

# VETERINARY PHARMACOVIGILANCE IN IRELAND

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## INTRODUCTION

In Ireland, the Irish Medicines Board (IMB) is responsible for the system of authorising and monitoring veterinary medicinal products which are subject to national authorisation. There are currently 1469 veterinary medicine products (VMPs) authorised by the IMB (the list of authorised products can be accessed at [www.imb.ie](http://www.imb.ie)). In addition, products authorised by the European Commission ([www.emea.europa.eu](http://www.emea.europa.eu)) may be supplied in Ireland.

Pharmacovigilance is one of a range of post authorisation activities designed to ensure the ongoing production and use of safe, effective, high-quality veterinary medicines following their introduction to the marketplace. Pharmacovigilance data, in particular reports of suspected adverse reactions (SARs) in treated animals, are collected and scientifically evaluated by the IMB. The scope of veterinary pharmacovigilance covers not only SARs in animals occurring after VMPs are used under normal conditions, but also includes the following aspects of post-authorisation surveillance:

- Adverse reactions in humans related to the use of VMPs;
- Reports of lack of efficacy of a VMP when used in accordance with label recommendations;
- Adverse reactions associated with 'off-label' use of VMPs;
- Reported violations of approved residue limits, possibly leading to investigations of the validity of the withdrawal period;
- Adverse environmental effects resulting from contamination with a medicine.

The monitoring of such events, known collectively as suspected adverse events (SAEs), is important as pre-authorisation safety studies, while extensive and robust, are typically conducted in relatively small numbers of animals, under controlled conditions of use. Therefore, information relating to post marketing experience is very valuable, in that certain safety issues (for example, adverse reactions that occur rarely or are specific for

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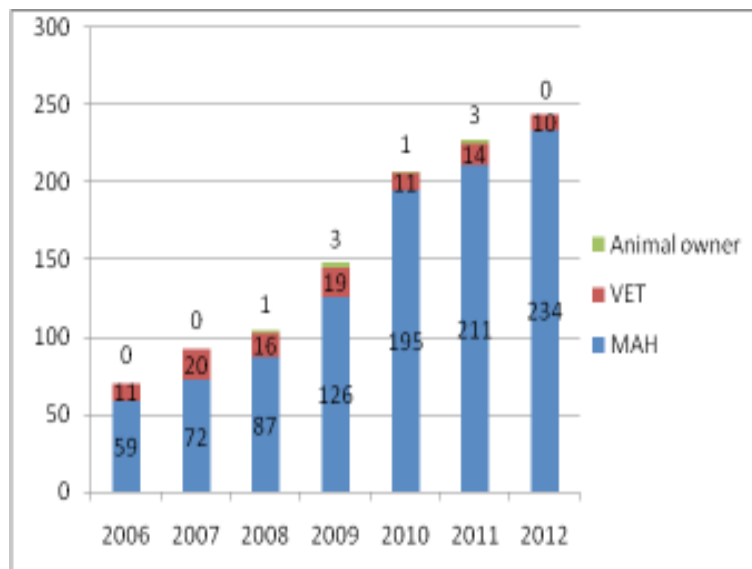
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certain breeds or groups of animals) may only come to light when the product is in the hands of the intended user and is being used on large number of target animals.

A well-defined safety profile of authorised veterinary products is essential for selecting the right treatment in veterinary practice. Therefore it is essential that all SAEs are brought to the attention of the IMB to enable it to continuously monitor the benefit:risk profile and to introduce labelling improvements as necessary. This is the basis on which the IMB can give appropriate advice on safe and effective use of authorised veterinary medicines.

### REPORTING OF SUSPECTED SAEs IN IRELAND

Typically these events are reported by veterinarians and animal owners either directly to the IMB, or to the company responsible for marketing the product, known as the Marketing Authorisation Holder (MAH). In accordance with Ireland’s national legislation (Animals Remedies Regulations, S.I. No. 786 of 2007), veterinary practitioners and other suppliers of VMPs are required to report suspected serious or unexpected adverse reactions or human adverse reaction to the IMB or the MAH within 15 days of receipt of such information. In turn, MAHs are required to report all serious SAEs to the IMB at the earliest opportunity and not later than 15 days following receipt of the information. The majority of SAE reports received by the IMB are from MAHs (Figure 1.)



**Figure 1. Number of SAE reports received by the IMB from 2006 to 2012.**

When a report of a SAE is received by the IMB directly from a veterinarian, other health care professional or animal owner, the MAH of the product is notified by the IMB, and may be asked to provide additional information that is necessary for the IMB to conclude its assessment. All information in the report is treated in the strictest of confidence and any individual's personal data, such as the name and address of the reporter, is not disclosed.

There are a number of ways in which animal owners or health professionals can report adverse events to the IMB, this includes downloading report forms from the IMB website for offline completion and submission via post, completing and submitting an on-line report form, or pre-paid self-addressed forms can be requested from the veterinary department of the IMB. MAHs and the IMB exchange SAE reports by electronic means using EudraVigilance Veterinary (EVVet), a European data-processing network and database management system for the exchange, processing, and evaluation of SAEs related to veterinary medicinal products; this provides a fast and secure way to share information.

A SAE report will be considered as valid provided that at least the following core data are available:

- An identifiable reporter (e.g. veterinary surgeon, pharmacist, animal owner)
- Animal/human details: species, age, sex
- Suspect product: name and authorisation number

#### - Reaction details

It should be stressed that these are minimum requirements and the reporter should endeavour to be as comprehensive as possible in order to facilitate a full scientific evaluation. Where relevant, this may include laboratory findings and post mortem examination findings.

Based on the available information an assessment of the casual relationship between the administration of the medicine and the reported reaction is made by the IMB. Typically, the receipt of single reports will not result in any action by the IMB. However, should a pattern of adverse reactions for a specific product emerge, regulatory actions to enhance the safety of the product will be initiated depending on the conditions under which the adverse reactions have appeared and on their seriousness (for example, labelling changes such as new safety warnings, contraindications or human safety information; suspension of the sale and supply of the product from the market until the safety issues are solved; etc.).

During 2012, there were 244 reports of suspected adverse events associated with the use of veterinary medicinal products received by the IMB. This represents an increase of 7% compared to the number of reports received in 2011.

The breakdown of the 244 reports is as follows:

- " 117 related to suspected adverse reactions in treated animals

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| " 116 related to suspected lack of expected efficacy   | • Reports related to off-label use   |
| " 10 involved suspected adverse reactions in individual users following exposure to a veterinary medicinal product | • Environmental problems   |
| " One related to a violation of approved residue limit in foodstuffs of animal origin.                             | • Investigations of the validity of withdrawal periods   |
|  | • All adverse reactions in humans  |
|  | • A benefit/risk assessment, revised to take into account of the post-authorisation safety experience. |

### **PERIODIC SAFETY UPDATE REPORT (PSUR) ASSESSMENTS**

In addition to receiving and recording individual adverse event reports associated with veterinary products, the veterinary pharmacovigilance department also assess PSURs (in 2012, PSURs for a total of 805 products were assessed which compares to 559 for 2011, this represents a 44% increase). A PSUR is intended to provide an update of the world-wide safety experience of a VMP and allow for detection of new signs or signals. They are submitted to the IMB by MAHs in respect of each authorised veterinary medicine, at defined intervals following the initial authorisation of the product. In accordance with EU legislation, the report should include information on all types of adverse events associated with the particular product received during the reporting period. PSURs are required to include:

- All (serious & non-serious) adverse reactions in animals
- Lack of expected efficacy reports

### **PHARMACOVIGILANCE INSPECTIONS**

The IMB also carries out inspections of pharmacovigilance systems of MAHs located within Ireland. To ensure their ability to efficiently monitor and report adverse events, the MAH is expected to:

- Have an appropriately qualified person responsible for veterinary pharmacovigilance permanently and continuously at its disposal.
- Establish a system that ensures detailed records of all SAEs occurring in the community or third country are maintained.
- Report serious SAEs and all human adverse reactions to the IMB within 15 calendar days.
- Prepare and submit PSURs to the IMB.

The IMB participated in two inspections of a pharmacovigilance system at a marketing authorisation holder's premises during 2012.

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