

GOVERNMENT NOTICES

DEPARTMENT OF HEALTH

No. R. 586

22 July 2011

MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965)

REGULATIONS RELATING TO MEDICAL DEVICES

The Minister of Health intends, in terms of section 35 of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) ("the Act"), in consultation with the Medicines Control Council, to make the regulations in the Schedule.

Interested persons are invited to submit any substantiated comments or representations in writing on the proposed regulations to the Director-General: Health, Private Bag x828, Pretoria, 0001 within three months from date of publication of this notice.

SCHEDULE

Definitions

1. In this Schedule, and any word or expression to which a meaning has been assigned in the Act shall have that meaning, and unless the context otherwise indicates—

"abbreviated assessment" means the assessment by the Council of a medical device that is already registered by a regulatory authority outside the Republic;

"Act" means the Medicines and Related Substances Act, Act No 101 of 1965, as amended;

"appropriately qualified person" means a person in possession of qualifications recognised by the Council as relevant to medical devices and

includes clinical engineers, biomedical engineers, technicians, pathologists and medical physicists;

“assessment” means the establishment by the Council of conformity of medical devices to standards of safety, quality and performance as determined by the Council;

“authorised representative” means a person designated in writing by a manufacturer or importer to represent that manufacturer or importer with regard to that manufacturer or importer’s obligations under these regulations;

“custom made medical device” means a medical device made in accordance with a prescription by a qualified health care professional;

“health establishment” means a health establishment as defined under section 1 of the National Health Act, 2003 (Act No. 61 of 2003);

“instructions for use” means information provided by the manufacturer on the proper use of a medical device or any precautions to be taken in respect thereof;

“reagent” means chemical, biological or immunological components, solutions or preparations intended by the manufacturer to be used as medical devices;

“unique identification number” means a number used by the Council to identify a medical device; and

“user error” means an act that has a different result than that intended by the manufacturer or different than that expected by the operator.

Categories of medical devices

2. The following are categories of medical devices:

- (a) Category C1: non-invasive medical devices which do not penetrate the body;
- (b) Category C2: invasive medical devices that in whole or in part, penetrate the body, either through a body orifice or through the surface of the body;
- (c) Category C3: active medical devices whose operation depend on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting energy;
- (d) Category C4: combination medical devices that incorporate, as an integral part, a substance which, if used separately, can be considered to be a medicine, and which act on the human body with action ancillary to that of the medical device;
- (e) Category C5: medical devices that are manufactured from or incorporating animal or human cell, tissue or derivative thereof;
- (f) Category C6: medical devices used for sterilizing or disinfecting other medical devices;
- (g) Category C7: medical devices used for contraception or the prevention of the transmission of sexually transmitted diseases; and
- (h) Category C8: *in vitro* diagnostic medical devices which, whether used alone or in combination, are intended by the manufacturer for the *in vitro* examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

Classes of medical devices

3. (1) Medical devices are classified as low risk, low moderate risk, moderate high risk and high risk.

- (2) The Minister may, by notice in the Gazette, determine further classes of medical devices.

Prohibition on sale of medical devices which are subject to registration and are not registered

4. (1) No person shall sell any medical device which is subject to registration by virtue of a resolution published in terms of subregulation (2) unless it is registered.
- (2) The Council may from time to time by resolution determine that a medical device or category or class of medical devices mentioned in the resolution shall be subject to registration in terms of these regulations.
- (3) Any such resolution shall be published in the Gazette by the Registrar and shall come into operation on a date specified in that notice.

Registration of medical devices

5. (1) An application for the registration of a medical device shall be submitted on the form determined by the Council.
- (2) Such an application shall be accompanied by an application fee prescribed by the Minister.
- (3) If after the consideration of the application the Council is satisfied that the medical device is safe, of good quality and performs as intended, the Council shall approve the registration of such medical device.
- (4) Registration under subregulation (3) may be made subject to conditions as may be determined by the Council to ensure the safety, quality and efficacy of the medical device.
- (5) The Council may, for the purposes of considering an application as contemplated in subregulation (3), subject a medical device to an assessment or abbreviated assessment process.

(6) The Council may require, in relation to an application, the submission of-

- (a) samples of the medical device for testing purposes;
- (b) brochures or technical documentation; or
- (c) any other material relating to the medical device.

(7) Custom-made medical devices are not subject to registration, but are subject to post-marketing surveillance including adverse event monitoring.

(8) When the Council has approved the registration of a medical device, the Registrar shall register such medical device and enter into the register such particulars as may required in terms of these regulations and shall issue to the applicant a certificate of registration in the form as determined by the Council.

(9) A register for medical devices shall include the following information with regard to a medical device:

- (a) name and address of the applicant;
- (b) name of manufacturer or importer;
- (c) address of manufacturer or importer;
- (d) name of the medical device;
- (e) unique catalogue, list or product number;
- (f) number according to an internationally recognised device nomenclature system as approved by the Council;
- (g) category and class of medical device;
- (h) brief description of the medical device and its use; and
- (i) any other information that the Council may deem fit.

(10) The certificate contemplated in subregulation (8) shall include the following information:

- (a) name and address of applicant;
- (b) name and address of manufacturer;
- (c) authorised representative of the applicant;
- (d) name of medical device, its description and purpose;
- (e) registration number;
- (f) unique identification number, where practicable;

- (g) number according to an internationally recognised device nomenclature system as approved by the Council;
- (h) category and class of medical device; and
- (i) date of issue of the certificate.

(11) The Registrar shall as soon as possible publish in the Gazette the details of medical devices registered during that year.

Notification of medical devices available on the market

6. (1) Manufacturers, importers or their authorised representatives shall, in respect of their medical devices that are available on the market in the Republic at the time of commencement of these regulations, within a period of two years, notify the Registrar of such availability by submitting the following information:

- (a) name of manufacturer or importer;
- (b) address of manufacturer or importer;
- (c) name of medical device;
- (d) unique identification number, where practicable;
- (e) number according to an internationally recognised device nomenclature system as approved by the Council;
- (f) category or class of medical device; and
- (g) brief description of the medical device and its use.

(2) The Registrar shall allocate a notification number for a medical device in respect of which information referred to in subregulation (1) has been submitted.

(3) Notification referred to in subregulation (1) is not registration as contemplated in regulation 4.

(4) Notwithstanding subregulation (1) the Council may require a medical device to comply with any requirements that the Council may determine in order to ensure that the medical device is safe and of good quality.

Combination devices

7. A medical device that has a medicinal component in it is subject to these regulations only in respect of its component that is not a medicinal component and its medicinal component shall be dealt with as a medicine. .

Amendments and update of registration

8. (1) The particulars of registration may on application by the holder of a certificate of registration be amended by the Registrar with the approval of the Council.

(2) The application referred to in subregulation (1) shall be accompanied by an application fee as determined by Council.

Transfer of certificate of registration or licence

9. A certificate of registration or licence contemplated in regulation 10 may with the approval of the Council be transferred by the holder thereof upon application accompanied by an application fee as determined by Council to another person.

Licensing of manufacturers, exporters and importers

10. (1) The Council shall upon application accompanied by an application fee as determined by the Council, issue a licence to a manufacturer, exporter, importer or distributor of a medical device if the Council is satisfied that the manufacturing, exportation or importation of the medical device is in accordance with the good manufacturing, exportation or importation practice as determined by the Council.

(2) An application referred to in subregulation (1) shall include the following information:

- (a) an indication of whether the applicant for licence is a manufacturer, an importer or a distributor;
- (b) the name and contact details of the place of business of the applicant for licence;
- (c) the name of an authorised representative;

(d) where the applicant for licence has contracted another party to apply for a licence on its behalf, the name and contact details of the place of business of that other party; and

(e) any other information as may be deemed necessary by the Council.

(3) Notwithstanding subregulation (1), a manufacturer, importer and distributor shall have a period of two years from the date of commencement of these regulations to obtain a licence.

(4) A licence issued under this regulation shall be valid for a period of five years and may be renewed upon payment of a renewal application fee as determined by the Council.

(5) No manufacturer, importer or distributor of a medical device shall, after two years from the date of commencement of these regulations, manufacture, import or distribute a medical device without a licence contemplated in subregulation (1).

Duties of licence holders

11. A person issued with a licence in terms of regulation 10 shall-

- (a) ensure that an instruction manual is made available with each and every medical device sold;
- (b) ensure that each medical device sold is labelled in accordance with these regulations and has instructions for use containing information as determined by Council including side-effects, contra-indications, warnings, and after-care maintenance; and

comply with good manufacturing practice.

Cancellation of registration or licence

12. The Council may order the Registrar to cancel the registration of a medical device issued in terms of regulation 10-

- (a) in case of non-compliance with these regulations or licence conditions; or

- (b) as a result of negative post market surveillance reports or misleading advertisements.

Advertisements and promotion

13. (1) Only registered medical devices or medical devices in respect of which notification in terms of regulation 6 was made may be advertised or promoted.

- (2) The Council may by notice in the Gazette prohibit or restrict the advertisement and promotion of certain medical devices to the general public.
- (3) No advertisement or promotion may contain a claim, statement or any other content which deviates from or is in conflict with the evidence submitted in the application for registration or which cannot be substantiated.
- (4) A written advertisement for a medical device shall contain-
 - (a) the name of the medical device;
 - (b) its description;
 - (c) the registration number allocated to it;
 - (d) the licence holder's contact information; and
 - (e) the intended use of the medical device.

Labelling and instructions for use

14. (1) The labelling and instructions for use for medical devices shall be in at least English.
- (2) The format, content and location of the label shall be appropriate to the particular device and its intended use.
 - (3) The label of a medical device shall, where practical, include-
 - (a) its name;
 - (b) a code linking the medical device to a number according to an internationally recognised device nomenclature system;
 - (c) a serial number, batch number and material number affixed to it; and
 - (d) its expiry date.

- (4) If labelling on each medical device is not practicable, the information shall be set out in the leaflet, package insert or other information supplied with, or applicable to, one or multiple devices.
- (5) Instructions for use shall-
- (a) make clear the intended use of the medical device;
 - (b) be in plain language and, where appropriate, supplemented with drawings and diagrams so that persons reading the instructions are appropriately informed;
 - (c) in the case of low or moderate risk medical devices, be abbreviated if they can be used safely and as intended without any such instructions;
 - (d) include a clear indication of any requirement for special facilities, special training, or particular qualifications to use it;
 - (e) contain warnings about foreseeable user error or possible harm and severity that could result from such user error and include recommended corrective action;
 - (f) have sufficient details for the person using the medical device to identify it;
 - (g) where applicable, provide for the expiry date;
 - (h) where applicable, provide for special storage or handling conditions at the appropriate packaging level;
 - (i) provide for warnings, precautions, limitations or contra-indications;
 - (j) in the case of reusable devices, provide information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of de-contamination and any restriction on the number of reuses; and
 - (k) comply with any other requirement set from time to time by the Council.

Importation or exportation of medical devices

15. (1) A person may export medical devices at any port of exit but shall only import medical devices through any of the following ports of entry —

- (a) Cape Town Airport or harbour;
- (b) Port Elizabeth Airport or harbour;
- (c) King Shaka International Airport or Durban harbour; and
- (d) OR Tambo International Airport.

(2) A person shall only import or export-

(a) a medical device if such person is in possession of license issued in terms of regulation 10 and the medical device is registered in the Republic;

(b) an unregistered medical device if such person has been specially authorised by the Council.

Post marketing surveillance

16. (1) A licence holder shall have in place a post-marketing surveillance system.

(2) A person using a medical device shall report to the Council or head of a health establishment any adverse event within 24 hours after being aware of such adverse event.

Recall of medical devices

17. (1) The Council may, on the basis of an adverse event report it received in terms of regulation 15, recall a medical device.

(2) No person shall sell a medical device that has been recalled in terms of subregulation (1).

(3) A licence holder shall inform the Council of recalls of its medical devices that occurred outside the Republic.

Disposal of medical devices

18. The head of a health establishment, a person using a medical device or licence holder shall ensure that the disposal of a medical device is, where applicable, done in accordance with manufacturer's instructions.

Persons using medical devices in health establishments

19. (1) The head of any health establishment must ensure that persons who are employed at such health establishment and who use medical devices are appropriately trained and competence to operate, use or otherwise deal with such medical devices.

- (2) The head of a health establishment shall ensure that any patient using a medical device at that health establishment is appropriately informed to use such medical device.

Duties of the heads of health care facilities

20. The head of a health establishment shall ensure that-

- (a) medical devices are used safely;
- (b) adverse events are reported as required;
- (c) medical devices are maintained according to the manufacturer's instructions;
- (d) a procedure for reporting complaints relating to the use of medical devices is in place;
- (e) a record is kept of-
 - (i) medical devices service and repairs history;
 - (ii) staff training records; and
 - (iii) adverse event reports.

Used or refurbished medical devices

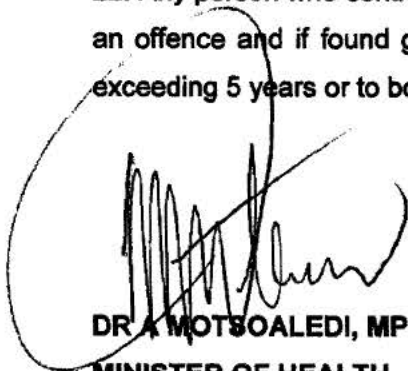
21. (1) A person selling a used or refurbished medical device shall-

- (a) provide the purchaser with a maintenance history of the medical device; and
- (b) when required, perform all the tests required by the purchaser or the Council in order to ensure proper functioning of the device.

- (2) The Council may from time to time publish guidelines in relation to the acquisition, use and safety of used or refurbished devices.

Offences

22. Any person who contravenes the provisions of these regulations shall be guilty of an offence and if found guilty, be liable to a fine or imprisonment for a period not exceeding 5 years or to both fine and such imprisonment.



DR A MOTSOALETSI, MP
MINISTER OF HEALTH