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SOUTH AFRICAN VETERINARY COUNCIL

HOW DO I ...

deal with scheduled medicines, dispensing and compounding?

19 March 2024 Presenter: Dinamarie Stoltz

Background

- Scheduled medicines-regulated by Medicines & Related Substances Act, Act 101/1965 (Act 101)
- Stock remedies - regulated by Fertilizers, Farm Feeds, Agricultural Remedies & Stock Remedies Act 36/1947
- Veterinary rules- drafted to ensure compliance with compliance with Act 101 – protect veterinarians to not inadvertently fall foul of Act
- As a professional - cannot say I did not know - expected to know rules and relevant legislation.

Rule 10

- **10. Use of veterinary medicine**

(1)Whenever a veterinary professional, administers medicine to an animal or prescribes the administering thereof, he/she must satisfy himself that the administering thereof is justified with due allowance for the benefits and risks which that medicine may hold for –

(a)The animal to which it is administered, including withdrawal times of residues where relevant in the animal and/or the effect on the environment;

Rule 10

(a) The person by whom it is administered; and

(b) The consumer of the products of that animal if residues of the medicine concerned should be present in those products.

(2) To tranquilise, sedate, chemically immobilise or anaesthetise wildlife, any schedule 5 or 6 medicine to be administered parenterally, must be administered by a veterinary professional personally.

Rule 10

(3) Notwithstanding the provisions of 10(2) a veterinary professional may prescribe, sell, or dispense the following substance(s) or medicine(s) to a client within a 'client-patient-veterinarian' relationship for the purposes of the treatment of a specified patient on condition that the requirements of the Medicines Act are complied with and said substance/medicine may only be made available for a reasonably acceptable period, but in any event for no longer than thirty (30) days consecutive treatment at a time:

Rule 10

(a) Perphenazine enanthate;
(b) Haloperidol;
(c) Zuclopenthixol acetate;
(d) Diazepam; and/or
(e) Azaperone.

Rule 10

(4) A veterinary professional must inform the owner of an animal to which medicine is administered, fully with regard to -

(a) The application and effect of and precautionary measures in connection with that medicine;

(b) The period, if any, during which the products of that animal are to be withheld from human consumption; and

(c) The period, if any, (also referred to as the detection time) during which the animal should not be entered for sports competitions where prohibited substance rules apply.

Rule 10

(5) When using or prescribing a medicine that has been compounded, veterinarians must comply with the following:

(a) Ensure that a suitable registered veterinary medicine or any combination of such medicines, as defined in the Medicines Act, or stock remedy, as defined in the Stock Remedy Act, or any relevant Act it may be substituted with, is not available for sale within the Republic of South Africa in a suitable size, volume and concentration; including extra-label medicine use;

Rule 10

b) Ensure that where there is no registered veterinary medicine available, a veterinarian may only compound medicine in a quantity not greater than the quantity required for treatment of the patient for a period of not more than 30 days;

c) Ensure that the preparation labelling of the medicines is done in labelling in accordance with Rule 21(4)(l);

Rule 10

(d) Ensure that there is a documented system for compounding in place and inform the Council, on its request, on the therapeutic efficacy and effect of such compounded medicine, the purpose and circumstances under which and the manner in which such compounded medicine should be used;

(e) Ensure that a compounded product does not contain substances as prohibited in terms of Section 36A of the Medicines Act in South Africa;

Rule 10

(f) Ensure that the purity of the medicines is guaranteed by procuring such medicines from a manufacturer(s) accredited for Good Manufacturing Practice, should the veterinarian personally compound the medicines;

(g) Should the compounding of medicines be outsourced to a third party, the veterinarian must make use of a registered compounding facility with the correct licensing to perform such compounding, who can contractually guarantee the purity of the ingredients, and must issue the third party with a compounding order specifying the product, quantity, packaging and labelling;

Rule 10

(h) Retain full responsibility for the product even when it is compounded by a third party, unless such third party commits a manufacturing error;

(i) Comply with all aspects of Section 22A of the Medicines Act;

(j) Ensure that the compounded products are not advertised or promoted as veterinary medicine trade name products or displayed for sale to the general public;

Rule 10

(k) The use of compounded medicine is not intended to circumvent the registration requirements of the Medicines Act and/or the Stock Remedy Act;

(l) Inform the owner of the lack of quality control and possible deficiencies in efficacy of the compounded product;

Rule 10

(m) Ensure that compounding is not done in the absence of a 'veterinarian-client-patient' relationship; and/or

(n) No compounded veterinary medicines or actives may be imported without approval from the Medicines Control Council.

Note: No compounded medicines may be exported

Rule 10

(6) A veterinarian may only use compounded veterinary medicine for a food producing animal(s), including wildlife intended for human consumption, subject to the following:

(a) The use of the compounded medicine is limited to the emergency management of a new disease/condition or the management of a disease/condition to which no local registered product exists, or is not readily accessible at the time, as restricted by the conditions in Rule 10(5)(a) to 10(5)(g) above;

Rule 10

b) The reason for compounding is not an attempt to enhance growth promotion in any food producing species in the absence of disease;

Rule 10

(a) The withdrawal period associated with its use as prescribed by the veterinarian must be approved in writing by the Food Safety and Security Committee of the Council or the Veterinary Clinical Committee of the Medicines Control Council, as the case may be, in accordance of the requirements of the Foodstuffs, Cosmetics and Disinfectants Act, Act 54 of 1972 or hundred and twenty (120) days, or otherwise ten times the half-life of the medicine, unless another withdrawal period is set by one of the two Committees;

Rule 10

b) The food produced by said animal is unsuitable for human consumption until such time that the withdrawal time is approved by either or both of the Committees listed in Rule 10(6)(c), unless any one of the conditions in Rule 10(6)(c) is met;

c) Medicines prohibited for use in food producing species as set out in Rule 10(11) may not be used in compounded medicines; and

Rule 10

(d) It is not intended for continued, sustained and/or frequent use on any one farm, by any one farm owner, by any one farm manager, by any one veterinarian or by any one person as this constitutes manufacturing, unless the use of the compounded medicine is reasonably justifiable and substantiated by facts.

(e) When a veterinarian compounds a veterinary medicine, it must be done from a registered suitable facility, unless the circumstances dictate otherwise.

Rule 10

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(7) When a veterinarian compounds a veterinary medicine, it must be done from a registered suitable facility, unless the circumstances dictate otherwise.

Rule 10

(8) A veterinarian may only compound, or have compounded on his/her behalf an autogenous vaccine, subject to the following:

(a) The veterinarian or third party contractor must be in possession of a permit in accordance with Section 20(b) of the Animal Diseases Act 1984, Act 35 of 1984;

(b) The production may only be undertaken or prescribed by a veterinarian for use in a particular patient in accordance with sections 14(4) and 22A(5)(e) of the Medicines Act;

Rule 10

c) An autogenous vaccine may only be used for a disease or strain of a disease for which there is no suitable veterinary vaccine or combination thereof registered and/or sold and/or available for sale in the Republic of South Africa;

d) The use of an autogenous vaccine is restricted to the specific farm where the infectious agent was identified. If grounds exist for the use of an autogenous vaccine on adjacent and non-adjacent farms, then an application in terms of section 20 of the Animal Diseases Act (Act 35 of 1985) must be submitted for approval;

Rule 10

e) In a disease outbreak situation the mass use of an autogenous vaccine may only commence in accordance with the requirements of section 20 of the Animal Diseases Act (Act 35 of 1985) and section 21 of the Medicines Act; and

f) The general sale of any autogenous vaccine to neighbouring farms or other districts/provinces must meet the requirements for general sale of a medicine in accordance with the Medicines Act and the Animal Diseases Act.

Rule 10

(9) If a veterinarian compounds a veterinary medicine, he/she must do so from a registered facility, suitable for compounding, unless the circumstances dictate otherwise.

(10) Extra label use: A veterinarian may use a registered medicine, veterinary medicine or stock remedy in a manner other than stated on the approved label or package insert, provided that there is justifiable reason for doing so. The veterinarian takes full responsibility for the supervision of the preparation, application and outcome of the application/administration of the said medicine, and …

Rule 10

10. ...and must be available to advise or intervene if there are any aberrant reactions to the said application/administration. If there is reason to expect any such aberrant reactions from the extra label use, the veterinarian must first explain his/her reasons to the client, and receive permission from the client to proceed.

Note: Keep permission on file or at least note it down in your clinical records.

Rule 10

(11) The following medicines are prohibited for use in food producing animals:

(a) Phenylbutazone;
(b) Chloramphenicol;
(c) Aristolochia spp. and preparations;
(d) Carbadox;
(e) Cefuroxime*;
(f) Chloroform;
(g) Chlorpromazine;

Section 34: Act 19/1982

- 34. **Dispensing of medicine**.—(1) A person who is registered or deemed to be registered in terms of this Act to practise a veterinary profession, may personally compound or dispense any medicine which is prescribed by himself or by any other person with whom he or she is in partnership or with whom he or she is associated as a principal or an assistant or a locum tenens, for use in the treatment of an animal which is under his or her professional care: Provided that he or she shall not be entitled to keep an open shop or pharmacy.

Section 34: Act 19/1982

- (2) A person referred to in subsection (1) shall not accept or obtain any commission or other reward from a pharmacist or other supplier in connection with medicine which is compounded or dispensed by virtue of a prescription.

Rule 21(4)

1) **Dispensary must comply with the following, which must be read in conjunction with the Medicines Act:**
   a) Must be a separate room dedicated to storage of medicines within practice;
   b) Application for temporary exemption from Rule 21(4)(a) may be submitted, provided that the application is fully substantiated.

Rule 21(4)

c) Medicine stored in cupboard in consulting room, following will apply:

i. All reference to temperature, climate control and practicality in Rules (d) to (r) below = equally apply to room in which cupboard is located;

ii. Cupboard = locked at all times when veterinarian is not present;

iii. Only schedule 2 to 4 medicines may be stored in cupboard. Schedule 5 and higher medicines = **locked in a safe**

iv. Amount of medicine stored = limited to two containers each of maximum of fifty medicines – to be removed next review of rules.

Rule 21(4)

d) Light conditions, temperature and humidity within dispensary or medicine room = comply with the requirements for storage of medicine, other pharmaceutical products, and packaging materials;

e) Working surface area in dispensary must be sufficient to accommodate volume of prescriptions dispensed;

f) All medicines must be stored at prescribed temperature;

g) Wash hand basin = accessible, which may be in another room;

h) No medicines may be stored on the floor;

Rule 21(4)

i) Schedule 5 and higher scheduled medicines = at all times under direct supervision of veterinary professionals and locked away in safe when veterinarian is not on premises;

j) Storage areas = large enough to allow orderly arrangement of stock and proper stock rotation;

k) Suitable means of counting tablets and capsules. This equipment must be cleaned regularly = avoid cross-contamination between products;

l) Refrigerator = accessible (even in another room): equipped with suitable thermometer and capable of storing medicines at temperatures 2°C - 8°C. Refrigerator = cleaned, defrosted and checked regularly = efficient running. Only pharmaceutical products;

Rule 21(4)

m) Suitable range of dispensing containers for medicine;

n) Dispensed medicines = sold, and correctly labelled in package containing the following information:

i. proprietary name, approved name, or name of each active ingredient of medicine, where applicable, or constituent medicine;

ii. name of the owner, as well as the name of the patient, if available, for whose treatment such medicine is sold;

iii. directions for the use of such medicine;

iv. name and business address of dispensing veterinarian; and

v. date of dispensing.

Rule 21(4)

o) Empty, time expired/or broken containers of medicines must be disposed of as legislated for dangerous substances in legislation controlling these substances;

p) Records of medicines purchased = kept for period of 5 years;

q) Receipt of medication for restocking of the dispensary = responsibility of veterinarian, and not lay persons at practice; and

r) Have access to pharmacological reference sources, and in case of compounding, access to protocols for compounding of medication.

Rule 13 - Advertising

13(3)

- An advertisement of Scheduled medicines must comply with Sections 18, 18A and 18B of the Medicines Act. Scheduled medicine may only be advertised to a person authorised to be in possession of the said schedule's medicine.
- In terms of the Medicines and Related Substances Act, Act 101 of 1965 - criminal offence to do so

Rule 15

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Requirements for prescriptions or orders for medicines

1) Every prescription, or order for medicine of Schedule 5 and higher = written in legible print, typewritten or computer generated + signed electronically in person by veterinarian + at least state the following:

   a) Name, qualification and registration number of veterinarian;

   b) Name, address, and registration number of facility involved;

   c) Name and address of person to whom the medicines are delivered;

Rule 15

d) Date of issue of the prescription or order;

e) Approved name or the proprietary name of the medicine;

f) Dosage form;

g) Strength of dosage form and quantity of medicine = supplied: Provided that in the case of Schedule 6 substances quantity must be expressed in figures + words: Provided further that where prescriber has failed to express quantity in figures + words, veterinarian or pharmacist dispensing medicine may, after obtaining confirmation from prescriber, insert words or figures omitted;

Rule 15

h) Prescription = instructions for administration of dosage, frequency of administration and withdrawal period in case of medicines for food producing animals;

i) Species, age and sex of patient, if applicable; and

j) Number of times the prescription may be repeated, with exception of Schedule 6 compounds - may not be repeated without re-consultation.

k) Electronic signature = document must be protected to prevent abuse of signature.

Rule 15

2) Veterinarian may not issue prescription to client on which name or address of pharmacist or pharmacy appears, except if using pre-printed prescription forms for ordering medicines scheduled in terms of Medicines Act from duly registered wholesaler.

3) Prescriptions must have unique number + must be issued in duplicate with copy attached to patient record and kept for period of five years.

4) Practices with electronic records must attach scanned copy of prescription to patient records = must be kept for period of five years.

Regulation 35: Act 101/1965

1) A prescription book or other permanent record in respect of Schedules 1, 2, 3, 4, 5 and 6 substances shall be kept in hard copy or electronically on all premises where such substances or medicines are sold or dispensed.

Note: Invoices can serve as a record

Regulation 36: Act 101/1965

Register for specified schedule 5 or schedule 6 medicines or substances

34.(1) Any-

(a) manufacturer, importer, exporter or wholesaler licensed in terms of section 22C(1*)(b)* of the Act selling specified Schedule 5 medicines or substances or Schedule 6 medicines or scheduled substances;

Regulation 36: Act 101/1965

b) person selling specified Schedule 5 medicines or substances, other than a community or institutional pharmacy, or a person licensed in terms of section 22C(1)(a); or

c) person selling Schedule 6 medicines or substances, shall keep a register of such medicines or substances.

Regulation 36: Act 101/1965

(2)The register referred to in subregulation (1) shall-

a) indicate the quantity of every such medicine or substance remaining in stock on the last day of March, June, September and December of each year; and

b) contain the following information:

(i) the date on which the medicine or substance was received or supplied;

Regulation 36: Act 101/1965

(i) the name, business address of the person from whom the medicine or substance was received or sent and in the case of imported medicine or substance, the import permit number;

(ii) the name and address of the person who purchased the medicine or substance;

Regulation 36: Act 101/1965

iv. the quantity, in words and figures, of such medicine or substance indicated per dosage unit, mass or volume;

v. in the case of the supply of the medicine or substance on prescription, the name and address of the authorised prescriber unless such prescription was issued at a hospital in which case the name of the authorised prescriber must be recorded;

Regulation 36: Act 101/1965

(i) in the case of the manufacturer, the quantity of the medicine or substance manufactured or used during the manufacturing process; and

(ii) any other information as may be required by the Authority.

(2) The register referred to in subregulation (1) shall be kept for a period of five years after the date of the last entry made therein.

Regulation 36: Act 101/1965

(2) In a case where the register is kept electronically, a printout shall be made monthly, dated, signed and filed.

(3) Records must be stored in an orderly manner so that they can be accessed easily.

Regulation 41: Act 101/1965

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Pricing Committee

- Veterinarians are not subject to the price regulation that pharmacists and medical doctors are.
- 2004-Government Gazette notice exempted veterinarians

- Note: Use privilege carefully, it may change if complaints are received by SAHPRA

Regulation 44: Act 101/1965

Destruction of medicines or scheduled substances

34.(1) A medicine or scheduled substance shall only be destroyed by a waste treatment facility authorised to destroy medicines or pharmaceutical waste in terms of the National Environmental Management: Waste Act, 2008 (Act No. 59 of 2008).

Regulation 44: Act 101/1965

(2) No medicines or scheduled substances other than those as determined by the Authority shall be disposed of into municipal sewerage systems.

(3) The destruction or disposal of medicines or scheduled substances must be conducted in such a manner to ensure that the medicines or scheduled substances cannot be salvaged and the medicine or scheduled substance has been denatured.

PRICING COMMITTEE
Regulation 44: Act 101/1965

(2) The waste treatment facility shall issue a certificate and maintain a record of the destruction contemplated in subregulations (4), (5) and (6) which shall contain the following information:

a) the name of the medicine or scheduled substance, if known; or the schedule of the medicine or scheduled substance concerned;

b) the quantity destroyed;

Regulation 44: Act 101/1965

c) the date of destruction of the medicine or scheduled substance;

d) the name and designation of the person in whose presence such destruction took place; and

e) any other information as determined by the Authority.

Questions

Is there a resource to find out stability of compounded medications e.g., suspended in syrup simplex?

- …….

How does the new rule that AHTs may dart animals and handle scheduled drugs, impact on their right to obtain immobilising drugs

- The new rules for the AHTs do not grant the right to access scheduled medicines, other than schedule 0 & 1
- It further does not grant AHTs the authority to dart wildlife with and/or handle chemical immobilisation medicines. In fact, AHTs can only gain access to scheduled medicines via vets

Questions

- Rule 2(2)(d)AHT rules: The administration of injections and medicines registered (excluding chemical immobilisation medicines) under Act 101, only as prescribed by a veterinary professional for a particular patient and dispensed by a **pharmacy**

What is the legal implications, i.e. Liability on the prescriber, when he/she prescribe a compounded product to a client's animal?

- You remain civilly liable for damages under the Consumer Protection Act
- You will remain liable to Council for unprofessional conduct if you contravene rule 10(5) & (6)

Questions

How can I write scripts when not currently associated with a specific practice (i.e., locum vet)?

- No, section 34

How does SAVC prevent unregistered persons acquiring scheduled drugs?

- The registration numbers of veterinarians are not published on the SAVC registers on the website, to prevent fraud.
- Report it to SAHPRA or Pharmacy Council- jurisdiction

Questions

How many cases did SAVC prosecute?

8

If there is a registered product available, may it be compounded for cheaper and be used in practice?

- No, refer to rule 10

Please discuss the legalities around prescribing scheduled medication via telemedicine.

- …

Questions

- …
- Established a Working Group to deal with that so that telemedicine can be regulated.
- First off, currently it is only allowed for triage purposes.
- A physical examination is regarded as best practice.
- Unlikely that practices will be registered for telemedicine only
- Risk to vet extremely high- civil liability and unprofessional conduct

Questions

If an owner asks for scheduled meds for an agro pet as O/C meds is not helping to bring pet in?

- Yes, enough for one time only

Can I prescribe drugs for myself and my staff?

- No, outside scope of practice

Questions

As veterinarian we may not fill scripts for other vets from other practices. How do we then deal holiday makers/referred pets?

- Contact the treating veterinarian, comply with rule 10(1)

Can compounded medicines be delivered directly to the client from the compounding pharmacy?

- Yes, if it was prescribed by a veterinarian (Exception- immobilisation medicines)

Questions

Can we sell dog vaccines over the counter in light of the changed registration?

- Jury still out – in the meantime, rather not

Does South Africa have any medicines for aquatic animals?

- Probably not, use off label

What are the legalities with recommending extra-label use of drugs to bona fide clients under veterinary instruction?

- Comply with rule 10(10)

Questions

Please would you include some info on the risks of compounded medicines / allegedly ' autogenous ' vaccines

- Compounded medicines- civil liability and possible unprofessional conduct
- Autogenous vaccines – Risk for civil damages very high – especially if not effective or disease spreads

Thank you

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