

## **Disbudding Goats – The Legal Perspective on Anaesthesia**

With changes in the Veterinary Medicines Regulations (VMR) since the GVS Disbudding DVD was produced and an increasing focus on food safety and medicines residues, The GVS believes it is time to clarify the legal situation with the use of anaesthetic agents in goats.

The anaesthetic protocols discussed and demonstrated in the DVD use agents which have been widely used in a range of species and are still believed by the Goat Veterinary Society to be safe and effective methods of inducing anaesthesia for the purpose of disbudding goat kids. Regrettably, many of the agents are not permitted under the VMR and their use would technically constitute a breach of the Regulations.

This addendum to the Disbudding DVD is intended to explain the legal situation; which agents may be used legally and which may not. The Goat Veterinary Society is aware that practitioners may well be put in difficult situations if they believe a particular, non-permitted agent is the most appropriate for a given clinical situation. Unfortunately, the Society cannot be prescriptive in telling veterinary surgeons how to act and the responsibility remains entirely with the individual. However, it is our intention that veterinary surgeons should at least be fully informed.

The Law.

1. Goats are considered a 'food producing species'. There is no legal provision for 'pet' goats and therefore the same legislation applies irrespective of whether or not the individual animal is being kept with the intention of producing meat or milk for human consumption.
2. Currently, Anaestamine (100mg/ml solution for injection of Ketamine, Animalcare Ltd) is the only anaesthetic agent licensed in the UK for use in goats. Veterinary Surgeons should also be aware that as from 30<sup>th</sup> November 2015, Ketamine was reclassified as a Controlled Drug from Schedule 4 to Schedule 2 with all the additional requirements for purchase, storage, prescribing, administering, disposal and record keeping. It is not within the remit of this document to list these.
3. There may be occasions where a clinician considers the condition of the animal or procedure being undertaken makes Ketamine unsuitable as an anaesthetic of choice and an alternative is necessary. In any event, when used for general anaesthesia, Ketamine is most usually used in combination with other agents which are unlikely to have marketing authorisations for goats in the UK.

Therefore, in most cases of anaesthesia in the goat, the provisions of the 'Cascade' apply.

a. The Cascade

*If there is no authorised veterinary medicinal product in the United Kingdom for a condition the veterinary surgeon responsible for the animal may, in particular to avoid unacceptable suffering, treat the animal concerned with the following (“the cascade”), cascaded in the following order—*

*(i) a veterinary medicinal product authorised in the United Kingdom for use with another animal species, or for another condition in the same species; or*

*(ii) if there is no such product that is suitable, either—*

*(a) a human medicinal product authorised in the United Kingdom; or*

*(b) a veterinary medicinal product not authorised in the United Kingdom but authorised in another member State for use with any animal species (in the case of a food producing animal, it must be a food-producing species); or*

*(iii) if there is no such product that is suitable, a veterinary medicinal product prepared extemporaneously by a pharmacist, a veterinary surgeon or a person holding a manufacturing authorisation authorising the manufacture of that type of product.*

*(iv) In the case of a veterinary medicinal product imported from another member State, if the veterinary surgeon has not obtained a certificate from the Secretary of State under regulation 25(5) permitting importation, the veterinary surgeon must obtain a certificate from the Secretary of State before administration.*

***(v) Any pharmacologically active substances included in a medicinal product administered to a food-producing animal under the cascade must be listed in Table 1 in the Annex to Commission Regulation (EU) No 37/2010. (emphasis added)***

Links to the full VMR, guidance on the Cascade and EU regulation 37/2010 are below:

[http://www.legislation.gov.uk/uksi/2013/2033/pdfs/uksi\\_20132033\\_en.pdf](http://www.legislation.gov.uk/uksi/2013/2033/pdfs/uksi_20132033_en.pdf)

<https://www.gov.uk/guidance/the-cascade-prescribing-unauthorised-medicines>

[http://ec.europa.eu/health/files/eudralex/vol-5/reg\\_2010\\_37/reg\\_2010\\_37\\_en.pdf](http://ec.europa.eu/health/files/eudralex/vol-5/reg_2010_37/reg_2010_37_en.pdf)

The practical effect of the provisions of the Cascade are that the active ingredient(s) of any medicine (including anaesthetics) used in goats must be listed in Table 1 of EU 37/2010.

Our understanding of this regulation is that the only products in Table 1 of potential use, either alone or in combination are:

Xylazine, detomidine, romifidine, isoflurane, ketamine (licensed), thiopental sodium, lignocaine/lidocaine, mepivacaine, procaine and butorphanol.

NB. The agent atipamezole, commonly used to reverse the sedative effects of alpha2 agonist sedative agents, is **NOT** listed on EU37/2010 and therefore its use is **NOT** legally allowed.

It should also be remembered that there are additional recording requirements for veterinary medicines used under the Cascade and a requirement to set appropriate meat and milk withdrawal periods. Readers are advised to refer to the VMR guidance:

<https://www.gov.uk/guidance/record-keeping-requirements-for-veterinary-medicines>

or BVA members can download the BVA's Good Practice Guide on Veterinary Medicines from

<http://www.bva.co.uk/Workplace-guidance/Medicines/veterinary-medicines-good-practice-guide>

It is acknowledged that there is no legal provision for the use of many safe and effective anaesthetic agents and the Goat Veterinary Society regrets that it is unable to resolve all conflicts between clinical need and legislation. Nevertheless, the Society welcomes any comments and debate around the subject.

**The information contained in this advice note is believed to be correct at the time of printing but veterinary surgeons should always check for any changes in the legislation or marketing authorisations (data sheets) of the relevant veterinary medicines.**

**Goat Veterinary Society     February 2016**