BRINGING BACK THE HUMAN: TRANSITIONING FROM ANIMAL RESEARCH TO HUMAN RELEVANT SCIENCE IN THE UK

SUMMARY OF A REPORT BY THE APPG FOR HUMAN RELEVANT SCIENCE

A series of evidence sessions held by the APPG for Human Relevant Science in 2020-2021 heard that human-relevant approaches and technologies, known collectively as 'new approach methodologies', or NAMs, are needed to advance the development of treatments for human diseases. Experts from relevant funding bodies (the MRC and NC3Rs), as well as some of their research beneficiaries, presented evidence on the scientific validity of NAMs, but scientists described a UK climate in which limited funding opportunities exist for NAMs research. This lack of funding was contrasted with the extensive resources available for research using established technologies and practices which are primarily based on animal experiments. It emerged that human relevant NAMs funding represents between 0.2% and 0.6% of total biomedical research funding in the UK and ~0.02% of the total public expenditure (£10.45B for 2019-2020) on R&D. This is woefully inadequate and will impede the UK's efforts to improve human health and retain its status as a world leader in the life sciences arena.

A member of the UK's medicines regulator, the Medicines and Healthcare products Regulatory Agency (MHRA) provided the APPG with an assessment of current regulatory requirements for pharmaceutical safety and a view on how NAMs data might be incorporated into regulatory decision making for new medicines. The current legal environment regarding the use of animals and NAMs in biomedical research and regulated testing was also discussed. Finally, the APPG was told how the transition to human relevant, animal-free research is being encouraged and managed in the Netherlands.

The evidence presented to the APPG indicated that important factors which restrict the routine use of NAMs in disease research and drug testing are a lack of awareness of their potential and a widely held belief that in vivo animal research is the only scientifically credible way to discover, develop and test new medicines. A culture of animal use is perpetuated within academia, industry, and regulatory agencies, with outdated guidelines hampering the adoption of NAMs for the safety testing of drugs and prolonging the use of poorly performing animal methods in basic research. This has catastrophic results for the UK's health and for the modernisation of biomedical research.

Increased funding in strategic areas devoted to the development and adoption of NAMs is patently needed. Until the development and use of NAMs is prioritised by the Government, UK science and the health of our nation will lag behind those of other countries, with devastating consequences. The APPG strongly believes that human relevant science offers a golden opportunity for the UK to make more effective use of its substantial expenditure on biomedical sciences to enhance the productivity of industry, improve public health and cement its status as a global science superpower.

RECOMMENDATIONS

FUNDING

We recommend that:

- the Government commits to increasing the funding of NAMs by strategically diverting resources away from animal-based approaches and towards NAMs.
- animal researchers should be legally obliged and financially supported to proactively shift their focus away from animal use and towards the development and use of NAMs, in line with current legislative requirements.

REGULATORY

We recommend that:

- the Home Office commits to a more robust application of the harm-benefit analysis when assessing project license applications for animal research and requires robust evidence that the use of NAMs has been thoroughly considered.
- an aspiration for animal free science is reintroduced into UK legislation.
- the Government commits to reviewing the current regulatory guidelines for animal research and pharmaceutical testing, with a view to updating these such that human relevant methods are recommended where appropriate in research and during the development and licensing of medicines.

STRATEGIC GUIDANCE AND SUPPORTIVE INFRASTRUCTURE

We recommend that the Government commits to:

- creating a dedicated ministerial position to lead an ambitious and detailed programme of work across all relevant departments to transition to human relevant NAMs with appropriate milestones, timelines, funding, and deliverables.
- establishing a UK Transition Programme for Innovation without animals to prioritise awareness of NAMs and to incentivise collaboration between stakeholder groups, including academic researchers, industry, funders, and regulators.
- evaluating preclinical research for its clinical relevance and allocates funds accordingly.



This is not an official publication of the House of Commons or the House of Lords. It has not been approved by either House or its committees. The All-Party Parliamentary Group (APPG) for Human Relevant Science is a cross-party group of Peers and MPs which was founded in 2020 and is currently chaired by Grahame Morris MP. Its agreed purpose is to support better science for better health, save lives – human and animal – through improved safety and efficacy testing of medicines and other chemicals and save money through more relevant Science. The Alliance for Human Relevant Science acts as the secretariat for the APPG for Human Relevant Science.

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