

Review of approach to issuing animal test certificates for veterinary medicines

Veterinary Medicines Directorate

RPC rating: validated

Description of proposal

The proposal amends the regulation of clinical field trials on animals by allowing trials that require more than one blood sample to be considered as recognised veterinary practice. The importance of the change is that field trials recognised as veterinary practice (i.e. those that observe the safety and efficacy of a medicine) require only an animal test certificate (ATC), whereas those that are of an experimental nature require both an ATC and a licence under the Animal (Scientific Procedures) Act (A(SP)A).

Previously, the number of blood samples taken from an animal during the trial could determine the classification of a field trial. If more than one sample was taken the trial would be considered experimental. The proposal amends this process to use an analysis of the benefit to risk ratio to determine how the trial should be classified. This means blood samples may be taken from animals at intervals throughout the trial, while still being considered recognised veterinary practice.

ATCs are issued by the Veterinary Medicines Directorate, with the Royal College of Veterinary Surgeons being consulted where the nature of a field trial is uncertain. The proposal also removes the Royal College of Veterinary Surgeons from the process of issuing ATCs.

Impacts of proposal

Allowing for blood samples to be taken intermittently throughout a trial will result in fewer trials requiring an A(SP)A licence. The regulator has estimated the cost of obtaining an A(SP)A licence to be £20,812 per field site. This figure includes staff time and fees for the mandatory training, in addition to the licence itself. The figure also includes admin costs, as well as costs to the Home Office. These costs to Home Office have been included in the business savings; this would only be correct if Home Office costs are recovered from industry.

The assessment explains that the number of field sites varies with each clinical trial; the regulator estimates that the average number of field sites is 10 per trial. The regulator estimates that the proposal will save business £208,120 for each clinical trial that was previously considered of an experimental nature but will now be considered recognised veterinary practice. The regulator expects that, on average, only one trial will fall into this category each year. Therefore, the regulator expects that the proposal will result in a saving to industry of £208,120 each year.

The RPC verifies the estimated equivalent annual net direct cost to business (EANDCB) of -£0.2 million. This will be a qualifying regulatory provision that will score under the business impact target.

Quality of submission

The level of information provided is sufficient to support the estimated reduction in costs to industry. However, the assessment would benefit from the following improvements:

Costs to Government – the assessment includes the savings to the Home Office of issuing fewer Animal (Scientific Procedures) Act (A(SP)A licences in the overall saving to industry figure. As this would only be the correct approach where the costs to government are recovered from industry, the assessment must explicitly state this. In this case, the RPC is still able to validate the EANDCB as this assumption is unlikely to have a material effect on the EANDCB.

Explanation of assumptions – The estimated savings to business are strongly dependent on the number of staff members that would need training. The regulator should ensure that each step in the logic chain is fully explained (i.e. why 10 sites requires 10 individuals to be trained, rather than one member of staff being able to cover multiple sites).

Source of data – The assessment would benefit from drawing on a wider range of data. Currently, all figures used in the assessment have been obtained from a single source. Although it seems reasonable to assume that this source is knowledgeable with regards to the costs associated with obtaining an A(SP)A licence, the EANDCB would be more robust if based on a wider source of data.

As it is unlikely that these improvements will lead to a material difference in the EANDCB, the RPC can validate the figure in this instance. However, in the future,

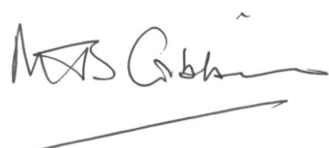
further evidence may be required for regulatory changes with greater impact on business.

Departmental assessment

Classification	Qualifying regulatory provision (OUT)
Equivalent annual net cost to business (EANCB)	‑£0.2 million
Business net present value	£1.72 million

RPC assessment

Classification	Qualifying regulatory provision (OUT)
EANCB – RPC validated ¹	‑£0.2 million
Business Impact Target (BIT) Score ¹	‑£1 million
Small and micro business assessment	Not required (deregulatory)



Michael Gibbons CBE, Chairman

¹ For reporting purposes, the RPC validates EANCB and BIT score figures to the nearest £100,000.