Mr Lea Reynolds
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey
KT15 3LS

PRACTICE AND QUALITY
IMPROVEMENT DIRECTORATE
Telephone: 020 7572 2612
Facsimile: 020 7572 2501
e-mail: lorraine.fearon@rpsgb.org

11th June 2008

Dear Mr Reynolds

Veterinary Medicines Regulations 2008

The Royal Pharmaceutical Society of Great Britain (RPSGB) is the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis, which is expected to become statutory under anticipated legislation. The primary objectives of the Society are to lead, regulate, develop and represent the profession of pharmacy.

The Society leads and supports the development of the profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

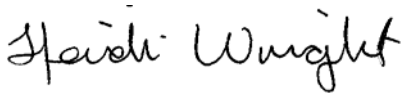
The Society has responsibility for a wide range of functions that combine to assure competence and fitness to practise. These include controlled entry into the profession, education, registration, setting and enforcing professional standards, promoting good practice, providing support for improvement, dealing with poor performance, dealing with misconduct and removal from the register. The Society also produces a Code of Ethics containing standards governing the conduct, the practice of pharmacists and pharmacist's competencies.

Pharmacists under their Code of Ethics are only able to operate within their range of competence. All pharmacists must adhere to the RPSGB Code of Ethics and it is enforced through the RPSGB regulatory machinery. The ultimate sanction would be removing the pharmacist's name from the Register. The Society's Pharmacists and Pharmacy Technicians Order 2007 also provides the ability to suspend or restrict practice and where necessary prevent a pharmacist prescribing.

The Royal Pharmaceutical Society of Great Britain welcomes the opportunity to participate in the consultation process and have the following comments: **see attached document.**

We hope these comments will be taken into consideration, and would like to thank the VMD for the opportunity to participate in the consultation. If you have any queries regarding the above, please do not hesitate to contact me.

Yours sincerely



Ms Heidi Wright
Head of Practice

ASSURING THE SAFETY, QUALITY AND EFFICACY OF VETERINARY MEDICINES

ANNEX D

DRAFT VETERINARY MEDICINES REGULATIONS 2008
CONSULTATION RESPONSE FORM

The closing date for this consultation is 9 June 2008.

You may find it helpful to set out your responses to the Consultation using this Response Form.

Name:	Ms Heidi Wright (Head of Practice)
Organisation (if applicable):	Royal Pharmaceutical Society of Great Britain
Address:	1 Lambeth High Street, London, SE1 7JN

Please return completed forms to:

Lea Reynolds
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey
KT15 3LS

Telephone: **01932 338321**
Fax: **01932 336618**
email: **l.reynolds@vmd.defra.gsi.gov.uk**

Please tick one box from the following list of options that best describes you.

	Small to Medium Enterprise
x	Representative Organisation
	Trade Union
	Interest Group
	Big Business
	Local Government
	Central Government

	Other (eg. consultant or private individual)

Question 1
i) Should the legislative provisions on appeals to an appointed person be clarified and extended to include Non-Food Animal Blood Banks (NFABBs), Autogenous Vaccine Authorisations (AVAs) and Approved Premises (retail)?

Please provide any comments you have, including information on any impact the change will have on you or your business.

Comments
The Society makes no comment.

Question 2
Should the legislative controls on the NFABB scheme be clarified to include blood products derived from donor blood via a closed-bag system of separation?

We would welcome views from businesses in this sector on whether the use of current practices, such as the separation technique would increase due to improved clarity on legislative controls and increased assurance about what is permitted under the authorisation. What would be the additional costs and benefits? We would also welcome views on the benefit of using the separation technique, in terms of requiring fewer blood donations, and the implications for animal welfare.

Please provide any comments you have, including information on any impact the change will have on you or your business.

Comments
The Society makes no comment.

Question 3
Should legislative controls on the collection and supply of equine stem cells be introduced? If so, are those proposed proportionate and adequate?

We would welcome views from businesses on the additional costs to them of completing registration procedures and complying with inspections. Would the policy result in reducing instances of deficient practice? What would be the implications for animal health and welfare? We would welcome views from race horse owners and vets on the potential loss of benefit that could result from a ban on stem cell use.

Please provide any comments you have, including information on any impact the change will have on you or your business.

Comments
The Society makes no comment.

Question 4
Is the introduction of compulsory variations for manufacturing authorisations necessary?

We would welcome views from businesses on the benefit to them from being able to continue compliant manufacturing activity and on the potential social benefit associated with this policy (e.g. due to reducing disruption in the quantity of veterinary medicinal products supplied to market).

Please provide any comments you have, including information on any impact the change will have on you or your business.

Comments
The Society makes no comment.

Question 5
Is the introduction of compulsory variations for wholesale dealer authorisations necessary?

We would welcome views from businesses on the benefit to them from being able to continue compliant wholesaling activity and on the potential social benefit associated with this policy (e.g. due to reducing disruption in the quantity of veterinary medicinal products supplied to market).

Please provide any comments you have, including information on any positive or negative impact the change will have on you or your business.

Comments
The Society makes no comment.

Question 6
a) Should SQPs be able to work from registered veterinary surgeon's premises or pharmacy premises without the need for dual registration?

Please provide any comments you have, including information on any impact the change will have on you or your business.

Comments
The Society makes no comment.

Question 7
Should the Animal Test Certificate (ATC) approval process be widened to cater for small-scale research projects carried out by veterinary surgeons? If so, are the proposals for a Type S ATC proportionate and adequate?

Please provide any comments you have, including information on any impact the change will have on you or your business.

Comments
The Society makes no comment.

Question 8
i) Should retailers of ornamental fish be exempted from the need to be approved to mix medicated feed? Views from ornamental fish premises are welcome on instances where excess mortality has occurred due to the lack of appropriate medication at the appropriate time.

ii) Should it be an offence to supply feed to be fed to an animal, which contains a veterinary medicinal product or specified feed additive not authorised for that species of animal?

Please provide any comments you have, including information on any impact the change will have on you or your business.

Comments
The Society makes no comment.

Question 9
Should the distributor's name and address be shown on the label of a product marketed under the Small Animal Exemption Scheme (SAES) as an alternative to the manufacturer's details?

Please provide any comments you have, including information on any impact the change will have on you or your business, including any costs or savings.

Comments
The Society makes no comment.

Question 10
i) Should manufacturers, importers and retailers of products marketed under the Small Animal Exemption Scheme (SAES) be required to record all suspected adverse reactions reported to them and report them to the VMD?

ii) Would this proposal result in faster detection of unsafe products? What would be the resulting animal health and welfare impacts?

Please provide any comments you have including information on any impact the change will have on you or your business, including any costs or savings.

Comments
The Society makes no comment.

Question 11
Will the proposals for above-inflation fee-increases have any impact on barriers to market entry or the structure of competition?

Please provide any comments you have including information on any impact the change will have on you or your business, including any costs or savings.

Comments
The Society makes no comment.

Question 12
a) Do you have any comments on the proposals for the register of veterinary practice premises?

b) Do you have any comments on the information relating to inspection of veterinary premises?

Please provide information on any impact the proposal will have on you or your business, including any costs or savings.

Comments
The Society makes no comment.

Question 13
Do you have any comments on the proposed drafting amendments?

Comments
Schedule 3, Paragraph 14(4)(b) states “the premises of a pharmacist”. Should this be changed to “premises registered as a pharmacy” as a pharmacist may not necessarily be on the premises or own the company, (although there is a requirement to have a superintendent who is a pharmacist).

Question 14
Do you have any comments on proposed changes to the guidance notes?

Comments
The Society makes no comment.

Question 15
It has been suggested by a number of stakeholders that a hard copy of a prescription should always be required before any products can be dispatched. However, we have not received any evidence of abuse/misuse of electronic prescriptions and therefore no change to legislation is proposed at present.
We would be interested in your comments on this.

Comments
The Society makes no comment.

Question 16

Would it be better for you if the legislation on Controlled Drugs affecting veterinary medicines was incorporated within the Veterinary Medicines Regulations?

We would be very interested in any comments you have on how this change would reduce the misuse of controlled drugs and if the consolidation of the legislation would result in a reduction in administrative burden for businesses.

Comments
The Society makes no comment.

Do you have any other comments that might aid the consultation process as a whole?

Please use this space for any general comments that you may have, comments on the layout of this consultation would also be welcomed.

Comments
Delegation Schedule 3, Paragraph 10, is silent on whether pharmacists must personally supply a veterinary medicinal product or can authorise another if they are competent to do so. This authority to delegate the supply is made clear for Veterinary Surgeons in Schedule 3, Paragraph 9, and for SQPs in Paragraph 14(5). Supervision by a pharmacist is clarified in the Medicines Act 1968 but since 2005 this applied only to 'human' medicinal products. We would suggest that delegation of supply of POM-V, POM-VPS and NFA-VPS is made clear in the regulations. **Pharmacy premises** The proposed 2008 Regulations allow for Veterinary Surgeons and SQPs to supply from a registered retail pharmacy business. The Medicines Act defines a retail pharmacy business as one that includes the retail sale of human medicinal products other than those on the GSL. A retail pharmacy must be registered with the RPSGB. A company intending to provide only veterinary medicinal products could register a retail pharmacy business. A non-pharmacist (i.e. a Veterinary Surgeon or SQP) could only own a retail pharmacy business as a corporate body. Section 71 of the Medicines Act therefore requires a superintendent to be in place. The superintendent must be a practising, registered pharmacist with the RPSGB. As veterinary medicinal products are not covered by the Medicines Act they could potentially be sold/supplied by retail from a registered pharmacy premises without a

pharmacist in “personal control”. Personal control is a requirement of the Medicines Act and basically requires the pharmacist to be physically on the registered pharmacy premises.

However, Section 78 of the Medicines Act restricted the use of the titles “Pharmacy” and “Chemist”. It provides that no retail sales (medicinal or non-medicinal) can be made under the title “pharmacy” or “chemist” unless a pharmacist is in personal control. In the case of Pharmacy (P) medicines or prescription only medicines (POM) medicines (human) this requires the additional control of “supervision” by the pharmacist. This is interpreted as being in a position to advise and intervene.

Therefore, in the future it could be envisaged that a SQP could supply POM-VPS and NFA-VPS from a registered pharmacy in the absence of the pharmacist. This could not be done if the premises trades under a name including the word “Pharmacy” or “Chemist” and the supply of a veterinary product, although not a human medicine, would be considered a retail sale/supply and is therefore caught by Section 78 of the Medicines Act.

If a veterinary surgeon or a SQP supplies a medicine “under the cascade” it is possible that this may be a human medicine. This could then have implications in terms of the Medicines Act and may require a pharmacist to be in personal control of the premises and be “supervising” any supply of a P or a POM human medicines.

There is also the potential that as a retail pharmacy business the veterinary surgeon or the SQP could wholesale medicines. This is an activity (except under MHRA licence) normally restricted to a registered pharmacy and under the supervision of a pharmacist. This could open up the possibility of medicines being wholesaled in a less controlled environment.

The restricted titles ‘Pharmacy’ and ‘Chemist’ are associated in the minds of patients and public with the Pharmaceutical profession and there is an expectation that services provided from such premises would be to the standards expected of that profession. We would not wish to see that professional identity undermined or eroded.

Due diligence clause

There is no due diligence clause in Schedule 3. This means that a pharmacist who receives a prescription that has a minor error on it cannot legally p.c. (prescriber contacted) the prescription. A suggestion would be similar wording to the Prescription Only Medicines (Human Use) Order 1997, (POM Order), which has a provision to allow pharmacist to exercise all due diligence to supply against a prescription that needs amendments. See POM Order wording below:

“(5) The prohibition on sale or supply imposed by section 58(2)(a) shall not apply where a prescription only medicine is sold or supplied other than in accordance with a prescription given by an appropriate practitioner and --

(a) the reason the sale or supply is not in accordance with such a prescription is that a condition specified in paragraph (2) or (4) is not fulfilled; and

(b) the person selling or supplying the prescription only medicine has exercised all due diligence and believes on reasonable grounds that the condition is fulfilled.”

The conditions in 58(2)(a) are that a legally valid prescription exists.

Thank you for taking the time to let us have your views. We do not intend to acknowledge receipt of individual responses unless you tick the box below:

Please acknowledge this reply X

Here at the Veterinary Medicines Directorate we carry out our research on many different topics and consultations. As your views are valuable to us, can we contact you again from time to time either for research or to send through consultation documents?

X☐ **Yes** ☐ **No**