Veterinary Medicines Directorate

Department for Environment Food & Rural Affairs

Review of the Veterinary Medicines Regulations 2013

Summary table for government response

Date: February 2024

This document is supplementary to the ‘Review of the Veterinary Medicines Regulations 2013: Summary of responses and government response’. In this report, published on Citizen Space, you will find a summary of responses and the full government response to the consultation on proposed changes to the Veterinary Medicines Regulations 2013.

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Chapter 1: General (regulations)

This chapter covers changes to the main regulations of the VMR. Where the changes to the regulations relate more closely to the areas covered in subsequent chapters (which deal with changes to the Schedules to the VMR), they are covered there instead.

Proposal	Response summary	Outcome
Minor drafting changes for clarification Minor drafting changes to clarify the regulations and Schedules or to improve consistency in wording. Introduce new definitions or amending existing ones. These changes are intended to ensure a clear, consistent understanding of the VMR by both stakeholders and the regulator.	Nil	Adopted
Providing information upon request To extend the requirement to provide the Secretary of State with information upon request to all businesses or persons regulated by the VMR.	This proposal is withdrawn as we have identified that we have sufficient powers throughout the VMR to request the information we need.	Removed
Record keeping for vets and food-producing animal owners/ keepers A vet who personally administers a medicine to a food-producing animal should provide records to the animal owner or keeper “as soon as reasonably practical”.	Nil	Adopted

Advertising To adjust the regulations on advertising to clarify what is allowed and required in terms of the advertising of a veterinary medicine. Make explicit that a medicine may only be advertised if it has an MA, which is not suspended. This change would not apply to medicines marketed under the exemptions for small pet animals. In addition, introduce a regulation setting out the conditions for inducements and hospitality in relation to veterinary medicines. Finally, with regard to POM-V medicines advertising targeted at professional keepers of animals, only allow this for immunological medicines, and such advert should state that the professional keeper of animals will need to consult a vet before using the medicine.	In response to the concerns raised, we have decided to not implement the proposed restriction on the advertising of POM-V and POM-VPS medicines to professional keepers of animals to immunological products. Instead, a statement must be included on the advert that it is the prescriber who decides on the product and the regulations will clarify that the advert is to only include factual statements in line with the Summary of Product Characteristics (SPC) of the medicine.	Amended
Powers of an inspector To allow inspectors to seize any goods included in this regulation, if they believe that a breach of the VMR has occurred and / or is occurring, provided they have reasonable grounds to do so. Introduce a power for inspectors to order an immediate stop to activities that they deem to be putting human and animal health at risk.	Nil	Adopted

Chapter 2: Marketing authorisations in Great Britain

Schedule 1 to the VMR sets out the requirements for applying for a new marketing authorisation (MA), applying to change an existing MA, labelling and packaging, post-authorisation monitoring (pharmacovigilance) and homeopathic remedies.

Proposal	Response summary	Outcome
Information for MA application and summary of product characteristics To adjust the information that we require to be provided with an application for an MA. The information would be similar to the requirements for an MA application submitted to the European Medicines Agency. The data requirements would be harmonised to the extent possible with those in Annex II to the Regulation (EU) 2019/6, which would remove divergence between the requirements for GB and Northern Ireland (NI) facilitating the process for UK-wide coverage. Additional information would have to be provided with an MA application for a product containing antimicrobials. This should include information on the direct and indirect risks to public or animal health or to the environment and on the methods of mitigating the development of antimicrobial resistance as a result from the use of the antimicrobial product in animals. To change the order of the information that must be included in the SPC and to update our minimum information requirements to	In response to the feedback received, we have decided to amend our proposals to ensure that the technical data that need to be submitted with the application for an MA, including the SPC, will be consistent with the EU rules. We recognise that the pharmaceutical industry is set up to cover the region of Europe, which includes the UK, and its regulatory requirements. These changes will ensure that companies can submit a single dossier for the European region. This will reduce burdens to the industry and help facilitate the continued availability of veterinary medicines in GB.	Amended

ensure that a product's SPC contains relevant information that supports safe and responsible use. To introduce the requirement that the SPC submitted for a generic veterinary medicine must be essentially similar to that for the reference product.		
Bibliographic applications To require an applicant for a bibliographic application to demonstrate that the active substances of the veterinary medicine have been in well-established veterinary use for at least 10 years, their efficacy is documented and they provide an acceptable level of safety.	After consideration of the concerns raised, we have agreed to continue with the proposed changes and provide clarification in guidance, where such a need was identified by respondents. We believe the proposals will positively impact availability of medicines. Our robust assessment processes and post-authorisation monitoring ensure safe and effective veterinary medicines remain on the market. Furthermore, veterinary medicine is a private service including the supply of medicinal products; the costs charged by individual veterinary practices vary widely due to the variable levels of overheads incurred. The government is not informed of the costs of individual products and the pricing structures of veterinary medicines is not subject to legislative controls. Therefore, the cost of a veterinary medicinal product is controlled by the market rather than legislation.	Adopted

	With regards to biologicals, we do not consider the standard generic approach to be appropriate. If an applicant can provide satisfactory justification a hybrid generic route might be an option.	
Generic/generic hybrid products To state in the VMR that an applicant for a generic hybrid MA must provide relevant data to support the difference with the reference product (for example active substance(s), indications for use, withdrawal period), or if bioavailability studies are not capable of demonstrating bioequivalence with a reference product and a biowaiver is inappropriate (new paragraph 10A in Schedule 1 to the VMR). To state explicitly that a generic or generic hybrid product may not be placed on the market before the end of the data protection period for the reference product. To move the option for generic immunological or biological products from a stand-alone provision to being included in the new Schedule 1C which sets out the technical documentation demonstrating the quality, safety and efficacy that is required for the various types of MA application.	Nil	Adopted
Marketing authorisation for parallel import To remove the option for MAs for parallel imports (MAPIs).	From the responses, there appears to have been some confusion over this proposal. We do not propose changes to the provisions for the importation of authorised veterinary medicines or	Adopted

	medicines prescribed under the cascade (and imported in accordance with the special import scheme), but only to remove the option of MAs for parallel imports (MAPIs). Parallel importing refers to when a product is bought from wholesalers in another country and imported into the GB for distribution. We considered this an appropriate route for approving MAs when the UK was part of the EU, when we allowed MAPI applications for products authorised in the EU. Post EU Exit we no longer consider this an appropriate route to market. As such, we will implement this proposal.	
Parallel assessment of application for maximum residue limit and MA To make it possible that applications for assessment of an MRL can be submitted at the same time as an application for an MA.	Nil	Adopted
Data protection periods To extend (some of) the data protection periods currently awarded to veterinary medicines and to introduce extensions to these periods in defined circumstances. Furthermore, to decouple the addition of species and pharmaceutical form, if packaged separately from the original product, and apply separate data protection periods.	After consideration of the responses, we have decided to implement these proposals to encourage innovation and maintain a thriving generics market. We will amend our guidance, if considered necessary, to provide further explanation on how to apply the data protection periods. A definition for ‘major species’ will be included in the VMR to ensure absolute clarity.	Adopted

Parallel assessment with other regulators To introduce a facility for a clock-stop in our timeline for procedures that are part of a parallel assessment with other regulators that we have an agreement with.	We would like to clarify that the intention with this change is to enable alignment of assessment timetables and that the regulators involved will perform separate assessments of the dossier. Timelines are already published online. Reduced assessment by the VMD of products authorised by other regulators is not currently possible. We have noted the request to discuss with the applicant if an extended clock stop is needed and plan to explore this further.	Adopted
MAH location To no longer require MAHs to be established in the UK, but instead to require MAHs to have a UK-based local representative to act as the local contact for regulatory and enforcement matters, to ensure recording and reporting of adverse events and to have the legal capacity to act for the MAH. This would also apply to those who wish to market registered veterinary homeopathic remedies.	We understand that requiring MAHs to be based in the UK may lead to a significant reduction in the availability of veterinary medicines in the UK. Due to ongoing uncertainties, we will continue with the current arrangement of allowing MAHs to be based in countries with equivalent regulatory standards. On the requirement for a local representative, we are aware of trepidation regarding the role of a local representative. Therefore, we will introduce this role on a voluntary basis – we will provide more information to MAHs on how they can appoint a local representative and the benefits of doing so, but this will not be a mandatory requirement.	Amended

The granting of an MA To introduce the option for the Secretary of State to require, in relation to medicines containing antimicrobials, MAHs to conduct post-authorisation studies to ensure that the benefit-risk balance remains positive.	Nil	Adopted
Withdrawal of an MA application To introduce the requirement that formal withdrawal of applications must be made in writing and must include a reason for withdrawal. To publish completed assessment reports for withdrawn MA applications in the future, protecting any commercially sensitive information, to assist other companies in understanding the requirements that are necessary when completing an MA application.	We would like to reassure respondents who have raised concerns over the potential disclosure of commercially sensitive information. The VMD is highly experienced in writing public assessment reports and will endeavour to ensure the contents of these remains confidential. However, in response to these concerns we will amend this proposal and instead provide a summary of the reasons for withdrawal.	Amended
Refusal of an MA To make reasons where the Secretary of State must refuse a marketing authorisation explicit in the VMR to aid transparency and to add additional reasons for refusal of an MA. Additional reasons include: • the product contains an antimicrobial that is reserved for human use,	Nil	Adopted

• the product is an antimicrobial veterinary medicine presented for use in order to promote the growth of or increase yield from treated animals, • the risk for public health in case of development of antimicrobial resistance, • antiparasitic resistance outweighs the benefits of the product to animal health. To insert established practice into the VMR, where the Secretary of State publishes when a marketing authorisation is refused, suspended or revoked, as well as the terms of a variation if the text of an MA is varied in relation to the SPC.		
Samples To expand the power to require a MAH to provide samples of starting materials or the veterinary medicine for testing to requiring the MAH to provide upon request the results of any control tests carried out in relation to the starting materials or finished product. We will limit what such samples may be used for.	Nil	Adopted
Information on shortages To introduce a new requirement for MAHs to report any current or upcoming shortages (i.e. when supply does not meet demand at a national level within the UK) where known.	Nil	Adopted

Renewal of marketing authorisations To remove the requirement to renew a marketing authorisation after the initial five-year period; so instead, unless the benefit-risk balance becomes unfavourable a MA has indefinite validity. This change would also apply to registrations of homeopathic remedies.	We would like to clarify that with these proposed changes there will be no new risks to our trigger mechanisms and monitoring with regard to safety concerns. MAHs are already required to immediately inform the Secretary of State on receipt of any new information that might adversely affect the benefit-risk balance of the veterinary medicine. The VMR also give the Secretary of State powers to request data at any time on the benefit-risk balance of any product. We also have internal procedures which allow for regular review, and the proposed removal of the requirement to renew an MA after the initial five-year period will not impact this.	Adopted
Variations To replace the variation types IA, IB, II and extension in the VMR with two categories of variations: variations requiring assessment (VRAs) and variations not requiring assessment (VNRAs). To include a provision for unforeseen variations: variations which the MAH is uncertain how to classify under the VMR. The Secretary of State would provide a recommendation of the categorisation upon request.	We have decided to retain the proposal in amended form. In response to the concerns raised, we will ensure that we have a suitably flexible procedure in place that makes it possible to update the VNRA list when needed.	Adopted

The variations not requiring assessment were to be consistent with the variations not requiring assessment under the EU rules. To remove the options for administrative and workshare variations as these would no longer be needed.		
Grounds for suspension of MA, prohibiting supply and temporary restrictions To allow the Secretary of State to suspend or revoke an MA or require the MAH to submit an application for a variation at any time. To add the following additional grounds for suspension or revocation: failure to comply with the VMR by the MAH or the Qualified Person for pharmacovigilance or there is no adequate pharmacovigilance system in relation to the veterinary medicine. To expand the reasons for which we can prohibit the supply of a veterinary medicine or require a medicine to be recalled. The additional reasons: • an unfavourable benefit-risk balance of the veterinary medicine • the qualitative or quantitative composition of the medicine is not as stated in the SPC • the recommended withdrawal period is insufficient to ensure food safety • the required control tests have not been carried out • the incorrect labelling of the medicine might lead to a serious risk to human or animal health.	We have decided to implement this proposal. We will continue to liaise with industry regarding the changes. We will provide guidance in response to concerns raised on the need for further clarity on our approach for adopting this proposal.	Adopted

To introduce powers for the Secretary of State to be able to put in place temporary restrictions on the supply or use of a veterinary medicine, when urgent action is needed for the protection of human health, animal health or the environment. To introduce a new provision to prohibit the manufacture, import, distribution, supply or use of immunological veterinary medicines in certain scenarios: • if the administration of the product would interfere with the implementation of a programme for diagnosing, controlling and eradicating a disease • if the administration of the medicine causes difficulty in certifying absence of disease in live animals or contamination of foodstuffs or other products from treated animals • if the strains of disease agents in relation to which the immunological is intended to confer immunity is largely absent in that locality.		
Labelling and package leaflets To adjust the labelling requirements to provide assurance that the necessary information is available with the product and where necessary on the immediate packaging, whilst that the right information is available for the medicine to be used safely and effectively without placing too much regulatory burden and cost on companies. The changes allow for more efficient means of labelling, utilising current thinking and technology (for example	After consideration of the feedback received, we have decided to amend the proposed changes and ensure full alignment with the regulatory requirements in NI (and the EU) related to labelling and packaging for veterinary medicines. This will help ensure safe and effective veterinary medicines continuing to be available in the UK.	Amended

QR codes), which is particularly important for smaller units of veterinary medicine. The changes would be harmonised to an extent with the EU legislation, with minor differences such as the inclusion of the distribution category. Information may be included in abbreviations or pictograms approved by the Secretary of State. To allow additional information on the leaflet concerning distribution, possession or any necessary precaution required, provided that this information is not promotional in character and it complies with the marketing authorisation.		
Electronic package information leaflet Allowing an electronic package information leaflet (EPIL) to be provided, where appropriate, as an alternative to a physical package leaflet.	Upon consideration of the responses received, we have decided to retain the introduction of the option of providing an electronic package information leaflet, which we also believe to benefit the environment. In line with other changes related to packaging, we will align with the regulatory requirements in NI (and the EU) on veterinary medicines so that joint labelling will remain possible. We will provide guidance to address the requests for clarifications and concerns raised by respondents.	Adopted
Pharmacovigilance (post-authorisation monitoring) Updating the requirements for pharmacovigilance and harmonise them, to the extent possible, with the approach taken in the EU to assist MAHs. We proposed:	Upon consideration of the responses received, we have decided to amend the pharmacovigilance proposals in some areas.	Amended

• removing the requirement to submit periodic safety update reports (PSUR) for a product and replacing it with annual benefit-risk reports • introducing a Signal Management system which should ensure that prompt action is taken when needed • moving from the Detailed Description of the Pharmacovigilance System (DDPS) to the Pharmacovigilance System Master File (PSMF) • amending the adverse event reporting timelines and conditions (from 15 to 30 days for serious cases and 30 days for non-serious). To allow the MAH to introduce urgent safety restrictions in the event of risk to human or animal health or to the environment. We would also be able to require MAHs to have a risk management plan should the pharmacovigilance data suggest that one is required. To include the provision to take action against any products that contain the same active substance as a product that has concerning pharmacovigilance data. To introduce the requirement for the Secretary of State to inspect MAH premises to verify compliance with the pharmacovigilance provisions – the frequency of these inspections would be risk-based.	We have introduced definitions to add clarity (for example for 'lack of efficacy') and updated the pharmacovigilance requirements to make them clearer. We have simplified the approach to the annual benefit-risk report and reduced the data requirements for this report. We have also amended the requirements for pharmacovigilance reporting for animal test certificates, requiring the reporting of all adverse event reports within 30 days rather than serious reports only within 15 days. We will provide further clarification and guidance on the proposed approach to pharmacovigilance.	

Registered homeopathic remedies To adjust the requirements in the VMR to clarify that the registration of homeopathic remedies is restricted to those with a topical or oral route of administration. To adjust the requirements for registration and exclude biological homeopathic remedies unless they are derived from plants. To no longer require a mock-up of the outer and immediate packaging with the application for a registration but would instead require to be provided with the text which will be included on any of the packaging or leaflets.	Upon consideration of the feedback, we have decided to implement the proposed changes. We will provide further clarification and guidance on these proposed changes.	Adopted

Chapter 3: Manufacture

Schedule 2 to the VMR sets out the rules for the manufacture of veterinary medicines, which includes authorisation of autogenous vaccines, blood banks, stem-cell centres and products manufactured for administration under the cascade.

Proposal	Response summary	Outcome
Manufacture activities To clearly state what activities constitute 'manufacture' and when a manufacturing authorisation is required, which includes manufacturing for export: any part of the manufacture of a veterinary medicine until the finished product is ready for sale in its final form as specified in the marketing authorisation. This includes any processing, assembling, packaging, repackaging, labelling, relabelling, sterilising, storing, importing or releasing for supply of the product as part of that process. It does not include preparation, dividing up of a product or changing in packaging or presentation of the product for retail purposes as permitted under Schedule 3 to the VMR.	Nil	Adopted
Manufacturing authorisation With regard to manufacturing authorisations, to insert established practice into the VMR. This includes: • a statement that a manufacturing authorisation is required to import a manufactured finished product for batch testing (if	Nil	Adopted

required) and certification by the authorisation holder's qualified person (QP) for their release to the market. • additional information for the manufacturing authorisation to improve the authorisation process. • a statement that a manufacturer outside the UK must hold a valid GMP certificate issued by us or a regulatory authority that we have a formal agreement with (or otherwise consider having equivalent regulatory controls to ours). To require manufacturers to record more detail on the products they manufacture, to improve traceability. To require that records are kept for 5 years (as now) or one year after the expiry date (for those medicines with a shelf life of over 5 years), whichever is longer. To provide more detail on the grounds for which we may compulsory vary, suspend or revoke an authorisation, including instances where the manufacturer has not paid applicable fees or if the manufacturer has not conducted any activity related to the authorisation for more than five years.		
Consistent approach for specific manufacturing authorisations To restructure Schedule 2 to introduce a consistent approach for specific manufacturing authorisation holders (autogenous vaccines, non-food animal blood banks, stem cell centres and manufacturers of products for administration under the cascade) (new Part 2 of Schedule 2 in the VMR). The existing offences have been amended accordingly.	Nil	Adopted

To adjust the requirements to state that authorised manufacturing sites must be under the supervision of a named 'person responsible for release' of the product. This can be a vet or someone else who in the opinion of the Secretary of State has sufficient qualifications and experience to manufacture the product safely. To expand the requirement of reporting any adverse events to the Secretary of State to all holders of specific manufacturing authorisations, to now include blood banks and stem cell centres, thus ensuring a consistent approach and monitoring of the safety of these products.		
Active substances To introduce new requirements for the manufacture, importation and distribution of active substances: • that any person who manufactures, imports or distributes an active substance must register with the Secretary of State at least 2 months before commencing one or more of those activities; or in the case of an existing manufacturer, within 2 months of the date on which the amended VMR come into force. To introduce an offence for failure to comply with this requirement. • that a manufacturer, importer or distributor of active substances complies with the principles and guidelines of good manufacturing practice or good distribution practice, as the case may be.	Nil	Adopted

To introduce a provision that enables the Secretary of State to inspect those businesses (not necessarily the active substances themselves) on a risk-basis to ensure the VMR are being complied with. A fee would apply for such inspections.		
Manufacturers of products for administration under the cascade To introduce a new offence of manufacturing an unauthorised product for administration under the cascade that is pharmaceutically equivalent to a product with a marketing authorisation – unless the Secretary of State has identified that there is a supply issue for that authorised product. To introduce the requirement that manufacturers of extemporaneous preparations must state on the label that the product does not have a MA. To introduce the requirement for these manufacturers to provide a list of formulations they have manufactured and product sales data to the Secretary of State on request.	Upon consideration of the responses, we have decided to implement the proposed changes. The VMR will set out a definition of 'pharmaceutically equivalent' to clear any confusion. The definition of what is 'pharmacologically equivalent' is already provided in the VMR. We will amend our guidance where necessary to address concerns raised.	Adopted
Stem cell centres To extend the authorisation and inspection requirements of equine stem cell centres to all non-food-producing animals.	Nil	Adopted

Chapter 4: Classification and supply, wholesale dealers and sheep dip

Schedule 3 contains the requirements for the classification and supply of veterinary medicines, including retail supply by veterinary surgeons, pharmacists and suitably qualified persons (SQPs), wholesale supply and sheep dip.

Proposal	Response summary	Outcome
Classification of POM-V medicines To adjust the requirements so that the categories of medicines that must be classified as POM-V (prescription only medicine – veterinarian) include medicines that contain antibiotics or beta-agonists, or that are used for euthanasia, or that are immunological or hormonal.	After consideration of the feedback, we have decided to implement the proposed changes in amended form. Immunological products will not be restricted to a POM-V classification, and these can continue to be either POM-V or POM-VPS subject to the usual assessments and procedures.	Amended
Requirements for wholesale dealers To bring the requirements up-to-date, the wholesale dealer must: • comply with good distribution practice. • only obtain veterinary medicines from other wholesale dealer's authorisation (WDA) holders or those with a manufacturing authorisation.	Nil	Adopted

• issue a document detailing key information when supplying medicines (including name and pharmaceutical form and batch number) and keep a copy for five years. • follow guidelines when destroying medicines and keep records of any destroyed medicines for five years. • inform the Secretary of State if it is offered counterfeit medicines. • report supply shortages to the Secretary of State, to improve the security of the supply chain. • We propose to introduce offences for failure to comply with the new record keeping requirements. To state explicitly that when a wholesale dealer supplies veterinary medicines to a vet or pharmacist, the supply must be to appropriately registered or authorised premises. Introduce a requirement to have the services of technically competent staff (including a Wholesale Qualified Person), as well as a requirement to have a procedure in place for withdrawing or recalling a product and a clearly documented and defined Quality System.		
Wholesale dealers' audits and record-keeping To introduce a new requirement for wholesale dealers to investigate and document any stock level discrepancies identified through their annual audit. To introduce a requirement for wholesale dealers to put in place a self-inspection plan in relation to good distribution practice.	Nil	Adopted

To amend the record-keeping requirements for wholesale dealers: all records, including records of stock audits and any investigations, self-inspection plans and purchase and sales records (which currently have to be kept for three years) must be made and kept for five years (in line with the other record-keeping requirements in the VMR).		
Wholesale dealing by MAHs To remove an MAH's ability to wholesale veterinary medicines without holding a WDA.	Nil	Adopted
Special Import Scheme To amend the regulation to clarify that a pharmacist does not need a wholesale dealer's authorisation to supply an unauthorised veterinary medicine imported under the scheme to a vet provided the vet holds the appropriate special import certificate.	Nil	Adopted
Distribution for promotional purposes To update the position on distributing medicines for promotional purposes. Medicines distributed for this purpose must be clearly labelled as samples and directly handed to those allowed to supply medicines. Medicines containing antimicrobials must not be distributed for promotional purposes. We propose to introduce an offence for failure to comply with this requirement.	Nil	Adopted

Registration of online retailers To introduce a new requirement for online retailers of veterinary medicines categorised POM-V, POM-VPS and NFA-VPS to register with the Secretary of State. Those retailers are required to display a registration logo issued by the VMD. To introduce offences for failure to comply with the requirement to register and other duties in relation to online supply.	Nil	Adopted
Retailer supply To amend audit and record-keeping requirements for retailers: all records, including records of stock audits and any investigations on discrepancies must be made and kept for five years. To introduce the requirement that retailers must store veterinary medicines in line with the storage instructions on the label. To introduce an offence for failure to comply with this requirement.	Nil	Adopted
Assessment by vet before prescribing POM-V To amend the requirements for prescriptions by a vet to allow vets the option of performing “a clinical examination or other proper assessment” of an animal or group of animals under their care when prescribing POM-V medicines.	Upon consideration of the responses received, we have decided to not implement this proposal. The current VMR text of ‘clinical assessment’ will be kept. By retaining this wording, the intended objective will still be achieved. We will endeavour to pass on any concerns raised, in relation to the Royal College	Removed

	of Veterinary Surgeons' (RCVS) change in guidance, to the RCVS for its attention.	
Prescriptions To require any person qualified to prescribe veterinary medicines who orally prescribes a prescription medicine – which includes pharmacists and SQPs orally prescribing POM-VPS medicines – to record their rationale for doing so. To update the information that should be contained in a prescription.	After consideration of the feedback received, we have decided to implement these proposals in amended form. To avoid confusion, the VMR will refer to any prescription that is not a written prescription, instead of referring to 'oral' prescriptions. This includes online prescriptions. The VMR will also clarify that the reason for prescribing of the product needs to be recorded, instead of the rationale. Clarification on this and what this may look like in practice will be provided in guidance.	Amended
Wholesale supply of premix by feed business operators To harmonise the provision allowing feed business operators to wholesale supply an amount not exceeding 5% of their total annual supply with that for emergency supply of veterinary medicines between retailers.	Nil	Adopted
Products supplied under the cascade To make explicitly clear in the VMR that medicines prescribed and / or supplied under the cascade are to be treated as if they	Nil	Adopted

were POM-V, in relation to record-keeping requirements, assessment of the animal before prescribing and supply.		
Remote supply by SQPs To allow delegation to a competent person by an SQP who has correctly prescribed/ advised on a product and who has authorised its supply in advance, the product selection and/or hand-over to the customer.	We will implement this proposal. We will provide further clarification in guidance which will address concerns raised.	Adopted
SQP registration bodies To clarify in the VMR, including the appeal procedure, that the Secretary of State can revoke or suspend the recognition of an SQP registration body and that the code of practice for SQPs applies to SQP bodies as well as SQPs.	Nil	Adopted
Sheep dip To clarify that the holder of a Certificate of Competence in the Safe Use of Sheep Dip is permitted to carry out the act of dipping (not just supervise the dipping).	Nil	Adopted

Chapter 5: Administration under the cascade

Schedule 4 to the VMR covers the rules and circumstances under which unauthorised medicines can be used or authorised medicines can be used not in accordance with their authorisation. If no UK-authorised suitable veterinary medicine is available to treat a condition in a species, a vet can – in particular to avoid unacceptable suffering – treat an animal under their care in accordance with the prescribing cascade. The cascade is an important tool for vets to increase the treatment options available to animals under their care. It is a risk-based decision tree and sets out the different options that a vet may consider.

Proposal	Response summary	Outcome
Cascade prescribing for food-producing animals To expand the current requirement that pharmacologically active substances included in medicines administered to food-producing animals under the cascade need to be substances for which a maximum residue limit is established, to all substances in that medicine to have an established maximum residue limit or to be included on the out-of-scope list.	Nil	Adopted
Appropriate use of the cascade To introduce a new offence of encouraging or facilitating the illegal use of the cascade and to explicitly state that an autogenous vaccine should only be used in exceptional circumstances and when there is no authorised immunological veterinary medicine for the target species, in accordance with the cascade.	We have considered the responses received to this consultation question and decided to implement the proposals in amended form. The VMR will refer to 'promoting' instead of 'encouraging'. This is intended to stop widespread promotion of cascade use. It is not the intention to limit treatment options or prevent individual vets from using their own clinical judgement when prescribing in accordance with the cascade, nor is it intended to	Amended

	prevent the vet from discussing treatment options with the owner of the animal under treatment. It is also recognised that clarity is required with regards to the prescription and use of autogenous vaccines and thus, we will slightly amend the proposed change to the VMR. An autogenous vaccine may only be prescribed in accordance with the cascade and administered to animals in exceptional circumstances where there is no suitable, authorised immunological veterinary medicine for the target species and indication. Our online guidance on the cascade will be amended to provide further clarity.	
Withdrawal periods To amend the statutory minimal withdrawal periods to ensure they are fit-for-purpose: ensuring food safety whilst not presenting a barrier to the treatment of animals.	Nil	Adopted

Chapter 6: Medicated Feed

Schedule 5 to the VMR covers manufacture, supply, prescription, etc. of medicated feed (also known as medicated feedingstuffs) and specified feed additives.

Proposal	Response summary	Outcome
Definitions To introduce additional definitions in Schedule 5, such as for batch, complementary / complete / compound feed and intermediate feedingstuffs. To refer specifically to premix as the veterinary medicine incorporated into feed and replace the confusing term ‘premixture’ with ‘intermediate feedingstuff’ throughout the schedule.	Regarding the concerns raised on terminology, we have taken these into consideration and agree to amend the term ‘premix’ to ‘medicinal premix’. This is to prevent any confusion with the term ‘premix’ in feed legislation which could also refer to non-medicinal feed supplements.	Amended
Prescription for medicated feed To strengthen the information that needs to be included in the prescription for feed containing a medicinal premix. To clearly state in the legislation that an authorised commercial manufacturer can manufacture a medicated feed in anticipation of a written medicated feed prescription being provided.	We appreciate the concerns raised but have decided to implement the proposals. Regarding manufacture in advance of receipt of prescription, for clarity, this is intended only for commercial feed mills and not for on-farm mixers. This is something that is already done, and the change is intended to make clear in the legislation that it is allowed.	Adopted

Labelling To introduce new labelling requirements for intermediate feedingstuffs and medicated feed that are in line with those for veterinary medicines. The main changes relate to requiring the use in line with the summary of product characteristics of the premix and warnings about inappropriate disposal.	Nil	Adopted
Storage and disposal of medicated feed To require keepers of animals to store any product regulated by Schedule 5 in accordance with the summary of product characteristics. They should also ensure that there is no contamination of products, feed material and environment. Products should be administered only to the correct animal and the withdrawal period should be complied with. To introduce a new requirement for feed business operators and professional keepers of animals to have a collection and disposal system in place for expired or unused medicated feed. To state explicitly that medicated feed that has passed its expiry date may not be fed to an animal and to introduce an offence for failure to comply with this requirement.	Upon consideration of the feedback received, we have decided not to implement the proposal for the collection and disposal system. We understand that the burden appears to be disproportionally high on FeBOs. We will instead commit to reviewing whether a collection and disposal system should be in place; the scale of the problem of unused medicated feed being used in animals for which it is not/no longer prescribed; and what a potential system should look like and how it could be introduced. For clarity, we will move forward with the change that expired feed must not be fed to animals.	Removed
Cross-contamination and carryover To introduce a new requirement for cross-contamination to be as low as reasonably achievable. We would require suitable testing to be carried out and for feed business operators to note any	Nil	Adopted

results over 1% and to conduct a root cause analysis for results over 3%. These analyses should be kept for 5 years. To require feed business operators to provide the Secretary of State with information on carryover testing, sampling and assessments. To introduce an offence for failure to comply with these requirements.		
Tolerance table To amend the tolerance table to support high quality of medicated and intermediate feedingstuffs with accurate levels of active ingredient.	We appreciate the feedback on this proposal. We have thoroughly considered these concerns raised and decided we will implement this change. This is because of the drive to reduce antimicrobial resistance and in comparison, with other regulatory regimes, the new tolerance table is considered fair. We will commit to working with the laboratories to improve testing capability.	Adopted

Chapter 7: Exemption for small pet animals

Schedule 6 sets out the exemptions from the VMR that allow certain veterinary medicines to be sold without a marketing authorisation.

Proposal	Response summary	Outcome
Registration and supply of information To introduce a requirement for companies that market products in accordance with Schedule 6 in Great Britain to register with the VMD and provide information annually on the medicines that have been marketed under this exemption. The information includes details of the manufacturer and the product. The registration and annual return would be a simple process. There would be no fee or inspection associated with registration.	Nil	Adopted
Reporting of adverse events by retailers To remove the requirement for retailers to record and report adverse events for products sold in accordance with Schedule 6 to the VMR.	Nil	Adopted

Chapter 8: Antimicrobial resistance

The UK Government is committed to the UK National Action Plan for AMR (2019- 2024) which seeks to work with stakeholders to reduce inappropriate antibiotic use in animals, with the primary aim of reducing the development and spread of antimicrobial resistance. Our goal is a culture change which embeds sustainable reduction of antibiotic use in animals through a combination of approaches, including improved biosecurity, stockmanship and good farming practices, disease prevention (including vaccination) and use of diagnostics.

Proposal	Response summary	Outcome
Antibiotic usage data To introduce a provision which allows the Secretary of State to require vets, producers and/or feedmills to provide information in relation to use of antibiotics, if, upon review, the voluntary model for antibiotic usage data fails to deliver. To introduce an offence for failure to comply with such a request for information.	We have considered the concerns raised and decided to implement the proposal. If the Secretary of State does request such data, we will provide guidance on how the legislation is to be implemented.	Adopted
Prophylactic use To only allow use of antibiotics for prophylaxis in exceptional circumstances, where the risk of an infection or an infectious disease is very high and the consequences are likely to be severe. To introduce an offence for failure to comply with this requirement.	We have taken the concerns raised into consideration and decided to implement the proposals with slightly amended text. We will provide clarity in guidance on the term “routine” which does not relate to elective procedures with a risk/evidence based clinical protocol. We have amended the text “any general duty in relation to animal welfare” to “professional obligations of a veterinary surgeon to ensure the health and welfare	Amended

Prophylactic use of antibiotics for administration to a group of animals would only be allowed if the use is not routine or predictable, the rationale is clearly recorded by the prescribing veterinary surgeon and a management review carried out as soon as reasonably practicable which identifies factors and implements measures to help control the infection of infectious disease, with the aim of eliminating the future or recurring need to administer antibiotics prophylactically to groups of animals.	of animals under their care", and we will provide guidance on the interpretation of this term. With regards to prophylactic use, we will provide guidance on the meaning of the terms "exceptional" and "predictable". The VMR text will be clear that the management review is to be carried out by a veterinary surgeon. Guidance will also be provided on how the management review will work in practice and we will liaise with industry partners on this. The VMR will also include a definition for 'metaphylaxis'.	
In-feed antibiotics Including the restrictions relating to medicated feed containing antibiotics: • the duration of treatment must comply with the SPC. If it is not specified in the SPC, the duration of treatment must be less than two weeks • the prescription would be valid from the date it is issued for a maximum period of five days • a vet may not prescribe medicated feed with more than one antibiotic premix • a vet may not prescribe medicated feed containing antibiotics for prophylactic purposes, but the exceptions set out in above apply here too.	Upon consideration of the concerns raised, we have agreed to implement the changes in amended form. In the case of a prescription which relates to antibiotics, the time between the prescription being issued and the course of treatment starting must be no more than 5 working days. The amended VMR text will no longer state that the SPC course lengths should be followed, or state maximum course lengths if no duration is included in the SPC, but it will state that a prescription for medicated feed may only confer authority for one course of treatment. We have removed the restriction that a vet may not prescribe medicated feed with more than one antibiotic as this may lead to	Amended

	unintended consequences such as clinical conditions not being treated effectively. We will provide guidance to clarify what is meant by one course of treatment and that the treatment duration of a course should be as short as clinically possible.	

Chapter 9: Fees

Schedule 7 to the VMR sets out the fees and charges for the regulatory services that we provide.

Proposal	Response summary	Outcome
Proposals to revise the fees and fee structure To introduce new fees for: • marketing authorisation applications for specific veterinary medicines • pharmacovigilance inspections to ensure marketing authorisation holders have good post-authorisation monitoring measures in place to identify and report any adverse events in relation to their medicines • providing scientific advice to companies • inspectors witnessing the destruction of authorised Schedule 2 controlled drugs and Schedule 3 and 4 controlled drugs that have been prepared extemporaneously for use under the cascade To change the existing fees for: • new and generic marketing authorisation applications and variations thereof • marketing authorisation applications based on informed consent	There were a number of responses from respondents which has assisted us in our assessment of the fees. All fees will be implemented, with one exception: we will not introduce a fee for an application for a Special Import Certificate made through the VMD's website. We recognise the need to not introduce barriers to the availability of medicines to treat our animals, especially in situations where there are supply shortages of authorised veterinary medicines.	Adopted

• manufacturing authorisations (including application, variations, inspections and annual fees) • wholesale dealers (including application, variations, inspections and annual fees) • feed business operators (including applications, inspections and annual fees) • SQP retailers (including authorisation, inspections and annual fees) • animal test certificates (including application, variation and renewal) • special import certificates • export certificates • veterinary practice premises (including inspections, registration and annual fees) To simplify the way we charge for applications for a marketing authorisation for a (generic) pharmaceutical veterinary medicine, to a base fee and a fee for each additional strength. To simplify the categories of feed businesses which also simplifies the fee structure for inspections of these businesses. To remove the fee for renewals of marketing authorisations and registrations of homeopathic remedies.		