

Without Prejudice

For Circulation among FECAVA PRC Group and other parties on request.

Medicated feed in Companion Animals

FECAVA has asked for contributions to this reflection paper from member organisations and Directors and any interested parties.

Framework of discussion

This discussion is framed on the basis that companion animal medicated feed is understood to be a medicine and falls under all existing EU (2001/82/EC) and national legislation covering the manufacture, distribution storage and sale of Animal Remedies. This means all companion animal medicated feed must show studies indicating amongst others, therapeutic benefits, dosages, specifics of administration, bioavailability, interaction with other medications within feed or sold separately and include data sheets for the owner and prescribing veterinarian.

FECAVA is against the licensing of any medicated feed that does not comply with Regulation 2001/82/EC

This discussion is also framed by the EU Regulation (EC) No 183/2005 that covers production and hygiene of animal feedstuffs. The possible production of medicated companion animal feedstuffs must be in compliance with 183/2005 **in addition** to EU 2001/82/EC.

Further EU legislation controlling production of pet food is detailed in Appendix 1. Any Companion animal medicated feed must also comply with this legislation.

FECAVA is against the licensing of any medicated feedstuff that does not comply with Regulation EU 183/2005.

The EU Commission have been working on a background basis for new medicated feed legislation at EU level since 2009. Below is the sole reference to companion animal medicated feed in the EU commissioned report by DG SANCO, (http://ec.europa.eu/food/food/animalnutrition/labelling/medicated_feed_report_20100224.pdf)

4.6. Medicated feed for non-food producing animals

There is a clear difference between farm animals and pets regarding the use of veterinary medicines. Pets are typically not held in large numbers; therefore, the risk of infections is much lower and individual treatment is easily feasible in case of an infection. Furthermore, the weight of pets is generally much lower; therefore the required quantities of active substances are much smaller. As a consequence, despite its large size, the pet market is by and large irrelevant with regard to the use of medicated feed, although there is a widespread lack of data. Only one of the 12 national feed manufacturers associations responding to our survey sees a market potential for medicated feed for non-food producing animals, two marked "no" and most associations did not know (see Annex 10). None of the 11 manufacturers of VMPs responding sees a potential market. The European Pet Food Industry Federation (FEDIAF) was also contacted to explore the current use of medicated feed for pets and the existence of a potential market in this respect. However, FEDIAF and its member associations do not include medicated feed for pets in the scope of their work and could therefore not provide any data.

Issues for practising veterinarians in Europe

Initial comments

The references above clearly illustrate a lack of data and a lack of research underway to determine animal or societal need or market size for companion animal medicated feed. There appears to be no demand or rationale FECAVA can see to allow for production of medicated feed for companion animals, particularly within legislation that is primarily focussed on production animals.

Nevertheless, we have consulted within the profession and discussed the proposed legislation. Pertinent issues are discussed below, followed by conclusions.

1. Animal welfare - administration

Dosage Gain

Lots of ingredients eg vitamin and mineral supplements and protein levels are related to the energy (calorie) content of the food. This means the amount of medication taken in by the animal could be regulated by control of calories, ie portion control. Theoretically, this should prevent overdosing.

If the medicated feed is less than 100% of the daily required intake of food and another non-medicated feed is added, it might be possible to lower or raise the dosage if necessary by changing the daily ratio of medicated and non medicated.

Compliance may often improve if medicated feeds were available, but it will only work if there is a single pet household with good existing diet control. Owners may find medicated food easier to give than tablets but they may not be compliant in terms of dose- see below

Dosage Problems

If a drug can be made palatable enough to mix in food and increase compliance it can be made palatable enough in tablet form to crush and mix in the pets normal food. This would make accurate dosing more accurate and get round the problem of multi pet households. The only problems pet owners have is where they have to pill their pets – either because the drug must be given on an empty stomach or because it is a sugar coated pill that tastes bitter if crushed or it is enteric coated to aid absorption in the small intestine. Medicated feed does not overcome the latter two situations. Investment should concentrate on increasing palatability and formulation of current drugs.

It is likely that there will be some owners who will deliberately medicate all their pets in a multi pet household as it is simpler than preparing separate diets and feeding separately. This already happens with prescription diets such as renal diets etc.

If medicated feed is the only daily feed, real-life scenarios are likely to lead to considerable incidences of overdosing. Many dogs are not fed according to need but instead to appetite. There is a range of methods in which people feed dogs. Free access, once, twice, three times a day feeding, adding water to dry feed etc are all examples of how feeding regimes could alter MIC levels achievement and bioavailability.

The feeding guides or equations suggesting daily calorie requirements of individual dogs are just that - guides. There is a big body of literature in both dogs and humans to show that there is a very wide variation in metabolic rates amongst the population and therefore daily calorie needs - almost nobody has 'average' metabolic rate. So how will the manufacturers' decide how much food and therefore medication an individual will eat every day? If they use the feeding guides, a large proportion of the population will be under or over dosed if the owners actually feed to maintain stable body weight.

If medicated feed is the only daily feed, under dosing is a risk due to poor appetite in unwell dogs and particularly cats.

Under dosing may also occur due to the common behaviour of owners offering more than one food type in addition to a medicated feed.

Under dosing may go unrecognised if a set amount of food is left all day. Medication that is required twice a day may peak at one time if all food is eaten in the evening and none in the morning.

The inclusion in a food of 1-4 different medications eg cardiac could be problematic as bioavailability for each medication would have to be researched individually and collectively. The veterinarian would be unable to alter dosages of just one medication if more than 1 medication is included in a medicated feed.

Linking dosages to calorific content may lead to difficulties when an alteration in dosage is required. Or indeed if the pet is overweight/underweight and you wish to increase or decrease the calorific content.

2. Broad Animal Welfare Issues

In multi pet households, there is a high risk of more than one pet of the same or different species receiving the medicated feed inappropriately. This could lead to illness or death eg a cat receiving a cardiac medicated feed. Even more so if a cat eats a dog's medicated feed or vice versa.

Safe storage of medicated feed in the home is more difficult than with conventional medicines, as they are larger, heavier and typically stored at waist level or lower in an unsecured kitchen unit, not a bathroom or medical cabinet. There is an increased risk of theft by an animal or even a small child.

Clients are used to giving themselves and their children medications as an "event" separate from meal times. While this is an imposition that can have the effect of refusal of treatment for a pet, the benefits are a heightened awareness of disease, the importance of medication and increased observation of the pet for the disease at the time of medication. It is likely clients will settle into using a medicated feed easily and have a lower "awareness" of their animal's medical condition or the importance of medication. In this context, owners may not maintain the frequency of visits necessary to keep good veterinary supervision of their animal's condition. Quality of life for the animal may not be optimal as it receives less frequent alterations in dosage.

The client, after using a medicated feed, may also decide prematurely that giving medications individually would not be possible if the veterinarian decided a different method of treatment is required. This may lead to increased euthanasia rates at this time and a reduction of the quality of the client-vet relationship.

Distribution control of medications is already very difficult due to the internet. Prescriptions and medicines are being issued in one member state and used in another or even outside the EU. Counterfeit medications are also commonplace. It is likely the vet-only channel for medicated feed will not be effectively policed or medicated food recognised as a medication at all. This will lead to increased welfare risk to animals from not receiving correct medication.

3. Antimicrobial resistance (AMR)

It is well known that sub-therapeutic antimicrobials in swine, fish and cattle food increase antimicrobial resistance. The enteric flora is also altered (as it is at therapeutic levels). It is likely that both these factors would be increased in companion animals due to owner behaviour patterns in feeding their pet and availability of other foodstuffs (domestic waste, feeding by children).

Any use of Anti-Microbial's (AMs) promotes AMR and so every use must increasingly be justified on clinical, therapeutic and not prophylactic grounds. Use only as much as needed; use as little as possible; where possible, use in a targeted fashion exposing only populations of pathogenic bacteria to AMs to which they are sensitive; use at therapeutic concentrations.

The key issue here is inappropriate usage – we are trying to move away from in-feed, aerosol and in-water AM use in food-producing animals. Currently two thirds of veterinary AMs are supplied this way in some member states eg Ireland (in tonnage terms). This is indiscriminate and disseminates AM into the environment – remember the common biosphere we share. Moving to permit AM medicated feed for new categories of animal is a retrograde step in the fight against AMR; unlike residues, the food chain is not a critical determinant of the spread of resistance genes between animal and human populations of bacteria. It is the relationship the animals and humans have (direct or via the environment we share) that is key. The animal-human bond is different and more intimate when we are talking of animals kept as companion animal species, in particular when the humans are immune-compromised elderly or very young.

4. Insurance

Practices will also have a duty of care as point of sale in quality of the medicated feed provided. In the event of the patient or another pet or child eating the food and receiving an inappropriate dose this could result in medical treatments and related costs. Hence there may be new liabilities for which veterinarians would need to hold additional insurance.

Pet insurance policies are likely to increase costs to owners if they decide to cover medicated feed.

5. Environmental Concerns

Relevant extract from DG SANCO paper.

The different ways of administering oral veterinary medicines can have an influence of the mentioned factors:

- *Accidents with highly-concentrated VMPs can occur in feed mills during the production of medicated feed. At farm-level, they can only occur only through other ways of administration*
- *Improper storage, improper disposal of leftovers or packaging material can occur with medicated feed and with highly-concentrated VMPs;*
- *Unintended losses can occur with all ways of administration through leakage. Water medication can result in losses through water that is not consumed by animals or if animals play with water.*
- *Residues in the excrements of animals, especially in case of overdosing, may occur with all ways of administration;*

Again, if safety and handling instructions are properly observed, the differences between medicated feed and alternative ways of administering oral VMPs are expected to be insignificant with regard to environmental consequences. However, in absence of scientific research on the issue, a final conclusion cannot be made.

Clearly there is a risk of non targeted animal species, such as wildlife, being unintentionally medicated, through poor biosecurity. Many owners feed their animals outside allowing theft by

wildlife. An example might be the likelihood of urban foxes or birds calling around for regular intake of antibiotic/insulin laced dog food. It makes more sense to devise medications that are more palatable, as is the current trend in veterinary pharmaceuticals.

Further to this, waste companion animal feed will need to be disposed of as a medicine. This will be a major concern for increased cost, route to safe disposal for pet owner and revision/new medicine disposal legislation will be required.

6. Companion farm animals

There are a significant number of backyard pigs and poultry flocks in the registered non-commercial category. These are a group that who do their own "diagnoses" on line and follow this up with an on-line order to a website, many of which are outside their own jurisdiction. Many of the treatments sent are un-licensed for poultry. Practitioners see a wide range of products from anti-coccidials to fluoroquinolones being used in feedstuffs in a hap-hazard fashion in non-commercial poultry flocks and pig herds. Administration of such medications is often poor, without regard to mgs per kg delivered in the daily water allowance to pigs or poultry of a given weight or age.

5. Financial implications

Financial gain

Potential vet-only channel for sales of prescription food with medication.

There may be increased quality in the vet-client relationship if client moves food purchases to clinic from supermarket allowing further sales and closer veterinary supervision.

Financial Problems

Food sales may increase, but only if vets retain right to sell prescription medicines. Not currently the case in Nordic countries, debated at EU Parliament level (June 2013) already and voted to be removed (although currently non-binding).

Distribution is unlikely to be effectively policed between member states. Illegal food sales or sales of counterfeit medicated food will not benefit practices financially and will affect the perception of the profession negatively. (See animal welfare section).

If medication included in food, veterinarians will not be selling the medications separately so that is potential loss to practices.

There is a financial loss of income for vets in reduced clinic visits from sales of large 15-20kg bag sizes. (see also animal welfare section for further rationale on reduced clinic visits).

Retail margins on pet food are largely controlled by pet food companies, as opposed currently to medications, where local economics in veterinary practices exert a much bigger influence on margins. Veterinary clinics would lose this margin control if companion animal medicated feeds were available.

Overall conclusions

1. This legislation is not a suitable vehicle or time-appropriate for the release of companion animal medicated feed. Companion animals are not *irrelevant* as stated in the 2009 research paper but a different subsection that cannot be adequately legislated for at the moment as there is a clear difference between farm animals and companion animals regarding the use of veterinary medicines. Further research is needed concerning the benefits and risks of medicated feed for pets. Separate legislation is necessary for companion animals.
2. AMR efforts would be undermined by the release of medicated companion animal feed onto the market compromising both animal and public health. AMs should **never** be included in medicated companion animal feed.
3. A single European market for veterinary medicines and medicated feed is essential before appropriate legislation and release of medicated companion animal feed onto the market is permitted.
4. Environmental risks must be addressed. There has been no research in this area and the EU discussion paper from 2009 already recommends this is carried out **in advance** of product being brought to market.
5. Animal welfare issues must be addressed. The many difficulties identified in Section 1. (Dosage) have to be researched and addressed before any companion animal medicated feeds are produced. This research needs to be independent, involve veterinarians as the guardians of animal welfare and not funded by vested interests.
6. Companion animal medicated feed is understood to be a medicine and falls under all existing medicines legislation i.e. EU (2001/82/EC). Companion animal medicated feed is therefore only prescribed by a veterinary surgeon.
7. Companion animal medicated feedstuffs is in compliance with EU Regulation 852/2004 (consolidated 2009) that covers production and hygiene of animal feedstuffs in addition to EU 2001/82/EC.
8. It is FECAVA's view it is not in the commercial interests of the profession to support licensing companion animal medicated feed.

Appendix 1.

All pet food manufacturers must also comply with EU Regulation (EC) No 767/2009 on the placing on the market and use of feed. This legislation covers matters such as safety and marketing requirements - special regard should be given to the species and type of pet you are manufacturing food for, stringent labelling, presentation and packaging requirements, including analytical declarations
manufacturer responsibilities
substantiation of any claims, including nutritional claims
prohibition on the misleading of purchasers
prohibition on making medicinal claims

This Regulation also transposes EU provisions on undesirable substances and particular nutritional purposes - for example: the maximum levels of various contaminants allowable in pet food (for example, arsenic, lead, dioxins and certain pesticides) i.e. certain substances that must not be used in feed.

Regulation (EC) No 1831/2003 on additives for use in animal nutrition contains provisions for the control of additives in pet food. These controls relate to the additives (including vitamins, colourants, flavourings, and binders) authorised for use in animal feed and covers matters such as:

- categorisation of feed additives
- authorisation of feed additives
- labelling and packaging of feed additives
- provisions relating to an EU register of additives

EU Regulation (EC) No 1069/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption relates to animal by products - for example, material of animal origin comprising those parts of animals that are either deemed surplus to human consumption or are not normally consumed by people, and derived from animals inspected and passed as fit for human consumption prior to slaughter. It may also include products of animal origin - for example, eggs, milk, butter, honey, etc.

Animal materials or animal products of this nature, which are not intended for human consumption, are classified as 'animal by-products' under this Regulation (usually category 3 ABP). Such material must be free of any transmissible disease, which therefore excludes material from dying, diseased or disabled animals. Approval by the Competent Authority is required for pet food manufacturers using category 3 ABP. This includes premises manufacturing pet food in domestic houses whether using meat fit for human consumption or category 3 AB