ASSURING THE SAFETY, QUALITY & EFFICACY
OF VETERINARY MEDICINES

VETERINARY MEDICINES GUIDANCE NOTE

No 16

GUIDANCE ON HORSE MEDICINES AND HORSE PASSPORTS

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www.vmd.defra.gov.uk

QUICK START GUIDE

This note details the requirements for veterinary surgeons and horse keepers regarding administration of medicines to horses. It also provides guidance on record keeping requirements set out in the legislation for medicinal products used to treat food-producing and non-food producing horses.

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.

Horses and other equidae are considered to be food producing species in the European Union (EU). Veterinary medicines used to treat animals, including horses, fall within the scope of Directive 2001/82, as amended, and the national legislation that transposes the EU legislation into national law. The VMR transpose Directive 2001/82/EC into UK law.

In accordance with Commission Regulation 504/2008, horses can be declared as either intended for human consumption (food producing horse) or not intended for human consumption (non-food producing horse) in the horse passport. This declaration determines what products can be administered to the animal and therefore consideration of what medicines may be used must be taken.

Horse passports
All horses and ponies are required to have a passport identifying the animal. All horses born after July 2009 must be microchipped.

Horse passports contain information relating to:
- horses appearance, which is illustrated in diagram called a 'silhouette'
- micro-chip details
- age
- breed/type
- all the medications administered (if the animal has been declared 'intended for human consumption')

Medicines for horses
All horses should be treated with veterinary medicinal products (VMPs) which have a UK marketing authorisation (MA) for use in horses as the first choice. However, if there is no suitable authorised product available, the veterinary surgeons may prescribe a medicine under the cascade for use in the animals under his care.

Under the cascade, a horse that is signed off from the food chain can be treated with any veterinary medicine authorised in the UK to treat another animal species, or another condition in the horse. If there is no suitable veterinary medicine authorised in the UK, a UK-authorised human medicine or veterinary medicine authorised in another Member State (MS) may be imported for use with permission from the Veterinary Medicines Directorate (VMD). The last option is to prescribe a medicine specially prepared for that animal by a veterinarian, a pharmacist or a person holding a manufacturing authorisation, or a medicine imported from a Third Country.

The prescribing cascade, explained above, also apply to food producing horses. However, a food producing horse can only be treated with a veterinary medicine that contains pharmacologically active substance(s) listed in Table 1 of Regulation EU 37/2010 for use

in a food producing species, and a suitable withdrawal period should be set by the responsible veterinary surgeons.

Commission Regulation 1950/2006 established, in accordance with Directive 2001/82, a list of substances essential for the treatment of equidae: this is European legislation that allows the use of certain substances in horses (declared as food or non-food producing in the passport) under the use of the cascade and with a statutory withdrawal period of six months.

If any substance which is **not** contained within Table 1 (the Allowed List) of Regulation EU 37/2010 or on the list of Essential Substances, such as phenylbutazone, is administered to an animal, that animal must be permanently excluded from the food chain and the passport declaration should be completed at Part II of Section IX by the owner or horse keeper, or by the veterinary surgeon who administers the product. If the owner/keeper does not sign Part II of Section IX, the veterinary surgeon must do so.

Record keeping requirements

According to Commission Regulation No 504/2008, all vaccines administered by a veterinary surgeon must be recorded in the Horse Passport regardless of whether or not the horse is intended for human consumption.

There is no statutory requirement to record any other medicines in the non-food horse's passport; however, veterinary surgeons have record-keeping obligations for all prescription medicines under the VMR.

Any substance on the essential substances list administered to a food-producing horse must be recorded in the passport. Recording medicines administered under the cascade in the passport is optional.

In addition to the Horse Passport Regulations, there are other record-keeping obligations within the VMR that apply to keepers of horses intended for human consumption and to veterinary surgeons, pharmacists and Suitably Qualified Persons (SQPs) supplying medicines for horses. These are set out within the body of the guidance document, but in summary, records of use for medicines of all distribution categories must be kept for all horses that have been declared as 'intended for slaughter for human consumption' in the Horse Passport, or have Part II of Section IX unsigned. It is not a legal requirement for the record to be kept in the medicines pages of the horse passport but it is acceptable for this to be done if preferred by the owner or keeper. Alternatively a separate written record must be kept.

FURTHER INFORMATION

- For more information on horse medicines please contact the VMD's Legislation team on 01932 338321 or alternatively contact VMD reception on 01932 336911 and quote "horse medicines". For horse passport inquiries please contact the Defra's Horse passport team on 0207238 6039; email: horse.passport@defra.gov.uk.

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Introduction and Summary

1. This is one of a series of Veterinary Medicines Guidance Notes (VMGNs) explaining the requirements under the Veterinary Medicines Regulations (VMR). The Regulations 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. The VMGN will be updated as necessary and the date of the most recent update is shown on the front cover.

2. The VMR 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) website, http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx provides information about the scope of the VMR and the requirements for Marketing Authorisations (MAs). This note details the requirements for veterinary surgeons and horse keepers regarding administration of medicines to horses. It also provides guidance on record keeping requirements set out in the VMR for medicinal products used to treat food-producing and non-food producing horses.

3. Record keeping requirements stemming from the EU legislation on methods for the identification of equidae are also included in this guidance note.

4. Please note that the Horse Passport legislation has been put in place separately by England and by each of the devolved administrations - Scotland, Wales and Northern Ireland have their own implementing legislation. Details are available at:

   www.scotland.gov.uk/topics/agriculture/animal-welfare

   www.wales.gov.uk/topics/environmentcountryside/ahw/horses

   www.dardni.gov.uk/index/fisheries-farming-and-food

5. Each law is individually recognised throughout the member states of the European Union (EU) and the additional three European Economic Area (EEA) countries.

Explanatory note on the legislation regulating the use of medicines

6. Horses and other equidae are considered to be food producing species in the EU. Veterinary medicines used to treat animals, including horses, fall within the scope of Directive 2001/82 as amended and the national legislation that transposes the EU legislation into national law.

7. Horses and other equidae are also subject to additional European and national legislation. Please find below the list of EU legislation applicable to the horse, and a brief explanation of its scope.

Veterinary Medicines

- Directive 2001/82 as amended on the community code relating to Veterinary Medicinal Products (VMPs): this is the European legislation that sets out all provisions on production, marketing, distribution and use of veterinary medicinal products

- VMR: transposes the Directive 2001/82 as amended into national legislation

Please note that a VMP is defined in this legislation as:
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.

Maximum Residues Limits (MRL)

- An MRL is the maximum concentration of a residue of a pharmacologically active substance which may be permitted in food of animal origin.

- The legislation that lays down the procedures for establishing MRL is Commission Regulation 470/2009; this legislation also repeals Regulation 2377/90, amends Directive 2001/82/EC and Regulation 726/2004.

- Commission Regulation 37/2010 on pharmacologically active substances and their classification regarding MRL in foodstuffs of animal origin: this is the European legislation that sets out the substances that are allowed or prohibited for use in food-producing animals:
  http://ec.europa.eu/health/files/eudralex/vol-5/reg_2010_37/reg_2010_37_en.pdf

Essential Substances for Horses

- Commission Regulation 1950/2006 establishes in accordance with Directive 2001/82 a list of substances essential for the treatment of equidae: this is the European legislation that allows the use of certain substances in horses (declared as food or non-food producing in the passport) under the use of the cascade and with a statutory withdrawal period of six months. This regulation is directly applicable into national legislation and is currently under review http://ec.europa.eu/health/files/eudralex/vol-5/reg_2006_1950/reg_2006_1950_en.pdf

Horse Passports

- Commission Regulation 504/2008 as regards methods for the identification of equidae. This is the current EU regulation on horse passports:
  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:149:0003:0032:EN:PDF

- Horse Passport Regulations 2009, SI 1611: this is the legislation that transposes the Commission Regulation 504/2008 into English law
  (http://www.legislation.gov.uk/2009/1611).

- The comparative legislation in Scotland is the Horse Identification (Scotland) Regulations SI 231: (http://www.opsi.gov.uk/legislation/scotland/ssi2009/ssi_20090231_en_1),

- In Wales it is the Equine Identification (Wales) Regulations 2009 No 2470 (W199): (http://www.opsi.gov.uk/legislation/wales/wsi2009/wsi_20092470_en_1)

- In Northern Ireland it is The Horse Passport Regulations (Northern Ireland) 2010 (http://www.opsi.gov.uk/sr/sr2010/pdf/nisr_20100040_en.pdf)

How to get further information

8. Further information about veterinary medicines 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).

9. Further information about Horse Passports is available from the Horse Passports team within Defra – tel: 020 7238 6039, email: horse.passports@defra.gsi.gov.uk, http://www.defra.gov.uk/wildlife-pets/pets/horses/

10. Information on authorised veterinary medicines can be accessed on the VMD Website via the Product Information Database. This database lists all the veterinary medicines that are authorised for use in the UK and for each product a Summary of Product Characteristics (SPC) is available to download. The SPC sets out a full description of the product, including its indications, dosage and contraindications.

    The Product Information Database can be used to search for all authorised medicines for horses and can be accessed from the Home Page of www.vmd.defra.gov.uk

PART 1

Guidance on Selection of Medicines for Horses

11. If you intend to administer, prescribe or dispense any medicinal substance for use in a horse the following procedure should be followed:

- ask to be shown the passport for the horse if you do not have prior knowledge of its status (if you have previously seen the passport and are aware of the horse's current status, it is not necessary to see the passport before every treatment with a medicine);
- satisfy yourself that the passport supplied relates to the horse in question;
- note whether the horse is declared as INTENDED for human consumption (Section B of the old Passport/Part III of Section IX) or there is no declaration or the horse is declared as NOT INTENDED for human consumption (Section A of the old Passport/ Part II of Section IX). The default position is that if Section IX contains no signature, the horse is INTENDED for human consumption;
- if the document does not contain Section IX, it is not a valid horse passport.

12. If you do not have prior knowledge of the horses status and a passport is not available, or if you are not satisfied that the passport relates to the horse in question follow the procedure at paragraph 35.

If the horse is declared 'not intended for human consumption'

13. In this case the horse should be treated with VMPs which have a UK MA for use in horses as the first choice. The VMD publishes a Product Information Database on its website, which holds information on every veterinary medicinal product authorised for use in the UK: http://www.vmd. defra.gov.uk/ProductInformationDatabase.

14. If there is no suitable authorised product available, the cascade may be used to prescribe an alternative medicinal product. The cascade must be used for clinical reasons.

15. Under the cascade, the non-food horse can be treated with any veterinary medicine authorised in the UK to treat another animal species, or another condition in the horse. If this option is not available to that particular animal, then a UK authorised human medicine or a veterinary medicine authorised in another Member State (MS) may be imported for use with permission from the VMD. Permission is granted via the issue of an Import Certificate which in most cases can be applied for online at www.vmd.defra.gov.uk/sis/default.aspx at no cost (a fee applies to postal applications). Products containing substances in the list of essential substances can also be used, as well as extemporaneous preparations. In exceptional circumstances, medicines may be imported from Third countries.

16. For further information please refer to VMGN 13 Guidance on the Use of the Cascade, which is published on the VMD's website.
http://www.vmd.defra.gov.uk/public/vmr_vmgn.aspx

17. According to Commission Regulation No 504/2008 all vaccines administered by a veterinary surgeon must be recorded in the Horse Passport regardless of whether or not the horse is intended for human consumption.

18. There is no statutory requirement to record any other medicines in the non-food horse's passport; however, you should note that veterinary surgeons have record-keeping obligations for all prescription medicines under the VMR. Further Guidance on record keeping is available in Part 2 of this VMGN and in 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

If the horse is declared 'intended for human consumption' or no declaration was made

At a glance

19. Where the horse is intended for human consumption the procedure set out below should be followed when selecting a medicinal product.

What product types can be used?	Withdrawal Period and Information to be entered on Passport.
Products authorised for food-producing horses, in the UK or EU (via the Special Import Certificate (SIC)) containing pharmacologically active substances which are listed in *Table 1 of Regulation EU 37/2010* and have a determined withdrawal period for horses.	Meat and milk withdrawal period as stated on the product label and in the SPC must be advised and recorded but this does not need to be in the passport.
UK or EU authorised medicines which have a withdrawal period set for food producing species other than horses (These products may only be prescribed by a veterinary surgeon under the Cascade provisions).	It is the responsibility of the veterinary surgeon to set a suitable withdrawal period. This must be recorded but this does not have to be in the passport. The withdrawal period must be at least 28 days (meat) or 7 days (milk) or the withdrawal period in the SPC of the product, whichever is longer.
Veterinary medicines authorised in the UK only for use in non-food producing horses but which contain an active substance which is allowed to be administered to one or more food producing species in accordance with Table 1 of Regulation EU 37/2010. Substances listed in Table 1 of this Regulation have an MRL or are confirmed as not requiring such a limit.	It is the responsibility of the veterinary surgeon to set a suitable withdrawal period. This must be recorded but this does not have to be in the passport.

To allow harmonisation of the labels of products authorised within the EU, some medicines may state on the label "*Treated horses may never be slaughtered for human consumption*." This statement does not apply if the product has been prescribed by a veterinarian in accordance with the cascade.	The withdrawal period must be at least 28 days (meat) or 7 days (milk) or the withdrawal period in the SPC of the product, whichever is longer.
Products containing active substances in the list of essential substances. This list relates to both authorised veterinary medicines and extemporaneous prepared medicines containing these substances: These products may only be prescribed by a veterinary surgeon under the Cascade provisions	The details of the essential substances administered and the date of last administration as prescribed must be recorded in the passport. A statutory six months' withdrawal period must be set and the owner or keeper notified of this.
What product type cannot be used?	
The use of any products that contain an active substance which is **not** contained within *Table 1 (the Allowed List) of Regulation EU 37/2010 or on the list of Essential Substances*, such as phenylbutazone, will automatically mean that the horse must be permanently excluded from the food chain.	**If a product from either of these categories is administered to an animal, that animal must be permanently excluded from the food chain and the Passport declaration should be completed at Part II of Section IX by the owner or by the veterinary surgeon**
Medicines containing substances included on the "Prohibited Substances", Table 2 of Regulation 37/2010. The list of prohibited substances is currently (2011) Aristolochia spp (and preparations thereof) Chloramphenicol Chloroform Chlorpromazine Colchicine Dapsone Dimetridazole Metronidazole Nitrofurans (including Furazolidone) Ronidazole Veterinarians should check this list regularly for changes: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:015:0001:0072:EN:PDF	

20. The withdrawal period is the period of time between the last dose given to the animal and the time when the level of residues in the tissues is lower than or equal to the MRL. Until the withdrawal period has elapsed, the animal or its products must not be used for human consumption.

Detailed information

(a) Use of VMPs in Table 1 of 'Allowed Substances' for food-producing Animals

21. A food-producing horse should be treated with a veterinary medicine authorised in the UK for use in food-producing horses which will have a specific withdrawal period defined in the product literature and SPC.

22. If there is no suitable authorised product available, the cascade may be used to prescribe an alternative medicinal product. Only medicines which contain substances listed in *Table 1 (Allowed Substances) of European Council Regulation 37/2010* can be used in a food producing horse.

23. Another provision of the cascade is that, if there is no suitable veterinary medicine authorised in the UK, a UK authorised human medicine or a veterinary medicine authorised for use in food-producing animals in another Member State (MS) may be imported for use with permission from the VMD. Permission is granted via the issue of an Import Certificate, which can be applied for online at www.gov.uk/government/organisations/veterinary-medicines-directorate at no cost (a fee applies to postal applications). Only a veterinary surgeon may apply for an import certificate. A wholesale dealer may also import products authorised in other MS by means of a Wholesale Dealers Import Certificate (WDIC), and retail it to a veterinary surgeon against an import certificate.

24. Extemporaneous preparations, that is, medicines tailor-made for a particular animal by a veterinary surgeon, a pharmacist or a person who holds an appropriate manufacturing authorisation, may be used under the Cascade. In exceptional circumstances, a product may be imported from a Third Country with a VMD Import Certificate, providing that a withdrawal period can be set. These are the last options in the prescribing cascade.

25. Where medicines are being used under the cascade a withdrawal period must be set by the veterinary surgeon. The minimum withdrawal period will be the statutory cascade withdrawal period (28 days for meat, 7 days for milk), or that defined in the SPC for the authorised medicine in question, whichever is longer. If a VMP has been imported from another MS and has a withdrawal period specified for horses in the SPC then this should be observed.

26. Some veterinary medicines have been authorised in the UK that contain active substances in the *Allowed Substances list*, but are indicated for use in non-food horses only on the label. This is because the manufacturers did not intend to market these products for food-producing horses and therefore did not undertake the tests that would be required to provide residue depletion data. To allow label harmonisation with such products authorised in several MS, some products may state on the label:

'Treated horses may never be slaughtered for human consumption'.

27. This statement does not apply if the product contains a substance in Table 1 and has been prescribed by a veterinary surgeon in accordance with the cascade provisions, as explained above. In this case, a suitable withdrawal period needs to be observed, that is, at least the minimum statutory cascade withdrawal period, or the withdrawal period indicated on the product's SPC for another food producing species, whichever is longer.

(b) Use of veterinary medicinal products NOT in TABLE 1 'ALLOWED substances (Regulation 37/2010)

28. It is recognised that the range of VMPs for horses destined for human consumption could be improved. As explained above, medicines for food producing animals normally require an MRL for the active ingredient. However, because of the relatively small market for horse medicines, there have been some conditions for which there are no authorised medicines.

29. To help address this, the European Commission (EC) introduced Council Regulation 1950/2006. This established a list of medicines that were considered essential for horses, and for which there is no authorised alternative. This list does not include phenylbutazone.

30. All substances within this list can be used in horses intended for human consumption and have a set minimum **six month** withdrawal period before horses can enter the food chain. Some substances are contained in VMPs authorised in the UK for use in other species and some may only be available as human medicines. Others may only be available if produced extemporaneously by a veterinary surgeon, pharmacist or a suitably authorised manufacturing site.

31. When a product containing a substance on this list is administered to a food-producing horse the medicines record in Part IIIB of Section IX of the Horse Passport must be completed with details of the product/s administered, including the date of the last treatment as prescribed as this will in effect declare the horse as temporarily not for human consumption until the 6 month withdrawal period is completed.

32. The list of Essential Substances may change.

(c) Prohibited substances for food-producing animals

33. Products containing substances in *Table 2 (Prohibited Substances) of European Council Regulation 37/2010* must not be administered to o a food producing animal. If any of these substances are administered the horse can NEVER be slaughtered for human consumption and the declaration in the horse's passport at Part II of Section IX must be signed by the owner or veterinary surgeon as 'not intended for human consumption'. This declaration is irreversible.

34. The prohibited substances (as of 2011) are:

Aristolochia spp (and preparations thereof)
Chloramphenicol
Chloroform
Chlorpromazine
Colchicine
Dapsone
Dimetridazole
Metronidazole
Nitrofurans (including Furazolidone)
Ronidazole

If the horse is presented WITHOUT a passport

35. If the owner or keeper of a horse does not have the passport for the horse to hand at the time of treatment, and the veterinary surgeon has not previously seen it, the veterinary surgeon should presume that the horse is intended for human consumption – the veterinary surgeon is not able to ascertain that the horse is signed out of the food chain if a passport has never been presented.

36. In this situation the veterinary surgeon must only prescribe/dispense/administer medicines that are authorised for use in food-producing horses, or those that are not authorised for use in horses but contain substances in *Table 1 of Commission Regulation 37/2010* for use in other food-producing animals. Please also refer to the table in Part 1 of this guidance note for information on withdrawal periods.

IN EMERGENCY SITUATIONS

37. In an emergency, where the health or welfare of a horse/foal is at risk and treatment with a substance that is not allowed for a food producing animal is required (e.g. Etorphine), in order to proceed with treatment the veterinarian surgeons must issue a document which details the medicines given and an instruction to the owner or keeper to exclude the animal from the food chain if necessary. An example of this document can be obtained from *British Equine Veterinary Association (BEVA)* – www.beva.org.uk. The veterinarian should retain a copy of this document.

38. Some scenarios are described below:

(a) No passport has ever been issued for the animal

- The veterinary surgeon should inform the owner or keeper that a passport will need to be acquired for the animal from the relevant Passport Issuing Organisation and that the horse, if above 1 year of age, will be declared as not intended for human consumption, which will be ***irreversible*** for the remainder of its life.

(b) Passport lost for a horse

- The horse owner or keeper should apply to the Passport Issuing Organisation for a replacement or duplicate passport which will be over stamped "*Not intended for human consumption*".

(c) Passport exists but is not available

- As explained above, the veterinarian must issue a document which details the medicines given to the horse and the owner or keeper to should exclude the animal from the food chain, depending on the substances given to the horse.

Information on phenylbutazone (bute)

39. The Directive 2001/82 as amended states that only products containing pharmacologically active substances listed in *Table 1 of Regulation 37/2010* may be administered to food producing animals. Medicines containing active substances included in *Table 2 of Regulation 37/2010* - Prohibited Substances - are banned from use in food-producing animals.

40. Phenylbutazone is in an anomalous situation because neither has it been listed in Table 1 nor has it been included in the list of prohibited substances. This means that, whilst not a banned active ingredient, it cannot be used in a food producing animal.

41. This situation occurs because data on phenylbutazone were submitted to the Committee for Veterinary Medicinal Products (CVMP) for consideration in the 1990s but they were not sufficient to establish an MRL. The applicant was given the opportunity to respond to the questions raised by the CVMP but no additional data were provided. Consequently the CVMP did not recommend the establishment of an MRL for phenylbutazone.

42. The main concerns raised by the CVMP related to the possible myelotoxic effects of phenylbutazone in humans, carcinogenic, nephrotoxic and hepatoxic effects in laboratory animals, and evidence of mutagenic activity in lymphocytes in human lymphocytes (*in vitro*). No adequate data on reproductive toxicity were made available to the CVMP. This information is in the public domain (*Vet Rec 23 April 2005, page 554, letter from the EMEA – Phenylbutazone and equine research*).

43. Phenylbutazone is a useful Non-steroid Anti-inflammatory Drug (NSAID) for the management of orthopaedic conditions. Conscious of the needs of the veterinary profession and the equine industry, the VMD has authorised products containing this active ingredient; but, mindful of food safety issues and the obligations imposed by the legislation, we have restricted the use of these products to non-food horses only. Horses which have been treated with phenylbutazone **must not enter the food chain**, and their passports must be signed at part II of section IX to indicate that the animal is not intended for human consumption. **This is an irreversible decision**.

PART 2

Guidance for Veterinary Surgeons, Retailers and Horse Owners/Keepers on Record Keeping Requirements

Veterinary Medicines Record Keeping Obligations

44. In accordance with the Horse Passports legislation, there are requirements to record all vaccines which are administered by a veterinary surgeon in the horse's passport and for any Essential Substances administered to food-producing horses to be recorded in the passport. Recording medicines administered under the cascade in the passport is optional.

45. In addition to these, there are other record-keeping obligations within the VMR that apply to keepers of horses intended for human consumption and to veterinary surgeons, pharmacists and SQPs supplying medicines for horses. 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

Record Keeping obligations for Horse Owners/Keepers

a) Horses declared as NOT INTENDED for human consumption

46. Except for vaccines administered by veterinary surgeons (paragraph 44 above), there are no record-keeping obligations for keepers of horses that are not intended for human consumption and where Part II of Section IX has been signed.

b) Horses Intended for Human Consumption

47. Records of use for medicines of all legal distribution categories must be kept for all horses that have been declared as 'intended for slaughter for human consumption' in the Horse Passport, or have Part II of Section IX unsigned, in accordance with the following categories. It is not a legal requirement for the record to be kept in the medicines pages of the horse passport but it is acceptable for this to be done if preferred by the owner or keeper. Alternatively a separate written record must be kept.

48. 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.

Administration:

49. If the product is administered by the animal owner or keeper, they must record the following:

- name of the product;
- date of administration;
- quantity administered;
- the withdrawal period;

- Identification of the animals treated.

Proof of Purchase

50. 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

51. If the product is disposed of, other than by treating an animal, the following must be recorded by the animal keeper or owner:

    - the date of disposal;
    - the quantity of product involved;
    - how and where it was disposed of.

52. 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

Record keeping obligations for veterinary surgeons, pharmacists and SQPs

Administration by a veterinary surgeon

53. If the product is administered by a veterinary surgeon, he or she must either enter into the owners or keepers 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;
- the withdrawal period

Supply of prescription medicines (POM-V and POM-VPS)

54. It is the responsibility of the veterinary surgeon, pharmacist or SQP who supplies POM-V (Prescription Only Medicine – Veterinarian) and POM-VPS (Prescription Only Medicines - Veterinarian, Pharmacist, Suitably Qualified Person) medicines on a retail basis, for both food producing and non-food producing horses, 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.

Supply of medicines under the cascade

55. A veterinary surgeon who administers or prescribes a medicinal product for a horse 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;
- withdrawal period.

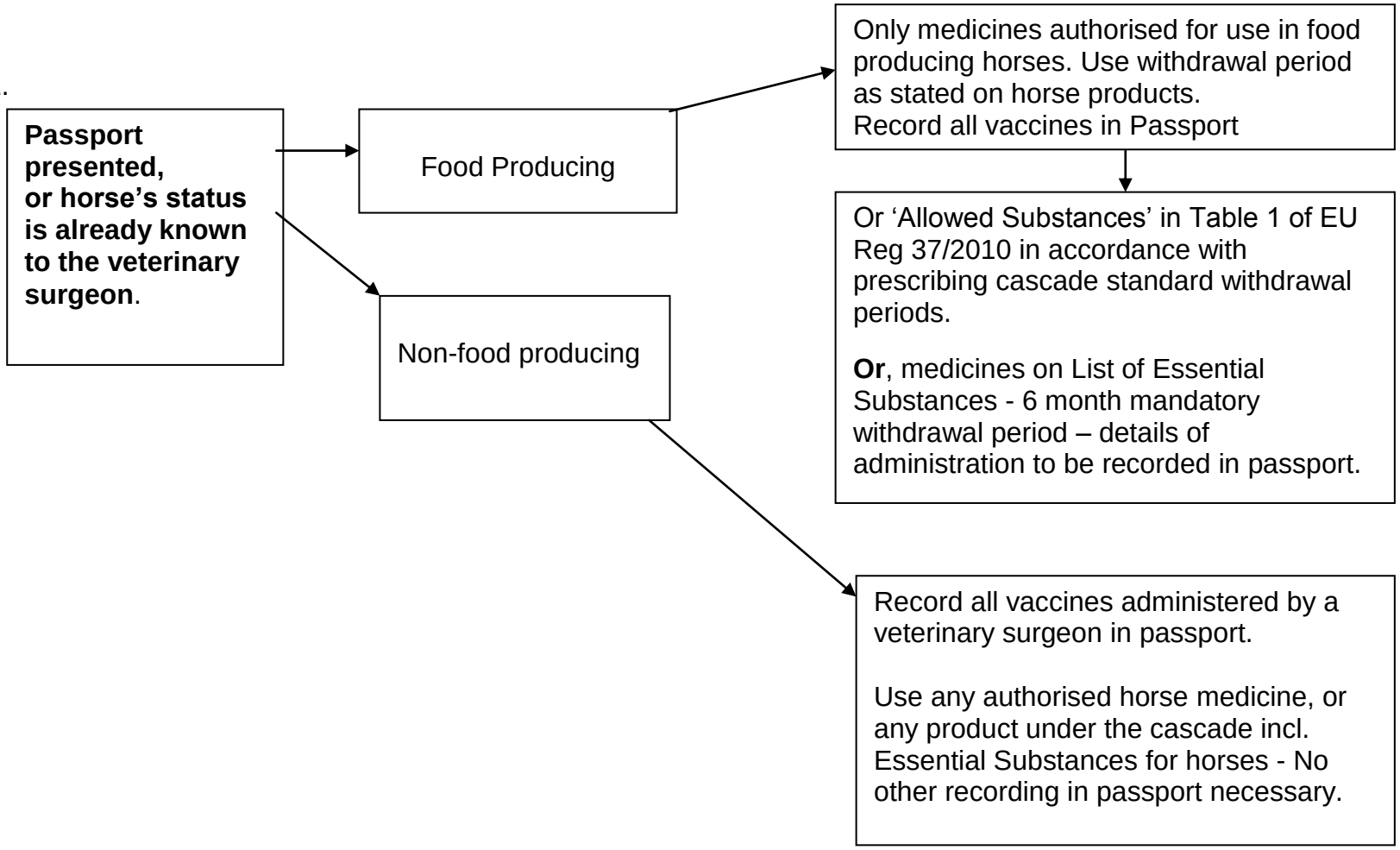
ANNEX

FLOW CHART FOR SELECTION OF MEDICINES FOR TREATMENT OF HORSES

ANNEX

FLOW CHART FOR SELECTION OF MEDICINES FOR TREATMENT OF HORSES

1.



2. **No passport presented and horse's status not known/ Passport does not match the horse/ Passport does not contain medicines papers**

Treat as a Food Producing horse (see 1 above); provide details of withdrawal periods to owner/keeper

OR **In an emergency only**
If horse needs to be treated with a medicine not authorised for use in a food producing animal proceed as follows:

No passport for horse

Vet to issue a document detailing medicines given and instruction to owner/keeper to exclude the animal from the food chain if necessary. The original copy of the document should be given to the owner or keeper and a copy retained by the vet.

Advise horse owner or keeper to apply for a Horse Passport.

Passport lost

Vet to issue a document detailing medicines given and instruction to the owner/keeper to exclude the animal from the food chain. The original copy of the document should be given to the owner or keeper and a copy retained by the vet.

Advise horse owner/ keeper to apply to the Passport Issuing Organisation for a replacement passport which will be overstamped "*Not intended for human consumption*".

Passport for horse exists but is unavailable for inspection

Vet should issue a document that details the medicines given and instruction to the keeper/owner to exclude the animal from the food chain if necessary. The original copy of the declaration should be given to the owner or keeper and a copy retained by the vet.

List of Abbreviations

AHDA	Animal Health Distributors Association
BEVA	British Equine Veterinary Association
CVMP	Committee for Veterinary Medicinal Products
Defra	Department for Environment, Food & Rural Affairs
EC	European Commission
EEA	European Economic Area
EU	European Union
MA	Marketing Authorisation
MRL	Maximum Residue Limit
MS	Member State
NSAID	Non-steroid anti-inflammatory drug
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
UK	United Kingdom
VMD	Veterinary Medicines Directorate
VMGN	Veterinary Medicines Guidance Note
VMP	Veterinary Medicinal Product
VMR	Veterinary Medicines Regulations
WDIC	Wholesale Dealers Import Certificate

ASSURING THE SAFETY, QUALITY & EFFICACY
OF VETERINARY MEDICINES

VETERINARY MEDICINES GUIDANCE NOTE

Veterinary Medicines Directorate
Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Telephone (+44) (01932) 336911 Fax: (+44) (01932) 336618
www.vmd.defra.gov.uk