

The International Comparative Legal Guide to:

Pharmaceutical Advertising 2009

A practical insight to cross-border Pharmaceutical Advertising work



Published by Global Legal Group with contributions from:

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1 General - Medicinal Products

1.1 What laws and codes of practice govern the advertising of medicinal products in South Africa?

There are a number of statutes and a code regulating the advertisement of medicines. The principal legislation is the Medicines and Related Substances Control Act 101 of 1965 (“the Medicines Act”) and the General Regulations promulgated in terms thereof (GN R501 in GG 24727, as amended by GN R1506). An amendment to the Medicines Act (“the Medicines Amendment Act”) has just been promulgated but is not effective at the time of writing. The proposed changes that the Medicines Amendment Act will introduce are incorporated in this chapter, where relevant.

Other legislation includes: Pharmacy Act 53 of 1974; Good Pharmacy Practice in South Africa; The Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972; Labelling and Advertising Regulation promulgated in terms of the Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972; Medical Schemes Act 131 of 1998; Copyright Act 98 of 1978.

The Minister of Health is empowered to develop a Code of Practice (“the Code”) following industry consultation. This Code is still in draft form but is expected to be finalised during 2009. Although a draft, pharmaceutical companies rely on the Code as a guideline document.

The Code of Advertising Practice (“the Advertising Code”), developed by the Advertising Standard Authority of South Africa (“ASA”), also applies and contains schedules dealing specifically with the advertising of medicinal and related products; advertisements containing health claims, and Over the Counter Medicines.

1.2 How is “advertising” defined?

“Advertising” and “Advertisements” are defined differently in the various statutes. However, these definitions are all very broad and incorporate any written, visual, aural representation or notice or other form of reference to a medicine which is intended to promote that medicine.

1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and Codes of Practice on advertising, such as “sign off” of promotional copy requirements?

In terms of the Code, any juristic person that sells or promotes medicines must appoint a responsible person as the “Company

Code Compliance Officer” (“CCCO”) to be responsible for the approval of promotional material, meetings and activities.

The CCCO may only approve promotional materials or activities in their finalised form by issuing a certificate to this effect. Appropriate documents must be available for audit purposes. In certifying the material, the CCCO must ensure: compliance with relevant advertising acts and regulations as well as the Code; that it is consistent with the product registration and the package insert; and that the promotional material is a fair and truthful presentation of the medicine.

1.4 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

The Code

- The Code does not require such approval. However it provides for the creation of a Marketing Code Authority (“MCA”) which has the power to monitor all the advertising of medicines and may request copies of the advertising material, the CCCO’s certificate and all briefing instructions relating to the advertisement.

The MCA must appoint an Executive Board made up of representatives from various industry associations, the Department of Health, the Forum of Statutory Health Councils and the Advertising Standards of South Africa. The Executive Board must manage and conduct the affairs of the MCA and exercise all powers (including disciplinary powers of the MCA).

The Executive Board must appoint a Chief Executive Officer (“CEO”) with the necessary powers including the receipt of complaints by aggrieved parties, review of promotional material and advertisements to ensure compliance with the Code, notifying parties of non-compliance with the Code, appointing adjudicating panels etc.

Any non-compliance with the Code may be referred to the Adjudicating Board for a hearing. The Adjudicating Board has power of penalty including:

- Audit of internal approval procedures.
- Giving undertaking of future compliance.

The penal powers are broad enough to include the requirement that advertising and promotional materials be approved by the CEO / Adjudication Board prior to publication. We suggest that such penalty would only be imposed in extreme cases, after continual breach of the Code.

The Advertising Code

Penalties for breach of the Advertising Code include a requirement

that the offending advertiser “submit the proposed amendment, original advertisement and relevant ASA ruling to the ASA Advisory Service for pre-publication advice; or direct the respondent to submit all future advertising to the ASA Advisory Service, at the cost of the respondent, prior to publication thereof”.

This latter penalty may only be imposed for repeat offenders in the previous 12-month period.

1.5 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

In addition to the penalties set out in question 1.4 above, under the Code the Adjudicating Board may also “issue a directive that any offending promotional activity or material or advertisement be ceased and / or withdrawn forthwith and that satisfactory proof be provided, within a stipulated time period, the CEO that this has been done”.

It may also order the offending party to take any necessary steps to publicly undo damage or potential damage caused by breaching the Code, including the issue of a corrective statement, if appropriate.

The Code provides for appeal to an Appeal Board, the finding of which is final and binding.

1.6 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? To what extent may competitors take direct action through the courts?

The Code

As stated, the Code and its complaint procedures are not yet effective. When effective, the Adjudication Board may:

- impose:
 - “a reprimand, caution or warning;
 - a fine; or
 - issue a directive that the offending party’s internal procedures be audited by a representative of the MCA and that a report be furnished by the CEO after the conclusion of such audit;
- issue a directive that:
 - any offending promotional activity or material or advertisement be ceased and / or withdrawn forthwith and ... satisfactory proof (thereof) be provided... that this has been done;
 - the offending party...furnish a written undertaking within a stipulated time period that the offending party will avoid similar breaches of the Code in the future;
 - such action be taken by the offending party to publicly undo the damage or potential damage caused by or as a result of the breach of the Code;
 - the offending party pay such costs and expenses as the Adjudicating Board considers just and equitable in the circumstances including an order that the offending party refund the aggrieved party the amount of the complaint fee;
 - the finding of the Adjudicating Board be published to the members of the MCA; or
 - such other order as may be considered appropriate to the Adjudicating Board in the circumstances”.

Medicines Act

Section 29 provides that non-compliance with section 18 thereof (governing advertising and labelling) constitutes an offence, punishable by a fine or up to 10 years’ imprisonment.

A court may even order that the medicine or scheduled substance in respect of which the offence was committed be forfeited to the State for destruction or disposal.

The Advertising Code

In addition to the penalties set out in question 1.4 above, the ASA Authority may impose:

- Publication of names of defaulting parties; a summarised version of the ASA ruling at the cost of the offending party.
- Withdrawal of the offending party’s advertising space until it has paid the above costs.
- Refer the matter to a disciplinary hearing.

1.7 What is the relationship between any self regulatory process and the supervisory and enforcement function of the competent authorities? Can, and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?

The self-regulatory process in the form of the Code is enforceable in terms of section 18 of the Medicines Act, in terms of which parties must comply.

The Code and therefore the regulatory body are not yet operative. In any event, an ASA member will sit on the Adjudication Board and it is unlikely that there will be duplication where a complainant submits a matter to the ASA and the Adjudication Board.

If the complainant wishes to proceed in terms of the Medicines Act, it must have first exhausted all its other remedies. This means that the complainant must have submitted a complaint in terms of the Code. If the matter proceeds to court, it will be dealt with in terms of the Medicines Act.

1.8 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?

- In terms of the Advertising Code, “all advertising should conform to the principles of fair competition in business”. This code lists certain principles applicable to all forms of advertising.

The Advertising Code also governs advertising of: (a) medicinal and related products; (b) health claims; and (c) over-the-counter medicines, which is dealt with elsewhere.

Any person may lodge a complaint of non-compliance with the Advertising Code with the ASA. It is accepted practice that the complainant should forward the complaint to the advertiser before lodging a formal complaint, requesting a response within a reasonable period. A copy is usually sent to the ASA, which will not take any action until it receives the ‘formal’ complaint.

- If not resolved between the parties (and the issue is not being considered by another competent regulatory body or court), the formal complaint is lodged with the ASA.

Complaints by competitors are subject to a fee but complaints by consumers require no fee.

The ASA Directorate (“Directorate”) first considers whether the ASA Committee will entertain the complaint, considering its nature,

and calls upon the party against whom the complaint is lodged to respond to the complaint. Thereafter it will either:

- make a ruling in respect of the dispute; or
- refer the matter to the ASA Committee of the ASA Tribunal for consideration.

The ASA Committee decides consumer complaints while the ASA Tribunal decides competitor complaints.

If the Directorate elects to rule on the dispute, the decision may be appealed to the ASA Committee or the ASA Tribunal as the case may be. Decisions of these bodies may further be appealed to the Final Appeal Committee.

2 Providing Information Prior to Authorisation of Medicinal Product

2.1 To what extent is it possible to make information available to health professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product?

Medicines must not be promoted before the product is registered by the Medicines' Control Council (which body will be replaced by a new registration authority and structure once the Medicines Amendment Act comes into force) or the registration application has been submitted in terms of section 14(3) of the Medicines Act which permits the sale, supply and use of the medicine.

The promotion of any medicine must be in accordance with the registration and the package insert.

2.2 May information on unauthorised medicines be published? If so, in what circumstances?

No, see above.

2.3 Is it possible for companies to issue press releases about medicinal products which are not yet authorised? If so, what limitations apply?

No, see above.

2.4 May such information be sent to health professionals by the company? If so, must the health professional request the information?

Please refer to question 2.1.

2.5 May information be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?

Please refer to question 2.1.

2.6 Is it possible for companies to involve health professionals in market research exercises concerning possible launch materials for medicinal products as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?

Please refer to question 2.1.

3 Advertisements to Health Professionals

3.1 What information must appear in advertisements directed to health professionals?

The package insert contained in the medicine registration application must form the reference for all promotional items and advertisements.

The advertisements must, as a minimum, comply with the Medicines Act and its regulations (see section 6). The Code also requires that the minimum requirements which must be included in the promotional material, be clear and legible and consistent with the recently approved package insert.

All advertising must state: "For full prescribing information refer to the package insert approved by the medicines regulatory authority".

Any printed promotional material longer than two pages must present the minimum information on the first or last page.

Promotional material, other than advertising, that appears in professional publications, must state the date and / or numbered code indicating when the promotional material was created or amended.

For promotional material of an audio-visual nature, the minimum information may be included in:

- a document handed to all of the viewers of the material;
- the audio-visual recording or interactive data system provided to the viewers; or
- an interactive data system, provided clear instructions for accessing this information are supplied.

In addition, all information relating to the medicine must:

- be "accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence"; and
- not place undue emphasis on certain elements of the medicine and must be sufficiently complete to allow the medical practitioners the ability to make an informed opinion as to the therapeutic value of the medicine.

All statements contained in the advertisement or promotional material must be capable of substantiation unless that information has been included on the approved package insert. If substantiation is requested from a medical practitioner, such substantiation must be furnished without delay.

Exaggeration or the use of superlatives in relation to medicines or their qualities is not permitted.

"All artwork, including illustrations, graphs, tables, logos and trade dress must conform to the letter and spirit of the Code. Graphs and tables must be presented in such a way as to give a clear, fair, balanced view of the matter with which they deal, and must not be included unless they are relevant to the claims or comparisons being made."

Promotional material may not use the words: "new" in respect of any product that has been available for more than 12 months; nor "safe" in any way to imply that the product does not have any side effects, risk of addiction or toxic or hazardous.

3.2 Is it a requirement that there be data from any or a particular number of "head to head" clinical trials before comparative claims are made?

No it is not.

- 3.3 What rules govern comparator advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product which had not yet been authorised in South Africa?

The Code

The Code indicates that comparisons in the marketing and promotion of medicines are only permissible where the promotional material is:

- not misleading or disparaging;
- comparing medicines or services which are used for the same purpose;
- one or more relevant, substantial and representative features of the medicines must be compared;
- clearly marketing the medicine and there is no confusion between the medicine that is being advertised and the competitor's product, its trademarks, its proprietary name or other distinguishing mark;
- the competitor's product, trademarks, proprietary name or distinguishing mark must not denigrated;
- not extorting an unfair advantage from the reputation trademarks, proprietary name or distinguishing mark of a competitor or another company; and
- not passing off the medicine or service as a replica or an imitation of the goods / services of another company.

The Advertising Code

The Advertising Code permits comparisons between products and / or services that:

- adhere to all legal requirements;
- only rely on facts that can be substantiated;
- make one or more claims that can be objectively determined and are relevant and verifiable;
- do not contain claims that are ambiguous or misleading;
- are not disparaging;
- any facts relied upon are relevant and representative and comparable;
- have similar characteristics or intended for the same use; and
- are based upon research, that the relevant body has authorised the use of such research.

The advertiser must assume all responsibilities in respect of the accuracy of any claims or research contained in the advertisement.

As a general rule, the Advertising Code requires that all comparisons should be based on promoting the merits of the products / services and not criticising the competitive product.

- 3.4 What rules govern the distribution of scientific papers and/or proceedings of congresses to doctors?

There are no general rules, however, the Code supplementary notes indicate that the "legitimate exchange of medical and scientific information during the development of a medicine is not prohibited, provided that any such information or activity does not constitute promotion" of the medicine as contemplated in the Act and the Code.

- 3.5 Are "teaser" advertisements permitted, which alert a reader to the fact that information on something new will follow (without specifying the nature of what will follow)?

As stated, a medicine may not be promoted prior to registration, but a "teaser" advertisement which does not provide any information regarding the medicine, would probably be permissible.

4 Gifts and Financial Incentives

- 4.1 It is possible to provide health professionals with samples of products? If so, what restrictions apply?

No person (including health professionals) may sample medicines. Sampling excludes the free supply of medicines for the purposes of clinical trials, donations of medicines to the State, tendering to the State and quality control by inspectors.

- 4.2 Is it possible to give gifts or donations of money to medical practitioners? If so, what restrictions apply?

The Code prohibits the enrichment of medical practitioners and other healthcare professionals by gift, money or other benefit as an inducement to prescribe, supply, stock, dispense, administer or buy any medicine. The Code permits provision of occasional gifts and promotional items that are inexpensive and of minimal intrinsic value to medical practitioners. These gifts must be of an educational or scientific value or relevant either to the practice or of benefit to the patients, and not for personal use.

- 4.3 Is it possible to give gifts or donations of money to institutions such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply?

Financial or other forms of donation may be granted to registered charities or institutions provided that such donations are properly recorded and approved by the donor.

Donations are permitted only if aimed at supporting healthcare or medical research and not inducement to prescribe, purchase, sell, or administer any medicine or medical device.

Donations must not be paid directly to any medical practitioner within that charity or organisation. The Code encourages transparency and public disclosure of donations, grants or benefits.

Donations which are part of corporate social responsibility are permissible provided they are judged on merit and made in good governance. The Code does not govern corporate social investment unless such donations are concerned with the over or under utilisation of a medicine.

- 4.4 Is it possible to provide medical or educational goods and services to doctors that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for or an increased market share for the products of the provider of the goods or services?

No, see question 4.2 above.

- 4.5 Do the rules on advertising and inducements permit the offer of a volume related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?

The Medicines Act prohibits the supply of any medicine subject to a bonus system, rebate system or any other incentive scheme.

4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed?

No, see question 4.5 above.

4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?

No, see question 4.5 above.

4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?

Companies may organise and/or sponsor Continual Professional Development (“CPD”) meetings provided that:

- the meeting/training must be clearly scientific or educational;
- the venue and hospitality should be secondary to the meeting/training in terms of time allocation and focus; and
- the venue should be appropriate to achieve the scientific/education objectives or purpose for which the meeting/training was created.

The Code requires that any hospitality, meals or entertainment should be modest and as a general rule, not exceed an amount that one of the health care practitioners would be willing to spend themselves. Furthermore, invitations should not be extended to the spouses of the healthcare professionals.

Inappropriate financial or material benefit may not be offered to the medical practitioners. A medical practitioner who is a speaker at a meeting may be paid reasonable honoraria and reimbursement of expenses, provided that these terms and conditions are set out in a written contract.

In respect of CPD particularly, the Company sponsoring a meeting:

- may not promote any product within the meeting room. Company-branded items, however, are permissible;
- must inform any speakers that he or she may only refer to the INN name of the products referred to during his or her presentation; and
- may display product promotional material outside of the CPD meeting room provided that this cannot be viewed by the general public.

In respect of local CPD meetings “product launches which are held in major cities, reasonable arrangements or travel reimbursement can be made to ensure that healthcare professionals that do not reside or practice in major cities are available to access the applicable information”. Note that this provision in the draft Code needs to be confirmed by the Health Professions Council of South Africa and may be amended in the final version of the Code.

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to health professionals? Does it make a difference if the hospitality offered to those health professionals will take place in another country?

As a general rule, the delegates to any meeting should be attracted by the nature of the training programme and not the associated

hospitality, venue or entertainment.

The Code provides that companies may provide hospitality in association with professional, scientific and promotional meetings and events which is reasonable and subordinate to the main purpose of the meeting or event. See also question 4.8 above.

The rules apply irrespective of where the event takes place, if initiated by a South African based company.

5.2 Is it possible to pay for a doctor in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?

Companies may pay reasonable travel and accommodation costs of a medical practitioner who is a speaker at the event.

Regarding delegates attending a meeting, the Code provides that any payment of “registration fees, travel and accommodation must be made to the professional associations / organisers and not directly to the healthcare professional or appropriate administrative staff, unless proof is received that the amount spent are in the name of the sponsored person and which corresponds to each and every line item as per the agreed sponsorship. No payment may be made to the professional / staff for the time spent at the event”.

5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of and the hospitality arrangements for scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual doctors to attend?

Companies can be held responsible in terms of the Code and the Act. See question 1.6 above.

5.4 Is it possible to pay doctors to provide expert services (e.g. participating in focus groups)? If so, what restrictions apply?

Healthcare professionals may provide consultancy or other genuine services to a company. If healthcare professionals are still practicing at the time that they are providing these services, the Code provides the healthcare professional must “declare their employment arrangement with the company whenever they write or speak in public about a matter that is subject of the employment or any other issue relating to the company”. This arrangement must be formalised in a written agreement between the parties.

The Code prohibits any payments to healthcare professionals for any other services.

5.5 Is it possible to pay doctors to take part in post marketing surveillance studies? What rules govern such studies?

Please see question 5.4.

5.6 Is it possible to pay doctors to take part in market research involving promotional materials?

Please see question 5.4.

6 Advertising to the General Public

6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?

Medicines which are categorised as either Schedule 0 or Schedule 1 medicines may be advertised to the general public.

Advertisement restrictions in the Code

An advertisement may not contain any statement which is in conflict with, exceeds or deviates from the approved medicine registration application with regard to the safety, quality or efficacy of the medicine.

Written advertisements must, in terms of regulation 45(4) of the General Regulations, set out:

- the proprietary name of the medicine;
- the approved name and quantity of each active ingredient; and
- the registration number, if the medicine has been registered. A medicine which did not previously require registration, but later does so, may be advertised provided that an application for registration has been submitted. The application reference number must be included on the advertisement.

If a medicine has another proprietary name, that name must also be included on any advertisement.

Presentation and lettering of the advertisement is subject to further detailed requirements.

If the medicine is a homeopathic medicine, the regulations require that the advertisement must state that the medicine must be administered in accordance with homeopathic principles.

When a medicine is advertised verbally for the first time to medical practitioners, it must be accompanied by written document containing the above information. Any subsequent verbal advertisement to medical practitioners, may exclude this information unless specifically requested.

In terms of the Act, Regulations and Advertising standards:

- no person shall publish or distribute any false or misleading advertisement concerning any medicine; and
- any advertisement in respect of a medicine may not contain any statements which deviate from, are in conflict with or go beyond the evidence contained in the medicine registration application.

The Code

The Code also lists a number of principles which regulate advertising medicines to the general public. These principles require that advertisements:

- should not be misleading, ambiguous, disparaging or contain claims which are unfair, untruthful, inaccurate, confusing or unjustifiable;
- should not exaggerate any claims in respect of the medicine;
- containing claims relating to the efficacy of a medicine must indicate whether the medicine must be taken over an extended period or is aimed at reducing / preventing risk of disease;
- may contain claims regarding prevention of symptoms in respect of chronic conditions provided that this is congruent with the medicine registration application;
- must not create anxiety, stress or fear in the reader with regard to a condition or that a condition will deteriorate without the medicine;
- should not state that use of the medicine shall enhance good normal health or be a substitute for a healthy lifestyle;
- should not be targeted at unsupervised children or show

children taking or within reach of medicine;

- should encourage responsible self-medication and not encourage exclusive self-diagnosis, especially where medical intervention is required;
- should never intimate that medical consultation is not required or that an operation or procedure is not necessary;
- should not diagnose a condition or advise treatment;
- should not guarantee the safety, effects or quality of a product;
- must not encourage the unnecessary or excessive consumption or use of medicine;
- should not be inappropriate;
- which are sponsored advertorials, should be identified as such;
- should not encourage any person using a prescribed medicine to discontinue its use without consulting a medical practitioner;
- may only be recommended by a scientist or medical practitioner unless there are justifiable grounds for doing so; and
- should not rely upon any celebrity endorsement or support for the use of medicine.

6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?

Prescription only medicines may not be advertised to the general public. However this does not prohibit a pharmaceutical company from informing the public of the prices, names, pack sizes and strengths of medicines which contain substances listed in Schedules 2 to 6.

See also question 6.1 above.

6.3 If it is not possible to advertise prescription only medicines to the general public, are disease awareness campaigns permitted, encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

General disease awareness campaigns as described are permitted provided that such a campaign complies with the general advertising requirements as set out in the Advertising Code.

6.4 Is it possible to issue press releases concerning prescription only medicines to non-scientific journals? If so, what conditions apply?

The legislation, regulations and the Code do not differentiate between scientific and non-scientific journals. The Code, however, does prescribe that advertisements that are published in journals:

- which exceed two pages must not be false or misleading when each page is read in isolation;
- in a loose form may not be a size larger than the page size of the journal itself; and
- must not resemble the editorial matter of the journal and must clearly be identifiable as an advert or sponsored feature.

6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?

Medicines may not be promoted or advertised prior to registration. Therefore, prior to registration, it is permissible to describe research

initiatives that are being undertaken. It is possible to exchange scientific and medical information during the developmental phase of any medicine provided that this does not constitute “promotion” as contemplated in the Code.

After registration, any medicine classified as a Schedule 0 or Schedule 1 may be advertised to the general public, and thus in corporate brochures and Annual Reports subject to the restrictions described in this chapter.

Medicines or scheduled substances which are Scheduled 2 to 6, may only be advertised to medical practitioners that prescribe medicines. Corporate brochures directed solely and exclusively to these persons would therefore be permissible.

6.6 What, if any, rules apply to meetings with and funding of patient support groups, including any transparency requirement as regards the recording of donations and other support in corporate reports?

The Code permits companies to sponsor patient support meetings and events, provided that proper records of the event are created and maintained and medicines are not promoted and the sponsorship is fully disclosed.

7 The Internet

7.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?

Internet advertising in relation to medicines is only regulated by the Code. Access to information relating to medicines listed in schedules 2 to 6 should be restricted in terms of a password protection scheme to healthcare professionals and appropriate administrative staff.

These medicines may be advertised in an independently produced electronic journal available to healthcare professionals or administrative staff which is also subject to a password protection.

The package inserts for these medicines may be made available online and accessible to members of the public, provided that the package inserts are not present in such a way as to classify as an advert or promotional item.

7.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for health professionals?

Please refer to question 7.1 above.

7.3 What rules apply to the content of independent websites that may be accessed by link from a company sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?

The Code states that promotional material relating to medicines which are placed on the internet by a company outside South Africa will be bound by the Code if that party is “a South African company, or an affiliate of a South African company, or at the instigation or with the authority of such a company and it makes specific reference to the availability or use of the medicine in South Africa”.

The internet user should be notified when he or she is entering or exiting any of the company sites whether that site is affiliated or not with the company.

7.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?

Any information which does not classify as “advertising” of medicines or promotional material, as well as advertising of Schedule 0 and Schedule 1 medicines may be supplied or advertised online.

8 General - Medical Devices

8.1 What laws and codes of practice govern the advertising of medical devices in South Africa?

The Medicines Act currently regulates medical devices. However there are no current provisions or codes regulating the advertising thereof. When the Medicines Amendment Act becomes effective, all the references to medicines set out in this chapter must be read to include medical devices. It is anticipated that the Code will be amended to include the marketing and promoting of medical devices.

8.2 Are there any restrictions on payments or hospitality offered to doctors in connection with the promotion of a medical device?

At present there are no restrictions on payments or hospitality offered to doctors in respect of medical devices. The Code relates only to medicines and medical devices are expressly excluded. However, the Medicines Amendment Act, when effective will incorporate medical devices into the definition of medicines. The revised section 18C of the Medicines Act will require that the Code regulates the marketing of medicines including medical devices.

9 Developments in Pharmaceutical Advertising

9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

The Medicines Amendment Act has been promulgated. This act is expected to come into force shortly. This will govern the advertising of products, medical devices and in vitro diagnostic medical devices. Interestingly, “products” includes medicines, medical devices and cosmetics and foodstuffs as contemplated in the Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972.

9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

It is anticipated that the South African Code for Marketing Medicines will be finalised and promulgated towards the latter half of 2009.

9.3 Are there any general practice or enforcement trends that have become apparent in South Africa over the last year or so?

If anything, there has been a trend to compliance with the Code, notwithstanding that it is not yet in force.

9.4 Has your national code been amended in order to implement the current version of the EFPIA Code of October 2007?

We are not specifically aware of adaptation for compliance, but the Code is later in time, although not yet in force.



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Stephen holds BA and LLB degrees from the University of the Witwatersrand and has over 24 years of experience.

As a director of the firm, Stephen specialises in corporate and commercial law, as well as competition law. His experience includes acting for multi-national firms on a range of corporate and commercial agreements, including mergers and acquisitions and regulatory work.

Stephen also heads up the related practice area of competition law, where he has successfully acted in numerous merger approvals, both local and international, prohibited practice and other anti-trust advisory work in the pharmaceutical industry.



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Matthew holds an LLB and LLM degree from the University of Cape Town. In 2008 Matthew was appointed as an associate at Bell Dewar and has been involved in advising various pharmaceutical companies on compliance with the various legislative and regulatory requirements which includes making submissions to the various regulatory authorities.

Matthew has also been involved in various commercial transactions relating to the manufacture, sale and distribution of pharmaceutical products.



Established in 1890, Bell Dewar is a large specialist law firm with expertise in select industries. For many years Bell Dewar has represented leading companies in the pharmaceutical and related industries. We have acted for major pharmaceutical manufacturers, distributors and retailers and medical schemes.

The pharmaceutical group advises a number of clients on the general legislative framework as well as specific issues affecting their businesses such as pricing, distribution, registration and advertising of medicines and licensing of pharmacies and doctors. The team also has experience in dealings with the regulatory bodies.

Our team has an in-depth knowledge of the Medicines and Related Substances Control Act, the Pharmacy Act, the Health Professions Act and the Medical Schemes Act and the recent amendments and regulations relating thereto.