

Community Manifesto

for HIV Long-Acting Injectable PrEP in Europe¹

17 October 2023

From approval in the USA (2012) and in Europe (2016) oral PrEP has had a significant impact on population HIV incidence, especially in gay and bisexual men and other men who have sex with men (GBMSM), in high-income settings.

Oral HIV PrEP is highly efficacious when taken as prescribed, and is largely acceptable as an HIV prevention technology in those who use it. Oral PrEP has been a significant new addition to combination HIV prevention approaches, along with condoms, PEP, and treatment-as-prevention.

However, significant barriers to accessing oral PrEP remain and these barriers result in significant health inequalities. Further, taking a (daily) oral medication is not an acceptable or feasible method of HIV prevention for many who could benefit from PrEP. The development of multi-methods of PrEP will increase adherence as well as PrEP acceptability and choice, and thereby improve uptake of PrEP regionally and globally.

New formulations of PrEP have been studied, with a number of highly effective methods becoming approved for use. These include vaginal-ring formulations, and long-acting injectable PrEP. ViiV's long-acting formulation of cabotegravir PrEP (LA-CAB) has been approved in, Australia, Botswana, Malawi, South Africa, US, and Zimbabwe and has been submitted for regulatory approval to the EMA and in over 10 countries thus far. Recent voluntary licensing agreements have been agreed, enabling generic LA-CAB to be manufactured and prescribed in over 90 countries, subject to pending regulatory approvals. However, due to a dearth of manufacturing facilities, drug stock is currently limited until new plants become fully functional in 2025.

This document results from a consensus meeting held in Paris in March 2023 between regional and international HIV prevention organisations and activists including: AIDES; AIDS Action Europe; AVAC; Coalition PLUS; EATG; Fundacja Edukacji Społecznej; GSSG - Germany's Charitable Foundation Sexuality and Health; and PrEPster at The Love Tank CIC.

At the consensus meeting, four key pillars for pushing for new PrEP technologies were identified and agreed as a collaborative approach to increasing access to LA-CAB in Europe for people who need it. They should be operationalised in parallel, and in part facilitate broader access to PrEP, beyond LA-CAB. These four pillars are:

¹ While this particular manifesto focuses on LAI PrEP, the signing organisations call for the implementation of comprehensive prevention programmes combining different strategies and tools as defined by [WHO](#) and UNAIDS.

- **Pillar one:** to push for the introduction of LA-CAB at the earliest opportunity
- **Pillar two:** to push for national LA-CAB implementation projects while collecting data to inform guidelines for full scale-up
- **Pillar three:** to advocate for the affordability of LA-CAB regionally and globally
- **Pillar four:** to challenge the social and structural barriers to the introduction of PrEP

Pillar one: to push for the introduction of LA-CAB at the earliest opportunity

Actions to address this pillar include:

- Ensuring a timely approval of LA-CAB through the European Medicines Agency (EMA)² or other relevant European medicines approval agencies
- As appropriate, ViiV submits country-specific regulatory approval of LA-CAB
- Ensuring that LA-CAB is included in national and regional PrEP guidance, including that of relevant professional bodies
- Ensuring funding, provider training, demand creation and communication processes are in place at the national level

Pillar two: to push for the introduction of national LA-CAB implementation projects while collecting data to inform guidelines for full scale-up

Actions to address this pillar include:

- Ensuring that implementation research projects are funded as a parallel process to regulatory approval to answer outstanding questions including testing algorithms and potential integrase inhibitor drug resistance
- Ensuring that clinical research and implementation data are made available in a transparent and open fashion to influence prescribing guidance for LA-CAB
- Ensuring that community-based organisations and people who use PrEP (or who will use PrEP) are central to decision making regarding on-going knowledge generation concerning PrEP development and implementation research
- Implementation of LA CAB is de-centralised, delivered through community-led initiatives targeting PrEP underserved populations

Pillar three: to advocate for the affordability of LA-CAB regionally and globally

Actions to address this pillar include:

- Ensuring that price-setting of LA-CAB is established at levels that injectable PrEP is affordable (not least because of the added burden of additional clinic visits of oral PrEP)
- Ensuring access to generic LA-CAB that is priced comparable to oral PrEP

Pillar four: to challenge the social and structural barriers to the introduction of PrEP

Actions to address this pillar include:

- Ensuring that LA-CAB is made available in settings that are acceptable and accessible to those who are currently underserved in prevention settings
- Ensuring LA-CAB programs are built and informed by community needs
- Ensuring community counselling and linkages for adherence and consistent LA-CAB uptake

² Since the statement was drafted and signed on, on 20 September 2023, the EMA authorised the use of cabotegravir for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection in high-risk adults and adolescents, weighing at least 35 kg.
<https://www.ema.europa.eu/en/medicines/human/EPAR/apretude#:~:text=Apretude%20contains%20the%20active%20substance,as%20a%20prolonged%2Drelease%20injection.>

- Decriminalising populations in need of PrEP, including undocumented migrants, sex workers and drug users

All four pillars above should be implemented in parallel. LA-CAB has the potential to largely reduce HIV transmission in Europe. However, the real-world population level impact will depend on uptake of this new prevention method and its retention in care. Let's not repeat the delays accrued in the rollout of oral PrEP. The time to implement LA-CAB in Europe is now.

Signatories:

1. Women and Modern World Social Charitable Centre	Azerbaijan
2. Plateforme Prévention Sida	Belgium
3. Health without Borders	Bulgaria
4. Czech AIDS Help	Czechia
5. Positiiviset ry, HivFinland	Finland
6. AIDES	France
7. Gemeinnützige Stiftung Sexualität und Gesundheit GSSG	Germany
8. ANLAIDS Lombardia	Italy
9. Fondazione LILA Milano	Italy
10. LILA - Italian League for Fighting AIDS	Italy
11. AGIHAS	Latvia
12. Association of HIV affected women and their families Demetra	Lithuania
13. Fundacja Edukacji Społecznej	Poland

14. PREKURSOR Foundation	Poland
15. ARAS	Romania
16. Association SKUC	Slovenia
17. Adhara - Sevilla Checkpoint	Spain
18. APOYO POSITIVO	Spain
19. BCN Checkpoint	Spain
20. Metzineres	Spain
21. SIDA STUDI	Spain
22. Hivstigmafighter	The Netherlands
23. Red Ribbon Istanbul Association	Turkey
24. menZDRAV Foundation - Ukraine	Ukraine
25. aidsmap	United Kingdom
26. Brigstowe	United Kingdom
27. The Eddystone Trust	United Kingdom
28. METRO Charity	United Kingdom
29. LGBT Foundation	United Kingdom
30. The Love Tank	United Kingdom

31. National AIDS Trust	United Kingdom
32. Queen Mary University of London - SHARE Collaborative	United Kingdom
33. Safe Only	United Kingdom
34. Sophia Forum	United Kingdom
35. Terrence Higgins Trust	United Kingdom
36. Yorkshire MESMAC	United Kingdom
37. AIDS Action Europe	International
38. AVAC	International
39. Coalition Plus	International
40. European AIDS Treatment Group	International
41. ILGA-Europe	International
42. Life4me.plus to fight AIDS, Hepatitis C and Tuberculosis	International
43. MPact Global	International
44. International Planned Parenthood Federation - European Network	International
45. The Global Network of People Living with HIV GNP+	International
46. Transgender Europe	International