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	Email:	
d Southampton	Our Ref:	9 January 2025
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Dear Mr Burge

The Castle Winchester SO23 8UL

Thank you for your Report to Prevent Future Deaths of 14 November 2024 informing us of the death of John Ellis on 6 November 2022. We were sorry to hear of his passing and pass on our sincere condolences to his family and friends.

For background, the Veterinary Medicines Directorate (VMD) is an executive agency of the Department of the Environment, Food and Rural Affairs (Defra). We promote animal health and welfare by assuring the safety, quality and efficacy of veterinary medicines.

However, we should explain that the Home Office is responsible for the legislation regarding controlled drugs. That includes controlled drugs used for veterinary purposes and/or human use. The VMD has no regulatory powers to make changes to controlled drugs legislation.

We do provide guidance on the use and storage of veterinary controlled drugs on our website and are producing an article which we aim to publish shortly on our blog page reminding vets of their responsibilities when ordering, storing, supplying and using controlled drugs.

The Royal College of Veterinary Surgeons (RCVS) also has published very useful guidance online for controlled drugs where they state that whilst pentobarbital is not subject to safe custody requirements, it should be kept locked in a suitable controlled drugs cabinet when not in use. We echo that guidance and during inspections we ensure vets are aware that they are responsible for these products, that they are stored appropriately, and access is only given to persons they have authorised to have access.

We also include a link to the Vetlife website in our inspection reports to vet practices. Vetlife is a charity that provides independent, confidential and free emotional, financial and mental health support to the veterinary community including veterinary nurses, students and nonclinical staff.

Your report highlighted concerns around how Mr Ellis was able to procure the drug in this situation and whether adequate controls are in place to stop such instances occurring in the future.

The Veterinary Medicines Regulations 2013 (as amended) (VMR) sets out the rules that must be followed for the supply of all veterinary medicines. These regulations were amended in 2024, however the previous version of the regulations were in effect at the time that Mr Ellis appears to have obtained the medicine.

The VMR in effect at the time states in Schedule 3 paragraph 2 regarding the wholesale supply of veterinary medicines that:

- (1) Only a holder of a marketing authorisation, the holder of a manufacturing authorisation or the holder of a wholesale dealer's authorisation granted by the Secretary of State may supply a veterinary medicinal product wholesale, or be in possession of it for that purpose.
- (2) A person mentioned in sub-paragraph (1) may only supply a veterinary medicinal product if
 - a. The authorisation in question relates to that product, and
 - b. The supply is to another person who is entitled to supply that product under these Regulations, either wholesale or retail.
- (3) If the supply is to a suitably qualified person, it must be to the premises approved in accordance with paragraph 14.
- (4) It is immaterial whether or not the supply is for profit.
- (5) This paragraph does not apply in relation to a retailer of veterinary medicinal products who supplies another retailer with such products for the purpose of alleviating a temporary supply shortage that could be detrimental to animal welfare.

For retail supply, Schedule 3 paragraphs 3, 4 and 5 apply which states that a medicine with the legal category POM-V (Prescription Only Medicine – Veterinarian) may only be supplied by a vet or pharmacist and must be supplied in accordance with a prescription from a vet.

The person supplying it either must have prescribed the medicine themselves or it must be supplied to them under a written prescription that includes all the information required by the VMR.

The person supplying the medicine under a written prescription may only supply the product specified in the prescription, must take all reasonable steps to be satisfied that the prescription has been written and signed by a person entitled to prescribe the product and must take all reasonable steps to ensure that it is supplied to the person named in the prescription.

Without having more information of how the supply took place it is difficult to state categorically whether the supply was in line with the VMR or not. If you can provide further information of where the medicine was procured, then we can investigate how the supply took place and whether it was in accordance with the VMR.

If we identify, or receive information to say that someone has breached the VMR then we take appropriate action in line with our published Enforcement Policy: <u>Enforcement policy</u> for animal medicines – GOV.UK

We also conduct risk-based inspections of vet practices and wholesalers to check their compliance with the requirements of the regulations. The RCVS conducts assessments of vet practices that are part of their Practice Standards Scheme where RCVS assessors will check compliance with the VMR as part of their assessment.

Guidance on our inspection processes and actions that we may take where we identify noncompliance can be found on our website: <u>Retail of veterinary medicines - GOV.UK</u> <u>Apply for veterinary medicine wholesale dealer's authorisation (WDA) - GOV.UK</u>

Yours sincerely

Head of the Inspections and Enforcement Division