

Veterinary
Medicines
Directorate

**VETERINARY MEDICINES
GUIDANCE NOTE**

No 17

**MEDICATED
FEEDINGSTUFFS
AND
SPECIFIED FEED
ADDITIVES**

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QUICK START GUIDE

This Veterinary Medicines Guidance Note (VMGN) is aimed at manufacturers and suppliers of veterinary medicinal products (VMPs) for incorporation into animal feedingstuffs, specified feed additives (SFAs) (i.e. coccidiostats, histomonostats and non-antibiotic growth promoters), premixtures, and feedingstuffs containing SFAs and VMPs and complementary feedingstuffs containing SFAs, as implemented in Schedule 5 of the Veterinary Medicines Regulations (VMR).

It also includes guidance to veterinary surgeons, keepers of animals and other members of industries involved in the use of VMPs and SFAs in animal feedingstuffs.

The quick start guide is a summary of the detailed information on the provisions of Schedule 5 of the VMR found in the body of this guidance note.

- Feed business operators (FeBOs) that manufacture SFAs, premixtures and complete feedingstuffs containing VMPs or SFAs, or complementary feedingstuffs containing SFAs
 - must operate from premises that have been inspected and approved by the Secretary of State
 - must comply with the full provision of the VMR.
- FeBOs that manufacture complete feedingstuffs using complementary feedingstuffs containing SFAs, exclusively for their feeding to animals on their own holdings, must operate from premises registered by the Secretary of State.
- Distributors that store, supply, wrap or package SFAs, premixtures containing VMPs or SFAs, complementary feedingstuffs containing SFAs and/or store and supply complete feedingstuffs containing VMPs
 - must operate from premises that have been inspected and approved by the Secretary of State
 - must comply with the provisions of the VMR.
- Medicated feedingstuffs (MFS) containing VMPs can only be supplied on receipt of a medicated feedingstuffs prescription (MFSp).

FURTHER INFORMATION

- For more information on medicated feedingstuffs or specified feed additives please contact the Veterinary Medicines Directorate's (VMD's) Legislation team via the VMD reception on 01932 336911 and quote "medicated feedingstuffs".

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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 shown in this VMGN. This VMGN will be updated as necessary and the date of the most recent update is shown on the front cover.
2. The VMGN set out the UK controls on veterinary medicines, including their manufacture, advertising, marketing, supply and administration. VMGN 1 Controls of Veterinary Medicines, which is published on the Veterinary Medicines Directorate's (VMD's) website http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx gives basic information about the scope of the VMR and the requirement for Marketing Authorisations (MAs).
3. This VMGN describes the requirements for the manufacture and supply of specified feed additives (SFAs), premixtures and complete feedingstuffs containing SFAs or veterinary medicinal products (VMPs), and complementary feedingstuffs containing SFAs, as implemented in Schedule 5 of the VMR (therefore collectively known as Schedule 5 products). The provisions in the VMR relate to both food and non-food producing animals, although there are exemptions which are explained in paragraph 16. This VMGN is aimed at veterinary surgeons, manufacturers and distributors of Schedule 5 products, keepers of animals and other members of industries involved in the supply or use of VMPs and SFAs in animal feedingstuffs.

Definitions

4. For the purpose of this VMGN, the following definitions apply:

Specified Feed Additive

Feed additives authorised under Regulation EU 1831/2003 belonging to the functional groups; coccidiostats, histomonostats and certain other zootechnical additives i.e. non-antibiotic growth promoters. All other feed additives are the responsibility of the Food Standards Agency and are covered by separate legislation and guidance, which is available from www.foodstandards.gov.uk.

Premixture

A premixture is defined as a mixture of a VMP or SFA with feedingstuffs materials, intended for further mixing with feedingstuffs before being fed to animals.

Complementary Feedingstuff

A complementary feedingstuff is a compound feed which has a high content of certain substances but which, by reason of its composition, is sufficient for a daily ration only if used in combination with other feedingstuffs.

Complete Feedingstuff

A complete feedingstuff is a compound feedingstuff which, by reason of its composition, is sufficient for a daily ration.

Compound Feedingstuff

A compound feedingstuff is a mixture of at least two feed materials, whether or not containing feed additives, for oral animal-feeding in the form of complete or complementary feedingstuffs.

Veterinary Medicinal Product (VMP)

Any substance or combination of substances presented as having properties for treating or preventing disease in animals; or any substance or combination of substances that may be used in, or administered to, animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Keepers of Animals

Persons who feed, or manufacture for feeding, feedingstuffs containing VMPs or SFAs animals on their own holdings.

Feed Business Operator (FeBO)

A collective term used for premises on which animal feedingstuffs containing VMPs and/or SFAs are manufactured and/or distributed.

Medicated Feedingstuff (MFS)

Any mixture of a VMP/s and feedingstuff which is ready prepared for supply and intended to be fed to animals without further processing.

Premixtures and Complementary Feedingstuffs Containing SFAs and VMPs

Article 8 of Regulation EC 767/2009, which came into force on 1 September 2010, sets levels of SFAs in products which provide a distinction between premixtures and complementary feedingstuffs. A product that contains SFAs at levels of up to five times higher than the relevant fixed maximum content for that SFA in complete feedingstuffs is considered to be a complementary feedingstuff, whilst a product containing SFAs at five times the maximum level permitted for complete feedingstuffs, or more, is considered to be a premixture.

This distinction does not apply to feedingstuffs containing VMPs and any product containing a VMP at a level greater than the maximum permitted for complete feedingstuffs, which is intended for further mixing with feed materials before being fed to animals, is considered to be a premixture. Complementary feedingstuffs containing VMPs at a level greater than the maximum permitted level for complete feedingstuffs which are intended for feeding to animals without further mixing with

feed materials, may be manufactured and placed on the market, provided the daily dose of the VMP is contained in a quantity of MFS corresponding to at least half the daily feedingstuffs ration of the animals treated, or, in the case of ruminants, corresponding to at least half the daily requirements of non-mineral supplementary feedingstuffs.

Approval – Requirements for Manufacturers of Schedule 5 Products

5. A FeBO that manufactures SFAs, premixtures and complete feedingstuffs containing VMPs or SFAs, or complementary feedingstuffs containing SFAs, must comply with the full provisions of the VMR. These include the requirement for the premises to be approved by the Secretary of State and regularly inspected. The VMD is responsible for approving and inspecting premises in Great Britain on behalf of the Secretary of State. In Northern Ireland, the Department of Agriculture and Rural Development (DARD) has responsibility for approving and inspecting such premises. Paragraph 32 provides the relevant contact details for the VMD and DARD. Any reference to VMD in this Guidance Note should be read as DARD for those FeBOs located in Northern Ireland. Annex A lists the categories of approved manufacturers and their activities.
6. In order to be approved, FeBOs must meet the applicable criteria set out in Annex II to Regulation EC/183/2005, which is reproduced in Annex B to this VMGN. In particular, FeBOs carrying out activities under this Annex must document and implement a Hazard Analysis and Critical Control Point (HACCP) plan. HACCP provides a standard way to monitor products and assess and manage risks at specified points in the manufacture of Schedule 5 products.
7. FeBOs that manufacture complete feedingstuffs using VMPs or SFAs, or using premixtures containing VMPs or SFAs, for feeding to their own animals on their own holdings, must also comply with Annex II of EC Regulation 183/2005. Those FeBOs that only manufacture complete feedingstuffs using complementary feedingstuffs containing SFAs must be registered rather than approved. The requirements for registration are explained further in paragraph 24.
8. With the exception of those FeBOs described in paragraph 16 (Exemption from Approval) all FeBOs, are inspected to ensure that they comply with the VMR. The frequency of inspection is risk based and depends on the nature of the feed business operator and its compliance with the VMR.

Designated Qualified Persons

9. The requirements for approval as a manufacturer of Schedule 5 products also includes a requirement to designate a qualified person responsible for production (Qualified Person for Feedingstuffs - Production (QFPF)) and, where appropriate, a person responsible for Quality Control (Qualified Person for Feedingstuffs Quality (QPFQ)). Whilst it is preferable to designate different people for production and quality, in a small business where this is not practical it is possible for the same person to be designated or to designate a QPFQ from outside the business.

10. The VMD considers that any person who is capable of competently performing the following duties would meet the requirements of a QPFP and Qualified Person for Feedingstuffs Control (QPFC) and therefore specific qualifications are not required.

Qualified Person for Feedingstuffs Production

11. A QPFP is responsible for:
- ensuring that the different stages of production are carried out according to pre-established written procedures and instructions aimed at defining, checking and monitoring the critical points in the manufacturing process;
 - ensuring that technical or organisational measures are taken to avoid or minimise, as necessary, any cross-contamination and errors. There must be sufficient and appropriate means of carrying out checks in the course of manufacture;
 - monitoring the presence of prohibited feed, undesirable substances such as banned or non-authorised medicinal products, antimicrobial growth promoters, coccidiostats and histomonostats, and other contaminants in relation to human or animal health;
 - ensuring appropriate control strategies are put in place to minimise risk;
 - ensuring that waste and materials not suitable as feed are isolated and identified and any such material containing hazardous levels of veterinary drugs, contaminants or other hazards are disposed of in an appropriate way and not used as feed;
 - ensuring that adequate measures are taken to ensure effective tracing of the products.

Qualified Person for Feedingstuffs Quality

12. A QPFC does not necessarily have to work on site or be part of the business. A QPFC is responsible for ensuring that they have access to a laboratory with adequate staff and equipment as part of a quality control system. They must also write up and implement a quality control plan. This should include:
- checks on the critical points in the manufacturing process;
 - sampling procedures and frequencies;
 - methods of analysis and their frequency;
 - compliance with specifications, from processed materials to final products; and
 - the destination of materials etc in the event of non-compliance.
13. A QPFC must implement documentation to enable traceability of feed materials (ingredients) from intake through to the manufacture and supply of final products. They must ensure that the documents are available to the competent authorities for an appropriate period, being at least until the shelf life of the manufactured product has passed. In the case of VMPs, SFAs, premixtures containing VMPs or SFAs, or complementary feedingstuffs containing SFAs, used to manufacture other Schedule 5 products, the QPFC must ensure that documentation enabling traceability from their intake to the supply of the final products is retained for 5 years and is available to the competent authorities.
14. They should ensure also that samples of sufficient quantities of feed materials and of each batch of products manufactured and placed on the market are taken and

retained for an appropriate period, being at least until the shelf life of the manufactured product has passed. In the case of continuous production samples should be taken during each specific part of production using a procedure pre-established by the manufacturer in order to ensure traceability. Where the manufacture is solely for the manufacturer's own needs such a procedure should be conducted on a regular basis.

15. The retained samples must be sealed and labelled for easy identification and stored under conditions that prevent any abnormal change or adulteration in the composition or the sample. They must be made available to the competent authorities for an appropriate period, being at least until the shelf life of the manufactured product has passed. In the case of feedingstuffs for animals not kept for food production, the QPFC only has to keep samples of the finished product.

Exemption from approval

16. The only exemptions from the requirement to be approved by the Secretary of State to incorporate VMPs into feedingstuffs are:
 - i) a person who incorporates a VMP into feedingstuffs in domestic premises for feeding on those premises:
 - non food producing animals; or
 - food producing animals kept purely for domestic purposes, including consumption by the keeper of those animals. The sale of animals or animal products to third parties, which includes farm gate sales of eggs, milk and meat, is not considered 'domestic purposes' and the exemption from approval does not apply.
 - ii) a person who incorporates VMPs into feedingstuffs for ornamental fish not intended for human consumption, providing that person does not use more than a total of 1kg of VMP annually for that purpose.
17. For both (i) and (ii) above, a prescription is still required in order to obtain the VMP. Under the exemption, the prescription can be either oral or in writing. However, if the prescription is not in writing, the VMP may only be supplied by the person who prescribed it, and that person should give advice on any contra-indications and warnings specified in the Summary of Product Characteristics (SPC).
18. The exemption also allows a veterinary surgeon, pharmacist or appropriately registered Suitably Qualified Person (SQP) to supply a premixture containing a VMP, or a feedingstuff containing a VMP, to such a keeper of animals providing that the keeper meets the requirement of being "domestic" and does not sell animals or their produce i.e. meat, milk or eggs. The same prescribing requirements apply to premixtures and feedingstuffs containing VMPs, as they do to VMPs.
19. An SQP is not permitted to use this exemption for the supply of premixtures or feedingstuffs containing VMPs with the legal category of Prescription Only Medicine – Veterinarian (POM-V).

What an Approval Inspection Covers

20. Following an application for approval as a manufacturer of Schedule 5 products, an inspector will carry out an initial inspection of the premises where the manufacturing activity will take place.
21. The aim of the inspection is to ensure that the FeBOs premises comply with basic, minimum standards set out in legislation, designed to safeguard operator, animal and consumer health. At inspections the emphasis will be on checking that the premises are capable of producing Schedule 5 products to the required standard. The inspector will look at the following:
 - facilities and equipment are suitable for the operation;
 - record keeping, particularly medicated feedingstuffs prescription (MFSp) and trace-ability. For further information please refer to VMGN 14 Record-Keeping Requirements for Veterinary Medicinal Products, which is published on the VMD's website.
http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx
 - hygiene standards;
 - storage arrangements for Schedule 5 products;
 - documentation relating to procedures and controls, including Quality Control and HACCP plan. Guidance on producing a HACCP plan can be found on the VMD's website www.vmd.defra.gov.uk.
22. Annex B to this VMGN contains the requirements that will be the subject of inspections.
23. At the approval inspection, the inspector will also provide advice to help the FeBO meet the requirements of the VMR. However, an application for approval can be refused if the inspector considers the premises, equipment or procedures do not meet the essential requirements set out in Annex B. In this case, the FeBO will not be able to manufacture Schedule 5 products. The inspector will explain the reasons for the refusal and the measures that the FeBO must take in order to obtain approval. A FeBO can appeal a refusal for approval. For further information about appeals please refer to VMGN 9 Guidance on Appeals Against Regulatory Decisions, which is published on the VMD website.
http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx

Registration – Requirement for Manufacturers of complete feedingstuffs using complementary feedingstuffs containing Specified Feed Additives for the exclusive requirements of their own holdings

24. FeBOs that manufacture or intend to manufacture complete feedingstuffs using complementary feedingstuffs containing Specified Feed Additives (SFAs) for the exclusive requirements of their own holdings, must be registered by the VMD on

behalf of the Secretary of State before they can undertake such an activity. These feed business operators must meet the applicable criteria set out in Annex II of Regulation EC/183/2005, with the exception of HACCP, which is reproduced in Annex B to this VMGN. FeBOs manufacturing complete feedingstuffs using complementary feedingstuffs containing SFAs are not subject to an inspection prior to registration.

25. Commercial FeBOs manufacturing and supplying complementary feedingstuffs that contain SFAs are still required to be approved under Annex II of Regulation EC/183/2005, including HACCP.

What a Registration Inspection Covers

26. Although FeBOs manufacturing complete feedingstuffs using complementary feedingstuffs containing SFAs are not subject to an inspection prior to registration, they will still be inspected to ensure that they are complying with the requirements of Regulation EC/183/2005.
27. The aim of an inspection is to check that FeBOs premises, equipment and procedures are capable of producing Schedule 5 products to the required standard. With the exception of a HACCP plan and documented procedures, the simplified list of requirements in Annex C also applies to registered FeBOs.

Approval Requirements for Distributors of Schedule 5 Products

28. A Distributor is a feed business operator who is approved to store, supply, wrap or package SFAs, premixtures containing SFAs or VMPs, complementary feedingstuffs containing SFAs and feedingstuffs containing VMPs. There is no requirement for approval to store or supply complete feedingstuffs containing SFAs. Distributors of Schedule 5 products must meet the criteria set out in the storage, transport, record keeping, complaints and product recall sections of Annex B to this VMGN. However, it should be noted that a Distributor may not retail VMPs.
29. Distributors who act purely as traders and do not hold products on their premises must still be approved by the VMD acting on behalf of the Secretary of State. However, such traders can either choose to have an on-site inspection or to be exempted from inspection by submitting a declaration as required by Article 17 of EU Regulation 183/2005, in which case they must supply documents detailing their sales of these products to an authorised inspector on request.
30. Approval as a feedingstuffs' manufacturer (other than category 6 or 7) permits the supply of that manufacturer's own product. However, manufacturers that also supply SFAs, premixtures containing VMPs or SFAs, or feedingstuffs containing VMPs, which are manufactured by 3rd parties, require additional approval as Distributors. Where businesses with more than one approval are inspected at the same time, the highest fee is payable plus 50% of all other inspection fees (Schedule 7, para 4 of the VMR).
31. A toll manufacturer is a manufacturer who provides a manufacturing service on behalf of another, to that manufacturer's specific request to specific specifications

and formulation (Contract manufacturing). Only toll manufacturers are permitted to supply another manufacturer in this way without being approved as a Distributor.

How to Apply for Approval or Registration

32. All enquiries relating to approval or registration as a FeBO should be made to the VMD or DARD, as follows:

Inspections Administration Team
VMD
Woodham Lane
New Haw
Addlestone
KT15 3LS
Telephone: 01932 338474/338475
Email: inspections@vmd.defra.gsi.gov.uk

Department of Agriculture and Rural Development
Dundonald House
Upper Newtownards Road
BELFAST
BT4 3SB
Telephone: 028 9054 7195
Email: gab.admin@dardni.gov.uk

Fees

33. The Secretary of State will charge fees to the industry for the inspections undertaken. The charges reflect the different responsibilities of each type of manufacturer and distributor and take account of the frequency and complexity of inspections. A table of categories of manufacturers and distributors is at Annex A.

Inspections

34. FeBOs manufacturing or supplying Schedule 5 products are subject to regular inspections by the VMD. Inspection enables the VMD to confirm that these premises are complying with the requirements of the VMR.
35. Inspections of FeBOs' premises are carried on a risk basis and the determined level of risk sets the frequency of inspection. Further explanation is given in Annex D.

Labelling of Schedule 5 Products

36. All Schedule 5 products placed on the market must be labelled in accordance with this section.

37. Labels must be clear, legible and indelible and be written in English. They may also contain other languages but the information in each language must be the same.
38. Authorisations for SFAs and VMPs stipulate the usable life for feedingstuffs into which they have been incorporated. Where more than one SFA or VMP is incorporated into a feedingstuff the shortest in-feed shelf life must be observed and must be shown on the label.
39. Authorisations for SFAs and VMPs also stipulate their withdrawal periods which must be shown on the label of feedingstuffs into which they have been incorporated. However, in the case of VMPs, if the prescription specifies a longer withdrawal period than that specified in the MA, then this is the one that applies and must be shown on the finished product's label. If there is more than one VMP used the withdrawal period must be the longest period specified in any of the SPCs for the VMPs or as specified in the prescription if this is longer.
40. If there is no prescription at the time of labelling, the withdrawal period must be that specified in the VMPs SPC (or the longest withdrawal period if there is more than one VMP) but the label must also state "If the prescription requires a longer withdrawal period that is the one that applies".
41. Labelling requirements for SFAs, premixtures containing SFAs and complementary feedingstuffs containing SFAs are covered by directly applicable EU legislation (Regulation 1831/2003) and therefore are not in the VMR. For ease of reference, the applicable provisions are listed here:
 - (a) the name of the functional group of the product followed by the authorised name of the additive;
 - (b) the name or business name and address of the person responsible for placing the product on the market;
 - (c) the net weight or, in the case of liquid additives and premixtures, either the net volume or the net weight;
 - (d) where appropriate, the establishment approval number;
 - (e) directions for use, any safety recommendations and, where applicable, the specific requirements mentioned in the authorisation, including the animal species and categories for which the additive or premixture of additives is intended;
 - (f) the identification number of the additive;
 - (g) the batch reference number and date of manufacture;
 - (h) the expiry date of the guarantee or the storage life from the date of manufacture,
 - (i) the directions for use, and
 - (j) the concentration.
42. In the case of a product manufactured by a toll manufacturer, the establishment approval number of the toll manufacturer and the name and address of the receiving manufacturer must appear on the label.
43. Labelling requirements for premixtures and feedingstuffs containing VMPs are set out in paragraphs 12 and 14 of Schedule 5.

44. Labelling requirements for feedingstuffs containing SFAs are set out in Articles 15 and 17 of Regulation 767/2009. These requirements can be located on the VMD website www.vmd.defra.gov.uk, under the UK & EU Legislation page, under the VMR section.

Containers/Packages

45. SFAs, premixtures, complementary feedingstuffs and complete feedingstuffs that are regulated under Schedule 5 of the VMR must be marketed in packages or containers which must be closed in such a way that the fastener is damaged on opening and cannot be re-used. This applies to the marketing of bulk packages and containers as well as smaller packages, and relevant documentation should accompany the bulk. This requirement is to ensure that any possible contamination after manufacture is minimised.

Record Keeping

46. All manufacturers and distributors of Schedule 5 products must retain records that permit effective traceability. Signatures and records can be made and stored electronically and/or as hard copies but must be retained for at least 5 years and be readily available to an appointed inspector.
47. The manufacturer or distributor of Schedule 5 products must keep records. Record keeping requirements are set out in Annex B.

Additional Requirements for Manufacturers of Premixtures and Feedingstuffs Containing Veterinary Medicinal Products

48. Additional requirements for the manufacture of premixtures and feedingstuffs containing VMPs are detailed in Directive 90/167/EC and set out in Schedule 5 of the VMR. Any FeBO that incorporates a VMP into a premixture or feedingstuff:
- (i) must incorporate it in accordance with the SPC or the product label, and must take account of any interactions listed there.
 - (ii) must ensure that the VMP does not contain the same active substance as any other additive already incorporated, or to be incorporated, into that premixture or feedingstuff. An exception can be made when preparing a feed which is to contain zinc or copper in any form. In order to avoid toxicity, the total amount of zinc or copper in the final feed must comply with the authorised maximum dosage stated in the SPC of any VMP used to prepare the premixture or feedingstuff.
 - (iii) must ensure that the VMP is incorporated in accordance with its SPC (unless it has been prescribed under the cascade) and the prescription;

- (iv) must ensure that the daily dose of the VMP is contained in a quantity of MFS corresponding to at least half the daily feedingstuffs ration of the animals treated, or, in the case of ruminants, corresponding to at least half the daily requirements of non-mineral supplementary feedingstuffs;
 - (v) must ensure that the prescribed VMP is thoroughly mixed into the feedingstuff to produce a homogenous and stable mix.
49. It is an offence to promote or label any VMP, or anything containing a VMP, as being suitable for top dressing unless the SPC specifically permits this method of use.

Medicated Feedingstuffs Prescriptions

50. Only a veterinary surgeon may prescribe the manufacture of a feedingstuff containing a VMP classified as POM-V, and the Medicated Feedingstuff prescription (MFSp) must be in writing. The veterinary surgeon who prescribes the MFS has responsibility for the details entered on the MFSp.

The veterinary surgeon may liaise with a feed mill over the completion of a particular MFSp but should only accept a request from a mill, in the vet's professional opinion, there is an actual need for a prescription. It is not considered best practice for feed mills to make unsolicited approaches to veterinary surgeons with "draft" prescriptions for their approval and such activity should be avoided. Keepers of animals who approach a feed supplier without an MFSp when one is required should be told to refer to their veterinary surgeon.

The Veterinary Medicines Regulations make it clear that a veterinary surgeon should carry out a clinical assessment of the animal or animals, which must be under his care, before issuing an MFSp for a feed containing a POM-V medicine. Therefore, if there is any doubt, the vet should discuss the matter with the keeper of the animals and undertake a clinical assessment of the animals.

In the case of an anthelmintic (wormer) classified as Prescription Only Medicine - Veterinarian, Pharmacist, Suitably Qualified Person (POM-VPS), the MFSp may be written by a veterinary surgeon, pharmacist or Suitably Qualified Person (SQP). The following paragraphs refer to the prescribing of MFS by veterinary surgeons, but the same requirements apply to pharmacists and SQPs prescribing feedingstuffs containing POM-VPS anthelmintics.

51. In the case of a person who is exempt from approval the prescription may be made orally or in writing. Refer to paragraph 16.
52. An MFSp must be written, in ink or other indelible format, or it may be produced and sent electronically or by fax. The MFSp must contain the following information:
- the name and address of the person prescribing the product;
 - the qualifications enabling the person to prescribe the product;
 - the name and address of the owner or keeper of the animal;
 - the species of animal, identification and number of the animals;

- the premises at which the animals are kept if this is different from the address of the owner or keeper;
 - the date of the prescription;
 - the signature or other authentication of the person prescribing the product;
 - the name and amount of the product prescribed;
 - the dosage and administration instructions;
 - any necessary warnings;
 - the withdrawal period if relevant;
 - the manufacturer or the distributor of the feedingstuffs (who must be approved for the purpose);
 - a statement that, if the validity exceeds one month, not more than 31 day's supply may be provided at any time. It is the veterinarian's responsibility to specify how much should be provided for each 31 day supply;
 - the name, type and quantity of feedingstuffs to be used;
 - the inclusion rate of the VMP and the resulting inclusion rate of the active substance;
 - any special instructions for the stockfarmer; and
 - the percentage of the prescribed feedingstuffs to be added to the daily ration;
 - If it is prescribed under the cascade, a statement to that effect.
53. An MFSp for an MFS used via a medicated premixture requires extra details. The MFSp must include clear instructions regarding:
- the inclusion rate of the VMP into the premixture;
 - the subsequent range of acceptable inclusion rate of the premixture into the final feedingstuffs; and
 - the range of acceptable levels of the active ingredients in the final feedingstuffs
54. The words "refer to the prescription for the exact inclusion rate" or equivalent wording should also appear.
55. When prescribing in accordance with the prescribing cascade, a statement to that effect must be added to the prescription.
56. The MFSp must be signed by the veterinary surgeon. A *per pro* signature is not acceptable. The veterinary surgeon is responsible for ensuring that the MFSp has been completed correctly before authorising its issue.
57. The veterinary surgeon who prescribes an MFS must issue a copy of the MFSp to:
- a) the person supplying the MFS to the keeper of the animals to be treated i.e. the manufacturer of the MFS or, the approved Distributor;
 - b) the keeper of the animals to be treated;
 - c) keep a copy himself.
58. A MFSp is valid for up to three months or a shorter period specified on the prescription by the veterinary surgeon (VMR Schedule 5, paragraph 19 (2)).

However, if the MFSp is for a medicated feed containing one or more antibiotics, veterinary surgeons are strongly advised to make medicated feed prescriptions valid for no more than one month.

The validity of an MFSp is from the date the veterinary surgeon signs it. Therefore if a veterinary surgeon prescribes a feed containing an antibiotic and specifies that the MFSp is valid for one month, the prescribed amount of medicated feed may only be supplied within one month from the date the MFSp was signed. After that date, no further medicated feed should be supplied against the MFSp and the veterinary surgeon will need to issue a new one.

If the MFSp is valid for a course of treatment lasting longer than one month, the manufacturer of the final feed may only supply one month's requirement of MFS in each 31 day period.

The veterinary surgeon must also ensure that an MFSp is sufficient for only one course of treatment.

59. The veterinary surgeon must prescribe the MFS only in such quantities as are necessary for one course of treatment for the number of animals stated on the MFSp and for the duration and frequency of treatment. The quantities must be within the maximum limits laid down in the SPC.
60. When two VMPs are being incorporated into the same feedingstuff, the veterinary surgeon may write one MFSp, provided that:
 - a) the VMPs are being mixed into the same final feedingstuff;
 - b) the MFSp clearly states that when the two products are incorporated into the feedingstuff the longest withdrawal period applies.
61. The veterinary surgeon who prescribes the MFS must be satisfied that:
 - a) there is no undesirable interaction between the VMP and any feed additive used in the feedingstuffs; and
 - b) the active substance of the VMP is not the same as an active substance in any feed additive used in the feedingstuffs.
62. An MFSp can authorise the supply of MFS to more than one site or premises, so long as the animals and sites are owned by the same person. The sites must all be named on the MFSp and the feeds must all be for the same species and have the same active substances. The feeds may differ nutritionally; for example one feed may be a starter, while another may be a grower. In the case of an MFS containing a POM-V medicine, all of the animals must also be under the care of the prescribing veterinary surgeon.
63. If an MFS also contains an SFA, it is not a legal requirement for the veterinary surgeon to include details of that SFA on the MFSp.
64. Antimicrobial resistance is of global concern in both human and veterinary medicine. The majority of veterinary antibiotics are prescribed and administered to livestock in medicated feed. In all cases where an antibiotic veterinary medicine is prescribed, farmers should consider reviewing the management practice of the animals in their care with a view to reducing the amount of prescribed antibiotics. The farmer's veterinary surgeon should be able to advise on all possible means to reduce the need for antimicrobial treatment of their animals in the future. The Responsible Use of Medicines in Agriculture (RUMA) Alliance has produced information on the use of

antibiotics for the different livestock sectors.
<http://www.ruma.org.uk/antimicrobials.htm>.

Supply relating to MFSp

65. It is the responsibility of the feed manufacturer or distributor to comply strictly with the terms of the MFSp. Where treatment lasts more than three months the veterinary surgeon (or in the case of an anthelmintic, the veterinarian, pharmacist or SQP) must issue a new prescription.
66. A veterinary surgeon who prescribes and/or supplies a VMP may only supply a feedingstuffs manufacturer approved to use that VMP. The only exceptions are those premises exempted in paragraph 16.
67. MFS containing POM-V medicines can only be supplied to the keeper of animals on receipt of a written MFSp issued by a veterinary surgeon. However, MFS may be supplied to an approved Distributor without an MFSp.
68. A VMP which is authorised for use in feedingstuffs, or a premixture containing such a VMP, may only be supplied to a keeper of animals, who is in possession of a valid MFSp and who is approved as a manufacturer of MFS; and the supply must be in accordance with that MFSp. An MFSp may be valid for up to 3 months from the date of veterinary signature and the keeper of animals may be supplied with a quantity of VMP required to fulfil the prescription. However, if the MFSp is valid for a course of treatment lasting longer than one month, the keeper of animals may be supplied with enough VMP (or premixture containing a VMP) to fulfil that MFSp, however only one month's requirement of the MFS may be manufactured in each 31 day period. A list of approved premises is available at:
http://www.vmd.defra.gov.uk/pdf/register_approvedpremises.pdf
69. SFAs, premixtures and complementary feedingstuffs only containing SFAs do not need to be prescribed but they may only be supplied to appropriately approved or registered manufacturers or distributors. Feedingstuffs containing only SFAs may be supplied without prescription to keepers of animals.

Record keeping relating to MFSp

70. An MFSp, including one produced electronically, must also be kept for a period of five years from the date the prescribing veterinary surgeon signed it.
71. An MFSp must be stored in such a way that it may be made available immediately on request by an authorised inspector acting on behalf of the Secretary of State for the Department for Environment, Food and Rural Affairs (Defra). For further information on record keeping please refer to VMGN 14 Record-Keeping Requirements for Veterinary Medicinal Products which is published on the VMD website.
http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx
72. There is no legal requirement for the MFS' manufacturer to possess a copy of the MFSp when they are selling the feed to an approved Distributor. However, in such cases it is advisable for the manufacturer to ask for the feed order in writing or for a

photocopy/fax of the MFSp, to ensure that the correct feed is manufactured and supplied.

Manufacture of Medicated Feed subject to an MFSp.

73. In fulfilling an order based on an MFSp the feed manufacturer should ensure that the medicated feed supplied complies precisely with the prescription. The amount of medicated feed supplied should not exceed that required by the animals in question. If the quantity of medicated feed ordered exceeds the quantity prescribed, the feed supplier should discuss this with their customer, who should then discuss with their prescribing veterinary surgeon. If the veterinary surgeon considers it appropriate to increase the amount of feed prescribed the vet should instruct the feed manufacturer to amend their copy of the MFSp. All such discussions should be clearly recorded by the feed manufacturer. It is an offence under the VMR to alter an MFSp issued by a veterinary surgeon.
74. An approved commercial MFS manufacturer may choose to prepare a feedingstuff containing a VMP in anticipation of an MFSp. However, the manufacturer may not supply the feedingstuff to a keeper of animals unless that keeper is in possession of a valid MFSp.
75. A VMP which is authorised for incorporation into feedingstuff must be thoroughly mixed into the feedingstuff. Top dressing of an in-feed VMP (i.e. sprinkling on top of feedingstuff) is only permitted where the product specifies this form of administration or in the absence of suitable authorised products, where a vet wishes to prescribe the product for off-label use under the cascade. In so doing the vet takes full responsibility for ensuring the correct dose is delivered and withdrawal period applied.
76. If prescribing or using oral medication of pigs in the UK that are fed via a liquid feed system, please refer to the VMD's Good Practice Note on "the Medication of Pigs via Liquid Feed" which has been provided to guide veterinary surgeons and farmers. In this document, liquid pig feed means porridge, meal and fully liquid feeds.

<http://www.vmd.defra.gov.uk/pdf/LiquidPigFeed.pdf>

Withdrawal Periods for Veterinary Medicinal Products Prescribed under the Cascade

77. If a VMP is incorporated into premixtures or feedingstuffs in accordance with its SPC, the minimum withdrawal period shown on the MFSp must be that of the SPC or product label. A veterinary surgeon prescribing a feedingstuff containing a VMP for a food-producing animal under the cascade must specify an appropriate withdrawal period.
78. The withdrawal period must ensure that, if there is a maximum residue limit (MRL) specified for the active substance in Commission Regulation (EU) No 37/2010 the level of residue of the active substance does not exceed the limit.

79. In any event, unless the Secretary of State has specified in writing a different withdrawal period for a particular VMP, the withdrawal period (irrespective of whether or not an MRL is specified in Commission Regulation (EU) No 37/2010 must not be less than:
- a) 7 days for eggs
 - b) 7 days for milk
 - c) 28 days for meat from poultry and mammals including fat and offal
 - d) 500 degree days for fish meat
80. Where more than one VMP is prescribed and all are used following the terms and conditions authorised in the SPC, the longest withdrawal period applies.
81. Where more than one VMP is prescribed and one or more are used outside the terms and conditions of the SPC, then the statutory withdrawal periods, as above, applies.

Importation of Medicated Feedingstuffs

From Member States

82. Where an MFS is imported from another EU Member State (MS), it must have been manufactured in accordance with the provisions of Council Directive 90/167/EEC and Regulation (EC) No. 183/2005. It must also contain a VMP that has the same quantitative and qualitative composition as a VMP authorised in the UK.

From Third Countries

83. FeBOs may not import MFS from third countries.

For Export Only

84. A manufacturer of a premixture or feedingstuff who imports a VMP authorised in another MS or third country for the purpose of incorporating it into premixture or feedingstuff for export only, does not commit an offence of importation or possession of an unauthorised VMP. However, it is an offence to place that premixture or feedingstuff on the market in the United Kingdom once the VMP has been incorporated into it.

Importation of Feedingstuffs Containing Specified Feed Additives

From Member States

85. FeBOs may import Community authorised feed additives and feedingstuffs containing them whose manufacture complies with Community feed and food law from other MS.

From Third Countries

86. FeBOs importing feed containing feed additives from third countries shall:
- a) ensure that the third country of dispatch appears on a list, drawn up in accordance with Article 48 of Regulation 882/2004, of third countries for which imports of feed are permitted;
 - b) the establishment of dispatch appears on a list, drawn up and kept updated by a third country in accordance with Article 48 of Regulation 882/2004 of establishments from which imports of feed are permitted;
 - c) the feed was produced by the establishment of dispatch or by another establishment appearing on the list referred to in point (b); and
 - d) the feed satisfies:
 - (i) the requirements laid down in Regulation 183/2005 and in any other community legislation laying down rules for feed;
 - (ii) or those conditions recognised by the Community to be at least equivalent to;
 - (iii) or where a specific agreement between the Community and the exporting country exists, the requirements are contained in the agreement.

For Export Only

87. Feed, exported or re-exported from the Community for placing on the market of a third country including feed for animals not kept for food production, must satisfy the following provisions:-

- 1) *Feed exported or re-exported from the Community for placing on the market of a third country should comply with the relevant requirements of feed law, unless otherwise requested by the authorities of the importing country or established by the laws, regulations, standards, codes of practice and other legal and administrative procedures in that country.*

In other circumstances, except in the case where feeds are unsafe, feed can only be exported or re-exported if the competent authorities of the country of destination have expressly agreed, after having been fully informed of the reasons for which and the circumstances in which the food or feed concerned could not be placed on the market in the Community.

Export of Unauthorised Substances or Feed Containing Them

88. FeBOs exporting or re-exporting unauthorised medicinal substances intended for feed, unauthorised SFAs, or feed containing them to a third country (i.e. a country outside the EU) either directly or via another member state are required to notify the VMD.

This also applies to re-export of imported substances and when the unauthorised substance is incorporated into a premixture for export. Therefore FeBOs exporting

unauthorised substances or feeds containing such substances (including premixtures) to third countries should:

- a) Notify the VMD of the export. This notification should contain all the details of the unauthorised substances being exported from the UK, the details of the Member States the substances will be moved through and the country receiving them.
- b) Unless there is alternative proof of authorisation of that substance in the importing third country FeBOs require the express consent from the third country competent authority prior to the export of unauthorised substances. They should retain a copy of the consent of the third country for inspection by VMD.

For more detailed requirements please see VMD website:

<http://www.vmd.defra.gov.uk/mswd.aspx>

Possession

89. It is an offence to possess a VMP, an SFA, a premixture containing either of these, or a feedingstuff containing either of these, or a complementary feedingstuff containing an SFA except in accordance with the VMR. This only applies, however, to possession of any such products intended for placing on the market within the UK and does not apply to any that are intended for export to third countries.
90. Inspectors appointed under the VMR may seize any VMP, or SFA that is not authorised in the UK, and any VMP, SFA, premixture or feedingstuff containing such a VMP or SFA if it has not been lawfully manufactured, incorporated or supplied in accordance with the Regulations. The person from whom the product is seized may be liable for the full costs of transport, storage for up to 28 days and destruction of the product, unless a claim is made to a court and the court directs otherwise. For further information on seizure of products and appeals, please refer to VMGN 10 Guidance on Enforcement, which is published on the VMD's website.
http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx

Non Compliance

91. Where an inspector identifies a non-compliance (deficiency) with the VMR in the FeBO's operations, they will deal with the deficiency in accordance with the VMD's Enforcement Strategy (<http://www.vmd.defra.gov.uk/pdf/EnforcementStrategy.pdf>) which includes providing written advice on compliance for minor deficiencies, sending a formal advisory letter and, in the most serious of cases, serving an Improvement Notice on the FeBO. Further details on categorising deficiencies are provided in Annex D.

A FeBO served an Improvement Notice must take the appropriate remedial action within the specified timescale and failure to comply with an Improvement Notice is an

offence that could lead to formal action being taken, including suspension or revocation of the FeBO approval and/or prosecution.

92. If an Improvement Notice is served, the VMD will charge the person on whom the Notice was served, the full economic cost of any subsequent inspection necessary to check that the Notice has been complied with. For further information on Improvement Notices, please refer to VMGN 10 Guidance on Enforcement, which is published on the VMD's website
http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx

Disposal of Feed Products

93. The Environment Agency is responsible for the VMR relating to disposal of feed products. Guidance is available on their website at www.environment-agency.gov.uk, or you may contact them on 08708 506506.
94. Additionally, local Waste Regulation Authorities can advise on the safe disposal of any unused product and empty containers. It is essential that any disposal be dealt with in accordance with the environmental legislation.

Further Information

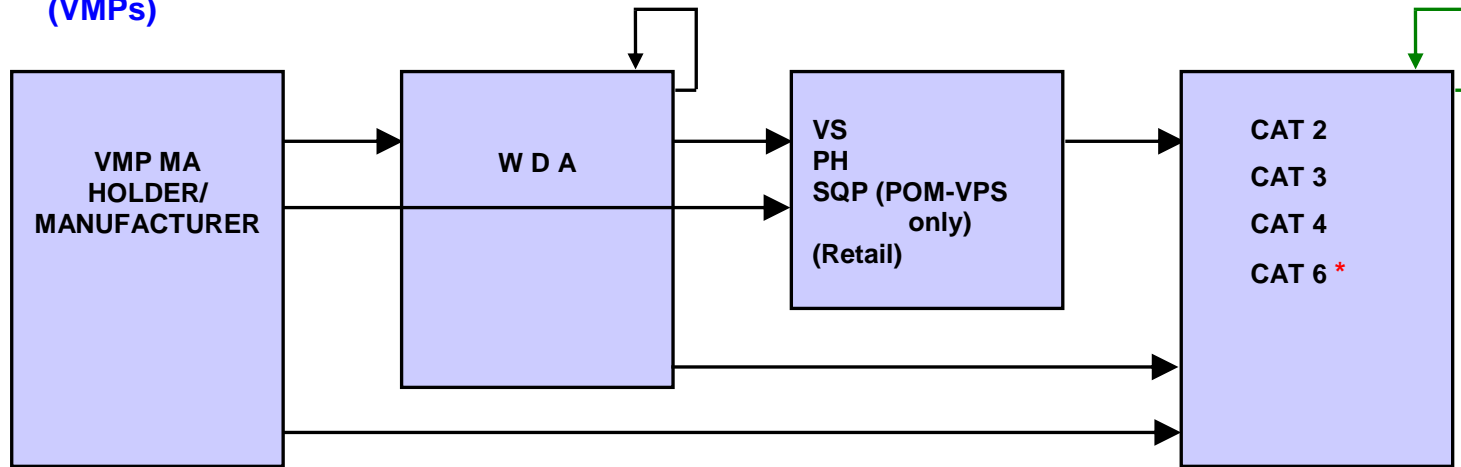
95. Further information is available from the Veterinary Medicines Directorate, Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS - Tel: +44 (0)1932 336911; Fax: +44 (0)1932 336618 or E-mail: VMGNotes@vmd.defra.gsi.gov.uk. Veterinary Medicines Guidance Notes and other information, including details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

ANNEX A

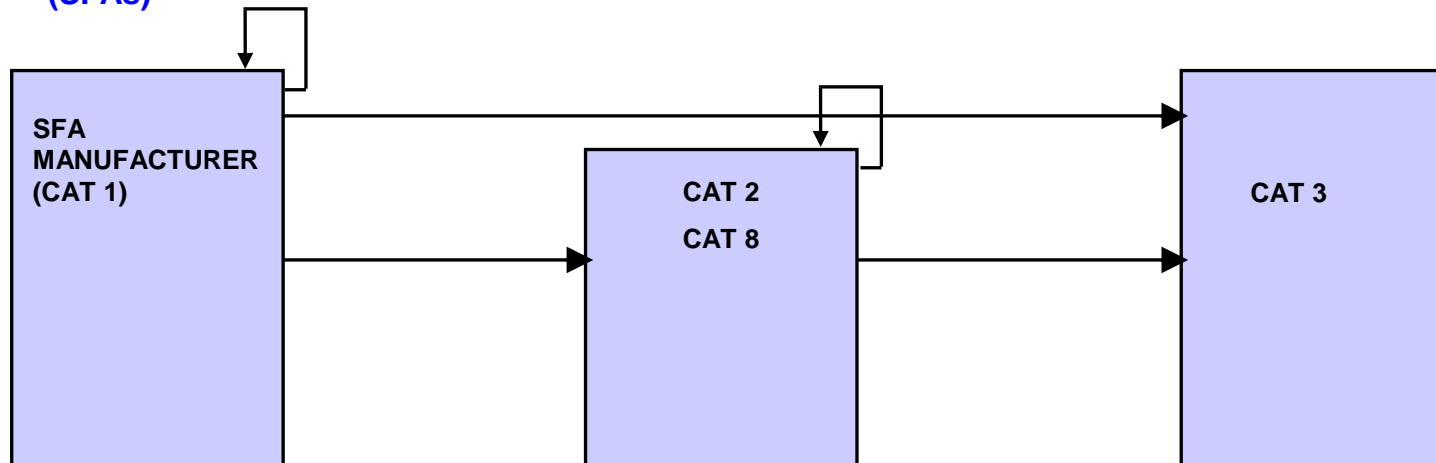
WHO CAN SELL WHAT TO WHOM?

Subject to the business having been approved within that category



IN FEED VETERINARY MEDICINAL PRODUCTS (VMPs)



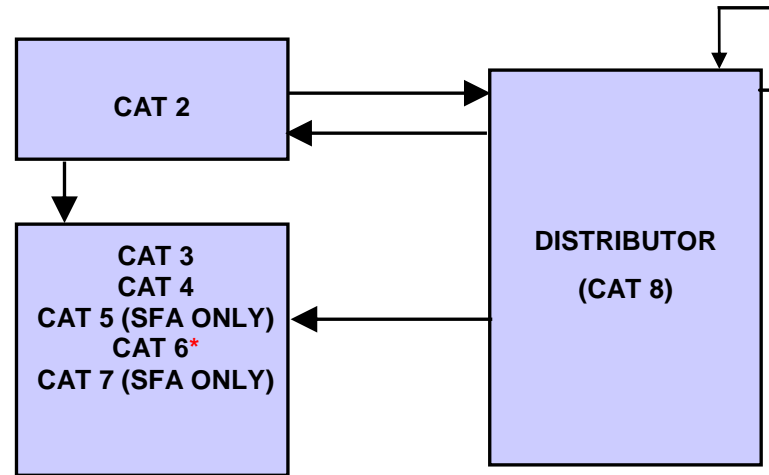
SPECIFIED FEED ADDITIVES (SFAs)



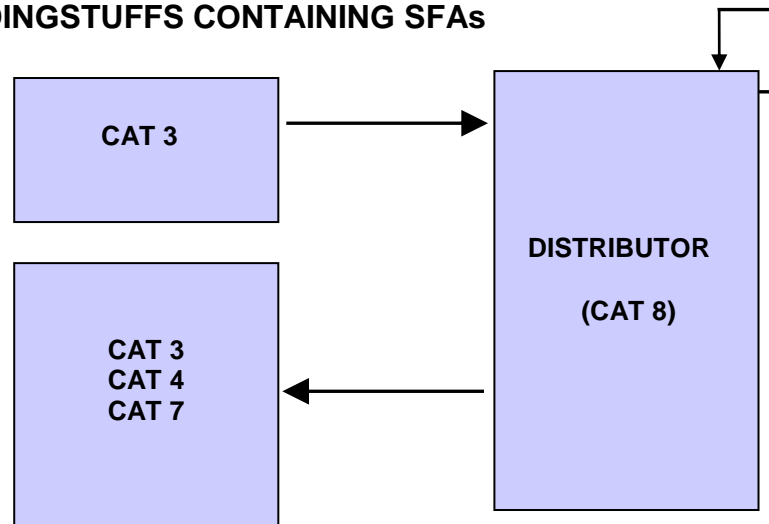
DEFINITIONS

- MAH** Marketing Authorisation Holder
 - CAT 1** Specified Feed Additive Manufacturer
 - CAT 2** Manufacturer of premixtures containing VMPs or SFAs
 - CAT 3** Complementary Feed Manufacturer and/or Compound Feed Manufacturer (incorporating VMPs and SFAs, or premixtures or complementary feedingstuffs containing such products, at any rate)
 - CAT 4** Compound Feed Manufacturer (incorporating VMPs or premixtures containing VMPs at a rate of at least 2kg per tonne)
 - CAT 5** Compound Feed Manufacturer (incorporating SFAs via premixtures or complementary feedingstuffs)
 - CAT 6** On Farm Manufacturer for own use (incorporating VMPs or premixtures containing VMPs at a rate of at least 2kg per tonne)
 - CAT 7** On Farm Manufacturer for own use (incorporating SFAs via premixtures or complementary feedingstuffs)
 - CAT 8** Distributor who handles/stores product and Distributors who act purely as traders
 - SQP** Suitably Qualified Person
 - WDA** Wholesale Dealer
 - VS** Veterinary Surgeon
 - PH** Pharmacist
 - *** To a valid MFS prescription
-  WHOLESALE – one can supply another person in the same category
-  The green arrow means an approved premixture or feedingstuffs manufacturer may wholesale supply to another approved premixture or feedingstuffs manufacturer, provided that in any one year the amount supplied by the manufacturer does not exceed 5% of value of turnover.

PREMIXTURES CONTAINING VMPs and/or SFAs




COMPLEMENTARY FEEDINGSTUFFS CONTAINING SFAs



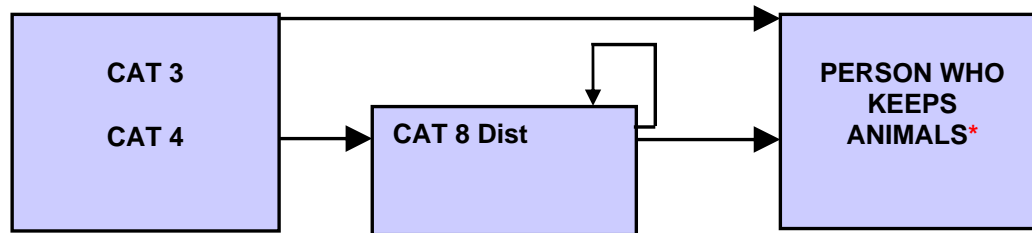
DEFINITIONS

- MAH** Marketing Authorisation Holder
- CAT 1** Specified Feed Additive Manufacturer
- CAT 2** Manufacturer of premixtures containing VMPs or SFAs
- CAT 3** Complementary Feed Manufacturer and/or Compound Feed Manufacturer (incorporating VMPs and SFAs, or premixtures or complementary feedingstuffs containing such products, at any rate)
- CAT 4** Compound Feed Manufacturer (incorporating VMPs or premixtures containing VMPs at a rate of at least 2kg per tonne)
- CAT 5** Compound Feed Manufacturer (incorporating SFA via premixtures or complementary feedingstuffs)
- CAT 6** On Farm Manufacturer for own use (incorporating VMPs or premixtures containing VMPs at a rate of at least 2kg per tonne)
- CAT 7** On Farm Manufacturer for own use (incorporating SFA via premixtures or complementary feedingstuffs)
- CAT 8** Distributor who handles/stores product and Distributors who act purely as traders
- SQP** Suitably Qualified Person
- WDA** Wholesale Dealer
- VS** Veterinary Surgeon
- PH** Pharmacist

* To a valid MFS prescription

 WHOLESALE – one can supply another person in the same category

FINAL MEDICATED FEEDINGSTUFFS



ANNEX B

ANNEX II OF EU REGULATION 183/2005

Requirements for feed businesses other than at the level of primary production of feed referred to in Article 5(1)

Facilities and Equipment

1. Feed processing and storage facilities, equipment, containers, crates, vehicles and their immediate surroundings shall be kept clean, and effective pest control programmes shall be implemented.
2. The layout, design, construction and size of the facilities and equipment shall:
 - (a) permit adequate cleaning and/or disinfection;
 - (b) be such as to minimise the risk of error and to avoid contamination, cross-contamination and any adverse effects generally on the safety and quality of the products. Machinery coming into contact with feed shall be dried following any wet cleaning process.
3. Facilities and equipment to be used for mixing and/or manufacturing operations shall undergo appropriate and regular checks, in accordance with written procedures pre-established by the manufacturer for the products.
 - (a) All scales and metering devices used in the manufacture of feeds shall be appropriate for the range of weights or volumes to be measured and shall be tested for accuracy regularly.
 - (b) All mixers used in the manufacture of feeds shall be appropriate for the range of weights or volumes being mixed, and shall be capable of manufacturing suitable homogeneous mixtures and homogeneous dilutions. Operators shall demonstrate the effectiveness of mixers with regard to homogeneity.
4. Facilities must have adequate natural and/or artificial lighting.
5. Drainage facilities must be adequate for the purpose intended; they must be designed and constructed to avoid the risk of contamination of feedingstuffs.
6. Water used in feed manufacture shall be of suitable quality for animals; the conduits for water shall be of an inert nature.
7. Sewage, waste and rainwater shall be disposed of in a manner which ensures that equipment and the safety and quality of feed is not affected. Spoilage and dust shall be controlled to prevent pest invasion.
8. Windows and other openings must, where necessary, be proofed against pests. Doors must be close-fitting and proofed against pests when closed.
9. Where necessary, ceilings and overhead fixtures must be designed, constructed and finished to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable moulds, and the shedding of particles that can affect the safety and quality of feed.

Personnel

Feed businesses must have sufficient staff possessing the skills and qualifications necessary for the manufacture of the products concerned. An organisation chart setting out the qualifications (e.g. diplomas, professional experience) and responsibilities of the supervisory staff must be drawn up and made available to the competent authorities responsible for inspection.

All the staff must be informed clearly in writing of their duties, responsibilities and powers, especially when any change is made, in such a way as to obtain the desired product quality.

Production

1. A qualified person responsible for production must be designated.
2. FeBOs must ensure that the different stages of production are carried out according to pre-established written procedures and instructions aimed at defining, checking and mastering the critical points in the manufacturing process.
3. Technical or organisation measures must be taken to avoid or minimise, as necessary, any cross-contamination and errors. There must be sufficient and appropriate means of carrying out checks in the course of manufacture.
4. The presence of prohibited feed, undesirable substances and other contaminants in relation to human or animal health shall be monitored and appropriate control strategies to minimise the risk shall be put in place.
5. Waste and materials not suitable as feed should be isolated and identified. Any such materials containing hazardous levels of veterinary drugs, contaminants or other hazards shall be disposed of in an appropriate way and not used as feed.
6. FeBOs shall take adequate measures to ensure effective tracing of the products.

Quality Control

1. Where appropriate, a qualified person responsible for quality control must be designated.
2. Feed businesses must, as part of a quality control system, have access to a laboratory with adequate staff and equipment.
3. A quality control plan must be drawn up in writing and implemented to include, in particular, checks on the critical points in the manufacturing process, sampling procedures and frequencies, methods of analysis and their frequency, compliance with the specifications – and the destination in the event of non-compliance – from processed materials to final products.
4. Documentation relating to the raw materials used in final products must be kept by the manufacturer in order to ensure traceability. Such documentation must be

available to the competent authorities for a period appropriate for the use to which the products are placed on the market. In addition, samples of ingredients and of each batch of products manufactured and placed on the market or of each specific portion of production (in the case of continuous production), must be taken in sufficient quantity using a procedure pre-established by the manufacturer and be retained, in order to ensure traceability (on a regular basis in the case of manufacture solely for the manufacturer's own needs). The samples must be sealed and labelled for easy identification; they must be stored under conditions which prevent any abnormal change in the composition of the sample or any adulteration. They must be kept at the disposal of the competent authorities for a period appropriate to the use for which the feed is placed on the market. In the case of feedingstuffs for animals not kept for food production, the manufacturer of the feedingstuff must only keep samples of the finished product.

Storage and Transport

1. Processed feeds shall be separated from unprocessed feed materials and additives, in order to avoid any cross-contamination of the processed feed; proper packaging materials shall be used.
2. Feeds shall be stored and transported in suitable containers. They shall be stored in places designed, adapted and maintained in order to ensure good storage conditions, to which only persons authorised by the feed business operators have access.
3. Feeds shall be stored and transported in such a way as to be easily identifiable, in order to avoid any confusion or cross-contamination and to prevent deterioration.
4. Containers and equipment used for the transport, storage, conveying, handling and weighing of feed shall be kept clean. Cleaning programmes shall be introduced, and traces of detergents and disinfectants shall be minimised.
5. Any spoilage shall be minimised and kept under control to reduce pest invasion.
6. Where appropriate, temperatures shall be kept as low as possible to avoid condensation and spoilage.

Record-Keeping

1. All FeBOs, including those who act solely as traders without ever holding the product in their facilities, shall keep in a register, relevant data comprising details of purchase, production and sales for effective tracing from receipt to delivery, including export to the final destination.
2. FeBOs, except those who act solely as dealers without ever holding the product in their facilities, shall keep in a register:
 - (a) Documentation relating to the manufacturing process and controls.

Feed businesses must have a system of documentation designed to define and ensure mastery of the critical points in the manufacturing process and to

establish and implement a quality control plan. They must keep the results of the relevant controls. This set of documents must be kept so that it is possible to trace the manufacturing history of each batch of products put into circulation and to establish responsibility, if complaints arise.

(b) Documentation relating to traceability, in particular:

(i) for feed additives:

the nature and quantity of the additives produced, the respective dates of manufacture and, where appropriate, the number of the batch or of the specific portion of production, in the case of continuous manufacture;

the name and address of the establishment to which the additives were delivered, the nature and quantity of the additives delivered and, where appropriate, the number of the batch or of the specific portion of production, in the case of continuous manufacture.

(ii) for products covered by Directive 82/471/EEC:

the nature of the products and the quantity produced, the respective dates of manufacture and, where appropriate, the number of the batch or of the specific portion of production, in the case of continuous manufacture;

the name and address of the establishments or users (establishments or farmers) to whom these products have been delivered, together with details of the nature and quantity of the products delivered and, where appropriate, the number of the batch or of the specific portion of production, in the case of continuous manufacture.

(iii) for premixtures:

the name and address of the manufacturers or suppliers of additives, the nature and quantity of the additives used and, where appropriate, the number of the batch or of the specific portion of production, in the case of continuous manufacture;

the date of manufacture of the premixture and the batch number where appropriate;

the name and address of the establishment to which the premixture is delivered, the delivery date, the nature and quantity of the premixture delivered, and the batch number where appropriate.

(iv) for compound feedingstuffs/feed materials:

the name and address of additive/premixture manufacturers or suppliers, the nature and quantity of the premixture used, with the batch number where appropriate;

the name and address of the suppliers of the feed materials and complementary feeds, and the delivery date;

the type, quantity and formulation of the compound feed;

the nature and quantity of feed materials or compound feedingstuffs manufactured, together with the date of manufacture, and the name and address of the buyer (e.g. farmer, other feed business operators).

Complaints and Product Recall

1. Feed business operators shall implement a system for registering and processing complaints.
2. They shall put in place, where this proves necessary, a system for the prompt recall of products in the distribution network. They shall define by means of written procedures the destination of any recalled products, and before such products are put back into circulation, they must undergo a quality-control reassessment.

ANNEX C

VMD CHECKLIST FOR FARMERS MIXING ANIMAL FEEDINGSTUFFS CONTAINING CONTROLLED PRODUCT

Checklist for farmers mixing animal feedingstuffs containing Controlled Products

Controlled Products

In this checklist, Controlled Products refer to:

- Veterinary Medicinal Products (VMPs) authorised for mixing into animal feed;
- Specified Feed Additives (SFAs) i.e. coccidiostats and growth promoters; and
- Premixtures containing VMPs or SFAs.

Premises & Equipment

Ensure that all parts of the premises and equipment used for mixing feeds, including associated storage areas, are:

- In a good state of repair.
- Clean and tidy.
- Free from spillages, old packaging and obsolete equipment.
- Protected from the entrance and harbouring of pests, vermin and domestic animals.
- Well lit, ventilated and dry.
- Suitable to accurately mix feeds and protect feeds from contamination.

Personnel

Ensure that:

- There is a designated person responsible for feed production.
- Staff are trained and knowledgeable in handling Controlled Products and mixing feeds.
- Appropriate staff facilities and personal protective equipment are available.

Production

Ensure that procedures are in place so:

- Feed materials are sourced from appropriate suppliers and measures are taken to minimise the risk from contaminants and prohibited/undesirable substances.
- Feeds are mixed according to written formulations and instructions aimed at minimising cross-contamination during mixing, storage and transport.
- Veterinary medicines are only used in accordance with a valid Medicated Feedingstuff prescription (MFSp).
- Other Controlled Products are only used 'as labelled'.
- Waste material not suitable for feed is isolated and identified for disposal.

Storage & Transport

Ensure that:

- Controlled Products are stored in their original packaging and in a secure location.
- Storage areas for feed materials and mixed feed are suitable to prevent contamination and pest damage.
- All feed materials and mixed feeds are labelled or otherwise clearly identifiable.
- Mixed feeds are transported in suitable vehicles or containers, which are cleaned as necessary to prevent cross-contamination.

Quality Control

Ensure that a Quality Control plan is drawn up which includes:

- Keeping samples of mixed feeds.
- Testing the efficiency of the mixer (homogeneity test).
- Testing samples of mixed feed for Controlled Products and other substances.
- Testing mixed feed for cross-contamination (carryover) where there is a risk.
- Monitoring feed materials and mixed feeds for harmful organisms and deleterious substances.

Record-keeping

Ensure that appropriate records are kept of the following:

- Controlled Products and feed materials purchased.
- Feeds mixed and details of the Controlled Products used (including batch numbers).
- MFS prescriptions to cover purchase and use of VMPs and medicated premixtures.
- Documented Procedures for feed production.
- Quality Control results:
 - mixer efficiency (homogeneity) tests
 - carryover (cross-contamination) tests
 - calibration of weighing/measuring equipment
 - analysis of mixed feeds and feed materials
- Cleaning and maintenance of premises, storage areas and equipment.
- HACCP plan.
- All records are kept for 5 years.

Further guidance is available from:

The Inspections Administration Team
VMD
Woodham Lane
New Haw
ADDLESTONE
Surrey
KT15 3LS

Tel: 01932 338475

E-mail: inspections@vmd.defra.gsi.gov.uk

VMD website: http://www.vmd.defra.gov.uk/mswd/feedingstuffs_guidance.aspx

ANNEX D

CATEGORISING DEFICIENCIES AND RISK BASED INSPECTION PLAN FOR FEED BUSINESS OPERATORS

Categorising Deficiencies and Risk Based Inspection Plan for Feed Business Operators

Minor (Other) Deficiencies

- A deficiency, which is minor and poses no potential risk to human or animal health, or the environment; or
- a deficiency which does not indicate a significant deviation from the requirements of the Veterinary Medicines Regulations (VMR), Codes' of Practice or Guidance; or
- a deficiency which cannot be classified as either critical or major, because there is insufficient information to classify it as such.

Major Deficiencies

- A non-critical deficiency which has produced, or has the potential to produce, a possible risk to human or animal health, or the environment; or
- a deficiency which indicates a major deviation from the requirements of the VMR; or
- a deficiency which indicates a failure to carry out satisfactory procedures to ensure that products are manufactured, stored or distributed in accordance with their specific requirements; or
- a combination of more than six other (minor) deficiencies, none of which on their own may be major, but which may together represent a major deficiency and should be explained and reported as such; or
- Other (minor) deficiencies that have been brought to the attention of the business on previous occasions but have not been resolved.

Critical Deficiencies

- Deficiencies that have produced, or have the potential to produce, a significant risk to human or animal health, or the environment; or
- a deficiency which indicates a significant deviation from the requirements of the VMR through serious negligence or intent.

Categories of Feed Business Operators

Inspection findings	Compliance rating	Max inspection interval (months) by Category		
		1, 2, 3	4,5, 6*	6, 6F, 7, 8
≤6 minor (other)	Good	24	36	48
> 6 minor ≤ 3 major	Acceptable	18	27	36
>3 ≤ 5 major	Poor	12	18	24
≥ 6 major; any critical	Unacceptable	Follow up inspection as specified on Improvement Notice, then next scheduled inspection within 9-12 months		

Category	Activity Description
1	Establishment approved to manufacture an SFA
2	Establishment approved to manufacture a premixture
3	Establishment approved to manufacture feedingstuffs using specified feed additives and VMPs directly at any concentration, or using premixtures.
4	Establishment approved to manufacture feedingstuffs for placing on the market using a VMP or premixture where the concentration of a VMP in the feedingstuffs is 2 kg per tonne or more.
5	Establishment approved to manufacture feedingstuffs using premixtures containing specified feed additives when the feedingstuffs are to be placed on the market.
6*	Establishment approved to manufacture MFS considered to be 'higher risk' for feeding to own animals e.g. medicated liquid pig feed manufacturers and farmers using 'neat' medicinal premixes (rather than premixtures).
6	Establishment approved to manufacture feedingstuffs for feeding to the manufacturers own animals, using a veterinary medicinal product or premixture where the concentration of veterinary medicinal product in the feedingstuffs is 2 kg per tonne or more.
6F	Establishment approved to manufacture feedingstuffs for feeding to the manufacturers own fish, using a veterinary medicinal product or premixture where the concentration of veterinary medicinal product in the feedingstuffs is 2 kg per tonne or more.
7	Establishment to manufacture feedingstuffs using premixtures containing specified feed additives when the feedingstuffs are to be used by the person manufacturing the feedingstuffs.
8	Distributor approved to sell, supply or store specified feed additives, premixtures or feedingstuffs containing specified feed additives, or premixtures or feedingstuffs containing VMPs.

List of Abbreviations

Defra	Department for Environment, Food & Rural Affairs
EU	European Union
FeBO	Feed Business Operator
HACCP	Hazard Analysis and Critical Control Point
MA	Marketing Authorisation
MAH	Marketing Authorisation Holder
MFS	Medicated Feedingstuff
MFSp	Medicated Feedingstuff prescription
MRL	Maximum Residue Limit
MS	Member State
POM-V	Prescription Only Medicine – Veterinarian
POM-VPS	Prescription Only Medicine – Veterinarian, Pharmacist, Suitably Qualified Person
QPFC	Qualified Person for Feedingstuffs Control
QFPF	Qualified Person for Feedingstuffs Production
QPFQ	Qualified Person for Feedingstuffs Quality
SFA	Specified Feed Additive
SPC	Summary of Product Characteristics
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

VETERINARY MEDICINES GUIDANCE NOTE

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