



MEETING	Advisory Committee
DATE	25 September 2008
TITLE	RCVS Register of veterinary Practice Premises
CLASSIFICATION	Unclassified
SUMMARY	From 1 April 2009, veterinary surgeons must supply medicines from registered premises; RCVS Council agreed that RCVS should hold the register, which was agreed by VMD. Work has been ongoing with the VMD to establish the register. As part of this, additional RCVS Guide advice is proposed.
DECISIONS REQUIRED	To approve additional advice for inclusion in the RCVS Guide to Professional Conduct and frequently asked questions (FAQs) on the RCVS Register of veterinary practice premises.
ATTACHMENTS	Annex A: Note of the meeting with VMD on 8 September 2008 Annex B: Draft Guide additions Annex C Draft FAQs on the RCVS Register of Veterinary Premises
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Summary

1. The Advisory Committee and RCVS Council have agreed:
 - a) that the RCVS should hold the register of veterinary practice premises, from which veterinary surgeons will be able to supply medicines;
 - b) broadly which premises are included within the meaning of veterinary practice premises and,
 - c) the annual cost per practice of maintaining the register.
2. At its meeting in April 2008, the Advisory Committee requested information on the register in the form of FAQs, to provide information on the Register.
3. In addition, the Committee is asked to note the plans for the introduction of the Register and consider the introduction of associated guidance in the RCVS Guide to Professional Conduct.

Legislation

4. The Veterinary Medicines Regulations 2008, SI 2008/2297, will come into operation on 1 October. Schedule 3 includes the following:

"Supply by a veterinary surgeon from registered practice premises

8.—(1) A veterinary surgeon who supplies a veterinary medicinal product from any practice premises not registered with the Royal College of Veterinary Surgeons under this paragraph as veterinary practice premises at which veterinary medicinal products are stored or supplied is guilty of an offence.

(2) This paragraph does not apply in relation to a veterinary medicinal product classified as AVM-GSL.

(3) The Secretary of State must publish a list of registered veterinary practice premises.

(4) This paragraph does not take effect until 1st April 2009."
5. The regulations do not directly require the registration of practice premises, but a veterinary surgeon who supplies medicines from unregistered premises will be breaking the law.
6. The Veterinary Medicines Directorate (VMD) has accidentally omitted the £40 statutory fee from the Regulations and is taking steps to rectify this.

Launch of the register

7. Veterinary surgeons who supply medicines from practice premises will need to ensure that those premises are registered by 1 April 2009. It is proposed to open the register and invite applications for registration with effect from the beginning of November. Publicity will include a letter to practices known to the College (through the Directory of Veterinary Practices and the Practice Standards Scheme) and a press conference in October. It is proposed that the register should be known as the RCVS Register of Veterinary Practice Premises.

Publication of the register

8. Arrangements for the publication of the register are under discussion with the VMD. They have no strong views on how it should be published, so long as it is freely available online. This may have implications for sales of the Directory of Veterinary Practices, since there will be a substantial overlap between the register and the directory.
9. VMD are discussing with the Home Office what arrangements should be made for the registration of the premises of scientific procedure establishments.

Handling of queries

10. There will inevitably be questions about the interpretation of the regulations, and in particular about the kind of premises which need to be registered. Strictly speaking VMD ought to offer the necessary advice, but the questions are likely to come to RCVS in the first instance. VMD are happy for the College to give advice to practices within an agreed framework, and a guidance note in the form of answers to frequently asked questions is being produced for this purposes. When novel queries arise it will be necessary to clear the answers with VMD.

Relations with the Practice Standards Scheme

11. Practices accredited under the Scheme will be subject to registration, but the registration fee will be deducted from the fees payable under the Scheme. Those practices which are not accredited, for example, those in the process of joining the Scheme, will have to pay the £40 annual statutory fee for registration of a veterinary practice premises.
12. VMD intend to set in hand a programme of inspections of premises of practices outside the Practice Standards Scheme in order to monitor compliance with the medicines legislation. There will be a fee of £250 per premises inspected, payable by the practices concerned to the VMD. VMD have confirmed that they will not inspect practices which are either accredited under the Scheme or seeking accreditation, except in the unlikely event of such a practice being the subject of a VMD enforcement investigation. The College is comparing notes with VMD to ensure that Practice Standards Scheme inspectors and the VMD's own inspectors work to the same standards, and arrangements are in hand for VMD inspectors to attend a training course for Practice Standards Scheme inspectors.

SQPs

13. The Veterinary Medicines Regulations 2008 require an SQP to operate from premises approved for the purpose, or registered as a pharmacy, or, from 1 April 2009, registered in the RCVS register of practice premises: paragraph 14((4) of Schedule 3.

RCVS Guide to Professional Conduct

14. The 2007 Veterinary Medicines Regulations provided that any *premises* from which veterinary surgeons supplied medicines would need to be registered. This could have included many premises which practising veterinary surgeons visit, and at which the supply or the assignment of the medicines takes place, for example, clients' premises, even though the purpose of the legislation was not to register such

premises. In addition, premises might include cars and therefore veterinary surgeons might be required to register all cars from which supplies of medicines were made. As a result, VMD agreed to amend the legislation to provide that only veterinary practice premises from which supplies were made needed to be registered and not to include cars within the understanding of premises for the registration purposes (cars are within the meaning of premises for inspection purposes).

15. The Advisory Committee agreed guidance on which premises should be within the meaning of veterinary practice premises and this was accepted by VMD.
16. Although VMD agreed to less onerous registration, it sought assurances that all premises and places (including cars) where veterinary surgeons store or keep medicines will be recorded, so that these premises and places can be inspected if necessary.
17. Therefore, the following additions to the Guide to Professional Conduct, at Part 2, H are proposed:
 - a) Information on this legislation,
 - b) guidance on which premises are considered within the meaning of veterinary practice premises and,
 - c) advice to veterinary surgeons that they record all premises where they store or keep medicines,

as set out in Annex B.

FAQs

18. Attached as Annex C are FAQs that have been discussed with the VMD.
19. The Committee is asked to consider and approve with any amendments the FAQs
20. The Committee may also wish to propose additional questions which should be included with answers.

Conclusion

21. The legislation will come into force on 1 October 2008, during October the RCVS proposes to write to all veterinary practices and from 1 November the RCVS Register of veterinary practice premises will open; the opening of the Register will be delayed until the £40 fee per premises is included in the Veterinary Medicines Regulations 2008.

REGISTRATION OF PREMISES: NOTE OF MEETING WITH VETERINARY MEDICINES DIRECTORATE, RCVS, 8 SEPTEMBER 2008

Introduction

1. The President (Jill Nute), the SVP (Bob Moore), the Registrar (Jane Hern), the Head of Professional Conduct (Gordon Hockey), the Head of Communications (Lizzie Lockett) and Jeff Gill met the Director of VMD (Steve Dean) and the VMD Director of Operations (John Fitzgerald) to discuss outstanding issues over the registration of veterinary practice premises under the Veterinary Medicines Regulations.

Frequently Asked Questions

2. VMD agreed to offer a revised answer to the third question, on the purpose of the register.
3. VMD queried the proposed answer to FAQ 14, on the provision of veterinary services on the premises of a charity or business. The final words - "and you make retail supplies of medicines to the charity/business or others from the premises" - did not seem to fit the rest of the answer. The question of registration would in any case only arise if a veterinary surgeon supplied medicines from the premises in question. It was noted that some charities would most naturally be regarded as clients of the veterinary surgeon, while others effectively operated as veterinary practices. VMD did not have strong views on the registration of such premises, so long as there was a route through which any premises from which medicines were supplied could be traced for inspection. It would be desirable, however, for the register to include the address of the veterinary surgeon on whose authority medicines were supplied wholesale to a charity. The 2008 regulations would not stop wholesalers supplying to unregistered premises, but that was likely to follow in 2009 or 2010.
4. It was noted that the last of the FAQs, concerning the traceability of satellite premises where medicines were stored, referred to the proposed requirement in the Guide to Professional Conduct that a note of such premises should be kept in the main practice premises. It was suggested that a reference to other provisions under the regulations requiring records and audit of those medicines should be included.

Publicity

5. RCVS planned to write to practices within the RCVS Practice Standards Scheme, and other practices listed in the Directory of Practices, during October to prompt them to register from the beginning of November. RCVS suggested reinforcing the message by holding a joint press conference in October. VMD were happy to take part, and agreed to keep the DEFRA HQ press office informed as necessary. RCVS would suggest possible dates. It was mentioned that Steve Dean would be speaking at the BVA Congress, and that RCVS had a slot in the BSAVA Congress in April 2009 which was

to be devoted to the Practice Standards Scheme. VMD would be willing to be involved in that session.

Handling of questions

6. RCVS expected to be in the front line in dealing with questions about the need to register particular premises. It was agreed that there would be no need to refer all such questions to VMD, so long as they were dealt with on agreed lines. VMD would particularly want to know of categories of premises where RCVS advised that registration was unnecessary, outside the terms of the agreed guidelines.

Publication of addresses

7. RCVS drew attention to the possibility that the publication of addresses of premises from which medicines were supplied would increase the risk of burglaries. VMD recognised this possibility but took the view that veterinary practice premises and the home addresses of veterinary surgeons were already at risk.
8. VMD were discussing with Home Office the registration of premises of establishments designated under the Animals (Scientific Procedures) Act 1986 as scientific procedure establishments. One possibility was for Home Office to register and inspect on behalf of VMD. It was for consideration whether the regulations should exclude such premises from the requirement to publish a list of registered premises.
9. RCVS mentioned that questions had arisen over the future sale of information on practice premises. The Directory of Veterinary Practices was currently on sale in hard copy, and was also sold in electronic form for commercial use. The publication of the register in electronic form was liable to undercut sales of the information in the Directory. VMD took the view that if RCVS already charged for the register of veterinary surgeons, charging for the register of veterinary practice premises would seem reasonable. VMD indicated it would have no objection to the register of premises being published together with other information, e.g. by the inclusion of the addresses in the Directory of Veterinary Practices, although that was a matter for the RCVS. VMD indicated that all that was required was publication of the list of addresses of veterinary practice premises.
10. VMD took the view that the published register should be brought up to date at reasonable intervals, say once a quarter.

VMD and Practice Standards Scheme inspections

11. RCVS had seen a copy of the VMD checklist for the inspection of practice premises and had some comments to offer. The appropriate contact in VMD was John Millward, the Head of the Animal Medicines Inspectorate (j.millward@vmd.defra.gsi.gov.uk, 07788 747513).

Standards

12. It was agreed that the aim should be to set the same standards for inspections by VMD and under the Practice Standards Scheme; Standard 8 of the RCVS Manual of Standards and the RCVS Inspection criteria to correlate, so far as was possible, with the VMD inspectors' checklist. RCVS indicated there were ongoing changes to the Scheme Standards due for implementation in 2010, but it was agreed that these issue should be resolved before 1 April 2009.

Enforcement

13. VMD were happy to make it known that they would not inspect premises within the Practice Standards Scheme unless an investigation for enforcement purposes had been set in hand. They would also not inspect the premises of practices which were candidates for accreditation under the Scheme. It was agreed that RCVS would inform VMD of practices which ceased to be accredited under the Scheme, and would also let VMD know if there were grounds for concern over the compliance of such practices with the medicines legislation. RCVS indicated there was provision for this in the existing rules of the Scheme.
14. RCVS indicated that any non-compliance with the Scheme was corrected by practices within a set number of months, although an ultimate measure was removal from the voluntary Scheme. VMD explained the use of Improvement Notices and the ultimate measure was prosecution for non-compliance with a notice. It was agreed that VMD should bring convictions to the attention of the RCVS and any other complaint by VMD against a veterinary surgeon would be dealt with in accordance with the standard RCVS complaints procedure.

Training

15. RCVS were happy for VMD inspectors to attend training sessions for Practice Standards Scheme inspectors, but would need to make sure that members of the Scheme did not carry higher costs as a result. Following the formal training RCVS would ask some practices to agree to a VMD inspector accompanying the Scheme inspector for training purposes.

Guide to Professional Conduct

16. VMD suggested that the last sentence of the text proposed record keeping requirement for inclusion in the Guide was superfluous.

Memorandum of understanding

17. VMD offered to produce a first draft.

Name of the register of premises

18. Since the 2008 regulations would expressly require the registration of premises with RCVS, it was agreed that the register could be termed the RCVS Register of Veterinary Practice Premises.

Guide to Professional Conduct

Part 2 H

Additional Guidance on:

Practice Registration

From 1 April 2009, veterinary surgeons must supply veterinary medicinal products from practice premises registered with the RCVS as 'veterinary practice premises', in accordance with the Veterinary Medicines Regulations; this regulation does not apply to Authorised Veterinary Medicines – General Sales List (AVM-GSL).

Premises likely to be considered as 'veterinary practice premises' are those:

1. from which the veterinary surgeons of a practice provide veterinary services; and/or,
2. advertised or promoted as premises of a veterinary practice; and/or,
3. open to members of the public to bring animals for veterinary treatment and care; and/or,
4. not open to the public, but which are the base from which a veterinary surgeon practises or provides veterinary services to more than one client; and/or,
5. to which medicines are delivered wholesale, on the authority of one or more veterinary surgeons in practice.

Main and branch practice premises from which medicines are supplied, are veterinary practice premises that must be registered with the RCVS.

Records

Veterinary surgeons should keep a record of premises and other places where they store or keep medicinal products, for example, homes where medicinal products may be kept for on-call purposes and practice cars; the record should be held at the practice's main 'veterinary practice premises' in accessible form.

**FREQUENTLY ASKED QUESTIONS
ON THE
RCVS REGISTER OF VETERINARY PRACTICE PREMISES**

GENERAL

1. What are these new requirements?

From 1 April 2009, veterinary surgeons must supply veterinary medicinal products from practice premises registered with the RCVS as 'veterinary practice premises' and maintain a record of all premises and places where they store or keep medicines.

2. How much will I have to pay for registration?

The annual statutory registration fee is £40 for each veterinary practice premises. For example, if a practice has one main practice premises and two branch premises, each premises must be registered at a total initial cost of £120 (3 x £40) each year.

3. When are the first fees due?

The first annual statutory fees for veterinary practice premises must be paid to the RCVS before 1 April 2009; payable with the application form.

4. How have the requirements been introduced?

The legal requirement for the registration of veterinary practice premises is in the Veterinary Medicines Regulations 2008 (paragraph 8 of Schedule 3 and for the fee, Part 6 of Schedule 7).

The professional requirement for recording where all medicines are stored or kept (and keeping that record at the practice's main veterinary practice premises in an accessible form) is in the RCVS Guide to Professional Conduct, Part 2H.

5. Why is there a related professional requirement?

The professional requirement avoids the need for wider ranging registration of premises and cars from which medicines may be supplied; only veterinary practice premises from which medicines are supplied, must be registered with the RCVS.

6. Is there guidance on what is considered to be a veterinary practice premises?

Yes, the RCVS has provided guidance on which premises are likely to be considered 'veterinary practice premises'. All practising veterinary surgeons who supply medicines will work from, or be associated with, a veterinary practice premises.

7. Who is responsible for the enforcement of the Veterinary Medicines Regulations?

The Veterinary Medicines Directorate (VMD) is responsible for the enforcement of the Veterinary Medicines Regulations (VMRs), including the registration and inspection of veterinary practice premises. Inspections by VMD inspectors will be targeted following an assessment of the risks involved; the statutory fee for a VMD inspection of a premises is £250. VMD inspectors may issue Improvement Notices and failure to comply with an Improvement Notice is a criminal offence.

8. How does the RCVS Practice Standard Scheme relate to these new *registration* requirements?

Registration of veterinary practice premises builds on the existing *registration* of practices under the RCVS Practice Standards Scheme (PSS). Those practice premises which are PSS Accredited pay an annual fee already which includes registration of the practice's premises. Therefore the current annual PSS fee will be split to provide the annual statutory registration fee for veterinary practice premises under the Veterinary Medicines Regulations; with the remainder the annual voluntary fee for the PSS.

9. If a practice is accredited under the RCVS Practice Standards Scheme, will it be inspected by VMD inspectors?

A PSS Accredited practice will not be inspected by VMD inspectors, unless there is an investigation for enforcement purposes. Veterinary practices with the PSS must comply with key aspects of the Veterinary Medicines Legislation and are inspected routinely by RCVS PSS inspectors.

10. Will I be inspected by the VMD if I have applied to join the RCVS Practice Standards Scheme?

The VMD has said it will not inspect practices applying to join the PSS, unless there is an investigation for enforcement purposes.

REGISTRATION OF VETERINARY PRACTICE PREMISES**11. I practise out of a number of premises; how do I know which are veterinary practice premises?**

Premises likely to be considered as 'veterinary practice premises' by the RCVS and the VMD are those:

- a) from which the veterinary surgeons of a practice provide veterinary services; and/or,
- b) advertised or promoted as premises of a veterinary practice; and/or,
- c) open to members of the public to bring animals for veterinary treatment and care; and/or,
- d) not open to the public, but which are the base from which a veterinary surgeon practises or provides veterinary services to more than one client; and/or,
- e) to which medicines are delivered wholesale, on the authority of one or more veterinary surgeons in practice.

This is not an exhaustive list of premises that may be considered as veterinary practice premises.

12. I practise at main practice premises and branch practice premises; are both of these veterinary practice premises?

Yes; all practice premises from which medicines are supplied, must be registered with the RCVS from 1 April 2009.

13. I store medicines at home; is my home a veterinary practice premises?

If you practise from your home and supply medicines from there, your home must be registered with the RCVS as a veterinary practice premises. Even if you store only small quantities of medicines at your home, you will need to register your home as a veterinary practice premises if you supply those medicines to others (supply includes administering medicines to other people's animals).

However, if you keep a small quantity of medicines at your home, for example, for on-call purposes, and that store of medicines is recorded at a registered veterinary practice premises, the home premises need not be registered.

14. I store medicines in my car or a practice car; are cars veterinary practice premises?

No, cars are not premises, but you must maintain a record of cars in which medicines are stored or kept (the record should be held at the main veterinary practice premises in accessible form).

15. I provide veterinary services at a charity/business; are the charity/business premises veterinary practice premises?

The charity/business premises may be veterinary practice premises, if, for example:

- (a) the premises are open to members of the public to bring animals for veterinary treatment and care (i.e. the animals are not owned by the charity/business); and/or,
- (b) the premises are used as a base to provide veterinary services to other clients; and/or,
- (c) medicines are delivered wholesale to the charity/business premises on your authority (e.g. you authorise a wholesaler to deliver the medicines to the charity/business)

If you take smaller quantities of (stock) medicines to the charity/business premises, the premises may not need to be registered as a veterinary practice premises, but you will need to keep a record of the premises (see FAQs 20 and 21).

If you authorise supplies of medicines to the charity/business, you are responsible for the medicines, for example, their correct storage and annual audit; responsibility may be shared with the charity/business.

16. Who may register veterinary practice premises with the RCVS?

Anybody involved with the practice may register it as a veterinary practice premises with the RCVS, but it would be helpful if within the practice there is agreement about who is to be the point of contact.

17. How do I register veterinary practice premises?

You will need to complete an application form and pay the appropriate annual statutory registration fee (£40 for each veterinary practice premises).

RCVS PRACTICE STANDARDS SCHEME

18. My practice is a member of the RCVS Practice standards Scheme, what do I need to do?

Your practice's application form will include the details of the practice premises registered under the Scheme. You need to confirm that the details are correct and, as appropriate, agree to inclusion of the practice premises in the new statutory register (sign and return the form to the RCVS). The RCVS already holds and administers the relevant information (and in the correct form) and is not incurring any significant extra costs for the statutory register, so the annual statutory registration fee is taken from the existing payments to the PSS (current PSS fees will be split to identify the annual statutory registration fees and the remaining annual voluntary fee).

You need to consider if you want to register any additional veterinary practice premises, for example, other premises to which medicines are delivered by wholesale on the authority of one of the practice veterinary surgeons (although such veterinary practice premises may be registered by the charity or client or organisation that runs the charity, business or organisation). An annual statutory registration fee will be payable for any premises that are not PSS Accredited.

19. My practice is not a member of the RCVS Practice Standards Scheme, but I want to register and join the Scheme?

If you complete the application form for the registration of the practice premises under the Veterinary Medicines Regulations (VMRs) you may elect to join the RCVS Practice Standards Scheme at the same time. You must still pay any annual statutory registration fees payable for veterinary practice premises, because these fees are only included in the annual PSS fees for Accredited practices and not included within the application fee for the PSS. If you apply to the PSS now, it is likely that you will pay your first annual PSS fees in March 2010 (for the year 2010) and these will include the 2010 annual statutory registration fees for any veterinary practice premises (for the year 1 April 2010 to 31 March 2011) that have been accredited.

Once you have applied to join the PSS, you will not be subject to inspection by the VMD, unless part of an investigation for enforcement purposes.

RCVS DIRECTORY OF PRACTICES

20. My practice is listed in the Directory of Practices what do I need to do?

Each practice premises listed in the Directory of Practices will be sent an application form with the details of that premises. You need to confirm that the details are correct and agree to inclusion of the practice premises in the new statutory register (sign and return the form to the RCVS) where medicines are supplied from a practice premises. The annual statutory registration fee for each veterinary practice premises is payable. You may also elect to have a future billing address for a number of practice premises and future update forms will be sent to this address.

The RCVS has maintained the Directory without cost to practices in the past because there has been minimal maintenance of the data, offsetting of costs by selling the data and bearing the remaining costs through the RCVS as a whole. The new register of veterinary practice premises will be maintained on an annual basis and will need to be self-funding; it will not rely on the sale of data, because the register may be published in electronic form.

RECORDS OF PREMISES AND PLACES WHERE MEDICINES ARE KEPT

21. What is this record requirement?

This is a professional requirement to ensure that stores of practice medicines at unregistered premises, or in other places, are recorded at registered premises. This applies, for example, to medicines kept at your home for on-call purposes, or those kept in practice cars. *For premises:* You should keep a written record of the address of the premises and, if relevant, the name of the premises/business/client; *For cars:* You should keep a written record of the car registration number.

22. Do I need to keep details of all the different medicines stored at the unregistered premises or other places?

You are accountable for your practice (stock) medicines stored at other premises, including, for example, stores at the homes of employees and at charity/business clients; as you are for medicines stored at your practice's veterinary practice premises. The requirements of the Veterinary Medicines Regulations apply to all practice (stock) medicines.

GAH Sept 2008

draft

This Statutory Instrument has been made in consequence of a defect in S. I. 2008/2297 and is being issued free of charge to all known recipients of that Statutory Instrument.

STATUTORY INSTRUMENTS

2008 No. 00

MEDICINES

The Veterinary Medicines (Amendment) Regulations 2008

<i>Made</i>	- - - -	2008
<i>Laid before Parliament</i>		2008
<i>Coming into force</i>	- -	2008

The Secretary of State is a Minister designated(a) for the purposes of making Regulations under section 2(2) of the European Communities Act 1972(b) in relation to measures in the veterinary and phytosanitary fields for the protection of public health.

The Secretary of State has carried out the consultation required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(c).

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972.

Title and commencement

1. These Regulations may be cited as the Veterinary Medicines (Amendment) Regulations 2008 and come into force on [] 2008.

Amendment to the Veterinary Medicines Regulations 2008

2. The Veterinary Medicines Regulations 2008(d) are amended by adding after paragraph 58 of Schedule 7—

“Fee for the registration of veterinary practice premises

58A. The annual fee for the registration of veterinary practice premises with the Royal College of Veterinary Surgeons to supply veterinary medicinal products is £40 (notwithstanding paragraph 2 of this Schedule, this is payable to the Royal College of Veterinary Surgeons).”.

(a) S.I. 1999/2027.
(b) 1972 c. 68.
(c) OJ No. L31, 1.2.2002, p. 1.
(d) S. I. 2008/2297.

Date

Name
Parliamentary Under Secretary of State
Department for Environment, Food and Rural Affairs

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Veterinary Medicines Regulations 2008 by providing for a fee of £40 for the registration of veterinary practice premises.

The fee is already reflected in the impact assessment prepared for those Regulations.