Title: Labelling of Medication

Author: Lee Grist

- [Lee] Hello, and welcome to this presentation on the labelling of veterinary medicines. My name is Lee Grist, and I am the head of the Distribution and Supply Chain Inspections Section at the Veterinary Medicine Directorate. The Distribution and Supply Chain Inspections Section deals with inspections of veterinary wholesalers, veterinary retailers, such as vet practises and SQPs, and medicated feed manufacturers and distributors. On completion of this module, participants should have a greater understanding of the regulatory requirements for labelling of veterinary medicines. This includes the differences between using medicines for the purposes they were authorised, and for cascade medicines.

Let's start by looking at the Veterinary Medicines Regulations 2013, the VMR, and what it says there. Labelling is covered in several sections. Schedule 1, Part 7 looks at labelling for authorised medicines. Schedule 2, Part 2 looks at labelling requirements for autogenous vaccines. Schedule 2, Part 3 is the labelling requirements for blood banks. Schedule 2, Part 4 is the labelling requirements for manufacturers of products to be used under the cascade. Schedule 2, Part 5 is labelling requirements for equine stem cell centres. Schedule 3, paragraph 12 is the labelling at the time of retail supply. Schedule 3, paragraph 13 is the labelling of cascade medicines at the time of retail supply. And Schedule 5, paragraph 12-14 deal with the labelling of medicated feeding stuffs.

So, whilst that seems like a long and exhaustive list, our main focus is going to be on two areas here. This is an authorised product's labels and how they have to be labelled at the time of retail supply, which is Schedule 1, Part 7 and Schedule 3, paragraph 12, and the labelling requirements for cascade medicines at the time of retail supply, which is Schedule 3, paragraph 13. Schedule 1, Part 7 deals with the labelling requirements for authorised medicines. In here, it lists all the information that must be included on a product's packaging, whether that's the label or the leaflet, such as wording to indicate that the product is authorised in the UK, the fact that it must be in English, the name, strength, and form of the medicine and of each active ingredient, the route of administration, if not immediately apparent, the batch number, expiry date, and details of content such as the weight and volume of product, the target species and marketing authorization number, the name and address of the marketing authorization holder or distributor, and space to record the discard date, if relevant. The label must state for animal treatment only and keep out of reach of children. It must include the distribution category, POM-V, NFA-VPS, et cetera, storage instructions and in-use shelf life, if appropriate, withdrawal period for each species for food-producing animals, any specific warnings and full indications, dosage instructions and contra-indications, disposal advice, any further information required in the marketing authorization, and space to state the dose required for the animal being treated, if applicable.

Now we look at labelling at the time of retail supply, Schedule 3, paragraph 12. If the medicine is in the authorised container, and has not been prescribed under the cascade, then there is no legal

requirement under the VMR to add any further labels. The label information on the product is specifically authorised to provide essential information for its safe and effective use. However, the RCVS and VMD both consider it good practise for dispensing labels to be used, and this is a requirement if you are part of the Practise Standards Scheme, the PSS. If a dispensing label is used, then you must ensure that none of the information is obscured on the authorised packaging. There will be warnings for the animal keeper or owner on there, and it's vital that they can clearly see this information. The only exception to this is if the vet, or pharmacist under a vet's prescription, amends the label to reflect the prescription, such as to change the dose. However, no other information can be obscured. If the medicine is not supplied in the authorised container, then the person supplying it must ensure that enough information is provided to enable the product to be used safely. This is achieved by suitably labelling the product and supplying sufficient written information such as the SPC or packaged leaflet. Suitably labelled is not specified in the VMR. However, the information required for the cascade labels may be classed as suitable.

Here we have two examples of unauthorised containers and unsuitable labelling being used. There's no information on target species, the expiry date of the product, or any safety warnings or contraindications. Let's now look at the labelling of cascade medicines at the time of retail supply. So cascade use covers the following situations: imported medicines, human medicines, medicines for different species, where the vet has decided that a reduced dose or greater dose is required for this specific situation, or an extemporaneous preparation. In this situation, there are specific labelling requirements, even if the authorised packaging is used.

We've highlighted a couple of things here because these are the requirements that are most frequently missed off of cascade labels. So one is the prescribing vet's name or identification, and the other is the species of animals being treated. But if we go down the full list, it's the name and address of the premise supplying the medicine, the name of the prescribing vet, the name and address of the owner, the identification of the animal or group of animals, including the species, the date of supply, the expiry date, the name or description of the product, which should include at least the name and quantity of active ingredients, dosage and administration instructions, any specific storage requirements/precautions, any necessary warnings for the user, target species, administration, or disposal, a very important one, the withdrawal period, and keep out of reach of children and for animal treatment only.

We're now going to look at broach date labelling. Some medicines will have specific broach limits on them or in-use shelf lives. This could be 10 hours, it could be immediate discard, but the most common one we see is 28 days. And product should be labelled appropriately so that everyone knows when they can be used up to and when they were opened. Once the broach limit has passed, it is an offence for anyone to administer that product to an animal. This is covered in the VMR by Regulation 8. So it's important to have a system in place to ensure that broach limits aren't exceeded. Whatever that system is, must be effective.

It's important to carry out regular stock checks to ensure that only in-date medicines are being used and are available to people. If a bottle has been broached and no date has been marked on the bottle, them this should also be immediately discarded, because you can not guarantee when that bottle was opened. You can find further information on the retail supply of veterinary medicines by using this link to the VMD's website