

South Africa

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REGULATORY OVERVIEW

1. Please give a brief overview of the regulatory framework for medicinal products/pharmaceutical products/drugs (as they are called in your jurisdiction), including the key legislation and regulatory authorities. If biotechnology products are treated differently, please specify the differences.

The regulation of medicines and related substances is governed by the Medicines and Related Substances Control Act No.101 of 1965 (Medicines Act), as amended, and the regulations issued under that Act.

The principal regulatory body, established by the Medicines Act, is the Medicines Control Council (Council). The Council is assisted by a number of directorates and committees when carrying out its functions, and is afforded wide-ranging regulatory competency relating to the regulation of medicines and related substances, and governs:

- Manufacturing.
- Marketing.
- Importing
- Exporting.

Any medicine that is manufactured or marketed in, and/or imported into, South Africa must first be registered with the Council. Following registration, a licence to manufacture, market and/or import must also be obtained from the Council before manufacturing, marketing and/or importation can be carried out. Licences are granted separately from the registration process, and are only granted where the applicant can show that they conform to the required standards and practices for manufacturing, marketing and/or importing.

Explicit provisions concerning biotechnology have not yet been incorporated into South African legislation. However, the Genetically Modified Organisms Act No. 15 of 1997 (GMO Act) regulates, in certain circumstances, the development, production, use and application of genetically modified organisms (GMOs), and regard must therefore be given to this Act where GMOs are employed in the manufacture of a medicine. The GMO Act establishes the Executive Council for GMOs, which is the regulatory body responsible for regulating the GMO-related matters to which the GMO Act applies.

PRICING AND STATE FUNDING

2. Please give a brief overview of the structure and funding of the national healthcare system.

National healthcare policy provides for free primary health care to be given to all citizens who have no source of income. Certain

groups, including pregnant women and children younger than five years old, receive medical care at primary healthcare facilities free of charge, regardless of their income. These services are fully funded by the government and are ultimately paid for by the taxpayer.

State health institutions purchase medicinal products from manufacturers through a state tender system, and tenders are awarded for two years. Tenders are only awarded for medicines on the Essential Drug List (EDL).

Currently, the government is considering establishing a public national health insurance scheme, which would be state funded and provide health insurance specifically to citizens who cannot afford to belong to a private medical aid or insurance scheme. To this end a national investigation and consultation process is being conducted by the National Health Insurance Advisory Committee. The focus of the process has, so far, principally taken the form of consultations conducted with interested parties. Whether the scheme will actually be established remains to be seen.

3. In what circumstances are the prices of medicinal products regulated?

The prices of all medicines sold in South Africa in the private sector have been regulated since 2004 by regulations issued under the Medicines Act. The principal legislation is the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances (pricing regulations).

Medicine prices are regulated under the pricing regulations by reference to the “Single Exit Price” (SEP) of the medicine. An SEP is defined in the pricing regulations as (**emphasis added**):

“The price **set by the manufacturer or importer** of a medicine or Scheduled substance in terms of these regulations combined with the **logistics fee and VAT** and is the price of the lowest unit of the medicine or Scheduled substance within a pack multiplied by the number of units in the pack.”

The SEP is determined, independently, by the manufacturer or importer of the medicine, following the guidelines provided by the pricing regulations.

The SEP, once determined, is subject to the approval of the Director-General of Health, before the sale of the medicine. Once the SEP has been approved, the SEP becomes a fixed price at which the manufacturer or importer must sell the medicine in South Africa. Wholesalers who buy the medicine for onward sale must sell the medicine at a price no higher than the SEP, as must pharmacists, whether they buy the medicine from the manufacturer, importer, wholesaler or distributor. The pricing regulations do, however, make provision for a “dispensing fee”, which can be raised over and above the SEP by pharmacists or other persons licensed to dispense medicines.

Once the SEP is set, it cannot be increased unilaterally, and an application must be made to the Minister of Health who will, in consultation with the Pricing Committee, decide the matter. Further, only one increase per year is permitted. In practice, the Department of Health determines, on an annual basis, an industry-wide price increase, based primarily (among other things) on the Consumer Price Index and average exchange rates over the preceding period. This increase can then be applied to all registered drugs. The increase is usually between 6% to 8%, and the decision whether or not to increase the price of products, and the extent of the increase to products, within the limits determined by the Minister of Health is then decided by the manufacturer, wholesaler or importer, as the case may be.

4. When is the cost of a medicinal product funded or reimbursed by the state? Please briefly outline the procedure and pricing for state funding or reimbursement (for example, is the reimbursement paid to the producer, pharmacist or end-user)?

No reimbursement scheme is provided for either by the Medicines Act or the regulations under that legislation. However, the national healthcare policy and the benefits it provides to end-users are discussed in *Question 2*.

The national healthcare policy is funded out of the Department of Health's budget, which is allocated according to what is agreed between the Department of Health and the Treasury. The supply of medicines to state hospitals is governed by a tender system in which both multinationals and generic companies participate.

MANUFACTURING

5. Please give an overview of the authorisation process to manufacture medicinal products. In particular:

- To which authority must the application be made?
 - What conditions must be met to obtain authorisation?
 - Are there specific restrictions on foreign applicants?
 - What are the key stages and timing?
 - What fee must be paid?
 - How long does authorisation last and what is the renewal procedure?
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Application

Application for a licence to manufacture or market medicinal products is made to the Council.

Conditions

There are a number of formal disclosures that are required for the licence to manufacture or market, including detailed specifications of the medicines to be manufactured or marketed. Applicants must also satisfy the Council that they are capable of complying with good manufacturing and marketing practices, as defined in the Guidelines on Good Manufacturing Practice, issued by the Council under the Medicines Act. These Guidelines include guidance on good wholesaling, best practice and marketing.

The Guidelines are prescriptive, not elective, and strict compliance is both required and enforced by the Council. The

most recent Guidelines were adopted by the Council in 2010 and cover aspects such as (among other things):

- Quality management.
- Personnel.
- Premises and equipment.
- Self inspection.

These Guidelines are based on the *Guide to Good Manufacturing Practice for Medicinal Products*, version PE 009-2 dated 1 July 2004, published by the Pharmaceutical Inspection Cooperation Scheme (PIC/S).

To ensure that the Council are satisfied of compliance with the Guidelines, applicants usually provide the Council with a manual outlining which practices and procedures will be put in place to ensure that the requirements are met.

Applicants must also appoint, and designate as such, a pharmacist who will control the manufacturing or distribution, together with a natural person, resident in South Africa, who will be responsible for ensuring compliance with the Medicines Act.

Restrictions on foreign applicants

An applicant for a manufacturing and/or marketing licence must be resident or have its place of business in the Republic of South Africa. Foreign entities usually comply with this requirement by applying through a local responsible pharmacy, which is designated in the application documents. Foreign applicants with locally resident subsidiaries can also apply through their subsidiary. In practice, a foreign entity usually does not apply in its own name, but in the name of its designated pharmacy, which itself can be represented by a locally established and incorporated pharmacy, or subsidiary of a foreign company.

The licence is therefore granted to the applicant (usually a local responsible pharmacy) and manufacturing or marketing must be completed in their name, and not in the name of the foreign entity (unless the two are the same: the applicant foreign parent and its subsidiary local branch company). Where the applicant has had no previous dealings with the Council, and particularly with applications for a marketing licence, an inspection of the applicant's manufacturing premises is made to evaluate compliance with the Guidelines. This is still the case where an application is made through a local representative but the actual manufacturing is conducted abroad.

The Council aligns their policies and guidelines with those of certain foreign regulatory authorities, including:

- Food and Drug Administration (US).
- Medicines and Healthcare Products Regulatory Authority (UK).
- European Medicines Agency (EU).
- The regulatory authority of Canada.
- Therapeutic Goods Administration (AU).

South Africa has Mutual Recognition Agreements (MRAs) with these jurisdictions. There is an abbreviated process for the registration of a medicine with these jurisdictions, but not for an application for a manufacturing and/or marketing licence. However, the Minister of Health has the power to exclude any medicine from the provisions of the Medicines Act. Potentially, an exemption from the provision to acquire a manufacturing and/or marketing licence is therefore possible.



Key stages and timing

Once an application is made, the Council appoints an inspector to inspect the applicant's site to ensure:

- It complies with good manufacturing practice standards.
- Information provided in the application concerning the applicant's good practice is put into practice at the site.

This process takes between 12 and 24 months.

The process is quicker where the local representative is granted an exemption from inspection because the foreign entity manufactures and/or markets in a foreign jurisdiction covered by an MRA and aligned with the Council. The Council decides whether to grant or refuse the licence, and can also request further information from the applicant within a period of 28 days.

Fee

Application fees are payable as follows:

- Licence to manufacture: approximately ZAR3,500.
- Licence to distribute: approximately ZAR2,400.
- Licence for wholesale: approximately ZAR2,400.
- Licence to import: approximately ZAR2,400.
- Licence to export: approximately ZAR2,400.

During the currency of the licence an annual retention fee of approximately ZAR625 is also payable.

The following inspection fees are also payable:

- Local manufacturing site: approximately ZAR160 per hour.
- International manufacturing site: approximately ZAR400 per hour.
- Wholesale sites: approximately ZAR800 per site.
- Distributor sites: approximately ZAR800 per hour.

(As at 1 November 2010, US\$1 was about ZAR0.14.)

Fees payable on applications for the registration of medicines are significantly higher than the amounts for licensing and inspection.

These fees do not include any professional charges that can be charged by a professional firm engaged to complete the application.

Period of authorisation and renewals

A manufacturing and/or wholesaling licence is granted for five years from its issue date. Licences can be renewed on application to either the Director-General or the Council, and must include substantially the same information provided in support of the original application. The application for renewal must be made 90 days before the expiry date of the existing licence. Renewal fees are the same as the original application fees (*see above, Fee*).

6. What powers does the regulator have to:

- Monitor compliance with manufacturing authorisations?
 - Impose penalties for a breach of a manufacturing authorisation?
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The Guidelines allow the Directorate: Inspectorate and Law Enforcement (Inspectorate) to carry out, on behalf and under the direction of the Council, regular inspections of manufacturing sites, both in South Africa and in countries with which the Council does not have an MRA. Inspection enables the Inspectorate to confirm that licence holders:

- Comply with the conditions of their licence.
- Comply with the provisions of the Medicines Act.
- Comply with good manufacturing practice.

Legislation requires that licence holders make their premises available for inspection by the Inspectorate, acting through inspectors, at any reasonable time and in accordance with the Guidelines. Where quality control testing is contracted out to a third party, the testing site must both:

- Be made available for inspection.
- Obtain a licence.

Non-serious deficiencies found during the inspection are notified to the licence holder by letter, which requests proposals to remedy them. Serious non-compliance with the Guidelines regarding good manufacturing practice is referred to the Council for formal action.

The Council, once certain of the accuracy of the report, can revoke (in full or in part), amend or suspend a licence. Licence holders are usually given an opportunity to be heard before formal action is taken. However, where the Council believes public safety is at risk, it can suspend a licence with immediate effect for an indefinite period, or revoke the licence.

Appeal can be made to the Minister of Health to challenge the validity of the Council's decision within 30 days of notification of the decision.

CLINICAL TRIALS

7. Please give an overview of the regulation of clinical trials. In particular:

- Which legislation and regulatory authorities regulate clinical trials?
 - What authorisations are required and how is authorisation obtained?
 - What consent is required from trial subjects and how must it be obtained?
 - What other conditions must be met before the trial can start (for example, the requirement for a sponsor and insurance cover)?
 - What are the procedural requirements for the conduct of the trial (for example, using certain medical practices and reporting requirements)?
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Clinical trials are regulated by Council under the Medicines Act and the regulations issued under it, including the Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa 2000 (Clinical Guidelines). Authorisation to conduct a clinical trial must be obtained by making an application to the Council.

Proof of consent is a prerequisite for authorisation to be granted. The applicant should submit, with the application, an "informed

consent document” which should also be used in the trial. This document, together with the trial protocol to be followed, should, among other things:

- Be endorsed by an ethics committee recognised by the Council.
- Outline the applicant’s approach in obtaining informed consent from trial subjects.
- Provide a comprehensive statement of the information to be communicated to the trial subjects.

The principal requirement for authorisation is compliance with the Clinical Guidelines, as determined by the Council. An undertaking that the trial will be conducted in accordance with the Clinical Guidelines must also accompany the application.

Certain pre-conditions must be met for an application for authorisation to be successful. In practice, ethical endorsement of the trial, together with compliance to the Clinical Guidelines, must both be present before an authorisation will be granted.

During the trial, progress reports must be made to the Council on a six-monthly basis from the date on which the trial commenced, and 30 days after the completion or termination of the trial. All practices during the conduct of the trial must comply with the Clinical Guidelines.

MARKETING

8. Please give an overview of the authorisation process to market medicinal products. In particular:

- To which authority must the application be made?
- What conditions must be met to obtain authorisation?
- What are the key stages and timing?
- What fee must be paid?
- How long does authorisation last and what is the renewal procedure?

Application

See *Question 5*.

Conditions

See *Question 5*.

Key stages and timing

See *Question 5*.

Fee

See *Question 5*.

Period of authorisation and renewals

See *Question 5*.

9. Please briefly outline the abridged procedure for obtaining marketing authorisations for medicinal products. In particular:

- Which medicinal products can benefit from the abridged procedure (for example, generics)?
- What conditions must be met?
- What procedure applies and what information can the applicant rely on?

The Council provides, under the provisions of the Medicines Act and its regulations, abridged procedures for the registration of medicines in certain circumstances. In particular, provision is made for an “expedited review process” and an “abbreviated medicine review process”.

Expedited review process

The expedited review process allows the Council to speed up the registration process for specific medicines that either have important therapeutic benefit, or are urgently required to deal with key health problems. In these instances an accelerated review system is applied.

A request for expedited review must be submitted to the Minister of Health, and a copy must be provided to the Registrar of Medicines, before submitting the full application. Only the following medicines can be considered for expedited review:

- Medicines on the EDL.
- New chemical entities that are considered essential for national health, but that do not appear on the EDL.

Abbreviated Medicine Review Process (AMRP)

The AMRP is a system created by the Council to limit the evaluation time for pharmaceutical products that are registered in countries with which the Council aligns itself, provided the evaluation report is readily available.

The AMRP is principally based on the expert reports of the pharmacotoxicological and clinical data. It should be noted that the AMRP is an abbreviated evaluation process, and not an abbreviated application.

10. Are foreign marketing authorisations recognised in your jurisdiction? If so, please briefly outline the recognition procedure.

Foreign marketing authorisations are not recognised in South Africa. However, the Council does align their policies with those of certain foreign regulatory authorities, and recognises these foreign regulatory authorities, which can facilitate Council approval of marketing authorisation applications (*see Question 5*).

11. What powers does the regulator have to:

- Monitor compliance with marketing authorisations?
- Impose penalties for a breach of a marketing authorisation?

See *Question 6*.



12. Are parallel imports of medicinal products into your jurisdiction allowed? If so, please briefly outline what conditions must be met by the parallel importer. Can intellectual property rights be used to oppose parallel imports?

Parallel imports are allowed. The Medicines Act allows the Minister of Health to prescribe the conditions under which parallel imports of any patented medicine can be imported. This is governed by regulations issued under the Medicines Act, and specific guidelines to the Council's approach to applications have also been issued.

Only medicines that are registered under the Medicines Act, and that are sold outside South Africa with the consent of the patent holder for the medicine in South Africa, can be parallel imported. The person importing must have an export licence from a regulatory authority recognised by the Council.

Application must be made for a parallel import permit from the Minister of Health. The comparative selling price is a significant factor influencing the Minister's decision to grant a permit, and documentary proof confirming the lowest selling price of the medicine in South Africa, and the price at which the parallel imported medicine will be sold, must accompany the application.

Once the parallel import permit is obtained, application to the Council must be made to register the medicine to be imported. The following characteristics of the imported medicine must be the same as the corresponding registered and already available medicine:

- The same formulation.
- The same quality and safety standards.
- The same proprietary name.

The provisions of the Patents Act (regarding the exclusive right of the patent holder to import) and the Trade Marks Act are rendered ineffectual for the medicine for which the permit is granted (the Trade Marks Act actually specifically allows parallel imports).

13. Please briefly outline the restrictions on marketing practices such as gifts or "incentive schemes" for healthcare establishments or individual medical practitioners.

The Medicines Act explicitly prohibits the supply of any medicine using a "bonus scheme, rebate system or any other incentive scheme".

14. Please briefly outline the restrictions on marketing medicinal products on the internet, by e-mail and by mail order.

No express provisions regarding internet, e-mail or mail order marketing are included in the Medicines Act, though the general provisions applicable to all marketing will still apply.

However, Schedule 2 to 6 medicines can only be sold with the intervention of a medical practitioner: the marketing of these medicines over the internet without the intervention of a medical practitioner before they are dispensed is therefore illegal.

Further, the marketing and advertising of Schedule 2 to 6 medicines by manufacturers or wholesalers can only be made to medical practitioners. This limits the audience that internet-based marketing is allowed to reach. A draft code on the practice of marketing medicines which provides explicitly for internet-related marketing is impending and expected to be implemented in the near future (*see Question 15*).

ADVERTISING

15. Please briefly outline the restrictions on advertising medicinal products. In particular:

- Which legislation applies and which regulatory authority enforces it?
 - What types of medicinal product cannot be advertised?
 - What restrictions apply to advertising that is allowed?
 - If advertising over the internet is treated differently, please identify the differences.
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The Medicines Act is the principal legislation governing the advertising of medicinal products.

The South African Code of Advertising Practice (Advertising Code), regulated by the South African Advertising Standards Authority (ASA), also applies to the advertising of medicinal products, although the Advertising Code does not have the force of law and forms part of a self-regulatory system. The provisions relating to medicines are now outdated, and a redraft is currently underway (this was expected in the latter part of 2010, but has not yet been released).

The Consumer Protection Act No. 68 of 2008 (CPA) also applies to the extent that it deals with general advertising or marketing to a consumer. The CPA came into force in October 2010.

There is no complete prohibition on advertising certain medicines. However, medicines containing a substance appearing in Schedule 2 to 6 of the Medicines Act can only be advertised to medical practitioners (and not to the general public). Advertising these medicines in a publication usually, or only, made available to medical practitioners is acceptable.

Generally, advertising to both medical practitioners and the general public must not conflict with the information (which has been incorporated into the package insert) submitted in support of the medicine's application to the Council for registration with regard to its:

- Safety.
- Efficacy.
- Quality.

Where a medicine includes more than one active ingredient, no reference can be made to the specific properties of any specific active ingredient unless that reference has been approved by the Council for inclusion in the package insert.

There are no specific provisions in the Medicines Act or Advertising Code concerning the internet. However, the South African Code of Practice for the Marketing of Medicines (5 February 2010 draft) (SA Code) covers internet advertising and marketing in section 21

(see Question 37, Advertising). Under the SA Code, promotional material for medicine containing Schedule 2 to 6 substances should be limited to healthcare professionals and administrative staff only by using a password protection scheme. Information placed on the internet outside the Republic of South Africa, but by a South African company, will fall within the ambit of the SA Code. Since the SA Code is not yet in force, no comment can be made on its successful application.

In practice, though the Council does not currently regulate the advertising of medicines, advertising-related complaints can be lodged with the Inspectorate which will then, along with the ASA, investigate complaints from a safety perspective. The Inspectorate has the authority to request an applicant to remove an advertisement or display, but has no further power to regulate advertising generally.

PACKAGING AND LABELLING

16. Please briefly outline the regulation of packaging and labelling of medicinal products. In particular:

- Which legislation applies and which regulatory authority enforces it?
- What information must the packaging and/or labelling contain?
- What other conditions must be met (for example, information being stated in the language of your jurisdiction)?

Packaging and labelling are regulated by the Medicines Act and the regulations created under that Act, and enforced by the Council through the Directorate: Inspectorate and Law Enforcement.

There are no provisions or regulations prescribing a particular type of packaging which must be used. Provisions relating to packaging are principally directed to labelling, and the information that must be included on the packaging.

It is a requirement that the immediate container of any medicine sold that is intended for administration to humans must have a label attached to it. The information on the label must be in English and at least one other official language of the Republic of South Africa. For further information on the specific information that must be included on the label (which is too substantial to repeat here), see Regulation 8 of the General Regulations issued in terms of the Medicines and Related Substances Act 1065 (GN R510 and GG24727 of 10 April 2003, as amended).

TRADITIONAL HERBAL MEDICINES

17. Please briefly outline the regulation of the manufacture and marketing of traditional herbal medicinal products in your jurisdiction.

No special provisions exist in relation to traditional herbal medicines and they are regulated by the same provisions and requirements as other medicine. Draft regulations providing exclusively for the regulation of traditional herbal medicine have, however, been drafted and published for comment (see Question 37, Regulation).

PATENTS

18. What types of medicinal products and related substances and processes can be protected by patents and what types cannot be patent protected? If process patents only are available for these products and substances, please give details including whether the situation is likely to change. What are the legal criteria to obtain a patent? Which legislation applies?

Patent protection is governed by the Patents Act No. 57 of 1978, as amended (the Patents Act) and regulations created under it.

The Patents Act provides that a patent can be granted for any invention which is:

- New.
- Involves an inventive step.
- Is capable of being used in trade, industry or agriculture.

The concept “invention” is not strictly defined intrinsically, but the legislation lists a number of exclusions: medicines and related substances (such as active pharmaceutical agents) are not listed as an excluded category. Medicines and related substances, and the processes by which they are obtained, are therefore patentable under the Patents Act.

The Patents Act provides that an invention consisting of a substance or composition “for use in a method of treatment” of the human or animal body can be patented, even though the substance (or substances) in the composition is previously known. It is the first medical use of a known substance that is patentable: the substance itself cannot, of course, be protected a second time.

19. How is a patent obtained? In particular:

- To which authority must the application be made?
- What fee must be paid?
- What are the key stages and timing?
- Does the patent office operate a deposit system or are applications subject to some form of scrutiny before acceptance?

The authority

Application is made to the Companies and Intellectual Property Registration Office (CIPRO).

Fee

The application fee (excluding professional fees raised by a local agent for attending to the application) is approximately ZAR590.

Process and timing

The Patent Office takes about nine to 18 months to examine an application and accept or reject the specification. No substantive examination occurs. Once the formal requirements have been met, the specification is accepted and notification of the patent is published in the Patent Journal. This publication constitutes the grant of the patent. There is no provision to oppose pending or granted patent applications. However, at any stage after the grant of a patent, any person can apply to the Registrar of Patents to

revoke the patent on one or more of a number of statutory grounds for invalidity. If the revocation proceeds, it will be determined before the Court of the Commissioner of Patents, a special court in the High Court that has national jurisdiction at first instance in all litigious patent matters.

The application process can be expedited on the payment of a fee. Acceptance of the specification can be delayed as of right for up to 15 months: further extensions are at the discretion of the Registrar of Patents (who can grant a request for delay indefinitely).

20. How long does patent protection last? How is a patent renewed or patent protection extended? If the patent itself cannot be extended, can the organisation's monopoly rights be extended by other means, such as supplementary protection certificates or (regulatory) data exclusivity periods?

A patent is valid for a period of 20 years from its effective filing date (the filing date differs depending on whether the application is made under the Paris Convention or the Patent Cooperation Treaty). Renewal fees are paid annually, and the patent cannot be extended once it has expired. There is no provision to extend the term of a patent, or extend the monopoly rights that it confers.

21. In what circumstances can a patent be revoked?

An application to the Commissioner of Patents can be made to revoke a patent. The Patents Act explicitly provides nine grounds on which a patent can be revoked, including (among other things):

- The invention to which the patent relates is not capable of being patented because it cannot be used or applied in trade, industry or agriculture.
- Lack of novelty or inventiveness.
- Insufficient disclosure.
- The invention as disclosed cannot be performed or does not lead to the results and advantages set out in the specification.
- Fraud.
- Lack of clarity or fair basis of the claims.
- The invention is contrary to public morals or well established natural laws.
- The patentee was not entitled to apply for the patent in that it is not the inventor, or did not obtain the right to apply from the inventor.

There are a number of additional grounds relating to non-compliance with certain requirements.

22. When is a patent infringed? How is a claim for patent infringement made and what remedies are available?

A patent is infringed when any person, without the consent of the patent owner, carries out acts which are exclusively reserved, under Patents Act, for the patent owner. This includes:

- Making the invention.
- Using the invention.
- Exercising (in the sense of "carrying out", which indicates that this has bearing particularly on methods or processes) the invention.
- Disposing, or offering to dispose of, the invention.
- Importing the invention.

An action for infringement can be brought in the Court of the Commissioner of Patents. An application for a preliminary injunction to cease the infringement can also be made.

The claimant is entitled, if successful, to:

- Relief by way of an injunction.
- Delivery up of any infringing product or article, or any product or article of which the infringing product forms an inseparable part.
- Damages.

Instead of damages, a claimant can elect to take a reasonable royalty, which would have been payable had the patent been licensed rather than used without consent.

TRADE MARKS

23. Can a medicinal product brand be registered as a trade mark? What are the legal criteria to obtain a trade mark? Which legislation applies?

A medicinal product brand complying with the following requirements can be registered as a trade mark.

Trade mark protection is governed by the Trade Marks Act No. 194 of 1993, as amended (Trade Marks Act), and the regulations created under that Act. A trade mark is defined as any sign capable of being represented graphically, and includes, among other things:

- Name.
- Signature.
- Word.
- Numeral.

To be capable of registration under the Trade Marks Act, a trade mark must distinguish the goods or services for which it is registered (or proposed to be registered) from the goods or services of another person.

A trade mark is capable of distinguishing the goods or services if (at the date of application for registration):

- It is inherently distinctive.
- It is capable of distinguishing by reason of prior use.

A trade mark is inherently distinctive if it does not describe the goods or services, or any qualities of the goods or services, in any way. This category of trade mark includes invented words (for example, NOKIA and KODAK) and also ordinary words with an accepted meaning but which are not descriptive of the goods or services in question (for example, APPLE for computers). In contrast, certain marks that do not possess this inherent capacity to distinguish (because they are descriptive of the goods or services in question), have nevertheless acquired distinctiveness through use. Consumers have come to associate the particular mark with one enterprise and no other.

24. How is a trade mark registered? In particular:

- To which authority must the application be made?
- What fee is payable?
- What are the key stages and timing?

The authority

Applications are made to CIPRO, to the Registrar of Trademarks.

Fee

The application fee is ZAR590. This fee does not include any professional charges which can be raised by a professional firm engaged to attend to the matter.

Process and timing

Once filed, the application is examined to determine both:

- Whether it is inherently registrable.
- Whether it conflicts with prior registrations or applications.

It takes about 12 months to issue a report on the examination. The report will either accept the application, or constitute a preliminary refusal of it. A preliminary refusal will indicate any conditions subject to which the application can be accepted. The applicant then has an opportunity to make representations to address, and overcome, the concerns expressed in the report.

Once a trade mark application is accepted, it is advertised in the *Patent Journal*. If no objections are raised by third parties within a three-month period from the date it is advertised, the trade mark is granted and a certificate of registration is issued within approximately 18 months.

25. How long does trade mark protection last? How is a trade mark renewed?

A trade mark registration is valid for ten years and can be renewed for the same period of time, in perpetuity.

A trade mark registration is renewed by making the necessary application to the Registrar of Trade Marks and paying the applicable fee. The application must be filed within the six-month period before the expiry of the registration but can also, subject to the payment of additional fees, be filed within six months following the expiry date.

26. In what circumstances can a trade mark be revoked?

A trade mark can be removed from the Register on application by an interested person on the grounds that either:

- The trade mark is used in a manner which does not comply with any condition entered in the register concerning its registration.
- The trade mark was registered without any genuine intention to use the trade mark in relation to the goods or services for which it has been registered, and there has been no actual use of the trade mark in relation to those goods or services from three months before the date of the application for removal up to the present time.
- From three months before the date of the application, a continuous period of five years (or longer) has lapsed from the date of issue of the certificate of registration during which there was no bona fide use thereof in relation to the goods or services for which it is registered.
- In the case of a trade mark registered in the name of a body corporate, or in a name of a natural person, the body corporate was dissolved or the natural person died not less than two years before the date of the application for the removal of the trade mark, and no application for the registration of an assignment of the trade mark has been made.
- The trade mark was wrongly entered on the register, or wrongly remains on the register. This will be the case where a mark is inherently unregistrable (for example, because it is offensive or not distinctive) or contrary to the prior rights of a third party.

The existence of any one of the grounds above is sufficient to obtain the removal of a registered trade mark from the register.

27. When is a registered trade mark infringed? How is a claim for trade mark infringement made and what remedies are available?

A registered trade mark is infringed by either:

- The unauthorised use, in the course of trade, of an identical or similar mark in relation to goods or services that are identical or similar to the goods or services protected by the trade mark, where that use is likely to cause deception or confusion.
- The unauthorised use, in the course of trade, of an identical or similar mark to the trade mark registered, where that trade mark is well-known in South Africa and the unauthorised use is likely to take unfair advantage of, or be detrimental to, the distinctive character or repute of the registered trade mark (irrespective of the absence of deception or confusion).

A claim for trade mark infringement is made to the High Court. Proceedings can be brought either:

- By way of application, on notice of motion, when there is no dispute of fact.
- By way of action, with the issuing of summons, when there is an anticipated dispute of fact.



The available remedies are:

- An injunction ordering the defendant to refrain from further infringement.
- An order for the removal of the infringing trade mark from all material and, where the infringing mark is inseparable or incapable of being removed from the material, an order that all such material be delivered up to the trade mark owner.
- Damages (which can only be claimed in proceedings brought by way of action).
- Instead of damages, a reasonable royalty (which can only be claimed in proceedings brought by way of action).

28. Is there a requirement for a patent or trade mark licence agreement to be approved by any government or regulatory body? If so, please provide details including anticipated timelines and cost.

Licence agreements that contain royalty payments which are paid to a foreign entity must be approved by the Department of Trade and Industry.

29. Is there a requirement for remittance of royalties payable under a patent or trade mark licence agreement to a foreign licensor to be approved by any government or regulatory body? If so, please provide details including anticipated timelines and cost.

Exchange control approval must be obtained from the South African Reserve Bank. Where a licence agreement is submitted to the Department of Trade and Industry for approval, the Department will usually refer the matter to the Reserve Bank for exchange control approval for the cross-border payment of royalties.

30. Is your jurisdiction party to international conventions on patent and trade mark protection?

South Africa is a signatory to the agreement on Trade Related Aspects of Intellectual Property Rights, the Paris Convention and the Patent Cooperation Treaty.

PRODUCT LIABILITY

31. Please give an overview of medicinal product liability law, in particular:

- Under what laws can liability arise (for example, contract, tort or statute)?
 - What is the substantive test for liability?
 - Who is potentially liable for a defective product?
-

Legal provisions

At common law a claim for a defective product is based on delict, and the defendant's fault must be proved. Liability for defective products, including medicinal products, is also imposed on

THE REGULATORY AUTHORITY

The Medicines Control Council

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Main areas of responsibility. The Council has the responsibility to screen and approve or refuse application for registration of medicines for sale in South Africa, keep a register of the medicines registered, govern the process of clinical trials and ensure the safety and efficacy of medicines manufactured, imported and sold in South Africa.

manufacturers to protect consumers from personal injury. The principal legislation is the Consumer Protection Act 2008 (CPA). The main effect of the CPA is that it imposes strict liability with regard to defective products. The CPA has been brought into force in an incremental manner, commencing in October 2010, and there are a few remaining provisions yet to be implemented that will come into force on 1 April 2011. The CPA provides that a producer, importer, distributor or retailer of any goods is liable for any harm, caused wholly or partly, as a consequence of:

- Supplying any unsafe goods.
- A product failure, defect or hazard in any goods.
- Inadequate instructions or warnings provided to the consumer.

Substantive test

The CPA provides that there should be a causal link between the defect and the harm suffered. Fault is not a requirement for the strict liability created under the CPA.

There are two principal types defectiveness in South African law:

- Consumer expectations.
- Risk-utility.

The CPA imposes the "consumer expectations" standard.

The basic test for defectiveness is as follows:

- Is there any material imperfection in the manufacture of the goods or components, or in the performance of the services, that renders the goods, or the results of the service, less acceptable than persons generally would be reasonably entitled to expect in the circumstances?
- Is there any characteristic of the goods or components that renders the goods or components less useful, practicable or safe than persons generally would be reasonably entitled to expect in the circumstances?

Liability

The following parties are liable for any harm caused by a defective product:

- Producer.
- Importer.
- Distributor.
- Retailer.

The harm for which liability will arise includes:

- Death or injury of any person.
- Illness of any person.
- Loss of, or physical damage to, any movable or immovable property.
- Any economic loss resulting from the above.

The term producer is widely defined, and includes the manufacturer or producer of the defective product, or person(s) applying their name or trade mark to the defective product. A distributor is defined as the person who, in the ordinary course of a business, is supplied with the defective product and in turn supplies it to another distributor or retailer.

The court has authority to:

- Assess whether any harm has been proven.
- Determine the extent of the damages or loss.
- Apportion liability among persons found to be jointly, or severally, liable.

32. What are the limitation periods for bringing product liability claims?

The limitation period generally is three years from the date the claimant becomes aware of the damage (*see also Question 33*).

33. What defences are available to product liability claims?

Under the common law, a variety of defences can be raised by the defendant to show the absence of fault on his part.

Under the CPA, liability does not arise in the following instances:

- When the product's unsafe characteristic, failure, defect or hazard causing harm is wholly attributable to compliance with any public regulation.
- When the product's unsafe characteristic, failure, defect or hazard:
 - did not exist in the goods at the time it was supplied to another person alleged to be liable; or
 - was wholly attributable to compliance with instructions, which were provided by the person who supplied the goods.
- Where it is unreasonable to expect the distributor or retailer to have discovered the product's unsafe characteristic, failure, defect or hazard, having regard to that person's role in marketing the goods to consumers.
- Where the claim for damages is brought more than three years after the:
 - death or injury of a person for whom liability can arise;
 - earliest time at which a person had knowledge of the material facts of an illness suffered and for which liability can arise;

- earliest time at which a person with an interest in any property had knowledge of the material facts about the loss or damage to that property for which liability can arise;
- date on which a person suffered any economic loss for which liability can arise.

34. What remedies are available to the claimant?

For both common law claims and claims brought under the CPA, the remedy is damages for the harm caused by the defective product.

35. Are class actions allowed for product liability claims? If so, are they common?

There is no sanction against class actions in South African common law. Provision is specifically made in the CPA for class actions, and a court can award damages against a supplier for collective injury to all, or a class of, consumers generally.

36. Are punitive damages allowed for product liability claims? If so, are they common? What comment can you make about likely quantum?

No provision is made in South African law for punitive damages. The claimant is limited to the damage that he can prove was actually suffered.

REFORM

37. Please summarise any proposals for reform and state whether they are likely to come into force and, if so, when.

Regulation

The Medicines and Medical Devices Regulatory Authority Bill has recently been tabled. This Bill, when enacted, will completely repeal the Medicines Act and replace the Council with the Medicines and Medical Devices Authority. The Bill provides much more extensively for the regulation of medicines, related substances and complementary medicines. There is, however, currently no indication when (or indeed if) this Bill will be enacted.

Advertising

It is envisaged that a South African Code of Practice for the Marketing of Medicines will be established under the Medicines Act, to be enforced both by a Marketing Code Authority and on a self-regulatory basis. The draft code (5 February 2010) is available at: www.piasa.co.za/downloads/Draft%20SA%20Code%20Marketing%20Medicines%20approved%20by%20all%20associations%205%20February%202010%20v.2.pdf.

Regulations relating to complementary and alternative medicines are also being considered. Draft regulations to the Medicines Act, intended to regulate complementary and alternative medicines, were published in 2008 for comment. These regulations are not yet in force, and there is no indication of when they are likely to be implemented.



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Qualified. South African Registered Patent Attorney, 1987

Areas of practice. High Court litigation with emphasis on pharmaceutical and chemical patents; case management in those areas.

Recent transactions

Advising multinational pharmaceutical clients on potential patent infringement and validity proceedings in conjunction with European and US counsel to co-ordinate parallel actions.

- Eli Lilly v Pfizer in relation to the "VIAGRA" patent in South Africa.
- Sanofi-Aventis v Cipla Medpro in relation to the "TAXOTERE" patent in South Africa.
- Eli Lilly v Cipla Medpro in relation to the "ZYPREXA" patent in the Republic of South Africa.



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Qualified. Attorney of the High Court. Qualified trade mark practitioner, 2005.

Areas of practice. High Court litigation with emphasis on unlawful competition, passing-off, trade mark infringement and trade mark cancellation matters; trade mark opposition and cancellation matters before the Registrar of Trade Marks; domain name disputes; and corporate name objections.

Recent transactions

Advising local and multinational clients on trade mark infringement, cancellation and opposition proceedings and numerous domain name disputes.

- Minister of Trade and Industry v E L Enterprises (193/10) [2010] before the Supreme Court of Appeal concerning the interpretation of a section in the Counterfeit Goods Act.
- An order for the transfer of the domain name hotelmissoni.co.za to Missoni S.p.A - Decision No. ZA 2010-0047.
- Successful represented Greengrass Productions, Inc (a Disney affiliate) in an opposition to the registration of the EXTREME MAKEOVER logo trade mark in the name of You Can Win Club CC.



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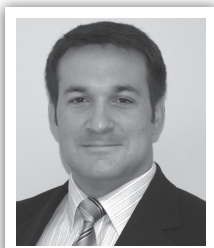
Qualified. South African Registered Patent Attorney, 1965

Areas of practice. Patents; industrial designs; copyright (with particular emphasis on pharmaceutical patents, international intellectual property developments, drafting, and interpretation of legal instruments in the intellectual property field).

Recent transactions

Assessing and advising on legal developments, both national and international, and drafting legal instruments in the area of intellectual property, including:

- WTO/TRIPS Agreement on Intellectual Property and its implementation in developing countries.
- Draft legislation to protect Traditional Knowledge.
- Draft Intellectual Property legislation (for neighbouring country).
- WTO/GATS Agreement on Services and its implementation in regard to legal services in Southern African region.



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Areas of practice. Patent drafting and prosecution; opinions in chemical engineering and chemical areas.

Recent transactions

Handling the international portfolios of several leading South African companies and research institutes.