Memorandum of Understanding

between the Veterinary Medicines Directorate and the General Pharmaceutical Council

1. Introduction

1.1 This memorandum of understanding (MoU) outlines the basis of cooperation between the Veterinary Medicines Directorate (VMD) and the General Pharmaceutical Council (GPhC). It supports the GPhC's role as the principal regulator responsible for inspections of registered pharmacies.

1.2 The aims of this MoU are to:

- maintain pharmacy user, public and animal safety and animal welfare
- promote confidence in pharmacy services, including the supply of veterinary medicines
- support the sharing of intelligence and information
- contribute to improving the regulatory oversight of pharmacy activities
- create the potential for reducing the burden of inspection activities in pharmacies
- define the circumstances in which the two organisations will act independently
- set out the responsibilities of the two parties in respect of the inspection of pharmacies and enforcement of the Veterinary Medicines Regulations (VMR).

1.3 This MoU is a statement of principle. The GPhC and VMD are already working together and more detailed operational protocols and guidance will be developed, as required. The VMD and the GPhC agree to adhere to the contents of this MoU. However, it is not intended to be a legally binding document. It does not override the organisations' statutory responsibilities or functions, nor infringe the autonomy and accountability of the VMD and the GPhC or their governing bodies.

1.4 Both organisations agree to abide by the Information Commissioners Office data sharing code of practice, and recognise their respective responsibilities under the Data Protection Act 1998 and the Freedom of Information Act 2000.

2. Roles and Responsibilities

2.1 The Veterinary Medicines Directorate

2.2 The VMD is the competent authority for veterinary medicines in the UK and is an executive agency of the Department for Environment, Food and Rural Affairs.

2.2 The VMD's aims are to safeguard public health, animal health and the environment and to promote animal welfare by ensuring the safety, quality and efficacy of all aspects of veterinary medicines in the UK.

2.3 Within the UK, the VMD is responsible for authorising the manufacture and supply of veterinary medicines, for monitoring suspected adverse reactions to veterinary medicines and for implementing the VMR.

2.4 The VMR are revoked and remade when the need is identified and so references to the VMR in this MoU mean those in force at the time. The VMD will discuss proposed changes to the VMR

relating to the responsibilities of pharmacists and inspection of pharmacies with the GPhC before public consultation.

2.5 The General Pharmaceutical Council

The GPhC is the regulator for pharmacists, pharmacy technicians and pharmacy premises in England, Scotland and Wales. The functions of the GPhC are set out in the Pharmacy Order 2010 and include:

- establishing and maintaining a register of pharmacists, pharmacy technicians and premises at which a retail pharmacy business is, or is to be, carried on
- setting and promoting standards for the safe and effective practice of pharmacy at registered pharmacies
- setting requirements by reference to which registrants will demonstrate that their fitness to practise is not impaired
- promoting the safe and effective practice of pharmacy by registrants
- setting standards and requirements in respect of education, training, acquisition of experience and continuing professional development that is necessary for pharmacists and pharmacy technicians to achieve in order to be entered in the Register or to receive an annotation in the Register and to maintain competence
- ensuring the continued fitness to practise of registrants.

In addition, the GPhC has enforcement powers and duties under the Poisons Act 1972, the Medicines Act 1968 and the VMR. These enforcement duties/powers mainly relate to the sale and supply of medicines from registered pharmacy premises.

2.7 The GPhC maintains an inspectorate. The GPhC's inspectors inspect all registered pharmacies in Great Britain (GB) for the purpose of ensuring its standards are met and compliance with the relevant legislation that the GPhC enforces.

2.8 The Secretary of State appoints inspectors under regulation 33 of the VMR for the purpose of enforcing those Regulations. Under regulation 36, in relation to a pharmacy, all the powers of an inspector to enforce those Regulations may also be exercised by an officer of the GPhC appointed for the purpose.

3. Retail Supply of Veterinary Medicines by Pharmacists

3.1 The VMR (Schedule 3 paragraph 10) permits a registered pharmacist to retail supply veterinary medicines classified as POM-V, POM-VPS or NFA-VPS from:

(a) premises registered as a pharmacy with the General Pharmaceutical Council or with the Pharmaceutical Society of Northern Ireland

(b) premises registered with the Royal College of Veterinary Surgeons (RCVS) veterinary practice premises (VPPs)

(c) premises approved by the Secretary of State for the storage and supply of veterinary medicines by suitably qualified persons (SQPs) (SQP retailers) in the case of a veterinary medicinal product classified as POM-VPS or NFA-VPS.

A pharmacist supplying a veterinary medicinal product (other than one classified as AVM-GSL) must be present when it is handed over unless the pharmacist:

(a) authorises each transaction individually before the product is supplied; and

(b) is satisfied that the person handing it over is competent to do so.

3.2 There are additional requirements for pharmacists supplying veterinary medicines (POM-V, POM-VPS and NFA-VPS) as set out in Schedule 3 of the VMR. In particular, pharmacists must comply with paragraphs 3, 5, 6, 7, 10, 11, 12, 13, 15, 22 and 23.

3.3 The VMD approves and inspects SQP retailer premises on behalf of the Secretary of State and inspects registered VPPs, other than those registered under the RCVS's Practice Standards Scheme (PSS).

4. Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP: wholesaling):

4.1 A pharmacist who is appointed as a qualified person (QP) by a Manufacturing Authorisation (ManA) holder under Schedule 2 paragraph 9 of the VMR must comply with paragraph 11 of that Schedule.

4.2 A pharmacist who is specified as a wholesale dealer qualified person (WQP) by a wholesale dealer authorisation (WDA) holder under Schedule 3 paragraph 19 must ensure that the requirements of the WDA are complied with.

5. Dealing with Breaches of the VMR

5.1 The VMD will deal with breaches of the VMR noted during its inspections, in accordance with its published Enforcement Strategy:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/373203/PCDOCS-_276944-v19-VMD_Strat_017_A_-_Enforcement_Strategy.pdf

5.2 Where a VMD inspector serves an improvement notice or a seizure notice on a pharmacist, or on a business due to the failure of a pharmacist to comply with the VMR (either fully or in part), the VMD will notify the GPhC when the notice is published.

5.3 If required and should circumstance arise, a GPhC inspector can serve an improvement notice or a seizure notice on a pharmacist, or on a pharmacy business, due to the failure of a pharmacist to comply with the VMR (either fully or in part). In which case, the GPhC will notify the VMD within 72 hours and send a copy of the notice to enable the VMD to publish the notice.

5.4 Failure to comply with an improvement notice may result in the person, on whom it was served, being prosecuted under the VMR. The VMD will inform the GPhC if any such prosecution is to be brought against a pharmacist.

5.5 The GPhC will deal with breaches of the VMR by registered pharmacists and pharmacy technicians through its Fitness to Practise procedures.

6. Principles of Co-operation

6.1 The VMD and the GPhC intend that their working relationship will be characterised by the following principles:

- Making decisions that promote and protect pharmacy users, public safety, animal health and welfare and the environment in relation to veterinary medicines generally
- Addressing overlaps and gaps in the regulatory framework
- Cooperating openly and transparently with the other organisation

- Respecting each other's independent status
- Using resources effectively and efficiently.

6.2 Details of key contacts within the VMD and the GPhC are contained in appendix A.

7. Sharing Information and Intelligence

7.1 If either organisation receives information (for example through professional whistleblowing or concerns raised by a member of the public) which:

- indicates a significant risk with regard to the supply of veterinary medicines, particularly in relation to the safety of pharmacy services or the conduct of a pharmacist or pharmacy technician
- is directly relevant to the delivery of the other organisation's functions
- requires a coordinated multi-agency response
- reveals a pattern of information indicating a potential issue or concern

then this information will be shared in confidence with the named contact in the other organisation at the earliest possible opportunity.

7.2 Both organisations are committed to the more effective use of information, as a means to reducing the burden of regulation.

7.3 The GPhC routinely publishes information about the sanctions it has imposed when pharmacists and pharmacy technicians are found to be not fit to practise. When appropriate, the GPhC will share more detailed information, supporting its assessments of registered pharmacies' compliance with its standards, with the VMD when reasonably requested. Requests for information should be sent to the named contact.

7.4 In pursuance of the parties' statutory functions, including but not exclusively those contained in this MoU, information will be shared between them in accordance with the Information Commissioner's Office data sharing code of practice, and, their respective responsibilities under the Data Protection Act 1998 and the Freedom of Information Act 2000. If needed, a further GPhC VMD data sharing agreement will be developed by the two organisations.

8. Inspection of Pharmacies

8.1 The GPhC alerts registered pharmacies to the possibility of inspection 4 to 6 weeks in advance, although it does not confirm the exact date and time of the inspection. Inspections are planned and undertaken by GPhC inspectors, who work in defined geographical areas. GPhC inspectors will share information about inspections with VMD when relevant risks or concerns are identified.

8.2 The aims of sharing this information will be:

- to create an opportunity to alert inspectors to any relevant intelligence or information
- to avoid potentially unnecessary regulatory burden
- to facilitate a coordinated inspection and monitoring visit if this is deemed necessary
- to endeavour to provide support to the other organisation when requested.

8.3 Both parties will facilitate regular liaison between their inspectors, including conducting joint inspections or training, when necessary.

9. Investigations

9.1 Where either organisation intends to undertake an investigation which is relevant to the other organisation (over and above any routine inspection activity) a named contact in the other organisation should be alerted, in confidence, at the earliest possible opportunity.

9.2 Outcomes arising from any relevant investigations will be shared with a named contact at the earliest possible opportunity.

9.3 Where joint or parallel investigations are required, preliminary discussions should resolve any potential areas of conflict or overlap arising from the organisations' respective powers.

9.4 Where the VMD decides to undertake an investigation into, or bring criminal proceedings against a registered pharmacist or person lawfully conducting a retail pharmacy business for an alleged breach of the VMR, it shall notify the GPhC as soon as is reasonably practicable.

10. Enforcement

10.1 Where either organisation has taken or intends to take enforcement action, the outcome of which is relevant to the other organisation, details will be shared at the earliest possible opportunity.

11. Liaison and Dispute Resolution

11.1 The effectiveness of the working relationship between the VMD and the GPhC will be ensured through regular contact, both formally and informally, at all levels up to and including chief executives of the respective organisations. Primary MoU contacts will meet at least twice a year to discuss the MoU and the inspection of pharmacies, including consideration of compliance with the VMR by pharmacy professionals and registered pharmacies.

11.2 The GPhC and the VMD are committed to holding shared learning opportunities for GPhC and VMD staff to increase awareness of the other organisation's objectives and responsibilities. In particular, the two organisations will work together to increase inspectors' awareness and understanding of the requirements under the VMR, including their application during inspection.

11.3 Any dispute between the VMD and the GPhC will normally be resolved at an operational level. If this is not possible, it may be referred to directors of the respective organisations who will try to resolve the issues within 14 days of the matter being referred to them.

11.4 Unresolved disputes may be referred upwards through those responsible for operating this MoU, up to and including senior executives of each organisation, who will be jointly responsible for ensuring a mutually satisfactory resolution.

12 Duration and Review

12.1 This MoU takes effect from the date of signing. It is not time-limited and will continue to have effect unless the principles described need to be altered or cease to be relevant. The MoU will be reviewed biennially, or more frequently at the request of either party, to ensure that it is kept up to date and to identify any emerging issues in the working relationship between the two organisations.

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Paul Green
Director of Operations
Signed on behalf of VMD
Date: 6 MARCH 2015

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Duncan Rudkin
Chief Executive and Registrar
Signed on behalf of the General Pharmaceutical Council
Date: 05 March 2015

Appendix A

General Pharmaceutical Council

MoU management:
Sarah Jennings, Policy Manager (Regulatory Development)
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Mark Voce, Head of Inspections
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Pharmacy inspections: Tim Snewin, Regional Manager (South), Inspections
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Other contacts: Hugh Simpson, Director of Policy and Communications
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Veterinary Medicines Directorate

Primary contact: John Millward, Head of the Inspections & Investigations Team (IIT)
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