



Veterinary
Medicines
Directorate



Department
for Environment
Food & Rural Affairs

Review of the Veterinary Medicines Regulations 2013

Summary of responses and government response

Date: February 2024

We are the Department for Environment, Food and Rural Affairs. We are responsible for improving and protecting the environment, growing the green economy, sustaining thriving rural communities and supporting our world-class food, farming and fishing industries.

We work closely with our 33 agencies and arm's length bodies on our ambition to make our air purer, our water cleaner, our land greener and our food more sustainable. Our mission is to restore and enhance the environment for the next generation, and to leave the environment in a better state than we found it.



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Introduction

This document provides a summary of responses to the Veterinary Medicines Directorate's (VMD's) consultation on the proposals to amend and supplement the Veterinary Medicines Regulations 2013 (VMR), and the government's formal response.

The VMR set out the controls on the marketing, manufacture, distribution, possession and administration of veterinary medicines. 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 technical advances and developments in the veterinary medicines industry. The VMR need to be updated to future-proof where possible the regulatory regime and to ensure balanced and proportionate regulation.

The proposed changes to the VMR, which we have consulted on, have the objective to:

- reflect developments and technical advances in the veterinary medicines sector, including the supply chain
- 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
- improve prescription and supply of veterinary medicines.

In addition, the VMD's fees and fee structure set out in the VMR have not changed since 2013. We are required to achieve full cost recovery for our regulatory services, in line with HM Treasury's guidance on [Managing Public Money](#). We proposed a revised fee structure and updated fees 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](#). The consultation was conducted in line with the consultation requirement in section 45(1) of the Act. We have consulted on the proposed changes to give stakeholders the opportunity to share their views to enable us to make proportionate and appropriate regulation.

The consultation was launched on 2 February 2023. It remained open for eight weeks and closed on 31 March 2023. We received responses to the consultation from 188 individuals and/or organisations. This report summarises the responses received and what actions we will take in light of the feedback.

Consultation process

The consultation was launched on 2 February 2023 for a period of eight weeks, closing on 31 March 2023.

On the launch of the consultation, we informed stakeholders of the launch and invited those with an interest to participate and provide feedback to the proposed changes in the consultation. Stakeholders on the VMD's mailing list were contacted by email on the start date of the consultation to make them aware of the consultation.

Information about the consultation was also displayed on the [VMD website \(gov.uk\)](#) and on [VMD Connect](#) to keep stakeholders informed and updated.

We encouraged stakeholders to share details of the consultation with relevant colleagues and anyone with an interest to ensure a fair, open and inclusive participation in the consultation process.

The consultation documents comprised:

- the consultation document, which set out the proposed changes and what we intended to achieve with these changes
- the consultation impact assessment (De Minimis Assessment)
- the consultation draft Statutory Instrument
- a draft of the amended VMR text with tracked changes to reflect the proposals.

All the consultation documents were made available on [VMD Connect](#) and [Citizen Space](#) (an online engagement platform), the latter of which participants were encouraged to use to submit their responses.

During the consultation period, from 27 February 2023 to 3 March 2023, we held a series of virtual focus sessions on the proposed VMR changes. The sessions were intended to provide a platform for stakeholders to ask questions related to the consultation to support them in providing a meaningful response. These sessions were well attended and stakeholders included representatives of the professions and sectors involved in the veterinary medicines industry. We reminded stakeholders who attended these sessions to complete the consultation questionnaire via [Citizen Space](#).

We compiled and published question and answer documents themed in line with the virtual focus sessions on [VMD Connect](#).

Overview of respondents

We thank all those who have responded for taking the time to consider the proposals and submit thoughtful and considered responses. We were very pleased to have a strong engagement from those representing stakeholders across the veterinary medicines industry, including the supply chain and end users.

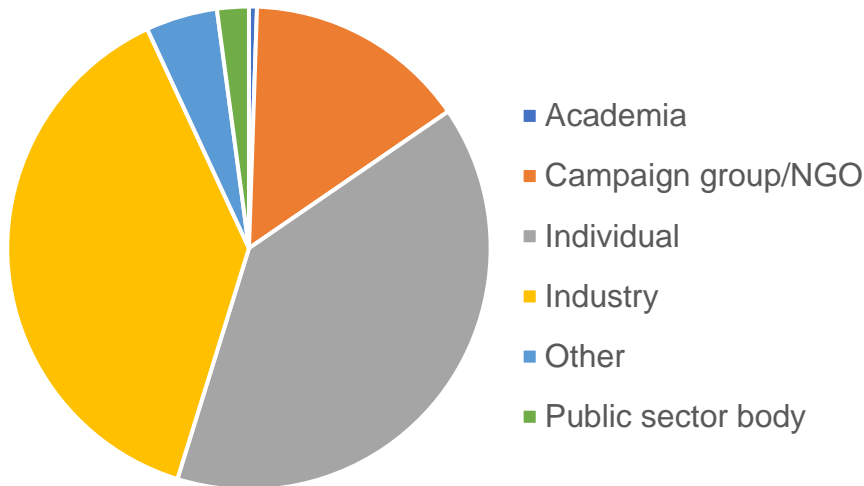
We received responses from a total of 188 respondents, including both individuals and those representing an organisation. The majority of responses were received through Citizen Space with 31 responses received via email. The tables in this section provide a breakdown of respondents and the different sectors and respondent types they represent.

Responses from individuals included those from veterinary surgeons, consumers and academics, and these accounted for 74 (39%) of the total responses received (see table and graph below). The other responses received were from those in an official capacity as a representative: 72 (38%) responses were from industry representatives, including marketing authorisation holders (including a response from the National Office of Animal Health which represents 97% of the UK veterinary medicine market), retailers of veterinary medicines, feed business operators and manufacturers. In addition, 28 (15%) responses were from Non-Governmental Organisations (NGOs) or campaign groups.

Number of respondents per respondent type

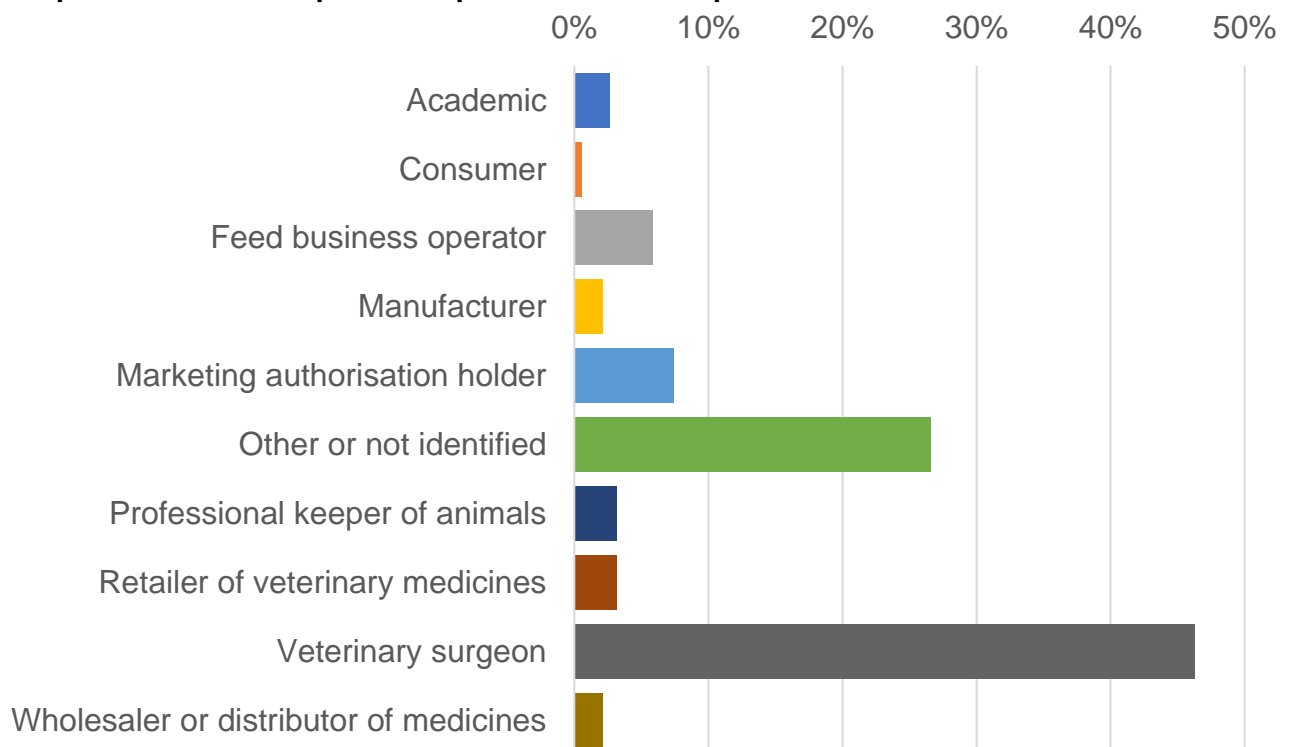
Respondent type	Number of respondents
Individual	74
Public sector body	4
Industry	72
Campaign group or NGO	28
Academia	1
Other	9
Overall total	188

Proportion of total respondents per type of respondent



With regard to role or field of profession, of the 188 responses received, 87 (46%) were indicated to be from veterinary surgeons, 14 (7%) from marketing authorisation holders, 11 (6%) from feed business operators and 50 (27%) were indicated to be from other roles or fields of profession, which included for example roles within animal welfare groups, campaign groups, trade associations, professional bodies, the public sector (see graph and table below)¹.

Proportion of total respondents per role or field of profession



¹ Due to confidentiality reasons, we have merged two respondents who were sole representatives for a specific role or field of profession with other categories reflective of their role or field.

Number of respondents per role or field of profession

Role or field of profession of respondents	Number of respondents
Academic	5
Consumer	1
Feed business operator	11
Manufacturer	4
Marketing authorisation holder	14
Other or not identified	50
Professional keeper of animals	6
Retailer of veterinary medicines	6
Veterinary surgeon	87
Wholesaler or distributor of medicines	4
Overall total	188

Summary of feedback

In this section we provide a high-level summary of the feedback received. In the next section we provide our response to those consultation questions where we have identified a higher level of disagreement or significant concerns raised in the free text sections of the questionnaire on Citizen Space. The consultation questions and quantitative response data are provided in the Annex to this report.

We analysed and carefully considered all responses received. We looked at the responses to the questions where we asked about the level of agreement with the proposal (strongly disagree, disagree, neutral, agree, strongly agree) and the information provided by respondents in the free text sections. For convenience, we have combined in this report the number of respondents who agreed and strongly agreed, and those who disagreed and strongly disagreed.

Respondents were able to focus on and respond to the questions related to their area of interest, meaning that some respondents did not answer all consultation questions. We determined the course of action in response to the consultation feedback received to each consultation question – the detail of which has been provided in this report.

We generally received agreement across all nine chapters of the consultation document with our proposals to update and improve our legislation. The statistics used below show the percentage of respondents who agreed, disagreed or were neutral towards some of the proposals per the 188 responses received overall.

There was strong support for the proposals set out in Chapter 1 of the consultation document, relating to the main regulations of the VMR. For example, 103 (55%) responses agreed with the approach to the as soon as reasonably practical issuing of records by vets and 119 (63%) of responses agreed with the changes in inspectors' powers, to ensure any potential breach of the VMR can be investigated. While there were 93 (50%) respondents who agreed with the proposed approach to advertising of veterinary medicines, there were several concerns raised on the proposed amendments to restrict the advertising of prescription-only veterinary medicines (POM-V, to be prescribed by vets, and POM-VPS, to be prescribed by a vet, pharmacist or suitably qualified person (SQP)) to professional keepers of animals, and these are addressed in the government response in the next section.

Although respondents strongly supported the endeavour to reduce administrative and regulatory burden, there was some disagreement with several of the proposals in Chapter 2, related to marketing authorisations (MAs). It is evident, however, that only minor changes to these proposals need to be made as the provision of guidance containing further clarification and reassurance will address most of the concerns raised. For example, respondents raised concerns in relation to the proposed changes for the summary of product characteristics, data requirements for an MA application, and labelling and package leaflets. Generally, while the proposals will bring greater alignment between

Great Britain (GB) and Northern Ireland (and the European Union (EU)), some concerns centred around lack of alignment of specific regulatory requirements. The concerns raised in response to the proposals have been carefully considered and addressed in the government response in the next section, introducing further alignment in areas such as technical data requirements in MA applications.

It is evident that there was a lot of agreement with the majority of the proposals on MAs in Chapter 2. For example, only 8 (4%) responses disagreed with the proposed approach to generic (hybrid) products, 6 (3%) responses disagreed with the proposal of assessing applications for MAs and maximum residue limits (MRLs) in parallel and 5 (3%) disagreed with the proposal for introducing flexibility into the assessment timeline for MA application assessments performed in parallel with other regulators. Additionally, 109 (58%) responses agreed with the proposed approach for making mandatory that Marketing Authorisation Holders (MAHs) report supply shortages to the Secretary of State and some respondents commented on the importance of this proposal to ensure that prescribers and vets receive information about the availability of veterinary medicines as soon as possible so that informed prescribing decisions can be made. Overall, respondents expressed their support for the proposals in Chapter 2 and commented that they hope that with these changes there will be increased accessibility, greater availability and a more reliable supply of veterinary medicines.

Respondents largely agreed with or were neutral towards the proposals set out in Chapter 3, relating to manufacturing. 46 (24%) responses agreed with and 88 (47%) were neutral towards the proposed approach for manufacturing authorisations with only 6 concerns raised overall. 63 (33%) agreed and 69 (37%) were neutral towards the proposal for a consistent approach for specific manufacturing authorisations. Respondents also agreed with the proposed approach for regulatory oversight of active substances, with only 5 (3%) responses that disagreed, and only 2 (1%) responses disagreed with the proposed approach to stem cell centres. Concerns raised highlighted the need for clarity around the approach for products manufactured for administration under the cascade (for example, clarity on the terms of what is considered 'pharmacologically equivalent' and 'pharmaceutically equivalent').

Respondents were also largely in agreement with the proposals set out in Chapter 4, which covers classification, supply, wholesale dealers and sheep dip. Only 4 (2%) of responses disagreed with the proposed changes for wholesale dealers, including the proposed offences, 4 (2%) with the requirement for retailers and wholesale dealers to investigate stock discrepancies, and only 3 (2%) with the proposal for a MAH to hold a Wholesale Dealer's Authorisation (WDA) to wholesale veterinary medicines. 128 (68%) responses agreed with the requirement for online retailers of veterinary medicines categorised POM-V, POM-VPS and NFA-VPS (non-food animal, to be supplied by vet, pharmacist or SQP) to register with the Secretary of State and generally it was considered that this new requirement would be proportionate and appropriate. However, there was strong concern among respondents with regards to the proposed change to the wording of the assessment that the vet is required to perform of an animal under their care before prescribing a POM-V medicine, with 58 (31%) responses disagreeing with this proposal.

Concerns raised highlighted that this proposal could pose an increased risk to animal welfare and antimicrobial stewardship, when seen in the context of recently revised guidance published by the Royal College of Veterinary Surgeons (RCVS) on 'under care' and prescribing prescription-only medicines. 66 (35%) responses agreed with the proposed approach to remote supplying by SQPs and while 89 (47%) responses agreed with the proposed additions to the POM-V classification, there were many concerns raised which focused on the potentially reduced availability of immunological products, which may lead to increased antimicrobial use and significant negative impacts for animal welfare.

Chapter 5 (veterinary medicines administered outside the terms of their MA) received some concerns with 35 (19%) responses disagreeing with the proposed approach to ensuring appropriate use of the cascade. However, only 10 (5%) responses disagreed with the proposed changes to the statutory minimum withdrawal periods. The respondents considered that the proposed changes to the cascade will help ensure the cascade continues to be an option for vets, ensuring animal health and welfare needs are met, where there are no suitable authorised products available for the animals being treated. Respondents also stated that the proposals ensure human health is protected while not placing unnecessarily long food chain exclusion on produce from animals treated under the cascade.

There was strong agreement for the proposals in Chapter 6 on medicated feed with only 9 (5%) responses in disagreement with the proposed changes to labelling of medicated feed and 4 (2%) responses in disagreement with the proposed approach to cross-contamination and carryover of medicated feed. Generally, there was support from respondents that cross-contamination targets should be as low as reasonably achievable, and respondents considered that these proposals relating to cross contamination are an appropriate response to reduce the risks associated with the accidental consumption of medicines by non-target animals. However, some concerns were raised with regards to prescriptions for medicated feed, the storage and disposal of medicated feed and the changes to the tolerance table. These concerns are addressed in the government response in the next section. Despite the concerns, only 11 (6%) responses disagreed with the proposed approach to prescriptions for medicated feed, 16 (9%) responses disagreed with the proposed approach to storage and disposal of medicated feed and 12 (6%) responses disagreed with the proposed changes to the tolerance table.

Generally, there was strong agreement with the two proposals regarding the exemptions for small pet animals in Chapter 7. Only 3 (2%) responses disagreed with the proposed approach to register companies that market products under these exemptions and require them to provide information annually. 21 (11%) respondents disagreed with the proposed approach to remove the requirement for retailers to record and report adverse events for products sold under the exemption for small pet animals.

We received concerns on Chapter 8 regarding antibiotic usage data, prophylactic use and in-feed antibiotics. Despite this, 99 (53%) respondents agreed with the collection of species or sector specific antibiotic usage data remaining a voluntary initiative but that the government can request such data if insufficient progress is made, and that it would be an

offence to fail to comply with such request. Comments from respondents suggested that there was strong support for the proposal to restrict prophylactic antibiotic use to exceptional circumstances where the risk of an infection or of an infectious disease is very high and where the consequences of not prescribing the product are likely to be severe, and overall, 99 (53%) responses agreed with the proposal to restrict prophylactic use. Generally, there was also agreement for the proposed approach to medicated feed containing antibiotics, with 69 (37%) responses in agreement, and comments from respondents supported the proposed restrictions as they will ensure continued efficacy, reduce risk of antimicrobial resistance and limit the impact on the environment. The concerns raised have been carefully considered and addressed in the government response in the next section of this report.

Finally, several comments were submitted in relation to Chapter 9 (fees) which have assisted us in our assessment of the fees. Generally, comments accepted the need to increase fees to support the VMD in our recovery of costs for the regulatory services we provide.

We have considered all concerns raised in the free text boxes and where such need is identified we will provide updated or additional guidance on our website. Our aim is to work with our stakeholders to help them comply with the regulations and ensure that the VMR are both clear, easy to understand, and straightforward to follow.

Government response

We have considered concerns raised by those directly and indirectly affected by the proposed changes. In this section we provide our response to those consultation questions where we have identified a higher level of disagreement or significant concerns raised in the free text sections of the questionnaire on [Citizen Space](#). The complete list of consultation questions and quantitative response data are provided in the Annex to this report. A summary table containing all proposals, response summaries and outcomes (implemented, amended or removed) is published alongside this report in a supplementary document available on [Citizen Space](#).

For convenience we have provided a high-level overview of the changes under discussion and the consultation questions; for the detail of the changes and the policy objectives they are intended to achieve, we refer to the [consultation document](#).

Chapter 1: General (regulations)

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

Proposals

Minor drafting changes for clarification

We proposed minor drafting changes to clarify the regulations and Schedules or to improve consistency in wording. Other drafting changes to the regulations introduce new definitions or amend existing ones.

Providing information upon request

We proposed to extend the requirement to provide the Secretary of State with information upon request to all businesses or persons regulated by the VMR.

Please note, this proposal is withdrawn as we have identified that we have sufficient powers throughout the VMR to request the information we need.

Record keeping for vets and food-producing animal owners or keepers

We proposed 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”.

Advertising

We proposed adjusting the regulations on advertising to clarify what is allowed and required in terms of the advertising of a veterinary medicine. We also proposed to make

explicit that a medicine may only be advertised if it has an MA, which is not suspended. This change would not apply to medicines marketed under the exemptions for small pet animals.

In addition, we proposed to introduce a regulation setting out the conditions for inducements and hospitality in relation to veterinary medicines. Finally, with regard to POM-V medicines advertising targeted at professional keepers of animals, we proposed to only allow this for immunological medicines, and that such advert should state that the professional keeper of animals will need to consult a vet before using the medicine.

Powers of an inspector

We proposed changing the regulations 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. We also proposed 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, or to apply conditions on a business, which included the introduction of an offence for failing to comply with a prohibition notice.

Key issues raised and government response

Proposals not discussed here will be implemented.

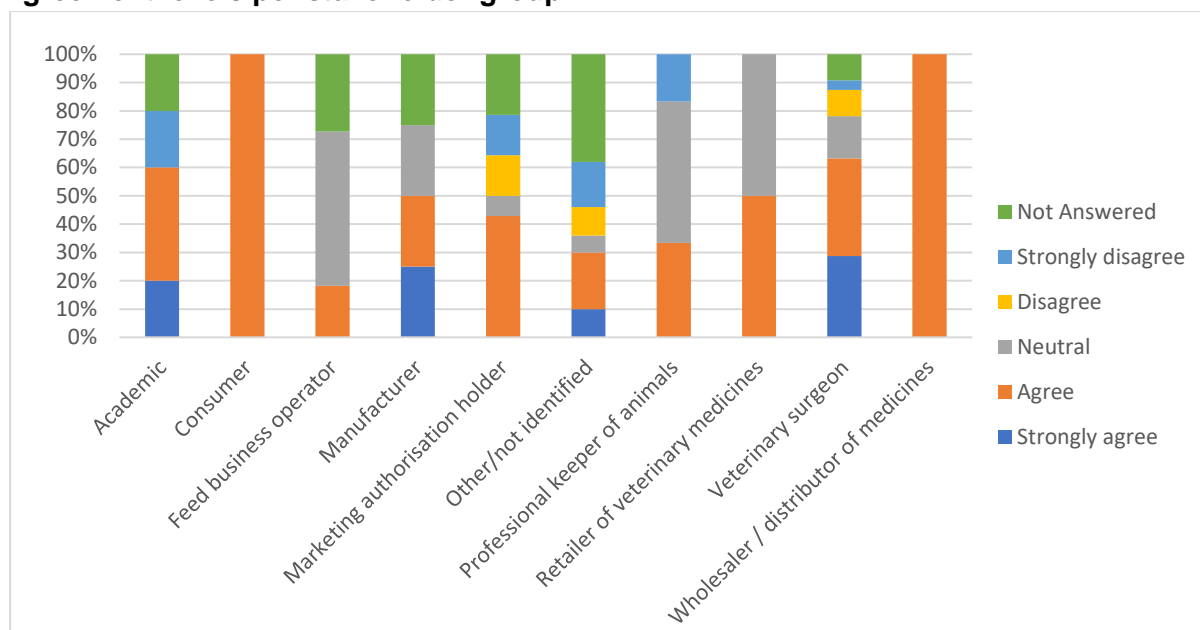
Advertising

Question 8: Do you support this approach to advertising of veterinary medicines?

153 out of 188 respondents answered this question.

- 93 of the respondents agreed
- 30 of the respondents disagreed
- 30 of the respondents were neutral

Agreement levels per stakeholder group



While respondents largely agreed with the proposed changes to the rules on advertising of veterinary medicines, there were still a significant number of concerns raised by industry representatives. These concerns were mainly against the proposed restrictions on the advertising of prescription-only veterinary medicines (POM-V, to be prescribed by vets, and POM-VPS, to be prescribed by a vet, pharmacist or suitably qualified person) to professional keepers of animals. The impacts identified were mainly centred on the loss of revenue for publications as such advertising was no longer allowed, and the potential lack of education and professional development for farmers which is mostly sponsored.

Government response

In response to the concerns raised, we have decided to not implement the proposed restriction on the advertising of POM-V and POM-VPS medicines to professional keepers of animals, where only immunological products could continue to be advertised to such audience. Instead, whilst POM-V and POM-VPS medicines can continue to be advertised to professional keepers of animals, a statement must be included on the advert that it is the prescriber who decides on the product. Furthermore, the regulations will clarify that the advert is to only include factual statements in line with the Summary of Product Characteristics (SPC) of the medicine.

Chapter 2: Marketing authorisations in Great Britain

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

Proposals

Information for MA application and summary of product characteristics

We proposed to adjust the information that we require to be provided with an application for an MA. The information we proposed to require would be consistent with the requirements for an MA application submitted to Northern Ireland (NI). This would reduce divergence between the requirements for GB and NI, thereby facilitating the application process for UK-wide coverage.

We also proposed 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.

Furthermore, we proposed to change the order of the information that must be included in the SPC and to update our minimum information requirements to ensure that a product's SPC contains relevant information that supports safe and responsible use.

Finally, we proposed to introduce the requirement that the SPC submitted for a generic veterinary medicine must be essentially similar to that for the reference product.

Bibliographic applications

We proposed to require an applicant for a bibliographic application to demonstrate that the active substances of the veterinary medicine have been in well-established veterinary use for at least 10 years, their efficacy is documented and they provide an acceptable level of safety.

Generic or generic hybrid products

We proposed that the VMR state 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. We also proposed 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.

We proposed to remove the option for generic immunological or biological products from a stand-alone provision to being included in the new Schedule 1C to the VMR which sets out the technical documentation demonstrating the quality, safety and efficacy that is required for the various types of MA application.

Marketing authorisation for parallel import

We proposed to remove the option for MAs for parallel imports (MAPIs).

Parallel assessment of application for maximum residue limit and MA

We proposed to make it possible that applications for assessment of an MRL can be submitted at the same time as an application for an MA, which would reduce burdens on applicants and make the process smoother and more efficient.

Data protection periods

We proposed extending (some of) the data protection periods currently awarded to veterinary medicines and to introduce extensions to these periods in defined circumstances. Furthermore, we proposed to decouple the addition of species and pharmaceutical form, if packaged separately from the original product, and apply separate data protection periods.

Parallel assessment with other regulators

We proposed to introduce a facility for a clock stop in our timeline for procedures that are part of a parallel assessment with other regulators that we have an agreement with.

MAH location

We proposed to no longer require MAHs to be established in the UK, but instead to require MAHs to have a UK-based local representative to act as the local contact for regulatory and enforcement matters, to ensure recording and reporting of adverse events and to have the legal capacity to act for the MAH. This would also apply to those who wish to market registered veterinary homeopathic remedies.

The granting of an MA

We proposed 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.

Withdrawal of an MA application

We proposed to introduce the requirement that formal withdrawal of applications must be made in writing and must include a reason for withdrawal. We also proposed publishing completed assessment reports for withdrawn MA applications in the future, protecting any

commercially sensitive information, to assist other companies in understanding the requirements that are necessary when completing an MA application.

Refusal of an MA

We proposed to make the reasons to refuse an MA explicit in the VMR to aid transparency and to add additional reasons for refusal of an MA. Additional reasons include:

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

We also proposed to insert established practice into the VMR, where the Secretary of State publishes when an MA is refused, suspended or revoked, as well as the terms of a variation if the text of an MA is varied in relation to the SPC.

Samples

We proposed to enable the Secretary of State to require the MAH to provide upon request the results of any control tests carried out in relation to the starting materials or finished product, but to limit what such samples may be used for.

Information on shortages

We proposed 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.

Renewal of marketing authorisations

We proposed to remove the requirement to renew a marketing authorisation after the initial five-year period; so instead, unless the benefit-risk balance becomes unfavourable a MA has indefinite validity. This change would also apply to registrations of homeopathic remedies.

Variations

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

The variations not requiring assessment were proposed to be consistent with the variations not requiring assessment under the EU legislation. We also proposed to remove

the options for administrative and workshare variations as these would no longer be needed.

Grounds for suspension of MA, prohibiting supply and temporary restrictions

We proposed 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. We also proposed 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.

We proposed to expand the reasons for which we can prohibit the supply of a veterinary medicine or require a medicine to be recalled. The additional reasons:

- an unfavourable benefit-risk balance of the veterinary medicine
- the qualitative or quantitative composition of the medicine is not as stated in the SPC
- the recommended withdrawal period is insufficient to ensure food safety
- the required control tests have not been carried out
- the incorrect labelling of the medicine might lead to a serious risk to human or animal health.

We also proposed 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.

Finally, we proposed introducing a new provision to prohibit the manufacture, import, distribution, supply or use of immunological veterinary medicines in certain scenarios:

- if the administration of the product would interfere with the implementation of a programme for diagnosing, controlling and eradicating a disease
- if the administration of the medicine causes difficulty in certifying absence of disease in live animals or contamination of foodstuffs or other products from treated animals
- if the strains of disease agents in relation to which the immunological is intended to confer immunity is largely absent in that locality.

Labelling and package leaflets

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

The proposed changes are consistent with requirements in NI, with minor differences such as the inclusion of the distribution category. Information may be included in abbreviations or pictograms approved by the Secretary of State. We also proposed to allow additional information on the leaflet concerning distribution, possession or any necessary precaution required, provided that this information is not promotional in character and it complies with the marketing authorisation.

Electronic package information leaflet

We proposed allowing an electronic package information leaflet (EPIL) to be provided, where appropriate, as an alternative to a physical package leaflet.

Pharmacovigilance (post-authorisation monitoring)

We proposed updating the requirements for pharmacovigilance and harmonise them, to the extent possible, with the approach taken in NI to assist MAHs. We proposed:

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

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

In addition, we proposed including the provision to take action against any products that contain the same active substance as a product that has concerning pharmacovigilance data.

Finally, we proposed to introduce the requirement for the Secretary of State's inspectors to inspect MAH premises to verify compliance with the pharmacovigilance provisions – the frequency of these inspections would be risk-based.

Registered homeopathic remedies

We proposed adjusting the requirements in the VMR to clarify that the registration of homeopathic remedies is restricted to those with a topical or oral route of administration. We also proposed to adjust the requirements for registration which will exclude biological homeopathic remedies unless they are derived from plants.

Finally, we proposed 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.

Key Issues raised and government response

Proposals not discussed here will be implemented.

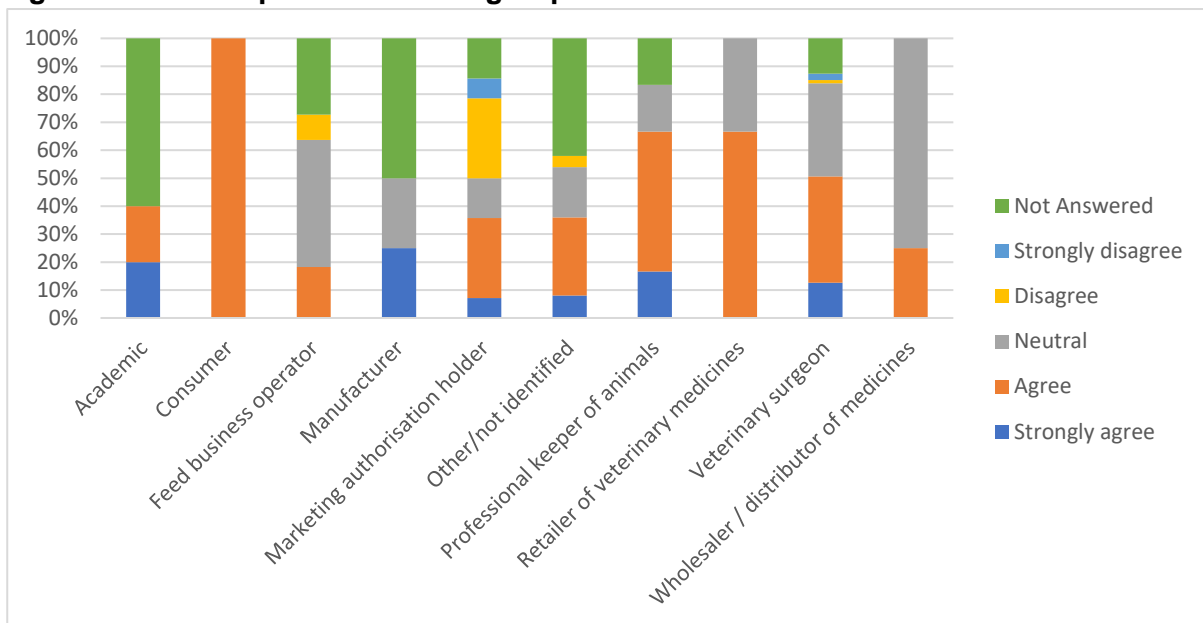
Information for MA application and summary of product characteristics

Question 12: Do you agree with the proposed changes to the requirements for the summary of product characteristics and data requirements for a marketing authorisation application?

145 out of 188 respondents answered this question.

- 82 of the respondents agreed
- 11 of the respondents disagreed
- 52 of the respondents were neutral

Agreement levels per stakeholder group



While there was strong support for the proposals, many respondents raised concerns with regards to the lack of alignment with the corresponding regulatory requirements in Northern Ireland (and the EU). It was evident that many respondents would like to see complete harmonisation with corresponding EU law to minimise potential administrative burden and additional costs for MAHs and enable the submission of one dossier to multiple regulators.

Government response

In response to the feedback received, we have decided to amend our proposals to ensure that the technical data that need to be submitted with the application for an MA, including the SPC, will be consistent with EU rules. We recognise that the pharmaceutical industry is set up to cover the region of Europe, which includes the UK, and its regulatory requirements. These changes will ensure that companies can submit a single dossier for the European region. This will reduce burdens to the industry and help facilitate the continued availability of veterinary medicines in GB.

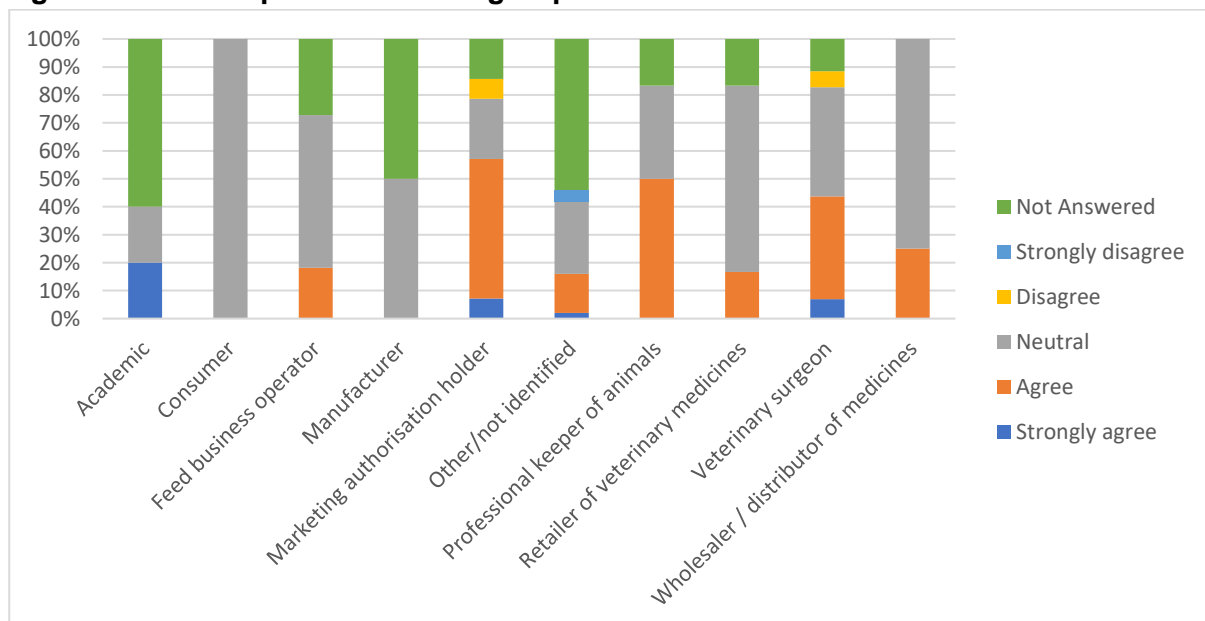
Bibliographic applications, generic or generic hybrid products

Question 13: Do you agree with this approach to generic or generic hybrid products?

139 out of 188 respondents answered this question.

- 62 of the respondents agreed
- 8 of the respondents disagreed
- 69 of the respondents were neutral

Agreement levels per stakeholder group



Respondents were largely neutral towards this proposal. However, there were several concerns raised with regards to potential supply issues, increased medicine costs, product safety issues and efficacy.

Government response

After consideration of the concerns raised, we have agreed to continue with the proposed changes and provide clarification in guidance, where such a need was identified by respondents. We believe the proposals will positively impact availability of medicines. Our

robust assessment processes and post-authorisation monitoring ensure safe and effective veterinary medicines remain on the market. Furthermore, veterinary medicine is a private service including the supply of medicinal products; the costs charged by individual veterinary practices vary widely due to the variable levels of overheads incurred. The government is not informed of the costs of individual products and the pricing structures of veterinary medicines is not subject to legislative controls. Therefore, the cost of a veterinary medicinal product is controlled by the market rather than legislation.

With regards to biologicals, we do not consider the standard generic approach to be appropriate. If an applicant can provide satisfactory justification a hybrid generic route might be an option.

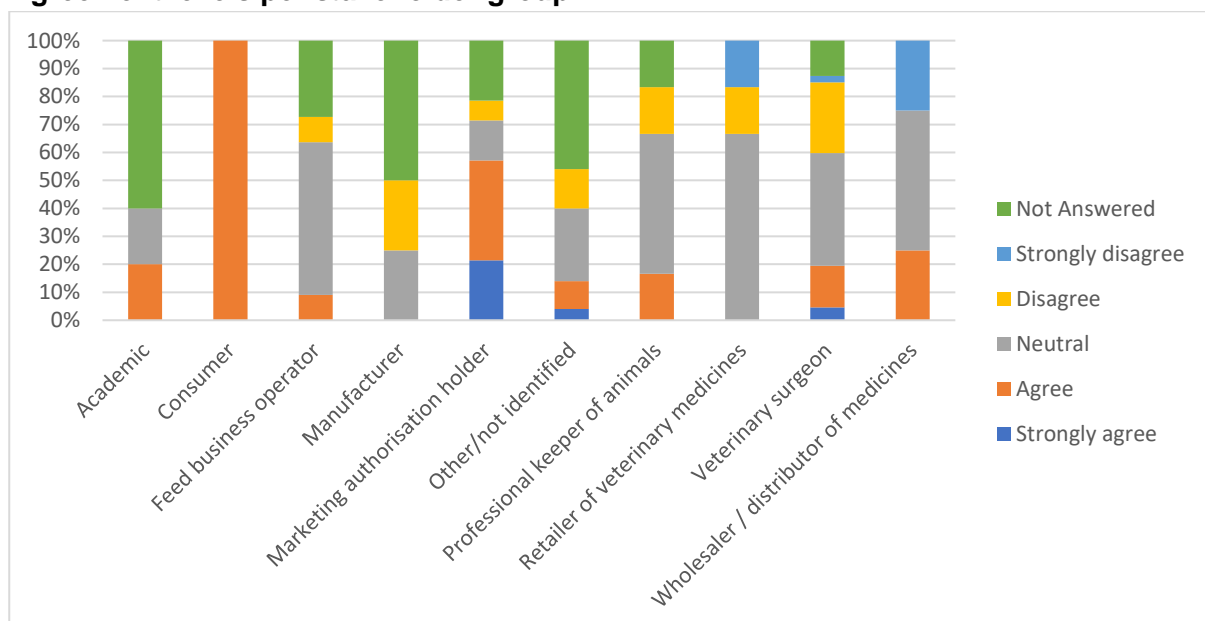
Marketing authorisation for parallel import

Question 14: Do you agree with the proposed removal of the option to have marketing authorisations for parallel import?

142 out of 188 respondents answered this question.

- 37 of the respondents agreed
- 38 of the respondents disagreed
- 67 of the respondents were neutral

Agreement levels per stakeholder group



While many respondents remained neutral towards this proposal there was some disagreement, with several concerns raised over the availability of medicines in GB and potential supply issues. There were also concerns that this could increase medicine prices in the UK as there will be less competition from other countries.

Government response

From the responses, there appears to have been some confusion over this proposal. We do not propose changes to the provisions for the importation of authorised veterinary medicines or medicines prescribed under the cascade (and imported in accordance with the special import scheme), but only to remove the option of MAs for parallel imports (MAPIs). Parallel importing refers to when a product is bought from wholesalers in another country and imported into the GB for distribution. We considered this an appropriate route for approving MAs when the UK was part of the EU, when we allowed MAPI applications for products authorised in the EU. Post EU Exit we no longer consider this an appropriate route to market. As such, we will implement this proposal.

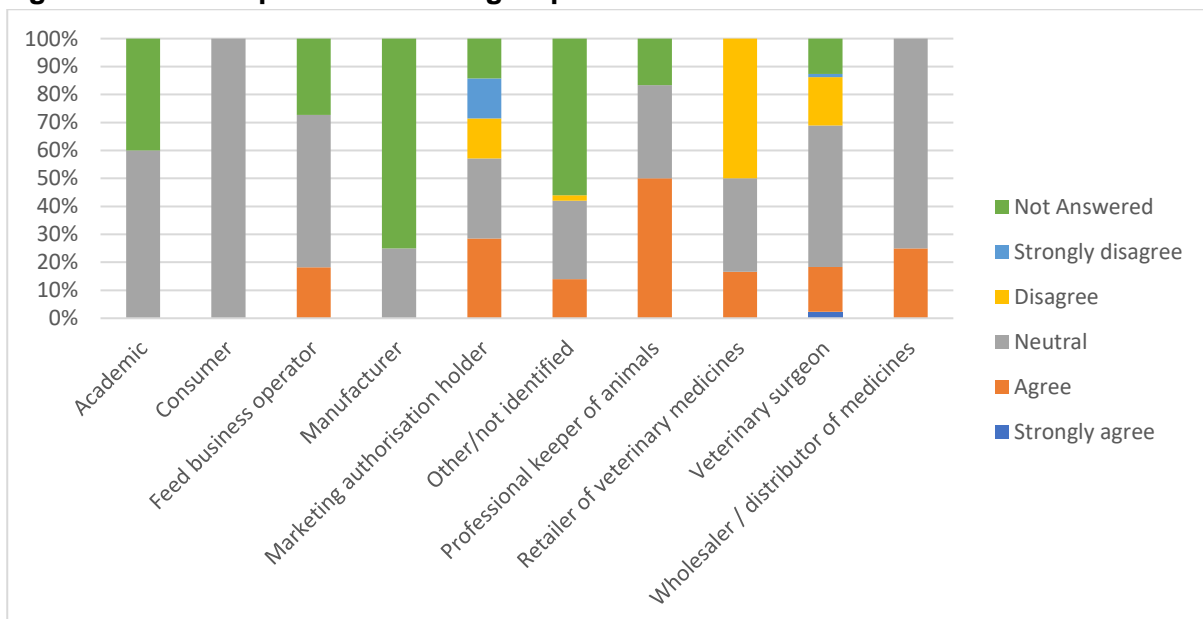
Data protection periods

Question 16: Do you agree with the proposal for amending the current data protection periods?

138 out of 188 respondents answered this question.

- 34 of the respondents agreed
- 24 of the respondents disagreed
- 80 of the respondents were neutral

Agreement levels per stakeholder group



The majority of respondents were neutral towards this proposal. However, there were several concerns raised focusing on the potential risk of increased veterinary medicine prices, supply issues and negative implications for availability of medicines for minor species. Respondents were also disappointed with the lack of full harmonisation with the data protection periods set out in EU legislation. Furthermore, some responses suggested that definitions of major and minor species should be included in the VMR.

Government response

After consideration of the responses, we have decided to implement these proposals to encourage innovation and maintain a thriving generics market. We will amend our guidance, if considered necessary, to provide further explanation on how to apply the data protection periods. A definition for 'major species' will be included in the VMR to ensure absolute clarity.

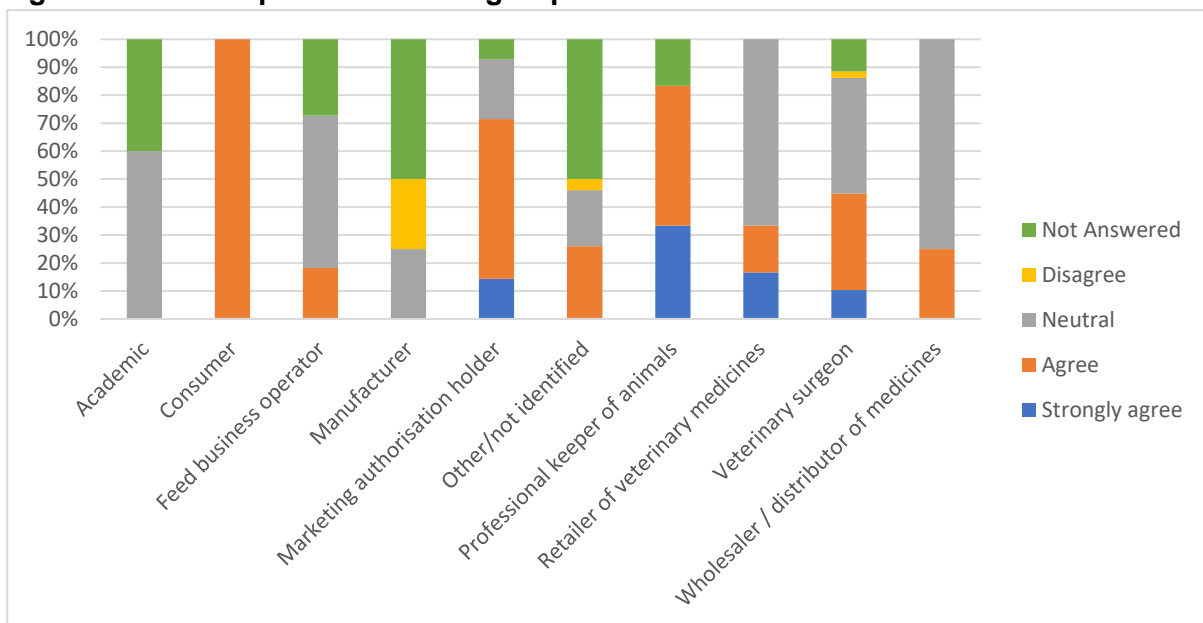
Parallel assessment with other regulators

Question 17: Do you agree with the proposal for introducing flexibility into the assessment timeline?

144 out of 188 respondents answered this question.

- 73 of the respondents agreed
- 5 of the respondents disagreed
- 66 of the respondents were neutral

Agreement levels per stakeholder group



Overall, responses were either in agreement with or neutral towards this proposal. However, some disagreed with the approach to introduce a facility for a clock stop and were concerned about the potential delays to MA application assessments due to factors which are outside of the applicant's control. Respondents also commented that they would welcome collaborative assessment, between VMD and other regulators, of the MA application dossier. Furthermore, respondents requested transparency on the assessment timeline so submissions can be planned appropriately.

Government response

We would like to clarify that the intention with this change is to enable alignment of assessment timetables and that the regulators involved will perform separate assessments of the dossier. Timelines are already published online. Reduced assessment by the VMD of products authorised by other regulators is not currently possible. We have noted the request to discuss with the applicant if an extended clock stop is needed and plan to explore this further.

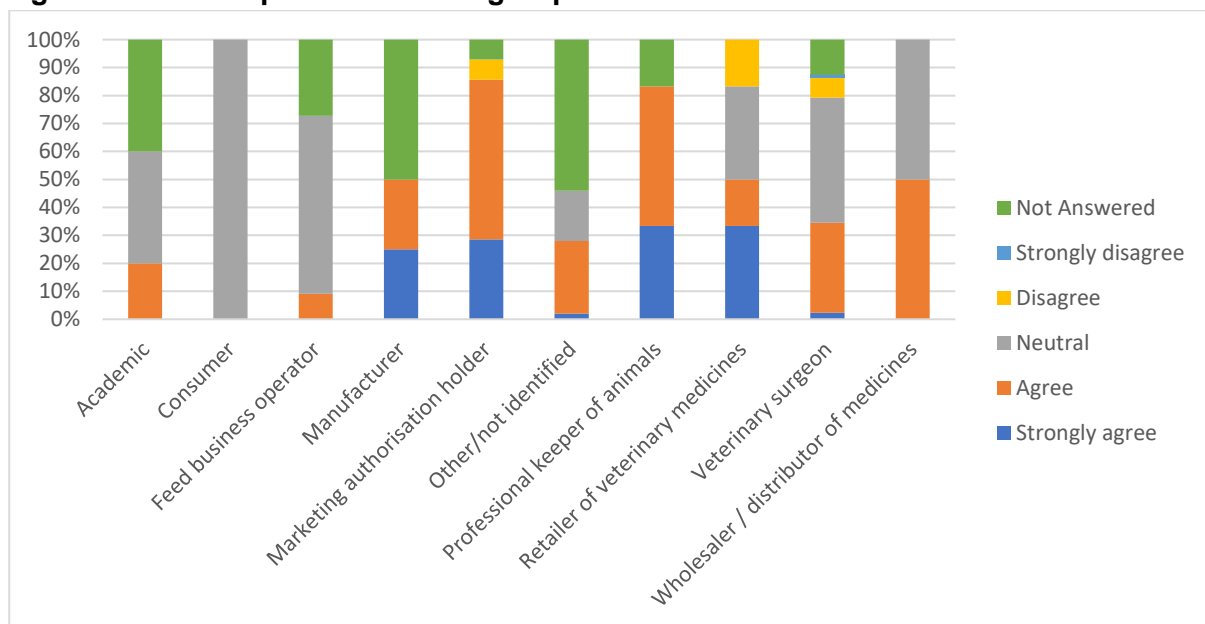
MAH location

Question 18: 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?

141 out of 188 respondents answered this question.

- 70 of the respondents agreed
- 9 of the respondents disagreed
- 62 of the respondents were neutral

Agreement levels per stakeholder group



Several concerns were raised with regards to the rationale behind this proposal, that it might not benefit UK-based MAHs. Clarification was requested by respondents about whether the local representative can be an established company instead of a natural person, and what responsibilities the representative would be required to cover.

Government response

We understand that requiring MAHs to be based in the UK may lead to a significant reduction in the availability of veterinary medicines in the UK. Due to ongoing uncertainties, we will continue with the current arrangement of allowing MAHs to be based

in countries with equivalent regulatory standards. On the requirement for a local representative, we are aware of trepidation regarding the role of a local representative. Therefore, we will introduce this role on a voluntary basis – we will provide more information to MAHs on how they can appoint a local representative and the benefits of doing so, but this will not be a mandatory requirement.

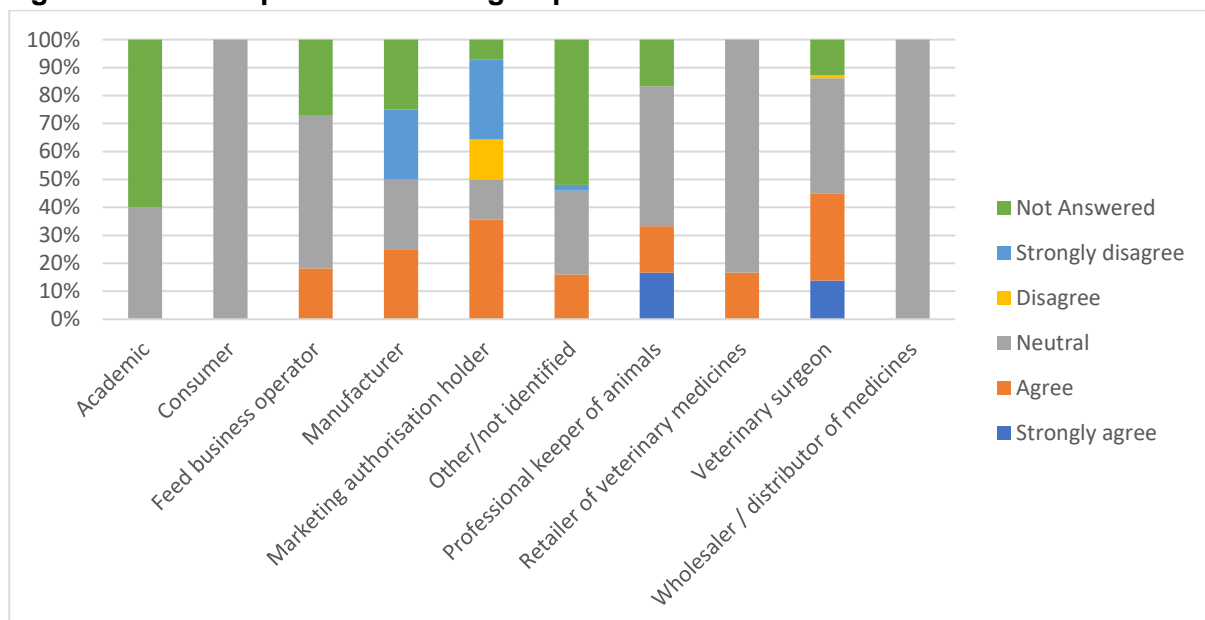
Withdrawal of an MA application

Question 19: Do you agree with this approach for publishing assessment reports?

142 out of 188 respondents answered this question.

- 58 of the respondents agreed
- 9 of the respondents disagreed
- 75 of the respondents were neutral

Agreement levels per stakeholder group



Most respondents were neutral towards this proposal. Concerns were raised that mainly focused on the potential disclosure of commercially sensitive information. Several comments suggested that if the intent of the proposal is to educate MAHs on the application requirements, this would be better achieved through guidance which could act as a consistent reference point for industry.

Government response

We would like to reassure respondents who have raised concerns over the potential disclosure of commercially sensitive information. The VMD is highly experienced in writing public assessment reports and will endeavour to ensure the contents of these remains confidential. However, in response to these concerns we will amend this proposal and instead provide a summary of the reasons for withdrawal.

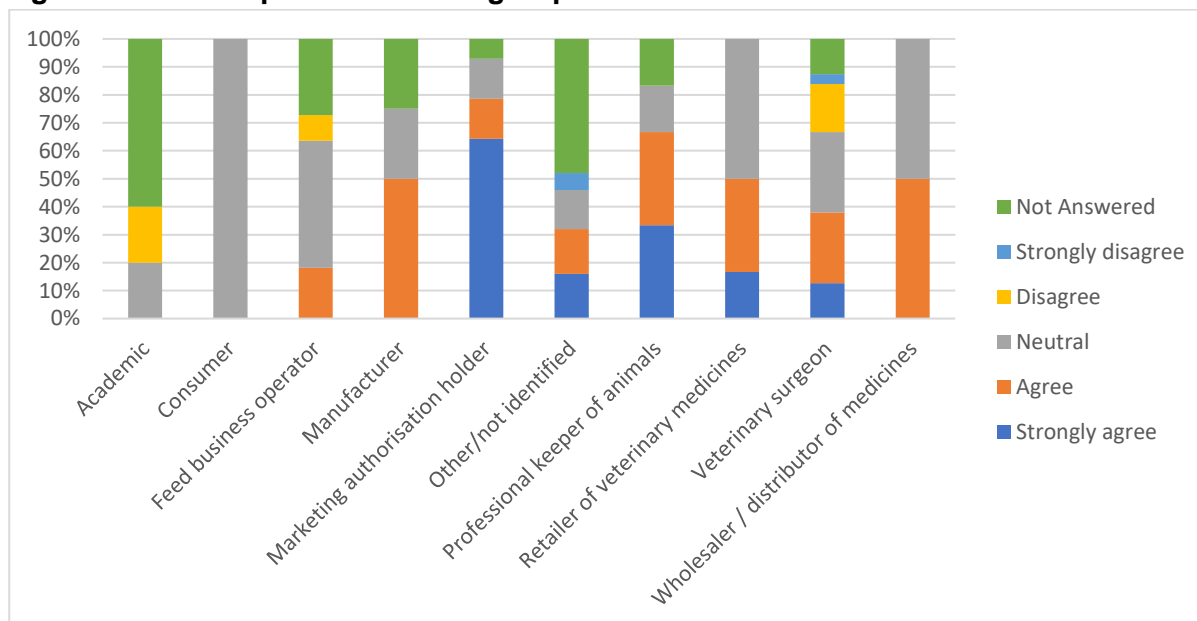
Renewal of marketing authorisations

Question 21: Do you agree with the proposed changes for renewing MAs?

144 out of 188 respondents answered this question.

- 73 of the respondents agreed
- 23 of the respondents disagreed
- 48 of the respondents were neutral

Agreement levels per stakeholder group



Several concerns were raised relating to the benefit-risk analysis becoming outdated and feedback from respondents supported the need for regular reviews. Other comments raised concerns about the implications for antimicrobial resistance, efficacy and the environment.

Government response

We would like to clarify that with these proposed changes there will be no new risks to our trigger mechanisms and monitoring with regard to safety concerns. MAHs are already required to immediately inform the Secretary of State on receipt of any new information that might adversely affect the benefit-risk balance of the veterinary medicine. The VMR also give the Secretary of State powers to request data at any time on the benefit-risk balance of any product. We also have internal procedures which allow for regular review, and the proposed removal of the requirement to renew an MA after the initial five-year period will not impact this.

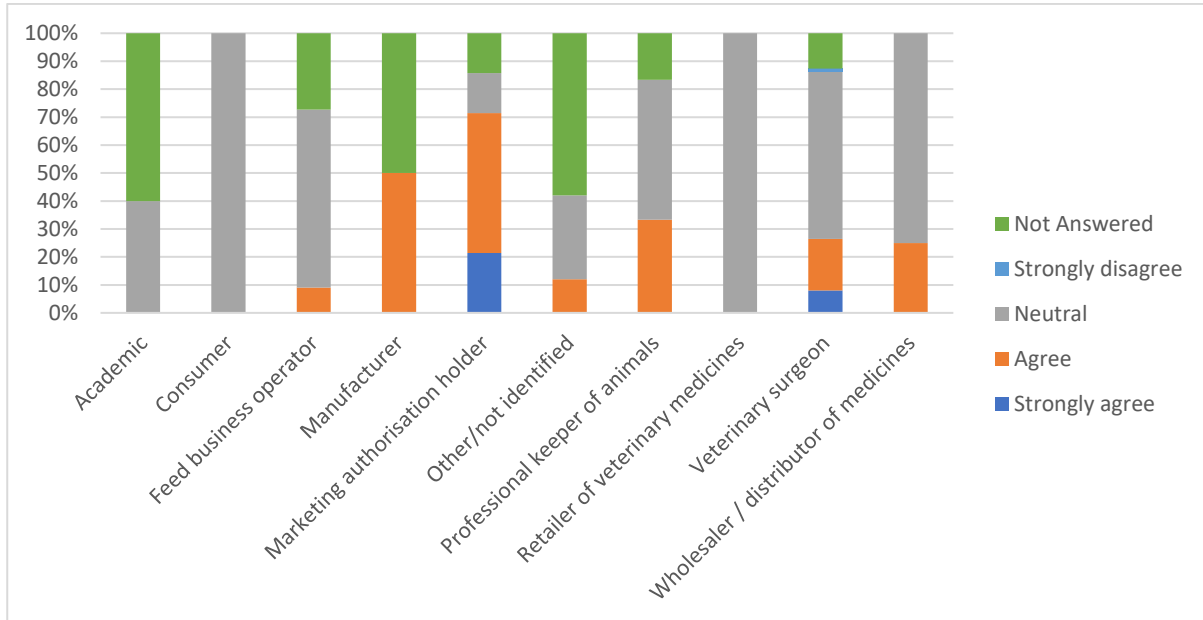
Variations

Question 22: Do you agree with the proposed changes for variations to MAs?

137 out of 188 respondents answered this question.

- 45 of the respondents agreed
- 1 of the respondents disagreed
- 91 of the respondents were neutral

Agreement levels per stakeholder group



Overall, respondents were neutral towards this proposal. Concerns raised mainly focused on the potential administrative burden of these proposed changes. Additionally, there were concerns that lack of alignment with NI (and the EU) could create unnecessary regulatory burden and some respondents requested a more harmonised approach to variations.

Government response

We have decided to retain the proposal in amended form. In response to the concerns raised, we will ensure that we have a suitably flexible procedure in place that makes it possible to update the VNRA list when needed.

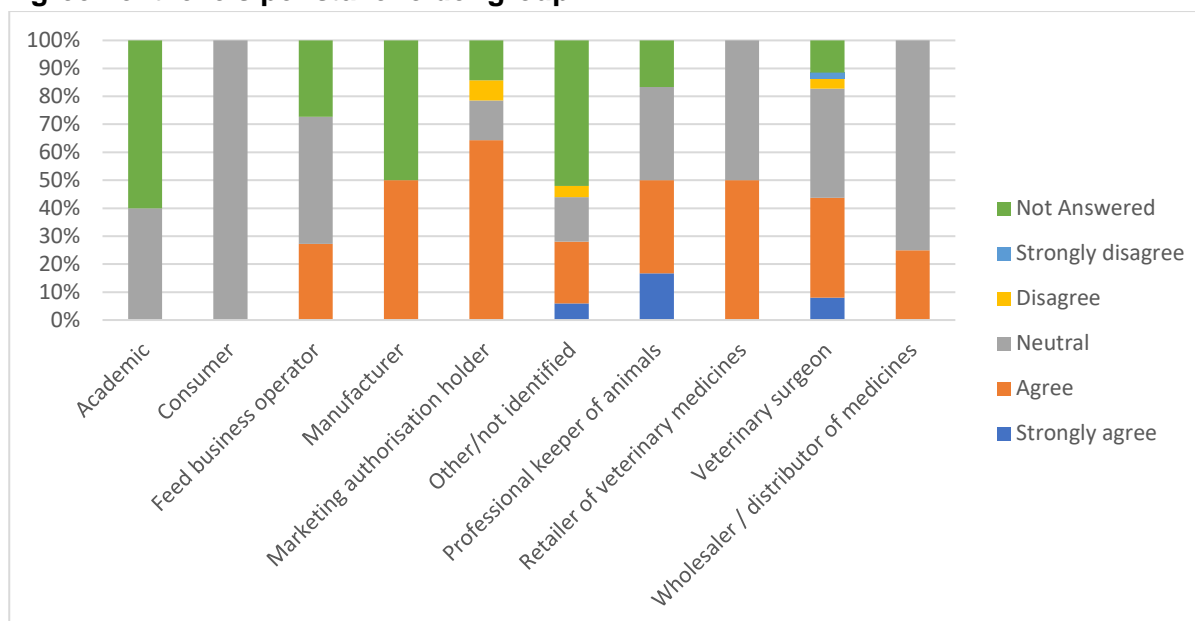
Grounds for suspension of MA, prohibiting supply and temporary restrictions

Question 23: Do you agree with this approach to suspension and revocation of MAs, prohibiting supply or restricting (immunological) medicines?

141 out of 188 respondents answered this question.

- 73 of the respondents agreed
- 8 of the respondents disagreed
- 60 of the respondents were neutral

Agreement levels per stakeholder group



Respondents mainly either agreed with or were neutral towards this proposal. Several respondents were concerned about potential political pressures and that this proposed approach could be open to abuse. Furthermore, there were concerns specific to the proposal which prohibits the manufacture, import, distribution, supply or use of immunological veterinary medicines in certain scenarios. Additionally, other comments sought further clarification on the proposed approach and the decision-making process involved, as well as a definition of 'unfavourable benefit-risk balance'.

Government response

We have decided to implement this proposal. We will continue to liaise with industry regarding the changes. We will provide guidance in response to concerns raised on the need for further clarity on our approach for adopting this proposal.

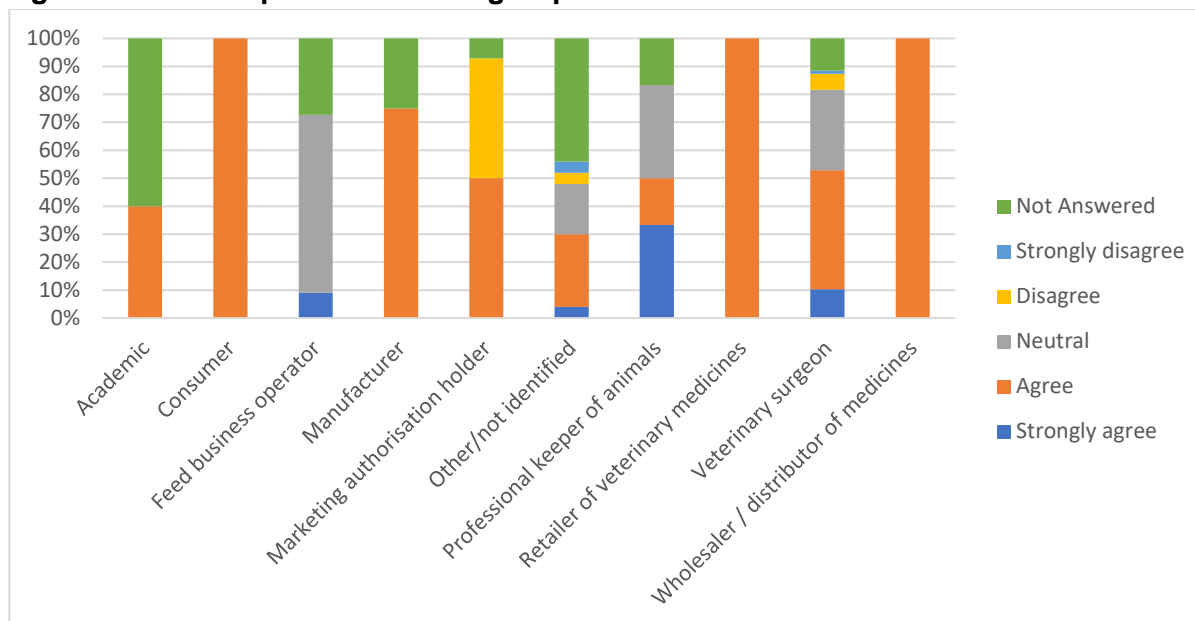
Labelling and package leaflets

Question 24: Do you agree with this approach to the labelling and package leaflet?

147 out of 188 respondents answered this question.

- 88 of the respondents agreed
- 16 of the respondents disagreed
- 43 of the respondents were neutral

Agreement levels per stakeholder group



Most responses agreed with this proposal. However, concerns were raised regarding the lack of full alignment with NI (and the EU). Respondents requested complete harmonisation with the EU to reduce the administrative and regulatory burden that these proposals could cause and to facilitate joint labelling. Respondents highlighted the need for and use of digital technologies, but others raised concerns about accessibility of digital information and risks associated with QR codes.

Government response

After consideration of the feedback received, we have decided to amend the proposed changes and ensure full alignment with the regulatory requirements in NI related to labelling and packaging for veterinary medicines. This will help ensure safe and effective veterinary medicines continuing to be available in the UK.

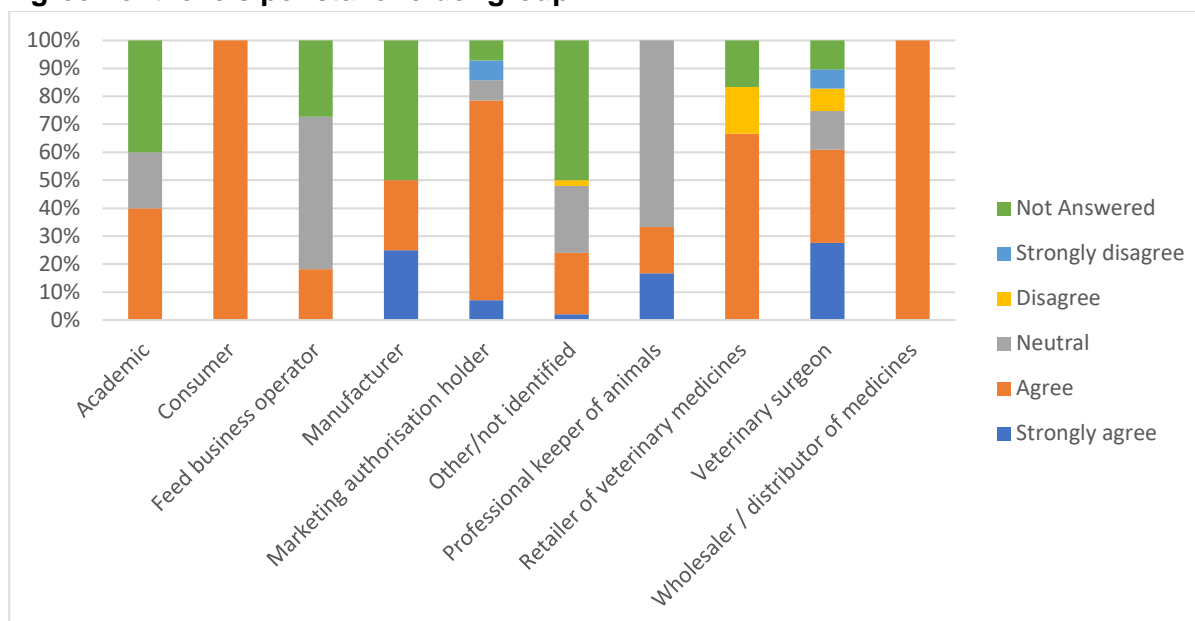
Electronic package information leaflet

Question 25: Do you agree with allowing electronic package information leaflets?

145 out of 188 respondents answered this question.

- 93 of the respondents agreed
- 16 of the respondents disagreed
- 36 of the respondents were neutral

Agreement levels per stakeholder group



Overall, respondents agreed with this proposal for allowing an electronic package information leaflet (EPIL) to be provided, where appropriate, as an alternative to a physical package leaflet. However, there were several concerns raised with regards to accessibility. Lack of technology literacy and access to the technological infrastructure that will be needed were of major concern for some respondents. Furthermore, several concerns commented on the security risks associated with QR codes and the contents of these.

Government response

Upon consideration of the responses received, we have decided to retain the introduction of the option of providing an electronic package information leaflet, which we also believe to benefit the environment. In line with other changes related to packaging, we will align with the regulatory requirements in NI on veterinary medicines so that joint labelling will remain possible. We will provide guidance to address the requests for clarifications and concerns raised by respondents.

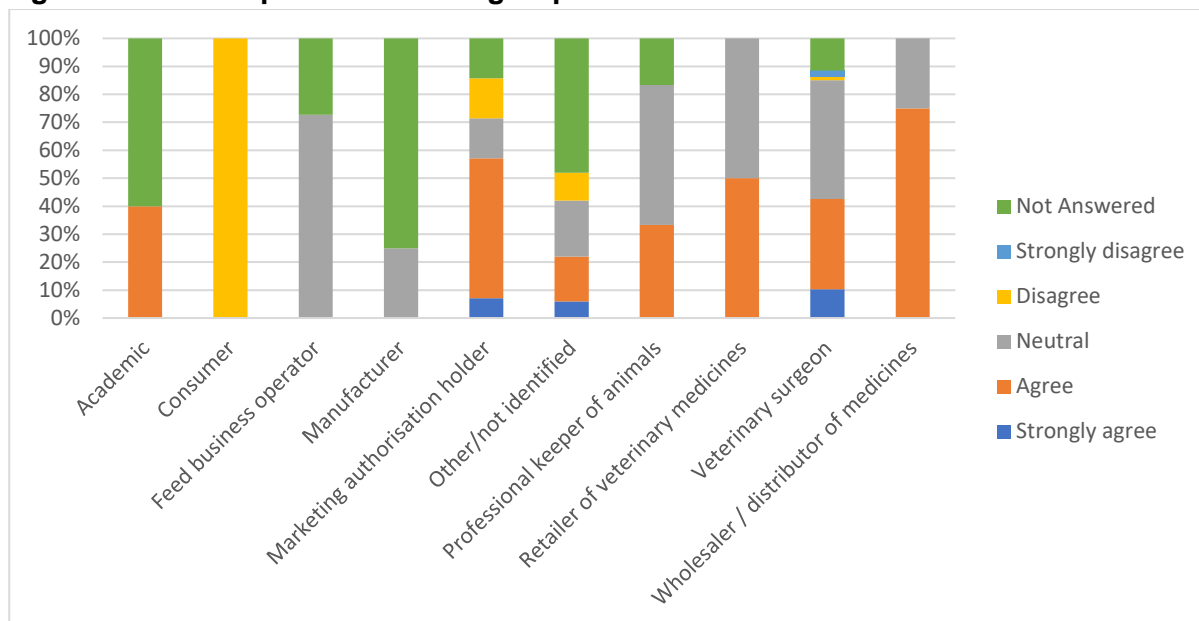
Pharmacovigilance (post-authorisation monitoring)

Question 26: Do you agree with this approach for pharmacovigilance?

142 out of 188 respondents answered this question.

- 66 of the respondents agreed
- 11 of the respondents disagreed
- 65 of the respondents were neutral

Agreement levels per stakeholder group



Respondents either agreed with or were neutral towards the proposed approach for pharmacovigilance. Concerns centred around increased regulatory burden and associated costs, the Benefit-Risk Report, the signal management system not aligning with the EU requirements, risks to animal welfare, the change in the reporting timelines for adverse event reporting, the implications for environmental monitoring and the lack of provision of definitions.

Government response

Upon consideration of the responses received, we have decided to amend the pharmacovigilance proposals in some areas. We have introduced definitions to add clarity (for example for 'lack of efficacy') and updated the pharmacovigilance requirements to make them clearer. We have simplified the approach to the annual benefit-risk report and reduced the data requirements for this report. We have also amended the requirements for pharmacovigilance reporting for animal test certificates, requiring the reporting of all adverse event reports within 30 days rather than serious reports only within 15 days. We will provide further clarification and guidance on the proposed approach to pharmacovigilance.

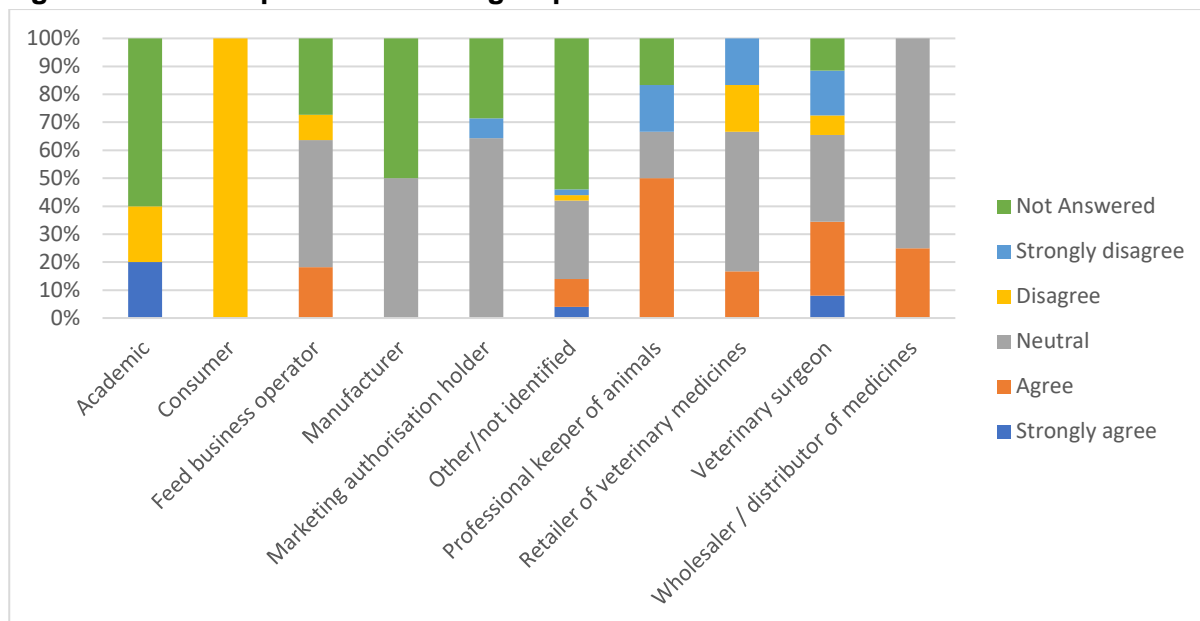
Registered homeopathic remedies

Question 27: Do you agree with this approach for homeopathic remedies?

138 out of 188 respondents answered this question.

- 45 of the respondents agreed
- 29 of the respondents disagreed
- 64 of the respondents were neutral

Agreement levels per stakeholder group



Respondents were largely neutral towards the proposals for homeopathic remedies. However, there was some disagreement with regards to registered homeopathic remedies not being subject to the same regulations as authorised veterinary medicines and concerns were raised around their overall safety and efficacy.

Government response

Upon consideration of the feedback, we have decided to implement the proposed changes. We will provide further clarification and guidance on these proposed changes.

Chapter 3: Manufacture

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

Proposals

Manufacture activities

We proposed to clearly state what activities constitute 'manufacture' and when a manufacturing authorisation is required, which includes manufacturing for export.

Manufacturing authorisation

With regard to manufacturing authorisations, we proposed 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
- additional information for the manufacturing authorisation to improve the authorisation process
- a statement that a manufacturer outside the UK must hold a valid GMP certificate issued by us or a regulatory authority that we have a formal agreement with (or otherwise consider having equivalent regulatory controls to ours).

We also proposed to require manufacturers to record more detail on the products they manufacture, to improve traceability.

Finally, we proposed providing more detail on the grounds for which the Secretary of State may compulsory vary, suspend or revoke an authorisation, including instances where the manufacturer has not paid applicable fees or if the manufacturer has not conducted any activity related to the authorisation for more than five years.

Consistent approach for specific manufacturing authorisations

We proposed 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). This included a proposal 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.

We proposed 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.

Active substances

We proposed new requirements for the manufacture, importation and distribution of active substances:

- that any person who manufactures, imports or distributes an active substance must register with the Secretary of State at least 2 months before commencing one or more of those activities; or in the case of an existing manufacturer, within 2 months of the date on which the amended VMR come into force. We proposed 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.

We also proposed to introduce a provision that enables the Secretary of State to inspect those businesses on a risk basis to ensure the VMR are being complied with.

Manufacturers of products for administration under the cascade

We proposed 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. We also proposed to introduce the requirement that manufacturers of extemporaneous preparations must state on the label that the product does not have a MA.

Furthermore, we proposed 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.

Stem cell centres

We proposed to extend the authorisation and inspection requirements of equine stem cell centres to all non-food-producing animals.

Key issues raised and government response

Proposals not discussed here will be implemented.

Products manufactured under the cascade

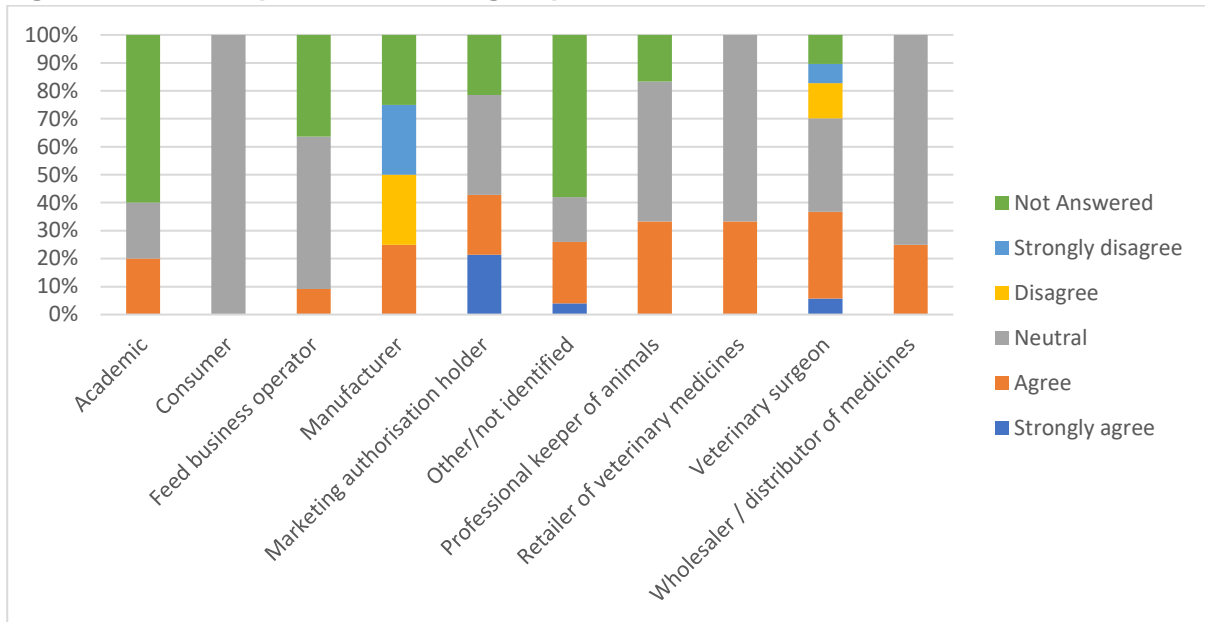
Question 34: Do you agree with this approach for products manufactured under the cascade?

138 out of 188 respondents answered this question.

- 59 of the respondents agreed
- 19 of the respondents disagreed

- 60 of the respondents were neutral

Agreement levels per stakeholder group



Several respondents raised concerns around the approach for products manufactured for administration under the cascade. Some expressed concerns around the difference between ‘pharmacologically equivalent’ and ‘pharmaceutically equivalent’ and the lack of a definition of the latter. Clarification was requested on the process for such events when manufacturing an unauthorised product for administration under the cascade that is pharmaceutically equivalent to an authorised veterinary medicine is allowed by the Secretary of State to address a supply shortage.

Government response

Upon consideration of the responses, we have decided to implement the proposed changes. The VMR will set out a definition of ‘pharmaceutically equivalent’ to clear any confusion. The definition of what is ‘pharmacologically equivalent’ is already provided in the VMR. We will amend our guidance where necessary to address concerns raised.

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

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

Proposals

Classification of POM-V medicines

We proposed to adjust the requirements so that the categories of medicines that must be classified as POM-V (prescription only medicine – veterinarian) include medicines that contain antibiotics or beta-agonists, or that are used for euthanasia, or that are immunological or hormonal.

Requirements for wholesale dealers

We proposed introducing new requirements for wholesale dealers:

- comply with good distribution practice
- only obtain veterinary medicines from other wholesale dealer's authorisation (WDA) holders or those with a manufacturing authorisation
- issue a document detailing key information when supplying medicines (including name and pharmaceutical form and batch number) and keep a copy for five years
- follow guidelines when destroying medicines and keep records of any destroyed medicines for five years
- inform the Secretary of State if it is offered counterfeit medicines
- report supply shortages to the Secretary of State, to improve the security of the supply chain

Moreover, we proposed to introduce offences for failure to comply with the new record keeping requirements.

We also proposed 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.

Finally, we proposed that the requirements for a WDA 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.

Wholesale dealers' audits and record-keeping

We proposed to introduce a new requirement for wholesale dealers to investigate and document any stock level discrepancies identified through their annual audit, and a requirement for wholesale dealers to put in place a self-inspection plan in relation to good distribution practice.

We also proposed 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).

Wholesale dealing by MAHs

We proposed removing an MAH's ability to wholesale veterinary medicines without holding a WDA.

Special Import Scheme

We proposed to amend the regulations to clarify that a pharmacist does not need a WDA 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

We proposed updating the position on distributing medicines for promotional purposes. We proposed to introduce an offence for failure to comply with this requirement.

Registration of online retailers

We proposed 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, an adaptation of the voluntary Accredited Internet Retailer Scheme, run by the VMD. We proposed to introduce offences for failure to comply with the requirement to register and other duties in relation to online supply.

Retailer supply

We proposed 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.

We also proposed to introduce the requirement that retailers must store veterinary medicines in line with the storage instructions on the label, including the introduction of an offence for failure to comply with this requirement.

Assessment by vet before prescribing POM-V

We proposed 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.

Prescriptions

We proposed 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.

We also proposed to update the information that should be contained in a prescription.

Wholesale supply of premix by feed business operators

We proposed to allow wholesale supply by feed business operators without a WDA in exceptional circumstances, to alleviate supply shortages and protect animal welfare. This is consistent with the provision for emergency supply of veterinary medicines between retailers.

Products supplied under the cascade

We proposed 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 in relation to record keeping requirements, assessment of the animal before prescribing and supply.

Remote supply by SQPs

We proposed the amendment that an SQP who has correctly prescribed and 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.

SQP registration bodies

We proposed to clarify in the VMR, including the appeal procedure, that the Secretary of State can revoke or suspend the recognition of an SQP registration body and that the code of practice for SQPs applies to SQP bodies as well as SQPs.

Sheep dip

We proposed to clarify in the VMR 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).

Key issues raised and government response

Proposals not discussed here will be implemented.

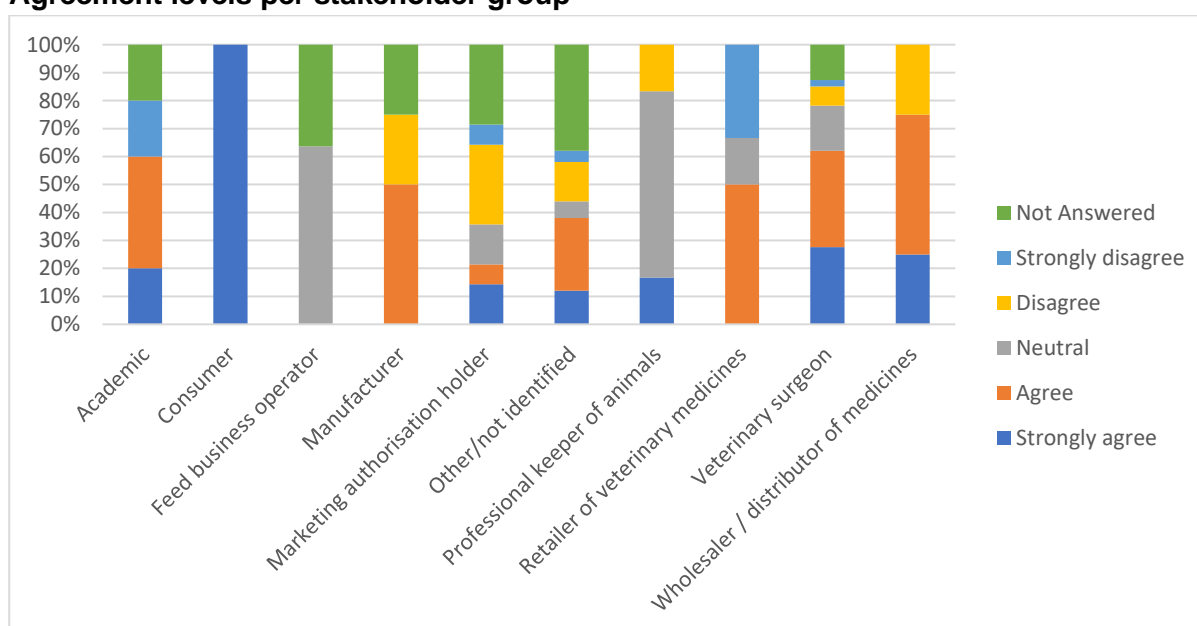
Classification of POM-V medicines

Question 39: Do you agree with the proposed additions to the POM-V classification?

148 out of 188 respondents answered this question.

- 89 of the respondents agreed
- 28 of the respondents disagreed
- 31 of the respondents were neutral

Agreement levels per stakeholder group



Although there was support for the proposal to adjust the requirements so that the categories of medicines that must be classified as POM-V include medicines that are immunological, many concerns were raised. These concerns focused on the potentially reduced availability of immunological products, which may lead to increased antimicrobial use and significant negative impacts for animal welfare.

Government response

After consideration of the feedback, we have decided to implement the proposed changes in amended form. Immunological products will not be restricted to a POM-V classification, and these can continue to be either POM-V or POM-VPS subject to the usual assessments and procedures.

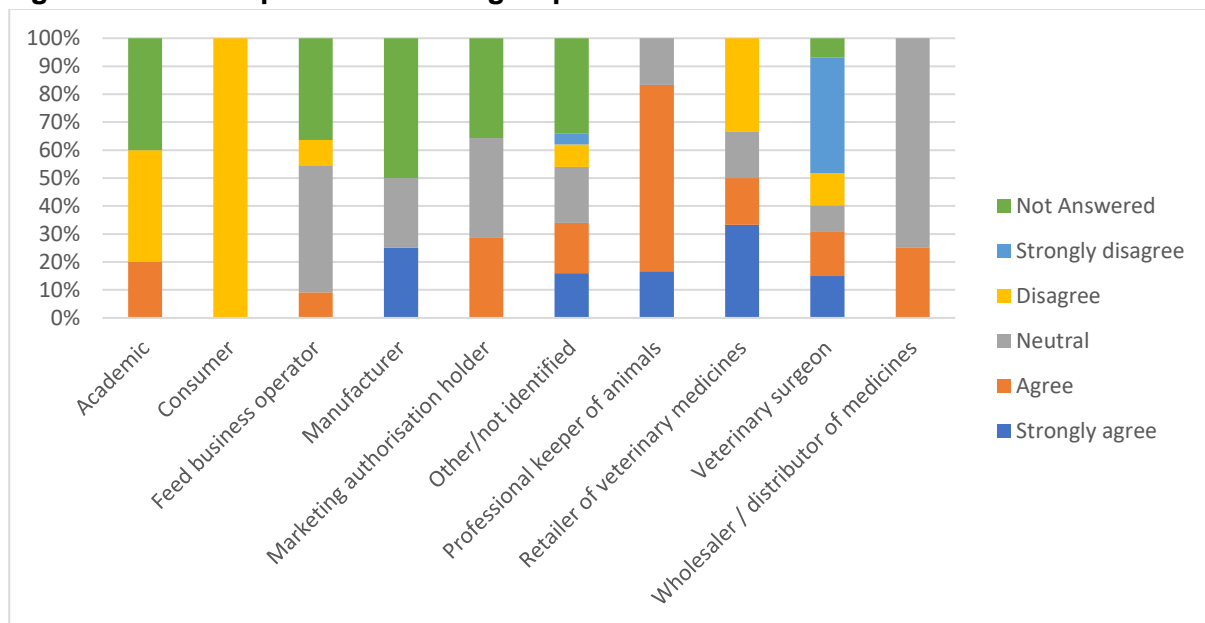
Assessment by vet before prescribing a POM-V medicine

Question 46: Do you agree with this approach to the assessment made of an animal or animals by the vet before the vet prescribes a POM-V medicine?

152 out of 188 respondents answered this question.

- 60 of the respondents agreed
- 58 of the respondents disagreed
- 34 of the respondents were neutral

Agreement levels per stakeholder group



While some respondents agreed with this proposal, there were also a similar number who disagreed. There were concerns raised on the concept of remote prescribing and ensuring due diligence in such prescribing, supporting safe, responsible and appropriate prescribing. Concerns mainly focused on the proposed new wording of 'clinical examination or other proper assessment' and how this could cause confusion or lead to misinterpretation. It was clear from respondents that maintaining the current wording of 'clinical assessment' would be preferred as it is a commonly understood term and believed to achieve the intended objective.

Government response

Upon consideration of the responses received, we have decided to not implement this proposal. The current VMR text of 'clinical assessment' will be kept. By retaining this wording, the intended objective will still be achieved. We will endeavour to pass on any concerns raised, in relation to the Royal College of Veterinary Surgeons' (RCVS) change in guidance, to the RCVS for its attention.

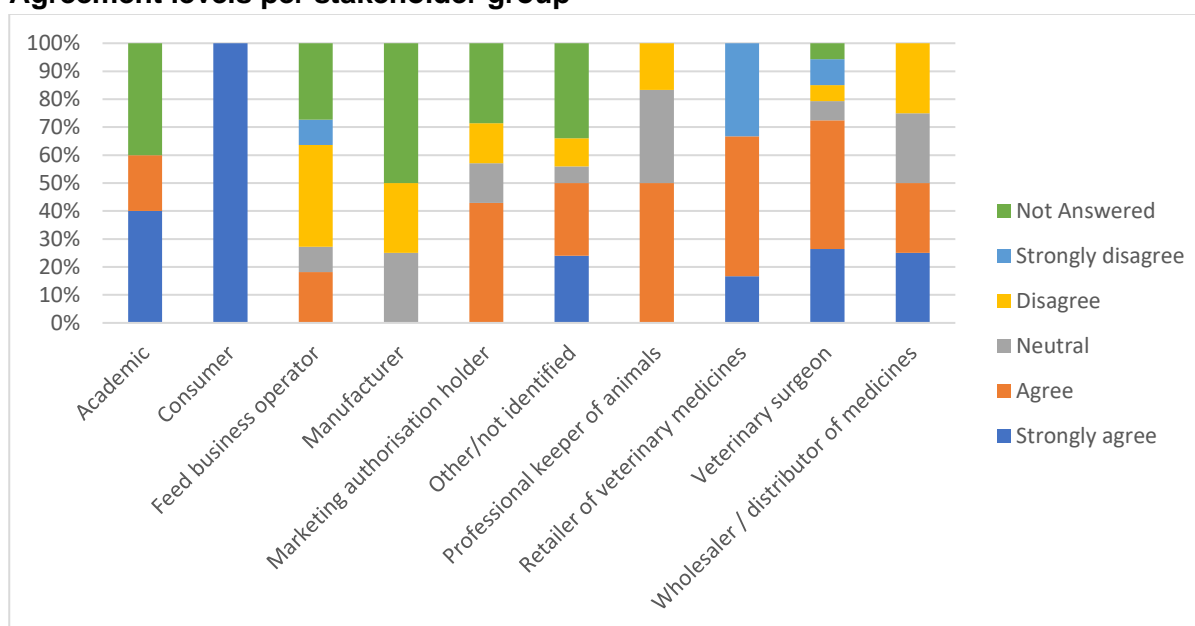
Prescriptions

Question 47: Do you agree with the changes to the requirements for prescribing medicines?

155 out of 188 respondents answered this question.

- 109 of the respondents agreed
- 30 of the respondents disagreed
- 16 of the respondents were neutral

Agreement levels per stakeholder group



Respondents largely agreed with this proposal, however there was still some disagreement on certain aspects. Concerns focused on the use of the word 'oral' and how this could cause confusion as it could relate to medicines given orally. Feedback from respondents suggested that the word 'verbal' would be preferred. There were also concerns regarding online and other non-written prescriptions and that these were not explicitly included in the scope of the proposed requirement for any qualified person to record their rationale for orally prescribing a prescription medicine (POM-V or POM-VPS). Several correspondents raised concerns that this requirement would cause an administrative burden and asked for clarification on the exact information needing to be recorded. The additional wording to be included on prescriptions was mostly supported but there was a request to introduce this with a reasonable timeline. Additionally, several respondents asked for clarity on the requirement for prescribers to keep records and whether this requirement applies to the prescribing practice or the individual prescribing vet.

Government Response

After consideration of the feedback received, we have decided to implement these proposals in amended form. To avoid confusion, the VMR will refer to any prescription that is not a written prescription, instead of referring to 'oral' prescriptions. This includes online prescriptions. The VMR will also clarify that the reason for prescribing of the product needs to be recorded, instead of the rationale. Clarification on this and what this may look like in practice will be provided in guidance.

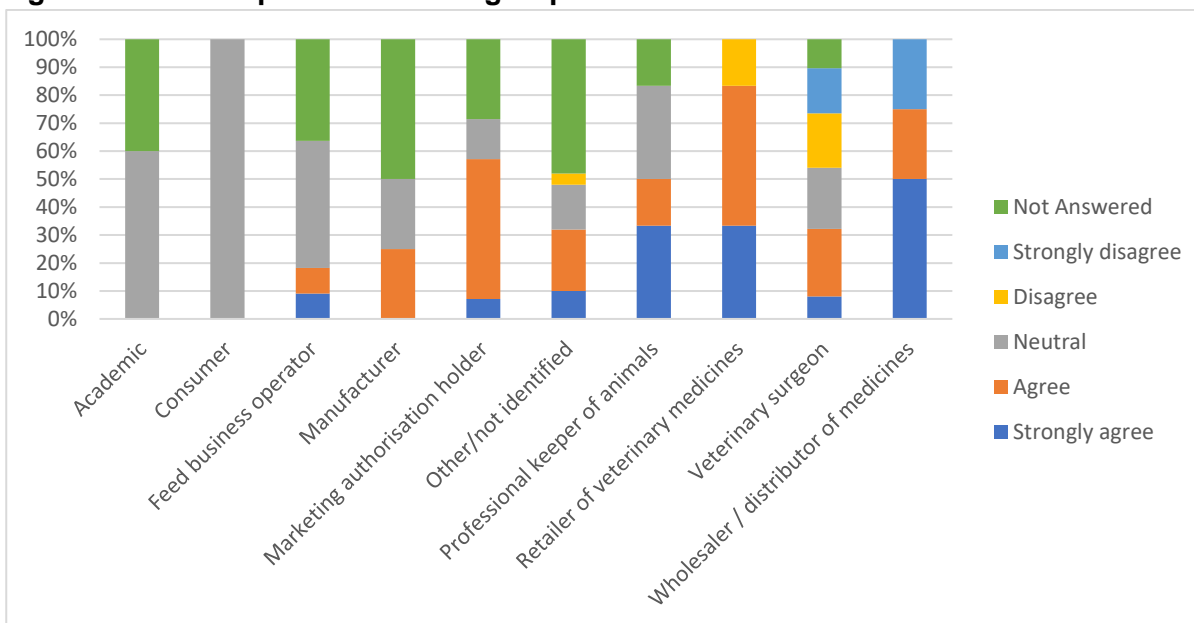
Procedure for SQPs to authorise retail supply

Question 49: Do you agree with this approach to remote supplying by SQPs?

142 out of 188 respondents answered this question.

- 66 of the respondents agreed
- 35 of the respondents disagreed
- 41 of the respondents were neutral

Agreement levels per stakeholder group



Many respondents agreed with this proposal. However, there were some respondents who either disagreed or were neutral. Concerns mainly focused on the potential risk of inappropriate or lack of advice being provided at the point of sale. Many concerns also raised the issue that the term 'competent person' needs to be defined. Furthermore, there were other comments suggesting that more training needs to be available to SQPs.

Government response

We will implement this proposal. We will provide further clarification in guidance which will address concerns raised.

Chapter 5: Administration under the cascade

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

Proposals

Cascade prescribing for food-producing animals

We proposed a suite of changes to improve the system of prescription and supply, which includes assurance that vets make responsible prescribing decisions under the cascade.

We proposed to expand the requirement that pharmacologically active substances included in medicines administered to food-producing animals must be substances for which a maximum residue limit is established or to be included on the out-of-scope list to all ingredients of a veterinary medicine.

Appropriate use of the cascade

We proposed to introduce a new offence of encouraging or facilitating the illegal use of the cascade and to explicitly state that an autogenous vaccine should only be used in exceptional circumstances and when there is no authorised immunological veterinary medicine for the target species, in accordance with the cascade.

Withdrawal periods

We proposed to amend the statutory minimum withdrawal periods to ensure they are fit-for-purpose: ensuring food safety whilst not presenting a barrier to the treatment of animals.

Key issues raised and government response

Proposals not discussed here will be implemented.

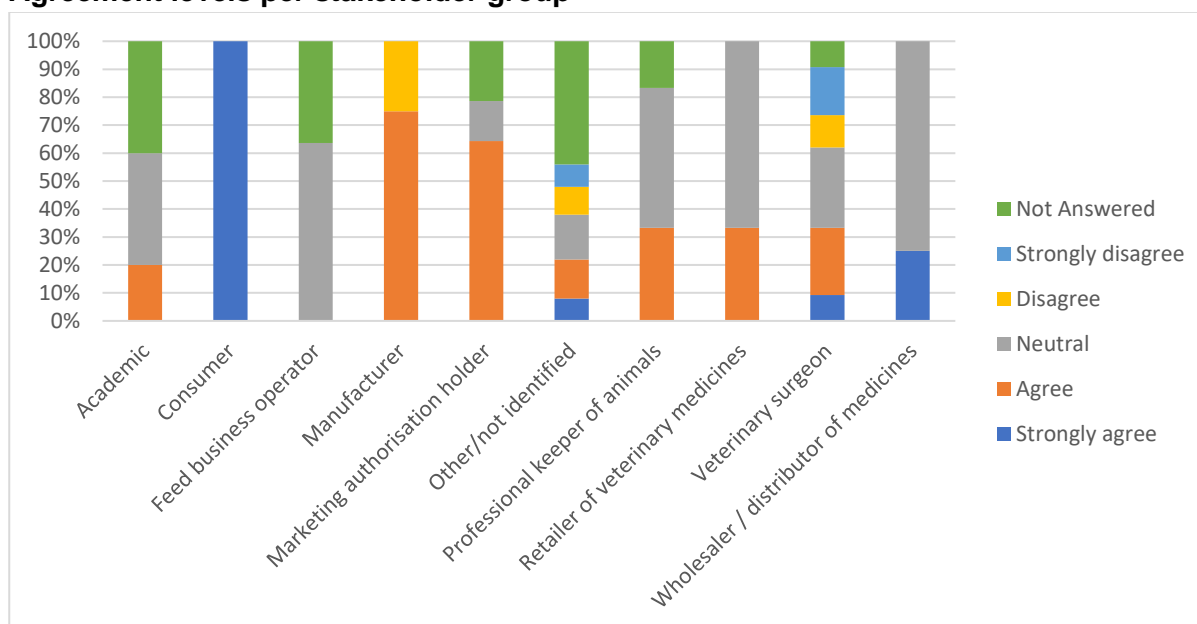
Appropriate use of the cascade

Question 53: Do you agree with this approach to ensuring appropriate use of the cascade?

148 out of 188 respondents answered this question.

- 59 of the respondents agreed
- 35 of the respondents disagreed
- 54 of the respondents were neutral

Agreement levels per stakeholder group



Concerns were raised regarding the use of the word 'encouraging' as it was considered ambiguous and could be misinterpreted. Respondents noted that definitions and examples would be required to determine exactly what is deemed as encouragement. There were also many concerns raised regarding the proposal 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. It was widely commented on that any restrictions on the use of autogenous vaccines could negatively impact disease management and the ability to reduce antimicrobial usage.

Government response

We have considered the responses received to this consultation question and decided to implement the proposals in amended form. The VMR will refer to 'promoting' instead of 'encouraging'. This is intended to stop widespread promotion of cascade use. It is not the intention to limit treatment options or prevent individual vets from using their own clinical judgement when prescribing in accordance with the cascade, nor is it intended to prevent the vet from discussing treatment options with the owner of the animal under treatment.

It is also recognised that clarity is required with regards to the prescription and use of autogenous vaccines and thus, we will slightly amend the proposed change to the VMR. An autogenous vaccine may only be prescribed in accordance with the cascade and administered to animals in exceptional circumstances where there is no suitable, authorised immunological veterinary medicine for the target species and indication.

Our online guidance on the cascade will be amended to provide further clarity.

Chapter 6: Medicated Feed

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

Proposals

Definitions

We proposed to introduce additional definitions in Schedule 5, such as for batch, complementary or complete or compound feed and intermediate feedingstuffs and to refer specifically to medicinal premix as the veterinary medicine incorporated into feed and replace the confusing term 'premixture' with 'intermediate feedingstuff' throughout the schedule.

Prescription for medicated feed

We proposed to strengthen the information that needs to be included in the prescription for feed containing a medicinal premix. We also proposed 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.

Labelling

We proposed introducing new labelling requirements for intermediate feedingstuffs and medicated feed that are in line with those for veterinary medicines.

Storage and disposal of medicated feed

We proposed to require keepers of animals to store any product regulated by Schedule 5 in accordance with the summary of product characteristics. They should also ensure that there is no contamination of products, feed material and environment. Products should be administered only to the correct animal and the withdrawal period should be complied with.

We also proposed 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.

Finally, we proposed to state explicitly that medicated feed that has passed its expiry date may not be fed to an animal and to introduce an offence for failure to comply with this requirement.

Cross-contamination and carryover

We proposed to introduce a new requirement for cross-contamination to be as low as reasonably achievable. We would require suitable testing to be carried out and for feed business operators to note any 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 proposed to introduce an offence for failure to comply with these requirements.

Tolerance table

The tolerance table sets out the permitted analytical tolerance when testing medicated feed for medicinal substances incorporated into that feed. We proposed to amend the tolerance table to support high quality of medicated and intermediate feedingstuffs with accurate levels of active ingredient.

Key issues raised and government response

Proposals not discussed here will be implemented.

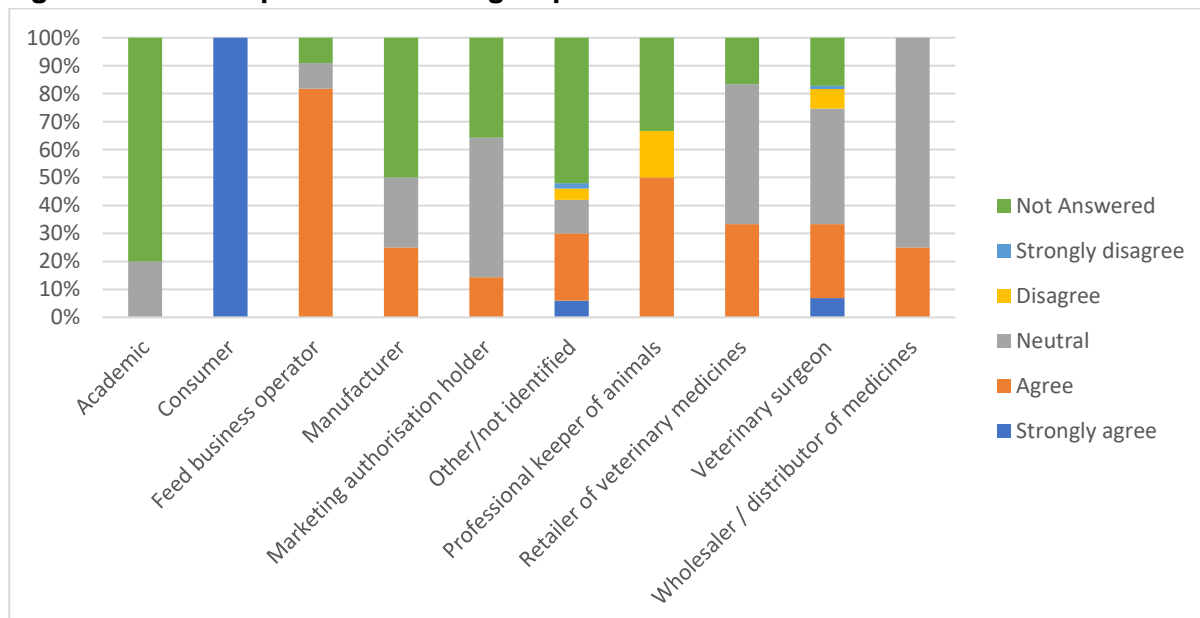
Prescription of medicated feed and terminology

Question 57: Do you agree with the approach to prescriptions for medicated feed?

132 out of 188 respondents answered this question.

- 63 of the respondents agreed
- 11 of the respondents disagreed
- 58 of the respondents were neutral

Agreement levels per stakeholder group



There were some concerns raised regarding the manufacture in advance of receipt as some believe it could lead to pressure, from both the client and the feed mixers, on the vet to provide the prescription when it may not be appropriate. Some raised concerns around

order cancellations which could potentially lead to medicated products being wasted and the cost issues associated with this. Also, there were concerns raised around the terminologies used ('premix' and 'premixture') and it was noted that these terms have different meanings in the feed sector which could potentially cause confusion in the industry.

Government response

We appreciate the concerns raised but have decided to implement the proposals. Regarding manufacture in advance of receipt of prescription, for clarity, this is intended only for commercial feed mills and not for on-farm mixers. This is something that is already done, and the change is intended to make clear in the legislation that it is allowed.

Regarding the concerns raised on terminology, we have taken these into consideration and agree to amend the term 'premix' to 'medicinal premix'. This is to prevent any confusion with the term 'premix' in feed legislation which could also refer to non-medicinal feed supplements.

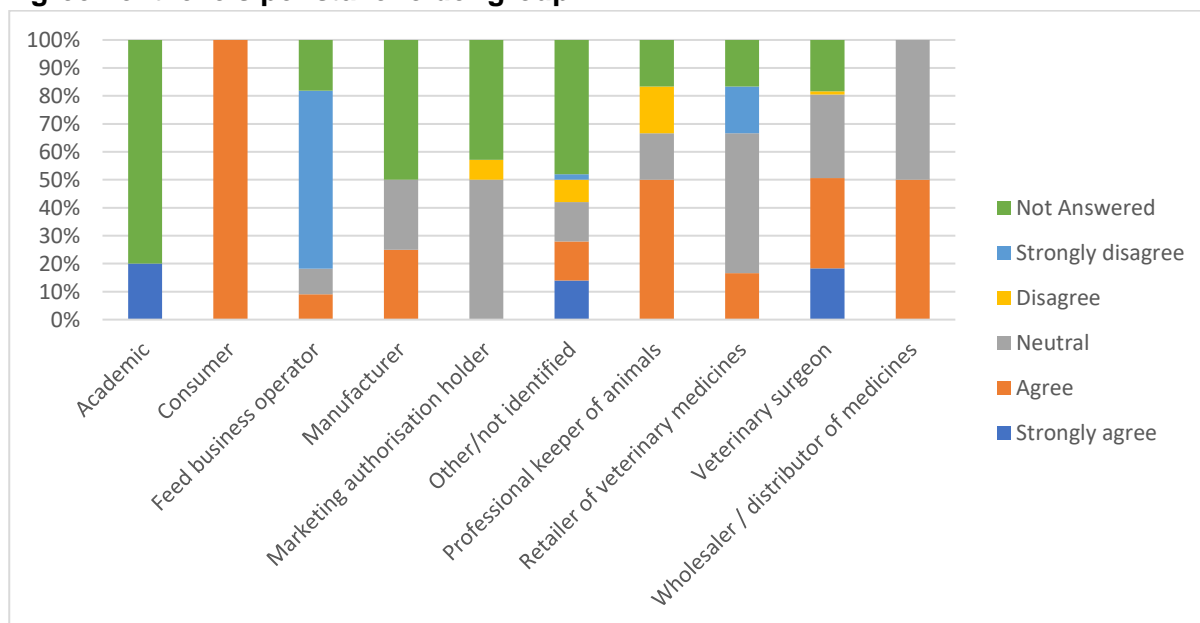
The storage and disposal of medicated feed

Question 59: Do you agree with this approach to storage and disposal of medicated feed?

132 out of 188 respondents answered this question.

- 68 of the respondents agreed
- 16 of the respondents disagreed
- 48 of the respondents were neutral

Agreement levels per stakeholder group



Several concerns were raised around the requirement for Feed Business Operators (FeBOs) to have a collection and disposal system for expired or unused medicated feed. Responses included that it would put significant strain on the industry and may lead to reduced production and sale of medicated feed, which would put animal welfare at risk. There were also biosecurity concerns with regards to the return of medicated feed to FeBOs sites. Concerns were raised around the significant costs to uplift feed and clean down vehicles after disposal to avoid contamination of subsequent loads. Some noted that it is only reasonable to expect FeBOs to dispose of medicated feed where they have erroneously supplied.

Government response

Upon consideration of the feedback received, we have decided not to implement the proposal for the collection and disposal system. We understand that the burden appears to be disproportionately high on FeBOs. We will instead commit to reviewing whether a collection and disposal system should be in place; the scale of the problem of unused medicated feed being used in animals for which it is not or no longer prescribed; and what a potential system should look like and how it could be introduced.

For clarity, we will move forward with the change that expired feed must not be fed to animals.

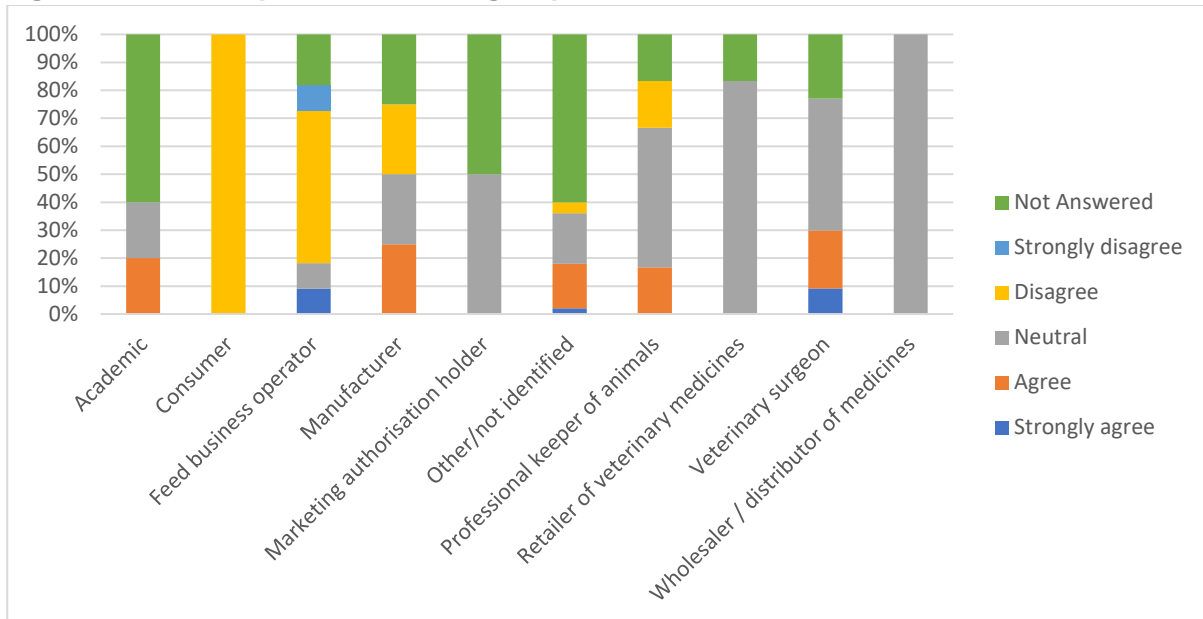
Tolerance table

Question 61: Do you agree with this change to the tolerance table?

123 out of 188 respondents answered this question.

- 39 of the respondents agreed
- 12 of the respondents disagreed
- 72 of the respondents were neutral

Agreement levels per stakeholder group



Some concerns were raised around the accuracy of analysis available within the UK and that it is not sufficient to make large reductions in tolerance. Requests were made for the proposed tolerance table to be amended as the respondent noted that the new tolerance levels would be challenging to meet. This is possibly due to the limitation of available laboratory methods. Some raised concerns that though the tolerance limits were within the scope of existing practice, for a specific POM-V product meeting the proposed tolerances would likely be challenging due to the limitations of the available analytical methods and sampling.

Government response

We appreciate the feedback on this proposal. We have thoroughly considered these concerns raised and decided we will implement this change. This is because of the drive to reduce antimicrobial resistance and in comparison, with other regulatory regimes, the new tolerance table is considered fair. We will commit to working with the laboratories to improve testing capability.

Chapter 7: Exemption for small pet animals

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

Proposals

Registration and supply of information

We proposed to introduce a requirement for companies that market products in accordance with Schedule 6 in Great Britain to register with the Secretary of State and provide information annually on the medicines that have been marketed under this exemption.

Reporting of adverse events by retailers

We proposed to remove the requirement for retailers of products marketed in accordance with Schedule 6 to report adverse events.

Key issues raised and government response

The majority of respondents were in favour of the proposals and there were no major concerns raised for this chapter.

Chapter 8: Antimicrobial resistance

The UK Government is committed to the UK National Action Plan for antimicrobial resistance (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.

Proposals

Antibiotic usage data

We proposed that, in addition to the legal requirement for provision of sales data by MAHs, 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 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 also proposed to introduce an offence for failure to comply with such a request for information.

Prophylactic use

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. We therefore proposed 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. We also proposed to introduce an offence for failure to comply with this requirement. When considering groups of animals, we additionally proposed 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.

In-feed antibiotics

We proposed including the restrictions relating to medicated feed containing antibiotics:

- the duration of treatment must comply with the SPC. If it is not specified in the SPC, the duration of treatment must be less than two weeks
- the prescription would be valid from the date it is issued for a maximum period of five days

- a vet may not prescribe medicated feed with more than one antibiotic premix
- a vet may not prescribe medicated feed containing antibiotics for prophylactic purposes, but the exceptions set out in above apply here too.

Key issues raised and government response

Proposals not discussed here will be implemented.

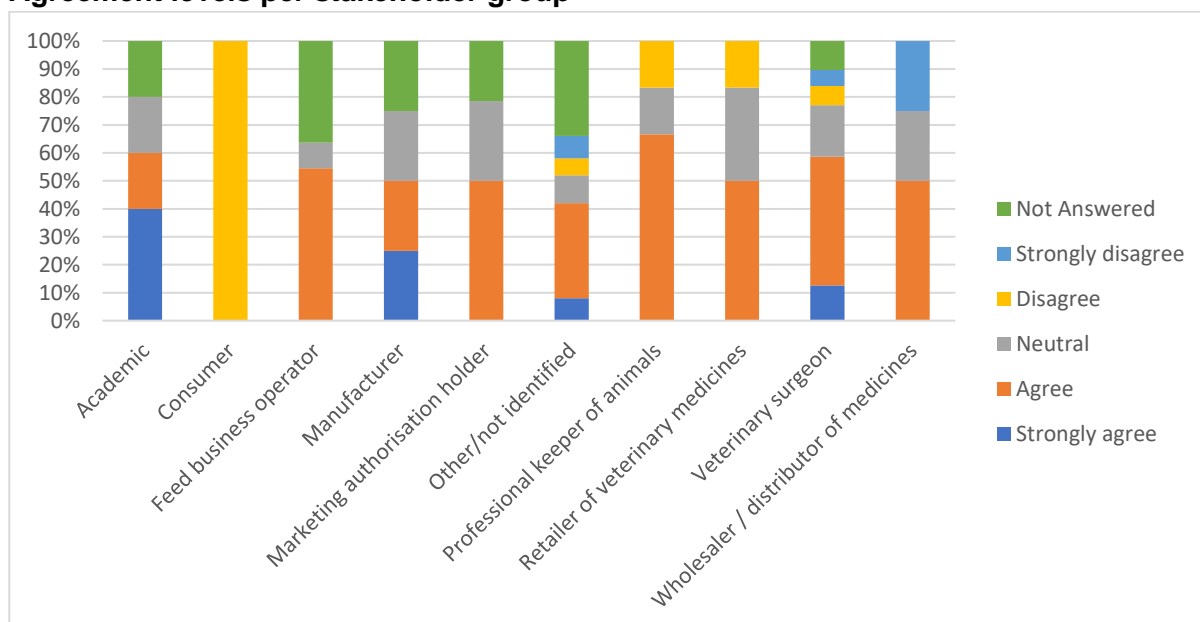
Antibiotic usage data

Question 70: 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?

153 out of 188 respondents answered this question.

- 99 of the respondents agreed
- 22 of the respondents disagreed
- 32 of the respondents were neutral

Agreement levels per stakeholder group



The majority of respondents agreed. Some respondents raised concerns around the voluntary approach leading to partial data sets and preferred that such data provision was mandatory. Others raised concerns around the definition of 'insufficient progress'. It was requested that any invocation of the requirement to provide usage data would have appropriate lead in time and engagement.

Government response

We have considered the concerns raised and decided to implement the proposal. If the Secretary of State does request such data, we will provide guidance on how the legislation is to be implemented.

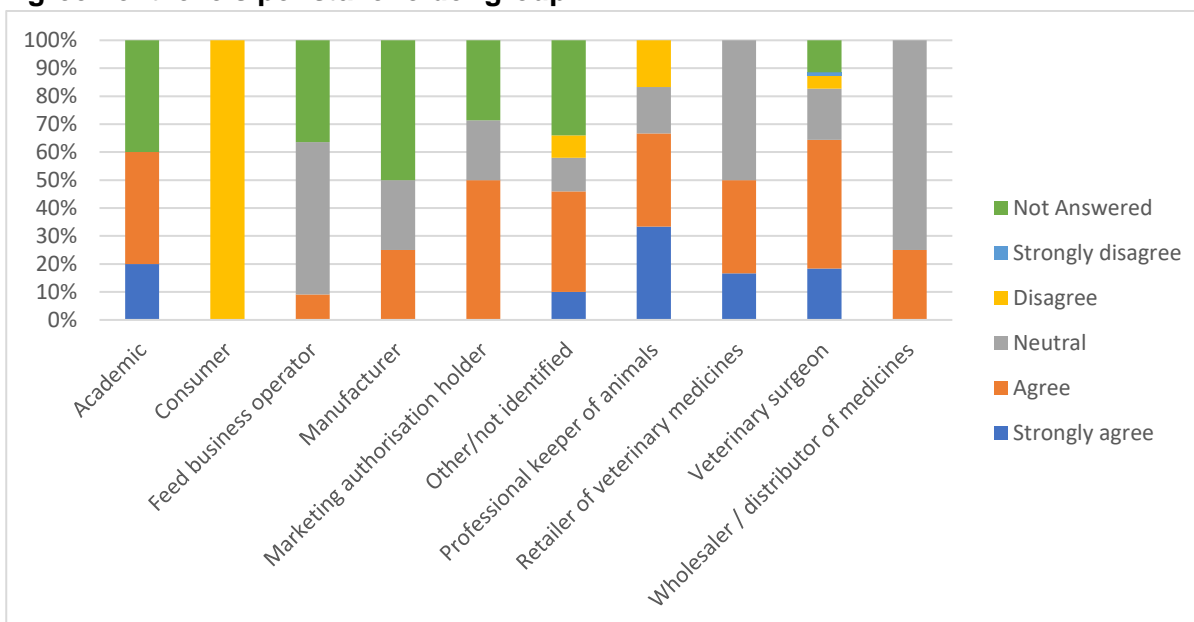
Restricting prophylactic use

Question 71: Do you agree with our proposals to restrict prophylactic use?

149 out of 188 respondents answered this question.

- 99 of the respondents agreed
- 11 of the respondents disagreed
- 39 of the respondents were neutral

Agreement levels per stakeholder group



The proposals relating to prophylactic use were generally well received and considered a pragmatic approach, although some had concerns that the proposed restrictions on prophylaxis did not go far enough. There was a call for clarity on the meaning of the terms “exceptional” and “predictable”. Some expressed confusion over the term “routine” as antibiotics can be used “routinely” in certain procedures. Concerns were also raised around the proposed requirement for a management review to be carried out as soon as reasonably practicable and how this would be enforced. With regards to metaphylaxis, feedback included suggestions that there should be more restrictions (in line with EU rules).

There were also concerns raised that the proposal could leave vets open to prosecution when prescribing antibiotics to protect the welfare of an animal.

Government response

We have taken the concerns raised into consideration and decided to implement the proposals with slightly amended text.

We will provide clarity in guidance on the term “routine” which does not relate to elective procedures with a risk or evidence based clinical protocol. We have amended the text “any general duty in relation to animal welfare” to “professional obligations of a veterinary surgeon to ensure the health and welfare of animals under their care”, and we will provide guidance on the interpretation of this term.

With regards to prophylactic use, we will provide guidance on the meaning of the terms “exceptional” and “predictable”. The VMR text will be clear that the management review is to be carried out by a veterinary surgeon. Guidance will also be provided on how the management review will work in practice and we will liaise with industry partners on this.

The VMR will also include a definition for ‘metaphylaxis’.

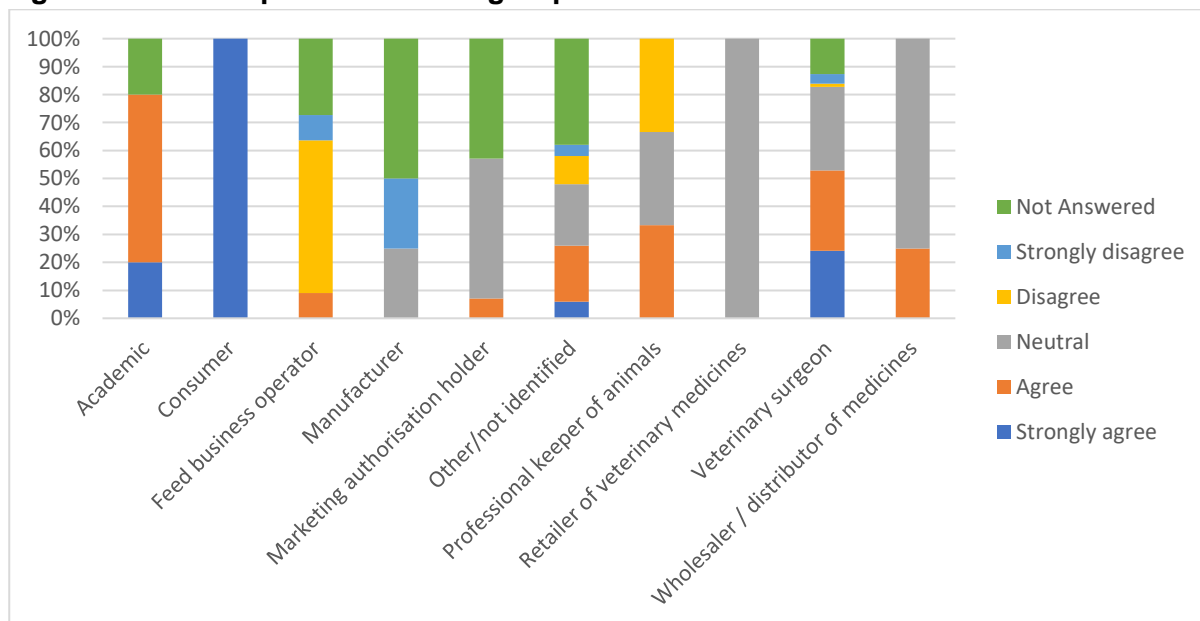
Medicated feed containing antibiotics

Question 72: Do you agree with this approach to medicated feed containing antibiotics?

146 out of 188 respondents answered this question.

- 69 of the respondents agreed
- 21 of the respondents disagreed
- 56 of the respondents were neutral

Agreement levels per stakeholder group



There were a number of concerns raised on the 5-day validity period not being long enough for FeBOs to fulfil a prescription and have medicated feed delivered to the farm, especially within a complicated supply chain structure and taking into account weekends and bank holidays. Clarification was requested on what the validity period refers to.

Government response

Upon consideration of the concerns raised, we have agreed to implement the changes in amended form. In the case of a prescription which relates to antibiotics, the time between the prescription being issued and the course of treatment starting must be no more than 5 working days.

The amended VMR text will no longer state that the SPC course lengths should be followed, or state maximum course lengths if no duration is included in the SPC, but it will state that a prescription for medicated feed may only confer authority for one course of treatment. We have removed the restriction that a vet may not prescribe medicated feed with more than one antibiotic as this may lead to unintended consequences such as clinical conditions not being treated effectively. We will provide guidance to clarify what is meant by one course of treatment and that the treatment duration of a course should be as short as clinically possible.

Chapter 9: Fees

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

Proposals

We proposed to revise the fees and fee structure so that we can recover the true cost of providing our regulatory services. We proposed introducing new fees for:

- marketing authorisation applications for specific veterinary medicines
- pharmacovigilance inspections
- providing scientific advice to companies
- inspectors witnessing the destruction of authorised Schedule 2 controlled drugs and Schedule 3 and 4 controlled drugs that have been prepared extemporaneously for use under the cascade

We also proposed changing the existing fees for:

- new and generic marketing authorisation applications and variations thereof
- marketing authorisation applications based on informed consent
- manufacturing authorisations (including application, variations, inspections and annual fees)
- wholesale dealers (including application, variations, inspections and annual fees)
- feed business operators (including applications, inspections and annual fees)
- SQP retailers (including authorisation, inspections and annual fees)
- animal test certificates (including application, variation and renewal)
- special import certificates
- export certificates
- veterinary practice premises (including inspections, registration and annual fees)

We proposed 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. We also proposed to simplify the categories of feed businesses which also simplifies the fee structure for inspections of these businesses.

Finally, we proposed to remove the fee for renewals of marketing authorisations and registrations of homeopathic remedies.

Government response

There were a number of responses from respondents, which has assisted us in our assessment of the fees. All fees will be implemented, with one exception: we will not introduce a fee for an application for a Special Import Certificate made through the VMD's website. We recognise the need to not introduce barriers to the availability of medicines to

treat our animals, especially in situations where there are supply shortages of authorised veterinary medicines.

Conclusion and next steps

We would like to thank all the respondents who participated in this consultation, sharing their considered views and suggestions. All responses have been taken into account and some proposals will no longer be implemented or will be implemented in amended form following thorough consideration of concerns raised.

Some responses included proposals not within the scope of the current consultation. We have noted these and where we, in the context of all such proposals, agree there is a need, we will consider the proposals for non-legislative action or a future update to the VMR.

We aim to work with our stakeholders to achieve compliance with the VMR, and we gratefully receive feedback on the workings of the VMR.

The next step is to lay the Statutory Instrument making the legislative changes, subject to Parliamentary approval.

List of respondents

A list of organisations of which representatives or individual respondents did not request confidentiality

ABN (Part of AB Agri)
Access VetMed
Agricultural Industries Confederation
AH UK Animal Health (PVT) Ltd
Alliance to Save Our Antibiotics
AMTRA
Animal Health Distributors
Animal Health Distributors Association (AHDA)
AnimalhealthEurope
Animed Veterinary Centre (CVS)
Apex Vets LTD
Aquatic Life Institute
Ark Veterinary Centre
Armac Vets ltd
Assentra Limited
Avondale Vet Group
BATA ltd
Beckys Beezzzs Ltd
Bimeda Animal Health Limited
Boehringer Ingelheim Animal Health UK Ltd
Botanical Veterinary Care
BOVA SPECIALS UK LTD
Bransby Horses
Brinkworth Apiaries
British Cattle Veterinary Association
British Equestrian Trade Association
British Equine Veterinary Association (BEVA)
British Hen Welfare Trust
British Horse Council (BHC)
British Poultry Council
British Veterinary Association
British Veterinary Nursing Association
British Veterinary Poultry Association
Buglife - The Invertebrate Conservation Trust
Burns Pet Nutrition
C D Parker
Castle Veterinary Clinic
Cats Protection
Centaur Services Limited, T/A MWI Animal Health
Chessington Veterinary Surgery
Chipping Norton Veterinary Hospital
Christine Paine Consulting
Compassion in World Farming
Cruelty Free International
Dairy UK
Desitin Arzneimittel GmbH/
Pharmacovigilance and Label Management
Dilliway & Bosley Equine vets
Dogs Trust
Downland Marketing Ltd
Dryfe Vets Ltd
East Yorkshire Sheep Services
Eden Veterinary Practice
Elizabeth Smith Veterinary Practice
FAIRR Initiative
Fenwold Veterinary Practice Ltd
Folly Gardens vets
ForFarmers UK Ltd
Forte Healthcare Limited
General Pharmaceutical Council
Grantham Institute, Imperial College London
Hadrian vets
Harbro Ltd
HPRA
Hunters Lodge Vets
Immune Macro Biotic Technology UK (IMBT)
IVC Evidensia
Kingswood vets4pets
Law Society of Scotland
Locum veterinarian
Locum veterinary services
Map of Ag

MCEB Services
Meadowbrook Equine Clinic
Moredun Research Institute
Moy Park Ltd
MSD Animal Health UK
Murray McGregor Ltd t/a Denrosa
Apiaries
National Office of Animal Health Ltd.
National Sheep Association
Natural England
Naturewatch Foundation
NDPB/AHDB Levy Board
NFU Scotland
Nimrod Veterinary Products Ltd
Northern Ireland Grain Trade Association
OphthoVet Ltd
ParksVets
PDSA
Pets At Home Group PLC which includes
Vets4Pets and Companion Care
Pets Choice UK Ltd
Pig Health and Welfare Council AMU
subgroup
Prionics Lelystad B.V.
R.M.Jones (Farmcentre) LLP
Responsible use of Medicines in
Agriculture – RUMA Ag
Rossgdales Ltd
Royal College of Veterinary Surgeons
Royal Pharmaceutical Society
Royal Society for the Protection of Birds
(RSPB)
RUMA Companion Animal and Equine
Salmon Scotland
SCOPS (Sustainable Control of Parasites
in Sheep)

Sevenside Veterinary Services
Sheep Veterinary Society
Soil Association
The Eye Vet Clinic
The Farmers' Union of Wales (FUW)
The George Farm Vets
The George Veterinary Group
The George Veterinary Group Pig
Practice
The National Farmers' Union (England &
Wales) (NFU)
The Ornamental Aquatic Trade
Association (OATA)
The Pig Veterinary Society
The Royal Association of British Dairy
Farmers
Trouw Nutrition GB
University of Central Lancashire
University of Edinburgh
University of Liverpool
Vet Sustain
Veterinary Schools Council
Vetpol Ltd
Vets Now
Village Vets Formby Ltd
VioVet Ltd
Wales Animal and Environment AMR
Delivery Group.
Wales Animal Health and Welfare
Framework
Westpoint Farm Vets
Windmill Veterinary Centre
World Animal Protection
Zoetis UK

Annex – Consultation questions and quantitative response data

Chapter 1 - General (Regulations)

6. Do you agree with the proposal for the Secretary of State to be able to require information on request?
152 out of 188 respondents answered this question.
- 109 of the respondents agreed.
 - 10 of the respondents disagreed.
 - 33 of the respondents were neutral.
7. Do you agree with this approach to the “as soon as reasonably practical” issuing of records by vets?
151 out of 188 respondents answered this question.
- 103 of the respondents agreed.
 - 10 of the respondents disagreed.
 - 38 of the respondents were neutral.
8. Do you support this approach to advertising of veterinary medicines?
153 out of 188 respondents answered this question.
- 93 of the respondents agreed.
 - 30 of the respondents disagreed.
 - 30 of the respondents were neutral.
9. Do you agree with this approach to the changes in inspectors’ powers?
156 out of 188 respondents answered this question.
- 119 of the respondents agreed.
 - 12 of the respondents disagreed.
 - 25 of the respondents were neutral.
10. 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?
96 out of 188 respondents answered this question.
11. What would be the consequences if we did not make these changes?
66 out of 188 respondents answered this question.

Chapter 2 - Marketing Authorisations in GB

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

145 out of 188 respondents answered this question.

- 82 of the respondents agreed.
- 11 of the respondents disagreed.
- 52 of the respondents were neutral.

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

139 out of 188 respondents answered this question.

- 62 of the respondents agreed.
- 8 of the respondents disagreed.
- 69 of the respondents were neutral.

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

142 out of 188 respondents answered this question.

- 37 of the respondents agreed.
- 38 of the respondents disagreed.
- 67 of the respondents were neutral.

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

141 out of 188 respondents answered this question.

- 71 of the respondents agreed.
- 6 of the respondents disagreed.
- 64 of the respondents were neutral.

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

138 out of 188 respondents answered this question.

- 34 of the respondents agreed.
- 24 of the respondents disagreed.
- 80 of the respondents were neutral.

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

144 out of 188 respondents answered this question.

- 73 of the respondents agreed.
- 5 of the respondents disagreed.
- 66 of the respondents were neutral.

18. 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?

141 out of 188 respondents answered this question.

- 70 of the respondents agreed.
- 9 of the respondents disagreed.
- 62 of the respondents were neutral.

19. Do you agree with this approach for publishing assessment reports?
142 out of 188 respondents answered this question.
- 58 of the respondents agreed.
 - 9 of the respondents disagreed.
 - 75 of the respondents were neutral.
20. Do you agree with this approach for making mandatory that to MAHs report supply shortages to the Secretary of State?
148 out of 188 respondents answered this question.
- 109 of the respondents agreed.
 - 11 of the respondents disagreed.
 - 28 of the respondents were neutral.
21. Do you agree with the proposed changes for renewing MAs?
144 out of 188 respondents answered this question.
- 73 of the respondents agreed.
 - 23 of the respondents disagreed.
 - 48 of the respondents were neutral.
22. Do you agree with the proposed changes for variations to MAs?
137 out of 188 respondents answered this question.
- 45 of the respondents agreed.
 - 1 of the respondents disagreed.
 - 91 of the respondents were neutral.
23. Do you agree with this approach to suspension and revocation of MAs, prohibiting supply or restricting (immunological) medicines?
141 out of 188 respondents answered this question.
- 73 of the respondents agreed.
 - 8 of the respondents disagreed.
 - 60 of the respondents were neutral.
24. Do you agree with this approach to the labelling and package leaflet?
147 out of 188 respondents answered this question.
- 88 of the respondents agreed.
 - 16 of the respondents disagreed.
 - 43 of the respondents were neutral.
25. Do you agree with allowing electronic package information leaflets?
145 out of 188 respondents answered this question.
- 93 of the respondents agreed.
 - 16 of the respondents disagreed.
 - 36 of the respondents were neutral.

26. Do you agree with this approach for pharmacovigilance?

142 out of 188 respondents answered this question.

- 66 of the respondents agreed.
- 11 of the respondents disagreed.
- 65 of the respondents were neutral.

27. Do you agree with this approach for homeopathic remedies?

138 out of 188 respondents answered this question.

- 45 of the respondents agreed.
- 29 of the respondents disagreed.
- 64 of the respondents were neutral.

28. 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?

61 out of 188 respondents answered this question.

29. What would be the consequences if we did not make these changes?

46 out of 188 respondents answered this question.

30. 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.

22 out of 188 respondents answered this question.

Chapter 3 - Manufacture

31. Do you agree with this approach for manufacturing authorisations?

135 out of 188 respondents answered this question.

- 46 of the respondents agreed.
- 1 of the respondents disagreed.
- 88 of the respondents were neutral.

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

133 out of 188 respondents answered this question.

- 63 of the respondents agreed.
- 1 of the respondents disagreed.
- 69 of the respondents were neutral.

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

137 out of 188 respondents answered this question.

- 69 of the respondents agreed.

- 5 of the respondents disagreed.
- 63 of the respondents were neutral.

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

138 out of 188 respondents answered this question.

- 59 of the respondents agreed.
- 19 of the respondents disagreed.
- 60 of the respondents were neutral.

35. Do you support this approach to stem cell centres?

133 out of 188 respondents answered this question.

- 67 of the respondents agreed.
- 2 of the respondents disagreed.
- 64 of the respondents were neutral.

36. 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?

41 out of 188 respondents answered this question.

37. What would be the consequences if we did not make these changes?

30 out of 188 respondents answered this question.

38. 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.

16 out of 188 respondents answered this question.

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

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

148 out of 188 respondents answered this question.

- 89 of the respondents agreed.
- 28 of the respondents disagreed.
- 31 of the respondents were neutral.

40. Do you agree with the proposed changes for wholesale dealers?

137 out of 188 respondents answered this question.

- 92 of the respondents agreed.
- 4 of the respondents disagreed.
- 41 of the respondents were neutral.

41. Do you agree with the requirement for wholesale dealers to investigate stock discrepancies and keep records for five years?
131 out of 188 respondents answered this question.
- 81 of the respondents agreed.
 - 4 of the respondents disagreed.
 - 46 of the respondents were neutral.
42. Do you agree with the proposal for a MAHs to hold a WDA to wholesale products (including products for which they are the MAH)?
131 out of 188 respondents answered this question.
- 69 of the respondents agreed.
 - 3 of the respondents disagreed.
 - 59 of the respondents were neutral.
43. Do you agree with this approach for medicines distributed for promotional purposes?
141 out of 188 respondents answered this question.
- 99 of the respondents agreed.
 - 11 of the respondents disagreed.
 - 31 of the respondents were neutral.
44. Do you agree with requirement for online retailers to register?
148 out of 188 respondents answered this question.
- 128 of the respondents agreed.
 - 2 of the respondents disagreed.
 - 18 of the respondents were neutral.
45. Do you agree with this approach to audits, record-keeping and storage by retailers?
139 out of 188 respondents answered this question.
- 97 of the respondents agreed.
 - 13 of the respondents disagreed.
 - 29 of the respondents were neutral.
46. Do you agree with this approach to the assessment made of an animal or animals by the vet before the vet prescribes a POM-V medicine?
152 out of 188 respondents answered this question.
- 60 of the respondents agreed.
 - 58 of the respondents disagreed.
 - 34 of the respondents were neutral.
47. Do you agree with the changes to the requirements for prescribing medicines?
155 out of 188 respondents answered this question.
- 109 of the respondents agreed.
 - 30 of the respondents disagreed.
 - 16 of the respondents were neutral.

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

146 out of 188 respondents answered this question.

- 100 of the respondents agreed.
- 4 of the respondents disagreed.
- 42 of the respondents were neutral.

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

142 out of 188 respondents answered this question.

- 66 of the respondents agreed.
- 35 of the respondents disagreed.
- 41 of the respondents were neutral.

50. 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?

66 out of 188 respondents answered this question.

51. What would be the consequences if we did not make these changes?

36 out of 188 respondents answered this question.

52. 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.

16 out of 188 respondents answered this question.

Chapter 5 - Administration under the cascade

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

148 out of 188 respondents answered this question.

- 59 of the respondents agreed.
- 35 of the respondents disagreed.
- 54 of the respondents were neutral.

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

138 out of 188 respondents answered this question.

- 65 of the respondents agreed.
- 10 of the respondents disagreed.
- 63 of the respondents were neutral.

55. 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?

49 out of 188 respondents answered this question.

56. What would be the consequences if we did not make these changes?
32 out of 188 respondents answered this question.

Chapter 6 - Medicated feed

57. Do you agree with the approach to prescriptions for medicated feed?
132 out of 188 respondents answered this question.

- 63 of the respondents agreed.
- 11 of the respondents disagreed.
- 58 of the respondents were neutral.

58. Do you agree with this approach to labelling?
133 out of 188 respondents answered this question.

- 64 of the respondents agreed.
- 9 of the respondents disagreed.
- 60 of the respondents were neutral.

59. Do you agree with this approach to storage and disposal of medicated feed?
132 out of 188 respondents answered this question.

- 68 of the respondents agreed.
- 16 of the respondents disagreed.
- 48 of the respondents were neutral.

60. Do you agree with this approach to cross-contamination and carryover?
131 out of 188 respondents answered this question.

- 75 of the respondents agreed.
- 4 of the respondents disagreed.
- 52 of the respondents were neutral.

61. Do you agree with this change to the tolerance table?
123 out of 188 respondents answered this question.

- 39 of the respondents agreed.
- 12 of the respondents disagreed.
- 72 of the respondents were neutral.

62. 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?
35 out of 188 respondents answered this question.

63. What would be the consequences if we did not make these changes?
24 out of 188 respondents answered this question.

64. 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.

17 out of 188 respondents answered this question.

Chapter 7 - Exemptions for small pet animals

65. 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?

134 out of 188 respondents answered this question.

- 78 of the respondents agreed.
- 3 of the respondents disagreed.
- 53 of the respondents were neutral.

66. 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?

133 out of 188 respondents answered this question.

- 60 of the respondents agreed.
- 21 of the respondents disagreed.
- 52 of the respondents were neutral.

67. If all changes to Schedule 6 were made, as set out in this chapter, what would be the impact on your business?

26 out of 188 respondents answered this question.

68. What would be the consequences if we did not make these changes?

20 out of 188 respondents answered this question.

69. 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.

14 out of 188 respondents answered this question.

Chapter 8 - Antimicrobial resistance

70. 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?

153 out of 188 respondents answered this question.

- 99 of the respondents agreed.
- 22 of the respondents disagreed.
- 32 of the respondents were neutral.

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

149 out of 188 respondents answered this question.

- 99 of the respondents agreed.
- 11 of the respondents disagreed.
- 39 of the respondents were neutral.

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

146 out of 188 respondents answered this question.

- 69 of the respondents agreed.
- 21 of the respondents disagreed.
- 56 of the respondents were neutral.

Chapter 9 - Fees

73. 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 or your business or wider aspects.

53 out of 188 respondents answered this question.

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

32 out of 188 respondents answered this question.