IGFA Briefing on the Manufacture of Medicated Feed

January 17 2022

New Regulation and Definitions

On 28 January 2022 EU Regulation 2019/4 comes into effect for the manufacture, placing on the market and use of medicated feed. It replaces Directive 90/167/EEC. The Irish Regulation SI No. 176/1994 will also be replaced by an updated version which will be published in the next few weeks.

Key definitions *(article 3.2 (EU) 2019/4 & article 4 (EU) 2019/6) (new veterinary medicinal products regulation)*

'medicated feed' means a feed, which is ready to be directly fed to animals without further processing, consisting of a homogenous mixture of one or more veterinary medicinal products or intermediate products with feed materials or compound feed

'intermediate product' means a feed, which is not ready to be directly fed to animals without further processing, consisting of a homogenous mixture of one or more veterinary medicinal products with feed materials or compound feed, exclusively intended to be used for the manufacture of medicated feed

'non-target feed' means feed, whether medicated or not, which is not intended to contain a specific active substance

'cross-contamination' means contamination of a non-target feed with an active substance originating from the previous use of the facilities or equipment

'veterinary prescription for medicated feed' means a document issued by a vet for a medicated feed

'antimicrobial' means any substance with a direct action on micro-organisms used for treatment or prevention of infections or infectious diseases, including antibiotics, antivirals, antifungals and anti-protozoals

'antibiotic' means any substance with a direct action on bacteria that is used for treatment or prevention of infections or infectious diseases

'metaphylaxis' means the administration of a medicinal product to a group of animals after a diagnosis of clinical disease in part of the group has been established, with the aim of treating the clinically sick animals and controlling the spread of the disease to animals in close contact and at risk and which may already be subclinically infected

'prophylaxis' means the administration of a medicinal product to an animal or group of animals before clinical signs of a disease, in order to prevent the occurrence of disease or infection;

Key changes under the new Regulation

Prescriptions

1. A prescription for antimicrobials must be filled within 5 days of being issued by the veterinary practitioner.
2. A prescription for any non-antimicrobial medicine must be filled within 3 weeks of being issued by the veterinary practitioner.
3. The length of treatment shall comply with the summary of product characteristics for the veterinary medicinal product but shall not exceed 1 month, or 2 weeks for antibiotics.
4. Each prescription shall only be used for treatment of animals on one occasion.
5. Prescriptions shall be recognised throughout the EU.

The National Veterinary Prescription System (NVPS), a secure electronic prescription system developed by DAFM will facilitate the prescribing of Medicated Feed. Mandatory requirement to use the NVPS has been deferred until 1st June 2022. However, vets may start to use it sooner so it is advised you register on the system as soon as you receive instructions from DAFM.

Advance manufacturing
Medicated feed can be manufactured in anticipation of receiving a prescription but it cannot be supplied to the end user without receipt of a valid prescription.

Labelling medicated feed and intermediate products
The labelling of medicated feed and intermediate products shall include the following particulars, in a simple, clear and easily understandable manner for the end user:

1. the expression 'Medicated feed' or 'Intermediate product for the manufacturing of medicated feed' must be noted.
2. the approval number of the feed business operator responsible for the labelling. In cases where the manufacturer is not the feed business operator responsible for the labelling, the following shall be provided: (a) the name or business name and address of the manufacturer; or (b) the approval number of the manufacturer;
3. the active substances with name, added amount (mg/kg), and the veterinary medicinal products with its marketing authorisation number and the marketing authorisation holder, preceded by the heading 'medication'.
4. any contra-indications of the veterinary medicinal products and adverse events in so far as those particulars are necessary for the use;
5. in the case of a medicated feed or of intermediate product intended for food-producing animals, the withdrawal period or the indication 'no withdrawal period';
6. in the case of medicated feed for non-food-producing animals, except fur animals, a warning that the medicated feed is only for the treatment of animals and a warning that it must be kept out of the sight and reach of children;
7. a free telephone number or other appropriate means of communication in order to allow the animal keeper to obtain, in addition to the mandatory particulars, the package leaflet of each veterinary medicinal product;
8. the instructions for use in line with the veterinary prescription for medicated feed or the summary of the product characteristics;
9. the minimum storage life, which shall take into account the expiry dates of the veterinary medicinal products and shall be expressed as 'use before…', followed by the date, and special storage precautions, if appropriate;
10. information that inappropriate disposal of medicated feed poses serious threats to the environment and may, where relevant, contribute to antimicrobial resistance.

Homogeneity
Feed business operators manufacturing medicated feed or intermediate products shall ensure that the veterinary medicinal product is homogeneously dispersed in the medicated feed and in the intermediate product. Standards to ensure that medicine is mixed evenly throughout the feed will be established.

Cross-contamination
Maximum levels of cross contamination for active substances in non-target feed will be set. These levels will be established based on a scientific risk assessment carried out by the European Food Safety Authority in conjunction with the European Medicines Agency. Until the completion of this work, and the establishment of these levels, national maximum levels of cross-contamination shall apply. DAFM will run a trial in line with this, whereby action will be taken on the basis of a detection level of 1% or greater of the active substance present in non-target feed manufactured after a medicated feed.

Personnel
A trained person responsible for the manufacture and a trained person responsible for quality control of medicated feed needs to be nominated.

Storage and transport

1. Medicated feed needs to be stored separately from any other feed.
2. Veterinary medicinal products must be stored in a separate secured room.
3. You need a designated area for the storage of expired, withdrawn or returned medicated feed intended for disposal.

Questions and Answers

IGFA has been in constant contact with DAFM to get as much clarity as possible for members. Below are answers to specific questions posed by members at a meeting in September.

- What is the situation on the use of the NVPS system in a scenario where a Northern Irish vet issues a script for medicated feed for a farm in Northern Ireland (NI) but the medicated feed is manufactured by a medicated feed mill in the Republic of Ireland? NI based vets prescribing to NI registered animals should not use the NVPS system.

- Will a script by a vet in NI for use on a farm in NI but manufactured in ROI be subject to the 5-day script validity period? It is likely that NI will adopt some elements of new regulations 2019/4 & 2019/6 ,therefore validity periods may be common to both jurisdictions. This decision rests with those authorities responsible for practices in NI.

- How will NVPS work for ROI vets prescribing for use in NI? All ROI, VCI (Veterinary Council of Ireland) registered vets can prescribe using the NVPS. However, NI animal keeper or herd details will need to be manually entered for all scripts written for non-ROI residents within the system. NVPS registered dispensing outlets may access these scripts via the NVPS.

- Should mills in NI contact DAFM to register for NVPS? Yes, all those outlets wishing to dispense should register with the Department. Registration details will be available in the near future on NVPS webpage.

- Will all vets sign up to use the NVPS? The NVPS will be available for all vets to register and use to enable regulatory submission of all veterinary prescriptions generated within the ROI.

- Are vets automatically linked into NVPS no matter where they are located? All vets with ROI clients should already be registered on our Corporate Customer System (CCS). This is the case if the vets carry out TB testing for those ROI clients. Vets that do not carry out such duties may not be on CCS and will need to register.

- Are all NI vets signed up? All NI vets not already registered on CCS and who wish to prescribe in ROI will have to register on CCS if they want to access the NVPS. A Communications strategy is being rolled out at present to alert vets outside ROI about NVPS.

- Who would dispense on the NVPS in a scenario where a keeper contacts Mill A for a specialised medicated feed and the mill outsources the manufacture to a 3rd party (Mill B). Mill B delivers the feed to Mill A who then delivers the feed to the keeper? In this scenario we would consider that Mill A, which received the initial order and ultimately delivered the feed to the keeper, to be the appropriate party to complete the dispensing portion of the prescription on the NVPS. It should be noted that any mill with the prescription ID number will be able to access the details of the prescription. It is important that Mill A has all the details required such as pack size, pack size unit etc of the premix(es) used in order to complete the prescription. The requirement of the NVPS is that the prescription is filled out satisfactorily on the NVPS system with all mandatory fields entered.

- Who would complete the dispense section on the NVPS in a scenario where a keeper contacts Mill A for a specialised medicated feed and the mill outsources the manufacture to a 3rd party (Mill B) and Mill B delivers the feed to the keeper? The requirement of the NVPS is that the prescription is filled out satisfactorily on the NVPS system with all mandatory fields entered. It is advised that all parties involved in supplying the feed in this situation have a clear line of communication and reach an understanding as to who will take responsibility for dispensing the prescription on the NVPS. It may be that there are several scenarios similar to this one and the prior nomination of, and agreement on, the party that will be responsible for filling out the dispensing section, by those involved in the supply chain, will allow the flexibility to suit each situation that arises.

- Are all registered licenced home mixers set up on CCS as dispensers? Yes, all registered licenced home mixers will have two roles on CCS - keeper and dispenser.

- Is it correct that medicated premix can be delivered to home mixers but feed cannot be incorporated until the script is valid? Home mixers have a licence to incorporate and therefore do not require a prescription to have medicated premix delivered. However Medicated premix cannot be incorporated until the script is valid and the dispensing section, including the date of mixing, must be recorded on the NVPS.