



**ASSURING THE SAFETY, QUALITY & EFFICACY
OF VETERINARY MEDICINES**

**VETERINARY MEDICINES
GUIDANCE NOTE**

No 14

**RECORD KEEPING
REQUIREMENTS
FOR
VETERINARY
MEDICINAL
PRODUCTS**

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QUICK START GUIDE

This Veterinary Medicines Guidance Note (VMGN) is aimed at Veterinary Surgeons, Suitably Qualified Persons (SQPs), Pharmacists, owners or keepers of food-producing animals, Wholesale Dealer Authorisation (WDA) holders, Manufacturing Authorisation (ManA) holders and Feedingstuffs' Manufacturers and Distributors. It is intended to provide guidance on what records must be kept when supplying or administering veterinary medicines in the UK.

The quick start guide is a summary of the provisions of the Veterinary Medicines Regulations (VMR); detailed information is found in the body of the guidance note.

The principle behind the record keeping requirements is to ensure the effective recall of a medicine should this be necessary for safety reasons, for example, because of contamination or a manufacturing defect in a particular batch or batches. In this case it may be necessary to have an audit trail that identifies who has been supplied with an affected batch. As well as effective recall, it may be necessary to identify animals that have been treated with affected medicines so that appropriate advice can be given or counter measures taken. In the case of food-producing animals it may be necessary to identify specific animals treated with an affected batch in order to prevent potentially harmful residues entering human food.

The following record keeping requirements apply in the UK:

- Veterinary surgeons, SQPs and Pharmacists must keep specific records for products supplied on prescription to both food and non-food producing animals.
- Veterinary Surgeons must also record specific information when:
 - administering a veterinary medicine to a food-producing animal themselves,
 - prescribing or administering a medicinal product under the prescribing cascade.
- Owners or keepers of food-producing animals, including horses intended for the food chain, must keep specific records:
 - at the time of purchase;
 - at the time of administration to the animal;
 - and if the product is disposed of, other than by treating an animal;
- WDA holders must keep detailed records for all incoming and outgoing transactions, including disposals.
- Holders of a ManA are responsible for making a record of all batches of a Veterinary Medicinal Product (VMP) manufactured, assembled or supplied.
- A Feedingstuffs Manufacturer who incorporates:
 - a Veterinary Medicinal Product (VMP) into a premixture;
 - a premixture containing a VMP into feedingstuffs; or
 - a VMP into feedingstuffs,

must maintain daily records relating to the quantities manufactured and dispatched that day.

- Manufacturers who supply feedingstuffs incorporating a VMP must also record the names and addresses of persons supplied and keep a copy of the prescription.
- An approved distributor of Feedingstuffs or Premixtures must maintain daily records relating to the quantities of all premixtures and feedingstuffs containing VMPs bought and sold that day. Records must also be kept in relation to each consignment supplied.

Annual Audit/Stock Reconciliation

- Anyone involved in the retail or wholesale supply of prescription VMPs, i.e. Veterinary Surgeons, Pharmacists, SQPs and Wholesale Dealers who supply POM-V and POM-VPS products must carry out an audit at least once a year. Any person supplying a product classified as NFA-VPS or AVM-GSL is not required to carry out an annual audit.
- The audit must reconcile all incoming and outgoing VMPs with products currently held in stock with any discrepancies being recorded. If discrepancies have occurred, e.g. from spillage or breakage, it is for the individual supplier concerned to consider whether any discrepancies are acceptable or whether further action may be required.

FURTHER INFORMATION

For more information on the requirements of record keeping please contact the VMD's Legislation team on 01932 338321 or alternatively contact VMD reception on 01932 336911 and quote the "Record-keeping requirements".

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Introduction

1. This is one of a series of Veterinary Medicines Guidance Notes (VMGNs) explaining the requirements under the Veterinary Medicines Regulations (VMR). The VMR are revoked and replaced on a regular basis, so the references to them should be read as referring to the ones that are currently in force. Therefore, the date and number of the Statutory Instrument are not included in this VMGN. The VMGN will be updated as necessary and the date of the most recent update is shown on the front cover. The VMR set out the UK controls on veterinary medicines, including their manufacture, advertising, marketing, supply and administration.
2. The purpose of this note is to provide guidance on provisions that require records to be kept by:
 - keepers of food-producing animals
 - persons permitted to supply veterinary medicinal products (VMPs) on prescription
 - holders of manufacturing authorisations (ManA)
 - wholesale dealers
 - feedingstuffs manufacturers and distributors
3. The purpose of record keeping is to provide traceability of specific batches of products. This is intended to:
 - provide a basis for effective recall of a batch or batches of a product should this become necessary; and
 - provide traceability of the use of medicines in food-producing animals.

Recording Keeping Requirements

4. The VMR set down what records must be kept; however they do not specify a set procedure or system needed to meet these requirements. All records must be durable, permanent and made available for inspection on request by a duly authorised person. The records may be kept electronically. It is up to individual suppliers to consider systems that fit best with their procedures.

Record Keeping for Horses

5. Community legislation defines the horse as a food-producing species. Therefore owners/keepers are required to maintain records for any transactions involving the retail sale of VMPs for administration to horses that will enter the food chain. It is not a legal requirement for the record to be kept in the medicines pages of the horse passport but it is acceptable to be done if preferred by the owner/keeper. Where administration of veterinary medicines is recorded in the passport only and the passport accompanies the horse to slaughter, it is a legal requirement that a copy or separate record is retained by the owner/keeper for five years after the last entry in the record.

6. If the horse has been declared as not intended for human consumption these record keeping requirements do not apply. However, according to the horse passport legislation, vaccination records must be kept in the horse passport.
7. Further information regarding the recording of VMPs administered to horses as stipulated by the Horse Passports (England) Regulations 2009 (SI 1611), can be found on the Defra website: <https://www.gov.uk/horse-passport>. Scotland, Northern Ireland and Wales have introduced their own domestic legislation that implements Commission Regulation (EC) No 504/2008 – Identification of Equidae in each of the devolved areas, links to which can be found on the Defra site.

Animal Keepers' Record Keeping for Food Producing Animals

8. Medicines records must be kept for food producing animals (including horses that have not been declared as 'not for slaughter for human consumption') in accordance with the following categories:

Administration - record to be kept by a veterinary surgeon

9. If the product is administered by a veterinary surgeon, he or she must either enter into the records, or give written notice to the owner or keeper in good time to ensure that the withdrawal period is respected, of the:
 - name of the veterinary surgeon;
 - name of the product; and the batch number;
 - date of administration;
 - amount administered;
 - identification of the animals treated;
 - withdrawal period;

Administration – record to be kept by animal keeper

10. At the time of administration by the animal keeper the following must also be recorded:
 - name of the product;
 - date of administration;
 - quantity administered;
 - the withdrawal period;
 - identification of the animals treated;

Proof of Purchase – record to be kept by animal owner or keeper

11. The owner or keeper of food-producing animals is responsible for keeping proof of purchase of all VMPs acquired for those animals. The following must also be recorded at the time of purchase:
 - name of the product; and the batch number;
 - date of each purchase of a VMP;

- quantity purchased;
- name and address of the supplier;

Disposal – record to be kept by animal owner or keeper

12. If the product is disposed of, other than by treating an animal, the following must be recorded:
- the date of disposal;
 - the quantity of product involved;
 - how and where it was disposed;
13. All records and proof of purchase must be kept for at least five years following the administration or disposal of the product, even if the animals concerned have been slaughtered or have died during that period.

Method of Recording

14. Farmers and other keepers of animals may like to know that there are publications available in which to record medicines administered to their animals. The National Office of Animal Health (NOAH) and the Animal Health Distributors Association (AHDA) publish an Animal Medicines Record Book. This is available from www.noah.co.uk. The Pig Veterinary Society also produces a Veterinary Medicines – Record of Administration booklet which is available from www.pigjournal.co.uk. The Fish Health Inspectorate produces an Aquatic Animal Medicine Record book which is available at <http://www.cefas.defra.gov.uk/our-services/aquaculture/fish-health-inspectorate.aspx>. A Bee record keeping card is also available on the British Beekeepers Association (BBKA) website <http://www.bbka.org.uk>.

Animal Keepers' Record Keeping for Non-Food Producing Animals

15. There are no record keeping requirements applicable to owners or keepers of non-food producing animals (e.g. horses declared in their passports as not for human consumption, cats, dogs and other domestic pets).

Retailers Records for Products Supplied on Prescription

16. It is the responsibility of the veterinary surgeon, pharmacist or suitably qualified person (SQP) who supplies POM-V and POM-VPS medicines on a retail basis, for both food producing and non-food producing species, to keep records for at least five years for each incoming or outgoing transaction. The information required is as follows:
- date and nature of transaction;
 - name of the VMP;
 - the batch number (except that, in the case of a product for a non-food-producing animal, this need only be recorded either on the date he receives the batch or the date he starts to use it);
 - quantity received or supplied;
 - name and address of the supplier or recipient;
 - if there is a written prescription, the name and address of the person who wrote the prescription and a copy of the prescription;

17. Once the VMP has started to be used the batch number and the date must be recorded. If the documents do not include this information the missing information must be recorded.
18. Further information on the supply of VMPs can be found in Veterinary Medicines Guidance Note 3 Guidance for Retailers which is published on the VMD's website http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx.

Products Administered under Cascade – additional records for food-producing animals

19. If there is no authorised medicinal product in the UK for a condition affecting a food-producing species the veterinary surgeon responsible for the animal may administer it personally or may direct another person to do so under his personal responsibility for an animal following the 'cascade' provision in the VMR. Further information on prescribing under the cascade can be found in VMGN 13 Guidance on the Use of the Cascade which is published on the VMD website http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx.
20. A veterinary surgeon who administers or prescribes a medicinal product under the cascade must keep a record, for at least five years, of the:
 - date of examination of the animal(s);
 - name and address of the owner;
 - identification and number of animals treated;
 - the result of the veterinary surgeon's clinical assessment;
 - trade name of the product if there is one;
 - manufacturer's batch number shown on the product if there is one;
 - name and quantity of the active substance;
 - doses administered or supplied;
 - duration of treatment; and
 - withdrawal period;

Wholesale Dealers' Records

21. An authorised wholesale dealer must keep detailed records for all incoming and outgoing transactions, including disposals, for at least three years. These records must include the:
 - date and nature of the transaction;
 - name of the VMP;
 - manufacturer's batch number;
 - expiry date;
 - quantity; and
 - name and address of the supplier or recipient;

Manufacturing Authorisation (ManA) Record Keeping

22. Holders of a ManA are responsible for making a record of all batches of a VMP manufactured, assembled or supplied. The record must include the:

- name of the product;
- quantity manufactured, assembled or supplied;
- date of manufacture, assembly or supply;
- batch number and expiry date;
- name and address of the recipient where relevant;

23. Records of all certification provided by the qualified person in relation to that batch must also be kept. All records and certificates must be kept for at least five years.

Feedingstuffs Manufacturers

24. Any person who incorporates a:

- VMP into a premixture;
- premixture containing a VMP into feedingstuffs; or
- VMP into feedingstuffs;

must maintain a daily record of the:

- types and quantities of all VMPs (and specified feed additives, if any) and premixtures used in the manufacturing process;
- quantity of feedingstuffs and premixtures containing VMPs manufactured that day;
- quantity held;
- quantity dispatched;
- name and address of the distributor, if there is one.

25. Manufacturers who supply feedingstuffs incorporating a VMP shall record the names and addresses of persons supplied and keep a copy of the prescription.

Approved Distributors of Feedingstuffs or Premixtures – Record Keeping

26. An approved distributor shall record daily the:

- types and quantities of all premixtures and feedingstuffs containing VMPs bought and sold that day;
- quantity held;

27. A record should also be kept in relation to each consignment supplied of the:

- date of delivery;
- name and address of each consignee;
- types of feedingstuff or premixture supplied;
- quantity;
- type of VMP incorporated into the feedingstuff; and
- expiry date;

28. Records must be kept for five years.

Audit Requirements

29. Anyone involved in the retail or wholesale supply of prescription VMPs, i.e. veterinary surgeons, pharmacists, SQPs and wholesale dealers who supply POM-V and POM-VPS products must carry out an audit at least once a year. Any person supplying a product classified as NFA-VPS or AVM-GSL is not required to carry out an annual audit.
30. The key purpose of this requirement is to ensure the effective recall of a medicine should this be necessary for safety reasons, e.g. due to contamination or a manufacturing defect in a particular batch or batches. In such a situation it may be necessary to have an audit trail that identifies who has been supplied with the affected batch or batches. As well as an effective recall procedure, it may also be necessary to identify animals that have been treated with affected medicines so that appropriate advice can be given or counter measures taken.
31. The audit must reconcile all incoming and outgoing VMPs with products currently held in stock with any discrepancies being recorded. If discrepancies have occurred, e.g. from spillage or breakage, it is for the individual supplier concerned to consider whether any discrepancies are acceptable or whether further action may be required.
32. The VMR do not specify a system or set procedure for conducting the audit, nor do they restrict the frequency with which it can be carried out except that it should be on at least an annual basis. It is up to individual suppliers to consider systems that fit best with their procedures.
33. Where an annual or more frequent stock take, which includes the main features set out in the example below, is carried out for another reason, i.e. tax purposes, the VMD would consider that the audit requirement is being met.

Example of how to fulfil the audit requirement

34. The following example demonstrates one of the ways in which the audit requirement can be met by retailers; however this should be considered as a guide only and is intended to illustrate the components that are considered necessary to meet the audit requirements.

Step one: Identify stock levels at the beginning of audit period

Step two: Record all incoming stock received during the audit period

Step three: Record outgoing stock supplied during audit period

Step four: At end of audit period compare incoming/outgoing records with current stock levels noting any discrepancies.

Further Information

35. Further information is available from the Veterinary Medicines Directorate, Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS - Tel: +44 (0)1932 336911; Fax: +44 (0)1932 336618 or E-mail: VMGNNotes@vmd.defra.gsi.gov.uk. Veterinary Medicines Guidance Notes and other information, including details of VMD contacts, are available on the VMD website (www.vmd.defra.gov.uk).

List of Abbreviations

AHDA	Animal Health Distributors Association
AVM-GSL	Authorised Veterinary Medicine – General Sales List
EC	European Commission
Man-A	Manufacturing Authorisation
NFA-VPS	Non-Food Animal – Veterinarian, Pharmacist, Suitably Qualified Person
NOAH	National Office of Animal Health
POM-V	Prescription Only Medicine - Veterinarian
POM-VPS	Prescription Only Medicine – Veterinarian, Pharmacist, Suitably Qualified Person
SQP	Suitably Qualified Person
VMD	Veterinary Medicines Directorate
VMGN	Veterinary Medicines Guidance Note
VMP	Veterinary Medicinal Product
VMR	Veterinary Medicines Regulations
WDA	Wholesale Dealers Authorisation



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