

COMMUNIQUE – 7 DECEMBER 2017

LICENSING OF VETERINARIANS TO COMPOUND AND DISPENSE MEDICINES : LEGALITY OF STATUTORY REQUIREMENT

1. On Monday, 4 December 2017, the South African Veterinary Council (“SAVC”) released a statement by its President, Dr Clive Marwick, entitled **“Is a dispensing license required for veterinarians, if so, why?”**. This statement was also published in the December 2017 Newsletter of the SAVC.
2. The SAVC statement deals with the interpretation and implementation of the new statutory requirement that veterinarians must obtain a license to dispense- or compound- and dispense medicines to a patient.
3. This statement by the SAVC does not, however, present veterinary professionals with the full picture regarding the licensing requirement now being imposed on veterinarians.
4. In terms of the Medicines and Related Substances Amendment Act, 14 of 2015 (“the 2015 Amendment Act”), the word **“veterinarian”** was inserted in section 22 C (1) (a) of the Medicines and Related Substances Act (“the Main Act”).
5. A veterinarian has always had the right to personally compound and dispense any veterinary medicine prescribed by the veterinarian for use in the treatment of an animal which is under his or her professional care. This right of a veterinarian is derived from the specific provisions of Section 34 (1) of the Veterinary and Para-Veterinary Professions Act, 19 of 1982.
6. The insertion of the word **“veterinarian”** in the amended section 22 C (1) (a) of the 2015 Amendment Act has the effect that veterinarians are now required to be licensed in terms of this section to compound and dispense medicines for the first time in South African veterinary history, which is a material limitation of the right of all South African veterinarians to compound and dispense medicines. It also constitutes a material amendment of the Medicines and Related Substances Act, as amended (“the Main Act”).
7. The Department of Health put forward the following reasons to justify the inclusion of the word **“veterinarian”** in the amendment to Section 22 C (1) (a) (*Medicines and Related Substances Amendment Bill: Response by Department of Health to submissions made during public hearings – 19 November 2014*):

“Amendments to Section 22C added that veterinarians would also now be issued with licenses to compound and dispense medicines on the prescribed conditions. Experience has shown that veterinarians lack knowledge on compounding and dispensing of medicine, although it was previously claimed that the pre-graduate curriculum for veterinarians included training on compounding and dispensing.”

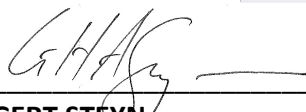
8. SAVA does not accept the Department of Health’s and the legislature’s superficial view of the veterinarian’s ability to compound and dispense medicines for animals under their care and strongly disagrees with this rationale for requiring veterinarians to acquire a license to compound and/or dispense medicines:
 - 8.1. veterinary compounding and dispensing is a specialised discipline within the field of veterinary medicine;
 - 8.2. compounding and dispensing do not solely “belong” to the profession of a pharmacist nor can pharmacists claim special knowledge about compounding and dispensing of veterinary medicines as veterinary compounding practices differ in material respects from human compounding techniques and are species specific;
 - 8.3. this subject (compounding and dispensing by veterinary professionals) is a matter between the South African Veterinary Council (the SAVC) and the veterinary profession. If there are shortfalls, these must be resolved within the profession by their regulator (SAVC) as the conduct of compounding and dispensing is part of daily veterinary practice. The Department of Health’s intervention in this veterinary discipline is misdirected;
 - 8.4. veterinarians work in their practices with a broad range of animal species (snakes, crocodiles, household pets, food producing animals, birds, lions, buffalo, giraffes, elephants, etc.) for which few if any registered medicines are available. Veterinarians are trained to master these animal diversities and are experts in this field of compounding and drug dosing. It goes to the core of their profession as few registered veterinary medicines, if any, are available to treat the diverse species under veterinary care;
 - 8.5. veterinarians are faced with challenges relating to the administration of veterinary medicines on a daily basis. For example, each species requires special medication, and for wild animals, drugs must be administered remotely (darting – not a human practice) to immobilise them for further treatment or relocation. Compounded drug cocktails are the order of the day as seldom is a single drug a suitable choice and multiple injections are not an option (veterinary patients bite, kick, flee and are difficult to restrain);
 - 8.6. although human dispensing and compounding standards are informative, they cannot dictate the practice standards of a veterinarian when dealing with the variety of species under treatment. Bearing in mind that many drugs are administered in inaccessible areas of the country where veterinarians can spend days on end in the bush under trying conditions and operating from mobile units (bakkies). Standards for compounding and

dispensing in these isolated locations must be developed as they do not exist. This practice environment is unique to the profession of a veterinarian. Human compounding practices offer no comfort in such situations and if applied must be done with extreme circumspection to prevent interference with tested veterinary practices.

9. Neither SAVA nor the South African Veterinary Council were informed of the alleged “*lack of knowledge*” of veterinarians pertaining to the compounding and dispensing of veterinary medicines. This conclusion and rationale of the Department of Health regarding veterinarians’ alleged “*lack of knowledge*” was arbitrary and capricious, lacking substance and factual validity. Accepting the premise of veterinarian’s “*lack of knowledge*” without affording the veterinary profession the opportunity to respond to this and to render input, was procedurally unfair and unreasonable.
10. After carefully reviewing the legislative process, SAVA has established that :
 - 10.1. the insertion of the word “*veterinarian*” in the amended section 22 C (1) (a) of the 2015 Amendment Act, took place without any public participation and consultation as is required by the Constitution of the Republic of South Africa. Whilst the Amendment Bill was the subject at public hearings, and of responses by the Department of Health and legal advisors and deliberations, the Bill, during these procedures never included the insertion of the word “*veterinarian*” in section 22 C (1) (a);
 - 10.2. the National Assembly, National Council of Provinces (NCOP) and certain Provincial legislatures failed to invite citizens, and especially the veterinary profession, including SAVA and the SAVC, to comment on the material amendment of section 22 C (1) (a), and failed to afford them the opportunity to be heard and render input about the proposed requirement for veterinary professionals to be licensed to compound and dispense medicines. The insertion of the word “*veterinarian*” was clearly not an amendment of a technical nature and was a material amendment which could not be effected without complying with the constitutional obligation to facilitate public involvement;
 - 10.3. the National Assembly, National Council of Provinces (NCOP) and certain Provincial legislatures thus failed to comply with their respective constitutional obligations in terms of the Constitution (sections 59 (1) (a), 72 (1) (a) and 118 (1) (a) of the Constitution of the Republic of South Africa) to facilitate public involvement in their legislative processes;
 - 10.4. the insertion of the word “*veterinarian*” in section 22 C (1) (a) also has consequences when interpreting the entire amended Medicines Act as amended by the 2008 and 2015 Amendment Acts due to the fact that there are several inconsistencies and conflicts between the provisions of section 22 C (1) (a) and other sections of the Medicines Act, and between section 22 C (1) (a) and several provisions of the new General Regulations under the Medical and Related Substances Act, as amended. This renders the implementation of the 2015 Amendment Act impossible without amendments. Consultation with the veterinary profession and the public is essential and necessary to remove the irreconcilable anomalies brought about by the 2015 Amendment Act.

11. At the beginning of 2017 SAVA directed an urgent and comprehensive document to the National Assembly Portfolio Committee for Health, which was also forwarded to the Minister of Health, Director General – Department of Agriculture, Forestry and Fisheries, and the South African Veterinarian Council :
 - 11.1. specifically pointing out in detail the failure by the Portfolio Committee, Health, the Department of Health, the National Assembly, the NCOP and certain Provincial legislatures, to comply with their constitutional obligations to facilitate public involvement before passing the 2015 Amendment Act;
 - 11.2. setting out in detail the inconsistencies and conflict between section 22 C (1) (a) and other sections of the Medicines Act, and between section 22 C (1) (a) and the new General Regulations under the Medicines and Related Substances Act, as amended;
 - 11.3. requesting the Portfolio Committee of the National Assembly, and the Portfolio Committee of Agriculture, Forestry and Fisheries, as well as the relevant Ministers of Health and of Agriculture, Forestry and Fisheries to seek an urgent solution to the aforesaid problem in conjunction with SAVA and the veterinary profession.
12. No response was received from the Portfolio Committee, Health of the National Assembly, or the Minister of Health or the Department of Agriculture, Forestry and Fisheries.
13. On 15 November 2017 SAVA directed a further urgent letter to the Ministers of Health and of Agriculture, Forestry and Fisheries, as well as the Portfolio Committee on Health, which letter was also sent to the SAVC, informing them that in view of the fact that the 2015 Amendment Act has already been enacted and came into operation on 1 June 2017, that the failure by Parliament and the Provincial legislatures to comply with their constitutional obligations, to facilitate public involvement before finally passing the 2015 Amendment Act, including the amendment to section 22 C (1) (a), will necessitate the Constitutional Court's intervention to declare the 2015 Amendment Act or portions thereof inconsistent with the Constitution and, therefore, invalid.
14. In the letter of 15 November 2017 SAVA also indicated its belief that the solution to this material problem lies in an agreement between the relevant Ministers and their Departments and the veterinary profession (SAVA and the SAVC) to suspend the implementation of the 2015 Amendment Act or portions thereof, pending a process of re-enactment of the 2015 Amendment Act or portions thereof by Parliament and the Provinces in a manner that is consistent with the Constitution. SAVA stated that it was also open to any other viable resolution of the problem as proposed by the relevant Ministers and the Portfolio Committee, Health.
15. SAVA, therefore, proposed urgent discussions with the Minister of Health and Minister of Agriculture, Forestry and Fisheries and their Departments regarding a solution of the constitutional invalidity of the 2015 Amendment Act which has major implications for our country in developing its new regulatory system for the control of medicines and medical devices.
16. No response whatsoever has been received from the relevant Ministers or from the Portfolio Committee, Health of the National Assembly.

17. The SAVC, despite being fully informed of the unconstitutional legislative process which was followed with the insertion of the word “veterinarian” in the amended section 22 C (1) (a) of the 2015 Amendment Act, requiring veterinarians to be licensed to compound and dispense medicines, and despite voicing certain concerns about the situation, has apparently decided to accept the licensing of veterinarians to compound and dispense medicines as a *fait accompli* and its statement of 4 December thus seeks to justify and facilitate the implementation of the statutory requirement requiring veterinarians to be licensed to compound and dispense medicines.
18. SAVA has, therefore, decided that it has been left with no other option but to launch an application to the Constitutional Court directly for an order of invalidity of the 2015 Amendment Act or portions thereof, including the requirement that veterinarians be licensed to compound and dispense medicines. The application will be launched as soon as possible and the veterinary profession will be informed from time to time about the progress of the application.
19. SAVA believes this action to be in the interest of the public, veterinary health and the veterinary profession and to also prevent a disruption of the supply of suitable veterinary medicines to animal patients as such a disruption may well have a negative impact on food security and general animal health in South Africa.



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CC South African Veterinary Council
Registrar of Medicines