The new rules and the profession’s input!

The completion of the rules is the culmination of a process embarked upon by Council in 2008, which commenced with an amendment to the Veterinary and Para-Veterinary Professions Act, Act 19 of 1982, as embodied in the Veterinary and Para-Veterinary Professions Amendment Act, Act 16 of 2012 (the Amendment Act). The Amendment Act introduces amongst others, compulsory community services, continuing professional development (CPD), a suspension process should a veterinarian not comply with CPD or poses a danger to the public or an animal in terms of his/her professional practice, an appeal process against decisions of any one of the Inquiry Bodies or the Suspension Committee appointed by Council, costs orders, the long awaited inspectorate of Council and for registered foreign veterinarians to continue practicing by either obtaining citizenship or permanent residency.

Further impetus was lent to the amendment of the rules by a finding during October 2013 by the Competition Commission that the rules relating to advertising and pricing was contrary to the provisions of the Competition Act, Act 89 of 1998. These rules were subject to a moratorium on their enforcement from 13 December 2013, as per Council’s agreement with the Competition Commission. In addition Council ceased publishing and/or utilizing the Guideline of Tariffs which Council published annually since 2004 from the same date, also in accordance with the agreement entered into with the Competition Commission as the mere publication of the Guideline of Tariffs allegedly constituted price-fixing.

The new rules were sent to the Competition Commission for its consideration and may be subject to additional amendments should the Competition Commission advise Council that the rules may not comply with the requirements of the Competition Act, Act 89 of 1998.

The regulations and the new rules for veterinarians have been drafted to support the amendments introduced by the Amendment Act. The rules are the product of a consultation process stretching over more than seventeen months, seventeen trips countrywide and four workshops (use of highly scheduled medicines, minimum standards for facilities, professional practice standards & new draft rules), as well as written comments invited from the profession, ending on 6 May 2015 and approved by Council on 9 June 2015.

The draft rules were put on the Council’s website on 15 April 2015 for comment by the profession. This was brought to the attention of each member of the profession by an sms. A lot of valuable, practical input was received and most of it was accommodated in the new rules. To those who contributed, a huge thank you from Dr A De Vos, Chairperson of the Review committee, the Review committee itself and then of course, yours truly!

Some of the comments could not be used, for a variety of reasons. These are addressed in this article, as well as some questions received, in order to explain the reasoning behind the decision not to use that particular input and to provide answers to the most common questions.

Questions (Statements) & answers

Q: Why only one hospital/clinic definition?
A: A veterinary clinic and a hospital have to comply with the same minimum requirements, hence no differentiation in the rules.

Q: Is Council thus going to include the place of work of all registered veterinarians in their register/database? Is this practical/achievable/necessary?
A: Currently it is only a requirement of the regulations for veterinary para-professionals to provide the details of employer. However, the employer has always been captured on the SAVC’s persons data base. It helps to trace members who neglect to update their details. On the FACILITY data base the physical address and the registered staff have always been recorded.

In terms of the new rule 4(3)(e)(viii) it would be incumbent on veterinary professionals to inform Council within thirty (30) days of entering into employment or partnership at another registered facility. It is necessary from the point of view that it keeps Council updated on the whereabouts of each veterinarian and to ensure that all veterinarians practice from a registered facility, complying with the relevant minimum standards. It would also assist the MCC to determine where the registers to be kept in terms of the Medicines and Related Substances Control Act, Act 101 of 1965, could be located.

Q: Rule 5(11) A paper copy of a certificate that is not certified surely can’t be worth more than an electronic or faxed copy. (An electronic scanned copy attached to computer records is much less likely to get lost or mis-filed, in this day and age.)

A: Original paper copies of documents are accepted as best evidence in our Courts and are accepted immediately, provided that it is an original document. The origin and authenticity of an electronic documents must be proved in a Court by leading oral evidence so as to ensure that it is a copy of an original document, as electronic documents can be tampered with easily.

Q: The MCC requires a facility number for a prescription or order for medicines to be legal – not a SAVC initiative.

A: The SAVC has since pre-1982 issued facility or “practice” numbers. It has always been a requirement of regulations 11 & 28 promulgated under the Medicines and Related Substances Control Act, Act 101 of 1965, that in order to write a valid prescription or order for medicines, a practice number was required. It was however not strictly enforced, which led to scheduled medicines ending up where they should not have.

Q: Rule 34(2)(a), according to the definition, a non-practicing facility is solely for the veterinarian’s own animals, surely the requirement for CPD can be lowered? i.e. the number of points per cycle reduced - the veterinarian remains up to date with conditions they are treating their animals for, but it is not necessary to maintain the full CPD points?

A: CPD means one single full day SAVA congress once a year or one 3 day event per 3 year cycle. A veterinarian who does not care enough to spend even one single day with his profession should not have access to scheduled medicines. In addition the privilege of having a registered facility goes with responsibility, especially to keep up to date with the latest legislation governing medicines and the veterinary profession and/or reading of twenty (20) articles then to answer questions about these articles on your telephone and answer 80% of the questions on each article correctly will give you one point per article.

Q: Rule 8: It is not clear what the rules with regard to laboratories are, and whether section 8 on covering applies to veterinary laboratories.

A: Ownership as such is not an issue. It is the laboratory standards and the services that are to be regulated. Obviously the “owner” would have to subject themselves to the required standards if the veterinarian or veterinary technologist (VT) is only in the owner’s employment and that veterinarian...
will maintain full responsibility to ensure minimum standards are complied with. This applies to all facilities.

Q: Why we can’t enforce the following:
   1) Persons making a complaint to Council must be prepared to pay a fee or deposit should the complaint be frivolous or unsubstantiated.
   2) Considerable legal costs may be involved by a veterinarian to defend him/her self.
   3) The investigative committee must ensure that time and monies are not wasted.

A: Frivolous complaints are not entertained- they are dismissed during the screening process by the Investigation Committee (IC). Many of these complaints are mediated. That said, however, all complaints must be investigated and considered, otherwise the profession may lose its privilege of self-regulation and assessment by peers. It is therefore important that a veterinarian participates in the investigation process to enable the IC to make an informed decision. It the veterinarian does not participate in the process, only one version serves before the IC on which to make a decision. Honesty, transparency and co-operation go a long way to absolve yourself. The legal defence is often the main cause for unnecessary costs, as they often advise veterinarians, to their detriment, not to participate in the process and/or to request postponements just a few days prior to the inquiry for flimsy reasons, after the Council has already incurred the costs of travel, accommodation and legal costs to appoint a pro forma complainant. It has to be borne in mind that the rules were drafted to ensure that there is a means to prove that self-regulation can be trusted as a means to regulate a handful of members who cause reputational damage to the profession. Reputational damage is sometimes valid and based on evidence and sometimes not. Reputational damage is used by the Department of Environmental Affairs and the Department of Health in attempts to further regulate the veterinary profession in terms of the legislation for which they are responsible. Such attempts are embodied in for instance the requirement of TOPS permits and the banning of Phenylbutazone.

Q: Responsibility at laboratory facilities
There must be clear definition of responsibility for the technical aspects/results produced by the laboratory, as well as for additional interpretation, diagnosis and recommendations. E.g. a veterinary technologist or other professional may be responsible for the technical aspects, but a veterinary professional for interpretation, diagnosis and recommendations. The issue of a principal for veterinary laboratories is not addressed.

A: The registration of a laboratory should be made possible- even a Veterinary Technologist should be able to register the facility and inspections should be held, provided that a veterinary technologist or other professional may be responsible for the technical aspects, but a veterinary professional for interpretation, diagnosis and recommendations. Veterinary Technologists are only trained to provide results and not to interpret them.

Rule 10.

The input was received from the TCV Forum and is included with its express permission in this Newsletter. The answers to the input from the TCV Forum was provided by Prof Vinny Naidoo, except where indicated otherwise. The TCV Forum input is in bold and the replies in ordinary script.

Q: Definition of compounding:

The new SAVC proposed definition of “compounding” means to prepare, mix, combine, package, and/or label a non-registered medicine(s) for dispensing as a result of a prescription for an
individual patient by a pharmacist or a veterinarian authorised in terms of the Medicines and Related Substances Control Act 1965, Act No. 101 of 1965, not intended for the treatment of a patient for more than 30 consecutive days from the date of compounding, or as a replacement for a registered medicine/stock remedy.

A: The latter does not preclude a veterinarian from continuing treatment for a period longer than 30 days, as long as a new batch of medicine is compounded for the patient in question every 30 days and a period not longer than 6 months without a repeat examination.

Q: “medicine” as defined in section 1 of act 101/1965 means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in-

(a) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in man; or

(b) restoring, correcting or modifying any somatic or psychic or organic function in man, and includes any veterinary medicine;

A: The definition is almost identical to that in Act 101 and as such is a valid definition. The definition is also a further summary in that that a veterinarian may directly or indirectly via a pharmacist compound a medicine. The point of contention are completed refuted based on the 30 day period:

a) The 30 period is already in place for pharmacists in terms of regulation 4 of Act 101/65 “to be used by the patient for not more than 30 consecutive days from the date of dispensing”. To argue that is has no basis for the veterinarian is not justifiable i.e.a vet is not more competent than a pharmacist.

b) The veterinarian should also take into consideration that prescriptions are only valid for 30 days, even for registered medicines. This has to do with stability and the potential for a person or owner to damage medicines when dispensed in large quantities i.e. this ties in with the needs for medicines to be stored in a proper dispensary.

c) The period of 30 days is based on the unknown stability of the molecule within the final formulation. Medicines are notoriously unstable due to factors such as thermal, UV, humidity instability and bacterial contamination. To argue that all medicines are stable is incorrect as pharmaceutical science determines otherwise and the extent of testing medicines formulations have to go through.

d) It should be emphasised that the stability is not only dependent on the active ingredient but also the inactives. As such even arguing that a registered medicine overseas has a longer shelf life won’t be applicable or valid. One should also realize that overseas shelf lives are not valid in South Africa as our climatic conditions are much harsher i.e. all products registered in SA has a distinct shelf life validated for our conditions even if registered in the USA or EU.

e) Stability testing is a very controlled process and is well described in the pharmaceutical guidelines of the MCC.

f) The argument that a veterinarian has the knowledge to diagnose and treat a disease is not up for questioning. The stability of the molecule is. There is no valid reason why a veterinarian cannot compound in smaller volumes for use within 30 days. The vet can then repeat the prescription of the product when necessary.

g) I disagree that the country is so vast that delivery of meds every 30 days would be impossible. Veterinarians should realise that medical doctors also prescribe compounded medication for chronic conditions. It is not often that one hears of people suffering because they stay more than 30 days away from their pharmacist.
"compound" as defined in section 1 of the General Regulations made in terms of the Medicines and Related Substances Act, 101/1965, as amended, means to prepare, mix, combine, package and label a medicine for dispensing as a result of a prescription for an individual patient by a pharmacist or a person authorised in terms of the Act;

"medicine" as defined in section 1 of the Pharmacy Act, 53 of 1974, means medicine as defined in section 1 of the Medicines and Related Substances Control Act, 1965;

"medicine" as defined in the existing Veterinary Rules means a medicine or veterinary medicine as defined in section 1 of the Medicines and Related Substances Control Act, 1965 (Act No.101 of 1965).

The purpose of act 101 of 1965 is inter alia, to provide for the control of manufacturers, wholesalers and distributors of medicines and medical devices; and for the control of persons who may compound and disperse medicines; and for matters incidental thereto.

It follows that the definition of compounding does not strike a rational balance between the provisions of act 101 of 1965 and the proposed rules which constitute subordinate legislation, rendering the definition of compounding and further provisions contained in the rules to which reference will be made herein, untenable.

Stating that a compound should be used within 30 days of compounding is impractical as a veterinarian has the right and expertise to diagnose a patient or patients and based on his assessment and diagnosis, issues the script for a specific medicine to be administered in a specific dosage and/or compounds the prescribed medicine. Proposed Rule 10(5) j correctly states that “a veterinarian must ensure that he/she compounds only sufficient medicine to comply with Section 14(4) of the Medicines Act and must further ensure that such medicine be administered to a patient for not more than 30 consecutive days from the date of dispensing the said medicine by a person so authorised in terms of the Medicines Act. Secondly not all medicines are compounded to lose their effectiveness after 30 days and this requirement is impractical if regard is had to the fact that numerous farmers in South Africa are situated in the outskirts of our country.

Compounding should be regulated rather than being outlawed and some guidelines can be obtained from the United States http://www.ahi.org/issues-advocacy/animal-drug-compounding/

Section 14(4) of act 101 of 1965 : “The provisions of subsection (1) shall not apply in respect of the sale of any medicine-

(a) compounded in the course of carrying on his or her professional activities by a pharmacist, veterinarian or person who is the holder of a licence contemplated in section 22C (1) (a), for a particular patient in a quantity not greater than the quantity required for treatment as determined by the medical practitioner, pharmacist, practitioner or veterinarian; or

(b) compounded by a pharmacist in a quantity not greater than that prescribed by regulation for sale in the retail trade, subject to the conditions likewise prescribed or in a quantity for a particular person or animal as prescribed by a medical practitioner or a dentist or a veterinarian or a practitioner or a nurse or other person registered under the Health Professions Act, 1974, and referred to in section 22A, as the case may be,“

We propose that the same definition of “compounding” be retained as in section 1 of the General Regulations made in terms of the Medicines and Related Substances Act, 101/1965, as amended. Nowhere has it ever been indicated or required that compounding only relates to non-registered medicines. It is common practice to compound medicines by using registered and/or unregistered medicines. Veterinarians often compound medicines by mixing two registered medicines together in a projectile dart to immobilize wildlife. It is also common practice to compound by dissolving tablets in an edible paste for ease of application to cats. By applying a different definition the SAVC will create legal confusion and contradiction.
It is important to also clarify that the prescription is only valid for 30 days and not that the compound should be used in 30 days. It is indeed often possible to determine the stability of a compounded medicine that may well extend past 30 days from date of compounding. This part of the definition of “compounding”, as stated above, is also in contradiction to the wording of Rule 10.5 j which states that a compounded medicine must be administered to a patient for not more 30 consecutive days from the date of dispensing the said medicine.

A: Off label use is defined as extra-label use. We should provide an essential cascade system. The cascade system in in place in the EU, whereby profession have to first use a registered product, then a registered product off-label before attempting to use a compounded medicines.

Q: Definition of patient.

The new SAVC rule proposed definition of “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;

A: This has in the past caused a great deal of concern and confusion and the new definition clarifies the position.

Q: Definition of extra label use.

The new SAVC rule proposed definition of “extra-label use” means the process of using a registered medicine, veterinary medicine or stock remedy in a manner other than stated on the approved label or package insert. This will include re-formulation or mixing together of registered medicines for ease of administration, or change in the prescribed dose or indication, and is considered to be in a different category to compounding.

A: I believe our definition is very clear and articulates with our definition of compounding

Q: It is proposed that the definition should state: “actual use or intended use of a drug in an animal in a manner that is not in accordance with the approved labelling. This includes, but is not limited to, use in species not listed in the labelling, use for indications (disease and other conditions) not listed in the labelling, use at dosage levels, frequencies, or routes of administration other than those stated in the labelling, and deviation from labelled withdrawal time based on these different uses (definition by the FDA since it is not defined in the South African Law”

The first part of the definition of “extra-label use” is correct. We, however, do not agree with the definition of extra-label use in terms of the “re-formulation or mixing together of registered medicines”, as this will be in contravention of the new proposed SAVC rule relating to the definition of “compounding” and it also contradicts the definition of compounding in section 1 of the General Regulations made in terms of the Medicines and Related Substances Act, 101/1965, as amended. It is common practice in veterinary science to use human medicines “extra label” and to use these medicines to compound.

A: Intended use cannot apply. This gives the veterinarian the right to mix medicines well in advance of intended use. There is no reason to combine registered products until their actual use.

Q: Rule 10(5) When using or prescribing a medicine that has been compounded, veterinarians must comply with the conditions of Regulation 18 of the Regulations of the Regulations promulgated in terms of the Medicines Act., and must:

a) Veterinarians are not required to be registered under the Health Professions Act and they cannot be compelled to apply for a license as contemplated in Regulation 18 as Veterinarians are exempt from obtaining a licence to dispense or compound medicines and do not fall under Regulation 18.
b) In terms of the provisions of section 34(1) of the Veterinary and Para-Veterinary Professions Act, 19 of 1982, a registered veterinary professional may personally compound or dispense any medicine which is prescribed by himself or herself 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.

A: Agree. Instead of making reference to regulation 18, its content needs to be included within out rules. (Comment-Dinamarie-The requirements were included in the rules)

Q: Rule 10 (5) m “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;”

It is common practice for a veterinary professional to re-issue a prescription for treatment of a chronic medical condition. Should the veterinarian satisfy himself that a compounded medicine is the best suitable treatment regime for the medical condition that exists on the farm or for the patient or is repeatedly required to immobilize or sedate animals on a specific farm, it is not rational to prevent him from re-issuing the prescription for a compounded medicine under the conditions as specified above. This rule should be amended to read as follows:

“(must) ensure that it is not intended for continued, sustained and/or frequent use on any one farm, by one farm owner, or by any one farm manager, by any one veterinarian or by any one person for an extended period of time unless the prescribing veterinarian has satisfied him/herself that no suitable registered medicine is available as contemplated in Rule 10.5(a) in respect of each renewal of the prescription which renewal can only be done after the expiry of 30 days from the date of issuing the previous prescription.”

A: I believe that the new definition of compounding may make this clearer. In reality, the clause is meant to encourage farmers to not only use a compounded vaccine on their farms but also available treatment as using only compounded vaccines may contribute to the spread of zoonoses if not effective or not relevant to the strain found on the farm.

Q: Rule 10(6) A veterinarian may only compound veterinary medicine in (a) production animal(s), including wildlife intended for human consumption, subject to the following;

a) The terms “production animal(s)” and “wildlife intended for human consumption” will need to be defined in the definitions to prevent confusion. Production animals are used to produce food and therefore a definition of “food producing animal” should rather be used.

b) The FAO and the EU define food producing Animals as follows: ‘food-producing animal’ is an animal that fed, bred or kept for the production of food for human consumption, including animals that are not used for human consumption, but that belong to a species that is normally used for human consumption in the community.

i. (http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32009R0767

c) We also propose that the provisions of the Foodstuffs and Disinfectants Act 54 of 1972 be considered in addressing this issue. The term “production animal” can be replaced with “food producing animal”.

d) Other International definitions include:

a. “production animal” means

e) a species of animal that may be used for human consumption or whose products may be used for human consumption, - http://faolex.fao.org/docs/pdf/al121188.pdf

For the purposes of this guide food-producing animals will be

b. defined as any form of animal life, whose products ordinarily constitute food for human consumption, or whose pelts are ordinarily used for human apparel.

c. Food-producing animals, examples include -

• Bees • Cattle • Chickens • Chinchillas
• Game birds • Mink • Sheep • Swine • Turkeys

A: Agree. But our definition makes sense as well. As long as we define what is meant by food producing. The definition in the Foodstuffs, Cosmetics and Disinfectants Act, Act 44 of 1972 does not cover wildlife meat, equine, crocodile or ostrich meat for that matter and is far from adequate.

Q: Rule 10(6)(c) 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.

We seriously caution against restricting veterinarians to only make use of compounded medicines in food producing animals if the requirements in Rule 10(6)(c) are met. It may not be practical for a veterinarian to wait until such approval is obtained and it may be detrimental to his/her patient’s well-being. We are all aware of capacity problems in regulatory councils and committees and unless a turnaround of 24 hours for a written approval can be guaranteed, it will be totally impractical for veterinarians to use compounded medicines only under these conditions.

A: This is being read incorrectly. The clause does not stop treatment but prevents slaughter is a withdrawal period is not set.

Q: We believe that veterinarians are suitably qualified and have the necessary expertise to access withdrawal data in respect of compounded medicines and extra label use of medicines in order to make the risk assessment of residues in food producing animals for consumers and that this clause should be removed from the rules. The recommendation of 120 days or ten times the half-life of the medicine, is surely purely arbitrarily determined and of little value and has no scientific basis. Veterinarians have the necessary expertise and can obtain the required information from published data, the registration holder or manufacturing companies, trial data and laboratory tests.
A: Veterinarians are not suitably qualified to set a withdrawal period. This is postgraduate pharmacology and is reliant on a 90 to 95% tolerance with 95% confidence of the slaughter test group in comparison to the MRL. The committee will set these difficult withdrawal periods. Once set, the vet can use them henceforth in the definition. It should be added that this process is not unheard of as the FDA used the Food Animal Residue Avoidance Database (FARAD) to set withdrawal periods for these type of cases. Veterinarians in South Africa should understand that no developed country accepts compounding in food producing animals as the safety of the consumer is paramount. The SAVC is being lenient and thereby provided for the more unusual South African farming conditions.

“120 days”-The Veterinary Clinical Committee of the MCC has decided to adopt a withdrawal period of 3 months for products with no pharmacokinetic data, as modern molecules are unlikely to have a long mean residence time. I should add that this can still lead to problems for those molecules like penicillin and phenylbutazone that cause toxicity by immune sensitization.

“Arbitrarily”- This proves that the person does not understand withdrawal periods. It takes 10 half-lived for a molecule to be 99.9% depleted. This is a method of determining the withdrawal period. “Data”-Published data is based on a specific formulation. One can have a look at registered products. It’s not uncommon to find a different withdrawal time as the excipients create different absorptive kinetic profiles. I’ve been involved with a case whereby a company made the same allegations. Three studies later they had to accept that they were wrong.

In addition, nothing stops a veterinarian from asking for ratification of their estimated withdrawal time by the committees above.

1. This proposed rule is, therefore, impractical and will seriously remove a right which has been accorded to them by statute and by the dictates of their profession.

Q: Rule 10(6)(d) 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)(b).

For the same reasons as set out above under the comment relating to Rule 10(6)(c), this rule is totally impractical, unreasonable and unjustifiable for the reasons set out above and should be removed from the rules. Rural areas should be considered and the ability of Veterinarians to determine withdrawal times as well as the need for the preservations and maintenance of the food chain. It should be a matter of substance over form.

Do not agree. The right to safety of a vulnerable public is far superior to the right of a professional to practice. The profession should also consider that there are numerous registered products available, making it unlikely that thousands of farms will routinely be exposed to compounded medicines and thus interfere with their livelihood. I would have considered this more favorably if they provided examples of these molecules which have to be compounded in these far removed areas of the country. I honestly cannot think of a compounded medicine that is used in mass which is not an illegal duplicate of a registered medicine.

Rule 10-the end.

Q: As an addendum to rule 15(1)(j), the following guidelines should be clearly stated and elucidated for practitioners, and they should be instructed to display said regulation to clients, in the
consultation and/or waiting room and their own pharmacy: The maximum period for dispensing of a medication without a full and proper re-examination of the patient is determined by the schedule of the medication:

- Schedule 1 – 3 = 12 months
- Schedule 4 = 6 months
- Schedule 5 = 3 months
- Schedule 6 = maximum 1 month supply
- Schedule 7+ = maximum 2 week supply

A: This is regulated by the Medicines and Related Substances Control Act, Act 101 of 1965, and the regulations promulgated under it.

Q: May a veterinarian dispense medication for another veterinarian?

A: No. Section 35 of the Veterinary and Para-Veterinary Professions Act, Act 19 of 1982, provides that a veterinarian may not keep an open shop. Dispensing for another veterinarian amounts to keeping an open shop. In addition, only persons with dispensing licences may dispense in terms of the Medicines and Related Substances Control Act, Act 101 of 1965.

Q: Should a veterinarian ensure that the purity of the ingredients in the compounded medicine is procured from a manufacturer(s) accredited for Good Manufacturing Practice if he does not do the compounding him/herself?

A: A veterinarian should provide a prescription to a pharmacist to do compounding, if he/she does not do it him/herself. The pharmacist is bound by the provisions of the Pharmacy Act, Act 53 of 1974, and the regulations promulgated under it. These ensure that Good Manufacturing Practices are adhered to.

Q: Veterinary shop

The Qualifying criteria of a Veterinary Retail outlet according to the proposed definition:

1) It has to be registered with the SAVC-
2) It has to be identified as a Veterinarianery Retailer-
3) It has to be owned exclusively by a veterinarian

Nothing within the definition prevents a lay person from having a Veterinary Retail Outlet except for the fact that the Veterinary Act prohibits a lay person from implying to be a veterinarian. (See below) Such a person can therefore own a “Pet Shop” that sells any Act 36 registered product they can lay hands on, including vaccines, provided that they don’t imply to be associated with a veterinarian. There is no legal grounds by which SAVC can exclude or regulate non-veterinarians from dealing in any products, both Act 36 and Act 101 products. Only inspectors appointed in terms of Act 36 and Act 101 have that power.

A: The only reason for SAVC to regulate veterinary retail shops is to protect the image of the profession and maintain a standard of businesses that happens to be owned by veterinary surgeons that elected to use the name of the profession to identify and promote their business by. The intent of the rule should therefore be: If you are a veterinary surgeon that has a business of any kind (Veterinary shop, Veterinary Kennel, Veterinary Grooming, Veterinary Game relocation etc.) and wants to use your professional qualification to promote such business, you need to adhere to a general code of conduct not to bring the profession in ill repute and to promote the wellbeing of animals. No clinical services may be rendered from a veterinary retail shop.

Q: What makes a veterinary shop different from a pet shop?
A: The pet shops are be allowed to sell Act 36 and S0 products, as long as the Act 36 medicines are not restricted for use by a veterinarian. Pet shops may keep live animals on the premises.

Q: What stops a layperson from naming their pet shop a veterinary shop?

A: The Veterinary and Para-Veterinary Professions Act, Act 19 of 1982, prohibits a lay person from implying to be a veterinarian.

Q: Can a veterinarian/veterinarian nurse vaccinate and offer primary health care clinics from these veterinarian shops (no procedures or diagnostics obviously)?

A: In theory yes. No, as they do not comply with the minimum standards of a consulting room or a clinic. A veterinary nurse may only sign a record of vaccination, as opposed to a certificate of vaccination.

Q: Should a small animal vaccination campaign not be subject to minimum standards? A clear standard was set out in the input received.

A: The decision not to include was based on input and motivation by colleagues who stand in the trenches and supported by Dr. Banderker. It’s non-inclusion also allows for the necessary flexibility to adapt the requirements of such a campaign to the exigencies of each campaign.

Q: General questions about the procedure and inquiries into professional conduct:
   a) Who is the Registrar and Investigation Committee (IC)?
   b) Who is entitled to elect the members of the Registrar and IC?
   c) What are prerequisites and qualification to be elected into the position and what is the duration of membership of the Registrar and IC?
   d) Can the Registrar and IC consist of the same members?
   e) Is the Registrar and IC an independent body to the Veterinary Council?
   f) If indeed the Registrar and IC are part of the Veterinary Council, would there be not a profound conflict of interest?
   g) I would like to see more transparency of the Registrar and IC in the future.
   h) These are general questions concerning the inquiries procedures conducted by the Veterinary Council.

A: In the same order:
   a) The Registrar is the Chief Executive Officer of the Council and the Chairperson of the Investigation Committee (IC) is elected by Council.
   b) The Council appoints the Registrar in terms of the Veterinary and Para-Veterinary Professions Act, Act 19 of 1982, (this is not an elected position) and the Investigation Committee [IC] (one of the committees of Council) is elected by Council, once the Council is properly constituted every three years.
   c) The Registrar is an employee of Council . The Registrar’s term of office is not restricted to a time period. Should the position become vacant by death, dismissal or resignation, it is advertised and filled after a selection process. Council sets up the job description and requirements. The Chairperson of the IC must be a Council member. The other members are co-opted, subject to the approval of the Council.
   d) The Registrar and the IC are not one and the same. The Registrar is an employee of Council and the IC consists of a Chairperson elected by Council and the other members approved by Council.
e) The IC is a committee of Council and is delegated by the Council to screen complaints and responses. Council is not involved in the screening of complaints at all, other than that the Chairperson of the IC is a member of Council. The reason for that is that Council can consider review applications at a later stage without being compromised by prior knowledge of the matter. The Chairperson of the IC recuses him/herself from the Council meeting for the purposes of a review application.

f) There is no conflict of interest, for the reasons set out above in point (e).

g) The Chairperson of the IC has the right to co-opt persons, provided that Council formally approves such co-option. The inquiries are open to the public and therefore transparent. The investigation process is treated as confidential so as to protect the veterinarian from vilification, until such time as he/she may be found guilty of unprofessional conduct. Should the verdict be one of not guilty, the veterinarian’s name is not released to the general public and no information is given out, other than, in the event of an enquiry, to say the veterinarian was found not guilty.

h) The Registrar acts upon the instructions of the IC.

i) All details of members of committees are published on the website.

Q: Amplification of clinical records.
Furthermore, I am under the impression that the clinical records 6.2(e) aspect of records are personal records made by and for the professional themselves (be it a medical doctor or veterinary surgeon), rather than enforced records available for the scrutiny of Council. I’m not sure it is fair to make it compulsory to release these clinical records specifically at this stage in an investigation. Instead allow the professional to use them to jog their own memory if needed later on in an investigation or inquiry.

A: Proper clinical records at the time of treatment of a patient are vital. If these are added to or amplified at a later stage, the only inference that the IC (and a Court) could make is that these additions or amplifications are tailored to exonerate the veterinarian and are therefore not necessarily the product of a good memory, but rather an instrument to tailor events to suit the version of the veterinarian. Clinical records serve to protect the interest and integrity of the veterinarian, the patient and the owner. These have helped to dismiss a large number of complaints at the screening stage. Should any amendments or additions be made to clinical records, such amendments or additions should be dated and initialled accordingly, so as to ensure that the veterinarian cannot be accused of tailoring his/her records to suit his/her case or tampering with evidence.

Q: Should, in terms of rule 38(1), the committee for investigation should include TWO specialists and ONE general practitioner, NOT the other way around, as a “peer” may not possess the relevant insight to make value judgements about the possible misconduct at a general practice level. For investigation of a specialist, the panel should include THREE specialists only.
A: Where it is possible and specialists are available, they are appointed to the Inquiry Body. It is however not practical to include three specialists on the Inquiry Body.

Q: Another concern: ‘Rules’ versus ‘Code of Conduct’
Something has occurred to me that I do not think has been made clear to the veterinary profession at large. I gather that these 55 pages of proposed rules have expanded to include much of what was previously only included in the document entitled ‘Code of Conduct’. I presume the term ‘Rule’ holds more legal implication than a ‘Code of Conduct’. A Code of Conduct would seem like a better way to guide professionals, along with the rules contained in the relevant Acts, especially with regards to matters of professional conduct and ethical issues.
If we are changing from being regulated in many instances by a ‘Code of Conduct’ to being regulated
in these same instances by ‘Rules’, then this must be clearly highlighted to the veterinary profession
as an explicit and separate point for input, before the new rules are sent to the Minister for approval
and published in the Gazette.

My particular concern still surrounds the rules that have been implemented pertaining to
professional conduct and ethical scenarios. (Ruling on more tangible things like buildings and
advertising are a different matter.)

If we need to ‘define the concept of professional and unprofessional conduct in order to move away
from price in order to maintain certain expected standards of service and shift the emphasis towards
professionalism’, then we should be allowing this definition to unfold through guidelines set out in
the CoC (and thereafter judging compliance on a case by case basis), not by using rules.

Members of a profession should be governed by codes of ethics.

A: Members of the veterinary profession are governed by the Veterinary and Para-Veterinary
Professions Act, Act 19 of 1982, its regulations, its rules and the Code of Conduct and Practice for
Veterinarians. There are other legislation that have to be complied with as well, such as Medicines
and Related Substances Control Act, Act 101 of 1965, amongst others.

It is unfortunate that the Inquiry Bodies are these days increasingly confronted by unscrupulous
legal representatives with arguments such as that because, the Act, regulations or rules do not
specifically provide for certain conduct to be unprofessional conduct, is cannot be regarded as
unprofessional conduct and therefore their client/member cannot be guilty of misconduct. It was
therefore necessary to attempt to elucidate on behaviour that would be consistent with
unprofessional conduct, whilst still allowing some flexibility as one can never legislate for all
occurrences.

Q: That in the definitions sections of unprofessional conduct, where it reads Rule 1(ix) performing
professional services outside the scope of his/her education, training and/or experience, regard
being had to both the extent and limits of his/her professional expertise; that this be expanded to
include the following: “...specifically the performance of procedures under list A of the specialist-only
procedures, which are not considered in the remit of the general practitioner regardless of
experience or equipment”. Said list should then be elucidated by each specialist college, but for my
tuppence worth these include:

a. Spinal fluid collection
b. Myelography and/or spinal surgery
c. Intracranial surgery
d. Intrathoracic surgery
e. Lapaoscopic, arthroscopic, endoscopic or thorascopic surgery
f. The performance or interpretation of fluoroscopic, MRI, CT or scintigraphic imaging
g. Radiation therapy (teletherapy, brachytherapy)
h. Photodynamic therapy
i. Intra-ocular surgery including phacoemulsion or lens replacement therapy
j. Echocardiography except for the basic diagnosis of dilative cardiomyopathy (canine)
or mitral valvular disease; the diagnosis and/or grading of hypertrophic
cardiomyopathy in cats, congenital cardiac disease, and breed-specific cardiac
pathologies (eg HCM screening in Maine Coon Cats and Sphynx, diagnosis of DCM ni
the Boxer/Dobermann)
k. Holter Monitor ECG
l. Chemotherapy with agents outside a prescribed list (Vincristine, Hydroxyurea)
   i. GPs should not be permitted to administer the following medicines without
      a relevant BVSc(Hons) degree and up-to-date, relevant CPD:

      1. Doxorubicin, Cyclophosphamide, Chlorambucil, Melphalan, Carboplatin
ii. GPs should never be permitted to administer agents from the following list:

1. Lomustine, Carmustine, Capecitabine, Fluorouracil, Cytarabine, Thiotepa, Mitramycin, Mitomycin, Idarubicin, Cisplatin, Ifosfamide, or any other agent not appearing on the above list (1)

A: It can be submitted for the workshop, but the principle will probably be objected to by veterinarians. The general consensus is that it would be over-regulation.

In closing, thank you to each and every one of you that gave input. It hopefully allowed us to present practical rules which would be valid for the next few years.