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Association of Australian
Medical Research Institutes

SUBMISSION TO

DRAFT TREASURY LAW AMENDMENT (RESEARCH AND DEVELOPMENT INCENTIVE) BILL 2018 AND EXPLANATORY MATERIALS

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About AAMRI

The Association of Australian Medical Research Institutes (AAMRI) is the peak body for medical research institutes across Australia. Our 49 member organisations work on a broad spectrum of human health issues such as preventive health, chronic disease, mental health, immunology and Indigenous health. Their research ranges from fundamental biomedical discovery through to clinical research and the translation of research findings from bench to bedside.

AAMRI's members and their 19,000 staff and research students undertake over one-third of all government funded medical research. Their combined revenue exceeds $1.65 billion per annum, and they received over $622 million in competitive grant funding in 2016. With over 900 active clinical trials and over 100 new patents awarded per year, our members have a firm focus on improving health outcomes and delivering great commercial returns for the nation.

AAMRI submission: Draft Treasury Law Amendment (Research and Development Incentive) Bill 2018 and Explanatory Materials

The R&D tax incentive has been reviewed multiple times in recent years and the Government has recently made policy decisions regarding how the program will work in the future. As such AAMRI does not intend to revisit the broader issues associated with making changes to the R&D tax incentive, and instead will limit comments in this consultation to issues arising out of the draft exposure Bill which has been released for comment.

1 Clinical trials exemption

AAMRI strongly supports the clinical trials exemption that will allow companies to exempt clinical trials expenditure from the $4m expenditure cap.

2 Definition of a clinical trial

A principles-based definition of a clinical trial would help ensure the legislation does not become outdated as the nature of medical research continues to evolve. The definition could be followed by a non-exhaustive list of clinical trial activity, or this could be included in the Explanatory Memorandum. The World Health Organization definition would be a more suitable definition for this purpose.

The World Health Organization (WHO) definition for a clinical trial is 'any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes'.

Clinical trial interventions include but are not restricted to:

- experimental drugs
- cells and other biological products
- vaccines
- medical devices
- surgical and other medical treatments and procedures
- psychotherapeutic and behavioural therapies
- health service changes
- preventive care strategies and
- educational interventions.

Researchers may also conduct clinical trials to evaluate diagnostic or screening tests and new ways to detect and treat disease

Figure 1 WHO definition and examples of clinical trial activities as published on the Australian Clinical Trials website[1]

[1] Australian Clinical Trials (2015) *What is a clinical trial?* Available at: https://www.australianclinicaltrials.gov.au/what-clinical-trial

3 Proposed amendments to the definition of a clinical trial

Should the TGA definition of a clinical trial which currently appears in the exposure draft be used then AAMRI proposes that it should be amended, with suggested changes highlighted below in red. An explanation as to why these changes are being suggested is provided below.

> *"A clinical trial is a planned study of the safety~~, or~~ efficacy, or cost-effectiveness in humans of an intervention (including a medicine, treatment, vaccine, medical device or diagnostic procedure) with the aim of achieving at least one of the following:*
>
> - *the discovery, or verification, of clinical, pharmacological or other pharmacodynamic effects;*
> - *the identification of adverse reactions or adverse effects;*
> - *the study of absorption, distribution, metabolism or excretion;*
> - *achieving healthcare savings."*

4 Explanation of proposed changes to the clinical trial definition

4.1 Testing medical devices

The definition does not include the testing of the safety or efficacy of medical devices. Examples of such devices include: artificial hips, blood pressure monitors, breast implants, catheters, lubricating eyedrops, MRI scanners, orthodontics, syringes and tongue depressors. A definition of a medical device is already provided for in the *Therapeutic Goods Act 1989* (Cth).

A large number of clinical trials are undertaken in Australia to test the safety and efficacy of such devices. The intent of the clinical trials exemption (refundable offset) is to include all clinical trials relating to genuine medical research, and trials relating to medical devices clearly fall within this.

4.2 Achieving healthcare savings

An increasingly important purpose of undertaking clinical trials can be to study the cost-effectiveness of a particular intervention, with a view to achieving healthcare savings. This is increasingly important to governments and other healthcare providers who need to ensure limited health expenditure investment can be spent most effectively. Clinical trials can not only help determine safety and efficacy of a proposed treatment, they can form an important part of determining cost differences between different interventions.

4.3 Vaccines

For the avoidance of doubt, vaccines should be specifically included in the definition of a clinical trial as an eligible intervention.

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