Association of Veterinary Consultants

Benefits of AE Reporting

Declan O'Rourke MVB FRCVS

Focus group on promotion of PhV for food producing animals

23 Nov 2016

Why Report?

Association of Veterinary Consultants

Table 1. Number of exposed animals needed to detect true frequencies of adverse events (AEs)

	Statistical power			
Frequency of AE	95%	90%	80%	63%
1 in 100	300	231	161	100
1 in 500	1,500	1,152	805	500
1 in 1,000	3,000	2,303	1,610	1,000
1 in 5,000	15,000	11,513	8,048	5,000
1 in 10,000	30,000	23,026	16,095	10,000
1 in 50,000	150,000	115,130	80,472	50,000

O'Rourke, D.J. (2016) Adverse events – vets have a key role. *Veterinary Practice Today*, 4(2):23-26.

Association of Veterinary Consultants

But then….Practice….

- larger number of animals
- combinations with ….
- other environmental conditions
- other species
- off label use: dosage/time
- age/condition
- ..sometimes….product failures

Association of Veterinary Consultants

The safety profile of a VMP evolves over its lifetime on the market

Front Line

Association of Veterinary Consultants

- Vets in practice are in the front line.

Association of Veterinary Consultants

IF IN DOUBT REPORT IT

Benefits of Reporting

Association of Veterinary Consultants

VACCINE-VACCINE REACTION

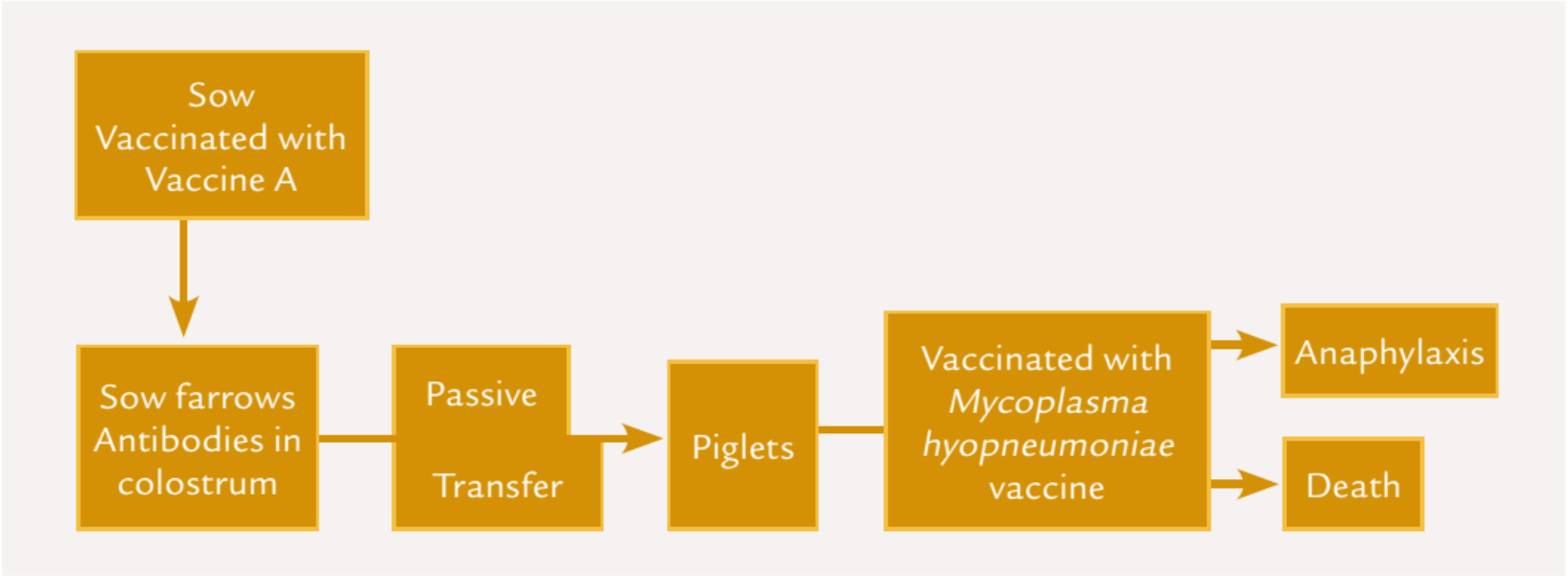


Figure 1. *Flow chart of the sequence of serious adverse events in piglets following the administration of a* Mycoplasma hyopneumoniae *vaccine*

O'Rourke, D.J. (2016) Adverse events in Livestock. *Veterinary Practice Today*, 4(3):46-49.

Association of Veterinary Consultants

LACK OF EFFICACY

- It is important that these reports are investigated as they can lead to identification of key issues in relation to the benefit-risk assessment of the product

- In 2007 the VMD received 67 reports (out of a total 166 SLEE reports) that involved ectoparasiticides indicated for the control of blowfly in sheep
- A heavy blowfly challenge in 2007 and product misapplication appeared to have been factors involved in treatment failure
- Climatic conditions that prevailed in 2007 may also have had an influence

Dyer F, Spagnuolo-Weaver M, Cooles S & Tait A (2008) Suspected adverse reactions, 2007. *VetRec* 163: 69-72

Benefits of Reporting

Association of Veterinary Consultants

- 83 groups of cattle reported suspected lack of expected efficacy, representing 1.6 per cent of the 804,618 BRD vaccine courses sold.
- It was possible to investigate 45 of these outbreaks in depth using a standard questionnaire and diagnostic protocol.
- The proportion of vaccination courses used where a pathogen contained in the vaccine was detected in the diseased cattle and vaccine use was consistent with the SPC was estimated at 0.12 per cent of the courses sold.
- Multiple pathogens were detected in 19 outbreaks (42.2 per cent), most commonly two pathogens, which were detected in 17 outbreaks (37.8 per cent).
- Bacterial pathogens were detected in 32 of 35 outbreaks where a diagnosis was made.

Crawshaw, WM and Caldow, GL (2015) Field study of pneumonia in vaccinated cattle associated with incorrect vaccination and *Pasteurella multocida* infection *Vet Rec* 176: 434

Benefits of Reporting

Association of Veterinary Consultants

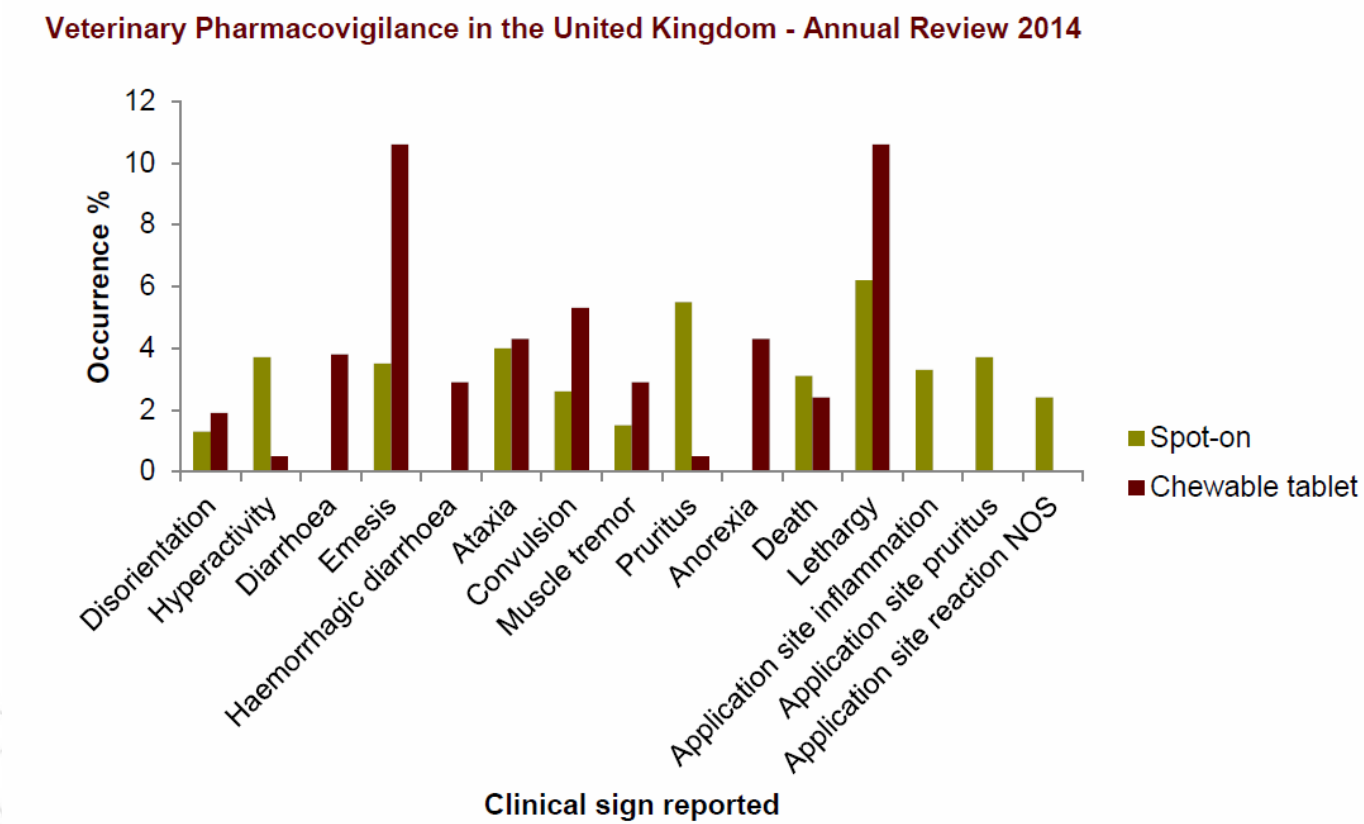


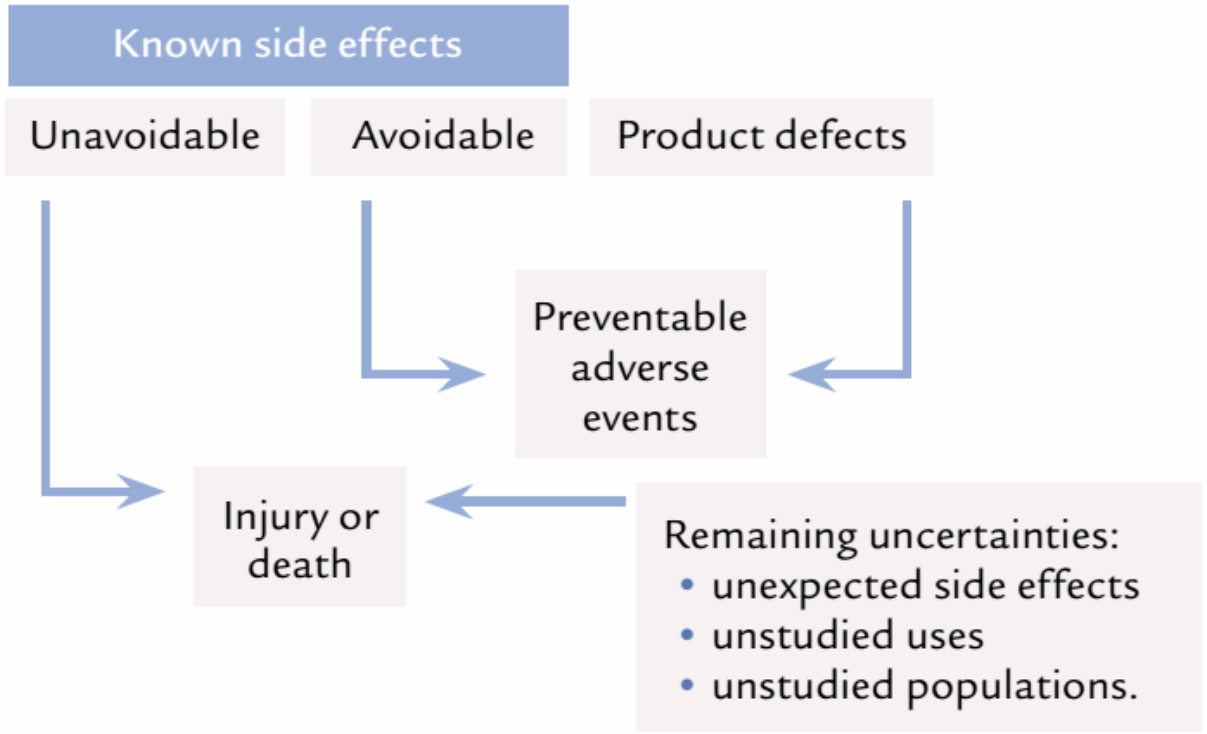
Figure 12. Comparison of the occurrence of the most commonly reported clinical signs for spot-on and chewable tablet products for the treatment of external parasites in dogs [NOS – not otherwise specified (not described)]

Veterinary Pharmacovigilance in the United Kingdom: Annual Review 2014
(https://www.gov.uk/government/publications/veterinary-medicinespharmacovigilance-annualreview-2014).

Adverse events are preventable

Association of Veterinary Consultants

Figure 3. *Sources of risk from veterinary medicinal products. (Adapted from FDA, 1999)*



O'Rourke, D.J. (2016) Adverse events – vets have a key role. *Veterinary Practice Today*, 4(2):23-26.

Association of Veterinary Consultants

I ♥ PHARMACOVIGILANCE