

**WRITTEN SUBMISSIONS BY DR BOTHA (VETSCRIPTS) REGARDING CURRENT
AND PROPOSED NEW RULES AND AMENDMENTS THERETO**

Please see below my written submissions on the proposed new Council Rules. In each case I have quoted the **current Rules**. This is followed by my suggestions on how the **Rule should read**.

Lastly the **justification** of my suggestions are given and where available a transcript of the relevant discussions pertaining to our suggestions are given.

As not everything was recorded and the quality of the recording was not always optimal these may be open to changes but are given as best possible. It would be Council's responsibility to have these transcribed professionally if they so choose.

MY SUBMISSIONS ARE DIVIDED INTO 3 CATEGORIES, NAMELY:

- 1) Proposed amendments to the Definition of Compounding;**
- 2) Rule 10(5)(a) - Interpretation of "Any Medicine"; and**
- 3) Rule 10(5)(b) - 30 days Prescription - Document or Medicine.**

I hereby formally submit that all my arguments are based on the Main Premise of the Legislation of South Africa as it pertains to Act 101 read with the Vets-Act / Rules. I submit that the basic principle hereto is that Act 101 is the CENTRAL Act that regulates Veterinarians in South Africa. Surely the Vets Act is there to provide further guidelines governing Veterinarians in specific, but the Vets Act (and certainly not the Rules to the Vets-Act) can never be contradictory to Act 101.

This submission has been supported in numerous instances by the SAVC itself. Two examples are contained in quotes from Prof Naidoo:

"...until the vet Council petitions for a change in Act 101, there is no deviation..."

"...either way the Vet Act can't override the per client clauses of Act 101..."

And another example appearing on the SAVC website when describing Act 101:

“Important aspects of this Act have been incorporated into the Rules Relating to the Practising of Veterinary Professions 2015. This Act controls veterinary medicines.”

It is therefore that when one reads MY written submissions, or listen to my oral arguments and the oral arguments made by my legal Counsel, one should always keep in mind that my, and Vetscrips', only goal is to bring the Vets-Rules inside the amid of Act 101 as it should be, seeing as Act 101 is duly comprehensive to deal and regulate Compounding as it pertains to Veterinarians in South Africa.

My three submissions to follow hereunder.

1) Proposed amendments to the Definition of Compounding

Current Definition of compounding in the Vets-Rules:

“compounding” means to prepare, mix, combine, package, and/or label a non-registered medicine(s), or to mix or combine a registered medicine with a non-registered medicine for dispensing as a result of a prescription for an individual patient, as defined by Rule 1, by a pharmacist or a veterinarian authorised in terms of the Medicines Act. Compounded medicines are not intended as a replacement for a registered medicine or stock remedy, or for the treatment of a patient for more than 30 consecutive days from the date of compounding. The latter however does not preclude a veterinarian from continuing treatment for a period longer than 30 days, provided that a new batch of medicine is compounded for the patient in question every 30 days, except if the stability of said compounded product has been proven by accepted stability trials

The suggested changes to the Rules reads as follows:

compounding” means to prepare, mix, combine, package, and/or label a non-registered medicine(s), or ~~an analogue of a registered medicine in a different concentration, size or volume as the registered product~~ to mix or combine a registered medicine with a non-registered medicine for dispensing as a result of a prescription for an individual patient **or group of patients**, as defined by Rule 1, by a pharmacist **on veterinary prescription** or **directly** by a veterinarian authorised in terms of the Medicines Act. Compounded medicines are not ~~intended as~~ a replacement for a registered medicine or stock remedy, **and may not be used** for the treatment of a patient for more than 30 consecutive days from the date of compounding **for stability reasons**. The latter ~~however~~ **thus** does not preclude a veterinarian from continuing treatment for a period longer than 30 days, provided that a new batch of medicine is compounded for the patient in question every 30 days. ~~; except if the stability of said compounded product has been proven by accepted stability trials;~~ Excluding veterinary (autogenous) vaccines???? Act 101 patient specific- Rule as it gives vets more rights. Or production of an autogenous vaccine in a registered facility??

Dr Botha - Vetscripts written submission suggests:

Remove both of the above Definitions in its entirety from the Rules.

Replace the definition with the exact Definition of Compounding in Act 101's Regulations with minor modifications that will better define it without contradicting the version in Act 101.

It will then read:

"Compounding" means to prepare, mix, combine, package and label a medicine for dispensing as result of a prescription or directly by a veterinarian for an individual animal or a group of patients by a veterinarian authorised thereto in terms of section 22 (5) of Act 101/1965.

Justification:

The definition of compounding should not in its essence contradict any law or Regulation. By using the above definition it is in line with the definition as promulgated in the Regulations of Act 101 and does not contradict section 14(4)(a) of Act 101, as it currently does.

The current definition in the existing Rules are clearly in contradiction to Act 101 and will be even more so if the new suggested Rules are promulgated. By ignoring the word "any medicine" in Section 14(4) of Act 101, Council will be promulgating a Rule that is in clear contradiction to Act 101.

This statement is fully supported by legal Counsel obtained by Dr Botha (Vetscripts) as well as others. Furthermore this was reiterated by Dr Lotter (MCC) when she stated:

"Rules that contradicts any Act because if that gets - if it goes to court an Act will always stand - an Act has a higher legal standing than a Rule. So when we draft Rules we cannot propose changes that will implicate a change to an Act. You can't!. Then you have to go the right route and Actually have the change made in the principal Act - otherwise your Rule is contradictory and has no legal standing. The risk to that is that your whole set of Rules not only the one Rule that implicate the entire set of Rules in its entirety then becomes a illegal document - which is opening you to massive massive issues".

(See full transcript below)

The reference to "more than 30 consecutive days from the date of compounding" should also not be included as it is not mentioned in the definition of compounding of Act 101.

More so the 30 days reference in Act 101 refers to the validity of the prescription once written by a Veterinarian and not the product once received by the veterinarian or once dispensed to the client. (see below)

Furthermore, Act 101 is clear that the veterinarian has the sole discretion in the amount of compounded product that he deems fit to prescribe and supply to the patient to effect effective treatment (see below). There is thus no justifiable reason to include the 30 day archaic time frame in the definition.

During all 3 of the workshops veterinarians made it clear that they are necessitated to break this Rule daily in the running of their practices to the best interest of their Clients / Patients. An excellent example is the non-availability of Primaquin tablets for treatment of Babesia felis. How should veterinarians script for each cat that needs 20 tablets? Should the cats rather die as result of Council enforcing a Rule that is not even close to being based on law? No veterinarian would be able to practice Good veterinary practice if this Rule, that has no basis in law, is effected and enforced.

Again as so many times in the past the question is why does Council want to enact a Rule that is not based in law and is contrary to all principles of best serving the welfare of our patients?

2) RULE 10(5)(a) and the Interpretation of “Any Medicine”

Current Rule in Black suggested changes in red:

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 ~~concentration~~ ~~size, volume and~~ concentration; including extra-label medicine use; ~~If the combination of registered products with individual Actives to obtain a fixed dosed combination e.g. Mixing drugs in the food/water is possible, this is sufficient grounds to use the registered products first~~

Dr Botha - Vetscripts written submission on Rule 10 (5) (a) suggests:

Change Rule 10(5)(a) as follows based on Section 14(4)(a) of Act 101.

Replace the Rule with wording that takes into account the wording of Section 14(4)(a) of Act 101 with minor modifications that will better define it without contradicting the version in Act 101.

It will then read:

10(5) when using or prescribing a medicine that has been compounded veterinarians must comply with the following:

- (a) The compounded medicine must be compounded in the course of carrying on his or her professional Activities by a pharmacist or a veterinarian for a patient in a quantity not greater than the quantity required for treatment as determined by the veterinarian.*

(A) When treating patients a veterinarian should base his choice of drugs on the Veterinary cascade system with the exception where the use of a registered Veterinary medicine or applicable Human Medicine is out of the financial reach of the client and thereby denying the patient any treatment at all. In these cases a compounded medicine may be offered to the client after having made the client aware that such a product is not registered and has thus not been evaluated by the Medicines control Council or Act 36/1947

Justification:

During workshop held 09 November Dr Botha Questioned Prof Naidoo on what Section within Act 101 states that it is not allowed to compound “any medicine”. He did not answer the question but referred back to good professional practice and not to the law as it stands.

Both Dr Gerber as well as Dr Lotter confirmed it was “any medicine”.

See Transcripts From 09 November workshop below:

Question Dr Botha to Prof Naidoo

Could Prof Vinnie and Medicines Control Council just please quote for me what section exactly says that it's not allowed to be done if there is already a registered one?

Prof Naidoo reply

It's the professional conduct. it's a Rule what we consider as being good professional practice.

Question from Unknown person to Prof Naidoo

According to the Act it does not say you may not?

Question Dr Botha to Prof Naidoo

So Act 101 does not specify that it may not? Does 101 specify anything can be compounded?

Prof Naidoo reply

No reply forthcoming from Prof Naidoo

Dr Gerber V -Tech states

Any Medicine

Lady voice believed to be Dr Lotter States

Any medicine

During the workshop held on 02 February 2017 Dr Botha Questioned Dr Lotter from MCC on the statement by Prof Naidoo that "we will be taking away the veterinarians right to compounding if we accept the definition in Act 101 and published in Council Rules".

Dr Lotter clearly answered "No" thus contradicting the previous statement from Prof Naidoo. In her answer Dr Lotter made it very clear that Council cannot make a Rule that contradicts any Act be it the Medicines Act, Pharmacy Act or Veterinary Act.

Further discussions followed from the floor. During these discussions it was highlighted by Dr Roos as well as Dr Botha that in certain cases the cost of prescribing registered medicines or even human generic medicines were far more than what a large portion of South African pet owners can afford. It was argued that patients would be better served by offering them much more affordable compounded products than having no option at all. Prof Naidoo argued that compounded medicines were of inferior quality and that it would not be good professional practice to prescribe compounded products when registered product or human generics were available.

Dr Lubbe (compounding pharmacist Vetscripts) argued vociferously against the statement that compounded products are of inferior quality, as did Dr Gerber (v-Tech). Dr Flemming stated that price of medicine should never be the determining factor in drug choice. She conceded that in some cases the cost of medicine were out of reach of certain pet owners. She made the point that choosing to use a compounded product should not be for self interest of a greater profit by prescribing veterinarians. She suggested that the Prescribing Cascade be included in the Rule 10 (5) (a). This was accepted by the floor as being an excellent suggestion. After these discussions the Chairman asked if there were "any meaningful changes to the definition that someone wants to make?"

Dr Gerber concluded by suggesting "So we use the 101 definition and we define the patient."

With regards to the Definition of Patient:

We suggest we keep the Definition as currently stated in the Vets Rules, seeing as same is not contradictory to Act 101, but gives clarity to the fact that the Veterinarian can identify a "GROUP OF ANIMALS":

“patient” means an individual animal or group of animals as a unit examined and/or treated, operated or consulted on by a veterinary professional in accordance with a ‘veterinarian-client-patient’ relationship”

The question of patent infringement when compounding any medicine was raised by Mrs Stoltz during a telephonic discussion with Dr Botha. This is completely devoid of Act as no patent holder will complain if a veterinarian mixes a registered medicine under patent with another product as there has then been no infringement of the sale of the product. Concerning compounding by a compounding pharmacy with API the responsibility of patent infringement lies with the compounding pharmacy and as such API under patent would not be available. This argument against allowing " Any medicine" is again not based in fact or in law and cannot be used.

See Transcripts From 02 February 2017 workshop below:

Question Dr Botha to Dr Lotter

Do you see it as Prof Naidoo sees it that we will be taking away the veterinarians right to compounding if we accept his definition?

Dr Lotter reply

No

Let me just start

Going back one step

I just want to reiterate you cannot have things in your Rules that contradicts any Act because if that gets - if it goes to court an Act will always stand - an Act has a higher legal standing than a Rule. A regulation in the same sense has a higher legal standing than a Rule. So when we draft Rules we cannot propose changes that will implicate a change to an Act. You can't!

Then you have to go the right route and actually have the change made in the principal Act - otherwise your Rule is contradictory and has no legal standing.

The risk to that is that your whole set of Rules not only the one Rule that implicate the entire set of Rules in its entirety then becomes a illegal document - which is opening you to massive massive issues.

Dr Botha States

Do not change an Act with a Rule because Council is going to get burnt with that!

Dr Lotter continues

You can't put in your Rules what you would like to do you have to put in the Rule what you are allowed to do. What you are allowed to do is prescribed by Act. I am not saying the Medicines Act is more important than the Pharmacy Act, is more important than your Act the veterinarians, but you cannot have the Rules of practice as a general principal as something that is not in accordance with what an existing Act or regulation says - you cannot have it.

Further discussion by Dr Flemming**Chair**

Any meaningful changes to the definition that someone wants to make?

Dr Gerber V-Tech

So we use the 101 definition and we define the patient

3) Rule 10(5)(b) and the 30 Day Prescription

Current Rule in Black suggested changes in red:

10(5) When using or prescribing a medicine that has been compounded, veterinarians must comply with the following:

- (b) Ensure that where there is no registered veterinary medicine available, a veterinarian may only compound medicine in a quantity/volume due not greater than the quantity required for treatment of the patient for a period of not more than 30 days, for stability reasons. The latter does not preclude a veterinarian to issue a repeat prescription of the said drug for up to six months if it is necessary (not schedule 6).

Dr Botha - Vetscripts Written submission on Rule 10 (5) (b) suggests:

Scrap Rule (b) in its entirety. The 30 day expiry Rule that Council wants to enact is a misinterpretation by Council of Act 101 as explained by Advocate Prinsloo (Vetscripts) and if enacted will again be contrary to Act 101 and its Regulations. See justification below.

It was argued strongly by Dr Gerber as well as Dr Botha and Dr Lubbe that there is no justification for the 30 day period in science. Only the compounding pharmacist can give some indication as to the stability of said compounded product. To enforce a random 30 day period that was mistakenly taken from Act 101 is ludicrous. Council will definitely be taken on review on this point and it is the opinion by Counsel of both Vetscripts and V-Tech that it will not stand in a court of law. Again this is the function of Act 101 MCC to enforce as they see fit and according to the law as it currently stands.

Replace with the following read together:

- Section 22A(6)(d) of Act 101:

“if a prescription document (not the prescribed drug itself) is not presented for dispensing within 30 days of issue it shall not be dispensed”

In essence the prescription (DOCUMENT) that the Veterinarian issues to the compounding pharmacist expires if it is not presented within 30 days, not the DRUG compounded.

- **Regulation 4 in Act 101's Regulations:**

“A Pharmacist ... shall only compound a quantity that is intended to be used by a patient or animal for not more than 30 days from the date of dispensing”

In essence the veterinarian may not dispense to a client for more than 30 consecutive day use / TREATMENT. It does not state that the veterinarian may not keep it on his shelf for more than 30 days or that the veterinarian may not script for more than 1 patient at a time in anticipation of the patients needing the product within a reasonable period.

- **Section 14(4)(a) of Act 101:**

“... for a particular patient in a quantity not greater than the quantity required for treatment as determined by the Veterinarian...”

- **Current Rule 10(3) of the current Vets-Rules:**

“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”

Justification:

As Act 101 clearly supersedes any regulations or Rules - the Veterinarian is clearly given the right to determine the quantity that he needs to have compounded. Patient is determined in Council Rules as a single animal or group of animals as a unit.

The veterinarians data base of patients in small animal practice will be considered as a group of animals as a unit. Nowhere in any Act does it implicitly state that a Veterinarian may not script a compounded product for the particular patient within his group of animals (data base of patients) furthermore no reference could be found in any of the Acts that a Veterinarian may not script in anticipation of a patient that will be needing the said compounded products within a reasonable period of time - as long as he can justify this via his patient record history.

Obviously it is in Council's mandate to charge a Veterinarian if it is found that such Veterinarian has exceeded the amount of product compounded that is reasonably justified for the sake of personal gain or in lieu of unethical practice, no one disputes this fact.

Council will definitely be taken on review on the 30 day expiry Rule and it is the opinion by Counsel of both Vetscripts and V-Tech as well as Dr Lubbe (Vetscripts) that it will not stand in a Court of Law. Similar to the above the enforcement of this Rule as it currently stands is detrimental to the public and the affordability of medicine for the public and their pets by denying them access to more affordable medication which cannot be justified.

Again this is the function of Act 101 MCC to enforce as they see fit and according to the law as it currently stands.

CONCLUSION

We strongly urge the review committee of Council to take the above submissions into account before publishing Rules that are in contradiction with Acts and Regulations. The function of Council is clearly to enforce ethical behaviour from Veterinarians and not to enforce or be the watchdogs of other Acts.

If these Acts or the Veterinary Act has shortcomings and needs to be changed so be it. For as long as these Acts stand in law the Council should be ever vigilant not to try and supersede these with Rules that are not based in law or even worse that is contrary to the law or Regulations of other Acts.

It has to be said that if this happens Council could very well find themselves again in the unenviable position that they did previously with the Competitions Act.

It should also be noted that as Council is aware the amendments of Act 101 by the Medicines and Related Substances Amendment Act 72 of 2008 and the Medicines and Related Substances Amendment Act 14 of 2015 is to commence in due course. To the best of our knowledge none of the Sections in Act 101 that we rely on in our arguments are to be amended and / or are proposed to be amended. It is our submission that should the MCC have had any reservations to the Sections pertaining to Veterinarians this would have been addressed by the new Amendments of Act 101, and it has not.

Please note that myself Dr Lubbe and our legal Counsel is at the disposal of Council to argue further these points during the meeting of the review committee.

We thank Council for their consideration hereof and trust our submissions will be taken into account and published to the Veterinarians. We will also be forwarding our submissions to the Veterinarians on our database purely for information purposes. This will be similar to articles published by Prof Naidoo and will be conveyed to the Veterinarians that it is only our submissions and to encourage Veterinarians to engage in fruitful discussions and to submit their own commentary, as formed by their own opinions.

Dr Ockert Botha (BVSc)

CEO Vetscripts

