



Veterinary  
Medicines  
Directorate



Department  
for Environment  
Food & Rural Affairs

# Review of the Veterinary Medicines Regulations 2013

A public consultation

Closing date: 31 March 2023



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## Contents

Executive summary .....	10
Introduction .....	12
Chapter 1 – General (regulations) .....	14
Minor drafting changes for clarification .....	14
Providing information upon request .....	14
Record keeping for vets and food-producing animal owners/keepers .....	15
Advertising .....	15
Powers of an inspector .....	16
Batch testing and batch release .....	17
Chapter 2 – Marketing authorisations in GB .....	18
Information for MA application and summary of product characteristics .....	18
Bibliographic applications .....	19
Generic / generic hybrid products .....	19
Marketing authorisation for parallel import .....	20
Parallel assessment of application for maximum residue limit and MA .....	21
Data protection periods .....	21
Parallel assessment with other regulators .....	22
MAH location .....	22
The granting of an MA .....	23
Withdrawal of an MA application .....	23
Refusal of an MA .....	23
Samples .....	24
Information on shortages .....	24
Renewal of marketing authorisations .....	24
Variations .....	25
Grounds for suspension of MA, prohibiting supply and temporary restrictions .....	26
Labelling and package leaflets .....	27
Electronic package information leaflet .....	28

Pharmacovigilance (post-authorisation monitoring).....	28
Registered homeopathic remedies .....	29
<b>Chapter 3 – Manufacture .....</b>	<b>31</b>
Manufacture activities.....	31
Manufacturing authorisation .....	31
Consistent approach for specific manufacturing authorisations.....	32
Active substances.....	32
Manufacturers of products for administration under the cascade .....	33
Stem cell centres .....	34
<b>Chapter 4 – Classification and supply, wholesale dealers and sheep dip.....</b>	<b>35</b>
Classification of POM-V medicines.....	35
Requirements for wholesale dealers .....	35
Wholesale dealers’ audits and record-keeping.....	36
Wholesale dealing by MAHs.....	37
Special Import Scheme .....	37
Distribution for promotional purposes .....	38
Registration of online retailers .....	38
Retailer supply.....	39
Assessment by vet before prescribing POM-V .....	39
Prescriptions.....	40
Wholesale supply of premix by feed business operators.....	40
Products supplied under the cascade.....	40
Remote supply by SQPs .....	41
SQP registration bodies.....	41
Sheep dip .....	42
<b>Chapter 5 – Administration under the cascade .....</b>	<b>43</b>
Cascade prescribing for food-producing animals .....	43
Appropriate use of the cascade .....	43
Withdrawal periods .....	44

Chapter 6 – Medicated feed.....	46
Definitions.....	46
Prescription for medicated feed .....	46
Labelling .....	47
Storage and disposal of medicated feed .....	47
Cross-contamination and carryover.....	48
Tolerance table.....	48
Chapter 7 – Exemptions for small pet animals.....	50
Registration and supply of information .....	50
Reporting of adverse events by retailers .....	51
Chapter 8 – Antimicrobial resistance .....	52
Antibiotic usage data .....	52
Prophylactic use .....	53
In-feed antibiotics .....	54
Chapter 9 – Fees .....	55
Annex A – Consultation questions .....	57
Annex B – Main areas impacting each business area .....	62
Annex C – Assessment of the matters set out in Section 10 of the Medicines and Medical Devices Act 2021 .....	63
Annex D – Proposed changes to fees .....	65

# General information

## Why we are consulting

This consultation sets out proposals to amend and supplement the Veterinary Medicines Regulations 2013 (VMR), as they apply in Great Britain. The VMR set out the controls on the marketing, manufacture, distribution, possession and administration of veterinary medicines in Great Britain. They are therefore a critical tool to help protect animal health, public health and the environment, by assuring the safety, quality and efficacy of medicines administered to animals.

We have only made minor changes to the VMR since they came into force on 1 October 2013. Since then, there have been significant advances in the veterinary medicines industry. The VMR need to be updated to reflect changes and technical advances in the veterinary medicines industry, including the supply chain, as well as to future-proof the regulatory regime. The proposed changes on which we are consulting intend to reduce regulatory burden where possible and tighten controls where necessary, resulting in a balanced and proportionate regulation.

In addition, the Veterinary Medicines Directorate's (VMD's) fees and fee structure set out in the VMR have not changed since 2013. The VMD is required to achieve full cost recovery for its regulatory services, in line with HM Treasury's guidance. A revised fee structure and updated fees are proposed as part of the update to the VMR.

We will amend and supplement the VMR using the powers in Part 3 of the Medicines and Medical Devices Act 2021. This consultation is conducted in line with the consultation requirement in section 45(1) of the Act. A summary of our assessment of the package of proposals included in the consultation document against the three factors set out in section 10 of the Act is provided in Annex C.

We are consulting on the proposed changes to give stakeholders the opportunity to share their views to enable us to make proportionate and appropriate regulation. Annex B highlights areas that are most relevant to different business types.

## Consultation details

Issued: 02/02/2023

Respond by: 31/03/2023

Enquiries to: [vmr@vmd.gov.uk](mailto:vmr@vmd.gov.uk) or VMD Legislation Office, Veterinary Medicines Directorate, Woodham Lane, Addlestone, KT15 3LS

Consultation reference: Review of the Veterinary Medicines Regulations 2013

Audiences: marketing authorisation holders, manufacturers, wholesale dealers, distributors, veterinary surgeons, suitably qualified persons (SQPs), pharmacists, retailers,

feed business operators, professional keepers of animals, consumers, interest groups, academics.

Territorial extent: This consultation relates to the regulation of veterinary medicines in England, Scotland and Wales only. As a result of the effect of the Northern Ireland Protocol, the legislation relating to veterinary medicines in Northern Ireland is currently separate to that in Great Britain.

## **How to respond**

Our preferred way of receiving responses is through the Citizen Space platform.

If you are unable to use Citizen Space, you can download the consultation documents and return your response via email to [vmr@vmd.gov.uk](mailto:vmr@vmd.gov.uk).

## **Confidentiality and data protection**

A summary of responses to this consultation will be published on the Government website at: [www.gov.uk/defra](http://www.gov.uk/defra). An annex to the consultation summary will list all organisations that responded but will not include personal names, addresses or other contact details.

Defra may publish the content of your response to this consultation to make it available to the public without your personal name and private contact details (for example home address, email address).

If you click on 'Yes' in response to the question asking if you would like anything in your response to be kept confidential, you are asked to state clearly what information you would like to be kept confidential and explain your reasons for confidentiality. The reason for this is that information in responses to this consultation may be subject to release to the public or other parties in accordance with the access to information law (these are primarily the Environmental Information Regulations 2004 (EIRs), the Freedom of Information Act 2000 (FOIA) and the Data Protection Act 2018 (DPA)). We have obligations, mainly under the EIRs, FOIA and DPA, to disclose information to particular recipients or to the public in certain circumstances. In view of this, your explanation of your reasons for requesting confidentiality for all or part of your response would help us balance these obligations for disclosure against any obligation of confidentiality. If we receive a request for the information that you have provided in your response to this consultation, we will take full account of your reasons for requesting confidentiality of your response, but we cannot guarantee that confidentiality can be maintained in all circumstances.

If you click on 'No' in response to the question asking if you would like anything in your response to be kept confidential, we will be able to release the content of your response to the public, but we won't make your personal name and private contact details publicly available.

There may be occasions when Defra will share the information you provide in response to the consultation, including any personal data, with external analysts. This is for the

purposes of consultation response analysis and provision of a report of the summary of responses only.

This consultation is being conducted in line with the Cabinet Office “Consultation Principles” which can be found at:

<https://www.gov.uk/government/publications/consultation-principles-guidance>.

Please find our latest privacy notice uploaded as a related document alongside our consultation documents.

If you have any comments or complaints about the consultation process, please address them to: [consultation.coordinator@defra.gov.uk](mailto:consultation.coordinator@defra.gov.uk).



## About you

1. Would you like your response to be confidential? (Select one option only)

- Yes
- No
- If you answered yes, please give your reason:

2. Who are you responding as? (Select one option only)

- Individual – You are responding with your personal views, rather than as an official representative of a business / business association / other organisation
- Public sector body – In an official capacity as a representative of a local government organisation / public service provider / other public sector body in the UK or elsewhere
- Industry – In an official capacity representing the views of a business
- Campaign group/NGO – In an official capacity as the representative of a non-governmental organisation / trade union / other organisation
- Academia – In an official capacity as a representative of an academic institution
- Other (please specify):

3. Which of the following best describes the role or field you belong to? (If you have multiple roles, please select the one which best represents your interests in this consultation response) (select one option only)

- Manufacturer
- Marketing authorisation holder
- Feed business operator
- Wholesaler / distributor of medicines
- Retailer of veterinary medicines
- Veterinary surgeon
- Suitably qualified person (SQP)
- Pharmacist
- Academic
- Consumer
- Professional keeper of animals
- Other, please state:

4. What is the name of your organisation?

5. Please select where you/your organisation is based (select all that apply):

- England
- Northern Ireland
- Scotland
- Wales
- Other

# Executive summary

This document sets out proposed changes to the Veterinary Medicine Regulations 2013 (VMR) which are intended to reflect developments and technical advances in the veterinary medicines sector, reduce regulatory burden where possible, encourage the submission and marketing of new and innovative products to support the aim of increasing availability of medicines, reduce the development and spread of antimicrobial resistance, and improve prescription and supply of veterinary medicines.

Chapter 1 sets out proposed changes to the main regulations in the VMR. These include changes to existing or new definitions and the powers that inspectors have to check and ensure compliance with the VMR. Also included in this chapter is a proposed updating, and where necessary strengthening, of the rules on advertising veterinary medicines.

Medicines are marketed in Great Britain by companies called marketing authorisation holders (MAHs). To market a medicine, MAHs require a marketing authorisation from us, the Veterinary Medicines Directorate (VMD) acting on behalf of the Secretary of State. Chapter 2 sets out the proposed changes to the regulations for marketing authorisations. Many of these changes will be similar to recent changes made by the European Union (EU). When we were a member of the EU, we played an active part in the negotiations and drafting of these changes. Therefore, the UK's position is consistent with the EU policy changes in many areas related to veterinary medicines as we believe the changes improve the regulation of medicines while reducing regulatory burden where possible. Furthermore, by making similar or corresponding provisions as those made in the EU legislation on veterinary medicines and medicated feed, we remove differences between the regulation of medicines in Great Britain and Northern Ireland so that the UK industry is working and complying with similar regulatory frameworks. In some areas, differences from the EU regulations have been proposed where we feel they would benefit the industry in Great Britain, for example changes in the data protection periods to encourage innovation.

We propose to introduce minor changes to improve the regulation of the manufacture of medicines, as set out in Chapter 3. These including adjusting the requirements for applying for manufacturing authorisations, ensuring consistency between the different types of manufacturer authorisation, as well as introducing new registration requirements for the manufacture, importation and distribution of active substances (the ingredients responsible for the activity of a medicine) to improve regulatory oversight.

Chapter 4 refers to the supply, distribution and administration of medicines. We propose introducing a suite of changes to improve the prescribing and supply of veterinary medicines. Other changes include introducing new requirements for wholesale dealers and making the voluntary registration scheme for online retailers mandatory. We also propose changes to reduce burden for vets and suitably qualified persons which should improve access to responsibly prescribed and supplied veterinary medicines.

Chapter 5 sets out rules around using unauthorised medicines in exceptional circumstances, when no suitable authorised medicine is available (called 'the cascade'). This chapter includes proposed changes to clarify when it is suitable to use a medicine manufactured for use under the cascade. We also proposed to update the withdrawal periods for medicines used under the cascade to ensure food safety whilst removing unnecessary barriers to treatment.

Chapter 6 sets out the proposed changes to medicated feed. Medicated feed is the administration of medicines mixed into the animals' feed. We propose introducing changes to improve the regulation of medicated feed, many of which will be similar to the legislative changes recently introduced in the EU. We also aim to achieve further reductions in the use of antibiotics in medicated feed and propose measures to do so.

The VMR contain an exemption to the requirement to have a marketing authorisation, for medicines for small animals kept as pets (for example, hamsters and guinea pigs, but not cats and dogs). We propose requiring companies that market medicines under this exemption to register with us and provide details of the medicines marketed on an annual basis, so that we can take appropriate measures when there is a safety concern. These proposed changes are set out in Chapter 7.

Chapter 8 highlights the proposed changes which are intended to help reduce the development and spread of antimicrobial resistance. One such proposed change is aimed at reducing the use of antibiotics by restricting their prophylactic use in groups of animals.

Chapter 9 and Annex D set out the proposed changes to the fees that we charge for regulatory services (which we are required to do as a cost recovery agency). These include changes to the fees for assessing and issuing marketing authorisations and manufacturing authorisations. They also set out new fees, including fees for pharmacovigilance inspections and providing advice on scientific matters to companies.

Details of the proposed changes that will have the greatest impact on the different business areas is included at Annex B.

# Introduction

Veterinary medicines are medicines authorised for use in animals. They play a vital role in maintaining animal health and ensuring that food that comes from animals is safe.

Veterinary medicines are also vital in reducing infection in animals and reducing the burden of some zoonotic diseases in animals which reduces the risk of them transferring to humans.

The Veterinary Medicines Directorate (VMD) is an Executive Agency of the Department for Environment, Food and Rural Affairs (Defra). We regulate veterinary medicines in the United Kingdom (UK). As with all medicines, veterinary medicines may cause harm if used inappropriately. Therefore, veterinary medicines, like human medicines, are highly regulated goods to ensure that users, animals, consumers of produce from treated animals and the environment are kept safe. The Veterinary Medicines Regulations 2013 (VMR) set out the rules on how medicines should be marketed, manufactured, supplied and used.

Apart from minor changes, the VMR were last updated in 2013. We are now consulting on proposed changes to the VMR as they apply in Great Britain, which aim to:

- reflect developments and technical advances in the veterinary medicines sector,
- reduce regulatory burden where possible,
- encourage the submission and marketing of new and innovative products, to support the aim of increasing medicines availability,
- reduce the development and spread of antimicrobial resistance, and
- improve prescription and supply of veterinary medicines.

We have also reviewed the VMR in light of feedback received from those regulated by the VMR indicating the need for clarification and adjustment of certain provisions, and to insert established practice into legislation, where appropriate, to improve transparency for our stakeholders.

When the UK was a member of the European Union (EU), we played an active role in the review of and negotiation for changes in the EU's legislation on veterinary medicines and medicated feed. Therefore, the UK's position is consistent with the EU policy changes in many areas relating to veterinary medicines and medicated feed. Many of the changes in EU legislation were introduced to reduce regulatory burden on industry, as well as to introduce better controls on the use of antimicrobials, and we are keen to introduce those changes that will bring the greatest benefit to the UK. We understand that many sections of the veterinary medicines industry see the UK as part of its wider European market and will benefit from closer harmonisation between the British and EU regulatory frameworks. We propose amendments to the VMR which reflect those EU changes where desirable from a UK policy perspective. This will also reduce divergence between the regulatory frameworks in Great Britain and Northern Ireland.

The VMR also set out the fees that the VMD charges for its regulatory services. As a cost-recovery agency, we are required to charge fees to cover the cost of the services that we provide to industry. These fees have not been updated since 2013 and no longer reflect the true cost of these services. The proposed changes to the fees are to ensure that the VMD can achieve full cost recovery and to increase transparency of our fees, simplifying our fee structure where possible.

The VMR contain schedules which set out the detail of the regulations for each part of the industry and supply chain; this consultation document has largely mirrored the schedules. In this document we highlight the main proposed changes and what we intend to achieve with these changes. For a complete picture of the changes we propose, we recommend reading this consultation document alongside the draft of the amended VMR text with tracked changes to reflect the proposals, and the consultation draft Statutory Instrument (SI) which sets out how the new legislation might look if all proposed changes were made. The draft SI text remains subject to change and does not constitute the law. References are included throughout the consultation document to the relevant provisions in the draft amended VMR text. These references are an indication and not intended to cover all places where consequential or relevant changes are made.

**We welcome your views on the proposed changes, as to whether they will achieve the intended objectives. We also seek information on the time and cost of familiarising your business with the new requirements, and the impact of the proposed changes on you, your business and wider aspects (such as social or environmental impacts). We are looking for the positive and negative impacts, as well as direct and indirect costs. We will use the information received to update and improve the pre-consultation impact assessment that is provided with the consultation.**

# Chapter 1 – General (regulations)

1.1 This chapter includes proposed changes to the main regulations of the VMR. Some of the proposed changes to the regulations relate more closely to the areas covered in subsequent chapters (which deal with proposed changes to the Schedules to the VMR) and so are covered there instead.

## Minor drafting changes for clarification

1.2 In response to feedback received from people and businesses regulated by the VMR, we propose minor drafting changes to clarify the regulations and Schedules (for example, clarifying the rules around expiry dates which also apply to intermediate / medicated feedingstuffs in regulation 7 in the VMR or clarifying what export certificates the Secretary of State must provide in regulation 31) or to improve consistency in wording (for example by referring to authorised premises throughout the VMR). Other drafting changes to the regulations introduce new definitions (for example antimicrobial, limited market, withdrawal period) or amend existing ones (for example benefit-risk balance, strength, veterinary medicinal product) (regulation 2).

1.3 These changes are intended to ensure a clear, consistent understanding of the VMR by both stakeholders and the regulator.

## Providing information upon request

1.4 The VMD is responsible for ensuring that safe and effective medicines of high quality are available in the UK. To fulfil our regulatory obligations, we currently have powers to request specific information from certain businesses, for example information on the benefit-risk balance of a product from marketing authorisation holders or information from wholesale dealers.

1.5 We propose to extend the requirement to provide the Secretary of State with information upon request to all businesses or persons regulated by the VMR. We would provide a justification for our request and ensure that any requests for information are reasonable.

*Do you agree with the proposal for the VMD to be able to require information on request?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact this may have on you, your business and wider aspects.*

## Record keeping for vets and food-producing animal owners/keepers

1.6 We want to ensure that a food-producing animal owner or keeper receives in a timely manner relevant information about the medicine administered to their animal by the vet, including the withdrawal period. This information helps ensure that food-producing animals do not enter the food chain until after the medicine's withdrawal period has passed, which will help ensure food safety. Currently, the legislation does not state when a vet must provide this information to the animal owner or keeper. We therefore propose that 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**" (regulation 18 in the VMR).

*Do you agree with this approach to the "as soon as reasonably practical" issuing of records by vets?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact this may have on you, your business and wider aspects.*

## Advertising

1.7 Advertising of veterinary medicines has changed and progressed since 2013, with more publication platforms and media available than previously. The VMD's enforcement officers regularly deal with usually unintended breaches of the VMR related to advertising. We want to ensure compliance with the VMR.

1.8 We therefore propose changes which are part of a suite of changes that we are introducing to improve the system of prescription and supply. We propose to adjust the regulations on advertising to make explicit what is allowed and required in terms of the advertising of a veterinary medicine (regulation 10 in the VMR). Specific changes include a requirement that the advertisement makes clear that the message is an advertisement for the purpose of promoting the supply, sale, prescription, distribution or use of the veterinary medicine, intermediate feedingstuff or compound feedingstuff.

1.9 We propose to make explicit that a medicine may only be advertised if it has a marketing authorisation, which is not suspended. This change would not apply to medicines marketed in accordance with Schedule 6 to the VMR (exemptions for small pet animals).

1.10 We also propose to introduce a regulation setting out the conditions for inducements and hospitality in relation to veterinary medicines (new regulation 10A).

1.11 We believe that there are specific training and knowledge requirements for prescribing and using veterinary medicines. Advertising medicines to people who cannot properly assess the risks associated with the use of the medicine may lead to misuse or abuse of medicines. This in turn may lead to risks to the animal, the people treating the animal and / or to the environment. This is why we restrict the advertising of prescription-only medicines to certain audiences.

1.12 With regard to POM-V medicines advertising targeted at professional keepers of animals, we propose to only allow this for immunological medicines (regulation 11) as the use of immunological products can help reduce disease and may contribute to a reduction in the use of antibiotics in farm animals. An advert for a POM-V immunological product aimed at professional keepers of animals must state that the professional keeper of animals will need to consult a vet before using the medicine. Companies would continue to be able to advertise POM-V medicines specifically targeted to vets, veterinary nurses and pharmacists.

*Do you agree with this proposed approach to advertising of veterinary medicines?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact (for example costs and savings) on you / your business / wider aspects of the proposed changes to update the advertising requirements.*

## **Powers of an inspector**

1.13 We want to strengthen the powers of an inspector to ensure a potential breach of the VMR can be properly investigated. The VMR contains a detailed list of what can be seized. The powers of seizure give inspectors the power to seize items for investigation if these items purport to be, or if an inspector reasonably believes they are something the inspector is entitled to seize (regulation 35(2) in the VMR). We propose changing this regulation 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.

1.14 We want to enable inspectors to put an immediate stop to an activity that breaches the VMR or to take immediate corrective action in the case of a serious risk to human or animal health, or the environment. Currently inspectors can issue improvement notices but these give the person / business a minimum of 14 days to take corrective action, which in certain cases may unduly prolong the serious risk identified to human or animal health or to the environment. We therefore propose to introduce a power for inspectors to order an immediate stop to activities that they deem to be putting human and animal health at risk



(new regulation 38A), or to apply conditions on a business. We also propose to introduce an offence for failing to comply with a prohibition notice issued under new regulation 38A.

*Do you agree with this approach to the changes in inspectors' powers?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact this may have on you, your business and wider aspects, and your views on the introduction of an offence.*

## **Batch testing and batch release**

1.15 Veterinary medicines that are to be placed on the market must be batch tested and certified by a Qualified Person before they can be released to the market. Since EU Exit, we have adopted a transitional approach to the batch testing and release of imported products. We intend to launch a separate consultation which will set out our proposals for batch testing and batch release of products to be marketed in Great Britain. We intend to make changes on batch testing and release at the same time as the other changes to the VMR.

***If all changes to the regulations were made, as set out in this chapter, what would be the impact (including familiarisation costs) on your business? What would be the consequences if we did not make these changes?***

## Chapter 2 – Marketing authorisations in GB

2.1 You can only place a veterinary medicine on the market in Great Britain if you have been granted a marketing authorisation (MA) for that medicine. This does not apply if you have been issued with a QNIG certificate for the medicine in accordance with Schedule 1B to the VMR or the medicine is marketed under the exemption in Schedule 6 (see Chapter 7 of this document). Schedule 1 to the VMR sets out the requirements for applying for a new MA, applying to change an existing MA, labelling and packaging, post-authorisation monitoring of any adverse events (pharmacovigilance) and homeopathic remedies.

### **Information for MA application and summary of product characteristics**

2.2 We want to reduce regulatory burden where possible. We therefore propose to adjust the information that we require to be provided with an application for a marketing authorisation (paragraph 2 of Schedule 1 and new Schedule 1C in the VMR). The information we propose to require would be similar to the requirements for an MA application submitted to the European Medicines Agency. This would enable companies to comply with similar frameworks across different regulatory jurisdictions and submit similar dossiers when applying for an MA in GB, Northern Ireland (NI) and the EU. The technical data requirements would be harmonised to the extent possible with those in Annex 2 to the Regulation (EU) 2019/6, which would remove divergence between the requirements for GB and NI. A list of proposed differences is available upon request.

2.3 As part of our efforts to limit the development and spread of antimicrobial resistance, we also propose that 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.

2.4 The summary of product characteristics (SPC) provides information to ensure the safe use of an authorised veterinary medicine and is part of the information that must be provided upon application. It includes information such as the ingredients, the indications for use, any specific safety warnings, withdrawal periods and details of the MAH.

2.5 To reduce regulatory burden we propose to change the order of the information that must be included in the SPC (paragraph 3). We also propose to update our minimum information requirements to ensure that a product's SPC contains relevant information that supports safe and responsible use, such as the composition of active substances and excipients and special restrictions for use.

2.6 In addition, we propose to introduce the requirement that the SPC submitted for a generic veterinary medicine must be essentially similar to that for the reference product.

*Do you agree with the proposed changes to the requirements for the summary of product characteristics and data requirements for a marketing authorisation application?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact (for example costs and savings) on you / your business / wider aspects of the proposed change with regard to paragraph 2.3.*

## **Bibliographic applications**

2.7 Bibliographic applications, also known as ‘well-established use’, make it possible to apply for an MA with a data dossier where some or all parts are addressed using published data. We currently require the applicant to demonstrate, using appropriate scientific literature, that the active substance has been used for at least 10 years in the target species for the indications applied for.

2.8 We propose to adjust the provision to require the applicant to demonstrate that the active substances of the veterinary medicine have been in well-established veterinary use for at least 10 years, that their efficacy is documented and that they provide an acceptable level of safety (Schedule 1 paragraph 7 in the VMR).

## **Generic / generic hybrid products**

2.9 Generic hybrid products are applied for using a combination of referring to data of an already authorised product and the applicant’s own data to support differences between the reference product and the generic hybrid. This allows companies to apply for a new MA without having to generate the full data package – thus stimulating competition and product availability. MA applications for generic hybrid products are currently already accepted by the VMD. We propose, however, 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).

2.10 We also propose 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 (paragraph 10).

2.11 As part of our drive to future-proof the VMR, we propose to move the option for generic immunological or biological products from a stand-alone provision (paragraph 15) 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. It would provide the applicant with the opportunity to justify the use of the generic route for immunological or biological products, but also provide a legal basis to refuse to accept such products through the biosimilar / generic route so we can assure the safety, quality and efficacy of such products. Finally, this change would provide future flexibility should we consider it appropriate for novel immunological products which could be chemically synthesised (for example nucleic acid vaccines or synthetic peptides) to be authorised via this route.

*Do you agree with this approach to generic / generic hybrid products?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact this may have on you, your business and wider aspects.*

## **Marketing authorisation for parallel import**

2.12 MAs for parallel import (MAPIs) require the applicant to prove that the product to be imported is identical or therapeutically equivalent to a UK authorised product (Schedule 1 paragraph 13 in the VMR). Parallel importing refers to when a product is bought from wholesalers in another country and imported into the UK 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 however, this was expanded to all countries.

2.13 We no longer consider this an appropriate route to market and therefore propose removing the option for MAPIs.

*Do you agree with the proposed removal of the option to have marketing authorisations for parallel import?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact this may have on you, your business and wider aspects.*

## **Parallel assessment of application for maximum residue limit and MA**

2.14 The maximum residue limit (MRL) is the maximum allowed concentration of a substance residue in a food product obtained from an animal that has received a veterinary medicine. Currently the VMR do not allow an application for a marketing authorisation for a medicine for food-producing animals to be made until at least six months after a valid application has been made for the establishment of an MRL – where none exists for that active substance (Schedule 1 paragraph 5 in the VMR).

2.15 We want to ensure that new veterinary medicines come to the market as soon as possible. The above requirement delays the assessment of medicines for food-producing animals which contain substances that do not have established MRLs. We therefore propose to remove this requirement so applications for assessment of an MRL can be submitted at the same time as an application for an MA.

*Do you agree with the proposal of assessing applications for MAs and MRLs at the same time?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact this may have on you, your business and wider aspects.*

## **Data protection periods**

2.16 To achieve an optimal balance between innovator and generic veterinary medicines coming to the market, so that both sectors can thrive, we propose extending (some of) the data protection periods currently awarded to veterinary medicines (Schedule 1 paragraph 11 in the VMR). We are also proposing to introduce extensions to these periods in defined circumstances (paragraph 12). Furthermore, we are proposing to decouple the addition of species and pharmaceutical form, if packaged separately from the original product, and apply separate data protection periods.

*Do you agree with the proposal for amending the current data protection periods?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact (for example costs and savings) on you / your business / wider aspects of the proposed changes.*

## **Parallel assessment with other regulators**

2.17 We provide the option for companies to submit an MA application to us in parallel with other regulators that we have an agreement with (for example, regulators in the USA, Canada, New Zealand and Australia). We want to make the parallel assessment process as smooth as possible. We therefore propose to introduce a facility for a clock stop in our timeline for procedures that are part of a parallel assessment with other regulators (Schedule 1 paragraph 17 in the VMR). This would help to maintain a collaborative assessment timetable, for example if we need to wait for longer validation periods to conclude for other regulators or whilst we await receipt of company responses to information requests not relevant to UK.

*Do you agree with the proposal for introducing flexibility into the assessment timeline?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact this may have on you, your business and wider aspects.*

## **MAH location**

2.18 As part of our drive to reduce regulatory burden, we propose to no longer require MAHs to be established in the UK (Schedule 1 paragraph 18 in the VMR). We propose 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 veterinary homeopathic remedies.

*Do you agree with the proposal for a UK-based local representative instead of the requirement for the MAH to be established in the UK?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, including any positive or negative impacts on you / your business / wider aspects.*

## **The granting of an MA**

2.19 As part of our commitment to reduce the development and spread of antimicrobial resistance, we propose 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 (Schedule 1 paragraph 22 in the VMR).

## **Withdrawal of an MA application**

2.20 We propose to introduce the requirement that formal withdrawal of applications must be made in writing and must include a reason for withdrawal (new paragraph 22A in Schedule 1 to the VMR).

2.21 Currently, we do not publish completed assessment reports for withdrawn MA applications. We propose publishing these in the future, protecting any commercially sensitive information, to assist other companies in understanding the requirements that are necessary when completing an MA application.

*Do you agree with this approach for publishing assessment reports?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially if you have any concerns around this proposal.*

## **Refusal of an MA**

2.22 The Secretary of State must refuse a marketing authorisation for specific reasons provided in the VMR. Currently, an 'unfavourable benefit-risk balance' covers several reasons to refuse an MA. We propose to make these reasons explicit in the VMR to aid transparency (Schedule 1 paragraph 24 in the VMR) and to add additional reasons for refusal of an MA. Additional reasons include:

- the product contains an antimicrobial that is reserved for human use,
- 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.

2.23 We also propose 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 (paragraph 25).

## **Samples**

2.24 The VMR currently provide the Secretary of State with the power to require a MAH to provide samples of starting materials or the veterinary medicine for testing (Schedule 1 paragraph 27 in the VMR). We propose to expand this 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 propose to limit what such samples may be used for.

## **Information on shortages**

2.25 We aim to mitigate against shortages of medicines to ensure a continuity of supply in the UK, but we can only do this if we are aware of the potential shortages. We currently rely on MAHs to voluntarily report supply shortages to us and many MAHs are very good at doing so. However, some MAHs are less willing to voluntarily report shortages to us, which can affect our ability to consider timely mitigations to maintain the supply of veterinary medicines. We therefore propose 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 (Schedule 1 paragraph 31 in the VMR).

*Do you agree with this approach on making it mandatory for MAHs to report supply shortages to the Secretary of State?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact this may have on you, your business and wider aspects.*

## **Renewal of marketing authorisations**

2.26 We want to remove unnecessary regulatory burden. We propose to remove the requirement to renew a marketing authorisation after the initial five-year period; so instead, a MA has indefinite validity (unless the benefit-risk balance becomes unfavourable) (Schedule 1 paragraph 32 in the VMR). We believe that this would make things easier for MAHs without compromising on safety. This change would also apply to registrations of homeopathic remedies.

*Do you agree with the proposed changes for renewing MAs?*

- *Strongly agree*



- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impacts on you / your business / wider aspects from this proposed change.*

## **Variations**

2.27 We believe, based on feedback from industry, that harmonising our variations system with the EU legislation significantly reduces burden on MAHs. We have already put changes in place to accommodate this through our guidance. We are now proposing to amend the legislation accordingly. This means that we propose 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).

2.28 The procedure for variations requiring assessment, including the information that needs to be provided with the application, would be set out in the proposed new paragraph 33A (Schedule 1 in the VMR). Such variations must be applied for by electronic means unless it is an emergency application. The Secretary of State may require additional information from the applicant during the assessment. Within 30 days of sending the assessment report to the applicant, the Secretary of State would amend the MA in line with the proposed variation or provide a reason for rejection of the variation.

2.29 We also propose to include a provision for unforeseen variations: variations which the MAH is uncertain how to classify under the VMR (new paragraph 33B). The Secretary of State would provide a recommendation of the categorisation upon request.

2.30 The variations not requiring assessment would be listed in the VMR and are currently proposed to harmonise with the variations not requiring assessment under the EU legislation. The procedure for these variations would be set out in the proposed new paragraph 33C. In short, within 30 days of implementing the change, the MAH would have to submit to the Secretary of State the SPC and labelling of the product to which the MA relates. If a variation were submitted as one not requiring assessment and the Secretary of State were to decide that this were not appropriate, we would end that procedure and require the provision of data to be provided under the procedure for variations requiring assessment. The Secretary of State would notify the MAH whether the variation is approved or not.

2.31 In line with the above proposed changes, we also propose to remove the options for administrative and workshare variations as these would no longer be needed (paragraphs 33 and 35).

*Do you agree with the proposed changes for variations to MAs?*

- *Strongly agree*

- Agree
- Neutral
- Disagree
- Strongly disagree

*Please provide additional information, especially on the impacts on you / your business / wider aspects from this proposed change.*

## **Grounds for suspension of MA, prohibiting supply and temporary restrictions**

2.32 Currently, the Secretary of State can suspend an MA and revoke it after the MA has been suspended for more than 28 days (unless there is a current appeal). We propose 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 (Schedule 1 paragraph 38 in the VMR). We also propose 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.

2.33 We also propose to expand the reasons for which we can prohibit the supply of a veterinary medicine or require a medicine to be recalled (paragraph 41). The additional reasons would be:

- 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, or
- the incorrect labelling of the medicine might lead to a serious risk to human or animal health.

2.34 We also propose 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 (new paragraph 41A).

2.35 Finally, we propose introducing a new provision to prohibit the manufacture, import, distribution, supply or use of immunological veterinary medicines in certain scenarios (new paragraph 41B):

- 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, or

- if the strains of disease agents in relation to which the immunological is intended to confer immunity is largely absent in that locality.

*Do you agree with this approach to suspension and revocation of MAs, prohibiting supply or restricting (immunological) medicines?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impacts on you / your business / wider aspects from these proposed changes.*

## **Labelling and package leaflets**

2.36 We want to adjust the labelling requirements to provide assurance that the necessary information is available with the product and where necessary on the immediate packaging. The proposed changes would ensure that the right information is available for the medicines to be used safely and effectively without placing too much regulatory burden and cost on companies. The changes would allow for more efficient means of labelling, utilising current thinking and technology (for example QR codes), which is particularly important for smaller units of veterinary medicine.

2.37 The proposed changes are harmonised to an extent with the EU legislation, with minor differences such as the inclusion of the distribution category. The detail is set out in Schedule 1 paragraph 48 in the VMR for the immediate packaging, paragraph 49 for the outer packaging, paragraph 50 for small immediate packaging units and paragraph 51 for the package leaflet.

2.38 Information may be included in abbreviations or pictograms approved by the Secretary of State.

2.39 We propose 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.

*Do you agree with this approach to the labelling and package leaflet?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact (especially costs and savings) on you / your business / wider aspects of the proposed changes. We are specifically seeking information on the following:*

- *potential savings for joint labelling,*
- *printing costs,*
- *redesigning (for example of artwork) costs,*
- *costs of disposal of out-of-date packaging material,*
- *risks associated with reduction of information on labelling, and the balance of this information being available through QR codes etc, and*
- *increasing availability of minor use and minor species medicines.*

## **Electronic package information leaflet**

2.40 We propose allowing an electronic package information leaflet (EPIL) to be provided, where appropriate, as an alternative to a physical package leaflet (Schedule 1 paragraph 51(5-6) in the VMR). There must be clear reference to the EPIL on the packaging and the necessary links. We would require that an MAH must be able to provide the physical package leaflet where necessary.

*Do you agree with allowing electronic package information leaflets?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact this may have on you, your business and wider aspects.*

## **Pharmacovigilance (post-authorisation monitoring)**

2.41 We propose to reduce regulatory burden by updating the requirements for pharmacovigilance and harmonise them, to the extent possible, with the approach taken in the EU to assist MAHs. We propose:

- removing the requirement to submit periodic safety update reports (PSUR) for a product and replacing it with annual benefit risk reports (Schedule 1 paragraph 59 in the VMR).
- introducing a Signal Management system which should ensure that prompt action is taken when needed (new paragraph 56C).
- moving from the Detailed Description of the Pharmacovigilance System (DDPS) to the Pharmacovigilance System Master File (PSMF) (paragraph 56).
- amending the adverse event reporting timelines and conditions (from 15 to 30 days for serious cases and 30 days for non-serious) (paragraph 57).

2.42 We also propose allowing the MAH to introduce urgent safety restrictions in the event of risk to human or animal health or to the environment (paragraph 56). We would also be able to require MAHs to have a risk management plan should the pharmacovigilance data suggest that one is required (paragraph 61).

2.43 In addition, we propose including the provision to take action against any products that contain the same active substance as a product that has concerning pharmacovigilance data (paragraph 61).

2.44 Finally, we propose 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 (paragraph 60A).

*Do you agree with this approach for pharmacovigilance?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact (especially costs and savings) on you / your business / wider aspects of the proposed changes for streamlined reporting, the PSMF and the required actions in response to adverse events.*

## **Registered homeopathic remedies**

2.45 By way of derogation from the provisions in the VMR requiring a marketing authorisation for a veterinary medicine, a homeopathic remedy may be placed on the market in accordance with a registration by the Secretary of State instead of in accordance with a marketing authorisation, provided it meets certain conditions (for example it must not be an immunological product, there must be a sufficient degree of dilution). An exemption applies to homeopathic remedies which have “grandfather rights” and are included in the list of such remedies as manufactured by a specified manufacturer. The application for a registration does not require proof of efficacy but is assessed for quality and safety of the remedy, requiring a favourable benefit-risk balance. There are currently seven registered veterinary homeopathic remedies in the UK – all are intended for oral administration.

2.46 We propose adjusting the requirements in the VMR to clarify that the registration of homeopathic remedies is restricted to those remedies with a topical or oral route of administration (Schedule 1 paragraph 63 in the VMR).

2.47 Due to the nature of (non-plant derived) biological products and their inherent risks, the data provided for a homeopathic registration is not suitable to guarantee safety and quality of these products. We are therefore proposing to adjust the requirements for

registration and exclude biological homeopathic remedies unless they are derived from plants (paragraph 63).

2.48 We propose 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 (paragraph 64).

*Do you agree with this approach for homeopathic remedies?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact this may have on you, your business and wider aspects.*

***If all changes to Schedule 1 were made, as set out in this chapter, what would be the impact (including familiarisation costs) on your business? What would be the consequences if we did not make these changes?***

***We will make transitional arrangements to cover applications already being processed for a marketing authorisation (either a new MA or a variation) or registration of a veterinary homeopathic remedy, changes in labelling and packaging requirements, and other new requirements, as appropriate. We welcome any views on such arrangements or other measures which might help address problems if the new requirements would be applied immediately upon the revised VMR coming into force.***

## Chapter 3 – Manufacture

3.1 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.

### Manufacture activities

3.2 We propose 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 (regulation 5 in the VMR). 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.

### Manufacturing authorisation

3.3 With regard to manufacturing authorisations, we propose 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 required) and certification by the authorisation holder’s qualified person (QP) for their release to the market (Schedule 2 paragraph 1 in the VMR).
- additional information for the manufacturing authorisation to improve the authorisation process (paragraph 2).
- 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) (paragraph 6).

3.4 We also propose to require manufacturers to record more detail on the products they manufacture, to improve traceability (paragraph 2 and regulation 21). We would 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 (paragraph 11 and regulation 21).

3.5 We also propose providing 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 (paragraph 5).

*Do you agree with this approach for manufacturing authorisations?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impacts on you / your business / wider aspects from this proposed change.*

## **Consistent approach for specific manufacturing authorisations**

3.6 We propose 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.

3.7 As part of this restructuring we propose 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 (new paragraph 16).

3.8 We propose 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 (new paragraph 24), thus ensuring a consistent approach and monitoring of the safety of these products.

*Do you agree with this consistent approach for specific manufacturing authorisations?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impacts on you / your business / wider aspects from this proposed change.*

## **Active substances**

3.9 Active substances are the ingredients that give the medicine its therapeutic effect. The current regulations do not include explicit provision for regulatory oversight of the manufacture, importation and / or distribution of active substances. To improve this, we propose new requirements for the manufacture, importation and distribution of active substances (new Part 3 of Schedule 2 to the VMR). The requirements are:



- 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. We propose 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.

3.10 We also propose 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 (new paragraph 31). A fee would apply for such inspections.

*Do you agree with this approach for regulatory oversight of active substances?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact (for example costs and savings) on you / your business / wider aspects of the proposed changes, and views on the proposed offence.*

## **Manufacturers of products for administration under the cascade**

3.11 Extemporaneous preparations are the final step of the cascade, as they are not authorised and therefore carry a greater safety risk compared to authorised products (see for more information on the cascade Chapter 5 in this document). We propose 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 (new paragraph 20 in Schedule 2 to the VMR).

3.12 We inform stakeholders and take appropriate and targeted measures in relation to reports of adverse events or in case of safety or efficacy concerns related to active substances. We want to ensure that we have complete and accurate information on the formulations marketed in accordance with this type of authorisation, to maximise our ability to take appropriate and targeted measures to ensure that all medicines are safe and effective. We therefore propose 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. This would also improve the VMD's capability to mitigate supply shortages as we can identify those who can supply certain active substances.

3.13 We also propose to introduce the requirement that manufacturers of extemporaneous preparations must state on the label that the product does not have a MA (new paragraph 22).

*Do you agree with this approach for products manufactured under the cascade?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impacts on you / your business / wider aspects from this proposed change, including views on the proposed offence.*

## **Stem cell centres**

3.14 The current legislation refers only to authorising stem cell centres for equines (horses). As technology and understanding have developed and improved, it is no longer a novel, emerging treatment option specifically for horses and the technology has become available for other animal species. We propose to extend the authorisation and inspection requirements of equine stem cell centres to all non-food-producing animals so we can bring these under appropriate regulation (new paragraph 19 in Schedule 2 to the VMR).

*Do you agree with this approach to stem cell centres?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact this may have on you, your business and wider aspects.*

***If all changes to Schedule 2 were made, as set out in this chapter, what would be the impact (including familiarisation costs) on your business? What would be the consequences if we did not make these changes?***

***We will make transitional arrangements to cover applications already being processed for a (variation of a) manufacturing authorisation and other new requirements, where appropriate. We welcome any views on such arrangements or other measures which might help address problems if the new requirements would be applied immediately upon the revised VMR coming into force.***

# Chapter 4 – Classification and supply, wholesale dealers and sheep dip

4.1 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.

## Classification of POM-V medicines

4.2 There are four categories of authorised veterinary medicines:

- Prescription-only medicines to be prescribed by a vet (POM-V).
- Prescription-only medicines to be prescribed by a vet, pharmacist or SQP (POM-VPS).
- Medicines for non-food animals (NFA) that do not require a prescription but still need to be supplied by either a vet, pharmacist or SQP (NFA-VPS).
- Authorised veterinary medicines that are available on the general sales list (AVM-GSL).

4.3 We propose to adjust the requirements so that the categories of medicines that must be classified as POM-V include medicines that contain antibiotics or beta-agonists, or that are used for euthanasia, or that are immunological or hormonal (Schedule 3 paragraph 1 in the VMR). Immunological products currently classified as POM-VPS would remain POM-VPS, subject to established procedures and regulation (for example assessment by the Veterinary Product Committee).

*Do you agree with the proposed additions to the POM-V classification?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact this may have on you, your business and wider aspects.*

## Requirements for wholesale dealers

4.4 As part of a suite of changes that we propose to introduce to improve the system of prescription and supply, we propose introducing new requirements for wholesale dealers as some of the current requirements are no longer considered fit-for-purpose and do not provide clear expectations of what is required of wholesale dealers. The changes would strengthen assurance of the security of the veterinary medicines supply chain and improve

the VMD's capability to mitigate supply shortages. To bring the requirements up-to-date, the new proposals are that the wholesale dealer must:

- Comply with good distribution practice (Schedule 3 paragraph 21 in the VMR).
- only obtain veterinary medicines from other wholesale dealer's authorisation (WDA) holders or those with a manufacturing authorisation (paragraph 2).
- issue a document detailing key information when supplying medicines (including name and pharmaceutical form and batch number) and keep a copy for five years (new paragraph 21B).
- follow guidelines when destroying medicines and keep records of any destroyed medicines for five years (new paragraph 21C).
- inform the Secretary of State if it is offered counterfeit medicines (paragraph 21).
- report supply shortages to the Secretary of State, to improve the security of the supply chain (paragraph 21).
- We propose to introduce offences for failure to comply with the new record keeping requirements (new paragraphs 21B-21E).

4.5 We also propose 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 (paragraph 2).

4.6 We propose that the requirements for a wholesale dealer's authorisation are updated. This includes 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 (paragraph 17).

*Do you agree with the proposed changes for wholesale dealers?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact (for example costs and savings) on you / your business / wider aspects of the proposed changes, especially with regard to reporting suspected counterfeit or falsified medicines or supply shortages, and your views on the offences.*

## **Wholesale dealers' audits and record-keeping**

4.7 We also propose to introduce a new requirement for wholesale dealers to investigate and document any stock level discrepancies identified through their annual audit (new paragraph 21D in Schedule 3 to the VMR). We further propose introducing a requirement

for wholesale dealers to put in place a self-inspection plan in relation to good distribution practice (new paragraph 21F).

4.8 We propose amending 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) (paragraph 21). This would ensure that they are available for inspection by inspectors.

*Do you agree with the requirement for wholesale dealers to investigate stock discrepancies and keep records for five years?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact this may have on you, your business and wider aspects.*

## **Wholesale dealing by MAHs**

4.9 Currently, an MAH can wholesale products that it has an MA for without holding a wholesale dealer's authorisation (WDA), which means MAHs are not subject to inspection in the same way as WDA holders are (Schedule 3 paragraph 2 in the VMR). We propose removing an MAH's ability to wholesale veterinary medicines without holding a WDA.

*Do you agree with the proposal for a MAH to hold a WDA to wholesale products (including products for which they are the MAH)?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impacts on you / your business / wider aspects from this proposed change.*

## **Special Import Scheme**

4.10 We want to reduce barriers for a vet to obtain medicines under the special import scheme (regulation 25 in the VMR). Therefore, we propose 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.

## **Distribution for promotional purposes**

4.11 We propose updating 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 (new paragraph 3A in Schedule 3 to the VMR). Medicines containing antimicrobials must not be distributed for promotional purposes. We propose to introduce an offence for failure to comply with this requirement.

*Do you agree with this approach for medicines distributed for promotional purposes?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact this may have on you, your business and wider aspects, including views on the proposed offence.*

## **Registration of online retailers**

4.12 We want animal owners or keepers who wish to buy veterinary medicines online to be able to distinguish legitimate, UK-based retailers from unlawful ones and so reduce the risk of them purchasing substandard or illegal medicines. Most internet retailers are already authorised to retail veterinary medicines.

4.13 We propose introducing a new requirement for online retailers of veterinary medicines categorised POM-V, POM-VPS and NFA-VPS to register with the Secretary of State (new paragraphs 3B-D in Schedule 3 to the VMR). We would require those retailers to display a registration logo issued by the VMD. This is an adaptation of the voluntary Accredited Internet Retailer Scheme, run by the VMD. This change would also enable the VMD to better enforce the legislation and identify and pursue illegal internet traders. We propose to introduce offences for failure to comply with the requirement to register and other duties in relation to online supply.

*Do you agree with requirement for online retailers to register?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, including views on the proposed offences, and the impacts on you / your business / wider aspects from this proposed change.*

## **Retailer supply**

4.14 We propose 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 (Schedule 3 paragraph 15 in the VMR). This would ensure that they are available for inspection by inspectors.

4.15 To provide assurance that the quality of medicines is maintained throughout the supply chain, we also propose to introduce the requirement that retailers must store veterinary medicines in line with the storage instructions on the label (new paragraph 3E). We propose to introduce an offence for failure to comply with this requirement.

*Do you agree with this approach to audits, record-keeping and storage by retailers?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, including views on the proposed offences, and the impacts on you / your business / wider aspects from this proposed change.*

## **Assessment by vet before prescribing POM-V**

4.16 We want to reduce burden on vets, in particular those in remote areas, whilst supporting responsible, safe and effective prescribing. One way to achieve this may be to enable vets to prescribe medicines remotely and more efficiently without reducing the oversight required for responsible and safe prescribing.

4.17 We therefore propose 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 (Schedule 3 paragraph 4 in the VMR). The current requirement is for the vet to carry out a 'clinical assessment'. Note that the Royal College of Veterinary Surgeons provides an interpretation of the term 'clinical assessment'.

*Do you agree with this approach to the assessment made of an animal/animals by the vet before the vet prescribes a POM-V medicine?*

- *Strongly agree*
- *Agree*
- *Neutral*

- *Disagree*
- *Strongly disagree*

*Please provide additional information, including any concerns raised by the proposed changes and impacts on you / your business / wider aspects from this proposed change.*

## **Prescriptions**

4.18 We want to provide assurance that veterinary medicines are prescribed appropriately and responsibly, especially where resistance is a concern. We therefore propose requiring 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 (Schedule 3 paragraph 5 in the VMR). This change would ensure that medicines can still be prescribed orally, but that there is evidence for the justification for use of the medicine.

4.19 We also propose to update the information that should be contained in a prescription (paragraph 6). This would include, to reduce tampering with prescriptions and (unintended) prescription fraud, the requirement for prescriptions to include the following text: “it is an offence under the Veterinary Medicines Regulations 2013 for a person to alter a written prescription unless authorised to do so by the person who signed it”.

*Do you agree with the changes to the requirements for prescribing medicines?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact this may have on you, your business and wider aspects.*

## **Wholesale supply of premix by feed business operators**

4.20 Feed business operators should not be wholesale dealing premixes without a WDA. The current provision allows feed business operators to wholesale supply an amount not exceeding 5% of their total annual supply (Schedule 3 paragraph 11 in the VMR). There is a need for such wholesale supply in exceptional circumstances, **to alleviate supply shortages and protect animal welfare**, therefore we propose to harmonise this provision with that for emergency supply of veterinary medicines between retailers.

## **Products supplied under the cascade**

4.21 Unauthorised veterinary medicines used under the cascade or authorised medicines used outside the terms of their MA carry a higher risk when administered to animals than



authorised medicines used in accordance with their MAs. We propose to make explicitly clear in the VMR that medicines prescribed and / or supplied under the cascade are to be treated as if they were POM-V (Schedule 3 paragraph 1 in the VMR) in relation to record-keeping requirements (regulation 23), assessment of the animal before prescribing (paragraph 4) and supply (paragraphs 7 and 10). This would ensure that products prescribed and / or supplied under the cascade are appropriately regulated.

*Do you agree with this approach to products prescribed and supplied under the cascade?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact this may have on you, your business and wider aspects.*

## **Remote supply by SQPs**

4.22 The current VMR places disproportionate regulatory burden on SQPs when supplying veterinary medicines in comparison to vets or pharmacists, as it does not allow the remote supply of products by the SQP. We propose to amend the VMR in relation to the supply of POM-VPS and NFA-VPS medicines by SQPs to be consistent with the requirements for vets and pharmacists. The proposed change would mean that an SQP who has correctly prescribed / advised on a product and who has authorised its supply in advance, does not necessarily have to be physically present when the product is selected and / or handed over to the customer. They can delegate that process to a competent person (Schedule 3 paragraph 14).

*Do you agree with this approach to remote supplying by SQPs?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impacts on you / your business / wider aspects from this proposed change.*

## **SQP registration bodies**

4.23 It is currently not clearly stated in the VMR 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 (Schedule 3 paragraph 14). We propose to clarify this in the VMR, including the appeal procedure (regulation 30).

## **Sheep dip**

4.24 We propose to adjust the text in Schedule 3 paragraph 23 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).

***If all changes to Schedule 3 were made, as set out in this chapter, what would be the impact (including familiarisation costs) on your business? What would be the consequences if we did not make these changes?***

***We will make transitional arrangements for new requirements, where appropriate. We welcome any views on such arrangements or other measures which might help address problems if the new requirements would be applied immediately upon the revised VMR coming into force.***

## Chapter 5 – Administration under the cascade

5.1 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.

5.2 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. Prescribing decisions in accordance with the cascade should be made on a case-by-case basis. The steps, in descending order of suitability, are using a medicine authorised for the species and condition to be treated, using a medicine authorised for use in a different species or for a different condition and either importing and using a medicine authorised outside the UK (with a special import certificate issued by the VMD) or using a medicine authorised in the UK for human use. The final option to be considered should the other tiers of the cascade not provide a solution, comprises extemporaneous preparations prepared by a vet, pharmacist or person holding an appropriate manufacturer's authorisation, located in the UK.

### Cascade prescribing for food-producing animals

5.3 We propose a suite of changes to improve the system of prescription and supply, which includes assurance that vets make responsible prescribing decisions under the cascade. Medicines prescribed under the cascade carry a higher risk than authorised medicines used within the terms of their marketing authorisation. In the case of food-producing animals there is the additional risk to human health through the food chain. We believe that the requirement in the VMR needs to be adjusted to further reduce the risk of inappropriate or unsafe medicines being used in food-producing species under the cascade.

5.4 The current requirement is that **pharmacologically active** substances included in medicines administered to food-producing animals need to be substances for which a maximum residue limit is established. We propose to expand this requirement to **all** substances in that medicine to have an established maximum residue limit or to be included on the out-of-scope list (Schedule 4 paragraph 1 in the VMR).

### Appropriate use of the cascade

5.5 We are aware that some vets are being encouraged to use the cascade inappropriately (for example, when UK-authorised medicines for that species and condition are available). We propose to introduce a new offence of encouraging or facilitating the illegal use of the cascade (new paragraph 9A in Schedule 4 to the VMR).

5.6 We also propose 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 (new paragraph 6A).

*Do you agree with this approach to ensuring appropriate use of the cascade?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact this may have on you, your business and wider aspects, including views on the proposed offence.*

## **Withdrawal periods**

5.7 Industry have raised concerns that some of the statutory minimum withdrawal periods of medicines used under the cascade are limiting treatment options. We have reviewed our existing minimum withdrawal periods and propose to amend them to ensure they are fit-for-purpose: ensuring food safety whilst not presenting a barrier to the treatment of animals (Schedule 4 paragraph 2 of the VMR). They are largely harmonised with the current EU withdrawal periods where these exist. The table below indicates the current and proposed periods.

<b>Withdrawal period</b>		
<b>Commodity</b>	<b>Current</b>	<b>Proposed</b>
<b>Eggs</b>	7 days	longest withdrawal period in SPC* for any species multiplied by 1.5  or  14 days if product is not authorised for animals producing eggs for human consumption
<b>Milk</b>	7 days	longest withdrawal period in SPC* for any species multiplied by 1.5  or  7 days, if product is not authorised for animals producing milk for human consumption  or  one day, if product has zero-hour withdrawal period
<b>Meat from poultry and mammals including fat and offal</b>	28 days	longest withdrawal period in SPC* for meat and offal, multiplied by 1.5  or

		28 days if product is not authorised for food-producing animals or one day, if product has zero-day withdrawal period
<b>Fish meat</b>	500 degree-days	longest withdrawal period for any aquatic species in SPC* multiplied by 1.5 and expressed as degree-days or if product is authorised for food-producing terrestrial animal species, longest withdrawal period for any food-producing animal species in SPC* multiplied by 50 and expressed as degree-days or 25 degree-days if highest withdrawal period for any animal species is zero

\* Summary of Product Characteristics

*Do you agree with this approach to the statutory minimum withdrawal periods?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact this may have on you, your business and wider aspects.*

***If all changes to Schedule 4 were made, as set out in this chapter, what would be the impact (including familiarisation costs) on your business? What would be the consequences if we did not make these changes?***

## Chapter 6 – Medicated feed

6.1 Schedule 5 to the VMR covers manufacture, supply, prescription, etc. of medicated feed (also known as medicated feedingstuffs) and specified feed additives. Medicated feed is one of the oral routes to administer veterinary medicines to animals and is generally used to treat diseases in large groups of food-producing animals, in particular pigs and poultry. The medicine (and specified feed additives) can either be incorporated into their feed by the animal owner or keeper on approved premises or by an approved commercial manufacturer of medicated feed and subsequently supplied to an animal owner or keeper.

### Definitions

6.2 We want to ensure a clear and consistent understanding of the VMR which is shared by stakeholders and the regulator. Therefore, we propose to introduce additional definitions in Schedule 5, such as for batch, complementary / complete / compound feed and intermediate feedingstuffs (Schedule 5 paragraph 1 in the VMR). We also propose to refer specifically to premix as the veterinary medicine incorporated into feed and replace the confusing term 'premixture' with 'intermediate feedingstuff' throughout the schedule.

### Prescription for medicated feed

6.3 As part of a suite of changes that we are proposing to introduce to improve the system of prescription and supply, we propose to strengthen the information that needs to be included in the prescription for feed containing a premix (Schedule 5 paragraph 19 in the VMR). The changes include for example the diagnosis and the amount of final feed to be supplied to ensure the correct amount of feed is being supplied and in the correct composition. Where the prescription relates to a premix with immunological or antiparasitic effects the prescription must contain a statement that the premix must not be re-used.

6.4 It is important that medicated feed is ready to be supplied to treat animals within effective timeframes. We therefore propose 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 (paragraph 18).

*Do you agree with this approach to prescriptions for medicated feed?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact (for example costs and savings) on you / your business / wider aspects of the proposed changes.*

## Labelling

6.5 We have identified potential information gaps in labelling of intermediate feedingstuffs and medicated feed, which could lead to inappropriate or incorrect use or disposal of the product or feed. We want to ensure there is an easily accessible way for users to obtain the information required for responsible use and disposal. We therefore propose introducing new labelling requirements for intermediate feedingstuffs and medicated feed that are in line with those for veterinary medicines (Schedule 5 paragraphs 12 and 14 in the VMR). The main changes relate to requiring the use in line with the summary of product characteristics of the premix and warnings about inappropriate disposal.

*Do you agree with this approach to labelling?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact (for example costs and savings) on you / your business / wider aspects of the proposed changes.*

## Storage and disposal of medicated feed

6.6 There are currently no requirements under the VMR to provide adequate assurances that medicated feed is being used safely and responsibly by keepers of animals. There is a risk to animal health, public health and the environment if medicated feed is not responsibly used, stored and disposed of, especially in the case of medicated feed containing antibiotics.

6.7 We propose 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 (Schedule 5 paragraph 26 in the VMR). Products should be administered only to the correct animal and the withdrawal period should be complied with.

6.8 We need to ensure unused, expired and waste feed is disposed of correctly and responsibly, particularly when it contains antimicrobials. We propose 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 (new paragraph 26A).

6.9 We also propose to state explicitly that medicated feed that has passed its expiry date may not be fed to an animal (new paragraph 26A). We propose to introduce an offence for failure to comply with this requirement.

*Do you agree with this approach to storage and disposal of medicated feed?*

- Strongly agree
- Agree
- Neutral
- Disagree
- Strongly disagree

*Please provide additional information, including views on the proposed offence and the impacts on you / your business / wider aspects from the proposed changes.*

## **Cross-contamination and carryover**

6.10 The risk of veterinary medicines, including antimicrobials, being inadvertently fed to non-target animals must be minimised. The use of veterinary medicines in feed production can lead to cross-contamination with an active substance from previous use of the equipment or facilities into non-target feed (this is known as carryover when caused by residual medicated feed from a previous batch).

6.11 We propose to introduce a new requirement for cross-contamination to be as low as reasonably achievable (new paragraph 22A in Schedule 5 to the VMR). We would require suitable testing to be carried out and for feed business operators to note any results over 1% and to conduct a root cause analysis for results over 3%. These analyses should be kept for 5 years. We would also require feed business operators to provide the Secretary of State with information on carryover testing, sampling and assessments. We propose to introduce an offence for failure to comply with these requirements.

*Do you agree with this approach to cross-contamination and carryover?*

- Strongly agree
- Agree
- Neutral
- Disagree
- Strongly disagree

*Please provide additional information, including views on the proposed offence and the impacts on you / your business / wider aspects from the proposed changes.*

## **Tolerance table**

6.12 We propose to amend the tolerance table to support high quality of medicated and intermediate feedingstuffs with accurate levels of active ingredient (paragraph 22(2)).

<b>Level of active substance specified on label</b>	<b>Current tolerance</b>	<b>Proposed tolerance</b>
<b>&lt;= 50 mg/kg</b>	± 50%	± 30%
<b>&gt;50 mg/kg &lt;= 500 mg/kg</b>	± 40%	
<b>&gt;500 mg/kg &lt;= 5g/kg</b>	± 30%	± 20%
<b>&gt;5g/kg &lt;= 50g/kg</b>	± 20%	± 10%
<b>&gt;50g/kg</b>	± 10%	



*Do you agree with this change to the tolerance table?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact (for example costs and savings) on you / your business / wider aspects of the proposed changes.*

***If all changes to Schedule 5 were made, as set out in this chapter, what would be the impact (including familiarisation costs) on your business? What would be the consequences if we did not make these changes?***

***We will make transitional arrangements for new requirements, where appropriate. We welcome any views on such arrangements or other measures which might help address problems if the new requirements would be applied immediately upon the revised VMR coming into force.***

## Chapter 7 – Exemptions for small pet animals

7.1 Schedule 6 sets out the exemptions from the VMR that allow certain veterinary medicines to be sold without a marketing authorisation. These exemptions currently cover medicines intended for specific animal species, for example small rodents, rabbits and homing pigeons (but not cats or dogs), provided that the animals are kept exclusively as pets and are not intended to produce food for human consumption. The medicines can only contain active substances which have been approved for the purposes of this exemption by the Secretary of State and are restricted to topical or oral administration routes.

### Registration and supply of information

7.2 We inform stakeholders and take appropriate and targeted measures in relation to reports of adverse events or in case of safety or efficacy concerns related to active substances included in products marketed under this exemption. We know which manufacturers have a GB authorisation for products regulated by Schedule 6, but we want to ensure that we have complete and accurate information on all products marketed in accordance with this Schedule.

7.3 We therefore propose 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 (new paragraphs 3A and 3B in Schedule 6 to the VMR). This would also improve the VMD's capability to mitigate supply shortages as we can identify those who can supply certain active substances. The information includes details of the manufacturer and the product. The registration and annual return would be a simple process and we would provide guidance on how to do this. There would be no fee or inspection associated with registration.

*Do you agree with our approach to register companies that market products under the exemption for small pet animals and require them to provide information annually?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impacts on you / your business / wider aspects from this proposed change.*

## **Reporting of adverse events by retailers**

7.4 We believe that it is disproportionate to require retailers to record and report adverse events for products sold in accordance with Schedule 6 as this requirement does not exist for the supply of authorised veterinary medicines. We therefore propose to remove this requirement from the VMR (Schedule 6 paragraph 9 in the VMR). The requirement remains for manufacturers and importers of such products, ensuring adverse events will be reported and can be acted upon as appropriate.

*Do you agree with our approach to remove the requirement for retailers to record and report adverse events for products sold under the exemption for small pet animals?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact this may have on you, your business and wider aspects.*

***If all changes to Schedule 6 were made, as set out in this chapter, what would be the impact on your business? What would be the consequences if we did not make these changes?***

***We will make transitional arrangements for new requirements, where appropriate. We welcome any views on such arrangements or other measures which might help address problems if the new requirements would be applied immediately upon the revised VMR coming into force.***

## Chapter 8 – Antimicrobial resistance

8.1 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. This approach has already proved successful in the absence of legislative requirements, with a 55% reduction in antibiotic use in food producing animals since 2014, and the aim is to use the revised VMR to support and build on that success.

This chapter sets out the major changes proposed to minimise the development and spread of antimicrobial resistance. Other changes are covered elsewhere: paragraphs 2.3, 2.19, 2.22 and 4.11 in this document.

### **Antibiotic usage data**

8.2 Paragraph 31 in Schedule 1 to the VMR requires marketing authorisation holders to provide upon request sales data for veterinary medicines to the Secretary of State. The VMD collates and reports sales data for antibiotic veterinary medicines in an annual report. The collection of antibiotic use data has many additional benefits, including the ability to measure trends, drive changes in behaviour through farm level benchmarking and set targets for reducing inappropriate use. We have therefore already been working on a voluntary basis with different livestock sectors and publish antibiotic use data representing 90% or more of the pig, meat poultry, laying hen, trout, salmon and gamebird sectors. The Medicine Hub for ruminants is also up and running with the aim of bringing together antibiotic use data for the dairy, beef and sheep sectors.

8.3 Given this progress, we believe that making antibiotic use data collection a legislative requirement is not necessary at this time. In addition, we think that having a voluntary approach, with data collected by a trusted industry partner, results in greater industry ownership and accountability.

8.4 We propose that, in addition to the legal requirement for provision of sales data by marketing authorisation holders, the collection of antibiotic use data by species or sector (which is collected from veterinary surgeons, producers and / or feedmills) remains voluntary. However, the VMR would contain a regulation (new regulation 24A in the VMR) which allows the Secretary of State to require vets, manufacturers, marketing authorisation holders or wholesale dealers to provide information in relation to sales and use of antibiotics, if, upon review, the voluntary model for antibiotic usage data fails to deliver. We propose to introduce an offence for failure to comply with such a request for information.

*Do you agree with the collection of species or sector specific antibiotic use data remaining a voluntary initiative but that the Secretary of State can request such data if insufficient progress is made, and that it would be an offence to fail to comply with such request?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact (for example costs and savings) on you / your sector if usage data collection were made mandatory, including your views on the introduction of an offence.*

## **Prophylactic use**

8.5 Prophylaxis is defined as “the administration of a medicinal product to an animal or group of animals before clinical signs of a disease in order to prevent the occurrence of disease or infection”. We do not support routine preventative use (prophylaxis) of antibiotics in animals or poor farming practices which rely on routine or predictable antibiotic use to be viable. Our proposal constitutes a significant increase in restriction and scrutiny of all antibiotic prophylaxis, in particular where it is used in groups of animals, with a view to dramatically reducing it. We are therefore proposing that use of antibiotics for prophylaxis is only allowed in exceptional circumstances, where the risk of an infection or an infectious disease is very high and the consequences are likely to be severe (new paragraph 7A in Schedule 3 to the VMR). We propose to introduce an offence for failure to comply with this requirement. When considering groups of animals, we are additionally proposing that prophylaxis 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. We would monitor the effectiveness of these measures through antimicrobial consumption and resistance surveillance programmes, and through continued engagement with stakeholders. A similar provision is introduced for prescribing medicated feed containing antibiotics (Schedule 5 paragraph 19).

8.6 We are not proposing a full, blanket ban on group prophylactic use as, if there is an infection or infectious disease on the farm, making improvements to farm infrastructure and management practices to reduce or eliminate this can take time. Banning group prophylaxis while these changes are being implemented could be harmful to animal welfare (as you would need to wait until some animals become clinically ill before treating) and increase the risk of the disease spreading (which would subsequently require higher antibiotic use and thus increase the risk of AMR developing). We believe it is better to take a stepwise approach that helps the UK farming industry, with the support of the veterinary

profession, continue to make sustainable changes towards reducing prophylactic use to groups of animals.

*Do you agree with our proposals to restrict prophylactic use?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact this may have on you, your business and wider aspects, including views on the proposed offence.*

## **In-feed antibiotics**

8.7 In-feed antibiotics can be a convenient way of administering antibiotics but currently account for a third of antibiotics prescribed to food-producing animals. Furthermore, animals should be treated within a relevant time-frame, for the treatment to be effective.

8.8 We propose including the following restrictions relating to medicated feed containing antibiotics (Schedule 5 paragraph 19):

- 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 paragraph 8.5 apply here too.

*Do you agree with this approach to medicated feed containing antibiotics?*

- *Strongly agree*
- *Agree*
- *Neutral*
- *Disagree*
- *Strongly disagree*

*Please provide additional information, especially on the impact this may have on you, your business and wider aspects.*

## Chapter 9 – Fees

9.1 Schedule 7 to the VMR sets out our fees. As a cost recovery agency, we are required to charge for the regulatory services we provide. The fees and fee structure were last updated in 2013. Since then, costs for providing our regulatory services have generally increased, although the VMD has identified and introduced savings where possible to ensure we perform our services as efficient as possible (for example, carrying out remote inspections where possible and introducing technology to reduce the time needed to draft reports). We also conduct regulatory services that we do not currently have a specific fee for.

We propose to revise the fees and fee structure so that we can recover the true cost of providing our services. See Annex D for detail on the proposed changes to the fees. For the full list of fees, including those that will not be changed, please see the draft amended VMR text published alongside this consultation document.

9.2 We propose introducing new fees for:

- marketing authorisation applications for specific veterinary medicines (new paragraph 7A in Schedule 7 to the VMR)
- 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 (new paragraph 63)
- providing scientific advice to companies (new paragraph 54A)
- 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 (new paragraph 57A)

9.3 We propose changing the existing fees for:

- new and generic marketing authorisation applications and variations thereof (paragraph 7, new paragraph 15A, paragraph 17)
- marketing authorisation applications based on informed consent (paragraph 11)
- manufacturing authorisations (including application, variations, inspections and annual fees) (paragraphs 28-38)
- wholesale dealers (including application, variations, inspections and annual fees) (paragraphs 39-42)
- feed business operators (including applications, inspections and annual fees) (paragraphs 43-44)
- SQP retailers (including authorisation, inspections and annual fees) (paragraph 46)
- animal test certificates (including application, variation and renewal) (paragraph 48)
- special import certificates (paragraphs 49 and 50)
- export certificates (paragraph 53)
- veterinary practice premises (including inspections, registration and annual fees) (paragraph 57)

9.4 We propose 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 (paragraph 7 and new paragraph 15A).

9.5 We propose to simplify the categories of feed businesses which also simplifies the fee structure for inspections of these businesses (paragraph 44).

9.6 We propose to remove the fee for renewals of marketing authorisations and registrations of homeopathic remedies (paragraphs 22 and 25).

9.7 More detail on the proposed changes is included in Annex D.

9.8 An initial assessment on the impact of these changes is included in the pre-consultation De Minimis Assessment and its Annexes.

***It would help us to improve this assessment if you are able to provide detailed information on the impact (including positive and negative) of these proposed changes to the fees on you / your business / wider aspects.***

***Please provide information as to how the proposed changes to fees will impact you / your business (including familiarisation costs).***



# Annex A – Consultation questions

## Chapter 1 – General

1. Do you agree with the proposal for the VMD to be able to require information on request?
2. Do you agree with this approach to the “**as soon as reasonably practical**” issuing of records by vets?
3. Do you agree with this proposed approach to advertising of veterinary medicines?
4. Do you agree with this approach to the changes in inspectors’ powers, including the introduction of an offence?
5. If all changes to the regulations were made, as set out in this chapter, what would be the impact (including familiarisation costs) on your business? What would be the consequences if we did not make these changes?

## Chapter 2 – Marketing authorisations

6. Do you agree with the proposed changes to the requirements for the summary of product characteristics and data requirements for a marketing authorisation application?
7. Do you agree with this approach to generic / generic hybrid products?
8. Do you agree with the proposed removal of the option to have marketing authorisations for parallel import?
9. Do you agree with the proposal of assessing applications for MAs and MRLs at the same time?
10. Do you agree with the proposal for amending the current data protection periods?
11. Do you agree with the proposal for introducing flexibility into the assessment timeline?
12. Do you agree with the proposal for a UK-based local representative instead of the requirement for the MAH to be established in the UK?
13. Do you agree with this approach for publishing assessment reports?
14. Do you agree with this approach on making it mandatory for MAHs to report supply shortages to the Secretary of State?

15. Do you agree with the proposed changes for renewing MAs?
16. Do you agree with the proposed changes for variations to MAs?
17. Do you agree with this approach to suspension and revocation of MAs, prohibiting supply or restricting (immunological) medicines?
18. Do you agree with this approach to the labelling and package leaflet?
19. Do you agree with allowing electronic package information leaflets?
20. Do you agree with this approach for pharmacovigilance?
21. Do you agree with this approach for homeopathic remedies?
22. If all changes to Schedule 1 were made, as set out in this chapter, what would be the impact (including familiarisation costs) on your business? What would be the consequences if we did not make these changes?
23. We will make transitional arrangements to cover applications already being processed for a (variation of a) marketing authorisation or registration of a veterinary homeopathic remedy, changes in labelling and packaging requirements, and other new requirements, as appropriate. We welcome any views on such arrangements or other measures which might help address problems if the new requirements would be applied immediately upon the revised VMR coming into force.

### **Chapter 3 – Manufacture**

24. Do you agree with this approach for manufacturing authorisations?
25. Do you agree with this consistent approach for specific manufacturing authorisations?
26. Do you agree with this approach for regulatory oversight of active substances?
27. Do you agree with this approach for products manufactured under the cascade?
28. Do you agree with this approach to stem cell centres?
29. If all changes to Schedule 2 were made, as set out in this chapter, what would be the impact (including familiarisation costs) on your business? What would be the consequences if we did not make these changes?
30. We will make transitional arrangements to cover applications already being processed for a (variation of a) manufacturing authorisation and other new

requirements, where appropriate. We welcome any views on such arrangements or other measures which might help address problems if the new requirements would be applied immediately upon the revised VMR coming into force.

#### **Chapter 4 – Supply**

31. Do you agree with the proposed additions to the POM-V classification?
32. Do you agree with the proposed changes for wholesale dealers, including the proposed offences?
33. Do you agree with the requirement for wholesale dealers to investigate stock discrepancies and keep records for five years?
34. Do you agree with the proposal for a MAH to hold a WDA to wholesale products (including products for which they are the MAH)?
35. Do you agree with this approach for medicines distributed for promotional purposes?
36. Do you agree with requirement for online retailers to register?
37. Do you agree with this approach to audits, record-keeping and storage by retailers?
38. Do you agree with this approach to the assessment made of an animal/animals by the vet before the vet prescribes a POM-V medicine?
39. Do you agree with the changes to the requirements for prescribing medicines?
40. Do you agree with this approach to products prescribed and supplied under the cascade?
41. Do you agree with this approach to remote supplying by SQPs?
42. If all changes to Schedule 3 were made, as set out in this chapter, what would be the impact (including familiarisation costs) on your business? What would be the consequences if we did not make these changes?
43. We will make transitional arrangements for new requirements, where appropriate. We welcome any views on such arrangements or other measures which might help address problems if the new requirements would be applied immediately upon the revised VMR coming into force.

#### **Chapter 5 – The cascade**

44. Do you agree with this approach to ensuring appropriate use of the cascade?

45. Do you agree with this approach to the statutory minimum withdrawal periods?
46. If all changes to Schedule 4 were made, as set out in this chapter, what would be the impact (including familiarisation costs) on your business? What would be the consequences if we did not make these changes?

## **Chapter 6 – Medicated feedingstuffs**

47. Do you agree with this approach to prescriptions for medicated feed?
48. Do you agree with this approach to labelling?
49. Do you agree with this approach to storage and disposal of medicated feed?
50. Do you agree with this approach to cross-contamination and carryover?
51. Do you agree with this change to the tolerance table?
52. If all changes to Schedule 5 were made, as set out in this chapter, what would be the impact (including familiarisation costs) on your business? What would be the consequences if we did not make these changes?
53. We will make transitional arrangements for new requirements, where appropriate. We welcome any views on such arrangements or other measures which might help address problems if the new requirements would be applied immediately upon the revised VMR coming into force.

## **Chapter 7 – Exemptions for small pet animals**

54. Do you agree with our approach to register companies that market products under the exemption for small pet animals and require them to provide information annually?
55. Do you agree with our approach to remove the requirement for retailers to record and report adverse events for products sold under the exemption for small pet animals?
56. If all changes to Schedule 6 were made, as set out in this chapter, what would be the impact (including familiarisation costs) on your business? What would be the consequences if we did not make these changes?
57. We will make transitional arrangements for new requirements, where appropriate. We welcome any views on such arrangements or other measures which might help address problems if the new requirements would be applied immediately upon the revised VMR coming into force.

## **Chapter 8 – Antimicrobial resistance**

58. Do you agree with the collection of species or sector specific antibiotic use data remaining a voluntary initiative but that the Secretary of State can request such data if insufficient progress is made, and that it would be an offence to fail to comply with such request?

59. Do you agree with our proposals to restrict prophylactic use?

60. Do you agree with this approach to medicated feed containing antibiotics?

## **Chapter 9 – Fees**

61. Please provide information as to how the proposed changes to fees will impact you / your business (including familiarisation costs).

## Annex B – Main areas impacting each business area

Profession or business	Section to review
<b>Feed Business Operator</b>	4.20 Chapter 6 Chapter 9
<b>Manufacturer</b>	1.4-1.5, 1.13-1.14, 1.15 Chapter 3 4.3, 4.21 5.5-5.6 Chapter 7 Chapter 9
<b>Marketing authorisation holder</b>	1.4-1.5, 1.7-1.12, 1.13-1.14, 1.15 Chapter 2 4.3, 4.9, 4.11 5.7 8.2-8.4 Chapter 9
<b>Pharmacist</b>	4.10
<b>Professional keeper of animals</b>	1.6 4.24 Chapter 6 8.5-8.6, 8.7-8.8
<b>Retailer</b>	4.12-4.15
<b>Suitably Qualified Person</b>	4.22, 4.23
<b>Vet</b>	1.6 4.3, 4.16-4.17, 4.18-4.19, 4.21 5.5-5.6 8.5-8.6, 8.7-8.8 Chapter 9
<b>Wholesale dealer</b>	1.13-1.14, 1.15 4.4-4.8 Chapter 9

# Annex C – Assessment of the matters set out in Section 10 of the Medicines and Medical Devices Act 2021

The proposals outlined in this consultation document would all require legislative changes. The Medicines and Medical Devices Act 2021 (the Act) came into force for these purposes on 11 April 2021. The changes would be made using powers in Part 3 of the Act, which provides powers to amend and supplement the Veterinary Medicines Regulations 2013. This consultation is conducted in line with the consultation requirement in section 45 of the Act.

Section 10 of the Act provides that, when making regulations, the overarching objective of the appropriate authority must be to promote animal health and welfare, public health and safety and / or protection of the environment. Section 10 requires that when assessing whether regulations would contribute to the overarching objective, the appropriate authority must have regard to three factors:

1. the safety of veterinary medicines,
2. the availability of veterinary medicines, and
3. the likelihood of the relevant part of the UK being seen as a favourable place in which to develop, manufacture or supply veterinary medicines.

As set out in section 10(4) of the Act, where regulations under section 10(1) may have an impact on the safety of veterinary medicines, the appropriate authority may make the regulations only if the authority considers that the benefits of doing so outweigh the risks.

Below we have assessed the package of policy proposals included in the consultation document against the three factors set out in section 10 of the Act.

**Safety:** We consider that the changes we propose will continue to provide for the safety of veterinary medicines authorised for use in Great Britain, in relation to animals, humans and the environment. This will be achieved through reducing the development and spread of antimicrobial resistance (chapter 8), supporting safe and responsible use of veterinary medicines (for example changes 1.9, 2.5, 2.37, 6.5, 6.11) and increasing our ability to take timely and targeted measures in case of concerns around safety or efficacy of active substances, or breaches of the VMR presenting a serious risk to human or animal health, or the environment (for example changes 1.13, 2.41, 3.8, 3.12, 7.3).

**Availability:** The changes we propose will increase access to veterinary medicines, for example by enabling suitably qualified persons to delegate handover of medicines to a competent person and vets to prescribe remotely, where appropriate (changes 4.22, 4.17). We recognise that some proposed changes may increase burden, mainly through increased record-keeping requirements, but we consider these changes necessary to improve the prescribing and supply of veterinary medicines. Other proposed changes will

improve our ability to mitigate against shortages of veterinary medicines by requiring businesses to report any current or upcoming shortages where known (changes 2.25, 4.4). Finally, amending the existing statutory minimum withdrawal periods will ensure they are fit-for-purpose: ensuring food safety whilst not presenting a barrier to the treatment of animals (change 5.7).

**Favourability:** We consider that our proposed changes will reduce regulatory burden for the pharmaceutical industry, thus ensuring that Great Britain remains a favourable place to develop, manufacture and supply veterinary medicines. We will achieve this for example by changing the data requirements for companies applying for a marketing authorisation (change 2.2), removing the requirement for renewal of a marketing authorisation (change 2.26) and streamlining the system for making variations to marketing authorisations (change 2.27). Favourability will increase through the future-proofing of our Regulations by incorporating a flexible approach to novel therapies, ensuring these can come to the GB market (change 2.11) and amending the data protection periods to encourage the submission and marketing of new and innovative products, whilst maintaining a healthy generics market (change 2.16).



## Annex D – Proposed changes to fees

We propose to make changes to the fees and fees structure. Some of the changes will result in a reduction in fees, some changes will see an increase in fees to reflect the increased cost to the VMD in providing these services, and other changes will change how the fees are applied. For some fees, no changes will be applied.

This annex seeks to explain the changes in a simple way. It does not contain the exhaustive list of fees which is included in Schedule 7 of the VMR. A draft of the amended VMR text (with tracked changes to reflect the proposals) is included with the consultation.

### Marketing authorisations

We propose to simplify the fees structure for national marketing authorisations. The current structure is complex, with various increments included in the total fee; this will be replaced by one overall base fee of £27,995 (or £45,000 for a complex medicine, for example a medicine containing a new active substance), as well as £4,590 for the first additional strength and £1,465 for each subsequent additional strength. Examples comparing the current and proposed fees are set out below.

#### Example 1

Medland is applying for a full known active pharmaceutical marketing authorisation for a veterinary medicine for cattle and sheep. Under the current fees structure, the base fee is £13,530, with an additional fee of £3,905 for a food-producing species application. The medicine also contains an additional active ingredient which attracts an additional fee of £6,465. The medicine is also targeted at more than one food-producing species, and therefore attracts an additional fee of £3,970. The total fee for the marketing authorisation application currently is £27,870. With the proposed changes, the fee for this application would be £27,995.

#### Example 2

BioComp is submitting a novel biological application, which has a base fee of £11,775. There is a fee of £1,350 as it contains two antigens, and an additional fee as both antigens are novel (£7,405 x2). The total fee for the marketing authorisation application currently is £27,935. With the proposed changes, the fee for this application would be £45,000 as it is a complex application.

We also propose simplifying application fees for generic medicines, with a standard fee of £12,390 (or £13,950 for generic hybrids). A comparison with the current fees for generics is shown below.

#### Example 3

Medland is applying for a marketing authorisation for a generic medicine (which has a base fee of £7,195). As this is for a food-producing species, there is an additional fee of

£2,155. This is also a simultaneous application with a medicine with a different strength but the same product, which attracts a fee of £2,895. Therefore, the total fee for the marketing authorisation application is £12,245. With the proposed changes, the fee for this application would be £12,390.

Most variations will change to variations requiring assessment (standard), variations requiring assessment (reduced) and variations not requiring assessment; the fees will not change.

We propose changes to grouped variations: after the first nine changes, lower fees will be charged for the first five additional changes (compared to the first 10 additional changes currently). These will be £2,250 for up to five changes, instead of £4,500 currently for up to 10 changes.

We propose introducing fees for pharmacovigilance inspections: this will be £3,600 for standard marketing authorisation holders and £1,650 for marketing authorisation holders who hold fewer than 30 marketing authorisations.

## **Manufacturing authorisations**

We propose changing how we charge fees for inspecting manufacturers. We propose changing the way we charge ManSA and AVA manufacturers, to bring them in line with other manufacturing authorisations. We propose significantly reducing the annual fee for manufacturing authorisations for ManSA and AVA manufacturers (to a flat fee of £575), increasing the inspection fee (for most but not all types of sites), and introducing tiers for the inspection fee. This will be based on the size of the manufacturing site, with the standard fee approximately doubled for major sites and approximately trebled for super sites (with a reduction for minor sites). The fees will vary depending on what is manufactured at the site (as is the case now). The examples below will help illustrate the changes.

### Example 4

Medimaker is a standard-sized manufacturer of immunological veterinary medicines. It currently pays an annual fee of £550 and an inspection fee of £6,661. Assuming an inspection every three years, the total fees charged to Medimaker over three years are £8,311 (or £2,770 per year). We propose that Medimaker would pay an annual fee of £575 and an inspection fee of £10,708. Assuming an inspection every three years, the total fees charged to Medimaker over three years would be £12,433 (or £4,144 per year, an increase of £1,374 per year).

### Example 5

AVAland is a standard-sized AVA manufacturer in the UK. It currently pays an annual fee (based on its turnover) of £4,249 and an inspection fee of £3,435. Assuming an inspection every three years, the total fees charged to AVAland over three years are £16,182 (or £5,394 per year). We propose that AVAland pays an annual fee of £575

and an inspection fee of £6,425. Assuming an inspection every three years, the total fees charges to AVAland over three years would be £8,150 (or £2,717 per year, a reduction of £2,677 per year).

### Example 6

Six Strings manufactures medicines that do not require a marketing authorisation (as they are exempt under Schedule 6). As a standard-sized manufacturing site, Six Strings currently pays no annual fee and an inspection fee of £5,055 (therefore £5,055 over three years, or £1,685 per year). Under the proposed fees structure, Six Strings would pay an annual fee of £575 and an inspection fee of £3,212 (therefore £4,937 over three years, or £1,646 per year).

### **Wholesale dealer's authorisations**

We propose significantly reducing the fees for wholesale dealers, with application fees reduced to £344 for all types (from £1,745 for standard applications and £785 for other applications, for example Schedule 6 medicines only). We also propose that the fee is reduced for variations to Wholesale Dealer's Authorisations, from £515 to £265 for those requiring a scientific or pharmaceutical assessment and from £430 to £105 for a change of owner (or another administrative change, which is currently £300).

We propose that inspection fees are reduced, from the current fee of £3,058 to £1,177, with a reduced inspection fee of £877 for sites with a low turnover (or that only deal in AVM-GSL medicines, homeopathic remedies or Schedule 6 medicines), which is reduced from the current fee of £1,442.

### **Feed business operators**

We propose that the application fee for authorisation to operate as a feed business is increased from £70 to £105. We propose that the annual fee is increased for all categories from £70 to £122. The categories of feed business operators are renamed, with some grouped together, and the fees for inspections will be amended to reflect the true cost of inspecting premises (with some reduced and some increased). We propose that the fees for those in the current categories 1-4 are reduced, whilst the fees for those in the current categories 5-8 are increased (apart from traders in category 8, where the fee is reduced). As an example, we propose that Cat 4 becomes part of Cat C and that the fee is reduced from £961 to £841, whereas Cat 6 becomes Cat F and that the fee is increased from £320 to £476.

### **Suitably Qualified Persons (SQP) retailers**

We propose that the fees for SQP retailers are amended from an annual duty only, which includes an element for inspection, to separate annual and inspection fees. We also propose that the application fees to authorise premises as SQP retailers are increased. For AM(L) premises, we propose that the new application for authorisation fee will be £338 (increased from £265); for other categories (including a new category for avian-only

retailers), we propose that the new application fee will be £285 (an increase from £110-£145). We propose introducing new fees for inspections (£285–£338). This will be off-set by a proposed reduction in the annual fee, from £70–£185 to £57.

### Example 7

Medisale Retailers is an already-registered AJ(E) establishment, which currently pays £95 per year (£570 over six years). Under the proposed fees structure, Medisale would pay £57 per year (£342 over six years), as well as £285 per inspection; assuming one inspection during this six year period, the total revised fee over six years would be £627 (or £104.50 per year, an increase of £9.50 per year).

### **Animal test certificates**

We propose that fees for animal test certificates are increased (except for those for small-scale non-commercial trials). We propose that the fee for a certificate is increased from £815 to £1,170. We also propose that the fee for renewal is increased from £130 to £190 and the fee for variations is increased from £265 to £390.

We propose that the fees for small-scale non-commercial trials are set at £40, which is a change from the current fee for applications (£30), renewals (£130) and variations (£265).

### **Special import certificates**

Currently, there is a charge of £30 for paper special import certificate applications, with no fee for online applications. We propose introducing a flat fee of £13 for all special import certificate applications, whether paper or online. This will allow the VMD to recover its costs for this service.

### **Export certificates**

We propose that the cost of providing an export certificate is increased from £30 to £54, with no fee for providing copies of export certificates (it is currently £15).

### **Veterinary practice premises**

We propose the current inspection fee of £350 is increased to allow the VMD to recover costs, with fees ranging between £451 and £698 depending on the type of practice (with most practices charged £536 for an inspection; the higher figure of £698 applying to mixed practice veterinary practice premises).