

The HIV Prevention Manifesto: we need PrEP now!

OPEN LETTER FROM HIV & LGBT EUROPEAN COMMUNITY ORGANISATIONS AND OTHER CONCERNED EUROPEANS TO PHARMACEUTICAL INDUSTRIES, EUROPEAN AND NATIONAL INSTITUTIONS

Background

In recent years, there has been considerable debate about the role that antiretroviral drugs (ARVs) could play in combined HIV prevention strategies. One way of using them is as pre-exposure prophylaxis (PrEP); this involves the use of specific ARVs to reduce the risk of infection in HIV-negative people who are exposed to HIVⁱ. In 2012, the US Food and Drug Administration (FDA) announced its approval of daily oral tenofovir and emtricitabine (Truvada(R)) for PrEP. In Europe, this combination is not available for prevention except to people enrolled in scientific studies.

Recently, two major European scientific studies, the English PROUD trialⁱⁱ and the French IPERGAYⁱⁱⁱ trial, reported the highest effectiveness rates yet seen in studies of pre-exposure prophylaxis (PrEP) for HIV.

These results are ground-breaking. A European licence for a measure that was approved by the US Food and Drug Administration in 2012, and which is already being used by at least 12,500 people in the US, is overdue.

Some of the questions raised by a possible licensed use of ARVs for PrEP in Europe are complex. How will people be assessed for PrEP? Where and how will it be delivered? Who will pay for it? How do we align it with the specific situations of different affected communities? None of these issues are unmanageable and, given the additional opportunity for HIV prevention and sexual health that PrEP is opening up, questions around its implementation and impact deserve an open discussion between communities affected by the HIV epidemic, health professionals, policy-makers and the companies producing the ARVs used for PrEP. Meanwhile, steps must be taken to make PrEP available.

This call from HIV and LGTB community organisations in Europe to both public health authorities and pharmaceutical companies is released as part of efforts to improve HIV prevention, sexual health and health seeking behaviour among gay men and other men having sex with men who are at risk of HIV infection.

As European community-based organisations we publicly raise the following points:

- The number of new HIV infections in Europe continues to increase, particularly among key populations (men who have sex with men, people in prison, people who inject drugs, sex workers, transgender people and migrants among others).
- We need to improve the HIV prevention tools and strategies for the key populations at increased risk for HIV acquisition.
- We need to have additional prevention tools and to develop strategies combining them. This is the only way to end the HIV pandemic^{iv}.
- The effectiveness of PrEP has been proven in high-quality randomised studies, in Europe; they show that PrEP dramatically reduces the risk of HIV transmission^{v,vi,vii}.

- PrEP is needed in Europe now and we are demanding it. The PROUD and IPERGAY studies and other community-based research show that there is demand for PrEP from people at high risk for HIV.
- There already exists some informal use of PrEP. This informal use lacks adequate medical follow-up. Key populations need to choose if they want to use PrEP, and do it safely^{viii,ix,x}.

We call on all stakeholders to make PrEP available and accessible in Europe:

- We ask that Gilead, the manufacturers of Truvada®, to immediately file for a PrEP indication for Truvada® to the European Medicines Agency (EMA). We ask the EMA to clarify the regulatory pathway for access to PrEP.
- We ask that pharmaceutical companies work with independent researchers to conduct implementation research on PrEP as part of programmes to make it available. PrEP must be effective, safe and easy to use.
- We ask the European Centre for Disease Control and Prevention (ECDC) to initiate a working group on European PrEP guidelines. This group should include civil society and clinical organisations. These guidelines should:
 - Help define when PrEP provides most benefit;
 - Address access across Europe;
 - Define a follow-up protocol for people taking PrEP.
- We ask European governments to examine ways to make PrEP reimbursable for those who need it.
- We demand that PrEP is integrated into a wider and holistic sexual health strategy, which should also include counselling, testing, treatment and vaccination for STIs, condom and lubricant provision, post-exposure prophylaxis and self-support groups. No single prevention method should set in competition with others.

The successful implementation of combination HIV prevention needs evidence and evidence-based strategies and scientific and civil society organisations need to work together to provide them. Key populations need up-to-date information on new choices in order to take the best decisions to improve the quality of their health, happiness and social efficacy.

NATIONAL SIGNATORIES

Belgium

1. Çavaria
2. Ex Aequo
3. Plate-Forme Prévention Sida
4. Sensoa

Bosnia and Herzegovina

5. NGO Action Against AIDS

Croatia

6. Iskorak - Centar za prava seksualnih i rodnih manjina
7. Association Lux Vitae, Pula

Czech Republic

8. Czech AIDS Help Association

Denmark

9. AIDS-FONDET

Estonia

10. The Estonian Network of PLWH

France

11. Act Up-Paris

12. AIDES

13. Nous sommes PrEP

Finland

14. Positiiviset ry, HivFinland

Germany

15. Deutsche AIDS Hilfe

16. Gemeinnützige Stiftung Sexualität und Gesundheit (GSSG)

17. Nicholas Feustel, Georgetown Media

Greece

18. Centre For Life

19. Positive Voice

20. Praxis

Hungary

21. Civil AIDS Forum

22. Hatter Society

Italy

23. Associazione Radicale Certi Diritti

24. Circolo di cultura omosessuale Mario Mieli

25. LILA

26. Nadir

27. Plus Onlus, Italy

Latvia

28. Apvienibahiv.lv

Lithuania

29. Demetra, Association of HIV affected women and their families

Macedonia

30. Hera

Norway

31. HIV Norway

Poland

32. Siec Plus

Portugal

33. ActiBlstas
34. AMPLOS - Associação de pais e mães pela liberdade de orientação sexual e identidade de género

35. APF - Associação para o Planeamento da Família
36. GAT
37. ILGA -Portugal
38. Não Te Prives
39. Opus Gay

40. Panteras Rosa
41. Poly Portugal
42. PortugalGay.pt
43. Rede ex aequo

44. Trombeta Bath

Serbia

45. AS - Center for the Empowerment Youth of people who are living with HIV and AIDS
46. Gay Straight Alliance

47. Hestija

48. Lawyers' Committee for Human Rights

49. Nova +
50. Q Club
51. Union of organizations dealing with protection of people living with HIV and AIDS (USOP)

Slovenia

52. Association SKUC

Spain

53. ACATHI, Associació Catalana per ala Integració d'Homosexuals, Bisexuals i Transsexuals Immigrants

54. Adhara
55. Afirmat
56. Apoyo Positivo
57. Coordinadora Asociaciones VIH SIDA, CALCSICOIVA

58. El Foro Español de activistas en tratamientos del VIH (FEAT)
59. La Fundació Enllaç
60. Fundació Lluita contra la sida
61. Hospital Universitari Germans

62. Fundación 26 de Diciembre
63. Grup d'Amics, Gais, Lesbianes, Transsexuals i Bisexuals (GAG)
64. Planet Salud
65. Projecte dels NOMS-Hispanosida
66. Grupo de Trabajo sobre Tratamientos del VIH (gTt-VIH)

67. ICV, Iniciativa per Catalunya Verds

Switzerland

68. Positive Council

United Kingdom

- 69. Beyondpositive
- 70. GMFA the Gay Men's Health Charity
- 71. International HIV Partnerships
- 72. National AIDS Trust
- 73. ReShape
- 74. UK- Community Advisory Board

Turkey

75. Positiv Living Association

INTERNATIONAL SIGNATORIES

- 76. AIDS Action Europe
- 77. AIDS Foundation East-West
- 78. Coalition Plus
- 79. Eastern Europe and Central Asia Union of People Living with HIV
- 80. European AIDS Treatment Group
- 81. HIV Justice Network
- 82. International Planned Parenthood Federation
- 83. NAM-AIDSMAP
- 84. Network of European Low Prevalence countries NELP
- 85. WECARe +

END NOTES

- ⁱ See <http://www.prepaccess.org.uk/>
- ⁱⁱ www.proud.mrc.ac.uk/
- ⁱⁱⁱ www.proud.mrc.ac.uk/
- ^{iv} Transformation of HIV from pandemic to low-endemic levels: a public health approach to combination prevention; Alexandra Jones et al. *The Lancet* - 19 July 2014 (Vol. 384, Issue 9939, Pages 272-279) DOI: 10.1016/S0140-6736(13)62230-8
- ^v Grant RM et al. Results of the iPrEx open-label extension (iPrEx OLE) in men and transgender women who have sex with men: PrEP uptake, sexual practices, and HIV incidence. 20th International AIDS Conference, Melbourne, abstract TUAC0105LB, 2014.
- ^{vi} PROUD study statement. PROUD study interim analysis finds pre-exposure prophylaxis (PrEP) is highly protective against HIV for gay men and other men who have sex with men in the UK. (16 October 2014). <http://www.proud.mrc.ac.uk/PDF/PROUD%20Statement%20161014.pdf> (PDF)
- ^{vii} IPERGAY press statement. Un grand succes dans la lutte contre le VIH./SIDA. Un médicament pris au moment des rapports sexuels réduit efficacement le risque d'infection. (29 October 2014). <http://www.ipergay.fr> Press release (English version) IPERGAY October 2014: <http://i-base.info/wp-content/uploads/2014/10/Press-release-IPERGAY-october-2014.doc> (Word.doc)
- ^{viii} Knowledge, Willingness And Intention To Use Pre-Exposure Prophylaxis - Prep - In France (2014). Preliminary Results From A Community-Based Survey; Trenado E. at al, HIV Research for Prevention conference, Cape Town, 28-31 October 2014; Poster LB, P19.07 LB.
- ^{ix} Would you use PrEP? Results from a national survey among MSM in Italy; Corbelli et al. <http://www.plus-onlus.it/ricerca-plus-useresti-prep/>
- ^x Prospective Attitudes to HIV-Pre-Exposure-Prophylaxis (PrEP); The Sigma Research: http://www.sigmaresearch.org.uk/files/Sigma_Panel_INSIGHT_BLAST_6_PreExposure_Prophylaxis.pdf