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The International Comparative Legal Guide to:

Pharmaceutical Advertising 2007

A practical insight to cross-border Pharmaceutical Advertising work

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Chapter 42

South Africa

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1 General - Medicinal Products

1.1 What laws and codes of practice govern the advertising of medicinal products in your country?

There are a number of relevant laws and codes. The advertising of medicines is primarily governed by the Medicines and Related Substances, 1965 ("the Medicines Act") and the regulations promulgated thereunder ("the Regulations"). A Marketing Code ("the Code") has been published in terms of the Medicines Act. Although the Code is still in draft form, many pharmaceutical companies are already abiding by it or by similar in-house codes. In view of the fact that the Code has not yet been promulgated, much of our law relating to the advertising of medicines is still uncertain.

The Pharmacy Act, 1974 is also relevant to the marketing of medicines, as medicines may only be sold by pharmacists. The Good Pharmacy Practice Manual, published by the Pharmacy Council, is relevant to the advertising of medicines by a manufacturing pharmacist; however it is merely a guideline document.

The Advertising Standards Authority of South Africa ("the ASA"), which is an independent body funded by the marketing communications industry, has developed a code, the ASA Code of Advertising Practice ("the ASA Code") which regulates the contents of advertisements, including those relating to medicines. Industry associations may also have their own codes that relate to the advertising of medicines which members are required to observe.

1.2 How is "advertising" defined?

An "advertisement" is defined in the Medicines Act, and similarly in the Code, to mean "any written, pictorial, visual or other descriptive matter or verbal statement or reference - (a) appearing in any newspaper, magazine, pamphlet or other publication; or (b) distributed to members of the public; or (c) brought to the notice of members of the public in any manner whatsoever, which is intended to promote the sale of that medicine."

The ASA Code defines an "advertisement" as "any visual or aural communication, representation, reference or notification of any kind - which is intended to promote the sale, leasing or use of any goods or services; or which appeals for or promotes the support of any cause. Promotional content of display material, menus, labels and packaging also fall within the definition. Editorial material is not an advertisement, unless it is editorial for which consideration has been given or received. The word "advertisement" applies to published advertising wherever it may appear. It does not apply to editorial or programming publicity."

1.3 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?

None of the above laws or codes requires advertising to be approved in advance before use, in general.

However, to the extent that the Regulations state that no advertisement for a medicine may contain a statement which conflicts with or goes beyond the evidence submitted to and accepted by the Medicines Control Council ("MCC") in the process of registration of the medicine, and incorporated into the approved package insert of the medicine, a degree of prior approval is involved.

Furthermore, the ASA may direct an advertiser who has breached the ASA Code to submit the proposed amendment to the advertisement to the ASA for pre-publication advice. Also, the ASA may require an advertiser who has been the subject of more than one adverse ruling in a period of 12 months to submit all future advertising to the ASA prior to publication for a period of 6 months.

1.4 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?

Advertisements made in contravention of the Medicines Act and the Regulations is a criminal offence (see question 1.5 below) and further publication will thus be discontinued. The draft Code may allow scope for this but it is currently unclear. The ASA Code empowers the ASA to order the withdrawal of an advertisement as well as the publication by the advertiser of a summarised version of the ruling in the media in which the advertisement appeared. The ASA Code also makes provision for rights of appeals. To the extent that industry associations have their own codes, these may contain such sanctions and make provision for rights of appeal.

1.5 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?

Under the Medicines Act and the Regulations it is a criminal

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offence to advertise a medicine which is not authorised or registered, a Schedule 2, 3, 4, 5 or 6 medicine to the general public, or if any advertisement for a medicine conflicts with or goes beyond the information which was submitted to and accepted by the MCC in the course of registration of the medicine and which forms part of the approved package insert of the medicine. The criminal offence is punishable by way of a fine or imprisonment for up to 10 years. One's licence under the Medicines Act may also be suspended or cancelled by the Director-General or the Medicines Control Council. Once promulgated under the Medicines Act, the contravention of various provisions of the draft Code may also be brought under the criminal offence provisions of the Medicines Act.

Under the Pharmacy Act, the Pharmacy Council may also institute disciplinary action against a pharmaceutical company which is found guilty of the above offences, and may impose a penalty including a reprimand, caution, suspension, removal from the register or a fine.

The ASA, as stated above, is responsible for enforcing the ASA Code and may impose a variety of sanctions, the most important of which are mentioned in questions 1.3 and 1.4 above.

As stated above, to the extent that industry associations have their own codes, these may contain certain sanctions.

1.6 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 process of any self-regulatory body is additional and separate to the functions of any competent authority. Competent authorities will investigate all matters drawn to their attention where it relates to breach of legislation or codes which they have jurisdiction over.

1.7 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?

The common law makes provision for a delictual (tortious) claim for unlawful competition. Importantly, our courts have recognised that this may flow from a breach of statutory duties, such as those contained in the Medicines Act. As such, there may be grounds for a claim for damages and/or a basis for obtaining an interdict preventing a competitor from continuing with its current advertising campaign, provided that the complainant can show some loss that flows directly as a result of the advertising campaign.

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?

As stated above, many of the issues below are covered by the draft Code. Since it has not been promulgated, these answers are provisional only. But to the extent that many pharmaceutical companies are already complying with the draft Code, it is relevant in practice.

A medicine may not be promoted before it is authorised or registered with the regulatory authorities. According to the draft Code, promotion in this context includes the sponsorship of continuing professional development scientific meetings.

The legitimate exchange of medical and scientific information during the development of a medicine is permitted, provided that it does not amount to a promotion. It may also be permissible to make information available to health professionals upon unsolicited request, provided that the information is accurate, does not mislead and is not promotional in nature.

Promotional material for unregistered medicines may not be distributed or displayed at national or international conferences held in South Africa even if the medicine is authorised in another country.

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

Provided that the information is not promotional in nature and amounts to the legitimate exchange of medical or scientific information, it would not be publishable. A declaration of sponsorship is required if the material is sponsored by a pharmaceutical company.

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

The legitimate exchange of medical and scientific information during the development of a medicine, including unsponsored editorial in the public media, is permissible provided that it does not constitute promotion. A declaration of sponsorship is required of a sponsoring pharmaceutical company.

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

It is permissible in terms of the draft Code to make information available to health professionals upon request, provided that the information is accurate, does not mislead, is not promotional in nature and the request has not been solicited by the company.

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?

This issue is not addressed in the draft Code.

3 Advertisements to Health Professionals

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

Advertisements to health professionals, in terms of the draft Code, must contain the following information:

- the name of the medicine and list of active ingredients;

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- at least one indication for use and a succinct statement of the dosage, method of use and route of administration, consistent with the package insert;
- a succinct statement of the side-effects, precautions and contra-indications, consistent with the package insert;
- any warning which the regulatory authority requires to be included;
- the single exit price of the medicine;
- the scheduling status and pharmacological classification; and
- the registration number and name and address of the part of the business responsible for sale or supply.

In the case of audio-visual material and interactive data systems, the above information is provided either by way of inclusion in this material or by way of a document made available to the viewers. Where the material is included on the internet, there must be a clear prominent statement as to where the information may be found.

Abbreviated advertisements, that is, advertisements which are no larger than an A4 page in size and which only appear in professional publications, only require the following information:

- the name of the medicine and list of active ingredients;
- at least one indication for use, consistent with the package insert;
- any warning which the regulatory authority requires to be included;
- the scheduling status and pharmacological classification;
- the name, address and telephone number of the registered licence holder or of the part of the business responsible for sale or supply; and
- a statement that further information is available on request to the holder of the registration or in terms of the package insert.

There are also requirements governing the size, typeface and legibility of promotional material and further requirements for journal advertising.

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?

Although the draft Code permits comparator advertising within certain parameters, including that the products and activities of other pharmaceutical companies may not be disparaged, the ASA Code prohibits all comparator advertisements, unless the comparison is with a placebo. Accordingly it is advisable to avoid comparator advertising.

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 your country?

The ASA Code prohibits all comparator advertisements save for those making comparisons with a placebo. It is not permissible to use another company's brand name as part of the comparison.

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

If the scientific papers amount to promotional material, it may only be sent or distributed to those health professionals whose need for or interest in the particular information may be reasonably assumed. Restraint must be exercised on the frequency of distribution and the volume of promotional material distributed. Requests from healthcare professionals to remove their names from promotional mailing lists must be complied with promptly.

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)?

In view of the requirement of advertisements set out in question 3.1 above, teaser advertisements are unlikely to 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?

The Medicines Act provides that no person shall sample any medicine. Sample means the free supply of medicines by a manufacturer or wholesaler or its agent to a medical practitioner. However it excludes the free supply of medicines for clinical trials, donations of medicines to the State and tendering to the State.

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

According to the draft Code, no gift or any other pecuniary advantage may be offered or given to healthcare professionals as an inducement to medical practitioners to prescribe or supply any medicine. Gifts in the form or promotional aids and prizes may be distributed to healthcare professionals only if the gift or prize is inexpensive and relevant to the practice of the healthcare professional.

A competition used for promotional purposes must be a bona fide test of skill and recognise the professional standing of the recipients. The maximum acceptable cost to the donor of a prize in a promotional competition is R1,000 including VAT and this would only be acceptable where the competition is serious and the prizes limited in number, relevant to the recipients' work and proportionate to the skill required in the competition.

Donations may only be made to charities and not directly to a medical practitioner. The donation must not be prohibited on some other ground under the draft Code.

Medical and educational goods and services which will enhance patient care or benefit the health system may be provided if this does not amount to an inducement to prescribe or supply any medicine. Goods which are so provided may not bear the name of any medicine but may bear a corporate name.

Medical practitioners, in terms of the good practice guidelines of their professional body (and in particular the Policy Statement on Perverse Incentives ("the Perverse Incentives Policy") of the Medical and Dental Professions Council), are prohibited from accepting any material rewards except those of insignificant value from companies that sell or market medicines.

Under the Pharmacy Act it is an offence for a pharmacist to pay a commission or in any manner reward any person in connection with a prescription issued by a medical practitioner. Such an offence is also punishable by the Pharmacy Council. The Pharmacy Council is, furthermore, empowered to impose sanctions for any improper conduct by a pharmacist, which may include the offer of perverse incentives.

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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?

Medical and educational goods and services which will enhance patient care or benefit the health system may be provided, as long as this does not amount to an inducement to prescribe or supply any medicine.

Goods which are so provided may not bear the name of any medicine but may bear a corporate name. There are detailed provisions on the funding of services and service providers by pharmaceutical companies, covering issues such as patient confidentiality and the provision briefing material to the service provider and of written protocols to the health institutions.

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?

As stated above, medical and educational goods and services which will enhance patient care or benefit the health system may be provided, if this does not amount to an inducement to prescribe or supply any medicine. Goods which are so provided may not bear the name of any medicine but may bear a corporate name.

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 according to a bonus system, rebate system or any other incentive scheme.

This definition is likely to be interpreted to include volume-related discounts, particularly in view of the definition of a "discount" in the Regulations relating to a Transparent Pricing System for Medicines and Scheduled Substances (GNR.553 of 30 April 2004), which definition includes volume or 'bulk purchase' discounts.

The draft Code also provides that no rebate, discount, kickback or any other pecuniary advantage may be given to members of the health professions as an inducement to prescribe or supply any medicine.

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?

This is likely to be viewed as a prohibited incentive scheme under the Medicines Act as well as an inducement to purchase medicines in contravention of the draft Code.

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?

The offer of a refund in the event of non-responsiveness may, depending on the circumstances of the case, amount to the supply of a medicine according to a rebate, in contravention of the Medicines Act. This applies to both prescription-only and over-the-counter medicines.

A refund scheme may also be viewed as an inducement to supply or buy a medicine, in contravention of the draft Code.

This would not apply to an ordinary contractual obligation to replace defective or damaged products.

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

Yes, provided that the meeting has a clear educational content and the hospitality associated with the meeting is secondary to the nature of the meeting, appropriate and not out of proportion to the occasion. The fact of the company's sponsorship must be disclosed in the papers relating to the meetings and in any publications, in a sufficiently prominent manner.

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?

Hospitality must be secondary to the scientific and medical purpose of the meeting, and the level of hospitality must be appropriate and not out of proportion to the occasion. It must not extend beyond members of the health profession and appropriate administrative staff.

It is not necessarily unacceptable to provide hospitality to South African healthcare professionals to attend meetings outside of South Africa; such hospitality is subject to the same criteria as meetings within South Africa.

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?

In certain circumstances the provision of hospitality may include the payment of reasonable and actual travel costs for delegates, provided that payment is made directly to the professional association organising the meeting. According to the Perverse Incentives Policy, it is permissible to sponsor delegates to attend international conferences, including travel, lodging and other expenses, provided that a fair and transparent selection process is followed and such sponsorships are earmarked for specific educational events or conferences and not for holiday purposes. Regarding events related to continuing professional development ("CPD") (that is, certain standards of continuing professional development that medical practitioners are required to meet in order to gain and maintain their registration as medical practitioners), the Perverse Incentives Policy provides that no travel or lodging costs or other expenses should be paid by the pharmaceutical and health care industry for individual health care professionals to attend a CPD event, but special funding to the organisers for disbursement on behalf of deserving health care professionals is permissible.

It is not permissible to pay a doctor for his time, unless the doctor is a speaker at the conference. The payment to speakers of reasonable honoraria and reimbursement of out of pocket expenses

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is permissible.

A distinction must be drawn between education and training on the one hand and product promotion on the other - no expenses may be paid for attendance at product promotion events or product launches.

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?

As stated above, the draft Code has not been promulgated. It is therefore unclear to what extent pharmaceutical companies will be held responsible in these circumstances. The draft Code only states that where an undertaking has been given in relation to a ruling under the draft Code, the party concerned must ensure compliance with that undertaking. Once promulgated under the Medicines Act, the contravention of various provisions of the draft Code may also be brought under the criminal offence provisions of the Medicines Act.

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

There is no clear guidance on this issue. In our view, if the expert services to be provided by the doctors are genuinely and objectively linked to the purpose of the conference and if the conference has a clear educational and scientific content, the doctors providing the expert services may be regarded as comparable to speakers and may therefore be paid for reasonable honoraria and out of pocket expenses.

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

There are no specific provisions on this issue. According to the Perverse Incentives Policy, doctors may not advertise or endorse or encourage the use of any medicine for the purposes of financial gain. To the extent that the post marketing surveillance studies may result in doctors advertising, endorsing or encouraging, whether directly or indirectly, the use of the relevant medicine, this is impermissible.

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

See question 5.5 above.

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?

In terms of the draft Code, it is possible to advertise non-prescription medicines to the general public, provided that, inter alia, the advertisement:

- is balanced, true, not misleading and does not contain any exaggerated claims;
- does not cause unwarranted anxiety to consumers that they are suffering from any ailment, or contain material which could lead to consumers making an erroneous self-diagnosis;
- does not suggest that the product improves normal good health or that normal good health may be adversely affected by not taking the product;
- is not aimed principally at children;
- does not claim or imply that a product's effects are guaranteed;
- does not suggest that a medical consultation or surgical operation is unnecessary or discourage consumers from seeking medical or pharmaceutical advice;
- is not misleading as to the nature of the product, its ingredients or indication;
- does not contain improper, alarming or misleading claims of a recovery;
- does not include a recommendation by a celebrity which would encourage the use of the medicine; or
- does not suggest that the product is free of side-effects.

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

No, this is impermissible.

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?

Disease awareness campaigns may be permissible, provided that they in no way amount to a promotion of any medicine and the purpose of the campaign is to enhance public awareness and education about the disease.

There are specific provisions in the draft Code on vaccination campaigns, which are permissible whether carried out by companies, organisations or individuals, provided that the campaign is approved by the Department of Health and the MCC and provided that the purpose of the campaign is to encourage members of the public to seek treatment for their symptoms while in no way promoting the use of a specific medicine.

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

Provided that the press release is limited to medical and scientific information and does not amount to promotional material, it would be permissible. However it must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or mislead with regard to the safety of the product. It must not be made for the purpose of encouraging members of the public to ask their doctors to prescribe a specific medicine.

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

Such information may relate to both authorised and unauthorised products, provided that it is factual and presented in a balanced way.

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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?

There does not appear to be nay specific guidance on this. However provided that the funding is not offered as an inducement to prescribe, supply, buy or request any particular medicine and provided that it involves no element of promotion or advertising of a prescription-only medicine to the general public, it would in our view be permissible.

7 The Internet

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

The same requirements apply to promotional material on the internet as for other forms of advertising. There must be a prominent statement as to where the prescribing information may be found.

Promotional material on the internet falls within the scope of the Code if it is placed on the internet in South Africa or if it placed on the internet outside of South Africa by a South African company or its affiliate or with the authority of such a company and it makes specific reference to the availability or use of the medicine in South Africa.

In view of the present draft status of the Code, we are unable to provide information on the success of its control.

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?

A password protection scheme must be applied to promotional material in relation to prescription-only medicines. This applies also to promotional material which is placed on the internet outside of South Africa by or with the authority of a South African company or its affiliate and which makes specific reference to the availability or use of the medicine in South Africa.

It must also be made clear when a user is leaving any of the company's websites and is being directed to a site which is not that of the company and is therefore, not necessarily covered by the Code.

8 General - Medical Devices

8.1 What laws and codes of practice govern the advertising of medical devices in your country?

The Medicines Act and Regulations make provision for the implementation of a code governing the advertising of medical devices, but at this stage no such code has been devised.

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

There are no specific laws or rules relating to the promotion of medical devices. However there are some ethical considerations. The Perverse Incentives Policy which has been adopted by the Medical and Dental Professions and applies inter alia to doctors, prohibits doctors from advertising or endorsing or encouraging the use of any medical device in an unfair manner. By accepting such payments or hospitality, the doctors may be viewed as accepting perverse incentives, and thus engaging in unprofessional conduct.

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?

There have been no significant developments in the last year.

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

It would lead to certainty if the Code could be finalised in the next year.

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

There have been no general practice or enforcement trends in the last year or so in South Africa.

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BG Bowman Gilfillan Attorneys

Bowman Gilfillan is one of South Africa's leading law firms, with offices in Johannesburg, Cape Town and London. The firm has advised many ethical pharmaceutical manufacturers over a long period. These include Pfizer, Merck Sharp and Dohme, Schering-Plough, Abbott Laboratories, Boston Scientific and others. Our work includes regulatory advice, advice on package inserts, constitutional litigation, unfair competition, ordinary litigation and general commercial work. In 2004/2005 the firm represented Innovative Medicines South Africa ("IMSA") in representations to the Government on medicine pricing regulations and in subsequent Constitutional Court litigation on this topic. IMSA is an association made up of Pfizer, Merck, Eli Lilly, Aventis, Roche and Novartis.

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