



Royal Pharmaceutical Society of Great Britain

Helping pharmacists achieve excellence

3 September 2010

Lorna Shelley
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey KT14 3LS

RUTH WAKEMAN

HEAD OF PROFESSIONAL SUPPORT

Telephone: 0207 572 2615

E-mail: ruth.wakeman@rpsgb.org

Dear Sir/Madam,

Re: Public consultation on the Veterinary Medicines Regulations 2010

Please find below the response of the Royal Pharmaceutical Society of Great Britain to the above consultation. This response has been prepared by the Society with the benefit of specialist input from the Veterinary Pharmacy Group.

The Royal Pharmaceutical Society of Great Britain is currently the professional and regulatory body for pharmacists in England, Scotland and Wales. There will be de-merger of the Society's regulatory and professional roles in September 2010 which will see the establishment of a new General Pharmaceutical Council and a new Professional body.

Proposal 1 – Advertising of antimicrobial veterinary medical products

The Royal Pharmaceutical Society supports the proposed change to restrict advertising of antimicrobial veterinary medicinal products to veterinary surgeons, veterinary nurses and pharmacists. We believe that unrestricted advertising may compromise animal welfare and agree that the proposed restriction will reduce pressure on veterinarians to prescribe antimicrobials unnecessarily.

Proposal 2 – EEA prescriptions

The Royal Pharmaceutical Society supports the principle of introducing enabling legislation to allow the recognition of prescriptions written by EEA Veterinarians. This would bring EEA veterinarians in line with EEA doctors and dentists who are already legally recognised as appropriate prescribers within the United Kingdom.

However, there are significant practical problems which must be addressed with supplementary guidance and/or additional legislation, prior to the introduction of this legislative change.

Issues Identified:

- Confirmation of registration
- 'due diligence' defence
- Prescription requirements
- Marketing Authorisation
- Narcotic and psychotropic lists
- Switzerland

Confirmation of registration

From experience with EEA doctors and dentists, confirmation of registration is a major professional issue with potential legal implications. It is unlikely that a complete list of EEA competent authorities for veterinarians currently exists, assuming this could be constructed, it is likely that many EEA countries will not have a register let alone an online register with English support. Therefore there are inherent and real problems in checking registration status. The Veterinary Medicines Regulations have requirements to check registration and therefore there is a potential legal impact.

'Due Diligence' Defence

With EEA doctors and dentists, there exists in legislation a "due diligence" defence, whereby if the supplying pharmacist has exercised all due diligence to check that a prescription is valid then they are exempt from provisions which require the prescription to be written by an appropriate prescriber. A similar defence would be beneficial here and would provide security for the supplying pharmacist or veterinarian when presented with a prescription which appears to satisfy prescription requirements.

Prescription Requirements

Prescription requirements for UK veterinary medicines are clear and stringent. There is likely to be a significant problem with EEA veterinary prescriptions not complying with the UK requirements, indeed this could be the case for the majority of EEA veterinary prescriptions received.

Marketing Authorisation in country of use

It is proposed that dispensing may only take place if the veterinary medicine holds a marketing authorisation in the country where the product is to be used. This represents a difference to the approach adopted for EEA Doctors and Dentists where the product must hold a marketing authorisation which is valid in the UK (including European wide marketing authorisations) before supplies can be made. The Society consider that the 'valid in the UK' approach makes more sense logically and practically.

Narcotic and psychotropic lists

It is proposed that EEA prescribers will not be able to prescribe narcotic or psychotropic veterinary products. It would be beneficial for an official list of narcotic and psychotropic veterinary products to be produced and made available by the VMD in time for the implementation of the legislation.

Switzerland

The EEA does not include Switzerland, however Switzerland does benefit from EEA rights and was therefore specifically included in legislation allowing EEA doctors and dentists to be recognised. Inclusion of Switzerland together with other EEA countries in the proposed changes would therefore be compatible and reduce confusion.

Proposal 3 – Internet Retailing Control

The Royal Pharmaceutical Society recognises the importance of accreditation schemes to reduce the presence of illegal rogue online websites selling veterinary medicinal products on the internet.

However, for registered pharmacy premises there already exists an accreditation system and associated internet pharmacy logo. This links into a registration check facility and aims to help the public identify that an online pharmacy is registered and bona-fide. This system is currently administered by the registration part of the Royal Pharmaceutical Society. By the time the Veterinary Medicines Regulations 2010 come into force, this will be the role of the General Pharmaceutical Council (GPhC) who will be the regulator for pharmacists, pharmacy technicians and registered pharmacies.

We believe that the introduction of a new online accreditation scheme for sites operated by veterinary surgeons or merchants is beneficial however pharmacies using the current regulatory online pharmacy accreditation should be exempt from this new scheme.

We would like to take this opportunity to clarify that our use of the descriptions 'online pharmacy' or 'internet pharmacy' apply only to pharmacies registered with the regulatory arm of the Royal Pharmaceutical Society and not to online veterinary retailers or merchant retailers of veterinary medicines, about whom these descriptions are commonly but wrongly used.

Proposal 16 - Reduction of fees for some categories for wholesale dealers' authorisations

In light of the concurrent proposals to remove the 5% exemption for wholesaling, this proposal to review the fees for some categories of wholesale dealers' authorisations would enable more pharmacies to become wholesale dealers and to abide by the standards required by this. The Veterinary Pharmacy Group is willing to provide evidence to the review process.

Comment on the Cascade

The Royal Pharmaceutical Society believes that there remain practical problems with the cascade which merit a solution. In some circumstances it is possible for an unlicensed medicine to be the most appropriate clinical product for an animal, even when a licensed veterinary medicinal product exists and this is not acknowledged in legislation.

We hope these comments are useful.

Thank you for contacting the Society.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Ruth Wakeman'. The signature is written in a cursive, flowing style.

Ruth Wakeman MRPharmS

Head of Professional Support