"We commit to apply and actively promote the 3Rs* (Reduction, Refinement and Replacement of animal studies), especially with regard to the research, development and implementation of methods and techniques which allow further replacement of animal studies, a reduction in the number of animals used or alleviation of the pain and stress of laboratory animals."

* 3R concept developed by Russell and Burch in 1959.

'We commit to ensure high-quality and state-of-the-art housing and care conditions for our laboratory animals and we strive to continuously improve these conditions."

"We commit to develop and foster education and training for all our employees and associates who work with animals."

"We commit to contractually oblige external partners to comply with our high standards of animal welfare when they conduct animal studies for us or supply us with animals."

"We commit to apply vigorous internal auditing systems,* which ensure compliance with the animal welfare standards agreed upon."

* Audit/auditing in the context of the Charter on Animal Welfare encompasses procedures and/or (control) processes which have been established in order to ensure compliance with sets of conditions of housing, care and handling of animals which have been agreed on by the signatories of the Charter. These sets of applicable conditions have as a minimum level the legal standards of animal welfare laid down in the US Animal Welfare Act extended to all vertebrates (i.e. AW Act [9 USC §3] and Regulations, and the US Guides for the Care and Use of Laboratory and Agricultural Animals [including all vertebrates]).** In countries where the legal requirements are above this level the minimum standard is adapted accordingly.

** Guide for the Care and Use of Laboratory Animals and Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching (FASS, 1999). The Guides are based on the Animal Welfare Act signed into law in 1966, last amended in 2007 and enforced by the USDA (United States Department of Agriculture), APHIS (Animal and Plant Health Inspection Service), and Animal Care agency. (www.nal.usda.gov/awic/legislat/usdaleg1.htm)

"We commit to join efforts in auditing our external partners on animal welfare standards and compliance on a global level."

"We commit to promote, in addition to regular authority inspections, the development of external, independent assessment programs of our animal welfare standards and facilities on a global level."

"We commit to promote the validation and regulatory acceptance of methods which are suited to replace, reduce or refine animal studies."

"We commit to contribute to a continuous, open and constructive dialogue on animal research and welfare with the public at large as well as with authorities, policy makers and other interested stakeholders."

"We commit to report annually on the progress made with regard to this Charter."

Animal welfare implementation in Switzerland

A successful stakeholder approach based on a joint Animal Welfare Charter

Background and objectives

Animal research is a highly emotive topic. Many people are critical of animal experiments but at the same time are demanding pharmaceutical products that meet the highest quality and safety standards. While it is common for pharmaceutical companies to have internal standards for animal research, no country has previously succeeded in aligning and extending them across a national industry. After identifying four key elements, (a) open and constructive stakeholder dialogue, (b) foster education and training, (c) promote all aspects of 3R, and (d) audits and certification, the 10 articles of the Animal Welfare Charter were developed.

The commitments of the Charter are not only applied within the companies but are also valid for all external research and development partners – on a global level (i.e., in countries with legal requirements below the Swiss or European standard or with no animal welfare acts in place). The annually published animal welfare report provides an overview of company initiatives and achievements. It gives proof that the commitments are sustainable and lead to constant progress in favor of the animals.

Selected examples

Open and constructive stakeholder dialogue

- Targeted communication to various stakeholders: member companies, politicians, federal and cantonal authorities, opinion leaders, academia, schools, media and public at large.
- Based on the Charter, industry working groups (Animal Welfare Working Group, Audit Group) were built and collaborations with different stakeholders such as animal rights organizations (STS-Interpharma Dialogue), academia and authorities (Foundation 3R and Severity Classification Group) have been partly reinforced or newly established.

Foster education and training E-learning

- The multilingual version of the e-learning tool for people who work with animal experiments, which was developed by the University of Marburg in Germany and initially supported by Interpharma, has been approved nationwide as a continuing education course over a total of $5\frac{1}{2}$ days.
- This now provides an outstanding opportunity for officially approved online training for anyone in Switzerland involved in animal experiments, whether from industry or from the academic world.

 The content is based on the recommendations of FELASA (Federation of European Laboratory Animal Science Associations). Topics include law, ethics, 3R, animal breeding, handling and application forms, anesthesia and analgesia, to assess the condition of experimental animals, as well as experimental interventions.

Internal trainings

- The member companies offer internal continuing education and training for their staff engaged in animal research in adherence to official regulations by law.
- These training events cover, e.g., issues in the field of the 3Rs and provide information on current law behavior by representatives of the cantonal veterinary office.
- One member company is focused on nonhuman primate (NHP) behavior and work with NHPs in a scientific setting. The workshop consists of a theoretical and practical/ interactive session. It covers "Primatology Basics" including topics such as phylogeny/anatomy, as well as living conditions in the wild and its relevance to life in captivity, social structure/hierarchy and behaviors (vocalizations, body postures, facial expressions).

Promote all aspects of 3R

3R Awards and working groups

- Various member companies of Interpharma award an annual 3R prize within the company. The aim is to reward new ideas in research, working methods and processes and also animal husbandry that are in keeping with the objectives of the 3Rs.
- A member company also initiated a cross-divisional working group to further advance the 3Rs.
- 3R projects are growing in popularity within the companies. The awareness of the 3Rs principles is also reflected in the increasing number of projects that are submitted for the annual awards ceremony. In one company 48 projects were submitted, which represents an increase of 30 percent.

Foundation 3R

- The aim of the Foundation 3R is to promote alternative research methods to animal experimentation through grants for research projects as well as to implement and promote the 3R principles.
- Since 1987 the Foundation 3R has been **funded by** the Swiss federal government and Interpharma and managed by an independent Board of Trustees.

- The Foundation has supported around **138 research** projects from around 450 requests for an amount totaling **CHF 18 million** in the past 27 years.
- The award of research grants is subject to the condition that the project results are published in recognized publications, and the results are made available for other researchers.
- An important indicator for the successful work of the Foundation is that the number of good-quality projects submitted annually has risen steadily in recent years.
- More details of all funded projects can be found on the website of the Foundation (www.forschung3r.ch)

Audits and certification

Joint Interpharma Audit

- Commitment to globally ensure high-quality and stateof-the-art housing and care conditions and to contractually oblige external business partners to comply with Interpharma's standards of Animal Welfare.
- Joint audits of external business partners on a global level will assure a transparent, harmonized and aligned decision-making process for the member companies and may reduce the number of individual company audits with the focus on laboratory/farm animal science and welfare aspects.
- Results will be shared within member companies but will be treated confidentially. The decision whether or not to perform business remains with the individual company.
- The audit is based on the "Interpharma Audit -**Questionnaire and Assessment Report for Audits** of Animal Breeders and Vendors."
- Findings are presented and graded and if necessary, a CAPA plan (Corrective and Preventive Action Plan) will be agreed with the external business partner. This CAPA plan will be reported to the Interpharma member companies and serves as an additional set of criteria for the decision whether or not to perform business.

AAALAC (Association for Assessment and Accreditation of Laboratory Animal Care International)

- Several sites of Interpharma member companies are certified by AAALAC (www.aaalac.org).
- Since 2013 Interpharma has also had a seat on the AAALAC Board of Trustees, where we can thus exert a direct influence in order to drive the promotion of independent animal welfare certification programs forward.
- Yet not only our member companies, but in many cases also their business partners are inspired by AAALAC and endeavor to ensure that the required standards are
- Our member companies also provide professional ad hoc consultants to perform accreditations at other companies, institutions and organizations in the spirit of AAALAC.

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Interpharma is the association of research-based pharmaceutical companies in Switzerland. We are committed to create conditions conductive to innovation in both Switzerland and abroad so as to promote pharmaceutical research, development and production.

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