Veterinary Medicines Directorate

Department for Environment Food & Rural Affairs

Post Implementation Review of the Veterinary Medicines Regulations 2013

Report of Post Implementation Review (PIR) by the Veterinary Medicines Directorate (VMD)

Date: 09 August 2023

Contents

Introduction

The Veterinary Medicines Regulations 2013 (VMR) set out the UK controls on the manufacture, distribution, marketing, possession, prescription, dispensing and administration of veterinary medicines. Their aim is to ensure that veterinary medicines are safe to animals, the person administering or handling the medicine or the treated animal, the environment and, in the case of medicines for food producing animals, the consumer of produce from treated animals.

In 2005 an exercise was undertaken to consolidate all the controls on veterinary medicines that were previously set out in the Medicines Act 1968 and the associated Statutory Instruments.

Between 2005 and 2013, the consolidated regulations were revoked and remade regularly to incorporate necessary changes to the legislation, both clarifying existing policy and adding new provisions, for example to ensure that statutory fees were kept up-to-date and to maintain legislative transparency.

The VMR transposed the requirements of Directives 2001/82/EC and 90/167/EEC (as amended) and implemented other relevant EU legislation on veterinary medicines and medicated feed.

Regulation 46 of the VMR requires the Secretary of State to carry out a review of the VMR and set out the conclusions in a published report.

The purpose of the review is to assess the effectiveness of the regulations, to evaluate the extent to which the regulation have achieved their original objectives, if the objectives are still valid, if the regulations are still required and remain the best option for achieving those objectives, and if the regulations can be improved to reduce the burden on businesses.

This report provides a summary of the Post Implementation Review (PIR) carried out by the Veterinary Medicines Directorate (VMD), acting on behalf of the Secretary of State, including an analysis of the evidence collected.

Objectives of the Regulations

The policy objective of the VMR is to ensure that veterinary medicines are safe to animals, the person administering or handling the medicine or the treated animal, the environment and, in the case of medicines for food producing animals, the consumer of produce from treated animals. The intended effect of replacing the previous veterinary medicines regulations was to produce updated and fit-for-purpose legislation that is meaningful and simple to use for both stakeholders and the regulators.

Scope of the PIR

Regulation 46 of the VMR requires the Secretary of State to carry out a review of the regulations (other than the fees provisions) within five years of their entry into force. The conclusions of that review must be published in a report, detailing the objectives of the VMR 2013, the extent to which those objectives have been achieved, whether they remain

appropriate and, if so, whether they could be achieved with less regulation. This document represents that report.

Analysis

This section covers the summary of the PIR of the VMR. The PIR has been informed using evidence from engagement with internal and external stakeholders by the VMD over the years. This includes regular engagement with other regulators and industry representative bodies; engagement with other government departments; information from our inspectors out in the field (who inspect manufacturers, retailers, vet practices, etc.); as well as our previous involvement in the negotiations and drafting of the changes in EU law on veterinary medicines and medicated feed.

The PIR addressed the following overarching research questions:

1. Have the VMR 2013 successfully achieved their objectives?
2. Do the VMR 2013 objectives remain appropriate?
3. Could the VMR 2013 objectives be achieved with a system that imposes less regulation?

What the VMR cover

Part 1 – Introduction

Part 1 of the VMR covers regulation 1 to 3. It includes the scope of the regulations as well as the definition of “veterinary medicinal products” and other terms used throughout the legislation.

Part 2 – Authorised veterinary medicinal products

Part 2 of the VMR on authorised veterinary medicines products covers regulation 4 to 16. It includes regulations on placing a veterinary medicinal product on the market; manufacture of veterinary medicinal products; marketing of products not in accordance with a marketing authorisation; classification, supply and possession of the products; administration of the products; importation of authorised veterinary medicinal products; advertising the products; advertising of prescription products and products containing psychotropic drugs or narcotics; wholesale dealing; feedingstuffs; exemptions; and fees.

Part 3 – Records

Part 3 of the VMR on records covers regulation 17 to 24. It includes regulations on the records that must be kept in relation to the acquisition and administration of veterinary medicinal products for food producing animals; the records that must be kept by manufacturers and wholesalers of veterinary medicinal products; as well as records of the receipt or supply of prescription products.

Part 4 – Unauthorised veterinary medicinal products

Part 4 of the VMR on unauthorised veterinary medicinal products covers regulation 25 to 27. It includes regulations on the importation, possession and supply of unauthorised veterinary medicinal products.

Part 5 – Miscellaneous provisions, enforcement and offences

Part 5 of the VMR on miscellaneous provisions, enforcement and offences covers regulation 28 to 47. It includes regulations on the Veterinary Products Committee; appeals; exports; time limits; appointment of inspectors; inspection powers; offences; penalties; review of the VMR; and revocations.

Schedules

There are also 7 Schedules to the VMR, which provide the detail on regulation of marketing authorisations; the manufacture of veterinary medicines products; classification and supply, wholesale dealers and sheep dip; administration of veterinary medicinal products outside the terms of a marketing authorisation; medicated feeding stuffs and specified feed additives; exemptions for small pet animals; and fees.

Have the policy objectives been successfully achieved?

The main objective of the VMR is to ensure that veterinary medicines are safe to animals, the person administering or handling the medicine or the treated animal, the environment and, in the case of medicines for food producing animals, the consumer of produce from treated animals. The intended effect of replacing the previous veterinary medicines regulations was to ensure that the existing regulatory regime was updated in a way that is meaningful and simple to use for both stakeholders and regulators. Since the coming into force of the VMR 2013, there have been significant developments and technical advances in the veterinary medicines industry that have impacted the continued successful achievement of those objectives.

Issues that hinder policy objectives being successfully achieved

Several main issues were identified that hinder the continued successful achievement of the policy objectives through the current VMR.

Advancement in Technology

It has been identified that the VMR do not fully support or allow for innovation in response to advancements in technology, such as the use of QR codes and online retail, and do not provide enough incentive to drive the development and marketing of new veterinary medicines. For example, with technological development, stem cell therapies that were once specifically for equines, have now become available for other animal species. Updates to the VMR could improve the regulation of manufacturers of veterinary medicinal products and assist in reducing the costs and burden for labelling, whilst still ensuring that the available information is appropriate for the safe and effective use of veterinary medicines. Updates could also help to further support a thriving industry marketing both innovative and generic products.

Lack of clarity in regulation

There have been several concerns raised around the lack of clarity to some of the terms, requirements and powers used in the VMR. This is reflected by the 1,390 queries sent to the VMD in the 2022/2023 financial year.[1] The lack of clarity comes from terms used within the VMR that have no legal definition, inconsistent wording for areas that expect the same (or similar) requirements, and from specific requirements, such as for prescriptions, not being clearly stated. This opens an avenue for different interpretation being given to these unclear terms that could lead to the inappropriate supply or use of veterinary medicines.

In the 2022/23 financial year, there were 968 enforcement cases relating to breaches of the VMR, which includes breaches caused by stakeholders misunderstanding their requirements, such as for advertising unauthorised and authorised medicines.[2]

Amending the VMR to adjust or clarify certain provisions will enable these requirements, terms and powers to be more transparent and increase compliance amongst stakeholders with the VMR.

Antimicrobial Resistance Risk

Antimicrobial Resistance (AMR) poses a risk to animal and public health as it reduces the effectiveness of antibiotics. The current VMR do not specifically address or provide assurance on the safe and appropriate use of antibiotics to reduce the risk of development and spread of AMR. It is noted that 1.27 million global deaths are attributed to AMR, with a further 4.95 million associated deaths every year.[3] In the UK alone, it is estimated that 12,000 people die each year from infections caused by resistant bacteria.[4] This highlights the need for strengthening of our legislation with respect of antimicrobial prescribing and use in animals which will reflect the UK's national action plan for antimicrobial resistance.[5]

Increasing regulatory oversight

There are currently no legal requirements to report an adverse event in the environment, it is however done on a voluntary basis. The total number of adverse event reports received by the VMD during the 2021/22 financial year covered 9,133 cases[6]. The number of animal adverse event reports during that period was 9,010. These include animal adverse reactions, suspected lack of efficacy cases, environmental cases and residue incidents. The number of human adverse event reports was 123[7].

It has been identified that there is potential to increase regulatory oversight so the VMD can maximise its ability to inform and take targeted and appropriate measures when there is a

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[1] Postmaster Figures, VMD, 2023.
[2] Enforcement Figures, VMD, 2023.
[3] "Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis", Antimicrobial Resistance Collaborative, The Lancet, 2022.
[4] "Save Our Antibiotics Appeal", Antibiotic Research UK, antibioticresearch.org.uk, 2017.
[5] "UK 5-year action plan for antimicrobial resistance 2019 to 2024", https://www.gov.uk/government/publications/uk-5-year-action-plan-for-antimicrobial-resistance-2019-to-2024, 2019
[6] Pharmacovigilance Reporting Data, VMD, 2023.
[7] Pharmacovigilance Reporting Data, VMD, 2023.

safety or efficacy concern related to a veterinary medicine or active substance, to protect animal health, public health and the environment. At the moment the VMD does not have complete and accurate information on the formulations marketed by manufacturers of products to be used under the cascade or marketed under the exemptions for small pet animals. Having such knowledge would also improve our ability to mitigate supply shortages as we would be able to identify those who can supply certain active substances.

Regulatory burden

Prior to the UK leaving the EU, the regulations set out in the VMR were harmonised with EU member states making trade and regulation adherence for stakeholders in the veterinary pharmaceutical industry easier. The majority of the veterinary pharmaceutical industry is set up to service the region of Europe, including the UK. Since the UK left the EU, the veterinary pharmaceutical industry now has to comply with different regulatory frameworks. The EU law on veterinary medicines and medicated feed was changed in January 2022. Whilst the UK was still a member of the EU, the UK contributed to, negotiated for and supported many of the changes in the EU legislation, with the aim of reducing regulatory burden. These changes did not come into force in Great Britain as we left the EU before they applied.

Further potential to reduce regulatory burden was identified. For example, the VMR contain several requirements that are no longer needed or justified and cause unnecessary regulatory burden for our stakeholders. Areas identified include the need for renewals of marketing authorisations, or adverse event reporting by retailers for veterinary medicines marketed under the exemptions for small pet animals.

For renewals, the pharmaceutical industry has identified that compliance with renewal requirements constitutes 13% of their total administrative burden[8].

Variations between countries on the required content of packaging and labelling are a major burden for industry. They have identified that compliance with labelling rules constitutes the largest part of their total administrative burden (34% of the total administrative burden)[9].

Reducing these regulatory burdens will assist in reducing marketing authorisation holders' costs and assist in their continued investment in new and innovative veterinary medicines as well as increase the availability of veterinary medicines.

[8] *"Commission Staff Working Document Impact Assessment on the Proposal for a Regulation of The European Parliament and of the Council on Veterinary Medicinal Products", European Commission, eur-lex.europa.eu, 2014, pp. 86-87.*

[9] *"Commission Staff Working Document Impact Assessment on the Proposal for a Regulation of The European Parliament and of the Council on Veterinary Medicinal Products", European Commission, eur-lex.europa.eu, 2014, pp. 86-87.*

Do the policy objectives remain appropriate?

From evidence collated, the policy objectives remain appropriate though an amendment of the VMR is necessary for the objectives to continue to be successfully achieved. The VMD conducted a public consultation from 2 February 2023 to 31 March 2023 seeking stakeholders' views on proposed changes to the VMR. The aim of the proposed changes is to:

- Reflect developments and technical advances in the veterinary medicines sector through the modernisation of the VMR,
- Reduce regulatory burden where possible,
- Encourage the submission and marketing of new and innovative products, to support the aim of increasing medicines availability,
- Reduce the development and spread of antimicrobial resistance, and
- Improve prescription and supply of veterinary medicines.

The summary of response and government response to the public consultation is intended to be published by September 2023 with the intention to lay the Statutory Instrument amending the VMR before Parliament subsequently.

Are there opportunities in imposing less regulations?

The VMD, through its regular review and engagement with stakeholders, has identified areas for reducing regulatory burdens where appropriate and tightening controls, which is intended to result in a balanced and proportionate regulatory system. Specific areas identified so far to reduce regulatory burdens on the veterinary pharmaceutical industries are around the need for renewals of marketing authorisations and adverse event reporting by retailers for veterinary medicines marketed under the exemptions for small pet animals. However, larger reduction in regulatory burden will result from intended changes to the VMR to make provisions similar to recent changes in the EU law on veterinary medicines and medicated feed, where we support from a UK policy perspective.

Conclusion and next steps

Overall, the PIR shows that the Regulations when updated in 2013 were indeed fit-for-purpose. The adjustments made to the existing powers of enforcement when the VMR came into force are very much relevant and still fit-for-purpose in the protection of animal health and welfare.

However, given the gap in years since there was an update to the VMR, the UK having left the EU and technical advancements and developments in the veterinary medicines industry, the VMR no longer meet the objectives as effectively as they could and require updating. Such an update will create regulations that reflect the developments and technical advancements in the veterinary medicines industry and reduce regulatory burden to stakeholders, which ultimately will help increase compliance. Work is currently on going to update the regulations in this regard, as well as to future-proof the regulatory regime so far as possible.

Title: The Veterinary Medicines Regulations 2013	Post Implementation Review
PIR No: N/A	**Date: 04/12/2023**
Original IA/RPC No: Defra 1442	**Type of regulation: EU**
Lead department or agency: Veterinary Medicines Directorate	**Type of review: Statutory**
Other departments or agencies: N/A	**Date measure came into force: 01/10/2013**
Contact for enquiries: legislation@vmd.gov.uk	**Recommendation: Amend**
	RPC Opinion: N/A

1. What were the policy objectives of the measure? (Maximum 5 lines)

The main objective of the VMR is to ensure that veterinary medicines are safe to animals, the person administering or handling the medicine or the treated animal, the environment and, in the case of medicines for food producing animals, the consumer of produce from treated animals. The intended effect of replacing the previous veterinary medicines regulations was to produce updated and fit-for-purpose legislation that is simple to use for both stakeholders and the regulators. Changes made in 2013 were as follows:

- Reductions to the existing fees for certain types of applications and inspections to avoid over recovery of costs of the regulatory services the VMD provides;
- Increase to the existing fees arising from additional responsibilities required by European legislation or in order to ensure full cost recovery of the regulatory services the VMD provides;
- Minor adjustments to inspectors' enforcement powers clarifying existing powers.

2. What evidence has informed the PIR? (Maximum 5 lines)

Evidence used to inform this PIR comes from data and information collated on the VMR over the years. This includes data and information from meetings with internal and external stakeholders and reviews done by staff in the VMD. The provision of fees review has not been included as per regulation 46(1)(a) of the VMR.

3. To what extent have the policy objectives been achieved? (Maximum 5 lines)

From the evidence collated, it is apparent that the policy objectives were successfully achieved but as time has progressed, some of the current regulations could be improved. There have been major advancements in the veterinary medicines industry which are not currently reflected in the VMR. This is mainly due to no significant changes being made to the VMR since 2013. The changes in the EU legislation on veterinary medicines that we negotiated for and supported when we were a member of the EU, are not currently incorporated in the VMR and stakeholders are now seeking clarity due to some industries working across different regulatory regimes (GB, NI and EU).

Sign-off for Post Implementation Review: Chief economist/Head of Analysis and Minister

I have read the PIR and I am satisfied that it represents a fair and proportionate assessment of the impact of the measure.

Signed: Ellie Simonsen (Social Researcher) Date: *20/07/2023*
Signed: Rachel O'Brien (G7 Economist) Date: *26/07/2023*

Signed: Richard Benyon. Date: 14/11/2023

Further information sheet

Please provide additional evidence in subsequent sheets, as required.

4. What were the original assumptions? (Maximum 5 lines)

The regulations setting out the regulatory regime for veterinary medicines were previously revoked and remade on a regular basis to reflect developments in the veterinary sector so the legislation remained fit-for-purpose and meaningful to stakeholders. An example of such development is that when the VMR 2013 were made, most retailers operated in physical premises, whereas now online retail has a strong place in the industry. The VMR transposed EU Directives and implemented relevant EU legislation – we have now left the EU. Our costs for the regulatory services we provide have gone up and the fees set in the VMR are no longer sufficient to recover our costs.

5. Were there any unintended consequences? (Maximum 5 lines)

From the evidence collated, there have been no main unintended consequences identified. However, the review has identified areas to reduce regulatory burden. This includes additional burden on those in the veterinary medicines industry servicing the European region and therefore having to abide to two regulatory regimes.

6. Has the evidence identified any opportunities for reducing the burden on business? (Maximum 5 lines)

The review identified that there is potential to reduce regulatory burden. Areas identified to reduce regulatory burden on the veterinary pharmaceutical industries are for example the need for renewals of marketing authorisations, or adverse event reporting by retailers for veterinary medicines marketed under the exemptions for small pet animals. Moreover, amending the VMR to make provisions corresponding to certain changes in the EU legislation on veterinary medicines will reduce regulatory burden for those companies servicing the region of Europe and as such now having to comply with different regulatory regimes.

7. How does the UK approach compare with the implementation of similar measures internationally, including how EU member states implemented EU requirements that are comparable or now form part of retained EU law, or how other countries have implemented international agreements? (Maximum 5 lines)

In 2013, the VMR amendments were in line with the EU law and requirements, transposing the Directives 2001/82/EC and 90/167/EEC. The EU has since made changes to its legislation on veterinary medicines and medicated feed, with the intention to reduce regulatory burden where possible and tackle the risk of antimicrobial resistance. These changes, many of which we negotiated and supported when we were a member of the EU, were adopted in 2019 but only applied from January 2022, and are therefore not part of retained EU law.
The VMR is part of retained EU law and the intention is for it to be revised and amended to reflect developments and technical advances in the veterinary medicines industry, maintaining our market as an attractive place to develop, manufacture and market new and existing medicines.

We are the Department for Environment, Food and Rural Affairs. We're responsible for improving and protecting the environment, growing the green economy 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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