



Media Release

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EU medicine regulators accused of allowing hundreds of thousands of unnecessary animal tests

The European Coalition to End Animal Experiments (ECEAE) has today condemned the unnecessary suffering over many years of hundreds of thousands of animals in particular experiments. The tests have only taken place because of inexcusable failures by the European Medicines Agency (EMA), the EU agency responsible. As a result the Agency and drug companies have systematically broken EU legislation.

This outrage was only discovered following research by the International Council on Animal Protection in Pharmaceutical Programs (ICAPPP), an international coalition of animal protection groups of which the ECEAE is a member. Yet incredibly the EMA has, despite repeated requests, refused to make it clear to EU governments and pharmaceutical companies that the tests are no longer needed in most cases and they therefore still take place.

Animals are subjected to a battery of tests before a new drug goes into a clinical trial. One of these tests has traditionally been the acute toxicity or single-dose toxicity test (SDT), designed to see what happens when a very large dose of a drug is taken (as with accidental overdoses). It is a particularly severe test, involving force-feeding or injecting high levels of potentially harmful drugs into rats, mice and hamsters, and observing them for signs of toxicity which could include diarrhoea, weight loss, convulsions and even death. In a conservative estimate, since 2003, around 340,000 animals may have suffered and died in such tests in Europe.

The European medicines directive, Directive 2001/83, says that the test must be carried out in accordance with guidelines issued by the EMA. Guidelines issued in 1987 required the test to be carried out on two species of mammal. However, the International Conference on Harmonisation (ICH), to which the EU belongs and which supersedes EMA guidelines, has accepted since the late 1990s that the data obtained from other animal tests, which happen

anyway, can be used instead of SDTs to assess acute toxicity. These are dose escalation studies.

The EMEA has recently conceded in correspondence with ICAPPP that '*the content of the [1987] guideline is not relevant*', except in particular circumstances.

And yet the EMEA has refused to clarify the situation for industry and ICAPPP has therefore now written to all EU governments and the major pharmaceutical companies asking them immediately to stop the routine use of SDTs. A large study recently carried out by the major pharmaceutical companies and the UK's National Centre for the Three Rs found that companies were unnecessarily still carrying out the tests, simply because they thought (wrongly) that they had to.

Michelle Thew, chief executive of the ECEAE, commented:

The European public will be outraged to learn that so many animals have had to suffer because of bureaucratic failings. Indeed, animals are continuing to suffer grievously without any benefit to human health. Once again this demonstrates that the assurances made by the EU and the animal research industry alike that animal experiments are a last resort and that alternative methods are used wherever possible are a nonsense. It also underlines why the animal experiments directive, currently being revised, needs to be considerably strengthened.

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For further information please contact the ECEAE BUAV media office 020 7619 6978; after hours, 07850 510 955 or E-mail: erin.seymour@buav.org.

Notes:

1. ICAPPP is an international coalition of animal protection groups with a combined supporter base of over 30 million people throughout Europe, Asia and North America. Its aim is to ensure the widest possible integration of alternative methods (replacements, reductions and refinements) in regulatory frameworks for therapeutic products, in the interests of animal protection, public health and sound science. Current member organisations are: Animal Alliance of Canada, British Union for the Abolition of Vivisection, Doris Day Animal League, Dr Hadwen Trust, Eurogroup for Animals, European Coalition to End Animal Experiments, Humane Society of the United States, Japan Anti-Vivisection Association, People for the Ethical Treatment of Animals, and Physicians Committee for Responsible Medicine.
2. The estimate of 340,000 is an extrapolation from statistics published by the European Commission, covering the years 2003 to 2008. The ECEAE can explain the figure on request.
3. The EMEA has a central role in the regulation of new medicines in the EU. It is based in London.

4. The medicines directive used to specify that two mammalian species should be used for SDTs. However, this was amended in 2003 by deferring instead to EMEA guidelines. These therefore assume central importance.
5. The study of major pharmaceutical companies was reported in an article by Robinson S et al *A European pharmaceutical company initiative challenging the regulatory requirement for acute toxicity studies in pharmaceutical drug development* in *Regulatory Toxicology and Pharmacology* 2008; 50: 345-52. Major international pharmaceutical companies around the world were involved in the study, and international regulators said they agreed with the scientific conclusions.
6. The ICH seeks to harmonise testing methods amongst its members – the EU, the US and Japan. It has been considering a revision to the current M3 guideline on SDTs and has just confirmed, once again, that dose escalation studies can normally be used instead. The revision does not alter the fact that SDTs are already, as the EMEA accepts, scientifically redundant in most cases and should therefore not be performed.
7. The EMEA has produced a concept paper (<http://www.emea.europa.eu/pdfs/human/swp/30241308en.pdf>) confirming that, in most cases, SDTs on animals are not necessary.
8. ICAPPP's correspondence with the EMEA and its letter to EU governments and the pharmaceutical companies are available on request.
9. The European animal experiments directive, Directive 86/609, makes it clear that particular animal experiments must not take place where the required information can be obtained by alternative means, as in this case.