UNAIDS PROGRAMME COORDINATING BOARD WORKING GROUP

THEMATIC SEGMENT:

Beyond 2025: Long-acting antiretrovirals: potential to close HIV prevention and treatment gaps

MEETING SUMMARY: SECOND MEETING OF THE WORKING GROUP

DATE: Tuesday, 4 November 2025

MEETING AGENDA

- Welcome and introduction
- Presentation of the first full draft of the Background Note and discussion
- Presentation of the draft agenda and discussion
- Next steps

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SUMMARY

1. Welcome and introduction

Mr. Morten Ussing, Director of Governance, UNAIDS Secretariat, opened the second meeting of the PCB Working Group on the thematic segment ***Beyond 2025: Long-acting antiretrovirals – potential to close HIV prevention and treatment gaps***. He welcomed the participants and thanked them for their contributions. He reminded participants that the main purpose of the meeting was to review and discuss the first draft of the Background Note that was shared with all ahead of the meeting and to provide steer and direction for necessary adjustments, as well as to review the draft agenda for the thematic day. This meeting would likely be the final meeting of the Working Group, with any additional comments to be submitted in writing within the following week.

Mr. Ussing recalled that the theme had been decided upon by the PCB following a Bureau-led process and highlighted that this PCB session will be a fully in-person meeting held in Brasilia, Brazil, with virtual participation enabled. The thematic day will run from 09:00 to 18:00, following the full-day format of the PCB. He underlined the importance of the Working Group's role in helping to prioritize discussion areas, as the thematic topic is broad enough for several days of deliberation. The Working Group's task is therefore to define the most strategic focus areas where the PCB can make the greatest difference.

He also emphasized the continued call for country case studies, which had been circulated to PCB members, permanent missions, and working group members on 22 October, with a reminder sent on 3 November. While the initial deadline was 7 November, he indicated it may be extended to ensure the inclusion of examples from all regions. He reminded participants that these case studies are valuable beyond the thematic segment, also informing World AIDS Day reports, the Global AIDS Update, and other UNAIDS publications.

2. Presentation of the first draft of the Background Note

Ms. Paula Auberson-Munderi, Head of Programme Innovation, Prevention, Treatment & Pediatrics at UNAIDS, introduced the draft Background Note, thanking the writer for her extensive work in developing the document and acknowledging the written feedback received from Working Group members. She noted that the first draft builds upon the annotated outline discussed during the initial meeting and that many of the key concerns raised earlier—such as community engagement, service integration, alignment with ongoing initiatives, the principle of choice, and addressing country-level barriers in the annotated outline discussed during the initial meeting and that many of the key concerns raised earlier— such as community engagement, service integration, alignment with ongoing initiatives, the principle of choice, and addressing country-level barriers — had been incorporated.

Ms. Auberson-Munderi explained that the document opens with a summary of trends in closing prevention and treatment gaps, which will be further refined to align with the forthcoming Global AIDS Strategy 2026–2031, expected to be presented to the 57th PCB meeting in December 2025 for adoption. It then reviews normative guidance and details of the products currently approved for marketing and use, while also presenting the development pipeline for long-acting products in the near- and medium-term future.

The Background Note includes a section on person-centered approaches, addressing both long-acting PrEP and long-acting treatment modalities. It also covers the delivery needs and system requirements for implementing long-acting interventions, drawing on WHO normative and implementation guidance related to service delivery and HIV testing.

Ms. Auberson-Munderi highlighted the section on pathways to equitable access, which uses the example of lenacapavir to illustrate the steps from innovation and clinical efficacy to registration, licensing, and financing. She noted that the concluding recommendations remain a work in progress but will ultimately evolve into actionable decision points for the PCB at its meeting in June 2026.

She invited Working Group members to provide comments on the balance and focus of the draft, particularly regarding whether it adequately reflects both long-acting PrEP and treatment, and whether it captures the current moment in the evolving field of access to long-acting antiretrovirals. She stressed that developments are moving rapidly. South Africa recently became the first country in Africa to register lenacapavir — and therefore it is critical that the background note remains current and relevant by December. She also encouraged members to comment on the balance between scientific precision and accessible language, ensuring that the document remains understandable for a broad PCB audience while retaining its technical accuracy.

Ms. Auberson-Munderi suggested that the recommendations might be structured according to the stakeholder spectrum, offering tailored guidance for different actors. She proposed categories such as recommendations for the Joint Programme, governments, communities and civil society, science and academia, and the private sector and innovation community. She invited members to suggest ideas for these recommendations, with the goal of producing a strong and actionable set of outcomes that could translate into PCB decision points in the immediate term.

She concluded her presentation by inviting Mr. Andy Seale, from the World Health Organization and co-lead of the thematic segment, to share his remarks on the Background Note. Andy acknowledged Ms. Michelle Rodolphe's participation, noting her contributions to the WHO's technical work on this topic.

Mr. Seale expressed appreciation to the writer for the excellent work in drafting the Background Note and confirmed that an initial WHO review had already been conducted. Responding to Ms. Auberson-Munderi's earlier question regarding the balance between prevention and treatment, he

noted that the current draft still leans more heavily toward prevention. He suggested that further expansion of the treatment dimension would be beneficial to ensure both areas receive equal attention within the paper. Mr. Seale will work to develop proposed language and provide additional input from WHO in the coming days.

He commended the Background Note for its strong and clear articulation of the lenacapavir case, which effectively illustrates the potential of long-acting antiretroviral technologies. However, he emphasized that the thematic segment should also encompass the broader pipeline of long-acting formulations, including those currently under development for both treatment and prevention. He noted that this scope should not be limited to injectable products, as innovation in oral long-acting formulations also holds considerable promise.

Mr. Seale cautioned that in some discussions, the terms “long-acting injectables” and “long-acting antiretrovirals” are used interchangeably, which can create confusion. He stressed the importance of maintaining a clear distinction between these concepts throughout the Background Note and the thematic discussions. Doing so, he said, would allow the Board to better appreciate the full range of technological and programmatic innovations shaping the HIV response beyond injectables alone.

He reiterated that the current draft represents an excellent foundation and provides a solid treatment of PrEP and lenacapavir, but could benefit from strengthening the treatment component and broadening references to other relevant initiatives. In particular, he recommended greater inclusion of the work of Unitaid, highlighting its significant contributions to value-chain development and market access for long-acting products, not only for lenacapavir but also for other forthcoming technologies in both prevention and treatment.

Ms. Michelle Rodolphe, WHO’s lead on long-acting PrEP and lenacapavir, thanked Mr. Seale for his remarks and the Secretariat for convening the discussion. She emphasized the importance of broadening the framing of long-acting antiretrovirals beyond injectables, highlighting that long-acting oral formulations also hold significant promise for the future. She noted that Merck and other companies have promising products in development, which should be acknowledged within the Background Note to reflect the diversity of innovations currently in the pipeline. Ms. Rodolphe indicated that she would share further information and references in writing to complement the group’s review.

She commended the writer for producing an “excellent and comprehensive draft” and confirmed that she was in the process of reviewing the document in greater detail. She observed that some sections — such as those describing testing regimens — may contain more technical detail than necessary for this type of policy-focused document. While emphasizing that she would defer to Mr. Ussing, Ms. Auberson-Munderi, and Mr. Seale on decisions regarding the appropriate level of technical depth, she suggested that the group consider streamlining certain sections to enhance readability and focus.

Turning to targets, Ms. Rodolphe noted that the Background Note references the goal of reaching 20 million people on PrEP by 2030. Drawing from the Global AIDS Monitoring (GAM) 2024 data, she recalled that 3.9 million people took PrEP at least once in the previous year. To achieve the 2030 target, she emphasized that the pace of progress must accelerate dramatically. She drew parallels with the “3 by 5” initiative launched two decades ago, observing that similar momentum and mobilization would be necessary to meet current prevention goals.

Ms. Rodolphe underscored that beyond meeting numerical targets, the central objective must remain to reduce new HIV infections. She stressed that this would require greater innovation,

particularly in service delivery models that are accessible, acceptable, and tailored to the needs of different populations.

She also encouraged the Working Group to consider the role of the private sector, noting that private entities have played a transformative role in condom social marketing and could contribute valuable experience and networks to expand demand for PrEP and other prevention options. She suggested that the Background Note include reflection on private sector engagement and demand generation strategies as key enablers for scale-up.

Ms. Rodolphe concluded by reiterating that whether the 20 million target is reached, the focus should remain on expanding coverage and impact, building sustained momentum, and reaching people who are currently left behind. She thanked colleagues once again and confirmed that she would provide additional written input in the coming days.

Ms. Susie McLean, speaking on behalf of the Global Fund to Fight AIDS, Tuberculosis and Malaria, thanked the UNAIDS Secretariat and the PCB for selecting such a timely and relevant theme, commending the Secretariat for positioning long acting antiretrovirals as a central discussion topic at this critical juncture. She expressed appreciation to the writer and the Secretariat and WHO for producing a strong and comprehensive first draft of the Background Note, which she described as an excellent foundation for further refinement.

Ms. McLean noted that her remarks were preliminary, as she had only begun to review the document, but she wished to flag several points for early consideration. She first underscored the importance of ensuring a clear connection between the Global AIDS Strategy 2026–2031 and the Global HIV Prevention Framework, stressing that alignment between these global frameworks is essential for coherence in policy direction and implementation. She echoed the earlier points raised by Ms. Michelle Rodolphe regarding the ambitious target of 20 million people on PrEP by 2030, and emphasized that, from a global financing perspective, these prevention targets are taken very seriously by the Global Fund.

Ms. McLean suggested that the thematic segment could benefit from centering part of its discussion around what it will take to reach the global prevention targets, highlighting the importance of identifying the financial, programmatic, and structural enablers needed to drive progress. She noted that, since the upcoming PCB will also coincide with the launch of the new Global AIDS Strategy, this alignment offers a timely opportunity to reflect progress and challenges toward meeting prevention goals.

She then raised an additional point concerning harm reduction, noting that while the focus of the thematic segment is on long-acting antiretrovirals, there is also significant ongoing work around long-acting buprenorphine[1] within the harm reduction field. Although not an antiretroviral, she explained, this long-acting formulation has transformative potential for people who use drugs, offering new models of service delivery and adherence support. She suggested that the Background Note could include a brief acknowledgment of the broader dimension of “long-acting” technologies and their implications for key populations.

Ms. McLean further welcomed the attention to prioritization and targeting within the draft, particularly the focus on geographic and population-level incidence as a basis for impact-oriented interventions. She emphasized that the Global Fund relies on UNAIDS and WHO for clear guidance on which

[1] See Unitaid guidance here.

populations and locations to prioritize in order to maximize prevention outcomes, and she appreciated that these elements were already reflected in the draft.

Finally, Ms. McLean echoed Ms. Rodolphe's call for innovation in service delivery, stressing that meeting ambitious prevention targets will depend not only on new biomedical tools but also on new delivery systems that reach people currently underserved. She noted that the Global Fund is actively exploring alternative service delivery models that expand access at lower cost and reach communities outside of traditional health service channels.

She encouraged the Working Group to consider showcasing examples of innovative delivery approaches and using the thematic segment to debate how such innovations could help scale up access to long-acting products. Ms. McLean concluded by confirming that the Global Fund had noted the proposed invitation to participate in the thematic segment and would coordinate internally — in particular with Dr. Izukanji Sikazwe, the new Head of the HIV Team at the Global Fund — to ensure appropriate representation at the meeting.

The writer of the Background Note thanked the participants for their detailed feedback and emphasized that her brief intervention was intended primarily as a clarification and request for further guidance from Working Group members. She referred specifically to the section on testing, which several participants had mentioned. She explained that the inclusion of this section — and the level of detail within it — was intentional, though perhaps understated in tone. The rationale, she said, was to acknowledge that in many contexts the community-based testing infrastructure that previously supported HIV prevention and linkage to care has been eroding or significantly weakened in recent years.

She further noted, with the guidance of the Secretariat, WHO and the working group that this decline in testing capacity has implications for the implementation of long-acting PrEP, as many of the systems and community delivery networks that once facilitated access may no longer be functioning at the same level. She included references to these issues in the Background Note in what she described as a "neutral but cautionary" manner — not to overstate the problem, but to recognize that some of the infrastructure once taken for granted may now require renewed attention and investment.

The Working Group was invited to consider how and where the document should reflect on these emerging ecosystem deficits — that is, the gaps in service infrastructure and delivery capacity that could constrain scale-up of long-acting ARVs — while ensuring that the paper does not become an exhaustive contextual analysis of the present moment.

Ms. Luciana de Melo Nunes Lopes, representing the Ministry of Health of Brazil, greeted participants and extended her congratulations to the Secretariat and the drafting team for the high-quality and detailed work reflected in the Background Note. She noted that the document clearly demonstrated significant effort and commitment, and she expressed appreciation for the inclusive and consultative approach of the Working Group.

Speaking from the access to medicines perspective, Ms. Lopes focused her intervention on the language used in the final section of the Background Note preceding the conclusions, particularly the portion addressing licensing and access barriers. She observed that the draft currently refers to "addressing license-related barriers to global access," but suggested that this framing might be too narrow.

She proposed instead that the document should refer more broadly to "addressing intellectual property (IP) or legal barriers to access", noting that licensing is only one of several strategies to

overcome IP constraints. Broadening the terminology, she said, would better capture the full range of mechanisms available to governments and stakeholders for expanding access to life-saving medicines.

Ms. Lopes also raised concerns about the way compulsory licensing is currently presented in the draft. She cited a section in which the text suggests that if a patent holder does not agree to broaden a voluntary license, an alternative could be the issuance of a compulsory license — but that this approach carries potential risks of economic sanctions or trade retaliation. While acknowledging that such risks exist, she cautioned that the current wording could be interpreted as discouraging compulsory licensing or portraying it as an undesirable measure to be avoided whenever possible.

She emphasized that compulsory licensing is a legitimate and recognized option under the World Trade Organization's TRIPS Agreement, and that it forms part of the TRIPS flexibility available to all countries. She therefore recommended that the language in the Background Note be adjusted to more clearly recognize compulsory licensing as a valid and lawful tool to promote equitable access, rather than as a last resort.

Ms. Lopes further suggested that TRIPS flexibility could be explored more extensively in the document. While the recommendations section does make reference to them, she noted that this perspective is missing from the earlier discussion on access pathways. Including these flexibilities earlier in the analysis, she said, would provide a more coherent and comprehensive framing of the legal and policy options available to countries.

She also pointed out that, as the document includes discussion of the development pipeline and specific references to ongoing partnerships such as the Medicines Patent Pool (MPP), it could usefully mention pre-grant patent opposition as another TRIPS-consistent mechanism. She explained that this allows stakeholders to challenge patents before they are granted, helping to ensure that future access barriers can be anticipated and mitigated at earlier stages. Ms. Lopes concluded by reiterating that a more balanced and inclusive treatment of licensing, IP management, and TRIPS flexibilities would strengthen the Background Note's section on access and align it more closely with international norms supporting equitable access to medicines.

Ms. Amrita Sarkar, speaking on behalf of the NGO Delegation to the PCB, expressed appreciation to Mr. Ussing and the Secretariat team for the inclusive process and constructive engagement with civil society representatives. She highlighted that, from the perspective of transgender communities, there remain some specific health-related concerns that merit more explicit consideration in the Background Note. In particular, she referred to the intersection between long-acting antiretroviral therapy (LA-ART) and gender-affirming care (GAC), noting that a significant proportion of transgender persons either currently receive or intend to receive gender-affirming healthcare, including hormone replacement therapy (HRT), gender-affirming surgeries (GAS), and mental health counselling.

She observed that these procedures and therapies may have clinical interactions or specific considerations for individuals who are also accessing long-acting ARV treatment or prevention. She therefore suggested that the Background Note include a reference to the healthcare needs of transgender people undergoing gender-affirming care, particularly where such processes coincide with ART or PrEP use. Explicitly acknowledging these unique medical needs, she said, would help ensure that the note is fully inclusive and reflective of diverse community realities.

Ms. Sarkar also conveyed that the NGO Delegation team had not yet had sufficient time to conduct a detailed review of the entire draft due to the short turnaround period, but she reaffirmed the

delegation's commitment to provide written comments within the requested deadline. She welcomed the Secretariat's reassurance that the final draft would maintain a stronger balance between global and national-level barriers, particularly regarding policy, legal, and access-related challenges faced by civil society and marginalized populations.

She concluded by thanking the Secretariat once again and confirming that further inputs from the NGO Delegation would follow in writing to ensure that the perspectives of communities most affected by HIV, including transgender persons, are comprehensively reflected in the final Background Note.

Ms. Michelle Rodolphe, provided an overview of significant country-level developments are expected soon. She stressed the value of including real-world implementation examples in the Background Note and thematic agenda. She cited Zambia's efforts under Professor Lloyd Mulenga, a key champion in PrEP, as a model of effective operationalization of new prevention tools. She concluded that developments in Eswatini, Zambia, and Botswana illustrate the growing momentum of long-acting technologies in Africa and should inform PCB discussions.

3. Presentation of the draft agenda and discussion

Ms. Paula Auberson-Munderi provided an overview of the proposed agenda for the day, noting that the working group had populated the schedule to guide discussion following the first session of keynote addresses. Keynotes are expected from the host country Minister of Health, a community member living with or vulnerable to HIV proposed by the NGO delegation, and the UNAIDS Executive Director.

Ms. Auberson-Munderi highlighted the next session, which will provide an overview of the Background Paper to set the scene, emphasizing the evidence base and transformative potential of long-acting antiretrovirals (LA-ARVs). She noted that Andy Seale would present in person, with Teresa Kasaeva offering a virtual presentation if needed.

She then outlined two panels. The first, Perspectives on Long-Acting Antiretrovirals, would feature Bruce Richman (Prevention Access Campaign) on treatment and prevention, a clinical lead from the Asia Pacific region on patient care and advocacy, a national program representative from Zambia on rollout experience, an access advocate (e.g., MSF Access), and Beatriz Grinsztejn, IAS President, on the role of science and community-driven innovation.

The second panel, Planning for Access, it is suggested to include advocacy (e.g., ABIA, Brazil), UNITAID, industry/private sector (e.g., Gilead, ViiV Healthcare), government programs (e.g., SANAC, South Africa), and funders (Global Fund), focusing on strategies to ensure equitable access to LA-ARVs. Ms. Auberson-Munderi concluded that these sessions and speakers will provide diverse perspectives on implementation, access, and innovation, ensuring that real-world experiences and practical insights inform the PCB discussions.

Mr. Andrew Seale emphasized the need for UNITAID representation in the second panel and supported the NGO delegation's role in proposing community speakers, suggesting Jeremy Tan as a potential candidate to ensure diverse regional perspectives. He highlighted the importance of allocating time for interventions from the floor, noting the participation of Latin American civil society as seen in previous PCBs.

Ms. Michelle Rodolphe stressed that access planning must address practical barriers, such as long waiting times for HIV testing in government facilities, noting that testing is a critical entry point for

prevention and treatment. She emphasized that community-based testing and accessible services should be included in the discussion on equitable access to long-acting ARVs.

Ms. Fionnuala Murphy outlined ongoing consultations with the CSAC to finalize speaker selections, noting the importance of including community-led delivery perspectives and voices from the Global South. She suggested that speakers such as Yvette Rafael or Anand Grover could bring unique insights on advocacy, access, and legal frameworks, and emphasized the need to balance regional representation and thematic coverage across both panels.

Ms. Paula Auberson-Munderi highlighted a gap in civil society representation on access to medicines and requested recommendations from Fionnuala and her colleagues for panel two, particularly from organizations active in the access chain, such as MSF Access and ABIA.

4. Next steps

Mr. Morten Ussing concluded the discussion by reiterating the Friday deadline for written input on the background note, agenda, and speaker proposals, and stressed the importance of offering multiple regional options to ensure balanced representation. He also highlighted a planned field visit to Brasilia to meet with members of Congress working on long-acting ARV access, linking it directly to the thematic agenda.

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