Distribution and Marketing of drugs in South Africa

by Jenny Pienaar, Partner and Jeanette Visagie, Senior Associate, Adams & Adams

The authors would like to thank Consultant, Elsabe Klinck, of Elsabe Klinck Associates (Pty) Ltd for her assistance in preparing the article.

Country Q&A | Law stated as at 01-May-2018 | South Africa

A Q&A guide to distribution and marketing of drugs law in South Africa.

The Q&A gives a high level overview of distribution and marketing of drugs law, including pre-conditions for distribution; licensing; wholesale distribution; marketing to consumers; marketing to professionals and engagement with patient organisations.

To compare answers across multiple jurisdictions, visit the Distribution and Marketing of Drugs Country Q&A Tool.

This Q&A is part of the global guide to Distribution and Marketing of Drugs.

Distribution

1. What are the legal pre-conditions for a drug to be distributed within the jurisdiction?

The distribution of medicines in South Africa is governed strictly by the Medicines and Related Substances Act No.101 of 1965, as amended (Medicines Act). The most recent amendments were brought into effect on 1 June 2017. Other pieces of legislation govern the movement of medicines in the supply chain and persons authorised to distribute medicines within the supply chain including the:

- Pharmacy Act No. 53 of 1974, as amended;
- Health Professions Act No.56 of 1974, as amended (HPA);
- National Health Act No 61 of 2003, on human tissue;
- Animal Diseases Act No 35 of 1984, on medicines with animal content.

Authorisation

The distribution of medicine requires a licence that must be obtained from the South African Health Products Regulatory Authority (SAHPRA), previously the Medicines Control Council (MCC). SAHPRA also issues licences to wholesalers, importers and retailers of medicines.
Exceptions
The use of medicines outside of the licensing regime is permitted in certain circumstances for compassionate use (see Question 2). SAHPRA can use its discretion, within the legal framework created by the Medicines Act, to decide whether:

- To grant a licence.
- A medicine can be sold.

A general exemption section exists in the Medicines Act. Any company can apply for an exemption from any provision in the Act or Regulations, for example, related to labelling, packaging or pricing.

2. Do any types of named patient and/or compassionate use programmes operate? If so, what are the requirements for pre-launch access?

Access to medicines in a compassionate use programme is granted on a case-by-case basis. Therefore, there are no named compassionate use systems, models or programmes that rely on named patients or any other basis. A new set of General Regulations (GNR 859 of 25 August 2017) now separate access to unregistered medicines for clinical trial purposes (Regulation 30) from access to medicines for other purposes (Regulation 29). Various requirements are provided under Regulation 29, for example:

- A product brochure containing relevant chemical, pharmaceutical, pre-clinical pharmacological and toxicological data and where applicable, human or animal pharmacological and clinical data with the medicine concerned must be provided.
- A witnessed patient informed consent document (where applicable).
- Details of registration or pending registration of the medicine with any other regulatory authority (if available).
- Evidence of compliance of the manufacturer of the medicine with Good Manufacturing Practice standards as determined by the Authority.
- Reasons why a South African registered medicine cannot be used.

Requirements are also set post the granting of such permission, including that:

- Any adverse event report is submitted to the South African Health Products Regulatory Authority (SAHPRA).
- Progress reports are submitted to SAHPRA every six months from the date following commencement of the use of the unregistered medicine.
- A progress report is submitted 30 days after the completion or termination of the use of the medicine.

SAHPRA may also withdraw the authorisation to treat the patient or animal if the authority believes the safety of any patient or animal is compromised, that the scientific reasons for administering the unregistered medicine have changed or for any other reason as determined by the Authority.
A medicine that is supplied must be properly labelled and the package must sufficiently identify information relating to the medicine.

It has become custom that the application for the supply and use of unregistered medicine be made in the name of a medical practitioner, or other authorised prescriber, who then takes legal responsibility for the administration. The actual importation and distribution is, however, done in the name of a licenced pharmaceutical company in most cases, but this is not a requirement in law.

Failure to obtain approval will result in an offence under the Medicines Act. For further information see the requisite application form at:

http://www.mccza.com/documents/786a43016.12_Section_21_Application_Form_Jun17_v2.pdf

**Licensing**

3. What is the procedural structure regarding licensing a drug for distribution?

**Structure**

The structure for the procedure is set out in the Medicines Act. The Medicines Act (read together with the General Regulations of 2017) provides details about the particular forms, application fees and information as required by the South African Health Products Regulatory Authority (SAHPRA).

Licensees are required to provide the requisite information in the application forms and also provide information that is stipulated in the General Regulations regarding the substance to be licensed. The application is then delivered to the SAHPRA and deliberated by the various technical and scientific committees established by the CEO and SAHPRA Board. A decision is then made about whether or not to license the medicine for distribution, and the implementation of conditions that will be applicable to the medicine for distribution purposes (including its scheduled status).

**Regulatory authority**

The SAHPRA is responsible for the licensing of drugs in South Africa.

4. Is there a simplified licence proceeding, or relaxed licensing conditions, for drugs that have already been licensed for distribution in another jurisdiction?
An expedited licensing procedure did exist under section 15 of the previous version of the Medicines Act, but has been removed from the law in the amendments that came into effect on 1 June 2017.

There are provisions in the Medicines Act for parallel imports to be accepted, provided that the Minister of Health, (who is ultimately responsible for the enforcement of the Medicines Act) agrees to the parallel import based on a need or requirement of public health. Section 15C of the Medicines Act provides that:

- Any patented medicine can be imported if already registered in South Africa.
- A person or company that wishes to import a patented medicine must apply to the Minister of Health for a permit to parallel import a medicine.
- The holder of a certificate of registration for a medicine in South Africa is not entitled to prevent the medicine's importation into South Africa or its sale, on account of the certificate of registration or the existence of a patent on the medicine.
- The parallel importer is responsible and liable for the parallel imported medicines, for example, he must notify the MCC in the event of a recall or adverse event.
- The parallel importer is responsible for destroying any expired, parallel imported medicines (for the duration of the permit and also after the parallel importation permit has expired).

Section 15C of the Medicines Act has not been used to date.

5. Is virtual drug distribution possible from your jurisdiction?

There is no specific provision contained in the Medicines Act or any other piece of legislation regarding the virtual distribution of medicines. The Medicines Act assumes that all factors and elements of the distribution of the medicine are physically present within South Africa, including the distributor and the substance being distributed. Physical inspections of all pharmacies (that is, manufacturers, wholesalers and retailers) also take place where courier services are used to distribute medicines.

It is unlikely that the South African Health Products Regulatory Authority would recognise virtual drug distribution. This is because the structure of the Medicines Act provides the Medicines Control Council with direct jurisdictional control over the process of distributing and selling medicines in South Africa.

6. What is the procedure to appeal (legal remedy) a licensing decision?
There is an appeal provision within the Medicines Act that allows applicants for a licence to appeal the decisions of the Medicine Control Council if they are dissatisfied with the outcome of the application. The appeal provisions are strengthened by the provisions relating to procedurally fair administrative law contained in section 33 of the Constitution of the Republic of South Africa, 1996, read together with the:

- Various pronouncements in the common law, most notably by the Constitutional Court of South Africa.

The appeal procedure is governed by the provisions of the General Regulations provided in relation to the Medicines Act. Any person aggrieved by a decision of the South African Health Products Regulatory Authority (SAHPRA) can appeal under section 24A of the Medicines Act. A separate appeal process exists for appealing against a decision of the Director General of Health, for example, on dispensing licences, or authorising the use of medicines by persons not ordinarily authorised to possess or use medicines, such as nursing professionals.

7. What are the costs of obtaining licensing?

The costs will vary depending on the nature of the licence that is required. The costs are published, from time to time, by the South African Health Products Regulatory Authority (SAHPRA) in the Government Gazette. The Government Gazette must be consulted when the licence application is made to the Medicine Control Council with regard to the costs of a particular licence.

**Distribution to consumers**

8. What are the different categories of drugs for distribution?

The categories of the medicines are determined by the Medicine Control Council.

The primary method for categorising medicines is based on schedules that range from Schedule 0 to Schedule 7. Various conditions attach to the distribution and sale of the medicine depending on the nature of the schedule that is applied. For example:

- Schedule 0 medicines are available off the shelf or without prescription in a supermarket.
- Schedule 1 and 2 medicines are available without prescription, but only from a pharmacist. They are referred to as “over the counter medicines”.
- Schedule 5 medicines are only available from a pharmacist on prescription by an authorised prescriber.
In addition, health supplements and complementary medicines are about to be regulated, and some categories have been called up for registration (licensing). If such a medicine contains scheduled substances, it becomes an allopathic medicine and falls into the above categories. Most health supplements and complementary medicines will be schedule 0, or fall into a general market access category, yet to be determined.

9. Who is authorised to distribute prescription drugs and over-the-counter drugs to consumers?

The sale of medicines to consumers is determined by:

- **Section 22C of the Medicines Act.** A person holding a dispensing licence can sell medicines to consumers.
- **Section 22A of the Medicines Act.** This section determines what types of medicines may be provided, at what frequency and/or quantity, by healthcare professionals to the public, and on which conditions (for example, repeat-prescriptions).
- **Pharmacy Act.** A person who is registered as a pharmacist can sell medicines directly to consumers.

Certain categories of medicines can be sold directly to consumers "off the shelf" and can be sold by anyone including retailers, such as supermarkets (who do not require a Section 22C license and sell Schedule 0 drugs). The licensing requirements under the Medicines Act provide that:

- A written application must be made.
- The applicant must adhere to certain criteria as determined by the South African Health Products Regulatory Authority (SAHPRA).

The sale of over-the-counter medicines to consumers is restricted to pharmacists who are licensed and registered under the provisions of the Pharmacy Act, and persons licensed under the provisions of section 22C of the Medicines Act. It should be noted that corporate ownership of pharmacies is permitted in terms of section 22A of the Pharmacy Act, provided that the existence of a pharmacy, within the confines of, for example, a retailer or other non-pharmacy setting, is governed by provisions in the Medicines Act and supervised by the Department of Health.

**Over-the-counter drugs**
The sale of over-the-counter medicines to consumers is restricted to:

- Pharmacists who are licensed and registered under the provisions of the Pharmacy Act.
- Persons licensed under the provisions of section 22C of the Medicines Act (*see above*) or under section 22A(15), such as optometrists, paramedics and nursing professionals.

Corporate ownership of pharmacies is allowed under section 22A of the Pharmacy Act, provided that the existence of a pharmacy is governed by provisions in the Medicines Act and supervised by the Department of Health.
10. What drugs can an attending physician distribute and under what circumstances?

Any substance that is registered as a medicine under the provisions of the Medicines Act is available for sale or distribution by an attending physician and can be provided to a consumer/patient by an attending physician.

The Medicines Act and the Pharmacy Act allow for the sale of medicines by attending physicians in circumstances where the medicine is needed to treat the consumer/patient's condition and the attending physician completes the correct prescription for the sale of that medicine. However, a generic substitution is required by law (unless the patient refuses this or the prescriber writes “no substitution” next to the line item) where a generic alternative exists for a prescribed medicine.

11. Who is authorised to prescribe prescription drugs to consumers?

Authorised prescribers can prescribe medicines under the provisions of the Medicines Act and the Health Professions Act No.56 of 1974 (HPA). The term “authorised prescriber” is defined in the HPA and recognised by the Medicines Act as persons who are admitted as medical practitioners.

The following persons are allowed to prescribe medicines:

- Medical practitioners (including psychiatrists).
- Dentists
- Other persons authorised in accordance with the licensing provisions of the Medicines Act and the Pharmacy Act read together with the HPA, such as optometrists and emergency healthcare workers, and, for nurses, read with the Nursing Act, 2005.

12. Is direct mailing/distance selling of drugs permitted in your jurisdiction?

Conditions
Distance selling of medicines is permitted, and various courier-type pharmacies exist that specialise in the movement of medicines across large distances. Typically, such arrangements exist within the context of private medical funding. Therefore, a medical scheme (being the vehicle for private medical funding) generally has an arrangement with a courier pharmacy that creates an obligation on the pharmacy to transport medicines within South Africa.

**Cross-border sales**

Cross-border sales are not normally authorised unless the:

- Receiving state has authorised the entry of medicines into the country through its own licensing regimes.
- Persons operating the importation of medicines into that state are authorised and licensed accordingly.
- The exporter is licensed to export the specific medicine.

In addition, under the Pharmacy Act, the distributor must be licensed to move medicines over distances, in a courier format.

---

13. What regulatory authority is responsible for supervising distribution activities?

Distribution activities are supervised by the:

- South African Health Products Regulatory Authority (SAHPRA) in relation to applications for licence for a medicines distributor.
- South African Pharmacy Council in relation to the dispensing functions of pharmacists or other authorised dispensers.

---

14. What is the procedure to appeal (legal remedy) a distribution decision?

Provisions exist in the Medicines Act and the Pharmacy Act for an applicant to appeal a decision by the South African Health Products Regulatory Authority (SAHPRA), the Director-General of Health or the South African Pharmacy Council in relation to an application for a distribution licence or the existence of a distribution licence.
15. What are the legal consequences of non-compliance with consumer distribution laws?

There are various legal consequences for a person who does not have the correct licence to distribute medicines or who sells medicines in circumstances that contravene the Medicines Act, the Pharmacy Act or the Health Professions Act No.56 of 1974 (HPA).

Penalties include civil and criminal liability. Under the Medicines Act a penalty of up to ten years imprisonment, and/or a fine may be levied. The level of fine or imprisonment will depend on the nature of the offence and the statutory requirement that has been violated. In addition, persons who endanger consumers/patients through the sale of medicines without the appropriate licenses can also contravene the Consumer Protection Act No.68 of 2008 (CPA). The CPA provides for additional penalties.

Wholesale distribution

16. What is the legal regime regarding wholesale distribution of drugs?

The wholesale of medicines is governed by the Medicines Act and a licensing structure imposed by the South African Health Products Regulatory Authority (SAHPRA). An important prohibition exists in section 22H, in that a wholesaler may only buy from the primary importer or manufacturer of a medicine, and may only sell to a licensed retailer (pharmacy or dispensing healthcare professional). An exemption from this prohibition is possible on application to the CEO of SAHPRA.

Any person who wishes to engage in the wholesale of medicines must be licensed to do so by the MCC in accordance with the requirements contained in the Medicines Act and the General Regulations provided in the Medicines Act, as well as the Pharmacy Act. Any person can apply to be a wholesaler of medicines subject to requirements that prohibit the existence of a wholesale licence within certain commercial companies that have a direct or indirect beneficial interest in a retail pharmacy or in a prescriber or vice versa.

17. What regulatory authority is responsible for supervising wholesale distribution activities?

Regulatory authority
The South African Health Products Regulatory Authority (SAHPRA) is responsible for supervising wholesale distribution activities.
Supervision
The SAHPRA is empowered through an inspectorate, created by virtue of provisions in the Medicines Act, to ensure that wholesale activities occur within the confines of the law.

Rights of appeal
A person has a legal right under the Medicines Act (sections 24 and 24A) to appeal any decisions made by the Director General of Health, SAHPRA or its inspectorate. The right to appeal is reinforced by the:

- Administrative law provisions set out in section 33 of the Constitution.
- Applicable pronouncements in the common law including those by the Constitutional Court of South Africa.

---

18. What are the legal consequences of non-compliance with wholesale distribution laws?

A person can be subject to criminal liability in the form of fines and imprisonment for the wholesale distribution of medicines without the required licence. The applicable penalties are provided in the Medicines Act and vary on a case by case basis depending on the nature of the offence committed.

Marketing

Promotion

19. What is the general legal regime for the marketing of drugs?

Legal regime
The Medicines Act and its Regulations, govern the marketing of medical substances and devices in South Africa.

In the area of self-regulation, the Code of Marketing Practice (Code) and its Guidelines were drafted to regulate the ethical marketing of medicines and medical devices in South Africa.

In particular, the Code regulates:
• Medical devices.
• Registered health products (including scheduled and unscheduled medication).
• All advertising and promotional activities where members of the medical field are influenced to purchase, prescribe, supply, administer, loan or lease a health product.

Limits to marketing activities
The Medicines Act provides that no person can advertise any medicine or scheduled substance for sale unless the advertisement complies with the prescribed requirements. The Medicines Act also prohibits the publication or distribution of any false or misleading advertisement relating to any medicine.

The Regulations under the Medicines Act provide that only the following can be advertised to the public:

• Medicines that do not contain a scheduled substance.
• Medicines that contain a substance appearing in Schedule 0 or Schedule 1 (see Question 8).

Medicines that contain a substance appearing in Schedules 2 to 6 (see Question 8) can be advertised for information purposes to:

• Medical practitioners.
• Dentists.
• Veterinarians.
• Pharmacists and other persons authorised to prescribe medicines.
• Persons in receipt of certain publications containing the advertising.

The Code deals with the appropriate advertising of medicines and regulates:

• Truthful advertising.
• Comparative advertising.
• Disparaging references.
• Inducements, gifts and promotional items and competitions.

In general, advertisements must not be misleading or disparaging (either directly or by implication). Information, claims and comparisons must be accurate, balanced, fair, objective, unambiguous and supportable and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. The use of medical terminology is acceptable provided that it does not confuse or mislead the consumer.

20. Are there other codes of conduct for the marketing of drugs (for example, by professional or industrial organisations)?
The Code of Marketing Practice (Code) was drafted by the Marketing Code Authority (MCA), in consultation with the pharmaceutical industry and other stakeholders. The Code is supported by the Department of Health.

The Code is enforced by the Marketing Code Authority (MCA), which is also the body responsible for adjudicating complaints and disputes relating to the Code. The Code is based on the principle of self-regulation through the health industry.

The Code is adopted by companies in the health industry, for example, the health products trade associations and the South African Medical Device Industry Association, in order to ensure that the marketing of health products to healthcare professionals (HCP) and the public is carried out in a reasonable, ethical and professional manner, based on information that is practical and scientifically validated.

Section 18C of the Medicines Act empowers the Minister of Health, after consultation with the pharmaceutical industry and other stakeholders, to make regulations regarding the marketing of medicines, scheduled substances, medical devices or in vitro diagnostics (IVDs), including an enforceable code of practice. The MCA intends to make an application to the Department of Health that the Code be recognised and acknowledged in terms of section 18C of the Act, in order to be legally enforceable in terms of the Medicines Act.

**Marketing to consumers**

21. What is the legal regime for marketing to consumers?

**Legal regime**
The Medicines Act and the Code of Marketing Practice (Code) govern the marketing of medicinal products to consumers.

The Consumer Protection Act of 2008 (CPA) promotes and advances the social and economic welfare of South African consumers. The CPA:

- Is applicable to all goods marketed for human consumption.
- Prohibits the application of a trade description to a product that is likely to mislead consumers.
- Provides that goods cannot be marketed in such a way that is reasonably likely to imply a false or misleading representation. When marketing a product, a supplier:
  - cannot make a false, misleading or deceptive representation to consumers regarding the material facts relating to a product;
  - must correct any misapprehension on the part of consumers.
The Advertising Standards Authority of South Africa’s Code of Practice (ASA Code) is the guiding document in the area of self-regulation of commercial advertising in South Africa. The Preamble of the ASA Code provides that advertising must be:

- Legal.
- Decent.
- Honest.
- Truthful.

The provisions of the ASA Code and the CPA are incorporated to a great extent in the Code and the Medicines Act and its Regulations. For this reason, only the relevant portions of the Code and the Medicines Act are discussed further. However, a complainant is not prohibited from seeking relief under the CPA and the ASA Code, if it believes that the marketing of a medicine contravenes any of the relevant provisions.

**Products**

Only over-the-counter medicines can be advertised to the general public. In terms of the Medicines Act, the following can be advertised to the general public:

- Medicines that do not contain a scheduled substance.
- Medicines that contain a substance appearing in Schedule 0 or Schedule 1 (see Question 8).
- Prescription medication cannot be advertised to the general public, but only to healthcare professionals (HCPs).

**22. What kinds of marketing activities are permitted in relation to consumers and the products which may be advertised to them?**

**The Medicines Act**

Under the Medicines Act, the term "advertisement" includes any written, pictorial, visual or other descriptive matter or verbal statement or reference that is intended to promote the sale of that medicine, scheduled substance, medical device or in vitro diagnostics by:

- Appearing in any newspaper, magazine, pamphlet, electronic media (including radio and television) or other publication.
- Being distributed to members of the public.
- Being brought to the notice of members of the public in any manner whatsoever.

The term "advertise" has a corresponding meaning.
The Code of Marketing Practice (Code)
Advertising and/or promotion and promotional materials or activities, includes the following:

- Advertorials.
- Branded materials relating to product sponsorship.
- Aerial promotions, for example hot air balloons.
- Booklets.
- Cinema commercials.
- Consumer leaflets.
- Consumer broadsheets.
- Direct mail materials.
- Website and other internet materials, including press releases intended for internet publication.
- Social media sites and other such mediums.
- On-pack statements.
- Outdoor advertising.
- Point of sale materials and posters.
- Print advertisements (for example, for use in newspapers and magazines).
- Promotional aids including those used for direct selling activities.
- Promotional scripts for use by telephone help lines.
- Promotional text messages.
- Consumer promoters.
- Telephone help lines.
- Television and radio/audio commercials.
- Sports, art and other sponsorships.
- Airport, washroom, shopping centre advertising and/or promotion.
- Touch screen advertising.
- Aisle, ceiling, floor advertising and other signs.
- Counter top advertising.
- Window displays.
- Gondola end advertising.
- Bunting.
- Advertising on electronic ordering systems.
- Bus, taxi and other vehicle advertising.
- Light box advertising.
In the marketing and/or advertising of Schedules 0 and 1 medicines (see Question 8), the Code provides that advertisements to the general public must be consistent with the requirements of the Medicines Act and other applicable legislation. Compliance with the Medicines Act includes that all advertising and/or promotional material:

- Must give the information necessary for the correct use of a product as approved by the medicines regulatory authority.
- Cannot deviate from, be in conflict with or go beyond the evidence submitted in the application for registration of the medicine (and that has been approved by the South African Health Products Regulatory Authority (SAHPRA) and incorporated in the approved package insert).
- Must not be misleading or disparaging (either directly or by implication).
- Must not be misleading as to the nature of the product, its ingredients or indications.
- Must not contain any other express or implied exaggerated claims as to the benefits that can be obtained from use of the health product.
- Must not cause consumers unwarranted anxiety with regard to any condition.
- Must not use language which causes fear or distress.
- Must not suggest that using a health product can enhance normal good health or be a substitute for a healthy diet and lifestyle.
- Must not be aimed principally or exclusively at children (under 12 years of age).
- Must not show children using, or within reach of health products without adult supervision.
- Must not encourage individuals to exclusively self-diagnose, particularly where medical intervention is required.
- Must not encourage consumers to discontinue the use of prescribed health products.
- Must not include a recommendation by a person who, because of his celebrity status, can encourage consumers to use a particular health product.

Advertising and/or promotion must not unfairly defame or discredit (either directly or by implication) a competitor product, ingredient or treatment type, or suggest that a product’s effects are better than or equal to another identifiable product or treatment.

Testimonials are allowed, provided that the testimonial complies with the approved package insert and the testimonial is not more than three years old. The use of healthcare professionals (HCPs) for marketing, promotion, endorsements or testimonials is allowed, provided that it takes place within the scope set by the professional codes applicable to such professionals.

23. Is it permitted to provide consumers with free samples? Are there particular restrictions on special offers (for example, "buy-one-get-one-free")?
The Medicines Act
The Medicines Act provides that no manufacturer or wholesaler or its agent can supply, free of charge, medicines, medical devices, or in vitro diagnostics to a pharmacist, medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act of 1974.

The Code
Under the Code of Marketing Practice (Code), the supply of products as samples is not permitted to extend beyond the conditions as prescribed under any relevant health legislation (which would include the Medicines Act). Furthermore, complementary and alternative medicines (CAMs) and personal care products cannot be provided together with any scheduled medicines.

24. Are there particular rules of practice on the use of the internet/social media regarding drugs and their advertising?

The advertising of Schedules 0 and 1 medicines to the public is permitted. Therefore, E-pharmacies are restricted to the promotion and online sale of Schedule 0 and Schedule 1 medicines.

The Code of Marketing Practice (Code) provides that internet access to promotional materials of Schedule 2 to Schedule 6 medicine that is directed at the South African public must be limited through a password protection scheme to healthcare professionals (HCPs).

Information or promotional material relating to Schedule 2 to Schedule 6 medicines that is placed on the internet outside of South Africa will be regarded as falling within the scope of the Code if the information is specifically placed on the web to target South African consumers.

Schedule 2 to Schedule 6 medicines can be advertised in relevant, independently produced electronic journals that are intended for HCPs or appropriate administrative staff, provided that the electronic journals cannot be accessed by non-HCPs.

Package inserts of Schedule 2 to Schedule 6 medicines can be made available on the internet and accessed by members of the public, provided that the package inserts are not presented in such a way as to be promotional in nature.

In addition, it must be made clear to an internet user:

• That they are leaving any of the company sites.
• When they are leaving any sites sponsored by the company.
• That they are being directed to a site that is not that of the company.
The promotion of all medicines by e-mail is prohibited, unless the option to opt out is given and the decision is respected. The opt out option must also be provided on all subsequent communications, even if the addressee has not opted out after the first point of contact.

25. What regulatory authority is responsible for supervising marketing activities to consumers?

Regulatory authority
The South African Health Products Regulatory Authority (SAHPRA) is the body authorised to supervise the marketing of medicines under the Medicines Act.

The Code of Marketing Practice (Code) is enforced by the Marketing Code Authority (MCA), which is also responsible for settling complaints and disputes under the Code. The Code is based on the principle of self-regulation through the health industry.

Supervision
The Medicines Act. The SAHPRA is empowered through an inspectorate, created in accordance with the Medicines Act, to ensure that wholesale distribution activities occur within the confines of the law.

Under the Medicines Act, an inspector can enter any premises if he suspects, on reasonable grounds that an offence under the Medicines Act is being, or may be committed in the future. The inspector can also inspect any medicine or scheduled substance, any book, record or documents that he believes, on reasonable grounds, to contain any information relevant to the administration or enforcement of the Medicines Act.

The Code. The MCA can process any dispute or complaint relating to the provisions of the Code, and an aggrieved party can, after exhausting all internal remedies in the Code, approach the SAHPRA for resolution of the matter. The MCA also has the authority to refer any matter to the SAHPRA if it considers that the matter warrants the referral.

Rights of appeal
Under the Medicines Act, any person aggrieved by a decision of the SAHPRA can appeal against the decision to an appeal committee.

Under the Code, it is possible to appeal against the decision of the Adjudication Committee. Appeals can, at the discretion of the Adjudication Committee, and depending on the complexity of the matter, be a face-to-face hearing, or a paper-based appeal. A decision against the Adjudication Committee must lie with an Appeal Committee and no other body.

26. What are the legal consequences of non-compliance with consumer marketing laws?
The Medicines Act

It is an offence to contravene the provisions of the Medicines Act, including those that prohibit the misleading advertising of medicines. Any person who is convicted of an offence will be liable to a fine, or to imprisonment for a period of up to ten years.

The court that convicts any person of an offence can declare that any medicine, scheduled substance, medical device or in vitro diagnostic device in relation to the offence committed can be forfeited to the state. Any medicine or scheduled substance forfeited to the state must be destroyed or otherwise dealt with as the CEO of the South African Health Products Regulatory Authority (SAHPRA) may direct.

The Code of Marketing Practice (Code)

A complainant can lodge a written, formal complaint with the Executive Officer of the Marketing Code Authority (MCA) setting out the details of the complaint. The respondent can then respond to the complaint. The complaint is then forwarded to the Adjudication Committee. Legal representation is only allowed if the Adjudication Committee considers it appropriate, based on the facts of the matter. If the Adjudication Committee finds in favour of the complainant, the Committee can impose one of the following sanctions:

- A reprimand, caution or warning.
- A fine (the amount is determined from time to time by the MCA).
- A directive ordering the infringing party to audit its internal policies and procedures to be in line with those prescribed by the Code.
- A directive prescribing that any offending promotional activity, material or advertisement is ceased and/or withdrawn.
- An order that the infringing party provides a written undertaking that it will avoid similar breaches in future.
- An order that the infringing party must make a public statement correcting its non-compliance with the Code.
- An appropriate costs order, including the costs of the complainant.

Marketing to professionals

27. What kinds of marketing activities are permitted in relation to professionals?

All forms of advertising and promotional activities must conform to the provisions of the Medicines Act and its Regulations. The following forms of marketing activities (although not exhaustive) to healthcare professionals (HCPs) are permitted:

- Journal advertising.
• Distribution of promotional material, including promotional aids and gifts.
• Hosting or sponsoring meetings and events.
• Hosting competitions.

28. Are there any restrictions on marketing to professionals?

There are many restrictions on marketing to professionals (see Question 22). In addition, promotional material and activities should not be disguised.

**Marketing activities**

**Reprints.** Under the Code of Marketing Practice (Code), reprints of articles in journals must not be provided to any healthcare professional unless the articles have been published in a peer reviewed publication in line with good principles of scientific review and publication. When providing a reprint of an article about a health product, it must be accompanied by prescribing information.

**Distribution of promotional material.** Promotional material must only be sent or distributed to categories of persons whose need or interest in the particular information can reasonably be assumed.

**Frequency**

A company must respect any requests by an addressee to cease or limit the volume of promotional material. Mailing lists must be kept up to date. Requests from healthcare professionals (HCPs) to be removed from promotional mailing lists must be complied with promptly and no name can be restored except at their request or with their permission.

**Provision of hospitality**

Companies, organisations or individuals are permitted to organise or sponsor meetings and events provided that:

• The merit and focus of the meeting is clearly scientific and/or educational.
• The venue and hospitality is secondary to the meeting (both in the allocation of time and focus).
• The venue is appropriate and beneficial to the scientific or educational objectives and the purpose of the event or meeting.
• Hospitality, meals and entertainment are modest. As a general rule, hospitality must not exceed what the HCPs would normally pay for themselves.
• Invitations are not extended to spouses or other guests, except if they are HCPs or administrative staff and form part of the trainees or invited attendees at the meeting/event.
• Inappropriate financial benefit or material benefits (including excessive hospitality) is not offered and/or extended to HCPs.
• Reasonable payment and reimbursement for out-of-pocket expenses, including travel, are permissible for speakers (provided it is included in the terms of a written contract).

Meetings organised for patients, the general public, individual or groups of doctors, other HCPs and/or for administrative staff that are wholly or mainly of an entertainment, leisure, social or sporting nature are not permitted.

29. What information is it legally required to include in advertising to professionals?

All advertising and/or promotional material must be based on the current approved South African package insert. Under the Medicines Act, the advertising and promotion of health products must:

• Conform to the applicable regulations under the Medicines Act.
• Form part of the promotional material and not be separate.
• Be included in all promotional material (except for promotional items such as promotional aids, on which limited information must appear).
• Be provided in a clear and legible manner.
• Be consistent with the most recently approved South African package insert for the medicine.

The statement "For full prescribing information refer to the package insert approved by the medicines regulatory authority" must appear or be stated in all forms of advertising and/or promotion (written, audio, audio-visual and the internet, except for promotional items such as promotional aids).

30. Are there rules on comparisons with other products that are particularly applicable to drugs?

The Code of Marketing Practice (Code) provides that a comparison in the marketing and promotion of health products is only permitted in promotional material if:

• It is not misleading or disparaging.
• Health products or services for the same needs or intended for the same purpose are compared.
• One or more material, relevant and representative feature(s) are compared.
• No confusion is created between the health product advertised and that of a competitor, or between the
advertisers' trademarks, proprietary names, other distinguishing marks and those of a competitor.

• The trade marks, proprietary names, other distinguishing marks, health products, services, activities or
circumstances of a competitor are not discredited or defamed.

• The trade marks or company names of another company are only mentioned with written permission from
the other company.

• No unfair advantage is taken of the reputation of a brand, trademark, proprietary name or other distinguishing
mark of another company.

• Health products or services are not presented as imitations or replicas of goods or services bearing another
company trademark or trade name.

• Hanging (open-ended) comparisons are not used.

Price comparisons must be accurate, fair and must not mislead.

31. What other items, funding or services are permitted to be provided to professionals?

The Medicine Act provides that no person can supply any medicine according to a bonus system, rebate system or
any other incentive scheme.

The Code Marketing Practice (Code) provides that there must be no personal enrichment of healthcare professionals
(HCPs) or other healthcare providers. No gift, benefit in kind, rebate, discount, kickback or any other pecuniary
advantage can be offered or given to HCPs, administrative staff, government officials, or the general public as an
inducement to prescribe, lease, loan, supply, stock, dispense, administer or buy any health product.

Discounts
Discounts are not permitted under the Medicines Act.

Free samples
The Medicines Act provides that no manufacturer or wholesaler or its agent can supply, free of charge, medicines,
medical devices, or IVDs to a pharmacist, medical practitioner, dentist, veterinarian, practitioner, nurse or other
person registered under the Health Professions Act of 1974.

Sponsorship of professionals
The sponsorship of professionals is regulated largely under the Code, particularly dealing with the attendance of
HCPs at conferences or meetings.

The Code provides that the rationale for any meeting or sponsorship of a professional to attend a meeting must be
transparent, valid and clear.
Payment of registration fees, travel and accommodation must be made to the professional associations/organisers and not directly to the HCP, unless proof is received that the amount spent is in the name of the sponsored person and corresponds to each and every line item as per the agreed sponsorship.

Sponsored speakers can receive reasonable payments.

**Other promotional items or activities**

*Gifts.* As a general rule, there may be no personal enrichment of HCPs or other healthcare providers. In terms of the Code, no gift, benefit in kind, rebate, discount, kickback or any other pecuniary advantage may be offered or given to members of the health profession, administrative staff, government officials, or the general public as an inducement to prescribe, lease, loan, supply, stock, dispense, administer or buy any health product. No cash or cash equivalents (for example, vouchers) are allowed as gifts.

That being said, occasional promotional aids or items to HPCs, appropriate administrative staff, sales and other staff are acceptable provided that they are:

- Inexpensive and of modest value.
- Not for personal use (for example, no entertainment CDs/DVDs, electronic items for entertainment, tickets to attend sporting events or other forms of entertainment may be provided as gifts).
- Educational and/or of scientific value, benefit the patient and/or are relevant to the practice.

*Competitions.* Competitions must fulfil the following criteria:

- The competition is based on medical/product knowledge or the acquisition of scientific knowledge.
- The individual prizes or educational items offered are within the price limit set from time to time by the Marketing Code Authority (MCA).
- The prize cannot consist of cash or a cash equivalent (for example, a voucher).
- Entry into a competition must not be dependent on prescribing, ordering or recommending a product and no such condition must be made or implied.

---

**32. What regulatory authority is responsible for supervising marketing activities regarding professionals?**

The South African Health Product Regulatory Authority (SAHPRA) and the Marketing Code Authority (MCA) are responsible for supervising marketing activities to healthcare professionals (HCPs).

*See Question 19.*
33. What are the legal consequences in case of non-compliance with professional marketing laws?

See Question 26.

**Engagement with patient organisations**

34. What kinds of activities are permitted in relation to engagement with patient organisations? What are the restrictions that are imposed on relationship with patient organisations?

**Written agreements**
When companies provide financial support, significant indirect support and/or significant non-financial support to patient organisations, they must have in place a written agreement that states the amount of funding and also the purpose.

**Use of logos and proprietary materials**
The public use of a patient organisation's logo and/or proprietary material by a company requires written permission from that organisation.

**Editorial control**
Companies must not seek to influence the text of any patient organisation material that they sponsor in a manner that is favourable to their own commercial interests. This does not preclude companies from correcting factual inaccuracies.

**Contracted services**
Contracts between companies and patient organisations where they provide any type of services to companies are only allowed if the services are provided for the purpose of supporting healthcare or research.

**Events and hospitality**
All events sponsored or organised by or on behalf of a company including scientific, business or professional meetings must comply with the requirements that deal with the appropriate provision of hospitality and the hosting of meetings and events.
Hospitality can only be extended to persons who qualify as participants in their own right. In exceptional cases, in case of clear health needs (for example, disability), the travel meals, accommodation and registration fees of an accompanying person considered to be a care giver can be provided.

Recent developments and outlook

35. Are there notable recent developments or regulatory projects in the field of distribution and marketing of drugs?

In December 2016, Regulations Relating to Medical Devices and In Vitro Diagnostics (IVDs) came into operation. The regulations require registration of medical devices and IVDs with the South African Health Product Regulatory Authority (SAHPRA), when call up notices are issued. In terms of these Regulations, only low/moderate risk medical devices can be advertised to the general public.

On 1 June 2017, the amendments to the Medicines Act came into operation. The previous administrative authority (Medicines Control Council (MCC)) has now been replaced with a new authority, the SAHPRA. A board of SAHPRA has been selected by the Minister of Health. At this stage, the MCC is transitioning to SAHPRA. It is envisaged that the SAHPRA will reduce the backlog of medicines registration and clinical trial approval, due to a higher staff count and internal evaluations.

On 25 August 2017, new General Regulations to the Medicines Act were provided, which repeal the previous General Regulations. The new Regulations amend the definition of a complementary medicine, and now make it clear that health supplements are also complementary medicines.

The authors would like to thank Consultant, Elsabe Klinck, of Elsabe Klinck Associates (PTY) Ltd for her assistance in preparing the article.

Contributor profiles

Jenny Pienaar, Partner
Adams & Adams

T +27 12 432 6396
F +27 12 432 6556
E jenny.pienaar@adamsadams.com
W www.adamsadams.co.za
Professional qualifications. Attorney, 1994; Trademark practitioner, 2004

Areas of practice. Trademark litigation, domain name registration and securing domains from unlawful proprietors, litigation relating to copyright, passing-off, unlawful competition, close corporation and company name objections and related issues.

Non-professional qualifications. BA degree, University of Stellenbosch, 1988; LLB, University of Cape Town, 1991

Jeanette Visagie, Senior Associate

Adams & Adams

T +27 12 432 6353
F +27 12 432 6599
E Jeanette.visagie@adamsadams.com
W www.adamsadams.com

Professional qualifications. Attorney, 2013; Trade mark practitioner, 2014

Areas of practice. Trade mark litigation, unlawful competition, passing off, copyright litigation, company name objections, litigation and advice relating to advertising, marketing and regulatory law, and related issues.

Non-professional qualifications. LLB (cum laude), North West University (Potchefstroom), 2009; LLM, University of Tilburg and North West University (Potchefstroom), 2011