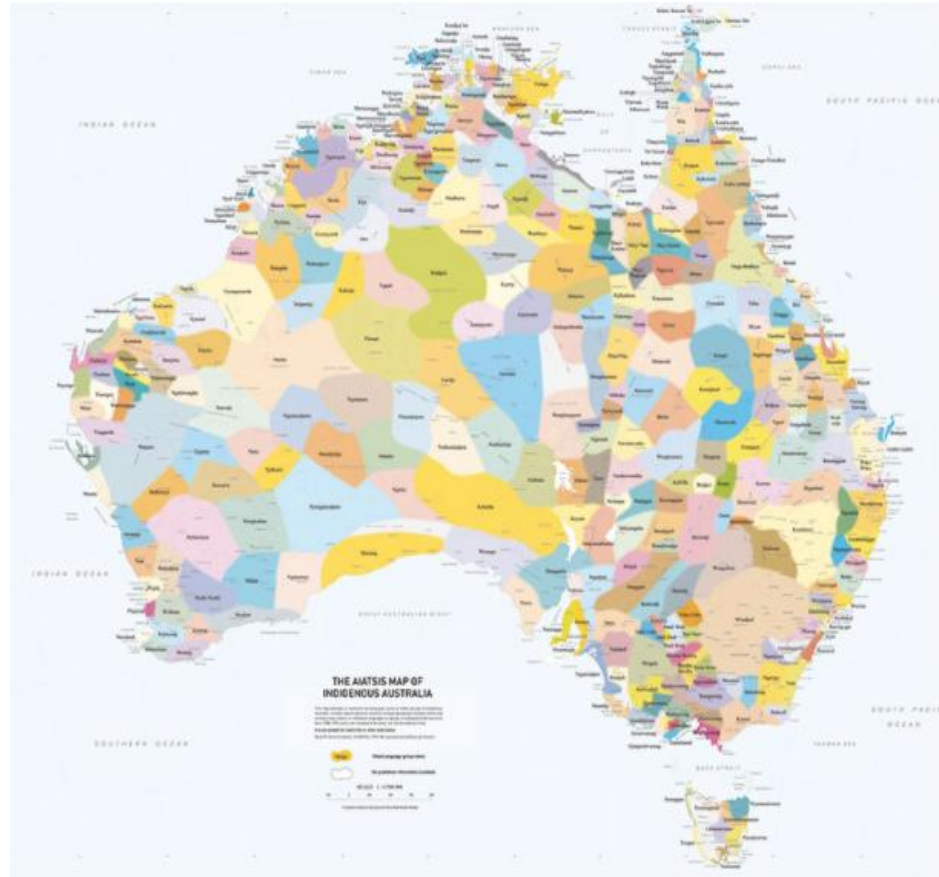


# The Future of PrEP in Australia-Pharmacy PrEP

Edwina Wright

ASHM Health Conference

September 15<sup>th</sup> 2025



This map attempts to represent the language, social or nation groups of Aboriginal Australia. It shows only the general locations of larger groupings of people which may include clans, dialects or individual languages in a group. It used published resources from 1988-1994 and is not intended to be exact, nor the boundaries fixed. It is not suitable for native title or other land claims. David R Horton (creator), © Aboriginal Studies Press, AIATSIS, 1996. No reproduction without permission. To purchase a print version visit: [www.aiatsis.ashop.com.au/](http://www.aiatsis.ashop.com.au/)

# Conflicts of Interest

- **During the past 4 years the following companies have paid monies to my institution:**
  - **Gilead Sciences:** educational events, advisory board, commemorative World AIDS Day event
  - **ViiV Healthcare:** unrestricted research funding, an educational event and work on a compassionate access scheme

# Overview

**To examine the future of PrEP in Australia via the**

**-place** of pharmacy

**-person** entering the pharmacy

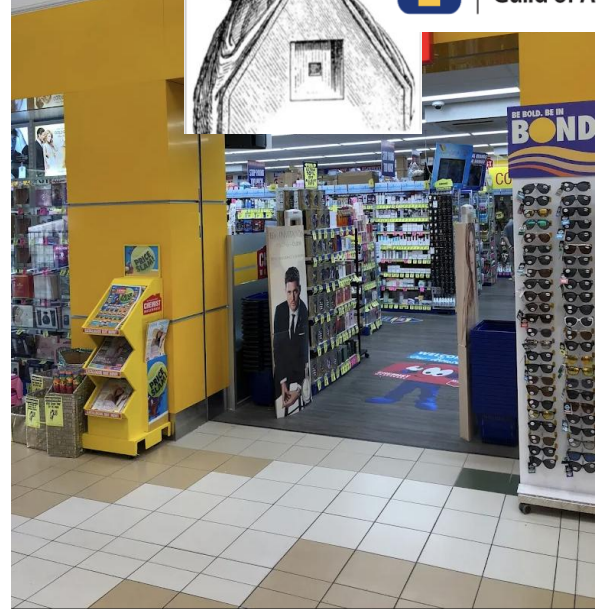
**-pathways** that deliver PrEP to people

**-progress** of PrEP delivery in Australia

# Pharmacy as Place



The Pharmacy  
Guild of Australia



# Pharmacy as Place: self care

## Treatment

- Pain
- Coughs and colds
- GIT upset
- Minor injuries



## Diagnosis

- Pregnancy
- HIV
- Respiratory viruses



## Prevention

Condoms- STIs and pregnancy



SPF products- skin cancer



Nicotine replacement therapy



Respiratory infections





# Pharmacy as Place: clinician-directed care



Pharmacist patient COPY

**TD\*/FTC**  
Take ii tablets 2-24 hours before sex, then i 24 and 48 hours after initial dose  
OR  
Take 1 tablet daily.  
30 tablets, 2 repeats

ONLY

Prescriber full name  
Prescriber qualifications  
Practice name  
Practice address  
Provider ID (if applicable)  
Phone num

Patient's Medicare  
Patient's  
Patient's  
Entitlement  
PBS Safety  
Entitlement  
(Tick apply)  
PBS

ONLY

Prescriber's or agent's signature  
Date  
Address  
Date of supply

**TAF/FTC**  
Take i tablet daily.  
30 tablets, 2 repeats

ONLY

Prescriber full name  
Prescriber qualifications  
Practice name  
Practice address  
Provider ID (if applicable)  
Phone num

Patient's Medicare  
Patient's  
Patient's  
Entitlement  
PBS Safety  
Entitlement  
(Tick apply)  
PBS

ONLY

Prescriber's or agent's signature  
Date  
Address  
Date of supply

**Cabotegravir 600mg IM**  
every 8 weeks.  
2 repeats

1 Supply Remaining



17DMYQKKMJFBHQ7522

Copy Token

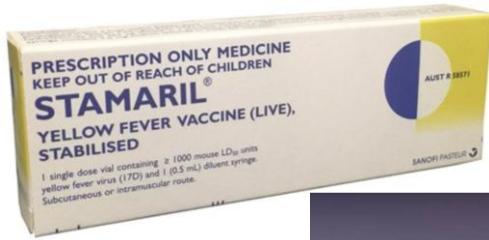
How can I get this prescription dispensed?

Delivered by eRx script exchange



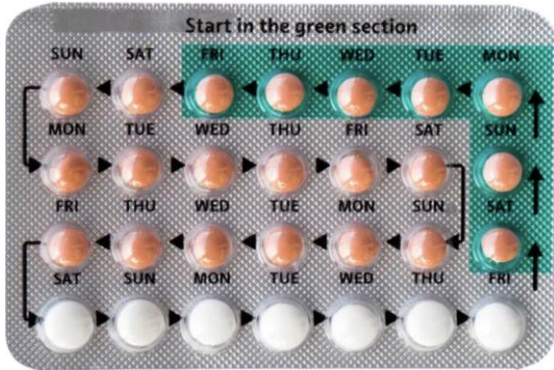
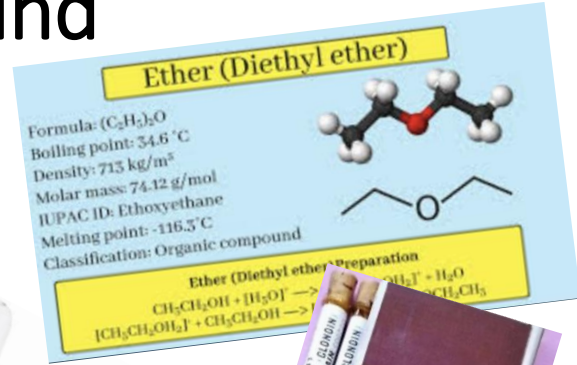
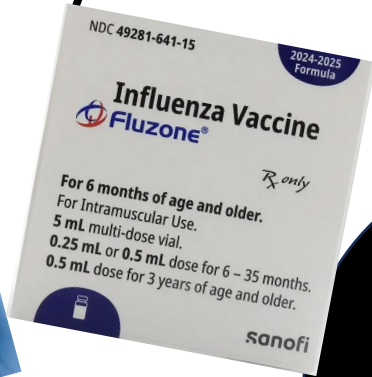


# Pharmacy as Place: hallowed ground

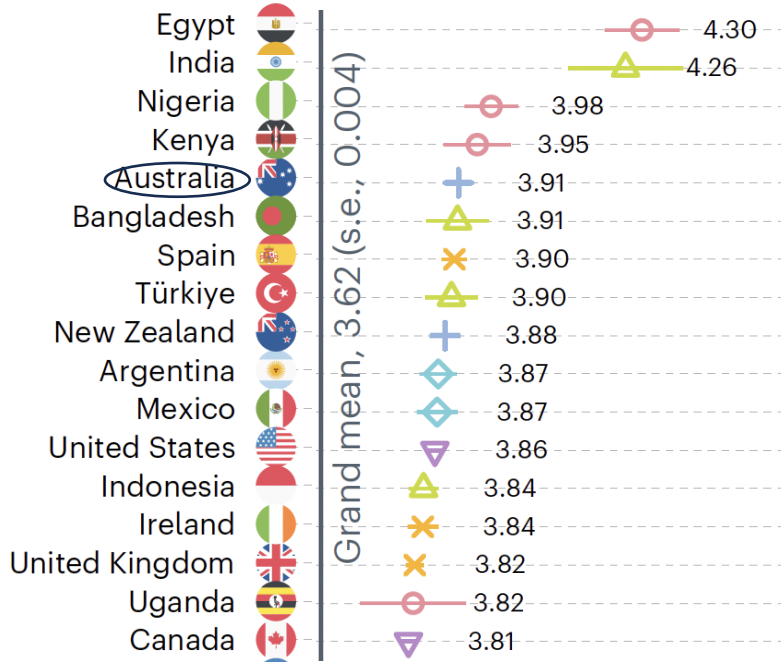




# Pharmacy as Place: hallowed ground



# Person: trust in scientists



- Cross-sectional online survey (2022-23) to determine trust in scientists and science
- Covered 31% of countries (79% global population)
- N= 71,922 people
- **Overall trust in scientists was moderately high (mean 3.62, s.d. 0.70)**
- Australia's score was 3.91

**Trust Index. 1= very low, 2= somewhat low, 3= neither high nor low, 4= somewhat high, 5= very high**

# Person- desired priorities of scientific research

How strongly do you believe that scientists should prioritize these goals and that science actually tackles them?

**People assigned  
their highest  
priority to  
improving public  
health**

**(mean 4.49 s.d. 0.84;  
1= low to 5 = high)**

**Improve public health**

**Solve energy problems**

**Reduce poverty**

**Develop defence and  
military technology**

"Science aims to  
tackle this goal."

"Scientists should  
prioritize this goal."

3.81

4.49

3.84

4.38

2.98

4.09

3.10

3.79

Difference

0.68 ( $P < 0.001$ )

0.54 ( $P < 0.001$ )

1.11 ( $P < 0.001$ )

0.69 ( $P < 0.001$ )

Average agreement

1

2

3

4

5



# Pharmacy as Place: clinician-directed care

Pharmacist patient COPY

**TD\*/FTC**  
Take ii tablets 2-24  
hours before sex,  
then i 24 and 48  
hours after initial  
dose  
OR  
Take 1 tablet daily.  
30 tablets, 2 repeats

**TAF/FTC**  
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tablet  
daily.  
30 tablets,  
2 repeats

Prescriber full name  
Prescriber qualifications  
Practice name  
Practice address  
Prescriber number  
Provider ID (if applicable)  
Phone num

Patient's Medicare n  
Patient's f  
Patient's i  
Entitlement  
PBS Safety  
entitlement  
(Tick apply)  
PBS

ONLY

Date of supply

Prescriber no.  
Patient's Medicare no.  
Pharmacist no.  
Patient's name  
Address  
Date  
PBS  
Brand substitution not permitted

**Lenacapavir**  
Day 1. Take two 300mg tablets  
AND 2x 1.5ml injections  
(927mg) subcutaneously  
Day 2. Take two 300mg tablets  
At 6 months repeat 2x 1.5ml  
injections (927mg)  
subcutaneously

ONLY

Cabotegravir 600mg IM  
every 8 weeks.  
2 repeats

1 Supply Remaining



17DMYQKKMJFBHQ7522

Copy Token

How can I get this medicine dispensed?

Delivered by ePBS





# Pathway: The TGA and PBAC



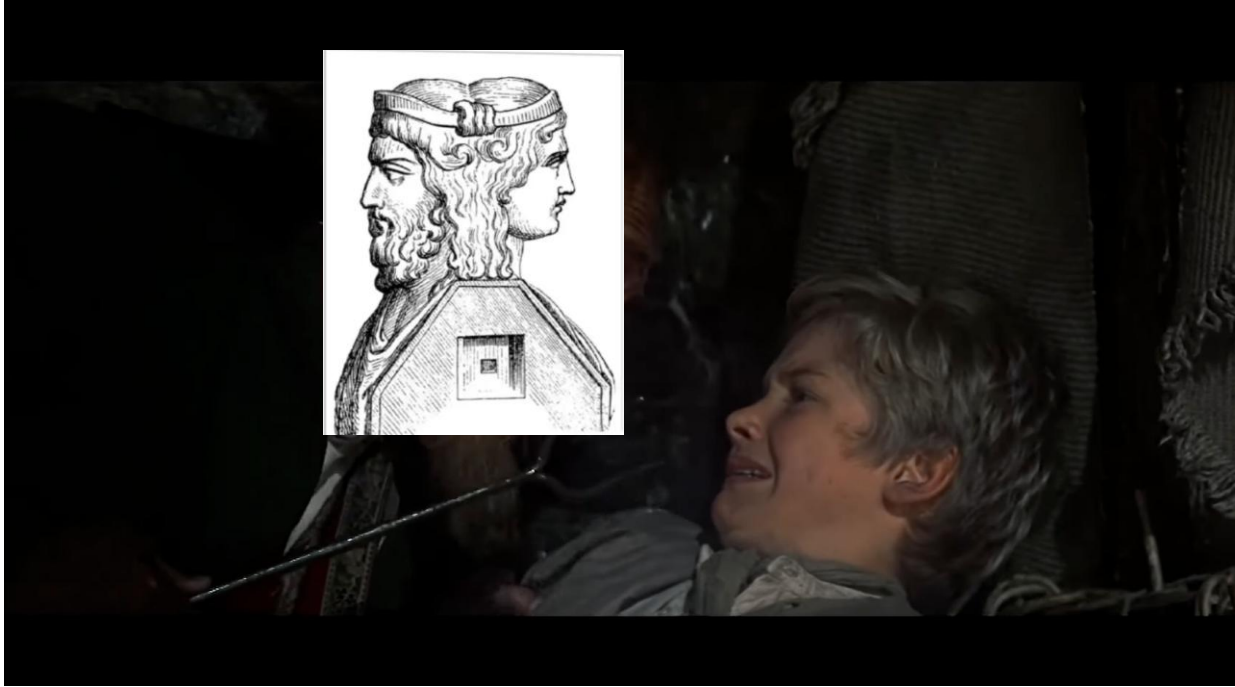


# Pathway: pharmaceutical companies





# Pathway: pharmaceutical companies



# Pathway- Pharmaceutical companies

**Research and patient care-focused Janus contends the following:**

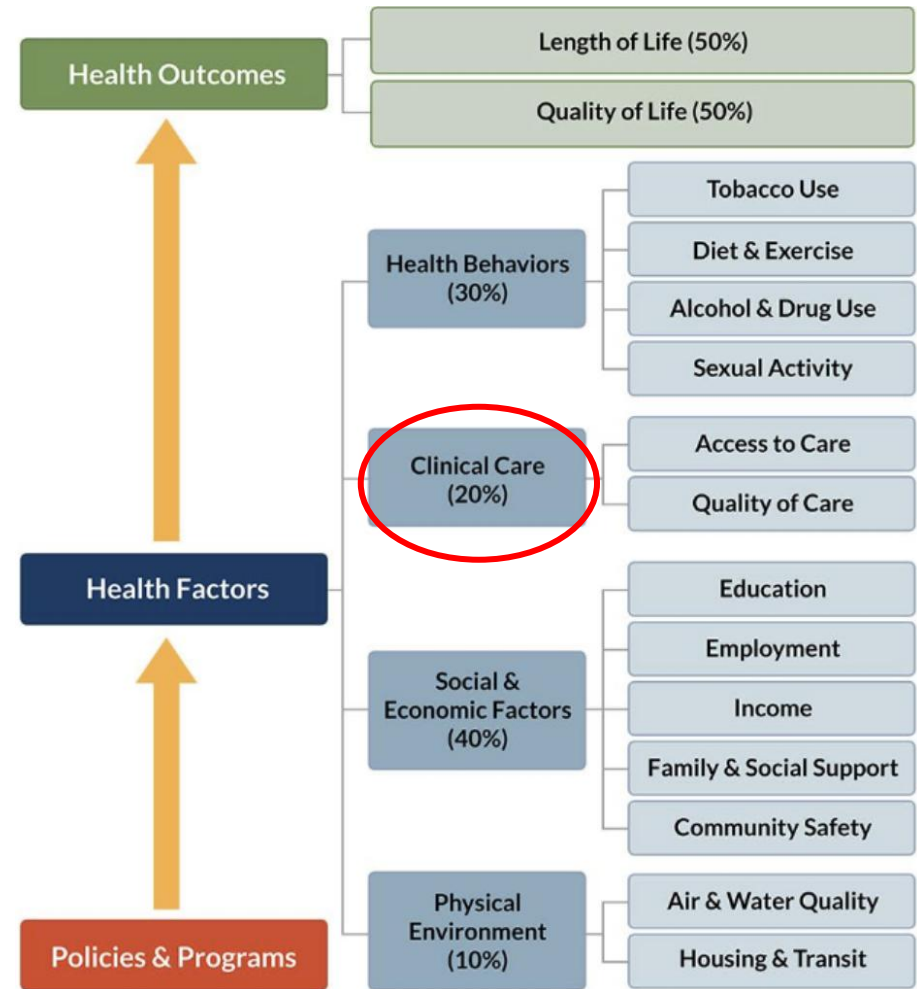
1. Drug discoveries have greatly helped humans
2. High costs of drug development
3. Companies' have shown largesse with long-acting injectable PrEP
4. High-income countries have capacity to pay a higher price for new HIV prevention drugs



# Pathway- Pharmaceutical companies

***‘Drug discoveries have greatly helped humans’***

*But clinical care may account for only 20% of health outcomes once other determinants of health are considered*

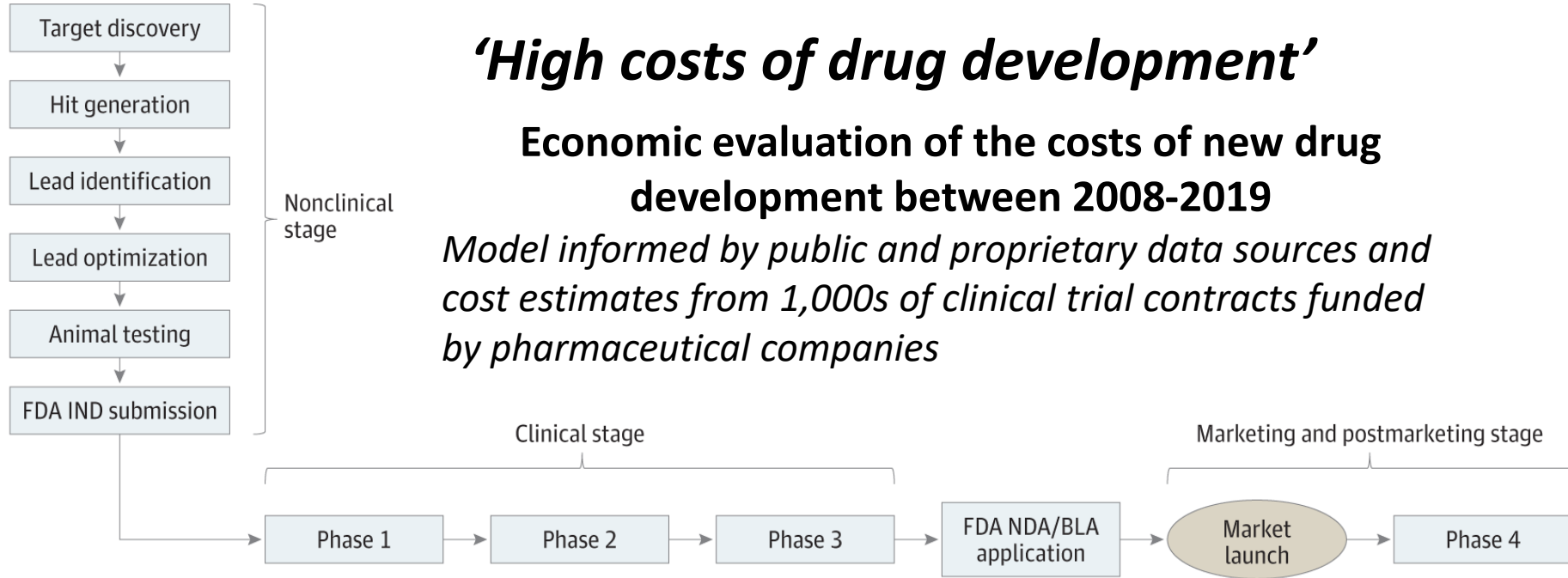


# Pathway- Pharmaceutical companies

## ***‘High costs of drug development’***

### **Economic evaluation of the costs of new drug development between 2008-2019**

*Model informed by public and proprietary data sources and cost estimates from 1,000s of clinical trial contracts funded by pharmaceutical companies*



Stages of Drug Development BLA indicates Biologic License Application; FDA, US Food and Drug Administration; IND, Investigational New Drug; NDA, New Drug Application

# Pathway- Pharmaceutical companies

	All therapeutic areas	Anti-infectives	Pain & Anaesthesia
Mean cost outlay for a single approved drug	172.7 million	109.4 million	297.2 million
Expected cost: costs of both successful & <i>failed</i> drugs	515.8 million	373.7 million	1756.2 million
Expected capitalized cost	879.3 million	373.7 million	1756.2 million

**Cheapest drug development costs are for anti-infective agents**

***'High costs of drug development'***

# Pathway- Pharmaceutical companies

*'High costs of drug development'*

## Key findings

1. Cost associated with *drug failures* was a major factor driving capitalized costs
2. Between 2008-19 large pharmaceutical companies had
  1. Minimal growth in R&D expenditure (< 3%)
  2. An increase in sales of 10%
  3. Relatively stable costs of drug development

# Pathway- Pharmaceutical companies

## NEWS

Mexico, and Peru, which were also sites in that trial, are excluded. Some critics have argued that this breaches the spirit of the Declaration of Helsinki, which stipulates that medical research should only be conducted among populations that stand to benefit from its results. While Gilead has made no formal announcement on the subject, a spokesperson told the New York Times that the company is "exploring several innovative strategies to support access, including tiered pricing" in Latin America.

In its 2024 report UNAIDS said that in the global effort to reduce new infections by 90% by 2030, "the cost of the new long acting injectable PEP options, and the speed with which they are made available to potential users, will be decisive."<sup>4</sup>

## The 120

**Botswana, Eswatini,  
Ethiopia, Kenya, Lesotho,  
Malawi, Mozambique,  
Namibia, Nigeria,  
Philippines, Rwanda, South  
Africa, Tanzania, Thailand,  
Uganda, Vietnam, Zambia,  
and Zimbabwe.**

1. Afghanistan  
2. Angola  
3. Argentina  
4. Australia  
5. Austria  
6. Azerbaijan  
7. Bahrain  
8. Bangladesh  
9. Belgium  
10. Bolivia  
11. Brazil  
12. Bulgaria  
13. Cambodia  
14. Canada  
15. Chile  
16. China  
17. Colombia  
18. Costa Rica  
19. Czechia  
20. Denmark  
21. Dominican Republic  
22. Ecuador  
23. Egypt  
24. El Salvador  
25. Estonia  
26. Ethiopia  
27. Finland  
28. France  
29. Germany  
30. Greece  
31. Guatemala  
32. Haiti  
33. Honduras  
34. Hungary  
35. India  
36. Indonesia  
37. Iran  
38. Iraq  
39. Israel  
40. Italy  
41. Japan  
42. Jordan  
43. Kazakhstan  
44. Kenya  
45. Korea, South  
46. Kuwait  
47. Kyrgyzstan  
48. Laos  
49. Latvia  
50. Lebanon  
51. Lithuania  
52. Luxembourg  
53. Macedonia  
54. Malawi  
55. Malaysia  
56. Maldives  
57. Mali  
58. Malta  
59. Mauritania  
60. Mauritius  
61. Mexico  
62. Moldova  
63. Monaco  
64. Mongolia  
65. Montenegro  
66. Morocco  
67. Mozambique  
68. Myanmar  
69. Namibia  
70. Nepal  
71. Netherlands  
72. New Zealand  
73. Nicaragua  
74. Niger  
75. Nigeria  
76. Norway  
77. Pakistan  
78. Panama  
79. Papua New Guinea  
80. Paraguay  
81. Peru  
82. Philippines  
83. Poland  
84. Portugal  
85. Romania  
86. Russia  
87. Rwanda  
88. Saudi Arabia  
89. Serbia  
90. Singapore  
91. Slovakia  
92. Slovenia  
93. South Africa  
94. South Korea  
95. Spain  
96. Sri Lanka  
97. Sweden  
98. Switzerland  
99. Taiwan  
100. Thailand  
101. Timor-Leste  
102. Tunisia  
103. Turkey  
104. Uganda  
105. Ukraine  
106. United Arab Emirates  
107. United Kingdom  
108. United States  
109. Uruguay  
110. Uzbekistan  
111. Venezuela  
112. Vietnam  
113. Wales  
114. Zambia  
115. Zimbabwe

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## ‘Company largesse’

### Lenacapavir, Gilead Sciences

- Rapid licensing to 6 generic companies to provide lenacapavir to 120 low- & middle-income countries<sup>1</sup>
- Time to market: Immediate for 18 countries; 2-3 years for others

### Cabotegravir- ViiV Healthcare

- Voluntary licensing agreement established with Medicines Patent Pool in 2023
- Time to market: 2-3 years

***Highly laudable precedents BUT demonstrates the immense power held by pharmaceutical companies***



# Pathway- Pharmaceutical companies

***'High-income countries  
have greater capacity to  
pay for new drugs'***

**Australia has the 13<sup>th</sup> largest economy in the world<sup>1</sup>**

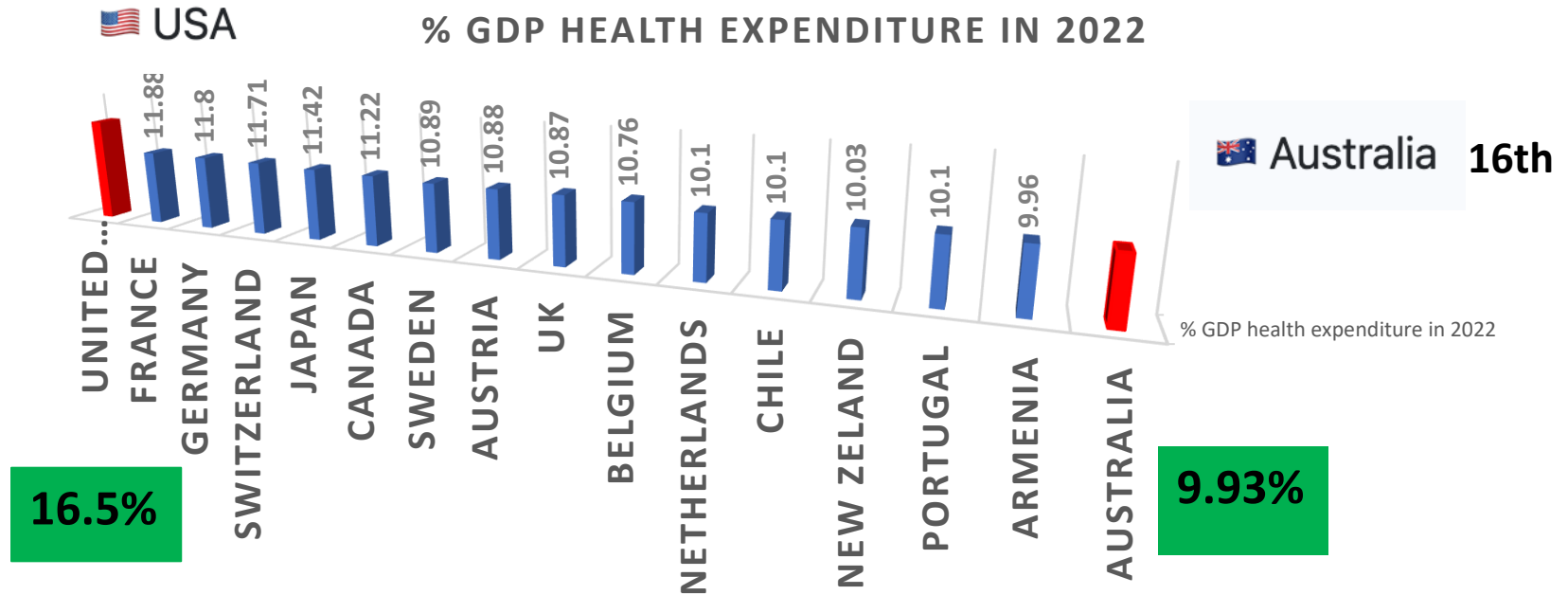
- Abundant natural resources- coal, gold, iron ore
- Wide free trade agreements with regional partners

***For a resource rich colony, we are very successful<sup>2</sup>***

- Low mortality in early colonisers in Australia
- Coloniser-settlers sought trials by jury, electoral representation, private property rights, which offset risk of profound resource corruption



# Pathway- Australia's health care expenditure as % GDP vs other wealthy countries



***'High-income countries have greater capacity to pay for new drugs'***

Pathway- Pharmaceutical companies



**Business-focused Janus contends the following:**

1. We have a duty of care to our shareholders

***‘We have a duty of care to our shareholders’***



## Pathway- Pharmaceutical companies

Company	PrEP product	Stock price (US\$) 2025	Market capital (US\$)
Merck & Co	MK-8527	\$85.00	\$ 322 billion
Gilead Sciences	Lenacapavir TAF/FTC	\$112.00	\$ 140 billion
ViiV Healthcare GSK Pfizer Shionogi	Cabotegravir	\$39.00	\$ 123 billion
		\$ 25.40	\$ 163 billion
		\$ 17.81	\$ 15 billion
TOTAL			<b>\$763 billion</b>

**Overall expenditure committed to Health and Aged Care by Australian Federal Government in 2024-2025 was \$146.1 billion dollars**

***'We have a duty of care to our shareholders'***

## Pathway- Pharmaceutical companies



- **Common practices that maintain high drug prices to ensure shareholder profits**
  - Use of patents- permits years of market exclusivity<sup>1</sup>
  - Patent extension<sup>1</sup>
    - Multiple overlapping patents on a single drug- '*patent thickening*'
- Lowering drug prices in individual markets like Australia can threaten the market price of the drug globally, especially in the USA

# Pathway- The Therapeutic Goods Administration



**Established 1990-** Subject to Therapeutic Goods Act, 1989

**Evaluates safety, efficacy & quality-** medicines, devices, blood products and biologicals

**Sets requirements for product listing** on the Australian Register of Therapeutic Goods (**ARTG**)

–93,545 products on ARTG 2021<sup>1</sup>

# Pathway- Pharmaceutical Benefits Advisory Committee (PBAC)

**Established 1953-** Subject to National Health Act, 1953

**Government appointed independent, expert body**  
-reports to the Minister for Health

**Chief role-** to recommend new medicines for listing on the Pharmaceutical Benefits Scheme Schedule. > 900 medicines listed

NATIONAL HEALTH.

No. 95 of 1953.

An Act relating to the provision of Pharmaceutical, Sickness and Hospital Benefits, and of Medical and Dental Services.

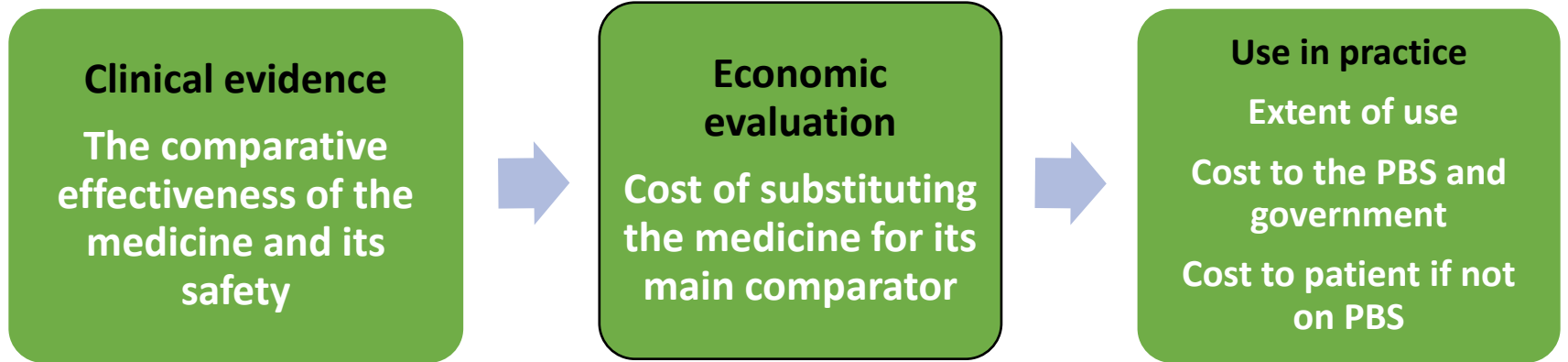
[Assented to 18th December, 1953.]





# Pathway- PBAC

## Quantifiable information required for a PBAC submission



**Many  
Drugs**

### Less quantifiable factors are considered also

- Equity issues e.g. age, SES, geography
- Availability of effective therapeutic alternatives
- **BUT** patient choice is not a consideration

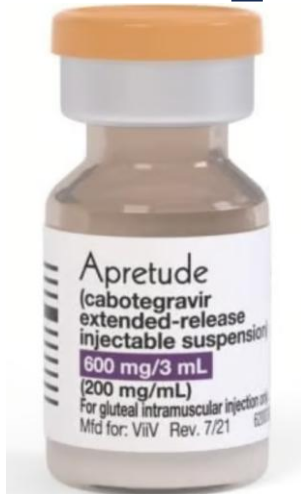


**New PrEP  
Drugs**

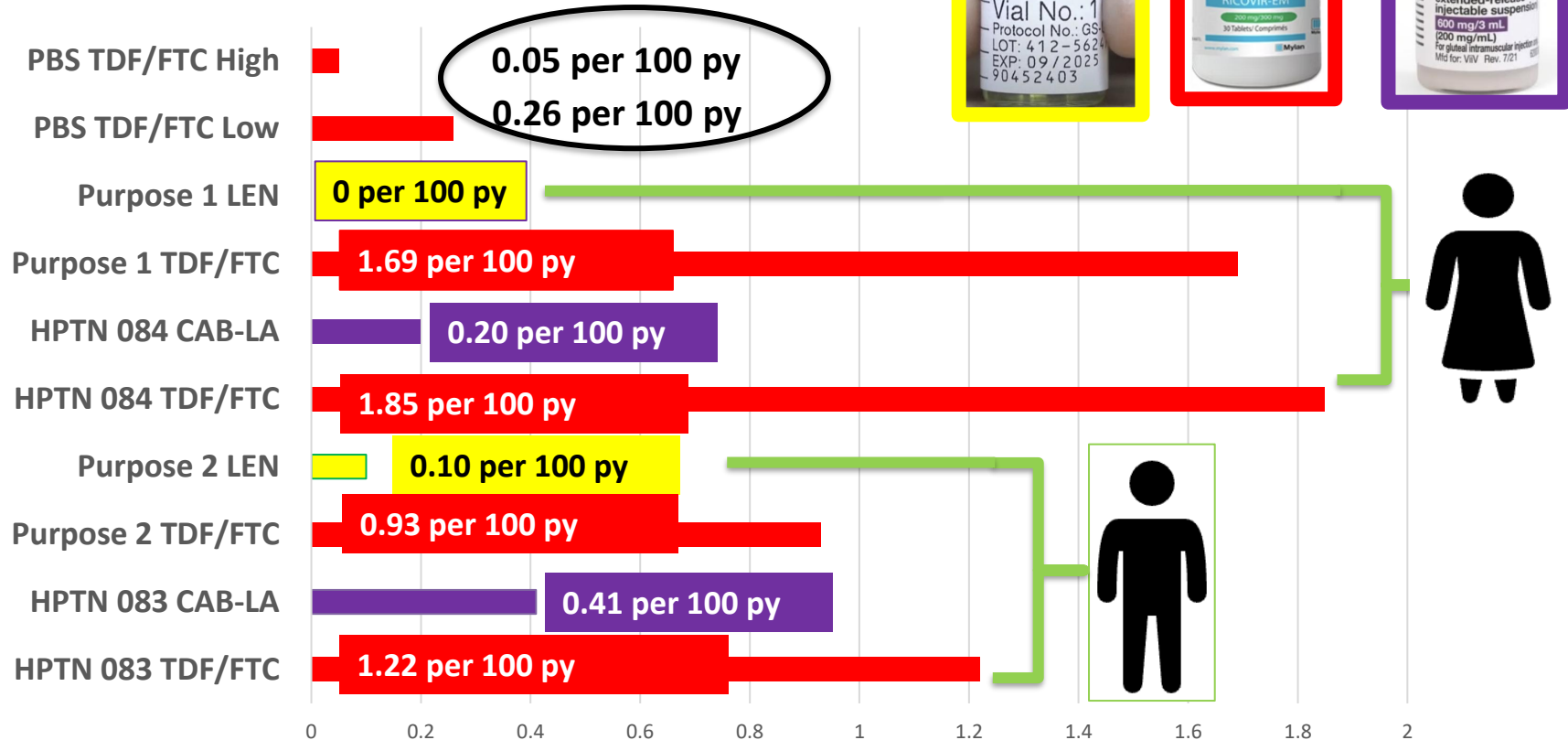
# Pathway-PBAC

**Clinical evidence**  
The comparative  
effectiveness of the  
medicine and its safety

**Comparator**



# HIV incidence in injectable PrEP trials & PBS oral PrEP users

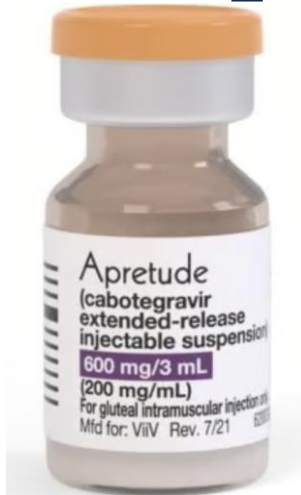


# Pathway-PBAC

## Economic evaluation

Cost of substituting  
the medicine for its  
main comparator

**Comparator**



**AUD\$ 42,446 per  
person per year**



**AUD\$ 400 per  
person per year**



**AUD\$ 42,377 per  
person per year**

# Pathway-PBAC

## Discount rates

**Society more highly values a treatment whose benefit occurs in the short-term than a treatment whose benefit occurs in the future**

Australia applies a discount rate of 5% per year to a drug's future costs and benefits if it offers life-extending benefits. This reduces the amount that the government is willing to pay for the drug

Prevention drugs can  
be sensitive to discount  
rates

$$\text{Present Value} = \frac{X}{(1 + r)^t}$$

**Present value of future costs & benefits**

X= costs and benefits of the drug  
r= rate (5%)  
t= years

# Pathway-PBAC

Are effective  
therapeutic  
alternatives available?

**NO- there are not despite the need!**

## Ascertainment of need

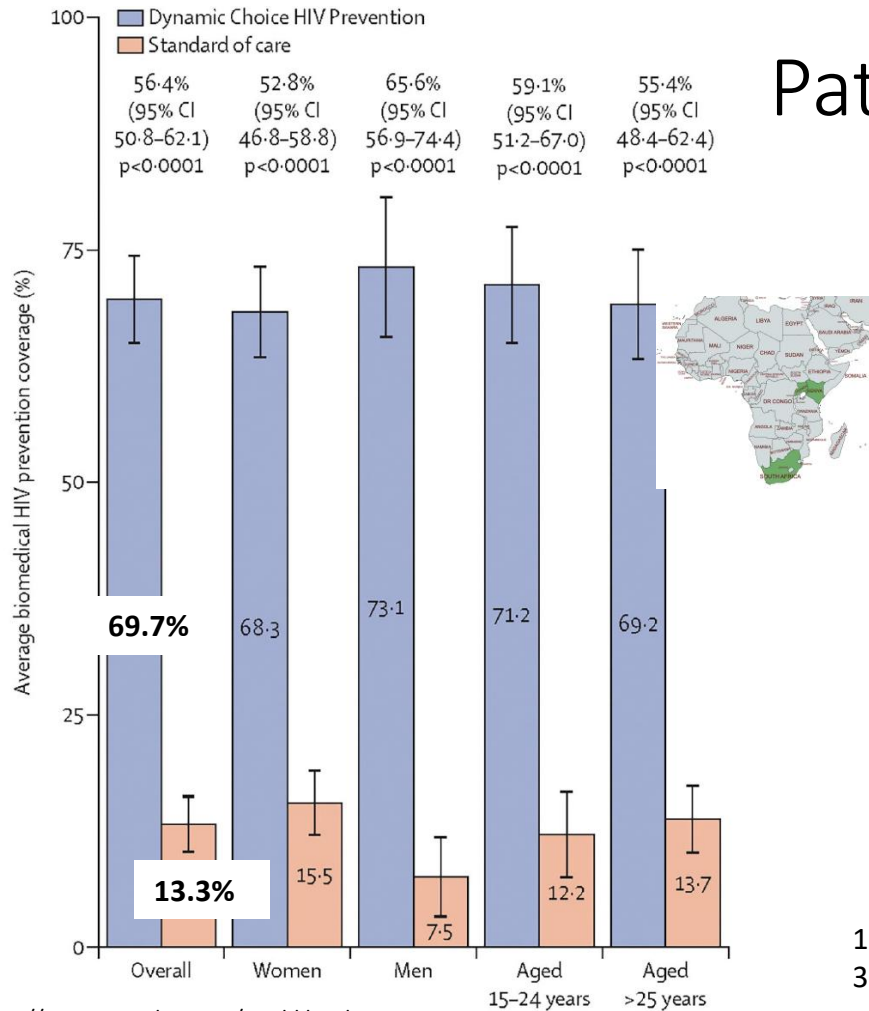
- ViiV CAB-LA Compassionate Access Scheme
- Data from 2024 ASHM workshop on CAB-LA<sup>1</sup>\* attended by clinicians from all States & Territories

This is a form titled "APRETUDE (CABOTEGRAVIR) FOR HIV-1 PREP COMPASSIONATE SUPPLY REQUEST FORM". It is divided into several sections: "Prescriber details" (Full name, Phone, Hospital/clinic, Email), "Patient details" (Gender, Sex assigned at birth, Age, HIV status, etc.), and "Clinical rationale APRETUDE for HIV-1 PREP". The form includes checkboxes for consent and medical necessity, and a section for clinical rationale. It is a red and white document.

1. Lamb R et al, ASHM June 2024. [https://ashm.org.au/wp-content/uploads/2024/09/Implementing-long-acting-injectable-HIV-pre-exposure-prophylaxis-using-Cabotegravir-LA\\_2024\\_Summary-Report.Final\\_.pdf](https://ashm.org.au/wp-content/uploads/2024/09/Implementing-long-acting-injectable-HIV-pre-exposure-prophylaxis-using-Cabotegravir-LA_2024_Summary-Report.Final_.pdf). \*Unrestricted funding from ViiV Healthcare

# Pathway-PBAC

**But patient choice  
is not  
a consideration**



**Emerging science** shows having dynamic choice in HIV prevention which includes injectable PrEP, leads to greater increase in HIV prevention coverage and reduces HIV incidence<sup>1,2</sup>

There is high demand for injectable PrEP in MSM in Australia<sup>3,4,</sup>

1. Kanya et al, Lancet HIV 2024. 2 Subedar et al, HIVR4P, Lima Peru 2024.  
3. Chan et al, AIDS Behav 2022. 4. Tieosapiaroen et al. Sex Trans Infect 2025



# Progress- How Australia could provide long-acting injectable PrEP to people at risk of HIV

## Reputation is important

Pharmaceutical companies who align with Australia to end HIV transmissions by 2030 through realistic price negotiations on long-acting PrEP would build greater reputational trust in high-income countries



### About Eight in Ten Across Parties Say Drug Company Profits Are a Major Contributing Factor to Prescription Drug Costs

Percent who say each of the following is a **major factor** contributing to the price of prescription drugs:

	Total	Democrats	Independents	Republicans
Profits made by pharmaceutical companies	83%	84%	78%	89%
The cost of research and development	54%	53%	56%	57%
The cost of marketing and advertising	45%	47%	47%	43%

# Progress- How Australia could provide long-acting injectable PrEP to people at risk of HIV

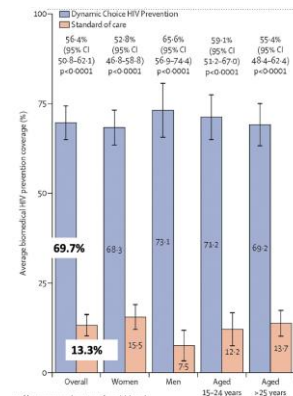
## PBAC has considerable flexibility

- Can use different comparator arms\*
- Has the discretion to use lower discount rates for pricing\*
- Uses risk sharing arrangements
- Can consider the new science of **flexible choice** in HIV prevention



$$\text{ICER} = \frac{\text{Cost of new drug} - \text{cost of comparator}}{\text{QALY new drug} - \text{QALY of comparator}}$$

$$\text{Present Value} = \frac{X}{(1+r)^t}$$



*\*Assessed in recent review of Australia's HTA process*

<https://www.health.gov.au/our-work/hta-review>

# Progress- How Australia could provide long-acting injectable PrEP to people at risk of HIV

An Act relating to  
Sickness  
Medical

NATIONAL HEALTH

(3.) The Committee shall make recommendations to the Minister from time to time as to the drugs and medicinal preparations which it considers should be made available as pharmaceutical benefits under this Part and shall advise the Minister upon any other matter concerning the operation of this Part referred to it by the Minister.

This can be interpreted to mean that the Government can state its desire and ask PBAC to ascertain if that desire is deliverable within the limits of the Act

*Recent example, GLP-1 agonists for obesity treatment*

# Progress- How Australia could provide long-acting injectable PrEP to people at risk of HIV



**Governments can create a program to provide drugs**

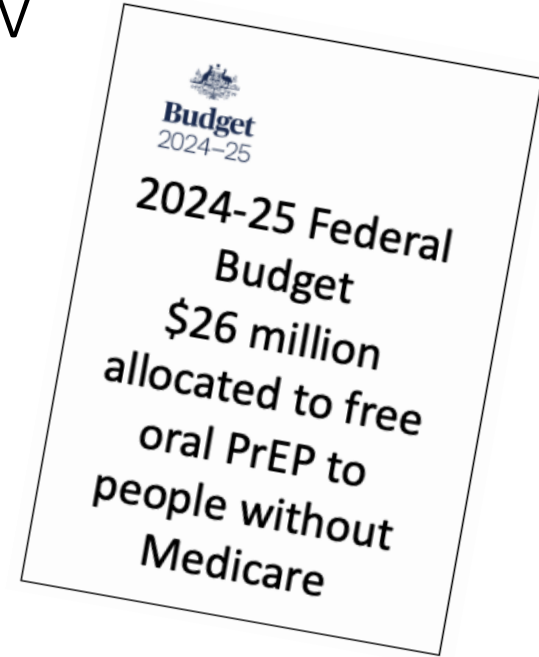
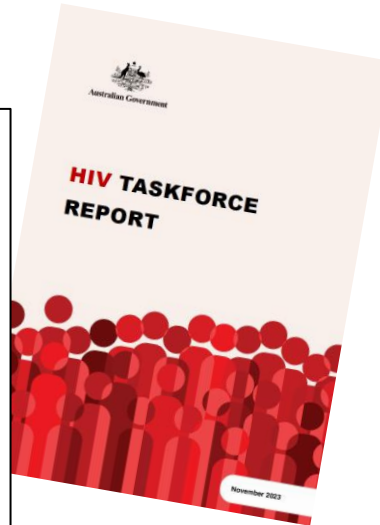
## ***Ministerial HIV Taskforce Report 2023***

### ***Recommendation 4:***

*The Australian Government should consider fast-tracking the availability of long-acting, injectable PrEP on the Australian market to reach PrEP users and to support ongoing use*

[https://archive.budget.gov.au/2024-25/bp1/download/bp1\\_2024-25.pdf](https://archive.budget.gov.au/2024-25/bp1/download/bp1_2024-25.pdf);

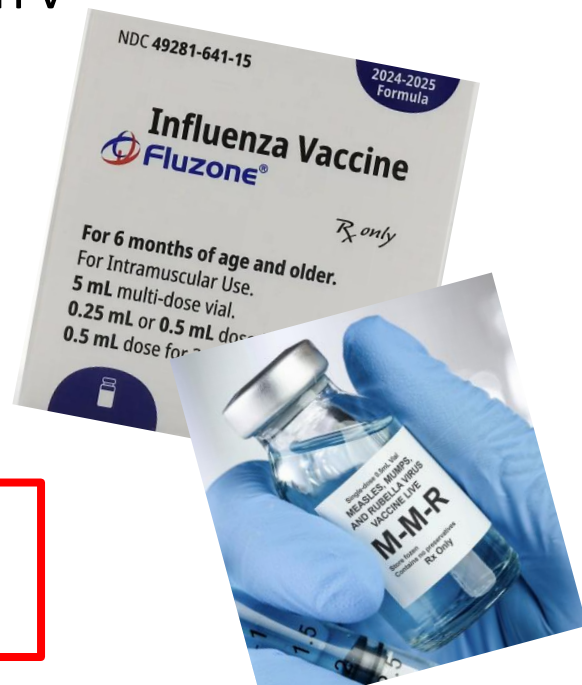
<https://www.health.gov.au/resources/publications/hiv-taskforce-report?language=en>



# Progress- How Australia could provide long-acting injectable PrEP to people at risk of HIV



**Australia procures vaccines, which are assessed by the TGA**



***Plausibly Australia could procure HIV prevention medications***



# Progress: Near Future of PrEP in Australia

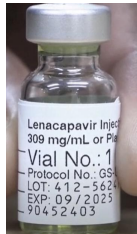


**In 2025-26 free oral PrEP will become available to people without Medicare in all jurisdictions as a federal government initiative**



**Injectable cabotegravir approved by PBAC September 2023 but price negotiations failed**

- ViiV Healthcare seeking extension of two-year grace period to re-establish price negotiations
- Answer expected after November 2025



**Injectable lenacapavir was submitted to the TGA in April 2025**

- Outcome expected late 2025
- ASHM will have lenacapavir PrEP guidelines ready by then!

## **SUMMARY: It is possible to make long-acting PrEP available in Australia in the near future**

- Public health is a global priority of the public
- Pharmaceutical companies can offer lower PrEP prices in Australia with great reputational gain
- Australia is a wealthy colony & can increase health spending
- PBAC has considerable inbuilt pricing flexibility
- Government can fund drugs outside of PBAC
- There is a clinical need and demand for long-acting PrEP in Australia
- Science shows flexible choice that includes injectable PrEP reduces HIV transmission



# Pharmacy as Place: clinician-directed care

**TD\*/FTC**  
Take ii tablets 2-24  
hours before sex,  
then i 24 and 48  
hours after initial  
dose  
OR  
Take 1 tablet daily.  
30 tablets, 2 repeats

**TAF/FTC**  
Take i  
tablet  
daily.  
30 tablets,  
2 repeats

ONLY

Pharmacist patient COPY

Prescriber full name  
Prescriber qualifications  
Practice name  
Practice address  
Provider ID (if applicable)  
Phone num

Patient's Medicare r  
Patient's b  
Patient's v  
Entitlement  
PBS Safety  
entitlement  
(tick apply)  
PBS

Date of supply

✓

**Lenacapavir**  
Day 1. Take two 300mg tablets  
AND 2x 1.5ml injections  
(927mg) subcutaneously  
Day 2. Take two 300mg tablets  
At 6 months repeat 2x 1.5ml  
injections (927mg)  
subcutaneously

ONLY

Prescriber full name  
Prescriber qualifications  
Practice name  
Practice address  
Provider ID (if applicable)  
Phone num

Patient's Medicare r  
Patient's b  
Patient's v  
Entitlement  
PBS Safety  
entitlement  
(tick apply)  
PBS

Date of supply

✓

**Cabotegravir 600mg IM**  
every 8 weeks.  
2 repeats

1 Supply Remaining



17DMYQKKMJFBHQ7522

Copy Token

How can I get this prescription dispensed?

Delivered by eRx script exchange

✓

*The time is now! Let's go!!!\**





# Image sources

- Janus: <https://www.mediastorehouse.com.au/>
- Pharmaceutical Society of Australia: [psa.org.au](https://www.psa.org.au/)
- Pharmacy guild of Australia: <https://www.guild.org.au/>
- Nobel prize: <https://www.britannica.com/>
- Scripts: <https://www.servicesaustralia.gov.au/>
- Yellow fever vaccine: <https://www.sssaaustralia.com.au/>
- Polio vaccine: <https://www.uclahealth.org/>
- mRNA vaccines: <https://www.thechemicalengineer.com/>
- Insulin: <https://www.webmd.com/>

# Image sources

- Penicillin: <https://www.medicalindependent.ie/>
- Vitamin C: <https://allieddigestivehealth.com/>
- Vitamin K: <https://www.ahpmedicals.com/>
- MMR vaccine: <https://today.uconn.edu/>
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- OCP: <https://www.gaals.com.au/>
- Morphine ampoules: <https://www.lavoisier.com/>
- Nitroglycerin: <https://theconversation.com>
- Ether: <https://chemistrypage.in/>
- Paracetamol: <https://pharmacyhealth.com.au/>

# Image sources

- TGA building: TGA business plan 2021 <https://www.tga.gov.au/>
- Flags: <https://companiesmarketcap.com/>
- Portrait of Gina Rinehart: <https://www.artshub.com.au/>
- Lenacapavir vial: <https://www.connectedtoindia.com/>
- Cabotegravir vial: <https://www.fiercepharma.com/>
- Oral PrEP bottle: <https://www.greencrosspharmacy.online/>
- Parliament house Canberra:  
[https://www.aph.gov.au/Visit Parliament/Things to Do/Take in some history](https://www.aph.gov.au/Visit%20Parliament/Things%20to%20Do/Take%20in%20some%20history)
- Medicare card: <https://www.servicesaustralia.gov.au/medicare-online-account-help-get-your-own-medicare-card-and-number>

# Acknowledgements

## **ASHM PrEP Guidelines Group**

Ian Anderson	Rebekah Lamb
<b>Benjamin Bavinton</b>	<b>Nicholas Medland RIP</b>
Charlotte Bell	Jessica Michaels
Doris Chibo	<b>Darren Russell</b>
<b>Vincent Cornelisse</b>	Eloise Williams
<b>Andrew Grulich</b>	Iryna Zablotska
<b>Dash Heath Paynter</b>	Jude Armishaw

**Andrew Wilson AO\***

**Dean Murphy**

Jo Watson

Colin Batrouney

Mark Stoové

Fraser Drummond

**ASHM** Alexis Apostolellis, Jessica Michaels,  
Bek Lamb, Neil Steetsel and many others!

**All human and animal  
subjects of PrEP studies**



THANK YOU

What can be done if all else fails?

What if injectable PrEP does not become available in Australia through PBS or a government funded program?

**What if injectable PrEP does not become available in Australia through PBS or a government funded program?**

- *Either way we need diversified PrEP services: pharmacists & nurses prescribing PrEP*
- *Explore over-the-counter oral PrEP*
- *Explore self importation of generic injectable PrEP*
- *Government funded drug discovery initiatives and PrEP*
- *An implementation group is reviewing 50 recommendations made to accelerate access to the best medicines for Australians now and into the future*



# Progress: Near Future of PrEP in Australia

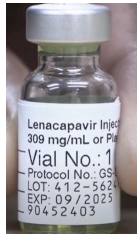


**In 2025-26 free oral PrEP will become available to people without Medicare in all jurisdictions as a federal government initiative**



**Injectable cabotegravir approved by PBAC September 2023 but price negotiations failed**

- ViiV Healthcare seeking an extension of the two-year grace period to re-establish price negotiations
- Answer expected November 2025



**Injectable lenacapavir was submitted to the TGA in April 2025**

- Outcome expected late 2025
- ASHM will have lenacapavir guidelines ready in late 2025

What can be done if all else fails?

# Acknowledgements

**Andrew Wilson AO**

**Dash Health-Paynter**

**Sharon Lewin AO**

**Levinia Crooks AM RIP**

Mark Stoové

Jo Watson

Colin Batrouney

Brian Price

Olga Vujovic

Fraser Drummond

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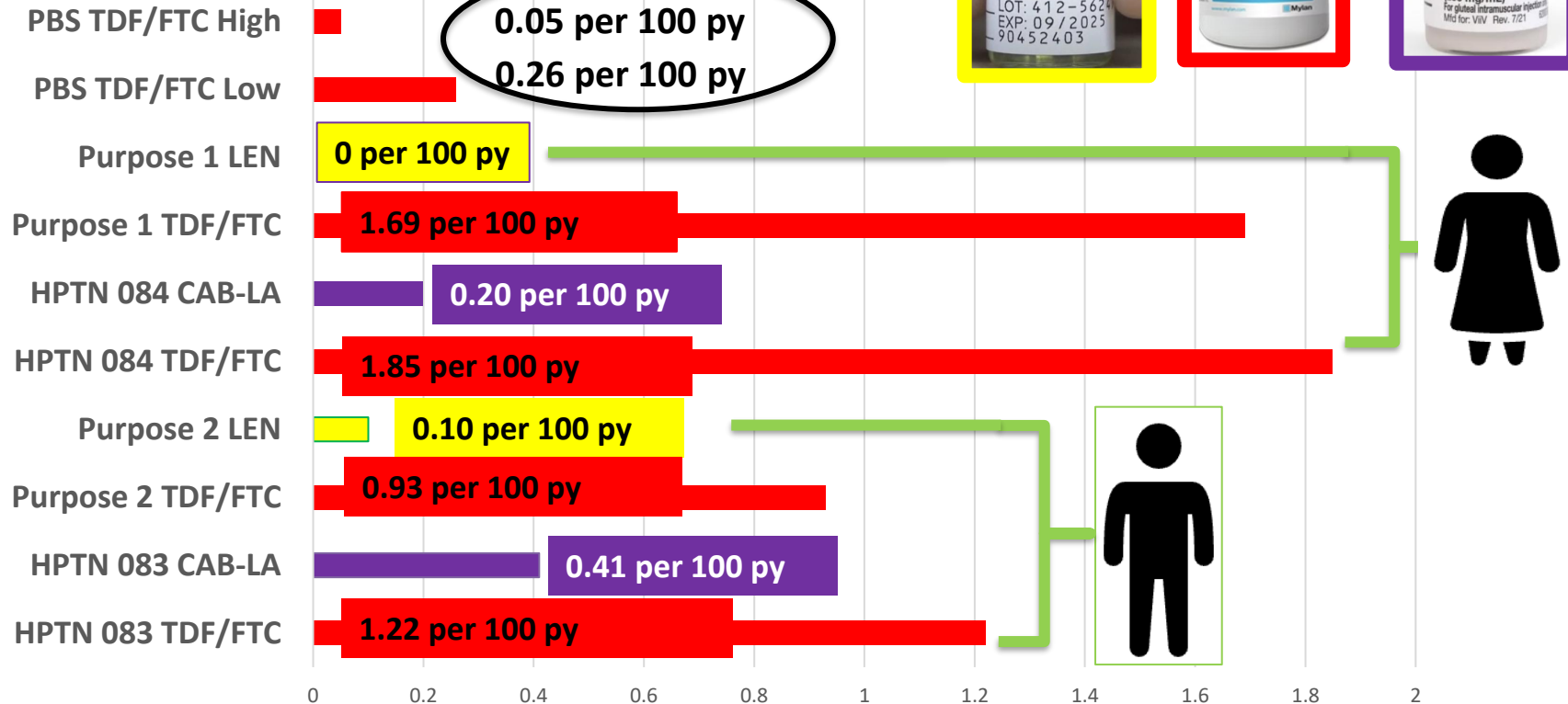
Dash Heath Paynter

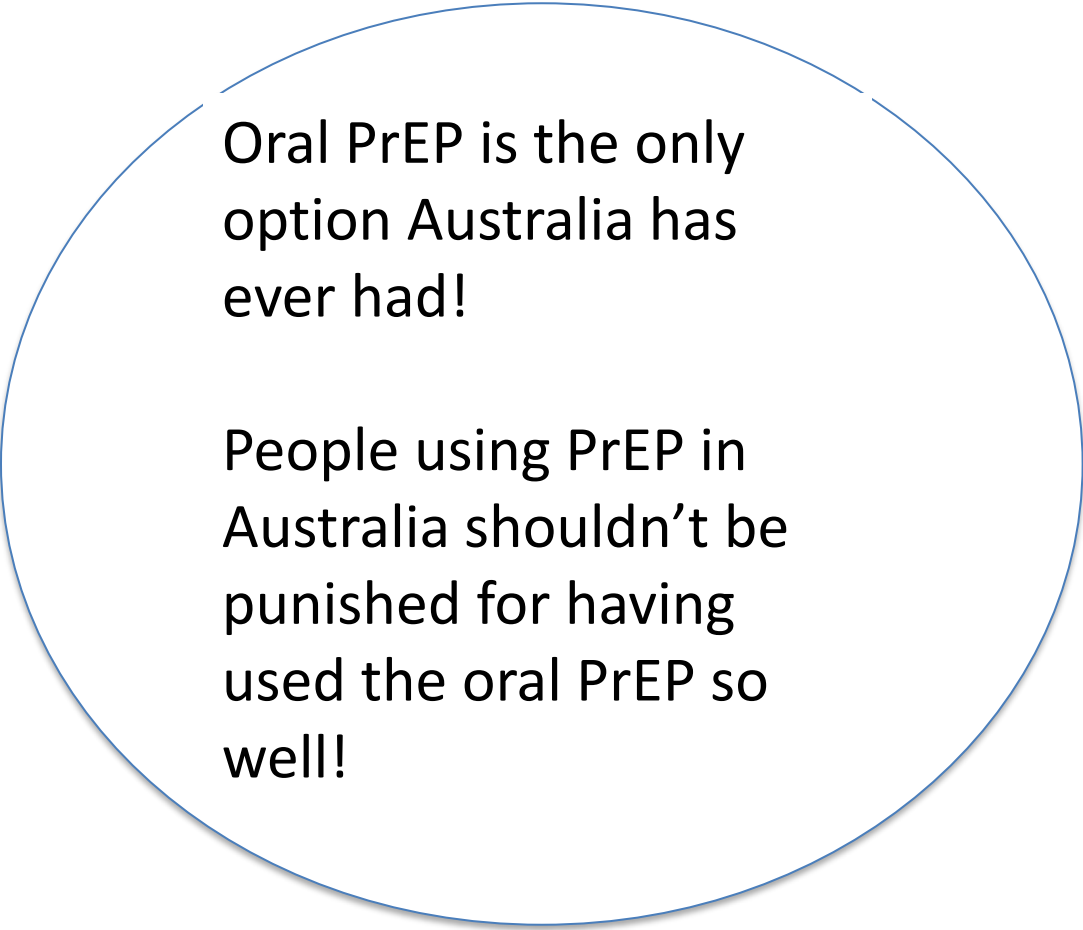
Jude Armisahw

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Bek Lamb, Neil Steetsel and many others!

**All human and animal  
subjects of PrEP studies**

# HIV incidence in injectable PrEP trials & PBS oral PrEP users





Oral PrEP is the only  
option Australia has  
ever had!

People using PrEP in  
Australia shouldn't be  
punished for having  
used the oral PrEP so  
well!

# Pathway- Pharmaceutical companies

***'High-income countries  
have greater capacity to  
pay for new drugs'***

**Australia has the 13<sup>th</sup> largest economy in the world<sup>1</sup>**

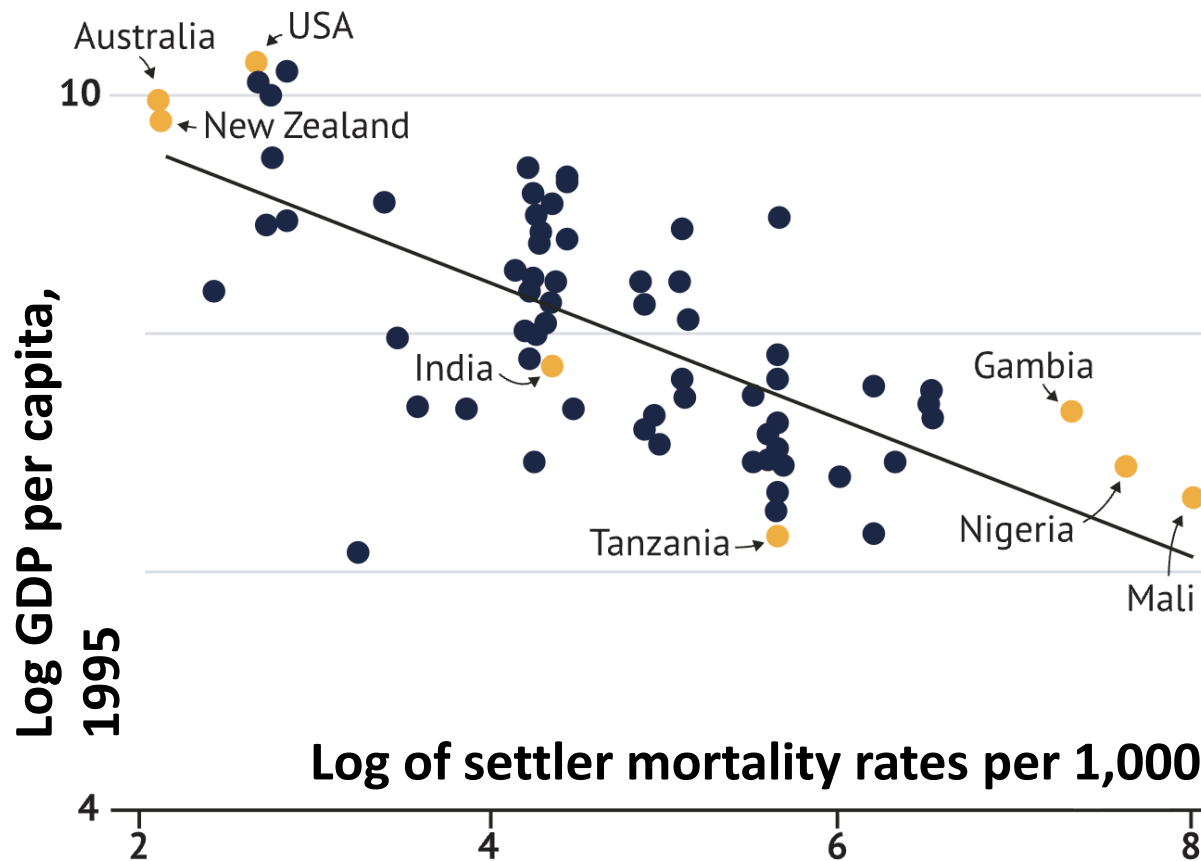
- Abundant natural resources- coal, gold, iron ore
- Wide free trade agreements with regional partners

***Why such a successful resource rich colony?<sup>2</sup>***

- Low mortality in early colonisers in Australia
- Coloniser-settlers sought trials by jury, electoral representation, private property rights, which offset risk of resource corruption



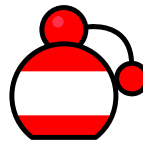
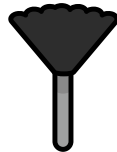
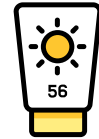
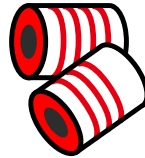
## Reduced-form relationship between income and settler mortality



# Pharmacy as Place: care for sense-of-self

## Care for sense-of-self

- Make-up
- Perfume
- Hair care
- Tanning agents
- Body lotions
- Anti-ageing products







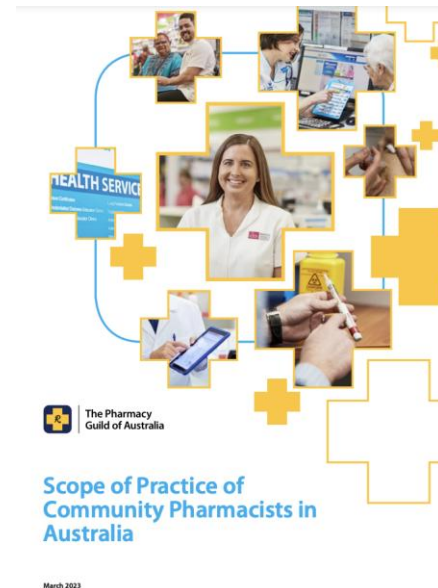
# Pharmacy as Place: clinician-directed care



## Pharmacist prescribing

### **Trials underway in QLD, NSW and Victoria**

- VICTORIA and NSW: UTIs, skin conditions and scripts for contraceptives
- QLD: GORD, GIT upset, skin conditions, shingles, contraception, travel health, minor wound management



# Pathway-PBAC

A tool that helps PBAC decision making is the Incremental Cost-Effectiveness Ratio (ICER)

$$\text{ICER} = \frac{\text{Cost \& outcomes of new drug} - \text{Cost \& outcomes of comparator}}{\text{QALY* new drug} - \text{QALY of comparator}}$$

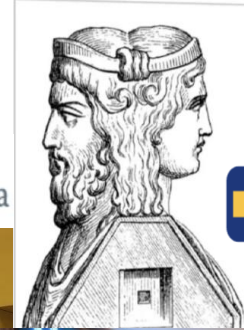
*If the **ICER** of a new drug is < \$50,000 QALY gained, PBAC generally recommends the drug*

*\*Quality adjusted life year (QALY) = one year of full health*

# Pharmacy as Place



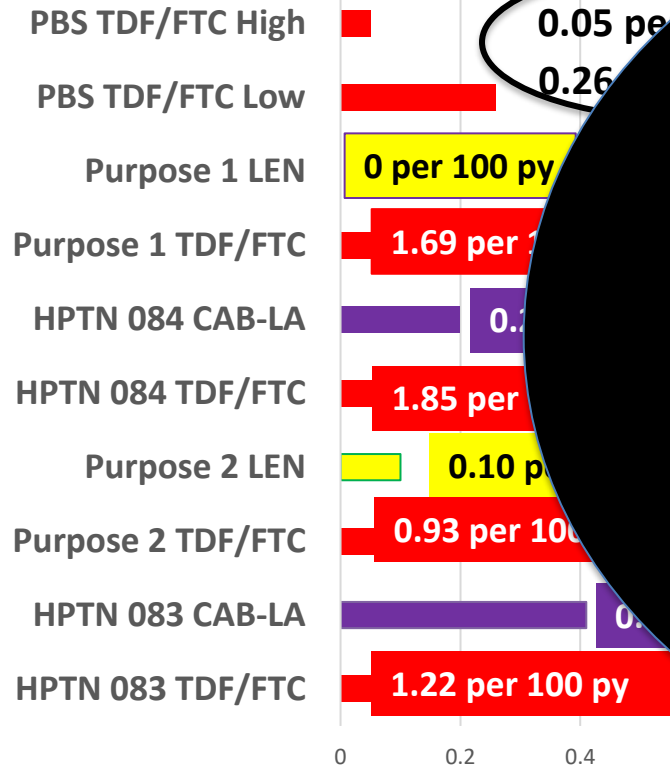
Pharmaceutical  
Society of Australia



The Pharmacy  
Guild of Australia



# HIV incidence in injectable PrEP trials & PBS oral PrEP users



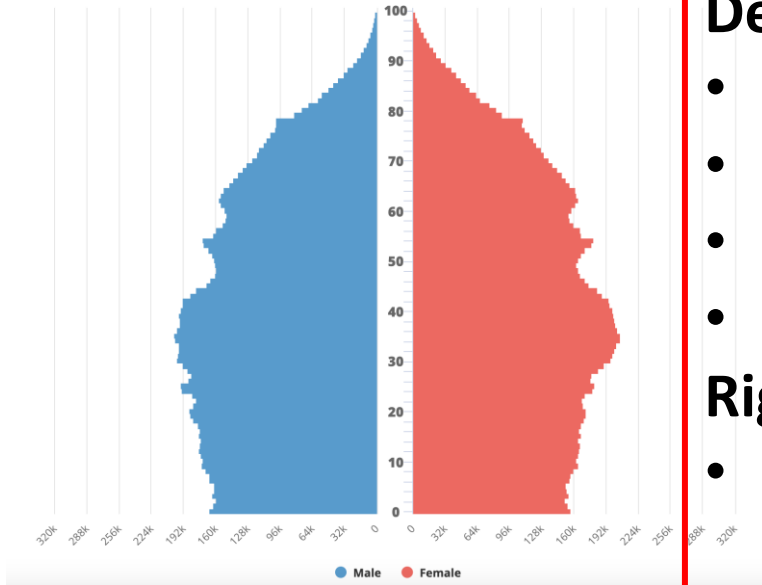
**Oral PrEP is the only option  
Australia has ever had!**

**People using PrEP in Australia  
shouldn't be punished for  
having used it so well!**



# Person- Persons

Australia: projected age structure in 2025



## Demography

- Average age: 39.6 years
- Life expectancy: 85.1 yrs♀, 81.1 yrs♂
- 80% at least 1 chronic health issue
- 70% filled PBS script in past 6 months

## Rights

- 100% subject to article 27 of the Universal Declaration of Human Rights

# Pathway- Pharmaceutical companies

NEWS

Mexico, and Peru, which were also sites in that trial, are excluded. Some critics have argued that this breaches the spirit of the Declaration of Helsinki, which stipulates that medical research should only be conducted among populations that stand to benefit from its results. While Gilead has made no formal announcement on the subject, a spokesperson told the *New York Times* that the company is "exploring several innovative strategies to support access, including tiered pricing" in Latin America.

In its 2024 report UNAIDS said that in the global effort to reduce new infections by 90% by 2030, "the cost of the new long acting injectable PrEP options, and the speed with which they are made available to potential users, will be decisive."

**The 120 countries that will have access to long-acting injectable PrEP**

- 1 Afghanistan
- 2 Angola
- 3 Anguilla
- 4 Antigua and Barbuda
- 5 Armenia
- 6 Aruba
- 7 Azerbaijan
- 8 Bahamas
- 9 Bangladesh
- 10 Barbados
- 11 Belarus
- 12 Belize
- 13 Benin
- 14 Bhutan
- 15 Bolivia
- 16 Botswana
- 17 British Virgin Islands
- 18 Burkina Faso
- 19 Burundi
- 20 Cabo Verde
- 21 Cambodia
- 22 Cameroon
- 23 Central African Republic
- 24 Chad
- 25 Comoros
- 26 Democratic Republic of the Congo
- 27 Congo, Rep
- 28 Cote d'Ivoire
- 29 Cuba
- 30 Djibouti
- 31 Dominica
- 32 Dominican Republic
- 33 Egypt
- 34 Equatorial Guinea
- 35 Eritrea
- 36 Eswatini
- 37 Ethiopia
- 38 Fiji
- 39 Gabon
- 40 Gambia
- 41 Georgia
- 42 Ghana
- 43 Grenada
- 44 Guinea
- 45 Guinea-Bissau
- 46 Guyana
- 47 Haiti
- 48 Honduras
- 49 Hungary
- 50 Iceland
- 51 India
- 52 Indonesia
- 53 Israel
- 54 Italy
- 55 Jamaica
- 56 Japan
- 57 Jordan
- 58 Kazakhstan
- 59 Kenya
- 60 Kiribati
- 61 Kosovo
- 62 Kuwait
- 63 Kyrgyzstan
- 64 Laos
- 65 Latvia
- 66 Lebanon
- 67 Lesotho
- 68 Liberia
- 69 Lithuania
- 70 Luxembourg
- 71 Macao
- 72 Madagascar
- 73 Malawi
- 74 Malaysia
- 75 Maldives
- 76 Mali
- 77 Malta
- 78 Marshall Islands
- 79 Mauritania
- 80 Mauritius
- 81 Mexico
- 82 Micronesia
- 83 Moldova
- 84 Monaco
- 85 Mongolia
- 86 Montenegro
- 87 Morocco
- 88 Mozambique
- 89 Myanmar
- 90 Namibia
- 91 Nauru
- 92 Nepal
- 93 Nicaragua
- 94 Niger
- 95 Nigeria
- 96 North Korea
- 97 Pakistan
- 98 Palau
- 99 Papua New Guinea
- 100 Philippines
- 101 Poland
- 102 Portugal
- 103 Qatar
- 104 Romania
- 105 Rwanda
- 106 Saint Kitts and Nevis
- 107 Saint Lucia
- 108 Saint Vincent and the Grenadines
- 109 Samoa
- 110 San Marino
- 111 Saudi Arabia
- 112 Senegal
- 113 Serbia
- 114 Seychelles
- 115 Singapore
- 116 Slovakia
- 117 Slovenia
- 118 South Africa
- 119 South Korea
- 120 Spain

**Botswana, Eswatini, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, Philippines, Rwanda, South Africa, Tanzania, Thailand, Uganda, Vietnam, Zambia, and Zimbabwe.**

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## ***'Company largesse'***

- Rapid licensing to 6 generic companies to provide lenacapavir to 120 low- and middle-income countries by Gilead Sciences<sup>1</sup>. Immediate product availability for 18 countries and 2-3 years for others
- Voluntary licensing agreements for CAB-LA established between Medicines Patent Pool and ViiV Healthcare in 2023. Time to market: 2-3 years

***Highly laudable precedents BUT this demonstrates the immense power held by pharmaceutical companies***