Submission No 202

INQUIRY INTO USE OF PRIMATES AND OTHER ANIMALS IN MEDICAL RESEARCH IN NEW SOUTH WALES

Organisation: CK Cell Technologies Pty Ltd

Date Received: 23 February 2022

Consultation: Parliamentary inquiry into the use of primates and other animals in medical research in NSW

Introduction

Developing alternative approaches to animal use for drug development particularly for the toxicological and pharmacological pre-clinical appraisals is not only important for animal welfare but imperative for increasing the reliability of the inference drawn as animals do not always represent faithfully the true human pathophysiology. During the last 2 decades or so with the discovery of pluripotent stem cells like human embryonic stem cells (hESC) and induced pluripotent stem cells (iPSC)(our group was pioneer in these regards), tremendous progress has been made to utilise these cells for developing cellular therapies and more importantly using these cells for pre-clinical drug development including developmental toxicology including organoid cultures derived thereof. These new alternatives in vitro assays coupled with state-of-the -art techniques such as tissue engineering and microfluidics to fabricate organ- on-a-chip, has led to new protocols which are amenable to high throughput screening to understand the adverse and toxic effects of chemicals and drugs like in haptic, neural and cardiac organoids in vitro. Some of these protocols are well refined currently available and being used for preclinical studies.

The successful implementation of new approaches will depend on sincere research and development efforts made cooperatively by industry partners and end user agencies for satisfying the proposed 3 R's, Replacement, Reduction, Refinement. Australia has made a big investment and progress in stem cell research since 2002 after the legislations were approved for stem cell studies in the parliament.

Recommendation re 'Term of Reference (c)'

Although some funding is made available for stem cells studies per see in Australia but nothing substantial investment in sincerely developing alternative assays for pre-drug development using these cells in the form of CRCs or development grants. European union and US have made big investment in this regard and Australia should consider making similar investment for local developments of these technologies and it has the necessary capabilities inhouse. This should be in parallel with upgrading the regulatory framework around it involving TGA accordingly at par with FDA and European Union.

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