

~~SENSITIVE~~Robert: MC15-002586  
Ref: CJHLTH/OUT/2015/R23278971Australian Government  
Department of Defence**MINISTERIAL ADVICE**

<b>Date for action:</b>	<b>Reason : Routine</b>
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**For Action: Assistant Minister****Through: VCDF**

For Info: Minister for Defence

Copies to: Secretary, CDF, CN, CA, CAF, HJE, FASMECC.

**Cessation of funding for Pre-exposure Prophylaxis for HIV infection - Truvada™****Purpose:**

To advise you that Joint Health Command (JHC) has funded the provision of Truvada™ for pre-exposure prophylaxis (PrEP) against Human Immunodeficiency Virus (HIV) infection for two Defence members since May 2015. JHC is now withdrawing this funding.

**Key Points:**

1. Defence funds medication for its members where the medication is clinically indicated and appropriately prescribed and approved.
2. PrEP is indicated for HIV-negative adults who are at ongoing high risk of HIV infection as a result of risk behaviours relating to sexual intercourse and or intravenous drug use.
3. Truvada™ is an antiretroviral drug (combined tenofovir and emtricitabine) registered in Australia by the Therapeutic Goods Administration (TGA) for the treatment of HIV infection, but not pre-exposure prophylaxis (PrEP). It is registered by the Food and Drug Administration (FDA) in the USA for both HIV treatment and (PrEP).
4. As Truvada™ is not registered in Australia for HIV PrEP, it can only be prescribed off-label for this purpose. Off-label prescription is permitted in Australia and in Defence, and Defence health policy provides guidance for how this is managed within Defence. Defence purchases pharmaceuticals outside of the Pharmaceutical Benefits Scheme (PBS) through a contract with a prime vendor.
5. In 2012 the World Health Organisation (WHO) released preliminary guidance on PrEP. Since the development of that guidance continuing trials have added to the evidence base that PrEP has the potential to reduce the risk of HIV infection by around 86 per cent. PrEP is an adjunct to other preventive measures, such as safe sexual practices.
6. The Australian Government is currently awaiting the outcomes of three Truvada™ based trials in Victoria, Queensland and New South Wales which will inform national policy on the use of PrEP.
7. The Australasian Society for HIV Medicine (ASHM) strongly supports the use of HIV PrEP in individuals who are at high risk of becoming HIV infected, in accordance with its endorsed clinical practice guidelines.
8. In May this year, JHC received requests to supply Truvada™ to two Defence members through extant off-label prescription approval processes. This medication had been recommended and prescribed by a specialist sexual health physician as PrEP against HIV infection in accordance with ASHM clinical guidelines.
9. The JHC Pharmacy and Therapeutics Committee considered these requests on 26 May 2015 and agreed that pre-exposure HIV prophylaxis, when assessed on a case by case base, should be

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supported for Defence funded supply. The committee considered that the risks of not providing the medication outweighed the potential cost. These risks included

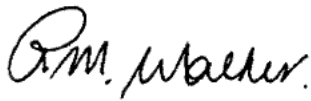
- a) the member becoming infected with HIV, which would then require lifelong antiretroviral treatment with several medications and have negative consequences for their career as they would be permanently non-deployable
  - b) the member sourcing the medications from overseas suppliers, which may be unregulated and of unknown quality, thereby compromising safety and effectiveness
  - c) the member not notifying Defence of the treatment. Antiretroviral medications can cause serious adverse effects and individuals taking these drugs need to be appropriately monitored.
10. The JHC Pharmacy and Therapeutics Committee decision was not advised to CJHLTH. The approximate cost for a one-month supply is around \$1125.00.
  11. On 6 August the Australian newspaper published an article entitled "ADF paying \$10k a year for HIV-blocking drug", detailing Defence use of the HIV treatment drug Truvada™ for HIV PrEP, which is not available to other Australian citizens.
  12. In the civilian sector, Truvada™ for HIV PrEP is only available on the private market or through public access (trial) programs in Queensland, New South Wales and Victoria, which provide the drug at no cost. Places in these programs are capped and only available to residents of those States.
  13. For individuals who cannot access Truvada™ through these programs, their options are to pay the market price (\$13,500 for 12 months) or to import generic drugs from overseas suppliers through the TGA's Personal Importation Scheme. Generic drugs are considerably cheaper (in the order of \$1,300 for 12 months supply), but their quality or safety has not been assessed by the TGA and cannot therefore be guaranteed.
  14. Advice has been sought from the Chief Health Officers of all Australian states and territories on their position on this issue. No state or territory provides PrEP free of charge to patients unless they are enrolled in a TGA endorsed trial. In these cases the drug company funds the cost of the drugs. Most Chief Health Officers agree that there is strong evidence for the use of PrEP and therefore they are providing policy guidance on how patients may self fund the drug themselves either as a recognised off label use or via generic suppliers via the internet.
  15. In line with the access available to all Australian citizens (and pending any government decision on the use and funding of PrEP) Defence has determined that Truvada™, will no longer be provided to the two Defence members at Commonwealth expense.
  16. Defence has facilitated their placement on a waiting list for their State's public access program, as that program is currently oversubscribed. In the interim, if they wish to continue taking Truvada™, they will have to self fund the medication.
  17. The Director General Garrison Health Operations will personally advise these members of this decision.
  18. JHC will not fund any future requests for Truvada™ until such time as it becomes registered for PrEP in Australia. The TGA is currently evaluating Truvada™ for extension of its indications to include HIV PrEP. JHC will review its policy of funding Truvada™ for HIV PrEP if TGA approves its use for this purpose.
  18. Defence will formally amend its policy on the Management of Blood Borne Illnesses to incorporate this decision. CJHLTH is also reviewing the governance arrangements of the Pharmacy and Therapeutics Committee to ensure appropriate senior oversight of any decision regarding off label use of medications.

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That you:

- i. **Note** that Truvada™ has been funded for provision to two Defence members for HIV PrEP in accordance with best practice clinical practice guidelines and Defence process for off-label prescription  
Noted / Please Discuss
- ii. **Note** that Defence funding for this medication is being withdrawn.  
Noted / Please Discuss
- iii. **Note** that Defence will not consider funding Truvada™ for PrEP until such time as it is registered in Australia for that purpose.  
Noted / Please Discuss

Approved By <b>R.M. WALKER</b> RADM, RAN CJHLTH 31 Aug 15	
<b>Contact Officer:</b> R.M. Walker	<b>Phone</b> s22
Stuart Robert / / <b>Comments / Supplementary tasking:</b>	
Kevin Andrews / /	

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**Resources:**

19. An annual supply of PrEP is approximately \$13500 per person.

**Consultation:**

20. State and Territory Chief Health Officers via the Australian Health Principal Protection Committee

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