Title: Storage of medicines at practice and on farm

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- [Presenter] Hello and welcome to this presentation on the storage of medicines. My name is Lee Grist and I am the head of the Distribution and Supply Chain Inspection Section at the Veterinary Medicines Directorate. The Distribution and Supply Chain Inspection Section is responsible for inspecting veterinary wholesalers, veterinary retailers, such as vet practises and SQP retailers and medicated feed manufacturers and distributors. On completion of this module, participants should have a greater understanding of the importance of storing medicines appropriately, as well as pickup important tips on general storage issues as well as issues specific to cold-chain storage and vehicle storage.

It's important for anyone storing for any medicines to store them responsibly. Veterinary medicines are granted Marketing Authorizations based on data submitted by marketing authorization holders and assessed by VMD assessors. Conditions may be listed as part of the marketing authorization that tells users how to store and use the medicines appropriately. This information can be found in a product summary of product characteristics, also known as the SPC. The VMD's product information database lists all UK authorised veterinary medicines and their SPCs. This information should also be found on a product label or package leaflet.

So what sort of storage conditions might a product have? There could be specific temperature ranges. For vaccines and cold-chain products, this may be to store them between two and eight degrees celsius. For ambient temperature products, this may be below 20 degrees or 25 degrees. For light sensitive products, this may be to store them away from lights or to keep them in their outer carton. Cold-chain storage. Maintaining the cold-chain ensures that products are transported and store according to the manufacturer's recommended temperature range, usually two degrees to eight degrees right up to the point of administration. It is vital to everyone involved in the supply chain from the manufacturer to the distributor, to the supplier and onto the end-user follows these directions. Correct store which ensures that products are administered in the way that has been demonstrated to be safe and effective. Here we list some cold-chain storage advice and guidance. There is no requirement to use a pharmacy fridge just as long as the domestic fridge you have is capable of doing the job. And you need to satisfy yourself that it is before using it routinely. Opening up the door should be kept to a minimum in order to maintain a consistent temperature around the fridge. And you should never store food or drink with medicines. You should ensure that air is able to circulate freely around the fridge, which means don't overstock it. Any cold-chain products transported in a vehicle still have to be stored between two and eight degrees. But wherever you're storing veterinary medicines, you need to be able to demonstrate that they have been stored according to the manufacturer's directions. And this should be backed up with appropriate temperature records.

Here we have two examples of inappropriate storage of veterinary medicines, In the fridge on the left, you can see a carton of milk and a tub of butter on the middle shelf, as well as other food and drink items on the bottom shelf. And in the picture on the right, as well as it being quite a well stocked fridge, again, you've also got food and drink items on the top two shelves. Here, we have an example of a domestic fridge being used for vaccine storage. You may be able to see on the top right that there's a great deal of ice buildup. This means that the vaccines that are being stored around that particular section may be stored at a much colder temperature than they should be. We're now going to look at the different types of instruments you may wish to use for monitoring temperatures. The most common we see are data loggers or maximum minimum thermometers. Some pharmacy fridges also have built-in thermometers that can be set to specific parameters. But if you use these, ensure that you are setting the parameters to the right level. They will then alarm if the temperature goes outside of the suitable range. Continuous data can also be recorded and stored on SD cards that will show the temperature of the fridge during the time the SD card is in there. This information should be downloaded at regular intervals and reviewed. When using a fridge maximum minimum thermometer, it's useful to have a thermal break. This means you put the sensor into a small pot or bottle and this keeps it protected from the air. This way when the door is opened when you're restocking the fridge, the sensor won't read the warm air that rushes into the fridge. It means that you will get much more accurate readings of what the temperature that the medicines are being stored at has been.

So what actions should you take? If you're using a maximum minimum thermometer, then this should be checked at regular intervals. You should note down the maximum temperature seen and the minimum temperature seen and then reset the thermometer. This should be repeated routinely. For cold-chain products it's recommended that this is done daily. This way, you get an idea of how hot or cold the fridge has got during the previous 24 hours. And you can then ascertain whether the products have been stored appropriately or not. For ambient products, this may be weekly, but during extreme periods of heat or cold, may need to be carried out more frequently. It depends on the results that you see. If the data logger alarms or the maximum minimum thermometer indicates that the temperature has gone below two degrees or above eight degrees, then you will need to carry out an investigation. You should keep a record of what has happened, how long the temperature has been out of range for, and then conduct a risk assessment. You may need to contact medicine manufacturers for information on product stability. You may also need to dispose of the products if you cannot be assured that the safety or efficacy has not been compromised.

Here we have the boot of the vet's car that we saw during one inspection. Would you say this demonstrates good vehicle storage and organisation? And here we have another example which demonstrates much better organisation. You can see there are specific compartments for each of the veterinary medicines. Everything is still in carton and put away neatly. And the cabinet is lockable. As we mentioned previously, if we're transporting cold-chain products in a vehicle, measures should be taken to ensure they are transported at the correct temperatures. For example, by using an in-car fridge or insulated cool boxes. The effectiveness of these measures should be demonstrated and backed up with appropriate records. This also applies to ambient temperature products where there is a risk that the correct range may be exceeded. For example, on hot summer days. On sunny days, if possible, you may need to park the car in the shadows as this may help to reduce the temperature within the car.

Here, we have some general rules for appropriate storage of veterinary medicines. Storage areas should always be an appropriate size, clean and tidy. A spill kit should be on hand to clean up any spillages, leakages or breakages quickly. And the storage area should be locked and only accessible

to authorised or approved persons. Food and drink should not be stored with medicines and that includes ambient areas as well as fridges.

Here, we have some useful tips for good storage. You may wish to have an appropriate sorting system, alphabetical by product name, or store similar products together, such as antibiotics. You may wish to operate a stock rotation system. So the shortest dated products were always used first. You should carry out regular stock checks according to a set timetable. Depending on your stock levels, this may need to be done weekly or monthly. Another system is to use color-coded stickers or labels on each of the product packets. For example, a green sticker would indicate that you have three months 'til the product expires. An orange sticker may indicate two months 'til the product expires or a red sticker may mean it's into its last month. An alternative to this is to list the products that are expiring shortly, clearly on a whiteboard after each stock check. This way, everyone within the premise is aware of when the expiry dates are and when they may use these up to.

If you're using small ampoules, then please remember blue-tack is not an appropriate cover for these. Here, you can see there's even some spare blu-tack left on the side of the cupboard. This is not appropriate. If you can no longer decipher any of the information on the packaging or it has leaked, then you should dispose of the product in an appropriate way.

It's important that you hold appropriate levels of stock at your premise. Excess stock can increase the risk of using out-of-date medicines. It may increase wastage and cost of disposals. It can increase the dangers of over-packed fridges which leads to poor air flow and products potentially freezing or poor stock rotation. There are increased costs if the fridge was to fail and you had to dispose of the medicines. There's also increased pressure on the fridges in times of high demand. We've looked at storage conditions but what sort of usage conditions may be set? The most common is an in-use expiry date for a medicine. This is commonly referred to as a broach limit. It's incredibly important that approach limit is followed. This is one of the most frequent deficiencies that we see during inspections. A product's SPC and label will state how long a product can be opened for before it has to be discarded. For the majority of injectable products that you see, this is 28 days. But there may be products that have longer or shorter limits. So it's up to you to ensure that you've checked the SPC and that you know how long the product can be in use for. So if the medicine has an in-use shelf life, then this must be adhered to. The easiest way to track this is to write both the date opened and the date it can be used up to on the bottle, as shown here.

So why is it important to follow the usage conditions? Well, when an authorization is granted, it is on the basis of study data that demonstrates that the product is safe and effective to use under set conditions. If a product states a broach limit, then the data has shown that it is safe, effective and is not diminished during that time. No data has been assessed to demonstrate that the product is still safe or will still work properly beyond that date. So if a product has an expiry date of 28 days after first opening, then this is what must be followed.

So in summary, you should follow the instructions from the manufacturer. The correct storage and the correct use are both important. Make sure you have appropriate records to back you up, you never know when you may need them. And if there are any concerns, then carry out a risk assessment and take the appropriate action to mitigate against future risks.