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MARKET ANALYSIS AND RECOMMENDATIONS FOR HIV ANTIRETROVIRAL DRUG REGISTRATION AND PROCUREMENT IN VIETNAM

Local Health System Sustainability Project

Task Order 1, USAID Integrated Health Systems IDIQ

March 2022

This document was produced for review by the United States Agency for International Development. It was prepared by the Local Health System Sustainability Project under the USAID Integrated Health Systems IDIQ.

Local Health System Sustainability Project

The Local Health System Sustainability Project (LHSS) under the USAID Integrated Health Systems IDIQ helps low- and middle-income countries transition to sustainable, self-financed health systems as a means to support access to universal health care coverage. The project works with partner countries and local stakeholders to reduce financial barriers to care and treatment, ensure equitable access to essential health services for all people, and improve the quality of health services. Led by Abt Associates, the five-year project aims to strengthen the capacity of governments to sustain strong health system performance, supporting countries on their journey to self-reliance and prosperity.

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USAID Contract No: 7200AA18D00023 / 7200AA19F00014

Recommended Citation: Local Health System Sustainability Project (LHSS) under the USAID Integrated Health Systems IDIQ. March 2022. *Market Analysis and Recommendations for HIV Antiretroviral Drug Registration and Procurement in Vietnam.* Rockville, MD: Abt Associates.

This report was made possible by the support of the American people through the United States Agency for International Development (USAID). The contents are the sole responsibility of the authors and do not necessarily reflect the views of USAID or the United States Government.

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ACRONYMS

ART	Antiretroviral Therapy
ARV	Antiretroviral
CPP	Certificate of Pharmaceutical Products
DAV	Drug Administration of Vietnam
GMP	Good Manufacturing Practice
LHSS	Local Health System Sustainability Project
MA	Marketing Authorization
MOH	Ministry of Health
NCDPC	National Centralized Drug Procurement Center
PLHIV	People Living with HIV/AIDS
SHI	Social Health Insurance
TLD	Tenofovir/Lamivudine/Dolutegravir 300/300/50mg
TLE400	Tenofovir/Lamivudine/Efavirenz 300/300/400mg
TLE600	Tenofovir/Lamivudine/Efavirenz 300/300/600mg
VAAC	Vietnam Administration of HIV/AIDS Control
VSS	Vietnam Social Security
WHO	World Health Organization

EXECUTIVE SUMMARY

Donor funding for HIV has declined in Vietnam as the country transitions to sustainable financing and management of its HIV prevention and treatment response. To date, the Ministry of Health (MOH) has centrally procured antiretroviral (ARV) drugs using the Social Health Insurance (SHI) fund three times. Despite successfully transitioning ARVs into the SHI fund, the MOH has confronted several barriers in procuring and supplying SHI-covered ARVs, particularly those with few marketing authorizations (MAs). Some drugs with only one or two registration numbers must be procured through price negotiation, which is a lengthy and complex process, often resulting in supply chain delays.

To improve efficient ARV procurement and ensure a consistent supply of affordable ARV commodities, the Local Health System Sustainability Project (LHSS) Vietnam Activity conducted a market analysis that examines four factors affecting SHI-covered ARV procurement and supply in Vietnam:

- The availability of and process for ARV MAs
- ARV importing versus domestic production
- The ARV procurement bidding process
- Private sector participation

This report summarizes findings and proposed recommendations across each of these factors to improve drug availability and sustainability and the efficiency of the Vietnamese ARV market. Recommendations are segmented into those targeted toward MOH stakeholders and those targeted toward pharmaceutical companies.

FACTOR 1: MARKETING AUTHORIZATION

There are currently 274 MAs for 32 ARVs eligible for purchase through the national centralized-procurement process using the SHI fund.[1] Many ARVs have a limited number of MAs. While some rare and critically essential ARVs get registration priority and are entitled to a fast-track appraisal process, most require a complex and lengthy registration process. This is due to the MOH's strict requirements, poor-quality MA application dossiers including provision of inadequate supporting documents, and insufficient staff at the Drug Administration of Vietnam (DAV) to review and manage the process.

Recommendations for the MOH:

- Ensure DAV staff are sufficiently trained, including on topics such as clinical reporting and bioequivalence reporting of medicines.
- Increase number of staff available to review and appraise drug registration dossiers.
- Transition to an online registration and application process to preserve human resources, shorten the appraisal time, and improve the management of drug registration records.

Recommendations for pharmaceutical companies:

- Carefully prepare MA applications before submission, ensuring information in application dossiers is sufficient and consistent.
- Keep up to date with the Good Manufacturing Practice (GMP) validity of drug manufacturers for the

[1] Ministry of Health, 2020, Circular No. 15/2020/TT-BYT dated August 10, 2020, promulgating the list of drugs procured through bidding, the list of drugs subject to centralized procurement, and the list of drugs subject to price negotiation.

purpose of drug registration and bidding participation.

- Consult with the DAV to understand the regulations, such as those around the fast-track appraisal process and exemption of clinical trials, before applying for MA.

FACTOR 2: IMPORTATION AND DOMESTIC PRODUCTION OF ARVS

Many pharmaceutical companies import ARVs, as the process is fairly straightforward given that ARVs are not subject to special controls like narcotic drugs. Most domestic drug producers can produce ARVs in all dosage forms such as tablets, syrups, and oral suspension. However, local producers are at a disadvantage because of high production prices and limited availability of imported materials to manufacture ARVs. Even if regulatory constraints were removed, international manufacturers could continue to undercut local manufacturers.

Recommendations for the MOH:

- Collaborate with Minstry of Finance to develop policies that encourage domestic enterprises to produce ARVs with low demand. For example, the government could consider a favorable tax for importing foreign ingredients, preferential loans for production investment, and honoring community contributions to promote company image and reputation.
- Collaborate with the Ministry of Science and Technology to support local enterprises in accessing advanced technology and the worldwide production chain, to help produce high-quality and new drugs.

Recommendations for the Ministry of Science and Technology:

- Support local production through favorable policies, capital, and technology in research and development of pharmaceutical ingredients, avoiding dependency on imported ingredients.
- Fast-track appraisal process for technical dossiers and grant import license to import elements of the drug production chain.

FACTOR 3: ARV BIDDING AND PROCUREMENT

The MOH's centralized procurement of ARVs through competitive bidding has kept drug prices under control and ensured sufficient medicines for HIV patients with SHI cards. However, the bidding process experiences the following challenges:

- Under- and over-quantification of drug demand by health facilities
- Lengthy procurement process
- Planned prices that do not correspond with increases in related drug costs
- Difficulty managing contracts, drug reallocation, and payment for different procurement methods
- Low interest among drug suppliers due to complicated contracting procedures and unattractive payment terms

Recommendations for the MOH:

- Regularly share information on estimated ARV drug demand with ARV suppliers and manufacturers to help forecast demand and develop a business case for entrance into the ARV market.
- Apply online tools to manage ARV bidding, procurement, contracting, supply, and reallocation.

- For ARVs procured by price negotiation, amend contract signing and payment to be similar to those in public centralized open bidding.
- Update policies to explicitly outline the roles of key stakeholders in the procurement process. These include establishing clear pricing guidance; harmonizing regulations on contract management and payment types; and developing policies to support domestic drug producers.

Procurement options:

- Continue national centralized procurement using either open bidding or price-negotiation method.
- For drugs with few or no registration numbers, low utility, or small value as well as those not locally produced or distributed (e.g., pediatric ARVs), the MOH should allow use of a mechanism similar to that for rare drugs or procurement through an international organization.

Recommendations for the pharmaceutical companies:

- Proactively look for domestic sources of ingredients for local production of ARVs in order to shorten production time.
- Ensure compliance with the bidding requirements, such as GMP, MA validity, and proof of stock.
- Ensure that production and supply plan comply with the framework agreement.[2]

FACTOR 4: PRIVATE SECTOR PARTICIPATION IN THE ARV MARKET

Current regulations support private sector participation in ARV supply. Currently, drug distribution in Vietnam is carried out exclusively by private local enterprises. Further, all awarded suppliers are either private companies or state-owned joint-stock companies with private capital contributions. However, private local manufacturers are unlikely to win bids because it is difficult for them to compete on price and supply capacity, particularly with manufacturers in India. The recommendations below aim to enhance local production capacity and competitiveness with foreign enterprises.

Recommendations for the MOH:

- Support the local manufacturers through favorable policies on local drug consumption in the market—for example, regulation on minimum consumption of local drugs at health facilities.
- Award higher score of the bidding evaluation for local manufacturers including private and joint-stock ones.
- Collaborate with Vietnam Trade Promotion Agency to find collaboration opportunities among local and international manufacturers through joint ventures to advance technology and production chain.

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[2] A framework agreement for ARV procurement is the agreement between the NCDPC and ARV drug suppliers that sets out the terms and conditions under which ARV drugs can be purchased throughout the period of the agreement.

1. INTRODUCTION

As of March 31, 2021, there were 155,654 patients on ART in Vietnam.[3] Funding from international donors, including the U.S. President's Emergency Plan for AIDS Relief and the Global Fund, to procure ARV drugs has been on the decline since 2015. In response, the Government of Vietnam has transitioned from donor funded ARVs to procurement using the SHI fund and government budget to ensure sufficient supplies for HIV/AIDS prevention and treatment. Between 2018 and 2020, national centralized procurement of ARVs using the SHI fund was conducted three times and served 63 percent of all patients.[4]

The Government of Vietnam is facing challenges with procuring and supplying SHI-covered ARVs, especially those with limited MA. Brand-name and some generic drugs with only one or two registration numbers must be procured through the price negotiation method. This approach is lengthy and complex and can delay the drug supply. Further, the guidance and policies promoting engagement of pharmaceutical companies in the bidding and supply of such drugs are insufficient.

To improve efficient ARV procurement and ensure a consistent supply of affordable ARV commodities, LHSS collaborated with the MOH/Vietnam Administration of HIV/AIDS Control (VAAC) to conduct a market analysis. The analysis identified factors that facilitate and impede efficient ARV procurement and continuous supply, including:

1. The current availability of and process for obtaining ARV MA
2. ARV importation versus domestic production, including rules and regulations affecting this
3. The ARV procurement bidding process
4. Private sector participation in the ARV market

Based on the analysis of these four factors, the report includes policy and implementation recommendations to relevant Government of Vietnam agencies including the DAV, MOH, Ministry of Finance, and Ministry of Science and Technology to strengthen efficient and sustainable ARV procurement processes under the SHI fund.

2. METHODS

LHSS Vietnam reviewed government regulations on and implementation of ARV registration, imports, procurement, public bidding processes, and price negotiation from 2018 (when ARVs were first centrally procured using the SHI fund) to 2021.

The project also conducted an ARV market availability context analysis, which included both the advantages and challenges of domestically produced ARVs, in order to make recommendations on improving ARV procurement and supply in Vietnam. That analysis was based on secondary data collected from the VAAC, the DAV, and the National Centralized Drug Procurement Center (NCDPC).

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[3] **Source: VAAC.**

[4] **Ministry of Health. 2021. Decision No. 1903/QD-BYT dated 19 April 2021, promulgating the "Plan for ARV drugs in the HIV/AIDS treatment program 2021."**

3. CONTEXT

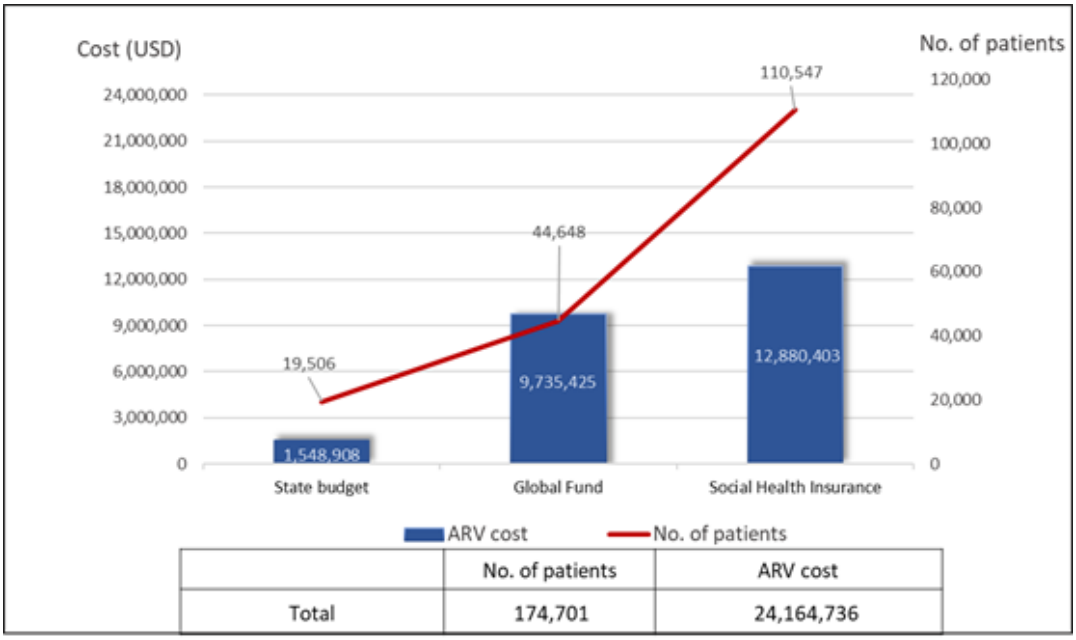
The MOH has segmented HIV funding streams based on differing ARV regimens and eligibility criteria.[5] The funding sources and their eligibility criteria have implications for which suppliers can enter the ARV market and in what capacity. The country's three funding sources are the SHI fund, the Global Fund, and the Government Budget. As specified in the MOH's "Plan for ARV drugs in the HIV/AIDS treatment program 2021":

- The SHI fund covers ARV drugs for children from age 10 with a valid SHI card and for patients who receive medical examinations and treatment at health facilities eligible for SHI reimbursement.
- The Global Fund covers pediatric ARVs, people living with HIV (PLHIV) on ART being treated at Global Fund-funded health facilities in 32 provinces/cities, and adults on ART regimens that are not covered by SHI or the government budget.
- The government budget covers special cases of PLHIV on ART. Examples include people exposed to or infected with HIV due to occupational accidents, children under age six infected with HIV, and PLHIV in compulsory education institutions, rehabilitation facilities, social protection facilities, or prisons.

Local manufacturers and suppliers can bid on ARVs covered under the SHI fund and government budget. However, ARVs procured using the Global Fund are restricted to bids from international manufacturers.

In 2021, the total market for ARVs in Vietnam was approximately $24.1 million. The SHI Fund covered 53.3 percent of the total value ($12.9 million), which includes seven ARV drugs to treat 110,547 patients. The Global Fund provided 19 types of ARVs, accounting for 40.3 percent of the market ($9.7 million) and treating 44,648 patients. The government budget covered the remaining $1.5 million to treat 19,506 patients. (See Figure 1.)

Figure 1: Expenditure of ARV drugs by funding source, 2021



	No. of patients	ARV cost
Total	174,701	24,164,736

[5] MOH Decision No. 1903/QD-BYT dated 19 April 2021, promulgating the "Plan for ARV drugs in the HIV/AIDS treatment program 2021."

The ARV market is small compared with that of other drug categories in Vietnam. For example, anti-parasites and antibiotic drug groups are valued at $406 million/year, and oncology and immunoregulation drugs were valued at $248 million/year.[6] Further, the top three ARV drugs—lopinavir/200/50mg, tenofovir/lamivudine/dolutegravir 300/300/50mg (TLD), and tenofovir/lamivudine/efavirenz 300/300/400mg (TLE400)—account for 82 percent of the ARV market. From January to December 2021, Acriptega (TLD) and Avonza (TLE400) accounted for 19 percent and 30 percent, respectively, of total ARV costs. Other drugs, such as zidovudine 10mg/ml, lamivudine-zidovudine 30/60mg, and nevirapine syrup, have much smaller demand (see Table 2), and are unlikely to attract suppliers and manufacturers to enter the Vietnamese market, as there is an insufficient business case. This provides a risk to sustainable and continuous procurement for the SHI fund, which will be responsible for procuring these drugs in the future as donor funding continues to decrease.

Table 1: Quantities and expenditure of ARV drugs in 2021

Market share (/ow)	Drug (active ingredient/s)	Concentration/ Strength	Dosage form	Quantity	Reference unit price (US$)	Total cost (US$)	Total cost (%)
High	Aluvia (lopinavir/ritonavir)	100mg/25mg	Tablet	13,945,848 tablets	7.82	7,846,662	32.5
	Avonza (tenofovir/lamivudine/efavirenz)	300mg/300mg/400mg	Tablet	32,254,579 tablets	0.23	7,281,121	30.1
	Acriptega (tenofovir/lamivudine/dolutegravir)	300mg/300mg/50mg	Tablet	20,433,805 tablets	0.23	4,701,552	19.5
Low	Nevirapine	10mg/ml	Syrup	3,735 bottles	2.43	9,061	0.04
	Lamivudine/zidovudine	30mg/60mg	Tablet	128,135 tablets	0.04	4,922	0.02
	Zidovudine	10mg/ml	Syrup	721 bottles	2.64	1,907	0.01

Further details are presented in *Annex 2: ARV drug quantities and cost by funding source in 2021*.

4. FINDINGS

4.1 FACTOR 1: MA OF ARVS IN VIETNAM

4.1.1 ARV MA POLICY FRAMEWORK AND REGISTRATION PROCESS

The "Law on Pharmacy"[7] is the primary legislation for pharmaceuticals in Vietnam. Subordinate legislation includes Decree 54, guiding the implementation of the Law on Pharmacy,[8] as amended by Decree 155.[9] These decrees focus on drug import/export, pharmaceutical business, pharmacy practice certificates, drug recalls, drug advertisement, and drug price management. The detailed regulation on the MA process is Circular 32, which guides the MA of drugs and medicinal ingredients.[10] The DAV, which is under the MOH, manages and coordinates the MA application process.

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6 Source: Social Health Insurance data.

7 National Assembly of the Socialist Republic of Vietnam. 2016. Law Ref 105/2016/QH13 dated 6 April 2016, effective 1 January 2017, stipulating the Law on Pharmacy.

8 Ministry of Health 2017. Decree No. 54/2017/ND-CP dated 8 May 2017, effective on 1 July 2017, guiding the implementation of the Law on Pharmacy.

9 Ministry of Health 2018. Decree 155/2018/ND-CP, dated 12 November 2018, amending Degree No. 54/2017/ND-CP.

10 Ministry of Health 2018. Circular 32/2018/TT-BYT dated 12 November 2018, on marketing authorization of drugs and medicinal ingredients.

Generic drug approval usually takes 14–22 months from the date of submitting the application dossier. By law, an extension to a current MA should be issued within three months of receipt of a complete application dossier.

An MA has a maximum term of five years. In certain cases, such as the first authorization for a new drug where the safety and effectiveness report of the drug is not available or is insufficient, the DAV will grant an MA with a three-year term. Mylan's MA for TLD is one such example. The MA holder must apply for an MA extension at least 12 months before the current MA expires.

4.1.2 ARV MA NUMBERS FOR LOCAL BIDDING AND PROCUREMENT

There are 274 MA registration numbers for 33 ARV medicines in Vietnam as recorded in the DAV system. However, only 140 ARV MA numbers are active, covering 29 ARV medicines. The remaining numbers are expired or are no longer valid in the Vietnam market. The drugs with the highest number of MAs include tenofovir 300mg (38), lamivudine 150mg (8), and lamivudine-zidovudine 150/300mg (6). The first two of these drugs have many MA numbers because they can be used for treating both HIV and hepatitis B. Conversely, there are five SHI-covered drugs with no MAs (Table 3). Therefore, these drugs are not eligible to be procured or imported in Vietnam. While the World Health Organization (WHO) guidance recommends dolutegravir 10mg and dolutegravir 50mg to treat HIV, and these two drugs are listed in the national HIV/AIDS treatment guideline, neither can be procured using the SHI fund because they do not have MAs in Vietnam and are not listed on the SHI-covered drug list.

Table 2: Number of ARV drugs and marketing authorization approved by MOH for procurement using SHI fund

Number of MAs	Number of drugs	Names of drugs
0	5 drugs	Abacavir 20mg/ml, atazanavir 100mg, atazanavir 300mg + ritonavir 100mg, zidovudine 10mg/ml, efavirenz 200mg
1	11 drugs	Lamivudine 10mg/ml, lamivudine/abacavir 30mg/60mg, lamivudine/nevirapine/zidovudine30mg/50mg/60mg, lopinavir/ritonavir (80mg/2mg)/ml, nevirapine 10mg/ml, ritonavir 100mg, lamivudine/tenofovir/efavirenz 300mg/300mg/400mg, tenofovir/lamivudine/dolutegravir 300mg/300mg/50mg, raltegravir 400mg, darunavir 300mg, darunavir 800mg
2	5 drugs	Atazanavir 150mg, atazanavir 300mg, efavirenz 50mg, lamivudine/abacavir 300mg/600mg, lamivudine/zidovudine30mg/60mg
3	1 drug	Lopinavir/ritonavir 100mg/25mg
≥ 4	10 drugs	Abacavir 300mg, efavirenz 600mg, lamivudine 150mg, lamivudine/nevirapine/zidovudine150mg/200mg/300mg, lamivudine/tenofovir/efavirenz 300mg/300mg/600mg, lamivudine/tenofovir 300mg/300mg, lamivudine/zidovudine150mg/300mg, lopinavir/ritonavir 200mg/50mg, nevirapine 200mg, tenofovir 300mg
Total	**32 drugs**	

There are 16 drugs with one or two MA numbers, meaning they can be procured through either centralized open procurement (public bidding) or price negotiation (see Box 1). According to Circular 15/2020, five[11] of these are on the list of drugs procured through price negotiation including TLE400

[11] Tenofovir/lamivudine/dolutegravir (300mg/300mg/50mg); tenofovir/lamivudine/efavirenz (300mg/300mg/400mg); raltegravir 300mg; darunavir 300mg, darunavir 800mg.

(Avonza) and TLD. These two drugs are currently used in HIV treatment as the preferred regimen for more than 80 percent of HIV patients in Vietnam. This poses a significant risk to sustainable HIV treatment due to the limited number of MAs and limited supplies sources.

For more detail, see *Annex 3. Detail on the number of MAs.*

Box 1: Centralized open procurement vs. price negotiations

Centralized Open Procurement (Public Bidding): This is the procurement method by which the NCDPC procures drugs through bidding without a limitation on the number of bidders. Bidder selection is based on the technical and financial criteria requirement in bidding dossiers. The successful bidder is the one who has the highest total score of technical and financial scores. Based on the bidder selection result approved by the NCDPC, Vietnam Social Security (VSS) signs a contract with the successful bidder for delivering drugs to the health facilities listed in the framework agreement and pays the bidder. Drugs procured by public bidding are listed in the Circular 15/2020.

Price Negotiation: This is the procurement method by which the price for the procured drug is negotiated directly between the Price Negotiation Committee and the supplier who is eligible under the requirements of the request for a technical proposal. This method is used for brand-name drugs, rare drugs, and drugs with one or two MA numbers. Based on the bidder selection result, which is approved by the MOH leader, the health facilities listed in the framework agreement sign a contract with and pay the awarded suppliers. Drugs procured by the price negotiation method are listed in Circular 15/2020/TT-BYT.

4.1.3 FACILITATORS AND BARRIERS TO GRANTING MA FOR ARVS

FACILITATORS

The MOH prioritizes ARV drugs for HIV/AIDS prevention and treatment, especially the registration process. Specifically:

- Nine ARV drugs are included in the list of rare drugs (Table 4) issued by the MOH.[12] They receive priority in the drug registration process and are considered for exemption or reduction of some parts of the application dossiers (exemption, reduction of clinical data, exemption of one or several phases of a clinical trial).[13] In addition, the drugs are prioritized by the MOH for import licensing.

Table 3: ARVs in the list of rare drugs

No.	Active ingredient(s)	Concentration/Strength
1	Lamivudine/abacavir	30mg/60mg
2	Efavirenz	50mg, 200mg, 600mg
3	Lamivudine/zidovudine	30mg/60mg
4	Lamivudine/nevirapine/zidovudine	30mg/50mg/60mg
5	Lopinavir/ritonavir syrup	80mg/20mg
6	Lopinavir/ritonavir	100mg/50mg
7	Nevirapine syrup	All strength
8	Raltegravir	All strength
9	Zidovudine	All strength

[12] Ministry of Health. 2019. Circular 26/2019/TT-BYT dated 30 August 2019, specifying the list of rare drugs.

[13] Point (b), Clause 2, Article 25 of Circular No. 32.: "Medicines for special treatment needs: available stability study data according to ASEAN or [International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use] guidelines decided by the Minister of Health with consultation of the Advisory Council for granting of marketing authorization of drugs and medicinal ingredients in case the registration establishment proves that the drugs cannot be stored in the climatic conditions of zone IVb according to the guidelines of ASEAN."

- The MOH fast-tracks applications for ARV drugs needed for treatment that have fewer than two MA numbers (meeting the provisions of Article 34 of Circular 32), to shorten the registration process and allow faster market entry. Companies can apply for fast-tracked MAs for these drugs if they attach a supporting letter from the VAAC in their application.

BARRIERS

There are numerous difficulties in preparing documents for ARV MA application dossiers, as outlined below.

Policy and regulatory:

- *Strict regulations on Certificate of Pharmaceutical Products (CPP):* The CPP is a document internationally recognized by national drug regulatory authorities for establishing the status of a pharmaceutical product under a national drug product licensing system. In Vietnam, the CPP of medicines must meet the requirements in Point (d), Clause 4, Article 23 of Circular 32. In applications produced by foreign manufacturers, pharmaceutical agencies often cannot get a CPP that meets requirements, given frequent missing information. For example, CPPs lack information on finished product standards, pharmaceutical substances, and ingredients and names and addresses of manufactures of pharmaceutical substances and ingredients.
- *The complicated, strict requirements and lengthy administration procedures for renewal or revision of unexpired MAs:* Clause 3, Article 40 of Circular 32 specifies complicated, strict requirements and lengthy administration procedures for renewal or revision of unexpired MAs, creating difficulties for both regulatory agencies and manufacturers. Any updates related to the drug after obtaining the MA, such as changes in product label or shelf life, require the manufacturer to submit additional documents to the DAV to revise or renew the MA. This process normally takes at least 6 to 12 months, which delays the marketing of the drug.

Quality of MA dossier application: Applications submitted by enterprises and companies often are of poor quality and do not meet the country's strict dossier requirements. Such problems include documents that needed to be legalized by the Vietnamese Embassy but were not; and issues with authentication of signatures or with information provided to be compliant with the Association of Southeast Asian Nations Common Technical Dossier and other of Vietnam's regulations. Further, applications often require amendment after being reviewed by the DAV, experts, and the MA Granting Advisory Council. The DAV provides requirements on generic drug registration dossiers, but there is not a standard set of dossiers. The technical documents and requirements vary, even for drugs with the same active ingredient and strength, based on variations in production machinery, production and testing methods, and laboratory and clinical studies across manufacturers. The application review process is lengthy, in some cases taking as long as five years to complete. According to the DAV's annual health report in 2020, about 95 percent of the application dossiers were poor, and manufacturers had to submit supplementary documents after the first appraisal. Roughly 60 percent of application dossiers required amendment after the second appraisal, and about 30 percent required amendment after the third appraisal. The common issues include low quality and accuracy of the CPP, the manufacturer's master file on the drug documents[14], and insufficient information on the sample label and user instruction sheet as per the requirements stipulated in Circular No. 01/2018.[15]

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[14] Master file consists of all information related to factory structure and production scale and capacity, human resources, production line, machines, produced drug list, GMP certificate etc.

[15] Ministry of Health. 2018. Circular No. 01/2018/TT-BYT dated 18 January 2018, regulating the labeling of drugs, drug ingredients, and instruction sheet.

MA validity: The five-year MA is granted only when full safety and efficacy data are available. As specified in Article 8 of Circular 32, several ARV drugs received an MA valid for only three years because of insufficient data on their safety and efficacy. (Previously, as outlined in Circular No. 44, such drugs received an MA valid for only two years.)[16] According to the DAV's statistical data from 2016 to 2020, of 274 ARV drugs authorized for circulation in Vietnam, 32 were foreign drugs with a two-year license (coded "VN2-"), 31 were foreign drugs with a three-year license (coded "VN3-"), and 17 were domestically produced drugs with a three-year license (coded "VD3"). The large number of two- and three-year licenses indicates that many drugs will have to be reauthorized, which is a time-consuming process, as outlined in previous sections. TLD is one of the medicines with the highest market volume in Vietnam, and it currently has a three-year MA, which will require renewal in October 2022.

Appraisal and granting of MA: Table 5 summarizes the standard time for the DAV to review an MA application and submit it to the Advisory Council as outlined in Circular No. 32. However, practice shows that this actually takes much longer (Table 6), averaging two years compared with the guidance of one year.[17]

Table 4: Standard time for MA appraisal process

No.	Items	No. of working days for the regular appraisal process		No. of working days for simplified/fast-track appraisal process	
		Normal application	The application that includes clinical profile*/bioequivalence profile**	Normal application	The application that includes clinical profile*/bioequivalence profile**
1	Initial application	152	218	101	146
2	Additional application document	90	112	56	86
3	Meeting of Advisory Council for issuance of MA and processing of application documents after the meeting	49	49	49	49
4	**Total number of working days to obtain the MA**	**291**	**379**	**206**	**281**

Source: DAV.

* Currently, 12 pharmaceutical substances are required to have dossiers to prove bioequivalence. For a detailed list of drugs, see Ministry of Health, Circular No. 08/2010/TT-BYT dated 26 April 2010, guiding report on bioavailability/bioequivalence study data in drug registration (no pharmaceutical substances for HIV/AIDS treatment).

** Required for pharmaco-chemical drugs with different content, concentration, route of administration, dosage, indications, and target patients compared with the original brand-name drug licensed for market in Vietnam or with a new dosage form that affects the biopharmaceuticals of the drug (per Article 16 or Circular 32).

[16] Ministry of Health. 2014. Circular Ref. 44/2014/TT-BYT dated November 25, 2014, stipulating drug registration.

[17] Acriptega (TLD) was a special case, obtaining MA within 565 days. Noting its effectiveness, safety, high barrier to resistance, and low cost, the U.S. President's Emergency Plan for AIDS Relief program, the Global Fund, and the WHO sent a letter to the DAV requesting easing of requirements on its clinical document in the initial application process and faster approval.

Table 5: Actual time to issuance of MA, three examples

No.	Drug	Submission date	MA issuance date	Total number of working days
1	Eltvir (tenofovir/lamivudine/efavirenz 300/300/600mg (TLE600))	July 14, 2017	November 24, 2020	1,229
2	Tenof EM (tenofovir/emtricitabine 300mg/200mg)	August 1, 2015	July 4, 2018	1,068
3	Acriptega (TLD)	March 16, 2018	October 2, 2019	565

Source: DAV.

High MA application volume: The DAV/Drug Registration Division has 34 staff to handle all MA applications. In 2020, the DAV received 36,296 applications, an 83 percent increase over the number of applications received in 2016. On average, roughly 4,091 applications are executed each year. The main causes for delays in appraising MAs include:

- Shortages and limited capacity of personnel and experts at the DAV to review an overwhelming number of MA applications
- Insufficient training for DAV personnel, particularly for dedicated staff whose job is to review clinical and bioequivalence profiles as part of reviewing the MA application
- Inadequate equipment and facilities for archiving drug registration dossiers and the appraisal process

4.2 FACTOR 2: DOMESTIC PRODUCTION VERSUS IMPORTATION OF ARV MEDICINES

4.2.1 DOMESTIC PRODUCTION OF ARVS

Vietnam pharmaceutical enterprises/manufacturers are eligible to produce and distribute all ARV drugs and have the capacity to do so**.** According to the DAV, more than 252 drug manufacturers in Vietnam meet the GMP standards and are capable of manufacturing all dosage forms. Of these, 238 facilities meet WHO standards, 13 facilities meet the European Union standards or the equivalent, and 1 meets the Pharmaceutical Inspection Co-Operation Scheme standards.

Most ARV drugs are orally administered, with simple dosage forms (tablets, film-coated tablets, capsules, oral solution, oral syrup), so enterprises in Vietnam can produce them using their existing manufacturing techniques. However, these enterprises rely on external sources to procure the ingredients required to produce ARVs.

The main sources of pharmaceutical ingredients for ARV production are in India, China, Pakistan, and Bangladesh.

Locally produced drugs have some advantages in a bidding process, including:

- Bidders offering drugs whose domestic production cost accounts for more than 25 percent of the total production cost receive a higher score on the price and technical criteria.

- Based on WHO-GMP production standards (technical group 4)[18], bidders are not allowed to offer imported drugs with the same technical group with domestic produced medicines (technical group 4 includes all generic medicines produced in Vietnam). For bidding packages of generic drugs falling into specific drug categories (e.g., European Union-GMP or WHO-GMP),[19], in case there is a demand for treatment from health facilities which is beyond the supply capacity of domestic manufacturers, the Minister of Health will take the decision on the accepting the offering of this imported drugs in a defined period. This is a government-sanctioned advantage to encourage production of domestic drugs.

Despite these advantages, local ARV providers report that some registered and locally produced ARV drugs are not available in the Vietnam market: abacavir 300mg, efavirenz 50mg, efavirenz 200mg, lamivudine/zidovudine 150mg/300mg, lamivudine/nevirapine/zidovudine 150mg/300mg/200mg, lopinavir/ritonavir 100mg/25mg, and lopinavir/ritonavir 200mg/50mg. This is because:

- The cost to import active ingredients and produce the drugs is high, so that the selling price of the domestically manufactured drugs is less competitive than that of the imported drugs.
- These drugs are used for HIV/AIDS treatment. If manufacturers produce the drugs in advance to prepare for national ARV bids and do not win the bid, they are not able to sell the drugs to health facilities. Therefore, the manufacturers produce the drugs only after winning the bid.

4.2.2 ARV IMPORTATION

Private enterprises take important role in the supply chain of medicines in Vietnam, including ARV. More than 240 enterprises across the country are eligible to import ARVs that meet Good Storage Practice standards, making it easy to import and distribute ARV drugs. Because ARV medicines typically are formulated in tablets, they can be stored at room temperature. The exception is lopinavir/ritonavir 80mg/20mg per ml syrup, which needs to be stored at 2–8 degrees Celsius (35.6–46.4 degrees Fahrenheit).

The duration and timeline of ARV importation in Vietnam depends on the readiness of manufacturers outside of the country, mostly Indian companies. Local enterprises are put in a difficult position, as they cannot control the timing of manufacturers' importation, and this can lead to supply chain interruptions. For example, the global outbreak of COVID-19 has made importing drugs and pharmaceutical supplies more difficult. Difficulties include increased transportation costs, prolonged customs clearance time, and transportation problems due to a reduced number of transportation routes, flights, and cargo ships, or schedule changes. Interrupted production has also made supplies scarce.

[18] Article 7 in Circular 15/2019.
[19] Circular 03/2019.

4.3 FACTOR 3: ARV PROCUREMENT BIDDING PROCESS

4.3.1 POLICIES FRAMEWORK FOR PROCUREMENT

The procurement of ARV drugs must comply with the provisions of the Bidding Law, the Decree guiding the Bidding Law, and four circulars issued by the MOH: Circular 15/2019,[20] Circular 15/2020, Circular No. 03/2020, and Circular No. 22/2020.[21]

SHI-covered ARVs in Vietnam are domestically procured by two methods:

- The price-negotiation method applies to five ARV drugs in List of drugs procured by price negotiation in Circular 15/2020. Two drugs already have negotiation results: Avonza (TLE400) and Acriptega (TLD).
- Centralized open procurement (public bidding) applies to 27 ARV drugs in the list of drugs for national-level centralized procurement. All drugs in the MOH's treatment regimens included in the list of national centralized-procurement drugs have been successfully procured.

The procurement of ARVs using the SHI fund started in 2018 with two ARV drugs, continued in 2019 with four ARV drugs, and increased to 10 ARV drugs in 2020, with centralized public bidding and central payment from the SHI fund. However, in 2021, two ARVs were procured through price negotiation, which is regulated under Circular 15/2020. That process is different from the public bidding process and is analyzed in greater detail below.

4.3.2 AGENCIES INVOLVED IN ARV DRUG PROCUREMENT

The MOH's VAAC organizes the procurement of ARV drugs under the government budget to ensure a sufficient supply of ARV drugs for HIV/AIDS prevention and treatment.

Donor funding for ARVs has been declining since 2019, and payment for these drugs has been gradually transitioning to the SHI fund. Table 7 summarizes institutional units participating in the procurement of SHI-covered ARVs.

Table 6: Government agencies and their responsibility in ARV procurement

Government Agency	Responsibility
VAAC	✓ Government budget covered ARVs: Responsible for all steps: aggregating ARV quantifications, planning, organizing bidding process, regulating ARV supply. ✓ SHI-covered ARVs: Consolidating ARV quantifications, managing and coordinating ARV supply, and allocating supply at the national level.
Department of Planning and Finance	✓ Appraisal and submission for MOH approval of the bidder selection plan for centrally procured drugs, price negotiation plan, and price negotiation results.
Drug Administration of Vietnam	✓ Focal agency in the development of Circular 15/2019 on the bidding of drugs at public health facilities, including lists of drugs procured through bidding, the list of drugs subject to centralized procurement, and the list of drugs subject to price negotiation. ✓ Directly carry out activities to support the bidding process, including:

[20] **Ministry of Health. 2019. Circular No. 15/2019/TT-BYT dated 11 July 2019, stipulating the procurement of drugs at public health facilities.**

[21] **Ministry of Health. 2020. Circular Ref. 22/2020/TT-BYT dated 2 December 2020, regulating the management of ARV drugs that are centrally procured at the national level using the Health Insurance Fund and subsidy of ARV copayment for HIV patients with health insurance cards.**

	▪ Announce price on the website as a basis for setting the plan price. ▪ Announce the declared and re-declared prices as a basis for the evaluation of bids. ✓ Publish the list of manufacturers with qualified drugs to help with evaluation of bids: ▪ Publish the list of original brand-name drugs and bioequivalent drugs. ▪ Publish the list of providers with bidding violations. ▪ Publish the list of drugs and the list of providers with drug quality violations as the basis for evaluation of bids.
Department of Health Insurance	✓ Develop the list of ARV drugs covered by the Health Insurance Fund.
NCDPC	✓ Organize the procurement of ARV drugs purchased through the Health Insurance Fund. ✓ Act as a standing member of MOH's Price Negotiation Council to negotiate drug prices.
VSS	✓ Appoint staff to participate in the entire provider selection process. ✓ Assign the Northern Region Center for SHI Verification and Multi-line Payment to directly sign contracts and make payments for drugs purchased through centralized procurement.

4.3.3 PROCUREMENT OF ARV MEDICINES FROM DIFFERENT SOURCES

There are currently three sources of funding for ARVs. The Global Fund provides in-kind support for ARVs through its global project international bidding. The government budget and SHI provide ARVs through annual domestic procurement. However, in the last three years, the government budget has covered only a small quantity of drugs for specific groups. As a result, the main funding sources for ARVs are the SHI and the Global Fund. SHI will cover the majority of PLHIV from 2021 onwards.

(For details on the quantity and cost of ARVs, see *Annex 4: ARV drugs procurement using government funds, from 2018 to 2020,* and *Annex 5: ARV drugs procurement using the SHI fund, from 2018 to 2021.)*

Since 2018, the VAAC has guided health care facilities in estimating ARV needs, consolidating ARV quantifications from health facilities nationwide, and sending findings to the NCDPC. The NCDPC then prepares and submits a bidder selection plan for approval, organizes the bidder selection, and signs a framework agreement according to Circular 22/2020 and Circular 15/2020.

The VAAC, Department of Planning and Finance, and the NCDPC will continue procuring ARV drugs for HIV treatment in the years 2022–2023 as follows:

- Government budget: One drug (TLD).
- SHI fund: Seven drugs, of which centralized procurement is applied to five drugs (efavirenz 600mg, lamivudine/zidovudine 150mg/300mg, lamivudine 150mg, lopinavir/ritonavir 200/50mg, and tenofovir 300mg), and price negotiation is applied to two drugs (TLE400, TLD).

4.3.4 STRENGTHS AND WEAKNESSES IN THE CURRENT PROCUREMENT AND SUPPLY OF ARV DRUGS

STRENGTHS

- The MOH has been developing and updating the policy and regulations on drug procurement since 2012. These regulations have facilitated the procurement of drugs in general and ARV drugs in particular. Circular 22 was developed to detail the procurement of ARV drugs.
- Consistent bidding document templates and detailed guidelines on planning, appraisal, and approval of the bidding process are available; regulations on open and transparent drug procurement at national and local levels and bidding information announcements on the MOH and DAV websites are available.

- There are more options for doctors in the selection of drugs to ensure a sufficient dispensing in health care examination and treatment. Flexible switch of drug technical criteria groups in drug quantification minimizes procurement failure. For example, one drug is quantified and allocated across three technical criteria groups by health facilities. If there is not any active MA in one or two lower technical criteria groups, VAAC can re-quantify the number of drugs for a higher group or groups to ensure sufficient drugs to be procured.
- Centralized procurement of ARV drugs helps unify ARV drug prices at treatment facilities across the country and free them to focus on HIV/AIDS prevention and treatment.

WEAKNESSES

Over the last few years, the centralized procurement of ARVs conducted by the MOH has kept drug prices under control and ensured sufficient medicines for targeted patients. However, the procurement process faces some challenges for the following reasons:

- Under- and over-quantification of drug demand by health facilities
- Planned prices that do not correspond to increases in related drug costs
- Limited choices of ARV drugs with different technical criteria for procurement
- Lengthy procurement process
- Difficulty managing contracts, drug reallocation, and payment for different procurement methods
- Low interest among drug suppliers due to complicated contracting procedures and unattractive payment terms

Under- and over-quantification of ARV drugs

Over- and under- quantification of ARV drugs is still an issue in health facilities. The drugs should be forecasted one or two years in advance based on various sources of supply such as donor aid, government budget, and SHI. Additional challenges include changes in treatment regimen, fluctuation of patient numbers including new enrollments, patients being transferred to other SHI health care levels, delayed delivery of drugs from awarded suppliers, and lengthy bidder selection process that place the health facilities at a temporary shortage of drugs.

For example, the lamivudine/nevirapine/zidovudine regimen was switched to lamivudine/tenofovir/efavirenz as a preferred regimen in 2019. Unused lamivudine/nevirapine/zidovudine remained in stock at health facilities at the end of the third quarter of 2020 and were valued as high as US$11,776.

Setting relevant planned drug unit cost

According to regulations, a drug's planned unit cost is set with reference to the winning bid price within 12 months. In practice, institutional units tend to use the previous winning bid price as a planned price for the following period. If the winning bid price has been deeply discounted to win national supply contracts but the provider is unable to maintain that price for the following period due to increases in costs (e.g., materials, labor, transportation) then the planned price for the next period is not relevant. As a result, potential bidders do not participate in the bidding because the planned price is not reasonable to them. The purchase of TLE600 drugs in 2021 was one example observed. There was no bid submission for the first post and only one bid submission for the second post, with the offer price higher than the planned price, so the bid was cancelled. If the planned price is modified to suit the actual situation, it takes significant time to prepare justifications to present to the appraisal council, which will lengthen the bidder selection process.

Limited choices of ARV drugs with different technical criteria group

Most ARV drugs have only one to two registration numbers for one strength or dosage form, especially for pediatric dosage forms (syrup, oral powder). This makes it very difficult to prepare a procurement list that ensures success in bidder selection. Low-value ARV drugs have fewer manufacturers and distributors, which limits the selection of drugs for different technical criteria groups when preparing a procurement list. Technical criteria groups are categorized based on production standards. The procurement of drugs in different technical criteria groups diversifies supply and saves costs because of different prices in different groups. For example, the MOH asked the national centralized drug procurement center to procure tenofovir 300mg for SHI 2021 in two technical groups: group 2, which is under the European Union-GMP production line, and group 4, which is locally produced and under the WHO-GMP production line. However, there was no bid for technical group 2 for a quantity of about 4,800 boxes, and the drug was successfully procured in technical group 4 only.

Lengthy procurement process

SHI-covered ARV drugs are purchased through either the centralized-procurement method or the price-negotiation method. The procurement process usually takes six to eight months from the point of provider selection planning until the provider is selected and the contract is signed. If suppliers are not successfully selected, a second or third procurement must be organized, and the time may be extended for another two to three months.

For example, 15 drugs had to be purchased for use in 2021, divided into four different groups. One of them, TLE600, was later replaced by TLD and TLE400. Three separate national bids were organized for these 15 drugs between September 2020 and June 2021 for a variety of reasons, including unqualified bidders or no bidders, and bid prices exceeded the planned price.

Difficulty managing contract signing, reallocation, and payment after getting bidding results

✓ *For SHI-ARVs purchased through price negotiation:*

The contract signing and payment are done between the selected provider and SHI health facilities providing ARV drugs to HIV patients. That creates the following problems:

- After signing a framework agreement with the NCDPC, the selected provider must sign contracts with health facilities nationwide (about 338 facilities in 2021). Accordingly, they have to conduct a large number of payments and contract liquidations. These take a great amount of time and effort.
- Some facilities are allocated a very small quantity of ARV drugs in the framework agreement and are in remote areas with difficult travel conditions. The transportation of drugs to these facilities is costly; providers may delay or refuse to sign supply contracts, resulting in interrupted drug supply to these facilities.
- Reallocation of ARV drugs among facilities after they have received the drugs and put them in stock cannot be conducted due to procedures within the tax authority. The result may be oversupply at some facilities and shortage of drugs for treatment at others.

✓ *For SHI-ARVs purchased through centralized procurement:*

The contract signing and payment are done between VSS's North Region Center for Health Insurance Verification and Multi-Payment and the bid-winning provider. This creates the following problems:

- Circular 22/2020 rules that a facility could commit to purchase 80 percent of the ARV drug amount allocated in the framework agreement, but there are no grounds for action if the facility fails to do so. If that happens, the ARV drug provider might lose interest and not attend the next bidding season.
- Some medical facilities are slow, and make mistakes, in the preparation of supporting documents and

procedures for the settlement of SHI-covered ARV drugs, resulting in delayed payment to providers. For example, a health facility could submit its SHI claims for ARV on the VSS claim system too late to comply with Circular 48/2017,[22] and because of this delay be unaware of its SHI claims being accepted or refused by VSS.

- The reallocation of drugs between facilities would increase the cost of transportation to the providers, making them less willing to participate in the next bidding season. Moreover, there are no specific guidelines for monitoring and controlling the quality of drugs reallocated between health facilities.

Low interest of suppliers and manufacturers in ARV drug bidding

Unsuccessful bidders must wait at least one year before they may participate in another bidding season, which makes providers less interested in production and bidding. In the long run, only previously successful bidders will continue to participate in the ARV bidding process, posing a risk of monopoly and increasing prices in the future. Other disincentives to suppliers' and manufacturers' joining the bidding include the lengthy procurement and contract signing process and liquidation regulations in SHI-covered ARV drugs purchased through price negotiation, as well as difficulties in and cost of transportation as discussed above.

Other issues related to the list of ARV drugs subject to centralized procurement at the national level

Some drugs under national centralized procurement have only one technical criteria group for one drug provided by an awarded supplier. Thus, if the supplier has problems and cannot deliver the drugs as needed, there will be no alternative drugs to other groups. In addition, treatment regimens and guidelines are regularly updated with active ingredients, with strength and dosage forms being replaced or supplemented. However, it takes substantial time to update, amend, and supplement the list of drugs under price negotiation, national centralized procurement, and covered by the SHI fund.

4.4 FACTOR 4: PRIVATE SECTOR PARTICIPATION IN ARV SUPPLY

In Vietnam, the private sector plays a very important role in ensuring the supply of drugs in the market, including HIV treatment commodities. In accordance with the provisions of Decree 54 and Decree 155, only qualified units (eligible for drug production, import, export, distribution) may register for MA, import, and distribute drugs. Additionally, the two decrees regulate that foreign and foreign-invested enterprises are not eligible to distribute pharmaceutical products. Therefore, the distribution of drugs in Vietnam is carried out only by local enterprises.

Enterprises that are licensed and eligible to manufacture drugs (more than 252 drug manufacturers) and to import drugs (more than 240 drug importers) are announced by the DAV on its website. These are private companies and equitized state-owned companies.

All bid-winning ARV distributors since 2018 are private companies (e.g., Hoang Duc Pharmaceutical and Medical Equipment Co., Ltd.; Vidipha Central Pharmaceutical Joint Stock Company) and state-owned joint-stock companies with private capital (e.g., Codupha Central Pharmaceutical Joint Stock Company, Central Pharmaceutical Joint Stock Company). Through monitoring ARV supply for nearly 400 health facilities across the country, the bid-winning contractors have prepared and implemented a plan for manufacturing and importing drugs to ensure timely and sufficient ARV supply as required by the facilities. These contractors have also carried out ARV reallocations across the country as requested by provincial centers of disease control and the VAAC to optimize the use of ARV drugs, avoid expiration, and address local drug shortages. ARV drugs delivered by these providers have all met the quality standards and are registered with the MOH.

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[22] **Ministry of Health. 2017. Circular 48/TT-BYT dated 28 December 2017 on prescribing transfer of electronic data used in management and payment of covered health care costs.**

However, due to the limited availability of MA numbers for ARVs, private sector and local manufacturers face challenges in joining the open bidding and procurement process. They have little chance to win the bidding, as it is hard for them to compete in price and supply capacity, particularly with medicines produced in India.

5. RECOMMENDATIONS

This section provides recommendations in terms of policies, guidance, and implementation to relevant stakeholders including the MOH, Ministry of Science and Technology, and pharmaceutical companies. This helps facilitate the drug registration process and overcome the limitations of drugs' local production, bidding, and supply implementation, encouraging more pharmaceutical enterprises and manufacturers to join the ARV drug market in Vietnam. The recommendations are presented across four factors: MA, importing and domestic production of ARVs, ARV bidding and procurement, and private sector participation in the ARV market.

5.1 FACTOR 1: MA

Given that MA applications are increasing while there is a limited number of staff at the DAV, the recommendations to the DAV and MOH aim to address the increased demands for obtaining a MA. Recommendations target change at the policy and implementation level of decision-making agencies and suppliers.

Recommendations for the MOH:

- Increase the number of staff available to review and appraise drug registration dossiers.
- Amend and supplement regulations regarding CPP and change of drug names.
- Provide training to enhance the capacity of dedicated staff on clinical and bioequivalence reviewing in MA application.
- Apply electronic, online registration system, and digitalization technology in the application, receipt, review, and executing of MA applications, to preserve human resources, shorten the appraisal time, and improve the management of drug registration records.

Recommendations for pharmaceutical companies:

- Carefully prepare MA applications before submission, ensuring information in application dossiers is sufficient and consistent.
- Keep up to date with the GMP validity of drug manufacturers for the purpose of drug registration and bidding participation.
- Carefully prepare the manufacturer assessment records to ensure consistency with the manufacturer's information in the application dossier, including the name, address of the drug manufacturer, and ARV dosage forms.
- Consult regulations on the fast-track appraisal process and exemption from clinical trials before applying for MA for ARVs that are new and for ARVs that have no more than two similar drugs (with same active ingredients, same dosage form, same strength, and concentration) and have valid MA in Vietnam at the time of application.

5.2 FACTOR 2: IMPORTATION AND DOMESTIC PRODUCTION OF ARVS

Many pharmaceutical companies import ARVs, as the process is fairly straightforward, since ARVs are not subject to special control like narcotic drugs. Most domestic drug producers can produce ARVs in all dosage forms such as tablets, syrups, and oral suspension. However, local producers are at a disadvantage because of high production prices and limited availability of imported materials to manufacture ARVs. Even if regulatory constraints were removed, international manufacturers could continue to undercut local manufacturers. Removing barriers to domestic production would help diversify ARV supply sources, which is especially important in health emergencies—such as the COVID-19 pandemic, when imports were restricted due to border closures.

Recommendations for the MOH

- Collaborate with the Ministry of Finance to develop policies that encourage domestic enterprises to produce ARVs with low demand. For example, the government could consider a favorable tax for importing foreign ingredients, preferential loans for production investment, and honoring community contributions to promote company image and reputation
- Collaborate with the Ministry of Science and Technology to support local enterprises in accessing advanced technology and the worldwide production chain, to help produce high-quality and new drugs.

Recommendations for the Ministry of Science and Technology

- Support local production through favorable policies, capital, and technology in research and development of pharmaceutical ingredients, avoiding dependency on imported ingredients.
- Fast-track appraisal process for technical dossiers and grant import license to import elements of the drug production chain.

5.3 FACTOR 3: ARV BIDDING AND PROCUREMENT

The MOH's centralized procurement of ARVs through competitive bidding has kept drug prices under control and ensured sufficient medicines for HIV patients with SHI cards. However, the bidding process experiences different challenges that lower the quality of quantification, distribution, and procurement implementation.

Recommendations for the MOH:

- Update policies to explicitly outline the roles of key stakeholders in the procurement process. These include establishing clear pricing guidance; harmonizing regulations on contract management and payment types; and developing policies to support domestic drug producers.
- Regularly share information on estimated ARV drug demand (i.e., list, quantities, procurement methods) so that manufacturers, importers, and distributors interested in the ARV market know and better plan to participate in the ARVs supply.
- Apply online tools and digitalization technology for the management of bidding, procurement, contracting, supplying, and reallocation.
- Train/coach staff on organizing bidding and procurement to minimize technical errors.
- Add regulation on equal benefit on SHI-covered ARVs copayment for all patients regardless of procurement methods.
- Develop regulations that specify responsibilities and sanctions for cases where health facilities fail to

purchase 80 percent of the framework agreement's committed amount without reasonable justifications. Also develop responsibilities and sanctions for bid-winning providers that fail to supply 80 percent of the contract quantity and fail to comply with the delivery schedule.

- Instruct procurement agency to set a planned price when preparing bidder selection plans in the event of significant changes of drug prices in the market and to ensure the harmonization of benefits to patients and enterprises, encouraging providers to participate in the supply process.
- Consider amending the provisions on health facility contract signing and payment for ARVs procured by price negotiation to be similar to that for ARVs centrally procured, for consistent monitoring and management of contract signing and payment for ARVs purchased with different methods.
- Regularly update the list of ARVs for centralized procurement to include new ARVs, such as dolutegravir 10mg, dolutegravir 50mg, and lopinavir/ritonavir 100/25mg granules.

Proposed alternative for procurement options:

National centralized procurement should continue with either the open bidding or price-negotiation process. However, the procurement of ARVs with few registration numbers, low consumption rate, and low value—especially pediatric ARVs—should be regulated similarly to that of orphan medicines. The MOH should regulate a procurement mechanism that enables direct price negotiation with manufacturers and grants quota for the import and procurement of ARVs, so that selected local companies can sign a contract for ARV import and supply to health facilities.

Alternatively, the MOH might consider ordering ARVs through an international organization. However, this option is not regulated in Decree No. 32,[23] so it must be proposed by the MOH to the Prime Minister for consideration (according to Article 26 of the Law on Bidding). This option would also need consensus from the Ministry of Planning and Investment, Ministry of Finance, and VSS on transferring funds for ARVs from the government budget and the Health Insurance Fund to bank accounts of international organizations, with 100 percent of the payment to be made in advance. The MOH can refer to the procurement of a 5-in-1 vaccine (Pentavalent vaccine: DPT-VGB-Hib) through the United Nations Children's Fund to consider a similar procurement for ARVs. International organizations can include the United Nations Development Program, a reputable entity with several years of experience in purchasing drugs for the diagnosis and treatment of infectious diseases such as tuberculosis, HIV, and hepatitis C, and some cancer drugs. Currently, this organization's programs are assisting in medical drug procurement and human resource strengthening for the health sector in 40 countries around the world.

- The MOH should continue national centralized procurement using either open bidding or the price-negotiation method.
- For drugs with few or no registration numbers, low utility, or small value, as well as those not locally produced or distributed (e.g., pediatric ARVs), the MOH should allow a mechanism similar to that for rare drugs or procurement through an international organization.

Recommendations for the pharmaceutical companies:

- Ensure production and supply plan comply with the framework agreement.[24]
- Proactively look for domestic sources of ingredients for local production of ARVs to avoid depending too much on imported drugs.

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23 Ministry of Health. 2018. Decree No. 32/2019/ND-CP dated 10 April 2019, stipulating the assignment of tasks, ordering or bidding for the provision of public goods and services using the recurrent fund from the state budget.

24 A framework agreement for ARV procurement is the agreement between NCDPC and ARV drug suppliers that sets out the terms and conditions under which ARV drugs can be purchased throughout the period of the agreement.

- Regularly update information and regulations on ARV procurement to ensure compliance with the bidding requirements, such as GMP, MA validity, and proof of stock.
- Always have a production and supply plan as required in the framework agreement.

5.4 FACTOR 4: PRIVATE SECTOR PARTICIPATION IN THE ARV MARKET

Current regulations support private sector participation in ARV supply. Currently, drug distribution in Vietnam is carried out exclusively by private local enterprises. Further, all awarded suppliers are either private companies or state-owned joint-stock companies with private capital contributions. However, private local manufacturers are unlikely to win bids because it is difficult for them to compete on price and supply capacity, particularly with manufacturers in India. The recommendations below aim to enhance local production capacity and competitiveness to foreign enterprises.

Recommendations for the MOH

- Support the local manufacturers through favorable policies on local drug consumption in the market—for example, regulation on minimum consumption of local drugs at health facilities.
- Award higher score of the bidding evaluation for local manufacturers including private and joint-stock ones.
- Collaborate with Vietnam Trade Promotion Agency to find collaboration opportunities among local and international manufacturers through joint ventures to advance technology and the production chain.

ANNEXES

Annex 1: HIV treatment regimens in Vietnam

Section	Regimens	Note
Adult	TDF + 3TC (or FTC) + DTG	Regimen I priority
	TDF + 3TC + EFV 400mg	Regimen I replacement
	TDF + 3TC (or FTC) + EFV 600mg AZT + 3TC + EFV 600mg TDF + 3TC (or FTC) + PI TDF + 3TC (or FTC) + RAL TAF + 3TC (or FTC) + DTG	Regimen I special (when the priority and replacement can't be used or are not available)
	AZT + 3TC + LPV/r (or ATV/r) AZT + 3TC + DTG[1] TDF[3] + 3TC (or FTC) + DTG[1]	Regimen II priority
	AZT + 3TC + DRV/r AZT + 3TC + LPV/r (or ATV/r or DRV/r) TDF[3] + 3TC (or FTC) + LPV/r (or ATV/r or DRV/r)	Regimen II replacement
Pediatric	ABC + 3TC + DTG	Regimen I priority
	ABC + 3TC + LPV/r	Regimen I replacement
	ABC + 3TC + EFV[3] (or NVP) AZT + 3TC + EFV[3] (or NVP) AZT + 3TC + LPV/r (or RAL)	Regimen I special
	AZT+ 3TC + LPV/r (or ATV/r[4]) AZT (or ABC) + 3TC + DTG[2] AZT (or ABC) + 3TC + DTG[2] ABC + 3TC + DTG[2]	Regimen II priority
	AZT + 3TC + DRV/r AZT (or ABC) + 3TC + RAL AZT (or ABC) + 3TC + LPV/r (or ATV/r4) ABC + 3TC + LPV/r (or ATV/r or DRV/r5)	Regimen II replacement
Newborn (below 1 month old)	AZT + 3TC + RAL	Regimen I priority
	AZT + 3TC + NVP	Regimen I replacement

Section	Regimens	Note
	AZT + 3TC + LPV/r ABC + 3TC + RAL TAF + 3TC (or FTC) + DTG	Regimen I special
Prevention of mother-to-child transmission	NVP syrup NVP + AZT AZT + 3TC + NVP: in case AZT and NVP syrup are not available	

Key: 3TC=lamivudine; ABC=abacavir; AZT=azidothymidine (also known as ZDV/zidovudine); DRV=darunavir; EFV=efavirenz; LNZ=lamivudine/nevirapine/zidovudine; LPV=lopinavir; NVP=nevirapine; RAL=raltegravir; TDF=tenofovir; TLD=lamivudine/tenofovir/dolutegravir 300/300/50mg; TLE600=lamivudine/tenofovir/efavirenz 300/300/600mg; TLE400=lamivudine/tenofovir/efavirenz 300/300/400mg; ATV/r=atazanavir/ritonavir.

Annex 2: ARV drug quantities and cost by funding source in 2021

Source	Drug (Active ingredient)	Concentration/Strength	Administration Route	Unit	Quantity	Winning bid price/reference price (US$)	Cost (US$)
Global Fund	Abacavir	300mg	Oral	Tablet	3,728,574	0.17	621,884
Global Fund	Efavirenz	50mg	Oral	Tablet	315,912	0.06	18,777
Global Fund	Efavirenz	200mg	Oral	Tablet	1,018,228	0.13	127,629
Global Fund	Efavirenz	600mg	Oral	Tablet	1,157,360	0.11	125,548
Global Fund	Lamivudine	150mg	Oral	Tablet	3,468,147	0.04	123,496
Global Fund	Lamivudine/abacavir	30mg/60mg	Oral	Tablet	1,392,433	0.13	174,533
Global Fund	Lamivudine/nevirapine/zidovudine	150mg/200mg/300mg	Oral	Tablet	23,700	0.13	3,090
Global Fund	Lamivudine/nevirapine/zidovudine	30mg/50mg/60mg	Oral	Tablet	2,587,601	0.07	175,772
Global Fund	Lamivudine/tenofovir/efavirenz	300mg/300mg/600mg	Oral	Tablet	229,131	0.21	48,815
Global Fund	Lamivudine/zidovudine	150mg/300mg	Oral	Tablet	3,513,643	0.17	589,681
Global Fund	Lamivudine/zidovudine	30mg/60mg	Oral	Tablet	128,135	0.04	4,922
Global Fund	Lopinavir/ritonavir	(80mg/2mg)/ml	Oral	Bottle	9,135	7.82	71,471
Global Fund	Lopinavir/ritonavir	100mg/25mg	Oral	Tablet	563,378	0.13	74,033
Global Fund	Lopinavir/ritonavir	200mg/50mg	Oral	Tablet	7,716,538	0.56	4,341,727
Global Fund	Nevirapine	10mg/ml	Oral	Bottle	3,735	2.43	9,061
Global Fund	Tenofovir	300mg	Oral	Tablet	1,219,203	0.07	91,069
Global Fund	Zidovudine	10mg/ml	Oral	Bottle	721	2.64	1,907
Global Fund	Tenofovir/lamivudine/dolutegravir	300mg/300mg/50mg	Oral	Tablet	4,830,395	0.23	1,111,411
Global Fund	Tenofovir/lamivudine/efavirenz	300mg/300mg/400mg	Oral	Tablet	8,951,031	0.23	2,020,598
National budget	Tenofovir/lamivudine/efavirenz	300mg/300mg/400mg	Oral	Tablet	6,861,494	0.23	1,548,908
SHI	Efavirenz	600mg	Oral	Tablet	1,519,888	0.11	164,875
SHI	Lamivudine	150mg	Oral	Tablet	2,350,780	0.04	83,708
SHI	Lamivudine/zidovudine	150mg/300mg	Oral	Tablet	4,834,402	0.17	811,339
SHI	Lopinavir/ritonavir (technical group1)	200mg/50mg	Oral	Tablet	6,229,310	0.56	3,504,935
SHI	Lopinavir/ritonavir (technical group 2)	200mg/50mg	Oral	Tablet	2,190,060	0.42	923,634
SHI	Tenofovir	300mg	Oral	Tablet	1,206,980	0.07	90,156

Source	Drug (Active ingredient)	Concentration/Strength	Administration Route	Unit	Quantity	Winning bid price/reference price (US$)	Cost (US$)
SHI	Tenofovir/lamivudine/dolutegravir	300mg/300mg/50mg	Oral	Tablet	15,603,410	0.23	3,590,141
SHI	Tenofovir/lamivudine/efavirenz	300mg/300mg/400mg	Oral	Tablet	16.442.054	5.192	3,711,615
						Total	24,164,736

Annex 3: Detail on the number of MAs

No.	Patient	Active ingredient(s)	Concentration/Strength	Administration route	Unit	Number of domestic MA	Number of foreign MA	Total MA
1	Pediatric	Abacavir	20mg per ml	Oral	Bottle	0	0	0
2	Adult	Abacavir	300mg	Oral	Tablet	2	4	6
3	Pediatric	Atazanavir (ATV)	100mg	Oral	Tablet	0	0	0
4	Pediatric	Atazanavir (ATV)	150mg	Oral	Tablet	0	2	2
5	Adult	Atazanavir (ATV)	300mg	Oral	Tablet	1	1	2
6	Adult	Atazanavir + ritonavir	300mg + 100mg	Oral	Tablet	0	0	0
7	Pediatric	Efavirenz	50mg	Oral	Tablet	3	0	3
8	Pediatric	Efavirenz	200mg	Oral	Tablet	4	1	5
9	Adult	Efavirenz	600mg	Oral	Tablet	6	6	12
10	Pediatric	Lamivudine	10mg per ml	Oral	Bottle	0	1	1
11	Adult	Lamivudine	150mg	Oral	Tablet	18	13	31
12	Pediatric	Lamivudine/abacavir	30mg/60mg	Oral	Tablet	0	2	2
13	Adult	Lamivudine/abacavir	300mg/600mg	Oral	Tablet	0	2	2
14	Adult	Lamivudine/nevirapine/zidovudine	150mg/200mg/300mg	Oral	Tablet	9	6	15
15	Pediatric	Lamivudine/nevirapine/zidovudine	30mg/50mg/60mg	Oral	Tablet	0	1	1
16	Adult	Lamivudine/tenofovir/efavirenz	300mg/300mg/600mg	Oral	Tablet	8	5	13
17	Adult	Lamivudine/tenofovir	300mg/300mg	Oral	Bottle	5	5	10
18	Adult	Lamivudine/zidovudine	150mg/300mg	Oral	Tablet	10	9	19
19	Pediatric	Lamivudine/zidovudine	30mg/60mg	Oral	Tablet	0	2	2
20	Pediatric	Lopinavir/ritonavir	80mg/2mg per ml	Oral	Bottle	0	2	2
21	Pediatric	Lopinavir/ritonavir	100mg/25mg	Oral	Tablet	2	1	3
22	Adult	Lopinavir/ritonavir	200mg/50mg	Oral	Tablet	4	3	7
23	Pediatric	Nevirapine	10mg per ml	Oral	Bottle	0	1	1
24	Adult	Nevirapine	200mg	Oral	Tablet	6	11	17
25	Adult	Ritonavir	100mg	Oral	Tablet	0	1	1
26	Adult	Tenofovir	300mg	Oral	Tablet	82	23	105
27	Pediatric	Zidovudine	10mg per ml	Oral	Bottle	0	0	0

No.	Patient	Active ingredient(s)	Concentration/Strength	Administration route	Unit	Number of domestic MA	Number of foreign MA	Total MA
28	Adult	Lamivudine/tenofovir/efavirenz	300mg/300mg/400mg	Oral	Tablet	0	1	1
29	Adult	Tenofovir; lamivudine; dolutegravir	300mg; 300mg; 50mg	Oral	Tablet	0	1	1
30	Adult	Raltegravir	400mg	Oral	Tablet	0	1	1
31	Pediatric	Darunavir	300mg	Oral	Tablet	0	1	1
32	Adult	Darunavir	800mg	Oral	Tablet	0	1	1
33	Adult	Tenofovir alafenamide	25mg	Oral	Tablet	4	1	5
34	Adult	Dolutegravir	50mg	Oral	Tablet	0	0	0
35	Pediatric	Dolutegravir	10mg	Oral	Tablet	0	0	0
36	Pediatric	Lopinavir/ritonavir	40mg/10mg	Oral	Granules	0	0	0

Source: MA of drugs and medicinal ingredients.

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Annex 4: ARV drugs procurement using government funds, from 2018 to 2020

No.	Active ingredient(s)	Concentration/ Strength	Drug name	Unit	Quantity	Unit price (US$)	Amount (US$)
2018 (Procurement method: Open bidding)							
1	Efavirenz 600mg	600mg	Efavirenz 600mg	Tablet	1,206,000	0.13	154,683
2	Lamivudine/tenofovir disoproxil fumarate/efavirenz	300mg/300mg/600mg	Eltvir	Tablet	6,600,000	0.25	1,627,043
3	Lamivudine/zidovudine	150mg/300mg	Lamivudine/ /zidovudine 150mg/300mg	Tablet	2,412,000	0.12	281,050
4	Lamivudine/nevirapine/zidovudine	150mg/200mg/300mg	Lamivudine/ nevirapine/zidovudine 150mg/200mg/ 300mg	Tablet	2,580,000	0.15	388,683
2019 (Procurement method: Direct procurement)							
1	Lamivudine/tenofovir disoproxil fumarate/efavirenz	300mg/300mg/600mg	Eltvir	Tablet	3,900,000	0.23	890,217
2020 (Procurement method: Direct procurement)							
1	Lamivudine/tenofovir disoproxil fumarate/efavirenz	300mg/300mg/600mg	Eltvir	Tablet	2,776,890	0.21	591,598

Annex 5: ARV drugs procurement using the SHI fund, from 2018 to 2021

No.	Active ingredient(s)	Concentration/ Strength	Drug name	Unit	Qty	Unit price, VAT included (US$)	Amount (US$)
2018: Drugs purchased in 2018 for use in 2019							
1	Lamivudine/tenofovir/efavirenz – N5	300mg/300mg/600mg	Trioday	Tablet	17,984,359	0.23	4,105,125
2	Lamivudine/nevirapine/zidovudine – N5	150mg/200mg/300mg	Lamivudine/ nevirapine/ zidovudine	Tablet	5,509,715	0.14	790,285
2019: Drugs purchased in 2019 for use in 2020							
1	Lamivudine/tenofovir disoproxil fumarate/efavirenz – N5	300mg/300mg/600mg	Eltvir	Tablet	16,397,629	0.21	3,493,408
2	Lamivudine/nevirapine/zidovudine – N5	150mg/200mg/300mg	Lamivudine/ nevirapine/zidovudine 150mg/200mg/300mg	Tablet	4,773,924	0.13	622,478
3	Efavirenz – N5	600mg	Aviranz tablets 600mg	Tablet	2,369,730	0.11	257,064
4	Lamivudine – N5	150mg	Lamivudine 150mg	Tablet	3,067,020	0.04	109,213
2020: Drugs purchased in 2020 for use in 2021							
1	Efavirenz – N2	600mg	Aviranz tablets 600mg	Tablet	565,755	0.11	61,372
2	Efavirenz – N5	600mg	Aviranz tablets 600mg	Tablet	954,133	0.11	103,503
3	Lamivudine/zidovudine – N2	150mg/300mg	Lamivudine/zidovudine 150mg/300mg	Tablet	1,064,080	0.17	178,580
4	Lopinavir/ritonavir – N2	200mg/50mg	Lopimune tablets	Tablet	1,122,330	0.42	473,330
5	Lopinavir/ritonavir – N1	200mg/50mg	Aluvia	Tablet	3,532,926	0.56	1,987,808
6	Tenofovir – N4	300mg	Jimenez	Tablet	573,03	0.07	42,803
7	Lamivudine – N4	150mg	Lamivudine 150mg	Tablet	588,006	0.04	20,804
8	Lamivudine – N5	150mg	Lamivudine 150mg	Tablet	1,348,726	0.04	47,719
9	Tenofovir disoproxil fumarate/lamivudine/efavirenz – N5	300mg/300mg/400mg	Avonza	Tablet	12,029,294	0.23	2,715,482
10	Lamivudine/tenofovir disoproxil fumarate/dolutegravir – N5	300mg/300mg/50mg	Acriptega	Tablet	7,895,750	0.23	1,816,709