

Promotional activities involving medicines: Selected regulatory and ethical requirements for healthcare professionals

Val Beaumont, MCA

SAHPRA (the SA Health Products Regulatory Authority) has recently advised the pharmaceutical industry of its intention to increase vigilance over the control of medicine advertising and promotion. It is therefore pertinent to consider specific issues that relate to the potential involvement of healthcare professionals (HCPs) in medicines promotion, either deliberately or inadvertently.



The promotion of medicines in SA is regulated through a combination of legislation, professional ethical standards and industry self-regulation. HCPs who prescribe, dispense, recommend or otherwise engage in pharmaceutical promotion should be familiar with these requirements, contained mainly in the medicines and health professionals legislation and the Marketing Code Authority (MCA) Code of Marketing Practice.

This article summarises selected provisions relating to off-label claims, healthcare professional testimonials and endorsements, promotional competitions, and the sampling and discounting of medicines.

Requirements for the promotion of medicines only for approved indications

Medicines may only be promoted in accordance with the conditions of their registration and the approved professional information (PI) authorised by SAHPRA.

The MCA Code further provides that all promotional material be accurate, balanced, current, capable of substantiation and consistent with the approved PI. Promotional claims should not be misleading or exaggerated, or omit material information that could influence prescribing decisions.

Off-label claims

The term "off-label" use refers to the prescribing, recommendation or use of a registered medicine outside of the SAHPRA-approved indications, dosage, patient population, route of administration or other conditions reflected in the approved PI.

The PI of a product provides information on the established efficacy and safety of a product when used as directed in the PI, and at the indicated dosage(s) approved

by the regulator. Straying outside of this framework constitutes off-label usage, and has liability implications for prescribers and dispensers.

The MCA Code therefore provides that: promotional activities remain within the approved registration of the medicine; claims made should reflect only approved indications; and usage of quotations, tables, graphs and illustrations from scientific literature accurately reproduce the findings of the original publication without creating a misleading impression.

In order to differentiate between regulation of promotional activities and legitimate scientific exchange, the Code provides guidelines on appropriate scientific exchange. These guidelines follow the HPCSA position on CPD activities. In short, the communication of scientific information, publication of independent research or discussion of emerging evidence should not constitute product promotion where it is presented in an appropriate scientific context.

HCPs should therefore distinguish between scientific discussion and promotional claims when evaluating information relating to medicines. Queries related to off-label use should be directed to medically qualified staff in companies, rather than to sales representatives.

HCP testimonials and product endorsements

HCPs occupy positions of public trust, and their opinions may significantly influence prescribing decisions and public confidence in medicines. Consequently, the use of HCPs in testimonials, endorsements and other promotional activities is regulated by the ethical rules of the HPCSA, and the industry by the MCA Code.

The MCA Code permits the use of testimonials and quotations in promotional material, provided they are genuine, current, accurately reproduced and used with the appropriate consent of the individual concerned. Testimonials must be consistent with the approved PI, and must not create misleading impressions regarding the efficacy, safety or performance of a medicine. Where names, photographs, recordings or professional affiliations are used, the necessary permission should be obtained.

HCPs participating in promotional activities remain bound by the HPCSA ethical rules. Rule 7 prohibits a practitioner from accepting "commission or any material consideration (monetary or otherwise)" in return for the purchase, sale or supply of goods, substances or materials used in professional practice. It further prohibits a practitioner from offering or accepting "any payment, benefit or material consideration" intended to induce him

or her to act, or refrain from acting, in a manner that is not scientifically, professionally or medically indicated.

Rule 23 regulates advertising and the use of professional status in commercial activities. It requires registered practitioners to ensure that their professional position is not used in a manner that is misleading or inconsistent with the ethical rules. The HPCSA ethical guidelines require practitioners to maintain professional independence, and to ensure that commercial relationships do not compromise their professional judgement or the interests of patients.

HCPs involved in pharmaceutical promotional activities should therefore ensure compliance with applicable HPCSA ethical requirements.

Any promotional activity intended to increase the prescribing or sale of a medicine is prohibited. HCPs should not engage in such promotions

These principles are not applied only to HCPs. Pharmaceutical companies are also subject to the SA Pharmacy Council's Code of Conduct. The code prohibits pharmacies and pharmacy owners from incentivising product use through offering, paying or giving any commission, discount, rebate, bonus, refund or other incentive to HCPs. Together, the HPCSA ethical rules, the Pharmacy Council Code of Conduct and the MCA Code establish complementary standards designed to preserve professional independence.

Competitions and promotional schemes

The MCA Code contains provisions regulating competitions and promotional activities intended to encourage the sale or prescribing of medicines.

Promotional competitions, prize schemes or similar activities should comply with the requirements of the Code, and should not undermine ethical prescribing or influence professional decision-making in a manner inconsistent with patient care.

The Code provides guidelines for what constitutes an ethical competition. Any competition or promotional scheme that has as a requirement the purchase or

prescription/recommendation of a product is prohibited on ethical grounds.

Healthcare professionals participating in promotional activities should ensure that such activities comply with both the MCA Code and the applicable professional ethical standards.

Sampling, single-exit pricing and discounting of medicines

Hand in hand with the restrictions on the sampling of medicines is the system of single-exit pricing (SEP). The Medicines and Related Substances Act No. 101 of 1965 (Medicines Act) requires that medicines may be sold only at the SEP at any point in the medicines chain, including by dispensing doctors. Dispensing fees are applied to the SEP at point of sale. Discounting and bonusing of the SEP of medicines purchases is prohibited, although dispensing fees may be discounted.

The Medicines Act prohibits the sampling for all medicines, including complementary medicines, to healthcare professionals. A temporary exemption exists for schedule 0 medicine to be excluded from the standard SEP requirements, and it can therefore be supplied at a reduced or no price.

The distribution of medicine samples at congresses is also not allowed, but provision is made for manufacturers to make demonstration packs available.

Key take-home on professional responsibilities

Promotional claims made for medicines may not go beyond the PI. HCP prescribing should typically be within the bounds of the PI, subject to practitioner discretion and legal and ethical boundaries.

Any promotional activity intended to increase the prescribing or sale of a medicine is prohibited. HCPs should not engage in such promotions.

An HCP should not benefit personally from offering a product testimonial.

Sampling of schedule 1 and above medicines is illegal. Similarly, discounting of schedule 1 and up medicine prices is a contravention of the Medicines Act, and would be seen as a perverse incentive if discounts or kickbacks were accepted by an HCP.

The HPCSA ethical rules and ethical guidelines complement medicine regulatory requirements by establishing professional standards, including the maintenance of professional independence and appropriate conduct in relation to advertising and endorsements.