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Committee for Medicinal Products for Veterinary Use (CVMP)

Statement of the Committee for Medicinal Products for Veterinary Use (CVMP) position on the ethical use of animals in the testing, development and manufacture of veterinary medicines

Animal welfare is a value of the Union that is enshrined in Article 13 of the Treaty on the Functioning of the European Union (TFEU[1]). The use of animals in scientific procedures including regulatory testing of veterinary medicinal products is strictly controlled within the European Union (EU), in accordance with Directive 2010/63/EU (hereinafter referred to as "the Directive")[2].

This legislation expounds the principles of 3Rs (replacement, reduction and refinement), lays down strict conditions for the conduct of animal studies, and further articulates the ultimate goal to replace the use of all live animals for scientific and educational purposes as soon as it is possible to do so.

The Directive also recognises, however, that the use of live animals continues to be necessary in some areas of scientific research to protect human and animal health and the environment, pending further scientific advancements in the development of alternative approaches.

The Directive has thus established European minimum standards that are applicable throughout EU Member States and the three additional countries that make up the European Economic Area (EEA)[3]. The legislation also recognises that differences exist in attitudes and in ethical values towards the use of animals for scientific purposes within the EU and enables more extensive animal welfare rules at national level. However, the EU common standards might not be recognised in countries outside the region. This may mean that certain animal models of disease or pain which are acceptable in countries outside of the EU would not conform to EU legislation, or EU ethical values and principles.

Examples include surgical operations for the purpose of modifying the appearance of a pet animal for non-curative purposes, such as docking of tails, cropping of ears, devocalisation, declawing and defanging[4]. Indeed, the Committee for Medicinal Products for Veterinary Use (CVMP) has had concerns

[1] Treaty on European Union and the Treaty on the Functioning of the European Union 2012/C 326/01
[2] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (L 276/33)
[3] EEA comprises the 28 EU Member States and Iceland, Liechtenstein, and Norway.
[4] Article 10 of the European Convention for the Protection of Pet Animals, Council of Europe, Strasbourg, 13.XI.1987 (European Treaty Series - No. 125) provides a list of surgical operations for the purpose of modifying the appearance of a pet animal or for other non-curative purposes which are prohibited

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recently regarding the use of certain animal models for the development of new medicines referring to the principle that the likely harm to the animal should be balanced against the expected benefits, e.g. declawing of cats used as a model for post-operative surgical pain. The procedure provides no identifiable benefit to the cat but such animals behave differently to intact animals, will suffer pain in the immediate post-surgical period and may suffer chronic effects or complications.

The expectation of CVMP is that the animal studies needed to support the evaluation of a medicine intended for veterinary use will take into account EU requirements whether or not those animal studies are conducted within or outside the EU. Applicants should therefore consider EU ethical values and welfare standards towards animals and requirements under EU legislation when developing medicines that are intended for marketing in the EU.

The EU legislation governing the scientific and technical requirements for the regulatory testing of human and veterinary medicinal products requires that all information which is relevant to the evaluation of the veterinary medicinal product concerned is included in the application dossier, whether favourable or unfavourable to the product. In particular, all relevant details shall be given of any incomplete or abandoned test or trial relating to the veterinary medicinal product[5].

In parallel, EU Member States have the responsibility to implement the Directive in their respective laws and ensure that animal experiments are conducted ethically[6]. Should such studies be contrary to the principles of EU legislation on protection of animals used for scientific purposes, the responsible authorities should take appropriate steps to ensure compliance with the Directive.

In addition to applying the 3R principles to reduce, remove or replace the use of animals as outlined in the Directive, the use of animals for the manufacture or for any control tests for any veterinary medicine intended for supply in the EU is expected to conform to EU ethical principles and welfare standards. Animal studies or husbandry practices that would not be allowed in the EU should not be undertaken instead outside of the EU. For example, for the production of Pregnant Mare Serum Gonadotropin (PMSG) the welfare standards for the treatment of mares should be equivalent whether or not the production facilities are based in the EU or third regions.

In conclusion, it is considered incumbent on marketing authorisation holders to integrate the 3Rs and ethical principles and welfare standards for the treatment of animals in all aspects for the development, manufacture and testing of veterinary medicinal products: from the sourcing of starting materials and active ingredients, through to the studies to generate safety and efficacy data and for any tests used as in process and final product controls for batch release of the product.

[5] Annex I to Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L311, 28.11.2001, p. 1)

[6] Annex I to Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L311, 28.11.2001, p. 1) states that "*Member States shall ensure that all experiments on animals are conducted in accordance with Council Directive 86/609/EEC*" (Council Directive 86/609/EEC on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes was repealed by Directive 2010/63/EU)