EXPLANATORY MEMORANDUM TO

THE VETERINARY MEDICINES (AMENDMENT ETC.) REGULATIONS 2024

2024 No. 567

1. Introduction

1.1 This explanatory memorandum has been prepared by the Veterinary Medicines Directorate ("VMD"), an executive agency of the Department for Environment, Food and Rural Affairs ("Defra"), and is laid before Parliament by Command of His Majesty.

2. Purpose of the instrument

2.1 The purpose of the Veterinary Medicines (Amendment etc.) Regulations 2024 ("instrument") is to ensure that the legislative regime for veterinary medicines and medicated feed is fit for purpose to protect animal health, public health and the environment by assuring the quality, safety and efficacy of veterinary medicines. This will be achieved by amending the legislative regime set out in the Veterinary Medicines Regulations 2013 (S.I. 2013/2033, as amended) ("VMR").

2.2 This instrument modernises the VMR by reflecting developments and technical advances in the veterinary medicines sectors, amends requirements to improve prescription and supply of veterinary medicines, introduces changes to encourage the submission of applications for and marketing of new and innovative veterinary medicines, and introduces measures to help reduce the risk of development and spread of antibiotic resistance. Moreover, this instrument updates the fees and fee structure which cover the regulatory services provided by the VMD, thus ensuring that the VMD can recover its costs for those services in line with HM Treasury's guidance 'Managing Public Money'.

3. Matters of special interest to Parliament

3.1 None.

4. Extent and Territorial Application

4.1 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is England and Wales and Scotland.

4.2 The territorial application of this instrument (that is, where the instrument produces a practical effect) is England and Wales and Scotland.

5. European Convention on Human Rights

5.1 The Minister for Biosecurity, Animal Health & Welfare, Lord Douglas-Miller, has made the following statement regarding Human Rights:

"In my view the provisions of the Veterinary Medicines (Amendment etc.) Regulations 2024 are compatible with the Convention rights."

6. Legislative Context

6.1 This instrument uses the powers under Part 3 of the Medicines and Medical Devices Act 2021 ("the Act") to amend and supplement the VMR. This is the first use of the Act in respect of veterinary medicines and medicated feed.

6.2 The VMR were made under section 2(2) of the European Communities Act 1972, transposing requirements under EU law, and set out the controls on the marketing, manufacture, supply, possession and use of veterinary medicines and medicated feed. These controls are required to protect the safety of animals, people handling the medicines and treated animals, consumers of produce from treated animals and the environment.

6.3 The VMR as originally made extended to the United Kingdom. However, under the Windsor Framework, EU law on veterinary medicines and medicated feed applies in respect of Northern Ireland. Accordingly, changes were made to the VMR in the following EU Exit SIs which applied in Great Britain but not in Northern Ireland:

- S.I. 2019/797 (as amended by S.I. 2020/1461)
- S.I. 2019/865
- S.I. 2020/1461.

6.4 Separate EU Exit SI amendments were made to the VMR which applied in Northern Ireland but not in Great Britain by S.R. 2020 No. 353.

6.5 In keeping with the distinction above, this instrument amends the VMR as they apply in Great Britain only.

6.6 Part 11 of this instrument contains a consequential amendment to retained direct EU legislation Commission Regulation (EC) No 1234/2008. That Commission Regulation, which has already been revoked in respect of medicinal products for human use (subject to transitional provisions) by S.I. 2019/775, is revoked in respect of veterinary medicinal products as it is superseded by provisions made in this instrument in respect of variations to the terms of marketing authorisations.

7. Policy background

What is being done and why?

7.1 Veterinary medicines are highly regulated goods to protect animals, users, consumers of produce from treated animals, and the environment. The VMR set out how medicines for animals must be marketed, manufactured, supplied and used. This instrument updates the VMR, including its seven Schedules, to reflect changes and technical advances in industry, as well as to introduce measures to help tackle antimicrobial resistance by increasing restrictions on use of antibiotics and antibiotics administered via feed and support a culture change which embeds sustainable reduction of antibiotic use in animals. It also updates the fees charged to industry by the regulator (the VMD) to meet its obligations as a cost-recovery agency (as required by HM Treasury). More than 200 amendments are made to the VMR, which include drafting changes, regulatory changes and fees changes. Here, we highlight the major changes.

7.2 The regulations are amended to require vets to provide owners of food-producing animals with records as soon as reasonably practical after administering a medicine to a food-producing animal, so that the owner is aware of the required withdrawal

periods (the length of time that must lapse between the final administration of the medicine and the point the animal can be slaughtered to enter the food chain or when produce is taken).

7.3 The instrument introduces a power for the Secretary of State to require a marketing authorisation holder, manufacturer, wholesale dealer, keeper of food-producing animals, feed mill or vet to provide information on the sales and usage of antibiotics.

7.4 Amendments enhance the powers of an inspector to seize items if they have reasonable grounds to suspect that a breach of these regulations has occurred in relation to, or by means of, that item, and for inspectors to order an immediate stop to activities if these are putting human or animal health or the environment at serious risk.

7.5 The rules on advertising veterinary medicines are tightened and clarified, including clarification that medicines can only be advertised if they are currently authorised to be marketed, or subject to the exemption for small pet animals (under which certain medicines for guinea pigs, cage birds and other small pets do not require a marketing authorisation).

7.6 The instrument updates the provisions on the marketing of medicines, included in Schedule 1 to the VMR. Amendments include:

(a) amending the requirements that the applicant needs to fulfil when submitting a marketing authorisation application, to facilitate the submission of one dossier to the two territories and the joint labelling of products by marketing authorisation holders across the UK.

(b) requiring additional information with an application for products that contain antimicrobials as part of plans to reduce the risk of development and spread of antimicrobial resistance.

(c) requiring additional information for an application for generic medicines to explain differences from the reference product.

(d) amending some of the data protection periods for medicines to encourage the submission of applications for and marketing of new and innovative medicines, to support the aim of increasing medicines availability.

(e) removing the requirement to renew a marketing authorisation after five years, to reduce unnecessary regulatory burden.

(f) amending the Summary of Product Characteristics, packaging and labelling requirements on medicines to increase alignment between requirements for Great Britain and Northern Ireland where beneficial, making it easier for companies to use UK-wide packaging.

(g) introducing more streamlined application and assessment procedures for applications for variations to marketing authorisations.

(h) requiring marketing authorisation holders to conduct and submit annual benefit- risk reports on authorised medicines and allowing the regulator to inspect marketing authorisation holders' premises to confirm compliance with the VMR.

(i) clarifying our requirements for registration of homeopathic remedies.

7.7 Amendments to Schedule 2 to the VMR, on the manufacturing of veterinary medicines, include the following:

(a) inserting into legislation established practice on manufacturing authorisations and requirements for Good Manufacturing Practice certificates for non-UK manufacturing sites.

(b) requiring manufacturers to record more detail on the medicines they manufacture, to improve traceability.

(c) amending the requirements for holders of specific manufacturing authorisations (for blood banks, stem cell centres, autogenous vaccines, medicines for use under the cascade) to ensure that the rules are consistent.

(d) requiring manufacturers, importers and distributors of active substances (the ingredients responsible for the activity of a medicine) to register with the regulator to improve regulatory oversight. This allows us to take appropriate measures when there is a safety concern or supply shortage.

(e) strengthening the rules for medicines that are made to-order for use under the cascade, so that they may not be manufactured when the product is the pharmaceutical equivalent of an authorised medicine, unless there is a confirmed supply shortage of that authorised medicine.

(f) extending the authorisation and inspection requirements for equine stem cell centres to bring all stem cell centres for non-food-producing animal species under regulatory oversight.

7.8 This instrument amends Schedule 3 to the VMR which covers the classification, prescription and supply of veterinary medicines. This suite of changes is intended in part to reduce the risk of development and spread of antimicrobial resistance, but also to improve prescribing and supply of veterinary medicines to help ensure the safety and security of the supply chain of veterinary medicines, and the safe and responsible use of them. Amendments include:

(a) clarifying the scope of medicines that can only be prescribed and / or supplied by vets.

(b) introducing new requirements on wholesale dealers, including increased requirements on record-keeping and supply of information to improve the security of the supply chain.

(c) requiring wholesale dealers and retailers to investigate and document any discrepancies in stock levels following a required internal audit.

(d) requiring online retailers of veterinary medicines to register with the regulator.

(e) requiring prescribers (vets, pharmacists and Suitably Qualified Persons) issuing non-written prescriptions to record their rationale for issuing the prescription.

(f) allowing Suitably Qualified Persons (SQPs; people who have undergone training and registration which allows them to prescribe and supply certain categories of veterinary medicines) to not be physically present when the medicine is handed over by another competent person – provided the SQP has correctly prescribed and advised on the medicine and has authorised its supply in advance. This brings these requirements in line with those for vets.

(g) restricting the prescription of antibiotic veterinary medicines, subject to the professional obligations of a vet to ensure the health and welfare of animals under their care, to those situations where the antibiotic is not used routinely, not used to compensate for poor hygiene, inadequate animal husbandry or

poor farm management practices, and not used to promote growth or increase yield.

(h) prohibiting the prescription of antibiotics for prophylactic purposes (where medicines are given to an animal before it shows clinical signs of disease, to reduce the likelihood of future infection or disease spreading within the group) except in exceptional circumstances, where the risk of an infection or infectious disease is very high and the consequences are likely to be severe. When prescribing an antibiotic for prophylactic purposes to a group of animals, the rationale for prescribing the antibiotic must be clearly recorded by the prescribing vet and a management review must be carried out by the vet.

7.9 Schedule 4 to the VMR contains rules on the use of veterinary medicines under the cascade. The cascade is a mitigation that allows vets, where there is no suitable authorised veterinary medicine, to use unauthorised veterinary medicines or to use authorised veterinary medicines not in accordance with their marketing authorisation. Amendments include:

(a) clarifying when it is suitable to use a medicine under the cascade.

(b) making it an offence to promote or facilitate any (purported) use of the cascade not in accordance with Schedule 4 so as to ensure that suitable authorised medicines are used when available.

(c) amending the minimum withdrawal periods for medicines used under the cascade to ensure food safety whilst removing unnecessary barriers to treatment.

7.10 This instrument also makes amendments to Schedule 5 to the VMR, which governs medicated feed and specified feed additives. Medicated feed is one of the oral routes to administer veterinary medicines to animals and is generally used to treat diseases in large groups of food-producing animals, in particular pigs and poultry. Amendments to improve the system of prescription and supply include:

(a) strengthening the information that needs to be included in a prescription and on the labelling for medicated feed.

(b) allowing the manufacture of medicated feed in advance of receiving an anticipated prescription.

(c) requiring that cross-contamination with an active substance from previous use of the equipment or facilities into non-target feed is as low as reasonably achievable, to reduce the risk of inadvertently feeding medicated feed to non-target animals.

(d) amending the tolerance table (which sets out the permitted analytical tolerance when testing medicated feed for active substances incorporated into that feed) to support high quality of medicated feed with accurate levels of active substance.

(e) limiting the time between a prescription for an antibiotic being issued and the course of treatment starting to no more than five working days.

(f) restricting a medicated feedingstuffs prescription for food-producing animals to one course of treatment.

(g) restricting the prescription of medicated feed containing an antibiotic for prophylactic use in line with the requirements set out in 7.8(g).

7.11 Changes to Schedule 6 to the VMR, which covers the exemption for small pet animals, require that companies that manufacture medicines under the exemption register with the regulator and provide an annual list with the products they have marketed. This allows the regulator to take appropriate measures when there is a safety concern or supply shortage.

7.12 The regulator – the VMD – is a cost-recovery agency, which means it must recover the cost of providing its regulatory services. The fees charged to industry are set out in Schedule 7 to the VMR and have not been updated since 2013. The instrument will amend the Schedule, setting out new fees and fees structure to enable the regulator to charge the full cost of providing its regulatory services. The changes to fees are complex and include changes to fees for marketing authorisation applications, as well as changes to fees for the applications and inspections of manufacturers, wholesale dealers, feed business operators and SQP retailers. There are also changes to the fees for registration and inspections of veterinary practices. In some areas, the fees will increase and in others they will decrease, in line with the expected cost to the regulator in providing these services.

8. European Union Withdrawal and Future Relationship

8.1 This instrument does not relate to withdrawal from the European Union.

9. Consolidation

9.1 This instrument amends the VMR (and makes a consequential revocation). There are no plans to consolidate the legislation.

10. Consultation outcome

10.1 A public consultation entitled 'Review of the Veterinary Medicines Regulations 2013 – a public consultation' was launched on 2 February 2023 for a period of eight weeks, closing on 31 March 2023. In total, responses were received from 188 respondents, including individuals, organisations and groups, and representing a wide range of stakeholders including veterinary surgeons, marketing authorisation holders, feed business operators, campaign groups, trade associations and professional bodies.

10.2 The consultation comprised 74 questions, covering proposed changes to the whole breadth of the VMR: record keeping; advertising; powers of an inspector; marketing authorisations; manufacture; classification and supply, wholesale dealers and sheep dip; administration under the cascade; medicated feed; exemptions for small pet animals; antimicrobial resistance; and fees.

10.3 Overall, the proposals were supported by the respondents and the majority of the proposals have been implemented by this instrument. The main areas where we have decided to amend or not implement the proposed changes relate to:

- advertising of prescription-only medicines to professional keepers of animals: we have decided to not implement the proposed restriction to immunological products on the advertising of prescription-only medicines to professional keepers of animals. This ensures that such keepers continue to receive relevant information that helps them maintain the health and welfare of their animals.
- information for an application for marketing authorisation, labelling, packaging and the summary of product characteristics: in recognition of the fact that the pharmaceutical industry is set up to cover the region of Europe,

which includes the UK, and its regulatory requirements, we have amended the proposed changes to ensure that companies do not have to unnecessarily duplicate the dossier they have to submit for an application for marketing authorisation for the European region. The amended changes also reduce unnecessary costs associated with the product information and packaging. This will reduce burdens to the industry and help facilitate the continued availability of veterinary medicines.

- pharmacovigilance (post-authorisation monitoring): upon consideration of the feedback received and to reduce burden, we have added clarity, simplified the approach where possible and reduced the data requirements for reporting whilst maximising our ability to take appropriate action in the case of a safety concern.
- classification of prescription-only medicines: in response to the feedback received, we will not restrict immunological products to a classification through which it can only be prescribed by a vet – instead, these products will continue to be classified either for prescription by a vet, or for prescription by a vet/ pharmacist/ suitably qualified person. Immunological products are crucial in maintaining animal health and welfare and therefore need to be appropriately accessible, subject to the usual assessments and procedures.
- prescriptions by a vet: based on the consultation feedback we have decided not to make the proposed change to the wording of the assessment which a vet must perform of the animal under their care before prescribing a medicine that may only be prescribed by a vet. This will still achieve the intended outcome of appropriate assessment before prescribing but maintains the commonly understood terminology.
- collection and disposal system for expired or unused medicated feed: we understand from the consultation responses that the burden appears to be disproportionally high on feed business operators. Instead of implementing the proposed change, we have committed to review 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.
- prophylactic use of antibiotics: we have implemented the proposals in slightly amended form, mainly to provide clarity on the requirements.

10.4 A copy of the summary of responses and the government's response can be found at: https://consult.defra.gov.uk/vmd/review-of-the-veterinary-medicines-regulations-201/.

11. Guidance

11.1 The VMD has published a collection of guidance documents to support stakeholders in implementing and compliance with the requirements in the VMR, which can be found here: https://www.gov.uk/government/collections/veterinary-medicines-guidance-notes-vmgns. This collection covers authorisation requirements, post-authorisation requirements, manufacturing, supply, using medicines, import and export, and appeals.

11.2 We fully recognise that guidance accompanying the legislation will be instrumental to the interpretation and implementation of this instrument. The guidance documents will

be amended in line with the changes to the VMR and made available to stakeholders at or shortly after the making of this instrument.

12. Impact

12.1 The estimated impact on business, charities or voluntary bodies is an equivalent annual net direct cost to business of £2.5 million per year.

12.2 There is no, or no significant, impact on the public sector.

12.3 A full Impact Assessment has not been prepared for this instrument because an economic impact analysis identified the level of impact to be less than £5 million a year. Therefore, in line with government guidance, a De Minimis Assessment was undertaken in place of a full Impact Assessment.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

13.2 To minimise the impact of the requirements on small businesses (employing up to 50 people), the approach taken is to provide transitional provisions for new regulatory requirements, where appropriate, and clear guidance explaining the amended and new requirements for our stakeholder groups.

13.3 The basis for the final decision on what action to take to assist small businesses is that veterinary medicines are highly regulated goods and the majority of businesses regulated by the VMR are smaller businesses. It is not possible to exempt small businesses from the requirements. Further information is available in the 'Small and Micro Business' and 'Impact on Medium Businesses' sections in the De Minimis Assessment. We have consulted smaller businesses through the public consultation on the changes to the VMR and we will continue to work with our stakeholders to support their implementation of the changes.

14. Monitoring & review

14.1 The approach to monitoring of this legislation is for the VMD, as part of its standard processes for developing and implementing policy, to continue engagement with stakeholders (including those representing the pharmaceutical industry, supply chain and prescribers, as well as livestock sectors and those with an interest in antimicrobial resistance) to keep the impact of the policy under review, to review whether the policy objectives are met and to ensure the statutory basis continues to be fit for purpose.

14.2 This instrument does not include a statutory review clause but does contain an amendment to the review clause embedded in the VMR, which requires the next report to be published before 31st December 2028, and then a report each successive period of five years thereafter.

15. Contact

15.1 Marian Bos at the VMD, email: m.bos@vmd.gov.uk, can be contacted with any queries regarding the instrument.

15.2 Abigail Seager, Chief Executive Officer of the VMD, can confirm that this Explanatory Memorandum meets the required standard.

15.3 Lord Douglas-Miller, Minister for Biosecurity, Animal Health & Welfare at Defra, can confirm that this Explanatory Memorandum meets the required standard.