Antimicrobial Resistance new elements applied from the Veterinary Medicines Regulations

Clarification for the interpretation of the new elements within the Veterinary Medicines Regulations (VMRs) relating to combating antimicrobial resistance (AMR).

Routine and prophylactic antibiotic use

The new VMRs contain the following provisions:

Paragraph 6

(1A) Subject to the professional obligations of a veterinary surgeon to ensure the health and welfare of animals under their care, a veterinary surgeon may only prescribe an antibiotic veterinary medicinal product where satisfied that the circumstances set out in sub-paragraph (1B) apply.

(1B) For the purposes of sub-paragraph (1A) the circumstances are that the product is not:

(a) used routinely

(b) used to compensate for poor hygiene, inadequate animal husbandry, or poor farm management practices; or

(c) used to promote growth or increase yield

Paragraph 7A

(1) Subject to the sub-paragraphs (2) and (3), a veterinary surgeon may not prescribe an antibiotic veterinary medicinal product for prophylactic purposes.

(2) Without prejudice to paragraph 6(1A), a veterinary surgeon may only prescribe an antibiotic veterinary medicinal product for administration to an animal for prophylactic purposes in exceptional circumstances where the risk of an infection or of an infectious disease is very high and where the consequences of not prescribing the product are likely to be severe.

(3) Subject to the sub-paragraph (2), a veterinary surgeon may only prescribe an antibiotic veterinary medicinal product for administration to a group of animals for prophylactic purposes where the circumstances set out in sub-paragraph 4 apply.

(4) For the purposes of sub-paragraph 3, the circumstances are:

(a) The rationale for prescribing the product to the group of animals is clearly recorded by the veterinary surgeon prescribing it.

(b) A management review is carried out by the veterinary surgeon at, or as soon as reasonably practicable, after administration of the product in order to identify factors and implement measures for the purpose of eliminating the need for any future such administration.

Professional obligations of a veterinary surgeon

The term ‘Subject to the professional obligations of a veterinary surgeon to ensure the health and welfare of animals under their care’ recognises that veterinary surgeons sign up to a Royal College of Veterinary Surgeons code of conduct. This means that they, above all, constantly endeavour to ensure the health and welfare of animals committed to their care. Farmers also have obligations under animal welfare legislation to protect animals from pain, suffering and disease, and this includes ensuring that hygiene, animal husbandry and farm management practices are adequate. Proactive disease prevention is vital in reducing the need to treat with antibiotics, and this is aided by government initiatives such as the annual health and welfare review and grant schemes in England, as well as devolved health and welfare programmes.

Prophylactic use

Prophylaxis use is defined as ‘the administration of a medicinal product to an animal or group of animals before clinical signs of disease in order to prevent the occurrence of disease or infection.’

For the purposes of interpretation of this definition, clinical signs of disease include visible outward signs of disease as well as sub-clinical disease detected through laboratory testing, for example, somatic cell counts in milk and/or other pathology testing.

Routine and exceptional use

Routine use refers to repeated, habitual use, such as treating every batch of animals without attempts to reduce the ongoing need to use antibiotics, and/or without a proper evidence/ risk-based assessment to determine whether antibiotic use is necessary.

Exceptional use refers to specific non-routine situations where there is an evidence/ risk based assessment showing that the risk of an infection or infectious disease is very high and the consequences are likely to be severe.

The terms routine use and exceptional use do not relate to elective procedures where there is a risk based clinical protocol to use antibiotics based on the most up to date evidence, for example orthopaedic surgery, gastrointestinal tract surgery, clean/contaminated surgery.

The risk of an infection or infections disease is very high

This means that there is a significant probability of the infection or infectious disease occurring. This requires knowledge of the diseases/ pathogens that are present on the farm/ local area and the associated risk factors for infection, such as immune status and management factors. Factors for the veterinary surgeon to consider when deciding this include:

- contagiousness
- host susceptibility, such as physiological, pathological and immune status of the animals
- mechanism of transmission, such as animal to animal, aerosol and/or vertical
- previous infections on the farm/ presence of pathogen in the environment

The consequences of not prescribing the product are likely to be severe

Factors to consider when deciding on whether the consequences of an infection of infectious disease are likely to be severe include:

- mortality and morbidity rate
- disease severity, for example, if a disease causes irreversibly progressive, long term damage
- level of harm to animal and/ or risk to public health

A group of animals for prophylactic purpose

This refers to situations where antibiotics are administered prophylactically via a group administration route, such as in-feed, in-water, in milk/ milk replacer or in liquid feed, to more than one animal at the same time.

Blanket dry cow therapy

Blanket dry cow therapy refers to situations where all dairy cattle in a group are administered antibiotics at drying off without an individual risk assessment. This constitutes routine antibiotic use, and therefore the restrictions in paragraph 6 relating to routine antibiotic use apply.

Selective dry cow therapy involves an individual risk assessment and may include consideration of, for example, somatic cell counts, mastitis history and teat-end quality. This allows for the identification of sub-clinical mastitis warranting treatment or, if the risk of an infection or infectious disease is very high and the consequences are likely to be severe, may justify prophylactic antibiotic use for the individual animal.

Blanket dry cow therapy does not constitute group prophylaxis, as intramammary is not a group administration route.

Management review

A management review should include a review of hygiene and management issues on the farm and focus specifically on underlying risk factors that could be controlled by recognised alternative measures, such as vaccination, biosecurity, hygiene, nutrition and animal husbandry, for the purpose of eliminating the need for any future prophylactic administration of antibiotics to groups of animals. We will collaborate with the different sectors to help create management review processes/templates that are adapted for each specific sector. We anticipate that this will primarily apply to farm animal sectors, but should the same circumstances arise in other sectors then the same principles apply.

Although only mandatory for group prophylaxis, management reviews should be considered whenever antibiotics are administered repeatedly for prophylactic or metaphylactic use, and recognized alternative measures to reduce the risk for future such antibiotic use should be implemented via the farm health plan.

In-feed antibiotic use

The following VMR provisions relate specifically to in-feed antibiotic use:

Paragraph 19

(2A) In the case of a prescription under this paragraph which relates to an antibiotic, the time between a prescription being issued and the course of treatment starting must be no more than 5 working days.

(2C) Subject to paragraph 7A in Schedule 3, a prescription for a medicated feedingstuff containing an antibiotic veterinary medicinal product may not be written for prophylactic purposes.;

(3) In relation to food-producing animals a medicated feedingstuffs prescription may not confer authority for more than one course of treatment.

One course of treatment

One course of treatment refers to one period of continuous exposure to the antibiotic. Course lengths are a decision made by the prescribing veterinary surgeon depending on clinical needs. However, the maximum course lengths in the Summary of Product Characteristics should be considered. All treatment courses should be for a limited period that is consistent with the risk to be addressed, and not continue beyond clinical/ bacteriological necessity.

Oral administration in drinking water and milk/ milk replacer

Unlike medicated feed, there are no stipulations on ensuring the accuracy of mixing/ distribution for oral antibiotic products added for groups of animals to drinking water and milk/ milk replacer. Administering the correct dose is essential for the safe and efficacious use of medicines and this requires homogenous incorporation of the antibiotic. It is the vet's responsibility to ensure that antibiotics are used appropriately and to therefore provide clear mixing and dosing instructions. Training should also be provided for those administering the products to animals on how to calculate and maintain the correct dose. Farmers/ professional keepers of animals should also be familiar with the dosing and/or mixing equipment they use and have the ability, knowledge and competence on how to store/ mix, prepare, administer and dispose of these antibiotics in accordance with the veterinary prescription. This includes the use, maintenance and cleaning of any equipment and/or dosing devices.

Antibiotic Use Data Collection

The following VMR provisions cover antibiotic use data collection:

Regulation 24A

Reporting of sales and usage data in relation to antibiotics

(1) Where the Secretary of State serves a notice in writing on any person mentioned in paragraph (2) requiring that person to provide any information held by that person in relation to sales and usage of antibiotics from any records made for the purposes of these Regulations the person must provide that information.

(2) The persons are:

(a) the holder of a manufacturing authorisation

(b) the holder of a marketing authorisation

(c) the holder of a wholesale dealer's authorisation

(d) a keeper of food-producing animals

(e) a feedingstuffs manufacturer

(f) a veterinary surgeon.

Requirement to provide antibiotic use data

We already ask vets and farmers to provide antibiotic use date voluntarily. The collection of antibiotic use data has many benefits for farmers, vets and government, including the ability to measure trends, encourage responsible prescribing through farm level benchmarking, and set targets for reducing inappropriate use.

Our work on a voluntary basis with different livestock sectors means that we now publish antibiotic use data representing 90% or more of the pig, meat poultry, laying hen, trout, salmon and gamebird sectors. The Medicine Hub for ruminants is also up and running with the aim of bringing together antibiotic use data for the dairy, beef and sheep sectors.

Given this progress, we do not plan to apply the above legal provisions to require antibiotic use data reporting at this time. In addition, where a voluntary approach is successful, with data collected by a trusted industry partner, we believe it results in greater industry ownership and accountability. However, regulation 24A allows the Secretary of State to require vets, keepers of food-producing animals, and/or feedingstuffs manufacturers to provide information in relation to the use of antibiotics, if, upon review, it is considered that the voluntary model for antibiotic use collection does not deliver the desired outcomes.