

Marketing Code Authority (MCA) Standard Operating Procedure Template: MCA Code Implementation and Compliance

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Version: 2

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Objective

This document is prepared as a guide only, to assist companies in the implementation of the MCA Code requirement for an SOP for approvals of promotional items and activities, sponsorships and CPD (Refer Chapter 6 of Code v 11 and Guidelines v9.). It is not a final document for implementation but sets out a framework and minimum standards of what should be covered by a compliance SOP as required by the Marketing Code.

Companies will need to develop in-house SOPs from this template for the implementation of the Code in companies.

Scope

SOP framework of minimum standards for implementation of Code compliance procedures and accountability for the approval of promotion material and activities.

Responsibilities

This should be the Company Code Compliance Officer (CCO) or as formally delegated by CCO.

Definitions and abbreviations

Definitions and abbreviations to be included as per the Marketing Code and as appropriate.

Flow diagram/summary

A flow diagram showing delegation of responsibilities for all aspects of the process should be included. It should indicate clearly who has the ultimate authority for approval of promotional items and events and what and to whom responsibility is delegated for individual processes including all technical and financial record retention.

Procedure: Suggested minimum standards for an SOP in respect of compliance with the MCA Code

Note: The SOP should reflect company standards adopted where they supersede the Code.

Responsibility for Code Implementation and Compliance

- The Company Code Compliance Officer (CCCO) appointed by the company is responsible for the implementation of the SOP for Code Compliance. This individual should be either the responsible pharmacist or a natural person with delegated responsibility for compliance with the Code
- The CCCO shall always have a current/valid MCA Code certificate filed with the company's compliance records.
- All company facing representatives should receive Code Compliance training and be "Code certified"
- The company SOP (tailored by the company from this template to meet its needs) and related documentation shall be available for auditing by the MCA or the Regulatory Authority, if required.

Approval of promotional items, events and activities, sponsorships and CPDs

The following should be covered by this SOP and are required to be approved by the CCCO:

- All Promotional Material and activities including, briefing material, training material, promotional meetings;
- Promotional aids & gifts;
- Sponsorships and CPDs or other educational events;
- Scientific or promotional presentations;
- Journal club meetings organised and/or sponsored by a Company (wholly or partly); and
- An event, parts of an event, a speaker or an attendee who is sponsored by the Company either directly or indirectly.

Proof of Approval – General Principles to be applied

Documentation of proof of the approval of promotional activities

- The proof of approval document must record the details of the approval and be signed off by the Company Code Compliance Officer.
- The proof of approval shall record/confirm the following information as relevant:
 - that the final form of the material or arrangement of activities has been approved;
 - that it is in accordance with the requirements of the relevant advertising and/or legislation relevant to promotion;
 - that it is in accordance with the Code;

- that it is not inconsistent with the Health Product registration and the Professional Information, Patient Information Leaflet or Instructions for Use of the Product; and
- That it is a fair and truthful presentation of the facts about the Health Product.

Documentation of proof of the approval of events/activities

The following information and documentation, as may be applicable, shall be retained:

- Details of the programme, both scientific/educational and entertainment/hospitality;
- Invitations;
- Details of and motivation for the choice of venue(s);
- The rationale for the meeting or sponsorship;
- Speaker and participant selection processes and criteria;
- FFS/Honoraria paid and rationale for determination of fair market value;
- The anticipated costs associated with the event, and that associated with all entertainment and hospitality;
- The records of the actual costs shall be retained by the Company's finance department and be available for auditing purposes.
- Promotional Material shall be preserved in the form approved, and should include:
 - details of Persons to whom it was addressed,
 - the method of dissemination, and
 - the date of first dissemination must be retained.

Document retention

- Details of events, campaigns and other activities, must be retained, including the agenda;
- Records shall be retained for the minimum period of 5 (five) years after the final use of the material or the date of the event;
- Compliance records must be produced on request to the MCA or the Regulatory Authority.
- Records may be stored in photographic or other electronic format.

Standards to be applied in adjudicating on compliance

Standards to be applied in the approval process shall in the first instance be those of the legislation and the Code. The Guidelines to the Code provide further guidance on certain issues and should be interrogated where applicable.

Re-Approval of Promotional Material

Promotional Material that is still in use shall be re-approved at intervals of no longer than 2 (two) years to ensure that it continues to conform to the relevant legislation and the Code.

Related documents

Marketing Code of Practice v11 and Code Guideline v11 (June 2018)

Attachments

Details of company documents relevant to the approval of promotional material and activities to be identified and attached.

Version History

A record of versions of the SOP released must be retained against a specific instruction.

SOP Authorisation

Details of SOP Preparation, review requirements, authorised signatories and effective date must appear on each page.

Include a directive for who is authorised to review the SOP and/or related documentation, sign against the SOP and update it.

Release date for current version.

To be recorded here

MCA Guidance Document initially prepared February 2019 (VJB) and updated March 2019.

For further information contact the MCA info@marketingcode.co.za