacy, which could result in increased morbidity. Overdosing could result in toxicity and compromise patient safety.

### **5.3 Safety**

Correct information with regard to contra-indications is essential for safety. On the one hand, it was promising to see that eleven of the thirteen products in the study were deemed compliant in reflecting the contra-indications as per the monographs. On the other hand, some products did not comply fully with the special warnings, such as the labels that did not contain the hepatotoxicity risk related to Pelargonium. Use of these products in susceptible patients could have detrimental consequences. Furthermore, product labelling without warnings could lead to a false perception of safety.

It was concerning to find that only two of the thirteen products complied fully with the monographs' information pertaining to pregnancy and lactation. Since all but one of the monographs stated that there was insufficient safety data to prescribe use during pregnancy and lactation, the product labelling should state that safety in this regard has not been established.

## 5.4 MCC Labelling Compliance

The MCC has mandated that CMs contain the statement that the CM has not been MCC-evaluated (MCC, 2013). Only 46% of the products in this study contained this statement. This is a significant non-conformance, since this requirement should have been implemented by May 2014 (MCC, 2013b).

The majority of the products complied only partially with the requirements of Regulation 8, and 77% of the products did not contain text in a language other than English. This poses a risk that patients who do not understand English could misuse the product. While these products were not required to comply with Regulation 8 at the time of this study, applicants will have to correct their labelling to align with the future requirements. All the products contained batch numbers (a necessary GMP requirement for product traceability), as well as expiry dates (which may affect product safety and efficacy).

Pharmacological classifications were provided for the majority of the products, but there were slight variations in the classification chosen. It must be considered that some of the products contained vitamins, minerals, and even other herbal ingredients not recognised by the EMA monographs. In such cases it would be difficult for the applicant to determine the appropriate pharmacological classification. It is recommended that the MCC provide CM companies with further guidance in the selection of correct pharmacological classifications. This could be done in a workshop or at a conference.

Based on the results of this study, CMs are not yet fully compliant with either the prescribed EMA monographs or the MCC's requirements. None of the products

investigated were compliant with the MCC's mandatory minimum labelling requirements. Applicants should urgently revise their product labelling to comply with the minimum labelling requirements.

The minimum labelling requirements are simpler to fulfil than those necessary for product approval. Therefore, if applicants are unable to meet these requirements, there is a likelihood that they will struggle to provide the complex data required for product registration.

Further research should be conducted regarding the challenges faced by the CM industry in obtaining the data they require for MCC evaluation and approval. It would also be beneficial to investigate what challenges the MCC faces in evaluating CM submissions. The CM industry and the MCC are encouraged to work together in this multifaceted challenge of CM regulation, to assure that marketed Complementary Medicines are of a suitable quality, are safe, and are effective.

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## **7 Appendices**

### **7.1 Appendix 1: Research Proposal**

#### **Title**

An evaluation of Western Herbal Complementary Medicine labelling in South Africa, to determine whether the product labelling information complies with established herbal monographs and whether it meets local regulatory requirements.

#### **Introduction**

In South Africa, Complementary Medicines (CMs) have come under increased scrutiny in the past few years. CMs are widely used by the South African public (MCC, 2013), and in 2013 the South African Medicines Control Council (MCC) published guidelines to improve the regulation of these products (MCC, 2013). An important component of these guidelines pertains to labelling requirements. Product labelling includes the container labels, package inserts and patient information leaflets. Appropriate labelling is necessary to provide consumers with information on how to use the product correctly and safely.

Western Herbal Medicines is categorised as a CM discipline (MCC, 2013). This research project aims to study the labelling of selected Western Herbal Medicines. Specifically, products falling under the category of “immune boosters” will be studied. The MCC has classified immune boosters under 32.16 (Other) and requires that these comply with the CM guidelines by May 2016 (MCC, 2013).

The labelling of the products selected will be assessed to determine whether pertinent information such as the indications, recommended dosages, contra-indications and side effects is in accordance with recognised herbal monographs. The labelling will also be assessed for compliance with the MCC’s regulatory requirements. The data obtained

from this research will provide further information into the current status of Western Herbal Medicine labelling compliance.

## **Methodology**

### Literature Search

A literature search will review the MCC's current CM guidelines, and the Medicines and Related Substances Act (Act No. 101 of 1965), to establish the requirements for the labelling of CMs. The European Medicines Agency (EMA) database of Community Herbal Monographs will be searched to obtain the relevant herbal monographs for the active ingredients contained in the products identified in this study.

### Demographic Area

The demographic area chosen for this study is the Northern Suburbs of Johannesburg. These suburbs are close to the Johannesburg and Sandton CBDs as well as the middle-class suburbs. There is a wide selection of large-chain pharmacies as well as smaller, privately owned pharmacies and health shops in these areas. These contain a wide selection of the various marketed brands of Western Herbal Medicines, and therefore the inclusion of these stores will provide a broad sample of the immune-boosting Western Herbal Medicines required for this study.

### Product Selection

The inclusion criteria of the products selected will include labelling which indicates that the product may be used for immune-enhancing effects, and contains one or more active ingredients listed in the EMA community herbal monographs, as these are recognised by the MCC (MCC, 2013).

### Labelling Assessment

A labelling assessment form will be created based on the MCC's requirements. This form will reference the information prescribed in the corresponding EMA herbal

monograph in order to compare it with the product's information. The assessment form will also include the information that the MCC requires all CM labelling to have with immediate effect, as well as the information that will be required by the May 2016 deadline.

Each product will be recorded on the data collection checklist using the product's trade name, and its corresponding labelling information will also be captured. The collected data will be then be analysed in order to determine the percentages of products in the sample that complied or did not comply with the various labelling requirements. These results will provide a conclusion as to the current status of labelling compliance of Western Herbal CMs.

### **Ethical Considerations**

The labelling assessment form will be submitted to the Ethics Committee for approval. This research does not involve patients nor healthcare professionals, therefore ethical approval for research subjects is not required. However, there are still ethical issues to consider regarding the promotion and marketing of these products. The names of the pharmacies and health shops from which products are bought will be kept confidential. However, the proprietary names of the products obtained will be used, as this information is freely available within the public domain. Furthermore, the results obtained are for the sole purpose of obtaining the information required for this research topic, and have no association with the promotion nor disparagement of the products. The manufacturing companies producing the products have no involvement with this research project and this research has no financial interests.

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## 7.2 Appendix 2: Data Collection Tool



### Western Herbal Complementary Medicines Labelling Assessment Form

Trade Name:

Active Ingredient/s:



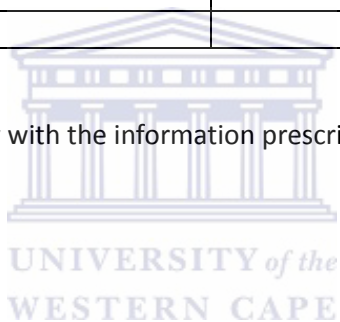
#### 1. EMA Herbal Monograph:

Date of compilation/last revision:

Heading	EMA Herbal Monograph	Product Label	Complies	Non-Compliant
Qualitative and quantitative composition				
Pharmaceutical Form				
Therapeutic indications				
Posology				
Duration of use				

Heading	EMA Herbal Monograph	Product Label	Complies	Non-Compliant
Method of administration				
Contraindications				
Interactions with other medicinal products and other forms of interaction				
Pregnancy and lactation				
Effects on ability to drive and use machines				
Undesirable effects				
Overdose				

Comments: (Does the product comply with the information prescribed by the EMA monograph?)

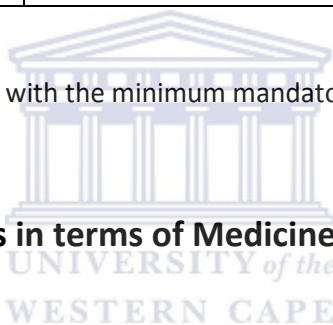


## 2. MCC prescribed minimum information (Required to have been implemented by 15 May 2014)

Criteria	Information on Label (Provide Description)	Complies	Non-Compliant
Written in English and at least one other official language			
Category of medicine			
Pharmacological classification of the medicine			
Discipline of medicine			
The words "This medicine has not			

Criteria	Information on Label (Provide Description)	Complies	Non-Compliant
been evaluated by the Medicines Control Council. This medicine is not intended to diagnose, treat, cure or prevent any disease”			
All claims relating to symptoms must be accompanied by the advice “If symptoms persist consult your healthcare practitioner”			
No medicinal claims:			
Immediate label			
Carton			
Package Insert			
Patient Information Leaflet			

Comments: (Does the product comply with the minimum mandatory labelling information?)



### 3. Labelling Requirements in terms of Medicines and Related Substances Act, 1965

Label Criteria	Information on Label (Provide Description)	Complies	Non-Compliant
<b>Label (Regulation 8 of the Act)</b>			
Present/Absent			
Affixed to immediate container			
Clearly legible indelible letters in English			
Clearly legible indelible letters in at least one other official language			
Scheduling status (where applicable)			
Proprietary name of the medicine			
Registration/Reference Number			

<b>Label Criteria</b>	<b>Information on Label (Provide Description)</b>	<b>Complies</b>	<b>Non-Compliant</b>
Dosage form			
Approved name of each active ingredient of the medicine			
Quantity thereof contained in a dosage unit, or per suitable mass or volume or unit			
Name and percentage of any bacteriostatic or bactericidal agent which has been added to the medicine as a preservative			
Approved name of any anti-oxidant contained in the medicine			
Quantity of sugar contained in the medicine			
Quantity of 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			
Content of the medicine package expressed in the appropriate unit or volume of the medicine			
Approved indications for use of the medicine			
Recommended dosage of the medicine			
Where applicable, the instruction 'Shake the bottle before use'			
Lot number			
Expiry date			
Name of the holder of certificate of registration (or name of applicant)			



Label Criteria	Information on Label (Provide Description)	Complies	Non-Compliant
Storage temperature and other precautions required for the preservation of the medicine			
The warning: 'Keep out of reach of children'			
If the medicine contains TARTRAZINE, the warning: 'Contains TARTRAZINE'			
<b>Carton (where applicable)</b>			
Clearly legible indelible letters in English			
Clearly legible indelible letters in at least one other official language			
Scheduling status (where applicable)			
Proprietary name of the medicine			
Registration/Reference Number			
Dosage form			
Approved name of each active ingredient of the medicine			
Quantity thereof contained in a dosage unit, or per suitable mass or volume or unit			
Name and percentage of any bacteriostatic or bactericidal agent which has been added to the medicine as a preservative			
Approved name of any anti-oxidant contained in the medicine			


<b>Label Criteria</b>	<b>Information on Label (Provide Description)</b>	<b>Complies</b>	<b>Non-Compliant</b>
Quantity of sugar contained in the medicine			
Quantity of 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			
Content of the medicine package expressed in the appropriate unit or volume of the medicine			
Approved indications for use of the medicine			
Recommended dosage of the medicine			
Where applicable, the instruction 'Shake the bottle before use'			
Lot number			
Expiry date			
Name of the holder of certificate of registration (or name of applicant)			
Storage temperature and other precautions required for the preservation of the medicine			
The warning: 'Keep out of reach of children'			
If the medicine contains TARTRAZINE, the warning: 'Contains TARTRAZINE'			
<b>Package Insert (Regulation 9 of the Act)</b>			
<b>Present/Absent</b>			
Clearly legible text in English			


Label Criteria	Information on Label (Provide Description)	Complies	Non-Compliant
Clearly legible text in at least one other official language			
Scheduling status (where applicable)			
Proprietary name and dosage form			
The approved name of each active ingredient  Quantity thereof contained in a dosage unit or per suitable mass or volume or unit of the medicine			
The approved name and quantity of any bactericidal or bacteriostatic agent included in the medicine as a preservative , expressed as a percentage			
The quantity of ethyl alcohol included in a preparation for oral or parenteral administration, if such quantity exceeds two per cent by volume			
The words " contains TARTRAZINE" should the medicine contain such ingredient			
"contains sugar" or "sugar free" whichever is applicable			
Pharmacological classification			
Pharmacological action			
Indications			
Contra-indications			
Warnings			
Interactions			



Label Criteria	Information on Label (Provide Description)	Complies	Non-Compliant
Pregnancy and lactation			
Dosage and directions for use			
Side effects and special precautions			
Known symptoms of over dosage and particulars of its treatments			
Identification			
Presentation			
Storage instructions, including storage temperatures			
Reference number (where applicable) followed by the expression " Act 101/1965"			
Name and business address of the holder of the certificate of registration/applicant			
Date of publication of the package insert (where applicable)			
<b>Patient Information Leaflet (Regulation 10 of the Act)</b>			
<b>Present/Absent</b>			
Scheduling status			
Proprietary name and dosage form			
The composition of the medicine			
The approved indications and use			
Instructions on how to take the medicine, including:			
Contra-indications			



Label Criteria	Information on Label (Provide Description)	Complies	Non-Compliant
Precautions			
Warnings (e.g. concerning sedative properties of the medicine or risks involved with sudden withdrawal of the medicine)			
Interactions			
<p>The following general statements: "If you are taking medicines on a regular basis, using the medicine at the same time with another medicine may cause undesirable interactions.</p> <p>Please consult your doctor, pharmacist or other health care professional for advice."</p> <p>"If you are pregnant or breast feeding your baby while taking this medicine please consult your doctor, pharmacist or other health care professional for advice.</p>	 <p>UNIVERSITY of the WESTERN CAPE</p>		
<p>Instructions on how to take the medicine, including the following statements: "Do not share medicines prescribed for you with any other person. "</p> <p>"In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre"</p>			
<p>Side effects, including the following general statement:  "Not all side-effects reported for this medicine are included in</p>			

Label Criteria	Information on Label (Provide Description)	Complies	Non-Compliant
this leaflet. Should your general health worsen 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."			
Presentation, which includes the number, volume or mass per package unit and a description of the packaging material, e.g. bottle, blister pack, etc			
Identification of the medicine, i.e. the description of its physical appearance as tablet, capsule, etc			
Registration number of the medicine			
Name, business address and telephone number of the holder of the certificate of registration/applicant			
Date of publication of the patient information leaflet			

Comments: (Does the product comply with the Labelling requirements of the Medicines Act? Product will be required to demonstrate compliance by latest May 2016)

## 7.3 Appendix 3: Criteria used to assess percentage of compliance

### Compliance with EMA monographs

Variable Included	Variable Excluded	Reason for exclusion
Pharmaceutical Form	Qualitative and quantitative composition	Not all products could be determined as there is not sufficient quality related data available
Therapeutic indications	Pharmaceutical Form	Not all products could be determined as there is not sufficient quality related data available
Posology		
Duration of use		
Method of administration		
Contraindications		
Special warnings and precautions for use		
Interactions with other medicinal products and other forms of interaction		
Pregnancy and lactation		
Effects on ability to drive and use machines		
Undesirable effects		
Overdose		


### Compliance with MCC minimum prescribed requirements

Variable Included	Variable Excluded	Reason for exclusion
The words "This medicine has not been evaluated by the Medicines Control Council. This medicine is not intended to diagnose, treat, cure or prevent any	Written in English and at least one other official language	Evaluated in the section of compliance with Regulation 8.


disease”		
All claims relating to symptoms must be accompanied by the advice “If symptoms persist consult your healthcare practitioner”	No medicinal claims	Only the immediate labels of two products did not comply with this.
Category of medicine		
Pharmacological classification of the medicine		
Discipline of Medicine		


### Compliance with Regulation 8 of Act 101 of 1965 (Label)

Variable Included	Variable Excluded	Reason for exclusion
Immediate container label only	Outer container label	Not all products contained one
Present	Approved name of any anti-oxidant contained in the medicine	Could not be determined if the products contained these ingredients, therefore this was not applicable to all products
Affixed to immediate container	Quantity of sugar contained in the medicine	
Clearly legible indelible letters in English	Quantity of 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	
Clearly legible indelible letters in at least one other official language	If the medicine contains TARTRAZINE, the warning: 'Contains TARTRAZINE'	
Scheduling status (where applicable)	Where applicable, the instruction 'Shake the bottle before use'	Not applicable to oral solid dosage forms
Proprietary name of the medicine		

Variable Included	Variable Excluded	Reason for exclusion
Registration/Reference Number		
Dosage form		
Approved name of each active ingredient of the medicine		
Quantity thereof contained in a dosage unit, or per suitable mass or volume or unit		
Name and percentage of any bacteriostatic or bactericidal agent which has been added to the medicine as a preservative		
Content of the medicine package expressed in the appropriate unit or volume of the medicine		
Approved indications for use of the medicine		
Recommended dosage of the medicine		
Lot number		
Expiry date		
Name of the holder of certificate of registration (or name of applicant)		
Storage temperature and other precautions required for the preservation of the medicine		
The warning: 'Keep out of reach of children'		

### Compliance with Regulation 9 of Act 101 of 1965 (Package Insert)

Variable Included	Variable Excluded	Reason for exclusion
Clearly legible text in English	The quantity of ethyl alcohol included in a preparation for oral or parenteral administration, if such quantity exceeds two per cent by volume	Not applicable to all of the products
Clearly legible text in at least one other official language	The words " contains TARTRAZINE" should the medicine contain such ingredient	
Scheduling status (where applicable)	Pharmacological classification	Discussed separately
Proprietary name and dosage form		
The approved name of each active ingredient		
Quantity thereof contained in a dosage unit or per suitable mass or volume or unit of the medicine		
"contains sugar" or "sugar free" whichever is applicable		
Pharmacological action		
Indications		
Contra-indications		
Warnings		
Interactions		
Pregnancy and lactation		
Dosage and directions for use		
Side effects and special		

Variable Included	Variable Excluded	Reason for exclusion
precautions		
Known symptoms of over dosage and particulars of its treatments		
Identification		
Presentation		
Storage instructions, including storage temperatures		
Reference number (where applicable) followed by the expression "Act 101/1965"		
Name and business address of the holder of the certificate of registration/applicant		
Date of publication of the package insert (where applicable)	