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The safety, quality, and effectiveness of pet parasite treatments is reviewed by independent scientific regulators before these products are placed on the market. This process considers the benefits and potential risks of treatment to animal, human, and environmental health. As the regulatory process helps identify the potential risks of treatments, it also help develop user and safety warnings, which can be found in the product information. Therefore, reading and following this information before using a treatment is important to reduce potential risks and to protect you, your pet, and the environment. Without the benefits of treatment outweighing the risks, pet parasite treatments would not be authorised and available to use. Share: A whole range of parasites can live inside or on our pets, affecting their health and wellbeing. Some parasites pose a risk to people too. As responsible pet owners we have a duty of care to proactively protect our pets and families from these risks. Authorised anti-parasitic veterinary medicines are widely available from veterinary practices, a range of pet supply stores and pharmacies to control common and important parasites. Introduction Companion animals are playing an increasingly important role in our lives. They often live in our homes, in close proximity, as family members. Enjoying the benefits of owning a pet also brings a responsibility to protect their health and welfare (1). Prevention is better than cure for many reasons. Putting in place a preventative plan of action for common parasitic infections has the benefit of avoiding clinical disease and unpleasant infestations of e.g. worms or fleas. While some signs of parasitic infection are noticeable, in most cases, we will not see any signs, which makes a proactive parasite control plan even more important. All authorised veterinary medicines available in the UK, including those indicated to control or treat parasitic disease in our pets, have met strict regulatory controls of safety, efficacy and quality and are widely available through a variety of pet supply stores, veterinary practices and pharmacies (2). Most pets are at risk of parasite infection. One reason for this is that many parasites have evolved features that help them to survive and spread. A good example is the large roundworm Toxocara, a very common parasite of dogs and cats, which can transfer to puppies across the placenta before they are born and via the milk after birth to puppies and kittens. Parasite eggs, which are produced in large numbers and shed in faeces contaminating the environment, are hardy and once mature can remain infective for months to years (3). Pets may also need protection when travelling abroad from parasites they aren't normally exposed to in the UK. This will also help prevent bringing unwanted and new parasites back to the UK. Responsible pet ownership can also reduce the risk of zoonotic disease – those diseases passed from animals to humans. Toxocara is responsible for a zoonotic disease, toxocarosis. Although infection is rare, these parasites usually affect younger children as they are spread when children put contaminated soil in their mouths. The migration of larvae around the body can sometimes reach the eye and cause blindness. When we consider the largely 'invisible' parasite world, where e.g. eggs shed in faeces cannot be seen by the naked eye, hand washing and cleaning up pet faeces helps to minimise the risk of infection for pets and people. However, regular preventative treatment can reduce this invisible contamination in the first instance, whether at home, in the garden or at the park. Many pets will have a similar risk of exposure to the most common internal and external parasites and all pets should be treated regularly to control these parasites. A recent report shows that UK pet owners take these risks seriously with an estimated 87% of dogs treated for worms and 82% treated for fleas (3). Each pet will also have individual risk factors for parasite infection. A comprehensive and tailored parasite control programme should consider factors such as their age (young and old are at greatest risk), health status, environment (outdoor access, staying in kennels/catteries), lifestyle (access to rodents, slugs, raw meat), location and travel (4). Internal Parasites: Endoparasites Parasites that live inside our pets include roundworms, tapeworms, lungworms, hookworms, heartworms and whipworms. Many of these worms live in the gut, airways, blood vessels or travel through tissues around the body. Focus on Roundworms (Toxocara spp) Toxocara are very common zoonotic roundworms, which affect dogs (e.g. Toxocara canis) and cats (e.g. Toxocara cati). Infections are heaviest and cause the greatest illness in puppies and kittens. Heavy infections in puppies before birth, when infected through the placenta, can result in severe disease with diarrhoea, constipation, vomiting, a 'pot belly' with poor growth and condition. However, puppies and kittens can also be infected when drinking their mother's milk. In adults, infection can occur when infective eggs are eaten or when e.g. a cat eats rodents which are infected. The myriad of ways that roundworms can spread and infect pets means they are very common parasites, which should be effectively controlled through regular preventative treatment. Focus on Lungworm (Angiostrongylus vasorum) Lungworms, although much smaller than roundworms, are potentially life-threatening parasites. Larvae not visible to the eye are passed in faeces and dogs can become infected when they eat infected snails and slugs. This increasingly important parasite can cause a variety of symptoms including neurological problems, coughing, poor appetite and weight loss, vomiting and diarrhoea and bleeding disorders. A comprehensive parasite control plan should consider the risk of lungworm infection alongside the other major parasite threats. External Parasites: Ectoparasites Parasites that live on our pets are called ectoparasites and include fleas, ticks, lice and mites. These parasites are important not only for the direct impact they have on our pets but also because some of them carry other diseases, which are important for both pets and people. Importantly with climate change and pets travelling more frequently and more widely, the distribution of these parasites is changing. Focus on Fleas Many pet owners will be familiar with flea infestations, which affect dogs, cats and other small mammals such as rabbits. It is difficult to avoid the risk of flea infestation at any time of the year. Flea bites can cause irritation and Flea Allergy Dermatitis (FAD) when fleas feed on blood and a pet reacts to flea saliva. There are many different types of products authorised to treat and prevent fleas, but it's important to remember that the vast majority, 95% of the flea population, made up of eggs, larvae and pupae, is found in the environment, which includes cracks and crevasses around the home, such as flooring, fabrics and bedding. This means it is not unusual to have some difficulty finding adult fleas on pets and when trying to prevent cycles of re-infestation, the environment around the home should also be treated along with vacuuming carpets and washing pets' bedding. To treat or prevent future flea infestations, it is best to treat all pets in the same household at the same time, but using a product authorised for a specific species – dog products should not be used on cats (4). Another aspect of flea infestation is their association with tapeworm infection. Fleas can be infected with tapeworm larvae and when a pet grooms and they can accidently swallow infected fleas, the tapeworm larvae will then develop into adult tapeworms. When controlling fleas we must also consider the associated risk of tapeworm infection. Focus on Ticks Ticks are blood sucking parasites, which can attach to animals and humans as they pass through vegetation. Ticks can cause irritation where they attach, but more significantly they are important in the transmission of serious Tick Borne Diseases (TBD's), including Lyme disease and Babesiosis. TBD's are a health risk to pets and people. As part of a comprehensive parasite control plan, a vet can assess the risk of exposure to ticks and TBDs. This will involve considering lifestyle factors, such as access to high risk tick areas or travel within the UK and abroad. Regular treatment is recommended for dogs travelling abroad (6). Importantly, with changes in climate and increased movements of pets, the geographical spread of endemic and exotic tick species, and TBDs, is changing – making it ever more important to consult with your vet. It also makes good sense to regularly check your pet for ticks and remove those attached with a tick removal device or fine pointed tweezers – as the risk of transmission of a TBD's increases significantly after 24 hours of attachment (6). Comprehensive Parasite Control Plan Understandably, people find the very idea of their pet passing worms in their faeces or seeing fleas unpleasant. These visual reminders can focus pet owners towards treating parasites and preventing re-infection. But parasites, along with their eggs or larvae, are mostly invisible to people. Parasites mostly live undetected in pets and contaminate the environment at home, in the garden or at the park. We can't therefore rely on these infrequent unpleasant visual reminders to prompt us to control parasites. A year round parasite control plan should include treatment for common parasites but also cover particular risks such as travel and specific lifestyle factors. Pet owners have access to a wide range of authorised anti-parasitic veterinary medicines, which are available from pet supply stores and veterinary practices. If unsure, pet owners can speak with their vet or SQP (Suitably Qualified Person). Importantly, not all products are suitable for all pets, there are important differences between dogs, cats and rabbits for example. All veterinary medicines, including anti-parasiticides, should be used as indicated on the product label or as directed by the vet or SQP. When we think about parasite control, we must also consider the bigger picture. Fortunately, there are effective veterinary treatments available for parasitic infestations, but there are also other sensible measures that we can be taken to reduce the risks. These include collecting and disposing of pet faeces, checking for ticks, covering sandpits and good hand hygiene. Parasite Control: Dogs Controlling parasites means thinking about their needs throughout their life from puppy to mature adults. As puppies face risks of roundworm infection, before birth and as very young puppies, they should be treated with a suitable product regularly from a young age and according to the label. Some of the other internal parasites of dogs that should be considered include tapeworm, lungworm, hookworm, whipworm and heartworm. Lungworm is important to consider if your dog could possibly have eaten snails or slugs. Dogs should be treated for tapeworm if they have had fleas. Environment risk factors for roundworms, hookworms, lungworms and whipworms include outdoor access and spending time in kennels (4). Dogs that eat rodents or eat raw meat are also at increased risk of certain types of internal parasites (4). Most external parasites can be difficult for pet owners to see so it makes sense to include controlling these in a complete parasite plan – taking into account their life-stage and lifestyle risk factors. Parasite Control: Cats Cats also face changing parasite risks as they develop from kittens into adult cats. Kittens can become infected with Toxocara in the weeks after birth from their mother's milk and should be treated from a young age according to label instructions and veterinary advice. Severe infestations of fleas in small kittens can, along with the irritation and potential allergy, cause anaemia. Ear mites can cause irritation and discomfort and are more common in kittens (5). Some cats will have access to the outdoors and may hunt and eat prey, which is associated with increased risk from certain types of worms (4). Tapeworm infection should also be considered when cats have fleas. Stray cats, those with outdoor access and cats in catteries are at a higher risk of parasite infection and need a parasite control plan adapted for these risks, which includes products that have been authorised for use in cats. Parasite Control: Rabbits Rabbits can also become infested with internal and external parasites and it is important for rabbit owners to be aware of the parasite risks. Blowfly strike is a serious and distressing condition where flies lay eggs that hatch into maggots and feed on the rabbit. This can occur at any time of year, but is more common in the summer months. It is important to seek veterinary advice to prevent and immediately treat any rabbit with flystrike. Rabbits can get fleas just like dogs and cats. Fleas can also spread an important viral disease called myxomatosis between rabbits. Preventing flea infestations is therefore key and if fleas do become a problem, rabbits and their environment should be treated. An example of an internal rabbit parasite is the very small parasite Encephalitozoon cuniculi (or E. cuniculi), which can cause neurological and kidney disease. This infection can be spread when rabbits eat food or grass contaminated with the urine from an infected rabbit. As part of a veterinary health visit, rabbit owners can discuss the parasite risks their rabbit may face and put in place a plan of action taking care to only use veterinary medicines licensed for use in rabbits or prescribed by your vet. Take Home Messages Pets are exposed to a great variety of internal and external parasites in their daily lives. Many parasitic infestations in pets go unnoticed. Contamination of the environment with parasite eggs or larvae is invisible. Some parasites are zoonotic, meaning they can be passed from animals to humans. Responsible pet ownership means proactively planning to prevent and control parasites regularly. This will help protect your pets' health and welfare and prevent the contamination of the surrounding environment. Each pet is unique and a parasite plan will address their particular risks. Authorised anti-parasitic veterinary medicines in the UK, whatever route they are sold, have met rigorous safety, quality and efficacy standards. All anti-parasitic medicines should be used as directed or as per label instructions. June 2017 References: UK Animal Welfare Act, 2006: legislation.gov.uk/ukpga/2006/45/contents Share: NOAH is the trade association representing the UK animal health industry. We support our members' businesses and ensure the sustainability of our sector by helping shape the regulatory, political and social climate. Find out more – watch our video 'Supporting the future for animal health' What do we do? We foster innovation and promote responsible use of our members' products. Our vision is to be at the forefront of UK animal health and welfare, championing licensed medicines and solutions for all animals. Our focus Support business continuity and opportunity for all medicines and animal health solutions, ensuring end users' access to licensed medicines Promote a robust regulatory environment, to ensure a high standard of UK animal health and welfare and meet the needs of our members Ensure appropriate access and responsible use of medicines for all animals, whilst protecting animal, human and environmental health (One Health) Support a political / social climate where our members' businesses can be successful Work collaboratively with members to define policy priorities; communicate effectively to ensure NOAH remains the trusted expert partner on all UK veterinary medicine and animal health issues, providing horizon scanning and thought leadership Email us at: noah@noah.co.uk Our Mission NOAH represents the UK animal health industry. We promote the benefits of licensed medicines and solutions for the health and welfare of all animals. NOAH also: Promotes and defends the responsible manufacture, promotion, sale, distribution, handling and use of animal medicines. Acts as a consultative body to the industry, Government, the media and the general public. Represents the views and interests of its members. Communicates the benefits of animal medicines to animal health and welfare, and sustainability. The animal health industry plays a key part in: Farm and companion animal welfare Safe food for consumers Farm sustainability and resilience Healthier pets supporting human wellbeing Environmental protection Scientific innovation Our strategy Our environmental policy NOAH's latest Environmental Policy can be found here. Share: Along with every other business, those who hold a stock of animal medicines for sale or supply will need to carry out a COSHH risk assessment. But what does this mean in relation to animal medicines? Is a 'safety data sheet' needed for each animal medicine? And where can businesses get the information on medicines to undertake a risk assessment? Advice from the RCVS Practice Standards Scheme – risk assessments and the veterinary medicines perspective The RCVS publishes its Practice Standards Scheme (Practice Standards Scheme – Professionals (rcvs.org.uk))In the Practice Team module, 16.1.19, it states: "The practice must have undertaken an assessment of the risks arising from the use of veterinary medicines and substances hazardous to health within the practice." The following guidance is given relating to COSHH: COSHH is the law that requires employers to control substances that are hazardous to health. You can prevent or reduce workers exposure to hazardous substances by: Finding out what the health hazards are Deciding how to prevent harm to health (risk assessment) Providing control measures to reduce harm to health Making sure they are used Keeping all control measures in good working order – Providing information, instruction and training for employees and others Providing monitoring and health surveillance in appropriate cases e.g. anaesthetic gas monitoring Planning for emergencies Examples given in the standards as hazardous substances are: Veterinary medicines – low risk can be grouped together e.g. antibiotics, high risk should be assessed specifically e.g. carcinogenic substances Cleaning products Agents that can cause allergies e.g. latex, penicillin Infectious agents e.g. bacteria, viruses Substances e.g. dust The standards also state: "A safety data sheet is not a risk assessment. Gathering information from safety data sheets is the first stage in the assessment process of gathering knowledge" While this advice is aimed at veterinary practices, other businesses, such as animal health distributors and pet shops will also need to go through the risk assessment process. In order to facilitate the risk assessment process, suppliers will need to have access to information about the veterinary medicinal products which they hold. Do I need a Safety Data Sheet? The answer is, it depends, but the important thing to note is that a Safety Data Sheet is not required for every medicine. In the eyes of the law, there is no such thing as a "COSHH data sheet." The correct term is "Safety Data Sheet" or "REACH safety data sheet". UK REACH is the legislation that replaces the EU REACH Regulation following the UK's exit from the European Union. UK REACH covers the Registration, Evaluation, Authorisation and restriction of CHemicals. UK REACH was brought into UK law in 2018, and the EU REACH in 2007. EU REACH replaced a number of pieces of older chemicals' legislation, including the Safety Data Sheet Directive. Veterinary (and human) medicines are exempt from some parts of REACH. In particular, medicinal products for veterinary use that are supplied in the finished state, intended for the final user are exempt from the requirement to supply a Safety Data Sheet. Therefore, as long as the veterinary medicine is supplied in its final formulation and packaging for the final consumer, a Safety Data Sheet (SDS) is not required. So, Safety Data Sheets are not legally required for veterinary medicines and many medicine companies do not produce them. So how can a risk assessment be done? Safety Data Sheets should not be confused with the Product Data Sheets and Summary of Product Characteristics (SPCs). Veterinary practices and other suppliers of animal medicines should ensure that they have access to the current version of either the SPC or the Data Sheet for each authorised medicine used or stored in the practice. These provide all the necessary information to carry out the required risk assessment. They are available in the current NOAH Compendium App and can also be found online at . Alternatively, SPCs for all veterinary medicines can be found at: Product Information Database – Home (defra.gov.uk) SPCs for human medicines used by veterinary surgeons under the cascade (where there is no licensed veterinary medicine available) can be found at: MHRA Products | Home. It should be noted that the lists mentioned are not exhaustive and practices and other businesses stocking animal medicines should consider their own individual medicine/substance usage. Further reading The REACH legislation can be accessed via the following link; The REACH etc. (Amendment etc.) (EU Exit) Regulations 2020 (legislation.gov.uk) For details from the Health and Safety Executive (HSE) on REACH exemptions, please refer to the HSE website via the following link; UK REACH: Scope and exemptions (hse.gov.uk) September 2021 Share: Fleas, ticks, and worms pose a year-round risk to our pets. For instance, it has been estimated that 1 in 4 cats and 1 in 7 dogs in the UK have fleas 1 and 86.6% of soil samples taken from UK & Ireland parks contained roundworm (Toxocara) eggs 2. Today, the risk of parasites to the UK pet population is growing. Increased travel and movement of cats and dogs combined with climate change are enabling parasites to thrive and spread into new areas. What does this mean for pets and people? Parasites risk the health and wellbeing of our pets, for example: Fleas cause persistent itching, scratching, and chewing. This can lead to open sores and wounds on the pet's skin which can leave them vulnerable to infection. Some cats and dogs can also be allergic to flea bites. Ticks can carry diseases which can be passed on to our pets when a tick feeds, causing disease in our pets, which can severely impact our pet's health and welfare. Worms can cause suffering, illness and sometimes even death if infestations are severe. The health and welfare implications of parasites can be a shared experience, as they also risk human health and wellbeing, as some diseases that fleas, ticks, and worms carry can also infect people (Zoonotic diseases). Additionally, infestations in our pets can result in the household becoming infested. For instance, adult fleas and eggs can survive in clothing, bedding, and carpets. It can be difficult to get rid of them when they infest the home environment, and they may require professional extermination. Parasiticide treatments Fleas, ticks, and worms in our pets can be prevented and controlled through the use of parasiticide treatments. As parasites can be a shared experience, preventing them helps protect the health and wellbeing of both animals and people. Many of these treatments are available on prescription from veterinary practices, with other treatment options also available at pharmacies, pet stores and supermarkets, and in some instances online. Your vet or a suitably qualified person (SQP) will advise on treatment options and frequency, as they can consider the individual needs and risk of parasites to your pet. As with all veterinary medicines, it is important to use parasiticide treatments correctly, safely, and responsibly, in the way they are intended to be used. Always read and follow the information provided with your pet's medicine to ensure the product is used correctly. For more information on how and why to read the information provided with pet medicines see NOAH's Paws to Protect campaign. Can pet owners have confidence in veterinary medicines? All veterinary medicines marketed in the UK are subject to strict regulation. They have undergone an independent scientific assessment with the Veterinary Medicines Directorate (VMD), a Government Agency, before they are allowed to be placed on the market and used. This independent assessment considers the product's quality, efficacy, and safety, including safety for pets, people, and the environment. Once they are on the market, their use and safety is kept under review by the VMD. Part of the regulatory process includes approval of the information provided with your pet's medicine (the leaflet and all packaging). This helps ensure you can use the product correctly and safely, whilst maximising its therapeutic benefit. For further information please visit Companion Animal Parasite Control on the NOAH website. References Abdullah S, Helps C, Tasker S, Newbury H, Wall R. Pathogens in fleas collected from cats and dogs: Distribution and prevalence in the UK – parasites & vectors. BioMed Central; 2019. Available from: Airs PM, Brown C, Gardiner E, Maciag L, Adams JP, Morgan ER. Wormwatch: Park soil surveillance reveals extensive toxocara contamination across the UK and Ireland. Veterinary Record. 2022;192(1). doi:10.1002/vetr.2341 6 November 2023 Share: This document provides an overview of the broad range of regulatory controls that are in place governing the authorisation, supply and monitoring of veterinary medicinal products. These comprehensive controls ensure that safe, effective and quality veterinary medicines are available for the health and welfare of our animals, whilst safeguarding people and the environment. The document was last reviewed in 2016. Introduction In the UK, the Veterinary Medicines Regulation (VMR) provides for legislative requirements concerning the manufacture, classification, supply, marketing and use of veterinary medicines (1). Additionally, there are a range of EU regulatory controls that also apply to veterinary medicinal products (VMPs) including controls on safety, licensing and monitoring (2). In the UK, the national competent authority and independent regulator is the Veterinary Medicines Directorate (VMD) (3). At the EU level, the European Medicines Agency (EMA) is responsible for the scientific evaluation and monitoring of medicines (4). All of the authorised veterinary medicines available in the UK for animals must undergo a strict regulatory approval process, before they gain a Marketing Authorisation (MA) or licence for sale and supply (5). Scientific studies by animal medicine companies and subsequent evaluation, by independent regulatory authorities, ensure that each authorised veterinary medicinal product meets the required standard of safety, efficacy and quality. This ensures that animal medicines are safe to use, they are efficacious (effective) and they meet quality criteria. In the UK, animal medicines can be classified based on their authorised supply route, which allows for control over the sale and distribution of medicines e.g. antibiotics are only available on prescription from a veterinary surgeon i.e. all antibiotics are POM-V (prescription only medicines – through a veterinary surgeon). On farm, there is a legal requirement, under the VMR, to record all veterinary medicines obtained and used in food-producing animals (1). When veterinary medicines are administered to farm animals, the safety of food from these animals and their products (e.g. meat, milk, eggs) is monitored through a statutory residue surveillance scheme (6). This scheme ensures that the UK meets an EU regulatory requirement to analyse samples for residues of veterinary medicines (7). For all authorised veterinary medicines, there is an ongoing process of safety and efficacy monitoring – called pharmacovigilance – that ensures the continued safe use of effective medicines (8). Only authorised veterinary medicines can legally be used in the UK. The enforcement division of the VMD proactively takes action, which can include prosecution, against any illegal marketing and use of unauthorised products in relation to breaches of the VMR (9). The Authorisation of Veterinary Medicines Before an animal medicine can be placed on the UK market it must be approved. This takes the form of a Marketing Authorisation (MA). Rigorous European and UK standards for the registration process ensures only those medicines that meet defined standard of quality, safety and efficacy are authorised. The discovery, research and development of an animal medicine is a lengthy and very expensive process with successful products taking 5-11 years to reach the marketplace (10). The process of applying for an MA includes the submission of an extensive and detailed dossier, which consists of data that supports the safety, quality and efficacy of the product in accordance with the legal framework. This information helps the national and European regulators to carry out an independent scientific assessment to ensure that all the regulatory criteria have been met. Safety, Quality and Efficacy The aim of an independent scientific assessment, for a marketing authorisation, is to evaluate the safety profile, the quality of the manufactured product and the effectiveness of the product. The submitted dossier of data, which supports this assessment, is the end result of years of discovery, pre-clinical laboratory development and clinical field trials. A marketing authorisation will only be granted if the experts, either at the VMD in the UK or EMA for products seeking EU-wide approach, and their advisory committees of independent experts (the Veterinary Products Committee (VPC) in the UK or Committee for Veterinary Medicinal Products (CVMP) in Europe), are fully satisfied (11, 12). Safety Stringent safety criteria are imposed during the evaluation of the medicine. Safety aspects of a medicine include its safety in animals; in those individuals administering the veterinary medicine e.g. farmers, pet owners, vets; and safety in the environment. In the case of farm animals, safety also means it will be safe for consumers to eat animal products e.g. meat, milk, eggs or honey from treated animals. For farm animal medicines there has to be a Maximum Residue Limit (MRL) for the active ingredient (the highest level of residue that does not pose a risk to the consumer) and set withdrawal periods – the time that must elapse since the last treatment before the animal or its products can enter the food chain, which ensures any remaining residues are below the MRL (13, 14). Large additional safety factors are also applied during the establishment of the withdrawal period to ensure consumer safety (more information can be found in the NOAH briefing document – veterinary medicines and the safety of food from animals). Quality An animal medicines manufacturer must demonstrate the required quality standard of the final veterinary medicine, the consistent quality of the ingredients and the manufacturing processes that were used to make the product. Quality is very important to ensure that product safety and consistency is assured – meaning all batches of a product meet the required standards. The stability of the product is important to ensure that the product retains its quality and efficacy at least until the stated expiry date. Efficacy All medicines must do what they claim to do when used as per label instructions. The animal medicines company must substantiate any and all claims for the effectiveness of the product. Field trials make sure that the product will work in practical 'real life' situations; demonstrating effectiveness in preventing or treating a particular medical condition – in agreement with the claims made on the product labelling or information sheet. More information on authorised veterinary medicinal products, including indications for use can be found on the SPC (Summary of Product Characteristics) in the VMD Product Information Database or in the NOAH compendium of datasheet (15, 16). Only when the independent regulator is satisfied on all three criteria can a marketing authorisation be considered, which may then be used to legally place a veterinary medicinal product on the UK market in accordance with the VMR. Veterinary Medicine Authorisation Routes There are four different routes (national, centralised, mutual recognition and decentralised) for obtaining marketing authorisations, resulting in products that are nationally authorised, centrally authorised or mutually recognised (5): Nationally authorised products: Applications are submitted to the national competent authority, which is the VMD in the UK. MA's granted under this procedure are valid in the UK only. This procedure does not involve any other member state. Centrally authorised products: The centralised procedure is used when an applicant wants to market a product throughout the EU. Centrally Authorised Products (CAPs) are evaluated by the EMA and issued by the European Commission – therefore they are assessed and approved at community level involving all member states. The authorisation is pan-European and allows marketing and sale in all member states, including the UK. The centralised procedure is compulsory for certain biotechnology products and may be requested for other innovative products. Mutually recognised products: These products are assessed and approved involving at least two member states via a mutual recognition procedure (MRP), where the product is already authorised in a least one member state and an authorisation is sought in one or more other member states. In this case, the reference member state (RMS) has authorised the product and submits their evaluation to the other concerned member states. The decentralised procedure (DCP) also results in a mutually recognised product. The decentralised route may be used if the product is not authorised in any member state and the applicant would like authorisation in several or all member states. This may occur where the centralised procedure is not mandatory, the product is not eligible for centralised procedure or where optional – the applicant does not wish to use the centralised procedure. Regulatory Controls Post-Authorisation The regulatory controls on veterinary medicines continue after the pre-authorisation and authorisation phases, when products are placed on market. These controls include restrictions on the supply and use of some products, depending on their classification. Controls also include the continued monitoring of safety and efficacy, through pharmacovigilance activities and the national statutory surveillance programme for residues in food from animals. To ensure our animals receive only those medicines that have been authorised and meet the strict criteria of quality, efficacy and safety, the illegal marketing and use of unauthorised products is monitored and action taken, where appropriate, by the VMD though its enforcement activities. Classification and Distribution of Medicines There are four legal categories of authorised veterinary medicines, which designates their distribution category and controls the supply route of these medicines. POM-V: (Prescription Only Medicine – Veterinary Surgeon). These medicines can only be supplied on prescription by a veterinary surgeon. Products such as antibiotics will always be POM-V medicines. POM-VPS: (Prescription Only Medicine – Veterinary Surgeon, Pharmacist, Suitably Qualified Person (SQP)). These medicines can only be supplied on prescription by a Registered Qualified Person (RQP) – i.e. a veterinary surgeon, a pharmacist or a Suitably Qualified Person (17). POM-VPS medicines include some wormers for livestock. NFA-VPS: (Non-Food Animal – Veterinary Surgeon, Pharmacist, SQP). These medicines for companion animals may be supplied by a veterinary surgeon, a pharmacist or a Suitably Qualified Person provided the requirements for supply are met. They do not require a prescription. AVM-GSL: (Authorised Veterinary Medicine – General Sales List). These medicines have no restrictions in the VMR and are commonly called 'over the counter medicines'. There are specific requirements, in terms of qualification and supply of medicines, for Registered Qualified Persons (RQP) – vets, pharmacists and SQPs (18). The distribution of animal medicines in the UK is strictly controlled by legislation including the VMR (1). Wholesalers are inspected and authorised by the VMD and are required to hold a marketing authorisation, a manufacturer's authorisation or a wholesale dealer's authorisation (WDA) (19). Manufacturers are required to comply with Good Manufacturing Practice (GMP) for the authorised veterinary medicinal products they produce. Additionally, they must hold a Manufacturing Authorisation for those products, unless they are for small non-food producing pet animals (20). Registered manufacturing facilities and processes are regularly inspected by the VMD with ongoing re-inspection at a risk-based frequency. The inspectors check the premises are suitable for the production of safe, effective medicines of a consistently high quality, and that they are being manufactured in accordance with their marketing authorisations. Vets' and merchants' premises and pharmacies are also all regularly inspected to ensure they meet the required standards. Veterinary Medicines and the Safety of Food Animal medicines for food producing animals are strictly controlled by the UK national law (VMR) and European law (13). Requirements on farm include the recording of all medicines bought and administered. To ensure consumers are provided with safe food from animals when medicines are used, farmers and vets must observe the withdrawal period for all medicines. This is the time that must elapse from last dose, until the animal or its products are allowed to enter the food chain. This scientifically assessed time period, which includes large safety margins, ensures that any residues that may be present have depleted to levels below the Maximum Residue Limit (MRL), meaning animal products are safe to consume. In the UK, the VMD oversees a statutory residue surveillance scheme that analyses samples from animal foodstuff and publishes results annually (6). The surveillance reports from the VMD show that the vast majority of samples tested are compliant. This provides assurance that the regulatory control measures and actions are safeguarding our food from animals. More information on this topic can be found in the NOAH briefing document: veterinary medicines and the safety of food from animals. Pharmacovigilance The ongoing post-authorisation monitoring of safety and efficacy of veterinary medicines is termed 'pharmacovigilance'. Pharmacovigilance also considers suspected lack of expected efficacy (where the medicine has failed to work) and any problems with residues of veterinary medicines, in food from animals, where the appropriate withdrawal period and dose rate has been followed. The monitoring and evaluation of Adverse Events (AEs) – any observation in animals, humans or the environment, whether or not considered to be product-related, that is unfavourable and unintended and that occurs after any use of a veterinary medicine – provides an opportunity to continually improve the safety profile of veterinary medicines. The VMD, as part of their pharmacovigilance activities, receive and evaluate reports of adverse events and lack of efficacy in animals and people (21). The most recent VMD annual review of pharmacovigilance in the UK reassuringly stated that 'the chance of an adverse event happening in any particular animal or person is very low' (22). Nevertheless, the controls and surveillance monitoring in place continue to safeguard animals, people and the environment as well as continually improving the safety profile of veterinary medicines. More information on this topic can be found in the NOAH briefing document: pharmacovigilance, monitoring the safety and efficacy of animal medicines. Conclusions UK and EU regulatory controls on veterinary medicines cover activities in the discovery, research and development phases, through authorisation of medicines and extend throughout the post-authorisation phase. Before medicines are authorised, they must meet strict safety, quality and efficacy standards to gain a marketing authorisation. There are a number of authorisation routes for veterinary medicines, which govern the countries where the animal medicine may be marketed and sold. In the UK, the classification of authorised veterinary medicines designates the supply and distribution of these medicines. Strict controls on medicines for food-producing animals, including record keeping and observance of withdrawal periods, ensures the safety from residues of veterinary medicines in food from treated animals. Pharmacovigilance and the monitoring and evaluation of adverse events allows for the ongoing improvement of the safety profile of medicines on the market. Reviewed May 2016 What is NOAH? The National Office of Animal Health Ltd represents the UK animal medicine industry: its aim is to promote the benefits of safe, effective, quality medicines for the health and welfare of all animals. For further information, including more briefing documents on animal medicines topics see www.noah.co.uk and follow @UKNOAH on Twitter. (For more information on authorised veterinary medicines see NOAH briefing documents on Veterinary Medicines and the Safety of Food from Animals and Pharmacovigilance). References: Animal Medicines Training Regulatory Authority (AMTRA), information on the regulatory of SQPs: www.amtra.org.uk/ Share: This document describes how we safeguard our food derived from animals that have been treated with a veterinary medicine to protect their health. Important topics such as Maximum Residue Limits (MRLs) and withdrawal periods are introduced in the context of how veterinary medicines are used and how residue controls and monitoring ensure the safety of food from treated animals. This document was last reviewed in 2016 Introduction To safeguard the health and welfare of our farmed animals, veterinary medicines are used as part of a herd or flock health plan. Authorised veterinary medicines used in farmed animals are subject to strict regulatory controls. An important consideration is observing a legally defined period of time after the last administration of medicine has been given, before allowing the animal or its produce to enter the food chain (the withdrawal period). Additionally, the independent regulator – the Veterinary Medicines Directorate (VMD) in the UK, oversees a national surveillance programme to monitor and report on residues of veterinary medicines in food from animals. Taken together, these practices provide an assurance that food from animals is safe with regards residues of veterinary medicines. Maximum Residue Limits (MRLs) and Withdrawal Periods Residues of pharmacologically active substances are described as active substances, excipients or degradation products and their metabolites, which remain in foodstuffs obtained from animals that have been treated with a veterinary medicinal product (1). The withdrawal period is a specific set period of time, after the last dose of the veterinary medicine has been administered, that must elapse before an animal or foodstuffs from an animal can enter the food chain. To determine the withdrawal period, regulatory authorities must employ a scientific process that includes establishing the Maximum Residue Limit (MRL) for that medicine (2, 3). The MRL is the maximum concentration of residue accepted by the European Union (EU) in a food product (e.g. meat, milk, eggs) obtained from an animal that has received a veterinary medicine (2). In the process of establishing an MRL, firstly a No Observed (Adverse) Effect Level (NO(A)EL) is identified through scientific studies with the active substance. The NO(A)EL is the highest dose that does not cause adverse effects. This figure is then divided by an 'uncertainty' or 'safety factor' e.g. by 100-1000 to determine the Acceptable Daily Intake (ADI). The ADI is the amount of the residue that is considered safe for an individual to eat every day for their lifetime taking into account a number of safety factors. The MRLs are such that consumers can ingest generous amounts of animal foodstuffs every day without exceeding the ADI. A number of factors are taken into consideration here including the amounts of each food eaten per day and how the substance is metabolised and distributed in the various tissues. A MRL is then set for each edible tissue and product to ensure the ADI is not exceeded. The independent European Regulator for veterinary medicines (the European Medicines Agency or EMA) and its Committee for Veterinary Medicinal Products (CVMP) is responsible for assessing the safety of residues from veterinary medicines available in the EU (2). The assessment of the safety of the pharmacologically active substances and their residues occurs before a veterinary medicine intended for food producing animals is authorised for use in the EU (2). Following assessment of pharmacological and toxicological studies by the regulatory authorities, substances that may be used are listed in Table 1 (allowed substances) of the annex to Commission Regulation (EU) No 37/2010 before the product can be authorised (4). Table 1 contains information on substance MRLs for different active ingredients for various target tissues and animal species, whilst Table 2 lists pharmacologically active substances that are prohibited and are considered a hazard at any level and must not be used under any circumstances in veterinary medicines for food-producing animals (4). When an MRL has been determined for a veterinary medicine, the withdrawal period is then calculated by taking into account the rate of residue depletion, to below the MRL, in all edible tissues and products (3). Withdrawal periods for veterinary medicines, which are specific for each farm species and foodstuff, are set out in the NOAH Compendium of Datasheets (5). The withdrawal period can also be found on the product leaflet and in the Summary of Product Characteristics (SPC) document on the VMD Product Information Database (6). The use of animal medicines is strictly controlled by European law, and requires observance of the withdrawal period, which must have elapsed before an animal or its products can be used for human consumption. The withdrawal periods have been calculated using rigorous scientific processes so that veterinary medicines can be authorised and administered to food producing animals, whist at the same time consumer safety is protected. Residue Controls and Monitoring Post-authorisation, when medicines are placed on the market and used in animals, their use on farms is also highly regulated with controls on use and statutory residue monitoring in place (7, 8). In the UK, the VMD operates a national surveillance scheme for residues (also called the National Residues Control Plan) that analyses samples from food producing animals and their products for residues of veterinary medicines and prohibited substances (8). This statutory surveillance programme fulfils the UK's obligations under EU law, Council Directive 96/23/EC (9). The samples taken include red meat, poultry meat, farmed salmon and trout, eggs, wild and farmed game, honey and milk (8). If any unacceptable residues are found in samples, an investigation is carried out to identify the cause. The Food Standards Agency (FSA) also has published industry guidance to accompany EC regulations on the testing of milk for residues (10). The results of the statutory surveillance scheme are published annually and show that the vast majority of samples are compliant (11). This means UK farmers and animal health professionals are taking their responsibilities seriously and that consumers can be assured of the safety of food from animals when it comes to residues of veterinary medicines. Responsible Use of Veterinary Medicines The responsibility, for ensuring our food from animals does not contain residues above the statutory limit, is shared by all those involved in the animal medicines sector. Vets, Suitably Qualified Persons (SQPs) and professional keepers of animals, including farmers all have a role to play (3, 12). Using animal medicines responsibly is a fundamentally important step in safeguarding our food. The Responsible Use of Medicines in Agriculture Alliance (RUMA) has published guidelines on the responsible use of all medicines in farmed animals (13). One important aspect of using medicines responsibly is using them according to their authorised use i.e. following instructions on the SPC or datasheet (6, 5) and following accurately the instructions of the prescriber. Treatments should be given appropriately (in terms of authorised route of administration, dose and duration of treatment) and withdrawal periods observed for animals and their animal products. Additionally, in the UK there are legal requirements, under the Veterinary Medicine Regulations, 2013, regarding keeping records for all veterinary medicines used in food-producing animals (7). On farm, this can be achieved by using an animal medicines record book (such as that produced by NOAH and AHDA) and keeping those records for a minimum of 5 years (7, 14). In the UK, farmers and vets have an excellent track record of adhering to the regulations and ensuring consumer food safety is upheld (11). Monitoring by the independent regulator, fulfilling statutory obligations with transparent reporting means we can continue to expect high standards of safe food from animals, where medicines are used. Conclusions Before medicines are authorised for food producing animals, considerable evaluation and scientific process must occur to assess their safety and determine MRLs and withdrawal periods. Once on the market, animal medicines continue to be highly regulated with national and European legislation in place that governs their use. In the UK, farm animal medicines are also closely monitored on farm with animal medicines records allowing for traceability. Under EU legislation, the VMD runs a national residue surveillance scheme, which analyses a variety of foodstuffs from different farmed species. The annually published results show that the vast majority of samples are compliant. Reviewed May 2016 What is NOAH? The National Office of Animal Health Ltd represents the UK animal medicine industry: its aim is to promote the benefits of safe, effective, quality medicines for the health and welfare of all animals. For further information, including more briefing documents on animal medicines topics see www.noah.co.uk and follow @UKNOAH on Twitter. (For more information on authorised veterinary medicines see NOAH briefing documents on Controls on Animal medicines and Pharm