European Federation of Pharmaceutical Industries and Associations (EFPIA)

About EFPIA

EFPIA represent the pharmaceutical industry operating in Europe. Through its direct membership of 18 national pharmaceutical industry associations, 6 liaison associations from acceding states and 43 leading pharmaceutical companies, EFPIA is the voice on the EU scene of over 582,500 employees committed to researching, developing and bringing to patients new medicines that improve health and the quality of life around the world.

One of the objectives of the consultation is to assess ways of regulating and enhancing good practice. In our contribution we would like to briefly sketch out the wider European context in which our industry is operating and demonstrate that animal research and welfare regulations have broader societal and economic implications.

Use of animals in biomedical research

As pointed out in the consultation document, experiments on living animals are a necessary part of the discovery and development of new medicines and vaccines.

Industry recognises that animal research is a source of concern of ethical nature. Ethical debates are inherent part of the development of the society and of science. Industry has moral obligation vis-à-vis the animal, and also morally and legally the industry is obliged to test potential new medicines rigorously to ensure that they are as effective and as safe as possible (Nuremberg Declaration, Good Clinical Practice principles, pharmaceutical legislation).

At the same time, EFPIA believes that the number of animals required should be kept to a minimum by making maximum use of in-vitro techniques and by using appropriate statistical methods. The animals used in experiments should be treated humanely and be subjected to the least stressful experimental methods and housing conditions. We cannot replace all animal experiments in the foreseeable future, but we can continuously refine the care and use of animals and develop procedures that reduce and/or replace animal experiments. Industry fully agrees with and supports the existing law requiring that experiments on living animals should only be carried out when no other suitable alternative methods are available. Indeed industry should be recognised as the major source of alternatives. The application of new research technologies has allowed extensive implementation of these alternatives.

How to tackle ethical issues?

The question is whether the existing legislation properly addresses all ethical issues that may arise. At EU level animal research is regulated by Directive

86/609 on protection of vertebrates used for research and other experimental purposes – it sets a common framework which must be adopted across the EU.

EFPIA considers that such a framework legislation providing for mandatory local ethical review process would address all future challenges. Since the progress is ongoing and new technologies are created every day, there is a need for a process, an ethical review process, which would be able to assess these developments on an ongoing basis. This allows for more transparency and on-going public debate on ethical issues to which all interested parties, including industry, would actively contribute.

No legislation, whatever its degree of detail is, would be able to address all future challenges raised by the scientific and technological progress. In addition, more detailed legislation would not necessarily mean more welfare for animals, but it may mean less research projects and fewer treatments developed in Europe for European patients.

It is difficult to legislate on ethics – ethical norms evolve over time and vary depending on the State, region, religion, etc. Discussions on ethical issues at EU level, e.g. on research on stem cells, showed that although it is possible to agree on common technical and regulatory standards, it is difficult to agree on common ethical rules fitting all. Union was more successful in adopting broad framework principles, such as the Charter on Fundamental Rights.

We strongly believe it is only possible to call for worldwide harmonisation of fundamental requirements on the basis of a framework of outputs rather than on the basis of a prescriptive detailed legislation.

European science base and competitiveness

In March 2000, The European Council in Lisbon set out a ten-year strategy to make the EU the world's most dynamic and competitive economy based on knowledge. Under the strategy, a stronger economy will drive job creation alongside social and environmental policies that ensure sustainable development and social inclusion.

Two years later, the European Council in Barcelona agreed that one way to achieve this aim is to strengthen European science base by creating better financial and legal environment for research.

The serious deterioration of the European pharmaceutical industry's competitiveness was demonstrated by a series of reports[1] and subject to discussion in a multi stakeholder high level group (G10) appointed by the European Commission which concluded inter alia that European research frameworks needs to be re-energised (recommendations 8 and 9 of the G10 report "Stimulating innovation and Improving EU Science Base").

[1] 'Global Competitiveness in Pharmaceuticals' prepared by Professor Pammolli and his team in 2000

It is therefore clear that development of science and research abilities will contribute to economic growth and Europe's competitiveness. And this would directly be reflected in jobs creation, more innovative medicines and treatments and thus very directly the well being of the citizens of the European Union. We believe this aspect must also be part of the overall ethical assessment.

This innovation, and at this stage mainly biotechnology, while providing new solutions brings new ethical challenges. Thanks to biotechnology the overall number of animals used in each project has decreased, often by half or more, since animals are used at a much later stage of research. On the other hand creation of genetically modified animals, which contributed to this decrease in number, raises new public concerns. The progress of science will certainly be source of many other questions of this kind.

As demonstrated above, ethics is an inherent part of society and science is not developed in a vacuum, but for and by the society. However, a too detailed and prescriptive legislation would not only fail to address all the future ethical challenges, but it could potentially stop the progress and would also have broader social and economic consequences.

We are not convinced that detailed legislation on ethics and animals is applicable across Europe, for example the approach of using a detailed formal harm and benefit assessment is not universally accepted. Unilateral strengthening of the legislation, whether at national or European level, would not prevent animal research from happening – it would be subcontracted or relocated outside the country or out of Europe.

This has a potentially disastrous impact on Europe's research abilities and competitiveness of European industry because relocating a research activity also means brain drain of highly qualified scientists and technicians, losses of jobs in sectors directly and indirectly linked with animal research.

Keeping animal research in Europe would not only contribute to strengthening of its economy. It is also in the interest of animals since ongoing debates on ethics of research contribute to improvement of animal research conditions. Such public debates, when well balanced, help to raise awareness of the public of the purposes of challenges of animal research, to raise awareness of industry about international best practice in this field, and to guarantee public scrutiny.

We support the Nuffield Council on Bioethics recommendation to stimulate public debate. However a sound public debate can only take place in a climate of serenity. Therefore, we endorse the new of the UK House of Lords report on the use of animals in scientific procedures that the extreme activities of those opposed to research using animals is stifling a transparent debate. The activities themselves are also quite unacceptable, a misuse of democratic freedoms, and should be condemned.

Conclusion

The Nuffield Council of Bioethics initiative on ethics of animal research is an important one since it shows the complexity of the problem and starts a discussion about the shape and future of European research. This discussion will raise awareness about the value of animals, and about existing laws and best practice.

The pharmaceutical industry recognises that animal research can raise ethical problems. These ethical questions should be addressed in a transparent way in the ethical review process and public debate involving informed opinion leaders and other stakeholders. This public debate is potentially more efficient for any scientific progress than over prescriptive and detailed legislation that neither serves openness nor animal welfare.