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Veterinary clinical trials in the UK

Further to the report on scientific procedures on animals (VR, July 27, 2013, vol 173, p81) colleagues may be interested to learn that the UK is currently failing to implement an important aspect of the new EU Directive 2010/63 mentioned in the report. This concerns veterinary clinical trials required to obtain a Marketing Authorisation for a veterinary medicine or a veterinary vaccine.

The new Directive states that it shall not apply to veterinary clinical trials required for the Marketing Authorisation of a veterinary medicinal product. However, the current UK system for field trial clearances is failing to comply with this exemption. This means that veterinary clinical trials are increasingly being performed in other EU Member States, with an estimated total loss of £22 million *per annum* to the UK. It is thought that due to the UK losing this veterinary trial work over £11 million *per annum* is being lost by UK veterinary surgeons, and several million pounds *per annum* being lost by their clients (farmers and pet owners). Additionally UK veterinary surgeons are now losing the opportunity to be involved in veterinary clinical trials with new medicines and vaccines. This means that they are contributing less to the development of safer and more efficacious treatments for their patients. Prolonging this situation is likely to cause a drastic decrease in UK veterinary medicine and veterinary vaccine Research and Development (R and D) , and this could lead to wider impacts in the longer term for UK veterinary R and D in general.

A simplified example of the importance of the failure of the UK to comply has recently happened regarding a field trial for a new vaccine. For such a trial there often needs to be at least two superficial blood samples collected (before and after the vaccination course) to confirm that during field use of the vaccine protective antibody levels have increased. In both France and Germany the same trial went ahead under rapid, cost-effective trial clearance systems and with excellent standards of animal welfare. In UK, the same trial clearance (for an identical trial protocol) was over 1000 times more expensive than the German system (£26,600 versus £250) and took 16 times longer to obtain (450 versus 28 days). Understandably in such situations the Animal Health industry has every incentive to work outside of the UK. The reasons for these huge discrepancies were due to the current UK system for trial clearances failing to comply with the new Directive. As such, it was necessary to collect the second superficial blood sample under the Animals (Scientific Procedures) Act 1986 (ASPA), because the Veterinary Medicines Directorate (VMD) would only grant a trial clearance (Animal Test Certificate or ATC) for one superficial blood sample. The Royal College of Veterinary Surgeons (RCVS) was surprised by this approach to the ATC, but confirmed that the second superficial blood sample was not Recognised Veterinary Practice, and consequently it had to be collected under the ASPA.

Additionally the use of ASPA for such veterinary field trials causes relative inflation of the UK annually recorded scientific procedures on animals when compared to the numbers in other Member States.

The major reason for the trial clearance system to be relatively cost-effective and rapid in other Member States is because it is under the control of a single agency. In most other EU Member States the body responsible for issuing the veterinary trial clearance is also the same organisation used to determine if field trial results are likely to be appropriate for the granting of a Marketing Authorisation. This is logical in that a single organisation requiring the data is also responsible for issuing the trial clearance such that appropriate data might be obtained (and this presumably is the intention of the current UK system). Unfortunately for trials similar to the example mentioned above this is not currently the situation in the UK where three organisations (VMD, RCVS, and the Home Office) all become involved.

The UK could, however, adopt a similar approach to other Member States. For example, it could be appropriate for the VMD to both issue the trial clearance (ATC) and have regulatory responsibility for the welfare of animals in the clinical trial which would be performed by UK veterinarians. To adopt such an approach, it would appear necessary for the RCVS to modify its Guide to Professional Conduct such that UK veterinary surgeons were permitted to perform the procedures allowed under an ATC.

After some delays, there has been a meeting with the VMD with representation from the Home Office and RCVS to consider this issue. It should be emphasised that all parties, including those performing the veterinary clinical trials, wish to maintain animal welfare standards at their current high levels.

Unfortunately at present the anomalous UK veterinary trial clearance system has not yet been modified in line with new Directive and consequently UK veterinary R and D, veterinary surgeons, their clients, and patients are all losing out to other Member States. It is hoped that the UK system for veterinary trial clearances will be rapidly modified such that UK veterinary surgeons, their clients, and patients are not increasingly excluded from this important area of veterinary research and development.

Julian Braidwood; *Triveritas, Bank Barn, How Mill, Brampton, Cumbria CA8 9JY*

E-mail: julian.braidwood@triveritas.com