Title: The Veterinary Medicines (Amendment) Regulations 2023 **Date**: October 2022 **BRU No:** *Provided by the BRU on sign-off* **Lead department or agency:** Veterinary Medicines Directorate **Other departments or agencies:** N/A	De Minimis Assessment (DMA)
	Stage: Consultation
	Source of intervention: Domestic
	Type of measure: Secondary
Summary: Rationale and Options	**Contact for enquiries:** legislation@vmd.gov.uk

Total Net Present Value		

Rationale for intervention and intended outcomes

1. The Veterinary Medicines Regulations 2013 (VMR), as they apply in Great Britain (GB), set out the controls on the marketing, manufacture, supply, possession and administration of veterinary medicines and medicated feed in GB. These controls are required to protect the safety of animals, people handling the medicines, consumers of produce from treated animals and the environment.
2. The last major update to the VMR was in 2013. We want to modernise the VMR in order to make them more effective and for the regulatory regime to reflect advances and developments in the veterinary medicines sector, to continue to allow for safe, fair and competitive markets. Engagement with industry has identified that certain provisions in the VMR are not clear, which can result in non-compliance. This also causes costs for stakeholders trying to understand the requirements under the VMR and achieve compliance. In addition, the Veterinary Medicines Directorate (VMD) is facing increased costs for providing its regulatory services. Those costs can no longer be fully recovered under the fees set by the current VMR.
3. The proposed changes are intended to remove outdated and unnecessary regulatory burden; reflect developments and technical advances in the veterinary medicines sector; encourage the submission and marketing of new and innovative products to support the aim of increasing availability of medicines; reduce development and spread of antimicrobial resistance (AMR); improve prescription and supply of veterinary medicines; increase transparency to reduce unnecessary cost for industry and increase compliance; and enable full cost recovery for the regulatory services the VMD provides.

Describe the policy options considered

4. The options considered are to do nothing (Option 0), implement proposed changes to fees only (Option 1), or implement all proposed changes to the VMR (Option 2).
5. Implementing all proposed changes (Option 2) is the preferred option. This would allow for the VMD to achieve full cost recovery, as well as modernise the VMR, make them more effective and maintain the UK as an attractive place to develop and market veterinary medicines. The changes would remove unnecessary regulatory burden where possible and introduce further measures to help tackle antimicrobial resistance.
6. Veterinary medicines, like human medicines, are highly regulated goods and the proposed changes are necessary to continue to protect animal health, public health and the environment, including in regard to the food chain and AMR where stringent requirements are necessary. We are not proposing to add disproportionate or unnecessary burden where voluntary or industry-led initiatives have successfully improved standards.

Rationale for DMA rating

7. The total expected annual net direct cost to business is £93,000, based on a cost of £998,000 and savings of £905,000.
8. The estimates in this pre-consultation assessment are based on our initial assessments. Where we have been unable to provide quantifiable costs, we have provided a qualitative analysis. We will use the public consultation on the proposed changes to the VMR to address evidence gaps and provide an updated assessment.

Will the policy be reviewed? Yes	If applicable, set review date: two years from coming into force			
Are these organisations in scope?	**Micro** Yes	**Small** Yes	**Medium** Yes	**Large** Yes

Senior Policy Sign-off: Date:

Chief Economist Sign-off: Date:

Better Regulation Unit Sign-off: Date:

Contents

1.0 Policy Rationale

Policy background

9. The Veterinary Medicines Regulations 2013 (VMR) set out the controls on the authorisation, manufacture, supply, possession and administration of veterinary medicines and medicated feed.[1] These controls are required to protect the safety of animals, people handling the medicines, consumers of produce from treated animals and the environment.

10. The Veterinary Medicines Directorate (VMD) is the regulatory and policy lead body responsible for issues concerning the use and manufacture of veterinary medicines and medicated feed in the United Kingdom (UK). Veterinary medicines are a reserved matter in England, Scotland and Wales but certain aspects are devolved to Northern Ireland (NI) under the UK's devolution settlements.

11. The proposed changes to the VMR covered in this pre-consultation De Minimis Assessment (DMA) are strictly concerned with the veterinary medicines sector in Great Britain (GB). As a result of the effect of the Northern Ireland Protocol ('the Protocol'), the legislation relating to veterinary medicines in Northern Ireland (NI) is separate to that for GB.

12. The government is clear that the Protocol, in its current form, is not delivering on its core objectives and is seeking a new, consensual approach to implementing the Protocol, that ensures it operates in an enduring way.

13. The rules on veterinary medicines in NI are currently subject to a UK-EU agreed 'grace period', which expires on 31 December 2025. The UK government is seeking a long-term solution that safeguards the availability of veterinary medicines in NI. We would prefer to agree a negotiated outcome with the EU but if that is not possible then the Northern Ireland Protocol Bill, introduced to Parliament in June 2022, will be used to provide long-term certainty for industry. Once there is a long-term solution on the availability of veterinary medicines in NI, we will look to update the VMR as they have effect in NI accordingly.

14. The last major update to the VMR was in 2013 (apart from minor amendments in 2014 and after EU Exit).[2] Since then, the VMD has considered a number of changes to the VMR, to modernise them, make them more effective, reduce regulatory burden on industry where possible, and maintain the UK as an attractive place to develop and market veterinary medicines.

15. The VMD has discussed the upcoming revision to the VMR with industry bodies and veterinary professionals; many of their proposals are included in the proposed changes to the VMR. The VMD has also considered changes that have been or will be introduced to regulatory regimes in countries with equivalent regulatory standards for veterinary medicines.

16. The market for authorised veterinary medicines is worth an estimated £738m in annual UK sales.[3]

Problem under consideration

17. We want to modernise the VMR in order to make them more effective and for the regulatory regime to reflect advances and developments in the veterinary medicines sector, to continue to allow for safe, fair and competitive markets. An up-to-date regime would, for example, enable pharmaceutical companies to save costs on labelling,

[1] HM Government, The Veterinary Medicines Regulations 2013, legislation.gov.uk, 2013.

[2] HM Government, The Veterinary Medicines (Amendment) Regulations 2014, legislation.gov.uk, 2014, and e.g. HM Government, The Veterinary Medicines and Residues (Amendment) (EU Exit) Regulations 2020, legislation.gov.uk, 2020.

[3] National Office of Animal Health, Industry Facts and Figures, noah.co.uk, 2021.

incentivise innovative products being brought to the market, and allow prescribers to make efficient use of their time through remote prescribing, where appropriate.

18. The veterinary pharmaceutical industry is largely set up to service the region of Europe, including the UK. New legislation for veterinary medicines and medicated feed applies in the EU since January 2022. This means that these companies now have to comply with different regulatory frameworks. Whilst still a member of the EU, the UK negotiated and supported many of the changes in EU legislation, with the aim to reduce regulatory burden. Therefore, we propose to make corresponding provisions in the VMR where we agree from a UK policy perspective but to deviate where it is beneficial to the UK.

19. Businesses regulated by the VMR have indicated that certain provisions are not clear, which could result in non-compliance. This also may cause costs for stakeholders trying to understand the requirements under the VMR and achieve compliance. 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 could also lead to unfair advantages being given to businesses who interpret the VMR in ways that result in the inappropriate or irresponsible supply or use of veterinary medicines.

20. The VMR contain some requirements that are no longer needed or justified and cause unnecessary regulatory burden for our stakeholders. This includes for example the need for renewals of marketing authorisations, or adverse event reporting by retailers, usually smaller businesses, for veterinary medicines marketed under the small pet animal exemption.

21. In addition, the VMD faces increased costs for providing its regulatory services due to increased charging rates and overheads. Our costs have also increased as we are no longer part of the EU regulatory network. This means, for example, that we cannot share assessment workloads with other regulators. Our costs have risen despite the VMD putting in place cost saving measures, such as carrying out remote inspections where appropriate. The costs can no longer be fully recovered under the fees set in the current VMR.

Rationale for intervention

22. The proposed changes will modernise the VMR and make them more effective. They will help ensure that high quality, safe and effective veterinary medicines continue to be available.

23. Veterinary medicines, like human medicines, are highly regulated goods because of their effect on animals, as well as potential negative impacts on humans (including via the food chain) and the environment. The VMR help protect the food chain by ensuring veterinary medicines are not present at unsafe levels in the food we eat. Poor-quality or unsafe medicines can pose a risk to animal health, and inappropriate and irresponsible use of medicines can reduce their effectiveness, for example through the development of resistance to the active substance. This means non-regulatory options are not always a viable option.

24. The VMD has worked with industry to establish non-regulatory alternatives where possible. For example, we have collaborated with other government bodies, farmers and the veterinary profession to half antibiotic use in livestock over recent years, and the UK is now one of the lowest users of veterinary antibiotics in Europe. This achievement has been based on improving best practice and reducing unnecessary use and has been driven by the livestock sectors themselves. The measures we will implement in legislation will further support these principles and the sustainability of responsible use of veterinary antibiotics in this country. We have also established earned recognition schemes with industry auditors for manufacturers of medicated feedingstuffs to encourage high standards and increase inspection intervals for compliant companies.

25. The VMD is required to recover fees and charges its costs for the regulatory services it provides, according to the principles laid down in HM Treasury's 'Managing Public Money'.[4] As the VMD is facing increased costs, the current fees no longer allow the VMD to fully recover its costs for those services.

Policy objective

26. The proposed changes are intended to modernise the VMR and make them more effective. They will remove outdated or unnecessary regulatory burden; reflect developments and technical advances in the veterinary medicines sector; encourage the submission and marketing of new and innovative products to support the aim of increasing availability of medicines; reduce development and spread of AMR; and improve prescription and supply of veterinary medicines. They will ensure that appropriate regulation is in place to protect animal health, public health and the environment. They will also increase transparency to reduce unnecessary cost for industry and increase compliance.

27. Schedule 7 to the VMR, which sets the fees for the regulatory services provided by the VMD, will be amended to allow the VMD to achieve full cost recovery for those services. The changes proposed to fee structures will improve transparency and consistency.

Options considered

Non-regulatory options

28. Veterinary medicines, like human medicines, are highly regulated goods because of their effect on animals, as well as potential negative impacts on humans (including via the food chain) and the environment. The VMR help assure authorised veterinary medicines are of high quality, safe and efficacious to avoid risk to animal health, public health and the environment. The VMD has sought non-regulatory options, such as supporting industry bodies in creating voluntary schemes to use antibiotics responsibly, or to maintain high standards for feedingstuffs manufacturers.[5] Non-regulatory approaches are not always an option where risks can result in severe consequences.

Option 0 – Do Nothing

29. Continue with the VMR as they currently apply in GB. This is the baseline against which the other options are measured.

Option 1 - Implement proposed changes to fees only

30. 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.

31. Fee changes are not covered by this assessment under the statutory exemptions for the Better Regulations Framework.[6] We have included this option in the assessment as a comparison for the impact on other costs.

Option 2 – Implement all proposed changes to the VMR (preferred option)

32. Implement all proposed changes to the VMR. The VMD proposes to make around 200 changes to the VMR (see Annex A for a list of changes).

33. This includes clarification of existing provisions, adjusting or introducing new requirements, removing unnecessary requirements and making changes to the fees.

[4] HM Treasury, Managing Public Money, publishing.service.gov.uk, 2022.

[5] Veterinary Medicines Directorate, Multi-sectoral Collaboration Contributed to Halving the Sale of Antibiotics in the UK Livestock Industry, gov.uk, 2022.

[6] Department for Business, Energy and Industrial Strategy, The Better Regulation Framework, publishing.service.gov.uk, 2020.

2.0 Rationale for De Minimis Rating

34. The total expected annual net direct cost to business is £93,000, based on a cost of £998,000 and savings of £905,000.

35. The changes are not expected to result in significant impacts between sectors or result in significant gross impacts. The majority of businesses in the veterinary medicines sector are small or micro businesses; the changes have been proposed with consideration given to smaller businesses and there should be no disproportionate burdens for smaller businesses.

36. These changes are not expected to have significant wider impacts, although they will provide some unquantifiable benefits to society and help protect the environment.

37. There are no changes with novel or contentious elements that have been proposed.

3.0 Costs and Benefits

Option 0 – Do nothing

38. This is the baseline for all other options.

39. Continue with the VMR as they currently apply in GB. This means maintaining the existing regulations which are no longer fully reflecting the (international) advances and developments in the veterinary medicines sector and do not address the government's intention to strengthen national legislation to support the government's commitment to reducing unnecessary use of antibiotics in animals. This would also mean the VMD can no longer fully recover its costs for the regulatory services it provides.

40. This would result in two significantly different regulatory frameworks in place in GB and Northern Ireland (EU), where closer mirroring is preferred by the pharmaceutical industry, who are set up to service the region of Europe, including the UK. If we continue with the current VMR, the pharmaceutical industry faces additional burdens in meeting different legislative requirements.

Option 1 – Implement proposed changes to fees only

41. Make changes to the existing fees and fee structure in the VMR. This would allow full cost recovery for the VMD's regulatory services by making changes to reflect the cost of the services provided by the VMD. 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 are recovered.

42. This option does not address the issues identified with the current regulations and it would not address the government's intention to strengthen national legislation to support the government's commitment to reducing unnecessary use of antibiotics in animals.

43. This would again result in two significantly different regulatory frameworks in place in GB and NI (EU), where closer mirroring is preferred by the pharmaceutical industry, who are set up to service the region of Europe, including the UK. If we continue with the current VMR, the pharmaceutical industry faces additional burdens in meeting different legislative requirements.

44. Fee changes are not covered by this assessment under the statutory exemptions for the Better Regulations Framework.[7] We have included this option in the assessment as a comparison for the impact on other costs.

Option 2 – Implement all proposed changes to the VMR (preferred)

45. Implement all proposed changes to modernise the VMR and ensure the VMR continue to be fit-for-purpose, allowing the effective regulation of the veterinary medicines sector.

[7] Ibid.

46. The changes proposed under option 2 will ensure the VMR continue to protect animal health, human health and the environment, enabling the continued supply of medicines to GB and contributing to achieving the UK 20-year vision for antimicrobial resistance.[8]

47. This option would allow full cost recovery for the VMD's regulatory services by making changes to reflect the cost of the regulatory services provided by the VMD.

48. It would also reduce regulatory burden to the industry, where possible.

4.0 Summary of Costs and Benefits

49. The estimates in this pre-consultation assessment are based on our initial assessments. Where we have been unable to provide quantifiable costs, we have provided a qualitative analysis. We will use the public consultation on the proposed changes to the VMR to address the evidence gaps and provide an updated assessment. **All changes discussed in this document are the subject of public consultation and are therefore subject to change.**

50. For regulatory changes, we have considered the expected additional costs and likely savings to the different parts of the veterinary medicines sector (including the supply chain) which will be affected in different ways. Included in these estimates are the familiarisation costs and the costs for compliance with the VMR, which for example can include collating information and dealing with queries from the VMD. An overview of our estimated figures is included in Table 1 (below).

Table 1 – The expected annual net direct cost to business of regulatory changes on different sectors (includes familiarisation costs)

Type of Business/Area	Sector size	Costs (£)	Savings (£)	Overall (£)
Marketing authorisation holders	187	55,443	137,030	-81,587
Manufacturers	123	48,172	0	+48,172
Wholesale dealers	135	2,966	0	+2,966
Veterinary practices	2,245	486,210	402,228	+83,982
Veterinary pharmacists	10	242	0	+242
SQP retailers	675	17,141	365,700	-348,559
Feed business operators	761	16,787	0	+16,787
Professional keepers of animals	92,100	371,070	0	+371,070
Total	96,236	998,031	904,958	+93,073

51. For the quantified cost estimates, the sector sizes have been calculated based on the number of premises authorised under the VMR, number of veterinary practices registered with the RCVS and the number of farmers according to Statista.[9] Wage estimates are based on the Office for National Statistics Annual Survey for Hours and Earnings 2021,

[8] HM Government, Contained and controlled: the UK's 20-year vision for antimicrobial resistance, publishing.service.gov.uk, 2019.

[9] D. Clarke, Farmers in the UK 2022, Statista.com, 2022.

calculated with an uplift of 22% for non-wage costs as recommended by the Regulatory Policy Committee.[10]

52. It has not been possible to quantify all expected impacts of the proposed changes to the VMR due to a lack of data and information, for example where there are no published studies or reasonable equivalents to calculate the impacts, or where it is not possible to put a monetary value on the impact. Where we have not been able to quantify impacts, we have carried out a qualitative analysis to outline the expected areas that will be directly and indirectly impacted, as well as any wider impacts, such as protection of the environment or increased access to veterinary medicines. This is discussed in further detail in the specific costs and benefits sections below.

53. We will hold a formal public consultation on the proposed changes to the VMR to gain the views of interested parties on the proposals. As part of this consultation, we will test our assumptions and gather more evidence of the impacts of the changes we are proposing.

General changes and familiarisation costs

54. General changes will increase clarity and transparency of the VMR by providing specific definitions and explicitly stating the intention of requirements, which will increase compliance, maintain high standards and ensure the requirements for the veterinary pharmaceutical industry and veterinary professionals are consistent and fair. The majority of the proposed changes fall under this category.

55. This will include:

- confirming the requirements for veterinary medicines in GB
- clarifying or reiterating the requirements under the VMR
- clarifying the Secretary of State's powers where non-compliance is identified
- providing definitions for words and terms used within the VMR

56. All sectors will have familiarisation costs from interpreting the changes and understanding the impacts on their sector; we estimate the total cost for familiarisation will be £528,512.

57. These costs are based on the average earnings for the responsible officer in each sector and the time taken to familiarise with the relevant changes for that sector based on the Business Impact Target for Appraisal of Guidance multiplied by the number of premises. This guidance indicates that 50-100 technical words can be read per minute, and that only 50% of industry will read the guidance.[11] For industry and veterinary professionals, we have increased this to expect 65% to familiarise themselves with the changes. We have also added a 22% uplift to include non-wage costs as recommended by the Regulatory Policy Committee.[12]

58. Table 2 shows a summary of these costs across industry sectors, a more detailed breakdown of these costs is available in Annex B.

[10] Office for National Statistics, Employee earnings in the UK, ons.gov.uk, 2021, and Regulatory Policy Committee, Short guidance note_-_Implementation costs, publishing.service.gov.uk, 2019.

[11] Department for Business, Energy and Industrial Strategy, Business Impact Target: appraisal of guidance - assessments for regulator-issued guidance, publishing.service.gov.uk, 2017.

[12] Regulatory Policy Committee, Short guidance note_-_Implementation costs, publishing.service.gov.uk, 2019.

Table 2 – The expected familiarisation costs for the different sectors

Sector	Sector size	Familiarisation cost for the sector (£)
Marketing authorisation holders	187	18,402
Manufacturers	123	6,643
Wholesale dealers	135	2,966
Veterinary practices	2,245	55,887
Veterinary pharmacists	10	117
SQP retailers	675	8,694
Feed business operators	761	16,787
Professional keepers of animals	92,100	371,070
Total	96,236	480,566

Antimicrobial resistance (AMR)

59. We propose tighter requirements for antibiotic veterinary medicines throughout the VMR, which we expect to result in further safeguards to tackle AMR, protecting public health and animal health. Every year, 1.27 million global deaths are attributed to AMR, with a further 4.95 million associated deaths.[13] There is also a cumulative global cost of $100 trillion by 2050 if no action is taken.[14] In the UK, an estimated 12,000 people die each year from infections caused by resistant bacteria.[15] AMR requires a One Health approach, requiring a combined effort from human, animal and environmental sectors to tackle it.

60. When applying for a marketing authorisation (MA), the applicant will be required to submit data on the AMR risks associated with the medicine to animal health, public health and the environment, and the mitigations put in place to limit AMR development, which will help ensure the efficacy and safety of these products in future. We will ask for evidence of any costs in relation to these changes to the pharmaceutical industry in the public consultation.

61. We propose new provisions to allow the VMD to refuse MA applications if they include an antibiotic that is critical for human use, that is intended to be used as a performance enhancer or growth promotor, or if there is an unmitigated or unjustified risk of AMR development. The familiarisation costs for these changes are covered under the marketing authorisation holders' familiarisation costs.

62. The proposed changes will also prevent the routine prescribing of antibiotics for group prophylactic use and set a 5-day maximum validity for prescriptions for antibiotics.

63. A proposed provision would make it possible for the Secretary of State to require provision of usage data of antibiotics. The VMD has worked in partnership with food-producing animal sectors to develop, facilitate and coordinate antibiotic usage data collection systems on a voluntary basis. This provision would only be used where necessary and where data is not already available through the voluntary approach. We expect this will not incur any additional costs to those sectors already providing usage

[13] Antimicrobial Resistance Collaborative, Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis, The Lancet, 2022.

[14] HM Government, Tackling antimicrobial resistance 2019 to 2024, publishing.service.gov.uk, 2019.

[15] Antibiotic Research UK, Save Our Antibiotics Appeal, antibioticresearch.org.uk, 2017.

data, although we will be seeking evidence of the costs to other sectors not yet providing such data at consultation.

64. These proposed changes will increase the burden on applicants to supply information as part of an MA application for a new antibiotic veterinary medicine. Familiarisation costs are covered in Table 2, however we would be looking to find out more about the expected impacts at consultation. We do not expect that new staff, equipment or systems will be needed to conduct these assessments.

65. They will also cause a greater burden on prescribers, increasing the time and information required to prescribe antibiotics for prophylactic use. Table 3 shows the estimated cost for veterinary practices based on the impact of an additional hour a week needing to be spent on evaluating and justifying prescription of antibiotic veterinary medicines.

Table 3 – Expected cost for vets of prescription requirements for antibiotic medicines

Number of vets in large/farm animal practice[16]	Time required per week	Cost per hour (£)	Overall cost (£)	Overall cost (£), +22% non-wage costs
247	1 hours	25.67	329,705	402,240

66. However, these changes will prevent unnecessary prescription of antibiotics, for example where alternative medicines are available, and prevent the use of antibiotics as an alternative to good animal husbandry.[17] This will help to protect the efficacy of these products.

67. These changes will ensure the safe supply of antibiotics, as well as ensuring they are supplied and administered responsibly and effectively. This will reduce the risk of development and spread of AMR.

Marketing authorisations

68. The requirements for MA applications will be updated to remove regulatory burden where appropriate and allow for innovation, such as allowing pictograms and QR codes on product labelling, and to better reflect the requirements for novel therapies. The proposed changes will incentivise MA holders to continue to invest in new and innovative veterinary medicines and increase the availability of veterinary medicines in GB.

69. Applications will need to be submitted electronically, unless there is an emergency situation, and the data to be submitted will be outlined within the VMR; this will mean that applications are no longer submitted in paper format. This change should not incur any additional costs for industry as it does not change the data requirements, only the format in which they must be supplied. All MA applications are currently submitted electronically, so this change will have no impact on MA holders, however provides additional certainty that applications from new MA holders will be accessible for assessment and that there are no delays in the authorisation process.

70. The criteria for refusal of MA applications will be updated, including refusal of antibiotics reserved for human use, indicated for performance enhancement or growth promotion, or where a risk related to AMR has not been addressed. The familiarisation costs for these changes are covered under the MA holders' familiarisation costs. The requirement for the VMD to publish decisions will now include decisions to refuse, suspend, revoke and amend MAs.

71. The provision setting out distribution categories will be amended to clarify the categories of veterinary medicines that should only be available on veterinary prescription. This will ensure the necessary checks are in place for medicines that require veterinary

[16] Dilys Robinson, Megan Edwards, Bethany Mason, James Cockett, Kate Arnill. Graham and Alex Martin, The 2019 Survey of the Veterinary Profession, Institute for Employment Studies, 2019.

[17] Responsible Use of Medicines in Agriculture Alliance, Responsible Use of Vaccines and Vaccination in Farm Animal Production - General Guidance, ruma.org.uk.

assessment of the animal before prescription, and that medicines which do not need to be as strictly controlled are more readily available.

72. Data protection periods will be extended to encourage development of new veterinary medicines, particularly for antibiotics, medicines with a new active substance, medicines for bees and medicines which demonstrate a reduction in AMR. The protection period will be amended so certain new products are decoupled from the global MA so that they can also benefit from data protection periods, provided they come in separate packaging. Data protection periods are used to encourage innovation by rewarding marketing authorisation holders with a period of exclusivity during which time a generic version of their product cannot be placed on the market. The data protection period starts from when a product first receives authorisation, and currently lasts for 10 years (13 years for fish and bees). Extending data protection periods may incentivise continued investment in new and novel products for minor species (such as bees), therefore enhancing the attractiveness of the market to develop and supply veterinary medicines, thus increasing the availability of medicines and having significant indirect impacts.[18]

73. We will remove the requirement for renewal of MAs and registrations for homeopathic remedies, but we continue to monitor the safety of the product through improved pharmacovigilance requirements for information submitted by MA holders. The pharmaceutical industry has identified that compliance with renewal requirements constitutes 13% of their total administrative burden.[19] We estimate that the average renewal application for an MA will take approximately 15 hours for an individual MA holder. We have assumed that the person preparing the application and associated data requirements would be a research and development manager. We estimate an annual cost saving to industry of £137,030. MA holders will also save the cost of the renewal application fee of £1,360 per application. Table 4 shows the total savings across the sector.

Table 4 – Expected savings from Marketing Authorisation (MA) renewals

Average number of renewals per year	MA holder time for each renewal	Cost per hour	Overall savings (£)	Overall savings (£), +22% non-wage costs
240	15 hours	31.20	112,320	137,030

74. Labelling requirements will be updated to ensure that the necessary information is captured, whilst minimising the burden for industry and providing opportunities for dual labelling and other cost saving benefits. These changes will facilitate joint labelling and reduce the costs for companies because they will be able to combine labels for products marketed in multiple countries, although there will be initial direct costs for designing new labels. 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).[20]

75. Any risks associated with the reduction of information provided on the packaging and labelling would be offset by placing the information on the product leaflet and by making the information available through other sources (for example, through QR codes). This would result in initial costs for companies who choose to redesign their labels but could lead to reduced annual costs for labelling and printing. If the costs of packaging are reduced, this may encourage companies to apply for authorisations for medicines for minor species or conditions, therefore increasing the availability of such medicines.

[18] RCVS Research Subcommittee, Veterinary Research in the UK: A Snapshot, Royal College of Veterinary Surgeons, 2013.

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

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

76. The average cost for updating the packaging and labelling for products is £9,000 for each pack size authorised.[21] This includes the costs of redesigning the artwork, print runs and disposal of out-of-date packaging material. We will aim to gather more information on the total costs and savings of these changes at consultation.

77. Electronic Package Information Leaflets (EPILs) will be accepted as an alternative to physical package leaflets, where appropriate, and labelling will be able to use QR codes to link to this, although it will not replace the requirement to provide a physical package leaflet where necessary. This may have initial costs for redesigned labels but will allow industry to save significant printing costs overall and allow for easier dual labelling of products.

78. There will be changes to facilitate simultaneous submission for MA applications in collaboration with other global regulators. This will encourage applications in GB and expand markets for GB MA holders. This may also reduce costs for the pharmaceutical industry, as this change could result in reduced labelling costs across these countries, and single company project teams working simultaneously across multiple regulatory jurisdictions.

79. MA holders will be required to report supply shortages to the VMD. This will allow early consideration of the issue and implementation of possible mitigations within reasonable timeframes, reducing the impact to supply and risk to animal welfare. Some companies already provide this information to the VMD. Table 5 shows the estimated cost to industry for reporting supply shortages.

Table 5 – Cost of reporting supply shortages

Additional number of reports	MA holder time for each report	Cost per hour	Overall cost (£)	Overall cost (£), +22% non-wage costs
20	0.5 hours	31.20	312	381

80. MA holders will no longer be permitted to wholesale supply veterinary medicines unless they hold a wholesale dealer's authorisation (or hold a manufacturing authorisation). This change will ensure we have appropriate oversight of wholesale dealing activities in GB. M A holders will already have the appropriate staff and systems in place for wholesale dealing, therefore we estimate that the only additional costs will be the application and inspection costs for obtaining a wholesale dealer's authorisation, shown in Table 6 and Table 7.

Table 6 – Expected preparation cost for MA holders to apply for wholesale dealer's authorisations

Number of companies affected	MA holder inspection preparation time	Cost per hour	Overall cost (£)	Overall cost (£), +22% non-wage costs
20	10 hours	31.20	6,240	7,613

Table 7 – Expected application cost for MA holders to apply for wholesale dealer's authorisations

Number of companies affected	Application fee cost (£)	Inspection fee cost (£)	Overall cost (£)
20	344	1,177	30,420

[21] Data from a survey of MA holders on the contingency plans for EU Exit.

81. Homeopathic remedies will be restricted to oral or topical routes of administration and may not be biological homeopathic remedies. The holders of a homeopathic registration will also be able to use a local representative, we will not require the holder to be based in GB. These changes will result in reduced burden for registration holders and will contribute to the safety of homeopathic remedies and protect animal welfare.

Manufacturers

82. The proposed changes for manufacturers give the option for VMD inspectors to grant conditional manufacturing authorisations where appropriate. This change will have no cost impact on new or established manufacturers as it is already a regulatory requirement.

83. Importers of veterinary medicines from other countries will need to ensure, where applicable, that the manufacturer holds a certificate of good manufacturing practice (GMP), or an equivalent confirmation recognised by the Secretary of State. This will ensure that the overseas manufacturer has the competent staff and facilities to manufacture high-quality, safe and effective veterinary medicines for placing on the GB market. This does not change the current expectations on manufacturers, however should increase transparency for the veterinary medicines sector.

84. The key personnel required for a manufacturing authorisation (ManA) will be listed in the VMR. ManA holders must name a Qualified Person (QP), a person responsible for Quality Control (QC) and a Production Manager (PM) with either the qualifications or experience to fulfil the role. This will not incur any additional costs to industry as these roles are a current requirement of GMP. Holders of other manufacturing authorisations must be under the supervision of a person who has the required qualifications or experience to be approved by the Secretary of State, removing the requirement for this person to be a vet. This will make the requirements clearer and provide a greater pool of qualified personnel for the positions. This will also not incur any additional costs to industry as this role is a current requirement in the VMR.

85. A new provision is being introduced that will require registration of manufacturers, importers and distributors of active substances for veterinary use. Active substances are the raw ingredients used to make finished medicines and give the medicine its therapeutic effect. The registration will allow the VMD to ensure that active substances manufactured and used for veterinary medicines in GB are safe and of high-quality. Active substance manufacturers are already required to comply with the principles of GMP, therefore there will be no additional costs for new personnel, equipment or processes. The only cost is expected to be the cost of registering, which would be a basic administrative process. We will be looking to gain more evidence on the number of businesses impacted by this change and the costs associated with registration, provided in Table 8.

Table 8 – Expected cost of active ingredients manufacturer registration

Number of companies	Company time for registration	Cost per hour	Overall cost (£)	Overall cost (£), +22% non-wage costs
55	1 hour	30.94	1,702	2,076

86. New requirements will be introduced that ensure the prescribing cascade (a decision tree for vets to be used when a suitable authorised veterinary medicine is not available) is used appropriately and responsibly. For example, we propose to make it an offence to manufacture an (unauthorised) extemporaneous product that is pharmaceutically equivalent to an authorised product. The changes will also require manufacturers of extemporaneous products to provide the VMD with a list of the formulations which they have manufactured. This will result in a greater burden for these manufacturers, but the

information should be readily available. The information will ensure that the VMD has the details of manufacturers of active ingredients in the event of a safety concern or a veterinary medicine incident and who we can approach in the event of a supply issue with a critically required authorised medicine. The changes will contribute to the protection of animal health, public health and the environment. They will also ensure fair competition, where MA holders who applied for, and have been granted, MAs are not inappropriately competing against unauthorised products. The cost of the provision of this information is outlined in Table 9.

Table 9 – Expected cost for submission of extemporaneous products manufactured

Number of companies	Company time for provision of information	Cost per hour	Overall cost (£)	Overall cost (£), +22% non-wage costs
22	5 hours	30.94	3,403	4,152

87. Stem cell centre authorisations will be required for all non-food producing species, in addition to horses. This will lead to more burden on stem cell centres providing treatments for non-equine species as they will have to apply for an authorisation and have an inspection of their site, but it will provide necessary safeguards for the manufacture and use of stem cell treatments. The expected costs for these applications are shown in Table 10 and Table 11.

Table 10 – Expected preparation costs for Stem Cell Centre Authorisations

Number of companies affected	Authorisation holder inspection preparation time	Cost per hour	Overall cost (£)	Overall cost (£), +22% non-wage costs
10	10 hours	31.20	3,120	3,806

Table 11 – Expected application costs for Stem Cell Centre Authorisations

Number of companies affected	Application fee cost (£)	Inspection fee cost (£)	Overall cost (£)
10	762	2,142	29,040

Pharmacovigilance

88. The total number of adverse event reports received by the VMD during the 2021-22 financial year covered 9,133 cases. 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.

89. There are currently no legal requirements to report an adverse event in the environment. Pharmacovigilance requirements under the VMR will be extended from the reporting of adverse reactions (lack of efficacy or side-effects caused to humans or animals) to include all adverse events (such as adverse impacts on the environment).

90. There will be new requirements for MA holders to establish more robust pharmacovigilance systems and take more action in response to adverse events where necessary. The Secretary of State will be given the power to carry out inspections to ensure pharmacovigilance activity is being carried out correctly. This will result in familiarisation costs, covered in Table 2, as well as direct costs for setting up new systems. However, we believe streamlining pharmacovigilance reporting will save significant costs for industry, by reducing the need to submit multiple different data sets to different regulators and reduce the administrative burden of the process by making the requirements simpler. We are proposing to move from the provision of a Detailed Description of the Pharmacovigilance System (DDPS) to a Pharmacovigilance Masterfile

System (PSMF) which means a reduction in burdens to industry. Currently any change to the DDPS needs to be applied to every product held by the MA holder, whereas the PSMF covers all products held by the MA holder, so only one change is required. The current system also requires a Periodic Safety Update Report (PSUR) every 6 months for the first year of a product's life, then every year for the next 2 years, and then every 3 years thereafter. Companies will have a range of product authorisations, from as small a number as 5 to up to 1,000. The pharmaceutical industry estimated that the average number of PSURs is 50 per year, indicative of as many as 500 workdays per PSUR.[22] It has not been possible to quantify the impacts on the changes to the pharmacovigilance systems; we will ask the pharmaceutical industry to provide data on the costs and savings as part of the consultation.

91. The changes will also help ensure medicines continue to be safe and effective and improve the VMD's capacity to respond to adverse events which will also help protect public health, the food chain and the environment.

Prescribing and supply

92. We will clarify that veterinary medicines that contain antibiotics or beta-agonists, or that are used for euthanasia, or that are immunological or hormonal are subject to veterinary prescription. This will not result in any additional costs.

93. We have reviewed the information required to prescribe a veterinary medicine. The proposed changes will standardise the requirements for all prescribers (vets, pharmacists and Suitably Qualified Persons (SQPs)) and discourage prescription misuse. This will increase responsible prescribing and availability of veterinary medicines across GB and improve animal welfare.

94. The changes, such as to state if the medicine is for prophylactic or metaphylactic use, will provide more assurance that the veterinary medicine is being appropriately prescribed and will be used responsibly. Prophylaxis is the administration of a medicine to an animal or group of animals before clinical signs of a disease in order to prevent the occurrence of disease or infection. Metaphylaxis is the administration of a medicine to a group of animals after a diagnosis of clinical disease in part of that group, with the aim of treating the clinically sick animals and controlling the spread of the disease to animals in close contact and at risk of contracting the disease.

95. SQPs will be given the ability to prescribe remotely, in line with the requirements for vets, which will reduce the regulatory burden on SQPs. We estimate this will allow an SQP to delegate certain tasks to non-qualified colleagues, which will benefit industry and present savings as demonstrated in Table 12.

Table 12 – Estimated prescriptions and supply savings for SQPs

Number of companies	Time delegated from SQP to assistant per week	Cost per hour (£)	Overall annual savings (£)	Overall savings (£), +22% non-wage costs
675	1 hour	20.52 (SQP) 11.98 (Assistant)	299,754	365,700

96. As the ownership of pets increases in GB, these changes will ensure that a wide range of veterinary medicines continues to be available to protect the pets' welfare.[23] The changes to prescribing veterinary medicines, such as extending the ability to prescribe

[22] European Commission, Commission Staff Working Document Impact Assessment on the Proposal for a Regulation of The European Parliament and of the Council on Veterinary Medicinal Products, eur-lex.europa.eu, 2014, p. 91.

[23] Statista Research Department, Pet ownership in the UK 2021/22, statista.com, 2022.

remotely to SQPs, will help ensure access to veterinary medicines across GB, including in rural areas where there generally are fewer prescribers available.

97. Vets and pharmacists will only be able to order veterinary medicines for supply to authorised premises, as is the current situation with SQPs. This will help encourage fair competition amongst prescribers. We do not expect there to be cost implications for this change.

98. We are proposing to amend the requirements for prescription by a vet. This will clarify that a product requiring a vet's prescription can be prescribed after a clinical examination or any other proper assessment of an animal under the vet's care – in other words, a physical examination may not be needed in all cases. These savings are shown in Table 13.

Table 13 – Estimated savings for vets from remote prescribing

Number of vets in large/farm animal practice[24]	Time saved per week (year)	Cost per hour (£)	Overall annual savings (£)	Overall savings (£), +22% non-wage costs
247	1 hour (52 hours)	25.67	329,705	402,240

99. Annual audit requirements will be strengthened for suppliers of veterinary medicines, including wholesale dealers, with a requirement to record any discrepancies in the stock of veterinary medicines. This may result in increased annual costs; however, it will help improve the security of the veterinary medicine supply chain and will only incur costs where discrepancies are found.

100. Wholesale dealers of veterinary medicines will be required to report veterinary medicines that are suspected to be counterfeit or falsified. This will help to provide a secure supply chain for veterinary medicines in GB. We will be seeking evidence on the costs to industry at consultation.

101. Online retailers will be required to register with the VMD and display a registration logo on their website. This will result in increased burden for retailers of veterinary medicines; however it will provide assurance for animal owners and help direct customers to legitimate businesses. The implementation of this option would ring-fence legitimate businesses in GB, as end users would be able to recognise legal internet retailers (those with a logo) from unregistered ones and so be able to make an informed choice when deciding to purchase veterinary medicines on the internet. The cost of registering websites is shown in table 14.

Table 14 – Estimated registration costs for online retailers

Number of companies	Company time for registration	Cost per hour (£)	Overall cost (£)	Overall cost (£), +22% non-wage costs
1,465	30 mins	20.52	15,031	18,338

102. We will introduce an offence for submitting one non-repeat prescription to multiple retailers. This will provide the Secretary of State with greater ability to tackle and deter prescription misuse and ensure the security and integrity of the supply chain to protect animal welfare.

[24] Dilys Robinson, Megan Edwards, Bethany Mason, James Cockett, Kate Arnill. Graham and Alex Martin, The 2019 Survey of the Veterinary Profession, Institute for Employment Studies, 2019.

Marketing under exemption for small pet animals

103. A register will be established by the Secretary of State for veterinary medicines marketed under the exemption for small pet animals. This may result in increased regulatory burden for those who market these medicines but will provide access for the Secretary of State to this information in the event of a safety concern or veterinary medicine incident. It will also enable small pet animal owners to recognise legitimate businesses, preventing unfair competition and ensuring the safety of medicines for small pet animals. The cost of this registration is outlined in Table 15.

Table 15 – Estimate cost of registration of products marketed under the small pet animal exemption

Number of companies	Company time for registration	Cost per hour (£)	Overall cost (£)	Overall cost (£), +22% non-wage costs
13	5 hours	30.94	2,011	2,454

Feedingstuffs

104. The proposed changes related to medicated feed and specified feed additives will provide definitions for specific terms and further clarify certain requirements under the VMR, such as stating that advertising regulations also apply to feedingstuffs. This will ensure the requirements for feed business operators are easy to find and transparent. These costs have been quantified with the overall familiarisation costs in Table 2.

105. The requirements for medicated feedingstuff prescriptions (MFSp) will be amended to ensure that an MFSp contains the necessary information for medicated feedingstuffs to be manufactured, supplied and used, and that supply of medicated feedingstuffs is only in accordance with a valid MSFp.

106. Labelling requirements will be extended to ensure that the use of a feedingstuff is in accordance with its authorisation. Medicated feedingstuffs which also contain specified feed additives will need to include the required labelling for those specified feed additives.

107. The consultation will seek to gain evidence of the costs these changes will add for industry and veterinary professionals.

108. We will amend the allowed analytical tolerance levels in the VMR to ensure they are achievable and still ensure the final medicated feed contains appropriate levels of active ingredient to ensure effective and safe treatment. We will be looking to gather more evidence at consultation to show the cost this change will have on industry.

109. We will also introduce carryover limits to ensure that the level of active ingredients present in non-target food (cross-contamination) is ‘as low as reasonably achievable’. This will help to ensure feedingstuffs do not contain unintended ingredients, including antibiotics, and that veterinary medicines are only administered to the target animals at the responsible and appropriate dosage. This principle is already followed by feed businesses as good practice and so should not result in increased costs.

110. These changes will result in increased compliance, fewer deficiencies for manufacturers and ensure high standards for feedingstuffs going into the food chain which contributes to more efficient and environmentally sustainable food production. This will also help to reduce the risk of a food incident caused as a result of deficiencies and reduce the severity of any incidents that do occur.

Advertising

111. Changes proposed to provisions on advertising will include defining what we mean by ‘advertising’, clarifying and updating which veterinary medicines may be promoted to

targeted professional groups, and explicitly stating that it is an offence to advertise an unauthorised veterinary medicine, such as those prescribed under the cascade or with suspended MA.

112. The changes will ensure that only authorised veterinary medicines are advertised. This will prevent unfair competition and prevent advertising of illegal veterinary medicines. This will also help industry to reduce the amount of resource wasted creating non-compliant advertising.

113. A compliant industry will incur no additional costs from the changes, other than familiarisation costs, but will benefit from not competing against non-compliant businesses or individuals. Clearer requirements will save MA holders, manufacturers and suppliers costs of seeking advice on promotional material and amending non-compliant advertising. We will seek further evidence of the cost savings at consultation.

Fees

114. Fee changes are not covered by this assessment under the statutory exemptions for the Better Regulations Framework.[25] Table 16 shows the impact costs and benefits associated with implementing fee changes only under 'Option 1', such as familiarisation costs and industry savings for MA renewals.

Table 16 – 'Option 1', fee changes only, total costs and savings (includes familiarisation costs)

Sector	Costs (£)	Savings (£)	Overall (£)
Marketing authorisation holders	3,233	137,030	-133,797
Manufacturers	1,685	0	+1,685
Wholesale dealers	410	0	+410
Veterinary practices	10,053	0	+10,053
Veterinary pharmacists	11	0	+11
SQP retailers	1,098	0	+1,098
Feed business operators	2,486	0	+2,486
Professional keepers of animals	0	0	+0
Total	18,976	137,030	-118,054

Risks and unintended consequences

115. We do not expect there to be risks to bringing any of the proposed changes into force. The VMD has already engaged with industry sectors to gain early insight into expected impacts and implementation considerations. This has included workshops to discuss proposed changes with key industry stakeholders.

Wider impacts

116. The proposed changes may lead to increased costs in certain areas, but they will also lead to increased benefits.

117. They will provide increased ability to tackle AMR, which would ultimately result in less cost for healthcare and fewer lives lost and help work towards realising the UK's 20

[25] Department for Business, Energy and Industrial Strategy, The Better Regulation Framework, publishing.service.gov.uk, 2020.

Year Vision for AMR. Bacterial infections unsuccessfully treated due to antibiotic resistance currently claim at least 700,000 lives per year worldwide and are projected to be associated with the deaths of 10 million people per year by 2050.[26]

118. The proposed changes will also help reduce development and spread of anthelmintic resistance by ensuring vets, pharmacists and SQPs record their prescribing decisions, thus encouraging proper assessment of the information obtained, including that provided by the animal owner, and therefore effective prescribing and treatment decisions. The overall annual cost of helminth infections in UK ruminants is estimated to be £266m, comprising approximately £198m in lost production and £68m in treatment costs.[27] These economic cost estimates do not reflect the potential longer-term financial and social impacts of anthelmintic resistance, where, if left unchecked, livestock production could become unprofitable, or even unsustainable on many properties. This could lead to significant damage to the UK livestock, meat and dairy sectors. The Gross Value Added of the livestock and meat processing and manufacturing sectors is estimated at around £10.9bn per year.[28]

119. The changes to data protection periods for MAs will encourage innovation and research and development of new veterinary medicines, whilst achieving an optimal balance between innovator and generic veterinary medicines coming to the market, so that both sectors can thrive.

120. There will be additional safeguards for veterinary medicines and medicated feedingstuffs for food-producing animals which will help ensure a secure and safe food chain. Updated pharmacovigilance requirements will give MA holders greater capacity to monitor the veterinary medicines they market and take action to provide the greatest benefit to animal welfare, whilst protecting human health and the environment.

121. As the ownership of pets increases in GB, the proposed changes will ensure that a wide range of veterinary medicines continues to be available to protect the pets' welfare.[29] The changes to prescribing veterinary medicines, such as extending the ability to prescribe remotely to SQPs, will help ensure access to veterinary medicines across GB, including in rural areas where there generally are fewer prescribers available.

122. Fee amendments will ensure the VMD is able to recover its costs for its regulatory services according to the principles laid down in HM Treasury's 'Managing Public Money'.

123. The proposed changes will also help secure the supply chain by ensuring veterinary medicines are stored, supplied and used safely and responsibly.

5.0 Post implementation review

124. We will monitor and evaluate the changes if they are brought into force. We will publish updated guidance on GOV.UK to help the veterinary industry understand and implement these changes.

125. The Medicines and Medical Devices Act 2021[30] requires any amendments to the VMR to be reported on within 24 months of those changes coming into force, with subsequent reports within a further 24-month period. We will start collecting the data for the first report at the point of the changes coming into force.

[26] The Review On Antimicrobial Resistance Chaired By Jim O'Neill, 160525_Final paper with cover.pdf (amr-review.org)

[27] J. Charlier et al., Initial assessment of the economic burden of major parasitic helminth infections to the ruminant livestock industry in Europe, Science Direct, 2020.

[28] Department for the Environment, Food and Rural Affairs, Defra analysis based on Agriculture in the UK (Defra) and the Annual Business Survey (ONS), publishing.service.gov.uk, 2020.

[29] Statista Research Department, Pet ownership in the UK 2021/22, statista.com, 2022.

[30] HM Government, Medicines and Medical Devices Act 2021, legislation.gov.uk, 2021.

1. **Review status:** Please classify with an 'x' and provide any explanations below.

	Sunset clause	X	Other review clause		Political commitment		Other reason		No plan to review

Regulations to be reviewed every two years to ensure continued suitability.

2. **Expected review date** (month and year, xx/xx):

		/			Two years from when the Regulations come into force

3. Rationale for PIR approach:

Circle the level of evidence and resourcing that will be adopted for this PIR (see Guidance for Conducting PIRs):

Describe the rationale for the evidence that will be sought and the level of resources that will be used to collect it.

- **Will the level of evidence and resourcing be low, medium or high? (See Guidance for Conducting PIRs)**
- **What forms of monitoring data will be collected?**
- **What evaluation approaches will be used? (e.g. impact, process, economic)**
- **How will stakeholder views be collected? (e.g. feedback mechanisms, consultations, research)**

Rationale for not conducting a PIR:

Describe the rationale for why a PIR will not be conducted and why this is deemed to be the suitable route to follow.

Annexes

Annex A: List of proposed changes in order of the VMR

General:

- Amend terminology throughout the VMR to refer to all inspected sites as “authorised”, with the exception of Veterinary Practice Premises (VPPs).
- Replace “antimicrobials” with “antibiotics” where appropriate.
- Substitute “adverse reactions” with “adverse events”.
- Substitute “veterinary medicinal product (VMP) for incorporation into feedingstuffs” for “premix”, mainly for Schedule 5.
- Substitute “premixture” for “intermediate feedingstuff”, mainly for Schedule 5.

Regulations:

- Regulation 2
    - Provide definitions for:
        - “active substance”
        - “advertising (of veterinary medicinal products)”
        - “antibiotic”
        - “antimicrobial”
        - “antimicrobial resistance”
        - “biological substance”
        - “biological veterinary medicinal products”
        - “environmental event”
        - “epidemiological unit”
        - “excipient”
        - “human adverse event”
        - “limited market”
        - “novel therapies”
        - “pharmacologically equivalent”
        - “pharmacovigilance”
        - “pharmacovigilance system master file”
        - “prophylaxis”
        - “reference veterinary medicinal product”
        - “residue event”
        - “wholesale dealing”
        - “withdrawal period”
    - Amend definitions for:
        - “veterinary medicinal product”
        - “immunological veterinary medicinal product”
        - “strength”
        - “benefit-risk balance”
- Regulation 5
    - Set out which activities require a manufacturing authorisation under the VMR.
- Regulation 7
    - Clarify it is an offence to supply or use a veterinary medicine, <u>including medicated feedingstuffs</u>, that has passed its expiry date.
- Regulation 10
    - Set out the requirements for advertisements of veterinary medicines.

    - Clarify it is an offence to advertise a veterinary medicine that does not hold an MA (which includes suspended MAs) and is not marketed under Schedule 6.
    - Clarify the advertising requirements also relate to medicated feedingstuffs.
- New regulation (10A)
    - Setting out the requirements for promotions for veterinary medicines in the form of gifts, monetary advantages and benefits.
- Regulation 11
    - Adjust the allowances to advertise prescription-only veterinary medicines so that only immunological veterinary medicines can be advertised to professional keepers of animals.
- Regulation 15
    - Extend the provisions for stem cell centre authorisations to include all non-food producing animals.
- Regulation 18
    - Clarify records of administration of a veterinary medicine to a food-producing animal by a vet must be provided to the animal keeper by the vet as soon as is reasonably practicable.
- Regulation 21
    - Adjust the manufacturing authorisation record keeping requirements, including for records to be kept for at least 5 years or 1 year after the expiry for the batch, whichever is longer.
- Regulation 22
    - Adjust the wholesale dealer authorisation (WDA) record keeping requirements, including for records to be kept for at least 5 years.
- Regulation 23
    - Adjust the record keeping requirements for retailers of prescription-only veterinary medicines.
- New regulation (24A)
    - Allow the Secretary of State to require the reporting of antibiotic sales and usage data.
- Regulation 25
    - Clarify that pharmacist may supply a product mentioned in paragraph (6) for use under the cascade without needing to hold a wholesale dealer's authorisation.
- Regulation 30
    - Clarify that a body recognised by the Secretary of State to register Suitably Qualified Persons (SQPs) can appeal a decision to suspend or revoke its recognition, and that the same applies to applicants for registration in relation to active substances.
- Regulation 31
    - Adjust the export certificate provisions to ensure these cover all types of veterinary medicines manufactured, such as products marketed under Schedule 6.
- Regulation 35
    - Allow an inspector to seize any item they believe (with reasonable grounds) relates to, or provides evidence of, a breach of the VMR.

- New regulation (38A)
    - Introduce prohibition notices which can order the immediate ceasing of an action or impose conditions upon an activity which ensure it is carried out in accordance with the VMR.

Schedule 1:

- Paragraph 2
    - Adjust the application requirements for MA applications, including:
        - for applications to be submitted electronically
        - providing a summary of the pharmacovigilance system master file (PSMF)
        - for antimicrobial veterinary medicines, the direct and indirect risks to public or animal health and to the environment, and mitigations to limit antimicrobial resistance (AMR).
- Paragraph 3
    - Adjust the requirements for the Summary of Product Characteristics (SPC).
- Paragraph 5
    - Omit this paragraph so MA applications for a medicine intended for food-producing animals may be submitted alongside related MRL applications.
- Paragraph 7
    - Amend so an MA applicant using the bibliographical application route to is required to demonstrate the active substances have been in well-established veterinary use for at least 10 years and that their efficacy is documented and provides an acceptable level of safety.
- Paragraph 10
    - Introduce the wording “generic” and “reference product”.
    - Introduce the requirement that the SPC for a generic veterinary medicine is essentially similar to that of the reference product (with the exception of parts relating to information covered by patents at the time of authorisation).
- New paragraph (10A)
    - Introduce requirements for an MA application for a hybrid generic product, using a combination of own data and data from a reference product.
- Paragraph 11
    - Adjust the data protection periods for veterinary medicines and increase the maximum protection period to 18 years.
    - Require the SPC of a generic product to be updated with the protected information via a variation when the patent for a reference product has lapsed.
- Paragraph 12
    - Adjust the extension periods for various data protection periods.
- Paragraph 13
    - Remove the provision for authorisation of parallel imports.
- Paragraph 15
    - Remove the provision for similar immunological products.
- Paragraph 17
    - Introduce the facility for a clock stop in the national timeline for procedures that are part of a simultaneous assessment with other countries.
- Paragraph 18
    - Adjust requirements to allow an MA holder based outside GB to market a veterinary medicine in GB if they have a local representative based in GB.

- Paragraph 22
    - Allow the Secretary of State to set out conditions for placing a product on the market when granting an MA, such as requiring post-authorisation studies of antimicrobial veterinary medicines to ensure the benefit-risk balance remains positive.
- New paragraph (22A)
    - Introduce the requirement for an applicant to provide a written reason for withdrawal of an MA application if that withdrawal takes place before the Secretary of State has produced an assessment report.
- Paragraph 24
    - Adjust the reasons for refusal of an MA, including if:
        - the product contains an antimicrobial that is reserved for human use
        - the product is an antimicrobial growth promotor
        - the risk of AMR outweighs the benefit of the product
        - risks to public health, animal health or the environment are not sufficiently addressed.
- Paragraph 25
    - The Secretary of State will publish decisions to refuse, suspend, revoke or vary an MA, as well as to grant an MA.
- Paragraph 26
    - Adjust the considerations for limited MA applications.
- Paragraph 27
    - Require MA applicants to have the results of control tests carried out on the veterinary medicine or the constituents and intermediate products.
    - Allow the Secretary of State to require an applicant to provide samples of their product to a reference laboratory.
- Paragraph 31
    - Require MA holders to report supply shortages to the Secretary of State, a supply shortage occurring when supply does not meet demand at national level within the UK.
- Paragraph 32
    - Remove the requirement to renew an MA.
- Paragraphs 33-35 (including new paragraphs 33A, 33B and 33C)
    - Revision of the classification of variations to MAs, providing for two types: variations requiring assessments and variations nor requiring assessment.
    - Adjusted procedures for (assessment of) variation applications.
- Paragraph 38
    - Adjust the grounds for safety restrictions that can be temporarily put in place by the Secretary of State in the event of risk to public health, animal health or the environment.
- Paragraph 41
    - Adjust the grounds for the prohibition of supply or recall of a veterinary medicine.
- New paragraphs (41A)
    - Introduce temporary restrictions to the supply or use of a veterinary medicine, or to suspend or require a variation to an MA, where urgent action is necessary to protect human or animal health or the environment.

- New paragraphs (41A)
    - Introduce a power and grounds for the Secretary of State to prohibit the manufacture, importation, distribution, supply or use of immunological veterinary medicines.
- Paragraphs 48-51
    - Adjust the labelling requirements for veterinary medicines.
    - Allow the use of electronic QR codes on the labelling of veterinary medicines.
    - Allow an Electronic Package Information Leaflet to be provided, where appropriate, as an alternative to a physical package leaflet.
- Paragraph 53
    - Adjust the labelling requirements for a registered homeopathic remedy.
- Paragraph 56, new paragraphs 56A, 56B, 56C
    - Adjust and clarify the duties of the MA holder and qualified person (pharmacovigilance) in relation to pharmacovigilance, including, but not limited to:
        - carrying out the signal management process.
        - establishment and maintenance of one or more pharmacovigilance system master files describing in detail the pharmacovigilance system with respect to its authorised veterinary medicinal products.
        - establishment and maintenance of a local system for the purpose of receiving reports of suspected adverse events.
        - establishment and maintenance of an adequate and effective quality management system for the performance of its pharmacovigilance activities.
- Paragraph 57
    - Update the list of adverse events to include environmental incidents, residues in products of animal origin and adverse events reported in scientific literature.
    - Require reporting within 30 days instead of 15.
- Paragraph 58
    - Remove the requirement for the routine submission of adverse events from outside of the UK.
- Paragraph 59
    - Remove Periodic Safety Update Reports and replace with an annual benefit-risk report, setting out what such a report entails.
- Paragraph 60
    - Adjust the provision regarding the release of information by the marketing authorisation holder.
- New paragraph (60A)
    - Introduce a requirement on the Secretary of State to inspect MA holders to ensure they are compliant with pharmacovigilance requirements.
- Paragraph 61
    - Allow the Secretary of State to take action in response to pharmacovigilance reports against all MAs that contain the same active or excipient ingredients as those involved in an adverse event.
    - Allow the Secretary of State to require MA holders to implement a risk management plan.
- Paragraph 63
    - Restrict homeopathic remedies to topical or oral administration routes.

    - Exclude biological homeopathic products form the homeopathic registration scheme.
    - Allow holders of veterinary homeopathic remedies based outside of the UK to have a local representative as an alternative to being established in the UK.
- Paragraph 64
    - Adjust the registration requirements for homeopathic remedies.
- Paragraph 65
    - Introduce a time limit of 210 days for the Secretary of State to assess applications for new registrations for veterinary homeopathic remedies.

Schedule 2:

- Paragraph 1
    - Clarify what activities require a manufacturing authorisation.
- Paragraphs 2-4
    - Adjust the provisions relating to the application for a manufacturing authorisation, specifying the minimum information and key personnel needed, and requiring an inspection before authorisation.
- Paragraph 5
    - Clarify that the Secretary of State can revoke all manufacturing authorisations, including AVA, NFABBA, ManSA, SCCA and SAM, and can also suspend or require a compulsory variation for manufacturing authorisations.
- Paragraph 6 and 7
    - Require manufacturers based outside of the UK to have a certificate of good manufacturing practice issued by the Secretary of State, or an equivalent certificate issued by an authority that the UK has a formal agreement with.
- Paragraph 8
    - Adjust the responsibilities of the holder of a manufacturing authorisation.
- Paragraphs 9 and 10
    - Specify the key personnel required for manufacturers and the criteria for qualified persons.
- Paragraph 11
    - Adjust the responsibilities for qualified persons.
- Paragraph 13
    - Adjust the requirements for test sites.
- Parts 2 to 5 have been replaced with provisions in new part 2.
    - Part 2 sets out the requirements for applications for an authorisation to manufacture autogenous vaccines, blood-banks, stem-cell centres and products manufactured under the cascade, including, but not limited to:
        - the information to be provided with the application
        - the procedures to be followed, including required inspections
        - requirement for a manufacturer of specific veterinary medicines to be under the supervision of a named person responsible for release
        - labelling
        - adverse event reporting
        - record-keeping.
    - Require manufacturers of products prescribed for use under the cascade to provide a list of the formulations they have manufactured to the Secretary of State upon request.

- Require manufacturers of products for use under the cascade to ensure they do not manufacture a veterinary medicine that is the pharmaceutical equivalent of an authorised product (except where there are known supply issues).
- Require manufacturers of products prescribed under the cascade to only supply product to a veterinary surgeon who has correctly prescribed that product under the cascade.

- Paragraphs 26-32
  - Introduce requirements for importers, manufacturers and distributors of active substances, including the requirement to register with the Secretary of State.

Schedule 3:

- Paragraph 1
  - Update the requirements for the classification of veterinary medicines as prescription only medicines – veterinarian (POM-V) to include:
    - products containing antimicrobial substances
    - products for euthanasia
    - immunological products
    - products with a hormonal/thyrostatic action
    - products containing beta-agonists.
  - Require products supplied under the cascade to be supplied and prescribed under the same requirements as a POM-V.
- Paragraph 2
  - Remove the wording that exempts an MA holder from wholesaling veterinary medicines without a wholesale dealer's authorisation (WDA).
  - Allow a WDA holder to:
    - Supply to authorised manufacturers of veterinary medicines.
    - Import an unauthorised veterinary medicine under the special imports scheme for a vet prescribing the product under the cascade.
  - Include veterinary surgeons and pharmacists in the requirement for prescription only veterinary medicines to only be supplied to approved premises.
- Paragraph 3
  - Allow a Secretary of State inspector to purchase a prescription only medicine for testing purposes.
  - Clarify that retail supply is supply to the end user and separate from administration.
- New paragraph (3A)
  - Require that a veterinary medicine must not be distributed for promotional purposes except for small quantities of samples as long as those samples do not contain antimicrobials.
- New paragraphs (3B-3D)
  - Require the registration of online retailers of POM-V, POM-VPS and NFA-VPS products and the requirement to display the online retailer logo on the website
- New paragraph (3E)
  - Introduce requirement that a retailer of veterinary medicines must store the medicines in accordance with the label of the product and in accordance with the relevant summary of product characteristics.

- Paragraph 4
    - Adjust the requirements for prescription by a veterinary surgeon to replace the need for a clinical assessment with “clinical examination or other proper assessment of the animal”.
- Paragraph 5
    - Require the recording of the justification for prescription when a medicine has been prescribed orally.
    - State that no person may submit one non-repeat prescription to multiple retailers.
- Paragraph 6
    - Adjust the required information to be included in prescriptions, including:
        - If the product has being prescribed for prophylaxis or metaphylaxis use.
        - a prescription to include a statement that “it is an offence under the Veterinary Medicines Regulations to alter a written prescription unless authorised to do so by the person who signed it”.
    - Change the validity of a prescription for an antibiotic veterinary medicine to be 5 days.
- Paragraph 7
    - Include specific reference to only prescribing antimicrobials for a limited duration to cover the period of risk.
- New paragraph (7A)
    - Restrict the prescription of antibiotic veterinary medicines for prophylactic purposes 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.
    - Provide conditions under which such prescription may occur.
- Paragraph 11
    - Allow Feed Business Operators to wholesale supply feedingstuffs to alleviate a temporary supply shortage that could be detrimental to animal welfare, whilst removing Schedule 3, 11(4) which allows the wholesale supply of up to 5% the value of veterinary medicinal product incorporated annually.
- Paragraph 14
    - Clarify the Secretary of State can revoke and suspend an SQP registration body for failing to comply with the Code of Practice.
    - Allow SQPs to prescribe veterinary medicines remotely.
- Paragraph 15
    - Require discrepancies in stock of prescription only veterinary medicines detected during an audit to be investigated.
- Paragraph 16-21 (including new paragraphs 21A-21E)
    - Update the requirements for holders of WDAs, including:
        - to have a Wholesale Qualified Person (WQP)
        - to comply with good distribution practice
        - to provide the Secretary of State with any information they hold which could impact the continued supply of veterinary medicines to meet animal health needs
        - to provide the Secretary of State information relating to suspected counterfeit or falsified products
        - for discrepancies in stock of prescription only veterinary medicines detected during an audit to be investigated

        - introducing requirements for registration
        - introducing requirements for recalled products and audits.
- Paragraph 23
    - Allow the awarding of a Certificate in the Safe Use of Sheep Dip by any educational body recognised by the Secretary of State.
    - Clarify that the holder of a Certificate of Competence in the Safe Use of Sheep Dip is permitted to carry out the act of dipping (not just supervise the dipping).

Schedule 4:

- Paragraph 1
    - Require all substances included in a medicine administered to a food-producing animal under the cascade to be listed in the GB MRL list or in the 'out of scope list'.
- Paragraph 2
    - Clarify the maximum residue limits and introduce amended withdrawal periods for veterinary medicines prescribed under the cascade for food-producing animals.
- Paragraph 4
    - Include “emerging disease” as a reason for the Secretary of State to permit the administration of an unauthorised immunological product.
- New paragraph (6A)
    - Limit the use of an autogenous vaccine to exceptional circumstances when used in accordance with the cascade.
- Paragraph 9
    - Substitute “research purposes” for “clinical trials”.
- New paragraph (9A)
    - Introduce an offence for encouraging or facilitating the illegal use of the cascade.

Schedule 5:

- Paragraph 1
    - Introduce definition for:
        - “animal keeper”
        - “batch”
        - “complementary feed”
        - “complete feed”
        - “compound feed”
        - “cross-contamination”
        - “daily ration”
        - “distributor”
        - “establishment”
        - “feedingstuff”
        - “feed additives”
        - “feed business”
        - “feed business operator”
        - “feed materials”
        - “intermediate feedingstuffs”
        - “label”
        - “labelling”
        - “medicated feedingstuffs”
        - “minimum storage life”
        - “mobile mixer”

        - “non-target feed”
        - “on-farm mixer”
        - “premix”
- Paragraphs 7
    - Require a premix or intermediate feedingstuff to be homogeneously dispersed within a manufactured feedingstuffs.
- Paragraphs 12 and 14
    - Labelling must include:
        - a statement directing the use of an intermediate feedingstuffs in accordance with the SPC of the premix
        - a free means of communicating the MA holder, to enable an animal keeper to obtain a copy of the package leaflet for the premix
        - a statement that inappropriate disposal poses a serious threat to the environment, and, if an antibiotic, to AMR.
- Paragraph 18
    - Clarify medicated feedingstuffs and intermediate products may be manufactured and placed on the market before the MFSp is issued, although the product must not be supplied to the end user before the MFSp has been provided (including supply to on-farm and mobile mixers).
- Paragraph 19
    - Adjust requirement for a prescription for a medicated feedingstuff (MFSp) to include:
        - the amount of final to be supplied
        - the diagnosed disease to be treated (or, in the case of immunological veterinary medicinal products or antiparasitics without antimicrobial effects, the disease to be prevented)
        - the name of any active substances
        - a statement that the prescription must not be re-used.
    - Change the validity of an MFSp for an antibiotic premix to 5 days.
    - Clarify that medicated feedingstuffs containing antibiotics should not be used for prophylaxis.
- Paragraph 20
    - Clarify that a copy of the MFSp must be given to the distributor if a distributor was involved in the supply.
- Paragraph 22
    - Adjust the table of tolerances.
- New paragraph (22A)
    - Introduce the requirement for cross-contamination to be as low as reasonably achievable.
    - Require feed business operators to carry out suitable testing for cross-contamination and note any results over 1%, and to conduct a root cause analysis for results over 3%.
- Paragraph 26
    - Introduce requirements for animal keepers to take measures to ensure medicated feedingstuffs are appropriately stored and used.
- New paragraph (26A)
    - Require feed business operators (FeBOs) and animal keepers to have collection or discard systems in place for expired or unused feedingstuffs.

Schedule 6:

- New paragraphs (3A and 3B)
    - Require companies marketing products under the Exemption for Small Pet Animals in GB to:
        - register with the Secretary of State as marketers of such products.
        - provide an annual overview to the Secretary of State of the products they have marketed in the preceding year under Schedule 6.
- Paragraph 9
    - Remove reference to adverse events recording and reporting for retailers of veterinary medicines marketed under the Exemption for Small Pet Animals.

Schedule 7:

- Paragraph 1
    - Clarify to which activities “manufacturing authorisation” applies in this Schedule.
- Paragraph 4
    - Clarify that reduced fees only apply when more than one inspection is carried out at the same premises at the same time belonging to the same legal entity.
- Paragraphs 7 and 9
    - Remove and replace the payment model for applications for full immunological and full and bibliographical pharmaceutical veterinary medicines.
- New paragraph (7A)
    - Create a new fee for complex MA applications, which would be used for products such as:
        - products developed by means of any biotechnical process involving recombinant DNA or the controlled expression of genes
        - veterinary medicines containing new active substances
        - products defined as biopharmaceuticals
- Paragraph 11
    - Adjust the fee for a marketing authorisation application based on informed consent.
- Paragraph 15
    - Remove the fee for parallel import MA applications.
- New paragraph (15A)
    - Create a new fee structure for generic MA applications.
- Paragraph 17-18
    - Adjust the MA variations fees and structure.
    - Adjust grouped fees for variations to marketing authorisations to change “for each subsequent group of up to ten changes” to “for each subsequent group of up to five changes” and reducing the cost by 50%.
    - Removing the fee for worksharing procedures.
- Paragraph 22
    - Remove the fee for the application for renewal of a marketing authorisation.
- Paragraph 25
    - Remove the fee for the renewal of a registration for a homeopathic remedy.
- Paragraphs 28-31
    - The fees for assessment of applications for a (variation to a) manufacturing authorisation have been simplified and adjusted, including the annual fee.
- Paragraphs 33 to 37
    - Adjust the fees for inspection of:

        - immunological veterinary medicine manufacturing sites.
        - sterile veterinary medicine manufacturing sites.
        - non-immunological and non-sterile veterinary medicine manufacturing sites.
        - schedule 6 veterinary medicine manufacturing sites.
        - veterinary medicine assembly sites.
        - test sites.
- Paragraph 38
    - Adjust the fees for inspection of animal blood banks and stem cell centres.
- Paragraph 39-42
    - Adjust the applications fees for a WDA to set a single fee for all applications regardless of turnover.
    - Adjust the fees for a variation to a WDA, the annual fee and the inspection fee.
- Paragraph 43
    - Adjust the application and annual fees for FeBOs.
- Paragraph 44
    - Adjust the fees for inspection of FeBOs.
- Paragraph 46
    - Adjust the fees for approval of premises for retail supply of VMPs by SQPs to create a single application fee and a single annual fee for all SQPs.
    - Introduce an inspection fee for standard SQP retailers and reduced SQP retailers (equine and companion) and amend the fee accordingly.
- Paragraph 48
    - Adjust the fees for Animal Test Certificates
    - Create a fee for the renewal and variation of animal test certificates to administer medicines in a small-scale trial.
- Paragraph 49
    - Adjust the fee for an import certificate for medicines under the cascade to have an application fee for all import certificates and remove the separation of online and paper applications.
- Paragraph 53
    - Adjust the fee for an application for an export certificate.
    - Provide export certificates electronically, removing the need for additional copies to be provided and charged for by the Secretary of State.
- New paragraph (54A)
    - Introduce a fee for the provision of written advice from the Secretary of State in relation to scientific matters.
- Paragraph 57
    - Amend the registration, annual and inspection fees for veterinary practice premises.
- New paragraph (57A)
    - Introduce a fee in relation to verifying the destruction of controlled drug.
- Paragraph 61
    - Allow the Secretary of State to administratively reduce fees where it is appropriate to do so.
- New paragraph (63)
    - Allow the Secretary of State to charge a fee for Pharmacovigilance inspections.

Annex B: Familiarisation costs for changes to the VMR

These costs are based on the average earnings for the responsible officer in each sector and the time taken to familiarise with the relevant changes for that sector based on the Business Impact Target for Appraisal of Guidance multiplied by the number of premises. The guidance indicates that 50-100 technical words can be read per minute, and that only 50% of industry will read the guidance.[1] For industry and veterinary professionals, we have increased this to expect 65% to familiarise themselves with the changes.

Sector sizes have been calculated based on the number of premises authorised under the VMR, number of veterinary practices registered with the RCVS and the number of farmers according to Statista.[2]

Wage estimates are based on the Office for National Statistics Annual Survey for Hours and Earnings 2021, calculated with an uplift of 22% for non-wage costs as recommended by the Regulatory Policy Committee.[3]

Option 1 – Fee Changes

Sector	Sector Impacted	Occupation	Yearly Salary	Cost per Hour	Cost per Minute	Familiarisation Time (hours)	Sector Size	Cost	Cost + non-wage cost of 22%	Sector Totals
Marketing Authorisation Holders	Marketing Authorisation Holders	Research and development managers	48,623	31.17	0.52	40	187	2,525.69	3,081.35	3,233.46
	All	Office managers	32,004	20.52	0.34	3	187	124.68	152.11	
Manufacturers	Manufacturers	Production managers and directors in manufacturing	48,260	30.94	0.52	35	110	1,290.28	1,574.15	1,663.63
	All	Office managers	32,004	20.52	0.34	3	110	73.34	89.48	
Schedule 6 Manufacturers	Schedule 6 Manufacturers	Production managers and directors in manufacturing	48,260	30.94	0.52	2	13	8.71	10.63	21.21

[1] HM Government, Business Impact Target: appraisal of guidance - assessments for regulator-issued guidance, publishing.service.gov.uk, 2017.

[2] D. Clarke, Farmers in the UK 2022, Statista.com, 2022.

[3] Office for National Statistics, Employee earnings in the UK, ons.gov.uk, 2021, and Regulatory Policy Committee, Short guidance note_-_Implementation costs, publishing.service.gov.uk, 2019.

	All	Office managers	32,004	20.52	0.34	3	13	8.67	10.57	
Wholesale Dealers	Wholesale Dealers	Managers and directors in retail and wholesale	28,824	18.48	0.31	8	135	216.18	263.74	410.16
	All	Office managers	32,004	20.52	0.34	3	135	90.01	109.81	
	All Suppliers	Office managers	32,004	20.52	0.34	1	135	30.00	36.60	
Veterinary Practices	Vet Practices	Vets	40,052	25.67	0.43	10	2245	6,244.22	7,617.95	10,052.83
	All	Office managers	32,004	20.52	0.34	3	2,245	1,496.85	1,826.16	
	All Suppliers	Office managers	32,004	20.52	0.34	1	2245	498.95	608.72	
Veterinary Pharmacists	Pharmacists	Pharmacists	43,847	28.11	0.47	0	10	0.00	0.00	10.85
	All	Office managers	32,004	20.52	0.34	3	10	6.67	8.13	
	All Suppliers	Office managers	32,004	20.52	0.34	1	10	2.22	2.71	
Suitably Qualified Persons	Suitably Qualified Persons	Office managers	32,004	20.52	0.34	2	675	300.04	366.05	1,098.14
	All	Office managers	32,004	20.52	0.34	3	675	450.06	549.07	
	All Suppliers	Office managers	32,004	20.52	0.34	1	675	150.02	183.02	
Feed Business Operators	Feed Business Operators	Production managers and directors in manufacturing	48,260	30.94	0.52	6	761	1,530.24	1,866.90	2,485.92
	All	Office managers	32,004	20.52	0.34	3	761	507.40	619.02	
									Grand Total	18,976.18

Option 2 – All Changes

Sector	Sector Impacted	Occupation	Yearly Salary	Cost per Hour	Cost per Minute	Familiarisation Time (hours)	Sector Size	Cost	Cost + non-wage cost of 22%	Sector Totals
Marketing Authorisation Holders	Marketing Authorisation Holders	Research and development managers	48,623	31.17	0.52	230	187	14,522.74	17,717.75	18,402.25
	All	Office managers	32,004	20.52	0.34	13.5	187	561.07	684.51	
Manufacturers	Manufacturers	Production managers and directors in manufacturing	48,260	30.94	0.52	137	110	5,050.54	6,161.66	6,564.31
	All	Office managers	32,004	20.52	0.34	13.5	110	330.04	402.65	
Schedule 6 Manufacturers	Schedule 6 Manufacturers	Production managers and directors in manufacturing	48,260	30.94	0.52	6	13	26.14	31.89	79.48
	All	Office managers	32,004	20.52	0.34	13.5	13	39.00	47.59	
Wholesale Dealers	Wholesale Dealers	Managers and directors in retail and wholesale	28,824	18.48	0.31	45	135	1,216.01	1,483.54	2,966.02
	All	Office managers	32,004	20.52	0.34	13.5	135	405.05	494.16	
	All Suppliers	Office managers	32,004	20.52	0.34	27	135	810.10	988.32	
Veterinary Practices	Vet Practices	Vets	40,052	25.67	0.43	41	2245	25,601.29	31,233.58	55,886.76
	All	Office managers	32,004	20.52	0.34	13.5	2,245	6,735.84	8,217.73	

	All Suppliers	Office managers	32,004	20.52	0.34	27	2245	13,471.68	16,435.45	
Veterinary Pharmacists	Pharmacists	Pharmacists	43,847	28.11	0.47	2	10	6.09	7.43	117.24
	All	Office managers	32,004	20.52	0.34	13.5	10	30.00	36.60	
	All Suppliers	Office managers	32,004	20.52	0.34	27	10	60.01	73.21	
Suitably Qualified Persons	Suitably Qualified Persons	Office managers	32,004	20.52	0.34	7	675	1,050.13	1,281.16	8,693.59
	All	Office managers	32,004	20.52	0.34	13.5	675	2,025.25	2,470.81	
	All Suppliers	Office managers	32,004	20.52	0.34	27	675	4,050.51	4,941.62	
Feed Business Operators	Feed Business Operators	Production managers and directors in manufacturing	48,260	30.94	0.52	45	761	11,476.83	14,001.73	16,787.34
	All	Office managers	32,004	20.52	0.34	13.5	761	2,283.29	2,785.61	
Professional Keepers of Animals	Professional Keepers of Animals	Farmers	26,037	16.69	0.28	5.5	92,100	91,590.57	111,740.50	371,069.83
	All	All	32,004	20.52	0.34	13.5	92,100	212,565.03	259,329.34	
									Grand Total	480,566.83