** *Business Guide Update*

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suspension of velactis following adverse events in dairy cattle

**Veterinary Medicines Directorate (VMD) has suspended the use of the veterinary medicine Velactis used in dairy cows at the time of drying off following reports of serious adverse events in cows, including recumbency and deaths**

Summary

* Velactis is used as an aid in the abrupt drying-off in dairy cows and has been linked to several cases of recumbency and deaths.
* As a result of the serious cases, the authorisation of Velactis is being suspended.
* Users are advised to stop using Velactis in dairy cows and use alternative methods for dry off.
* Users who have any questions should contact their veterinarian or national veterinary medicines authority.

Background

1. The VMD has suspended the marketing and use of Velactis in the UK.
2. This prescription only veterinary medicine, marketed by CEVA Sante Animale, the Marketing Authorisation Holder (MAH) contains the active substance cabergoline, and is used in the herd management programme of dairy cows as an aid in abrupt drying-off, by reducing milk production.
3. The product was authorised through the European Medicines Agency (EMA) in December 2015 and was first sold in the UK in April 2016.
4. The withdrawal follows reports of adverse events in 319 dairy cows after treatment with Velactis. Many of the adverse events were serious, including recumbency (lying down and being unable to stand) in 208 animals, which generally occurred within 24 hours of administering Velactis. In total, there were 71 reported deaths in cows, most after a period of recumbency.
5. Anecdotal evidence suggests that hypocalcaemia treatments may be successful in reversing clinical signs.
6. Although the exact cause of these adverse events is yet to be determined, there is evidence to suggest that they may be linked to the use of Velactis. Given the number and severity of adverse events following use of the medicine in otherwise healthy dairy cows, the European Medicines Agency (EMA) concluded that, at present, the risks outweigh the benefits of the product.
7. CEVA Sante Animale stopped further distribution of the product in Europe last month pending the outcome of an (urgent) review by the EU’s scientific committee, The Committee for Medicinal Products for Veterinary Use (CVMP). The CVMP has now advised the European Commission to suspend the authorisation of Velactis and to order Ceva Sante Animale to recall the product from the supply chain pending the outcome of further investigations to assess a possible causal link between the product and the adverse events reported. The nature and use of the product means that there is no risk to human health or consumer safety.
8. The use of Velactis in the UK is now suspended.
9. CEVA Sante Animale has initiated a voluntary product recall.
10. We strongly encourage vets and farmers to submit to the VMD any outstanding reports of adverse events associated with use of Velactis using our [online reporting form](https://www.gov.uk/report-veterinary-medicine-problem) or directly to CEVA Sante Animale for further investigation by the MAH as necessary.