hra
humane research australia
ending animal experimentation

12 October 2020

The House of Representatives Standing Committee on Health, Aged Care and Sport
PO Box 6021
Parliament House
CANBERRA ACT 2600

Re: Inquiry into approval processes for new drugs and novel medical technologies in Australia

Humane Research Australia is pleased to make a submission into the above inquiry. This submission is predicated on the assertion that there is an over-reliance on animal–based research in Health and Medical Research in Australia which does not typically produce reliable, verifiable outcomes.

Indeed, it is shown that there is a 95% failure rate of clinical trials following 'successful' animal trials (1).

By 'alternative' research methods we are referring to non-animal or new approach methodologies, including the many in-vitro, in-silico methods available, as detailed in the publication 'Better Ways to Do Research' (2)

We would also like to refer the Committee to a UK White Paper Accelerating the Growth of Human Relevant Life Sciences in the United Kingdom, which further details the benefits of human relevant science to revitalise medical research, save money, create wealth and improve public health and holds much relevance internationally (3).

Our key points relate to the below terms of reference:

1. The range of new drugs and emerging novel medical technologies in development in Australia and globally, including areas of innovation where there is an interface between drugs and novel therapies;

As new technologies emerge, the range of non-animal methods continues to grow, which are more dependable and produce more accurate results than tests on species who differ from humans in their metabolism of toxins, absorption of chemicals, mechanisms of DNA repair and lifespan – all factors that have a profound effect on the efficacy of drugs.

Around the world, government-funded initiatives are acknowledging the need to further develop and validate non-animal methods of research, investing millions of dollars in alternatives grants and validation centres, and reflecting practical commitment to the replacement of animal research. This may be enshrined in legislation. In South Korea new federal legislation has been proposed that would prioritise funding for human biology-based

approaches in biomedical research; whilst the UK Animals in Scientific Procedures Act 2012 revision has enshrined the concept of the development of 'alternatives' as a legal requirement.

Over 30 years ago, In 1989, the Senate Select Committee on Animal Welfare, in its report to the Australian Government, recommended 'that the Commonwealth Government establish a separate fund for research into the use of alternatives to animal experimentation and that grants be disbursed from this fund by a board composed of representatives from the scientific community, animal welfare organisations, ACCART [now ANZCCART] and government authorities'. As confirmed by ANZCCART, this fund has never been established.

Currently, Australian researchers interested in the field of alternatives are reliant on limited overseas funding and whilst there are some exciting projects underway in Australian via this funding source, additional funding would facilitate more innovative research of this nature.

Researchers will 'follow the money' yet currently there is stagnation as no institution is taking responsibility for funding alternatives, despite a legislative obligation to only conduct research for which there is no alternative. If no funding is committed to develop, refine and validate alternatives, progress will remain stalled. Whilst it is argued that Australian researchers can rely on international alternatives data, a cultural change is needed to encourage adoption of alternatives and that can only be achieved through leadership, commitment and mentorship of Australian researchers, leading to generational change in research practices. Funding is a crucial first step.

Many of the new research technologies require expertise in areas such as bioengineering or computational systems and may fall outside the skills set of biomedical researchers; therefore, investment is required to develop this specialist workforce and infrastructure. Incentives could include scholarships, grants, sponsorships to attend relevant conferences and mentoring.

2. Incentives to research, develop and commercialise new drugs and novel medical technologies for conditions where there is an unmet need, in particular orphan, personalised drugs and off-patent that could be repurposed and used to treat new conditions;

HRA is supportive of drug repurposing. Developing a new drug takes 10 to 15 years and is very expensive. Drug repurposing is faster, costs less, and requires fewer or no animal tests. One reason for this is that potential side effects of the drug are already known. For example, the RepoTrial project uses computer-based algorithms to find out whether already registered drugs may work for other diseases that have some similar characteristics, but may relate to different organs or body parts. The drugs will be tested on virtual patients, and finally on real patients (4).

3. Measures that could make Australia a more attractive location for clinical trials for new drugs and novel medical technologies;

HRA would like to see publically available research registries as well as registries for all clinical trials conducted in Australia, with links to published outcomes. This would prevent unnecessary duplication of research and contribute to improved research quality, as well as more thorough scrutiny.

4. Without compromising the assessment of safety, quality, efficacy or cost-effectiveness, whether the approval process for new drugs and novel medical technologies, could be made more efficient, including through greater use of international approval processes, greater alignment of registration and reimbursement processes or post market assessment.

Scientific literature raises questions about the reliability and predictive value of animal testing in research for humans (5, 6). Systematic reviews continue to show that animal experiments are not sufficiently predictive of human outcomes and can be dangerously misleading. Humans differ from animals anatomically, genetically and metabolically, and interspecies variations are a high cause of clinical trial failure of pharmaceutical products. Not only does this mean that results cannot be accurately extrapolated to humans, but it also means that some possibly successful treatments are being ruled out pre-clinically due to adverse reactions or responses in animals.

Additionally, not all drugs approved following animal testing are safe in human patients. Many currently used medicines have suboptimal efficacy, while others may cause adverse effects which restrict their use and can result in serious illnesses. It has been estimated that adverse drug reactions (ADRs) kill more than 10,000 people in the UK (7) and 100,000 in the United States each year (8).

A KPMG report on the economic value of Australia's medical research (9) concludes that with an increased focus on translation and commercialisation of medical research, return on investment will increase.

HRA proposes that intensifying efforts to develop, validate and implement human-relevant research will result in increased translation and commercialisation of medical research. Where there is the potential to minimise or eliminate animal testing, this should be encouraged, not only due to the requirement for human-relevant research, but also to fast track research without the need to perform unnecessary or duplicative animal research, which may require many months to refine the most appropriate animal 'model'. It is time to reconsider our outdated scientific practices as well as the obsolete regulations that still impose them. HRA is calling for:

- **An ongoing federally funded research funding stream for the development of non-animal based medical research**

- **A commitment to developing an Australian Centre for the Development and Validation of Alternatives.**

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