April 2015

VMD REVIEW OF APPROACH TO ISSUING ANIMAL TEST CERTIFICATES FOR VETERINARY MEDICINES CONSULTATION – BVA RESPONSE

1) The British Veterinary Association (BVA) is the national representative body for the veterinary profession in the United Kingdom and has over 15,000 members. Our primary aim is to represent, support and champion the interests of the veterinary profession in this country, and we therefore take a keen interest in all issues affecting the profession, including animal health and welfare, public health, regulatory issues and employment matters.

2) The BVA welcomes the opportunity to respond to the Veterinary Medicines Directorate (VMD) consultation on the approach to issuing animal test certificates (ATCs). We understand that the VMD introduced this consultation following comments received as part of the Government Red Tape Challenge, which identified that the VMD should determine whether procedures can be permitted under an Animal Test Certificate (ATC).

3) Defra’s Red Tape Challenge commitments include “simplifying the authorisation of clinical trials required for the marketing authorisation of veterinary medicines by making the VMD their sole regulator in the UK.” In contrast, this review document indicates the potential use of the Animals (Scientific Procedures) Act 1986 (A(SP)A) and consultation with the Royal College of Veterinary Surgeons (RCVS) and the Food Standards Agency (FSA).

4) Paragraph 7 states that the purpose of a clinical field trial is to make “observations on the safety and efficacy, or both, of an unauthorised veterinary medicine administered by a veterinary surgeon in the course of treating or preventing a disease in client-owned animals.” It goes on to state that “trials of this nature require an ATC provided all treatments and clinical observations are made for the benefit of enrolled animals in accordance with Recognised Veterinary Practice (RVP)” otherwise “the trial will be regulated under A(SP)A.” We are concerned this may continue to disadvantage the UK because most safety trials and some efficacy trials will not be of benefit to the animal(s) treated; the safety and efficacy profile of any unauthorised veterinary medicinal product (VMP) remains unknown until a Marketing Authorisation (MA) is granted and consequently cannot be considered of benefit to an animal or take place under an ATC. Nonetheless, BVA understand it is important to find a balance between veterinary surgeons appropriately sampling clinically ill animals under their care and the unnecessary sampling of clinically normal animals without proper regulation of those procedures by the Home Office.

5) Currently, where an application for a clinical trial proposes to take more than one blood sample, it is viewed as experimental and referred to the Home Office (HO) to license under the Animals (Scientific Procedures) Act 1986 (A(SP)A). EU Directive 2010/63, of which A(SP)A is a transposition, indicates that it “shall not apply to the following: (a) non-experimental agricultural practices; (b) non-experimental clinical veterinary practices; (c) veterinary clinical trials required for the marketing authorisation of a veterinary medicinal product.” Consequently, we understand that veterinary clinical trials that take place under A(SP)A would be in breach of Directive 2010/63. BVA understands that the Veterinary International Conference on Harmonisation (VICH) produce a guidance document on ‘Good Clinical Practice’
otherwise referred to as VICH GL9, which is recognised by the VMD, may be appropriate guidance to ensure animal health and welfare during a veterinary clinical trial where the investigator is likely to be a practising veterinary surgeon and as such has the appropriate training and expertise to ensure the welfare of client owned animals under their care.

6) Where doubt exists that a proposed clinical trial should be considered as being Recognised Veterinary Practice (RVP), the VMD has previously sought advice from the Royal College of Veterinary Surgeons (RCVS). We understand that the VMD is seeking to formalise this arrangement, but we are concerned that this could slow the process even further and deter applicants. We understand that the voluntary committee at RCVS has no time targets for their assessment, does not necessarily provide expert knowledge of the data requirements to gain approval for veterinary medicines, and offers no right of appeal on their decisions. We would be grateful if you could clarify the rationale behind the proposed requirement to consult the RCVS for queries on RVP and provide information as to whether there has been any incidence of questionable animal welfare connected to field trials in the UK.

7) The BVA is concerned that these draft proposals will mean the UK operates differently to the general principles applied by all other EU Member States and the USA by not having a sole regulator for the authorisation of veterinary clinical trials. This would make the UK even more unsuitable for product development and would disadvantage UK vets, their patients, veterinary research and development and reduce veterinary employment opportunities. Our specialist division the Association of Veterinarians in Industry (AVI) has, we understand, responded to you separately with the same views and we are fully in support of their submission.

8) In conclusion, the BVA believe this review serves to further complicate an already complex system that fails to meet the needs of stakeholders. We urge major revision to the document and full and in-depth involvement of stakeholders in an appraisal and revision of the existing ATC system.