



Therapeutic Goods Administration consultation: Criteria for comparable overseas regulators

Enhanced international collaboration in the regulation or prescription medicines.

Submission from the Clinical Oncology Society of Australia and Cancer Council Australia

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The **Clinical Oncology Society of Australia (COSA)** is the peak national body representing health professionals from all disciplines whose work involves the care of cancer patients.

Cancer Council is Australia's peak national non-government cancer control organisation and advises the Australian Government and other bodies on evidence-based practices and policies to help prevent, detect and treat cancer.

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Australia is a relatively small market and it can be difficult to attract applications from pharmaceutical sponsors to register their products in Australia. The potential for return is lower than countries in Europe, and in the United States and Canada, given Australia's smaller population size and the fact that the fees and time associated with the application review process are sometimes considered commercially prohibitive. However, it is critical that Australian cancer patients have access to therapies that have the potential to be beneficial to the treatment of their disease. The registration process in Australia has provided the population access to high quality medicines, and while we want to improve the time to access to these therapies, Australians still expect that a product that is prescribed is safe and effective.

We support the Therapeutic Goods Administration (TGA) continuing to maintain control of the final decision to bring products to market. Depending on the approach taken, this reduces the chance of compromising quality and safety and ensures that the Australian clinical context is taken into account. It is important that stakeholder confidence in the regulatory actions undertaken by the TGA, including the choice of which overseas regulators the agency engages with, independent decision making processes and transparency of those decisions, is maintained. The recommendations from the Medicines and Medical Devices review adopted

by the Australian Government, aim to work towards greater international harmonisation of review processes for therapeutic products to reduce duplication of work and support the earlier introduction of prescription medicines to market. If the TGA introduces the use of comparable overseas regulators report based assessments and/or workshare arrangements, it is critical that criteria used to identify trusted overseas regulators is applied as the first step. Regardless of which arrangement is used, the overseas agency must be classified as a trusted comparable regulator.

Further detail of both possible arrangements is required, as without practical application, the feasibility of processes is uncertain.

Selection criteria for comparable overseas regulators:

We agree that overseas regulatory frameworks must be evaluated to determine if they are aligned with that of the TGA, and that based on the arrangement, either report-based assessments or work sharing, we would support general criteria to identify a trusted overseas regular and then specific considerations or criteria based on the arrangement.

Criteria that must be met in order for a regulator to be considered a comparable overseas regulator, regardless of the arrangement, should include:

- The comparable overseas regulator must have a framework for the review of prescription medicines, with a focus on rigorous evaluation of the product's safety, quality and efficacy;
- The comparable overseas regulator must demonstrate pre- and post-market evaluation processes similar to the TGA, including how applications are assessed, ongoing review of listings, and the monitoring and reporting of adverse events;
- Comparable overseas regulators must demonstrate a commitment to transparency and adopt similar public reporting to support a comprehensive review of the regulator's methodology applied to make their decision;
- The comparable overseas regulator must provide pathways for communication with sponsors, other regulators involved in the assessment and the general public;
- Assessment reports should be prepared using methodology, guidelines and standards consistent with those used by the TGA. The TGA must be able to use assessment reports and any supplementary information generated during the evaluation process in its public reporting;
- The comparable overseas regulator must be internationally recognised, and have a commitment to being involved in promoting international standards and guidelines;
- The comparable overseas regulator must demonstrate a track record of approving safe and effective medicines and medical devices;
- To ensure that the review of an application is consistent, the comparative overseas regulator must have similar resourcing capacity and expertise available to support timely review of the application and reporting of outcomes;
- The overseas comparable regulator's population should have a similar composition, and disease and socioeconomic profile, and similar level of health system capacity to adopt the therapy being assessed;

Other issues to consider in the feasibility of the initiative:

The TGA must retain the ability to provide local clinical context to the assessments utilised from identified comparable overseas regulators, and in considering this arrangement, ensure that the process will be adaptive to this;

- Consideration of the clinical pathway in Australia for rationale for the product's availability in Australia. Explore the reasons why a product may not be suitable
- Production of patient information and consumer medicines information in the context of the Australian population
- Authority to conduct a scientific rapid review where there is doubt around the methodology, clinical expertise or decision provided by the overseas comparable regulator.

Fees associated with these arrangements must ensure the TGA can continue to function under a cost-recovery model and the TGA must have the resources required to be involved in the review.

Recognise interaction of legislation and amendments to existing legislation, requirement to develop mutual agreements including confidentiality arrangements, ability to develop regulatory agreements between Australia and the overseas comparable regulator.

Consider the current level of willingness of potential overseas comparable regulators in working with Australia to develop these arrangements, and given many have larger markets, what flexibility would the TGA be willing to accept to attract these regulators.

Assess whether these arrangements will bring products approved in other jurisdictions to the Australian market earlier. The review process involving comparable overseas regulators must be streamlined and efficient to support earlier introduction of approved products. A favourable incentive for the sponsor is also reducing the need to submit multiple full dossiers to each market to which it is seeking registration.

The consideration of arrangements with overseas comparator regulators is a positive move towards enhanced international collaboration in the regulation of prescription medicines to support reduced duplication of effort, and the earlier introduction of safe and effective therapies to the Australian market. Given this complex initiative, we look forward to receiving more details as these arrangements are further considered.