

Policy on use of animals in research

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1. Purpose

This Corporate Policy (the “**Policy**”) sets out the rules for the ethical and responsible use of animals in research and laboratory experiments.

2. Scope

This Policy applies to Almirall S.A., the legal entities in Almirall group (altogether “**Almirall**” or the “**Company**”) and their respective employees, researchers, and third-party contractors involved in the use animals in research. It covers all research projects conducted internally by Almirall as well as research services funded or managed by our organization and outsourced to external companies or institutions. The Policy ensures that all researchers comply with good animal-welfare practices before initiating any research involving the use of animals.

3. Policy elements

3.1 Introduction:

Almirall is a leading skin-health focused global pharmaceutical company that partners with healthcare professionals, applying science to provide medical solutions to patients & future generations.

We use laboratory animals (in our facilities or in those of third parties) to investigate models of different dermatological pathologies and their treatment with different therapeutic agents. The studies carried out with laboratory animals are essential – though minimal- during our research process. None of our currently developed medicines would have reached the patients without the previous use of laboratory animals in preclinical studies.

We are highly committed to the use of non-animal, alternative methods and actively work in this direction. However, in a highly regulated environment such as the pharmaceutical sector, current guidelines still require the use of animals in certain stages of preclinical research and drug development¹. This includes evaluating safety and efficacy to ensure that clinical trials can proceed with the highest safety standards and that approved treatments can benefit patients effectively.

3.2 Ethical principles:

In Almirall we acknowledge that animal research brings great benefits either for human and animal health. We accept that nowadays it is impossible to completely avoid the

¹ Moreover, especially in the study of immune-mediated diseases, no alternative model has yet been able to fully replicate the complexity of the immune system.

use of animals for the research of new drugs and that this is a topic of great concern for the public.

The welfare of the laboratory animals housed in our facilities (as well as those of external companies/institutions that work with us) is a top priority for Almirall. We do have a moral responsibility with the animals we use for research, and we are highly committed to their responsible use.

We strictly follow the principles of Replacement, Reduction and Refinement (the “3Rs” of Russell and Burch², which means:

- Replacement: We shall not use animals if there is an alternative non-animal method (*in vitro*, *in silico*...) able to provide us with the same scientific results we would have expected *in vivo*. We strive to contribute to the development and use of predictive and robust models and tools, based on the latest science and technologies, to replace the use of animals in addressing important research questions where they would otherwise have been used.
- Reduction: If we must use animals, we shall use the minimum number to achieve the scientific results. We get this by appropriately designed experiments that are robust and reproducible.
- Refinement: When animals must be used, we shall apply all our knowledge and skills to alleviate or minimize pain, suffering or distress, and to enhance animal welfare. We strive to know the latest *in vivo* technologies to minimise pain, suffering and distress and improve understanding of the impact of welfare on scientific outcomes.

3.3 Use of animals in Almirall premises:

In Almirall we strictly adhere to the European³, Spanish⁴ and Catalan⁵ regulations related to the care and use of animals for research. Moreover, in accordance with the statements of the European Federation of Pharmaceutical Industries and Associations (EFPIA), “the research-based pharmaceutical industry not only complies fully with the letter of the law, it goes beyond compliance”.

The animal facilities comply with all the structural, environmental and design requirements specified in current regulations and guidelines and are regularly subjected to inspections by the competent authority. Special care has been taken to house the animals in a way that promotes their well-being, and they can express the behaviours that they would develop in the wild or in their natural habitat.

The animals housed in our facilities come from suppliers accredited by the competent authorities and are subjected to a period of acclimatization under veterinary supervision before being used in experimental procedures. The health and welfare of the animals are monitored on a regular basis by competent persons, and veterinary

² Russell, W.M.S. and Burch, R.L., (1959). *The Principles of Humane Experimental Technique*, Methuen, London.

³ 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.

⁴ Real Decreto 53/2013, de 1 de febrero, por el que se establecen las normas básicas aplicables para la protección de los animales utilizados en experimentación y otros fines científicos, incluyendo la docencia.

⁵ Decret 214/1977, de 30 de juliol, pel qual es regula la utilització d'animals per a experimentació i per a altres finalitats científiques.

care is available at all times. There is a program of environmental enrichment and socialisation.

Animal research staff (personnel carrying out procedures, designing procedures and projects, and taking care of animals) have the training and competence required for the tasks they are going to do, and are aware of all the ethical issues involving the use of laboratory animals. Staff must participate in continuous training programs to stay up to date with the latest advances in animal management and welfare techniques, and certifications may require periodic re-evaluations to ensure continued compliance with standards.

Every procedure or project with animals is carefully reviewed and approved by an internal Ethics Committee and, in addition, by the competent authorities. This Committee is a regulated body which ensures ethical compliance and adherence to the laws, and is formed by the Specialist in Animal Welfare, who is responsible on site for the supervision of the welfare and care of the animals in the facilities, and by expert scientist members. The Ethics Committee also receives input from the Designated Veterinarian (who is a specialist in laboratory animal medicine charged with advisory duties in relation to the health status and treatment of the animals). The main duties of the Ethics Committee are:

- advise the staff dealing with animals on matters related to the welfare of animals, in relation to their acquisition, accommodation, care and use,
- advise the staff on the application of the requirement of replacement, reduction and refinement, and keep it informed of technical and scientific developments concerning the application of that requirement,
- establish and review internal operational processes as regards monitoring, reporting and follow-up in relation to the welfare of animals housed or used in the facilities,
- advise on rehoming schemes, including the appropriate socialisation of the animals to be rehomed,
- follow the development and outcome of projects, taking into account the effect on the animals used, and identify and advise as regards elements that further contribute to replacement, reduction and refinement.

3.4 Responsibilities of staff working with research animals in Almirall:

Staff who work with animals at Almirall must comply with this Policy, regardless of whether they are staff hired by Almirall or come from an external company.

Any incident affecting animal health or welfare should be reported immediately to the Ethics Committee, which will evaluate it internally and take the appropriate measures depending on its seriousness.

3.5 External companies working with Almirall (Contract Research Organisations, Academic institutions or suppliers):

Contracted external companies must comply with this Policy regarding aspects that refer to ethical issues in the use of animals in research and provide evidence of compliance when requested by Almirall.

Prior to procurement, Almirall may evaluate companies/institutions to ensure that they meet ethical and legal standards and are at least AAALAC⁶ certified (or are eligible to). This evaluation (periodic inspections or audits) may also be carried out at any time during the duration of the relationship with Almirall to safeguard compliance.

Any incident affecting animal health or welfare should be reported immediately. In the event of any breach of this Policy being detected or reported, Almirall will initiate the corresponding investigation and reserves the right to take action that may lead to the termination of the relationship between the two parties.

3.6 Review and update:

This Policy will be reviewed and updated periodically to reflect advances in the science and ethics of the use of animals in research.

4. Governance

Corporate Policy Sponsor: Chief Scientific Officer
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Corporate Policy Owner: Responsible of Animal Welfare and Designated Veterinarian

All employees are required to report any suspected violation of the Corporate Policies in accordance with Almirall Code of Ethics and other internal guidelines. Suspected violations can be reported to the direct manager, People & Culture, the local Compliance Officer, the Legal representative or through the [SpeakUp! channel](#)

⁶ AAALAC International (www.aaalac.org) is a private, nonprofit organization that promotes the humane treatment of animals in science through a voluntary accreditation program.