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The European Association of Nuclear Medicine's Statement on Animal Testing in the EU

The potential adverse effect of a ban on biomedical research

The European Association of Nuclear Medicine (EANM) would like to express its **reservations about the [European Citizen's Initiative \(ECI\)](#) titled 'Save Cruelty Free Cosmetics - Commit to a Europe without animal testing'**. This initiative called on the European Commission to commit to a 'legislative proposal plotting a roadmap to phase-out all animal testing in the EU before the end of the current legislative term', under the pretext of the existing ban of animal experiments in the field of cosmetics development. As this European Citizen's Initiative has triggered several reactions from European policymakers, the EANM would like to draw attention to the **detrimental aspects of the above-mentioned petition and to the serious consequences** that a general ban on animal experiments could have on healthcare in the EU.

First, phasing-out animal testing would significantly **hinder medical innovation in Europe and would ultimately impact EU patients' health**. Most major medical advances that came out over the last century were highly dependent on research involving animal testing. Nowadays, **animal experiments in research help EU researchers to advance their medical understanding of diseases and enable them to develop and test potential new medicines and therapies**. Thus, banning animal testing would significantly **limit the translation of research into new therapeutic approaches**.

In fact, since **not all preclinical investigations done through animal experiments can yet be replaced by *in vitro* assessment**, abolishment of animal testing would have serious effects on the translation of new therapeutic agents and imaging tracers. While biological effects (i.e., biodistribution and possible toxicity) of novel therapeutic agents and imaging tracers can, to some extent, be evaluated using *in vitro* model systems and computer modelling, ***in vivo* assessment remains crucial to determine the real-life level of toxicity, biodistribution and feasibility potency**. This also explains why animal testing has been **required by regulatory authorities** worldwide to ensure the **quality, efficacy and safety of medicines and therapies**.

Consequently, the absence of preclinical evaluation of new treatment options prior to the clinical implementation stage would lead to restrictions at later stages of drug and tracer development, as preclinical testing is still required to further exclude the possibility of late clinical failures. As such, it can be expected that **without proper and extensive (*in vivo*) testing methods,**

the number of novel therapeutic and imaging agents that would be made available on the market would considerably decrease.

A ban would be premature - a plan, including the needed data for approval of first-in-human applications while a total ban of pre-clinical experiments involving animals is in place, should be first developed by European and national health authorities. This is only with such a plan that alternatives can be evaluated and implemented.

Furthermore, it is noteworthy that despite the research community's commitment to reduce animal experiments through the progressive development of alternative methods, **non-animal models do not provide yet as many information as animal studies.** In this respect, it is likely that **animal experiments for biological and medical research will remain necessary in the foreseeable future.**

The nuclear medicine community therefore believes that the existing legal requirements for performing animal experiments in biomedical research - notably the EU Directive 2010/63/EU, specifying the 3Rs principle (Replacement, Reduction, Refinement) - already weigh the benefits and the harms for the animals, and assess their ethical justifiability. In fact, within the EU, animal experiments can only be carried out by researchers with demonstrated knowledge in the field, for research projects that were approved by the relevant authorities.

It is well acknowledged **that nuclear medicine physicians using animals in pre-clinical studies are compliant with the 3Rs principle.** They notably use modern imaging equipment, follow a careful planning of any study design, and collaborate with professionals that are specialised in animal treatment.

In sum, the EANM considers that **the current legislative framework for animal experiments remains fit for purpose, as alternatives to animal testing are not yet suitable to the needs of the nuclear medicine community.**

The ECI would not only **threaten Europe's leading role in the development of medical diagnostics and treatments opportunities but would also have a huge impact on future diagnostic and therapeutic options for patients and the healthcare system.**

A more gradual outlooks towards decreasing animal experiments in medical research, where and when scientifically possible, should be preferred.