Therapeutic Goods Administration consultation: Comparable overseas regulators – medical devices

Criteria and implementation

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

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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.

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.

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Cancer Council and the Clinical Oncology Society of Australia contributed to the Therapeutic Goods Administration (TGA) public consultation on *Criteria for comparable overseas regulators: Enhanced international collaboration in the regulation or prescription medicines*.[i] The submission addressed the proposed selection criteria for comparable overseas regulators and provided additional general considerations required to support the appropriate engagement with international therapeutic regulators.

Comments and considerations submitted to that consultation apply in the context of medical devices. For convenience, a short summary of these points is provided below, and note that these are reflected generally within the current consultation[ii].

A comparable overseas regulator must:

- maintain a focus on rigorous evaluation of a product's safety, quality and efficacy.
- adopt similar pre and post market evaluation processes to the TGA, and ongoing review of listings and monitoring and reporting of adverse events.
- demonstrate a commitment to transparency and public reporting, and clear pathways of communication.
- be internationally recognised, and involved in developing and promoting international standards and guidelines.
- demonstrate a track record of approving safe and effective medicines and medical devices.
- serve a comparable population composition and sociodemographic profile to Australia.

While Australians demands earlier access to medicines and medical devices, the population still expect that a registered product is safe and effective for use. Cancer Council Australia and the Clinical Oncology Society of Australia support the TGA maintaining authority to recommend a product be marketed in Australia. The TGA's ability to request a full dossier where clinical evidence is limited or required for the Australian context is an important element to reducing the chance of compromising quality and safety.

Sections in this consultation:

a. Use of overseas regulatory approvals

It is appropriate for the TGA to consider situations where it would be advantageous to utilise international regulators in the assessment of medicines and medical devices. However, entering into a workshare arrangement or the use of an overseas regulator's assessment report of the proposed product are complex engagements that must be entered into with great consideration. An agreed arrangement must be feasible and practical, and deliver on the purpose of reducing duplication of assessment and provide earlier access to products without compromising on a rigorous review of safety, quality and efficacy.

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. 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 first be classified as a trusted comparable regulator.

b. Proposed criteria

The proposed criteria generally reflect our contribution to the December 2016 consultation.

1. **Comparability of the regulatory framework**
   The scope and operational alignment of the potential overseas comparator presented in the paper are practical and important to ensure that the TGA continues to deliver on legislative requirements.
2. **IMDRF membership**
   It is appropriate that the potential comparable overseas regulators are members of the International Medical Device Regulators Forum. The complexity of the products being assessed and the variances between regulator assessment and the populations they represent, should demand an ongoing shared commitment to accelerate international medical device regulatory harmonisation and progress towards recognised standards. However, the TGA should identify situations where there are potential comparable overseas regulators that are not a member of the IMDRF and any restrictions this criterion may place on partnerships.
3. **Life cycle approach and post-market vigilance**
   One of the main benefits of these cooperative arrangements is the potential for information sharing, such as outcomes of post-market monitoring and safety of devices, adverse events or changes to registration. Comparable overseas regulators, like the TGA, must maintain a commitment to ongoing performance monitoring and safety of devices. The outcomes of these reviews must be freely shared across regulators.
4. **Communication and cooperation with overseas regulators**
   Agreements that the TGA holds in partnership with overseas regulators currently, and membership to the IMDRF demonstrates a willingness across regulators to share information. Given IMDRF membership indicates a commitment to seek harmonisation in the regulation of medical devices, it could be assumed that these existing cooperative arrangements could be leveraged to support workshare or sharing of assessment reports. However, there is no indication that these agencies are interested in participating in such arrangements or whether they would meet each criterion.
5. **Expertise of overseas regulator**
   The overseas regulator is required to demonstrate experience in reviewing assessments, against a comparable scientific framework, similar to those of interest to the TGA.

c. Proposed implementation

The consultation paper lacks detail regarding the proposed implementation process for identifying comparable overseas regulators and how this will feed into the process for applicants seeking expedited review of a product. The TGA should also demonstrate a commitment to the evaluation of these activities. This would enable a review of the TGA resources allocated and the fees charged to applicants. Additional evaluation of TGA and stakeholder perspectives of the ability of the activities to meet expectations would be beneficial. Further detail, including process documentation and guidance's for applicants, is required, as without practical application, the feasibility of the criteria and the proposed arrangements is uncertain.

d. Comments on Attachment A – TGA assessment of medical devices

Nothing to add.

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[i] Cancer Council Australia & the Clinical Oncology Society of Australia. December 2016. Criteria for comparable overseas regulators: Enhanced international collaboration in the regulation or prescription medicines. http://www.cancer.org.au/content/pdf/CancerControlPolicy/Submissions/tga_consultation_criteria_for_comparable_overseas_regulators_final_12122016.pdf#_ga=2.236748930.2044991061.1497930797-68620469.1439359802

[ii] Department of Health, Therapeutic Goods Administration. May 2017. Comparable overseas regulators for medical devices: Criteria and implementation. Version 1.0. https://www.tga.gov.au/sites/default/files/consultation-comparable-overseas-regulators-medical-devices.pdf