The Veterinary Medicines Regulations (Amendment) 2023

Lead department	Veterinary Medicines Directorate
Summary of proposal	To make 259 changes to the Veterinary Medicines Regulations 2013 (VMR). This includes clarification of existing provisions, introducing new regulations, removing unnecessary regulations and making changes to the fees.
Submission type	De Minimis Assessment (DMA) – 5th October 2023
Legislation type	Secondary legislation
Implementation date	TBC
Policy stage	Final
RPC reference	RPC-DEFRA-VMD-5257(2)
Opinion type	Formal
Date of issue	16th November 2023

RPC opinion

Rating[1]	RPC opinion
Fit for purpose	It should be noted that the DMA was submitted voluntarily by the Department and provides a relatively detailed assessment of impacts, which is not expected for DMAs; the Department should therefore be commended for this. The RPC's comments in this opinion are proportionate to the assessment that was conducted – all comments should be viewed in this context. The IA's rationale for intervention presents the issues arising from the existing VMR; however, it could be expanded by explaining the consequences of these issues to industry. Whilst the IA has explored non-regulatory measures and deemed them inappropriate to address the problems under consideration, it could benefit from exploring a wider range of regulatory options. Despite not being required for DMAs, a SaMBA has been included with explanations for why exemptions would not be appropriate and potential mitigations against disproportionate impacts. The cost-benefit analysis is adequate but could benefit

[1] The RPC opinion rating is based only on the robustness of the EANDCB and quality of the SaMBA, as set out in the Better Regulation Framework. RPC ratings are fit for purpose or not fit for purpose.

	from making visible the calculations that underpin the monetised estimates. The IA has provided a comprehensive breakdown of direct and indirect costs and benefits, but some clarifications are required. Wider impacts could benefit from discussing trade and competition. The Department has committed to a post-implementation review (PIR) five-years after the changes come into force.

Business impact target assessment

	Department assessment	**RPC validated**
Classification	Non-qualifying regulatory provision (de minimis)	Non-qualifying regulatory provision (de minimis)
Equivalent annual net direct cost to business (EANDCB)	£2.5 million (final stage IA estimate)	*De minimis*
Business impact target (BIT) score	N/A	N/A
Business net present value	-£20.6 million	
Overall net present value	-£20.6 million	

RPC summary

Category	Quality[2]	RPC comments
EANDCB	**Green**	The IA presents a comprehensive breakdown of direct and indirect benefits and costs to different stakeholder groups. However, it could benefit from greater visibility of calculations that underpin such estimates.
Small and micro business assessment (SaMBA)	**Not required**	Whilst not required, the IA includes a detailed SaMBA, which is commendable. Mitigations and exemptions have been discussed.
Rationale and options	**Satisfactory**	An adequate rationale has been presented, which discusses the issues with the existing VMR; however, further discussion could be included on the consequences of this on key stakeholders. The IA explores the consequences of not intervening but could be improved by exploring a wider range of regulatory options. The IA could also benefit from discussing the extent to which the options considered address issues of compliance.
Cost-benefit analysis	**Satisfactory**	Whilst comprehensive quantification and transparency around areas of non-monetisation has been provided, the IA could benefit from making visible the calculations underpinning quantified estimates. The IA should also explain its rationale for the chosen parameters (90 and 110 per cent of the central estimates) for the sensitivity analysis.
Wider impacts	**Satisfactory**	The IA discusses the beneficial wider impacts of the regulatory amendments such as encouraging innovation, reducing the spread of antimicrobial resistance (AMR) and protecting animal welfare and human health. However, the IA should expand on its discussion of potential trade impacts and explore competition impacts.
Monitoring and evaluation plan	**Good**	The Department commits to a PIR five-years after the changes come into force and each successive five-year period following. The monitoring and evaluation plan (MEP) discusses the Department's intention to use ongoing stakeholder engagement and feedback to measure the effectiveness of the changes.

[2] The RPC quality ratings are used to indicate the quality and robustness of the evidence used to support different analytical areas. Please find the definitions of the RPC quality ratings here.

Summary of proposal

The VMR, as they apply in Great Britain (GB), set out the controls on the authorisation, production, supply, possession and administration of veterinary medicines and medicated feed in GB. The last major update to the VMR was in 2013, with the Government now seeking to update the regulatory regime to reflect advances and developments in the veterinary medicines sector.

Industry engagement has found that certain provisions in the VMR are ambiguous and unclear, which risks non-compliance in the form of inappropriate or irresponsible supply or use of veterinary medicines.

The Veterinary Medicines Directorate (VMD), which is the regulator of veterinary medicines in the United Kingdom (UK), is facing rising costs for providing its regulatory services and these costs can no longer be fully recovered under the fees in the current VMR.

The options under consideration are as follows:

- **Option 0 (Do Nothing) –** Continue with the VMR as they currently apply in GB. This is the baseline against which the other options are measured.
- **Option 1 (Implement changes to fees only) –** Make changes to the existing fees and fee structure in the VMR. The changes include amending fee structures to make them more transparent, removing redundant fees and amending or adding appropriate fees to ensure the costs of all regulatory services provided by the VMD are recovered.
- **Option 2 (Implement drafting changes only) –** Make changes to the VMR that do not have a regulatory impact but increase the clarity and transparency of the VMR.
- **Option 3 (Implement all changes to the VMR) –** This is the preferred option that will implement all changes to the VMR. The VMD intends to make 259 changes to the VMR including drafting and fee changes.

The proposed changes to the VMR covered in the IA are strictly concerned with the veterinary medicines sector in GB. As a result of the effect of the Windsor Framework, the legislation relating to veterinary medicines in NI is separate to that for GB.

The IA reports a total net present value of -£20.6 million (2019 prices and 2020 present value), over a ten-year appraisal period. The business net present value is estimated at -£20.6 million, with an equivalent annual net direct cost to business (EANDCB) of approximately £2.5 million.

EANDCB

Table 4 of the IA includes a comprehensive breakdown of costs and benefits for the preferred option (Option 3). The IA's classification of direct and indirect costs and benefits, along with those that are one-off and annual, appears correct for a DMA; however, clarifications on the directness of some identified impacts would be

beneficial, e.g., homeopathic remedies and local representatives (81) and pharmacovigilance (103) in Table 4. The IA also helpfully breaks down the impacted stakeholder groups by the different costs and benefits they will incur, across sections 7.0.1 to 7.0.4. Paragraph 126 states that the calculations resulting in the central estimates in Table 4, could be found in Annex A; however, Annex A does not contain any such calculations or data sources.

SaMBA

The IA includes a detailed SaMBA that explains why exemptions are not appropriate for small and micro businesses (paragraph 216) as the veterinary medicines sector is comprised largely of such businesses. Table 8 breaks down the composition of the affected industries by employee size bands, with the classification of business sizes being in line with RPC guidance. Table 7 sets out the different sectors impacted and ways to mitigate disproportionate impacts. Whilst this is good to see, the IA could explore additional mitigations to those set out in the IA of updating and producing guidance on the gov.uk website as businesses such as SMBs, may not always utilise such resources and such guidance will not necessarily reduce the large costs set to be incurred by vets for example.

Rationale and options

Rationale for intervention

The IA explains the issues under the existing VMR, e.g., breaches to the VMR due to stakeholders misunderstanding the requirements (paragraph 23) as a result of inconsistent wording and ambiguity of terms in the VMR. The IA notes that stakeholder engagement has also found that the existing VMR, which has not been updated since 2013, is creating market inefficiencies and is not enabling the utilisation of new technologies (paragraphs 29 and 30). In Annex A, the IA provides helpful discussions on the impacts of not intervening.

To strengthen the case for intervention, the IA would benefit from discussing the consequences of breaches to the VMR on industry. Furthermore, the IA should be clearer about how the existing VMR worsens the spread of antimicrobial resistance (AMR) as one of the points for intervention is a reduction in the development and spread of AMR (paragraph 33). The IA could also be improved by explaining how the change impact calculations in figures 1 and 2 are calculated.

Options

The IA has considered non-regulatory measures to address each of the problems under consideration (annex A) and has explained why non-regulatory options would not be appropriate. In addition, the IA discusses the suitability of each of the regulatory options in meeting the policy objectives set out. However, the IA could have considered a broader range of regulatory options as Options 1 and 2 make relatively trivial changes, whilst the preferred option includes every single regulatory

change. It would therefore be beneficial for the IA to discuss whether there is scope for breaking down the preferred option into sub-options.

The IA focuses heavily on the proposed changes to the VMR increasing clarity and transparency, which in turn is expected to increase compliance. As there is no guarantee that compliance would drastically increase due to revised wording in the VMR, it would be beneficial for the IA to include case studies or examples of where amending regulatory wording to reduce ambiguity, has positively impacted compliance with regulations.

Consultation feedback
The IA would benefit from detailing the number of stakeholders that were contacted during the consultation period, to enable better understanding of whether responses from 188 individuals and organisations (paragraph 50) was adequate. The IA should break down the types of stakeholders that have been labelled as 'Other' in Figure 3.

The IA has demonstrated how the consultation feedback has been used to inform the appropriateness of the proposed changes to the VMR (paragraph 51), with the Department taking action to withdraw and amend some of the proposed changes in response to the feedback. The IA should discuss how the disposal of unused medicated feed would take place, as it has withdrawn the requirement for feed businesses to have collection and discard systems in place.

Cost-benefit analysis

The IA has been transparent about where quantification of estimates has not been possible (e.g., the public health benefits of reducing the risk of AMR), with qualitative analysis being provided in these instances. The IA also states that costs are likely to be overestimates as a worst-case scenario approach was taken, for caution. The IA includes a sensitivity analysis to show how impacts on costs and benefits would vary with changing inputs. However, the IA should explain why 90 and 110 per cent of the central scenario estimate, were used for the low and high scenarios respectively; there is no rationale for this, therefore 90 and 110 per cent appear to be arbitrary proportions.

Whilst fee changes are not in scope of the assessment, the IA nonetheless includes an overview of familiarisation costs and wider impacts of fee changes.

Annex C and section 7.1 of the IA explain the data sources and assumptions that support the derivation of familiarisation costs. The calculations that underpin the familiarisation cost estimates should also be made explicit.

Wider impacts

The IA discusses the beneficial wider impacts of the regulatory amendments such as encouraging innovation, reducing the spread AMR and protecting animal welfare and human health. However, the IA should expand on its discussion of potential impacts

on trade to establish whether there could be additional costs for importing from the European market for example, which is mentioned in paragraph 237, or trade with Northern Ireland if they operate under a different system. The IA should also use the Competition and Market Authority's Competition Checklist to explore whether there could be any competition impacts.

Monitoring and evaluation plan

The IA's MEP discusses the Department's intention to actively seek views on the changes and their impacts, through regular stakeholder engagement. The Department commits to a PIR five-years after the regulations come into force and each successive five-year period following. The Department will use the ongoing feedback from stakeholder engagement to inform decision-making on the suitability of the regulations or whether they may need further amendments.

Regulatory Policy Committee

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