Over the last ten years, a number of questions on the correct handling and use of veterinary medicines and stock remedies have been put to me by vets, regulators and pharmaceutical companies. Hereunder is a list of the most common question posed. The answers provided are from my understanding of the law and regulations of the Republic of South Africa. I do accept that at times my opinion may be just that and therefore may be open to interpretation or may be wrong if challenged in a court of law. I have as a result taken extra care in ensuring that the answers provided are a consensus view of other members of our profession who are intimately involved in drug regulatory control. However I would add, that in cases of extreme disputes in the reading of an Act, as for all Acts of this land, only a sitting judge may make a ruling to resolve said dispute.

For the purposes of this article, the Medicines and Related Substances Control Act (Act 101 of 1965) will be referred to as Act 101, the Veterinary and Paraveterinary Professions Act (Act 19 of 1982) as the Vet Act, and the Farm Foods, Fertilizers, Stock Remedies and Agricultural Act (Act 36 of 1947) as Act 36.
1) **Do I need a drug dispensary?**
Yes. According to the requirements of the Act 101 any person using medicines registered therein or contained within the schedules (e.g compounded products) of the Act are required to have a physical dispensary wherein their medicines must be stored. These dispensaries need to comply with the minimum set of standards contained within the Act e.g.
- The facility needs to be lockable,
- It must have proper covered floors like a tiled surface
- It must have an impermeable surface to work on
- It must have running water
- It may not be used for other functions
- It must have a reference pharmacology text book readily available (Yes by law every person running a dispensary must own a pharmacology text)
- Must have proper temperature control, heat as well as cooling.
- Must have a lockable safe therein for the storage of schedule drugs.
- Must have a fridge when temperature sensitive drugs are in use.

As a result, vets need a base of operation i.e. there is no such thing as “roving vets” who can keep their medicines in a mobile clinic. This is important as the act does not provide provision for drug storage in a place other than a physical dispensary. Since act 101 does not dictate where such a facility may be housed, one would have to default to the Vet Act for standards for a veterinary practice.

2) **Can I leave my drugs in my bakkie at night?**
No. This needs to be considered with the minimum requirements for a dispensary under Act 101. Medicines, especially those in S5 and S6 must always be securely stored in a safe within a dispensary, when not in use. According to Act 101 the theft of any medicines from the higher schedules opens one up to prosecution if proper steps were not in place to protect said drug i.e. improper storage is equivalent to illegal drug peddling.

3) **What steps do I need to put in place when driving with S5/S6 medicines to a farm?**
The drugs at all times need to be properly locked away. This would be most practically achieved through the use of a lock-box (metal) with a secure lock in the locked boot of the car. When not near the vehicle, the said lock-box needs to be securely locked in the boot of the car i.e. do not leave your S5/S6 drugs in places of open access when not in your direct observation. Failure to keep S5 and S6 medicines properly secured could lead to prosecution under Act 101 for illegal drug peddling.

4) **What constitutes a schedule registers**
According to Act 101 a register needs to be kept for all S5 and S6 medicines bought and used. Historically, this has always been kept as a separate book by veterinarians as an add-on to their patient records. Realistically this is probably a remnant from the days of manual record keeping. Act 101 allows vets to keep their registers electronically, on condition that said registers are kept properly and are printed out four times a year, balanced and signed. Said registers need to be balanced in specified period which is within 14 days of the end of March, June, September and December. In most modern record keeping systems, this can be downloaded from the patient records. Most systems even allow for of capture stock bought and their batch numbers.
5) Can I prescribe a S5 of S6 medicine for use by an owner?
Yes, but with restrictions. Firstly a bone fide client relationship needs to be in place. The prescription of the medicine must be for a valid reason e.g. treatment of a sick animal as opposed to being per the chance they might need it e.g. some future emergency. Said prescription can also only last for a maximum of 30 days. In addition said prescription must be read in conjunction with the Vet Act whereby one cannot prescribe the use of a medicine for a procedure scheduled as a veterinary procedure e.g. anaesthesia. This is where most vets are unclear with the amendment to rule 10, as its recent gazetting made it seem that that the said amendment only now curtails such action. In reality when the prescription requirements for scheduled medicines of Act 101 are read in conjunction with the Vet act, it has always been illegal for vets to prescribe any sedative/tranquilizer/anaesthetic agent unless there it has immediate use i.e. leaving etorphine on a farm for an owner to keep for emergencies has always been illegal. Likewise the prescribing of any drug to facilitate veterinary anaesthesia is not allowed i.e. the opioids such as etorphine and fentanyl are anaesthetic agents when used for immobilisation.
6) What details need to be on the packaging when I dispense drugs?
This piece of information is contained within the regulations of Act 101. It needs to contain the name of the medicine or the name of each active ingredient or alternatively clearly marked with the words non nomen propium; the name of the person to whom such medicine has been sold; description of the animals for which the treatment is intended; the directions for the use of such medicine; the name and address of the veterinarian who has sold such medicine; the reference number allocated to the sale of the medicine and if applicable the withdrawal period.

An example is presented below. The name of the dispensing vet can be pre-printed on the label. I’ve included the batch number and expiry date in the label below. This is a recommendation and not a legal requirement. The reason for this recommendation is to allow for traceability if a recall is issued. It also prevents the dispensing of expired medication.

7) Do I need to keep a schedule register for all drugs
All S5 and S6 active ingredients contained as such within the schedules must be entered into the register e.g. compounded drugs with S5 or S6 active ingredients must also be entered into a schedule register. The anaesthetics (gas or parenteral), sedatives, tranquilizers and the behavioural modifying agents (e.g. Clomicalm) fall into S5; while the opioids into S6. Pentobarbitone when used as an euthanizing agent also falls under S6 as do the partial opioid agonists are like butorphanol. You may notice that under restricted conditions some products for only certain indications (like phenobarbitone when used for epilepsy) get moved into a lower schedules (S5 to S3 for phenobarbitone). This is merely to allow said drug to be prescribed for chronic use and is a decision taken by the MCC after lengthy deliberation.
8) **What do I do with my empty S5 and S6 vials**
Empty vials need to be destroyed by incineration. No provision is made in the Act for storage of the vials or specific means of destruction. The Act only controls the destruction of medicines falling into these schedules. These need to be destroyed in a specific manner which is not the entitlement of a veterinarian unless authorisation has been obtained from MCC.

9) **Can I store my unused dart?**
A tricky question to answer, so this is purely my interpretation. I would say that this is not possible. I based my premise on the clause in the regulations of Act 101 which allows vets to compound medication per patient while preventing vets from pre-packing. I would also not recommend such an activity as this has the potential for contamination, bacterial growth, inactivation, and long-term chemical incompatibilities.

10) **What are my rights with regards to compounding?**
- A veterinarian may compound any product for use in a patient on condition that said use is scientifically justifiable and that no alternate registered product (medical or veterinary) is available for use.
- The veterinarian on use of the said product takes full responsibility for the use of said product in terms of harm to the animal or consumer in terms of a food-safety This specific clause is covered in the Vet Act, where it is made clear that a veterinarian must at all times consider public health and safety. Please note that the setting of a proper withdrawal period is required for any animal that could end up in the human food chain. (Please note that medical mal-practice insurances may exempt cover on extralable drug use).
- A veterinarian may compound said product oneself or make use of the services of a registered pharmacy.
- Said product is legal tender for only 30 days from date of compounding. In addition said product may only be compounded or prescribed for use in a particular patient after consultation and not retrospectively.
- Compounding in bulk for storage is not allowed. Likewise the pre-ordering and storage of compounded products at your practice is also not allowed.
- Advertising of compounded products by the vet or pharmacy is not allowed.
- When a product is scripted for a pharmacist to compound, said veterinarian is no longer allowed to make a profit on the sale of the drug as this would be considered as a commission on sale as per the Vet Act.

11) **Can I sell drugs wholesale from my practice?**
No. Wholesaling is a right of only the pharmacist. In addition wholesaling requires the facility to be registered with Act 101 under the auspices of a quality system referred to as good wholesaling practice.

12) **Can I write a script for a pharmacist to fill?**
Yes. It is the right of every veterinarian to write a script for any pharmacist to fill out. As a veterinarian we can charge a scripting fee. Since the script transfers dispensing rights to the pharmacist, the veterinarian will not be entitled to receive any commission on the sale of the medicine. An example of a script is provided below. Scripts need not be written on
a proper pre-printed script pad as long as all required information is kept. It is recommended that all scripts are counter-foiled and kept in the practice record in duplicate. The script must contain a practice number.

**HIMALAYAN VETERINARY CLINIC**

789 Elevated Heights, Mountain Top, 9870
Tel: (000) 3019 663/4    Fax: (000) 3019 665    Practice Number: XXX9901
E Hillary [BVSc, MMedVet (Poultry)]

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Date: 23/04/07    Ref. No: 03: 1001

Owner Name: *Miss E Sykes*    Animal Name: *Poultry house 1*

Address: **374 Diamond Street, Old Mines Down, Maritzburg, 0110**

Species: *Poultry*    Breed: *Ross Broilers*    Age: 4 weeks

**Drug Details:**

*Amoxycin:* **Mix 1kg of Amoxicin into 1 tonne of feed. Keep birds on medicated food for 7 days.**

**Special Instructions:** *Do not slaughter animals within 4 days of withdrawing the medicated feed*

*Do not repeat. No generic substitution.*

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*E. Hillary*

**DR E Hillary**
13) Can a pharmacist sell drugs to my clients without consulting me
A pharmacist can only sell veterinary medicines (Veterinary medicines are restricted for animal use only) under S0 to S2 to an owner without instruction from a veterinarian. The same applies to the stock remedies. For all veterinary medicines from S3 to S6 and all medicines (S0 to S6), a prescription is required from a veterinarian for a pharmacist to legally dispense.

14) Can my receptionist dispense drugs on my behalf?
No. Receptionist staff is considered lay-persons. Lay-persons have no dispensing rights according to Act 101. The Act is also specific in that receptionist staff may not have access to the dispensary in any manner.

15) Can the paraveterinarian working with me dispense drugs
Yes. A paraveterinarian may dispense any S0 to S4 medicine on verbal or written instruction of a veterinarian. A paraveterinarian may also use any Schedule drug that has been prescribed for use by a patient under their care. Please note that this does not give a paraveterinarian free access to the dispensary. The control of the schedule medicines shall at all times be under veterinary control e.g. the nurse can’t be in control of all the anaesthetics agents at the practice even if they facilitate the anaesthesia.

16) Can my vet nurse induce anaesthesia while I do the surgery
Yes. On condition they don’t have access to all the practice’s anaesthetic drugs i.e. the bottles of anaesthetic for use on a particular day may be made available to the vet nurse prior to the start of the day’s work. Remaining stock should be locked up or disposed by the veterinarian whichever the case may be.

17) What responsibilities can I assign to my kennel man?
None in terms of drug control. An animal caretaker is not allowed to induce and monitor anaesthesia.

18) Who should manage my dispensary stock?
This can only be done by a veterinarian. When stocked is ordered in, the receptionist may receive the stock. Opening of the boxes and physical storage within the dispensary is the responsibility of the veterinarian. In a multi-man practice, one of the veterinarians, must take charge of the dispensary?

19) What else can I keep in my dispensary?
Nothing but drugs may be stored therein. A dispensary is not meant to be the general store of the practice.

20) Can I sell drugs to person(s) I work with?
No. A veterinarian may only make drugs available for use in a veterinary patient.

21) Can I treat family members, friends or owners?
No. The scope of practice as described in the Vet Act, limits our responsibility to animals. This will apply even to S0 drugs. A clause is the Vet Act also prevents vets from running
open pharmacies or shops with regards to the dispensing of medicines. As such our professional responsibility cannot extend to people, even if they are family or veterinary students.

22) Can I let farmers dart animals on my behalf?
In terms of rule 10, this is no longer allowed. While this has been read by farmers as preventing them from immobilising their own animals, this in reverse has the same restriction on vets. Read carefully it implies that unless a veterinarian can’t dart an animal themselves, they have no right to use these drugs.

23) Can I dispense drugs for patients seen by another vet practice?
No. In terms of the Vet Act, a veterinarian may only dispense drugs for vets working at the same practice. If a veterinarian has no stock, said veterinarian may script for the product. Since we as vets are not allowed to run open pharmacies, we may not dispense on a script for any vet other than those working at the same practice as us. Realistically this implies that when an owner wants to renew their chronic script and can’t get to their treating vet, you may not dispense for them. However in the case of drugs for which the patient is stabilised (e.g. anti-epileptics), you may dispense emergency stock for a period not exceeding three days. Nonetheless I always recommend that the said dispensing vet re-examines the patient (even if no consult is charge) as this is the easiest method of dispense the incorrect drug.

24) How much drug can I dispense at one moment?
A reasonable amount it 30 days, even if a chronic med is involved e.g. if a pack size is 30 tablets and the animal only required 15 tablets for the month, one cannot dispense the entire pack.

25) How long is my script valid
Scripts are valid for 30 days in general. The only scripts valid for longer periods are repeat scripts in which a pharmacist is specifically instructed to repeat the said script. The latter only applies to drugs up to S4 and this instruction must be clearly stated on the script. No script may be issued for longer than 6 months. Legally a patient on chronic medication must be re-evaluated every 6 months prior to re-initiation of therapy. Nonetheless even if a script is repeatable a pharmacist may not dispense for a period in excess of 30 days i.e. even if you prescribe for the maximum allowable period of 6 months, the owner may only collect their medication once monthly. Please note that S5 and S6 drugs scripts are not repeatable. Ideally S5 and S6 drugs should not be recorded on the same script as lower scheduled drugs.

26) Can I accept expired drugs and consumables from medical hospitals?
No, if you intend on using the expired stock directly. However, the answer can be yes if the stock in question can be re-sterilised prior to use. Please note that welfare organisation have no authority to ignore this portion of the Act.

27) Can I re-use syringes?
No. This is poor veterinary practice.
28) Can I accept medicines from owners if their animals die within the course of treatment?
Yes, but with condition that the said medication is destroyed and not re-used. As a veterinarian our licence to practice is limited to buying medicines from a registered wholesaler. The reason of this is to ensure that the cold chain is always maintained e.g. when dispensed we have no control on how drugs are stored by the owner. In addition tampering by owner cannot be ruled out.

29) Can I treat “street-cases” with expired drugs?
No. No person has the right to use an illegal product in any patient i.e. do your best as even a non-owned animal deserve reasonable care. By definition drugs are illegal products once expired. Penalties for the use of an expired drug can be up to two years in prison and a fine of R10 000-00. The Vet Act does have authority to initiate other punitive measures.

30) What are the requirements for bringing in drugs registered for use in other countries?
Any medicine (which includes vaccines), requires prior approval from the MCC via a section 21 permit.

- Permits are only issued on a named patient basis except for case of emergency stock (e.g. butorphanol for colic management in horses).
- Each permit is charged at R200. In the case of emergency stock, the MCC reserves the right to charge an individual permit fee for every patient treated retrospectively.
- Permits are valid for only 6 months from the date of issue and are restricted to the amount approved by the MCC and the area where the drug is sourced (the drug has to be sourced from the EU, USA, Canada, UK, Japan, New Zealand or Australia).
- For permit approval applicants are required to prove that alternate products are not effective or available. The MCC reserves the right to question diagnoses and may request specific diagnostic test(s) results for drugs known to be abused.
- Every Section 21 permit is awarded on condition that a follow-up report gets submitted to the MCC.
- Section 21 permits are issued to a person and not to a pharmaceutical company. As such you may not buy an unregistered product without a section 21 in the name of the owner. Without said permit, purchasing the product even if imported legally by the company is considered an illegal sale.

31) Can I buy my drugs from the internet?
Yes, on condition that you have a section 21 permit from the MCC for foreign purchase, on condition they are sourced from MCC recognised regulators (FDA, Canada, Australia, UK, EU and Japan). Please be aware that the FDA has conclusively proven that no online wholesaler is present within their jurisdiction. The general opinion of international regulators is that internet-purchased drugs are off poor quality or more importantly are counterfeit ineffective drugs. At present, it appears that these counterfeit drugs are from China. Please also be aware that these drugs are not shipped correctly and most often are inactive due to incorrect storage conditions during freight.
32) What are requirements for the use of compounded products?
A bone fide client relationship must exist as the process is strictly per patient following consultation. Other than this, the rules for extra-label drug use applies.

33) Can I compound vaccines (autogenous vaccine) for used in a bona-fide patient?
Yes. On condition that this is used solely for the patient it has been created. In terms of production animals, this should be limited to the immediate farm of sample collection (not even neighbours) or a single managed unit e.g. a single poultry house.

34) Can I sell an autogenous vaccine I’ve produced to my other clients or for general sale
No. Vaccines are controlled as medicines in South Africa. Compounded vaccines are to be used on a farm on which the disease has been identified (please note that he requirements of the animal diseases act, must be given consideration). No person has the right to compound a product for general sale. Said product is a de facto unregistered product and therefore require section 21 approval from the MCC or authorisation from the Minister of Health for sale. Even in an outbreak situation permission needs to be attained before the neighbouring farms can be vaccinated with the isolated vaccine strain.

Organisations that produce autogenous vaccines for general sale are in direct contravention of Act 101. This stems from a general misunderstanding that only Act 36 controls vaccines. The incorrect assumption comes from misreading of Act 101. By strict definition all products are controlled by Act 101. Said products can only be controlled by Act 36 when exempt from the schedule for such control in addition to being registered under Act 36 i.e. exemption for the Act 101 schedules is only applicable on the receipt of a registration certificate from Act 36. In addition, exemption from the schedules of Act 101 for control by Act 36 by no means implies that the said vaccine cannot still be controlled by Act 101 (as a S4 product). On the contrary until such time that the product is physically registered with Act 36, said product is considered unregistered according to the requirements of Act 101 and therefore remains under the strict control of the Act. In other words Act 101 is the Republic’s primary Act in control of illegal trade of drugs i.e. Act 101 de facto makes South Africa a closed market in terms of the sale of any medicine until registered as a stock remedy.

35) What are my rights in terms of vet shops or similar?
In addition to trade agreements on the use of the name, a veterinarian or any person may sell any Act 36 product from an open shop (unless restricted). Some confusion exists as to whether a practice waiting area may serve as this may open shop. It has been suggested by the SAVC that the clause in the Vet Act on open shops restricts such activity. I’m in disagreement with this stance as the restriction in the Vet Act is contained under the clause for the dispensing of medicines. By definition in Act 101, stock remedies are not medicines as they are controlled by a different Act. As such please consult the SAVC if one intends on selling stock remedies from the practice waiting area.

36) What are my rights when selling prescription dog food?
None. The term is a misnomer as prescription is not defined in terms of Act 36, nor does the act indicate control measures for such products. As such said products may only be considered a food. No restriction is present on the sale on pet food in terms of Act 36. As such one may only restrict sale by limiting access to these products. Nonetheless, if
requested by an owner, one has no authority to refuse sale on the premise that a consultation is required.

37) Can I keep drugs in my consulting room?
Yes. On condition that the amount kept is at a minimum and they are general use drugs (S4). The proper storage area must still be the practice dispensary. In addition, said drugs must always be locked when the veterinarian is not within the room. S5 and S6 drugs must always be stored in the dispensary.

38) What should I do if I suspect that some of my schedule medicines have gone missing?
Legally this needs a case of theft to be opened with the South African Police Services.

39) What profit can I make on my drug sales?
No restriction has been placed on any veterinary drugs. Drugs used extralabel may also be sold at any reasonable price set by the practice. Please note that owners are well aware of costs of their own medication and do shop around for best deals. As such I would not suggest excessive mark-ups on any medicine or stock remedy.

40) Is it legal for me to make my own sterile medications?
Yes. This falls under our right to compound. I would not, however, suggest this unless one has access to a laminar flow cabinet in a clean room, a 0.2μM filter and sterilised bottles to handle such a product. Please also consider that filtration and proper control only removes gross particulate, and unlikely to remove chemical contaminants and endotoxins.

41) What are my rights when using drugs extra-label?
All veterinarians have the right to use any product extra-label on condition we take full responsibility for said use. According a high court ruling, it has been stipulated that extra-label use must involve informed consent (reasonable explanation is for a person with a Grade 10 education), and the absence of registered alternate.

42) Is there a difference between compounding and extra-label drug use?
In general they are the same with one exception. Extra-label use involves the use of a registered product for an alternate use than specified on the package insert while compounding is making up of your own drug. Legally the use of registered products extralabel has slightly less risk as these products would have produced under a defined quality control processes known as good manufacturing practice.

43) Can I make a profit on compounded drugs?
Only if the product is made directly by yourself. When the product is scripted, the veterinarian is only allowed to earn a commission on the process of scripting. Any profit on the compounded product is illegal as thus constitutes an illegal commission on sale.

44) Are generic drugs by definition poor quality drugs?
No. Generics are usually cheaper for a number of different reasons such as cheaper manufacturing, less total costs to recoup or generally lower profit margins. Quality is enforced by law and as such both the generic and the innovator must have the same quality standards in manufacture.
45) Can I sell stock remedies from my practice
Yes. There is some confusion as to whether this can be in the manner of an open shop i.e. the SAVC is of the opinion that these drugs may not be on open shelves. I do believe that this may an incorrect interpretation of the Vet Act, as this restriction appears to be limited to only medicines.

46) Can I sell little bottles of stock remedies which I decant from larger bottles
Not in general. This may only be facilitated if the product comes with pre-labelled smaller bags for said dispensing e.g. certain dog anthelminthics which comes in bottle of 100 are also supplied with individually bags that are properly marked for re-sale. For other product like the large containers of sheep dips and anthelminthics, they may not be broken up e.g. no sending owners home with a syringe full of Panacur.

47) Can I pre-divide my larger bottles of veterinary medicines in smaller packages for easier dispensing?
Yes, with restrictions. According to Act 101, veterinarians have the right to break up packages into dispensing packages at the time of dispensing to a sick patient. We do not have the right to pre-package medicines into patient ready vials i.e. patient ready packs.

48) What gifts am I allowed to receive from the pharmaceutical industry?
Only small gifts are allowed like promotional shirts, caps and bags. No large gifts such as free trips and holidays are allowed to be accepted. This is a combined result of both Act 101 and the Vet Act. In addition kick-backs on sale, bonusing, sampling and preferential pricings are not allowed in terms of Act 101.