

16<sup>th</sup> November 2020

Attn: Clinical Director Prescription Medicines  
Clinical unit 2  
Prescription Medicines Authorisation Branch  
Therapeutics Goods Administration

**Re: Peak Community Organisation submission for registration of CAB+RPV LA (TGA/ACM)**

Dear Sir/Madam,

NAPWHA has been requested by Viiv Healthcare Australia to provide a community opinion on the proposed registration of Cabenuva (Cabotegravir(CAB)+Rilpivirine(RPV) Long Acting (LA)) for the treatment of HIV. We have not been given any remuneration for the provision of this opinion.

The National Association of People with HIV Australia (NAPWHA) is the peak non-government organisation representing community-based groups of PLHIV in all jurisdictions across Australia. We provide advocacy, policy, health promotion, effective representation, and outreach on a national level. Our work includes a range of health and education initiatives that promote the highest quality standard of care for HIV-positive people. Our vision is a world where all people with HIV can reach their full potential free from stigma and discrimination.

NAPWHA has been engaging with members of the Australian HIV positive community about the development progress of long acting injectable treatments for some time. We are well placed to articulate here some of the nuanced reasons why Australian HIV-positive people may benefit from this development.

NAPWHA supports HIV positive people in Australia having the widest possible access to the broadest possible range of the most effective and safest antiretroviral (ARV) medications. If, as the research suggests, long acting injectable anti-retroviral therapies are satisfactorily safe and effective, this new treatment format would offer people with HIV a suite of benefits not offered by existing treatment options.

Fear of unwanted disclosure of HIV status is an ongoing concern for HIV positive people. The ability to control the circumstances of disclosure—and to whom disclosure is made—are important tools that HIV positive people use to protect themselves from stigma, discrimination, and personal violence. Traditional ARV administration in tablet form has generally allowed HIV-positive people to avoid many unwanted disclosures in their daily lives as they move through the public sphere. However, there are situations in which unwanted disclosure is still possible.

As long acting injectable ARVs are stored and administered by a health professional, they obviate the need to store HIV medications at home. This reduces the risk of inadvertent disclosure to sexual partners, family, or flatmates. This benefit is particularly useful in situations where HIV status disclosure could expose a person to a risk of domestic violence.

Long acting injectable ARVs also have the potential to make travel for HIV-positive people easier because of the possibility of travel without the need to carry several weeks of ARV medications. Carrying medications through airport security is always accompanied by the risk of intrusive questioning by border authorities. The threat of HIV-related discrimination when passing through customs is anxiety-producing for many.

Further, several jurisdictions around the world have discriminatory immigration rules which deny entry to HIV-positive people. If HIV status is discovered in these situations, people with HIV face the terrifying possibility of detention in a foreign jurisdiction pending return to their country of origin. I note here that a feature of the Qantas-Emirates partnership is the use of Dubai as the main hub for all Qantas flights to Europe and many other destinations. Dubai is one such jurisdiction which refuses entry to HIV-positive people. Use of the national carrier to Europe is therefore not without risk for Australian residents with HIV.

The longer the interval between injectable treatment doses, the longer PLHIV would be able to travel without the threat of unwanted disclosure before the need to return to their doctor. Therefore, if safety is appropriately demonstrated, NAPWHA would support the longest safe interval (two months) between doses. However, we would also support a monthly option, should research show that adherence is more likely with more regular doctor visits.

Many HIV positive people also report that daily treatment adherence comes with significant mental challenges. The pills can be a daily reminder of one's HIV status which conflicts with the common desire of many people with HIV to minimise the effects of HIV on their lives. This effect, when compounded daily, can produce significant mental health challenges that make daily adherence difficult. Long-acting injectable treatments have the potential to remove this daily reminder of HIV status and allow people to focus on the non-HIV related parts of their lives with fewer treatments concerns. Further, fear of missing a dose (or doses) and the possibility of developing a detectable viral load can also cause stress and anxiety which would be mitigated by monthly or two-monthly injections.

NAPWHA, and many in the public health sector, are also hopeful that long-acting injectable treatments may have application in the management of behaviours which may place others at risk of HIV transmission. In particular, the hope is that long-acting injectables will reduce the possibility that people who place others at risk of HIV transmission will come into contact with the criminal law or the coercive powers of the State under the various public health Acts in Australia. NAPWHA cautiously welcomes this possibility with some important caveats.

Where people with HIV whose behaviours place others at risk of HIV transmission are being managed by health departments, a five-staged response allows health professionals to put in place increasingly interventionist supports to assist PLHIV to adhere to daily treatments and achieve an undetectable viral load. Health staff must often go to great lengths to track down individuals to administer daily treatment. This is particularly challenging in rural areas. Where there is persistent failure to adhere to medications, a referral to the police can be made. This can be catastrophic and result in prosecutions, incarceration, and deportation (for non-Australian citizens).

Long-acting injectable ARVs have the potential to reduce the burden of daily treatment in complex cases. This would enable many people to achieve an undetectable viral load while also significantly reducing the number of occasions on which they must interact with health professionals; thereby also reducing the stress of these interactions and the burden of adherence. Where a sustainable undetectable viral load can be achieved in this way it would mean that fewer people must be

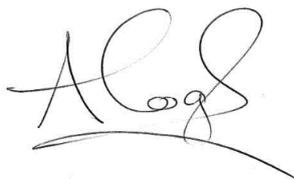
coercively managed by the State. It would also mean fewer cases of referral to the police. Thus, NAPWHA would support the use of long-acting injectable ARVs in this group providing their use is voluntarily consented to by the HIV-positive person.

An additional benefit of the use of long-acting injectable treatments in this group is a reduced cost burden on health departments. This is broadly to be welcomed. However, NAPWHA cautions that no undue pressure should ever be placed on any person with HIV to select a particular model of treatment administration to suit the cost-saving requirements of government. Uptake of long-acting injectable ARVs should only ever be voluntary and without pressure or coercion.

NAPWHA also notes that where mandatory treatments orders are made under the public health Acts, the use of long-acting injectable ARVs could reduce the stress of these situations by minimising the number of times treatment must be mandatorily administered. In these situations, we emphasise that even though treatment is mandated under the treatment order, the person with HIV must be free to choose the mode of administration that they prefer and to refuse injections.

For these reasons, NAPWHA welcomes and supports the addition of long-acting injectable antiretroviral medications to the treatments landscape in Australia. We note the important caveat that use of these medications must be freely and voluntarily selected by people with HIV in all circumstances. We would also support the option of both two-monthly and one-monthly options.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'A. Cogle', with a horizontal line underneath.

Aaron Cogle

Executive Director