

Title: Legal and responsible use

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- This module, we'll talk about the responsible and legal use of antibiotics. My name's Pam Mosedale. I'm a vet, I'm the QI clinical Lead of RCVS knowledge. The module in total, I will talk about prescribing, supplying, dispensing POM-V antibiotics, storage, recording and labelling. The cascade pharmacovigilance, and how it all applies to the RCVS Practise Standards Scheme. This part of the module, we'll talk about the legal and ethical prescribing, supplying and dispensing of POM-V antibiotics.

So the most important thing, is that we keep medicine safe and that we use them responsibly and within the law. And that we're happy that the medicines that we used are going to work. So how does that happen? Well, the things are on the chain to make sure the medicines are going to work are, making sure that medicines are manufactured in a consistent way and are always high quality, controlling the supply proportionate to risk which VMD do, and providing the appropriate level of professional advice with the medicines, which is what they do by classifying medicines according to who can prescribe them. So, we're going to talk about that now.

So, all medicines, when they are manufactured, have to comply with certain standards of safety, quality, and efficacy. This picture shows, and this is an old picture, I would admit, because, now, the data to the VMD goes on memory sticks, so it doesn't look quite sort of impressive. But this picture shows the amount of data required to get one medicine, which is authorised for one indication of one species only, through its safety, quality and efficacy, which is what those three piles are. So, you can say that for a medicine, which has multiple indications, or is used for multiple species, the amount of data that goes to VMD, used to arrive on pallets. But these days, a Sage, some memory sticks. So, not so spectacular to look at in a photograph. So how can we know that medicines have gone through that, while they're given a marketing authorization? So, all medicines that are authorised veterinary medicines, have either a VM number or an EU number. The VM number has the first numbers to do with the company, and the second number for the product. The EU number is also shown there. And gradually, since Brexit, all medicines were transported having a VM number, But these numbers on the pack, showing that it is a proper authorised veterinary medicine. Why can we not rely on that? Because it's been tested for safety, efficacy and quality, as I said, safe for who? Or safe for the animal obviously, safe for the user or the farmer, obviously, and safe for the environment too. Efficacy just means it works, does what it says on the tin run sale. If it says, it kills a particular kind of worm in sheep, then that's what it should do. Quality, every batch is the same, every batch pure and stable.

Also, on the pack you should find a batch number and that's there for traceability. So it ensures if there's a problem with the project, there's a problem with a specific batch, that batch can be traced.

And that's the reason for having to record the batch number all the time. If we're food producing animals, So it's easy to do a product recall if necessary, or easy to see which animals have had the medication. There's also an expiry date. There should be an expire date on the pack of all medicines, and it is illegal to sell, supply, or use out-of-date medicines. So stock control is very important. VMD control the supply of medicines proportionate to their risk.

So medicines divided into distribution categories, and there are four main distribution categories of authorised veterinary medicines. POM-V, prescription only medicine vet. POM-VPS, prescription only medicine vet pharmacist or SQP. NFA-VPS, non-food animal vet pharmacist or SQP, and authorised veterinary medicine, GSL. Authorised by medicine general sales list, AVM-GSL. They're the four main distribution categories. And they're put into the categories, proportional to the risks they might be into how much supplies needs to go along with them. All authorised antibiotics or POM-V. So they can only be prescribed by a vet, but they can be supplied by a vet or a pharmacist. They can be prescribed by a vet, following the clinical assessment of animals under their care, and we'll talk about that. It must be supplied from a registered premises practise. And the reason POM-V, as I say, is because they have as narrow safety margin, but particularly because they require specialised knowledge.

Prescribing, is the act of deciding what medicine to... Assessing the animals requirements and client's requirements, on deciding what medicine to use. And that can either be prescribed, supplied, and administered all in one, go. When visiting a farm, you decide what to use. Use it on an animal that is prescribing, supplying, and administering, all in one game. For POM, so the POM medicines have to be prescribed POM-V and POM-VPS, and POM-V after clinical assessment by vet of the animal, or group of animals under their care. So what is this under your care thing then? When it comes from the RCVS code of conduct, and this is what it says, it's on the screen. "The vet must have been given the responsibility "for the health of the animal or herd of animals "by the owner or the owner's agent. "And that responsibility must be real, and not nominal." So that means, a farm at one end of the country could not appoint a vet at the other end of the country, who's never going to visit and not going to know what's happening on that farm, has to be a real responsibility. The next part says, "The animal or herd, "must have been seen immediately before prescription, "or recently enough, or often enough "for the vet to have personal knowledge "of the condition of the animal "or current health status of the herd or flock, "in order to make a diagnosis and then prescribe." It does not say, how recent enough or often enough is. There is no definition of a time period. That's sort of, a lot of people think it's six months, but there's nothing actually defined, and under his or her care, it's the vet professional judgement, it's entirely up to your professional judgement, in each individual case to decide if you feel, that you are sufficiently knowledgeable of what's happening, to prescribe the medication. That researcher must also maintain clinical records for that herd flock, or individual, every time a POM-V medicine is used.

So, we've said a prescription, can either be oral at the time followed immediately by supply and administration, or it can be written. And if it's not supplied by the person who prescribed it, it must be written. On the written prescription there needs to be the name and address of the telephone number, the person prescribing and their qualifications, the details about the owner or keeper, the identification, including the species of the animal or herd. The premises at which it's kept, if this different to the owners address, the date to the prescription, signature, name and amount of the product, dosage and administration, warnings and withdrawal period, even if that's now. So all these things need be on a written prescription.

So, once medicines have been prescribed they then need to be supplied. So it's up to supply procedure for POM-V medicines which show evidence that every transaction has been authorised by

a vet, or in the case of prescribing against a prescription of pharmacist. So this must be evidence that the vet has prescribed the medication. So this could happen, by the vet actually at the time, prescribing and supplying and administering, on a visit to a farm, or the vet might make a note on the client's records that repeat prescriptions can be supplied for a set time. Maybe note that this farm is allowed to have this medication for this time period, and that might be on the records, and it might also be part of a herd or flock health scheme. Or, when the farmer rings up, the member of the team would take the telephone call, and would either call the vet out on the farm, and ask them to okay it, or make a note on the vet when they come in to okay it. But there must be an audit trail, so that if VMD have a look at the records, they can always see that any POM-V medication has been prescribed by a vet on that, that it has been authorised by a vet, that the supply has been authorised by vet.

For all the medicines POM-V and POM-VPS and NFA, as well as POM-V there also must be evidence that the prescriber has checked, the person who's administering the medicine, is competent to do so safely. I'm just going to use it for purpose for which is authorised and they must advice that the farmer on the safe administration of the medicines, and on any warnings or contraindications on the label or the package leaflet. So that was really important that's the prescriber does that, that they make sure that the person who has the medicine, and the farmer knows how to use it properly and knows the importance of giving protocols, et cetera. If the vet's not there, so in other words, for a repeat prescribing when someone's rung up for another prescription, or another fill up of some medication for that animal, there still has to be evidence, that each individual transaction must be authorised by in vet. And the vet also has to be satisfied, the person handing over the medicine to the client is competent to do so. And how they do that, I will talk about in a moment, is by the fact they've been trained. And that person who hands over the medicine, if they are a receptionist or someone else working in the practise, must advise the person they're handing over to, on the safe administration or warnings for use, in other other words, must check that they know what they're doing and how to use it and maybe read through the label. And ensure these was competent to use, and make sure they know what they're doing. So, if the vet doesn't personally hand over the product, the VMR tells us that they must be satisfied that the person handing over the product is competent to do so.

So how'd you do that? Well, it's by making sure they're trained, by having SOP standard operating procedures in place. Training team members. So, people shouldn't be put in the dispensary or put on the counter to hand over medicines, unless they have been properly trained in-house, or externally, but in-house is fine, so that they know what they're doing. That they're always, because it is the last sense check, to make sure the handing over here is what it says on the invoice. And make sure the client knows what is said on the label. And, again, to advise on those warnings so they're going to ensure the user's competent to use it. So, it's really important that team members are trained, because at the end of the day, this is still the vet's responsibility. If something goes wrong with this process, it's not the team member who's going to be liable, it's the vet's responsibility. So, very important to make sure that your team are all trained properly if they're going to be working in the dispensary, or on reception handing over medicines. So, therefore it's good to have a really clear dispensing protocol, how requests for repeat medication is recorded, whether it's in a book or on the practise management system, how the vets authorises it. If it's an advance where how that's recorded, that certain farms are allowed to have certain medicines, or how long they're allowed to have them for. If it's on the day, how does that happen? Who dispenses the medicine? Who double checks the medicine? Don't have to be a qualified dispenser in veterinary practise because as I said before, you have to be trained and it's a vets responsibility. We're doing it. So anyone dispensing medicines in the team, is doing it on the vet's responsibility. The vet's responsible, but then that

team members can do it on their behalf, but they need to be trained. So that's good to know who's doing that, it's good to have a double checking system. It's not a legal requirement, but it's a very good idea. And, obviously, they need to understand about that, and make sure that's done properly. Who does that? How's it stored? When was last time they ever checked? As I say, just checking, you've got the right medicine, the client farmer knows exactly how they're going to use it. There's no misunderstandings. So therefore, team members need to know their products. So, it's important that the products that are commonly handed over, that people know what happens with them, and should keep up to date with changes to data sheets, in order to make sure that clients know about contraindications. And team members should know what Contraindications are, basically, do not use for certain things, or warnings may cause may cause scouring, whatever. So the VMD product information database is very useful source of information. It has information of all veterinary medicines in the UK, and you can search by species or you can search by types. You can search by antibiotics, or search by legal distribution category. Thank you.

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