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DEPARTMENT OF HEALTH

NO. R. 2295 **21 July 2022**

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

REGULATIONS MADE IN TERMS OF THE MEDICNES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965: AMENDMENT

The Minister of Health has, in terms of section 35 of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), and in consultation with the South African Health Products Regulatory Authority (SAHPRA), made the regulations in the Schedule.

Interested persons are invited to submit any substantiated comments or representations on the proposed regulations, to the Director-General of Health, Private Bag X828, Pretoria, 0001 (for the attention of the Director: Public Entities and Relations Management, mihloti.mushwana@health.gov.za), within one month of the date of publication of this Notice.

DR M.J. PHAAHLA, MP
MINISTER OF HEALTH
DATE: 23/06/2022

SCHEDULE

Definitions

1. In these Regulations any word or expression to which a meaning has been assigned in the Act, has the meaning so assigned, and unless the context otherwise indicates—

"the Act" means the Medicines and Related Substances Act, 1965 (Act 101 of 1965); and

"the Regulations" means the General Regulations as published under Government Notice 859 in *Government Gazette* 41064 of 25 August 2017.

Amendment of regulation 1 of the Regulations

2. Regulation 1 of the Regulations is hereby amended by the substitution for the definition of "compounding" of the following definition:

"compound" means the preparation, mixing, combining, packaging and labelling of a medicine—

(a) by a pharmacist, pharmacist intern or pharmacist's assistant practising in accordance with the Pharmacy Act, 1974 (Act No. 56 of 1974);

(b) by a veterinarian practising in accordance with the Veterinary and Para-Veterinary Professions Act, 1982; or

(c) by a person licensed in terms of section 22C(1)(a) of the Act and practising in accordance with their scope of practice;"

Amendment of regulation 3 of the Regulations

3. Regulation 3 of the Regulations is hereby amended —

(1) by the substitution for sub-regulation (1) of the following sub-regulation:

"(1A) A pharmacist compounding a medicine for sale in terms of section 14(4)(a) of the Act—

(a) must only compound a quantity that is intended to be used by a particular patient—

(i) for not more than 30 consecutive days from the date of compounding: Provided that the date of compounding and the statement "Use within 30 days" are clearly indicated on the label; or

(ii) in accordance with good compounding practice as determined by the Authority; and

(b) may, based on the amount of medicine compounded previously for a particular patient, compound such medicine in anticipation of supply thereof to such patient.

(1B) A pharmacist compounding a medicine for sale in terms of section 14(4)(b) of the Act—

(a) must only compound a quantity that is intended for sale in the retail trade, or in accordance with a prescription for a particular person, animal, or group of animals—

(i) for not more than 30 consecutive days from the date of compounding: Provided that the date of compounding and the statement "Use within 30 days" are clearly indicated on the label; or

(ii) in accordance with good compounding practice as determined by the Authority;

(b) may, in the case of medicine intended for sale in the retail trade, based on the amount of such medicine compounded previously for a particular period, compound such medicine in anticipation of supply thereof within such period; and

(c) may, based on a history of receiving a prescription for a medicine for a particular person, animal, or group of animals, compound such medicine in anticipation of receipt of the required prescription and thereafter supply the medicine upon receipt of the prescription.

(1C) A veterinarian compounding a medicine for sale in terms of section 14(4)(a) of the Act—

(a) must only compound a quantity that is intended to be used for a particular animal or group of animals—

(i) for not more than 30 consecutive days from the date of compounding: Provided that the date of compounding and the statement "Use within 30 days" are clearly indicated on the label; or

(ii) in accordance with good compounding practice as determined by the Authority; and

(b) may, based on the amount of medicine compounded previously for a particular animal or group of animals, compound such medicine in anticipation of supply thereof to such animal or group of animals.

(1D) A person licensed in terms of section 22C(1)(a) of the Act to compound a medicine for sale in terms of section 14(4)(a) of the Act—

(a) must only compound a quantity that is intended to be used by a particular patient —

(i) for not more than 30 consecutive days from the date of compounding: Provided that the date of compounding and the statement "Use within 30 days" are clearly indicated on the label; or

(ii) in accordance with good compounding practice as determined by the Authority; and

(b) may, based on the amount of medicine compounded previously for a particular patient, compound such medicine in anticipation of supply thereof to such patient."

(2) by the deletion of paragraph of sub-regulation (3)(a).

(3) by the substitution for paragraph (*b*) of sub-regulation (3) of the following paragraph:

"(b) which has been declared undesirable in terms of section 23 of the Act or prohibited in terms of section 36A of the Act in the case of a veterinary medicine;

(4) by the substitution for paragraph (*f*) of sub-regulation (3) of the following sub-paragraph:

"(f) for purpose of export, unless:

(i) authorised in terms of the Pharmacy Act, 1974; and

(ii) where applicable, is the holder of a permit issued in terms of section 22A(7)(a) and/or 22A(11)(a) of the Act; or"

(5) by the insertion in paragraph (*g*) after the expression "in accordance with good", of the word "compounding".

(6) by the insertion after sub-regulation (3) of the following sub-regulation:

"(4) The Authority must, within six months of promulgation of these Regulations publish draft guidelines on good compounding practice for public comment."

Short title

4. These Regulations are called Regulations Made in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965: Amendment.

SUBJECT: PUBLICATION FOR COMMENTS OF THE GENERAL REGULATIONS MADE IN TERMS OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965): AMENDMENT

35 Regulations

(1) The Minister may, in consultation with the council, make regulations-

(i) prescribing the categories of persons by whom application may be made for the registration of any medicine or to whom a certificate of registration may be transferred;

(ii) prescribing the forms which shall be used for any application for the registration of any medicine and the particulars which shall be furnished with any such application (including particulars regarding the method by which the medicine in question or any component of such medicine is manufactured and the premises at which such medicine or any such component is manufactured);

(iii) providing for the classification of medicines into classes or categories for the purposes of this Act;

(iv) prescribing the samples of any medicine and the quantity thereof which shall accompany any application for the registration of a medicine;

(v) prescribing the form in which the medicines register shall be kept and the particulars which shall be entered therein in respect of any registered medicine;

(vi) prescribing the form of any certificate of registration of any medicine;

(vii) prescribing the circumstances in which, the conditions on which and the persons or categories of persons to whom any medicine or Scheduled substance may be sold;

(viii) prescribing the manner in which any package containing any medicine or Scheduled substance shall be labelled, packed or sealed;

(ix) prescribing the particulars in regard to the use thereof which shall be furnished with any medicine or Scheduled substance sold, and the manner in which such particulars shall be furnished;

(x) prescribing the particulars which shall appear in any advertisement relating to any medicine or Scheduled substance, or prohibiting the inclusion of any specified particulars in such advertisement, or the distribution of any such advertisement to a specified person or a specified category of persons or to a specified organisation or a specified category of organisations;

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(xi) prescribing the requirements with which any medicine or any component thereof shall comply in regard to composition, therapeutic suitability and effect, purity or any other property;

(xii) prescribing the particulars which shall be published in the Gazette in respect of any application for registration referred to in section 15 (11);
[NB: Para. (xii) has been substituted by s. 41 (b) of the Medicines and Related Substances Amendment Act 72 of 2008, a provision which will be put into operation by proclamation. See PENDLEX.]

(xiii) prescribing the procedure at meetings of the council and of any committee appointed under section 9 (including the quorum in the case of committees) and the manner in which meetings of any such committee shall be called;
[NB: Para. (xiii) has been substituted by s. 41 (c) of the Medicines and Related Substances Amendment Act 72 of 2008, a provision which will be put into operation by proclamation. See PENDLEX.]

(xiv) prescribing the particulars which shall appear on a prescription or an order for a medicine or a Scheduled substance, the number of issues of a medicine or a Scheduled substance that may be made on any such specified prescription or order, the manner in which any such prescription or order shall be issued and the period for which any such prescription or order shall be retained;

(xv) prescribing the forms of licences, registers, prescription books, records and other documents which shall be kept or used in respect of Scheduled substances, the manner in which they shall be kept, the particulars which shall be entered therein and the place where and the period for which they shall be retained;

(xvi) requiring the furnishing of returns, reports and information in respect of Scheduled substances and plants from which any such substance can be extracted, derived, produced or manufactured, and in respect of any medicine or other substance of which any such Scheduled substance is a component;

(xvii) as to the transhipment or the exportation from or importation into the Republic of any Scheduled substance, specifying the ports or places at which such substance may be brought into the Republic;

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(xviii) authorising and regulating or restricting the transmission through the Republic of Scheduled substances;

(xix) prescribing the manner in which packages containing Scheduled substances shall be labelled when imported into or manufactured in the Republic and the persons by whom and the manner in which they shall be kept;

(xx) authorising and regulating the purchase, acquisition, keeping or use of preparations of cocaine by managers or persons in charge of factories or workshops in connection with the treatment of eye injuries or for other essential purposes;

(xxi) authorising and regulating the purchase, acquisition, keeping or use of Scheduled substances by particular persons or categories of persons;

(xxii) authorising and regulating the possession by persons entering or departing from the Republic of specified quantities of Scheduled substances for personal medicinal use;

(xxiii) as to the disposal or destruction of a medicine or a Scheduled substance, and the records which shall be kept in respect thereof;

(xxiv) as to the importation, exportation, conveyance, keeping, storage, processing and packing of medicines and Scheduled substances, and the manner in which medicines and Scheduled substances shall be kept and controlled in different categories of hospitals;

[Para. (xxiv) substituted by s. 12 (a) of Act 59 of 2002.]

(xxv) prescribing the methods in accordance with which samples may be taken under this Act and the form of the certificates to be issued by inspectors in respect of such samples;

(xxvi) prescribing the methods to be employed and the form of the certificates to be issued in connection with the testing, examination or analysis of samples taken under this Act;

(xxvii) authorizing, regulating, controlling, restricting or prohibiting the registration, manufacture, modification, importation, exportation, storage, transportation, sale or use of any medical device or class of medical devices or medicines in respect of its safety, quality and efficacy;

[Para. (xxvii) substituted by s. 12 (b) of Act 59 of 2002.]

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(xxviii) with regard to any matter to ensure the safety, quality and efficacy of medicines and medical devices;

(xxix) as to the summary seizure and disposal of any Scheduled substance found in the possession or custody of any person not entitled under this Act to keep or use it;

(xxx) as to the disposal or destruction of a Scheduled substance which has become unfit for use, and the report to be furnished in respect thereof;

(xxxi) prescribing the fee to be paid to the registrar in respect of an application for the registration, and in respect of the registration of a medicine, Scheduled substance or medical device, the fee to be paid annually to the registrar in respect of the retention of the registration of a medicine, Scheduled substance or medical device and the date on which such annual fee shall be paid;

[NB: Para. (xxxi) has been substituted by s. 41 (d) of the Medicines and Related Substances Amendment Act 72 of 2008, a provision which will be put into operation by proclamation. See PENDLEX.]

(xxxii) prescribing the fee payable in respect of the authorisation of the use of unregistered medicines, the issuing of permits and certificates under this Act, the issuing or renewal of any licence under this Act, the performance of inspections to assess the quality of medicines, Scheduled substances or medical devices for the purpose of registration and the evaluation of changes to the particulars contained in registers;

(xxxiii) relating to appeals against decisions of the Director-General or the council;

[NB: Para. (xxxiii) has been substituted by s. 41 (e) of the Medicines and Related Substances Amendment Act 72 of 2008, a provision which will be put into operation by proclamation. See PENDLEX.]

(xxxiv) relating to the conditions under which medicines or Scheduled substances may be sold;

(xxxv) relating to the repackaging of medicines in patient-ready packs;

(xxxvi) relating to the safety, quality and efficacy of any interchangeable multi-source medicine;

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(xxxvii) relating to the scientific, pharmaceutical, clinical and other skills required by a member of the council or by a member of the executive committee of the council to evaluate the quality, efficacy and safety of medicines;
[NB: Para. (xxxvii) has been substituted by s. 41 (f) of the Medicines and Related Substances Amendment Act 72 of 2008, a provision which will be put into operation by proclamation. See PENDLEX.]

(xxxviii) relating to the safety, quality and efficacy of imported medicines;

(xxxix) relating to the control and conduct of clinical trials;
[NB: Paras. (xl), (xli), (xlii) and (xliii) have been inserted and paras. (xl) and (xli) have been renumbered by s. 41 (g) of the Medicines and Related Substances Amendment Act 72 of 2008, a provision which will be put into operation by proclamation. See PENDLEX.]

(xl) with regard to any matter which in terms of this Act shall or may be prescribed; and

(xli) generally, for the efficient carrying out of the objects and purposes of this Act, and the generality of this provision shall not be limited by the preceding paragraphs of this subsection.
[NB: Sub-s. (1) has been amended by s. 41 (a) of the Medicines and Related Substances Amendment Act 72 of 2008, a provision which will be put into operation by proclamation. See PENDLEX.]

(2) The Minister shall, not less than three months before any regulation is made under subsection (1), cause the text of such regulation to be published in the Gazette, together with a notice declaring his or her intention to make that regulation and inviting interested persons to furnish him or her with any comments thereon or any representations they may wish to make in regard thereto.

(3) The provisions of subsection (2) shall not apply in respect of-

(a) any regulation which, after the provisions of that subsection have been complied with, has been amended by the Minister in consequence of comments or representations received by him or her in pursuance of the notice issued thereunder; or

(b) any regulation in respect of which the Minister is, after consultation with the council, of the opinion that the public interest requires it to be made without delay.

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[NB: Para. (b) has been substituted by s. 41 (h) of the Medicines and Related Substances Amendment Act 72 of 2008, a provision which will be put into operation by proclamation. See PENDLEX.]

(4) A regulation under subsection (1) (xxxi) and (xxxii) shall be made only in consultation with the Minister of Finance.

(5) Regulations made under subsection (1) (xi) may prescribe that any medicine or any component thereof shall comply with the requirements set out in any publication which in the opinion of the council is generally recognised as authoritative.

[NB: Sub-s. (5) has been substituted by s. 41 (i) of the Medicines and Related Substances Amendment Act 72 of 2008, a provision which will be put into operation by proclamation. See PENDLEX.]

(6) Regulations may be made under this section in respect of particular medicines or Scheduled substances or classes or categories of medicines or Scheduled substances or in respect of medicines or Scheduled substances other than particular classes or categories of medicines or Scheduled substances, and different regulations may be so made in respect of different medicines or Scheduled substances or different classes or categories of medicines or Scheduled substances.

[NB: Sub-s. (6) has been substituted by s. 41 (j) of the Medicines and Related Substances Amendment Act 72 of 2008, a provision which will be put into operation by proclamation. See PENDLEX.]

(7) (a) Regulations made under this section may prescribe penalties for any contravention thereof or failure to comply therewith of a fine, or imprisonment for a period not exceeding 10 years.

(b) Notwithstanding anything to the contrary in any law contained a magistrate's court shall be competent to impose any penalty provided for in paragraph (a).

(8) Notwithstanding the provisions of subsection (1), the Minister may, if he or she deems it to be in the public interest, after consultation with the executive committee appointed under section 9, make regulations relating to any matter referred to in subsection (1) or amend or repeal any regulation made in terms of that subsection.

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[NB: Sub-s. (8) has been substituted by s. 41 (k) of the Medicines and Related Substances Amendment Act 72 of 2008, a provision which will be put into operation by proclamation. See PENDLEX.]

[S. 35 amended by s. 5 of Act 29 of 1968, by s. 1 of Act 88 of 1970, by s. 7 of Act 95 of 1971, by s. 3 of Act 19 of 1976, by s. 14 of Act 17 of 1979, by s. 7 of Act 20 of 1981, by s. 7 of Act 71 of 1991 and by s. 16 of Act 94 of 1991 and substituted by s. 31 (1) of Act 65 of 1974 and by s. 23 of Act 90 of 1997.]

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