



Veterinary Medicines Guidance Note

Record Keeping Requirements for Veterinary Medicinal Products

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ASSURING THE SAFETY, QUALITY AND EFFICACY
OF VETERINARY MEDICINES



THESE NOTES ARE ONLY A GENERAL GUIDE AND MUST NOT BE TREATED AS A COMPLETE OR AUTHORITATIVE STATEMENT OF THE LAW ON ANY PARTICULAR CASE

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INTRODUCTION

1. This is one of a series of Veterinary Medicines Guidance (VMG) Notes explaining the requirements under the Veterinary Medicines Regulations ('the Regulations'). The Regulations are revoked and replaced every year, 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 VMG Note. The VMG Notes will be updated as necessary and the date of the most recent update is shown on the front cover. The Regulations 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 (ManAs);
 - wholesale dealers.
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.

RECORD KEEPING REQUIREMENTS

4. The Regulations 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. The record may be kept within the passport or elsewhere as desired. 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 to all horses in the horse passport.

6. Further information regarding the recording of VMPs administered to horses as stipulated by Horse Passports (England) Regulations 2009 (SI 1611), can be found on the Defra website:

www.defra.gov.uk/animalh/id-move/horses/index.htm

Scotland, Northern Ireland and Wales have introduced their own domestic legislation that implements Commission Regulation 504/2008 in each of the devolved areas, links to which can be found on the Defra site.

7. **ANIMAL KEEPERS' RECORD KEEPING FOR FOOD PRODUCING ANIMALS**

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:

8. **Administration - record to be kept by a veterinary surgeon**

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, 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

9. 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

10. 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 veterinary medicinal product;

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

Disposal – record to be kept by animal owner or keeper

11. 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;
12. 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

13. 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 Medicine Record Book. This is available from www.noah.co.uk The Pig Veterinary Society also produce 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 www.cefas.co.uk/fish-health-inspectorate.aspx.

ANIMAL KEEPERS' RECORDS FOR NON-FOOD PRODUCING ANIMALS

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

RETAILERS RECORDS FOR PRODUCTS SUPPLIED ON PRESCRIPTION

15. 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)

RECORD KEEPING REQUIREMENTS FOR VMPS

- 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;
16. 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.
17. Further information on supply of VMPS can be found in Veterinary Medicines Guidance Note 3.

PRODUCTS ADMINISTERED UNDER CASCADE –

ADDITIONAL RECORDS FOR FOOD-PRODUCING ANIMALS

18. 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, under his direct personal responsibility treat an animal following the 'cascade' provision in the Regulations. Prescribing under the cascade is explained in VMG Note 15: *Controls on the Administration of Veterinary Medicines*.
19. 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

20. 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.

AUDIT REQUIREMENTS

21. Anyone involved in the retail or wholesale supply of prescription VMPs, i.e. veterinary surgeons, pharmacists, suitably qualified persons 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.
22. The key purpose of the 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.
23. 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.
24. The Regulations 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.
25. 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 FULFILL THE AUDIT REQUIREMENT

26. 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 is 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

RECORD KEEPING REQUIREMENTS FOR VMPs

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

MANUFACTURING AUTHORISATION (MANA) RECORD KEEPING

27. 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;
28. 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.
29. 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.
30. Manufacturers who supply feedingstuffs incorporating a veterinary medicinal product shall record the names and addresses of persons supplied and keep a copy of the prescription.

APPROVED DISTRIBUTORS OF FEEDINGSTUFFS OR PREMIXTURES - RECORD KEEPING

31. An approved distributor shall record daily the:
- types and quantities of all premixtures and feedingstuffs containing VMPs bought and sold that day;
 - quantity held;
32. 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;

33. Records must be kept for five years.

FURTHER INFORMATION

34. 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: VMGNotes@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.gov.uk).

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