



Veterinary
Medicines
Directorate

AMTRA

MEMORANDUM OF UNDERSTANDING

**BETWEEN THE VETERINARY MEDICINES DIRECTORATE AND THE
ANIMAL MEDICINES TRAINING REGULATORY AUTHORITY**

THIS MEMORANDUM OF UNDERSTANDING (MoU) was made on 20 January 2016 between:

(1) the **Veterinary Medicines Directorate** of Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS (the 'VMD')

and

(2) the **Animal Medicines Training Regulatory Authority** of 1c Windmill Avenue, Woolpit, Bury St Edmunds IP30 9UP ('AMTRA').

The above being together called the 'parties' to this MoU.

WHEREAS:

- (A) The VMD is an executive agency of the Department for Environment, Food and Rural Affairs, and is the competent authority for veterinary medicines in the UK.
- (B) AMTRA is an independent regulatory body recognised by the Secretary of State to keep a register of Suitably Qualified Persons (SQPs) entitled to prescribe and supply veterinary medicines classified as POM-VPS and NFA-VPS.
- (C) The purpose of the MoU is to set out the responsibilities of the parties under the Veterinary Medicines Regulations currently in force, in respect of the:
- registration of SQPs
 - publication of the list of registered SQPs
 - procedures to be followed for dealing with deficiencies (non-compliances) relating to the prescribing and or supply of POM-VPS and NFA-VPS medicines by SQPs.
- (D) The MoU sets out the provisions and general principles which shall govern the relationship between the VMD and AMTRA regarding the activities listed in (C) above.

CONTENTS

1. Introduction
2. Definitions
3. Duration of the agreement
4. Obligations of the parties
5. Agreement co-ordinators and principal agreement managers
6. Charges
7. Variations
8. Confidentiality and data sharing
9. Managing the agreement
10. Termination
11. Signatories to the agreement

ANNEX A - DETAILS OF THE SERVICES TO BE PROVIDED

1. Key deliverables to be provided by the VMD
2. Key deliverables to be provided by AMTRA
3. Key Performance Indicators
4. Agreement Co-ordinators

ANNEX B – CHARGES

1. INTRODUCTION

- 1.1 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.
- 1.2 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.
- 1.3 This MoU is not legally binding and it does not supersede the statutory duties and powers of each party. It is not intended to create a partnership, to authorise either party to act as an agent for the other, or to create a legal relationship between the parties.

2. DEFINITIONS

The following definitions shall have the following meanings:

- **Agreement Co-ordinators** shall mean officers of the parties to this agreement who will provide day-to-day operational control.
- **Code of Practice for Suitably Qualified Persons (CoP)** shall mean a Code of Practice for SQPs issued by the Secretary of State in accordance with the VMR.
- **Principal Agreement Manager** shall mean officers of the parties to this agreement duly authorised to commit their respective agencies to this agreement.
- **Suitably Qualified Person (SQP)** shall mean a person who has passed examinations specified by, and is registered with, a body recognised by the Secretary of State.
- **SQP Retailer Premises** shall mean premises approved by the Secretary of State for the storage and supply of veterinary medicines by an SQP.
- **Veterinary Practice Premises (VPP)** shall mean premises registered as such with the Royal College of Veterinary Surgeons.

3. DURATION OF THE AGREEMENT

- 3.1 This agreement starts on 20 January 2016 and continues in force until terminated or amended in accordance with the provisions of this MoU. Otherwise, it will be reviewed when changes are proposed to the VMR.

4. OBLIGATIONS OF THE PARTIES

4.1 Annex A sets out the key deliverables that each party shall provide.

5. AGREEMENT CO-ORDINATORS AND PRINCIPAL AGREEMENT MANAGERS

5.1. The agreement managers are:

- for the VMD, the Head of the Inspections & Investigations Team (IIT)
- for AMTRA, the Secretary General

5.2. The principal agreement managers are

- for the VMD, the Director of Operations
- for AMTRA, the Chairman

6. CHARGES

6.1. The charges for the services provided by the VMD are set out in Annex B of this agreement.

6.2 AMTRA will pay the VMD within 28 days of receiving an invoice.

6.3 Disputed charges will be subject to the arrangements under section 9 of this agreement.

7. VARIATIONS TO THIS MOU

7.1. Either party may ask to vary this MoU. Each party will do its utmost to respond to any request as quickly as possible, within any agreed deadline.

7.2. The MoU may not be varied unless agreed by both parties in writing.

7.3 Where a change to the MoU is required due to changes in the VMR, the VMD shall endeavour to give AMTRA at least 3 months prior notice of that change. The parties shall use all reasonable endeavours to reach agreement for effecting these changes.

8. CONFIDENTIALITY AND DATA SHARING

8.1 Each organisation shall meet its obligations according to the appropriate legislation (the Data Protection Act 1998 (DPA) and the Freedom of Information Act 2000 (FOIA)), ensuring that appropriate controls are in place. The VMD and AMTRA will inform each other about any request(s) received for protectively marked information.

- 8.2 Both the VMD and AMTRA undertakes that it shall not use any Personal Data (as defined by the Data Protection Act 1998) that may be disclosed to it by the other party under this agreement, for any purposes that have not been previously agreed.
- 8.3 Both the VMD and AMTRA will ensure that it has the appropriate operational and technological processes and procedures in place to safeguard against unauthorised access, loss, destruction, theft, use or disclosure of Personal Data that are disclosed to it by the other party under this agreement.
- 8.4 AMTRA agrees to assist the VMD, when necessary, with all requests for information made under the Freedom of Information Act 2000, that the VMD receives relating to the information processed under this agreement. AMTRA agrees to respond to as the VMD's request as soon as possible but no later than 14 days from the date of the VMD's request so that the VMD is able to meet its obligations under the Act.



9. MANAGING THE AGREEMENT

- 9.1 The effectiveness of the working relationship between the VMD and AMTRA will be ensured through regular contact, both formally and informally, at all levels up to and including senior executives of the respective organisations. Agreement Co-ordinators will meet at least twice a year to discuss the key deliverables set out in Annex A.
- 9.2 A representative of the VMD will be invited to attend AMTRA Council meetings.
- 9.3 The Agreement Co-ordinators will aim to resolve any dispute in relation to implementing this MoU at an operational level within 14 days.
- 9.4 Unresolved disputes may be referred to the Principal Agreement Managers.

10. TERMINATION

- 10.1 This MoU may be terminated at any time by either party on giving at least 3 months' written notice unless a shorter period is agreed between the parties.

11. SIGNATORIES TO THE MoU:

Signed on behalf of the VMD	Signed on behalf of AMTRA
Signature: 	Signature: 
Date: 20/1/2016	Date: 20-1-16
Name in capitals: PAUL GREEN	Name in capitals: PHILIP SKETCLEY
Position/job title: Director of Operations	Position/job title: Chairman

ANNEX A – KEY DELIVERABLES

1. KEY DELIVERABLES TO BE PROVIDED BY THE VMD

The VMD will:

- 1.1 publish an abridged version of the list of registered SQPs on the internet, in a format agreed with AMTRA.
- 1.2 not amend or alter the format of the abridged registered SQP list without AMTRA's prior agreement.
- 1.3 discuss proposed amendments to the VMR relating to the prescribing and supply of POM-VPS and NFA-VPS medicines by SQPs with AMTRA, before consulting publicly.
- 1.4 discuss proposed amendments to the CoP with AMTRA before consulting publicly.
- 1.5 notify AMTRA of any improvement or seizure notices published that relate to an SQP or SQP Retailer premises for failing to comply with the VMR.
- 1.6 notify AMTRA of any prosecution brought against an SQP or SQP Retailer premises for failing to comply with the VMR.

2. KEY DELIVERABLES TO BE PROVIDED BY AMTRA

AMTRA will:

- 2.1 whenever there are more than five additions or deletions, or in any case at least every six weeks, provide the VMD with a list of registered SQPs in an agreed format.
- 2.2 not amend or alter the format of the registered SQP list without the VMD's prior agreement.
- 2.3 discuss with the VMD proposed amendments to its registration process, CPD programme, training course material or disciplinary procedures, before making any changes.
- 2.4 notify the VMD of the outcome of any disciplinary hearing brought against an SQP for failing to comply with the VMR or CoP.
- 2.5 reimburse the cost of a VMD inspector attending an AMTRA disciplinary hearing, at the request of AMTRA, as set out in Annex B.
- 2.6 pay the VMD's invoice for the cost of a VMD inspector attending an AMTRA disciplinary hearing, at the request of AMTRA, within 28 days.

2.7 respond to the VMD as soon as possible but no later than 14 days from a request for information that will assist the VMD to meet its obligations under the FOIA.

3. KEY PERFORMANCE INDICATORS

3.1 The key performance indicators for the services set out in this agreement are as follows:

- AMTRA to provide a list of registered SQPs to the VMD whenever there are at least five additions or deletions, or in any case at least every six weeks
- The VMD to notify AMTRA of improvement or seizure notices relating to SQPs or SQP Retailer premises within 5 days of publishing it on the GOV.UK website.
- The VMD to notify AMTRA of the outcome of prosecutions relating to SQPs or SQP Retailer premises within 5 days of publishing it on the GOV.UK website.
- AMTRA to respond to the VMD as soon as possible but no later than 14 days from a request for information that will assist the VMD to meet its obligations under the FOIA.
- The parties to meet at least twice a year to discuss the key deliverables set out above.

4. AGREEMENT CO-ORDINATORS

4.1. The Agreement co-ordinators are:

On behalf of the VMD	On behalf of AMTRA
<p>Head of the Inspections & Investigations Team</p> <p>The Veterinary Medicines Directorate</p> <p>Woodham Lane</p> <p>New Haw</p> <p>Addlestone</p> <p>Surrey</p> <p>KT15 3LS</p>	<p>Secretary General</p> <p>AMTRA</p> <p>1c Windmill Avenue</p> <p>Woolpit</p> <p>Bury St Edmunds</p> <p>Suffolk</p> <p>IP30 9UP</p>

ANNEX B – CHARGES

Reimbursement of costs incurred by a VMD inspector attending an AMTRA disciplinary hearing at AMTRA's request.

Daily rate - £450 (min £225 per half day)

Overnight accommodation - actual costs up to £75 (£115 in London)

Overnight subsistence - £20

Lunch allowance - £5.00

Travel:

Car - the current HMRC rate for company car business mileage

Rail - actual cost of Standard class travel

Buses/taxis - actual costs not exceeding £10 per journey

Air - actual cost of travel