

PUTTING ANIMAL WELFARE PRINCIPLES AND 3Rs INTO ACTION



European Federation of Pharmaceutical Industries and Associations



The pharmaceutical industry works to implement 3Rs to ensure high animal welfare and high quality science. We strive to go beyond what is legally required and ultimately improve the lives of the people and animals that stand to benefit from the research.

The use of animals in research and testing can be a controversial subject and therefore it is important to support an open dialogue and collaboration on the use of animals for scientific purposes.

The pharmaceutical industry continues to support the objectives of the Directive 2010/63/EU on the protection of animals used for scientific purposes which has enhanced animal welfare standards and mandated the application of the 3Rs across the EU while ensuring Europe remains a world leader in biomedical research.

Since the adoption of this EU legislation, EFPIA and its members have been publishing reports to visibly highlight our achievements on putting animal welfare principles and the 3Rs into action.



I have seen through the years the passion and commitment of individuals and their companies to responsible animal use, with tangible outcomes leading to improved animal welfare and high-quality science as demonstrated with these examples.

Sally Robinson, AstraZeneca
Chair of the EFPIA Research and Animal Welfare Group

We work together to leverage our passion, knowledge and resources to best advance the 3Rs as we drive to discover and develop new and innovative medicines and technologies to improve the health and quality of life of patients worldwide.

Chris Petursson, DVM, DACLAM Bristol-Myers Squibb
Chair of the EFPIA 3Rs focus group



REPLACE

animal experiments wherever possible with alternatives.



REDUCE

the number of animals used.



REFINE

experiments to minimise the impact on animals.

BEYOND COMPLIANCE



3Rs and welfare in everyday practice: Researchers work continuously to drive new ways of working with the 3Rs.



Science and technology drive 3Rs and welfare - We invest continuously in changing research paradigms



Staff training is an essential element of good science and good welfare

In the pharmaceutical industry, researchers go beyond the regulatory requirements to develop systems leading to improved 3Rs and animal welfare in every day practice.

In our 5th report, it includes a non-exhaustive list of over 70 examples of activities and successes of the pharmaceutical industry covering Replacement, Reduction and Refinement, which indicates the passion and commitment of individuals and their companies to responsible animal use, with tangible outcomes leading to improved animal welfare and high-quality science.

Our researchers are doing this by working to address scientific questions better, using novel or refined technologies. Furthermore, we are using scientific advancements to influence regulatory changes leading to removal of obsolete tests for regulatory acceptance of drugs.

Supporting R&D for better science and more welfare



EPAA – European Partnership Alternative Approaches to Animal Testing. From bench to industrial application EFPIA and a number of its members are founding members of the EPAA – a cross-sectorial and multidisciplinary partnership between five European Commission services and eight industry sectors. The mission of the EPAA is to promote 3Rs in regulatory testing, and facilitate the development and implementation/regulatory acceptance of alternative testing strategies.



IMI - The Innovative Medicines Initiative is a public-private partnership between the European Union and EFPIA. It is pursuing the goal of developing the next generation of vaccines, medicines and treatments by improving research practice; getting new healthcare solutions to patients faster; and improving health outcomes thanks to new tools, methodologies, research infrastructure and big data. The IMI consortia (involving industry, academia, SMEs, patients, regulators, etc.) are contributing enormously to animal welfare:

- ◇ IMI helps to drive animal welfare and 3Rs – Presently numerous IMI consortia impact on the use of animals and IMI projects contribute to the 3Rs.
- ◇ IMI successes have addressed and brought results in 3Rs or new research paradigms or more predictive testing tools that do not require – or require fewer – animals
- ◇ IMI projects are contributing to a better understanding of the challenges faced in using animal models and are impacting on the use of laboratory animals in research and development.



LEADING BY EXAMPLE



Full and correct implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes is the responsibility and endeavor of the whole scientific community



Dissemination beyond own department and own establishment drives improvement in welfare and general quality of science

Implementation of Directive 2010/63/EU on the protection of animals used for scientific purposes is the responsibility and endeavor of the whole scientific community

EFPIA and its members remain committed to full and correct implementation of Directive 2010/63/EU and enhance the cultures of care, and challenge and openness for research involving animals. The Directive is vital to ensure that necessary research involving animals can continue whilst requiring enhanced animal welfare standards.

We call upon all stakeholders (regulators, users, academia, civil society) to join forces to:

- ◇ Facilitate access to guidance and information for those responsible for research programmes;
- ◇ Support and provide resources to EU and national initiatives that enable the development and validation of new research paradigms and the integration of new sciences or technologies into research and regulatory practice;
- ◇ Support the exchange of good practice;
- ◇ Promote continued open dialogue about the realities of current scientific research and future prospects of science and technologies.

Activities of EFPIA and its members driving for change within the pharma industry:

- ◇ **Learning from others:** EFPIA invites external stakeholders to share tools and inform industry.
- ◇ **Joining forces:** EFPIA remains open to a constructive dialogue and engagement with all stakeholders and EU institutions.
- ◇ **User community workshops:** EFPIA organizes workshops with experts from industry, academia, research funding organisations and regulators to exchange good practice.
- ◇ **Rehoming of animals:** Companies see the value in rehoming animals and the majority have rehoming policies or programmes in place.
- ◇ **Metrics to assess the progress of 3Rs:** Companies either measure or support the importance of measuring 3Rs by measuring progress either yearly or more than once a year, externally or internally.
- ◇ **Culture of Care:** Industry has worked on defining the concept of Culture of Care and how it is understood and applied across Europe. EFPIA has developed a Framework with the aim to help organizations identify gaps or potential areas for improvement in support of a positive Culture of Care*.
- ◇ **Experimental Design:** Effective experimental design and statistical analysis are critical means of minimising the use of animals whilst achieving study outcomes. EFPIA has produced a report identifying key factors and gaps with recommendations for organisations to implement, which will improve the quality of science and maximize the uptake of 3Rs opportunities*.
- ◇ **Audits:** Internal audits by independent auditors, sometimes including animal welfare NGOs, assures that internal standards are followed and that they meet corporate expectations. Likewise, monitoring external collaborators, such as CROs and/or academia, is essential to assure that corporate animal welfare standards are globally applied just as if they were conducted in-house.
- ◇ **Sharing of tissues and organs:** Industry invests significantly in reducing animal numbers by sharing tissues and organs from euthanized animals from studies or projects that were completed or animals that were no longer required.
- ◇ **Improving housing and care standards:** Companies have been investing in improving the housing and care of animals with the aim to improve their welfare, including enrichment material, to prompt more natural behaviours such as rooting, foraging and exploration. Furthermore many animals caging space exceeds the legal guidelines and allow for group-housing.

* See reports on efpia.eu

OPEN COMMUNICATIONS



Communication, transparency and dialogue with the public

Corporate statements - Communicate on the 3Rs through dedicated sections in publicly available Corporate Social Responsibility reports.

Disseminating openness and transparency - Many companies have signed transparency agreements and their websites are important tools in making available information and explaining the use of animals in experiments, including videos of housing and animal handling.

Open laboratories - The general public, NGOs and policymakers are offered the opportunity to visit laboratories or take virtual tours to see the housing and learn about the uses of animals and multiple efforts of industry to enhance the 3Rs in daily practice.

Dialogue with NGOs and academia - Companies proactively engage in constructive dialogue. They inform each other and share experiences and expertise through various collaborations on practical and operational issues.

Global collaborations to improve global standards - The majority of EFPIA companies are international and have several research sites around the world. It is important for them to ensure they globally implement high corporate standards for animal welfare, veterinary care, education and training. Some companies have established official corporate policies on animal ethics.



#WeWontRest in our efforts to ensuring high standards of animal welfare in the research process

Kirsty Reid, Science Policy Director, EFPIA

The full report and other reference materials can be accessed on the EFPIA website as well as the previous reports “Putting Animal Welfare Principles and 3Rs into Action”

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