

Technical Briefing Note

Accelerating the introduction of long-acting depot buprenorphine and low dead space syringes and needles for harm reduction service delivery

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Background

In the [HIV prioritization guidance for grant cycle 8 \(GC8\)](#), the Global Fund outlines that harm reduction services for people who use drugs are a program essential – or a set of evidence-based interventions that are critical for achieving impact.

The Global Fund supports national harm reduction programs to ensure they are offering a [comprehensive package for people who use drugs \(PWUD\)](#). Within these programs, and through GC8 planning, where appropriate in the national context and in line with community values and preferences, **the Global Fund encourages national harm reduction programs to consider introducing and scaling two new health products: long-acting depot buprenorphine (LADB) and low dead space syringes and needles (LDSS/N).**

This Briefing Note outlines the key information to support the budgeting, procurement and implementation of both health products within Global Fund grants.

Long-Acting Depot Buprenorphine

Key considerations for national harm reduction programs wanting to adopt and implement LADB.

- **Product overview.** LADB is an extended-release injectable formulation of buprenorphine administered subcutaneously using prefilled syringes. The product is administered weekly or monthly, maintaining therapeutic levels while reducing the need for frequent clinic visits.
- **Benefits.** Given its long-acting nature, LADB offers a more discreet, less stigmatizing, and more convenient form of treatment compared with daily dosing models. As an additional option within opioid agonist maintenance treatment (OAMT) programs, it expands choice for individuals who may prefer a long-acting formulation and has the potential to improve retention in care. By reducing the need for daily clinic attendance, LADB may also support greater stability for beneficiaries, including improved economic stability, time for work, education, family and other daily life responsibilities.

- **Product use in low- and middle-income countries (LMICs) to date.** Until recently, LADB had been limited to no use in LMICs. This has since changed as Egypt, India, Kyrgyzstan, Nigeria, South Africa, Tanzania, Ukraine and Vietnam, with funding from Unitaid and support from PATH, PSI, MDM and Frontline AIDS, are now implementing LADB as part of a study on the feasibility, acceptability, effectiveness and cost-effectiveness of its use in LMICs. Preliminary findings from early implementation sites in Kyrgyzstan, Nigeria, South Africa and Ukraine indicate that LADB can be introduced within existing OAMT programs and delivered safely in routine program settings.
- **World Health Organization (WHO) guidance.** WHO has issued a [rapid communication](#) on selected recommendations for opioid dependence treatment and overdose prevention including a conditional recommendation for LADB. Full guidelines will be published later in 2026 or early 2027.
- **Manufacturing and global regulatory.** Globally, several LADB manufacturers have received stringent regulatory authority (SRA) approvals. As of July 2026, the only LADB manufacturer known to the Global Fund and planning to supply to low- and middle-income settings is Camurus. Camurus has SRA approval from European Medicines Agency and U.S. Food and Drug Administration, amongst other SRA bodies.
- **National regulatory.** To support timely national authorization, Camurus plans to pursue national filings using SRA reliance pathways, including the WHO Collaborative Registration Procedure (CRP) where applicable. Countries participating in the WHO CRP are therefore encouraged to consider using this reliance pathway to support accelerated authorization of LADB. In settings where national registration may take longer, countries may consider nationally recognized authorization mechanisms, such as import waivers or special access provisions, to enable program implementation while full registration processes are underway.
- **Product specifications.** The prefilled long-acting buprenorphine injectable formulations appropriate for LMIC supply settings are available as room temperature stable products and must not be refrigerated or frozen. These formulations are administered either weekly or monthly, with the following strengths: **Weekly:** 8 mg, 16 mg, 24 mg, 32 mg; **Monthly:** 64 mg, 96 mg, 128 mg, 160 mg. Further guidance on product use will be shared in the WHO guidelines mentioned above.
- **Supply chain.** The product is supplied in cases of 30 units, with 72 cases per pallet (2160 units). Each shipment includes a temperature monitoring device. The product should be stored at room temperature (<25°C) and should not be refrigerated or frozen. The current lead time for the product is approximately four to five months, with expected biannual product runs.
- **Pricing.** The supplier has set an indicative price of €120 per month for Global Fund eligible countries, which can be used for GC8 budgeting. Countries should assess the cost of LADB through the broader lens of harm reduction service delivery rather than a strict product-to-product comparison. While LADB's commodity cost is higher than standard OAMT, its less frequent dosing can substantially lower service delivery costs relative to daily dosing models. Preliminary modeling from South Africa

suggests that, under the model assumptions, these delivery savings can offset the higher commodity cost: reducing LADB drug costs below approximately US\$180 per month could make LADB cost-saving compared to the country's standard of care - a threshold below which the indicative price falls. Unfunded demand should be reflected in the Prioritized Above Allocation Request (PAAR) to enable integration and/or scale up on an agile basis as market dynamics evolve.

- **User preferences and quantification.** Programs are advised to engage with community stakeholders to understand the values and preferences of people with opioid dependence in relation to LADB, including the benefits, barriers and preferred models of care for service delivery. Based on preliminary coverage estimates, programs should determine the prospective patient population that could transition to LADB during the upcoming funding cycle. LADB should be delivered in a way that is accessible, acceptable, safe, voluntary and respectful of each person's privacy, confidentiality and autonomy. Programs are advised to calculate the required LADB inventory and estimate the corresponding budget for procurement using the LADB quantification tool (see 'Resources' section).

Low Dead Space Syringes and Needles

Key considerations for national harm reduction programs wanting to implement LDSS/N:

- **Product overview.** LDSS/N reduces the risk of onward transmission of blood-borne viruses when injection equipment is shared. Despite global WHO guidance recommending LDSS/N since 2012, high dead-space syringes/needles remain the predominant syringe type distributed in LMICs. LDSS/N are designed to retain less residual fluid after injecting and therefore lower blood-borne virus risk in situations where equipment may be re-used or shared which may significantly reduce HIV and HCV transmission and other injecting related infections and injuries.
- **WHO guidance.** WHO recommends that needle and syringe programs (NSPs) provide LDSS/N as an option alongside other equipment, following a community values and preferences assessment to ensure the needles and syringes and other harm reduction supplies meet community preferences and local use patterns.
- **Specifications/quantification.** Needle and syringe specifications should be assessed and selected by the community as outlined in [Annex 2 of the WHO Operational Guide: Needle and syringe programs for people who inject drugs](#)¹ to understand context-specific needs, preferences, cost-considerations and patterns of use among people who inject drugs. Importantly, supplies should be of sufficient quality to minimize harm and maintain the trust of the community. Careful consideration needs to be made to understand user needs and preferences to assess the type (fixed vs detachable) of syringe, barrel size, needle gauge and needle length, plunger action and other attributes – as well as other equipment needed (i.e., sterile water, cottons, cookers, and others).

¹ WHO. 2026. Operational Guide: Needle and syringe programs for people who inject drugs. <https://www.who.int/publications/i/item/9789240116214>

- **Supply and pricing.** Principal Recipients (PRs) can use eligible product lists for decision-making and budgeting. An indicative price of US\$1.20-US\$2.00 per piece can be used in the absence of country-specific market intelligence on LDSS/N.
- **Regulatory.** According to the Global Fund's Quality Assurance policy, LDSS/N shall be manufactured at a site compliant with the requirements of ISO 13485 or an equivalent Quality Management System recognized by one of the Regulatory Authorities of the Founding Members of the GHTF or by a WLA². For LDSS/N products not yet registered, countries should assess regulatory considerations, including potential barriers, and facilitate importation waivers where required.

General Considerations

- **Community engagement.** Community (people with lived/living experience of drug use) should be central to decisions in relation to product selection, values and preferences assessment, design of rollout messaging, user education materials, implementation monitoring, and identification of access barriers after introduction. Community involvement will strengthen demand generation, product uptake, counseling, and ongoing feedback to quickly address gaps and inequities.
- **Importance of establishing values and preferences.** Involving people who inject drugs in decisions about the harm reduction supplies to be procured and distributed ensures that services are effective, acceptable and equitable. Too often, decisions are made without input from the people who use the equipment, resulting in poor uptake, unsafe practices and unnecessary waste.
- **Transition planning.** Countries should follow the standard practice of adequate planning for the phased introduction of new products while avoiding any risk of product wastage or stock shortfalls of existing OAMT and NSP products. In parallel, countries should update national policies and guidelines and streamline training plans and quality reference materials to account for new products. This includes updates to health management information systems (HMIS) and logistics management information systems (LMIS). To minimize risk, the community should be involved in product selection and rollout.
- **Budgeting.** Beyond direct product costs, PRs can use Global Fund grants to fund activities to support the adoption and implementation of LADB and LDSS/N.

Resources

Partners have developed resources to support LADB and LDSS/N adoption and implementation, including quantification tools, global guidance, and client-facing demand generation materials and guides for peer counselors. These tools and resources are available on the [Global HepC Community Advisory Board webpage](#). Additional tools will be uploaded and existing resources updated as they become available.

² Global Fund Quality Assurance Policy for Medical Devices (including In-Vitro Diagnostics) and Core Personal Protective Equipment
https://www.theglobalfund.org/media/hc5hxug2/psm_qa-medical-devices_policy_en.pdf