



Veterinary Medicines & the Safety of Food from Animals

Summary

This document describes how we safeguard our food derived from animals that have been treated with a veterinary medicine to protect their health. Important topics such as Maximum Residue Limits (MRLs) and withdrawal periods are introduced in the context of how veterinary medicines are used and how residue controls and monitoring ensure the safety of food from treated animals.

Introduction

To safeguard the health and welfare of our farmed animals, veterinary medicines are used as part of a herd or flock health plan. Authorised veterinary medicines used in farmed animals are subject to strict regulatory controls. An important consideration is observing a legally defined period of time after the last administration of medicine has been given, before allowing the animal or its produce to enter the food chain (the withdrawal period). Additionally, the independent regulator – the Veterinary Medicines Directorate (VMD) in the UK, oversees a national surveillance programme to monitor and report on residues of veterinary medicines in food from animals. Taken together, these practices provide an assurance that food from animals is safe with regards residues of veterinary medicines.

Maximum Residue Limits (MRLs) and Withdrawal Periods

Residues of pharmacologically active substances are described as active substances, excipients or degradation products and their metabolites, which remain in foodstuffs obtained from animals that have been treated with a veterinary medicinal product (1).

The withdrawal period is a specific set period of time, after the last dose of the veterinary medicine has been administered, that must elapse before an animal or foodstuffs from an animal can enter the food chain. To determine the withdrawal period, regulatory authorities must employ a scientific process that

includes establishing the Maximum Residue Limit (**MRL**) for that medicine (2, 3).

The MRL is the maximum concentration of residue accepted by the European Union (EU) in a food product (e.g. meat, milk, eggs) obtained from an animal that has received a veterinary medicine (2).

In the process of establishing an MRL, firstly a No Observed (Adverse) Effect Level (**NO(A)EL**) is identified through scientific studies with the active substance. The NO(A)EL is the highest dose that does not cause adverse effects. This figure is then divided by an 'uncertainty' or 'safety factor' e.g. by 100-1000 to determine the Acceptable Daily Intake (**ADI**). The ADI is the amount of the residue that is considered safe for an individual to eat every day for their lifetime taking into account a number of safety factors. The MRLs are such that consumers can ingest generous amounts of animal foodstuffs every day without exceeding the ADI. A number of factors are taken into consideration here including the amounts of each food eaten per day and how the substance is metabolised and distributed in the various tissues. A MRL is then set for each edible tissue and product to ensure the ADI is not exceeded.

The independent European Regulator for veterinary medicines (the European Medicines Agency or EMA) and its Committee for Veterinary Medicinal Products (CVMP) is responsible for assessing the safety of residues from veterinary medicines available in the EU (2). The assessment of the safety of the pharmacologically active substances and their residues occurs before a veterinary medicine intended for food producing animals is authorised for use in the EU (2).

Following assessment of pharmacological and toxicological studies by the regulatory authorities, substances that may be used are listed in Table 1 (allowed substances) of the annex to Commission Regulation (EU) No 37/2010 before the product can be authorised (4). Table 1 contains information on substance MRLs for different active ingredients for

various target tissues and animal species, whilst Table 2 lists pharmacologically active substances that are prohibited and are considered a hazard at any level and must not be used under any circumstances in veterinary medicines for food-producing animals (4).

When an MRL has been determined for a veterinary medicine, the withdrawal period is then calculated by taking into account the rate of residue depletion, to below the MRL, in all edible tissues and products (3).

Withdrawal periods for veterinary medicines, which are specific for each farm species and foodstuff, are set out in the NOAH Compendium of Datasheets (5). The withdrawal period can also be found on the product leaflet and in the Summary of Product Characteristics (SPC) document on the VMD Product Information Database (6).

The use of animal medicines is strictly controlled by European law, and requires observance of the withdrawal period, which must have elapsed before an animal or its products can be used for human consumption. The withdrawal periods have been calculated using rigorous scientific processes so that veterinary medicines can be authorised and administered to food producing animals, whilst at the same time consumer safety is protected.

Residue Controls and Monitoring

Post-authorisation, when medicines are placed on the market and used in animals, their use on farms is also highly regulated with controls on use and statutory residue monitoring in place (7, 8).

In the UK, the VMD operates a national surveillance scheme for residues (also called the National Residues Control Plan) that analyses samples from food producing animals and their products for residues of veterinary medicines and prohibited substances (8). This statutory surveillance programme fulfils the UK's obligations under EU law, Council Directive 96/23/EC (9). The samples taken include red meat, poultry meat, farmed salmon and trout, eggs, wild and farmed game, honey and milk (8). If any unacceptable residues are found in samples, an investigation is carried out to identify the cause. The Food Standards Agency (FSA) also has published industry guidance to accompany EC regulations on the testing of milk for residues (10).

The results of the statutory surveillance scheme are published annually and show that the vast majority of samples are compliant (11). This means UK farmers and animal health professionals are taking their responsibilities seriously and that consumers can be assured of the safety of food from animals when it comes to residues of veterinary medicines.

Responsible Use of Veterinary Medicines

The responsibility, for ensuring our food from animals does not contain residues above the statutory limit, is shared by all those involved in the animal medicines sector. Vets, Suitably Qualified Persons (SQPs) and professional keepers of animals, including farmers all have a role to play (3, 12). Using animal medicines responsibly is a fundamentally important step in safeguarding our food.

The Responsible Use of Medicines in Agriculture Alliance (RUMA) has published guidelines on the responsible use of all medicines in farmed animals (13). One important aspect of using medicines responsibly is using them according to their authorised use i.e. following instructions on the SPC or datasheet (6, 5) and following accurately the instructions of the prescriber. Treatments should be given appropriately (in terms of authorised route of administration, dose and duration of treatment) and withdrawal periods observed for animals and their animal products. Additionally, in the UK there are legal requirements, under the Veterinary Medicine Regulations, 2013, regarding keeping records for all veterinary medicines used in food-producing animals (7). On farm, this can be achieved by using an animal medicines record book (such as that produced by NOAH and AHDA) and keeping those records for a minimum of 5 years (7, 14).

In the UK, farmers and vets have an excellent track record of adhering to the regulations and ensuring consumer food safety is upheld (11). Monitoring by the independent regulator, fulfilling statutory obligations with transparent reporting means we can continue to expect high standards of safe food from animals, where medicines are used.

Conclusions

- Before medicines are authorised for food producing animals, considerable evaluation and scientific process must occur to assess their safety and determine MRLs and withdrawal periods.
- Once on the market, animal medicines continue to be highly regulated with national and European legislation in place that governs their use. In the UK, farm animal medicines are also closely monitored on farm with animal medicines records allowing for traceability.
- Under EU legislation, the VMD runs a national residue surveillance scheme, which analyses a variety of foodstuffs from different farmed species. The annually published results show that the vast majority of samples are compliant.

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What is NOAH? The National Office of Animal Health Ltd represents the UK animal medicine industry: its aim is to promote the benefits of safe, effective, quality medicines for the health and welfare of all animals. For further information, including more briefing documents

on animal medicines topics see www.noah.co.uk and follow @UKNOAH on Twitter.

(For more information on authorised veterinary medicines see NOAH briefing documents on Controls on Animal medicines and Pharmacovigilance).

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