



MCA Sanction Policy Document v3

This policy document is issued by the MCA Board in terms of clauses 8.2.13 and 1.2.21 of the MCA Constitution and the MCA Marketing Code of Practice (Clauses 3.54 and 16.22) to guide complaint and appeal committees in the imposition of sanctions and fines in the event of Code breaches.

This MCA Sanctions Policy Document is the subject of a review to ensure relevance and ability to be implemented in the context of the current Marketing Code.

Approval by MCA Board at a duly constituted MCA Board meeting: 12th November 2024

Signed:

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MCA Executive Officer
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PRINCIPLES FOR DETERMINING SANCTIONS

- 1.1 The Adjudicating or Appeal Committee ruling on a complaint or appeal, as the case may be, will make all decisions regarding the imposition of sanctions and penalties.
- 1.2 The reasoning behind the imposition of a sanction or penalty should be transparent and set out in sufficient detail in the relevant ruling.
- 1.3 Such imposition of a sanction or penalty must be aligned with this MCA policy document as set by the MCA Board from time to time.
- 1.4 It must be acknowledged that sanctions are not static. The upper limits of monetary sanctions will be reviewed as part of the periodic review of the Code. However, within the limits identified in the Code, the MCA has the discretion to apply a range of monetary fines and other sanctions based on consideration of these principles.
- 1.5 Uniform solutions may not be suitable or applicable for every situation. The Adjudicating or Appeal Committee is encouraged to take a tailored approach and consider all eventualities when imposing sanctions and penalties, including but not limited to the principles outlined below without however compromising accountability.
- 1.6 The following includes some of the principles which will be taken into consideration by the MCA in determining an appropriate sanction following a finding of breach/es of the Code.

PRINCIPAL FACTORS IN DETERMINING THE LEVEL OF A SANCTION

- 2.1 The nature and extent of the activity/material, including its impact on the market and the reputation of the industry.
- 2.2 Whether the breach should have been clearly evident to the Company.
- 2.3 Whether the Complainant and Respondent have respectively acted in good faith as regards the conduct complained of, and the complaint / appeal lodged subsequent thereto;
- 2.4 Length of time that the materials have been in use.
- 2.5 The number and type of alleged breach/es which were the subject of the complaint.
- 2.6 Previous breaches by the Company (whether similar or not) including but not limited to:
 - 2.6.1 *history of previous breach/es of the Code in relation to a specific therapeutic area;*
 - 2.6.2 *sanctions previously imposed on the Company by the MCA (whether in relation to the same or similar types of breach/es in comparable circumstances, or otherwise);*
 - 2.6.3 *repeated or multiple breaches;*
 - 2.6.4 *any evidence that previous breaches or sanctions have not successfully*



improved compliance within the Company (not necessarily within the same therapeutic area);

2.6.5 any evidence that the breach related to an activity that was not sanctioned by the Company's operating procedures or training of personnel; and

2.6.6 cooperation/acknowledgement of offence and evidence of internal procedures implemented to avoid similar breaches in future.

2.6.7 Non-implementation of previously imposed sanctions and / or corrective action and / or failure to implement undertakings previously made;

2.7 Impact or harm to patients, competitors, providers and/or healthcare service provision.

2.8 Multiple confirmed breaches in one complaint. The Committee may impose a sanction in respect of each breach of the Code including a financial sanction, however in the alternative they could issue one composite sanction for all complaints deemed valid in a particular hearing.

2.9 Circumstances i.e. the environment in which the activity took place.

The potential costs to be incurred by a company for corrective action – the MCA will consider the overall monetary cost of the package of sanctions, for example the cost of issuing a corrective letter in combination with a fine. The cost of the penalty imposed should be assessed taking account of the ability of the company to comply with a financial sanction. Such considerations could include, nature of the transgression, size of the company, nature of business e.g. manufacturer, agent, 3rd party provider etc. The size of the Respondent company will be taken into consideration where relevant.

GUIDELINES IN RELATION TO SPECIFIC TYPES OF SANCTIONS

3.1 In the case of a penalty requiring a corrective letter or a republication/retraction of an advertisement etc., the Committee that made the ruling must specify all necessary requirements for such publication / advertisement. The Committee should generally reflect the audience that may have received the material found to be in breach of the Code.

3.2 Where the sanction includes a corrective advertisement, the placement thereof must be in the same journal / publication / media channel as that of the advertisement found in breach of the Code. The corrective advertisement must be of the same size and prominence as the original advertisement.

3.3 A copy of the distributed corrective letter (on company letterhead bearing the signature of the company Chief Executive Officer or Code Compliance Officer) and published corrective advertisement (or copy of any other form of correction duly ordered) should be provided to MCA for the file records. If the correction is a radio / television advertisement, then it must be broadcast at approximately the same time and on the same days of the week as the original advertisement was broadcast.



- 3.4 The number, format, size, wording, mode of publication, prominence, timing (including duration of publication) and method of distribution of corrective statements must be approved by the Executive Officer of the MCA prior to release.
- 3.5 The Executive Officer of the MCA shall finalise details of the letter/republishing or retraction notice of an advertisement and follow up to ensure full implementation of the penalties/s subject to Chapter 16 of the Code.
- 3.6 Consideration must be given as to whether the corrective action applied is inadvertently increasing attention and publicity for the aggressor, and caution is encouraged when imposing such a sanction.

MCA SANCTIONS FRAMEWORK TO SUPPORT COMPLAINT COMMITTEES

Classification of Breach	Nature of Code Breach	Corrective Action/ Public Disclosure (may include one or more of the following, either in isolation or combination with an appropriate fine).	Fine	Period allowed to comply with sanction.
Minor	May have impact on one or more of the following criteria <ul style="list-style-type: none"> • No safety implications for patients for any breach found by the committee. • May have impact on how healthcare professionals will use product. The potential impact could be harm to patients or economic harm to the complainant or other companies. 	One or more of the following as appropriate <ul style="list-style-type: none"> • Immediate withdrawal of material/activity from the market. Reconciliation of withdrawn material against material issued. Submit to MCA. • Company to issue a corrective statement, if and as determined by MCA, including target audience and media. • Publication of summary report on the MCA website. 	R10k – R50k	30 days



<p>Moderate</p>	<ul style="list-style-type: none"> • May have safety implications for patients. • Could or will affect how healthcare professional will use product. The potential impact could be harm to patients or economic / reputational harm to the complainant or other companies. • May undermine the relationship between patients and healthcare professional 	<ul style="list-style-type: none"> • Immediate withdrawal of material/activity from market. • Company to issue a corrective statement, as and if determined by MCA, including target audience and media to be used. • Written reprimand to company by MCA. • Publication of correct advertisement, as determined by MCA, including target audience and media. • Publication of summary report on the MCA website. 	<p>R50k – R200k</p>	<p>30 days or as otherwise directed by the committee</p>
<p>Serious/ Severe</p>	<ul style="list-style-type: none"> • Will have safety implications for patients. • Will have effect on how healthcare professionals will use product. • Commercial impact on relevant market players. • Activities that bring disrepute to industry or reduce confidence in the industry. 	<ul style="list-style-type: none"> • Immediate withdrawal of material/activity from market. • Written reprimand to company by MCA. • Company to issue a corrective statement as and if determined by MCA including target audience and media. • Issue a corrective letter to healthcare professionals/public, as determined by MCA. • Publication of summary report on the MCA website. 	<p>R201k – R500k</p>	<p>30 days or as otherwise directed by the committee</p>

A committee may also take account of multiple breaches in a single complaint, repeated breaches whether or not the same product and/or corrective action not previously implemented/fines not paid. The committee may use their discretion to override the above sanctions provided such a decision is unanimous and substantiated.



Classification of Breach	Nature of Code Breach	Corrective Action/ Public Disclosure	Fine	Timelines
Multiple breaches in one complaint	<ul style="list-style-type: none"> A committee, in considering the aggregate of the breaches determined in response to a single complaint, should consider the number of Code principles breached rather than considering the overall listings within a complaint i.e. the principles should be the main determination rather than for example the number of advertising elements inappropriately published. 	<ul style="list-style-type: none"> The Committee may impose a sanction in respect of each breach of the Code as well as a fine or alternatively issue one sanction/fine. 	To be taken account of in the guidelines above.	30 days or as directed by the committee
Repeated Breaches	<ul style="list-style-type: none"> >2 valid complaints in 4-year period. 	<ul style="list-style-type: none"> Refer to the MCA Board to review membership of MCA. 	A Committee may decide at its discretion to impose a separate sanction in such a case. Refer to table above for (non-binding) guidance.	30 days
Corrective Action not implemented / fines not paid	<ul style="list-style-type: none"> Where corrective action has not been complied with. Any other sanction including notices, orders as to cost and fees not complied with. 	<ul style="list-style-type: none"> Code provides for Executive Officer to appoint an Appeal Committee to review and make a ruling. Referral to appropriate Regulatory body if company does not comply. 	Additional fine or sanction.	To be specified (including timelines) by the Appeal Committee as appropriate



<p>Frivolous, unjustified or vexatious complaints</p>	<ul style="list-style-type: none"> • <u>Upon submission:</u> Complaint does not comply with requirements of complaint as defined in Code (Section 6.11.3). • Complaint lodged in bad faith / with materially "unclean hands" (6.11.3) • <u>Upon rejection of a submission on the grounds of being frivolous, unjustified or vexatious by the Executive Officer:</u> 	<ul style="list-style-type: none"> • Executive Officer informs complainant in writing. Complaint not accepted. • The Complainant may appeal the decision of the Executive Officer to not accept the complaint on frivolous, unjustified or vexatious grounds. (16.11.6). The Executive Officer must then refer the "appeal" to an adjudicating committee following usual processes. The committee so appointed will be called the Adjudicating committee and it must first deal with the point about the complaint being frivolous, unjustified or vexatious as a <i>Point in Limine</i>) the outcome of which will determine whether the complaint should proceed to the merits of the matter. • If the committee finds that the complaint was in fact frivolous, unjustified or vexatious, it must impose a fine. 	<ul style="list-style-type: none"> • R20 000 payable to the MCA 	<p>30 days</p>
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		<ul style="list-style-type: none"> Should the Complainant take the Adjudication committee on Appeal and the Appeal Committee finds that the complaint is indeed frivolous, unjustified or vexatious, then the Appeal Committee shall impose another fine of the same quantum. The fine will be payable by the Complainant, to the MCA. 	<ul style="list-style-type: none"> If matter is appealed, then payment of fine must be suspended until the outcome of the appeal. If appeal ruling upholds that the complaint is frivolous, vexatious, unjustified, then the fine is payable immediately. R20 000 payable to the MCA 1. 	
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Note:

For the purpose of determining whether a complaint / defence (referred to below as "a submission") is frivolous, vexatious and / or in bad faith (contra bonos mores), the following is to be considered:

- i. Frivolousness refers to a submission being of no practical use or value, and / or that wastes time or money.
- ii. Vexatiousness refers to a submission being made (primarily) so as to cause annoyance, embarrassment or harm to the respondent.
- iii. A submission lodged in bad faith relates to an intention to deceive; dishonesty or the absence of sufficient transparency as to one's own conduct.

The above prospective findings ought not to be arrived at lightly, and must be adequately substantiated in any ruling (or in the case of a decision by the Executive Officer, reasons for such decision).



IMPLEMENTATION AND ENFORCEMENT OF SANCTIONS

- 5.1 The Executive Officer shall oversee the implementation of any penalties imposed by a Committee. Penalties must be complied with within timelines required by the Code and subject to committee rulings and Chapter 16 of the Code.
- 5.2 The Executive Officer shall publish a summary of any matter heard by an Adjudicating or Appeal Committee on the MCA website. This shall be done in consultation with the chairperson of the relevant Committee and in his/her absence by another member of the relevant Committee provided that a matter heard by an Adjudication Committee shall be published only if no appeal has been lodged within the prescribed time period or after an appeal in respect of the matter has been concluded. (16.20.1)
- 5.3 The party against whom a ruling was made by an Adjudicating or Appeal Committee shall notify the MCA in writing of measures implemented while also providing copies of any supporting documentation requested by the MCA. This communication shall be submitted to the MCA within 14 (fourteen) days of the date by which the party has complied with all aspects of the ruling, including compliance with any sanction imposed. Failure to comply with this requirement shall constitute a failure to comply with the ruling. (16.21.2).
- 5.4 The sanctions policy shall be annexed to all committee rulings.

REVISION CONTROL

- 6.1 The initial sanctions policy was approved by the MCA Board on **21st September 2010**.
- 6.2 At the Special General Meeting with members on the **13th March 2013**, these sanctions were revisited and adopted by the Board of the MCA.
- 6.3 Update October 2017 Version 2 created:
 - 6.3.1 *Minor: R6k – R100k changed to R10k – R100k;*
 - 6.3.2 *Moderate: R100k – R200k changed to R101k - R200k;*
 - 6.3.3 *Serious / Severe: R200k – R300k changed to R201k – R500k;*
 - 6.3.4 *Invalid / unjustified / vexatious complaints: Fine(R10k) removed;*
 - 6.3.5 *Bringing the Code into Disrepute: Entire row has been removed;*
 - 6.3.6 *All reference to the MCC has been removed.*
- 6.4 **November 2024 v3. Totally new Sanctions Policy.** The need has arisen for this complete review due to challenges experienced in implementation of the policy.

For Further Information contact Val Beaumont (Executive Officer)

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