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Medicines and Medical Devices Regulations Consultation
Expedited Pathways for Prescription Medicines
Reform Coordination and Support Section
Regulatory Services and Improvement Branch
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: Expedited pathways for prescription medicines: Eligibility criteria and designation process*.

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. The eligibility for expedited pathways must be flexible enough to incorporate applications for the approval of changes to the mode of administration of approved medications as well as new medications.

2. The TGA should publish the outcomes of applications for Priority Review and/or Provisional Approval designation.

Discussion

The discussion paper proposes three criteria for expedited pathways for particular medication. These criteria limit the expedited pathway to medicines that:

- treat a 'serious condition'
- address 'unmet clinical need' and
- are of 'major therapeutic advantage'.

We welcome the criteria and, in particular, the scope of *Criterion one: Serious condition* which covers medicine indicated for treatment, prevention, or diagnosis. This will provide scope to consider important innovations in prevention science, such as HIV pre-exposure prophylaxis (PrEP).

HIV is a chronic and complex condition. Left untreated people living with HIV are exposed to opportunistic infections which greatly increase the risk of ill-health, disease progression and death. Fortunately, developments in HIV science mean that people living with HIV who are on treatment can look forward to a longer life where they can work and are less reliant on the public health system.

A more recent development in HIV medicine is the use of HIV medication by HIV negative people to prevent HIV acquisition. HIV PrEP reduces the risk of acquiring HIV by 92%. The combination of treatment for people living with HIV and PrEP for those at risk of HIV has the potential to support Australia to reach its target of virtually eliminating HIV transmission by 2020. Expedited pathways provide an avenue for more and safer treatments to enter the market more quickly.

There are barriers to realising the opportunities presented by HIV treatment and PrEP. These barriers include adherence to the treatment regimen, drug resistance and behavioural factors that jeopardise treatment uptake. Sub-optimal use of treatment or PrEP compromises their effectiveness and undermines the public health investment in HIV.

To address sub-optimal use, manufacturers are developing alternative methods of administering HIV drugs. This involves the development of injectable medications enabling effectiveness to be prolonged across a time-span without the need for daily adherence. The development of injectable medications is an innovation that has the potential improve the health outcomes of people living with HIV who are on treatment, as well as people who can benefit from PrEP.

It is essential that the eligibility criteria for expedited pathways support the rapid availability of innovative alternatives to administering approved medications as well as approving new medications.

AFAO also supports a system that is transparent. We therefore support the publication of outcomes of applications for Priority Review and/or Provisional Approval designation, both ‘eligible’ and ‘ineligible’ designation decisions, and whether a medicine has been registered through one of the expedited pathways. This will benefit the community in better understanding how the system works, including which medicines are assessed to meet the TGA’s standard for expedited assessment. Such information also allows for sponsors to better gauge the most appropriate pathway for potential applications. This should lead to more efficient assessments, with consumers being able to access important medicines sooner.

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