Agenda item 3

UNAIDS/PCB (58)/26.6

# FOLLOW-UP TO THE THEMATIC SEGMENT FROM THE 57TH PCB MEETING

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

UNAIDS

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**Additional documents for this item**: N/A

**Action required at this meeting—the Programme Coordinating Board is invited to**:

86. *Take note* of the background note (UNAIDS/PCB (57)/25.37) and the summary report (UNAIDS/PCB (58)/26.6) of the Programme Coordinating Board thematic segment on "Beyond 2025: Long-acting antiretrovirals—the potential to close HIV prevention and treatment gaps";

87. *Request* Member States, in collaboration with community-led HIV organizations and other relevant HIV-related organizations, with the support of the Joint Programme, to:

    a. Ensure the inclusion of long-acting antiretrovirals in the national HIV prevention and treatment monitoring framework, based on the global WHO guidelines and recalling the HIV prevention and treatment targets and goals of the Global AIDS Strategy 2026-2031;

    b. Promote equitable access to long acting antiretrovirals including through reaffirming the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) as amended, and also reaffirms the 2001 WTO Doha Declaration on the TRIPS Agreement and Public Health, which recognizes that intellectual property rights should be interpreted and implemented in a manner supportive of the right of Member States to protect public health and, in particular, to promote access to essential health tools for all, and notes the need for appropriate incentives in the development of new health products;

    c. Explore local and/or regional pharmaceutical manufacturing capacities and implement mechanisms to foster technology transfer on mutually agreed terms for long-acting products;

    d. Use pooled procurement mechanisms to support accurate demand forecasting and market shaping as well as improve national regulatory systems for continued and accelerated national regulatory approvals;

    e. Strengthen primary prevention ensuring that all effective prevention options are available to all, and integrate long-acting antiretrovirals into national health systems, both in national health facilities and through differentiated service delivery;

    f. Ensure equitable access to affordable and high-quality long acting antiretrovirals, including through ensuring an enabling legal and policy environment that effectively addresses HIV-related stigma and discrimination;

    g. Utilize the existing scientific evidence on U=U to address legal, socio-cultural and economic barriers that prevent people living with HIV from accessing and sustaining treatment and attaining the highest achievable quality of life;

    h. Provide support and resources to communities of people living with, affected by, or most at risk of HIV to increase community leadership across programme and policy design, implementation and accountability, including demand creation of long-acting antiretrovirals, acknowledging the role of communities in reaching HIV targets;

**Cost implications for the implementation of the decisions**: none

## Introduction and keynote addresses

1. The thematic session focused on recent innovations of long-acting ARV medicines and how rapid, equitable access to these medicines could close gaps in HIV prevention, treatment and care and advance the goal of ending AIDS as a public health threat.

2. The moderators for the session were introduced: Andy Seale, Global Coordinator and Technical Officer at WHO; and Paula Auberson-Munderi, Team Lead, Science, HIV Treatment & Pediatrics at UNAIDS. Mr Seale introduced the first speaker, Mariângela Simão, Secretary of Health and Environmental Surveillance, Brazil.

3. Ms Simão said long-acting technologies had a transformative potential when used in addition to existing, proven technologies. She noted, though, that implementation studies were needed to understand how well new technologies worked in real-life conditions, which were not the same as the controlled environments of clinical trials.

4. Brazil had about 150 000 people using oral pre-exposure prophylaxis (PrEP) and expected to double that number by end-2026, she said. Technical evidence indicated that, with high enough coverage, PrEP would contribute to a decline in new HIV infections, but she cautioned against relying on a single approach. In public health, there were no “silver bullets”, she said. She also reminded that while efficacy of a tool may be high, actual impact in real-life settings required that people who need the tool could actually access and use it. Affordable prices therefore mattered.

5. Long-acting antiretrovirals (ARVs) for prevention should be an additional choice in the prevention package, Ms Simão said. She advised against narratives that oppose daily oral PrEP to long-acting versions: they were complementary and both effective. Noting that two long-acting ARVs for PrEP were in the global market, she said it was necessary to discuss demand generation; address how research and development incentives were being set up; and deal with intellectual property issues that affect long-term access to these technologies. It was also important, she said, to examine ways to increase investments in products that lack investment because they do not seem to be profitable enough for companies. That related not only to HIV and neglected tropical diseases, but potentially also to an HIV cure. Finally, she said it was crucial to increase local production of essential medicines.

6. Yvette Raphael, co-founder and co-director of Advocates for Prevention of HIV and AIDS, South Africa, paid tribute to the activists and organizations who were holding governments and advisory boards accountable by using tools like the Choice Manifesto and the People's Research Agenda. Evidence from Africa showed that community-led actions tailored interventions to people’s real needs, increased uptake of HIV services, reduced stigma and improved health outcomes, she told the meeting. Community-led organizations were trusted by communities.

7. Integrated actions were more effective and efficient for addressing co-occurring needs and morbidities, she said. Community involvement in designing and delivering integrated services ensured that they were people-centered and context-appropriate. Throughout, it was vital to use a human rights lens and ensure equity: the HIV response must be rooted in rights and must tackle punitive laws and gender and other inequalities, she insisted.

8. Ms Raphael said that long-acting innovations had the potential to transform the AIDS epidemic in Africa and globally. However, rapid and equitable rollouts would depend on community understanding, acceptance and readiness. Communities should be engaged as partners in shaping demand, dispelling myths and ensuring that the innovations reach those who need them. She underscored the need to prioritize community and youth leadership, integrated service delivery and rights-based, gender-

sensitive approaches.

9. Winnie Byanyima, Executive Director, UNAIDS, reiterated that AIDS was not over, but said the HIV response could be in a radically different position by 2030 if it achieved wide, equitable access to long-acting ARVs for prevention and treatment.

10. She said that once-a-month oral PrEP tablet was in late-stage trials; long-acting, twice-monthly injections of cabotegravir were already available and trials were underway for a version that would be administered only three times a year; the first doses of injectable lenacapavir, which is administered once every six months, had already arrived in Eswatini and Zambia; and trials for a once-per-year dosage of lenacapavir had begun. These innovations were a prevention option for people for whom current options were not ideal; this was the closest the world had come to a vaccine for HIV, she said.

11. Ms Byanyima said she was grateful to the pharmaceutical companies which had developed long acting ARVs, but added it was vital that the innovations reach everyone who needs them. She briefly discussed ViiV Gilead's licensing of local production but said more could be done to expand access. For example, in Brazil, where lenacapavir for PrEP had been trialed, there was no reliable timeline yet for achieving affordable access, she said. Like much of Latin America, Brazil had been excluded from the generics agreement and a realistic price for lenacapavir was not yet on offer. She reminded the Board that Brazil had proposed a coalition for local and regional production of medicines at the previous meeting of the G20.

12. It was also necessary to increase demand for, and investments in innovations. Purchasing them at scale would also reduce prices, she said and noted that Unitaid and the Gates Foundation had secured a price of US$ 40 per person per year for lenacapavir for PrEP, and that evidence showed sufficient demand could lower that to US$ 25 per person per year.

13. She said the model of tiered pricing had shown that monopolies were not the only way to reward innovation, that technology sharing did not destroy profits, and that generic competition and licensing benefited everyone involved. She told the meeting that if the approaches used for HIV technologies in years past had been applied during the COVID-19 pandemic, the mRNA technologies could have been licensed to capable producers around the world, virus variants would have been controlled, the lockdowns would have ended sooner, trillions of dollars would have been saved, and the pharmaceutical companies would still have made billions of dollars in profit. The HIV model allowed for both profits and saving lives.

14. Ms Byanyima stressed that civil society was key for raising demand and enforcing accountability. UNAIDS modeling showed that the world needed to have 20 million people on PrEP, 13 million of them on long-acting PrEP, to reach the global AIDS targets. Noting the absence of plans for generic production of these innovations in Africa, where the need was greatest, or in Latin America, she urged all stakeholders to ensure that long-acting ARVs reach everyone who needs them.

## Session overview

15. This session focused on current evidence for the transformative potential of long-acting ARVs and the enablers and barriers to equitable, affordable access.

16. Tereza Kasaeva, Director, Department on HIV, Tuberculosis, Hepatitis and Sexually Transmitted Infections at the World Health Organization (WHO), said that life-long adherence to treatment was challenging and coverage of effective prevention interventions was falling short. However, the evidence indicated that rapid introduction

of long-acting tools could dramatically change the HIV response. She explained that five long-acting agents were now available. WHO had recommended injectable cabotegravir for PrEP in 2022 and had endorsed cabotegravir and rilpivirine for HIV treatment in July 2025. Lenacapavir had been approved for PrEP in 2025 and had been pre-qualified immediately. This showed how quickly stakeholders can work together, Ms Kasaeva said.

17. Long-acting agents could address ongoing hindrances such as pill fatigue, adherence difficulties, stigma and the daily burdens of HIV management, she said, and they were safe, effective and acceptable. Research suggested that about 60% of users may prefer injectables, potentially reaching 13 million users by 2030, she said. For lenacapavir in high-incidence settings, modeling suggested that coverage of 2–5% could reduce HIV incidence by 25–45% over the next decade. That required integrating it into comprehensive, person-centred packages alongside oral PrEP, condoms, harm reduction and gender-transformative, community-led programmes.

18. Access in low- and middle-income countries was still almost non-existent, however. Ms Kasaeva warned of a risk that long-acting ARVs could be regarded as a “luxury”, similar to the way in which ARVs had been portrayed in the mid-1990s. For lenacapavir, current manufacturing capacity could meet demand for up to 7.5 million people by 2028, yet the current target was to reach only about 2 million people in low- and middle-income countries.

19. Prices in high-income countries ran to the tens of thousands of dollars. This was not just a “market issue”: it tested the commitment to solidarity, shared responsibility and the right to health, she said.

20. Ms Kasaeva insisted that national guidelines, regulatory pathways and monitoring must support a mixed delivery approach for long-acting ARVs, based on national context and demand. Long-acting PrEP should be integrated in WHO-recommended packages and delivered through differentiated models, and target setting must reflect projected demand and manufacturing capacity, which can be revised as markets expand and generic products become available. Gender-transformative, human rights-based approaches were essential for achieving sufficient uptake and adherence, she said.

21. Experience showed that markets can be shaped in the public interest, she said. Public health-oriented intellectual property management, TRIPS flexibilities, accelerated regulatory approvals, pooled procurement and local manufacturing, along with technology transfers and cold chain investments, should be used to reduce prices and increase access, and financing must be mobilized for those actions, she advised. Making the most of long-acting ARVs required quick, joint actions and strong collaboration between governments, civil society, industry and global health institutions.

22. Mary Mahy, Director for Data for Impact Practice at UNAIDS, said approximately 40.8 million people were living with HIV in 2024, but 9 million of them were not on treatment and 11 million were not virally suppressed. She said there had been about 1.3 million new infections and 630 000 AIDS-related deaths in 2024 despite the existence of effective treatment. The current situation was likely considerably worse due to the funding cuts and service disruptions of 2025.

23. In addition, she said viral suppression levels were still too low, especially for children and men. Recent studies showed that about 80% of people were retained on treatment 12 months after having started treatment. Long-acting ARVs could improve treatment retention and reduce AIDS-related deaths by about 19% over ten years, she said, referring to other recent study findings.

24. Regarding prevention, Ms Mahy said HIV infections were still increasing in some regions, especially among key populations in several countries. The target had been to attain a little over 21 million people with oral PrEP users by 2025 yet only 3.9 million people had used PrEP at least once in 2024. While uptake had increased, mostly in eastern and southern Africa, continuation of use was low, with one study showing 65% retention among gay men and other men who have sex with men after 12 months and another showing 34–62% retention among postpartum women after only one month. It was clear that oral PrEP was not an ideal option for everyone, she told the meeting.

25. She said a UNAIDS study had found that if lenacapavir were used by the 5% of people at highest risk for HIV in high-burden countries, it could avert 25–35% of new infections over 10 years. In concentrated epidemics, if lenacapavir reached 60% of key populations (about 2% of the total population), it could avert 45% of new HIV infections. Programme managers would have to consider how all prevention options could be made available to the populations who are most in need, she noted.

26. Lenacapavir also held promise for pregnant and breast-feeding women, Ms Mahy said. She explained that many new HIV infections in children were occurring where mothers seroconverted while pregnant or breast-feeding or where mothers stopped taking antiretroviral therapy (ART). Lenacapavir could help in those situations. To reach the 2030 AIDS targets, it was necessary to reach 90% of people in need of prevention with effective, appropriate prevention options. The aim therefore was to reach about 20 million people at high risk of HIV infection with ARV-based prevention, including having 13 million people using long-acting PrEP.

27. Ms Mahy said that having options for effective and accessible treatment and prevention was critical. Communities should help build demand and design programmes that can achieve epidemiological impact with these long-acting agents. While reiterating that these innovations were not a “silver bullet”, she said they could help reach prevention goals and change individuals’ lives for the better. That, however, also required reducing the cost of long-acting agents to they can be used at an impactful scale.

28. Speaking from the floor, members and observers thanked participants for the insightful presentations. They said that pharmaceutical innovations had helped bring the world closer to ending AIDS, but unequal access to medicines still stood in the way. Long-acting medications were potentially revolutionary tools, but they had to be accessible to everyone who needs them, including people who use drugs, they said.

29. Speakers applauded the Global Fund and PEPFAR for committing to provide these medicines to two million people over the next three years and said that the first deliveries of lenacapavir had arrived in Eswatini and Zambia. However, they reminded that Gilead had production capacity for 2.5 million doses *per year* if sufficient orders were placed and called for greater ambition. A robustly funded Global Fund and PEPFAR were needed to boost momentum and reach the scale and equity that could achieve impact.

30. Speakers noted that several middle-income countries were still excluded from generic licensing arrangements for lenacapavir, which compromised their HIV responses. Equitable access required reduced prices and expanded generic production, they said: countries must be able to scale up local production, improve supply chains and achieve affordable prices. It was unreasonable to assume that middle- and high-income countries (where about 40% of new HIV infections were occurring) could achieve the required access and uptake at the current high costs. They reiterated that evidence showed that lenacapavir could be manufactured at scale for about US$ 40 per person per year while still generating reasonable profits for producers. Presenters

were asked for further information regarding the return of investment for new long-acting ARVs and the scope for social enterprises to be involved in their rollout.

31. Speakers called for a balanced process that preserves incentives for innovation while enabling equitable access to new technologies in public health programmes. It was suggested that the next Political Declaration should include a statement in support of equitable access to generic medicines.

32. A speaker asked whether long-acting generic ARVs produced in Egypt would have low-tariff access in the rest of Africa, and said the African Union, Africa Centres for Disease Control and Prevention, and other regional bodies should be working together to expedite wider access to these long-acting medicines. Another speaker urged that access to life-saving medicines be separated from geopolitical conflicts and the use of unilateral coercive measures.

33. In reply, Ms Kasaeva thanked the speakers for their remarks and said that WHO would continue to assess the evidence, update guidelines accordingly, and provide technical support as requested. She agreed with speakers that communities must be involved in building demand, which also would help drive down prices. The lenacapavir situation showed the need for a much stronger focus on primary prevention and for ensuring that all effective prevention options are available. She assured speakers that the needs of the most vulnerable communities, including people who use drugs, were not being forgotten. For example, WHO had recently updated guidance on opioid agonist maintenance therapy and syringe distribution programmes, which would be published soon.

34. Replying to a question, Ms Mahy said a quantified return on investment was not yet available, though the need for further price reductions was clear. In the meantime, the focus should be on providing all relevant prevention options to the people who need them.

35. Ms Raphael called for greater access and affordability, with time-bound commitments, and said long-acting ARVs must be integrated into national health systems from the outset.

## Panel 1: Perspectives on long-acting antiretrovirals

36. Speakers discussed the policy and programme implementation experiences of people at risk of, or living with HIV, and of decision-makers. A short video was screened depicting the experience of a young woman in Zimbabwe who was using PrEP.

37. Bruce Richman, founding Executive Director of Prevention Access Campaign in the United States of America, discussed the undetectable = untransmissible (U=U) concept and said it was a liberating fact that people with undetectable levels of HIV cannot transmit HIV to others. When people learned about U=U, a range of outcomes improved, including increased testing, improved treatment adherence and higher levels of viral suppression. U=U showed that investing in sustainable treatment and care HIV ultimately benefitted everyone, he said.

38. Long-acting treatment could be transformative, he told the meeting. Taking ARVs each day could be a challenge, he said, especially for people facing stigma, criminalization and other barriers. Long-acting agents potentially addressed those challenges and promised an era of convenience, privacy, safety, normalcy and freedom for people living with HIV.

39. He said four actions could ensure that long-acting treatment helped people reach and

sustain U=U. Firstly, U=U should be central to people's understandings of HIV treatment. Secondly, people living with HIV should be partners in the design, delivery and monitoring of the rollout of long-acting treatment to ensure relevancy, equity and accountability. Thirdly, transparent and trustworthy information should be provided on long-acting treatment to ensure informed choice, uptake and adherence. And fourthly, access and affordability should be prioritized by addressing structural, legal and policy barriers, especially for marginalized and vulnerable populations, and by implementing public health-driven intellectual property management and procurement.

40. Lloyd Mulenga, national HIV Programme Coordinator for the Ministry of Health in Zambia, said that Zambia had started using long-acting cabotegravir in early 2024 and had recently introduced lenacapavir (500 doses had been received). It expected to receive about 240 000 doses of lenacapavir from PEPFAR and about 44 000 doses from the Global Fund. One of the lessons was that communities must be at the centre of policymaking and the rollout of these ARVs, he said, and policymakers should be cautious about reserving long-acting agents—whether for prevention or treatment—only for certain populations. He reminded, though, that funding for community responses was declining, which would affect efforts to use these long-acting tools effectively and equitably.

41. Veriano Terto, Vice-President of the Associação Brasileira Interdisciplinar de AIDS in Brazil, discussed the perspectives of Brazilian civil society. He said it was a difficult time to sustain and expand HIV programmes in countries in the South. Regulatory systems for intellectual property enabled product monopolies to be established, which affected equitable access to health technologies. He reminded that Brazil and other countries in Latin America were excluded from the licensing agreement for lenacapavir, even though new HIV cases were increasing. He urged countries to unite to resist the use of patents and unfair commercial agreements that damage public health and said there were possibilities in the TRIPS agreement, like compulsory licensing, for achieving fairer access, technology transfers and affordable prices. Those flexibilities should be used. An intersectoral approach was important for achieving political solutions that can reduce or remove unfair commercial barriers, he added.

42. Beatriz Grinsztejn, President of the International AIDS Society, said that even though HIV science was stronger than ever, inequalities in access had rarely been wider. The huge potential of long-acting ARVs could only be realized if the tools reach the communities who need them the most, she stressed.

43. Long-acting agents were not a "silver bullet": stigma, discrimination and social and economic inequities continued to shape access to HIV tools and retention in care, she said. But these options could expand feasibility and choice. It was important to gather evidence on how they work in real-world circumstances, she said and mentioned the ImPrEP study in Brazil, one of the few studies evaluating real-world implementation of lenacapavir. This work was vital to guide national scale-ups.

44. Ms Grinsztejn reminded that the epidemic in Latin America was highly concentrated among key populations who face major social and legal barriers; long-acting agents could be very useful in those contexts. However, current licensing concessions were limited and many middle-income countries were still excluded from generic access agreements for long-acting ARVs. She called for a broader and more equitable approach to voluntary licensing, pricing and supply of long-acting agents: innovation without access was not progress, she said.

45. In addition, she stressed that cuts to HIV programmes were a major threat. They would lead to delayed regulatory submissions, stalled procurement, underfunded community

programmes and weakened implementation capacity. But she also reminded that HIV responses were driven not only by science but by community leadership, activism and human rights. Referring to the continued criminalization of key populations, attacks on transpeople's right to health, increasing violence and discrimination, and shrinking civic space, she said rollout strategies would fail if people feared arrest or discrimination when seeking services. Protecting human rights was not an accessory, but a prerequisite for success.

46. Ms Grinsztejn highlighted the importance of investing in systems that enable implementation and of integrating long-acting options into routine care, both in standard health facilities and through differentiated service delivery. That required strong public health systems, robust primary care, trained providers, predictable supply chains, digital infrastructure, friendly environments, and meaningful community engagement. The experience of Brazil's unified health system, the SUS, showed this clearly, she said. Science had provided the tools to end AIDS. What was needed now was the political commitment and global solidarity to make them accessible to the people who need them.

47. Speaking from the floor, members and observers thanked the presenters for their contributions. They agreed that long-acting ARVs widened the scope for progress against the AIDS pandemic by offering opportunities to reduce pill burden, improve adherence and counteract factors, such as stigma, that can make daily oral treatment difficult.

48. However, realizing that potential required building awareness, ensuring affordability and regulatory readiness, and facilitating equitable access. They said that high prices were limiting access to these innovations in low- and middle-income countries. Even though trials demonstrating the efficacy of lenacapavir had been done in Brazil, the country could not yet access the ARV at an affordable price, they reminded the meeting.

49. Although one speaker questioned whether expectations of low-cost access, including through relaxing patent protections, were compatible with the ongoing need for costly new innovations, there was wide support for price reductions, including through cheaper, generic production. Speakers supported the use of TRIPS flexibilities when necessary and appropriate, including compulsory licensing, as affirmed in the Doha Declaration on Public Health, as well as exemptions for least-developed countries. Stakeholders were urged to work with African partners and regional bodies to achieve sufficiently wide access to long-acting ARVs.

50. The Board was told that the size of the market for ARVs in a country like Brazil limited economic incentives for strictly market-driven investments. The country’s success in providing HIV treatment had been due to it and countries like South African leading a global effort to ensure that patent protections do not override global health imperatives.

51. Speakers highlighted the importance of awareness building, demand generation, and the involvement of communities. Evidence showed, for example, that many people who could benefit from PrEP did not know about it or how to obtain it. They emphasized that people living with HIV must be centrally involved in planning the rollout of long-acting ARVs and that these medicines must be integrated into stigma-free and gender-responsive services.

52. Several priorities were suggested, including: operational research led by people living with HIV to understand acceptability and real-world barriers; the collection of disaggregated data; focused rollouts in settings with the highest unmet needs; pricing models that allow for prompt access across low- and middle-income countries; expanded viral load testing capacity; support for pooled procurement, voluntary

licensing and technology transfers to sustain supplies; and integration into strengthened frameworks for prevention and care of advanced HIV disease.

53. Speakers noted that ARV-based prevention, treatment and care were most effective and cost-efficient when targeted, which required continuous research, data collection and analysis. However, asked how Zambia approached the allocation of the long-acting doses, Mr Mulenga said community facilities were prioritized, with a focus mostly on adolescent boys and girls and young women. However, that approach left out other people who clearly could also benefit from these tools.

54. Asked to summarize their key messages, Mr Richman emphasized advocating for and publicizing U=U, while Mr Mulenga noted the need to examine and reform legal barriers that block access to long-acting therapies. Mr Terto called for forms of intellectual property regulation that serve the needs of societies broadly, rather than securing privilege for the few. Collective actions could make it easier for countries to use existing flexibilities and pursue local production, he said. Ms Grinsztejn said commercial barriers were affecting access and widening prevention and treatment gaps; solutions were needed to overcome those barriers.

### Panel 2: Planning for access—what will it take?

55. This session discussed the steps for having sustained access to long-acting ARVs.

56. Carmen Perez-Casas, Technical Manager at Unitaid, highlighted three factors, starting with research and development. She said lenacapavir had been approved in record time because the necessary evidence had been gathered during trials in low- and middle-income countries among populations who were the anticipated users. This had sped up approval processes. Also important was consideration of the target product profile from early on, including for example whether the product had cold chain requirements, which could complicate use in many countries.

57. The manufacturing element also had to be considered early on to ensure a sufficient and geographically diversified supply base. That included ascertaining whether it would be possible to organize markets with high volumes and low cost for quality-assured products. Early licensing was vital, Ms Perez-Casas said. In addition to gathering evidence, companies must consider voluntary licensing so countries and funders can plan accordingly.

58. Regarding prices, it was important to seek rough parity with the current standard of care, which (for lenacapavir) was oral PrEP. This had been done by negotiating generic production, which could reduce the cost of lenacapavir to about US$ 40 per person per year. However, not all countries were included in the deal, hence the ongoing work with civil society to broaden the deals, she explained.

59. Another factor related to the adoption of innovations. Ms Perez-Casas said Unitaid was supporting early adopters so the necessary steps (e.g. guidance, training, demand generation and treatment literacy) were taken promptly. There were also opportunities to document evidence on the most effective and impactful ways to introduce these products. Two such studies, involving lenacapavir, were already underway in Brazil and South Africa. She said she expected low-cost, quality assured long-acting products to be available quickly for prevention and hopefully soon for treatment, as well.

60. Jared Baeten, Senior Vice-President, Clinical Development at Gilead Sciences, said that the HIV response was in a new era partly due to the promise of long-acting ARVs, which offered the potential to close critical prevention and treatment gaps. He stressed that innovation and access must go hand in hand. He told the meeting that by working

with PEPFAR, the Global Fund, national programmes and community and clinical partners, Gilead was striving to bring innovative medicines to high-incidence, resource-limited countries. The first shipment of six-monthly ARVs had already been dispatched to Eswatini and Zambia, he said. The broader scale up now had to follow.

61. Mr Baeten said Gilead had entered into voluntary licensing agreements with generic manufacturers to enable broad access in 120 low- and middle-income countries prior to regulatory approvals of the ARV anywhere in the world. A guaranteed supply, with no profit for Gilead, would be available for at least two million people in those countries for the next three years. Regulatory approvals were also widening.

62. Turning to middle-income countries, he said Brazil's regulatory submission was under review and a filing process has been initiated for Mexico, as well as Argentina and Peru. Gilead was also engaged with the Pan-American Health Organization to identify practical regional routes towards access. He said Gilead was committed to working with partners and communities so lenacapavir could reach as many people as possible.

63. He also noted that lenacapavir had been approved for people with multidrug-resistant HIV in several countries. Looking ahead, he said lenacapavir was being developed further as a foundation for future HIV therapies, with flexible dosing scheduling. The pipeline was focused on eventually reaching an HIV cure, he said.

64. Bryn Jones, Global Medical Lead for HIV at ViiV Healthcare, reminded that his had been the first company to bring a long-acting ARV to market. He agreed that choice was important and said long-acting treatment and prevention had the potential to address stigma and other factors that made adherence difficult. He said it required years of partnerships to bring a product to approval and licensing and reiterated the importance of implementation research and careful planning to get a product to people. Partnerships were vital also to drive ongoing access. He said access agreements had already been signed with the Medicines Patent Pool for generic cabotegravir, which had followed licensing agreements for dolutegravir. He also stressed the importance for partnerships in countries, with governments, regulatory bodies and NGOs.

65. Thembisile Xulu, Chief Executive Officer of the South African National AIDS Council, told the meeting that her country’s early adopter experience with lenacapavir had allowed it to move the access process along quickly. Implementation had been approved by the Director-General of Health, and the next step was to turn policy into action while preventing inequities and stop-start services.

66. She stressed that lenacapavir must complement existing prevention tools and should be used to revitalize the entire HIV prevention system. That meant delivering it as part of routine combination prevention through primary health and community systems. Without integration, she said, access would be compromised. The cost of lenacapavir had been reduced, she noted, but further price reductions would enable a bigger rollout. It was important for HIV prevention to be financed from domestic funds, and to protect users against user fees. Funds were also needed for strengthening national procurement and other systems; parallel systems should not be introduced for products like lenacapavir, she advised.

67. Ms Xulu said countries that achieve early policy clarity, credible demand planning, community education and delivery readiness (including training health workers) would shape global access patterns for long-acting agents. Regulatory reforms, including those envisaged through the African Medicines Agency, were critical to reduce delays between innovation, registration and access. Local and regional manufacturing, supported by voluntary licensing, technology transfers and predictable demand, would

strengthen sub-Saharan Africa's resilience, she said. Regional manufacturing was key for sustainability, he said and thanked Gilead Sciences for showing flexibility regarding the import of active pharmaceutical ingredients.

68. Mike Reid, Chief Science Officer for PEPFAR in the Bureau of Global Health Security and Diplomacy in the U.S. State Department, said PEPFAR had played a central role in shaping the long-acting PrEP landscape by making large-scale adoption viable for cabotegravir and lenacapavir. That had required market shaping, early demand signaling, regulatory coordination, price negotiations and procurement planning, all of which had been done through partnerships. He said PEPFAR remained committed to get lenacapavir to the populations who need it the most and was working with governments to predict supply and ensure sustainable pricing, and was supporting the rollout of lenacapavir in 10 countries.

69. Regarding long-acting treatment, Mr Reid said it was deeply concerning that long-acting treatment was already available in high-income countries, but not in the countries where PEPFAR worked. This reflected a failure of access and planning. He said PEPFAR had convened partners in 2024 to help define a research and access agenda for long-acting treatment; it was also leading the development of a target access profile for long-acting treatment in low- and middle-income countries. He said that a scale up of long-acting treatment was feasible and the lessons learned in reducing the prices of the fixed-dose combination dolutegravir/lamivudine/tenofovir remained salient. That experience reflected the kind of role PEPFAR would continue to play in shaping the access agenda, he told the meeting. The central risk was not scientific failure but delayed or inequitable access. Strategic U.S. Government engagement could help shape markets by signaling demand, supporting regulatory readiness, and engaging manufacturers early.

70. Michael Ighodaro, Executive Director of Global Black Gay Men Connect, Nigeria and the U.S., said that commitments to equity and inclusion were being rolled back in policy, rhetoric and propaganda, which was causing real damage. While commending scientific advancements, he said innovation should not stop at product development: access had to be ensured for everyone who needed the products.

71. Forecasting, market assessment and access planning work for long-acting prevention had benefited from the support of Gilead Sciences and ViiV Healthcare, he noted. However, science alone would not deliver impact; equity-driven planning was needed. By 2030, at least 60% of PrEP users should be members of key populations, Mr Ighodaro said, yet the infrastructure for delivering the prevention tools was being actively dismantled.

72. When PEPFAR funding was frozen in early 2025, he said, the effects were immediate, with clinics shutting down, outreach halted and staff laid off. Key populations were affected particularly hard. In Nigeria, Kenya and Uganda more than 2.2 million people were currently left without access to key population-focused HIV prevention services, he told the meeting. New prevention tools could not be rolled out with collapsing infrastructure and systems. In addition, he called for more investment demand creation by key population-led organizations that know how to reach people, create trust and drive demand.

73. Izukanji Sikazwe, Head of HIV at the Global Fund, highlighted five pillars for sustained and equitable access to long-acting ARVs. First was a secure, affordable and predictable supply chain, which maintains trust and reassures manufacturers of ongoing demand. Where feasible, affordable originator supply should be facilitated to catalyze access, she said, adding that it was also important to prepare systems to address regulatory requirements, procurement needs and the transition to generic

versions once they become available.

74. Secondly, long-acting ARVs must be integrated into health and community systems, which involves embedding them in routine HIV prevention and delivery packages. That should be done in ways that maintain choice, she advised. Thirdly, community leadership must be central to the planning, rollout and monitoring of new interventions, while, fourthly, innovative financing mechanisms must be used to achieve scale and sustainability, including private sector donor support. Resources should be channeled to high-impact interventions and populations, based on need and epidemiological evidence. Finally, a strong focus on monitoring and evaluation was needed to track integration, equity and impact and inform continued investments and strategies.

75. Silas Holland, Director of Global Public Policy at Merck, discussed some of the long-acting products that were in the pipeline. They included a weekly oral treatment (in partnership with Gilead); another weekly oral treatment which was in phase two trials; and a monthly oral PrEP. which was in phase three trials. He said the weekly oral treatment regimens would help people start and then stay on treatment by reducing daily pill burdens and easing stigma. The oral PrEP candidate had the advantage of quick onset of action and demedicalized delivery.

76. He said Merck would build on its long history of working with governments and other partners to ensure simultaneous access across low-, middle- and high-income countries through, for example, voluntary licensing strategies, bilateral agreements, the Medicines Patent Pool and technical support. Noting that delivering the products required training, strengthened awareness and trust in community platforms, he said the company was committed to work with ministries of health, communities, procurers and advocacy groups to ensure these innovations have real, equitable impact.

77. In discussion from the floor, speakers underscored the importance of fair and affordable pricing for translating scientific innovations into real public health impact. Prices of long-acting ARVs would determine national decisions on their procurement and use, they said. They reiterated that several Latin American countries had been excluded from the initial voluntary licensing agreements for lenacapavir. Implementation challenges should not be ignored, speakers added, noting that rolling out long-acting injectable treatment or PrEP require suitable healthcare infrastructure, trained healthcare providers and clinics that can provide regular follow-up.

78. Speakers insisted that adolescent girls and young women must be able to access long-acting prevention tools safely, affordably and on their own terms. The tools should be part of a comprehensive package that includes actions to improve gender norms and tackle gender inequalities. Adolescent girls and young women must be recognized not just as beneficiaries but as leaders and decision-makers.

79. They underlined the need to remove legal, policy and social barriers that limit access and impede sustainability, along with the need to invest in demand generation. Awareness remained a major gap, with many affected populations knowing too little about their prevention and treatment options, speakers told the Board. In addition, HIV-related misinformation persisted, as did misunderstandings about the actual benefits of long-acting ARV injections (e.g. the mistaken notion that one injection would provide life-long protection). This highlighted the importance of community capacity building to support the rollout of innovations.

80. Speakers highlighted the value of community-led monitoring for collecting data on impact, resistance and safety; for understanding how the tools perform among diverse groups; and for informing policy adjustments that can improve health outcomes. Placing communities at the centre of monitoring also helps ensure accountability and responsiveness, they said.

81. Also emphasized was the importance of strengthening local manufacturing capacity, facilitating technology transfers, coordinating partnerships and investments, and aligning efforts with global access initiatives to promote equitable access. Local production reduced dependence on imports, shortened supply chains and could improve resilience to global disruptions, the meeting was told.

82. Asked for brief key messages, Mr Ighodaro said the aim should be to have 11.5 million person years of PrEP use by 2030, with 60% of new PrEP use occurring among key populations. This required investing in literacy and demand generation and rebuilding infrastructure that was being destroyed. Mr Baeten said innovations should be aimed at achieving impact, while Mr Jones said the discussion had highlighted the importance of partnerships, working with communities, providing choice and acting with urgency.

83. Ms Xulu said every missed prevention opportunity represented a lifetime of treatment costs, while Mr Reid emphasized the need for scaling up and ensuring equitable access to prevention tools. Ms Sikazwe said it was not innovations alone but delivery systems that stopped new infections; community participation and a rights-based approach to implementation were vital.

## Conclusion

84. The concluding session summarized the main messages from the thematic segment. Angeli Achrekar, Deputy Executive Director for Programmes at UNAIDS, emphasized that access connected innovations with impact. She encouraged more resources to go to programmes and community systems that can deliver access.

85. She said the session had illustrated the uniqueness of the PCB, which brought together multiple sectors and stakeholders to share experiences and lessons. It was clear from discussions that speed, scale and equity were essential, along with partnerships that put affected communities at the centre. The struggle continued, she said, though victory was not yet certain: it depended on the political will, investments and focus stakeholders bring to bear in the push to end AIDS.

## Proposed decision points

**The Programme Coordinating Board is invited to:**

86. *Take note* of the background note (UNAIDS/PCB (57)/25.37) and the summary report (UNAIDS/PCB (58)/26.26) of the Programme Coordinating Board thematic segment on “Beyond 2025: Long-acting antiretrovirals—the potential to close HIV prevention and treatment gaps”;

87. *Request* Member States, in collaboration with community-led HIV organizations and other relevant HIV-related organizations, with the support of the Joint Programme, to:

    a. Ensure the inclusion of long-acting antiretrovirals in the national HIV prevention and treatment monitoring framework, based on the global WHO guidelines and recalling the HIV prevention and treatment targets and goals of the Global AIDS Strategy 2026-2031;

    b. Promote equitable access to long acting antiretrovirals including through reaffirming the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) as amended, and also reaffirms the 2001 WTO Doha Declaration on the TRIPS Agreement and Public Health, which recognizes that intellectual property rights should be interpreted

and implemented in a manner supportive of the right of Member States to protect public health and, in particular, to promote access to essential health tools for all, and notes the need for appropriate incentives in the development of new health products;

c. Explore local and/or regional pharmaceutical manufacturing capacities and implement mechanisms to foster technology transfer on mutually agreed terms for long-acting products;

d. Use pooled procurement mechanisms to support accurate demand forecasting and market shaping as well as improve national regulatory systems for continued and accelerated national regulatory approvals;

e. Strengthen primary prevention ensuring that all effective prevention options are available to all, and integrate long-acting antiretrovirals into national health systems, both in national health facilities and through differentiated service delivery;

f. Ensure equitable access to affordable and high-quality long acting antiretrovirals, including through ensuring an enabling legal and policy environment that effectively addresses HIV-related stigma and discrimination;

g. Utilize the existing scientific evidence on U=U to address legal, socio-cultural and economic barriers that prevent people living with HIV from accessing and sustaining treatment and attaining the highest achievable quality of life;

h. Provide support and resources to communities of people living with, affected by, or most at risk of HIV to increase community leadership across programme and policy design, implementation and accountability, including demand creation of long-acting antiretrovirals, acknowledging the role of communities in reaching HIV targets;

*[End of document]*