MCA
Marketing Code Authority
ethical marketing leadership for health products

# TIPS & FAQs

## To whom should the CCO in a pharmaceutical or medical device company report?

Some confusion seems to have crept in with the introduction into the Code of the 'Authorised Person' applicable to medical device companies.

In Short:
The CCO in health product companies must report to the **Responsible Pharmacist** (appointed in terms of the Pharmacy Act) in pharmaceutical companies and to the **Authorised Person** (appointed in terms of the Medicines Act) in the case of medical device and IVD companies. The CCO does not need to be a pharmacist but must be accountable to the Responsible Pharmacist or the Authorised Person as appropriate. Responsibilities should be formally delegated in compliance with the requirements of the legislation (Pharmacy Act and Medicines Act). The argument below, in support of this statement, is based on the Pharmacy Act, the Medicines Act and the Code of Marketing Practice requirements in respect of advertising.

At a glance:

| Pharmaceutical Manufacturers (Registered as a pharmacies) | Medical Device Companies Registered with the DoH |
|---|---|
| **Responsible Pharmacist (RP)**<br>**Pharmacy Act**: The RP is responsible for company compliance with the **Medicines Act** and the **Pharmacy Act.** This responsibility includes compliance with advertising legislation (General regulation 42 of the Medicines Act) and ethical rules for pharmacy (SAPC Rules Relating to the of Conduct for pharmacist and other persons registered in terms of the Pharmacy Act). | **Authorised Person (AP)**<br>**Medicines Act** (SAHPRA):<br>AP legally responsible for all aspects of the medical device or IVD, including compliance with conditions of registration.<br><br>Responsibility includes compliance with the **Medicines Act** in respect of advertising (Reg. 21of regulations relating to medical devices). |
| Some of these duties can be delegated to the:<br><br>**Company Compliance Officer (CCO)** | Some of these duties can be delegated to the:<br><br>**Company Compliance Officer (CCO)** |
| What does the Code require?<br>Every company shall appoint a person as the CCO, who is authorised to be responsible for the enforcement of and compliance with the Code. (S3.1) | |

The Code S6.2.2 provides that the proof of approval shall state that the CCO has examined the final form of the material or arrangements for an event and that:

- it is in accordance the requirements of the relevant advertising and/or promotional regulations and the Code;
- that it is not inconsistent with the Health Product registration and the Professional information/Patient information leaflet/Instructions for use; and,
- is a fair and truthful presentation of facts about the Health Product.

**Notes:**

*The Pharmacy Act requires that all medicine manufacturers must register as a Pharmacy with the Pharmacy Council and be under the supervision of a Responsible Pharmacist who is responsible for compliance with all legislation relating to the scope of practice of pharmacy, including the Medicines Act and the Pharmacy Act.*

*1) Pharmacy Act - relevant provisions*

*a) Pharmacy Act Definition:*

***Responsible Pharmacist** means a natural person who is a pharmacist and who shall be responsible to the [Pharmacy] Council for complying with the provisions of this [Pharmacy] Act and other legislation applicable to services which specially pertain to the scope of practice of a pharmacist, and the legislation applicable to the pharmacy which is under his or her personal supervision.*

*b) Rules Relating to the of Conduct for pharmacist and other persons registered in terms of the Pharmacy Act*

***1.7 Advertising…..***

*(l) **the responsible pharmacist must be responsible for the form and content on any publicity whether placed by the responsible pharmacist personally or by another staff member or organisation on behalf of the pharmacy**, and for any other publicity which the responsible pharmacist expressly authorises. Where the responsible pharmacist becomes aware of any impropriety in any publicity appearing on his/her behalf, he/she must forthwith use his/her best endeavours to have the publicity rectified or withdrawn.*

*2) The Medicines Act: relevant provisions*

*a) Medical Devices and IVDs : The Medicines Act, Regulations relating to Medical Devices and In-vitro Diagnostic Medical Devices*

*(Definition): **Authorised person** means a natural person, resident in the Republic of South Africa who…….(c) **is responsible for all aspects of the medical device or IVD,***

***including performance, quality, safety and compliance with conditions of registration, clinical trials or clinical investigations.***

*b) Regulation 21 prescribes conditions for the advertising of medical devices or IVDs.*

*2) Medicines: General Regulations*

*a) General Regulation 42 prescribes conditions for the advertising of medicines*

*The Code: relevant provisions*

*The Code takes the Pharmacy Act definition of a* ***Responsible Pharmacist.***

*The Code S1.1, provides that words and phrases used in the Code and defined in the Medicines Act have the meanings assigned to them in the Medicines Act, unless otherwise stated or inconsistent with the context.*

*The Code S3.11 Definition****: Company Compliance Officer*** *is defined in the Code and means any natural person duly authorised by the Company, or appointed by the Company in writing, to sign documents or give instructions on behalf of the Company with regard to compliance with the Code. Every Company shall authorise or appoint a person as the Company Code Compliance Officer (Definition).*

*The Code S6.1.1 provides that the CCO shall either be the responsible pharmacist and/or natural person responsible for the enforcement of and compliance by the company with the Code. This should be read as the Responsible Pharmacist or someone to whom the Responsible Pharmacist has delegated authority for compliance with the legislation, in the case of a pharmaceutical company, or the Authorised Person or someone to whom the Authorised Person has delegated responsibility for compliance with the legislation in the case of a Medical Device or IVD company.*

*The Code S6.2.2 provides that the proof of approval shall state that the CCO has examined the final form of the material or arrangements for an event and that:*

*a) it is in accordance the requirements of the relevant advertising and/or promotional regulations and the Code;*

*b) that it is not inconsistent with the Health Product registration and the Professional information/Patient information leaflet/Instructions for use; and,*

*c) is a fair and truthful presentation facts about the Health Product.*

*It can be deduced from the above that a CCO must not only be appointed or delegated to in terms of legislation but should also have a knowledge of the law relating to the Pharmacy Act the Medicines Act. Further, they should be familiar with the product registration details.*

***These notes reflect the opinion of the EO. They are an aide to interpreting the Code but do not represent official MCA positions.***