

MCA Sanction Policy Document v2

This policy document is issued by the MCA Board in terms of clauses 5.11 and 9.6 of the MCA Constitution and v11 of the MCA Marketing Code of Practice.

Date of Approval by MCA Board:

1 PRINCIPLES FOR DETERMINING SANCTIONS

- 1.1 Subject to the Constitution and the Code, companies should provide evidence that they have exhausted all reasonable options to resolve complaint at company level, as per the Marketing Code.
- 1.2 The reasoning behind the imposition of a sanction should be transparent to both the complainant and respondent company.
- 1.3 Such imposition of a sanction must be aligned with the sanctions document and policy as set by the Board of the MCA from time to time.
- 1.4 The Adjudicating or Appeals Committee will make decisions regarding penalties.

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.

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.

2 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 breadth of activity or campaign, including its impact on the market;
- 2.4 length of time that the materials have been in use;
- 2.5 the number and type of alleged breach/es;
- 2.6 previous similar breaches, including but not limited to:
 - 2.6.1 history of previous breaches of the Code in relation to a specific therapeutic area;
 - 2.6.2 sanctions previously imposed on the company by the MCA in relation to the same or similar types of breach/es or in comparable circumstances;
 - 2.6.3 repeated or multiple breaches;

- 2.6.4 any evidence that previous breaches or sanctions have not successfully encouraged 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.
- 2.7 impact on patients, providers and/or healthcare service provision;
 - 2.8 harm to competitors, patients, providers and/or healthcare service provision;
 - 2.9 non-implementation of previously imposed sanctions and/or corrective action and/or failure to implement undertakings previously made;
 - 2.10 circumstances i.e. the environment in which the activity took place; and
 - 2.11 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.

3 DOUBLE JEOPARDY

The MCA will not rehear a complaint against a particular section or sections of the Code in relation to the same activity or same material irrespective of whether there was a finding of a breach of the Code, unless there is an allegation that the material has not been withdrawn or the activity has not ceased. If a complaint is received in relation to an activity or material already considered by the MCA the complainant will be referred to the outcome of the previous complaint.

4 GUIDELINES IN RELATION TO SPECIFIC SANCTIONS:

- 4.1 In the case of a corrective letter the specific Committee of the MCA who heard the matter will specify to whom the letter must be sent. This will reflect the audience who may have received the material found in breach of the Code.
- 4.2 Where the sanction includes a corrective advertisement the placement must be in the same journal 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.
- 4.3 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 should be provided to MCA for the file records. (Refer to Section 24.2 of Code).
- 4.4 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 MCA prior to release.

MCA Sanctions Framework

Classification	Expanded definition	Corrective Action/Public Disclosure	Fine	Timeline
Minor	No safety implications for patients' well-being.	Immediate withdrawal of material/activity from the market.	R10K-R100K	30 days
	May have on how healthcare professionals will use product.	Company to Issue a corrective statement, as determined by MCA, including target audience Written reprimand to company by MCA Notify HCP of breach, if relevant		
Moderate	No safety implications to patients' wellbeing	Immediate withdrawal of material/activity from market	R101K-R200K	30 days
	May have effect on how healthcare professionals will use product	Company to Issue a corrective statement, as determined by MCA, including target audience Written reprimand to company by MCA Notify HCP of breach, if relevant Publication of corrective advertisement, as determined by MCA, including target audience		
Serious/ Severe	Will have safety implications to patients' wellbeing	Immediate withdrawal of material/activity from market	R201K – R500K	30 days
	Will have effect on how healthcare professionals will use product	Written reprimand to company by MCA		
	Commercial impact on relevant market	Company to issue a corrective statement as determined by MCA including target audience. Issue a corrective letter to healthcare professionals/public, as determined by MCA		
	Activities that bring disrepute to industry or reduce confidence in the industry			
Fines not paid	When a monetary fine is not paid within the required time period from receipt of the decisions and the reasons for the decisions of the MCA		Further fine of R50K	60 days
Corrective Action not implemented	Where corrective action has not been actioned within required timelines Any other sanction including orders as to cost and fees	The matter will be raised by MCA with the subject company and may be taken to MCA for consideration	Further fine of R100K	60 days

Repeated Breaches	>3 infringements in 1 year	The MCA may publish the decision in a newspaper with national circulation along with the name of the offending company. Publication of the infraction on MCA website All postings will remain on website for 12 months	First: R10K + original fine Second: R15K + original fine; Third: R25K + original fine R200K max	60 days
	When a company repeats any breach, as classified by MCA, in the promotion/activity of any of the company's products/activity			

Multiple breaches	company: MCA will usually consider the aggregate of the breaches to determine whether a sanction should be imposed	The MCA may publish decision in a newspaper with national circulation along with the name of the offending company. Publication of the infraction on the action on MCA website MCA may impose a sanction in respect of each breach of the Code, but may choose to impose an additional financial sanction.	60 days
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Invalid/unjustified/vexatious complaints	Does not comply with requirement of complaint as defined in Code	MCA informs complainant in writing
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Revision Control:

- The initial sanctions policy was approved by the MCA Board on 21st September 2010.
- At the Special general meeting with members on the 13th March 2013, these sanctions were revisited and adopted by the Board of the MCA
- Update October 2017 Version 2 created:
 - Minor: R6k – R100k changed to R10k – R100K
 - Moderate: R100k – R200K changed to R101K to R200K
 - Serious / Severe: R200K – R300K changed to R201K – R500K
 - Invalid / unjustified / vexatious complaints: Fine (R10K) removed
 - Bringing the Code into Disrepute: Entire row has been removed
 - All reference to the MCC has been removed