



Veterinary Medicines Directorate

Summary of responses to the consultation on the review of the approach to issuing Animal Test Certificates for veterinary medicines

Introduction

This is a summary of responses to the consultation on the review of the approach to issuing Animal Test Certificates (ATCs) for veterinary medicines. The consultation ran for 8 weeks between 27 February and 24 April 2015.

Background

ATCs are used for clinical trials to generate data demonstrating efficacy and/or safety of an unauthorised veterinary medicinal product in the intended species under field conditions.

The Government's commitment to the Red Tape Challenge was to simplify the authorisation of clinical trials required for marketing authorisations by making the Veterinary Medicines Directorate (VMD) sole regulator. In reply the VMD undertook to review its policy on ATCs with the aim of reducing burden on industry. The proposed changes were laid out in a business engagement assessment for industry's views along with draft revised guidance.

Summary of responses

The VMD is grateful to all those who replied to the consultation. Eleven responses were received from nine stakeholders.

A clear message from the responses was that the changes proposed by the VMD did not adequately address the concerns raised during the Red Tape Challenge.

Stakeholders still consider that the UK ATC process is too complex and time consuming, which in turn may have a detrimental effect on industry.

Specific areas of concern raised by stakeholders were:

- companies will look to other countries to conduct clinical field trials where the process is considered to be less burdensome. This in turn may have the potential to affect the participation of the UK veterinary research community in the development of veterinary medicinal products
- as the UK Competent Authority authorised for the assessment and approval of veterinary medicines, the respondents would like to see the VMD as the sole regulator for the authorisation of clinical field trials. It is considered this would reduce the bureaucracy and speed up the process of granting an ATC
- the Home Office should only be involved in applications relevant to the Animal (Scientific Procedures) Act
- the VMD needs to consider what can be carried out under an ATC without referring applicants to the RCVS for advice
- the revised guidance makes no mention of the requirements for an ATC for minor species.

Specific amendments/comments on the reviewed Guidance Note (VMGN No 6) were also received.

Next steps

The VMD has carefully considered the responses and will be coming forward with a revised proposal outlined in draft guidance by the end of summer. We intend to share the changes with the stakeholders who commented on the business engagement assessment. The key issue is to ensure a high standard of animal welfare.