An Roinn Talmhaíochta,
Bia agus Mara
Department of Agriculture,
Food and the Marine

National Veterinary Prescription System
Med Feed Prescription Details Requirement

Food Producing Animals Only
October 2021

October 2021
www.dafm.gov.ie

Contents

1. Introduction

The new EU 2019/6 and 2019/4 Veterinary Medicinal Products and Medicated Feed Regulations come into effect from 28 January 2022.

One of the main objectives of the Regulations is to address the growing issue of antimicrobial resistance (AMR) across Member States (MS).

In attempts to put in place measures and processes to reach that objective the EU Commission are making several changes to prescribing protocols and to the details required on all veterinary prescriptions. The Commission are also seeking greater information (Article 57) Annex II (EU 2019/6) in its battle against AMR and have indicated that prescription information will be accepted as submissions from each MS on its official antimicrobial usage.

From Jan 28th 2022 Veterinary Written Directives are being replaced with Veterinary prescriptions. Annex V 2019/4 sets out the MINIMUM data requirements for each of these prescriptions from 28 January 2022.

The National Veterinary Prescription System (NVPS) is being developed as a central database repository for all veterinary prescriptions generated in the State. With the introduction of the NVPS, there will be a requirement for all prescriptions to include a specific standard set of prescription variables. These variables are outlined in this document along with information and context regarding the need for each.

As you will see there are changes to the data required from a Veterinary Written Directive to the new Prescription format, with some extra information required such as, VCI number of the veterinary practitioner, category and sub species of animal, active substances in medication and statements if products are being used or not for metaphylactic purposes along with seeking confirmation that a Culture and Susceptibility test has or has not been performed if a High Priority Critically Important Antibiotic (HPCIA) has been prescribed.

2. Current Software Provider Prescription Requirements

Whilst the NVPS itself will collect all the regulatory information from its outset there will be several amendments necessary to any current bespoke software prescription offerings to ensure the full prescription data set is captured for each generated prescription. We recognise however, that there were no digital systems producing Veterinary Written Directives but there are several changes to the variables required from the old VWDs to the new Med Feed Prescriptions.

These changes and required data fields are outlined in this document.

Importantly, it must be highlighted that as per the existing practices and in line with Regulation 4 (5) (iii) of SI No. 558/ 2017 all electronic prescriptions that are generated must be marked as "DISPENSED". Only fully dispensed electronic scripts may be printed and presented to an animal keeper/farmer. Undispensed scripts are NOT to be issued in any circumstances in electronic format.

This document along with other prescription supporting and technical documentation are currently available on the NVPS Government Webpage https://www.gov.ie/en/service/d93ee-national-veterinary-prescription-system/

3. Current Software Provider NVPS Integration Information

As mentioned previously, the NVPS will not be replacing current digital prescription software solutions. Instead, it is intended that veterinarians using an industry proprietary prescription offering can continue to do so. However, all prescriptions including new digital Med Feed ones will be automatically sent seamlessly via backend technology to the centralised NVPS database.

Non dispensed Med Feed prescriptions will be generated by the prescribing vet and details sent to a preferred and agreed Feed Mill dispenser.

For any software stakeholder, either Prescription generator or Dispenser, wanting to interact with the NVPS system through their own bespoke software a set of Application Programme Interfaces (API) have been developed for this purpose. These documents will be sent directly to all software providers. They will also be made available and accessible through Swagger. https://swagger.io/

> Swagger is a set of tools that allow developers to create, view and consume API services. Tools include Swagger editor, Swagger UI, Swagger Hub.
>
> The editor allows you to edit the API at a YAML or JSON file level (like a text editor.)
>
> The UI provides an easy-to-use interface that allows you to drill down on each service and this is the API documentation part.
>
> The Hub provides all the above on one page.

Demonstration of the Swager toolset is available from Smartbear:
https://www.youtube.com/watch?v=XL5jyPOiED8
You'll see in this video that the swagger toolset allows a development team to develop API to the Open API standard and the tool also allows developer partners to test the request response flows on the mock service.

These documents are dynamic and may be updated on a weekly basis.

A number of Technical Clinics whereby software providers can meet directly with the NVPS development team to discuss the details of the API interface and SWAGGER are being arranged by the Department. All software providers known to the Dept will be contacted.

Any queries regarding the content of either document can be forwarded to nvps@agriculture.gov.ie

It should be noted that Phase 1 release of the NVPS will not include prescriptions for Companion animals, however, the prescribing protocols laid out under Article 105 do apply to this animal group.

4. Article 16 Med Feed Reg 2019/4

Article 16

Prescription

1. The supply of medicated feed to animal keepers shall be subject to:

(a)the presentation and, in case of manufacturing by on-farm mixers, the possession of a veterinary prescription for medicated feed; and

(b) the conditions laid down in paragraphs 2 to 10.

2. A veterinary prescription for medicated feed shall be issued only after a clinical examination or any other proper assessment of the health status of the animal or group of animals by a veterinarian and only for a diagnosed disease.

3. By way of derogation from paragraph 2, a veterinary prescription for medicated feed containing immunological veterinary medicinal products may be issued also in the absence of a diagnosed disease.

4. By way of derogation from paragraph 2, if it is not possible to confirm the presence of a diagnosed disease, a veterinary prescription for medicated feed containing antiparasitics without antimicrobial effects may be issued based on the knowledge of the parasite infestation status in the animal or group of animals.

5. By way of derogation from point (h) of Article 3(2) and paragraph 2 of this Article, a Member State may allow a veterinary prescription for medicated feed to be issued by a professional person qualified to do so in accordance with applicable national law on 27 January 2019.

Such prescriptions shall exclude prescription of medicated feed containing antimicrobial veterinary medicinal products or any other veterinary medicinal products where a diagnosis by a veterinarian is necessary and shall be valid only in that Member State.

The professional person referred to in the first subparagraph shall, when issuing such a prescription, make any necessary verifications in accordance with national law.

Paragraphs 6, 7, 8 and 10 of this Article shall apply, *mutatis mutandis*, to such prescriptions.

6. The veterinary prescription for medicated feed shall contain the information set out in Annex V.

The original veterinary prescription for medicated feed shall be kept by the manufacturer or, where appropriate, the feed business operator supplying the medicated feed to the animal keeper. The veterinarian, or the professional person referred to in paragraph 5, issuing the prescription and the keeper of food-producing or fur animal shall keep a copy of the veterinary prescription for medicated feed.

The original and copies shall be kept for five years from the date of issuance.

7. With the exception of medicated feed for non-food-producing animals, other than fur animals, medicated feed shall not be used for more than one treatment under the same veterinary prescription for medicated feed.

The duration of a treatment shall comply with the summary of product characteristics of the veterinary medicinal product incorporated in the feed and, where not specified, shall not exceed one month, or two weeks in case of a medicated feed containing antibiotic veterinary medicinal products.

8. The veterinary prescription for medicated feed shall be valid from the date of its issuance for a maximum period of six months for non-food-producing animals other than fur animals and three weeks for food-producing animals and fur animals. In the case of medicated feed containing antimicrobial veterinary medicinal products, the prescription shall be valid from the date of its issuance for a maximum period of five days.

9. The veterinarian issuing the veterinary prescription for medicated feed shall verify that that medication is justified for the target animals on veterinary grounds. Furthermore that veterinarian shall ensure that the administration of the veterinary medicinal product concerned is not incompatible with another treatment or use and that there is no contra-indication or interaction where several medicinal products are used. In particular, the veterinarian shall not prescribe medicated feed with more than one veterinary medicinal product containing antimicrobials.

10. The veterinary prescription for medicated feed shall:

(a) comply with the summary of the product characteristics of the veterinary medicinal product, except for veterinary medicinal products intended to be used in accordance with Article 112, Article 113 or Article 114 of Regulation (EU) 2019/6;

(b) indicate the daily dose of the veterinary medicinal product which is to be incorporated in a quantity of medicated feed that ensures the uptake of the dosage by the target animal considering that the feed uptake of diseased animals might differ from a normal daily ration;

(c) ensure that the medicated feed containing the dosage of the veterinary medicinal product corresponds to at least 50 % of the daily feed ration on a dry matter basis and that, for ruminants, the daily dose of the veterinary medicinal product is contained in at least 50 % of the complementary feed except for mineral feed;

(d) indicate the inclusion rate of the active substances, calculated on the basis of the relevant parameters.

11. Veterinary prescriptions for medicated feed issued in accordance with paragraphs 2, 3 and 4 shall be recognised throughout the Union.

12. The Commission may, by means of implementing acts, set a model format for the information set out in Annex V. That model format shall also be made available in electronic version. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 21(2).

5. Annex V – EU Med Feed 2019/4

ANNEX V

INFORMATION TO BE INCLUDED IN THE VETERINARY PRESCRIPTION FOR MEDICATED FEED AS REFERRED TO IN ARTICLE 16(6)

VETERINARY PRESCRIPTION FOR MEDICATED FEED

1. Full name and contact details of the veterinarian including, if available, the professional number.
2. Issue date, unique number of prescription, expiry date of prescription (if the validity is shorter than that referred to in Article 16(8)) and signature or an equivalent electronic form of identification of the veterinarian.
3. Full name and contact details of the animal keeper, and identification number of the establishment, if existing.
4. Identification (including category, species and age) and number of animals or, where appropriate, the weight of the animals.
5. Diagnosed disease to be treated. In the case of immunological veterinary medicinal products or antiparasitics without antimicrobial effects, disease to be prevented.
6. Designation (name and marketing authorisation number) of the veterinary medicinal product or products, including the name of the active substance or substances.
7. If the veterinary medicinal product is prescribed under Article 107(4), Article 112, Article 113 or Article 114, of Regulation (EU) 2019/6, a statement to that effect.
8. Inclusion rate of the veterinary medicinal product or products and active substance or substances (quantity per weight unit of medicated feed).
9. Quantity of medicated feed.
10. Instructions for use for the animal keeper, including the duration of the treatment.
11. Percentage of medicated feed in the daily ration or quantity of medicated feed per animal and day.
12. For food-producing animals, withdrawal period, even if such period is zero.
13. Any warnings necessary to ensure the proper use including, where relevant, to ensure prudent use of antimicrobials.
14. For food-producing animals and fur animals, the mention ‘This prescription shall not be re-used’.
15. The following mentions to be completed by the supplier of the medicated feed or the on-farm mixer, as appropriate:
    - — name or business name and address,
    - — date of delivery or of on-farm mixing,
    - —batch number of medicated feed delivered under the veterinary prescription for medicated feed, except for on-farm mixers.
16. Signature of supplier to the animal keeper or of on-farm mixer.

6. Prescription Details

The following table outlines the fields necessary to complete a Veterinary prescription from 28 January 2022.
Some fields are species specific, and this is outlined within the table.

This is a working Document and details may change

Field	Species Specific	Mandatory on NVPS	Context
Prescription Number		Y	
Prescription Date		Y	
Expiry Date			
Herd Id	Specific to Bovine, Ovine, Porcine, Cervine, Caprine and Avian For Piscine – a fisheries id	Y	This is required to enable the Department link the prescription directly to animal owners on DAFMs Central Customer Service database Fishery Ids will be forwarded to all Fish Vets
Species to be treated	NVPS related species only include Bovine, Ovine, Porcine, Cervine, Caprine, Piscine, and Avian	Y	NVPS will not include Companion Animals in Phase 1. List for Phase I: Bovine, Ovine, Porcine, Cervine, Caprine, Piscine, and Avian
Category of Animal		Y	**AVIAN**: Chicken, Turkey, Duck, Ostrich, Geese, Guinea Fowl, Pheasant, Partridge, Pigeon, Quail, Rhea, Emu, Other Farmed Birds **Piscine:** Atlantic Salmon, Trout
Sub Species	Piscine, Avian		**CHICKEN**: Breeder, Broiler, Commercial, Layer **TURKEY**: Breeder, Commercial **DUCK:** Breeder, Commercial **OSTRICH:** Breeder, Commercial **GEESE**: Breeder, Commercial

Field	Species Specific	Mandatory on NVPS	Context
			GUINEA FOWL: Commercial **PHEASANT**: Commercial **PATRIDGE** Commercial **PIGEON**: Commercial **Quail**: Commercial: **RHEA**: Commercial **EMA**: Commercial **OTHER FARMED BIRDS:** Commercial **BOVINE**: Beef/Dairy **CAPRINE**: Chevon (Goat Meat), Commercial, Dairy **CRVINE**: Commercial, Venison **OVINE:** Hoggets, Lambs, Wethers. **PISCINE**: Atlantic Salmon commercial, Trout commercial. Other commercial. **PORCINE**: Breeders, finishers/fatteners, Piglets/weaners
Forename of Animal Keeper		Y	
Surname of animal keeper		Y	
Keeper Phone Number			Phone or email required/mandatory for one or other
Keeper Email			Phone or email required/mandatory for one or other
Keeper Address 1		Y	
Keeper Address 2		N	
Keeper Address 3		N	
Keeper Address 4		N	
Keeper Eircode		N	
Location	Avian/Porcine/Piscine	N	Avian/Porcine/Piscine
Site - House	Avian/Porcine/Piscine	N	Avian/Porcine/Piscine
Site Manager Name	Piscine only	N	Piscine only. If you are prescribing for fish these fields will be required for collection

Field	Species Specific	Mandatory on NVPS	Context
Site Manager Phone Number	Piscine only	N	Piscine only. Either email or Phone required
Site Manager Email	Piscine only	N	Piscine only
Company Name	Piscine only	N	Piscine only
Vet VCI Registration No		Y	
Vet Phone Number		Y	
Vet Email Address		Y	
Vet Practice No		Y	These will be sent to all software providers prior to go live to enable correct submission of information
Vet Practice Name		Y	
Practice Address 1		Y	
Practice Address 2		N	
Practice Address 3		N	
Practice Address 4		N	
Number of Animals			
Ailment to be treated or prevented		Y	Id - Description A - Alimentary tract and Metabolism B - Blood and Blood Forming Organs C - Cardiovascular System D - Dermatological System G - Genito Urinary System & Sex Hormones H - Systemic Hormonal Preparations (Excluding Sex Hormones) J - Anti-microbial for Septicaemia L - Antineoplastic & Immunomodulators M - Musculoskeletal System N - Nervous System P - Antiparasitic, insecticides & Repellents R - Respiratory System

Field	Species Specific	Mandatory on NVPS	Context
			S - Sensory System V - Various/Miscellaneous
Ailment other			To be used if V – Various/Misc selected if Ailment to be teared or prevented
Age			Species | Unit Other | Days Other | Months Other | Weeks Other | Years Piscine | Eggs Piscine | Larvae Piscine | Juvenile Piscine | Parr/Fingerling Piscine | Smolts Piscine | Other
Biomass of Fish	Piscine only		Piscine only
Remedy/Product ID		Y	Id of product required. This will standardise all submissions
Quantity of Feed		Y	
Quantity Unit/Form		Y	Capsules Tablets Sachets Millilitres Grams / Kilogrammes (premix) Intramammary Tubes Applicators Vials International Units Tonnes Kg

Field	Species Specific	Mandatory on NVPS	Context
Route of Admin		Y	I/M - by intramuscular injection I/V - by intravenous injection S/C - by subcutaneous injection P/O - Orally I/O - by intraosseous injection I/P - by intraperitoneal injection TOP - to be applied topically I/N - to be administered intranasally
Dosage Regime		Y	
Duration of treatment		Y	
Included Amount & Rate		Y	
Withdrawal Period - Days	Beef	Y	
Withdrawal Period - Hours	Milk	Y	
Warnings/Advice		Y	Freetext – advice from Vet on product usage
Statement if product used metaphylactically		Y	Vet to confirm if product used Metaphylactically or not
Statement if product prescribed in accordance with Article 112-114		Y	Statement if product prescribed in accordance with Article 112-114
Statement: This prescription shall not be reused		Y	“This prescription shall not be reused” This DESCRIPTION must be included on all Med Feed Scripts

7. Dispensing

Field	Species Specific	Mandatory on Script	Context
Batch Number/s		Y	Maybe more than one number
Quantity dispensed		Y	
Expiry Date		Y	
Batch Number/s Premix			
Expiry Date Premix			
Date dispensed		Y	
**Pack size			Numerical value: Description: Numerical value only to disclose the pack size (e.g. 100 for 100 tablets or 100 intramammary injectors; 10 for 10 ml injection; 2 for a package of 2 kg premix; 300 for a box of 10 blisters of 30 tablets; 12 for a box of 12 injectors.).
**Pack size unit			Description: Content unit of measurement to select corresponding value from the defined list (e.g. ml, l, g, kg, piece (for example, for tablets, capsules, boluses and intramammary injectors). The pack size unit should be compatible with the strength unit.
**Number of Packs Sold			Number of packages sold Description: Numerical value only, to disclose number of packages of product presentation sold within the reporting period (year) in the reporting country.
Signature of Veterinarian		Y	

** Currently under review by the EU Commission