

3. Horse without a Passport

- If the owner or keeper of a horse does not have the horse's passport to hand at the time of treatment, and the veterinarian has not previously seen it, the veterinarian should presume that the horse is intended for human consumption – the veterinarian is not able to ascertain that the horse is signed out of the food chain if a passport has never been presented.
- The veterinarian must only prescribe/dispense/administer medicines that are authorised for use in food-producing horses, or those that are not authorised for use in food-producing horses but contain substances in Table 1 of Regulation EU 37/2010 for use in other food-producing animals.
- **In an emergency** where the health or welfare of a horse/foal is at risk and medicines outside of the above are required to be administered, in order to proceed with treatment the veterinarian must issue a document which details the medicines given and an instruction to the owner to exclude the animal from the food chain if necessary. An example document is available at www.beva.org.uk/vets. For further guidance please contact the Horse Passport Team at Defra: Tel: 020 7238 6039, e-mail horse.passports@defra.gsi.gov.uk.

4. Important information on Phenylbutazone (Bute)

Phenylbutazone must not be used in food-producing horses.

This is because Maximum Residues Limits (MRLs) and withdrawal periods have not been set for this substance. Data on phenylbutazone were submitted for consideration to the Committee of Veterinary Medicinal Products but were not sufficient to enable the Committee to set an MRL. Phenylbutazone has not been included in the list of Prohibited Substances either. This means that, whilst not a banned active substance, it cannot be used in a food-producing animal. Phenylbutazone is not currently on the list of essential substances for horses (in 2011).

Phenylbutazone is a useful anti-inflammatory for the management of musculoskeletal conditions. Conscious of the needs of the veterinary profession and the equine industry, the VMD has authorised products containing this active substance; but, mindful of food safety issues and the obligations imposed by the legislation, we have restricted the use of these products to non food-producing horses only. Horses which have been treated with phenylbutazone must not enter the food chain due to consumer safety concerns, and their passports should be signed to indicate that the animal is "Not intended for human consumption". This is an **irreversible** decision.

5. Record-Keeping Requirements

a) All Persons

In accordance with the Horse Passports Regulations 2009, there are requirements to record **vaccines** administered by veterinarians in all horse passports and for **any Essential Substances** administered to food-producing horses to be recorded in the passport. Recording in the passport of medicines administered under the cascade is recommended.

In accordance with the Veterinary Medicines Regulations, the following record keeping requirements apply:

b) Veterinarian's, SQP's and Pharmacist's records

i) Prescription medicines (POM-V and POM-VPS)

POM-V and POM-VPS medicines retailed for both food-producing and non food-producing horses must have the following records retained by the supplier for at least five years for each incoming or outgoing transaction (including administration by a veterinarian):

- 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.

ii) Products supplied under the cascade (Veterinarians only)

A veterinarian 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
- result of the veterinarian'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.

c) Horse Owner's / Keeper's records

i) Horses declared as "Not intended for Human Consumption"

There are no record-keeping obligations for keepers of horses that are not intended for human consumption.

ii) Horses "Intended for Human Consumption"

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 four groups below. 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.

Administration by a Veterinarian

If the product is administered by a veterinarian, he or she must either enter into the keeper's records, or give written notice to the owner or keeper:

- name of the veterinarian
- name of the product and the batch number
- date of administration
- amount administered
- identification of the animals treated
- withdrawal period.

Administration by Animal Owner / Keeper

At the time of administration by the animal owner/keeper the following must be recorded:

- name of the product
- date of administration
- quantity administered
- identification of the animals treated
- withdrawal period.

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

The owner or keeper of food-producing animals is responsible for keeping proof of purchase of all VMPs acquired for those animals including:

- name of the product
- batch number
- date of each purchase of a veterinary medicinal product
- quantity purchased
- name and address of the supplier.

Disposal – record to be kept by animal owner or keeper

If the product is disposed of, other than by treating an animal, the following must be recorded:

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

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.

There are publications available in which to record medicines administration. 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.

For more details on horse medicines please review VMGN16 on www.vmd.defra.gov.uk/public/vmr_vmgn.aspx.

For horse passport enquiries please contact:

Defra:

Tel: 020 7238 6039

e-mail horse.passports@defra.gsi.gov.uk

www.defra.gov.uk/foodfarm/farmanimal/movements/horses/index.htm

You can also phone the VMD on 01932 336911 for any additional assistance about veterinary medicines, or visit our website at www.vmd.defra.gov.uk

You can also reach us by e-mail at: postmaster@vmd.defra.gsi.gov.uk

Printing of this leaflet has been funded with the help of the Horse Passport Agency

Information correct at time of writing: August 2011

VMD/Leaflet/014/A



ASSURING THE SAFETY, QUALITY & EFFICACY OF VETERINARY MEDICINES



Prescribing Veterinary Medicines for Horses



The Veterinary Medicines Directorate is an Executive Agency of the Department for Environment, Food & Rural Affairs

Horses and other equidae are considered by law to be food-producing species in the European Union and therefore the medicines selected to treat them must take this into account. For full details please refer to VMGN16 (www.vmd.defra.gov.uk/public/vmr_vmgn.aspx). You should always check the labelling of the veterinary medicinal product (VMP) that you wish to use, to determine if it is authorised for use in food-producing horses or not. If it is authorised for use in food-producing horses, a withdrawal period for horses will be clearly displayed.

Always check the Passport

If you intend to administer, prescribe or dispense any medicinal substance for use in a horse you must:

- ask to be shown the passport for the horse (if you don't have prior knowledge of its status)
- satisfy yourself that the passport supplied relates to the horse in question and
- note whether the horse is INTENDED for human consumption or NOT INTENDED for human consumption or if there is no declaration at all.

If a passport is not available or if you are not satisfied that the passport relates to the horse in question, follow the procedure in section 3.

1. Horse declared "Not Intended for Human Consumption"

No specific prescribing restrictions apply to these horses and the prescribing cascade can be used as for any non food-producing animal. The only passport requirement is to record all vaccines administered by a veterinarian in the passport, regardless of whether or not the horse is food-producing:

- The horse should be treated with VMPs which have a UK marketing authorisation for use in horses as the first choice.
- If there is no suitable authorised product available, the cascade may be used as appropriate to prescribe an alternative medicinal product.
- Under the cascade the non food-producing horse can be treated with any VMP authorised in the UK to treat another animal species, or another condition in the horse.
- If there is no suitable VMP authorised in the UK, a VMP authorised in another Member State (MS) may be imported for use with permission from the VMD, or a UK authorised human medicine may be used.
- If there are no suitable UK or EU products available through the cascade, then a product may be specially prepared by a veterinarian, pharmacist or person holding a manufacturing authorisation to prepare that type of product.
- All retailers of VMPs have record-keeping obligations for all prescription medicines that they receive and supply.

2. Horse declared "Intended for Human Consumption" OR no declaration made

When making prescribing decisions in a food-producing horse the first choice should always be a VMP authorised for use in food-producing horses.

The prescribing cascade may also be applied to these animals, but VMPs may only be used if they are authorised for use in another food-producing species and a suitable withdrawal period applied. In addition products may be selected from the "Essential Substances" list (see table), which details additional active substances, available for use in food-producing horses with a mandatory six month withdrawal period to be applied.



WHAT PRODUCT TYPES CAN BE USED?	WITHDRAWAL PERIOD & INFO TO BE ENTERED ON PASSPORT
<p>A) Products authorised for food-producing horses, in the UK or EU (via Special Import Certificate) containing active substances which have a withdrawal period set for horses.</p>	<p>Meat and milk withdrawal period as stated on the product label and in its Summary of Product Characteristics (SPC) must be advised and recorded but this does not need to be in the passport (see section 5).</p>
<p>B) UK or EU authorised products with active substances which have a withdrawal period set for food-producing species other than horses. (These may only be prescribed by a veterinarian under the cascade provisions.)</p>	<p>It is the responsibility of the veterinarian to set a suitable withdrawal period. This must be recorded but this does not have to be in the passport (see section 5).</p> <p>The withdrawal period must be at least 28 days (meat) or 7 days (milk) or the withdrawal period stated in the SPC of the product, whichever is longer.</p>
<p>C) VMPs 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 a Maximum Residue Limit (MRL) or are confirmed as not requiring such a limit (see link below): http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:015:FULL:EN:PDF</p> <p>[To allow harmonisation of the labels of these products authorised within the EU, some products may state on the label: <i>'Treated horses may never be slaughtered for human consumption'</i>. This statement does not apply if the product has been prescribed by a veterinarian in accordance with the cascade].</p>	<p>A suitable withdrawal period needs to be observed.</p> <p>It is the responsibility of the veterinarian to set a suitable withdrawal period. This withdrawal period and all treatment details must be recorded but this does not have to be in the passport (see section 5).</p> <p>The withdrawal period must be at least 28 days (meat) or 7 days (milk) or the withdrawal period stated in the SPC of the product, whichever is longer.</p>
<p>D) Products containing active substances in the list of Essential Substances. This list relates to both authorised VMPs and extemporaneously prepared products containing these substances: www.vmd.defra.gov.uk/vet/horses.aspx (These may only be prescribed by a veterinarian under the cascade provisions.)</p>	<p>The details of the essential substance/s administered and the date of last administration must be recorded in the passport. A statutory six month withdrawal period must be set and owner or keeper notified of this.</p>

WHAT PRODUCT TYPES CANNOT BE USED?	INFO TO BE ENTERED ON PASSPORT
<p>A) Use of any product that contains 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.</p> <p>B) Medicines containing substances included on the "Prohibited Substances" list.</p> <p>If any of these substances are administered the horse can NEVER be slaughtered for human consumption and the declaration in the horse's passport must be signed at section IX by the veterinarian or the owner as 'not intended for human consumption'. This is irreversible.</p> <p>The list of prohibited substances is currently (2011):</p> <p>Aristolochia (and preparations thereof)</p> <p>Chloramphenicol</p> <p>Chloroform</p> <p>Chlorpromazine</p> <p>Colchicine</p> <p>Dapsone</p> <p>Dimetridazole</p> <p>Metronidazole</p> <p>Nitrofurans (including Furazolidone)</p> <p>Ronidazole</p> <p>Veterinarians should check this list regularly for changes.</p> <p>http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:015:0001:0072:EN:PDF</p>	<p>If a product from either of these categories is administered to a food-producing horse, that animal must be permanently excluded from the food chain and the passport declaration should be completed at section IX by the veterinarian or the owner.</p>

Information on all UK authorised veterinary medicines can be accessed on the VMD Website via the Product Information Database. The Product Information Database can be found on the Home Page of www.vmd.defra.gov.uk.