

ADVICE NOTE 12

THE USE OF NEW TECHNOLOGY TESTS

Veterinary surgeons involved with the use of tests using genomic or other similar new technology (including proteomic and metabolite technology) within the context of 'recognised veterinary practice', are subject to the same restrictions, safeguards and guidance as those involved with tests using biochemical or other technology, such as:

- 1) compliance with the Veterinary Surgeons Act 1966, to ensure that, subject to the specified exemptions in the Act and subordinate legislation, only veterinary surgeons practise veterinary surgery (See note 1, below);
- 2) consideration of the *RCVS Guide to Professional Conduct* and its annexes, including the ten guiding principles (see the *RCVS Guide to Professional Conduct* Part 1, B) and the interface between the Veterinary Surgeons Act and the Animals (Scientific Procedures) Act 1968 (see this annex to the *Guide* and note 2, below);
- 3) consideration of the published information on the clinical benefits of the test, particularly if the test is new;
- 4) consideration of the test as predictive or diagnostic;
- 5) consideration of the specificity and sensitivity of the test;
- 6) consideration of positive and negative predictive values;
- 7) consideration of the environmental or other factors when the test relates to a complex condition;
- 8) publicity is legal, decent, honest and truthful and therefore with no misleading claims (see the *Guide* Part 2, C, Publicity);
- 9) publicity is of a professional nature (see the *Guide* Part 2, C, Publicity);
- 10) consideration of responsibilities to patients and clients, such as informed consent from the client and, if appropriate, informed consent for the use of any excess collected with a sample and not used in the test (see the *Guide* Part 1, C and D respectively);
- 11) appropriate professional guidance and advice when test results are communicated to clients (see also the *Guide* Part 1, I and Part 2, F); and,
- 12) consideration of responsibilities to the general public, including the use of professional status to provide only factual information to the general public about veterinary products and services and the need for cooperation with colleagues and other health care professionals when appropriate (see the *Guide* Part 1, E).

These usual safeguards should be applied, as appropriate, even if the genomic or other test provides no diagnosis of disease. For example, such information may be used for breeding purposes and may have a significant effect on the welfare of the animal or animals concerned.

Note 1 (see paragraph 1 above)

The Veterinary Surgeons Act 1966 provides that, subject to specific exemptions, the practice of veterinary surgery must be carried out by veterinary surgeons whose names are on the RCVS register of those eligible to practise.

The Veterinary Surgeons Act 1966 states:

“Subject to the following provisions of this section, no individual shall practise, or hold himself out as practising or as being prepared to practise, veterinary surgery unless he is registered in the register of veterinary surgeons or the supplementary veterinary register” (S. 19(1) of the Act)

In the Act ‘veterinary surgery’ is interpreted as:

“‘veterinary surgery’ means the art and science of veterinary surgery and medicine and, without prejudice to the generality of the foregoing, shall be taken to include—

- (a) the diagnosis of diseases in, and injuries to, animals including tests performed on animals for diagnostic purposes;
- (b) the giving of advice based upon such diagnosis;
- (c) the medical or surgical treatment of animals; and
- (d) the performance of surgical operations on animals.’ (S. 27 of the Act)

Note 2 (see paragraph 2 above)

The following is an extract of the “Report of the working party to consider the interface between the Veterinary Surgeons Act 1966 and the Animals (Scientific Procedures) Act 1986” adopted by RCVS Council in 1997.

“CLINICAL INVESTIGATION ACCEPTED AS RECOGNISED VETERINARY PRACTICE

21. When conducting clinical investigation (without A(SP)A authorities) care must be taken to ensure that appropriate veterinary treatment and care is provided for all animals used in the study. The use of untreated ‘control’ groups needs careful consideration, to ensure that no avoidable suffering results as a consequence of

- withholding treatments. The inclusion of placebo treated 'control' groups will require A(SP)A authority if likely to cause pain, suffering, distress or lasting harm to the animal.*
22. *The use of any novel treatments must reasonably be expected to result in a similar or better outcome than that following conventional treatment. The veterinary surgeon must have some background knowledge of the treatment in order to make a professional judgement. When what is to be done has an experimental component, authority under A(SP)A may be necessary.*
23. *When there is a desire to pursue scientific investigation on clinical cases and with the owner's informed consent, it may be possible to bring the animals into A(SP)A authority and discharge them at the end of the investigation.*
24. *Veterinary surgeons conducting clinical trials within the terms of an Animal Test Certificate (ATC) issued by the Veterinary Medicines Directorate do not generally require A(SP)A authority.*
25. *The circumstances described above highlight the interface between VSA and A(SP)A with respect to clinical investigation. In these and similar circumstances veterinary surgeons are invited to approach the RCVS and a Home Office inspector at a preliminary stage to determine whether A (SP)A authority is needed."*

"DIAGNOSTIC TESTS AND APPLICATION OF NEW THERAPIES

26. *The working party was asked to consider drawing up criteria that could be used to determine the point at which a veterinary diagnostic test moved from the conceptual stage, when it should be regulated under A(SP)A, to the point at which there was a clinical application and it might be regarded as recognised veterinary practice. During the course of discussion it was decided to examine the same criteria as they might apply to the introduction and application of new therapies into recognised veterinary practice.*
27. *There are many examples where veterinary surgeons apply diagnostic tests and techniques to clinical cases that have already been developed for use in other species or human patients. Similarly, treatments used in human medicine may be introduced for use in animals where potential benefits might be expected for the individual animal or its immediate group, for veterinary public health or environmental protection. This is legitimate.*
28. *Unless regulated under A(SP)A it would NOT be acceptable, and may bring the profession into disrepute, for a veterinary surgeon to use an animal in the development of a diagnostic test or a new form of treatment where:*
- *The test or treatment has not previously been made available to the veterinary profession and there is no background evidence to predict a clinical application in the species or other veterinary benefit,*
 - *There is deliberate deception that would enable a veterinary surgeon or a non veterinarian to avoid regulation under A(SP)A."*

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