MCA
Marketing Code Authority
ethical marketing leadership for health products

Chairman's Report AGM 2018 (21st June, 2018)

Introduction

This past year has been eventful for the MCA. The objectives for 2018 have remained aligned with 2017 to ensure consistency of approach and continuity and, to ensure clear focus on what we ultimately wish to achieve - formal recognition of the Code under S18C of the Medicines and Related Substances Act.

2018 is the first year in the existence of the MCA where good traction has been gained in all areas:

- Good progress in terms of S18C,
- Updating of the MCA Policy and Guidelines,
- Improvements in all internal processes and governance,
- Revitalising the MCA brand and raising awareness across all Stakeholders.

As with everything in business, each area has room for improvement and these will be discussed in detail below.

The purpose of the MCA – a reminder

Notwithstanding that the MCA is made up of members who are active in the pharmaceutical industry, the ultimate purpose of the MCA's existence is to place the patient first in all interactions related to the marketing of medicines to Healthcare Practitioners (HCP). It is the responsibility of the MCA to ensure that policies and guidelines developed by the MCA and intended to guide the industry in respect of how stakeholders market their medicines and medical devices, do not interfere with the independence of the HCP to stock, order, prescribe or dispense pharmaceutical or medical device products by offering incentives which do not place the patient at the centre. This is paramount and non-negotiable.

It is therefore so much more important to drive the formal recognition of the MCA as a self-regulating body; making membership compulsory to all industry stakeholders, to ensure that the Rule of Engagement is fair and equitable for all and, where members are found to deviate from the MCA Code, an acceptable and enforceable form of sanction is in place.

It is problematic for me that the current MCA members abide by non-binding MCA Policy and Guidelines both in spirit as well as intent, but there are far too many stakeholders in the industry who do not – to the ultimate detriment of the patient!

This is the single biggest focus of the MCA Board and we shall not rest until we achieve this.

Progress on S18C Regulation recognition

A number of encouraging formal and informal engagements have taken place over the last year. Government issued a draft regulation pertaining to S18A of the Act and called for industry comment. The MCA grabbed at this opportunity to voice its opinion by submitting a formal response focusing on how formal recognition of the Code will support Government's initiatives to better align all stakeholders behind a common understanding of the ethical marketing of medicines. Whist comment was requested on S18A, the principals of S18A and S18C are not mutually exclusive.

Formal submissions (Regulations to Medicines Act)

- In response to publication of Draft General Regulations to the Medicines Act calling for a regulation to S18C. The MCA proposal recommended the publication of guidelines/standards for ethical codes and for organisations/authorities to enforce these codes. Most importantly, licensing of manufacturers should be conditional on commitment to an enforceable code. Unfortunately, we were advised by the Regulator that this matter would be dealt with only after the General Regulations had been finalised.
- In response to S18A Regulations. The MCA proposed the principle that whilst promotional activities intended to incentivise the purchase of health products should be prohibited, that the marketing code provided a template to guide promotion in an ethical manner. Regulations must be published to S18A and 18C to provide an appropriate and implementable framework.

During the past year, the MCA has enjoyed a number of engagements at Department of Health level, engagements the MCA did not have in the previous year. Some of these include the Pricing Committee, the Department of Health (Health Regulations and Compliance Management), SAHPRA and the Inspectorate and Law Enforcement.

All these interactions were positively received and are extremely valuable on the road to recognition of the MCA. They have raised awareness to a new level with the Regulator as to who the MCA is and what the MCA stands for.

Update of the South African Code of Marketing Practice and Guidelines

The Code was last updated in 2016 to accommodate CAMS manufacturers and was therefore due for upgrade. The healthcare industry is dynamic, changing daily. Markets are creative, inventing new ways to promote products and it is therefore important that the Code remains valid and is a living document that serves its constituents.

The executive team working in conjunction with the Trade Association representatives on the Code Technical Advisory Committee (CTAC) have slaved away for the better part of the past 12 months to produce a document that is a significant improvement on the previous version. Whilst a large part of the upgrade has to do with making the document more user friendly in its structure, updates have also been made in respect of implementation at company level, adding value to industry on a daily basis.

The new Code has one set of principles that applies equally to HCP and consumer marketing.

Revitalising the MCA brand and raising awareness across all Stakeholders.

As we increased focus on achieving S18C recognition, it became apparent that we needed to improve our public footprint and awareness of who the MCA is and what it stands for. We embarked on a process to revitalise the MCA brand and make it more relevant to its members, both patient and consumers. We contracted with a professional PR consultant with over 30 years healthcare industry knowledge to assist us in developing a professional MCA Awareness PR campaign, write relevant industry PR, attend industry seminars and symposia to promote the MCA and to significantly improve the MCA's website and internet presence. As the MCA is not a bricks and mortar institution, it is critical that the MCA has a 'real' presence and to this end the website has been totally revamped and structured to strategically serve several key purposes in the future:

- Be the face and presence of the MCA in all issues related to the ethical marketing of medicines,
- Showcase the value proposition of the MCA and act as a Best Practice for other industry codes,
- Provide key stakeholders such as Government and other self-regulating bodies confidence of what the MCA does and how it does it, in a transparent manner,
- Be a place where patients and HCPs can anonymously raise complaints in respect of false, misleading advertising or inappropriate incentives offered,
- Be the 'go to place' for standards related to healthcare industry marketing guidelines,
- The portal through which Code Certification can take place, smoothly and efficiently,
- Acts as a repository for all MCA related governance requirements

The current status of the Health Product Association (HPA) as an MCA member

Last year we reported on significant progress with the on-boarding of the HPA. A key objective for 2017 was the signing of the MOU with the HPA, completed in May 2017. This was a positively anticipated event that held much promise for the MCA and the

industry in general as it would herald the broadening of the membership base beyond just pharmaceutical and medical device companies. Significant work was done to change the MCA Code to accommodate health products including the Code and Guidelines.

The much anticipated increase of HPA members to the MCA member base did not materialise. The Board has been in continuous engagement with the HPA Executive with a view to amicably resolving the impasse and we expect resolution before end 2018.

MCA Finance

The finances of the MCA is in good health. This is despite the decrease in revenue (-30.2% YoY). Revenue was in line with budget as it consists of membership fees. The decline is attributed to the -183% decline in certification fees over 2017. Revenues from certification renewals is seasonal due to the two-year validity period.

Total operating costs decreased marginally (-1.25% YoY) due to good management of costs. Unsurprisingly the decline in revenue impacted the profit of the MCA. Profit before Tax declined by 52.8% (YoY).

Both revenue and profit must be seen in the context of the MCA as a non-profit organisation. It is not the intention of the MCA to make any profit. However, it is good governance to maintain a healthy reserve to weather any storms that may lie ahead in the form of legal or other actions. In addition, the MCA will look to increase investment in marketing aligned with MCA strategies. This will be particularly relevant when formal recognition of MCA and S18C is obtained as this will broaden the membership base significantly, requiring investment to expand. The MCA Board remains risk averse and financially prudent.

Retained income for 2017 is R3 499 359, an improvement of 22%.

The MCA going forward

2018 has been used to ensure that all the critical building blocks of a good self-regulatory body in respect of structures, processes and governance are in place in anticipation of MCA recognition for S18C. In our opinion, Government and the Regulatory Authority have two meaningful options to regulation at their disposal:

- Develop from scratch their own Government Regulatory Body to enforce and monitor S18C requirements or;
- Endorse through formal recognition of an already existing self-regulatory body, already resourced with skilled, knowledgeable and experienced people in the field of pharmaceutical regulation.

In the first instance, this process will take years of consultation and input from industry before it is finally adopted. This will have a direct negative impact on the very people a regulatory body is supposed to protect – the patient. Government would need to write the S18C policy and guidelines and implement enforcement, oversight and governance structures. All of which already exist in a mature form through the constructs of the MCA.

Although not impossible, it will require significant resources both of time and financial investment at a point when South Africa has other major priorities in the healthcare space.

In the second instance, the MCA has developed the Policy and Guidelines in consultation with key healthcare stakeholders to a level where is it is considered best practice on the Africa continent. The Department of Health has constantly been updated and informed along the journey. The enforcement and adjudication processes already exist and have been tested via industry complaints. These complaints have enabled the MCA to refine and improve processes, governance and skill sets of panellists.

The point is the MCA as a healthcare industry self-regulatory body is ready and perfectly positioned to take on this very important role.

Further, the MCA constantly reflects on its role as a self-regulatory body to ensure it remains relevant to its member's needs. Importantly the MCA cannot be all things to all people. The membership base represents a broad cross section of the industry and to this end it would be neither possible nor desirable to develop polices and guidelines for specific members and their business models. The complexities of enforcing specifics would be onerous and a prescriptive Code would discount far too many members who would perhaps not be able to comply, but want to.

The Board scans developments in both the local as well as international markets and takes learnings from regulatory bodies across geographies. From this we have identified a clear shift from a purely rules based policy to a more principle based decision making philosophy. Rules are rigid and in most instances require a Yes / No response. Whereas ethical principles, when applied correctly and maturely lead to much better outcomes in terms of ethical marketing of medicines. At the centre of the principle discussion is the Patient and all decisions flow from this.

Therefore, it is critical that the healthcare industry makes the paradigm shift from a purely **rules-based** approach to a **principled based decision** making approach with the patient at the centre of the ethical dilemmas.

Conclusion

Your self-regulatory Marketing Code Authority is in good health with many new prospects and opportunities that lie ahead. The Board remains at the service of its members with a priority focus of ensuring HCPs are free to make independent decisions when it comes to patient care.

The MCA stands by the commitment of its members and to this end is only as good as the support received from its member base.

In the short term the success of the Board will be measured against S18C recognition by the Department of Health or other regulatory Authority. In the long term we will be measured by how the healthcare industry stakeholders view the MCA's contribution.

But ultimately we will be measured by the patient.

Finally I wish to extend my thanks and appreciation to the people behind the scenes that make the MCA happen. Without Val Beaumont and Tasmirah Mall, the MCA would exist in name only. I am sure many will attest to their willingness to make a difference when they contact the MCA.

Both ladies have been instrumental in laying the foundation for the future and to deliver on the objectives set by the Board in 2017/8. I am deeply thankful to both for their support to achieve our key objectives of formal recognition.

Thank you, Val and Tas!

Yours Sincerely

Wayne Mc Duling

Chairperson, Marketing Code Authority