

This protocol does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

Veterinary Medicinal Product Shortages

Protocol for notifying shortages of Veterinary Medicinal products

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1 GLOSSARY OF TERMS

Impact assessment

An impact assessment is performed in order to determine the impact of a potential or actual shortage on its market.

Manufacturer

The manufacturer is a stakeholder that has been authorised to produce veterinary medicinal products. The manufacturer may or may not also be the marketing authorisation holder (MAH).

Marketing authorisation holder (MAH)

The MAH is the stakeholder in whose name the marketing authorisation for a medicinal product has been granted. The MAH is responsible for all aspects of the medicinal product, including quality and compliance with the conditions of the marketing authorisation.

Marketing authorisation number

Each authorised medicinal product has a specific reference number associated with it and that is detailed on the product packaging. The marketing authorisation number takes the form of a sequence of letters followed by numbers. The letters can be VPA or EU.

Notification

A notification is a communication of a shortage from a marketing authorisation holder (MAH), (or their representative) manufacturer, wholesale distributor, healthcare professional, farm sector interest, or the HPRA to DAFM.

Wholesale distributor

Wholesale distribution means all activities consisting of procuring, holding, supplying or exporting veterinary medicinal products whether for profit or not, apart from retail supply of veterinary medicinal products to the public.

Veterinary Healthcare Professional

- **Veterinary Practitioner**
Veterinary practitioners prevent, diagnose and treat diseases and injuries in relation to animal health as set out in the Veterinary Practice Act, 2005. They must be registered with the Veterinary Council of Ireland.
- **Veterinary Nurse**
Carry out technical work and are skilled in undertaking a range of diagnostic tests, medical treatments and minor surgical procedures, under veterinary direction. They must be registered with the Veterinary Council of Ireland.

Pharmacists

A **veterinary pharmacist** is a qualified **pharmacist** who dispenses **veterinary** medicines and advice to owners of companion animals and livestock.

2 PURPOSE

The aim of the Protocol is to help avert potential shortages from occurring or escalating, and to reduce the impact of shortages on market by co-ordinating with stakeholders the management of potential or actual shortages as they arise. There is no single stakeholder responsible for managing a continued supply of VMPs on the Irish market which highlights the importance of cooperation and information sharing amongst stakeholders in the interests of animal health and welfare and more broadly in supporting the agriculture sector.

This Protocol focuses primarily on the requirement to notify the key stakeholders of potential or actual shortages through enhancing procedures for notification of shortages, their evaluation and outward communication. The particular circumstances of each notification will be dealt with on a case by case basis.

3 DEFINITION

Causes of medicine shortages are multi-factorial and involve multiple stakeholders. The approach outlined is designed to manage the response to a veterinary medicine shortage using a multi-stakeholder approach, where collaboration with stakeholders is the foundation of an informed and practical response. Timely communication of critical information amongst stakeholders is central to this.

Developing long-term strategies focused on the underlying causes of shortages can reduce the likelihood of shortages occurring.

The definition of a shortage, per the definition agreed by EMA-HMA (European Medicines Agency – Heads of Medicines Agency) in their “Guidance on detection and notification of shortages of medicinal products for Marketing Authorisation Holders (MAHs) in the Union (EEA)” which applies to prescription and non-prescription medicines alike, is when:

'A shortage of a medicinal product for human or veterinary use occurs when supply does not meet demand at a national level'.

Consequently, a shortage occurs when the supply of a veterinary medicines product is inadequate to meet the needs of the agricultural sector and creates a potential animal health and/or welfare risk.

The impact on animals and the potential critical nature of a shortage are important components in determining the response to a shortage. These concepts are complex and have been built into the assessment component, where multiple factors are considered, on a case-by-case basis (see Section 5.2).

Examples of what may not be considered as medicine shortages are highlighted below;

- Where a medicine is **not yet authorised**, or which is authorised and not marketed in Ireland for commercial reasons.
- A delay in supply of a veterinary medicine to a retailer due to **logistical reasons** or an error in delivery would not be considered as a medicine shortage as it is, in essence, a logistics issue and the medicine is generally available.
- Where normal supply to a wholesale distributor has been delayed, but there is **sufficient stock at wholesale level** that normal supply will not be impacted.
- Where **only one wholesaler** is not in a position to supply the particular medicine and others can supply the medicine.
- A shortage of a particular medicine where there are alternatives available on the market.

4 ROLE OF STAKEHOLDERS

All stakeholders involved in the medicine supply chain have a role in ensuring access to veterinary medicines. Therefore, all stakeholders in the supply chain have important roles in the prevention and management of shortages. The sections below outline the roles of different stakeholder groups in the management of shortages.

4.1 Marketing Authorisation Holders

The Marketing Authorisation Holders should notify the competent authority if the product ceases to be placed on the market of the Member State, either temporarily or permanently. Such notification shall, otherwise than in exceptional circumstances, be made no less than two months before the interruption in the placing on the market of the product.

Where an actual or potential shortage occurs, the MAHs assess the circumstances, perform an impact assessment to determine the potential impact of the shortage and notify both the HPRA and DAFM as soon as possible. MAHs may also propose a proportionate response to reduce the impact using the templates referenced in this document.

4.2 Manufacturers

Manufacturers also have responsibility, to ensure appropriate and continued supplies of products manufactured by them. Capacity to manage reasonable demand fluctuations should be built into operating and planning procedures to allow adjustments to be made to supply to the market thereby preventing a shortage. Manufacturers also implement risk-based strategies to preventing shortages due to the manufacturing process.

4.3 Wholesale distributors

Wholesale distributors have a responsibility to ensure, within the limits of their responsibility, appropriate and continued supplies of medicines. Wholesale distributors act as the interface between the MAH or manufacturer and persons entitled to supply or use veterinary medicines; they may be well-placed to identify signs of a medicine shortage.

During a veterinary medicine shortage, wholesale distributors are in a position to source medicines, monitor and communicate stock levels, and manage equitable distribution to veterinary practices and licensed retailers through the proportional allocation of remaining stocks. In some cases, the wholesaler may be in a position to supply an alternative remedy to the veterinary professional.

4.4 Department of Agriculture, Food and the Marine (DAFM)

DAFM has an overarching policy and direction role and is required to ensure that the supply of veterinary medicines is in compliance with legislative requirements. This includes the development and review of legislation, representing stakeholder interests in an international context and contributing to initiatives to mitigate the risk and disruption caused by veterinary medicine shortages. DAFM's role in veterinary medicine shortages is to receive the initial notifications and co-ordinate the response to a shortage amongst stakeholders so that the impact is mitigated as much as possible.

DAFM has no role in the sale or supply of veterinary medicinal products and is not responsible for shortages or any costs arising from a shortage or any other misalignment between supply and demand for veterinary medicines in the marketplace.

4.5 Health Products Regulatory Authority (HPRA)

The HPRA's role in veterinary medicine shortages is to notify DAFM when they become aware of issues affecting product supply and availability to the Irish market.

The HPRA provides general information on veterinary medicine availability through its website. The HPRA's regulatory remit does not extend to certain areas, for example shortages of particular veterinary medicines, pricing, sourcing medicines, clinical practice, nor can it compel a company to manufacture and supply a specific medicine.

4.6 Veterinary Healthcare Professionals

Healthcare professionals (e.g. Veterinary Practitioners, pharmacists and veterinary nurses) and Licenced Merchants use their professional expertise to identify alternative medicines or therapies if a medicine is unavailable due to a shortage. Animal healthcare professionals can be involved in clinical guidance on appropriate treatment alternatives during a medicine shortage. They also play an important role in promoting appropriate use and the ethical and fair distribution of veterinary medicines to meet the needs of the sector. For example, in some cases, the action of stockpiling has been reported to precipitate a shortage.

4.7 Sectoral representative groups

Sectoral interests need timely access to veterinary medicines. In the case of some medicine shortages, stakeholders may need to be involved in both notifying the regulatory bodies of potential shortages but also communicating with their members of actions being taken to address the shortages. They can also provide their members with information on the shortage and possible alternative medicines.

5 PRINCIPLES OF THE PROTOCOL

The framework for dealing with a veterinary medicinal shortage is based on a commitment by all key stakeholders to the communication and management of a shortage according to the following principles:

- The health and welfare of animals is a top priority in all veterinary medicine shortage communication and responses.
- Veterinary medicine shortages are a multi-stakeholder responsibility, requiring the co-ordinated involvement of all stakeholders across the supply chain.
- Early notification and reports of a potential or actual veterinary medicine shortage is critical to helping to prevent or mitigate a shortage.
- The assessment of and response to veterinary medicine shortages may involve the co-ordination of advice and activities by a range of stakeholders and experts.
- Impact assessments, notifications, reports and updates to DAFM are reliable, timely, consistent and comprehensive.
- A co-ordinated response and communication of appropriate information are essential in handling shortages.
- The nature of a shortage can be varied and therefore responses to veterinary medicine shortages will be on a case-by-case basis and may require flexibility.
- Not all potential shortages will ultimately result in actual shortages.

6 VETERINARY MEDICINE SHORTAGES FRAMEWORK

Once a potential shortage has been identified, it is important to establish the nature of the shortage, the potential impact on the sector and to identify mitigation measures. The sections below provide details for stakeholders on these steps.

6.1 Notification or report of a medicine shortage

All stakeholders may report a possible shortage. Before reporting a possible shortage to HPRA/DAFM/Farming Associations/Wholesaler/MAHs, stakeholders should have exhausted other possible reasons for supply delays. The initial communication of an actual or potential shortage to DAFM is confidential. This is to allow potentially sensitive information relating to the shortage, including possible solutions, to be discussed between the stakeholder

and DAFM. However, it may be necessary for DAFM to communicate with other stakeholders and the public as appropriate in particular cases.

How and when to notify or report a shortage

For the purposes of clarity, a notification of a shortage comes from the MAH whereas a notification of a possible shortage may come from all other stakeholders. What form to use;

1. Where the notification comes from an MAH manufacturer or wholesaler, the notification form at Section 8 should be used (**Industry Notification Form**).
2. A notification to DAFM from all other sources, except the HPRA, is set out at Section 9.
3. The HPRA notification form to DAFM is set out in Section 10

For ease of use, the form should be completed electronically and emailed as an attachment to the dedicated email address: (vetmedshortages@agriculture.gov.ie).

The forms are also available for download on DAFM's website at the following link:

<https://www.agriculture.gov.ie/animalhealthwelfare/veterinarymedicinesresidues/veterinarymedicines/>.

In the event of a Shortage Notification to DAFM

Following notification to DAFM of a potential product shortage from HPRA or other stakeholders, DAFM will engage in discussions with the relevant stakeholder(s) to assist the industry in finding a solution. Each strategy will be particular to its own set of facts and circumstances and it is not possible for this protocol to map out all the possible variables and how to deal with each of them.

6.2 Impact assessment

The method described below is used by the HPRA for human medicines and may be used by stakeholders to assist them in determining the impact of the actual or potential shortage within the veterinary medicines sector. The impact assessment combines two main considerations:

- the availability of therapeutic alternatives and
- the expected impact on the sector.

Determination of impact level

Once the availability of therapeutic alternatives and expected impact on the sector are determined, the impact level of the shortage can be identified using the examples described below.

Impact levels

The impact assessment classifies medicine shortages into three types: low, medium and high impact shortages.

Low impact shortages

The potential response to a low impact shortage is based on the assumption that veterinary professionals will be able to manage the situation through professional expertise and access to information on the availability of the product.

Example: (Classification): *A shortage of one antibiotic product where there are several alternative products available*

Medium impact shortages

The potential response to a medium impact shortage is based on the assumption that veterinary professionals are reasonably able to manage the situation if they have access to timely information about supply arrangements.

Example: (Classification): *A shortage of a specific product e.g. pig sedative where there are no authorised alternative products in Ireland and a veterinary medicines special import licence may be sought to import a substitute product.*

High impact shortage

The required response is based on the assumption that veterinary professionals require highly specific and urgent information on the nature and anticipated duration of the shortage as well as details about supply arrangements and clinical guidance on substitute medicines or therapeutic alternatives.

Example: (Classification): *A batch failure of a large scale widely used vaccine where there is limited alternative product available.*

In cases where ‘impact’ cannot be determined, then ‘high’ impact status shall be applied.

6.3 Communication

Stakeholders, particularly animal healthcare professionals are better placed to address a shortage if there is appropriate communication. For example, timely communication of actual or potential shortages to animal healthcare professionals can facilitate changes to prescriptions, give time to source and introduce alternative therapies and reduce the impact on healthcare systems. The timing of the communication depends on the dynamics of the particular shortage. Not all potential shortages result in an actual shortage and therefore, communication of potential shortages may not be required.

Shortages will be communicated via the DAFM email address specifically set up for this purpose, particularly medium and high impact shortages. Low impact shortages will usually not be communicated nationally as many of these cases can be resolved by the Veterinary Practitioner / Pharmacist as part of good professional practice. The key information to be reported includes:

- The name of the medicinal product
- Target Species
- The active ingredient
- The marketing authorisation number
- The reason for the shortage
- The expected return date
- Company details for further information
- Additional information as needed (e.g. communication from the MAH)

On completion and transmission of the Notification Form to the DAFM dedicated email address, DAFM will undertake to consult with the key stakeholders involved in the notified shortage. DAFM will facilitate discussions to identify possible alternative products and issue the appropriate import licence(s).

As noted above, DAFM will not be held liable for any costs to industry arising from a shortage(s) solution.

High impact shortages may involve a range of stakeholders working together, sharing expertise and information, in which case additional communication media or additional communication by DAFM, the HPRA or MAH may be used.

Once normal supply has resumed and confirmation is sent to DAFM, either by the MAH or their representative (such as its nominated primary wholesaler), DAFM may then update their website to reflect the status of the shortage situation and closes the shortages case.

Veterinary Medicines Division will maintain a Register of products that are notified as being unavailable in the Market for monitoring purposes only. This register will not be publicised.

7 PREVENTATIVE STRATEGIES

In addition to the protocol for handling shortages, another feature of the multi-stakeholder approach is that through communication, stakeholders can develop and implement preventative strategies to reduce the likelihood of shortages occurring in the first instance. In many instances, these will be aimed at the underlying causes of shortages and would ensure that shortage prevention is actively considered as part of the life cycle management of the veterinary medicine.

8 SUMMARY

The purpose of the document is to outline a protocol for stakeholders to reduce the impact of shortages on the veterinary medicines sector. The protocol is part of an iterative process for the development of appropriate responses and efforts to mitigate against the risk of shortages. Whilst DAFM has a co-ordinating function, the importance of all stakeholders contributing to the management of shortages is essential to addressing the issue of veterinary medicine shortages in Ireland.

9 INDUSTRY NOTIFICATION FORM

Formal 'Industry Notification' of anticipated Veterinary Medicine Product Shortage

1 PRODUCT DETAILS

Product name

Target Species

Authorisation number(s)

Active substance(s)

Pharmaceutical form(s) and strength(s)

Name and address of authorisation holder

2 DETAILS OF THE SHORTAGE

What is the outcome of your assessment of the impact of a shortage of this product on the sector?

Low impact Medium impact High impact

Justification for the rating of the impact on this sector.

(please give consideration to the product's market share for this active/combination of actives in this strength and dosage form, target species and the possible impact of a shortage of a product with a large market share on the subsequent availability of suitable alternatives):

Reasons for shortage *(please give as much detail as possible; this helps us understand the impact on possible alternative products)*

What countries are impacted?

Global Multiple EEA countries Ireland and UK Ireland only

Please quantify the level of, and the expected duration of the shortage? Please indicate current available stock levels, if any?

What is the expected start date of the shortage?

(If the product is already short, please specify the date the shortage began)

What is the remaining inventory (in terms of weeks) within the entire supply chain?

(Please also include details of inventory at primary and secondary wholesale level)

What is the realistic expected return date of the product to market *(including the time required by wholesale distributor to complete quality checks)?*

Who is the primary wholesale distributor in Ireland?

3 COMPANY RESPONSE TO THE SHORTAGE

Please describe the proposed response to mitigate or resolve the shortage.

(taking into account the possibility of a batch specific request application to the HPRA, use of different strengths as possible mitigation actions)

What are the alternative medicinal products? *(This could include alternative products, which are placed on the market in Ireland, indicated for the condition and target species from different MAHs.)*

Is the company planning communication with animal healthcare professionals?

(If yes, please include the draft communication.)

Yes No

Please include any further relevant information if necessary. If the product is specialist use or has limited customers, please identify the customers.

All “Notifications” are to be forwarded to **vetmedshortages@agriculture.gov.ie** and a copy forwarded to **Vet Meds (ERAD) Division** at the address set out below;

An Roinn Talmhaíochta, Bia agus Mara,
Veterinary Medicines Section
Campas Bhacastúin,
Ascaill Steach Cuimne,
Cill Droichid,
Co. Chill Dara,
W23 X3PH.

Department of Agriculture, Food and the Marine,
Veterinary Medicines Section
Backweston Campus,
Stacumny Lane,
Celbridge,
Co. Kildare,
W23 X3PH.

10 SECTOR NOTIFICATION FORM

FORMAL NOTIFICATION BY END-USER (FARMER, VETERINARY INSPECTOR, PHARMACIST, LICENCED MERCHANT) OF VETERINARY MEDICINE PRODUCT SHORTAGE

1	VETERINARY MEDICINE DETAILS – WHERE AVAILABLE
<p>Product name</p> <p>Target Species</p> <p>Authorisation number(s) If known;</p> <p>Active substance(s), if known</p> <p>Pharmaceutical form(s) and strength(s) (e.g. 30 mg tablet, 300 mg/ml oral solution)</p> <p>Name and address of authorisation holder, if known;</p>	
2	DETAILS OF THE SHORTAGE
<p>What is the outcome of your assessment of the impact of a shortage of this product in your business?</p>	
<p><input type="checkbox"/> Low impact <input type="checkbox"/> Medium impact <input type="checkbox"/> High impact</p>	
<p>Please see 5.2 Impact Assessment for guidance here.</p>	
<p>Justification for the rating of the impact on your business</p>	
<p><i>(please give consideration to the product's market share for this active/combination of actives in this strength and dosage form, target species and the possible impact of a shortage of a product with a large market share on the subsequent availability of suitable alternatives):</i></p>	
<p>Reasons for shortage as you understand it <i>(please give as much detail as possible; this helps us understand the impact on possible alternative products)</i></p>	
<p>Date on which you became aware of the shortage?</p>	
<p>What is the remaining inventory (in terms of weeks) available to you? <i>(please give details if you are aware of other supplies of this product at primary and secondary wholesale level)</i></p>	
<p>Who is your primary provider of this product in Ireland?</p>	
3	DETAILS OF PERSON NOTIFYING
<p>Name</p> <p>Address</p> <p>Business/Occupation</p> <p>Email Address</p> <p>Telephone</p> <p>Date</p>	

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An Roinn Talmhaíochta, Bia agus Mara, Veterinary Medicines Section Campas Bhacastúin, Ascaill Steach Cuimne, Cill Droichid, Co. Chill Dara, W23 X3PH.	<i>Department of Agriculture, Food and the Marine,</i> Veterinary Medicines Section Backweston Campus, Stacumny Lane, Celbridge, Co. Kildare, W23 X3PH.
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11 HPRA NOTIFICATION FORM

'HPRA Notification' of anticipated Veterinary Medicine Product Shortage

<p>1 PRODUCT DETAILS</p> <p>Product name</p> <p>Target Species</p> <p>Authorisation number(s)</p> <p>Active substance(s)</p> <p>Pharmaceutical form(s) and strength(s)</p> <p>Name and address of authorisation holder</p>
<p>2 DETAILS OF THE SHORTAGE</p> <p>Please indicate what the HPRA expect will be the likely impact of a shortage on the sector?</p> <p><input type="checkbox"/> Low impact <input type="checkbox"/> Medium impact <input type="checkbox"/> High impact</p> <p>Reasoning for the rating of the impact on this sector</p> <p><i>Please outline reasons for this rating:</i></p> <p>Reasons for shortage (<i>please give as much detail as possible; this helps us understand the impact on possible alternative products</i>)</p> <p>What countries are impacted?</p> <p><input type="checkbox"/> Global <input type="checkbox"/> Multiple EEA countries <input type="checkbox"/> Ireland and UK <input type="checkbox"/> Ireland only</p> <p>If reported, please quantify the level of, and the expected duration of the shortage? Please indicate current reported known available stock levels, if any?</p> <p>What is the expected start date of the shortage?</p> <p><i>(If the product is already short, please specify the date the shortage began)</i></p> <p>If known, what is the remaining inventory (in terms of weeks) within entire supply chain?</p> <p><i>(Please also include details of inventory at primary and secondary wholesale level)</i></p> <p>If known, what is the realistic expected return date of the product to market (<i>including the time required by wholesale distributor to complete quality checks</i>)?</p>
<p>3 DETAILS OF PERSON NOTIFYING</p> <p>Name</p> <p>Email</p> <p>Telephone</p> <p>Date</p>

All "Notifications" are to be forwarded to vetmedshortages@agriculture.gov.ie and a copy forwarded to **Vet Meds (ERAD) Division** at the address set out below;

An Roinn Talmhaíochta, Bia agus Mara, Veterinary Medicines Section Campas Bhacastúin, Ascaill Steach Cuimne, Cill Droichid, Co. Chill Dara, W23 X3PH.	<i>Department of Agriculture, Food and the Marine,</i> Veterinary Medicines Section Backweston Campus, Stacumny Lane, Celbridge, Co. Kildare, W23 X3PH.
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