

# **Guide to Definition of a Veterinary Medicinal Product and the Classification Process**

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## ABBREVIATIONS

|      |                                        |
|------|----------------------------------------|
| CJEU | Court of Justice of the European Union |
| HPRA | Health Products Regulatory Authority   |

## RELEVANT LEGISLATION

This document is intended as a guideline only and should not be assumed to be a definition of the law in this area. It may be subject to change in the light of new developments over time or as appropriate.

The guide should be read in conjunction with the various relevant legislation, in particular the following:

### EU Regulations

|                            |                                                                                           |
|----------------------------|-------------------------------------------------------------------------------------------|
| Regulation 2019/4          | Medicated Feed                                                                            |
| Regulation 2019/6          | Veterinary Medicinal Products                                                             |
| Regulation No. 528 of 2012 | Biocidal Products                                                                         |
| Regulation 2020/354        | Establishing a list of intended uses of feed intended for particular nutritional purposes |

### Act

|                    |                           |
|--------------------|---------------------------|
| Act No. 29 of 1995 | Irish Medicines Board Act |
| Act No. 23 of 1993 | Animal Remedies Act       |

### National Regulations

|                     |                                                                                    |
|---------------------|------------------------------------------------------------------------------------|
| S.I. No. 36 of 2022 | European Union (Veterinary Medicinal Products and Medicated Feed) Regulations 2022 |
|---------------------|------------------------------------------------------------------------------------|

## 1 INTRODUCTION

The Health Products Regulatory Authority (HPRA) is the statutory authority in Ireland for determining applications for marketing authorisations (provided for in Article 5 of Regulation (EU) 2019/6) in respect of veterinary medicinal products.

Regulation 2019/6 states that a veterinary medicinal product shall be placed on the market only when a competent authority has granted a marketing authorisation for the product. The granting of such authorisation ensures that the product complies with the required standards of quality, safety and efficacy.

A *veterinary medicinal product* is defined in Regulation 2019/6 as being 'any substance or combination of substances which fulfils at least **one** of the following conditions-

- (d) it is presented as having properties for treating or preventing disease in animals;
- (e) its purpose is to be used in, or administered to, animals, with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action;
- (f) its purpose is to be used in animals with a view to making a medical diagnosis;
- (g) its purpose is to be used for euthanasia of animals;

In most cases, the classification of a product as a veterinary medicinal product is clear in that the nature of the substance, its effects on the body, the indications for use/contraindications, and the manner of marketing are consistent with the definition of a veterinary medicinal product.

However, there are products, which could be said to occupy a 'borderline' position between, for example:

- Veterinary medicines and nutritional products
- Veterinary medicines and shampoos or other surface agents
- Veterinary medicines and herbal or other feedingstuffs
- Veterinary medicines and biocidal products

This document is intended to describe HPRA policy in recommending whether products should be classified as *veterinary medicines*, or whether they can be considered as out of the scope of the veterinary medicines legislation.

When a product is determined by the HPRA as 'out-of-scope' (i.e. not a veterinary medicine), it must carry the following statement on the product labelling: *'This is not a veterinary medicine which is subject to authorisation by the Health Products Regulatory Authority'*. Its product literature is also reviewed by the HPRA to ensure that it does not include any statements that constitute medicinal claims. Such products must also not be promoted as being medicinal, e.g. in any packaging material or promotional literature.

## 2 THE HEALTH PRODUCTS REGULATORY AUTHORITY

The general powers and functions of the HPRA are set out in the Irish Medicines Board Act 1995, as amended, referred to above. The HPRA is the competent authority for the licensing and supervision of veterinary medicines in Ireland in accordance with S.I. No. 36 of 2022. The regulation of these products is founded on science and law to ensure their purity, potency, safety, efficacy and stability as appropriate during storage, transport and distribution.

The HPRA participates in systems designed to ensure the quality, safety and efficacy of medicines throughout the European Union.

### 3 THE REQUIREMENTS OF A VETERINARY MEDICINE

Before a *veterinary medicine* can be authorised for use by the HPRA, an application must be made for a veterinary product authorisation to that body (or, in the case of centrally authorised products, to the European Medicines Agency). Such applications must contain the data necessary to demonstrate the quality, safety and efficacy of the product. The application is reviewed and a decision on the application reached, based upon the likely balance of the benefits versus risks associated with the product. The HPRA requires that the interests of users of veterinary medicines and consumers of treated animals should be protected, particularly in the following areas:

- 1 A *veterinary medicine* should be of such quality that its contents and its pharmaceutical performance conform to acceptable standards.
- 2 The risk to animals and users of administering a *veterinary medicine* should be acceptable and reasonable, taking into account that the use of any medicine carries a risk which should be considered in the light of the intended benefit.
- 3 There should be a demonstrable therapeutic benefit. If a medicinal claim is made, the purchaser is entitled, within reason, to expect a benefit and the application process should protect the consumer, in so far as possible, from products which do not offer a potential for such benefit.
- 4 Whenever appropriate, the holder of a product marketing authorisation must ensure that their product does not present any threat to consumers of food-producing animals.

In addition, there is a requirement that the holder of a product marketing authorisation should keep the HPRA informed of the discovery of any adverse effects or any events with potential safety consequences for their products.

### 4 WHAT IS A VETERINARY MEDICINE?

The clear definition of a veterinary medicinal product is given in Article 4(1) of Regulation (EU) 2019/6.

The definition covers both the presentation of the product as well as the purpose for which it is administered.

#### 4.1 Presentation

The Regulation refers to the presentation of the product (any substance or combination of substances) as fulfilling the definition of a veterinary medicinal product as follows:

‘It is presented as having properties for treating or preventing disease in animals’.

In reviewing a product application in this context, the HPRA examines the ‘totality’ of the product, for example:

- 4.1.1. Products which (explicitly or implicitly) claim to cure, alleviate or prevent disease will be considered by the HPRA as *veterinary medicines*. Any particular words or phrases which imply such a claim will be taken into account.

While not intended to be exhaustive, the following list contains examples of such words or phrases:

'Prevents, cures, heals, treats, restores, remedies, clears, relieves, repairs, stops, protects, helps with, alleviates, controls, combats, counters, traditionally used for, strengthens the immune system, calms, aids in the healing of, helps maintain normal water balance, helps in the prevention of.'

- 4.1.2. Products which are presented so that the labelling, the packaging, the pharmaceutical form or the promotional material implies a medicinal usage are considered as *veterinary medicines*.
- 4.1.3. Once a given product has been classified by the HPRA as a *veterinary medicine* it is possible that closely related products may be similarly classified.

## 4.2 The purpose for which a product is administered

Article 4(1) of the Regulation refers to the purpose of the product as fulfilling the definition of a veterinary medicinal product with at least one of the following:

- (b) its purpose is to be used in, or administered to, animals, with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action;
- (c) its purpose is to be used in animals with a view to making a medical diagnosis;
- (d) its purpose is to be used for euthanasia of animals;

In relation to the purpose of a product being administered, the Animal Remedies Act (1993) states the following:

- treating, preventing or modifying disease,
- improving the health or condition of animals (except for a feeding stuff commonly known and solely used as such).

Any product containing a substance with a pharmacological, immunological or metabolic action on physiological function at the dosage used will usually be classified as a *veterinary medicine* by the HPRA irrespective of the presence or absence of claims in the product packaging or literature. In order not to be considered as a *veterinary medicine*, the onus rests with the applicant to suitably demonstrate the absence of a pharmacological, immunological or metabolic action on physiological function at the dosage used.

### 4.3 HPRA policy and practice

CJEU judgements, the evolution of scientific and regulatory opinion, changes in legislation or in marketing practices, and other changing circumstances have required corresponding changes to the way the HPRA assesses applications.

In particular, the HPRA takes full account of the CJEU view that competent authorities of Member States should consider all the characteristics of the individual products. The HPRA is also obliged to consider what impression of the product an averagely well-informed person would be likely to gain.

Thus, in practice, the HPRA considers each individual product on its merits and any information which may have a bearing on the product's status, such as:

- a) the claims made for the product (including any claims made on linked 'help-lines', websites or publications, or in the product's actual name)
- b) the pharmacological, immunological or metabolic properties of the ingredient(s) and any significant effect(s) they have on animals
- c) the labelling, and the packaging literature, including any pictorial descriptions
- d) the promotional literature (including testimonials and any literature issued by a third party on behalf of the manufacturer or producer) and advertisements
- e) the product form (e.g. tablet, capsule, ointment, etc.) and the way in which it is intended to be used or administered (e.g. by injection)
- f) to whom the product or information about the product is directed
- g) whether there are similar authorised veterinary medicines on the market fulfilling similar functions
- h) the potential presence or not of residues of the product in food-producing animals
- i) whether the product is controlled under alternative legislation, e.g. feedingstuffs intended for particular nutritional purposes or biocidal products
- j) whether the product has its effects by physical or biochemically mediated means
- k) the purpose of the use of the product
- l) whether the product is ingested by the animal as a food

- m) whether the product is applied to the animal directly or to the local environment in which the animal is kept

## 5 BORDERLINE PRODUCTS

This guideline has been drawn up to explain the HPRA's policy and practice on borderline products, and the principles on which they are based.

In general, the presence of substances such as antibiotics, antifungal agents, hormones and anaesthetics in products can only be justified on the basis that the products are medicinal and as such will require product marketing authorisations.

Preparations comprised of xenobiotics that are intended to be ingested, inhaled, injected or implanted in the animal body are generally considered to fall within the definition of a veterinary medicinal product. Similarly, preparations for use in the eye (e.g. artificial tears), on horn buds for de-budding animals, for intramammary or intra-uterine use are considered as medicinal products, by virtue of their route of administration and their potential risks.

Other specific examples are given below.

### 5.1 Foods and feedingstuffs

In general, most foods are not medicinal products. However, some manufactured preparations contain substances such as vitamins, minerals, amino acids, zinc oxide and herbal ingredients, presented in certain forms which are usually associated with medicines (e.g. capsules, tablets, drenches, premixes). Such preparations may be classed as medicinal products even in circumstances where they may be described by the manufacturers concerned as 'foods' or 'food supplements'. In these cases, the use by the purchasers and users of the products (the primary objective) will be taken into account by the HPRA in classifying the products.

The following is an outline of those products, which are presented in a form usually associated with *veterinary medicines*.

#### 5.1.1 Products containing nutrients, vitamins and/or mineral ingredients

Some proprietary preparations are products which are foods, feed additives or feedingstuffs. These do not come within the scope of the veterinary medicines legislation when labelled and used in accordance with the legislation concerned.

However, proprietary preparations are considered to be *veterinary medicines* when:

- a) their labelling or accompanying or associated literature makes any preventative, curative or remedial claim (e.g. prevention of nutrition deficiency); or

- b) the use of a product intended for administration to food producing animals may require a withdrawal period in order to avoid violative residues; or
- c) the product is intended for parenteral administration (any injectable product is a veterinary medicine); or
- d) the intake of any constituent at the recommended dosage could be toxic to normal animals

#### 5.1.2 Herbals (products containing medicinal herbal ingredients)

Herbal remedies are considered by the HPRA to be *veterinary medicines* when they are present in a product for the purpose of preventing or treating a disease in the animal.

However, it should be noted that preparations consisting of dried or crushed herb(s) which form a minor component of a product intended for oral administration to healthy animals, as part of the animal's diet, are not regarded as *veterinary medicines* provided that:

- no indication for use of the product as a *veterinary medicine* is made,
- none of the herbal substance(s) has pharmacological, immunological or metabolic actions on physiological function at the dose administered to the target animal, or the quantity of herb(s) is representative of that which might reasonably be expected to be ingested by an animal grazing on native pasture.

#### 5.1.3 Feed intended for particular nutritional purposes

Regulation (EC) No. 767 of 2009 establishes the definition and the conditions of use, manufacturing and marketing of certain feedingstuffs, which are not considered as *veterinary medicines*. These feedingstuffs exclude any medicated substance or additive as described in Regulation (EU) 2019/4, which are made from a premix that requires a product marketing authorisation.

Commission Regulation (EU) 2020/354 establishes a list of intended uses of feed intended for particular nutritional purposes. Where a product is considered to meet the provisions as listed in Commission Regulation (EU) 2020/354, the Department of Agriculture, Food and the Marine, as the competent authority responsible for administering this legislation, should be consulted.

#### 5.1.4 Zinc Oxide

Where zinc oxide is being prescribed for inclusion in diets for pigs, for the prevention of diarrhoea, it will be regarded by the HPRA as a *veterinary medicine*.

#### 5.1.5 Colostrum products

Pure colostrum and colostrum substitutes are regarded as nutritional supplements and not *veterinary medicines* provided:

- no preventative or treatment claim is made
- no reference to immunological content, antibodies or immunity is made.

While the word 'colostrum' is not considered medicinal, where medicinal claims are made for a product, the product will be regarded by the HPRA as a *veterinary medicine*.

## 6 HOMEOPATHIC MEDICINES

Homeopathic medicines represent special types of *veterinary medicines* for which particular rules apply, in accordance with the requirements of Regulation (EU) 2019/6.

Under Article 85, all homeopathic veterinary medicinal products that meet the conditions set out in Article 86 are considered to be *veterinary medicines*. Such products must be subject to a registration procedure.

Further information can be found in the [HPRA's Guide to Registration of Homeopathic Veterinary Medicinal Products](#).

## 7 DISINFECTANTS/TEAT DIPS

If no medicinal claims are made, disinfectants/antiseptics intended for application to the skin for general hygiene use may be classified as biocides, and are subject to registration under the Biocidal Products Regulation (Regulation (EU) No. 528 of 2012), rather than as a veterinary medicine. This also applies to insect repellents for use on animals, as long as they have no lethal effect on insects. Applicants are advised to make the usual classification enquiry to the HPRA in the first instance.

A disinfectant/antiseptic preparation which is intended to treat wounds or other skin lesions is considered to be a *veterinary medicine* requiring a product marketing authorisation. However, reference to use of such a preparation on minor abrasions and scratches will generally not result in a product being classified as a veterinary medicine.

Any disinfectant intended for administration into the uterine tract or into a body cavity (e.g. uterine wash) is considered by the HPRA to be a *veterinary medicine*.

Further to clarification from the EU Commission in September 2008, teat dips are classified as biocidal products and are to be authorised in accordance with the requirements of Regulation (EU) No. 528 of 2012 **as long as no medicinal claim is made** [emphasis added].

## 8 PRODUCTS NOT REGARDED AS VETERINARY MEDICINES

There are certain products which are not *veterinary medicines*.

If:

- 1 no medicinal claims are made on the product literature,
- 2 the product does not contain active substances that exert a pharmacological, immunological or metabolic action,
- 3 the product does not fulfil the criteria described in section 4 above,
- 4 the product is not for use in animals for the purpose of making a medical diagnosis,
- 5 the product is used as intended,

the following products would not be regarded as *veterinary medicines* by the HPRA:

- products used solely for the treatment of the environment of the animal
- nutritional preparations intended for oral administration to healthy animals for several days or weeks to achieve a nutritional benefit
- non-nutrient substances added to a food (or to a diet) of animals to improve preservation, colour, palatability, texture or nutritive value of food, including (for example) preservatives, antioxidants, emulsifiers, stabilisers, acids, non-stick agents, firming agents, anti-foaming agents, colourants and flavourings
- topical physical barriers, e.g. topical paraffin based (non-medicated) ointment and creams
- non-medicated shampoos and baths
- hoof oil
- footbaths used for hardening hooves
- marking sticks or paints used for animal identification or 'heat' detection
- medical devices, such as sutures, controlled by Council Directive 93/42/EEC (medical devices for human use)
- semen extenders used in artificial insemination
- fly repellent sprays
- salt or mineral licks

## 9 CLASSIFICATION PROCEDURE WITHIN THE HPRA

It is clear that classification of veterinary products occupying the borderline area between veterinary medicines and, for example, nutritional substances, is important since the producers and users of such products need to be aware of the more stringent legislation which exists for marketing of veterinary medicinal products.

Any company or individual, who attempts to market a borderline product may discover that the product might in fact be subject to veterinary medicines legislation and prior authorisation/registration is required. It is for this reason that the HPRA has set up a classification procedure whereby applicants can request an opinion on the classification of a given product

prior to placing it on the market. In this way, applicants can obtain an opinion and avoid the risk of breaking the law by placing a veterinary medicinal product on the market without the necessary marketing authorisation.

### **9.1 Applying for classification of a veterinary product by the HPRA**

To apply for classification of a borderline veterinary product by the HPRA, download the form 'Request for Classification of a Borderline Product for Animal Use' from the 'Publications and Forms' section of [www.hpra.ie](http://www.hpra.ie).

Complete the appropriate sections of the form, entering N/A if any one section is not applicable. In order to arrive at a decision regarding classification of the product, the HPRA must be provided sufficient accurate information about the product and its intended use. This includes any labelling and promotional material relating to the product.

Evidence should be provided to suitably demonstrate the absence of pharmacological and/or toxicological effects as well as immunological and metabolic effects on physiological function at the dosage used.

The form must be signed by the applicant. All applications (including the supporting data) must be in English. The electronic format for applications is preferred. Hard copy submissions can be accepted if electronic submission is not possible.

Submit the signed form with attachments, fee form and proof of payment to the Receipts and Validation section of the HPRA as indicated on the form.

See the 'Guide to Fees for Veterinary Products' on the 'Publications and Forms' section of [www.hpra.ie](http://www.hpra.ie) for details of the fees and the method of fee payment. The fee should be sent on the same day as the application form and data. The application will not be considered until the fee has been paid. All fees must be paid in full including any associated bank charges.

Requests to amend the labelling and/or product literature, subsequent to a decision regarding classification of the product, will be treated as a new determination and thus will be subject to the appropriate fee. To apply for an amendment, an application should be submitted as detailed above.

### **9.2 The classification process**

The application details and associated product information are assessed by the Veterinary Sciences department to determine whether the product:

- is outside the European Union (Veterinary Medicinal Products and Medicated Feed) Regulations 2022 and Regulation (EU) 2019/6 and is therefore 'out-of-scope',
- falls within the legislation and requires a veterinary medicinal product authorisation from the HPRA, or

- is regulated by the Biocidal Products Regulation (EU) No 528/2012 or Commission Regulation (EU) 2020/354 establishing a list of intended uses of feed intended for particular nutritional purposes, in which case the applicant is referred to the Department of Agriculture, Food and the Marine.

The classification query may be referred to HPRA experts for an opinion if necessary.

### 9.3 Duration of the classification process

Usually, provided the applicant has provided clear and comprehensive information as detailed in the application form, the HPRA can give an opinion within 40 days of validation of the application. In the case of applications which are novel or complex, necessitating consultation with HPRA experts, the procedure to complete the evaluation may take up to six months.

### 9.4 Right to appeal the classification decision

Should an applicant disagree with a negative determination, they may appeal within 14 days of receiving the HPRA's notification. The request for the appeal should be directed to the classification administrator together with all supporting information for consideration of the appeal and the appropriate fee. The decision of the HPRA following appeal shall be final.

## 10 SUMMARY

- 10.1** The definition of a *veterinary medicine* used in Ireland and throughout the European Community is based on that contained in Article 4 of Regulation (EU) 2019/6 and the Animal Remedies Act, 1993.

This definition (as outlined in the Introduction) is in two parts, covering the presentation of the product and the purpose for which it is administered.

- 10.2** A summary of the HPRA's policy is as follows:

- 10.2.1** Products which claim to cure, alleviate or prevent disease are considered *veterinary medicines*. The HPRA takes into account in its decision the words used, the presentation and relationship to similar products.
- 10.2.2** Products which contain substances of a type and in amounts such as to exert a pharmacological, immunological or metabolic effect on physiological functions will also be considered as *veterinary medicines*.
- 10.2.3** Products presented as nutritional substances will be considered as *veterinary medicines* if medicinal claims are made or if they contain ingredients which have significant pharmacological, immunological or metabolic effects.

- 10.3** It is the express responsibility of the person or organisation marketing such a product to ensure compliance with the relevant legislation. Failure to comply with the legislation may result in prosecution, with liability for fines or prison terms as specified in the Irish Medicines Board Act 1995, as amended and the Animal Remedies Act 1993.

## APPENDIX 1 REFERENCES

- 1 Animal Remedies Act, 1993 (S.I. No. 23 of 1993)
- 2 European Union (Veterinary Medicinal Products and Medicated Feed) Regulations 2022 (S.I. No. 36 of 2022)
- 3 Irish Medicines Board Act 1995, as amended (S.I. No. 29 of 1995)
- 4 Regulation (EU) No. 528 of 2012 of 22 May 2012 Concerning the Making Available on the Market and Use of Biocidal Products
- 5 Commission Regulation (EU) 2020/354 of 4 March 2020 Establishing a List of Intended Uses of Feed Intended for Particular Nutritional Purposes
- 6 Regulation (EU) No 767/2009 of 13 July 2009 on the Placing on the Market and Use of Feed,
- 7 amending European Parliament and Council Regulation (EC) No. 1831 of 2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC
- 8 Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on Veterinary Medicinal Products and repealing Directive 2001/82/EC.
- 9 Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the Manufacture, Placing on the Market and Use of Medicated Feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC.