Title: The Veterinary Medicines Regulations 2013 IA No: Defra 1442 **Lead department or agency:** Veterinary Medicines Directorate **Other departments or agencies:** -	Impact Assessment (IA) **Date:** 14/03/2013 **Stage:** Final **Source of intervention:** EU **Type of measure:** Secondary legislation **Contact for enquiries:** Jo Cawthorne j.cawthorne@vmd.defra.gsi.gov.uk 01932 338317

Summary: Intervention and Options

RPC Opinion: GREEN

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, One-Out?**	**Measure qualifies as**
£0m	£0.085m	-£0.077m	No	NA

What is the problem under consideration? Why is government intervention necessary?

The Veterinary Medicines Regulations (VMR) implement EC Directive 2001/ 82 (as amended) and other relevant EU legislation on veterinary medicines. The VMR sets out the controls on the production, distribution, possession, dispensing and administration of veterinary medicines that are required in order to protect the safety of treated animals, people handling the medicines, consumers of produce from treated animals and the environment. The VMR is revoked and remade on a regular basis to incorporate necessary changes to legislation, both clarifying existing policy and adding or removing new provisions. The main points of the updated legislation are listed in the Evidence Base section of this report.

What are the policy objectives and the intended effects?

The policy objectives are to produce updated and fit-for-purpose legislation that is simple to use for both stakeholders and the regulators and, where appropriate, to achieve full cost recovery.

The intended effects are to maintain the existing regulatory regime whilst transposing the requirements of Directive 2001/82 (as amended) and EU legislation relating to medicated feeds and feed additives.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 0 - Do nothing base line.
Option 1 - There are a number of changes proposed for option 1 which are detailed in 'Description of Options Considered'. Option 1 is the preferred option.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** 10/2014

Does implementation go beyond minimum EU requirements?			No		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** Yes	**< 20** Yes	**Small** No	**Medium** No	**Large** No

What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)	**Traded:** N/A	**Non-traded:** N/A

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs.

Signed by the responsible Minister: David Heath Date: 06 June 2013

Summary: Analysis & Evidence Policy Option 1

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2011	PV Base Year 2011	Time Period Years 1	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** 0

COSTS (£m)	Total Transition (Constant Price)	Yea	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate			0.266	**0.266**

Description and scale of key monetised costs by 'main affected groups'

These costs relate to fee changes.
Industry: £90,263 (Change 10: £38,000; Change 11: £50,000; Change 12: £1,063; Change 14: £1,200)
VMD (taxpayer): £175,295 (Change 8: £1,065; Change 9: £135,000; Change 13: £9230; RCVS: Change 15: £30,000)
For description of changes see evidence base of this IA

Other key non-monetised costs by 'main affected groups'

Maximum of 5 lines

BENEFITS (£m)	Total Transition (Constant Price)	Yea	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate			0.266	**0.266**

Description and scale of key monetised benefits by 'main affected groups'

These beneftis relate to fee changes. These are treated as transfers and therefore reflect the costs in the section above ie industry cost above equals VMD (taxpayer) benefit and vice versa.
Industry: £175,295 (Change 8: £1065; Change 9: £135, 000; Change 13: £9230; Change 15: £30,000)
VMD (taxpayer): £90,263 (Change 10: £38,000; Change 11: £50,000; Change 12: £1063; Change 14: £1,200.)

Other key non-monetised benefits by 'main affected groups'

For description of changes please see body of the report:
Changes 1, 2 and 3: Improved controls on veterinary medicines;
Change 8: Decreased regulatory burden for the industry;
Changes 4, 5, 6, 7, 9, 10, 11, 12: Fairer and more transparent fee system;

Key assumptions/sensitivities/risks **Discount rate (%)**

The VMRs are amended on a regular basis and the time period considered is 1 year only.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0.090	**Benefits:** 0.175	**Net:** 0.085	No	NA

Evidence Base (for summary sheets)

1. The Veterinary Medicines Regulations (VMR) implement the requirements of Directive 2001/82/EC, as amended by Directive 2004/28/EC. This Directive outlines the rules and requirements for the regulation of medicines for animal use. The VMR also implement the following Directive and Regulations relating to medicated feeds:

   - Council Directive 90/167/EEC laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community;
   - Regulation (EC) 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety;
   - Regulation (EC) 1831/2003 on additives for use in animal nutrition;
   - Regulation (EC) 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare;
   - Regulation (EC) 183/2005 laying down the requirements for feed hygiene.

2. The VMR first came into force in October 2005. The Veterinary Medicines Directorate (VMD) aims to revoke and remake the VMR on a regular basis as this allows us to respond quickly to the demands of the veterinary sector and therefore to formulate fit-for-purpose legislation that is meaningful to stakeholders.

3. At the last revision in 2011, eighteen policy changes were assessed for their impact on the main stakeholders that would be affected. Fourteen of these changes were finally agreed and progressed. Four of the progressed changes resulted in a monetary savings to industry of approximately £60,000 per annum. The savings were achieved through the reduction, removal and correction of fees. The increases were achieved by applying below inflation increase to existing fees. Six of the progressed changes had neutral monetary cost implications to industry. These six changes reduced the regulatory burden on farmers and the veterinary pharmaceutical industry and improved availability of medicines for animals. This was achieved by the simplification and unification of procedures and by making for a fairer system. The remaining four changes presented a monetary cost to industry of approximately £76,700 per annum. These changes were brought about to recover more accurately the costs of the work involved.

4. The VMD held a six week public consultation and received 33 responses about the 14 proposals. In response to particular comments on two of the proposals to restructure and increase fees, the proposal has either been withdrawn, pending further detailed investigation, or the proposed fees have been reduced.

PROBLEMS UNDER CONSIDERATION

5. Change 1: There is a problem in the UK with individuals importing illegal veterinary medicines, both for use on their own animals and for onward supply. The onward supply can be large or small, and means that not only the importer of the products benefits

illegally, but others do too. At present we can only use the VMRs to help us tackle the importation and the possession of unauthorised veterinary medicines so we are proposing to amend the relevant provisions to allow us to take enforcement action where necessary.

6. Change 2: The VMR permits an authorised inspector to seize certain products, including unauthorised products, authorised veterinary medicines not supplied in accordance with the Regulations, and products purporting to be veterinary medicinal products. The term 'purporting' implies that the product is claiming or contending to be a veterinary medicine. In some circumstances, such as unlabelled products, no such claim may be made, but an inspector may have reason to believe that a product is in fact a medicinal product and want to seize it. We are therefore, proposing to amend Regulation 35 (1) (g) of the VMR to permit an inspector to seize anything they believe (with reasonable grounds) to be a veterinary medicine. This is to address situations where we have reason to believe that a product has been decanted into an unlabelled bottle ready to be relabelled and marketed.

7. Change 3: The Regulations require all premises from which veterinary surgeons supply veterinary medicines to be registered as veterinary practice premises (VPPs) with the Royal College of Veterinary Surgeons (RCVS). However, unlike other types of premises authorised/approved under the VMR, where very serious non-compliance is detected there is no means of suspending or removing a VPP from the Register. We are therefore proposing to introduce a clause within Schedule 3 of the VMR to allow the removal of a veterinary practice premise from the register if the practice is not up to the standards.

8. Changes 4 – 13: Approximately 80% of the VMD's annual expenditure is recovered from industry by fees and charges for our work as regulator. The fees and charges are set in the VMR and as such can only be revised by amending or revoking and replacing the VMR. It is inevitable that over time the cost of individual activities changes for a number of reasons. Examples are cost reductions from efficiency savings in front-line or support costs or cost increases from additional responsibilities required by European legislation. A review of costs has highlighted that a number of fees are no longer sufficiently aligned with the costs of the activities they are recovering. It is also evident that an alternative fee structure for some types of work would give a fairer distribution of cost recovery. It is therefore necessary to revise a number of fees and fee structures to ensure that the VMD recovers the costs of its authorisation and inspection activities equitably and without cross-subsidy.

9. Change 14: Premises in Northern Ireland (NI) which carry out activities under Schedule 5 of the VMR are inspected, approved and the legislation is enforced by the Department of Agriculture and Rural Development (DARD) in NI. The DARD inspection team work independently from the VMD's inspectors in Great Britain (GB). Therefore, owing to the differences in feed enforcement arrangements in NI from GB, DARD has decided to retain the current fee structure as it better suits its needs. However in light of enhanced procedural checks on aspects such as traceability and carryover a 5% (rounded) rise in fees is essential this year to ensure full cost recovery is achievable. This will also help address inflationary issues.

10. Change 15: In order for the RCVS to recover the initial start up and operating costs to set up the register for VPPs and provide support to members, a fee of £40 per annum was introduced. Now that the software to enable the system has been fully developed and with a

reduction in number of queries received from its members, it is possible to reduce the current fee by 15%.

POLICY OBJECTIVE AND RATIONALE FOR INTERVENTION

11. The purpose of enforcement is to secure compliance with the requirements of the VMR and therefore to ensure that the aims of the VMD are met. The VMD seeks to work with businesses and assist them in complying with the legislation through the provision of sound advice and guidance. However, it is essential that the VMD has more formal means of enforcement to secure compliance when necessary. The proposed changes at 1 and 2 will strengthen inspectors' enforcement powers and aim to prevent the illegal distribution and use of illegal medicinal products.

12. Change 3 will allow the VMD to deal with VPPs that fail to comply with the requirements of the VMR, in the same way as other premises that are authorised/approved under the Regulations. Ultimately the change will help to ensure that veterinary medicines are stored and distributed in accordance with specified requirements, thereby maintaining their safety, quality and efficacy.

13. Changes 4 – 13 relate to fees charged. As a supply-funded net control agency, the VMD is required to recover the majority of its costs from fees and charges according to the principles laid down in HM Treasury's document "Managing Public Money" (MPM). The VMD is given an annual target of achieving 100% cost recovery. MPM requires that fees are set at a level designed to ensure that, as far as possible, they cover the cost of each activity without cross-subsidy between activities or industry sectors

14. The VMD regularly reviews its processes to make them more efficient and where possible passes on the savings. An example is Import Certificates: Previously all applications for Import Certificates attracted a fee. Following a review of this process, an on-line system was developed. Now that the costs of developing this system have been recovered, all online applications for Import Certificates are free.

15. Change 14 relates to the increase for the application and subsequent annual fee for manufacturers and distributors of feedingstuffs in Northern Ireland (NI). The fee structure in NI requires an increase to ensure that cost recovery is maintained by the enforcement authorities as a result of them addressing the detailed requirements of the relevant legislation.

16. Change 15 Veterinary surgeons are required to register their premises with the Royal College of Veterinary Surgeons (RCVS) in order to supply a veterinary medicinal product. Currently this annual fee is £40. Reducing the fee to £34 will reflect more accurately the cost of the work to maintain the register of veterinary practice premises (VPPs). This change will represent a savings to Veterinary Practices.

DESCRIPTION OF OPTIONS CONSIDERED

Option 0 ('do nothing') – Make no changes to the Veterinary Medicines Regulations 2011

17. Make no changes to the Veterinary Medicines Regulations 2011 and maintain the existing control and fees. This is the baseline against which option 1 is measured.

Option 1 – Introduce proposed changes to the Veterinary Medicines Regulations 2011

18. The VMR first came into force in October 2005. The VMD aims to revoke and remake the VMR on a regular basis as this allows us to respond quickly to the demands of the veterinary sector and therefore to formulate fit-for-purpose legislation that is meaningful to stakeholders. The VMD is a net running cost control agency with a target of 100% cost recovery so we also use this opportunity to update our fees where necessary in order to meet this target. Therefore we only have one Policy Option which is to revoke and remake the VMR.

19. A table of the proposals showing the sectors affected is at Annex A. A summary of proposed changes are as follows:

- Change 1: Amend the provisions relating to importation and possession of unauthorised veterinary medicines.
- Change 2: Amend Regulation 35 (1) (g) to permit an inspector to seize anything they believe (with reasonable grounds) to be a veterinary medicine.
- Change 3: Introduce a clause within Schedule 3 to allow the removal of a veterinary practice premise from the register if the practice is not up to the standards.
- Change 4: Clarification of fees for applications for Marketing Authorisations relating to "biosimilar" products.
- Change 5: Introduce a fee for the renewal of a registration of a homeopathic remedy.
- Change 6: Amendment of category descriptions for extensions to Marketing Authorisations.
- Change 7: Simplify the fees for appeals to the Veterinary Products Committee.
- Change 8: Removal of the fee for additional member states on application for a Marketing Authorisation relating to a Parallel Import.
- Change 9: Reduction to fees for Decentralised applications for Marketing Authorisations where the UK is Concerned Member State or for recognition of a product authorised in another member state.
- Change 10: Rebalancing of fees for manufacturers and wholesale dealers.
- Change 11: An increased charge for inspections of veterinary practice premises to achieve full cost recovery for this work.
- Change 12: Changes to fee structure for inspections of Manufacturers and Distributors of Feedingstuffs.
- Change 13: Reduction in fee for specific batch control applications relating to subsequent batches of product.

- Change 14: Increase for the application and subsequent annual fee for fees relating to manufacturers and distributors of feedingstuffs in Northern Ireland.
- Change 15: Changes to the fees applied by the RCVS for the registration VPPs.

20. Option 1 is the preferred option as option 0 does not address the issues that have been identified.

PROPOSED CHANGES

21. There are 15 separate proposed changes to the VMR 2011. Changes 1 - 7 have no cost impact to industry and changes 8 - 13 do. An Explanation of Terms is provided at Annex B. The 15 changes are as follows:

Change 1: Amend the provisions relating to importation and possession of unauthorised veterinary medicines

22. The purpose of the proposed change is to amend these individual offences within the VMR.

    a) Amend Regulation 25(1) from "to import" to "being concerned in the importation of"
    b) Amend Regulation 26(1) to include: "for the purpose of/with intent to supply"

23. Like human medicines, veterinary medicines are designed to treat or prevent disease which typically can be caused by viruses, bacteria or parasites. Medicines can include very dangerous substances and introducing a medicine into a live animal generates its own risks. Additionally for veterinary medicines it is necessary to protect the person administering the medicines or consuming animal foodstuffs. Lack of adequate regulation proportionately enforced can lead to improper use which can have a range of effects from being ineffective to being positively dangerous. Controls are required to ensure manufacturing quality and to enable the safe use of efficacious medicines. Inadequate controls on veterinary medicines would increase the risk of human and/or animal health scares leading to major political controversy and impacting on the economy.

24. The VMD's approach to enforcement is set out in our Enforcement Strategy (http://www.vmd.gov.uk/General/Enforce/Enforcement_Strategy.pdf). It is a proportionate and iterative approach, and follows the recommendations of the Hampton Report 2005 (*Reducing Administrative Burdens: Effective Inspection and Enforcement)* and the Macrory Review 2006 (*Regulatory Justice: Making Sanctions Effective*) and is consistent with Defra's Enforcement Policy Statement.

25. The current Regulations only allow enforcement action to be taken against those who are physically importing or in possession of unauthorised veterinary medicines. The proposed changes will allow the VMD to take enforcement action against those, not only physically importing illegally, but anyone involved or benefiting from the activities. This may also help to deter anyone who intends to import or possess medicines illegally in the future.

26. In addition, the amendment to Regulation 26 to include "for the purpose of/with intent to supply", will distinguish between someone who has bought an unauthorised product to use on their own animals and someone who possesses the drug because they make money out of selling it on. This will allow enforcement action to be focused on those who encourage and promote the illegal supply of unauthorised veterinary medicines for profit.

27. We expect that these proposed changes will have a minimal impact on resource costs to the VMD as the activities will be part of wider investigations. If there are costs incurred through an investigation, then there is also the possibility of recovering these costs through the Proceeds of Crime Act 2002. There should be no resource implications to an industry which

already complies with the VMR. Whilst the amendments increase our regulatory powers, there are no additional responsibilities placed on industry to conform with the legislation.

Change 2: Amend Regulation 35 (1) (g) to permit an inspector to seize anything they believe (with reasonable grounds) to be a veterinary medicine.

28. The purpose of the above change is to permit an inspector, approved for the purpose by the Secretary of State, to seize anything that they believe, with reasonable grounds, to be a veterinary medicine. This will also help to deter anyone who intends to supply medicines illegally. The right to appeal against a seizure notice will not be affected by this change.

29. Currently the Regulation permits an Inspector to seize anything that *purports* to be a veterinary medicine. This helps to ensure the safety, quality and efficacy of veterinary medicines by allowing inspectors to remove products that may pose a risk the safety of human and animal health, and the environment.

30. VMD inspectors have experienced situations where they have reason to believe that a product has been decanted into an unlabelled bottle ready to be relabelled and marketed with no controls. As these bottles are not labelled as, and therefore not purporting to be, veterinary medicines the grounds for an inspector to seize these medicines are unclear, this amendment is intended to clarify this issue.

31. We do not foresee any additional cost to the VMD as a consequence to this proposed change, as this will simply clarify the scope of powers to enforce the VMR. There should be no resource implications to an industry which already complies with the VMR. Whilst the amendments clarify our regulatory powers, there are no additional responsibilities placed on industry to conform with the legislation.

Change 3: Introduce a clause within Schedule 3 to allow the removal of a VPP from the register if the practice is not up to the required standards.

32. There is no provision in the VMR to remove a veterinary practice premises (VPP) from the Register of VPPs held by the Royal College of Veterinary Surgeons (RCVS), if they are unsuitable for the storage and supply of veterinary medicines. Unless veterinary medicines are stored under the conditions required by their Summary of Product Characteristics (SPC), and in accordance with legislation (e.g. in the case of certain Controlled Drugs), their quality and efficacy may be compromised, and the safety of human and animal health, and the environment, put at risk.

33. With the exception of VPPs, all other premises and sites, approved or authorised under the VMR, may have their approvals/authorisations suspended or revoked if the Secretary of State is satisfied that they are no longer suitable for their approved/authorised activity.

34. The VMD seeks to obtain compliance with the VMR through advice and/or enforcement, in accordance with its published Enforcement Strategy http://www.vmd.defra.gov.uk/pdf/EnforcementStrategy.pdf. The Strategy adopts an 'escalator' approach to enforcement, which aims to initially deal with non-compliances at the lowest appropriate level, but where continuing non-compliance is noted, enforcement action is successively increased, which may involve the serving of an improvement notice. Ultimately, a person or business can be prosecuted and, in the case of authorised/approved premises other than VPPs, the premises' authorisation or approval can be suspended or revoked.

35. Including a provision to remove a VPP from the Register would lead to consistent sanctions with other regulated businesses, and ensure that those premises that are not suitable for the storage and supply of veterinary medicines, and whose owners fail to take notice of formal advisory letters or improvement notices, can be removed from the Register.

36. The VMR has an appeal procedure for an approval/authorisation holder aggrieved by a decision to suspend or revoke the approval or authorisation of its premises/site. This appeal procedure would be extended to VPPs.

37. There is no fee set for the appeal in the VMR so the only cost would be to the appellant for any preparation necessary. We would estimate this to be <£200 as this is a written appeal which can only be based the data available to the Secretary of State at the time of the original decision. We anticipate very few, if any appeals as, in line with our Enforcement Strategy, the VPP will be given plenty of opportunity to take corrective action.

Change 4: Clarification of fees for applications for Marketing Authorisations relating to "bio-similar" products

38. Schedule 1 of the VMR gives the legal basis for pharmacologically-equivalent and immunological veterinary medicinal products and Schedule 7 of the VMR include fees for applications for Marketing Authorisations (MAs) relating to products of this type. However, the current fees intended to cover the cost of this work do not specifically include applications for bio-similar products.

39. The fee for a bio-similar application is the same as for a "full" application for an immunological product (Schedule 7, paragraph 9). Amending the VMR to clarify that the fee for the application for a MA relating to immunological products also applies to bio-similar products would allow us to recover the cost of this work.

Change 5: Introduce a fee for the renewal of a registration of a homeopathic remedy

40. Schedule 7 of the VMR provides a number of fees for an application to register a homeopathic remedy. The fees vary from £160 to £985, depending on the type of application. A registered homeopathic remedy is valid for five years following grant of the initial Registration. After this time the Registration must be renewed in order for it to continue to be registered. Once renewed the Registration then remains valid indefinitely, unless the VMD considers that an additional renewal is justified on the grounds of pharmacovigilance five years after the first renewal.

41. There is currently no fee to recover the cost of work on renewal applications. Work recording data indicates a fee of £320 would be sufficient to recover the costs of performing such work. We therefore, propose to amend the VMR to introduce a fee of £320 for the renewal of a homeopathic remedy.

Change 6: Amendment of category descriptions for extensions to Marketing Authorisation (MAs)

42. Schedule 7 of the VMR provides fees for several different types of extensions to MAs. Over time the possible types of extensions have developed and this has not been reflected in the descriptions of the corresponding fees. Currently there are six specific fee categories ranging from £5,390 to £9,620 with a seventh fee of £8,415 applying to any type of

extension other than those specifically listed. For the purpose of clarity it is proposed to extend the list of fees to a total of twelve specific types of extension while retaining the £8,415 fee for any other category not specifically listed. As the fees for the additional categories, all at £8,415, will be the same as the "other" fee, there is no cost implication.

Change 7: Simplify the fees for appeals to the Veterinary Products Committee (VPC)

43. Schedule 7 to the VMR includes a number of different fees for appeals made by the Marketing Authorisation Holders to the VPC against decisions made by the VMD relating to existing authorisations or applications for new ones. The current fees vary from £205 to £1,960 with different application types attracting a different level of fees. However, in reality, all appeals require a very similar amount of resources and expertise. The required resource includes the assessment of the appeal data, the cost of holding a VPC meeting and fees for the VPC experts involved. Therefore, to ensure cost recovery is achieved, and to eliminate potential cross-subsidisation between different appellants, we propose that one fee of £1,500 is appropriate. This is an estimate of the average cost of dealing with an appeal to the VPC.

44. We therefore propose to amend the VMR to replace all the current VPC appeal fees with a single fee of £1,500 for any type of appeal to the VPC. This will simplify the fees structure and will have a negligible impact on cost to the industry as only one appeal fee has been charged in the last three years.

Change 8: Removal of the fee for additional member states on application for a MA relating to a Parallel Import

45. Schedule 7 of the VMR includes fees for an application for an MA relating to a Parallel Import, where the imported product has been authorised in accordance with the mutual recognition procedure or decentralised procedure and the United Kingdom is included in these procedures. The fees payable are £1,755 for import from one member state plus £355 for each additional member state.

46. An analysis of work recording data cannot establish a clear link between the number of member states included and the total cost of the work. The additional fee of £355 for each subsequent member state is therefore unnecessary. We therefore, propose to amend the VMR to remove the additional fee of £355 for each additional member state and revise the text so that the fee of £1,755 applies regardless of the number of member states.

Change 9: Reduction to fees for Decentralised applications for MAs where the UK is Concerned Member State or for recognition of a product authorised in another member state

47. Schedule 7 to the VMR provides fees for applications for MAs for pharmaceutical and immunological veterinary medicinal products. These fees cover a number of types of application, which include a Decentralised application where the UK is Concerned Member State, an application for recognition of a product authorised in another member state and variations to existing authorisations of these types. Work recording data indicates that the current fees for these two types of application are too high and that a reduction would be appropriate.

48. Specifically, the fees for variations appear to require a 40% reduction.

49. In addition to the above, a supplementary fee of £1,280 applies for each additional target species or £805 if the target species is a non-food-producing animal. An analysis of costs indicates that the extra cost incurred by the addition of each target species is negligible once the number of additional species reaches three or more. Therefore it is appropriate to cap the supplementary fee to a maximum of two additional species.

50. We therefore propose to amend the VMR to:
    - apply a 40% reduction to all fees for variations to authorisations where the UK is Concerned Member State.
    - limit the supplementary fee to two additional target species for Decentralised applications where the UK is Concerned Member State and for applications for recognition of a product authorised in another member state.

Change 10: Rebalancing of fees for manufacturers and wholesale dealers

51. Schedule 7 to the VMR provides fees for applications, variations, inspections and annual service costs for manufacturers and wholesale dealers of authorised veterinary medicinal products. Work recording data indicates that the fees are not sufficient to recover the full cost of the above activities. Based on estimated activity volumes in 2012/13, we estimate that the current fees would result in an income shortfall of £53,000 from wholesale dealers and excess income of £15,000 from manufacturers.

52. In response to feedback received during the consultation the proposed fee increases to Schedule 6 wholesalers have been withdrawn. The impact of the proposed increased costs would have been disproportionate given the small size of the trade and the low risk posed by the medicinal products concerned.

53. We propose to amend the VMR to introduce revised fees as shown in Annex C.

Change 11: Fee increase for inspections of veterinary practice premises

54. Schedule 7 to the VMR provides a fee of £250 for the inspection of a veterinary practice premises. Work recording data indicates that the average cost of this type of inspection is currently in excess of £350. However the average cost is expected to be managed down to £350 within the next 12 to 18 months as the initial cycle of inspections will be complete and subsequent inspections will take less time. A fee of £350 is therefore appropriate. This is a 40% increase.

55. If the fee is maintained at its current level the VMD will be unable to cover the costs of inspecting veterinary practice premises.

Change 12: Changes to the fee structure for inspections of Manufacturers and Distributors of Feedingstuffs

56. The VMR provide fees to cover the cost of inspections and administration of Manufacturers and Distributors of Feedingstuffs. The fee structure for these activities is out of line with the fee structure for other types of inspections. They are comprised of an application fee (which covers an initial inspection) and an annual fee (which covers subsequent inspections irrespective of their frequency). There is no separate inspection fee.

57. For other inspection types (Wholesale Dealers and Manufacturing Authorisation Holders), the fees are comprised of an application fee (which covers the cost of processing the application), an annual fee and an inspection fee.

58. The VMD operates a risk based inspection policy. Fully compliant businesses are inspected less frequently than less compliant businesses, with the latter therefore generating a higher cost to the VMD.

59. The impact of the current fee structure is that fully-compliant Manufacturers and Distributors of Feedingstuffs pay the same fee as less compliant businesses regardless of how often each is inspected. The introduction of an inspection fee alongside a reduced annual fee would result in a fairer distribution of costs, collecting fees that are more closely aligned to the costs of each inspection.

60. An informal consultation was held in 2011, with key organisations representing each sector being consulted. The results were that Manufacturers and Distributors of Feedingstuffs supported our proposals to amend the application and subsequent annual fees to a lower amount as they will no longer cover the cost of an inspection and introduce inspection fees payable on each inspection.

61. The consultation also included a proposal to restructure and increase the fees for Suitably Qualified Person (SQP) premises. However, in response to consultation comments received on the impact of the fee increases, this proposal has been withdrawn pending further detailed investigations. Alongside this, in response to consultation comments, the proposed inspection fees for Manufacturers and Distributors of Feedingstuffs have been reduced, again pending a more detailed investigation.

62. The proposed revised fee structure is shown at Annex D.

Change 13: Reduction in fee for specific batch control applications relating to subsequent batches of product.

63. Schedule 7 of the VMR includes fees for an application for an authorisation to release a veterinary medicinal product under specific batch control. The fees payable for this authorisation is £560. An additional fee of £455 is also applied to any subsequent batch if a number of specific batch control applications are made at the same time and all the batches are affected by the same issue.

64. An analysis of work recording data suggests that we are over-recovering on specific batch control applications where multiple batches are involved. We therefore, propose to amend the VMR to reduce the subsequent fee from £455 to £100 to reflect the cost of undertaking this work.

Change 14: Increase for the application and subsequent annual fee for fees relating to manufacturers and distributors of feedingstuffs in Northern Ireland.

65. The VMR provide fees to cover the cost of the application and subsequent annual fee for manufacturers and distributors of feedingstuffs in the UK. The fees are split between Great Britain (GB) and Northern Ireland (NI) with the VMD having responsibility for the GB manufactures and distributors and The Department of Agriculture and Rural Development in Northern Ireland (DARD(NI)) having responsibility in NI. As you will see from Change 12 above, the VMD is proposing to amend the fee structure for feedingstuffs in GB, however, NI wish to keep the existing fees structure from the 2011 VMR due to the different feed enforcement arrangements which exist in Northern Ireland.

66. In order for DARD(NI) to achieve full cost recovery we are proposing a 5% increase to the existing fees, which are set out at Annex E. Costs are determined by calculating time spent on inspection and enforcement work as well as travelling costs.

Change 15: Changes to the fees applied by the RCVS for the registration VPPs.

67. Since 1 April 2009, VPPs have been required to be registered with the RCVS in order for veterinary surgeons to supply medicines from them. The RCVS hold the register of VPPs on behalf of the VMD.

68. The purpose of the register is to enable the VMD to fulfil its obligations under European law to maintain and improve traceability of and accountability for veterinary medicines. Registered premises are inspected by either the VMD or, for those VPPs accredited under the RCVS's Practice Standards Scheme, the RCVS.

69. There is an initial fee for registration and an annual registration fee for VPPs.

70. Schedule 7 to the VMR provides fees relating to VPPs. An analysis of costs indicates that current fees for initial registration and the annual registration fees are too high and that a reduction would be appropriate.

71. In order to recover the initial start up and operating costs to set up the register for VPPs and provide support to members, a fee of £40 per annum was appropriate. Now that the software to enable the system has been fully developed and with a reduction in number of queries received from members, it is possible to reduce the current fee by 15%.

72. Therefore, we propose to amend the VMR to revise the initial registration fee and annual fee for the registration of VPPs with the RCVS to £34.

COST AND BENEFITS OF OPTIONS UNDER CONSIDERATION

73. Option 0 – There are no cost or benefits with a do nothing option.

74. Option 1 – Changes 1–7 do not have any cost implications, however there will be benefits through these changes to industry. Changes 8- 15 do have cost implications.

The size and nature of the expected costs and benefits

75. **Change 1** - We expect that these proposed changes will have a minimal impact on resource costs to the VMD as the activities will be part of wider investigations. If there are costs incurred through an investigation, then there is also the possibility of recovering these costs through the Proceeds of Crime Act 2002. There should be no resource implications to an industry which already complies with the VMR. Whilst the amendments increase our regulatory powers, there are no additional responsibilities placed on industry to conform with the legislation

76. **Change 2** - We do not foresee any additional cost to the VMD from this proposal as it will clarify the scope of power to enforce the VMR. There should be no resource implications to an industry which already complies with the VMR. Whilst the amendments clarify our regulatory powers, there are no additional responsibilities placed on industry to conform with the legislation

77. **Change 3** - It is not possible to quantify the costs at this stage**.** However, we anticipate very few if any appeals. Suspension or removal of a VPP from the Register would mean that veterinary medicines could no longer be supplied (which includes administered to animals) from the premises. The change to policy would not present a monetised benefit but it would ensure the continued quality of veterinary medicines distributed through the supply chain.

78. Changes to fees and charges relating to existing regulation like in the following cases are treated as transfers in cost benefit analysis (see summary pages above) i.e. they transfer the cost between businesses and the taxpayer. For example an increase in fees raises business costs but increases by the same amount the revenue received by VMD and is therefore also a benefit to taxpayers.

79. **Change 4** - rebalances the fee charged to the sector so that they are more closely aligned to the cost of individual activities. This net change results in no net change in revenues.

80. **Change 5** - The estimated additional cost to industry is negligible, as there are currently a very low number (7) of homeopathic remedies registered with the VMD with no prospect of this increasing significantly in the future. All of the currently registered remedies have recently been through renewal, and so will not incur this fee for at least five years, if at all. However, if a fee of £320 is introduced then the estimated cost of work on any future homeopathic renewal applications can be recovered.

81. **Change 6** - Will add clarity to the existing fees to avoid any confusion regarding the applicable fee but will have no impact on the sums collected relative to the baseline option 0.

82. **Change 7** - The fees structure will be simplified by reducing from the current eight fees when applying for an appeal to the Veterinary Products Committee (VPC) to one that more accurately reflects the cost of the work.

83. **Change 8** – This change represents a saving to industry as we propose to remove the fee for additional member states on applications for MA relating to Parallel Import applications. An analysis of the costs of administering these applications indicates that there is no clear link between the number of member states included and the total cost of the work. Due to the very low volume of applications of this type, (assuming an average of 3 applications per year at £355 per application), we anticipate that the total industry benefit will be no more than £1,065 per year.

84. **Change 9** – This change will represent a saving to industry as we propose to amend the VMR to:
    - apply a 40% reduction to all fees for variations to authorisations where the UK is Concerned Member State.
    - limit the supplementary fee to two additional target species for Decentralised applications where the UK is Concerned Member State and for applications for recognition of a product authorised in another member state.

85. This change is expected to represent a saving to industry of £135,000 per year. This is calculated based on an assumption of 245 variation applications per year giving an average saving of £550 per application per year. A breakdown of the costs is provided at Annex F.

86. **Change 10** – This will represent an overall cost of £38,000 to industry through rebalancing of the fees for manufacturers and wholesale dealers. Based on anticipated activity volumes in 2013/14, the revised fees are expected to cost the wholesale dealer sector an additional £53,000 per year and save the manufacturing sector £15,000 per year. A rebalancing of the fees for manufacturers and wholesale dealers will ensure that the costs will be adequately recovered from the relevant sector without cross-subsidy.

87. There are approximately 140 authorised veterinary-only wholesale dealers and 50 authorised veterinary-only manufacturers. Annex C shows that there are 75 different fee types within this category. Some of the fees relate to inspection activity, the volumes of which are largely within the VMD's control and predictable, while others relate to application activity, which are not. The estimated volumes are based on 2011/12 volumes as these tend to be fairly consistent year on year. The average increase per wholesale dealer is £393 per year and the average saving per manufacturer is £300 per year. However the actual impact on an individual authorisation holder will depend on the number of applications and authorisations they hold as well as the inspection frequency, which depends on an assessment of their compliance.

88. **Change 11** – The change will add a cost to industry through an increase fee charged for a veterinary practice premises inspection fee. The additional cost to the sector, based on an annual inspection plan of 500 inspections a year, will be £50,000. As a compliant site can expect to be inspected once every four years, the additional annual cost to a compliant site is £25.

89. This type of inspection was first introduced during 2009/10. A full year's volume of inspections was therefore first recorded in 2010/11 and amounted to 432. We expect

approximately 500 inspections in 2011/12 and the same in subsequent years. The proposed new inspection fee at £350 is an increase of £100, which at an annual volume of 500 gives an expected increase in income of £50,000 per year.

90. **Change 12** - The introduction of an inspection fee alongside a reduced annual fee would result in a fairer distribution of costs, by collecting fees that are more closely aligned to the costs of each inspection. There will also be a financial incentive for less compliant businesses to become more compliant and the revised fee structures would be consistent with those for other sectors.

91. The overall additional cost to the sector, based on the anticipated number of inspections, is approximately £1063 per year. The additional cost for an individual operator will depend on the category of site and the frequency of inspection, which will depend on the level of compliance of each operator. Less compliant operators will pay a higher amount per year than a compliant business as they will be inspected more frequently.

92. Annex D shows that there are currently 8 different fee types falling within this category and this will increase to 16. The anticipated number of registered premises and inspections of these is expected to be consistent with those recorded in 2011/12 and the anticipated additional costs to industry are based on this assumption.

93. **Change 13** – This change represents a saving to industry as we propose to reduce the fee for specific batch control applications relating to subsequent batches of product. An analysis of work recording data suggests that we are over-recovering on specific batch control applications where multiple batches are involved. We therefore, propose to amend the VMR to reduce the subsequent fee from £455 to £100.

94. This change is expected to represent a saving to industry of £9230 per year. This is calculated based on an assumption of an average of 26 applications per year giving a saving of £355 per application.

95. **Change 14 –** The change will add a cost to industry through an increase fee charged for an application and subsequent annual fee for manufacturers and distributors of feedingstuffs in NI. The additional cost to the sector, based on 120 applications per year and an average rise of £10 in annual fees, will be £1,200.

96. **Change 15** - Will represent a saving to the industry and reflect more accurately the operating costs incurred by the RCVS to maintain the register of VPPs. This will be a savings of £30,000 to the sector, based of 5000 members and a reduction in fees by £6.00.

SUMMARY TABLE OF COSTS AND BENEFITS ('000£ per year)

Change No:	8	9	10	11	12	13	14	15	Total
VMD	-1.1	-135	+38	+50	+1.1	-9.2	+1.2	-30 (1)	-85
Industry	+1.1	+135	-38	-50	-1.1	+9.2	-1.2	+30	+85

Positive sign indicates benefit/negative sign indicates cost
(1) Cost to RCVS

OVERALL IMPACT ACROSS VARIOUS BUSINESS SUB-SECTORS

Business sector	**Overall costs/benefits ('000£ per year)**
Pharmaceutical Industry (changes 8, 9 and 13)	+145.3
Manufacturers (change 10)	+15
Wholesalers (change 10)	-53
Veterinary Practice Premises (changes 11 and 15)	-20
Manufacturers and distributors of feedingstuffs (changes 12 and 14)	-2.3

97. The VMD does not have statistics on any secondary impact there may be from the above costs and benefits. However, it is expected that if there is any secondary impact then it would be small.

OITO and Moratorium on micro-business regulation

98. OITO and the moratorium on micro-businesses do not apply as the VMR is implementing Directive 2001/82 (as amended). Similarly changes to fees and charges are out of scope with respect to OITO and the moratorium.

Approach taken

99. The appropriate fees required to recover the costs of the VMD's authorisation and inspection activities are determined from an analysis of the average cost of each activity based on historic data, adjusted for the impact of any known or assumed inflationary, efficiency or operational changes in the future.

100. It is also necessary to estimate the annual number of occurrences of each activity, to determine how many fees of each type will be charged each year to ensure that each fee charged makes an appropriate contribution to the VMD's support and overhead costs.

101. The VMD is able to analyse the historic costs of its activities by reference to a staff work recording system. The estimated number of each activity per year is determined

based on historic trends, adjusted for known or assumed future changes. This process is enhanced through regular consultation with the industries involved.

SPECIFIC IMPACT TESTS

Statutory Equality Duties Impact Test

102. There are no limitations on meeting the requirements of the proposal on the grounds of race, disability or gender. The proposal does not impose any restriction or involve any requirement which a person of a particular racial background, disability or gender would find difficult to comply with. Conditions apply equally to all individuals and businesses involved in the activities covered by the proposed changes.

Economic Impacts:

Competition Assessment Impact Test

103. Overall, the proposed changes are likely to affect a number of markets related to veterinary medicines. The proposed changes to the VMR are not considered likely to affect the market structure or to impose higher costs for new companies than for existing ones, or to affect the current position in respect of companies' ability to choose price, quality, range or location of their products.

104. The competition filter test was completed in respect of four markets considered to be most affected:

A – the veterinary pharmaceutical industry;
B – veterinary practices;
C – SQP Retailers;
D – veterinary wholesale dealers.

Veterinary Pharmaceutical Industry

105. Veterinary medicine differs from human medicine because it is more complex, with a large number of species and different requirements for medicines for food and companion animals. It is private medicine, and has a much smaller market than human medicine (the UK annual turnover of veterinary medicines is around £475 million, the same turnover for some of the larger human products). The veterinary pharmaceutical industry comprises approximately 256 companies who between them currently hold Marketing Authorisations (MAs) for some 2,000 veterinary medicinal products authorised in the UK. In some cases two or more of these may be owned by a "parent" company. The companies range from large multinationals to small businesses. A period of 10 years is accepted as an illustrative norm for the time taken to develop and bring to the market a new product. The provisions of the VMR that impact upon the veterinary pharmaceutical industry will apply across the board and are not considered to affect some companies substantially more than others. The provisions are not considered likely to affect the market structure or to impose higher costs for new companies than for existing ones. The changes to the VMR will not affect the current position in respect of companies' ability to choose price, quality, range or location of their products.

B. Veterinarians

102. The Royal College of Veterinary Surgeons (RCVS) estimates that there are 4500 veterinary practices premises registered in the UK. The RCVS Report "RCVS Facts 2009" indicates that 53.7% of practices focus mainly on small (i.e. non-food) animals, 2.7 % on large animals, 30.5 % on mixed animals (i.e. small animals and food animals) and 3.9% on equines (horses and ponies). The sector is not characterised by rapid technological change.

The provisions in the VMR that impact upon veterinary practices will apply to all practices. They are not considered likely to affect the market structure or to impose higher costs for new companies than for existing ones. The VMR will not affect the current position in respect of a veterinary practices' ability to choose price, quality, range or location of their products.

C. Agricultural Merchants, pet shops, pharmacists and SQP retailers

103. Approximately 1,300 premises in the UK are registered for the supply of veterinary medicines by SQPs. These vary in size from small, single outlet businesses to larger chains owning several outlets. Typically, agricultural merchants will be based in rural areas and will supply farming requisites which may range from animal feed and protective clothing through to agricultural machinery. To sell Prescription Only Medicine – Veterinarian, Pharmacist, SQP (POM-VPS) and Non-Food Animal – Veterinarian, Pharmacist, SQP (NFA-VPS) veterinary medicines, merchants need to register with the VMD (or the Department of Health, Social Services and Public Safety in Northern Ireland). To be registered they need to have suitable premises and staff, to have the services of a Registered Qualified Person to authorise each sale of medicines and to comply with specified operational requirements. Registration is annual and premises are subject to inspection. Some veterinary surgeries and some registered pharmacies are also registered as agricultural merchants. The Competition Commission Report referred to above indicates that animal health products account for between 15% and 25% of the business of a typical agricultural merchant. The sector is also not characterised by rapid technological change. The changes to the VMR are not considered likely to affect the market structure in general or to impose higher costs for new companies than for existing ones.

D. Wholesale Dealers

104. Approximately 160 wholesalers are authorised to deal in veterinary medicines. These include enterprises dealing solely in veterinary medicines as well as others that wholesale both human and veterinary medicines. Authorisation holders include smaller companies operating from single sites as well as larger businesses operating from a number of sites. Some companies who hold Marketing Authorisations also hold wholesale dealer authorisations. Individuals, partnerships, limited companies and corporate bodies are all eligible to hold wholesale dealer authorisations provided they meet the necessary requirements. These primarily relate to having sufficient and suitable staff, premises, equipment and facilities for the handling, storage and recording of the products concerned. Individual authorisations specify the categories of product (i.e. Prescription Only Medicine – Veterinarian (POM-V), POM-VPS, NFA-VPS and Authorised Veterinary Medicine – General Sales List (AVM-GSL)) and types of product (e.g. ointments, tablets, sterile liquids etc) that they relate to as well as listing all sites at which the relevant activities may be carried out. The sector is not characterised by rapid technological change. The proposed changes to the VMR are not considered likely to affect the market structure or to impose higher costs for new companies than for existing ones, or to significantly affect the current position in respect of companies' ability to choose price, quality, range or location of their products.

Small Firms Impact Test

105. As a result of a continual process of informal consultation with our stakeholders on proposed legislative developments (such as stakeholder meetings, regular industry liaison and attendance by key personnel at high profile industry events throughout the year) the VMD feels that the proposed changes will not have a significant nor disproportional impact

on small firms. It is possible, however, that an indirect side-effect of some of the measures may be that the handling costs to small firms could be somewhat higher, pro rata, than for larger ones. Having given the matter due consideration, we have concluded that the proposed measures are appropriate. This is because EU law applies to all veterinary medicinal products as the risks of illegal use are the same irrespective of the size of the company dealing with the product and for this reason we cannot make an exemption to small firms. Like human medicines, veterinary medicines are designed to treat or prevent disease which typically can be caused by viruses, bacteria or parasites. Medicines can include very dangerous substances and introducing a medicine into a live animal generates its own risks. Additionally for veterinary medicines it is necessary to protect the person administering the medicines or consuming animal foodstuffs. Lack of adequate regulation proportionately enforced can lead to improper use which can be ineffective and dangerous.

106. The majority of businesses that are within the scope of the VMR are likely to fall into the 'Small Firm' category. However, the VMD does not have statistics on the proportion of small businesses affected directly by the proposals set out in the IA and no further information has come forward during the consultation.

Environmental Impacts:

Greenhouse Gas Assessment and Wider Environmental Issues Test

107. We do not expect that the changes proposed will affect greenhouse emissions, climate change, waste management, landscapes, water and floods, habitat and wildlife or noise pollution or will affect sustainable development.

Social Impacts:

Health and well being Impact Test

108. The proposal will not directly impact on health or well-being and will not result in health inequalities.

Human Rights Impact Test

109. The proposals are not expected to impact on the rights and freedoms of individuals as set out in the Human Rights Act 1998.

Justice System Impact Test

110. We do not consider that the changes proposed will have an impact on Legal Aid but have carried out a Justice Impact test.

Rural Proofing Impact Test

111. The proposals are considered to have an equal effect in both rural and urban areas.

Sustainable Development Impact Test

112. The changes proposed are not expected to have any significant impact on sustainable development.

Annex A
Summary of the proposals showing sectors affected

Proposed changes	**Main sectors likely to be affected by the proposal**	**Likely benefits**	**Possible new annual costs to the sector**
Change 1: Amend the provisions relating to importation and possession of unauthorised veterinary medicines	Pharmaceutical industry, retailers of veterinary medicines, purchasers of veterinary medicines.	Improved clarity of offences within the VMR.	None.
Change 2: Amend Regulation 35 (1) (g) to permit an inspector to seize anything they believe (with reasonable grounds) to be a veterinary medicine.	Pharmaceutical industry, retailers of veterinary medicines, purchasers of veterinary medicines.	Improved clarity of offences within the VMR.	None.
Change 3: Introduce a clause within Schedule 3 to allow the removal of a veterinary practice premise from the register if the practice is not up to the standards.	Veterinary practice Premises from where veterinary surgeons supply medicines	Brings veterinary practice premises into line with other businesses approved/authorised under the VMR; and permits the Enforcement Strategy to be fairly and consistently applied to all businesses.	Not identified yet
Change 4: Clarification of fees for applications for Marketing Authorisations relating to bio-similar products	Holders of Marketing Authorisations relating to Veterinary Medicinal Products	Fees charged to the sector will be rebalanced so that they are more closely aligned to the cost of individual activities.	None.
Change 5: Introduce a fee for the renewal of a registration of a homeopathic remedy	Registered manufacturers of homeopathic remedies.	The cost of this work will be recovered from the applicant rather than being subsidised by other types of applications from the same sector.	None

Proposed changes	Main sectors likely to be affected by the proposal	Likely benefits	Possible new annual costs to the sector
Change 6: Amendment of category descriptions for extensions to Marketing Authorisations	Holders of Marketing Authorisations relating to Veterinary Medicinal Products	A simple text clarification with no cost implication.	None
Change 7: Simplify the fees for appeals to the Veterinary Products Committee	Holders of Marketing Authorisations relating to Veterinary Medicinal Products	Fees will be more aligned with estimated underlying costs.	None.
Change 8: Removal of the fee for additional member states on application for a Marketing Authorisation relating to a Parallel Import	Holders of Marketing Authorisations relating to Veterinary Medicinal Products	Removal of the fee will prevent the possibility of fees charged to industry for Parallel Import applications exceeding the costs.	No additional cost to the sector. Savings of £1,065 per year
Change 9: Reduction to fees for Decentralised applications for Marketing Authorisations where the UK is Concerned Member State or for recognition of a product authorised in another member state.	Holders of Marketing Authorisations relating to Veterinary Medicinal Products	Fees charged to industry for these types of applications will more accurately reflect the cost of the work, realising significant savings to the sector.	Savings of £135,000 per year
Change 10: Rebalancing of fees for manufacturers and wholesale dealers.	Manufacturers and Wholesale Dealers of Veterinary Medicinal Products	Fees charged to industry for applications and inspections will more accurately reflect the cost of the work.	Savings of £15,000 per year for manufacturers. Additional costs of £53,000 per year for wholesale dealers.

Proposed changes	Main sectors likely to be affected by the proposal	Likely benefits	Possible new annual costs to the sector
Change 11: Increased fee for inspections of Veterinary Practice Premises.	Veterinary Practice Premises	Fees charged to industry for inspections will more accurately reflect the cost of the work.	£50,000 per year. (Equates to £25 per year for a compliant practice).
Change 12: Changes to fee structure for the application and inspections of Manufacturers and Distributors of Feedingstuffs	Manufacturers and Distributors of Feedingstuffs	Brings the fee structure into line with other types of premises inspected: reduced application fee plus reduced annual fee plus an inspection fee *instead of* an application fee plus an annual fee	£1063 per year
Change 13: Reduction in fee for specific batch control applications relating to subsequent batches of product.	Marketing Authorisation Holders.	Reduction in the fee will prevent the possibility of fees charged to industry exceeding the costs.	None
Change 14: Increase for the application and subsequent annual fee for fees relating to manufacturers and distributors of feedingstuffs in Northern Ireland.	Manufacturers and Distributors of Feedingstuffs	Due to the different feed enforcement arrangements in Northern Ireland it has been decided to retain the current fee structure. However in light of enhanced procedural checks on aspects such as traceability and carryover a 5% (rounded) rise in fees is essential this year and possibly next to ensure full cost recovery is achievable. This will also help address inflationary issues.	The additional cost to the sector, based on 120 applications per year and an average rise of £10 in annual fees, will be £1,200.

Proposed changes	Main sectors likely to be affected by the proposal	Likely benefits	Possible new annual costs to the sector
Change 15: Changes to the fees applied by the RCVS for the registration of veterinary practice premises.	Veterinary Practice Premises	Fees charged to industry for registration and annual renewal will more accurately reflect the cost of the work.	No additional cost to the sector. Savings of £30,000 (£6 reduction x 5000 members)

ANNEX B

EXPLANATION OF TERMS

Authorised Veterinary Medicine – General Sales List (AVM-GSL)
There are no legal restrictions in the Veterinary Medicines Regulations for the retail supply of veterinary medicines classified as AVM-GSL ("over the counter" medicine) but a responsible approach to the supply of these medicines is still expected.

Biosimilar
A biosimilar is a biological product (a medicine) that is similar but not identical to a reference biological product that has already been authorised. Therefore, it does not meet the conditions as defined for a generic veterinary medicinal product. The differences could be in the raw materials used or in manufacturing processes of the respective products. In such cases the results of appropriate safety and residue tests and pre-clinical tests or clinical trials relating to these conditions must be provided with the application for a biosimilar product.

Concerned Member State
A member state of the EU involved in either the mutual recognition or decentralised authorisation procedures. The concerned member state recognises the marketing authorisation issued by the reference member state or the assessment of the reference member state

Department of Agriculture and Rural Development (DARD)
DARD has responsibility for food, farming, and environmental policy and the development of the rural sector in Northern Ireland. It provides a business development service for farmers and growers, and a veterinary service with administration of animal health and welfare. It is responsible to the Department of the Environment, Food and Rural Affairs (Defra) in Great Britain for the administration in Northern Ireland of schemes affecting the whole of the United Kingdom. The Department also oversees the application of European Union agricultural and rural development policy to Northern Ireland.

Decentralised
One of the European authorisation procedures. An applicant may submit an application for a new marketing authorisation simultaneously to a number of member states. The applicant will choose a reference member state to lead on the assessment. The concerned member states will then recognise that assessment.

European Medicines Agency (EMA)
The European agency that is responsible for assessment of all applications for medicinal products via the centralised procedure and advising the European Commission accordingly. It is located in Canary Wharf, London.

Feedingstuffs
'Feed' or ('feedingstuff') means any substance or product, including additives, whether processed or partially processed or unprocessed, intended to be used for oral feeding to animals.

Hampton Review
In the 2004 Budget, the Chancellor invited Philip Hampton to consider the scope for reducing administrative burdens by promoting more efficient approaches to regulatory inspection and enforcement, without compromising regulatory standards or outcomes. The final report was subject to scrutiny/ validation through the review process and was published in March 2005.

Immunological product
A class of product usually referred to as vaccines.

Marketing Authorisation (MA)
An authorisation given by the national competent authority after successful evaluation of the data dossier provided by the applicant. The MA provides the holder with the authority to sell and supply a veterinary medicinal product.

Marketing Authorisation Parallel Import
The import of an authorised veterinary medicinal product from another member state for relabeling for sale in the UK.

Non-Food Animal – Veterinarian, Pharmacist, SQP (NFA-VPS)

A veterinary medicine classified as NFA-VPS may be supplied by any Registered Qualified Person (RQP - a veterinarian, a pharmacist or an appropriately qualified SQP) provided the requirements for supply are met. These medicines do not require a prescription.

Premixtures
A mixture of a veterinary medicinal product or a specified feed additive with feedingstuffs materials, intended for further mixing with feedingstuffs before being fed to animals"

Prescription Only Medicine – Veterinarian (POM-V)

A veterinary medicine that has been classified as a POM-V may only be supplied to the client once it has been prescribed by a veterinary surgeon following a clinical assessment of an animal, or group of animals, under the veterinary surgeon's care.

Prescription Only Medicine – Veterinarian, Pharmacist, SQP (POM-VPS)

A veterinary medicine classified as POM-VPS may be prescribed by any Registered Qualified Person (RQP - a veterinarian, a pharmacist or an appropriately qualified SQP). A clinical assessment of the animal(s) is not required when prescribing this category of veterinary medicine and the animal does not have to be seen by the prescriber. However sufficient information about the animal and the way it is kept must be known to the prescriber in order to prescribe and supply appropriately.

Royal College of Veterinary Surgeons (RCVS)
The RCVS register veterinary surgeons and veterinary nurses to practise in the UK, and regulate their educational, ethical and clinical standards.

Their role is to safeguard the health and welfare of animals committed to veterinary care through the regulation of the educational, ethical and clinical standards of veterinary surgeons and veterinary nurses, thereby protecting the interests of those dependent on animals, and assuring public health.

Specified feed additive
A feed additive authorised in accordance with Regulation 1831/2003 and included in the category of (a) coccidiostats, (b) histomonostats and (c) all *other zootechnical additives except (i)

digestibility enhancers; gut flora stabilisers; and substances incorporated with the intention of favourably affecting the environment.

*"Other" zootechnical additives included would generally be regarded as additives that make a medicinal claim, such as one that claims to promote growth in animals.

Suitably Qualified Person (SQP)
An SQP is a category of professionally qualified persons who are entitled to prescribe and/or supply certain veterinary medicinal products under the VMR.

Summary of Product Characteristics (SPC)
An SPC is prepared for every authorised veterinary medicine in the UK as an information resource for that particular medicine. Included in this summary are warnings and information for those professionals who will prescribe and supply the medicines.

Veterinary Products Committee (VPC)
The VPC is an independent advisory body who offers advice to the VMD on behalf of the Secretary of State on request.

Veterinary Practice Premises (VPP)
RCVS register VPPs on behalf of the Veterinary Medicines Directorate.

Work Recoding
The VMD uses a work recording system in order to establish the cost of its various activities and to provide the basis for allocating all costs across its separate business categories. Cost analysis at a detailed activity level and cost allocation are essential in order to meet the HM Treasury requirement of full cost recovery with no cross-subsidy. To calculate the above proposed fee changes, work recording data was used to determine the average time spent on each activity by VMD staff per grade. This was multiplied by the hourly grade rate. The hourly rate comprises staff salary costs and an uplift to include non chargeable time and other VMD overheads.

Annex C

Proposed fee changes for manufacturers and wholesale dealers (Change 10)

DESCRIPTION	CURRENT FEE	PROPOSED FEE	Change %
	£	£	%
1. MANUFACTURER'S AUTHORISATION			
Application	3,040	3,040	0%
Application - Schedule 6 products	530	530	0%
Variation requiring scientific or pharmaceutical assessment	545	636	17%
Variation - change of ownership	380	443	17%
Variation - Schedule 6 products	180	210	17%
Variation not requiring scientific or pharmaceutical assessment	300	350	17%
Autogenous vaccine - authorisation for each UK manufacturing site	3,435	3,435	0%
Autogenous vaccine - authorisation for each non-UK manufacturing site	3,270	3,270	0%
Autogenous vaccine - single batch	1,635	1,635	0%
Autogenous vaccine - variation requiring inspection - UK site	3,435	3,435	0%
Autogenous vaccine - variation requiring inspection - non-UK site	3,270	3,270	0%
Autogenous vaccine - variation not requiring inspection	305	305	0%
Annual Fee - other than autogenous vaccines	495	550	11%
Annual Fee - autogenous vaccines - % of turnover in previous calendar year	0.67%	0.67%	0%
Annual fee - Schedule 6 products	no fee	no fee	0%
2. MANUFACTURING SITE INSPECTION FEES			
NOTE: IF A SITE IS INSPECTED FOR MORE THAN ONE TYPE OF AUTHORISATION AT THE SAME TIME, THE INSPECTION FEE PAYABLE IS THE HIGHEST INSPECTION FEE PLUS 50% OF ANY OTHER APPLICABLE INSPECTION FEES.			
NOTE: FOR NON-UK SITES ONLY, TRAVEL AND SUBSISTENCE COSTS AND, IF APPLICABLE, TRANSLTION COSTS ARE PAYABLE IN ADDITION TO THE INSPECTION FEE.			
2.1 IMMUNOLOGICAL SITE INSPECTIONS - UK SITES			
Super site	26,745	24,071	-10%
Major site	18,650	16,785	-10%
Standard site	6,055	6,661	10%
Minor site	5,285	4,757	-10%
Autogenous Vaccine Site Inspection	3,435	3,779	10%
2.2 IMMUNOLOGICAL SITE INSPECTIONS - NON-UK SITES			

Super site	25,480	22,867	-10%
Major site	17,760	15,946	-10%
Standard site	5,765	6,327	10%
Minor site	5,035	4,519	-10%
Autogenous Vaccine Site Inspection	3,270	3,590	10%
(Note: travel & subsistence costs are payable in addition to the above fees).			
2.3 PHARMACEUTICAL SITE INSPECTIONS - UK SITES			
Super site - Sterile	25,915	23,324	-10%
Major site - Sterile	14,455	13,010	-10%
Standard site - Sterile	9,160	8,244	-10%
Minor site - Sterile	4,565	5,022	10%
Super site - non-sterile	15,755	14,180	-10%
Major site - non-sterile	9,250	8,325	-10%
Standard site - non-sterile	7,615	6,854	-10%
Minor site - non-sterile	4,210	3,789	-10%
Super site - Assembly of products only	12,250	11,025	-10%
Major site - Assembly of products only	6,610	5,949	-10%
Standard site - Assembly of products only	4,470	4,917	10%
Minor site - Assembly of products only	1,850	2,035	10%
Minor site - Schedule 6 products only	2,480	2,728	10%
Standard site - Schedule 6 products only	4,595	5,055	10%
2.4 PHARMACEUTICAL SITE INSPECTIONS - NON-UK SITES			
Super site - Sterile	24,680	22,157	-10%
Major site - Sterile	13,770	12,359	-10%
Standard site - Sterile	8,725	7,832	-10%
Minor site - Sterile	4,350	4,770	10%
Super site - non-sterile	15,015	13,471	-10%
Major site - non-sterile	8,810	7,909	-10%
Standard site - non-sterile	7,250	6,511	-10%
Minor site - non-sterile	4,010	3,600	-10%
Super site - Assembly of products only	11,665	10,474	-10%
Major site - Assembly of products only	6,295	5,652	-10%
Standard site - Assembly of products only	4,255	4,671	10%
Minor site - Assembly of products only	1,760	1,933	10%
Minor site - Schedule 6 products only	2,365	2,592	10%
Standard site - Schedule 6 products only	4,380	4,802	10%
(Note: travel & subsistence costs are payable in addition to the above fees).			
2.5 TEST SITES, BLOOD BANKS, STEM CELLS			
Test site inspection - UK site	3,040	3,344	10%

Test site inspection - non-UK site (travel & subsistence costs charged in addition to fee)	2,900	3,177	10%
Blood bank - authorisation to operate	2,830	3,113	10%
Blood bank - subsequent inspection - UK site	2,970	3,113	5%
Blood bank - subsequent inspection - non-UK site[1]	2,830	2,966	5%
Variation of a blood bank authorisation	305	320	5%
Stem Cell product - authorisation	3,270	3,427	5%
Stem Cell product - subsequent inspection - UK site	3,435	3,092	-10%
Stem Cell product - variation	305	320	5%
3. WHOLESALE DEALER'S AUTHORISATIONS:			
Application - turnover more than or equal to £35,000	1,760	1,745	-1%
Application - turnover less than £35,000 or AVM-GSL or homeopathic products only	785	785	0%
Application – Schedule 6 products only	785	785	0%
Variation requiring scientific or pharmaceutical assessment	515	515	0%
Variation only involving change of ownership	430	430	0%
Variation not requiring scientific or pharmaceutical assessment	300	300	0%
Annual Fee - turnover more than or equal to £35,000	330	483	47%
Annual Fee - turnover less than £35,000 or AVM-GSL or homeopathic products only	215	315	47%
Annual Fee – Schedule 6 products only	215	215	0%
Inspection - AVM-GSL or homeopathic products only	830	1,442	74%
Inspection - turnover in previous calendar year less than £35,000	830	1,442	74%
Inspection – Schedule 6 products only	830	830	0%
Inspection - otherwise	1,760	3,058	74%
Wholesale Dealers Import Certificate*	760	1,320	74%
* only payable if, in the twelve month period immediately before the application, the applicant has supplied the veterinary medicinal product to which the certificate relates in accordance with at least 100 certificates.			

Annex D

Changes to the fee structure for the application, annual fee and inspections of Manufacturers and Distributors of Feedingstuffs and Suitably Qualified Persons (SQP) Premises (Change 12)

DESCRIPTION	CURRENT FEE £	PROPOSED FEE £	Change % %
1. FEES RELATING TO FEEDINGSTUFFS			
NOTE: WHERE MORE THAN ONE OF THE MANUFACTURING ACTIVITIES BELOW IS CARRIED OUT AT ONE PREMISES, ONLY ONE ANNUAL FEE (THE HIGHEST) IS PAYABLE. SIMILARLY ONLY ONE INSPECTION FEE (THE HIGHEST) IS PAYABLE. (a) Manufacturers			
APPLICATION AND ANNUAL FEES			
Category 1 - approval of an establishment to manufacture a specified feed additive and the subsequent annual fee (no fee is payable for premises that already have a manufacturing authorisation relating to veterinary medicinal products for incorporating into feedingstuffs).	975	70	-93%
Category 2 - Approval of an establishment to manufacture a premixture.	615	70	-89%
Category 3 - Approval of an establishment to manufacture feedingstuffs, using specified feed additives or veterinary medicinal products directly at any concentration, or using premixtures.	615	70	-89%
Category 4 - Approval of an establishment to manufacture feedingstuffs for placing on the market using a veterinary medicinal product or premixture where the concentration of veterinary medicinal product in the feedingstuffs in 2kg per tonne or more.	415	70	-83%
Category 5 - Approval of an establishment to manufacture feedingstuffs using premixtures containing specified feed additives when the feedingstuffs are to be placed on the market.	205	70	-66%
Category 6 - Approval of an establishment to manufacture feedingstuffs for the manufacturer's own use using a veterinary medicinal product or premixture where the concentration of veterinary medicinal product in the feedingstuffs is 2kg per tonne or more.	150	70	-53%
Category 7 - Application for the approval of an establishment to manufacture feedingstuffs using premixtures from specified feed additives when the feedingstuffs are to be used by the person manufacturing the feedingstuffs, and the subsequent annual fee.	130	70	-46%
INSPECTION FEES			

Category 1 - Approved establishment to manufacture a specified feed additive and the subsequent annual fee (no fee is payable for premises that already have a manufacturing authorisation relating to veterinary medicinal products for incorporating into feedingstuffs).	n/a	1810	-
Category 2 - Approved establishment to manufacture a premixture.	n/a	1090	-
Category 3 - Approved establishment to manufacture feedingstuffs, using specified feed additives or veterinary medicinal products directly at any concentration, or using premixtures.	n/a	1090	-
Category 4 - Approved establishment to manufacture feedingstuffs for placing on the market using a veterinary medicinal product or premixture where the concentration of veterinary medicinal product in the feedingstuffs in 2kg per tonne or more.	n/a	961	-
Category 5 - Approved establishment to manufacture feedingstuffs using premixtures containing specified feed additives when the feedingstuffs are to be placed on the market.	n/a	405	-
Category 6 - Approved establishment to manufacture feedingstuffs for the manufacturer's own use using a veterinary medicinal product or premixture where the concentration of veterinary medicinal product in the feedingstuffs is 2kg per tonne or more.	n/a	320	-
Category 7 - Approved establishment to manufacture feedingstuffs using premixtures from specified feed additives when the feedingstuffs are to be used by the person manufacturing the feedingstuffs, and the subsequent annual fee.	n/a	240	-
(b) Distributors			
APPLICATION AND ANNUAL FEES			
Category 8 - Approval as a distributor of specified feed additives, premixtures or complementary feedingstuffs containing specified feed additives, or premixtures or feedingstuffs containing veterinary medicinal products.	145	70	-52%
INSPECTION FEES			
Category 8 - Approved distributor of specified feed additives, premixtures or complementary feedingstuffs containing specified feed additives, or premixtures or feedingstuffs containing veterinary medicinal products.	n/a	227	-

Annex E

Proposed fee changes for manufacturers and distributors for feedingstuffs in Northern Ireland (change 13)

APPROVAL AND ANNUAL FEES RELATING TO FEEDINGSTUFS IN NORTHERN IRELAND	CURRENT FEE	PROPOSED FEE	CHANGE %
Application for the approval of an establishment to manufacture a specified feed additive, and the subsequent annual fee(a):	520	545	4.81%
Application for the approval of an establishment to manufacture a premixture, and the subsequent annual fee:	415	435	4.82%
Application for the approval of an establishment to manufacture feedingstuffs using specified feed additives and veterinary medicinal products directly at any concentration, or using premixtures or specified feed additive complementary feedingstuffs, and the subsequent annual fee:	415	435	4.82%
Application for the approval of an establishment to manufacture feedingstuffs for placing on the market using a veterinary medicinal product or premixture where the concentration of veterinary medicinal product in the feedingstuffs is 2 kg per tonne or more, and the subsequent annual fee:	305	320	4.92%
Application for the approval of an establishment to manufacture feedingstuffs using premixtures or specified feed additive complementary feedingstuffs containing specified feed additives when the feedingstuffs are to be placed on the market, and the subsequent annual fee:	160	170	6.25%
Application for the approval of an establishment to manufacture feedingstuffs for the manufacturers own use using a veterinary medicinal product or premixture where the concentration of veterinary medicinal product in the feedingstuffs is 2 kg per tonne or more, and the subsequent annual fee:	125	131	4.80%
Application for the approval of an establishment to manufacture feedingstuffs using premixtures containing specified feed additives when the feedingstuffs are to be used by the person manufacturing the feedingstuffs, and the subsequent annual fee:	105	110	4.76%
Application for approval as a distributor of specified feed additives, premixtures or feedingstuffs containing specified feed additives, or premixtures or feedingstuffs containing veterinary medicinal products, and the subsequent annual fee:	65	70	7.69%

Costs for Change 9

VARIATION TYPES FOR REQUESTS TO CHANGE A MARKETING AUTHORISATION	CURRENT FEE	PROPOSED FEE	FEE REDUCTION	2011/12 VOLUME FORECAST AT JANUARY 2012	FEE REDUCTION X VOLUME
	£	£	£	Nr	£
Variation Single Concerned Member State (CMS) Type 1A	455	273	-182	31	-5,559
Variation Single CMS Type 1B	885	531	-354	21	-7,370
Variation Single CMS Type II	3,120	1,872	-1,248	15	-19,060
Variation Group CMS Type 1A <=9	885	531	-354	46	-16,348
Variation Group CMS Type 1A >9	4,500	2,700	-1,800	4	-7,855
Variation Group CMS Type 1B <=9	1,770	1,062	-708	24	-16,799
Variation Group CMS Type 1B >9	885	531	-354	30	-10,459
Variation Group CMS Type II <=9	6,280	3,768	-2,512	5	-12,560
Variation Group CMS Type II >9	3,120	1,872	-1,248	21	-26,095
Variation Work Sharing (W/S) Mutual Recognition (MR) CMS Type 1B <=9	1,590	954	-636	0	0
Variation W/S MR Company Ref Type 1B <=9	1,910	1,146	-764	1	-833
Variation W/S National Ref A Type 1B <=9	2,650	1,590	-1,060	1	-1,156
Variation W/S National Ref A Type 1B >9	4,500	2,700	-1,800	1	-1,964
Variation W/S MR CMS Type II <=9	5,620	3,372	-2,248	0	-409
Variation W/S MR CMS Type II >9	4,500	2,700	-1,800	0	0
Variation W/S EMA Co-ordinated	455	273	-182	3	-596
Type 1A CMS - W/S Grouped	870	522	-348	3	-1,139
Type 1A CMS - Other	455	273	-182	39	-7,098
					-135,299

Note: the 2012/13 budget assumed all application volumes in this category will be the same as in 2011/12.
The 2011/12 volumes shown are those forecast in January 2012 and will not necessarily agree to the actual results.
This is because the budget is signed off before the end of the preceding financial year.

Type definitions:
Type IA - a simple request to change an existing Marketing Authorisation (MA)
Type IB - a request to make a scientific change to an existing MA
Type 2 - a request to make a more in-depth scientific change to an existing MA