MCA
Marketing Code Authority
ethical marketing leadership for health products

To: The members of the Marketing Code of South Africa

25 June 2019

In re: Chairman's Letter to members – Annual General Meeting of the Marketing Code of South Africa held 25 June 2019 at the Johannesburg Country Club

Introduction

I am happy to report that good progress has been made in most areas of operation since June 2018. All activities announced at the AGM of 2018 have been implemented and have shown positive results. The one area of concern remains regulatory recognition of S18C.

Whilst S18C remains at the centre of the MCA's plans, there are many other areas that the MCA continues to develop as building blocks towards the ultimate implementation of a regulatory recognized self-regulating code under S18C of Act 101.

Integrity and Credibility of the Code.

At this present time, the Code is not enforceable under law and therefore, members have volunteered to follow the tenants of the Code in good faith and spirit. This is critical for us to have a functional Code that has credibility and integrity

The responsibility for ensuring the credibility and integrity of the Code does not lie with the MCA Board who are merely custodians of the Code and who serve at the will of the members. It is the responsibility of each member company to function in the market place within the ambits of the Code, thereby giving it the credibility and integrity it deserves. This is easily enough achieved by placing the needs of the patient first and ensuring that all HCP's are free from any influence to prescribe and dispense what they believe is the best for the patient.

MCA Membership Survey

We asked for your honest opinion, and we received it! As tough as the feedback was, it was most valuable. We have listened and we have heard, and we have actioned your comments and suggestions. Overwhelmingly, members asked for an electronic newsletter, the first of which has already been published. We hope you find this informative and the MCA welcomes bricks and bouquets to improve content.

The responses were varied and broad which succinctly highlights the cosmopolitan nature of the MCA. The South Africa health industry landscape is very broad; our member companies are based in Europe, the East and locally. Each one has a different need and use of the Code.

What is of keen interest is the fact that not a single comment was focused on placing the patient first in all decisions where ethics, risk and compliance is involved. This suggests a more inwardly looking view versus an outwardly, patient orientated perspective.

Aligning MCA with international codes

In terms of developing and implementing a self-regulatory code in South Africa, the Board must adopt a strategic position. It is my humble opinion that the work of the MCA and the development of the Code should be broad enough to embrace the needs and ethical aspirations of all stakeholders in the South African healthcare milieu.

A key question the Board must answer is to which code should the MCA align with and whether the MCA should in fact align with any code at all? What regulatory laws might be applicable to our members both locally and internationally? Europe functions under IFPMA, the Middle East and North Africa under their own Code of Good Practice and the Far East has their own codes. All of our MNC members must comply with the FDA rules and are subject to the Foreign Corrupt Practices Act of 1977 and to a lesser extent, the US Sunshine Act. They are also subject to the requirements of the UK Bribery Act for example. Very few local healthcare stakeholders are subject to these laws and codes. Locally all companies operating in South Africa are only subject to the requirements of the Medicines and Relate Substances Act 101 and the Prevention and Combatting of Corruption Act 12 of 2004.

The survey voiced a strong desire to have the MCA closely aligned with IFPMA. Is this practically implementable and enforceable, all things considered in South Africa? By way of example, IFPMA requires full and transparent disclosure of all honoraria payments to HCPs for services rendered. Are we, as a healthcare industry and total membership base, ready and willing to implement this? My personal opinion is that we should never wait for other codes to show us what we should be doing. The broader healthcare industry, via the MCA as the vehicle, should be in control of their own destiny and should be implementing ethical decisions based on what is the right thing to do for the patient.

An excellent example regards the matter of gifts to HCPs. As of January 2019, IFPMA has totally banned the giving of gifts to HCPs for non-medical or scientific reasons. Why then have the local MNCs who are *de facto* members of IFPMA not implemented this prohibition in the local market themselves, without the need for the MCA to write it into the Code and 'enforce' it.

These are the vexing dichotomies the MCA Board deals with regularly. What is the solution?

One solution presents a Morton's Fork i.e. i) The Code is narrow in definition and is focused on the needs of the local members and excludes the needs of European and Eastern MNC's or, ii) The Code is narrow and focused on the specific needs of the MNC's who follow stricter European compliance standards. If the MCA follows

the latter, this would by definition alienate and exclude all local players who are not subject to the stricter IFPMA requirements. What, therefore, is the best position to adopt for all stakeholders in the South African healthcare industry?

All European MNC's are bound by their Global Head Office's Ethics, Risk and Compliance codes. More often than not, the local entity is required to apply the stricter of the local code juxtaposed with that of their HO requirement. Operationally therefore, the European MNC's are in fact unaffected by the tenants of the local code. This leaves the playing fields broad enough for local stakeholders to apply the Code in spirit and good faith; to the benefit of the patient.

This is not as big a challenge as what it initially appears to be. The direct answer lies in the adoption of 'principle-based' ethical decision making versus 'rules-based' decisions which are being phased out of all codes. This is as a result of maturing global ethics, risk and compliance strategies

Transgressions of MCA Code

Before escalation to the MCA, the complaint process requires an inter-company dialogue between the parties involved. If no resolution can be reached between the parties, the complaint can be escalated to the MCA for investigation and adjudication.

Only one formal complaint was received by the MCA in the past 12 months. After investigation and review by the expert MCA panel, the complaint was found to have no merit and no further action was required.

Two anonymous complaints received directly from the marketplace were brought to the attention of the MCA. These were raised with the companies concerned who were both very grateful for the MCA contact as they were not aware of the market activity. These were the actions of individual medical representatives who may (or may not) have been aware of their transgressions. This highlights the importance for companies to ensure Code Compliance and to regularly conduct awareness and training interventions internally.

Key MCA activities

Thirteen face to face training sessions were conducted in the past 12 months with 786 attendees across all companies with 1470 online training interventions. These results are indicative of the level of support for MCA training by members thereby enhancing the integrity and credibility of the MCA.

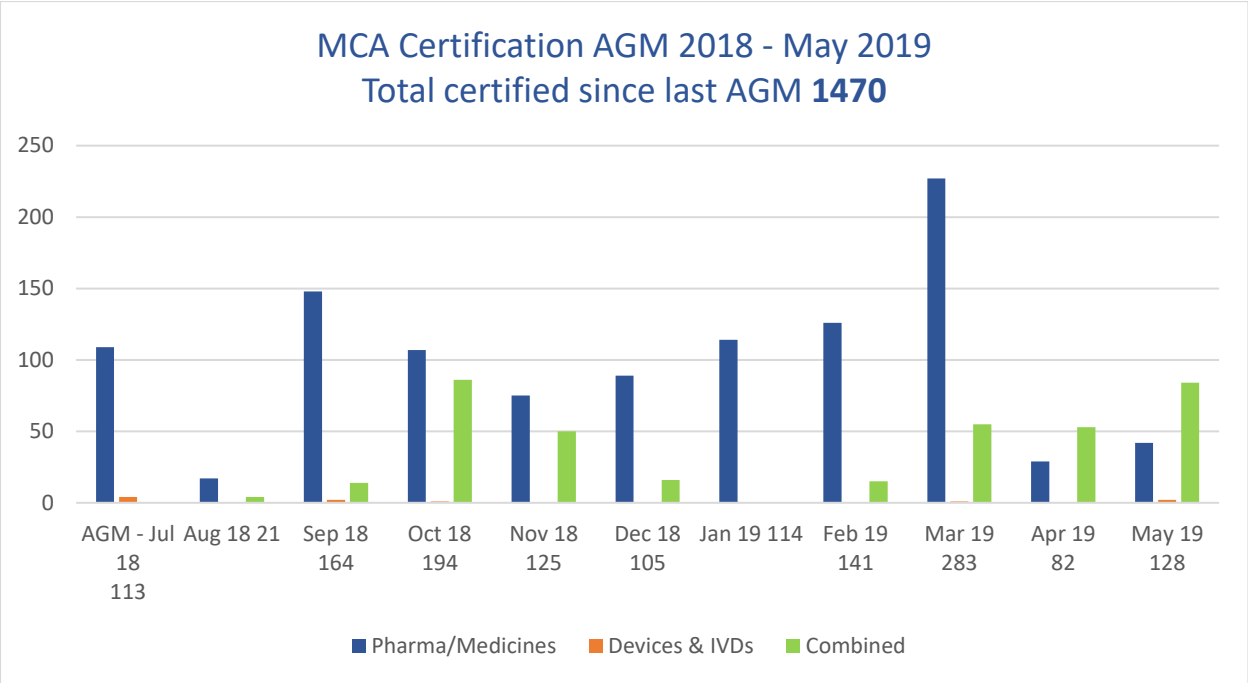

Exhibit I – Completed MCA Certification July 2018 – end May 2019

Exhibit I illustrates the online MCA Certification completion rate over the past 12 months. A total of **1470** healthcare industry stakeholders completed the online certification. By far the majority remains allopathic medicines, but in recent times there has been a resurgence of combined medicines and medical devices certification. The fact that the certification is spread out over a period of 12 months indicates a high level of awareness for the value amongst members i.e. not driven by a once off MCA campaign that sparked interest.

Of particular pleasure to the Board has been the website traffic. At the AGM of 2018 we announced certain brand refreshment and enhancement activities all of which have been fully implemented. This past year, the website has had **11,198** unique landing page sessions with **54, 88%** being new sessions. There were a total of **23,503** page views of which **17,543** were unique page views. This is indeed a positive indication that the MCA website is a regular source of information and is well received.

Progress on S18C recognition

Despite the efforts of myself and the Executive Officer to advance the MCA's cause for S18C regulatory recognition, the regulatory entity responsible for S18C appears to be in a state of mortal funk. The dire need in South Africa for an ethics, risk and compliance regulatory body (government or self-regulatory) is perspicuous. However, the authorities have displayed no intention nor inclination to implement S18C as set out in Act 101. This is in spite of the many representations by the MCA over the past 3 years to a wide audience within the Department of Health.
To be clear, Government establishes the policy and this has been adequately achieved via S18C. It is the responsibility of the regulatory authority under whose

jurisdiction S18C falls, to develop and implement the regulatory framework, without which the policy cannot become active.

As of today, there does not appear to be any change in the regulatory authority's disposition. This makes the need for a self-governing code, with robust process and good governance and that has integrity and credibility as witnessed by its membership base, all the more important. Without such a self-regulatory body, supported in good faith and spirit by its members, the healthcare space will fall into a free for all where the commercial imperatives of the entity will transcend the needs of the patient. A sad state indeed.

It is for these reasons that members of the MCA must maintain peer pressure to do the right thing within the industry.

Member base

As at June 2019, the MCA has 73 (64 PY) members, a 14% increase over June 2018 and represented as follows:

- IPASA 26 (35.6%)
- PHARMISA 6 (8.21%)
- SMASA 22 (30%)
- Independents 18 (26%)

MCA Finance

The finances of the MCA are on a sound footing.

Statement of Comprehensive Income as at 31 December 2018

Revenue remained flat at R1 684 330 over prior year representing the membership fees. MCA management has been active in respect of various training courses including MCA Online Re-Certification which has contributed an additional R478 606.00 revenue, an increase of 19.76% over prior year. The MCA earned an additional R190 819 investment income, up 23% over prior year.

Operational expenses increased 17.05% over prior year, driven primarily by a 19% increase in indirect operational expenses to support the expanded marketing and training activities announced in 2018. Expenses relating to the use of marketing consultants has decreased by 30% over prior year.

Total comprehensive income declined by 7% to R728 648 (R781 760 PY).

Statement of Financial Position as at 31 December 2018

Retained Income for 2018 was R4 228 008, an increase of 20.8% over prior year. This was a factor of the MCA training courses (R478 606) and online MCA Re-Certification (R190 819) as membership revenue was flat with total expenses well controlled.

Total Assets is made up of Cash and Cash Equivalents (97% versus 99% PY) with Total Liabilities consisting primarily of Trade and Other Payables (94% versus 81% PY).

The MCA going forward

Regardless of the challenges we face to obtain regulatory recognition of the MCA, we shall persist and push on in these endeavors. But it is just as important that we, the industry and the MCA members accept the responsibility to ensure that the MCA can function as a self-regularity body even in the absence of regulatory recognition. We must not underestimate this task and must not become complacent as a result of the regulatory authority's recalcitrance.

The MCA Board will continue to focus on the survey outcomes to improve what we can and where we can. Constant and consistent improvement is a key focus area for the MCA.

The year ahead will be highlighted by increased focus on the transition from 'rules-based' ethics to 'principle-based' ethical decision making. Although I have raised this before, we have not focused on it as a key strategy. This will change in 2019/20.

Compliments and recognition

It is with appreciation and thanks that I recognise the efforts of my Executive Officer – Val Beaumont and Executive Assistant – Tasmirah Mall, for their continued support and dedication to the MCA cause. The good work of the MCA can be directly attributed to their hard work this past year.

Conclusion

Taken all together, the MCA has made another step in the right direction. However, this is still not enough. We are not in a position to pat ourselves on the back. As we continue our endeavors to achieve S18C regulatory recognition, we also need to continue being innovative and creative in respect of how we can better serve the broader healthcare industry, our members and most important of all, the patients.

When regulatory recognition is finally granted to the MCA, we must be in a position to move fast to implement the authority and responsibility that comes with this recognition; to level the playing fields by putting the patient first.

Yours Sincerely

Wayne McDuling
Chairman – The Marketing Code of South Africa