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the Health Programme  
of the European Union



# Policy Paper on Access to PrEP in the EU/EEA Countries

## Introduction

Pre-exposure prophylaxis (PrEP) with the use of oral antiretroviral medication<sup>1</sup> is a highly effective, evidence-based HIV prevention tool. Oral PrEP does not only reduce the risk of acquiring HIV, it also provides a certain level of flexibility, freedom and control over one's sexual life and HIV prevention choices.<sup>2</sup> Moreover, rolling out PrEP programs as a part of HIV combination prevention includes sexual and other health function monitoring services that have the additional benefit of linkage to treatment and care.

## Global Political Commitments and HIV Targets

Despite its high clinical efficacy, practical efforts to expand the use of oral PrEP face challenges worldwide. The world did not meet the 2020 targets of the "2016 Political Declaration on HIV and AIDS".<sup>3</sup> The PrEP related target set by UNAIDS was not met either.<sup>4</sup> Subsequently, a new set of political documents reaffirmed the goal of strengthening the HIV response globally in order to end the AIDS epidemic by 2030 (SDG 3).<sup>5</sup> The international community committed in the "Political Declaration on HIV and AIDS: Ending Inequalities and Getting on Track to End AIDS by 2030" to ensure the availability of pre-exposure prophylaxis (PrEP), and specifically defined that by 2025, 95% of people at risk of HIV infection should have access to effective combination prevention.<sup>6</sup> "The Global AIDS Strategy 2021–2026" focuses on reducing the inequalities that drive the AIDS epidemic and calls on states to guarantee that 95% of people at risk of HIV use combination prevention.<sup>7</sup> All the above-mentioned documents acknowledge that in order to meet these targets and address the inequalities it is necessary to safeguard the fundamental human rights of people living with HIV (PLHIV), as well as key populations.

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1 The most commonly used combination is tenofovir (TDF) and emtricitabine (FTC).

2 UNAIDS, Pre-exposure prophylaxis, Questions and answers, 2015.

3 Political Declaration on HIV and AIDS: Ending Inequalities and Getting on Track to End AIDS by 2030

4 Note: target of 3 million people having access to PrEP by 2020. UNAIDS, World AIDS Day Report, 2020,

5 Sustainable Development Goals (SDGs), Goal 3, Target 3.3: By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases

6 Political Declaration on HIV and AIDS (A/RES/75/284)

7 Global AIDS Strategy 2021–2026

## International Human Rights Framework<sup>8</sup>

Several international human rights treaties define states' obligations and principles that are especially critical for people living with or being at risk of HIV, such as the right to freedom of movement, the right to work, freedom from cruel, inhuman or degrading treatment, the principles of non-discrimination and equality, the right to health, and others. The right to health, as defined by Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) is one of the most central and unquestionable human rights provisions. Notably, the majority of countries in the world including all EU/EEA Member States have signed and ratified the ICESCR.<sup>9</sup>

In particular, Article 12 of the ICESCR obliges States to ensure the right of everyone to the enjoyment of the highest attainable standard of health. Furthermore, Article 12.2 (c) of the ICESCR recognizes that for the full realisation of this right, States must take steps necessary for the prevention, treatment and control of diseases, and promote social determinants of health and gender equity. Therefore, international human rights law requires the provision of PrEP as part of HIV combination prevention, and provides guidance on how to implement this obligation.

In line with the authoritative interpretation of the ICESCR's treaty body, the right to health requires States to guarantee the availability, accessibility, acceptability and quality of health services and goods. Additionally, it incorporates the principles of non-discrimination and equality for all sections of the population, especially vulnerable marginalized groups.<sup>10</sup>

States are specifically obliged under international human rights law to respect, protect and fulfil the right to health. The obligation to respect means that States must refrain from denying or limiting equal access to goods or health services for all people. The obligation to protect entails taking legal and other measures to ensure equal access to health services, and make sure that third parties do not limit access to those services. The obligation to fulfil requires states to recognize health access through their national policies with a detailed plan for implementation.<sup>11</sup>

## European Union (EU) and its Member States

On the one hand, a legally binding Charter of Fundamental Rights of the European Union guarantees all EU citizens the right to access health care as well as prohibition of discrimination. National public health policies and systems, on the other hand, lie within the jurisdiction of the member states.

The EU/EEA countries have been facing a gradual decline in the annual number of new HIV diagnoses in over the last decade. However, there are significant discrepancies in the burden of new HIV infections between countries and key populations.<sup>12</sup> The findings of the Rapid Assessment on Access to PrEP conducted by AIDS Action Europe in 2022 support the preceding statement.

## Key Findings of the Rapid Assessment on Access to PrEP in the EU/EEA

In the EU/EEA, twelve countries have no reimbursement scheme for PrEP. In some of these countries, out-of-pocket expenses are not only limited to PrEP medication but also extend to the costs of doctors' visits for prescription, and/or testing and diagnostics. Such a situation only exacerbates health inequalities within the EU.

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8 The current paper primarily focuses on the "hard law"

9 OHCHR, Status of Ratifications <https://indicators.ohchr.org/>

10 General comment N° 14 (2000) E/C.12/2000/4

11 General comment N° 14 (2000) E/C.12/2000/4

12 ECDC, Monitoring HIV pre-exposure prophylaxis programmes in the EU/EEA

People living in countries where PrEP costs are not reimbursed frequently order it online through unofficial channels because it is more expensive in local pharmacies, which ultimately leaves them outside of the relevant healthcare continuum and prevents them from receiving necessary medical checks. When PrEP medication is purchased unofficially online, there are no safeguards in place to ensure security of supply or quality control.

PrEP related services often remain excluded from public health insurance coverage because national governments or public health authorities do not regard them as a part of HIV combination prevention. Even countries that fully reimburse PrEP medication through their public health systems may not have the adequate capacity to meet the needs of key populations or have additional barriers in accessing to PrEP. For instance, these countries commonly have national guidelines that often restrict eligibility for PrEP as well as the scope of medical specialists who can prescribe it. Furthermore, only public healthcare providers are authorized to offer PrEP-related services. Stigma and discrimination experienced by gay and bisexual men and other men who have sex with men (GBMSM), transgender people, and sex workers in public healthcare settings often drive them away from seeking much needed services.

The prices for generic PrEP vary from 60€ to 271€ per box of 30 pills in the countries that fully reimburse PrEP medication, yet many of them pay more than 140€ per box. These high prices may influence the decision of public health authorities not to expand the accessibility of PrEP as well as on future health expenditures, while also being a sign of unjustifiably high prices negotiated by some pharmaceutical companies.

## Conclusion

There is a wide consensus among researchers and medical experts, communities affected by HIV, NGOs, and international organisations that the rollout of oral PrEP must be accelerated in all countries worldwide. This should be done not only to achieve the global or EU HIV prevention targets but also because it has the potential to reduce inequalities and improve the quality of life and health outcomes for key affected populations.

The design, the provision, and the implementation of PrEP and PrEP-related services are not purely medical or public health matters, and their success depends on the level of fulfilment of human rights obligations by states and the meaningful integration of principles of equality and non-discrimination into national legal and policy documents as well as their practical implementation.

## Policy Recommendations

All EU/EEA member states have ratified the ICERCS, thus they are legally obliged to guarantee access to HIV prevention services, including access to PrEP.<sup>13</sup> They must respectively ensure the availability, accessibility, acceptability and quality of PrEP medication and related services in a non-discriminatory way.<sup>14</sup>

In line with their international human rights obligations to respect, protect and fulfil the right to health, EU/EEA member states must:

- refrain from denying or limiting equal access to PrEP medication and PrEP-related services for all people, including undocumented migrants or people without insurance;
- implement legal and other measures to ensure equal access to oral PrEP medication and PrEP-related services;
- and recognize access to PrEP in their national policies with a clear implementation strategy.<sup>15</sup>

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13 ICESCR, Article 12.2 (c), General comment N° 14, para 16

14 ICESCR, Article 12, General comment N° 14, para 12

15 ICESCR, Article 12, General comment N° 14, para 33-37

All EU citizens are entitled to the right to access health care without any discrimination.<sup>16</sup> To prevent disparities in PrEP access across the EU, national governments must fulfil their responsibilities in the field of public health. In order to do that, countries like Austria, Bulgaria, Cyprus, the Czech Republic, Greece, Hungary, Italy, Latvia, Lithuania, Malta, Poland, and Romania that have no reimbursement scheme for PrEP are called on to include PrEP medications and PrEP-related services under the scope of public health reimbursement.

In order to improve the accessibility and acceptability of PrEP services in EU/EEA countries, it is urged to establish and promote low-threshold community-based and -led service delivery, with community-based organizations playing a direct role in PrEP services.

All EU/EEA member states are encouraged to work towards improving existing access to PrEP and are invited to:

- Review the pricing policy for PrEP medication and push for the lowering of prices
- Review national health policies with a goal to include PrEP and PrEP-related sexual health services as HIV combination prevention
- Review and define the gaps in the current availability and accessibility of PrEP and PrEP-related sexual health services for the community groups
- Remove financial and structural barriers related to access to STI/HIV testing, PrEP monitoring and doctors' visits
- Review national guidelines to make eligibility criteria for access to PrEP more inclusive
- Expand the list of medical practitioners that can prescribe PrEP
- Incorporate non-judgmental service delivery as a standard of care into the guidelines
- Scale up information campaigns on PrEP focused on foreign GBMSM, transgender people, women with migration background, heterosexual men and women through public and international support.

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<sup>16</sup> The Charter of Fundamental Rights of the EU, articles 21, 26, 35