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Medicines and Medical Devices Regulations Consultation
Criteria for Comparable Overseas Regulators
Reform Coordination and Support
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

To whom it may concern

The Australian Federation of AIDS Organisations (AFAO) welcomes the opportunity to provide comments to the Therapeutic Goods Administration on the *Consultation: Criteria for comparable overseas regulators*.

As the peak national organisation for Australia's community HIV response, AFAO is renowned both globally and nationally for the leadership, policy expertise, coordination and support we provide. Through advocacy, policy and health promotion, we champion awareness, understanding and proactivity around HIV prevention, education, support and research. AFAO provides a voice for communities affected by HIV and leads the national conversation on HIV. AFAO is particularly concerned to ensure communities affected by HIV are able to gain access to important therapeutic medicines as soon as possible, while simultaneously ensuring the safety and effectiveness of medications.

Key points

1. AFAO supports the principle of the TGA making use of assessment reports conducted by Comparable Overseas Regulators (CORs), assuming that there is alignment of standards between those of the TGA and the overseas regulators.
2. With respect to stage 2 criteria, AFAO believes that consideration should be given to the demographic profiles underpinning evidence in any COR's report as a point of comparison with the relevant Australian demographic.

Discussion

Comparable overseas regulators

AFAO supports the goals of the consultation paper recommendations to allow more efficient and effective approval processes of medicines and devices by taking advantage of assessments undertaken by CORs.

As stated in our submission to the *Review of Medicines and Medical Devices Regulations Consultation Paper*, AFAO supports the principle of the TGA making use of assessment reports conducted by CORs, assuming that there is alignment of standards between those of the TGA and the overseas regulators.

AFAO supports the two stage process recommended by the Review for assessing frameworks for CORs to ensure their alignment with that of the TGA (stage 1) and for ensuring that an overseas COR's assessment report for a particular medicine or device aligns with TGA standards (stage 2).

Stage 1 criteria

Stage 1 criteria which assess whether overseas agencies' regulatory frameworks align with the TGA ensures that the framework for assessments by overseas agencies meet Australia's quality, safety and efficacy standards. This approach helps to retain trust in the system, which is crucial to Australian consumers. This criteria is welcomed and supported.

Stage 2 criteria

Stage 2 criteria assess the weight to be given to a COR's report on a particular medicine in a sponsor's submissions to the TGA. AFAO believes that consideration should be given to the demographic profiles underpinning evidence in any COR's report as a point of comparison with the relevant Australian demographic. For example, it would be useful to identify if a COR report on medicine for HIV Pre-Exposure Prophylaxis is based on evidence from men who have sex with men in the overseas jurisdiction. Such information would inform a TGA assessment of PrEP given the profile of Australia's HIV epidemic where the largest population affected by HIV is gay men and other men who have sex with men, and for whom access to PrEP is of particular significance.

We would welcome the opportunity to further discuss this submission if it would be of assistance.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'D O'Donnell', written in a cursive style.

Adj A/Prof Darryl O'Donnell
Chief Executive Officer