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DESIGN AND IMPLEMENTATION OPTIONS FOR A CENTRAL PROCUREMENT UNIT AND ARV FINANCING IN VIETNAM

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CONTENTS

1. BACKGROUND

As international guidelines and the President's Emergency Plan for AIDS Relief (PEPFAR) policies for HIV epidemic control increasingly focus on "test and treat" (UNAIDS 90-90-90 and fast-track mandates), expanding access to and coverage of antiretroviral treatment (ART) for people living with HIV (PLHIV) has received heightened attention. This focus highlights the greater need to manage the procurement and supply chain systems for antiretroviral drugs (ARVs) and pharmaceuticals to treat key opportunistic infections among PLHIV. While many pharmaceuticals are available in Vietnam at prices and quality on par with international standards, procurement for some (such as ARVs) is not. This is due to several factors, such as (a) no viable domestic market and lack of international procurement; (b) fragmented, decentralized procurement; (c) limited competition (e.g., monopolies) among suppliers; (d) bidding limited to spot tenders (no use of longer-term framework agreements); (e) local tenders with high unit cost and high elasticity for drug quantities; and (f) drugs currently unregistered for circulation in Vietnam.

These obstacles drive up ARV prices and inhibit access, particularly in markets where domestic sourcing has been limited (e.g., tenofovir combinations, second-line medicines, and certain pediatric ARV formulations). Prices paid by the National Target Program (NTP) for HIV/AIDS for the procurement of imported ARVs have historically been higher than those paid by the Global Fund or PEPFAR. When donors reduce or eliminate funding in 2018, the Government of Vietnam (GVN) will be forced to procure these ARVs at higher prices unless it addresses the situation. At best, this will lead to substantial inefficiencies in HIV/AIDS spending; more likely it also will result in reduced coverage of ARVs for PLHIV. To avoid either scenario and realize its 90-90-90 objectives by 2020, the GVN must take action to eliminate these obstacles.

The Ministry of Health (MOH) on behalf of the Prime Minister of Vietnam has therefore requested that the Health Finance and Governance (HFG) project present a proposal for the introduction of a Central Procurement Unit (CPU) for pharmaceutical products (including ARVs) offered in the public health system. However, the design, governance, and implementation of a CPU are not yet clear. HFG also is to identify practical, short- and long-term options for domestically financing and purchasing ARVs. While the CPU is expected to be Vietnam's long-term vehicle for procuring ARVs, the GVN needs financing strategies that address methods for generating new (or existing) ARV resources and improving efficiencies through ARV payment and reimbursement mechanisms.

In the first phase of this activity, HFG conducted qualitative research (in-person and in-depth interviews) with key government stakeholders. These included the Vietnam Administration of AIDS Control (VAAC), the National TB Program, the Expanded Program on Immunizations (EPI), the Drug Administration of Vietnam (DAV), the Department of Planning and Finance (DPF), the Department of Health Insurance (DHI), and Vietnam Social Security (VSS). The research provided insights into the current discussions and in-country dialogue on preferred policy options for domestically financing ARVs, plans for designing a well-governed CPU, and requirements for effectively procuring ARVs. These interviews also improved HFG's understanding of Vietnam's technical, institutional, and regulatory challenges.

In this brief, HFG presents reform options based on (a) initial discussions with key government stakeholders and (b) HFG's experiences and expertise, which stem from global best practices, particularly in East and Southeast Asia. HFG anticipates that key stakeholders will review and select the options they would like to explore in greater depth.

Policy design is an iterative process. In selecting preferred reform options, HFG will schedule future meetings with government stakeholders and donors to discuss ways to design and implement

options in this brief. These meetings will help determine the types of technical assistance the MOH and VSS will require from HFG to achieve these objectives. Stakeholders will likely have different interests and priorities; some of this brief's proposed options will require partnerships and technical negotiations to achieve their goals. For these reasons, HFG will need to facilitate discussions and improve coordination between domestic stakeholders and international development agencies, particularly donors.

Once the GVN and stakeholders have identified reform options, HFG will work with the GVN and other partners to design and validate a roadmap that presents the steps and milestones involved with these reforms. Such a document will include a timeline for implementing the desired short- and long-term reforms and indicators to monitor and evaluate the implementation of these reforms. HFG will provide technical assistance to the GVN to legalize the reforms' required governance and financing arrangements. HFG will work with the MOH to draft a legal document outlining the implementation of the institutional arrangements of the CPU, including regulatory and reporting arrangements, appropriate staffing structures with defined roles and responsibilities, a capacity development plan, and a system of checks and balances to ensure transparent bidding, selection, and procurement processes.

2. IMPLEMENTATION TIMELINE

Drawing on the qualitative research HFG conducted, we present the following timeline of activities, policy options, and recommendations as a guide for implementation.[1] Sections 3 and 4 contain a more detailed explanation of the activities in this timeline.

[1] The RFP document stipulates that ARVs are manufactured domestically.

3. SHORT-TERM POLICY OPTIONS (2015-2017)

3.1 Governance

Governance addresses the roles and responsibilities of organizations tasked with implementing health policies, the relationship between these organizations, as well as the resources needed for such entities to carry out their functions. Governance can strengthen or weaken the effect that such policies have on their intended outcomes. For this reason, in the absence of strong governance, even well-designed policies can be ineffective (or hinder) the goals they set out to achieve.

In the context of this brief, the GVN has expressed interest in eventually developing a CPU that would be tasked with pharmaceutical procurement (including ARVs). It is thus critical that the GVN formally and legally define the CPU's roles and responsibilities. This is also necessary for other governing institutions, including departments within the MOH and MOF, which may procure ARVs in the short term, regulate the CPU, monitor its performance, and ensure that all governing bodies are transparent and accountable for their actions. The GVN must fill gaps in institutional, human-resources, and financial capacity for these institutions, including the eventual CPU, to fulfill their responsibilities. We discuss recommended short-term governance options below, while medium-term options are in Section 4.1. A comprehensive list of governance dimensions, roles, and responsibilities is in Annexes A and B.

3.1.1 Central Procurement Unit Structure

The DAV, DPF, and DHI, all departments within the MOH, have not yet decided where to house a nascent CPU. However, during a short-term pilot phase, they have proposed to house the unit in the DAV. HFG agrees that this is a feasible option given limited short-term funding, the absence of legal autonomy for any new institution, and under-developed technical capacity. Unlike other MOH agencies, the DAV already regulates drug quality and pricing. It thus has some capacity to carry out key CPU functions. However, to minimize potential conflicts of interest, the DAV's regulatory function should be separate from the CPU's drug procurement function. The absence of an independent regulatory function could affect the type, safety, quality, efficacy, price, and access to pharmaceuticals.

If the GVN chooses this option for the pilot phase, it must put in place critical policies and legal structures for the CPU to become, in the medium or long term, an autonomous or semi-autonomous body. Such a body would need to operate independently from the DAV and be accountable to other government entities, such as the MOF's Public Procurement Authority or parliament. More details on this long-term structure are in the "Medium-Term (2018-20)" options.

3.1.2 Decision-Making Structures

Central Procurement Unit

During this pilot phase, HFG proposes that the CPU should limit tasks to conducting sourcing and establishing maximum pricing frameworks. It should base eligible suppliers on forecasted volume for roughly five drugs. This is also the GVN's preferred option. DPF, DAV, and DHI anticipate that these would include non-communicable disease (NCD) drugs such as those for diabetes, cardiovascular disorders, cancer, and blood diseases. These departments and our team agree that the CPU will require technical assistance to build staff capacity in procurement management and development of standard bid documents for domestic bidding, negotiations, and contracting.

Vietnam Administration of AIDS Control

HFG recommends that VAAC, or the NTP more specifically, continue to procure first-line ARVs from domestic suppliers through domestic bidding; however, it should also seek strategic partnerships with foreign sources (pharmaceutical companies) for fixed dose combinations (FDCs), specifically formulated pediatric ARVs, and second-line ARVs. The ARV procurement agency must go beyond merely fulfilling the purchasing element and have a detailed understanding of the entire procurement and supply management (PSM) chain to ensure ARV supply meets population demand. As a result, we recommend that in the short term, VAAC should maintain control of ARV procurement rather than outsource that function to a nascent CPU.

Drug Administration of Vietnam

HFG recommends that the DAV continue its key roles as a regulatory body of pharmaceutical prices and quality, licensing of importers, and oversight of manufacturers. This includes medicines procured under the CPU pricing framework and ARVs (first-line, second-line, and pediatrics) that VAAC manages.

The DAV processes for regulatory approvals and registration fees are effective tools in the commercial market for essential drugs. However, GVN must improve such regulations to allow for effective competition among foreign drug manufacturers.

HFG has proposed that DAV develop further procedures within existing laws and decrees to enable VAAC to import un-registered drugs such as pediatric and second-line ARVs. This would be for the "purpose of public health." The standard for the drugs could be World Health Organization (WHO) pre-qualification or stringent regulatory authorities (SRA) registration status and quality control of imported drugs. Unlike commercial drugs, ARVs are a public health priority and a shortfall can lead to externalities (e.g., increased HIV/AIDS prevalence). Moreover, the importation of unregistered ARVs would increase competition by enabling multiple bids by generic distributors. In the short term, full pre-registration from competitors is not technically feasible.

The VAAC would accept proposals from eligible sources and evaluate them based on predicted volumes and global reference unit prices (product registration should not be a pre-condition). Tender documents would require the manufacturer's commitment to submit an application and product registration to the DAV's regulatory body within one year of the award. DAV was receptive to this suggestion; however, further discussions are needed to outline the details of such an option.

Department of Health Insurance (DHI) & Vietnam Social Security

HFG suggests that the DHI provide input to the CPU on pharmaceutical prices and drug types under the CPU's pricing framework. This input is critical given that negotiated prices and drug types directly affect the SHI fund's solvency. Both HFG and DHI agree that DHI would base its input on the selection of pharmaceuticals included in the SHI Basic Health Services Package (BHSP). However, given that the BSHP will likely not be defined until 2017, any short-term DHI recommendations would be for the few drugs the CPU pilots.

Department of Planning and Finance

Per their recommendations, the Health Minister and the DPF head would appoint the CPU's supervisor/director. Ideally the candidate would be an MOH official with technical qualifications, training, and experience in international-drug and health-product procurement.

Ministry of Finance

The MOF, to whatever extent possible, will finance the CPU through general tax revenues. HFG recognizes that through 2017, additional revenues will be limited due to short-term budgetary constraints.

Donors

HFG recommends that in addition to their existing roles, donors may need to invest in capacity-building activities that will strengthen VAAC's ability to procure and coordinate ARVs (see below). VAAC has agreed with this proposal. In the absence of short term domestic funding and technical capacity, VAAC also would need to support the operationalization and implementation of the CPU.

3.1.3 Capacity

The DPF and the DAV anticipate that, during the CPU pilot period, limited funding will create a shortage in staffing (in terms of both quantity and quality), infrastructure, and finances. Existing staffers may need to transition from their current job posts to work with the CPU. Inadequate capacity and resources are major bottlenecks for achieving a fully autonomous, operational CPU.

Both HFG and VAAC believe that VAAC will need to strengthen its capacity around ARV procurement and coordination (given that multiple organizations procure ARVs). This is particularly the case for international bidding.

HFG's discussions with the MOH have made it clear that there is a need to develop public sector health management information systems (HMIS) and strengthen the capacity of health facility staff to use data for planning and decision-making. While applicable for broader health service delivery, this is particularly relevant for ARV and pharmaceutical forecasting.

3.1.4 Transparency & Accountability

The DPF and the DAV acknowledge that housing the temporary CPU within the DAV creates accountability issues, as the DAV could both manage pharmaceutical pricing frameworks and act as regulator. According to the DPF, the CPU cannot be housed within its department because it lacks legal and financial autonomy. If the CPU is housed in the DAV, HFG and DAV agreed that few short-term options are available to mitigate these obstacles.

3.1.5 Regulation & Enforcement

The GVN will need to develop new laws and regulations to govern the CPU. Any options will require further discussions with key government stakeholders to determine legal and political feasibility.

3.2 Procurement

In the context of this brief, procurement addresses the mechanisms for purchasing first-line, second-line, and pediatric ARVs from pharmaceutical vendors. Such mechanisms aim to improve competition among vendors for contracts, establish lower ARV prices and more accurate quantities, select competent vendors, and improve the quality and types of procured ARVs. The following section presents short-term options and recommendations for procuring ARVs while Section 4.2 outlines medium-term options. These recommendations, if the VAAC designs and implements them well, should improve the technical and allocative efficiency of HIV/AIDS spending and enable sustainable GVN financing of ARVs.

When procured only from Vietnam's domestic market, ARV prices are multiple times those paid on the international market. These higher prices inhibit the scale-up of treatment to PLHIV in Vietnam, increase the treatment gap, and accentuate inefficiencies. It is therefore critical that the GVN encourages competition among suppliers in order to procure ARVs of the highest quality and lowest price.

The GVN has spent up to three million USD of domestic funds to procure two locally manufactured, first-line ARVs. These are limited to zidovudine-based formulations, which only 30% of clients use. Excluding Mylan, our understanding is that Cipla and Hetero[2] are the only Tenofovir Triple, fixed-dose combination (TDF/3TC/EFV) on which a majority of first-line clients depend. They have been submitted to the DAV for registration. In the absence of effective competition, these drugs have been procured at artificially high prices.

Policy Recommendations for Procurement (Short Term)

☑ The MOH should allow for competitive procurement of more cost-effective ARVs, such as the TDF/3TC/EFV triple and TDF/3TC double combination tablets.[3] Procurement should be opened to foreign manufacturers at the lowest possible cost through local bidding (national competitive bidding in Vietnamese[4]).

☑ While donor support is still available, VAAC should establish framework agreements with local suppliers to cover at least the zidovudine-based formulations (preferably from domestic manufacturers).[5] This framework could be expanded to include TDF formulations once funding is available (either through the MOF or VSS) and bulk purchasing (to benefit from economies of scale). This, in turn, would open up procurement to a larger group of suppliers, reducing prices and improving drug quality.

To achieve this:

1. DAV and DPF should approve the tender plan, which will allow VAAC to secure local supply contracts for TDF/3TC/EFV tablets manufactured by Indian sources. These have historically been procured under supply chain management system (SCMS) / pooled procurement mechanism (PPM) and imported through a local supplier. However, the cost, insurance, and freight (CIF) price (~11 USD per pack is above the 2014 Clinton Health Access Initiative ceiling price (USD10.80/30 tabs[6]). It is also significantly above the most recent PPM reference free-on-board (FOB) price (USD9.50/30 tablets[7]) manufacturers offer directly to international donor organizations. There are also provisions in the law to import non-registered medicines for

2 Drug name needs to be confirmed, as HFG has received conflicting information.

3 SCMS indicated that they are not seeking to use the double. Further comment from VAAC would be helpful.

4 The Planning Dept. is in charge of this process in VAAC, which is largely based on the World Bank Standard Bid Document (SBD) and a pre-approved bidding plan (including state-funded budget), signed by the Vice Minister. Bid advertising is by law for a minimum of 20 days, and a team with representatives from VAAC (Care/Treatment), DPF, and DAV (VAAC Task Force) does the evaluation. Results are published via MPI Gazette. The process is subject to internal and independent audits.

5 A draft RFP is attached.

6 http://45.55.138.94/content/uploads/2015/05/CHAI-ARV-Ceiling-Price-2014-Final_English.pdf

7 www.theglobalfund.org/.../PPM_ARVReferencePricing_Table_en/

special cases (e.g., ARVs procured through VAAC), which, in principle, pave the way for more competition – even in local markets.

2. VAAC should improve coordination with donors on ARV procurement to avoid interruptions of HIV treatments or duplication that may waste valuable donor resources.

3. VAAC, DAV, and DPF should begin formalizing and using the legal pathways (e.g., Pharmacy Law Article 38) to allow the importation of ARVs, which could account for 99% of first-line (TDF/3TC/EFV and TDF/3TC) and 99% of the second-line (LPV/r or ATV/r tablets[8]) drugs.

4. For products not yet registered with the DAV, the DAV should fast-track applications to meet regulatory requirements for safety, efficacy, and quality. Under laws regulating the importation of non-registered drugs for Vietnam's NTP, a permit to import non-registered drugs is valid for up to one year after its signing (PM Decision No. 151/2007/QD-TTg of September 12, 2007).

If successful, the existing, 60 billion Dong (approx. 2.6 million USD) in expenditures for 2015 can be used to procure ~150,000 packs, which would treat 10,000 to 15,000 first-line clients for 12 months.

3.3 Financing

Health financing has three primary functions: resource mobilization, risk pooling, and purchasing. Resource mobilization is the mechanism to generate revenue to pay for health; risk pooling is the accumulation of prepaid revenue on behalf of a population; purchasing is the transfer (or payment) of pooled funds to health care providers on behalf of a population. Each of these functions has the capability, if designed and implemented well, to improve access to and quality of ARVs and efficiency of ARV spending. Efficiency improvements may be technical (improving the mix of inputs used to generate a specified output) or allocative (improving the distribution of resources to areas that maximize a desired output).

The following are recommended, short-term health financing interventions that are both pertinent to Vietnam and can improve the long-term sustainability of ARV financing. These policy options are presented for four stakeholders: donors, VSS (for SHI), the MOF, and the MOH. Medium-term options are in Section 4.3.

3.3.1 Donors

Existing Landscape

HFG anticipates that through 2018, donors are likely to continue financing ARVs at or slightly below existing levels. However, it is expected that even in the short term, donor spending on ARVs will decline as Vietnam's MOH absorbs a greater share of these costs.

Proposed Options

8 A recent case study published by CHAI here (http://www.clintonhealthaccess.org/content/uploads/2015/08/Case-Study_ATVr_Uptake.pdf) could be considered by Vietnam VAAC to phase in ATV/r in second line (one tablet per day compared with two times two tablets LPVr per day) with additional potential cost savings in the longer term (currently still quite limited, approximately 1.5 USD per patient in second-line per month).

Policy Recommendations for Donor Financing (Short Term)

☑ Over the next 1-2 years, donors should consider designing and piloting a joint financing policy with the MOH or MOF whereby donors "match" a certain dollar contribution by their partner.

If implemented well, fund-matching policies can be extremely effective at stimulating domestic investments in health, with evidence stemming from countries such as the United States, Thailand, China, Philippines, Rwanda, Tanzania, the United Kingdom, across Latin America, and among organizations such as GAVI. Globally, most fund-matching policies occur between domestic stakeholders (e.g., federal and state governments), and these policies focus on generating revenue to finance or subsidize health insurance. There are also several global examples of fund matching for diseases such as HIV/AIDS between international agencies and private-sector stakeholders.

Under one potential scenario, donors would contribute $1 toward health insurance premium subsidies for PLHIV enrolled in SHI for every $2 that the MOH invests (a 1/2 ratio). Given that PLHIV need subsidies to enroll in SHI, but current laws prevent the MOF from providing direct subsidies to groups of specific diseases or clinical conditions, this would offer one method to increase enrollment. The MOH would pool resources into a joint fund, which the MOH would manage. But donor funding would not be freed until the MOH provided its contribution. Donors would reduce their contribution over time until it reached a ratio of 1/4 or 1/5, after which they would end the matching program. Note: This is one possible example of fund matching. It is unclear whether the GVN would be interested in fund matching. Moreover, the details of such an agreement, including the use, management, and release of funds, would need to be discussed with both donors and the MOH.

3.3.2 Social Health Insurance

Existing Landscape

Both the DHI and VSS indicate that the SHI fund could absorb the full cost of ARVs immediately if desired. As total ARV expenditures account for roughly 1% of total SHI expenditures, this would not jeopardize the fund's solvency. (NHA, 2015).

However, there are three obstacles that currently prevent the SHI fund from absorbing ARV costs for all PLHIV in Vietnam:

- SHI covers only curative HIV/AIDS services for enrolled PLHIV; the fund does not cover preventative care or reimburse first-line, second-line, and pediatric ARVs costs
- Only 30-40% of PLHIV are enrolled in SHI; VSS cannot finance ARVs for non-enrolled PLHIV
- PLHIV frequently use outpatient centers (OPCs) for HIV/AIDS services, including ARVs, yet the VSS does not contract with these health facilities.

Other challenges include:

- SHI member groups are categorized by income and employment, not clinical condition. Subsidies covering member premiums and other forms of cost-sharing (i.e., co-pays) are 100% for the poor, but 70% for the near poor and 0% for non-poor groups. While many are poor, some PLHIV fall in the near-poor or non-poor categories. Global evidence suggests that the informal sector, particularly the non-poor and near-poor, will not enroll in SHI unless subsidies are provided at or above 90% of premiums. This is done for two reasons. First, health insurance premiums can represent a significant share of income even for non-

poor or near-poor groups. Second, these groups have little incentive to enroll without receiving subsidies and being mandated to do so. As many PLHIV fall into this group, targeting PLHIV for SHI subsidies will not be easy.

- SHI is mandatory only for the poor and formal sector, but is voluntary for the informal sector. Most PLHIV belong to the informal sector, and thus are likely unwilling to enroll in SHI without being mandated to do so and receiving subsidies

Proposed Options

Policy Recommendations for SHI (Short Term)

☑ Vietnam's SHI fund should cover first-line ARVs, and the VSS should pilot payment/reimbursement mechanisms for first-line ARVs among the 30-40% of PLHIV enrolled in SHI.

Payment/reimbursement options that have been discussed with VSS and MOH departments include:

Option A

This is the option preferred by the DAV, DPF, VSS, and DHI. SHI would forward a large portion (~80%) of ARV funding to contracted health facilities. Those facilities would purchase ARVs from suppliers in accordance with the VAAC's drug pricing framework. HFG's assessment is as follows:

a) Past experience suggests that pharmaceutical vendors negotiate prices with a national body (VAAC, CPU) under the expectation that they will sell a pre-agreed quantity of drugs. However, health facilities may alter their demand for those drugs based on real-time need, and the quantities purchased at the end of the year may be less than the anticipated quantity. For this reason, drug suppliers need confidence that they can sell at least 80% of the agreed-upon quantity. Hence, health facilities need this revenue up front in the event that they do not reach the expected purchase volume.
b) This reimbursement option recognizes that health facilities have limited technical capacity to forecast ARV needs and financial resources to advance payment for ARVs. Because it is similar to a prospective, capitation-based payment mechanism, this method takes a step toward a more output-based payment system in Vietnam and could eventually be integrated into a capitation or Diagnosis Related Groups (DRG)-based payments for health services.
c) However, VSS – not health facilities – would currently incur most of the financial risk. To avoid solvency issues, this reimbursement method will require VSS to adjust the risk of payments based on facility needs and characteristics. Better information systems and facility-level data are needed. In their absence, VSS may under-reimburse some facilities (creating supply issues) while over-reimbursing others. For the latter group, there will be little incentive for facilities to improve performance or allocate ARVs efficiently.

Option B

Under another option discussed by VSS, SHI would reimburse ARVs by directly reimbursing contracted suppliers for the entire cost of ARVs for Vietnam in accordance with VAAC's ARV pricing agreements. Conceivably, these ARVs would then be distributed to health facilities for use. HFG's assessment is as follows:

a) The VAAC and drug suppliers prefer this option, which takes into account evidence that VAAC has greater capacity to predict ARV needs than do facilities. Financial risk would be entirely borne by VSS under such a payment system. It does not encourage allocative or technically efficient spending, and it takes a step backward from output-based payment

systems and targeted contracting (based on quality and costs). At present, VSS is not legally allowed to forward funding (especially such large quantities) to a third party.

Option C

Under such a scenario, health facilities would purchase ARVs from suppliers in accordance with the VAAC's drug pricing framework. These ARVs would be dispensed to PLHIV during clinical visits. VSS would reimburse health facilities for the cost of those ARVs using existing payment mechanisms. It does not appear, based on HFG's discussions with VSS and other health ministries, that this is a preferred option. Their rationale is similar to ours, with our assessment as follows:

a) While this retrospective reimbursement option incentivizes health facilities to manage budgets efficiently and forecast ARV needs, substantial risk is borne by those facilities. This is not a preferred option until facilities and VSS strengthen their health information systems, facilities build capacity to interpret data, VSS is able to audit and regulate facilities, and facilities become financially autonomous (particularly primary- and secondary-care facilities). It also places suppliers at significant financial risk, as the quantity of ARVs demanded may not meet the expected supply.

3.3.3 Ministry of Finance

Existing Landscape

While the DHI designs SHI policies and VSS implements them, the MOF currently subsidizes, through general tax revenue, roughly 50% of SHI expenditures. The MOF also funds the MOH, including VAAC. The NTP uses a portion of these finances to purchase ARVs. It is unclear to HFG how stable this funding is and how it will change in the future.

Proposed Options

Policy Recommendations for MOF (Short Term)

☑ The MOF and the MOH should identify politically feasible ways of generating additional revenue to offset subsidies for SHI or directly finance ARVs. This may include the renegotiation or reallocation of ear-marked taxes, such as those on alcohol and tobacco.

Ear-marked taxes can generate substantial revenue, according to a study by Katz et al. (2014) and as evidenced by countries such as Zimbabwe, Kenya, Thailand, the United States, Australia, and Korea. These may include excise taxes, such as those on alcohol, tobacco, or airfare purchases. At present, cigarette tax rates in Vietnam are below the global average and thus could provide a source of funds.

3.3.4 Ministry of Health

Existing Landscape

First-line ARVs procured through Vietnam's NTP currently account for 5% of total, national first-line ARV expenditures. However, the NTP (or the GVN more broadly) currently spends nothing on second-line or pediatric ARVs. ARVs procured through the NTP are channeled to VAAC. Among other MOH departments, the DHI designs SHI policies that can stimulate PLHIV enrollment in SHI or alter premiums for those individuals enrolled in SHI.

Proposed Options

Policy Recommendations for MOH (Short Term)

- ☑ VAAC should increase total ARV expenditures either as a percentage of its total budget or by negotiating with the MOF for a larger budget envelope.
- ☑ The DHI should develop policies to stimulate demand for and enrollment of PLHIV into SHI by subsidizing premiums and cost-sharing (i.e., co-pays) among enrolled PLHIV.
- ☑ The DHI should consider designing other demand-side policies, depending on the existing evidence base, that cap enrolled PLHIV out-of-pocket expenditures and improve education and awareness of SHI and covered benefits for PLHIV.
- ☑ The DHI and VSS should consider removing co-pays for ARVs for PLHIV enrolled in SHI to prevent them from obtaining free ARVs from the public system by not showing their SHI card.
- ☑ The DHI should revise policies that allow VSS to contract with OPCs to deliver HIV/AIDS services (including ARVs).

1) VAAC will need to absorb a greater share of total ARV first-line expenditures for the roughly 60-70% of PLHIV not enrolled in SHI, and it will likely become a procurement agent for second-line and pediatric ARVs. Even though PLHIV enrolled in SHI will rise over time, VAAC must increase total ARV expenditures either as a percentage of its total budget or by negotiating with the MOF for a larger budget envelope. It is unclear whether VAAC can successfully negotiate a larger budget envelope from the MOF.

2) The DHI should develop policies to stimulate enrollment of PLHIV into SHI by subsidizing premiums and cost-sharing (i.e., co-pays) among enrolled PLHIV. It is, however, both illegal and politically difficult for the MOF or VSS to provide direct subsidies funded through general tax revenues to members with specific clinical conditions such as HIV. This means that policies will need to target population groups by income or employment. Studies from Vietnam, Thailand, and other developing countries suggest that subsidies for the near-poor should be raised from 70% to at least 90% (World Bank, 2012). Countries such as Taiwan, the United States, Germany, Japan, the Philippines, Thailand, China, and Korea have found that providing substantial subsidies (90%+) and mandating enrollment have been an effective means to enroll the non-poor informal sector.

3) In addition to SHI subsidies, the DHI should consider designing other demand-side policies, depending on the existing evidence base, that cap enrolled PLHIV out-of-pocket expenditures and improve education and awareness of SHI and covered benefits for PLHIV. These are only two possible options for increasing PLHIV enrollment in SHI. Before developing additional strategies to increase PLHIV demand for and enrollment in SHI, the GVN should conduct studies to determine reasons PLHIV are not enrolling. This is a highly complex issue, and data are lacking. It is therefore not within the scope of this report to outline an array of strategies for enrolling PLHIV into SHI, aside from the removal of proven financial and educational barriers.

4) To prevent PLHIV enrolled in SHI from obtaining free ARVs using the public system, the DHI and VSS should consider removing co-pays for ARVs. Even if VSS were to begin reimbursing first-line ARVs for PLHIV enrolled in SHI, it is unlikely that PLHIV would use their SHI to obtain these ARVs. At present, ARVs are free for PLHIV without health insurance. There is thus no reason why PLHIV enrolled in SHI would purchase ARVs using their SHI card, which would require them to incur co-pays and other forms of out-of-pocket spending. Because the MOH is

unlikely to begin charging PLHIV for ARVs obtained through the public system, VSS should match the MOH by removing co-pays and other forms of cost-sharing for enrolled PLHIV when purchasing ARVs through SHI.

5) The DHI should revise policies to allow VSS to contract with OPCs to deliver HIV/AIDS services (including ARVs). A significant number of PLHIV, particularly the poor, rely on primary and secondary health facilities, such as commune health stations. However, VSS is not currently allowed to reimburse OPCs for HIV/AIDS services. If the GVN wants to increase PLHIV enrollment in SHI, it must allow VSS to contract with providers that PLHIV commonly use. Adopting such reforms also addresses efficiency and solvency concerns because services are less costly when delivered at primary and secondary health facilities. For a given bundle of services, input prices are lower than at hospitals or tertiary facilities.

4. MEDIUM-TERM POLICY OPTIONS (2018-20)

4.1 Governance

4.1.1 Central Procurement Unit Structure

The DAV and the DPF propose that the CPU should become a semi-autonomous (operationally, financially, and legally) agency. However, these departments prefer it to be housed in the MOH rather than exist as an external agency (e.g., VSS). The reasons for this are still unclear. This option can lead to a number of governance failures, including poor accountability, transparency, and overall effectiveness of the CPU. As is the case globally, there may be political reasons for this preference. The CPU is likely to have significant power and control over resources, and the MOH may not want to give this up.

HFG and several MOH departments (e.g., DPF, DAV) recommend that the CPU should have its own departments based on required roles and responsibilities. For instance, separate departments would (a) assess the value of drugs to be procured, (b) price and quantify pharmaceuticals, and (c) select vendors. Our team has also recommended that the CPU conduct international, competitive drug procurement (i.e., pharmaceuticals not developed in Vietnam). If implemented, the GVN would need to set up the tender process in English and publish it via international media and websites.

HFG recommended that the CPU absorb technical experts from other government agencies, such as the DPF, the DAV, the DHI, and VAAC (i.e., those working on ARV procurement). Greater funding would enable hiring of new staff trained domestically or internationally from multiple fields (e.g., health providers, economists, lawyers, and pharmacists). Some MOH departments such as DPF are amenable to these ideas. HFG was not able to address these issues with other MOH departments, such as VAAC.

The DPF and the DAV recognize the importance of central procurement for medical supplies and technologies. They believe that either another CPU could be developed and housed in the MOF or a single CPU would eventually incorporate pricing frameworks for medical supplies and technologies in addition to pharmaceuticals.

4.1.2 Decision-Making Structures

Roles and responsibilities will remain the same as those described in the "Short Term 2015-2017" scenario, except:

Central Procurement Unit

HFG, DPF, DAV, and DHI feel that, in the medium to long term, the CPU should establish pricing frameworks for an array of pharmaceuticals, including ARVs. The selection of pharmaceuticals would be contingent on a number of factors. Through discussions with EPI, VAAC, and the National TB Program, all parties have expressed their reservations about handing over procurement for their respective drugs (e.g., ARVs). However, they were relatively more amenable to this idea as a long-term solution.

Vietnam Administration of AIDS Control

If the above roles and responsibilities of the CPU expand to include disease-specific drug procurement (e.g., ARVs), HFG believes that VAAC should maintain its existing roles and

responsibilities but no longer be responsible for ARV sourcing and pricing frameworks. Under such a scenario, VAAC would need to downsize. Ideally its staff, which has been trained and works on ARV procurement, would join the CPU. This idea has been shared with VAAC, and its leaders appeared receptive; however, their thoughts on this topic were not entirely clear.

It is HFG's opinion that Vietnam cannot afford to have ARV stock outs, treatment interruptions, or unplanned regimen changes due to a transition in VAAC's roles and responsibilities. If such a transition were to occur, VAAC would need to closely monitor ARV procurement processes during this transition, particularly the selection of products, regimens, ARV consumption trends, and supply.

Ministry of Finance

Under our recommendation for the medium to long term, the MOF would need to earmark a greater share of resources to fund the CPU through general tax revenues. The CPU would use the funds to hire staff and support supplies and infrastructure. It is not clear how the MOF will respond to these recommendations, as no discussions have yet occurred on the topic.

Donors

Under our short-term options, we suspect that donors may play an innovative role in financing HIV/AIDS services for PLHIV, including ARVs, though this may be through SHI subsidies or other indirect mechanisms. It is likely that some continued support to strengthen capacity for ARV procurement would be needed.

4.2 Procurement

4.2.1 Central Procurement Unit and VAAC

From 2018 onward, by using the national bidding process, VAAC in principle could access all pooled first-line ARV formulations, plus LPV/r (or ATV/r) for second-line ARVs. This could be achieved either through local manufacturers or by foreign (e.g., Indian) imports. VAAC could select domestic manufacturers on a preferential price basis, as margins allowed for them are typically 15%.

Policy Recommendations for Procurement (Medium Term)

☑ Pathways for International Competitive Bidding (ICB), under Article 15 of the Bidding Law, should be explored and applied when local bidding of ARVs is expected to result in high prices without gains in quality relative to those manufactured internationally.

In a more competitive environment, drug manufacturers should lower prices to compete for business rather than monopolize the market and willingly inflate prices. International procurement offers the advantage of fresh batches, higher maximum shelf lives, and quality specifications (e.g., Vietnamese labeling). It enables the procuring entity (VAAC/CPU) to select the International Commerce (INCO) terms and compare unit prices based on these terms. Finally, it allows those entities to develop direct agreements with forwarders and clearing agents to control costs of freight, insurance, and importation, and tender between competing manufacturers on Free On Board (FOB or Cost, Insurance and Freight (CIF) unit prices. With ICB in place, foreign bidders may be more interested in working with the MOH so that bids for CIF unit prices can be received directly from manufacturers. This would increase pressure on domestic suppliers to lower their prices.

4.3 Financing

4.3.1 Donors

It is assumed that, in the medium to long term, donors and the GVN will consider fund-matching policies as a viable mechanism for maintaining international support and generating additional domestic revenues for HIV/AIDS. Under such an assumption,

Policy Recommendations for Donors (Medium Term)
☑ Donors should begin implementing matching policies that have been designed and negotiated with and agreed upon by the MOF and MOH.

4.3.2 Social Health Insurance

Under the assumption that, in the short term, VSS implements pilots to evaluate and select ARV reimbursement mechanisms,

Policy Recommendations for SHI (Medium Term)
☑ VSS should learn from its ARV reimbursement pilots and expand desired ARV payment mechanisms to all contracted health facilities. Over time, HFG recommends that ARV payments be integrated (bundled) with those for all HIV/AIDS services SHI covers.
☑ VSS and the DHI should consider a range of structural, technical, and legal reforms to expand SHI for PLHIV. Such reforms would eliminate bottlenecks that currently prevent VSS from efficiently reimbursing health facilities for ARVs.

Possible payment reforms could include:

1. Strengthen VSS's role as an active purchaser; introduce provider payment reforms to primary, outpatient, and inpatient care
2. Revise contracting agreements with health facilities based on quality and cost metrics, which will give health facilities an incentive to improve performance and efficiency. This should also curb medical-cost inflation, which includes HIV/AIDS services
3. Regulate and enforce balanced billing of health facilities; eliminate fraudulent claims/reimbursements. These measures will minimize PLHIV out-of-pocket payments
4. Enforce existing gatekeeping mechanisms (e.g., greater co-pays among enrolled members who bypass primary care facilities), which will control long-term costs by ensuring that PLHIV use, where clinically appropriate, cost-effective HIV/AIDS services. This also requires strengthening the quality of primary health care providers, such as Commune Health Stations.
5. Include preventive and primary HIV/AIDS services in the SHI benefit package to reduce long term HIV/AIDS costs and control the spread of Vietnam's HIV epidemic.

4.3.3 Ministry of Finance

Policy Recommendations for MOF (Medium Term)

☑ The MOF should implement revenue generation policies that have been designed and negotiated with the MOH and agreed upon. Under short-term options previously cited, these may include, for instance, earmarked taxes for ARVs.

4.3.4 Ministry of Health

While the number of PLHIV enrolled in SHI is expected to rise from its existing 30-40%, it is unlikely that insurance coverage will reach 100% for PLHIV by 2018 even if strategies are implemented to stimulate enrollment. As a result, HFG recommends that:

Policy Recommendations for MOH (Medium Term)

☑ VAAC should continue to fund a portion of total ARV costs until all PLHIV are enrolled in SHI. To ensure that all PLHIV receive drugs and treatment when needed, we recommend that PLHIV continue to receive free ARVs in the public sector if they are not enrolled in SHI.

☑ VSS should design studies to evaluate factors promoting PLHIV enrollment in SHI and then implement policies to stimulate enrollment in health insurance once DHI has designed them and the MOF has approved them.

Under the proposed medium-term options, these may include (but will depend on future research):

- Increase enrollment of PLHIV into SHI via
  - Premium/co-pay subsidies for key member groups
  - Caps to PLHIV out-of-pocket expenditures
  - Education and awareness campaigns
- Allow VSS to contract with OPCs for HIV/AIDS services, including ARVs

ANNEX A: GOVERNANCE QUESTIONS, BY DIMENSION

The following represent key questions that GVN stakeholders posed during meetings. Very few answers were provided to HFG by MOH departments, in part because these governance questions have not yet been thought through by the GVN. These questions were thus intended to stimulate discussion and help the MOH think through governance issues that will need to be addressed during the design and implementation of a CPU.

Governance Dimensions	Key Questions for Vietnam's Drug Procurement Reforms (CPU)
Decision-making Structures	Who are the key government agencies involved designing and governing the CPU? What are these agencies' formal roles and responsibilities? Will these roles and responsibilities be legally binding? How? By whom? Will these agencies have informal roles? If so, what are they? Will these informal roles impact formal decision-making structures? How? What mechanisms are or will be in place to resolve conflicts of responsibility between these key agencies? What level of decentralization will exist with regard to these decision-making structures?
Capacity	How will these agencies' roles and responsibilities correspond with their decision-making authority? How will you ensure that agencies have the resources and institutional capacity to effectively fulfill their roles and responsibilities?
Monitoring & Evaluation	How will feedback channels be developed to ensure that reliable, clear, and timely information is received and acted upon by these government agencies? Will tools/data/instruments be available to monitor and evaluate the link between drug procurement (CPU) policies, governing agencies' responsibilities, and health system performance?
Transparency & Accountability	Will drug procurement (CPU) policies be publicly available, easily understandable, and legally binding? To whom will each governing agency be accountable? How will consequences of non-performance by governing agencies be defined and implemented? How will you ensure that official and actual consequences of non-performance by these agencies remain the same? How will both autonomy and accountability for each agency be achieved?
Stakeholder Voice	Will non-governmental stakeholders play a role in policy decision-making and implementation of CPU reforms? If so, how? What procedures will be in place for civil society and private sector stakeholders to voice grievances? How will you ensure that stakeholder participation is equitable? How will you ensure that government agencies avoid being captured by private sector and civil society interest groups?
Regulation & Enforcement	What tools/instruments will be in place to ensure that drug procurement reforms (CPU) are effectively enforced? How will compliance and sanctions for governing agencies be clearly defined and enforced?
Stability	Will policies be in place to ensure that reforms to Vietnam's drug procurement system (CPU) endure and remain stable over time?

ANNEX B: GOVERNANCE ROLES, BY STAKEHOLDER

The following represent key roles and responsibilities that various stakeholders, such as GVN ministries, departments, donors, and civil society, must consider when designing a CPU. These cells were intentionally left blank, as they were not answered during HFG's meetings. In subsequent meetings, as stakeholders think more concretely about the design of CPU reforms and an implementation road map is developed, this table will be filled out.

Stakeholder	President	Prime Minister	National Assembly	Judiciary	Supply Chain Management System
Reform Process					
Design drug procurement (CPU) policy					
Steward of drug procurement (CPU) reform					
Decision Making Structures					
Appoint roles and responsibilities of governing agencies and stakeholders					
Appoint CPU supervisory/management board					
Capacity					
Set budgets and prioritize governing agencies' funding					
Allocate/ensure funding for governing agencies					
Determine staffing and institutional resources					
Allocate/ensure staffing and institutional resources					
Monitoring/Evaluation					
Collect data for health system performance					
Monitor and evaluate impact of CPU reforms on health system					
Regulation, Accountability, Transparency					
Define regulatory, accountability, and enforcement mechanisms					
Determine and enforce legal frameworks					
Monitor and enforce regulations					
Stakeholder Voice					
Monitor feedback channels between stakeholders and governing agencies					
Monitor stakeholder voice and grievances					
Revenue Collection					
Define revenue sources for CPU drug procurement					
Collect revenue for CPU drug procurement					
Pool revenue collected for drug procurement					
Set cost sharing and user fees for drugs					
Determine drug fund financial reserves					
Procurement					
Set drug pricing					
Define drug types and quantities					
Contract and determine vendors					
Set licensing agreements					
Purchasing / Provision					
Determine health provider payment/reimbursement methods					
Health service contracting					

Stakeholder	VAAC, MOH	DAV, MOH	DPF, MOH	DHI, MOH
Reform Process				
Design drug procurement (CPU) policy				
Steward of drug procurement (CPU) reform				
Decision Making Structures				
Appoint roles and responsibilities of governing agencies and stakeholders				
Appoint CPU supervisory/management board				
Capacity				
Set budgets and prioritize governing agencies' funding				
Allocate/ensure funding for governing agencies				
Determine staffing and institutional resources				
Allocate/ensure staffing and institutional resources				
Monitoring/Evaluation				
Collect data for health system performance				
Monitor and evaluate impact of CPU reforms on health system				
Regulation, Accountability, Transparency				
Define regulatory, accountability, and enforcement mechanisms				
Determine and enforce legal frameworks				
Monitor and enforce regulations				
Stakeholder Voice				
Monitor feedback channels between stakeholders and governing agencies				
Monitor stakeholder voice and grievances				
Revenue Collection				
Define revenue sources for CPU drug procurement				
Collect revenue for CPU drug procurement				
Pool revenue collected for drug procurement				
Set cost sharing and user fees for drugs				
Determine drug fund financial reserves				
Procurement				
Set drug pricing				
Define drug types and quantities				
Contract and determine vendors				
Set licensing agreements				
Purchasing / Provision				
Determine health provider payment/reimbursement methods				
Health service contracting				

Stakeholder	Department of Public Asset Management, MOF	Agency of Public Procurement, Ministry of Planning and Investment (MOPI)	CPU Management and Supervisory Board	Vietnam Social Security
Reform Process				
Design drug procurement (CPU) policy				
Steward of drug procurement (CPU) reform				
Decision Making Structures				
Appoint roles and responsibilities of governing agencies and stakeholders				
Appoint CPU supervisory/management board				
Capacity				
Set budgets and prioritize governing agencies' funding				
Allocate/ensure funding for governing agencies				
Determine staffing and institutional resources				
Allocate/ensure staffing and institutional resources				
Monitoring/Evaluation				
Collect data for health system performance				
Monitor and evaluate impact of CPU reforms on health system				
Regulation, Accountability, Transparency				
Define regulatory, accountability, and enforcement mechanisms				
Determine and enforce legal frameworks				
Monitor and enforce regulations				
Stakeholder Voice				
Monitor feedback channels between stakeholders and governing agencies				
Monitor stakeholder voice and grievances				
Revenue Collection				
Define revenue sources for CPU drug procurement				
Collect revenue for CPU drug procurement				
Pool revenue collected for drug procurement				
Set cost sharing and user fees for drugs				
Determine drug fund financial reserves				
Procurement				
Set drug pricing				
Define drug types and quantities				
Contract and determine vendors				
Set licensing agreements				
Purchasing / Provision				
Determine health provider payment/reimbursement methods				
Health service contracting				

Stakeholder	Provincial Government	Local Government	Private Health Insurance	Health Care Providers	Civil Society
Reform Process					
Design drug procurement (CPU) policy					
Steward of drug procurement (CPU) reform					
Decision Making Structures					
Appoint roles and responsibilities of governing agencies and stakeholders					
Appoint CPU supervisory/management board					
Capacity					
Set budgets and prioritize governing agencies' funding					
Allocate/ensure funding for governing agencies					
Determine staffing and institutional resources					
Allocate/ensure staffing and institutional resources					
Monitoring/Evaluation					
Collect data for health system performance					
Monitor and evaluate impact of CPU reforms on health system					
Regulation, Accountability, Transparency					
Define regulatory, accountability, and enforcement mechanisms					
Determine and enforce legal frameworks					
Monitor and enforce regulations					
Stakeholder Voice					
Monitor feedback channels between stakeholders and governing agencies					
Monitor stakeholder voice and grievances					
Revenue Collection					
Define revenue sources for CPU drug procurement					
Collect revenue for CPU drug procurement					
Pool revenue collected for drug procurement					
Set cost sharing and user fees for drugs					
Determine drug fund financial reserves					
Procurement					
Set drug pricing					
Define drug types and quantities					
Contract and determine vendors					
Set licensing agreements					
Purchasing / Provision					
Determine health provider payment/reimbursement methods					
Health service contracting					

BOLD THINKERS DRIVING
REAL-WORLD IMPACT