Consultation outcome: Great crested newt pilot scheme in Woking: outcome

Updated: Link to consultation outcome added.

Woking borough council would very much welcome your feedback on this proposed new approach. This is your opportunity to help refine the process before the pilot begins this spring.

The consultation is open until 5pm on Wednesday 10 February 2016.

To find out more about the proposed pilot and how you can comment, see Woking borough council's consultation.

Background

The pilot scheme represents a milestone in Natural England's drive to reform regulation. It will:

- make it easier for industry to observe environmental laws
- achieve more for the natural environment

It's an exciting win-win opportunity that moves Natural England from tackling the challenges caused by great crested newts on development sites in a reactive site-by-site approach to one that's proactive and genuinely strategic.

Natural England is confident this approach will secure long-term improvements to the conservation status of great crested newts in Woking borough. The pilot also seeks to establish a planning and licensing framework which could be adopted for other protected species and other areas of the country.

Collection: National Waste Programme Quarterly Reports

Updated: Latest edition added (Q1 2018/2019)

LLW Repository's National Waste Programme Quarterly Reports show progress being made within the National Waste Programme community.

Find out more about the National Waste Programme; established to implement

the UK LLW Strategy. An industry-wide collaboration led by LLWR on behalf of the NDA.

Statutory guidance: Delegated Marine Enforcement powers for Inshore Fisheries and Conservation Officers

Updated: Page updated

Appointed officers have full Marine Enforcement Officer (MEO) powers, but are restricted to enforcing the legislation specified within this schedule and can only exercise MEO enforcement powers within the jurisdiction specified in the counterparts to their warrant.

Detailed guide: Animal Test Certificates

Updated: Guidence reviewed and updated

When you need an Animal Test Certificate

You need an Animal Test Certificate (ATC) to carry out the veterinary field trial of a medicine.

EU Directive 2001/82 defines a veterinary medicinal product as:

(a) any substance or combination of substances presented as having properties for treating or preventing disease in animals; or

(b) any substance or combination of substances which may be used in or administered to animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

The medicine(s) used during a veterinary field trial might include a veterinary medicine under development and/or an authorised human or veterinary medicine.

You must submit an application for an ATC to the VMD.

An ATC permits:

- the use of a veterinary medicine during a veterinary field trial, including outside of the terms of its marketing authorisation
- the procurement and supply of that medicine
- the import of any medicine specified in the certificate in accordance with the conditions of that certificate
- the produce from treated animals to enter the food chain if appropriate
- the use of randomisation and/or blinding within the study protocol
- the administration of a placebo product

Types of Animal Test Certificate

There are two types of Animal Test Certificate; an ATC and an ATC-S.

ATC:

Pharmaceutical companies and veterinary researchers that want to conduct a veterinary field trial to generate data to support a marketing authorisation (MA) application require an ATC.

An ATC may also be required by veterinary researchers wishing to conduct a non-commercial clinical trial of a product that does not meet the criteria for an ATC-S.

To obtain an ATC you must apply using the Type A or Type B application procedure:

Q.1	Is the product authorised as a human or veterinary medicine in the EU or EEA?	Yes go to Q.2	No = Type B
Q.2	Is the product: an immunological / biological product?	Yes go to Q.4	No go to Q.3
Q.3	Is the medicine a pharmaceutical product?	Go to Q.5	
Q.4	Is the trial to be conducted in the species included in the existing MA?	Yes = Type A	No = Type B
Q.5	Is the trial to be conducted exclusively in companion animals?	Yes = Type A	No go to Q.6
Q.6	Is the trial to be conducted in the authorised food species using the authorised dosage regimen (or lower), and using the same method of administration?	Yes = Type A	No = Type B

The Type A procedure is used where the product is already authorised as a human or veterinary medicine in the EU or EEA and one of the following applies:

1. The medicine is a veterinary immunological product and the veterinary field trial is to be conducted in species included in the existing marketing authorisation.
2. The medicine is a pharmaceutical product and the trial is to be

conducted in:

- 2a. companion animals, or
- 2b. a food-producing species and the dosing regimen to be tested is the same as (or lower than) the dosing regimen authorised for use in that species via the same route of administration.

The Type B procedure should be used where the product does not meet the criteria set out under Type A.

Applicants for an ATC will be required to confirm that the trial will be carried out in accordance with the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) Topic 9: Guideline on Good Clinical Practices.

ATC-S:

You will require this type of certificate if you are a researcher or practising vet and you want to carry out a small-scale non-commercial trial. These trials investigate the safety and/or efficacy of a human or veterinary medicine authorised in the EU, EEA, USA, Canada, Japan, New Zealand or Australia.

As small-scale non-commercial trials these will usually involve no more than 50 animals. However, you may use more than 50 animals where this is justified to permit meaningful statistical analyses. Before initiating your trial, you should contact the MA holder of the product under investigation.

To obtain an ATC-S, you must apply using the ATC-S application procedure.

Where possible, veterinary field trials conducted under an ATC-S should be conducted in accordance with Good Clinical Practice (GCP). As these trials are specifically intended for small scale non-commercial research trials conducted by vets, this may not be possible in all situations. To ensure robust study design and appropriate consideration of how to reduce, refine and replace the use of animals, the work should be subjected to an ethical review and conducted to recognised quality standards for published research, such as the Defra Joint Code of Practice for Research (JCoPR). On completion of the trial it is expected that the results will be reported in compliance with the principles set out in the Animal Research: Reporting In Vivo Experiments (ARRIVE) Guidelines.

For immunological products: if you wish to use an immunological product that is not the subject of a valid MA in the EU or EEA, contact the VMD before submitting an application under the ATC S application procedure.

For pharmaceutical products: researchers or practising vets who want to carry out small-scale non-commercial trials may occasionally need to apply for an ATC using the type B procedure. Therefore, to conduct a small-scale, non-commercial veterinary field trial of a medicine either an ATC-S or an ATC (Type B) application procedure is required. Use the following tables to

determine the required application procedure.

Decision table for pharmaceutical products to be tested in non-food animals:

- companion animals
- horses declared never to enter the food chain
- other animals (or their products) declared to never enter the food chain

Q.1	Is the product authorised as a human or veterinary medicine in: the EU (incl. UK), EEA, the United States, Canada, Japan, New Zealand, or Australia?	Yes go to Q.2	No = ATC (Type B)
Q.2	Is there published literature supporting the safety^1 and efficacy of the active substance(s) in this target species for the proposed indications and using the proposed dosage regimen?	Yes = ATC-S	No = Data unlikely to be sufficient to support an ATC-S application^2.

1: If the product is a veterinary medicine to be administered to the authorised species using the authorised dosage regimen (or lower) additional safety data will not usually be required.

2: Refer to submission guidance and Annex 2 of the ATC-S application form for further information on the data requirements for target species safety and efficacy.

Decision table for pharmaceutical products to be tested in food producing animals:

Q.1	Is the product a human or veterinary medicine authorised in the EU (incl. UK) or EEA?	Yes go to Q.2	No = ATC (Type B)
Q.2	Is the product a veterinary medicine to be used in the authorised species, using the authorised dosage regimen (or lower), and observing the withdrawal periods in the SPC?	Yes go to Q.6	No go to Q.3
Q.3	Are the pharmacologically active substances in the product listed in Table 1 of the Annex to Commission regulations 37/2010?	Yes go to Q.4	No go to Q.5
Q.4	Will the statutory or label withdrawal period (whichever is highest) be applied?	Yes go to Q.6	No go to Q.5
Q.5	Is the medicine to be used for the treatment of horses, are the active substances listed as ‘essential for the treatment of equidae’ according to regulation (EC) 122/2013, and will a 6 month withdrawal period be applied?	Yes go to Q.6	No = ATC (Type B)
Q.6	Is there published literature supporting the safety^1 and efficacy of the active substance(s) in this target species for the proposed indications and using the proposed dosage regimen?	Yes = ATC-S	No = Data unlikely to be sufficient to support an ATC S application^2 .

1: If the product is a veterinary medicine to be administered to the authorised species using the authorised dosage regimen (or lower) additional safety data will not usually be required.

2: Refer to submission guidance and Annex 2 of the ATC S application form for further information on the data requirements for target species safety and efficacy.

Hereafter the term ATC refers to all types of Animal Test Certificate (ATC and ATC-S).

Assessment of the application

The VMD will conduct a benefit risk assessment based on the data submitted with each application in order to determine whether an ATC can be granted. In addition, the VMD will require confirmation that veterinary field trial protocols are to be conducted in compliance with GCP. You must also ensure your trial will be conducted in compliance with UK animal welfare legislation.

A veterinary field trial is conducted to evaluate the safety and/or efficacy of a medicine under conditions of field use, and will usually be conducted in client-owned animals. The evaluation of field safety and/or efficacy may include the taking of a blood sample prior to the administration of a medicine to establish a baseline for parameters. It may also include additional sampling at key points after administration of the medicine to monitor these parameters, where this is clinically justified.

It is anticipated that animals treated during a veterinary field trial with the product under investigation will be compared with a control group. Therefore, the veterinary field trial may include either:

- a group of animals designated as positive controls and treated with either an existing medicine or an established procedure
- a group of animals designated as negative controls and treated with a placebo

The VMD assessment of each application will focus in particular on the risks associated with the proposed trial and will evaluate whether adequate safeguards are in place to ensure the safety of the following:

- animals participating in the trial
- those people using the medicines under investigation or handling treated animals
- consumers of produce from treated animals
- the environment (where applicable)

For more information on the ATC application process (e.g. data requirements and timescales), please refer to the guidance.

Number of trials and products per ATC

Each veterinary field trial requires a separate ATC and should normally only investigate one therapeutic indication in a single species. Exceptions to this include trials of ectoparasiticides, endectocides, or multivalent vaccines.

A trial may involve more than one product if:

- the second product is a placebo
- the second product is a positive control that is authorised in at least one EU or European Economic Area (EEA) Member State for administration to the same species for the same indication
- the second product is a human product, its use is well supported by literature references, and there is no suitable authorised veterinary medicine
- the products are of the same pharmaceutical form and contain the same ingredients, but they differ in the strength or dosage of the active or inactive ingredients
- the products are vaccines and differ only in the inclusion or exclusion of particular antigens under investigation
- the products are of two or more dilutions of either the same allergen extract or mixture of allergen extracts used for desensitisation therapy; or the products used for in-vivo diagnosis of an allergy are manufactured by the same method from closely related substances, e.g. pollen
- more than one product is expected to be required to produce therapeutic efficacy; for example, the administration of sedative or analgesic combinations, or allergens.

An ATC may not be required in certain cases:

A veterinary field trial involving a non medicinal therapy does not require an ATC. For example, the trial of a food supplement (nutraceutical) that is not a medicine, or the trial of a surgical intervention.

A veterinary field trial carried out by a vet who will administer a medicine in accordance with the provisions of the prescribing ‘cascade’ or a veterinary medicinal product in accordance with its Summary of Product Characteristics (SPC) may not require an ATC. Examples of when an ATC would be required include those cases where:

- the study design prevents the prescribing vet from using their professional judgement when making treatment decisions (e.g. due to randomisation)
- the medicines used during the field study will not be labelled in accordance with the VMR (e.g. to facilitate a ‘blinded’ study)

Studies licensed in full by the Home Office under the Animals (Scientific Procedures) Act 1986, including laboratory studies, do not require an ATC if they are conducted in a non food species or in animals that have been declared as not to enter the food chain. However, you must apply for an ATC

if you intend for the produce from treated animals to enter the food chain and study animals will be treated with a medicine that is not authorised for use in that target species at the proposed dose (or above).

The retrospective analysis of clinical observations is not a veterinary field trial and does not require an ATC.

You can find more information on ‘the cascade’ by referring to the following guidance: The Cascade: Prescribing unauthorised medicines. Further information on how the Home Office regulates the use of animals in research can be obtained from the Home Office Animals (Scientific Procedures) Inspectorate.

Post authorisation steps

Validity of an ATC

An ATC is initially valid for a period of two years following approval. In most cases the authorised trial will be completed within this period. However, if the trial will still be in progress at the end of its period of validity you must renew the ATC to allow the trial to continue. If you wish to make any changes to the terms or conditions of an ATC you must do this by means of a variation application, unless otherwise agreed by the VMD.

For more information on the renewal or variation of an ATC please refer to the following guidance

While the ATC remains valid, if evidence becomes available which casts doubt on the safety, quality or efficacy of the product(s) involved, or alters the benefit risk assessment, the VMD may revoke, suspend or compulsorily vary the certificate. If the VMD becomes aware that an ATC holder has changed any of the approved specifications of the ATC without the prior approval of the VMD, the ATC will be suspended immediately. The suspension will remain in force until the changes have been approved, or the product is brought into line with the terms and conditions of the certificate.

Pharmacovigilance

You are responsible for reporting adverse events to the VMD and must name a person responsible for pharmacovigilance in your application. This person, usually a vet, must have overall responsibility for investigating any suspected adverse events, monitoring them and, when necessary, reporting them to the VMD. You should ensure that study investigators notify them if serious adverse events occur. You should also put in place appropriate arrangements to ensure that ‘blinding’ of products does not interfere with pharmacovigilance responsibilities.

Any serious adverse events to any substance used under an ATC which results in:

- death or increased rates of death in a species for which there is an accepted death rate

- life-threatening clinical signs
- significant disability or incapacity
- congenital anomalies or birth defects
- permanent or prolonged signs
- a reaction involving a human

including suspected lack of efficacy, must be reported to the VMD within 15 days. For further information on reporting adverse events, see the Veterinary Pharmacovigilance: your responsibilities page.

You should keep appropriate records of adverse events that may occur following administration of the medicine, control or placebo including those which are not serious. A summary of all adverse events that occur during the trial will be required if the ATC is to be renewed. For studies conducted under GCP the study protocol should include procedures for observing, recording and reporting adverse events.

Contact us

Email: postmaster@vmd.defra.gsi.gov.uk

Collection: Household Energy Efficiency National Statistics

Updated: Household energy efficiency statistics October 2018 published.

This series presents statistics on the Energy Company Obligation (ECO) and Green Deal (GD). It incorporates changes as set out in response to the user consultation of National Statistics on the Green Deal, Energy Company Obligation and Insulation statistics. The headline releases present monthly updates of ECO measures and quarterly updates of in-depth ECO statistics, carbon savings and the Green Deal schemes. The detailed report presents annual updates on in-depth Green Deal statistics and insulation levels.

Historical releases are available on the National Archives.