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Bia agus Mara
Department of Agriculture,
Food and the Marine

National Veterinary Prescription System
Vet Med Prescription Details Requirement

Food Producing Animals Only
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1. Introduction

The new EU 2019/6 Veterinary Medicinal Products Regulation comes into effect from 28 January 2022.

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

In attempts to put measures and processes in place to reach that objective the EU Commission is instructing a number of changes to prescribing protocols and to the details required on all veterinary prescriptions (Article 105) – Annex I. The Commission are also seeking greater information (Article 57) Annex II in its battle against AMR and have indicated that prescription information will be accepted as submissions from each MS on its official antimicrobial usage.

Article 105(5) sets out the MINIMUM data requirements for each prescription from 28 January 2022. The Article also allows MS to add additional fields of information as they see fit. Ireland will be availing of this option to include additional variables.

The same Article will underpin part of Ireland's new Statutory Instrument which will provide guidance on the details required when generating a Veterinary Prescription from 28 January 2022. This new Statutory Instrument will replace SI 786/2007 and SI 558/2017 which have been the guidelines in place on Veterinary Prescription for more than the last decade within Ireland.

This document will outline the new regulatory requirements along with those that have been retained from SI 786/2007 and 558/2017 for the purposes of electronic prescribing.

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 notice there are several additional fields – such as VCI number of the veterinary practitioner, species of animal, category and sub species of animal, active substances in medication and statements if products are being used or not for prophylactic or 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 a number of amendments necessary to current bespoke software prescription offerings to ensure the full prescription data set is captured for each generated prescription.

These changes and required data fields can also be identified in this document from the detailed dataset.

The NVPS will not be replacing current software offerings.

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/

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.

3. Current Software Provider NVPS Integration Information

As mentioned previously, the NVPS will not be replacing any current digital prescription software solution. Instead, it is intended that veterinarians using an industry prescription offering can continue to do so. However, all prescriptions will be automatically sent seamlessly via backend technology to the centralised NVPS database, to allow:

1. Non dispensed prescriptions be made available to all registered dispensing outlets and stakeholders on the NVPS application and
2. For effective and efficient collection of VMP usage for ease of reporting to the EU Commission.

A set of Application Programme Interfaces (API) have been developed for any software stakeholder, either Prescription generator or Dispenser, wanting to interact with the NVPS system through their own bespoke software. 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 2019/16/ Article 105

Article 105

Veterinary prescriptions

1. A veterinary prescription for an antimicrobial medicinal product for metaphylaxis shall only be issued after a diagnosis of the infectious disease by a veterinarian.

2. The veterinarian shall be able to provide justification for a veterinary prescription of antimicrobial medicinal products, in particular for metaphylaxis and for prophylaxis.

3. A veterinary prescription 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.

4. By way of derogation from point (33) of Article 4 and paragraph 3 of this Article, a Member State may allow a veterinary prescription to be issued by a professional, other than a veterinarian, who is qualified to do so in accordance with applicable national law at the time of entry into force of this Regulation. Such prescriptions shall be valid only in that Member State and shall exclude prescriptions of antimicrobial medicinal products and any other veterinary medicinal products where a diagnosis by a veterinarian is necessary.

Veterinary prescriptions issued by a professional, other than a veterinarian shall be, *mutatis mutandis*, subject to paragraphs 5, 6, 8, 9 and 11 of this Article.

5. A veterinary prescription shall contain at least the following elements:

(a) identification of the animal or groups of animals to be treated;

(b) full name and contact details of the animal owner or keeper;

(c) issue date;

(d) full name and contact details of the veterinarian including, if available, the professional number;

(e) signature or an equivalent electronic form of identification of the veterinarian;

(f) name of the prescribed medicinal product, including its active substances;

(g) pharmaceutical form and strength;

(h) quantity prescribed, or the number of packs, including pack size;

(i) dosage regimen;

(j) for food-producing animal species, withdrawal period even if such period is zero;

(k) any warnings necessary to ensure the proper use including, where relevant, to ensure prudent use of antimicrobials;

(l) if a medicinal product is prescribed in accordance with Articles 112, 113 and 114, a statement to that effect;

(m) if a medicinal product is prescribed in accordance with Article 107(3) and (4), a statement to that effect.

6. The quantity of the medicinal products prescribed shall be limited to the amount required for the treatment or therapy concerned. As regards antimicrobial medicinal products for metaphylaxis or prophylaxis, they shall be prescribed only for a limited duration to cover the period of risk.

7. Veterinary prescriptions issued in accordance with paragraph 3 shall be recognised throughout the Union.

8. The Commission may, by means of implementing acts, set a model format for the requirements set in paragraph 5 of this Article. 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 145(2).

9. The medicinal product prescribed shall be supplied in accordance with applicable national law.

10. A veterinary prescription for antimicrobial medicinal products shall be valid for five days from the date of its issue.

11. In addition to the requirements set out in this Article, Member States may lay down rules on record-keeping for veterinarians when issuing veterinary prescriptions.

12. Notwithstanding Article 34, a veterinary medicinal product classified as subject to veterinary prescription under that Article may be administered without a veterinary prescription by a veterinarian personally, unless otherwise provided for under applicable national law. The veterinarian shall keep records of such personal administration without prescription in accordance with applicable national law.

5. 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. If certain fields are species specific and your vets don't treat that species, then those fields will not apply to your system.

This is a working document and information may change

Field	Species Specific	Mandatory on NVPS	Context
Prescription Number		Y	
Prescription Date		Y	
Herd Id	Specific to Bovine, Ovine, Porcine, Cervine, Caprine and Avian For Equine – this field will require EPRN number For Piscine – a fisheries id	Y	This is required to enable the Department to link the prescription directly to animal owners on DAFMs Corporate Customer Service database Fishery Ids will be forwarded to all Fish Vets from the Department.
Species to be treated	NVPS related species only include Bovine, Ovine, Porcine, Cervine, Caprine, Piscine, Equine and Avian	Y	NVPS will not include Companion Animals in Phase 1. List for Phase I: Bovine, Ovine, Porcine, Cervine, Caprine, Piscine, Equine and Avian

Field	Species Specific	Mandatory on NVPS	Context
Sub Species		N	**AVIAN**: Chicken, Turkey, Duck, Ostrich, Geese, Guinea Fowl, Pheasant, Partridge, Pigeon, Quail, Rhea, Emu, Other Farmed Birds **Piscine:** Atlantic Salmon, Trout
Category of Animal	Species Dependent	Y	**CHICKEN**: Breeder, Broiler, Commercial, Layer **TURKEY**: Breeder, Commercial **DUCK:** Breeder, Commercial **OSTRICH:** Breeder, Commercial **GEESE**: Breeder, Commercial **GUINEA FOWL:** Commercial **PHEASANT**: Commercial **PATRIDGE** Commercial **PIGEON**: Commercial **QUAIL**: Commercial: **RHEA**: Commercial **EMU**: Commercial **OTHER FARMED BIRDS:** Commercial **BOVINE**: Beef/Dairy **CAPRINE**: Chevon (Goat Meat), Commercial, Dairy **CERVINE**: Commercial, Venison **EQUINE:** Colt, Filly, Gelding, Mare, Stallion, Teaser. **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	

Field	Species Specific	Mandatory on NVPS	Context
Keeper Address 2		N	
Keeper Address 3		N	
Keeper Address 4		N	
Keeper Eircode		N	
Vet Name		Y	
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
Practice Name		Y	
Practice Address 1		Y	
Practice Address 2		N	
Practice Address 3		N	
Practice Address 4		N	
Number of Animals			If more than 4 animals are being prescribed for, then this field is optional. If individual animal is to be identified, then Tag number field to be used.
Tag Numbers	Species Specific	N	Bovine, Equine, Ovine, Cervine, Caprine, Porcine
Horse Name	Equine	Y	
UELN	Equine	N	One of UELN, Microchip or Welfare Required under new EU equine identification legislation
Microchip Number	Equine	N	
Animal treated on Welfare Grounds - indicator	Equine	N	This is to be completed only when a vet cannot identify an Equine animal under any of the 3 previous identification fields
Age	Piscine & Avian	N	Species Specific – Piscine & Avian

Field	Species Specific	Mandatory on NVPS	Context
Age descriptor	Piscine & Avian	N	Avian - Days, Months, Weeks, Years, Piscine- Eggs, Larvae, Juvenile, Parr/Fingerling, Smolts, Other
Location	Avian/Porcine/Piscine	Y	
Site - House	Avian/Porcine/Piscine	Y	
Site Manager Name	Piscine	Y	If you are prescribing for fish these fields will be required for collection
Site Manager Phone Number	Piscine	Y	Either email or Phone required
Site Manager Email	Piscine		Either email or Phone required
Company Name	Piscine	Y	
Remedy/Product ID		Y	Id of product required. This will be standardised for all submissions
Active Substances		Y	Can be more than One.
Pharmaceutical Form & Strength			
Quantity Required		Y	Numeric field i.e. **Number of** millilitres, tables etc
Quantity Unit		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	Free text (e.g., Daily, or twice a day)
Withdrawal Period - Days		N	
Withdrawal Period - Hours		N	
Warnings/Advice		Y	Freetext – advice from Vet on product usage
Statement if product used Prophylactically/metaphylactically or Neither		Y	Vet to confirm if product used P, M or N
Statement if product prescribed in accordance with Article 112-114		Y	Statement if product prescribed in accordance with Article 112-114
Indicator if Culture and Susceptibility test carried out if HPCIA product prescribed		Y	

6. Dispensing

Field	Description	Mandatory on Script	Context
Batch Number/s		Y	Maybe more than one number
Quantity dispensed	4 tab	Y	
Date dispensed		Y	
** Pack size	12		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	Tablets		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