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Options for Integrating Procurement and Supply Chain Systems for ARVs, Methadone, and anti-Tuberculosis Drugs in Vietnam



August 2014

This publication was produced for review by the United States Agency for International Development. It was prepared by Kashi Barbara Carasso, Grace Chee, Altea Cico, Duong Hoang Quyen, Phan Cam Tu, Alexei Sitruk for the Health Finance and Governance Project.

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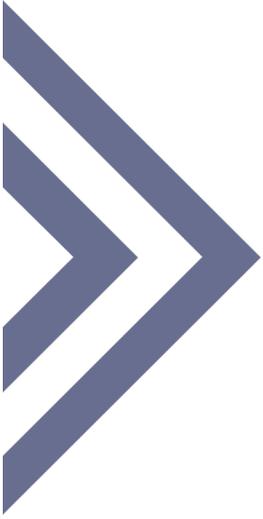
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ACRONYMS

ACTR	Asean Common Technical Requirements
AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral
ASEAN	Association of Southeast Asian Nations
CDC	United States Centers for Disease Control and Prevention
CHAI	Clinton Health Access Initiative
CPC-I	Central Pharmaceutical Company No. 1
CPMU	Central Program Management Unit
CPU	Central Procurement Unit
DAV	Drug Administration of Vietnam
DHI	Department of Health Insurance
DOH	Department of Health
DPF	Department of Planning and Finance
FDC	Fixed-Dose Combination
FLD	First-line anti-TB drugs
FSW	Female Sex Workers
GLC	Green Light Committee
The Global Fund	The Global Fund to Fight AIDS, Tuberculosis, and Malaria
GDF	Global Drug Facility
GPA	Government Procurement Agreement
GVN	Government of Vietnam
HAARP	HIV/AIDS Asia Regional Program
HCMC	Ho Chi Minh City
HFG	Health Finance and Governance Project
HIV	Human Immunodeficiency Virus
HR	Human Resource
ICB	International Competitive Bidding
IDA	International Dispensary Association Foundation
INCB	International Narcotics Control Board

LMIS	Logistics Management Information System
MDG	Millennium Development Goals
MDR-TB	Multidrug-resistant tuberculosis
MMT	Methadone Maintenance Treatment
MOF	Ministry of Finance
MOH	Ministry of Health
MOIT	Ministry of Industry and Trade
MPI	Ministry of Planning and Investment
MSH	Management Sciences for Health
MSM	Men who have Sex with Men
NCB	National Competitive Bidding
NFM	New funding model
NHTD	National Hospital of Tropical Diseases
NTP	National Targeted Program
OPC	Outpatient clinic
PAC	Provincial AIDS Center
PEPFAR	President's Emergency Plan for AIDS Relief
PFSCM	Partnership for Supply Chain Management
PPC	Provincial People's Committee
PPM	Pooled Procurement Mechanism
PO	Purchase Order
PQM	Promoting the Quality of Medicine Project
PR	Purchase Request
PSM	Procurement & Supply Chain Management
PWID	People Who Inject Drugs
SCMS	Supply Chain Management System
SHI	Social Health Insurance
SLD	Second-line anti-TB drugs
SMART TA	Sustainable Management of the HIV/AIDS Response and Transition to Technical Assistance
SOP	Standard Operating Procedure
TA	Technical Assistance
TB	Tuberculosis
TPPA	Trans-Pacific Partnership Agreement

UNAIDS	Joint United Nations Programme on HIV/AIDS
US FDA	US Food and Drug Administration
USAID	United States Agency for International Development
USP	U.S. Pharmacopeia Convention
VAAC	Vietnam Administration of HIV/AIDS Control
VSS	Vietnam Social Security
WB	The World Bank
WHO	World Health Organization
WTO	World Trade Organization
XDR-TB	Extensively drug-resistant tuberculosis

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EXECUTIVE SUMMARY

Introduction

The goal of Vietnam's Administration of HIV/AIDS Control (VAAC) is to ensure the provision of antiretroviral therapy (ART) to 105,000 people and of methadone maintenance treatment (MMT) to 81,047 people by 2015. Approximately 100,000 tuberculosis (TB) cases are treated with first-line anti-TB drugs (FLD) every year, and there is a target of providing treatment to 2,900 multidrug-resistant tuberculosis (MDR-TB) patients by 2015.

Currently, antiretroviral drugs (ARVs), methadone and anti-TB drugs are provided through different and parallel supply chains and to a large extent reliant on external donor funding from the President's Emergency Plan for AIDS Relief (PEPFAR) and The Global Fund to Fight AIDS, Tuberculosis, and Malaria (The Global Fund). In light of the significant decreases in donor resources planned for the coming years and the ambitious program scale-up plans, there is an urgent need to optimize utilization of resources by harmonizing and integrating existing procurement and supply chain systems, and transitioning to efficient government-led systems to ensure financial sustainability.

The primary purposes of this evaluation are to describe the current procurement and supply chain management (PSM) systems for ARVs, methadone, and anti-TB drugs in Vietnam managed by PEPFAR, The Global Fund and the National Targeted Programs (NTPs), with the aim of moving towards a government-led procurement and supply chain management system; analyze the content of relevant laws and decrees, in relation to supporting government-led centralized procurement; and assess pros and cons of various financing options in supporting government-led centralized procurement.

Procurement & Supply Chain Management of ARVs, Methadone & anti-TB drugs

The report provides a description of the different PSM systems for ARVs, methadone and anti-TB drugs using the different steps outlined in the PSM cycle: product selection, quantification, procurement, storage & distribution, reporting and ordering. In addition, human resource capacity of staff involved in the management of each specific commodity is discussed. Key findings of this section are as follows:

- 1) There have been little to no stock-outs or expiry of ARVs, methadone and anti-TB drugs over the past years. However, donors have played a key role in preventing shortages of these life-saving commodities.
- 2) Multiple parallel procurement and supply chain management systems exist, and each program – PEPFAR, The Global Fund and the NTPs – has its own mechanism of budget approval, quantification, procurement, distribution and reporting structure.
- 3) There is no common national ARV quantification & forecast between all programs, but first steps towards more coordination and harmonization have been made.
- 4) A unified ARV Logistics Management Information System (LMIS) is urgently needed to inform quantification and forecasting of need based on actual consumption and stock levels, and provide VAAC with the tools to monitor both needs coverage and performance of the supply chain at all levels and at all times.
- 5) In line with the national strategy on Vietnam's pharmaceutical industry's development, domestically manufactured first-line anti-TB drugs are procured with domestic resources, while the Government of Vietnam (GVN) is expected to procure locally produced methadone in 2014. Currently, very few first-line ARVs are produced locally.

- 6) Technical assistance to strengthen the limited human resource capacity on PSM is provided in an uncoordinated manner, and there is currently no strategic framework to transfer skills between partners.

Policy & Legal Analysis

The most important laws and regulations that were identified in relation to transitioning to a government-led centralized procurement system include the Pharmaceutical Law, Regulations on Drug Importation, the Bidding Law, the Prime Minister's Decision No. 68, and a number of international agreements that Vietnam signed or is considering to sign. The key legal findings are:

- The Pharmaceutical Law (2005) states, amongst others, that drugs can only be imported and distributed by Vietnamese entities. This regulation limits the possibility for international suppliers to directly sell their medicines in the country, or compete in tenders without a Vietnamese representative. It also gives priority to local products, when drugs are purchased with state budget.
- The Pharmaceutical Law and its guiding regulations on drug registration require all drugs circulating in Vietnam to have registration numbers issued by the Ministry of Health (MOH). Although following the Association of Southeast Asian Nations (ASEAN) Common Technical Requirements (ACTR) for drug registration, the laws only allow organizations that have a license to operate in Vietnam to apply for drug registration numbers. This would put an additional burden on any international suppliers.
- Drugs that have no registration numbers can be imported into Vietnam under a one-year valid Import License when they are procured under national target programs. Not all ARVs currently supplied by PEPFAR and The Global Fund are currently registered in the country. This situation could negatively impact on competition in the context of a government-led procurement.
- The Bidding Law (2013) and its related Decree (Jun 2014) outline the move towards 'concentrated' procurement whereby orders are pooled and procurement of certain medicines (to be defined) is conducted at the national level, starting from 2016 onwards. This regulation paves the way for the establishment of a procurement unit at central level to conduct the concentrated procurement of medicines with domestic resources.
- Prime Minister's Decision No. 68 supports the domestic pharmaceutical industry and aims to increase the share of domestically produced drugs to 80% of the total amount of drugs consumed during a year. This further promotes the procurement of locally manufactured drugs through national bidding at the expense of procurement from international sources, and especially applies to all procurement conducted with domestic resources.
- Lastly, Vietnam is an observer of the World Trade Organization's (WTO) Agreement on Government Procurement (GPA), and currently in the process of negotiating the Trans-Pacific Partnership Agreement (TPPA). Vietnam's strong preference for national bidding and procurement of domestically manufactured medicines may go against the international trade agreement's objectives of ensuring open, fair and transparent conditions of competition in the government procurement markets.

Financing of ARVs, Methadone & anti-TB Drugs

PEPFAR and The Global Fund provide approximately 95% of the funding for ARVs, with the remainder provided by the GVN. Funding for ARVs totaled \$21.2 million in 2014, compared with \$17.6 million in 2013. The GVN has affirmed its commitment to identify sustainable financing options for HIV/AIDS via the Prime Minister's Decision 1899. A significant barrier to successful transition to GVN-led procurement is that historically, prices paid by GVN for ARVs are two to six times higher than prices

paid by donors. Applying the local ARV prices to the existing population would mean total funding requirements of \$40 - \$120 million.

Methadone is primarily financed by PEPFAR and The Global Fund, with small contributions from the GVN and the Australian-funded HIV/AIDS Asia Regional Program (HAARP). Total funding for 2014 is \$6.0 million, compared with \$4.6 million in 2013. Prices for locally procured and domestically produced methadone are slightly lower than prices paid by PEPFAR and The Global Fund to procure internationally manufactured methadone (approximately \$33 versus \$38-40.) Nonetheless, the estimated cost of methadone to reach the target of 81,047 patients is \$11.6 million, approximately double the total funding for 2014 from all sources. The GVN has already begun to implement a transition plan to provide funding for methadone from domestic sources, including provincial budgets and user fees.

The GVN assumes full responsibility for financing, procuring, and distributing first line anti-TB drugs. In practice, however, national budget has been insufficient, and has only covered approximately 70-80% of estimated drug needs. Remaining drugs are provided through an ad hoc mix of provincial budgets, patient self-purchase and one-time international donations. Total NTP funding for FLD was \$5.3 million in 2014 and \$1.5 million in 2013, with 2014 representing the first time in many years that budget was available to cover 100% of the estimated drug needs. There is significant variability between prices available through the Global Drug Facility (GDF) and prices paid by NTP, with NTP paying lower prices for some drugs, but higher prices for others.

Second line anti-TB drugs (SLD) are financed through Vietnam's grant from The Global Fund. Total funding for SLD is \$4.0 million in 2014, compared with \$2.7 million in 2013. At the 2014 patient levels, the total cost of SLD is equal to approximately 80% of the cost of FLD, and expected increases in second line patients will require additional funding.

There are three key sources of potential financing for ARVs, methadone, and anti-TB drugs, each with challenges that must be addressed:

- **Central budget.** The key challenge to central budget financing for ARVs and anti-TB drugs is the legal framework, requiring procurement from domestic manufacturers and suppliers. Direct procurement through an international procurement agent is possible but would require government authorization of each procurement.
- **Provincial budget.** Provinces have begun to pool procurement across facilities, but ARVs would require procurement at the central level to obtain competitive prices because of their small quantities. Use of framework contracts or other financing mechanism would be required for payment from provincial budgets.
- **Social Health Insurance (SHI).** The SHI administrator, Vietnam Social Security (VSS) contracts with facilities for services and does not have a mechanism to pay a central drug facility. Furthermore, VSS can only pay facilities under the curative health system, but about half the facilities providing ARVs fall under the preventive health system.

Transitioning to a Government-Led PSM System

In order to transition to a government-led procurement and supply chain management system, different scenarios for the procurement of ARVs, methadone and anti-TB drugs to government institutions with domestic resources are described, taking into account the legal and financial analyses.

For the immediate term, until a central procurement unit (CPU) is set up and sufficient capacity has been built, procurement of ARVs with domestic resources can either be conducted through national bidding for the two ARVs that are relatively cheaper, or via direct procurement through an international supplier with previous experience in Vietnam. In parallel, urgent efforts should be deployed to establish a CPU and transfer skills to government staff responsible for different functions of the PSM cycle. For

the medium to longer term, the most likely scenario is a combination of national and international bidding, whereby competitively priced quality ARVs available on the domestic market are purchased locally and other products internationally through an international procurement agent.

The procurement of methadone through a national competitive bidding at central level is preferred to the decentralized procurement. A possible exception is decentralized procurement by Ho Chi Minh City (HCMC), which has a high burden of methadone users (and therefore a relatively large quantity to be procured) and an established CPU with capacity to tender and manage the procurement process. There is an urgent need to build capacity at the central level (even though a national tender with limited number of suppliers is easier to manage than an international competitive bidding) and set up a central procurement unit to manage the tendering and procurement process.

It is advised that the mechanism for the procurement of FLD and SLD should continue as is: *“If it works, don’t touch it”*. FLD are purchased with domestic resources through a national competitive bidding, although procurement responsibility should be delegated to the CPU once it is established. Given the serious public health threat of further spread of MDR-TB and extensively drug-resistant tuberculosis (XDR-TB), assured availability of quality affordable SLD is a priority. For this reason, it is proposed that the procurement of SLD through the Green Light Committee (GLC) remains under the funding responsibility of the donor community, until the CPU has been established, sufficient capacity has been built, and funding for SLD from the national budget firmly committed.

Recommendations

As donors are reducing or withdrawing their financial support, it is important that the coming years are used to build on lessons learned and scale up existing approaches that have proven effective, with a clear objective of transitioning responsibilities to government institutions. A number of overall recommendations to contribute to a successful transition of the procurement functions for HIV/AIDS and TB supplies to the Government of Vietnam are outlined below. In addition, Section 5 of the report lists specific activities that can be deployed by development partners, including the United States Agency for International Development (USAID) and The Global Fund, in the immediate, short to medium, and medium to longer term, and a summary of recommended activities is included in Annex D.

1) Develop a unified PSM strategy

A unified PSM strategy for ARVs and methadone should be developed, detailing the transition from the current parallel systems to one harmonized and government-led system. The PSM strategy should include specifics on the approach, roles & responsibilities for each step of the PSM cycle, and outline a coordinated approach and strategic framework for the provision of technical assistance. The development of this strategy should be spearheaded by VAAC, and discussed and updated in strategic working group meetings or joint forum with all key stakeholders.

2) Support preferred procurement mechanism (direct, national, international competitive bidding)

Once the preferred mechanism for the procurement of ARVs, methadone and anti-TB drugs from domestic resources is decided upon, strong support should be provided to the national targeted programs in implementing this strategy and overcoming possible bottlenecks in the process.

3) Establish a Central Procurement Unit

The preferred procurement mechanism for ARVs, methadone and first-line anti-TB drugs relies on the establishment of a Central Procurement Unit within the Ministry of Health, with sufficient capacity to manage all processes related to the procurement and management of international competitive biddings.

- 4) Set up a comprehensive single Logistic Management Information System for quantification & reporting

A comprehensive single LMIS from the peripheral level to the central level is urgently needed to ensure the collection, processing, reporting and use of information for decision-making; inform quantification and forecasting of need; and provide VAAC with the tools to monitor performance of the supply chain at all levels and at all times.

- 5) Mobilize resources from national and provincial government budgets

To ensure uninterrupted supply, the GVN will need to incorporate financing for these drugs within its national and provincial budgets. USAID and other donors are providing support to assist the GVN to identify appropriate financing sources and financing mechanisms.

- 6) Improve transparency of budgeting between central and provincial levels

Although there may be transparency in budgeting at the highest levels, it was difficult to understand the processes around coordination of budget contributions to the NTPs from various sources (i.e., provincial vs. central government allocations). Lack of coordination may lead to unexpected gaps in resource needs, or possibly over-allocations that are spent hastily.

- 7) Achieve full population coverage under Vietnam Social Security, including ARVs, methadone, and anti-TB drugs in the benefits package

Coverage of these drugs through VSS is most feasible if the entire population is enrolled in VSS. Full population coverage would more strongly support inclusion of these drugs within the benefits packages, and simplify planning and budgeting.

I. INTRODUCTION

Background

The goal of Vietnam's Administration of HIV/AIDS Control (VAAC) is to ensure the provision of antiretroviral therapy (ART) to 105,000 people and of methadone maintenance treatment (MMT) to 81,047 people by 2015. While significant progress has been made toward achieving those goals, Vietnam is largely reliant on international donors for provision of ARVs and methadone. The National Tuberculosis Control Program was established more than 30 years ago, with responsibility for ensuring availability of critical anti-TB drugs at national, district, and commune levels. To address the challenge of multi-drug resistance, the TB program relied on donors for second line drugs. As a result, multiple donors operate parallel systems to procure and distribute ARVs, methadone, and anti-TB drugs for Vietnam.

The HIV epidemic in Vietnam remains concentrated primarily among three populations defined by high levels of HIV-transmission risk behaviors: people who inject drugs (PWID), female sex workers (FSW) and men who have sex with men (MSM), but there are early warning signs of the epidemic spreading into the general population. According to a 2013 HIV sentinel surveillance in 41 provinces, prevalence among PWID, FSW and MSM (8 provinces) averaged 10.3%, 2.6% and 3.7% respectively¹. Overall adult HIV prevalence (ages 15-49) remained at 0.45% in 2012, which makes for a total 250,000 people living with HIV/AIDS in the country.² The overall prevalence among pregnant women attending antenatal care is estimated at 0.2%.¹ The distribution of HIV cases is heavily concentrated in urban centers, but rural areas are not spared especially in mountainous, remote and ethnic minority locations where people still have limited knowledge and services do not yet address the needs.

The ART program was introduced in the public sector in Vietnam in 2005, and is provided free of charge at 364 HIV stand-alone outpatient clinics (OPCs) and integrated facilities³. As of December 2013, the ART services were available in all 63 provinces, and over 25% of districts, covering a total of 82,687 patients, of which 4,204 were children. About 3% receive second-line ARV treatment.⁴ In its efforts to provide and scale up ARV treatment, the Government of Vietnam (GVN) is supported by international organizations, including the President's Emergency Plan for AIDS Relief (PEPFAR) and The Global Fund to Fight AIDS, Tuberculosis, and Malaria (The Global Fund). Donor contribution to ARV treatment has more than doubled over the past five years, with the 2014 budget for ARVs totaling US\$ 21 million, comprised nearly entirely of The Global Fund and PEPFAR funding.

MMT was started in Ho Chi Minh City (HCMC) and Haiphong in May 2008, and has since been expanded to cover 101 MMT clinics in 32 provinces and cities with a total of 18,157 patients receiving their daily methadone dose in June 2014.⁵ Currently, methadone medication is being supplied by PEPFAR and The Global Fund (US\$ 4.3m and US\$ 1.3m for 2014, respectively), with plans for the first government procurement from domestic resources in 2014.

Tuberculosis (TB) is a major public health concern in Vietnam. Vietnam ranks 12th among the 22 countries that comprise 80% of the global TB burden, and 14th among the 27 countries with the highest

¹ Vietnam AIDS response progress report 2014.

² <http://www.unaids.org/en/regionscountries/countries/vietnam/>

³ D28 Routine Program Report. VAAC, MoH 2013.

⁴ National Plan on Coordination of ARV Supply for 2014.

⁵ Conference Report: Mid-term Review of HIV/AIDS Activities in 2014 and Plans in 2015, Ha Noi, July 9, 2014



burden of multidrug-resistant tuberculosis (MDR-TB). Despite having met the targets for case detection and treatment success (85% case detection rate smear-positive cases and 93% treatment success rate) and the Millennium Development Goal (MDG) targets for reductions in TB cases and deaths, TB remains a challenge with an estimated 147 new cases and 20 deaths per 100,000 in 2012. Approximately 100,000 TB cases are treated with first-line anti-TB drugs every year, with a 5% annual increase. The number of new MDR-TB cases each year is approximately 3,500. A total of 916 multi-drug-resistant cases were diagnosed and enrolled for treatment in December 2013, with a target of providing treatment to 2,900 MDR-TB patients by 2015.

Problem Statement

Currently, ARVs, methadone and anti-TB drugs are provided through different and parallel supply chains and to a large extent reliant on external donor funding from PEPFAR and The Global Fund. In light of the significant decreases in donor resources planned for the coming years and the ambitious program scale-up plans, there is an urgent need to optimize utilization of resources by harmonizing and integrating existing procurement and supply chain systems, and transitioning to efficient government-led systems to ensure financial sustainability.

USAID/Vietnam recognized the need to evaluate the procurement and supply chain systems for ARVs, methadone and anti-TB drugs, in order to identify options for integration and transition to government management. Findings from this evaluation will assist development partners to support the Government of Vietnam in a successful transition toward government-led, financially sustainable procurement and supply chain systems.

Objectives of Evaluation

The primary purposes of this evaluation are to:

- Describe the current supply chain systems for ARVs, methadone, and anti-TB drugs in Vietnam managed by PEPFAR, The Global Fund and the National Targeted Programs, with the aim of moving towards a government-led procurement and supply chain management system.
- Analyze the content of relevant laws and decrees, in relation to supporting GVN-led centralized procurement.
- Assess pros and cons of various financing options in supporting GVN-led centralized procurement.

2. METHODOLOGY

The assessment was carried out from 9 to 27 June in Hanoi, HCMC and Haiphong. The team was composed of two health financing specialists, a legal expert, a public health expert and two procurement and supply management specialists.

Key informant interviews were conducted using a semi-structured questionnaire, which left sufficient room to obtain more in-depth information on specific topics relevant to the informant. A total of 39 interviews were conducted. The same team of interviewers led all but three of the interviews conducted in order to ensure consistency of interpretation. Responses were validated through subsequent interviews with other staff members of the same organization or department and with other stakeholders from different organizations. The responses' validation process involved discussing findings from the literature review during interviews as well as crosschecking related findings from province and facility level with views from national level.

The selection of the provinces was based on the observation that HIV prevalence was the highest amongst PWID, MSM and FSW in Hanoi, HCMC and Haiphong. Moreover, TB prevalence is the highest in the southern part of the country; HCMC accounts for 13-15 percent of all new cases.

The team carried out a desk review of key documents prior to the mission to Vietnam. These include inter alia national policy documents, strategies, laws, decrees; previous reports and assessments, annual reports of national programs; and PSM & finance specific documents and reports from PEPFAR, The Global Fund and the National Targeted Programs.

The team identified key informants and interviewed representatives of the following organizations: VAAC, Department of Planning and Finance (DPF), Department of Health Insurance (DHI) and Drug Administration of Vietnam (DAV) within the Ministry of Health (MOH); Ministry of Planning and Investment (MPI); Ministry of Finance (MOF); Vietnam Social Security (VSS); National Hospital of Tropical Diseases (NHTD); Central Pharmaceutical Company No 1 (CPC-1); PEPFAR/the Supply Chain Management System (SCMS); Central Project Management Unit (CPMU) of The Global Fund; USAID; World Health Organization (WHO); the Joint United Nations Programme on HIV/AIDS (UNAIDS); The World Bank (WB); FHI 360's Sustainable Management of the HIV/AIDS Response and Transition to Technical Assistance (SMART TA); and Clinton Health Access Initiative (CHAI). In order to collect the views of provinces and health facilities, the team had meetings organized with Department of Health (DOH), Provincial AIDS Committee (PAC), Out Patient Clinics, methadone clinics and TB clinics in Hanoi, HCMC and Haiphong.

General limitations that pertain to any assessment related to the timely availability or the lack of documentation, especially on budgets, expenditures and products (to allow in-depth review of sub categories such as pediatric anti-TB or ARV drugs). A second limitation relates to the challenge of obtaining inconsistent information from key informants. Sometimes the team collected confusing and contradictory information from different sources, which made the triangulation more difficult. Considering the short timeframe available to carry out the assessment, only two provinces and few facilities could be visited, which does not provide a fully representative sample. The limited time for the assessment did not allow for organizing additional in-depth interviews (follow-up meetings) with technical staff following the high-level meeting with managers. Lastly, the team's recommendations will have to be reviewed in light of new developments that may substantively change the environment, such as the Bidding Law Decree, Trans-Pacific Partnership Agreement (TPPA) negotiation, and the expansion of the domestic manufacturing of methadone.



3. FINDINGS

The following sections outline in turn the findings related to procurement and supply chain management, to the policy and legal analysis, and to the current financing of the procurement of ARVs, methadone and anti-TB drugs in Vietnam.

3.1 Procurement & Supply Chain Management of ARVs, Methadone and anti-TB drugs

This section is structured by commodity type – ARVs, methadone and anti-TB drugs – using the different steps outlined in the PSM cycle: product selection, quantification, procurement, storage & distribution, reporting and ordering. In addition, human resource capacity of staff involved in the management of each specific commodity is discussed. Then, key findings for the procurement and supply chain management of the three commodities in Vietnam are outlined.

3.1.1 ARVs

Selection

The selection of first-line, second-line and pediatric ARVs is in line with the 2010 revision of WHO guidelines. The Vietnam MOH's Guidelines for Diagnosis and Treatment of HIV/AIDS (2009) feature initiation at CD4 cell count at less than 250 cells/mm³ and combinations of zidovudine (AZT) or stavudine (d4T), lamivudine (3TC), and nevirapine (NVP) or efavirenz (EFV) as MOH-preferred first-line regimens. However, in 2011, the CD4 threshold for starting ART was increased to 350 cells/mm³ and tenofovir (TDF)-based regimens were recommended for first line treatment (Decision No. 4139/ QĐ-BYT dated November 2011) and in 2013 stavudine (d4T) has been successfully phased out from first line treatments, to be replaced by a TDF-based regimen. Currently, 90% of new patients are started on the 3-in-1 fixed-dose-combination 3TC/TDF/EFV, and 10% on 3TC+TDF+NVP. Patients needing second-line protocols mostly receive ritonavir-boosted lopinavir (LPV/r) as protease inhibitor (together with 3TC+TDF or 3TC/ZDV). Most of the children are under AZT-based protocols, while a small percentage use abacavir (ABC)-based or second-line regimens.

In addition, the range of different ARVs and formulations has been brought down from 37 to 21 today by rationalizing treatment protocols and using fixed-dose combination where possible. This facilitates procurement by consolidating relatively small quantities of especially second-line and pediatric ARVs.

Quantification & Forecasting

Each of the three programs – the National Targeted Program (NTP) for HIV/AIDS, PEPFAR and The Global Fund – conducts its own quantification and forecasting of need independently from each other.

PEPFAR, through the SCMS⁶, undertakes morbidity- and consumption-based quantification based on patient number targets in PEPFAR-supported sites and stock levels of the different ARVs. The final gross

⁶ The Supply Chain Management System (SCMS) is implemented by 13 organizations, led by the Partnership for Supply Chain Management (PFSCM), a partnership of JSI and MSH. SCMS provides global procurement and distribution for essential HIV/AIDS medicines and supplies needed to provide care and treatment of people living with and affected by HIV. It is funded by the President's Emergency Plan for AIDS Relief (PEPFAR) through the U.S. Agency for International Development.

results are also checked with the service-level projection method. It uses the software Quantimed and Pipeline to conduct quantification and order planning.

The quantification of ARVs procured under The Global Fund grant is conducted by its Central Program Management Unit, and uses a morbidity-based method to estimate the need. As for PEPFAR, it is also reliant on the same clinic-level data on patients treated in the supported sites (patients by treatment protocol, as well as dispensed quantity by formulations) and takes into account the year-end target (number of adults and children receiving ART) of the performance framework.

The NTP for HIV/AIDS conducts its quantification primarily based on available funding, and purchases the widely used double and triple zidovudine (ZDV)-based fixed dose combinations, which are relatively less costly (see also: procurement). The NTP-supported OPCs receive complementary ARVs from The Global Fund and PEPFAR.

In 2011, under VAAC leadership, a national quantification team was established. This team consists of the Care and Treatment Unit of VAAC, quantification teams of SCMS and CPMU/The Global Fund and program managers of USAID and CHAI. Each of the partners estimates the need and order quantity for their respective program, and during the 5-day quantification meetings, a coordination and distribution plan is made based on potential over- or under-stock in the different program sites. The quarterly meeting is also attended by other partners from different organizations including WHO, the United States Centers for Disease Control and Prevention (CDC)-LifeGap, SMART TA/FHI 360. In early 2014, the quantification team also conducted an exercise to come up with an estimate of annual national ARV need for Vietnam.⁷

The quantification exercises by the different programs attempt to combine separate forecasts from the different partners, which are based on unsynchronized sources of data, data processing and calculation methods. According to the single ARV supply system orientation of VAAC, in the future these separate forecasting activities will be gradually harmonized and integrated into one single national forecast.

Procurement

Procurement of ARVs is carried out by each of the partners separately. All three partners procure first-line ARVs (even though the NTP for HIV/AIDS only procures two formulations), while both PEPFAR and The Global Fund buy second-line ARVs, and pediatrics are currently only procured by The Global Fund.

Firstly, the procurement of ARVs with PEPFAR-funding is conducted by SCMS, for the PEPFAR-supported OPCs. Established in 2005 with funding from PEPFAR and managed by USAID, SCMS supplies products for HIV/AIDS programs in PEPFAR-supported countries. Procurement has to adhere to requirements that all medicines are approved or tentatively approved by the United States Food and Drug Administration (US FDA) regulations or WHO pre-qualified/approved or stringent regulatory authority.⁸ Additionally all medicines must comply with the import requirements of Vietnam including original certificates of analysis and origin verification. SCMS places four orders per year, which allows ample flexibility to adjust orders throughout the year. Delivery time after ordering is about 6 months, while for emergency orders it is 3 months or less.

The Central Program Management Unit conducts the procurement of ARVs with funding from The Global Fund by using the Pooled Procurement Mechanism (PPM). Under The Global Fund requirements, all ARVs procured with its funding need to be prequalified by WHO or approved by a stringent regulatory authority or reviewed by an Expert Review Panel. Since the end of 2013, The Global Fund

⁷ National Plan on Coordination of ARV Supply for 2014, April 2014.

⁸ <http://www.fda.gov/InternationalPrograms/FDABeyondOurBordersForeignOffices/AsiaandAfrica/ucm119231.htm>

informed Vietnam that ARV drugs could only be ordered once a year⁹ (one order for adults and one for pediatric ARVs), and the quantity to be delivered cannot be adjusted by more than 10%. Delivery time after ordering with PPM mechanism ranges between 8 and 10 months, while it is 6 months for an emergency order.

SCMS is managed by the Partnership for Supply Chain Management (PFSCM), which also holds the contract for The Global Fund's PPM. However, apart from differences in delivery time and order frequency as mentioned above, it was reported that documentation for PPM orders is often missing, incorrect or late, resulting in order delays and additional cost incurred, potentially affecting quality of medicine.¹⁰ As in the end the same agent (i+ solutions) is responsible for procurement of ARVs for both SCMS and PPM, the problems experienced specifically with PPM reflect the lower capacity of the partner managing the process upstream, i.e. the CPMU (compared to SCMS for PEPFAR). This partner is amongst others responsible for products specifications, accurate quantification based on quality data reported through a reliable information system, proper import procedures and clear communication; if this is not in place, the procurement process is undermined.

Lastly, VAAC has outsourced the procurement of ARVs with domestic (NTP for HIV/AIDS) resources to the National Hospital of Tropical Diseases. Once the annual forecast for ARVs has been finalized, the basic steps for procurement are bureaucratic, and releasing funding for procurement – even if it has been earmarked for drug procurement – is a lengthy process.¹¹ It takes nearly one year from the planning to the tendering phase, during which time the treatment situation and protocols can change considerably. The National Targeted Program's procurement plan therefore can become relatively obsolete over time. Currently, tendering (exclusively domestic) takes 3-4 months, approval is time-consuming, and once approved, the plan may not be modified. This leads to major delays and outdated drugs orders.

The other major bottleneck is that all drugs procured with domestic resources have to be bought on the local market (either locally manufactured or imported), where prices of ARVs are two to six times higher than international reference prices^{12,13}(see also: Section 3.3.1.1). It has therefore been agreed with PEPFAR and The Global Fund portfolio manager that Vietnam's NTP for HIV/AIDS would procure the relatively less costly ARVs, while The Global Fund's grant would be used to procure ARVs to supplement the supply of ARVs to both The Global Fund and NTP for HIV/AIDS supported OPCs.¹⁴

⁹ Previously ARVs could be ordered 4 times per year. This was changed to once a year to minimize the workload for the CPMU. However, also less flexibility.

¹⁰ Letter by Ministry of Health, VAAC dated May 2014: "The procurement and supply of ARVs through procurement mechanism in Vietnam and International" (translated from Vietnamese).

¹¹ Steps are: 1) Procurement request is sent by the technical group to the Care & Treatment Sub-committee; 2) The Care & Treatment Sub-committee meets, reviews, and comments on the procurement request; 3) The technical group revises the procurement request accordingly and prepares a draft Decision on the approval of the procurement list, including drug names, quantities, estimated prices, etc. The procurement plan, draft Decision and the Care & Treatment Sub-committee meeting minutes are submitted to the VAAC leadership; 4) The plan is reviewed and approved by the leader of the VAAC by his signing off on the Decision, 5) The MOH Department of Planning and Finance reviews and approves the procurement plan Supply Chain of the HIV/AIDS Program in Vietnam. 6) The National Program technical group sends the approved plan to the National institute of Tropical Diseases, 7) (Local) tendering is conducted by NHTD staff according to the Law on Tendering.

¹² Letter from PEPFAR to Dr Long/VAAC on ARV supply harmonization for Vietnam's HIV/AIDS response; June 11, 2013.

¹³ A quick check in the private pharmacies in Hanoi showed that 3TC (lamivudine) 100mg from STADA local manufacturer sold for VND 11,000 per tab (selling by tab!). This comes to VND 12 m or USD 600 per year for MONO-therapy, compared to the international reference price of USD 25 per year. It is very dangerous to sell mono-therapy, and to sell by tab, as it greatly increases the risk of resistance. In addition, the selling price is 24 times the global reference price.

¹⁴ PEPFAR letter to VAAC "ARV Supply Harmonization for Vietnam's HIV/AIDS Response", dated June 11, 2013.

Table I: ARV 1st line Regimen Cost per Patient per Year

	Name of regimen	ARV Cost per patient per year (VND)			NP/PEPFAR
		PEPFAR	Global Fund	National Program	
1	TDF/3TC/EFV	2,646,000	2,809,800	11,224,800	424.2%
2	TDF/3TC/NVP	1,927,800	1,877,400	8,128,800	421.7%
3	AZT/3TC/EFV	2,517,480	2,361,240	8,280,000	328.9%
4	AZT/3TC/NVP	2,041,200	2,021,040	4,248,000	208.1%

Source: USAID [Dao Nguyen]

Storage & Distribution

All three partners use the state-owned Central Pharmaceutical Company No. 1 (CPC-1) for storage at central level (Hanoi), whereas ARVs for PEPFAR-supported sites in the south are delivered directly at CPC-1 in HCMC. For The Global Fund's and NTP's ARVs, CPC-1 warehouse in HCMC is merely used as a transit warehouse rather than a storage facility. There are no specific challenges about storage and warehousing.¹⁵

Since November 2013, all ARVs funded by The Global Fund and PEPFAR are delivered from central warehouses directly to the treatment sites – as opposed to via the Provincial AIDS Center as is still currently done by the NTP for HIV/AIDS – in order to reduce lead-time to sites, lower stock at decentralized levels, and reduce paperwork.

As one of the outputs of the quarterly meeting, VAAC coordinates with The Global Fund and SCMS the development of an overall distribution plan for ARVs and methadone for all sites and sends it to CPC-1 for distribution to those sites. Distribution to The Global Fund and PEPFAR supported sites happens bi-monthly, on the odd and even months, respectively. In reality, one site may receive ARVs from the different partners every month to prevent under-stock of certain ARVs.

Reporting

There is no national logistics management information system (LMIS) per se. Each partner manages the information relating to its site using parallel systems and different tools although the paper forms used are relatively harmonized. OPC sites report on a monthly basis to PACs on number of patients by ARV regimen and stock balance, in soft (Excel-based) and hard copy. Reports are consolidated at PAC level, and the aggregated demand is sent to VAAC while some PACs also send the site-level reports. Sites supported by PEPFAR and The Global Fund also send their reports directly to SCMS and CPMU, respectively.

The timeliness, accuracy and completeness of reporting on patient numbers and stock balances – from sites to provincial level, and from provinces up to central level – was said to be low in sites supported by The Global Fund and the NTP for HIV/AIDS, and significantly higher in sites supported by PEPFAR. Variation in performance between the sites supported by the different donors could be attributed to the fact that until 2013, SCMS has put significant emphasis on recruiting additional staff at OPC level and building capacity at sites to ensure proper management of data, which in turns feeds into proper quantification and forecasting at central level. This type of additional technical assistance has not been available to sites supported by The Global Fund and the NTP for HIV/AIDS.

¹⁵ Tomsej, Xavier and Tran, Lam Quan. 2013. *Drug Supply Chain of the HIV/AIDS Program in Vietnam: Report on the VAAC's National Assessment*. Submitted to the US Agency for International Development by the Supply Chain Management System (SCMS).

In addition, for PEPFAR, The Global Fund and NTP for HIV/AIDS, it is unclear how the data collected is actually used at different levels. At site and provincial level, their function seems to be limited to inventory control and some redistribution between sites. However, staff interviewed did not know key measures such as months of stock on hand, or requested vs. received quantity of specific ARVs. Capacity at central level to use the collected (often incomplete) data for proper quantification and forecasting also seemed to be limited, especially at VAAC and CPMU.

Ordering (Push & Pull)

For The Global Fund supported sites, the responsibility of ARVs ordering (estimate of need for different ARVs) has been decentralized to provincial level (pull system), whilst for sites supported by the NTP for HIV/AIDS ordering is also supported by VAAC staff at central level. The emphasis has been on using ASUMAT (an Excel®-based tool developed with the support of WHO) to promote the use of data at peripheral level. It is deployed at PAC level with the objective of improving inventory control and data management. The estimate is based on the number of patients by ARV regimen and stock balance and on the number of patients per regimen expected to receive ARV treatment over the next three months (morbidity based), with a correction factor taking into account actual consumption and stock balance. It is not clear, however, whether ASUMAT includes any alert system that would flag risk of stock out or excess stock, and to what extent it is actually implemented.

For PEPFAR-supported sites, until recently the estimate of need was managed at central level by SCMS staff. Here, data on number of patients by ARV regimen and stock balance at OPCs were used to calculate need using morbidity-based methodology for new OPCs and consumption-based methodology for stable OPCs.

SCMS recently introduced a new ARV Management Tool and organized trainings at eight PACs and HCMC in an attempt to strengthen national quantification capacity, place more responsibility on PACs in terms of control and oversight, improve data management and decentralize distribution planning (see below). SCMS envisages that once capacity for needs estimate and quantification is sufficiently strengthened at provincial level, PAC staff will in turn train OPC staff who will eventually be responsible for quantification and forecasting of need.

It should be noted that one PAC oversees a number of OPCs, which may be supported by PEPFAR, The Global Fund and/or the NTP for HIV/AIDS. This means that PEPFAR's focus on improving site-level data with one type of software introduced at site and provincial level may not be aligned with The Global Fund and NTP's approach of strengthening capacity with a different system at provincial level. It is thus far unclear which of the approaches will be formally introduced in all sites in order to ensure one harmonized and integrated LMIS and reporting system.

Human Resource Capacity

Human resource capacity – both in terms of numbers as well as in technical knowledge on procurement supply management – especially within the VAAC and The Global Fund CPMU is limited.

Within VAAC, there is currently one full-time staff who is responsible for quantification, distribution planning, ordering and data analysis for decision-making; compared to five staff members (funded by donors) to carry out these activities in the past. At CPMU, capacity was also described as limited. This results for instance in [1] more problems encountered with procurement through the PPM versus through PFSCM reflecting the lower capacity of the partner managing the process upstream (CPMU vs SCMS) [2] less tools, capacity and resources to monitor ARVs availability across facilities supported by The Global Fund and the NTP for HIV/AIDS, identify risks of stock outs and excess stocks and proactively act upon them (to prevent treatment interruption). A number of staff members work both at the VAAC and at The Global Fund CPMU; this represents an opportunity for harmonization and coordination between The Global Fund and NTP for HIV/AIDS, but also potentially creates some

confusion over the roles and responsibilities of each party. Procurement is outsourced to the NHTD, which has conducted procurement from domestic sources through national competitive bidding. This arrangement also means that no procurement capacity has thus far been developed within VAAC. By contrast, SCMS has sufficient well-trained staff to conduct all PSM-related activities for PEPFAR-supported sites. The unit in charge of quantification, reported data review and analysis, and distribution is well-staffed and capable of managing all aspects of the PSM cycle, which results in satisfactory ARV availability and limited loss to expiry.

At peripheral level, SCMS has been providing technical assistance to site, provincial and national level. Recently, under VAAC leadership and with USAID support, SCMS has introduced technical documents, training materials, standard operating procedures (SOPs) and a new SQL-based software ("ARV dispensing & distribution management tool") at eight focused PACs and in HCMC. The tools are built to focus on four components of supply chain, including supportive supervision; training and capacity building; inventory management; and information management & distribution. SCMS is now working closely with VAAC to build the measurable indicators to help them control the quality of reports and distribution, and the knowledge and skills for supply chain, which are transferred by SCMS to GVN.

Capacity was said to often be inadequate at provincial (PAC) and site (OPC) level. For instance, validation of data and supervision by PACs was deemed insufficient, as was reporting capacity at site level. PEPFAR has devoted considerable resources and attention to ensuring sufficient human resources in the PEPFAR-supported OPCs. As a result of the decrease in funding, the number of staff hired through the PEPFAR-program is currently scaled back.

3.1.2 Methadone

Selection

The product selection is straightforward, as there is only one formulation used: methadone HCl 10mg/ml, optional cherry-flavored.

Quantification

Quantification is mostly funding driven, and is based on patient targets of the different programs: The Global Fund, PEPFAR and the Australian-funded HIV/AIDS Asia Regional Program (HAARP). For 2014, the targets are to provide methadone for 12,500 patients under PEPFAR, 12,500 patients under The Global Fund, and 2,000 patients under HAARP. The latter program will be discontinued at the end of this year. In addition, the NTP/VAAC will procure methadone from domestic resources in 2014, covering the need for 3,000-4,000 patients. A technical subcommittee (on MMT, syringe exchange and HIV prevention) under the National Technical Working Group on Harm Reduction holds meetings on a monthly basis with representatives from VAAC, CDC, FHI 360, CPMU and USAID, during which information is shared on progress in methadone provision and scale-up of clinics.

It should be noted that methadone is a controlled substance, and subject to the international treaty regulating availability of opioids. Every year, national authorities prepare an estimate of the amount of controlled substances that will be needed in the country during the following calendar year. The treaty requires the International Narcotics Control Board (INCB) to confirm the national estimate before the national government may permit the export and import of controlled substances to a country.¹⁶ The restriction on quantity purchased could limit the potential for the very rapid scale-up of the program from 18,000 currently to 81,047 patients by the end of 2015.

¹⁶ A 'step-by-step' algorithm for the procurement of controlled substances for drug substitution treatment. United Nations Office on Drugs and Crime (UNODC), 2007.

Procurement

The procurement process for methadone resembles that for ARVs. Methadone financed with PEPFAR-funds is procured by SCMS through PFSCM, while The Global Fund-funded methadone is procured through PPM. Due to the special import license for controlled substances that is required, only one order per year is placed for Global Fund-funded methadone, while for PEPFAR SCMS usually places four orders per year.

As of June 2014, a total of five local manufacturers have the capacity and were granted authorization by the Drug Administration of Vietnam to produce methadone in the country (of which one, VIDIPHA, has been registered thus far), while one local importer of methadone (produced in India) is in the process of registering its product. The USAID-funded Promoting the Quality of Medicine (PQM) project, implemented by the U.S. Pharmacopeial Convention (USP), has provided technical assistance to support the local production of methadone and procurement of methadone finished product.

At the end of 2013, the first procurement of domestically manufactured methadone in Vietnam was conducted by HAARP (this program will discontinue this year). It is expected that VAAC will procure locally manufactured methadone with domestic resources later in 2014. This was already planned to have happened in 2013, but due to the slow and bureaucratic procurement processes and the lack of experience and capacity in procurement at VAAC, this could not happen before the budgetary cut-off date (September).

Similarly, HCMC, through its recently established Central Procurement Unit, is planning to locally procure both domestically manufactured and imported methadone from provincial resources in 2014.

The price of domestically manufactured methadone is comparable with that purchased on the international market; approx. VND 700,000 or US\$33 per liter, plus 12% for storage and distribution, totaling US\$37 per liter (compared to up to US\$38-40 per liter for the methadone procured through PFSCM); and includes distribution costs to MMT clinics.

Storage & Distribution

As is the case for ARVs, the methadone is received at CPC-I at central level, and from there distributed directly to site level. Supplies are stored in separate secure warehouses and strictly earmarked for either The Global Fund or PEPFAR-supported methadone clinics. For the HAARP funded methadone locally procured and domestically manufactured, the manufacturer, VIDIPHA, will be in charge of the storage and distribution to MMT clinics, as it has been granted authorization by DAV to act as a distributor. VAAC's Harm Reduction Unit is in charge of putting together the distribution plans for all MMT clinics.

Reporting

The methadone clinics report to the provincial-level PAC on a monthly basis on the number of patients on methadone maintenance treatment and on consumption of the drug, as well as directly to the CPMU and PEPFAR unit at VAAC (for The Global Fund and PEPFAR-supported sites, respectively). The PAC in turn reports to Department of Health at province level, as well as to VAAC at central level. It is unclear to what extent the DoH actually exercises the control and oversight of the controlled substances used in its province.

Ordering (Pull & Push)

For PEPFAR, sites submit their report and requests to PAC for consolidation and to DoH for approval, where these are subsequently submitted to VAAC for final consolidation and approval. For The Global Fund supported sites, the CPMU conducts the needs estimate calculated using the MMT clinics reports

on patients and methadone consumption. VAAC is responsible for putting together the plans for distribution to all clinics.

Human Resource Capacity

The capacity of staff at VAAC to manage tasks related to the quantification, storage & distribution and reporting of methadone seems satisfactory. SCMS and The Global Fund CPMU are currently primarily responsible for the procurement and VAAC's lack of experience and capacity in procurement, compounded by the slow and bureaucratic government budgetary and procurement processes, could undermine the local procurement of domestically manufactured methadone using domestic resources.

3.1.3 Anti-TB drugs

Selection

In 2013, the National Tuberculosis Program issued new guidelines stipulating the 6-month regimen (2HRZE/4HRE) as first-line treatment for tuberculosis in new patients, and the 8-month regimen (2SHRZE/HRZE/5HRE) for previously treated patients. Children with TB are treated with the 6-month HRZ(E)/4RH regimen.¹⁷ These guidelines are in line with WHO recommendations for treatment of new TB patients in populations with known or suspected high levels of isoniazid resistance, and for retreatment regimen with first-line drugs.¹⁸

The emergency consignment of first-line anti-TB drugs (FLD) supplied through the Global Drug Facility (GDF) consists of 2HRZE/4RH regimen for new patients and 2SHRZE/HRZE/5HRE regimen for previously treated patients, which is not in line with the current preferred first-line regimen in Vietnam.¹⁹

Furthermore, the dosage of the drugs provided by the national program and by GDF is different; for instance, RH used for the continuation phase is provided as RH 150/100 by the NTP for TB and as RH 150/75 by the GDF. Similarly, pyrazinamide 500mg is supplied by the NTP for TB vs. the 400mg-formulation by GDF. In addition, it appears that the 4-in-1 fixed-dose combination (FDC) HRZE may not be available from local manufacturers (and possibly other formulations either). Fixed-dose combinations reduce pill burden for patients and increase adherence. Varying dosage and reduced treatment compliance can contribute to sub-optimal treatment outcomes in patients. Lastly the recurrent shortage of E 400mg could be related to the fact that The Global Fund does not supply it, although it is featured in the MDR-TB treatment regimens.

For the treatment of patients with multi-drug resistance to at least rifampicin (R) and isoniazid (H), two different second-line anti-TB drug (SLD) regimens are used, for a duration of 19-24 months:

- Cat IV(a): E Z Km Pt Lfx Cs (PAS) / E Z Pt Lfx Cs (PAS) Cat I&II failures
- Cat IV(b): E Z Cm Pt Lfx Cs PAS / E Z Pt Lfx Cs PAS Chronic patients

The intensive phase lasts a minimum of six months (and on average 12 months, of which the patient may have to be admitted during the first two months), while 12 months is reserved for the continuation phase. Each of the above drugs are administered daily, a number by injection, and can cause severe and irreversible side effects.

¹⁷ Vietnam National Tuberculosis Guidelines 2009

¹⁸ Treatment of Tuberculosis Guidelines, 4th Edition. World Health Organization 2009

¹⁹ At the time of requested for the grant, this is in line with the preferred first line regimen in Vietnam and NTP requested for this regimen and the GDF approval what the NTP asking for. However, after that (requested for grant from GDF in March 2013), in August 2013, NTP has been issued the new guideline followed WHO guideline of regimen 2HRZE/4HRE and 2SHRZE/HRZE/5HRE



Quantification

For first-line anti-TB drugs, the NTP for TB at the central level carries out annual quantification of needs using the number of cases notified in the previous year (approx. 100,000/year), the targeted number of new TB cases in the following year and the number of re-treatment cases (10,000 on average). To refine the forecast, the NTP for TB also takes into account the National Lung Hospital's stock balance and the available budget.

The quantification of needs for second-line anti-TB drugs is carried out twice a year based on the estimated number of patients with multi-drug resistance, and targets set to treat a certain number of patients with MDR-TB. A new tool to support quantification of SLD – QuanTB – was recently introduced, supplementing e-TB Manager, which is the main reporting tool on patients and stocks; some members of the NTP for TB said that it has actually increased their workload rather than facilitated quantification.

Procurement

Procurement of FLD from domestic resources is conducted by the NTP for TB on an annual basis, and should cover approximately 70-80% of need (see also Section 3.3.1). FLD are procured through national competitive bidding, whereby the tender is advertised and bids from approximately five local manufacturers and importers are typically evaluated. As shown in table 2, lead-times between submission of procurement budget for approval, actual issue of purchase order to supplier and actual delivery of orders in the central warehouse is extremely long. The FLD purchased with the 2014-government budget are expected to arrive in the central warehouse towards the end of 2014, thereby covering the need for the subsequent calendar year (see also Section 3.3.2 on financial flows for NTP-funded procurement). Buffer stock is set at 3 months for central, 6 months at provincial and 3 months at site level.

Table 2: Timeline – procurement with domestic resources

Month	Action
March	Submission procurement plan & budget
June	Final approval procurement plan & budget MOH & MOF Advertisement tender in newspaper (2 weeks)
July	Bidding period, evaluation bids
August	Signing contracts
Oct-Dec	Purchase orders delivered in central warehouse

Provinces are expected to procure the remaining 20-30% of first-line anti-TB drugs, sometimes complemented by patient self-purchase and one-off international donations.

From May 2014 onwards, there have been shortages of ethambutol (E) in some provinces and at the central level. This prompted the NTP for TB to issue an official directive to change to alternative (sub-optimal) first-line regimens: HRZE/4RH or 2SHRZ/4RH for new patients, and 2SHRZE/HRZE/5HRE for previously treated patients. Provinces (i.e., HCMC) that were able to mobilize funding from local authorities for the procurement of ethambutol were advised to stay with the preferred first-line regimens.

Second-line anti-TB drugs are financed by The Global Fund, and their procurement follows a different process. The NTP for TB submits its forecast to the MOH and The Global Fund for approval, and funds are transferred directly from The Global Fund to the International Dispensary Association Foundation

(IDA), which is the procurement agent for Green Light Committee-approved programs.²⁰ (See section 3.3.2 for additional information on the budgetary, planning and disbursement process.) Lead-time between submission of the procurement plan and product arrival in country was said to be 6-8 months, whereby delays were attributed to slow approval processes by both The Global Fund and the MOH.

Storage & Distribution

After the procurement is completed, FLD and SLD are received and stored at the central warehouse, and from there they are distributed to three regional warehouses based at National Lung Hospital (regional warehouse A), Da Nang Tuberculosis and Lung Diseases Hospital (regional warehouse B1) and Pham Ngoc Thach Hospital (regional warehouse B2). From these regional warehouses, the drugs are distributed to provincial warehouses based at tuberculosis prevention units at provincial level, and onwards to district TB treatment centers. The TB treatment centers are responsible for distribution to community level for dispensing to patients.

In principle, distribution from central, regional and district levels happens on a quarterly basis, and usually it is the lower level structures' responsibility to collect the medicine in the regional or central warehouses. However, more frequent trips to the higher-level warehouses are carried out, whereby small amounts of FLD or SLD are collected to prevent shortages of drugs.

Reporting

Each TB treatment center reports the number of TB patients per category and per phase, as well as stock balance reports for FLD and SLD, on a monthly basis to the provincial level hospital or to the provincial social disease control. Here, data are aggregated and subsequently reported to the regional hospital, which in turn reports to the NTP for TB at national level on a quarterly basis. Data are used for quarterly distribution planning and quantification for procurement.

Overall, some issues around quality and completeness of patient and stock level data were reported – from sites to provincial level, and from provinces up to central level for both FLD and SLD. The e-TB Manager was said not to be updated on a regular basis by the TB treatment centers, which deprives the NTP for TB from critical data for SLD needs quantification and to inform inventory management.

For FLD, there was mention of a specific software program named VITIMES used to support inventory management at provincial level along with another Excel spread sheet used by the provincial pharmaceutical department for inventory management and consumption forecasting based on case notification. VITIMES is a web-based database that includes case-based data as well as aggregated data.

For SLD, e-TB Manager was introduced by Management Sciences for Health (MSH) in 2012 to support case reporting and drug inventory management of SLD, but has not yet been properly rolled out and is currently not fully compatible with national reporting requirements. The NTP for TB receives support by CHAI to properly implement e-TB Manager, including training of staff at provincial level on its use.

Ordering (Push)

The provincial TB program is responsible for estimating TB medicine needs for health districts based on the monthly reports summarizing number of patients under treatment and stock levels. Similarly, the NTP for TB at the central level uses provincial quarterly TB reports, which provide an aggregated picture of districts needs and stock level for the province. The NTP for TB is responsible for estimation of TB medicine needs at the regional and provincial levels based on these quarterly reports.

Human Resource Capacity

²⁰ http://www.who.int/tb/challenges/mdr/greenlightcommittee/faq6_secondline_drugs/en/

All steps of the procurement & supply chain cycle are managed by the NTP for TB, which shows considerable ownership, technical experience and knowledge.

It is unclear to what extent the slow process for the procurement of FLD with domestic resources can be attributed to limited capacity within the NTP for TB, or to bureaucratic approval processes within the MOH and MOF, but the NTP for TB reported that the process was complex and involved many people and organizations. For SLD, human resources at NTP for TB may not be sufficient to manage data collection from the treatment sites, updating of e-TB Manager and needs quantification.

As noted in previous evaluations of the NTP for TB²¹, the implementation of the NTP's activities, particularly at provincial and district levels, is hampered by human resource constraints, including low salaries paid by the government, lack of staff, and high staff turnover.

3.1.4 Key PSM findings

Little to no stock-outs or expiry of ARVs, methadone and anti-TB drugs

The first key finding is that over the past years, there have been little to no stock-outs or expiry of ARVs, methadone or anti-TB drugs in the country. TB patients are sometimes asked to buy selected anti-TB drugs (especially ethambutol) from their own resources to complement their regimen. Nominal wastage was reported for pediatric ARVs (which are difficult to quantify) and of stavudine-formulations (as a result of the phasing out of this drug). The continuous availability and minimal wastage of medicine is a key indicator of a successful supply chain system, and a very encouraging and positive key finding.

However, it should be noted that donors have played a key role in preventing shortages of these life-saving commodities. Firstly, PEPFAR had to make several emergency procurements of ARVs over the past years to prevent stock-outs in The Global Fund and NTP for HIV/AIDS-supported sites (notably in 2011 for approx. US\$ 2.2m). During the quarterly quantification meetings, PEPFAR also regularly has to adjust its quarterly orders (which The Global Fund can only do to some extent and the NTP for HIV/AIDS cannot) to accommodate for over- and under-stock in the partners' programs.

For anti-TB drugs, the GDF provided an 18-month emergency supply of first-line drugs in 2014 to prevent an imminent stock-out. In addition, sites and hospitals have to make regular trips to collect small quantities of drugs from higher-level warehouses outside of the planned quarterly distributions. Provinces are also expected to complement the (insufficient) national supply of anti-TB drugs with procurement from own resources, and patients are sometimes asked to buy their own TB drugs.

Multiple parallel procurement & supply chain management systems

As described in the previous section and illustrated in figure 1, the procurement and supply chains run parallel by commodity group, and each program – PEPFAR, The Global Fund and the NTPs – has its own mechanism of budget approval, quantification, procurement, distribution and reporting structure.

First-line ARVs are procured by all three programs, whereas PEPFAR and The Global Fund buy second-line drugs, and pediatrics are only procured by The Global Fund. Quantification of ARVs is done by the three partners separately and subsequently combined and adjusted where needed between partners, while quantification for methadone is target-based. Each funding source uses its own procurement mechanism – PFSCM, PPM, and NHTD – for ARVs and methadone. CPC-I is used by all three partners for storage and distribution of ARVs and methadone, but supplies are earmarked by funding source. The number of patients per regimen and stock balance is reported to PAC and then to VAAC, but, at least for ARVs, different reporting tools and formats are used depending on the partner. Clear guidance and

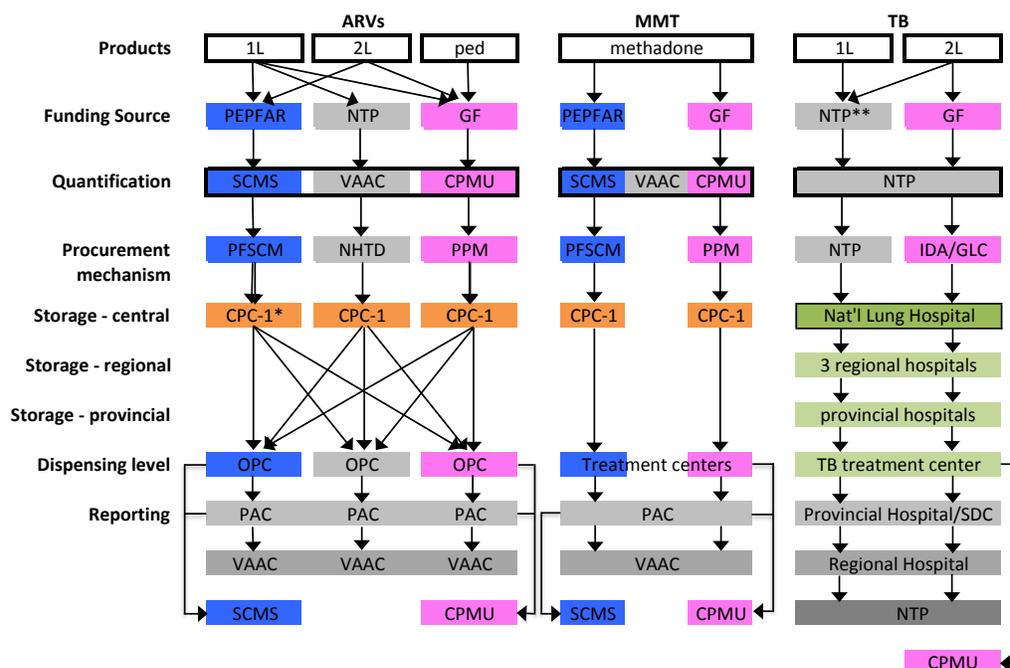
²¹ Review of National Tuberculosis Control Program for period 2007-2011

leadership from VAAC on types of tools and formats to be used by all partners in the country is required.

The supply chain for anti-TB drugs is more integrated, with the NTP for TB in charge of financing and procurement of FLD, quantification of both FLD and SLD, and distribution and reporting on all TB-commodities. SLD are funded through The Global Fund and procured through the procurement agent of the Green Light Committee, IDA, and patient numbers and stock levels are not only reported to the NTP for TB, but also to The Global Fund CPMU. Overall, there is considerable national ownership of the procurement and supply chain of anti-TB drugs.

Multiple parallel procurement and supply chain systems complicate drug management, duplicate work, increase risks of over- and under-stock, reduce efficiencies, and hamper transition of components of the supply chain to the government. Moreover, handling project management through separate units at different levels parallel to existing health structures runs counter to the concept of strengthening existing health systems that all donors strive for.

Figure 1: Overview of procurement & supply chain systems for ARVs, methadone and anti-TB drugs



* = PEPFAR delivers drugs for South Vietnam directly to CPC-1 in HCMC

** = NTP procured, but supplies are complemented by provincial resources and one-off donations (i.e. GDF emergency order in 2013)

No national ARV quantification & forecast (but first step made)

There is no common national quantification and forecast between all programs that captures the full demand for first-line, second-line and pediatric ARVs in the country, thereby taking into account current stock levels, pipeline stock, lead time and buffer. In addition, the site-level data that feed into the quantification and forecasting of demand – number of patients by ARV regimen, and stock balance – are of varying quality.

Over the past years, progress towards coordination of quantification of ARV supply between partners has been made. Under the leadership of VAAC, quarterly quantification meetings have been taking place since 2011 with all key stakeholders to review demand for ARVs, current treatment regimens and stock

balance, and adjust orders. The latest national coordination plan of ARV supply has been developed in April 2014. Progress towards more coordination and harmonization has been made, but a common methodology and approach for the quantification and forecasting of ARVs based on national targets needs to be agreed upon between all partners, in order to come to one national forecast.

Lack of a unified ARV Logistics Management Information System

Even though all OPCs report on patient per treatment regimen and stock balance, different tools are used at all levels to manage stock, plan for distribution and estimate need. The Global Fund and VAAC have focused on provincial level with the implementation of ASUMAT, while SCMS has recently introduced the “ARV Management Tool” for data management at OPCs. SCMS has recently started providing trainings to sites supported by the NTP for HIV/AIDS on the tool. Overall, however, programs may place more focus on collecting data to meet their own reporting requirements than taking a more comprehensive strategic approach of ensuring a continuous supply of ARVs to meet national needs.

There is an urgent need to build one single unified information system from the peripheral level to the central level that will inform quantification and forecasting of need based on actual consumption and stock levels, and provide VAAC with the tools to monitor both needs coverage and performance of the supply chain at all levels and at all times. At the moment, there seems to be a lack of strategic guidance from VAAC and MOH on deciding on the way forward – what system to use, what level to focus on, what performance indicators to use, what capacity needs to be built – and consensus on the introduction of a single comprehensive LMIS needs to be reached between all partners.

Procurement of domestically manufactured drugs with domestic resources

In line with the national strategy on Vietnam’s pharmaceutical industry’s development, domestic manufacturing of medicine – including ARVs, methadone and anti-TB drugs – is expanding.

The first procurement of domestically manufactured methadone was conducted by the HAARP project management unit in late 2013, and it is envisaged that the Ministry of Health (through VAAC) will purchase its first methadone consignment from domestic resources in 2014. Similarly, all tuberculosis FLD are procured with domestic resources from local manufacturers and importers and the GVN is committed to dedicate more resources for the procurement of FLD following the 18-month emergency supply provided by GDF.

If ARVs, methadone and FLD are locally available (through local manufacturers or importers), competitively priced and of assured quality (meeting DAV standards), a national tender can be launched for the procurement of these commodities with domestic resources. As national tendering is arguably less complicated than purchasing on the international market (and has clear national preference), this will facilitate transition of the responsibility of procurement functions to government institutions.

Uncoordinated provision of TA to strengthen limited HR capacity on PSM

Despite extensive expertise available in country, there is currently no strategic framework to transfer skills between partners. Ad-hoc, topic-based or ‘friendly’ informal technical assistance takes place, especially from SCMS to VAAC and CPMU. For instance, trainings have been conducted by SCMS on the use of Quantimed and Pipeline (Jan 2014), and the quarterly ARV quantification meetings were seen as an opportunity for knowledge transfer. Also, the potential procurement of ARVs with central budget funding (in 2014) through PFSCM was mentioned as an opportunity for SCMS to build capacity of VAAC staff on procurement and order management. PEPFAR has repeatedly offered provision of technical assistance to improve VAAC’s capacity on quantification and procurement²², but this has thus far not

²² For instance, in the PEPFAR letter dated June 15, 2012 to VAAC.

resulted in a clear technical assistance (TA) strategy. Only very recently, there has been renewed focus on improving the capacity of staff operating e-TB Manager for second-line anti-TB drugs, and CHAI is working together with the NTP for TB to address this. There is insufficient information on current technical assistance provided to VAAC on procurement and supply chain management of methadone, but as the processes are more straightforward this may be less urgent. Limited human resources capacity at all levels calls for a more coherent and coordinated approach to capacity development, and a move from capacity substitution to capacity building.

3.2 Policy & Legal Analysis

3.2.1 Introduction

Although donors operate in Vietnam with their own funds to provide needed ARVs, methadone and anti-TB drugs to Vietnamese patients, they are required to abide by the general legal environment of Vietnam. Because donors play a substantial role in filling the demand, their operations tend to have a “special status” under the law. Similarly, the National Targeted Programs have also been given certain exceptions by the laws. The current system of legal regulations, with focus on the Pharmaceutical Law and the Bidding Law, was analyzed to show how the current and draft regulations in this field affect different options for procurement of ARVs, methadone and anti-TB drugs with domestic resources in future.

3.2.2 Impact of the current legal environment on procurement

The legal framework for drug procurement in Vietnam has recently reached a new level of development with more specific provisions provided by the newly passed Decree on the implementation of the Bidding Law - Decree 63/2014/ND-CP dated June 26, 2014.

For ARVs and anti-TB drugs, the current procurement through donors (PEPFAR/The Global Fund) has followed rules established by these donors that made the system somehow “independent” of the heavily regulated domestic laws for the pharmaceutical industry. The significant decrease in external funding for ARVs, methadone and anti-TB drugs and imminent shift towards procurement with domestic resources means that the purchase of HIV/AIDS and anti-TB drugs will be ‘localized’ and subject to domestic laws. Once the source of funding mostly comes from domestic resources, mutual agreements between donors and the Government of Vietnam, which normally provide certain waivers and exceptions to the foreign players, might no longer be applicable.

In this new environment where “special” decisions for donor programs are no longer be applicable, the procurement of ARVs, methadone and anti-TB drugs will be governed directly by the relevant domestic laws and regulations. The most important laws and regulations that affect this procurement process include the Pharmaceutical Law, Regulations on Drug Importation, the Bidding Law, the Prime Minister’s Decision No. 68, and a number of international agreements that Vietnam signed or is considering to sign. Each will be discussed in more detail in the following sections.

Pharmaceutical Law No. 34/2005/QH11 (27 Jun 2005)

The Pharmaceutical Law passed nearly 10 years ago and is mainly focused on resolving the shortage of medicines for Vietnamese patients. It outlines criteria and requirements for trading, manufacturing, drug export and import, wholesale, retail, quality, registration and rational use of pharmaceuticals. Ten years later, the Law is under amendment to address new issues, one of which is the heavy dependence of

Vietnam's pharmaceutical market on imported products.²³ Support for local production is considered to be one of the main policies of the government in the pharmaceutical industry. Under the current Pharmaceutical Law, priority is given to local products where the drugs are purchased with the state budget (Article 49.2.a). This policy is emphasized in the Draft Amended Pharmaceutical Law to be applicable to all state health facilities and national health programs and in all tenders that use the state budget.

The Pharmaceutical Law provides strict price control mechanisms in three ways, namely drug price declaration, drug price announcement, and ceiling prices for drugs that are purchased with the state budget. Accordingly, drugs circulated on the market, including imported drugs, must have prices that are no higher than prices of drugs sold in other countries in the region which have healthcare and commercial conditions similar to Vietnam's. For drugs procured through bidding, the winning-bidder's prices must not be higher than prices periodically announced by competent authorities. However, these pricing requirements have not been implemented as the list of the above-mentioned countries has not been issued by the MOH in cooperation with Ministry of Industry and Trade (MOIT) and other relevant ministries and agencies. Similarly, a list of drug ceiling prices has never been issued; due to the large number of drugs on the market, this requirement is considered not feasible.²⁴ Under the Pharmaceutical Law, the MOH is the key agency to make decisions on drug prices, but this task will likely be transferred to the MOF, which is believed to have more appropriate capacity.²⁵

Chapter II of the Pharmaceutical Law regulates drug trading that includes importation of drugs, and, importantly, states that drugs can only be imported and distributed by Vietnamese entities. This regulation limits the possibility of international suppliers to directly sell their medicines in the country, or compete in tenders without a Vietnamese representative. This stipulation in the Pharmaceutical Law is not in line with Vietnam's commitment under the World Trade Organization (WTO) on lifting restrictions on the right to import drugs into Vietnam.²⁶

Regulation on Drug Importation: Decision No. 151/2007/QĐ-TTg (12 Sept 2007) and its amendment Decision No. 42/2013/QĐ-TTg (15 July 2013)

Decision No. 151 provides for the importation of drugs that have no registration number in Vietnam. Request for pharmaceutical products registration in Vietnam is possible if it emanates either from domestic pharmaceutical manufacturers, foreign-invested companies licensed to manufacture pharmaceuticals within Vietnam, domestic entities that are permitted to trade in pharmaceuticals, or foreign entities that hold trading licenses. This means that foreign manufacturers producing their pharmaceuticals outside of Vietnam have to partner with domestic importers/distributors to register their products and to be able to get them distributed in the country. Drugs without a registration number can be imported into Vietnam in accordance with the Importation License, which is only valid one year from the issuing date. All ARVs purchased with domestic resources are registered in the country and therefore by definition meet minimum quality criteria set by the DAV.

The registration process requires manufacturers to set the price of the product they wish to register. It is also the role of DAV to collect information from facilities on the price paid for drugs and to publish it

²³ More than 50% of drugs in the market are imported drugs and more than 90% of the materials for drug production are imported - "Report on 6 years of implementation of the Pharmaceutical Law, MOH".

²⁴ "Vietnam has more than 25000 products with more than 1500 ingredients therefore it is not feasible to provide ceiling prices for all of them" - MOH (2011), Report on 5 year implementation of the Pharmaceutical Law's regulations on drug pricing control.

²⁵ Submission and Draft of the Law on Amendment and Supplement of the Pharmaceutical Law.

²⁶ Decision 10/2007/QĐ-BTM of MOIT provides that as from January 1st 2009 limitation on imported rights of foreign entities is lifted.

on DAV website in order to control prices against the registered price, but also to increase transparency.

Based on the list of non-domestically manufactured drugs registered in the country as of January 2014 and available on DAV website, it appears that few fix-dosed combinations are registered by DAV. This means that drugs procured and delivered to Vietnam by PPM or PFSCM are not all registered in the country; if not registered, these are imported to Vietnam in accordance with special provision catered in Decision No. 151. In the event of procurement through national competitive bidding (NCB) on the basis of the ARVs currently registered, the selection of ARVs would be more limited, resulting in a higher pill burden and possibly lower adherence by patients.

The Bidding Law No.43/2013/QH13 (Nov 2013)

Other important regulations that will have significant impact on the procurement of ARVs, methadone and anti-TB drugs are the Bidding Law, and Decree 63 (dated June 26, 2014) which guides implementation of the Law. It should be noted that the Bidding Law became effective on Jul 1 2014 and is in the process of being implemented. The Bidding Law governs, among other things, drug procurement using the central and provincial budgets, and revenue from social health insurance and socialization. The legal framework for drug bidding follows policies set out in the Pharmaceutical Law where strong preference is given to local entities and local products. A number of specifics outlined in the Law and its Decree are highlighted, namely the MOH's increased responsibility in drug procurement, restrictions on International Competitive Bidding (ICB), concentrated procurement and direct price negotiations.

The MOH has been authorized by Decree 63 to undertake many important responsibilities, including:

- a) Issue lists of drugs that need to be procured through bidding, drugs that are required to be procured through concentrated bidding and drugs that can be bought with price negotiation as suggested by the National Advisory Committee on Drug Bidding;
- b) Organize concentrated bidding at national level and take the lead in price negotiations;
- c) Develop a plan for concentrated bidding process and provide instruction to conduct concentrated bidding at national and provincial levels to ensure that concentrated biddings will be conducted nationwide in 2016;
- d) Based on basic criteria including the published registration number, the drug price declared by business with the competent agency, the quantity of minimum registration numbers of dosage forms and combination forms and other necessary factors, issue a list of domestically manufactured drugs meeting the needs of treatment and supply capacity - (Article 77.1)

The MOH will also be responsible for the establishment of the National Advisory Committee on Drug Bidding that will have representatives from MOH, MOF, VSS, Pharmaceutical Enterprise Association and other relevant organizations. This Committee will advise the MOH on all matters that relate to MOH's responsibilities as outlined in the Bidding Law and Decree 63.

In the Bidding Law, procurement from international suppliers through International Competitive Bidding is allowed under certain conditions specified in Article 15 of the Bidding Law:

- I. International bidding shall be held to select tenderer only when it meets one of the following conditions:
 - a) The donor of bidding package requests for holding international bidding;
 - b) Tender packages for procurement of goods where the goods are not yet able to be manufactured domestically or able to be manufactured but fail to meet technical, quality or price

requirements. Cases of common goods, already been imported and offered for sale in Vietnam, do not organize international bidding;

Condition I.a only applies to donors (i.e. PEPFAR, The Global Fund) and not to procurement of pharmaceuticals from domestic resources. Under condition I.b, it is unclear how 'failure to meet technical, quality or price criteria' is defined, as in principle all medicines registered on the local market meet national quality criteria, and ceiling prices for drugs have not yet been set. The Article also clearly states that an ICB is not to be launched if goods are already imported in Vietnam through a local importer, further limiting the scope for applying this mechanism.

The Bidding Law also introduces the new concept of 'concentrated' procurement, whereby orders are pooled and procurement of medicines is conducted at national level. Decree 63 further outlines this mechanism, which is to be implemented nationally starting in 2016 (Article 75 & 77). As stated in article 77, it is the MOH's responsibility to develop a roadmap and guide the drug concentration from national to peripheral level, to support implementation of the provision of the bidding law relating to concentrated procurement by 2016. This regulation paves the way for the establishment of a procurement unit at central level to conduct the concentrated procurement of medicines with domestic resources.

Direct price negotiation – as opposed to competitive bidding – is also introduced, and is only allowed for drug procurement bidding packages where there are only one to two producers of original proprietary medicines, rare drugs, drugs that are still under patented period, and other particular cases. Direct appointment of contractor for drug procurement is allowed but only applied to bidding packages that are less than US\$50,000 in value (Article 22 of the Bidding Law and Article 54 .1 of Decree 63).

With these new mechanisms of concentrated procurement and limitations on direct price negotiations, the Bidding Law and its Decree aim to resolve the serious problems experienced in the existing system where the same drugs might be purchased at very different prices at different medical facilities. However, there seems to be many institutional arrangements that need to be resolved in order for the regulations to be executed and implemented in practice.

Prime Minister's Decision No. 68/QD-TTg (10 Jan 2014)

To support the domestic pharmaceutical industry, the Prime Minister's Decision No. 68 (dated January 10, 2014) approved the National Strategy for the Development of Vietnam Pharmaceutical Industry which aims "...to increase the share of domestically produced drugs to 80% of the total amount of drugs consumed during a year...". This Decision further promotes the procurement of locally manufactured drugs through national bidding at the expense of procurement from international sources, and especially applies to all procurement conducted with domestic resources. In comparison, local pharmaceutical production accounted for nearly half of Vietnam's drug needs in 2012, whereas imports accounted for more than 70 percent of the pharmaceuticals market by value during the same year.²⁷

Importation of drugs from world-reputable class drug trading companies can be conducted under DAV's permission where the drugs imported are needed for disease prevention and treatment but local manufacturers cannot meet the demand. The importation permission, however, will only be granted to foreign traders that have operating license in medicines and medicine materials in Vietnam.

²⁷ Brief sector notes on the pharmaceutical industry in Vietnam. Italian Trade Agency (ITA), Dec 2013

Impact of International Agreements on Government Procurement

As an observer of the WTO's Agreement on Government Procurement (GPA), Vietnam has not yet put in place all the regulations required according to international standards on procurement by government agencies.

Vietnam is also in the process of negotiating the Trans-Pacific Partnership Agreement, whereby agreements related to government procurement are yet to be specified. As a general requirement, Vietnam will need to be clear on (1) the level of government agencies that need to call for ICB; (2) the thresholds above which ICB is required to be conducted; and (3) goods that need to be procured through an ICB.

Vietnam's strong preference for national bidding and procurement of domestically manufactured medicines may go against the WTO's objective of ensuring open, fair and transparent conditions of competition in the government procurement markets. In addition, the TPPA requires for government agencies to call for international (as opposed to national) competitive bidding (I), which would apply to goods over and above the threshold of around US\$95,000 to US\$130,000²⁸ (II), and includes pharmaceuticals (III).

Additional Analysis of Legal Framework

Section 3.2.2 highlights the most important legal issues affecting government-led, centralized procurement. Because most of the laws in Vietnam cannot be self-implemented (i.e., their implementation depends significantly on additional guidance issued by the government or various ministries), it is important to review all related regulations²⁹ in the process of analyzing laws. Appendix C presents the findings of the legal analysis in further detail, organized by findings related to laws governing 1) roles of key parties, 2) procurement actions, 3) distribution activities, and 4) financing sources. This table refers to specific regulations that govern all parties involved in the procurement and distribution of drugs in Vietnam and is intended to further clarify and provide additional information to the findings presented in this section.

3.3 Financing of ARVs, Methadone and Anti-TB Drugs

3.3.1 Financing Contributions from Various Sources

3.3.1.1 ARVs

The procurement of ARVs is financed through three main sources: PEPFAR, The Global Fund, and the NTP for HIV/AIDS. The two donors provide 95% of the funding for the procurement of ARVs, with PEPFAR providing more than 50% of the total funding, while the NTP for HIV/AIDS provides only 5% of the funding. A gradual decrease in donor funding for ARVs has been officially announced and communicated to the GVN. However, in reality an increase in donor funds for ARV procurement has been noted in the recent years. PEPFAR/SCMS's actual expenditures on ARV procurement increased from \$5.6 million³⁰ in FY 2012 to \$9.3 million³⁰ in FY 2013, and a budget of \$11.6 million is approved for FY 2014, as shown in table 3. For The Global Fund, both the budgeted amount (\$8.1 million³¹) and the

²⁸ <http://muasamcong.mpi.gov.vn/>

²⁹ Since Vietnam does not have a Code for all issued regulations govern specific areas and healthcare is the area that is heavily regulated, it's hard to say that everything was reviewed, but it is expected that the Backbone table has touched upon the most important regulations on this field.

³⁰ Amount provided by SCMS.

³¹ National Plan on Coordination of ARV Supply for 2014

actual expenditures (\$6.9 million³¹) on ARV procurement in 2013 are lower than the amount committed in 2014 (\$8.5 million³¹).

Table 3: Funding for ARVs (millions, USD)

Source of Funding	2013*	2014**
PEPFAR	\$9,651,910 ¹	\$11,561,910 ¹
The Global Fund	\$6,912,268 ¹	\$8,525,160 ¹
NTP for HIV/AIDS	\$1,015,471 ¹	\$1,083,264 ¹
Total	\$17,579,649	\$21,170,334

* Actual expenditures on ARV procurement in 2013

** Approved budgets for ARV procurement in 2014

¹ National Plan on Coordination of ARV Supply for 2014

In the future, funding for the procurement of ARVs is expected to decrease significantly. PEPFAR does not intend to continue financing ARV procurement in Vietnam after 2016. Actual figures of expected funding for the coming years were not available from the donors or the NTP for HIV/AIDS, and therefore it is not clear what share of the total cost of ARVs the GVN will need to take on in the near future.

As shown in table 4 the prices paid by the government of Vietnam for the procurement of ARVs are higher than those paid by PEPFAR or The Global Fund. For instance, the prices paid by the NTP for HIV/AIDS for efavirenz 600mg and tenofovir 300mg are almost 500% higher than those paid by the GF for the same drugs. The prices paid by PEPFAR and The Global Fund for the same drugs are very similar.

Table 4: Comparison of Prices Paid by PEPFAR, The Global Fund, and NTP for HIV/AIDS for ARVs, in USD (only ARV drugs procured by more than one source are included)

Drug	PEPFAR	The Global Fund	NTP for HIV/AIDS	Percent difference (lowest vs. highest)
Efavirenz 600mg	0.12	0.11	0.67	509%
Lamivudine 150mg	0.03	0.03	0.05	67%
Lamivudine/Zidovudine/Nevirapine 150/300/200	0.14	0.13	0.28	115%
Lamivudine/Tenofovir/Efavirenz 300/300/600	0.35	0.37		6%
Lamivudine/Zidovudine 150/300	0.11	0.10	0.21	110%
Nevirapine 200mg	0.04	0.04	0.13	225%
Lopinavir/Ritonavir 200/50	0.51	0.51		0%
Lopinavir/Ritonavir 80/20/ml	12.16	12.16		0%
Tenofovir 300mg	0.12	0.12	0.71	492%

If the GVN continues to obtain prices that are 500% higher than those paid by donors, the funding required for the procurement of ARVs once the country shifts to domestic financing will also be significantly higher than the current total funding for ARVs from all sources. The limited financial data obtained during the assessment (see Section 2 on the discussion of limitations) did not enable us to conduct a detailed estimation of the future expected cost of ARVs under the domestic financing scenario. However, according to the current trend illustrated above, the total funding required to cover the same target population could range between US\$40,000,000 and US\$120,000,000. Furthermore, costs are expected to increase as coverage increases and as more patients move to second line treatment. These factors are expected to place an even greater burden on the GVN to finance the

entire ARV procurement needs. The GVN has already affirmed its commitment to identify sustainable financing options for HIV/AIDS via the Prime Minister's Decision No. 1899. However, that decision remains a policy statement, with no clear guidelines in place on how to operationalize it.

3.3.1.2 Methadone

The procurement of methadone is also mainly financed by PEPFAR and The Global Fund, with the NTP for HIV/AIDS and the HAARP only contributing very small amounts in 2014, as illustrated in table 5. PEPFAR and The Global Fund are covering a target population of 11,230 and 6,353 patients respectively in 2014. The prices paid by PEPFAR and The Global Fund for methadone are similar. In 2013, SCMS paid a unit price of US\$40/L for over half of the total amount it ordered and US\$38.5/L for the remainder of the amount. The Global Fund estimated a unit price of US\$37.8/L for its 2014 orders. The GVN intends to procure methadone from local manufacturers in the future. The estimated unit price of this locally produced methadone is 700,000 VND or approximately \$33/L, which makes procurement from domestic manufacturers a feasible option if quality requirements are met.

Table 5: Funding for methadone (millions, USD)

Source of Funding	2013	2014
PEPFAR	\$2,172,240 ¹	\$4,275,622 ¹
The Global Fund	\$2,191,007 ²	\$1,340,296 ²
NTP for HIV/AIDS	\$230,000 ³	\$230,000 ³
HAARP	-	\$150,000 ⁴
Total	\$4,593,247	\$5,995,918

¹ Provided by SCMS

² Provided by GF

³ Provided by VAAC. Funds were available, but unspent.

⁴ Provided by PQM

The GVN is planning a rapid scale-up in the provision of methadone, and has set the target of reaching 81,047 people with methadone in 2015, according to Prime Minister's Decision No. 1008/QD-TTg. This fourfold increase in the target population will need to be translated into a significant increase in funding. User fees of approximately US\$0.50, which are currently being piloted in three provinces, will help to pay for operational costs, if they are instituted. Donor funds for the procurement of methadone may also increase in the near term. PEPFAR currently has a cap of 15,000 patients for which it can procure methadone, but an increase to a cap to 30,000 is currently being considered. The GVN is highly committed to providing funding for methadone maintenance programs and there is currently a transition plan in place for procurement through domestic resources, but nonetheless, the scale-up will impose a significant burden on the GVN to mobilize and allocate the required funding for methadone. Table 6 below provides an estimate of the total annual funding needed to cover the desired target population of 81,047, if methadone is procured from domestic manufacturers at the price of US\$33/L mentioned above. An average daily dose of 105 mg, consistent with the dose currently being used for quantification, was assumed for the estimation.

Table 6: Estimated Future Cost of Methadone (millions, USD)

Target population	81,047
Quantity required (liters)	310,613
Price per liter	\$33
Drug costs	\$10,353,754
Storage and distribution costs (12%)	\$1,242,451
Total estimated cost	\$11,596,205

The total estimated cost of US\$1 1,596,205 represents a 93% increase over the total 2014 budget from all sources for methadone.

3.3.1.3 Anti-TB drugs

Funding for first line anti- tuberculosis drugs is quite distinct from funding from second line anti-tuberculosis drugs. FLD are mostly financed through government budgets, while SLD rely on external funding.

3.3.1.4 First-line anti-TB drugs

In principle, the GVN assumes full responsibility for financing, procuring and distributing FLD, incorporating funding into the budget for the NTP for TB. In practice, however, there have been persistent shortages in government budget, leading to various measures needed to avoid stock-outs of FLD. In general, national budget has been available to cover approximately 70-80% of the estimated drug needs. In 2013, however, national budget only covered 30% of estimated drug needs. The remaining drugs are provided through an ad hoc mix of provincial budgets, patient self-purchase, and one-off international donations. In 2010, the Netherlands made a one-time donation valued at EUR 3.0 million. Most recently, the Stop TB Partnership contributed 18 months of supply to replenish the depleted buffer stock.

In 2014, budgets for all NTPs were reduced significantly, with the budget for the TB program reduced from VND 104 billion in 2013 to VND 63 billion initially. Significant advocacy resulted in an additional allocation of VND 75 billion, increasing the total budget to VND 138 billion, allowing the NTP for TB to fully cover the estimated drug need for the first time in several years. Table 7 below shows the total funding for FLD in 2013 and 2014.

Table 7: Funding for First Line anti-TB Drugs (millions, USD)

Source of Funding	2013	2014
Stop TB Partnership ¹	3,808,854	
NTP for TB	1,538,095 ²	5,285,714 ²
Total	\$5,346,949	\$5,285,714

¹ Value of one-time donation made in 2013, with delivery dates in 2014.

² Information from National TB Program.

Although provinces are expected to procure drugs as needed and to provide other resources to support TB treatment, the process through which the NTP for TB/MOH and provincial Departments of Health coordinate their resources is not clear. For example, in 2013, the NTP for TB allocated a significant portion of its budget for staff incentives. The cost of this incentive was cut from the NTP's 2014 budget, and it is unclear whether any provinces provided funding for staff incentives. It is also unclear whether the NTP for TB considers each province's economic ability when allocating drugs, i.e. fully allocating needed drugs to less well-off provinces, while expecting higher contributions from wealthier provinces.

There is significant variability between prices available through the GDF³² and prices paid by the NTP for TB. We were not able to compare the fixed dose combinations because the combinations procured by the NTP for TB are not available through the GDF. For single formulation drugs, prices paid by the NTP for TB for Ethambutol and Isoniazid were 32% and 77% higher than prices through the GDF,

³² Stop TB Partnership, Global Drug Facility. <http://www.stoptb.org/gdf/drugsupply/pc2.asp?CLLevel=2&CParent=4>, accessed July 1, 2014.

respectively, while the price paid by the NTP for TB for Streptomycin was 79% lower than the GDF price, as shown in Table 8.

Table 8: Comparison of Prices Paid by NTP for TB and GDF for TB Drugs

Drug	NTP for TB Expected Price 2014 (USD)	GDF Price (USD)*	Percent difference (NTP for TB vs GDF)
S (bottle 1g)	0.168	0.799	-79%
RH (blister, 150/100mg)	0.048	NA**	NA**
RHZ (blister, 150/75/400mg)	0.100	NA**	NA**
E (blister, 400mg)	0.055	0.042	32%
H (blister, 50mg)	0.021	NA**	NA**
H (blister, 100mg)	0.021	0.012	77%

* GDF list price adjusted to include freight (20%) insurance (0.2156%) and IPA fee (4.51%).

** This formulation and dosage is not available from the GDF.

Because there were no GDF comparators for the drug combinations purchased by the NTP for TB, we estimated the cost per treatment using prices of both the combination and single formulation drugs procured by the NTP for TB, and compared that with the GDF prices of the FDCs. Using this estimate, the prices obtained by the NTP for TB result in a treatment cost of 21% lower to 54% higher than the prices available through the GDF, as shown in Table 9. The lower cost for Category II treatment is primarily driven by the very low price for Streptomycin in the local market.

Table 9: Comparison of Drug Cost per Treatment given NTP for TB and GDF Prices

Treatment*	NTP Expected Price 2014 (USD)	GDF Price (USD)*	Percent difference (NTP vs. GDF)
Category I	55.2	35.7	54%
Category II	85.2	108.1	-21%

* Category I treatment based on RHZE for two months, followed by RHE for four months. Category II treatment based on three months RHZE, combined with 1g Streptomycin for the first two months.

** GDF list price adjusted to include freight (20%), insurance (0.2156%) and IPA fee (4.51%).

While domestic procurement of TB drugs through domestic suppliers is well-aligned with GVN policies, consideration of other procurement alternatives may be warranted in cases where domestic procurement results in significantly higher prices.

3.3.1.5 Second-line anti-TB drugs

SLD are financed through Vietnam's grant from The Global Fund. As shown in Table 10, total funding for SLD was US\$2.7 million in 2013, increasing to US\$4.0 million in 2014. The increase was driven by additional patients expected to be treated with SLD, a trend that will continue.

Table 10: Funding for Second Line anti-TB Drugs (millions, USD)

Source of Funding	2013	2014
The Global Fund	2,739,648 ¹	4,023,239 ¹
NTP for TB		
Total	\$2,739,648	\$4,023,239

¹ Information from National TB Program.

Under The Global Fund's New Funding Model (NFM), the TB program has been allocated US\$33.0 million for the three years, 2014-2016. This funding level appears to be a reduction from the original

grant of US\$59.4 million for 2011-2015, which included budget of US\$27.4 million for 2014-2015.³³ Although treatment of MDR-TB is a global health priority, funding beyond 2016 is uncertain.

It would be challenging for the GVN to absorb the costs of SLD. At the 2014 patient levels, SLD represent approximately 80% of the cost of FLD (US\$4.0 million for SLD vs US\$5.3 million for FLD.) Expected increases in second line patients will require additional funding for SLD. Also, drug costs may be higher than current levels, based on the NTP for TB's experience conducting domestic procurement of FLD.

3.3.2 Review of Financial Flows

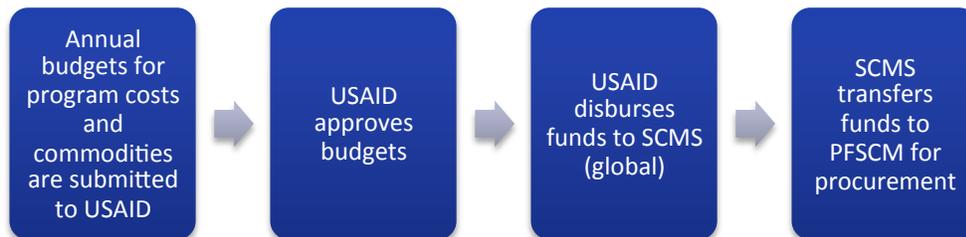
The procurement of ARVs, methadone, and anti-TB drugs from different funding sources involves varying financial cycles and flows depending on each funder's processes and requirements. The flow of funds for each of the major donors and for the HIV/AIDS and TB national targeted programs is described below.

3.3.2.1 PEPFAR

For PEPFAR-funded procurements, the flow of funds is simple. All funding for commodities remains outside of Vietnam, with transfers only between USAID and the SCMS project. SCMS's financial cycle follows the U.S. Government's fiscal year (October-September). SCMS submits annual budgets to USAID by September for approval, and receives annual funding at the beginning of the fiscal year, in October. SCMS's commodity budget is approved separately from the programmatic budget. Once approved for the year, the budget is flexible and allows variations in the order quantities when needed.

Figure 2 illustrates the budgeting and disbursement process for the PEPFAR-funded procurements.

Figure 2: Planning, budgeting and disbursement process for PEPFAR-funded procurement



3.3.2.2 The Global Fund

Vietnam's current grant with The Global Fund for support on HIV/AIDS is a consolidation of the round 8 and 9 proposals under a single stream of funding. A budget broken down by quarters, which links to the performance framework, has been presented along with the proposal and is used as the basis for disbursements. Every six months, funding for two quarters and a buffer of one additional quarter is disbursed to the country based on past performance. However, funding for drug procurement, which is done via the PPM, is not included in these disbursements. Using the procurement plan as a reference, a new quantification is prepared by the CPMU, approved by The Global Fund and subsequently a purchase request (PR) is sent to the procurement agent (PPM) for each order. PPM collects the necessary information from suppliers, and sends a purchase order (PO) to the principal recipient to sign. Once the

³³ Global Fund Proposal Form – Round 9.

PO is signed, The Global Fund transfers the funds for the procurement directly to the PPM. Like PEPFAR, funding for commodities remains outside Vietnam, flowing only between The Global Fund and the PPM.

Vietnam is currently preparing a concept note for the New Funding Model, which, once approved, will be in effect by 2015. Under the NFM, two types of financial commitments from the GVN are required in order to access the funding. The first requirement is a counterpart financing requirement of 20%, which must be met by GVN in order to access 85% of the grant funding. All domestic public resources allocated to the National Targeted Programs for HIV/AIDS and TB as well as the overall health sector can be counted towards the counterpart financing requirement. These may include personnel, equipment or infrastructure related costs borne by GVN using its revenues, loans, social health insurance and debt relief proceeds. The counterpart financing policy requires a gradual increase of the government contribution to the NTPs each year in order to mitigate a potential negative impact of external assistance on domestic resource allocations. According to The Global Fund Secretariat, the GVN already exceeds the 20% threshold for counterpart financing requirement.

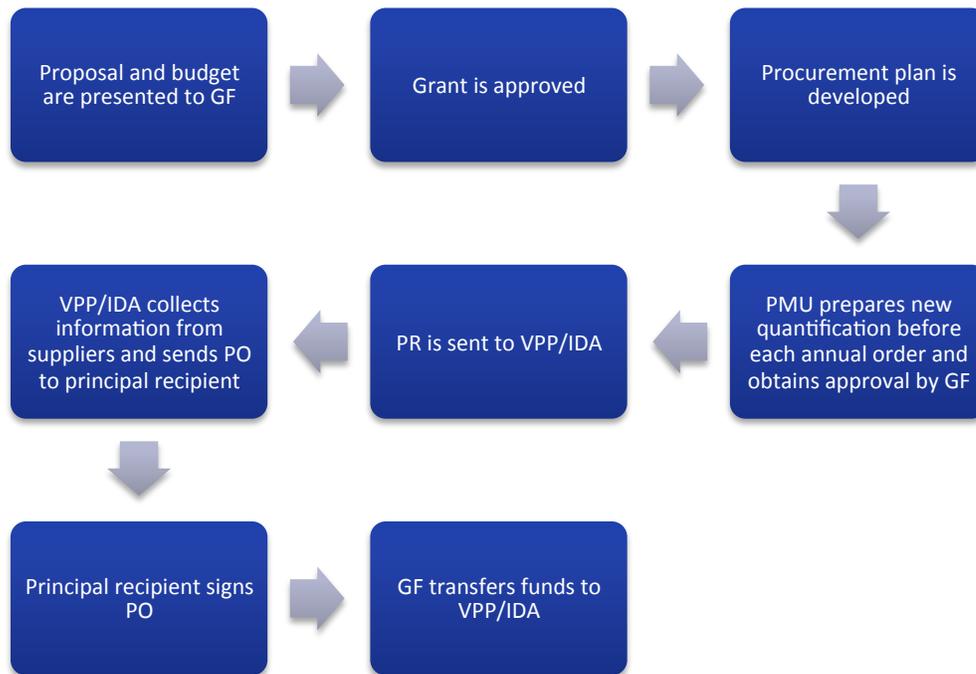
The Global Fund requires governments to meet the counterpart financing requirement before they are able to access the second component of the allocation: the willingness-to-pay. The willingness-to-pay requirement, which mandates annual increases in the national budget allocations, must be met in order to access the remaining 15% of the grant funding. The actual level of government commitments required to meet the willingness-to-pay requirement is agreed upon during discussions between The Global Fund and the country; and depends on factors such as existing commitments, past spending trends, country income, fiscal space, and others. The level of annual increase required for Vietnam is not known at this time.

These requirements lay the foundations for greater domestic financing for HIV/AIDS.

The process described above also holds true for the funding that the NTP for TB receives from The Global Fund, with the exception that the funds for the procurement of second line TB drugs are transferred to IDA, the relevant procurement agent in this case.

Figure 3 illustrates the budgeting and disbursement process for the Global Fund-funded procurements.

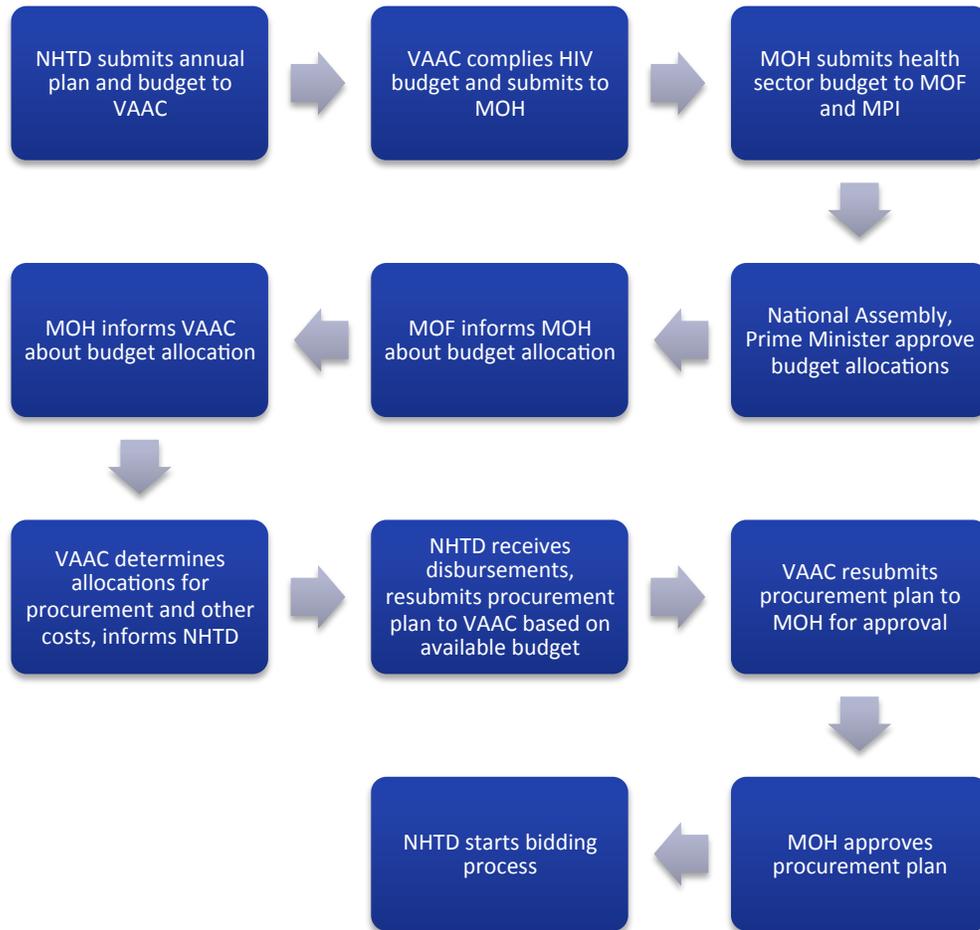
Figure 3: Planning, budgeting and disbursement process for GF-funded procurement



3.3.2.3 National Targeted Program for HIV/AIDS

The process of obtaining budget approvals and disbursements from the central government budget through the National Targeted Program is lengthy and complex. It requires several levels of planning and approvals, which start with the development of an annual procurement plan and budget by the National Hospital for Tropical Diseases. The budget submitted by NHTD is reviewed by VAAC and compiled with the overall HIV/AIDS budget, which is in turn submitted to the Department of Planning and Finance at the Ministry of Health. The MOH then compiles the entire health sector budget and submits it to the Ministry of Finance and the Ministry of Planning and Investment. Budget allocations are approved by the National Assembly and by the Prime Minister. Once the information on the approved allocations is available, the MOH is informed, and it in turn informs VAAC on the available budget for HIV/AIDS. VAAC determines how much of the available budget it can allocate to pharmaceuticals and informs NHTD, which then develops a new plan based on the available budget amount and resubmits it to VAAC. VAAC resubmits the plan to the MOH to obtain the Minister’s approval, after which NHTD can start the bidding process. Although the budget is approved during the first quarter of the year, and NHTD usually receives its disbursements by June, the lengthy process of obtaining approval on the procurement plan often leaves very little time to prepare the bidding and to place orders, which creates the risk of not being able to procure and release the funds on time. If funds remain unspent, this could have negative consequences on the following year’s funding. Figure 3 below illustrates the financial flows for the procurement through the NTP for HIV/AIDS.

Figure 3: Planning, budgeting and disbursement process for NTP-funded procurement



3.3.2.4 National Targeted Program for TB

A similar flow of funds and budgeting process is applied to the central government budget allocations to the NTP for TB. However, the flow and process are slightly less complex since the procurement is conducted directly by the NTP, instead of being delegated to another institution, as is the case with the HIV-related procurements.

4. TRANSITIONING TO A GOVERNMENT-LED PSM SYSTEM

The following sections describe the steps towards a government-led PSM system for ARVs, methadone and anti-TB drugs, and then zooms in on different scenarios for transitioning the procurement component to government institutions with domestic resources, including analysis of financing options.

4.1 Steps Towards a Government-led System

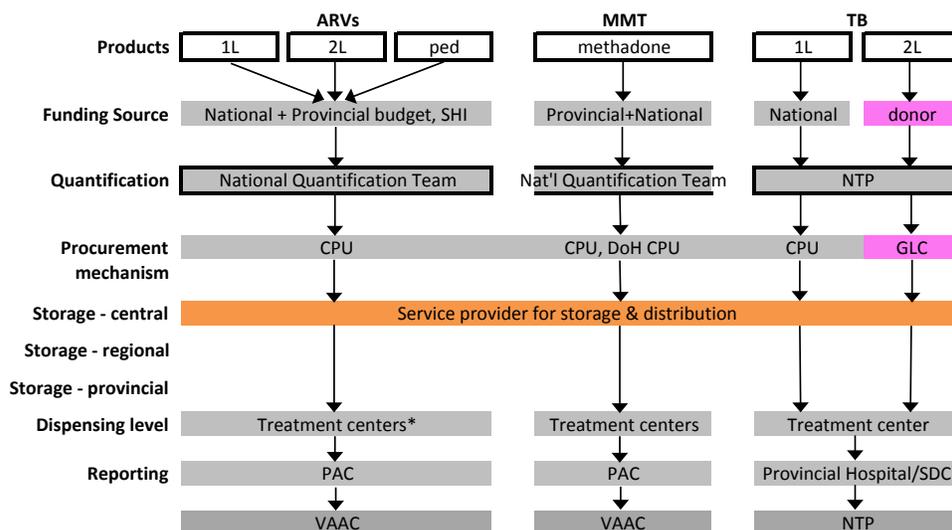
What would a more integrated, harmonized, financially sustainable and government-led supply chain look like? Figure 4 illustrates a proposed structure for such a system for ARVs, methadone and anti-TB drugs. This figure can be contrasted to the current situation (figure 1, page 15), whereby the PSM system is fragmented and donor-dependent. It should be noted that harmonization and integration of specific PSM components can happen simultaneously to transition to government institutions. For instance, on quantification, partners should agree upon the methodology and assumptions for the national quantification of needs and entrust VAAC to lead this exercise. Also, it is not envisaged at this stage that all supply chains for ARV, methadone and anti-TB drugs are merged into a single one although all three will share some resources (such as a central procurement unit and potentially a single operator for storage and distribution).

In summary, the objective is that all first-, second-line and pediatric ARVs will be funded from domestic resources (national budget, complemented by provincial budget, social health insurance, and possibly some external funds). This requires a national quantification team to conduct quantification and forecasting for the whole country, and a Central Procurement Unit within the MOH to carry out procurement of all ARVs. The integrated supply chain for methadone looks similar, whereby the funding comes from national or provincial budget allocations combined with user fees, the national quantification team makes a forecast and the CPU at national and possibly at provincial level (through the Department of Health) conducts the procurement. For TB, the supply chain is not so dissimilar to the situation today. FLD are procured using domestic resources and are procured by CPU, while SLD continue to benefit from donor funding and are purchased through the Green Light Committee (GLC). See the following section (4.2) for a more detailed description of different scenarios for the procurement of ARVs, methadone and anti-TB medicine with domestic resources.

Storage and distribution for all selected commodities will be outsourced to a service provider (CPC-I or other) that delivers the commodities directly to HIV/AIDS, methadone or TB treatment centers. These in turn report to provincial level, and on to the relevant department at central level. A comprehensive single LMIS is introduced, and ensures the collection, processing, reporting and use of information for decision-making.

Importantly, the harmonized and government-led PSM system is guided by an overarching PSM strategy underpinned by strong government ownership and reflecting consensus among all stakeholders.

Figure 4: A harmonized and government-led PSM system for ARVs, methadone and anti-TB drugs



* = for SHI, reform of status OPC from preventive to curative, definition of basic package of services

4.2 Procurement of ARVs, Methadone and Anti-TB Drugs from Domestic Resources

The major procurement methods used by public health systems are national or international competitive bidding through an open or restricted tender, competitive negotiation, and direct procurement. All methods vary with respect to their effect on price, delivery times and workload of the procurement office.

For each of the methods, the buyer can either go directly to the manufacturer, or make use of a procurement agent that sources the drugs from the different manufacturers and often has its own quality assurance systems. For larger procurements consisting of a wide range of items, the drawback of dealing directly with a number of different manufacturers (i.e., a maximum of 21 different ones, for 21 different ARVs!) is that it complicates the PSM process, requires more capacity building and transitioning to a government-led system would take longer. It also leads to fragmented procurement and inefficiencies, and is not sustainable in the long term. It is also worth mentioning that procurement, directly from the manufacturer, of second line or pediatric ARVs may not be successful because quantities are too small to generate manufacturers' interest. This option is therefore not preferred and not considered in the below section.

In the next section, only the procurement mechanisms that are deemed most realistic and feasible to pursue are described, and advantages and disadvantages of each of the options are mentioned. Some others – like decentralized procurement of ARVs (not recommended and not compliant with Article 48 of the bidding law on concentrated procurement of drugs), or international competitive bidding for methadone (not compatible with national policies) – seem highly unlikely to be taken forward, and are thus not discussed.

4.2.1 Procurement of ARVs from domestic resources

National competitive bidding

Under this scenario, the government procures ARVs from local manufacturers and local importers of internationally produced ARVs. This is the current mechanism used by the NHTD, and is in line with the

national strategy on Vietnam's pharmaceutical industry, which aims to increase the share of domestically produced drugs to 80% of the total value of drugs consumed during a year by 2020.³⁴ It also complies with the Bidding Law that states that drugs for which domestic production costs exceed 25% of the total cost should be given preference (Article 14) and imported drugs cannot be offered by tenderers if the same drug is produced domestically and meets national requirements (in terms of treatment, price and quantity) (Article 50). The law does not specify whether an imported three drug fixed dose combination would be considered equivalent to domestically produced three single formulations.

On the downside, the price of ARVs purchased locally (either locally manufactured or imported) is currently two to six times higher than the international reference price (see also section 3.3.1.1). It is possible that these prices can be brought down at least partially by increasing competition on the market (i.e. more manufacturers and importers registering their ARVs)³⁵ and by increasing volume of procurement. However, prices of domestically procured ARVs will most likely remain several times higher than international reference prices (partly driven by the high cost of active pharmaceutical ingredients for domestically manufactured ARVs and partly as a result of the preference given to domestically manufactured ARVs regardless of their cost and how it compares to international reference price) – which implies that the budget will also need to be several times higher than the current annual budget of US\$21 million for the procurement of ARVs. Given the current government allocation of US\$1 million for the procurement of ARVs, this means an even more drastic increase in budget.

Apart from the substantially higher price, not all ARVs needed in the national HIV/AIDS program may be available on the domestic market. Especially for the low-volume products like pediatric or second-line ARVs, manufacturers may not have sufficient incentive to register their products on the market, or alternatively offer them for very high prices.

Direct appointment of an international supplier

Under this option, domestic resources would be used to directly procure ARVs for a listed price from a supplier already operating in the country and familiar with the context, without a competitive bidding process. This option is specifically discussed in light of the procurement of ARVs with the government's budget for 2014 (VND 18 billion) in the near future. Under this scenario, the supplier would be either one used by the other partners, PFSCM (used by PEPFAR) or PPM (used by The Global Fund).³⁶ The Government of Vietnam would use its domestic resources to access ARVs of assured quality at international reference prices, keeping the procurement process as simple as possible. It would make use of existing procurement and supply chain systems that are proven to work, integrating two parallel mechanisms. Also, it would provide an opportunity for SCMS to work closely together with VAAC and build capacity on quantification and procurement processes.

On the downside, direct procurement and direct appointment of a supplier, although provided for under Vietnam's Bidding Law, requires a special authorization. Direct procurement is restricted to repeat procurement for the supply of similar products. The selected supplier should be a company that has previously won a tender (during the previous 12 months) for similar products in nature, size and price. Direct appointment of a contractor for the procurement of drugs is possible in the case of emergency in order to carry out the work of prevention and fighting of epidemics in urgent cases. However, in reality, this procurement mechanism is frequently used by the Government of Vietnam, and hence obtaining a waiver in principle depends mostly on political will. Direct procurement also abolishes

³⁴ Decision No. 68/QĐ-TTg dated January 10, 2014.

³⁵ Clinton Health Access Initiative (CHAI) is engaged in facilitating registration and incentivizing ARV manufacturers in order to increase competition and bring down prices.

³⁶ CHAI used to procure and supply pediatric ARVs in Vietnam until 2011 and also conducts global negotiations on ceiling prices for ARVs, but is not a supplier who could actually manage the procurement process.

competition and is prone to corruption as the process of selection of the single supplier may not be transparent. This latter point does not really apply to the procurement of ARVs, because the rationale for selection of PFSCM (or PPM) as the supplier for ARVs in this case is clearly supported by lower prices and previous experience in the country. However, this does not apply to direct procurement from a procurement agent other than PFSCM or PPM. Lastly, direct procurement through PFSCM perpetuates the reliance of the GVN on structures managed by donors, and is therefore not the most sustainable solution for the longer term.

International competitive bidding

In this case, the government of Vietnam launches an international tender, inviting national and international suppliers to bid. The tender document could either split up the items to procure in different lots – which would mean signing contracts with multiple suppliers – or combine all items into one lot, thereby dealing with only one supplier who wins the tender. ICB could also be preceded by a process to prequalify suppliers based on certain prerequisites (i.e. quality assurance criteria, ability to deliver). This would facilitate the tendering process afterwards, as only bids from a limited number of quality suppliers would be evaluated.

Launching an international competitive bidding process gives Vietnam access to the full range of quality-assured ARVs used in the national program against international reference prices, and is also a feasible longer-term procurement strategy.

One risk is the fact that international suppliers may not be interested to participate in the tender, so there would be insufficient bids to evaluate, or no bids at all for certain lots. Vietnam's relatively small quantity and relatively large range of ARVs to be purchased – especially pediatric and second-line ARVs – in combination with requirements to have Vietnamese labeling & inserts, results in small profit margins for suppliers. Indeed, some interviewees said that PFSCM and PPM do Vietnam 'a favor' by supplying the ARVs under PEPFAR and The Global Fund programs against reference prices. This issue could at least be partially addressed by strategically dividing up the tender in different (or only one) lot, or prequalifying (not-for-profit) procurement agents who commit to delivering the required medicines.

Importantly, a dedicated central procurement unit will need to be set up within the Ministry of Health and staff capacity built in order for the government to manage an international competitive bidding. Limiting the number of suppliers to deal with (i.e. only one international procurement agent instead of dealing directly with a number of different manufacturers) and prequalification of suppliers will make the workload and required expertise more manageable.

In all scenarios outlined above, procurement with domestic resources is conducted at central level (concentrated procurement as defined in the Bidding Law). These central level resources either consist of central budget, or combine funds from other financial sources – provincial budget, social health insurance, user fees, external funds – which are then channeled through a newly established mechanism to central level. Decentralized procurement, whereby provinces conduct procurement of ARVs separately, is not included as a preferred mechanism (unless it is done using a framework contract managed at central level) because the supply chain will be even more fragmented and difficult to manage, and few provinces (with the possible exception of HCMC) will have the capacity to procure on the international market.

In conclusion, for the immediate term, until a CPU is set up and sufficient capacity has been built, procurement of ARVs with domestic resources can either be conducted through national bidding for the two ARVs that are relatively cheaper, or via direct procurement through an international supplier with previous experience on the market. In parallel, urgent efforts should be deployed to establish a CPU (location within MOH to be decided) and transfer skills to government staff responsible for different functions of the PSM cycle. For the medium to longer term, the most likely scenario is that a

combination of national and international bidding, whereby competitively priced quality ARVs available on the domestic market are purchased locally and other products internationally through an international procurement agent.

4.2.2 Procurement of methadone from domestic resources

National competitive bidding - central level

Under this option, methadone is procured by launching a national competitive bidding process at central level, whereby local manufacturers and importers are invited to bid. Currently only one manufacturer has produced, sold and registered its product, but this is expected to be expanded to five manufacturers and one importer in the near future, ensuring sufficient competition and availability on the local market.

If methadone is financed from both central budget and other sources of funding (provincial budget, social health insurance, user fees: see Section 4.3), a framework contract can be set up whereby provinces buy directly from manufacturers for a centrally negotiated price. In this type of arrangement, the bidding process itself is thus conducted at central level, and the contract is signed between central level and manufacturer/supplier. Subsequently, other partners (i.e., provincial level) can use the existing contract to directly procure from the manufacturer/supplier for the negotiated price. A single central bidding instead of multiple tenders at provincial level ensures availability (especially in light of controlled substances) and more competitive prices. It also reduces the required capacity to conduct bidding at provincial level. It will, however, require a new financing mechanism to channel funding to a basket with which procurement can be conducted.

National competitive bidding – decentralized level

Here, a competitive bidding at decentralized (province) level to procure methadone is launched, and national manufacturers and importers can submit their bids. As mentioned above, it is expected that there is sufficient competition and availability of methadone on the local market in the near future. As a plus, this procurement mechanism may result in shorter lead-times and more flexibility, as well as more ownership by the provinces.

However, with the exception of HCMC, the capacity of provinces is likely insufficient to efficiently manage the procurement process, and ensure constant availability of competitively priced methadone for the people in need in their province. It will also further fragment the supply chain. Importantly, as methadone is a controlled substance, permission needs to be obtained at central level before the procurement process can start, thereby countering at least part of the advantages.

In conclusion, the procurement of methadone through a national competitive bidding at central level is preferred to the decentralized procurement. A possible exception is decentralized procurement by HCMC, which has a high burden of methadone users (so a relatively large quantity to be procured) and an established CPU with capacity to tender and manage the procurement process. As highlighted in the previous section, there is an urgent need to build capacity at the central level (even though a national tender with limited number of suppliers is easier to manage than an international competitive bidding) and set up a central procurement unit to manage the tendering and procurement process.

4.2.3 Procurement of anti-TB drugs from domestic resources

FLD: National competitive bidding (central level)

This option is the current system in place for the procurement of first-line anti-TB drugs. A national competitive bidding is launched to procure domestically manufactured FLD, and drugs imported through local suppliers, whereby the National Lung Hospital is in charge of managing the procurement process. There is considerable national ownership of this supply chain, which is in line with the national strategy

to procure domestically manufactured drugs, and capacity within the National Lung Hospital to conduct the procurement process seems sufficient. The main issues affecting availability of FLD are insufficient state budget to cover 100% of demand, and cumbersome administrative procedures before a tender can actually be launched. All FLD procured locally from domestic resources are registered and therefore meet minimum quality criteria as set by DAV, and prices are comparable to international references.

One drawback of domestic procurement of FLD is that not all formulations are available on the local market, or are available in different (potentially sub-optimal) dosage forms.³⁷ For instance, the intensive-phase (RHZE) regimen is supplied as a combination of fixed-dose and single formulations through the national program, whilst it is available as a 4-in-1 single tablet fixed-dose on the international market (e.g. through GDF, which provided this 4-in-1 FDC through its emergency supply).

FLD: International competitive bidding

Under this scenario, FLD are procured through ICB. This mechanism has as advantages that all FLD formulations and dosage forms can be accessed, and drugs would meet international quality criteria. On the downside, moving from domestic to international bidding is contrary to the pharmaceutical strategy that strongly favors domestic procurement. In addition, this is a longer-term scenario as capacity within the National Lung Hospital is currently insufficient to conduct an ICB.

SLD: National competitive bidding

Here, second line anti-TB drugs are procured through a national competitive bidding process. This process is in line with the national strategy to procure drugs locally.

However, it is unclear to what extent the local market can assure the constant availability of the (highly specialized) SLD. If available, prices are likely to be several times higher than international reference prices, and quality may be compromised. The treatment of MDR-TB patients with partial or interrupted regimens, or with non-quality assured drugs, can fuel the spread of multi- and extensively drug resistant TB (XDR-TB), which is a serious public health threat.

SLD: Direct procurement

Under the current scenario, the direct procurement of SLD is conducted through the GLC, which ensures access to high-quality, affordable SLD for the treatment of MDR-TB. GLC also provides technical assistance to countries with planning, implementing, managing and monitoring the scale-up of MDR-TB services. Direct procurement is justified as GLC consolidates demand between countries and ensures availability of SLD from a limited number of manufacturers.

On the downside, direct and international procurement is not in line with the national strategy to procure domestically manufactured drugs, and with the Bidding Law.

An ICB for the procurement of SLD is not a preferred way forward, due to the highly complicated market for SLD with few manufacturers, and the very small amounts of highly specialized SLD needed in Vietnam.

In conclusion, it is advised that the mechanism for the procurement of FLD and SLD should continue as is: “If it works, don’t touch it”. FLD are purchased with domestic resources through a national competitive bidding, although procurement responsibility should be delegated to the CPU once it is established. Given the serious public health threat of further spread of MDR- and XDR-TB, assured availability of quality affordable SLD is a priority. For this reason, it is proposed that the procurement of SLD through GLC remains under the funding responsibility of the donor community, until the CPU has

³⁷ A list of registered FLD could not be obtained from DAV; potentially a full range of FLD formulations is registered in the country, but these were not available in the TB clinics visited.

been established, sufficient capacity has been built, and funding for SLD from the national budget firmly committed.

4.3 Analysis of Future Financing Options

4.3.1 Central Budget

The central government budget is considered a key source of financing for the procurement of pharmaceuticals for the HIV/AIDS and TB national targeted programs. The central budget currently provides some funding for domestic procurement of these pharmaceuticals. Central government commitment is evident with the supplementary budget for anti-TB drugs, and Decision No. 1899 affirming government responsibility for sustainable HIV/AIDS services. An important advantage of funding procurement by a central procurement unit through the central budget is that the funding flow is simple. Funding would flow easily from the central level budget to a central level procurement unit.

A key challenge to central budget financing for ARVs and anti-TB drugs is the legal framework guiding procurement. According to the recently approved bidding law and Vietnam's pharmaceutical strategy with a vision to 2020, funding from the central budget would require the procurement of drugs from domestic manufacturers and suppliers. In the past, domestic procurement has resulted in higher prices. International competitive bidding is possible, but is unlikely to generate interest/bids from international suppliers, due to the small quantities required; and although direct procurement from an international procurement agent (e.g. PFSCM) can be authorized in order to obtain more competitive prices, such authorization is not guaranteed and would need to be obtained on an annual basis (see also section 4.2).

Funding procurement through the central budget would likely require advocacy to ensure that the adequate amount of funding is received each year in order to maintain an uninterrupted supply of pharmaceuticals. Allocation decisions may depend on changing national priorities, as demonstrated by significant fluctuations in the past. In 2013, funds for NTPs were cut by 50%, which, in the case of the NTP for TB, led to cutting other important costs in order to ensure the availability of first line anti-TB drugs. Furthermore, the National Assembly is currently discussing the cost effectiveness of the NTPs in general, and as a result of these discussions, it is possible that the NTPs will be discontinued after 2015.

4.3.2 Provincial Budget

The provincial budgets are another important source of funding for the procurement of NTP drugs. Provinces currently provide approximately 80%³⁸ of the funding for health, and also partly contribute to the NTP budgets. Provinces have begun to play a role in pooling procurement across facilities. However, the drugs for the TB and HIV/AIDS NTPs would need to be procured at the central level in order to obtain competitive prices and/or interest from suppliers, given that the drug quantities required per province would be relatively small. Funding cannot easily flow from provinces to a central level agency, and therefore in order to enable a flow of funds across the two levels, a new mechanism (e.g. framework contracts) (see Section 4.2.2) would need to be introduced. As is the case with funding allocations from the national budget, provincial budget allocations may also fluctuate depending on the priorities of the provincial level government, and therefore may pose a risk for the uninterrupted supply of pharmaceuticals for HIV/AIDS and TB. Furthermore, the availability of provincial-level funding varies significantly among the provinces, depending on the economic development in each province, with most provinces relying on some level of central budget transfers for health.

³⁸ Figure provided during interview with the Ministry of Finance.

4.3.3 Social Health Insurance

Social Health Insurance through Vietnam Social Security has been identified as a key option for financing the procurement of HIV/AIDS and TB pharmaceuticals in the future. Although VSS is seen as a new source of funding, it currently relies primarily on government budget. Approximately half of VSS revenues in 2010 were direct transfers from government, not including premiums paid through government funding for civil servants and pensioners.³⁹ Nonetheless, financing these drugs through VSS is aligned with Vietnam's goal of universal health coverage, and serves to ensure HIV/AIDS and TB treatment is integrated within general health services.

VSS currently covers approximately 60% of the population. A system that includes central government-funded drugs and VSS-reimbursed drugs distributed through the same facilities may be difficult to manage. However, a new amendment to the health insurance law introduced a compulsory enrollment requirement, and the government aims to cover 80% of the population with health insurance by 2018. This new requirement makes social health insurance a more feasible option for financing procurement in the future.

The current structure and legal framework, however, poses several challenges that must be addressed. VSS currently contracts directly with health facilities to advance and reimburse funding for the provision of services; it does not have a mechanism in place to pay a national drug facility directly. Furthermore, VSS can only pay facilities which are under the curative system. This setup has implications for ARVs, since approximately half of the OPCs are under the curative system, while the rest are under the preventive system and not eligible for reimbursement by VSS. These issues must be addressed in order for VSS to be able to pay for ARVs and other centrally procured pharmaceuticals.

4.3.4 Socialization (user fees)

User fees are a previously untapped funding source, but are currently being introduced for methadone treatment, where patients in three pilot provinces are charged a small fee of approximately US\$0.50 per user per day. User ability or willingness to pay for other types of drugs including ARVs and anti-TB drugs has not been studied, and charging user fees could negatively impact access and utilization. Regardless, due to the higher cost of ARVs and anti-TB drugs compared to methadone, user fees are unlikely to generate a significant portion of the total procurement costs.

4.3.5 External Donors

In the short term, Vietnam will likely continue to seek donor support, where possible, to fund the procurement of HIV/AIDS and anti-TB drugs. Procuring with donor funding is advantageous because donors are able to access more competitive prices for the same drugs. However, since donor funds are likely to decrease in the near future, this is not a sustainable financing option. Given that each donor has its own requirements, reliance on donor funding inevitably leads to parallel procurement and supply chain systems, as has been the case in Vietnam to date.

³⁹ Moving Toward Universal Coverage of Social Health Insurance.

5. RECOMMENDATIONS FOR DEVELOPMENT PARTNERS TO SUPPORT THE TRANSFER TO THE GOVERNMENT

Over the past years, significant effort and resources have been invested in supporting Vietnam's HIV/AIDS and TB programs. Much progress has been made, notably an impressive scale up of the number of patients on ARV treatment, provision of methadone maintenance treatment in clinics across the country, and a strong TB program with high detection and cure rates and diagnosis and treatment of MDR-TB.

However, there are still significant gaps that must be addressed before these programs can be fully transitioned to the Government of Vietnam. Parallel systems need to be harmonized and strengthened, and all stakeholders involved must work together to build capacity of local counterparts. A clear commitment by the Government of Vietnam to take full ownership for these programs is needed, including mobilization of adequate financial resources from domestic sources.

As donors are reducing or withdrawing their financial support, it is important that the coming years are used to build on lessons learned and scale up existing approaches that have been proven effective, with a clear objective of transitioning responsibilities to government institutions. We outline here a number of overall recommendations to contribute to a successful transition of the procurement functions for HIV/AIDS (ARVs and methadone) and anti-TB drugs to the Government of Vietnam. For each recommendation, specific activities for consideration by development partners, including USAID, are outlined for the immediate, short to medium, and medium to long term to support the transition. A summary of recommended activities for development partners is included in Annex D.

I. Develop a unified PSM strategy

A unified PSM strategy for ARVs, methadone and anti-TB drugs should be developed, detailing the transition from the current parallel systems to one harmonized and government-led system. The PSM strategy should include specifics on the approach, roles and responsibilities for each step of the PSM cycle, and outline a coordinated approach and strategic framework for the provision of technical assistance. The development of this strategy should be spearheaded by VAAC, and discussed and updated in strategic working group meetings or joint forum with all key stakeholders.

2. Support preferred procurement mechanism (direct, national, ICB)

Once the preferred mechanism for the procurement of ARVs, methadone and anti-TB drugs from domestic resources is decided upon, strong support should be provided to the national targeted programs in implementing this strategy and overcoming possible bottlenecks in the process. For instance, improving price transparency will likely encounter resistance from those benefiting from the current (non-transparent) systems. This should also lead to the issuance of a regulation that helps to clarify pricing provision in the current bidding regulations, which require drugs that are selected through a bidding process to have a 'reasonable price' and are 'suitable with drug quality, delivery and storage situation as well as other relevant conditions'.

3. Establish a Central Procurement Unit

The preferred procurement mechanism for ARVs, methadone and first-line anti-TB drugs relies on the establishment of a Central Procurement Unit (CPU) within the Ministry of Health, with sufficient capacity to manage all processes related to procurement and international competitive biddings. The Government of Vietnam already planned the establishment of a central procurement mechanism in its Decree 63/2014/ND-CP (Aug 2014) in relation to the Bidding Law, and the WHO and the World Bank are also discussing longer-term plans to support the MOH in setting up a CPU. All these discussions should be taken forward and made into concrete action plans.

4. Set up a comprehensive single LMIS system for quantification & reporting

A comprehensive single LMIS from the peripheral level to the central level is urgently needed. This LMIS will ensure the collection, processing, reporting and use of information for decision-making; inform quantification and forecasting of need; and provide VAAC with the tools to monitor performance of the supply chain at all levels and at all times. Tools that have been successfully implemented in the past need to be scaled up (instead of new approaches piloted), and harmonized between donors.

5. Mobilize resources from national and provincial government budgets

To ensure uninterrupted supply of ARVs, methadone and anti-TB drugs as donor funding decreases, the GVN will need to incorporate financing for these drugs within its national and provincial budgets. Assistance is required in order for the Government of Vietnam to understand the resource needs and the rationale for prioritizing this investment, to identify mechanisms which will combine budget allocations from multiple levels of government, and to identify potential efficiency gains.

6. Improve transparency of budgeting between central and provincial levels

Although there may be transparency in budgeting at the highest levels, central and provincial budget allocations to the NTPs do not seem to be coordinated to ensure that they supplement and complement each-other. Lack of coordination may lead to unexpected gaps in resource needs, or possibly over-allocations that are spent hastily. Development partners could target their support to improve clarity and coordination in the budgeting process in order to ensure that the NTPs' funding needs are met.

7. Achieve full population coverage under Vietnam Social Security, including ARVs, methadone, and anti-TB drugs in the benefits package

Coverage of ARVs, methadone and anti-TB drugs through VSS is most feasible if the entire population is enrolled in social health insurance. Full population coverage would more strongly support inclusion of these drugs within the benefits packages, and simplify planning and budgeting. The GVN will require assistance to implement the compulsory enrollment envisioned by the amended Health Insurance Law and to establish the necessary foundations (e.g., benefits package, information systems, supporting policies, etc.) to enable reimbursement of these drugs by social health insurance.

Development partners, including USAID, can support the above-mentioned key recommendations through carrying out the following activities, outlined for the immediate, short to medium, and medium to longer term.

Immediate term

The very first activity focuses on supporting the development of the unified PSM strategy through a participatory and transparent process with all stakeholders involved in health system strengthening in Vietnam. Development partners should support the creation of a strategic working group or joint forum that will be responsible for the implementation of the PSM strategy and that will facilitate synergies with existing initiatives and programs (GAVI and The Global Fund HSS grants for instance) in the area of system strengthening. USAID can use the presentation of the current report as an opportunity to bring all stakeholders together, discuss the findings and start creating a common vision on how to reach commodity security for HIV/AIDS, TB and MMT programs and agreeing on a plan to move towards a more sustainable procurement & supply system for ARVs, methadone and anti-TB drugs (see figure 4 visualizing the longer-term situation as a potential starting point for discussion) that could eventually benefit to the supply of all essential medicines. The plan should include clear timelines and milestones for handing over activities to the GVN.

Development partners can facilitate the process by supporting VAAC and other relevant MOH departments with setting up regular (possibly quarterly) meetings, clearly outlining roles and responsibilities of each partner, drafting clear minutes with points for follow-up, organizing the meeting venue, etc. The group should also be responsible for ensuring that key objectives and features of the PSM strategy are adequately reflected in the new Five-Year Plan for the Health Sector as commodity security underpins healthcare services delivery.

For the immediate future, development partners should also support VAAC in accessing quality affordable ARVs through facilitating linkages with PFSCM or PPM. Discussions on direct procurement of ARVs with the government's budget for 2014 (VND 18 billion) through an international supplier with previous experience on the market are already underway (see also report MOH May 2014 on procurement of ARVs). SCMS is particularly well placed to support VAAC with this activity, through its current established supply chain through PFSCM. In addition, it provides a good opportunity to build capacity at VAAC; SCMS should work closely with VAAC on the different steps in procurement process and planning of orders.

In order to lay the foundations for the eventual reimbursement of ARVs, methadone and anti-TB drugs by social health insurance, the development of a basic benefits package, which can eventually include all these drugs is needed. Given the positive momentum within the GVN to develop the package, it is necessary for development partners to work closely with VSS and Department of Health Insurance (DHI) in the MOH to support the process in the immediate term. USAID has begun to support the development of the benefits package through HFG, and it is necessary for this support to continue in the near future.

Short to medium-term activities

Following on the development of a unified PSM strategy, development partners should support VAAC and relevant departments at the MOH in ensuring momentum is maintained and in implementing the plan aiming at harmonizing and transitioning to a government-led system. This would include providing logistical and administrative support to the working group secretariat. The strategic working group will also provide the forum for discussion and agreement on a number of key decisions that need to be taken. These include the operational aspects for the establishment of the CPU, as well as the choice for the type of LMIS system to be implemented nation-wide, and ensure ownership on the way forward.

The working group will also provide an environment to exchange comparative pricing information and best procurement practices, which will help foster competition and improve price transparency.

For supporting the preferred mechanism for the procurement of ARVs, methadone and anti-TB drugs from domestic resources, development partners should assist MOH and DAV in the development of their capacity to properly assess drug quality during the bidding evaluation process. The drug quality criteria should ensure patient safety and be in line with WHO recommendations regarding medicine quality (pre qualification scheme and good manufacturing practice), with the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme and ASEAN requirements in coordination with the PQM project. In addition, development partners, including USAID, should support improving price transparency of especially ARVs – but also other drugs – on the local market. Activities include providing support to DAV in fulfilling its role in publishing local reference pricing in the form of short-term technical assistance for the collection and dissemination of the required information on DAV website. In addition, USAID or other development partners can fund a study on elucidating price structure of locally available drugs, and mark-ups at different levels throughout the supply chain especially for medicines that can be purchased at reduced price through differential pricing scheme. Lastly, development partners can facilitate the exchange of comparative pricing information and best procurement practices, thereby increasing competition among stakeholders; the strategic working group could be used as a forum for exchange.

Specifically for methadone, USAID should consider continuing or extending its support to PQM/USP for local production of quality methadone, including lessons learned to apply to quality domestic manufacturing of ARVs. This could include increasing the number of staff working on the project currently, and actively liaising with domestic ARV manufacturers on quality standards and the WHO prequalification process. This support could include a market survey to inform manufacturers, preparation to audit manufacturing sites and follow up on audit recommendations.

Development partners through the strategic working group and as part of the PSM strategy implementation activities, should liaise with the National Advisory Committee on Drug Bidding and other agencies (i.e., WHO, WB) to support the establishment of a Central Procurement Unit. As mentioned above, the establishment of the CPU should be a priority point on the strategic working group's agenda, and this forum could be used to consensually develop a comprehensive operational plan with detailed steps geared towards effective implementation. The plan would define the best location within MOH, as well as the unit's mandate, roles & responsibilities, etc. Once it is officially established, development partners including USAID should also provide technical assistance to the CPU based on a careful capacity gap analysis and focused on the development of procurement guidelines, framework contracts (if applicable), standard operating procedures, bidding documents, specifications, etc., based on national guidelines and international best practices. Detailed procedures should be developed to conduct concentrated procurement, and should include specific provisions for drugs that are not available in Vietnam.

The second priority on the strategic working group's agenda is the establishment of a comprehensive single LMIS system that would allow data to flow from the peripheral to the central level. The LMIS would also include some non-financial incentives mechanism whereby information and feedback is provided to peripheral users. Development partners, as members of the group, should facilitate discussions and decision making process on the type of system to adopt, ownership (VAAC vs. MOH), selection of most appropriate and simple tools that have been successfully implemented in the past (exploring the possibility of integrating/piggybacking LMIS on the national computer based HMIS), required capacity-building, financial resources, etc. The type of LMIS system to be introduced could be further informed by learning from experiences from countries in the region with a well-developed LMIS system. As part of this reflection on information management, development partners could support the development of a dashboard that would provide an overview of patient numbers and stock status at all

levels of the healthcare system and include an alert system in case existing stocks in the country are insufficient to cover patient needs.

While donors have announced a decrease in funding for the procurement of ARVs, methadone and anti-TB drugs, funding has not actually declined in the recent years. In order for the GVN to justify the need for increasing domestic funding for these drugs, it is necessary for donors to actually demonstrate a decrease in funding, consistent with the communications made to the GVN regarding this matter. This gradual decrease in funding should be combined with increased assistance to successfully manage the transition to domestically-financed procurement. The GVN will require evidence on the full cost of this transition and the resources it will need to mobilize in order to ensure uninterrupted supply. Furthermore, development partners can support VAAC, the National TB Program, and the MOH to develop their investment cases to enable them to advocate for increased resource allocations from the central and provincial budgets. Evidence to will need to be generated to demonstrate to high level policy makers at both the central and provincial levels that investments in these programs are worthwhile. At the same time, due to competing priorities both within the health sector and with other sectors, the GVN would greatly benefit from the support of development partners to identify efficiency gains so that the use of limited resources can be rationalized.

As the provincial level will continue to be an important source of funding for the procurement of these drugs, but the ability of provinces to contribute varies, an analysis of the fiscal space at the provincial level to determine ability to increase contributions would be beneficial. Furthermore, the flow of funding from the provincial level to a central procurement unit requires the development of supporting mechanisms, such as framework contracts. Development partners should provide technical assistance to the GVN to understand and establish such mechanisms. It is critical, however, for the provincial budget allocations to be fully coordinated with central budget allocations in order to ensure that the total funding allocated meets but does not exceed the needs of the NTPs as estimated in their annual planning process. Technical assistance should be provided to the GVN at both levels to identify coordination gaps and develop specific recommendations and guidelines for sharing information and coordinating planned allocations to ensure complementarity in budget planning.

In the short and medium term, support should also continue to enable future reimbursement of ARVs, methadone and anti-TB drugs by social health insurance. VSS's current monitoring and evaluations systems are weak and do not capture reliable utilization and cost data. Development partners should provide support to VSS to strengthen these systems, so that more efficient provider payment mechanisms can be implemented, resulting in greater cost containment. Additionally, social health insurance can presently reimburse only for curative services, and therefore those HIV/AIDS OPCs which are part of the preventive system are not eligible for VSS reimbursement. This issue can be addressed either through an amendment to the health insurance law, so that it can allow for reimbursement for preventive services, or a change in the status of those OPCs which are in the preventive system. Development partners can support the GVN to implement the necessary policy or structural changes which will enable the reimbursement of all OPCs by VSS.

Medium to long-term activities

In the medium to longer-term scenario, it is envisaged that the main procurement and supply chain activities have been handed over to the GVN and are financed with domestic resources, and the role of development partners, including USAID, would be limited to providing technical (and some financial) assistance. In this scenario, technical assistance should be focused on supporting and mentoring staff at CPU in management of the procurement and supply chain (including LMIS data analysis) to ensure that it has adequate capacity to fulfill its role. In addition, longer-term on-the-job mentoring of staff involved in quantification should be provided, as well as data management at central level. Lastly, development partners, including USAID, should consider continuing to support the national quantification based on

unified LMIS data through the strategic working group.

Although the newly amended Health Insurance Law introduces compulsory enrollment, key informants interviewed during the course of this assessment acknowledged that the implementation of this requirement will be challenging in practice. In the medium to long term, development partners should support the GVN to design and implement the appropriate strategies (e.g., enforcement, communication and social marketing, etc.), which will result reaching the GVN target of covering 80% of the population by health insurance by 2020.

ANNEX A: EVALUATION SCOPE OF WORK

INTRODUCTION

Background

The antiretroviral therapy (ART) program has been implemented in Vietnam since 2000 and was expanded in late 2005. With efforts from the government and support from international organizations (e.g. President's Emergency Plan for AIDS Relief (PEPFAR), Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM), and the Clinton Health Access Initiative (CHAI)), ARV treatment for HIV is provided free of charge.

As of 06/30/2013, the ART program has deployed in 63 provinces, covering over 25 % of districts, the number of people infected with HIV are receiving ART in the country is 77,226 , an increase of 29 times higher than in late 2005. In which, PEPFAR and GFATM programs have been covering 42,537 patients (55%) and 29,550 patients (38%) respectively. In addition, Methadone Maintenance Therapy (MMT) was started in Ho Chi Minh City and Hai Phong with 6 treatment facilities in May 4,2008. After 5 years, services have expanded to 61 MMT clinics in 20 provinces and cities with a total of nearly 14,000 patients. Currently, methadone medication is being supplied by PEPFAR and GFATM only. The goal of the National HIV/AIDS Program in Vietnam is to ensure the provision of ART services to 105,000 people and methadone substitution treatment for 80,000 people by 2015. In achieving that goal, PEPFAR and GFATM still serve as the largest donors in provision of HIV /AIDS commodities. Tuberculosis (TB) is another public health concern in Vietnam. Vietnam is one of 22 countries that comprise 80% of the global TB burden, and also one of the 27 countries with the highest multidrug-resistant tuberculosis (MDR-TB) burden. It is estimated that Vietnam has 170,000 TB cases per year, 18,000 annual deaths, and it is estimated that the number of new MDR-TB cases each year is 3,500. In response to this situation, the TB supply chain was established under the Vietnam National TB Program (NTP) more than 30 years ago to ensure availability of critical TB drugs at national, district, and commune levels.

Problem Statement

The components of the supply chain of TB and HIV drugs and commodities are currently managed by different actors (PEPFAR, GFATM, and National Targeted Programs) with wide differences in mode of selection, quantification, pricing, procurement. Following are further details and characteristics of the issues affecting the supply of these critical products.

HIV and AIDS commodities supply

Each donor/program has its own regulations for the implementation of the supply chain cycle, leading to inconsistency in the practice of supply chain management. Since its expansion in late 2005, the HIV and AIDS commodities supply in Vietnam relies entirely on the donors. The Vietnam Authority for HIV/AIDS Control (VAAC) was established in 2005 with a mandate to coordinate the donors' response. When the VAAC was established, capacity in quantification for HIV and AIDS commodities, especially for ARVs, was extremely limited. The National Targeted Program (NTP) locally procures ARVs once a year based on the given budget for the year, which meets 30-50% of the treatment needs for NTP program. This procurement was carried out by National Hospital for Tropical Diseases, an institution that lacks procurement expertise. In addition, the reports from the treatment facilities were not accurate and timely, leading to continuous ARVs shortages at both the central warehouse and the facility level.

Since 2006, PEPFAR has implemented centralized international procurement of HIV and AIDS commodities through Supply Chain Management System/Partnership for Supply Chain Management (SCMS/PFSCM) mechanisms,

while GFATM procured through UNICEF. As a result of a serious stock out in 2011 which required PEPFAR to provide emergency support, the GFATM has started procuring through the Voluntary Pool Procurement (VPP) mechanism, which is similar to SCMS/PFSCM. This has significantly improved the HIV and AIDS commodities supply situation in Vietnam over last two years, but there are still challenges and concerns. For example, GFATM will apply yearly quantification with two shipments/one order per year from 2014 instead of quarterly orders as had been the previous practice. This increases the potential for stock outs, excess, or shortage of some drugs, especially pediatric ARVs, due to the currently limited capacity of officials in quantification and procurement methods. Limiting the supply to one order and two shipments per year would leave the country with little to no room for error in securing the GFATM supply. This may also increase the risk of PEPFAR resources being requested to perform emergency procurements in order to ensure the availability of ARVs to those who need them.

TB drugs supply

Since 2005, first line TB drugs (FLDs) have been funded through a central government allocation. The annual allocation for FLDs is only sufficient to cover 8 months (66%) of the annual drug needs. In 2009, Vietnam NTP faced a stock out and the Government of the Netherlands provided emergency support for a one year buffer. This buffer was exhausted in 2012. There will be another stock out in 2014 due to the budget allocation issue, the National TB program has submitted an application to the Global Drug Facility (GDF) for emergency first line drug support. GDF has committed to support the NTP with enough FLDs to cover one year of treatment needs, including a 6-month buffer with clear conditions to ensure adequate FLDs supply from local funding. The second line TB drugs and other new testing commodities (like Xpert MTB/RIF) are still being fully supported by donors, including GFATM, UNITAID, PEPFAR.

Given the conditions described in the above sections, USAID/Vietnam has recognized the need to carry out an evaluation of the supply chain and the procurement systems for HIV and TB drugs and commodities in Vietnam. The expected impact of this evaluation is to contribute to a successful transition of the procurement functions for HIV and TB supplies to the Government of Vietnam.

Evaluation Purposes

The primary purposes of this evaluation are to:

- Assess and describe how the current HIV and AIDS commodities and TB drug supply chain systems work in Vietnam as there are three parallel procurement systems for HIV and AIDS commodities in Vietnam managed by PEPFAR, The Global Fund and the National Targeted Program. The focus will be on reviewing, describing and evaluating the current practices, focusing on weaknesses around product selection, quantification, price negotiation, bidding practices, importation, storage, inventory management, distribution, pharmacy services.
- Analyze the content of the Bidding law and Pharmaceutical law and their relevant decrees, to provide an opinion on current proposals, and recommendations on alternative options, for a reformed system for supply of health commodities including HIV and TB medications managed by the Government of Vietnam.

The evaluation will take place with SCMS, GFATM Project Management Unit office, National Hospital for Tropical Diseases (NHTD), National TB Program, Vietnam Social Security, Central Pharmaceutical Company No 1 (CPC1), Drug Administration of Vietnam (DAV), Legislation Department, Department of Health Insurance, four related units within Vietnam Authority for HIV/AIDS Control (VAAC) including General Planning, Care & Treatment, Harm Reduction and Monitoring & Evaluation Units and other related stakeholders at the provincial level.

The timing of this evaluation is appropriate for informing recommendations on a possible new integrated supply model for Vietnam. The report will be shared with PEPFAR, GFATM and the MoH/VAAC. The Health, Finance and Governance Project has been selected as the implementing mechanism for this evaluation.

Relevant Evaluation Questions (non exhaustive)

1. Are current practices of supply chain management functioning properly in terms of product selection, quantification for procurement, procurement & importation, storage, inventory management, quantification for distribution, and pharmacy service for HIV/AIDS commodities and TB drugs in these systems?
 - a. How does the product selection work?
 - b. What are the differences in quantification for procurement (tools and procedures) among these systems?
 - c. How does Vietnam team interact with the HQ and other Vietnam stakeholders (VAAC, DAV, CPCI and MoF) on procurement & distribution?
 - d. How does the assigned distributor manage the inventory at the central warehouse?
 - e. What are the practices of quantifications for distribution in both program?
 - f. What is the capacity of GVN agency on managing the supply chain?
2. What factors would enable the uninterrupted supply chain for HIV/AIDS commodities in Vietnam? (Donors' regulations, staff capacity, policy & legal framework including national, subnational level regulatory framework, HIV and AIDS commodities market...)
3. What are the possible scenarios for centralizing procurement under the new Procurement decree and what new structures and systems would be necessary?
4. How would the current legal and regulatory frameworks support the possible new structures, and what revisions/amendments would be needed to support different scenarios?
5. What level of centralization and managed by which entity, would provide the most benefits?
6. What type of support would be needed to implement the possible scenarios?

Evaluation Design and Methodology

This will primarily be an assessment to collect information on the current procurement and supply chain practices for the HIV and AIDS commodities at both PEPFAR and GFATM via qualitative and quantitative methodologies.

We propose the use of cross-sectional descriptive study. There are many possible sources of data for the evaluator to consider and select based on the final evaluation timeline, finances, and technical constraints.

Review of existing data shall include:

- Quantification tools
- Procurement & distribution related documents
- Information systems for recording, reporting/collecting, and transmitting data from various levels
- Governance system i.e. policies, procedures, guidelines
- Legal system: Bidding law, Pharmaceutical law, related decrees
- SCMS & GFATM PMU Program monitoring plans (PMP)

Additional data will be generated by:

- Key informant interviews with VAAC, DAV, Provincial health Service (PHS), PAC, treatment facilities staff, GF PMU, HQ, CCM, National TB Program and CPCI and others as relevant and feasible.
- Stakeholder meetings;

The Consultants shall perform both qualitative and quantitative analysis as part of this evaluation, based on their review of existing data and collection of supplemental data. The qualitative component will include assembling interview information, completing thematic analysis, and writing a report. The quantitative components will include further analysis and synthesis of the stock out, excess or shortage frequency, different lead-time, number of steps for procurement approval, etc.

All data that will be analyzed should be directly related to the objectives listed above.

Deliverables

The Consultant team will undertake a 6 weeks evaluation assignment of which approximately 3 weeks is expected to be in-country. The team will use approximately one week in pre-evaluation preparations, and another one week post-evaluation report finalization. The assignment is expected to span over a total of approximately 4 months, starting from June 1 to September 30, 2014 (tentatively).

USAID/Vietnam team members will arrange for an initial introductory meeting with appropriate stakeholders, donor and implementing partners. Where necessary and appropriate, a USAID/Vietnam member may participate in these. A general list of relevant stakeholders and key partners will be provided to the assessment team at the time of arrival, but the evaluation team will be responsible for expanding this list as they deem it fit or appropriate to develop a comprehensive understanding of the HIV/AIDS commodities and TB drugs supply chain management in Vietnam.

Prior to conducting field work, the consultants will review various existing documents and reports. The USAID /Vietnam and GFATM team will provide the relevant documents for review. Consultants will prepare a draft evaluation tool which will be reviewed with the USAID team.

The evaluation team members will meet with key representatives of USAID/Vietnam at the beginning of the assignment. This time will be used to clarify team's roles and responsibilities, deliverables, development of tools and approach to the evaluation and refinement of agenda. The consultant team must work closely with SCMS, GFATM PMU and other stakeholders.

The Consultant team shall arrange to visit the central warehouse, PHS, PAC and health facilities if necessary. In selected circumstances, member of staff from USAID/Vietnam or/and GFATM will participate in the field site visits but will not attempt to influence the team's findings. Prior to site visits, the team will meet with key unit of VAAC or National TB Program.

The important meetings over the course of the assignment will include:

- Initial organizational/introductory meeting with USAID, Implementing Partner, and other stakeholders at which the consultant will present an outline and explanation of the design of the evaluation, including a draft evaluation tool.
- Mid-evaluation review with USAID/Vietnam Team to outline progress and implementation problems; and
- Final evaluation debriefs/summary of the data and draft recommendations, to be held with USAID/Vietnam and other key stakeholders after field work is completed. The objective of de-brief, will be to share the draft findings and recommendations, solicit comments and inputs, and clarify any remaining questions or issues before the consultant departs.

The deliverables will be:

- Concrete recommendations for moving forward under a Government-led integrated supply management model, and on what inputs will be the most critical for the GF and PEPFAR to provide.
- Recommendations and proposed roadmap for integrating public commodities supply chains into a broader PSM system as outlined by the plan for the Essential Medicines Procurement Unit.

Team Composition

The Evaluation Team shall consist of 3 international experts with 5+ years of experience in procurement of pharmaceuticals, supply chain management and relevant legal expertise in mid and low-income countries with USAID and/or other donors. The team will be led by a senior member who should have considerable experience

in evaluation design and demonstrable management skills. The team will be further supported by local technical experts and an English-Vietnamese translator if needed for the in-country period.

Team Leader – The team leader will serve as the primary point of contact between the USAID and Evaluation Team. The incumbent must:

- Be able to communicate effectively with senior U.S. and host country officials and other leaders;
- Have a 5+ year proven track record in terms of leadership, coordination, and evaluation delivery for development projects and programs;
- Have excellent writing/organizational/management skills and proven ability to deliver a quality written product (Evaluation Report and PowerPoint).

In addition, the Team Leader may provide his/ her technical expertise in one or more areas to support this Evaluation. We expect the team to exhibit senior-level technical expertise, evaluation expertise, and the expertise and ability of the team's leadership to manage the team's budget and staff resources. USAID/Vietnam will designate staff to provide logistical and administrative support to the team; however, the Team Leader will have the primary responsibility for ensuring the final deliverables are completed in a timely manner and are responsive to the Scope of Work and USAID comments.

The required areas of technical (subject matter) expertise that should be represented on the team correspond roughly to the technical foci (BCC) of the program being evaluated are:

- Current practices of HIV/AIDS commodities and TB drugs supply chain management in all programs.
- The issues during implementation HIV/AIDS commodities and TB drugs supply

Scheduling and Logistics

The HFG/Vietnam office will provide primary support for logistics and provide additional technical support as needed.

The USAID/Vietnam point of contact for the evaluation will be Dao Nguyen.

The USAID team will assist the Evaluation Team in their work by reviewing reports, responding to questions from the team and resolving administrative or logistical obstacles.

Reporting Requirements

Preliminary finding and de-briefing will be done in power point

Below is the format for writing the evaluation report.

Executive Summary

The Executive Summary will state the development objectives of the program/project evaluated; purpose of the evaluation; study method; findings; conclusions, lessons learned and future design implications.

Table of Contents

Introduction

The context of what is evaluated including the relevant history HIV/AIDS commodities and TB drugs supply chain in Vietnam

Body of the Paper

- The purpose and study questions of the evaluation. Include brief description of the supply chain practices in Vietnam.
- Methodology
- Evidence, findings and analysis of the study questions.
- Conclusions drawn from the analysis of findings stated succinctly.
- Recommendations

Appendices shall include:

- Evaluation scope of work
- List of documents consulted
- List of individuals and agencies contacted
- Technical topics including study methodology if necessary
- Schedule of activities in an Excel format.

All reports are to be submitted in English in both electronic and hard copies. The Team will provide 5 printed copies of the Draft and Final Evaluation Reports and 5 printed copies of the PowerPoint presentation.

The Final Evaluation Report should not exceed 30 pages in length in its body, not including title page; Table of Contents; List of Acronyms; usage of space for tables, graphs, charts, or pictures; and/ or any material deemed important and included as Annexes. The executive summary with brief evaluation findings, conclusions and recommendations will be included in the final report.

The Final Evaluation Report and PowerPoint addressing the USAID's comments should be submitted in both Word and PDF formats. Once the PDF format has been approved by USAID, the Team will submit the Final Evaluation Report to the Development Experience Clearinghouse (DEC) for archiving- www.dec.usaid.gov

ANNEX B: INDIVIDUALS AND AGENCIES VISITED

ID	Name	Position	Agency
1	Dr. Nguyen Hoang Long	Director	Vietnam's Administration for HIV/AIDS Control (VAAC)
2	Dr. Pham Duc Manh	Vice Director/Harm Reduction and MMT	
3	Dr. Do Thi Nhan	Head/Care and Treatment ARV	
4	Dr. Le Anh Tuan	Head/General Planning Department	
5	Pharm. Pham Lan Huong	Officer – ARV Quantification Management (ARV)	
6	Dr. Bui Duc Duong	Vice Director/ Care and Treatment ARV of VAAC	Central Project Management Unit/ The Global Fund
7	Dr. Vu Chi Lung	Vice Head/General Planning Department of VAAC	
8	Phar. Ngo Thi Nam Phuong	Officer – ARV Quantification	
9	Phar. Nguyen Thi Thuy Nguyen	Officer – ARV Quantification	
10	Phar. Tran Thi Lan Huong	Officer - Procurement & Logistics	
11	Ms. Pham Thi Thu Huong	Officer - Procurement & Logistics	
12	Ms. Ha Thuy Huong	Director	Supply Chain Management System (SCMS)
13	Phar. Doan Thi Nga	Quantification Manager	
14	Ms. Phung Thi Ngoc Thuy	Procurement & Logistics Manager	
15	Mr. Ngo Dang	Country Director	Clinton Health Access Initiative (CHAI)
16	Phar. Luu Ho Thanh Tuan	Program Manager	
17	Dr. Nguyen Binh Hoa	Secretary of NTP Coordinator GF TB project	National TB Control Program (NTP)
18	Dr. Le Hong Hinh	Officer	
19	Dr. Nguyen Thi Mai Phuong	Officer	
20	Phar. Nguyen Tat Dat	Vice Director	Drug Administration of Vietnam/Ministry of Health
21	Phar. Phan Cong Chien	Head/Business Administration Dept.	
22	Dr. Nguyen Quang An	Vice Director	Department of Planning and Finance/Ministry of Health
23	Dr. Le Van Kham	Vice Director	Department of Health Insurance/Ministry of Health
24	Dr. Duong Tuan Duc	Vice Director/Implementation Health Insurance Dept	Vietnam Social Security (VSS)

ID	Name	Position	Agency
25	Dr. Nguyen Thi Hong Van	Vice Head of Medicine and Medical equipment	
26	Dr. Nguyen Van Kinh	Director	National Hospital for Tropical Diseases (NHTD)
27	Mr Truong,		Budget Department of Ministry of Finance
28	Ms Ha,		Administration of Ministry of Finance
29	Ms Ngo Chi Linh Ms Phan Thi Quynh Van	Experts	Ministry of Planning and Investment (Bidding Management Department)
30	Dr. Nguyen Huu Hung	Vice Director	HCMC Health Department
31	Dr. Thinh	Vice Director	HCMC PAC
32	Phar. Dang Thi Ngoc Diep	Office - Pharmaceutical Management	HCMC PAC
33	Pharm. Huynh Van Son	Expert	Pham Ngoc Thach Hospital
34	Mr. Dao Huong Sang	Officer in charge of supply and logistics	
35	Ms. Quynh Anh	Health of Pharmaceutical Department	
36	Dr. Pham Thu Xanh	Vice Director	Hai Phong Health Services
37	Dr. Pham Minh Thu	Director	Hai Phong PAC
38	Dr. Pham Hung Cuong	Officer	Hai Phong Lung Hospital
39	Dr. Socorro Escalante	Technical Officer - Pharmaceuticals	WHO Vietnam
40	Dr. Gary West	Country Director	FHI 360
41	Dr. Kristan Schoultz	Country Coordinator	UNAIDS Vietnam
42	Ms. Nguyen Thi Bich Hue	Communication Officer	
43	Kari Hurt	Health Program Cluster Leader	WB Vietnam

ANNEX C: ANALYSIS OF LEGAL FRAMEWORK

Foundational Analysis of Legal Framework Related to Procurement and Distribution of Antiretroviral (ARV), Methadone, and Anti-Tuberculosis Drugs in Vietnam

I) ROLES OF KEY ACTORS		
ACTORS	KEY FINDINGS	GOVERNING DOCUMENTS
MOH (Ministry of Health)	<ul style="list-style-type: none"> Take lead in implementing new mechanisms for drug procurement under the Bidding Law (Article 77 Decree 63) Take lead in State management on drug price (Article 5 Pharmaceutical Law) Approve drug bidding schedule and contractor selection plan for State owned medical facilities under MOH's management (Article 76 Decree 63; Article 4 Joint Circular No. 01) Take the main responsibility in determine quantity, price and appoint companies and agencies to manufacture and import ARV drugs for emergency cases (Decision No 173/2008/QD-TTg) Approve assistance plan in respect of PEPFAR projects (Clause II, Joint Circular No. 12/2007/TTLT-BYT-BTC) 	<ul style="list-style-type: none"> Law on State's budget and its guiding documents; Law on Medicines and its guiding documents; Law on Bidding and its guiding documents; Law on HIV/AIDS prevention and control; Joint Circular No.01/2012/TTLT-BYT-BTC drug procurement in hospital (as emended and supplemented by Joint Circular No. 36/2013/TTLT – BYT-BTC); Decree No. 108/2007/ND-CP guiding and detailing several provisions of Law on HIV/AIDS prevention and control (as partially amended and supplemented by Decree No.96/2012/ND-CP). Decree No. 63/2012/ND-CP providing functions, duties, authorities and organization of Ministry of Health. Decision No. 173/2008/QD-TTg providing the implementation of necessary steps taken to meet demand of anti- HIV drugs in case of emergency,
Ministry of Finance (MOF)	<ul style="list-style-type: none"> Coordinate with Ministry of Health to determine prices of anti-HIV drugs manufactured and/or imported as well as the total budget to satisfy the demand of anti-HIV drugs in case of emergency to submit to the Prime Minister for approval. (Article 8 Decision No. 173/2008/QD-TTg) 	<ul style="list-style-type: none"> Decision No. 173/2008/QD-TTg providing the implementation of necessary steps taken to meet the demand of anti- HIV drugs in case of emergency, -
People's	<ul style="list-style-type: none"> Approve bidding schedule [Article 4 TTLT 01] 	<ul style="list-style-type: none"> Joint Circular No.01/2012/TTLT-BYT-BTC drug procurement in

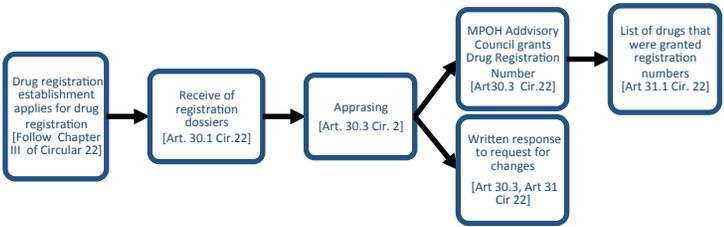
Committees at provincial levels (Health Departments)	<ul style="list-style-type: none"> • Approve estimated drug demand for addictive drugs [Chapter V Article 16.2 of Circular 19] 	<p>hospital;</p> <ul style="list-style-type: none"> - Circular 19/2014/TT-BYT provides regulations on management of addictive drugs, psychotropic and pro-drug.
Vietnam Administration of HIV/AIDS control (VAAC)	<ul style="list-style-type: none"> • Ministry of Health assign the authority of state administration, law implementation and enforcement, guiding, managing, examining, supervising over the anti-HIV/AIDS operations throughout the country for VAAC. (Art 1.1 Decision No. 288/2013/QĐ-BYT); • Organize bidding in drug procurement under the management of MOH (Art 26.2 Circular No. 01). 	<ul style="list-style-type: none"> - Decision No. 288/2013/QĐ-BYT governing functions, missions, authorities and organization of VAAC. - Joint Circular No.01/2012/TTLT-BYT-BTC drug procurement in hospital;
Provincial center for HIV/AIDS prevention and control	<ul style="list-style-type: none"> • Negotiate and conclude contracts on supplying drugs with winning tenderers (in accordance with the bidding results from provincial Department of Health [Art. 26.3.a Circular No. 01]) 	<ul style="list-style-type: none"> - Decision No.25/2005/QĐ-BYT governing functions, duties, authorities and organizations of provincial centers of HIV/AIDS prevention and control. - Joint Circular No.01/2012/TTLT-BYT-BTC drug procurement in hospital; - Decree No. 108/2007/NĐ-CP detailing and guiding some provisions of Law on HIV/AIDS prevention and control.
National Hospital for Tropical Diseases	<ul style="list-style-type: none"> • Import medicines in case of emergency under the direction of MOH [Art.11 Decision No. 173] 	<ul style="list-style-type: none"> - Decision No. 173/2008/QĐ-TTg providing the implementation of necessary steps taken to meet demand of anti- HIV drugs in case of emergency.
Central Pharmaceutical Company No.1	<ul style="list-style-type: none"> • State owned one member limited liability company since 2010. This is one of only five companies in Vietnam are specifically authorized to import addictive drugs. 	<ul style="list-style-type: none"> - Decision No. 45/QĐ-TCTD dated 20 June 2010 - Circular 19/2014/TT-BYT provides regulations on management of addictive drugs, psychotropic and pro-drug.
PEPFAR and Global Fund	<ul style="list-style-type: none"> • Co-ordinate with Vietnamese competent agencies to compile schedules as well as to import and distribute anti-HIV drugs annually. (Art 1,2 Circular No. 12) • Note: Joint Circular No. 12/2007/TTLT-BYT-BTC provides that medicines and medical tools donated by PEPFAR program are incomes of State budget on central level, hence, it must be administered properly in accordance with provisions of Law on State Budget as well as commitments in Bilateral Trade 	<ul style="list-style-type: none"> - Decree No. 93/2009/ND-CP promulgating the regulation on management and use of foreign non-governmental aids. - Framework agreement signed on 22 June 2005 between the government of the Socialist Republic of Vietnam and the Government of the United States of America; - Joint Circular No. 12/2007/TTLT-BYT-BTC guiding on financial management mechanism for medicines and medical equipment provided under the U.S. President's Emergency Plan for AIDS Relief

	Agreement between Vietnam and The United States.	(PEPFAR)
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2) PROCUREMENT ACTIVITIES

ISSUES	KEY FINDINGS	GOVERNING DOCUMENTS
<p>Domestic purchase</p>	<ul style="list-style-type: none"> • The Bidding Law requires all procurement using the State Budget will have to be conducted through bidding process as provided for by the Law. Drug procurement has to follow also specific regulations in other regulations of which the most important one is Joint Circular No.01/2012/TTLT-BYT-BTC drug procurement in hospital. • The laws provide in details on: <ul style="list-style-type: none"> - Compiling of bidding plans; - Developing of bidding invitation dossier; - Specific steps to conduct bidding; - Approving procedure and coming up with bidding results. • The Pharmaceutical Law is amended to include other forms of order based on plans. This forms of goods supplying comply with Decree 130/2013/ND-CP on priority ranking for goods supplying for the public which is (1) Bidding; (2) Order; and (3) Assigned plans. 	<ul style="list-style-type: none"> - <i>Law on State Budget and its guiding documents</i> - <i>Law on Bidding 2013 and Decree 63/2014</i> - <i>Joint Circular No.01/2012/TTLT-BYT-BTC drug procurement in hospital</i> - <i>Decree 130/2013/ND-CP dated 16 October 2013 on produce and supply goods and services for the public</i>
<p>International Bidding/Importation of drugs</p>	<p>International Bidding</p> <ul style="list-style-type: none"> • Drug purchase from foreign sources using the State Budget can be done through international biddings under specific conditions as provided in Article 15 of the Bidding Law. <ul style="list-style-type: none"> - The donor of the bidding package requests for holding international bidding; - Tender packages for procurement of goods where the goods are not yet able to be manufactured domestically or able to be manufactured but fail to meet technical, quality or price requirements. <p>Drug Importation</p>	<ul style="list-style-type: none"> - <i>Bidding Law</i> - <i>Law on import, export</i> - <i>Decree 58/2013/ND-CP dated 29 May 2003 on management of addictive drugs</i> - <i>Decision 151/QD-TTg dated 12 September 2007 on importation of drugs without registration numbers (and its amendments in Decision 42/QD-TTg dated 15 July 2013)</i> - <i>Circular 47/2010/TT-BYT dated 29 December 2010 guiding the importation of drugs and packages in direct contact with drugs (and its amendments in Circular 38/2013/TT-BYT dated 15 November 2013)</i> - <i>Circular 19/2014/TT-BYT dated 2 June 2014 on management of addictive drugs</i>

	<ul style="list-style-type: none"> Depending on types of drugs (e.g. normal drugs vs addictive drugs), usage purposes (drugs import for NTP) and the status of registration numbers (i.e. drugs valid registration numbers vs drugs have not yet had registration numbers), drugs will be imported into Vietnam in accordance with particular regulation. Many of specific regulations on these related documents are overlapped. In principle, addictive drugs are required importation license from MOH. Drugs with no registration numbers imported under NTP can only be granted 1 year importation license by MOH. Drugs with valid registration numbers required no import license from MOH and can be imported using direct procedure through customs [Circular 06 on drug and cosmetics importation]. Drugs imported through National Targeted Program must be imported by enterprises that have the function to directly import drugs [Article 4.29 (c) of Circular 06 on drug and cosmetic importation]. Addictive drugs can only be imported by one of the 5 assigned companies as required by Circular 19 /2014 of MOH. 	
Drug registration	<ul style="list-style-type: none"> In general drugs being produced or imported into Vietnam are required to have registration numbers before can be distributed in Vietnam [Circular 22/2009/TT-BYT. HIV drugs are specifically required to have registration numbers by Decree 108/2007/ND-CP [Article 12.1]. In some cases, including drug importation for NTP, drugs without registration numbers can be imported into Vietnam under MOH's importation license which has the maximum validity date of 1 year from the issuing date (Decision 151/2007/QD-TTg). Registration procedures are as follows: 	<ul style="list-style-type: none"> - <i>Pharmaceutical Law and Decree 79</i> - <i>Circular 22/2009/TT-BYT on drug registration</i> - <i>Decree 108/2007/ND-CP guiding the Law on HIV/AIDS</i>

	 <ul style="list-style-type: none"> On average it takes 6 months for the first time registration and re-registration. Changes registration only takes 2 months. [Article 32 Circular 22] 	
<p>Drug quality</p>	<ul style="list-style-type: none"> Drug quality is governed at the same time by the Pharmaceutical Law and other laws relating to good qualities including Law on Standards and Technical Quality and Law on Goods Quality. The National Standards for drugs are specified in the Pharmacopoeia of Vietnam which is prepared by the Vietnam Board of Pharmacopoeia and issued by MOH. National Drug Standards are collection of drug standards issued by the Ministry of Science and Technology (MOST) and Pharmacopoeia is prepared and issued by MOH based on MOST's National Drug Standards. 	<ul style="list-style-type: none"> - <i>Pharmaceutical Law</i> - <i>Law on Standards and Technical Quality</i> - <i>Law on Goods Quality</i> - <i>Circular 09/2010/TT-BYT dated 28 April 2010 on drug quality management</i> - <i>Joint Circular 11/2008/TTLT/BYT-BKHCHN dated 29 December 2008 guiding on development, appraisal and make public the National Drug Standards</i>

3) DISTRIBUTION

ISSUES	KEY FINDINGS	GOVERNING DOCUMENTS
<p>General distribution procedure</p>	<ul style="list-style-type: none"> General distribution procedure below [Art 13.3 Decree No. 108]: <div data-bbox="457 435 1129 613" style="text-align: center;"> <pre> graph LR A[Suppliers] --> B[Enterprises in charge of stocking and distributing as assigned by MOH] B --> C[HIV treatment facilities] </pre> </div> <ul style="list-style-type: none"> Foreign invested enterprises are not allowed to directly import and distribute drugs in Vietnam. These enterprises can only import and distribute drugs through Vietnamese enterprises approved to import and export drugs by competent authorities (Part I Article 3.2b Circular 06 and Circular 34). Drugs imported through National Targeted Program must be imported by enterprises that have the function to directly import drugs [Article 4.29 (c) of Circular 06 on drug and cosmetic importation). Addictive drugs can only be imported by one of the 5 assigned companies as required by Circular 19/2014. 	<ul style="list-style-type: none"> <i>Law on HIV/AIDS prevention and control.</i> <i>Decree No. 108/2007/NĐ-CP detailing the implementation of Law on HIV/AIDS prevention and control.</i> <i>Circular 34/2013/TT-BCT dated 24 December 2013 publicizing the roadmaps of the exercises for goods trading and directly related activities to goods trading of FIEs in Vietnam.</i> <i>Circular 19/2014/TT-BYT dated June 2, 2014 on management of addictive drugs.</i>
<p>Roles of Key Actors in Distribution</p>	<ul style="list-style-type: none"> VAAC <ul style="list-style-type: none"> Function as the focal point for mobilization, management the use of resources serving the HIV/AIDS prevention and control activities Administer, direct the operation of HIV/AIDS prevention and control activities throughout the country; to function as focal point to manage and direct the projection activities on the field conducted by different State agencies. Collect and synthesize statistics related to HIV/AIDS prevention and control activities all across the country. Such statistics will act as a basis for the compilation of 	<ul style="list-style-type: none"> <i>Decision No. 288/2013/QĐ-BYT regulation functions, duties, authority and organization of VAAC</i> <i>Decision No. 28/2008/QĐ-BYT about reporting mechanism and reporting forms for HIV/AIDS prevention and control activities.</i> <i>Decision No. 2051/QĐ – BYT about procedure on treatment of HIV/AIDS by ARV drugs.</i> <i>Circular No. 09/2011/TT-BYT provides conditions and professional scope of treatment for medical facilities using ARV drugs on their treatment.</i> <i>Circular No. 125/2007/TT-BTC guiding the management and use the budget for administer, caring, consulting, and medical treatment</i>

	<p>distributing medicines. [Art. 6 Decision No. 28/2008/QĐ-BYT]</p> <ul style="list-style-type: none"> • Labs/ PMTCT/ OPCs/MMTs/VCTs <ul style="list-style-type: none"> ○ To ensure professional conditions for recipients of supplied medicines. • Re-education establishments, medical establishments, social charity establishments, prisons and remand houses <ul style="list-style-type: none"> ○ Provide care, consultation and treatment for HIV-infected patients 	<p>for HIV-infected patients in re-education establishments, medical establishments, social charity establishments, prisons and remand houses</p>
Stock and reserve medicines	<p>Reserve medicine</p> <ul style="list-style-type: none"> • MOH assign the task of reserving medicines for the three following enterprises: <ul style="list-style-type: none"> ○ Central Pharmaceutical Company No. I ○ Central Pharmaceutical Company No. II ○ Central Pharmaceutical Company No. III • Imported enterprises for addictive drugs are required to have storages that meet GSP and have sufficient methods to secure imported drugs (Article 14.4 Circular 19/2014). • The laws require sufficient reserves of drugs for treatment of HIV-exposed patients due to occupational risks or accidents in provincial HIV/AIDS treatment facilities. <p><i>Currently, there is a list of reserve medicines promulgated by MOH, however, it is still unclear whether ARV drugs are among those medicines or not.</i></p> <ul style="list-style-type: none"> • PEPFAR <ul style="list-style-type: none"> ○ Safety reserve equivalent to 8 months use of medicines ○ Desired reserve equivalent to 11 months use of medicines • Global Fund <ul style="list-style-type: none"> ○ Safety reserve equivalent to 10 months use of medicines ○ Desired reserve: equivalent to 16 months use of medicines. 	<ul style="list-style-type: none"> - Law on Pharmacy and its guiding documents; - Decision No. 110/2005/QĐ-TTg on the plan of “national reserve of medicines serving the disease treatment and prevention for the people “ - Circular No. 48/2011/TT-BYT on Good Distribution Practice (GDP). - Circular 19/2014/TT-BYT dated 2 June 2014 on management of addictive drugs - Decree No. 108/2007/NĐ-CP detailing the implementation of some provisions of Law on HIV/AIDS prevention and control.
Withdrawal of Drugs	<ul style="list-style-type: none"> • Legal basis for withdrawing drugs in general is notices issued by administrating and consolidating State agencies in charge of 	<ul style="list-style-type: none"> - Law on Pharmacy and its guiding documents; - Law on Standards and Technical Regulations and its guiding

	<p>pharmacy on returning medicines (Drug Administration of Vietnam or Provincial Departments of Health). Manufacturers, importers or entrusted importers can also withdraw drugs on voluntary basis [Art. 13.5, 13.6.b Circular No. 09].</p> <ul style="list-style-type: none"> • Aside from sub-standard drugs or counterfeit drugs...the laws also require drugs that have no registration numbers and drugs that do not meet labeling requirements to be withdrawn [Circular 09]. 	<p>documents,</p> <ul style="list-style-type: none"> - <i>Law on Products and Goods Quality and its guiding documents;</i> - <i>Circular No. 09/2010/TT-BTC on management of quality control,</i>
Accounting	<ul style="list-style-type: none"> • Accounting requirements for medicine establishment follows general requirements as provided for by the Law on State Budget with some distinctions between different investment sources and agencies using the budget: <ul style="list-style-type: none"> ○ Each NTP has PM's Decision approving that specific NTP which provide the exact budget for the NTP. Accounting management of NTPs follow the State Budget's Law and Regulations on management of NTPs issued by Decision 135/2009/QĐ-TTg dated November 11, 2009. ○ Other medical establishments including hospitals follow self-financial management provided for in various regulations. ○ Organizations used donor's sponsors funding follow MOH's guiding for these types of financial sources (such as Circular 291/2009/TT-BTC dated 19 November 2009 on expenditures of ODA projects) 	<ul style="list-style-type: none"> - <i>Law on State Budget</i> - <i>Decision 135/2009/QĐ-TTg dated November 11, 2009 issuing regulations on management of NTPs</i>
Report and disclosure of information	<ul style="list-style-type: none"> • Periodic reports required from health facilities (every quarter or every year) or report on unexpected circumstances [Art. 4 Decision No. 28] • The procedure below [Art. 6 Decision No. 28] 	<ul style="list-style-type: none"> - <i>Law on Pharmacy and its guiding documents;</i> - <i>Decision No. 28/2008/QĐ-BYT on Reporting procedures and reporting forms on HIV/AIDS prevention and control activities.</i> - <i>Decree No. 108/2007/NĐ-CP detailing the implementation of some provisions of Law on HIV/AIDS prevention and control.</i>

	<ul style="list-style-type: none"> On a monthly basis, HIV treatment facilities bear the responsibility to report on the quantity of ARV drugs used as well as the quantity of ARV drugs in-stock, treatment method, treated methods to the provincial Department of Health, and other focal units on HIV/AIDS prevention and treatment at provincial level. Such agencies, in turn, will report to MOH for synthesizing statistics and proposing proper reaction. 	
<p>PEPFAR</p>	<ul style="list-style-type: none"> HIV treatment facilities (on quarterly and yearly basis) conduct the finalization of medicines and medical tools and report to MOH (for facilities directly sub-ordinated to MOH) or provincial Department of Health (for facilities directly sub-ordinated to DOH) in accordance with current accounting regime. 	<p>- Charter III Joint Circular No.12/2007/TTLT-BYT-BTC</p>

4) FINANCING

ISSUES	KEY FINDINGS	GOVERNING DOCUMENTS
Financial resources from the State budget	<ul style="list-style-type: none"> • Funding included for National Target Programs for different periods (currently the period of 2012-2015). Funding sources for the NTPs are determined as “Regular Spending by State budget” which is given more priority than other non-regular spending missions of the State. • Annually, before each fiscal year, based on demand and missions of economic-social development, the Government will direct the compilation of schedule and budget estimate of the following year. The schedule and estimation will then be discussed and approved at the second National Assembly session of each year. 	<ul style="list-style-type: none"> - <i>Joint Circular No. 113/2013/TTLT-BTC-BYT governing the management and use of funding serving national target programs on healthcare during the period of 2012-2015.</i>
Funds supporting HIV-infected people (in both local and central levels)	<ul style="list-style-type: none"> • Central funding supporting HIV-infected people set by the Minister of Health. • Local funding supporting HIV-infected people set by Chairmen of the provincial People’s Committee • Operating funding: <ul style="list-style-type: none"> ○ Contribution, donation through fundraising department ○ Financial support from the State budget at the time of establishment ○ Support from the HIV/AIDS prevention and control project of the NTP 	<ul style="list-style-type: none"> - <i>Law on State Budget</i> - <i>Law on HIV/AIDS</i>
Social Health Insurance	<ul style="list-style-type: none"> • Social Insurance Agency & Healthcare facilities <ul style="list-style-type: none"> ○ Healthcare facilities sign contracts on treatment using insurance funding with Social Insurance Agency. [Art. 24, 25 Law on Health Insurance ; Art 11, 12 Joint Circular No. 09]] ○ Private-owned healthcare facilities participating in treatment using health insurance fund must comply with certain conditions provided for in Art 11.2 Joint Circular No. 09 	<ul style="list-style-type: none"> - <i>Law on Health Insurance dated 13 June 2014;</i> - <i>Decree No. 62/2009/ND-CP guiding implementation of Law on Health Insurance;</i> - <i>Joint Circular No. 09/2009/TTLT-BYT guiding the implementation health insurance (as amended by Circular No. 39/2011/TTLT- BYT- BTC).</i>

	<ul style="list-style-type: none"> ○ Payment of treatment cost between Insurance Agency and healthcare facilities based on signed contracts. (Art. 31.1 Law on Health Insurance, Chapter V Joint Circular No. 09). ○ Payment and finalization between insurance agency and healthcare facilities is conducted quarterly. (Art. 32 Law on Health Insurance, Art. 18 Joint Circular No.09). • Social Insurance Agency & Health Insurance Policy Holders <ul style="list-style-type: none"> ○ In most cases, treatment costs are paid by insurance agency directly to the healthcare facilities. However, in some particular situations, patients shall pay the treatment costs to the healthcare facilities and they will be reimbursed partly or wholly by the insurance agency. ○ Such special situations included: Patients receive treatment from facilities which have not sign contract with insurance agency, patients receive treatment overseas, patients receive treatments from facilities different from those assigned to them. [Art 31.2 Law on Health Insurance] ○ Payment period: within 40 – 60 days from the date of receipt of required dossiers [Art. 19.2 Joint Circular No. 09] 	
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ANNEX D: SUMMARY OF RECOMMENDED ACTIVITIES FOR DEVELOPMENT PARTNERS

Immediate term

- Organize a meeting to present findings of current study and kick off strategic working group;
- Provide administrative and logistical support to VAAC and other relevant MoH department with quarterly strategic working group meeting, and help shape the terms of reference and agenda;
- Work with SCMS to link MoH with PFSCM to facilitate direct procurement of ARVs with domestic resources (VND 18 million in 2014);
- Encourage SCMS to transfer its operational unit to VAAC to facilitate capacity transfer in ARV procurement and planning of orders procured through PFSCM;
- Support development of the basic benefits package.

Short to medium-term

- Continue providing administrative and logistical support to VAAC and relevant MoH department with quarterly strategic working group. Issues for discussion/agreement amongst all members of the strategic working group include:
 - Exchange of comparative pricing information and best procurement practices,
 - Establishment of the CPU, location, and way forward,
 - Choice of uniform LMIS system and tools to be used;
- Arrange for short-term technical assistance to MoH and DAV to develop capacity to assess drug quality during the bidding evaluation process, as well as publication of local reference pricing;
- Fund a study on elucidating price structure of drugs locally available, and mark-ups at different levels throughout the supply chain;
- Continue and/or increase funding to the PQM/USP project to support local production of quality methadone and possibly ARVs in future (market survey, support in view of manufacturing site audit and follow up on audit recommendations);
- Proactively liaise with the National Advisory Committee on Drug Bidding and other agencies (i.e. WHO, WB) involved in setting up a CPU, and discuss way forward in strategic working group;
- For the establishment of the CPU, following a careful capacity gap analysis provide longer-term technical support focused on the development of procurement guidelines, procedures for concentrated procurement, framework contracts (if applicable), standard operating procedures, bidding documents, specifications etc. based on national guidelines and international best practice;
- Organize a study tour for GVN officials to a country in the region with a well-developed LMIS system to share best practices;
- Support the selection and development of the LMIS;
- Support the development of a Dashboard that would provide an overview of patient numbers and stock status at national and lower levels (with an alert system);
- Both communicate and demonstrate a decrease in funding, in order to spur government action;

- Provide assistance to quantify resource needs and justify investments;
- Conduct analysis of fiscal space at provincial level to determine ability to increase funding for HIV/AIDS;
- Provide recommendations to allow the flow of provincial funding for central level procurement through the use of framework contracts or other mechanisms;
- Support analysis to rationalize the use of resources to improve efficiency of current programs;
- Develop concrete recommendations for information sharing and coordination to ensure complementarity in budget planning;
- Improve the monitoring and evaluation systems under VSS to capture reliable utilization and cost data;
- Support the MOH to analyze options for policy changes to allow Social Health Insurance to reimburse OPCs.

Medium to long-term

- Provide long-term technical support and mentoring to CPU staff in management and in procurement supply management (including LMIS data analysis) to ensure that it has adequate resources to fulfill its role;
- Provide longer-term on-the-job mentoring of staff involved in quantification and data management at central level, and support the national quantification based on unified LMIS data;
- Assist the Department of Health Insurance (DHI) and VSS to implement compulsory enrollment under the amended Health Insurance Law.



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