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To whom it may concern

The Australian Federation of AIDS Organisations welcomes the opportunity to provide this submission to the Therapeutic Goods Administration on the *Consultation: Accelerated assessment of medical devices – Priority Review pathway*.

As the peak national organisation for Australia's community HIV response, AFAO is recognised nationally and globally 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 medical devices as soon as possible, while simultaneously ensuring the safety and effectiveness of devices.

Key points

1. The 'principles for priority review' should include the need for timely access to important medicines and medical devices.
2. The 'criteria for priority review' should be expanded to allow devices other than in vitro devices to be considered for priority review where they offer a recognised public health benefit.
3. The inclusion of a 'criteria for priority review' for in vitro devices whose early availability will result in a major public health benefit is very welcome and strongly supported.
4. An additional consideration for 'criteria for priority review' is Australian Government policy such that the TGA's consideration of priority review is informed by policies (such as national health strategies) that call for access to essential new technologies in particular areas of need.
5. The decision on whether a device is accepted for priority review should be informed by the expert opinion of stakeholders beyond the medical profession, including organisations representing consumers.
6. The setting of fees for priority applications must not be engineered to 'discourage disingenuous applications' as this establishes a barrier which is contrary to the intent of the Review.

Discussion

1. *The 'principles for priority review' should include the need for timely access to important medicines and medical devices.*

   While the principles for priority review for medicines and medical devices are framed within the context of expedited pathways, the principles themselves do not point to 'timely access' as a guiding driver or priority. To give full meaning to the intentions of the Review, we would encourage the

inclusion of a principle that expressly points to this as an important consideration. We would suggest as wording "Health professionals and consumers must have timely access to important medicines and medical devices", or some other form of words consistent with the review and its recommendations. This principle should be the first principle articulated, followed by the current first principle regarding the safety, performance and quality of therapeutic goods.

2. *The 'criteria for priority review' should be expanded to allow devices other than in vitro devices to be considered for priority review where they offer a recognised public health benefit.*

   The discussion paper proposes criteria that must be met for a device to receive designation for priority review, including:

   - "the device represents a breakthrough technology with evidence of a major *clinical* advantage over existing technology, OR
   - there is evidence that the device offers a major *clinical* advantage over existing alternatives included in the ARTG."

   The rationale for the emphasis in the criteria on *clinical* advantage is not made clear in the discussion paper and arguably may restrict consideration of devices that are safe, of high quality and that provide a public health benefit. These criteria, together with reference to "unmet clinical need in Australian patients" (as opposed to populations), if narrowly interpreted, could limit consideration of priority review for important innovations. In particular, we would be concerned if a situation arose where a device that is potentially of public health benefit, but that was not evidently superior to an existing registered device, were declined for priority assessment. Public health benefit (but not individual clinical benefit) may be conferred where a device is preferred by patients (or, indeed, health professional) and therefore more likely to be utilised or adopted, even if its performance is no better than existing devices. The manner of utilisation, the setting of its use, or other characteristics may be important in consideration of priority assessment.

3. *The inclusion of a 'criteria for priority review' for in vitro devices whose early availability will result in a major public health benefit is very welcome and strongly supported.*

   AFAO welcomes and strongly supports the inclusion of this criteria. The process of screening, testing and diagnosis is critical to addressing communicable diseases such as HIV. Testing enables the individual to know their status, which builds the capacity of key populations and individuals at risk of HIV to minimise the risk of transmission. Testing supports healthcare workers or peer testers to engage an individual in a discussion about HIV risk. For an HIV negative person this can involve a discussion that reinforces the need to adopt risk reduction strategies to avoid exposure to HIV. For a person who returns a positive result, diagnosis provides a critical opportunity to support the individual into appropriate care arrangements and commence treatment.

   Many gay and bisexual men report exposure to judgemental attitudes when attending mainstream health services for testing. These experiences act as barriers to testing and compromise the public health investment in HIV by reducing the frequency in which people at higher risk of HIV get tested. In response to these barriers, community-based testing using rapid or point of care tests have been approved and widely used.

   In jurisdictions where community-based testing exists, gay men who had never previously been tested, or who had irregular patterns of testing, are more likely to test and then return for routine testing. These men also report very high levels of satisfaction with the services.

Gay men have expressed a strong preference for rapid HIV testing over conventional HIV testing reporting high-levels of satisfaction in having HIV testing in a welcoming, culturally-appropriate environment delivered by peers.[1] Gay men also report finding rapid HIV testing more convenient, more comfortable and less stressful than conventional HIV testing settings, which are clinical.

Point of care testing has supported Australia to improve the frequency of HIV testing rates, clearly demonstrating its public health benefit.

More recently, research has emerged showing that Australia could benefit from the approval of HIV self-testing to achieve its public health goal of increasing HIV testing frequency. Domestic trials of HIV self-testing show that testing among higher risk gay men doubled, while among infrequent testers, the increase in testing frequency was five-fold.[2]

Within this context, AFAO strongly supports the inclusion of criteria that allows for priority review designation to be conferred on in vitro devices that may offer public health benefit.

4. *An additional consideration for 'criteria for priority review' is Australian Government policy such that the TGA's consideration of priority review is informed by policies (such as national health strategies) that call for access to essential new technologies in particular areas of need.*

   The discussion paper asks if the proposed criteria cover all issues that should be considered in assessing a medical device for priority review designation. An additional criteria that should be considered is where the priority review of a device is consistent with the Australian Government's policy objectives. In the case of Australian HIV policy, it is frequently the case that National HIV Strategies are developed based on environmental analysis of emerging technologies and their future potential to contribute to policy goals. It is important that the TGA is responsive to expressions of policy intent in instances where health policies adopted by the Australian Government indicate that new technologies are important to the achievement of health priorities. Including this as a criteria would allow sponsors to point to the contribution a device may make to expressed policy goals. It would also mitigate circumstances where expressions of Australian Government policy intent are not able to inform action by the TGA. The inclusion of such a criteria would in no way alter the appropriate consideration by the TGA of safety, performance and quality issues associated with a medical device.

5. *The decision on whether a device is accepted for priority review should be informed by the expert opinion of stakeholders beyond the medical profession, including organisations representing consumers.*

   The discussion paper indicates that a "designation decision will be informed by expert opinion of the medical profession ... as to the novelty, patient need and clinical advantage of the medical device". It is our view that this is inappropriately narrow and that additional stakeholder input, including from consumer organisations such as AFAO, should be provided for.

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1 Rapid HIV Testing Is Highly Acceptable and Preferred among High-Risk Gay And Bisexual Men after Implementation in Sydney Sexual Health Clinics, accessible at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4405382/

2 M.S. Jamil et al, *Access to HIV self-testing doubles the frequency of HIV testing among gay and bisexual men at higher risk of infection: A randomised controlled trial,* AIDS 2016, 21st International AIDS Conference, 18 – 22 July 2016, Durban, South Africa

6. *The setting of fees for priority applications must not be engineered to 'discourage disingenuous applications' as this establishes a barrier which is contrary to the intent of the Review.*

   In its exploration of the operational impacts of priority review on the TGA, the discussion paper suggests that the application fees for priority review will be set at a level that "will also serve to discourage disingenuous applications". AFAO has no concerns that inappropriate applications should be discouraged and, if submitted, rejected, however the means of rejection should be through the setting of clear and effective criteria, and assessment against these, rather than through imposing fees at a rate that discourages applications. The use of fees to discourage applications would appear to be excessively crude, and risks discouraging applications for genuinely important new devices. AFAO is aware of circumstances already where potential sponsors have been discouraged from entering the Australian market due to the small size of the market and the high regulatory barriers to entry. Most particularly however, the use of fees to discourage applications is directly contrary to the intentions of the review in ensuring that Australians have timely access to important medicines and medical devices.

Thank you again for the opportunity to provide comment on the discussion paper. We would welcome the opportunity to further discuss this submission if it would be of assistance.

Yours sincerely,

Adj A/Prof Darryl O'Donnell
Chief Executive Officer