SHPA response to TGA consultation on Clinical Trial Approval (CTA) Scheme, May 2024

The Society of Hospital Pharmacists of Australia (SHPA) is the national, professional organisation for the 6,100+ Hospital Pharmacists, and their Hospital Pharmacist Intern and Hospital Pharmacy Technician colleagues working across Australia's health system, advocating for their pivotal role improving the safety and quality of medicines use.

SHPA convenes a Clinical Trials Specialty Practice stream, with over 470 members who are leaders and experts in the provision of quality and safe clinical trials pharmacy services to clinical trial participants in Australian hospitals. Many of these members are clinical trial pharmacists who sit on National Mutual Acceptance certified Human Research Ethics Committees (HREC).

SHPA welcomes the opportunity to respond to the targeted consultation on the TGA Clinical Trials Approval (CTA) Scheme and has the following responses to the Question 10 of the consultation paper. The SHPA Clinical Trials Leadership committee would welcome the opportunity to engage further on this matter. We would also welcome the consumer's perspective on the regulators role for assessing scientific and medication quality when considering scope for CTA expansion.

Q10. Does the scope of the TGA's evaluation of clinical trials under the CTA scheme align with your HREC's expectations? If not, please describe the differences.

As noted by the TGA in the consultation, there is minimal utilisation of the CTA pathway. This can be attributed to the very limited scope of the CTA Scheme.

In contrast to the TGA's CTN and CTA Schemes, regulators in other jurisdictions take on a much more involved role in the review of new clinical trials. For instance, clinical trials involving medications in the USA must be submitted to the Food and Drug Administration (FDA) under an Investigational New Drug (IND) Application. In the UK and EU, a Clinical Trial Authorisation application is submitted to the Medicines & Healthcare products Regulatory Agency (MHRA) and European Medicines Agency (EMA), respectively.

These regulators perform comprehensive assessments of the scientific rigour of clinical trial protocols and the manufacturing quality of the proposed investigational products. These reviews are conducted alongside reviews performed by Institutional Review Boards (IRBs) and HRECs. A significant body of work has been undertaken by these regulators to ensure that regulatory review remains timely and has minimal impact on study start-up timelines.

This contrasts with Australia, where the scientific and ethical review of clinical trials is performed entirely by volunteer members of HRECs. The *National Statement on Ethical Conduct in Human Research 2023* does not formally require HREC to include the technical expertise that a regulator would contribute when assessing molecules for use as human therapeutics. It is the observation of our members who sit on HRECs that there are frequently significant scientific, safety and quality deviations with many clinical trials, primarily sponsored by domestic collaborative groups, universities or investigator institutions. In the absence of an assessment by the TGA or a comparable international regulator, the responsibility for review falls entirely to the HREC.

Given the volunteer nature of HRECs, these committees may not possess the necessary skill mix to advise or assess the suitability of clinical trials on certain specialised technical matters that would normally sit within the remit of a regulator if the therapeutic good in question was not administered under the auspices of a clinical trial. Such an example might be assessing compliance with PIC/S Guide to Good Manufacturing Practice (GMP) or equivalent standards to ensure that the medication procured by the Sponsor is safe for human use.

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The TGA is well placed to perform comprehensive scientific review and approval of clinical trials, in line with comparable overseas regulators, as the regulator possesses the required expertise in many areas, including Good Clinical Practice (GCP) compliance and manufacturing quality.

SHPA believes that the CTA Scheme should be expanded to perform a comprehensive review of clinical trials that have not already been assessed by comparable overseas regulators. This would ensure that Australians have access to quality therapeutic goods that have been appropriately evaluated for safety and quality by the regulator in the clinical trial setting.

These assessments would minimise public risk related to manufacturer or sponsor legislative non-compliance and poor scientific quality. Regulator oversight is preferable to relying exclusively on the variable knowledge of volunteer HRECs and would support the HRECs to fulfill their obligations to safeguard the rights and safety of clinical trial participants. The introduction of this regulator expertise would benefit the entire Australian clinical trial landscape by increasing the scientific quality of clinical trial research conducted in Australia.

We acknowledge that the expansion of the CTA scheme to include this assessment could impact start-up timelines. However, we also note that this may be mitigated during the design of the national One Stop Shop platform, where the TGA is likely to integrate the CTA and CTN system. We understand that efficiencies gained during this platform development may offset start-up delay concerns.

If you have any queries or would like to discuss our submission further, please do not hesitate to contact Jerry Yik, Head of Policy and Advocacy on jyik@shpa.org.au.