Market and Patent on Key ARVs, DAAs and TB Medicines

In Bangladesh, Cambodia, Indonesia and Malaysia

A Report by

Asia Pacific Network of People Living with HIV/AIDS (APN+) Regional Secretariat

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FOREWORD

The APN+ Bangkok Regional Secretariat is proud to submit this advocacy report, which demonstrates our steadfast commitment to Universal Health Coverage (UHC) for all those living with HIV, Hepatitis, and Tuberculosis in Bangladesh, Cambodia, Indonesia, and Malaysia. With a strong emphasis on fighting for equitable access to vital pharmaceuticals, this research illuminates the complex interaction of market forces and patent regimes that shape medication availability and pricing in our area.

Our advocacy efforts are founded on the notion that healthcare is a basic human right, not a luxury reserved for a select few. However, the unpleasant fact is that market pressures and patent rights often act as strong hurdles to receiving life-saving therapies. Through this study, we want to highlight the voices of individuals who are disproportionately impacted by these obstacles and advocate for legislation that prioritizes people above profits.

In Bangladesh, Cambodia, Indonesia, and Malaysia, the fight for access to ARVs, DAAs, and TB medications is not just economic but also moral. The issue is whether we, as a global society, are willing to stand up and guarantee that no one falls behind in the battle against these fatal illnesses. The issue is whether we are willing to confront the current quo and demand a healthcare system that prioritizes the needs of the most disadvantaged among us.

This study is a call to action for governments, legislators, pharmaceutical corporations, and civil society organizations. It advocates for legislation that encourages generic competition, makes it easier to produce low-cost generic pharmaceuticals, and protects everyone's right to obtain vital medicines by eliminating patent restrictions, accessing cheap therapies and exacerbating health disparities.

As advocates for universal health coverage, we understand that our job is far from finished. The problems of guaranteeing access to ARVs, DAAs, and TB medications are daunting but not insurmountable. Let it motivate us to work harder to ensure that access to vital medications is a universal right rather than a luxury. Together, we can build a future in which every person, regardless of health or socioeconomic background, may enjoy a healthy, dignified, and hopeful life.

In solidarity,

APN+ Bangkok Regional Secretariat

ACRONYMS

/r	Ritonavir- boosted
3TC	Lamivudine
ABC	Abacavir
AIDS	Acquired Immunodeficiency Syndrome
APN +	Asia Pacific Network of People Living with HIV/AIDS
ARV	Antiretroviral
ATV	Atazanavir
Cobi	Cobicistat
DAA	Direct-Acting Antiviral
DCV	Daclatasvir
DDIs	Drug-drug interactions
DRV	Darunavir
DTG	Dolutegravir
EFV	Efavirenz
EVG	Elvitegravir
FTC	Emtricitabine
HIV	Human Immunodeficiency Virus
INSTIs	Integrase Inhibitors
LGBTQ+	Lesbian, Gay, Bisexual, Transgender, Queer Plus
LPV	Lopinavir
MOH	Ministry of Health
NRTI	Nucleoside Reverse Transcriptase Inhibitors
NNRTIs	Non-Nucleoside Reverse Transcriptase Inhibitors
NVP	Nevirapine
PIs	Protease Inhibitors
PLHIV	People Living with HIV
RAL	Raltegravir
RFP	Rifapentine
RIF or R	Rifampicin
RPV	Rilpivirine
SOF	Sofosbuvir
TAF	Tenofovir Alafenamide
TB	Tuberculosis
TDF	Tenofovir Disoproxil Fumarate
WHO	World Health Organization

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INTRODUCTION

> "If it is to be truly universal, why universal health coverage will not succeed without people living with HIV and other key populations, women and young people?" -UNAID Meeting, 2019

The aforementioned subject was posed during the 2019 UNAID Meeting in Geneva, Switzerland while discussing the significance of global health access. Universal Health Coverage (UHC), which aims to provide access to high-quality, affordable health care, is a critical objective for international development. It provides social security for everyone, especially the weakest parts of society.

Since 2012, UHC has been promoted as a global agenda, and it was expanded in 2015 to align with the 2030 Agenda for Sustainable Development Goals by including financial risk protection, quality essential healthcare services, and effective, safe, and affordable essential medicines and vaccines for all. In 2017, Global Health and Foreign Policy were enhanced by incorporating various stakeholders, such as civil society, academia, and the commercial sector, in order to increase health objective implementation. Since then, the UN has declared UHC Day on December 12, 2017, to promote awareness of the importance of robust and resilient health systems and universal health coverage with multi-stakeholder partners (UHC2030, 2019).

In fact, the 2019 UNAID Meeting reflected doubt about its implementation, especially in link to people living with HIV/AIDS and other key populations, women and young people. Those key populations were in challenging circumstances towards stigmatizing discrimination, triggering political strategy. This Political Declaration is important to be more inclusive as the people with HIV/AIDS are decriminalized in all key populations (UNAIDS, 2019). Following the circumstance of HIV/AIDS, Tuberculosis (TB) is the leading cause of morbidity and mortality globally. Of more than 40 million HIV/AIDS infections, roughly 23% are associated with Tuberculosis, with the East, Southeast Asia, and Pacific regions having a high risk of infection (Zhang, Kern-Allely, & Price, 2019).

In Bangladesh, poor healthcare coverage, particularly in rural regions, continues to be a significant challenge. With just 2.5% of the population having health insurance, the majority is still subject to financial difficulties from healthcare expenses (Mostari & Mohona, 2023). In the case study of Cambodia, fewer than 20% of the population has financial health insurance and access to health care, with more than 70% of Cambodian women earning the lowest income (World Bank, 2016). As a

result, access to excellent health care remains a challenge, particularly for low-income and vulnerable populations. Furthermore, in Indonesia, controlling infectious and noncommunicable illnesses continues to be difficult in 2021, resulting in a fall in the UHC index rank from 56 to 55 (WHO, 2023). Similarly, in Malaysia, unsustainable UHC programs owing to irregular funding allocation continue to be an issue (Hussin, 2023).

BACKGROUND

❖ Universal Health Coverage (UHC) Encouragement, Inclusion, and Sustainable Development Goals

> All children, youth, persons with disabilities, people living with HIV, older persons, indigenous peoples, refugees, and internally displaced persons and migrants must access to health – the Political Declaration on UHC, 2019

The following sentence is taken from the Political Declaration adopted at the 2019 UN High-Level Meeting. This political proclamation was criticized for failing to explicitly include important groups critical to HIV response, such as homosexual men and other men who have sex with males, drug users, sex workers, and transgender persons. This paradox serves as a beginning point to raise awareness to people about the HIV movement's significance to the Lesbian, Gay, Bisexual, Transgender, and Queer Plus (LGBTQ+) community, health as a human right, and advocacy efforts to ensure UHC is genuinely universal.

By definition, The UHC is a situation in which all people who need health services (prevention, promotion, treatment, rehabilitation, and palliative care) obtain them without undue financial burden (WHO, 2010). UHC is made up of three interconnected components: 1) a comprehensive range of health care based on need, 2) financial protection from direct payment for health services received, and 3) coverage for the whole population (World Bank, 2014). Furthermore, to track progress toward these objectives, the World Bank suggests two broad goals: financial protection and service delivery. However, hurdles have been encountered in order to attain this aim. Effective stakeholder participation, fair resource and service allocation, and program governance.

Often, tedious laws and regulations for HIV/AIDS and gender-responsive health settings lead to stigma and prejudice. Healthcare practitioners routinely

confront insensitive behaviors. Indeed, HIV/AIDS prevention, treatment, care, and support services vary by neighborhood, making universal health coverage programs and policies necessary. As a result, the goal of UHC is to provide additional opportunities for unreached individuals to get care (UNAIDS, 2019). All UHC indicators and goals are expressed in the United Nations 2030 agenda as part of the Sustainable Development Goals (SDGs) in Priority 3 Health and Wellbeing, particularly target 3.8, which measures: 1) coverage of essential health services (SDG indicator 3.8.1) and financial protection (indicator 3.8.2) (World Bank, 2023).

Furthermore, domestic money is essential for realizing the aim of universal health coverage. This HIV/AIDS and TB service must emphasize treatment availability, affordability, quality, and medication accessibility. Various solutions must be proposed, such as inclusion in national health care, the use of specific government funds, or distinctive tax-related health expenses (Aidsfond, 2024). Suppose HIV/AIDS and tuberculosis programs and treatments are effective. In that case, this trend will align with SDG 3.3, which states that "end epidemics of AIDS, tuberculosis, malaria, and neglected tropical diseases by 2030, as well as hepatitis, water-borne infections, and other communicable diseases." (Singh, 2023). As a result, UHC for HIV/AIDS and TB services must be included in UHC implementation at both the national and local levels.

As a successful case study, countries as diverse as Brazil, France, Japan, Thailand, and Turkey have achieved universal population coverage, demonstrating how UHC programs can improve citizens' health and welfare while laying the groundwork for economic growth and competitiveness based on equity and sustainability. Beyond health and wellbeing, UHC promotes social inclusion, equality, poverty eradication, economic progress, and human dignity (World Bank, 2014).

Following the successful achievement of the prior goal of giving antiretroviral medicine (ART) to 15 million people by 2015, the global community sought to meet the Fast-Track or 90-90-90 targets by 2020. By the end of 2020, almost 25 million people were getting treatment, with an annual increase rate of 1.6 million, showing the progress of the test and start effort (WHO, 2022). Given this context, we at APN+ see this report as an opportunity to advocate for improved access to treatment and medicine, particularly generic production, patent and regulatory challenges for antiretrovirals (ARV), direct-acting antivirals (DAAs), Tuberculosis (TB), and other life-saving drugs in the Asia Pacific. As a result, we hope that this report will give us the confidence to speak out for the voiceless and highlight societal realities.

❖ Universal Health Coverage (UHC) in Bangladesh

Bangladesh's health system is dealing with a double burden of diseases, limited service coverage, and a lack of effective financial risk protection mechanisms. Bangladesh has a varied healthcare system that is mostly deregulated and controlled by four major actors: the government, the private sector, the not-for-profit private sector (primarily non-governmental organizations (NGOs), and foreign development organizations. Aside from the people who use the healthcare system, money has been infused into public healthcare. The government significantly subsidizes public healthcare, with consumers paying extremely little costs, especially for outpatient care. Health expenditure is insufficient, with just 2.64 percent of GDP devoted to health, the lowest in South Asia (Joarder et al., 2019). Inequality in healthcare access has mostly occurred in rural Bangladeshi areas. Because health financial coverage is so restricted, nine percent of families experience catastrophic health costs, 5.6 percent go bankrupt, and seven percent utilize distress finance (borrowing or selling family assets to pay for healthcare). As a consequence, in Bangladesh, less than 1% of the population has access to a health insurance plan that covers catastrophic medical expenditures (Rahman 2019).

In terms of HIV prevalence, an estimated 14,513 persons were living with the virus in 2022. One-third of the 1,676 new cases diagnosed between 2021 and 2022 were in the general population, 18% in migrant workers and their partners, and 13% in Myanmar-displaced people (Singh, 2023). According to national statistics, 11% of HIV/AIDS patients are also afflicted with Tuberculosis. As a result, these difficulties are linked to the socioeconomic determinants of individuals at the highest risk of Tuberculosis, such as poverty, class inequality, poor education levels, and gender. This is especially true in rural and remote regions, where two-thirds of Bangladesh's population lives and poverty rates are 8-10% greater than in cities. The previous review defined human rights as being linked to a variety of societal concerns, including barriers to treatment and pharmaceutical availability. This study elaborates on current drug specifications and provides an outline of therapy.

❖ Universal Health Coverage (UHC) in Cambodia

Cambodia is a shining example of how a low-income country may make quick progress toward health targets; improvements and innovation in health financing and service delivery have contributed to the achievement of all health-related Millennium Development Goals and SDGs. Cambodia continues to face challenges in basic health outcomes such as nutrition, vaccination, and newborn mortality, especially when using an equity lens to reduce health disparities and lay the groundwork for addressing emerging concerns such as pandemics and non-communicable diseases

(NCDs) (World Bank, 2016). In 2017, rising healthcare expenditure drove around 3.7% of families into poverty. More precisely, female-headed families were more vulnerable than male-headed ones (USAID, 2023).

Impressive progress has been made in providing financial protection for health services, including the Health Equity Fund (HEF) for the Poor, voucher systems, and social health insurance schemes for the formal sectors (NSSF). Despite this progress, government spending remains low and out-of-pocket expenditures still make up 60% of total health expenditures, which is a serious impediment to the country's progress towards universal health coverage (UHC).

Cambodia has consistently lowered the frequency of human immunodeficiency virus (HIV) in the general adult population aged 15 to 49 years, from 1.7% in 1998 to 0.5% in 2019. Cambodia is also one of three Asia-Pacific nations that have met the UNAIDS 90-90-90 objectives (Tuot et al., 2021). As of December 2022, 64,931 HIV-positive persons were receiving antiretroviral medication, with 83 percent of them being female entertainment workers, homosexual men, and other males who have sex with men, transgender women, drug users, and injectors, and their sexual partners (UNAIDS, 2023). From a larger perspective, the devastating effect of HIV/AIDS stems from socioeconomic factors such as poverty, food security, and access to health and education, all of which affect access to public healthcare (UNDP, 2013). In reality, this situation is related to internal stigma and discriminatory attitudes from family members, coworkers, acquaintances, and health providers, which may lead to suicide ideation (UNDP, 2013).

❖ Universal Health Coverage (UHC) in Indonesia

Indonesia, a low-middle-income nation with a population of over 242 million people, has experienced significant health advances in recent decades, particularly in terms of improved life expectancy and lower newborn and child mortality rates (World Bank, 2014). Between 1990 and 2010, cerebrovascular illness, cardiovascular disease, diabetes, and lung cancer increased by 80% (World Bank, 2014). As a result, the central government has committed to attaining universal health coverage (UHC) by 2019, as outlined in the National Health Insurance Program's Road Map.

Indonesia began providing antiretroviral medication (ART) to persons living with HIV (PLHIV) in the late 1990s, eventually establishing UNAIDS 95-95-95 objectives (Hutahaean et al., 2023). According to the statistics, in 2021, only 66 percent of 610,000 PLHIV are aware of their HIV status, with just 26 percent taking ART (Hutahaean et al., 2023). In fact, HIV prevalence among young gay men and other men who have sex with men more than doubled in Indonesia from 6 percent to 13 percent

between 2011 and 2019 (UNAIDS, 2023). In Indonesia, HIV treatment adherence is a significant concern. PLHIV, like those in other nations, have faced public stigma and prejudice at the social level, as well as stigma in healthcare, settings, and inside individuals.

Furthermore, although the national health insurance (Jamkesmas) is non-discriminatory in principle, it has certain practical challenges. There is stigma and prejudice against those living with HIV, and treatment is determined by hospital policy. Furthermore, provincial variations and local government commitments have altered its execution. Furthermore, the criminalization of the LGBTQ+ group results in a new criminal code that includes provisions that violate the rights of women and individuals from sexual minorities (UNAIDS, 2023). Furthermore, extra finances for antiretroviral (ARV) access have been restricted in the nation (ILO, 2015).

❖ Universal Health Coverage (UHC) in Malaysia

Malaysia is recognized as having one of the best healthcare systems in the world, ranked 49th according to the World Health Organization. The government has consistently invested in improving treatment standards, including initiatives aimed at rural and low-income people, propelling it to the top of Asia's healthcare providers. Since the 1980s, Malaysia has achieved universal health coverage via public providers and a general budget. However, there is considerable evidence of disparities in health outcomes across socioeconomic categories, including a greater prevalence of health issues among lower-income groups (KRI, 2021). One of the issues facing Malaysia's public healthcare system is growing healthcare costs.

In reality, HIV and HIV-related disorders are not covered by private medical and health insurance in Malaysia. People living with HIV are refused insurance coverage because of their pre-existing illness, and there are no HIV/AIDS-specific insurance plans in Malaysia (ILO, 2021). Between 2015 and 2018, the human immunodeficiency virus (HIV) prevalence grew marginally from 0.17 to 0.18 percent. HIV transmission has increased from needle sharing to sexual transmission (MOH, 2020), and it is expected to continue until 2030. Prevention coverage has not altered in response to the transmission mode changes.

Similarly, Malaysia set 95-95-95 objectives for Universal Health Coverage. From 2015 to 2018, HIV testing coverage among HIV-positive patients fell from 98 percent to 86 percent. However, throughout the same year, antiretroviral medication (ART) coverage increased steadily from 31% to 55%. As a result, Malaysia continues to face ART limitations while improving peer support and case management quality.

Tuberculosis incidence increased from 79 to 81 per 100,000 people between 2015 and 2019. The poor rate of TB diagnosis, as well as the lateness with which symptomatic TB patients seek TB treatment at healthcare institutions, has led to the spread of infections in the population. The public's lack of education and awareness of Tuberculosis is also a contributing factor (MoH, 2020). As a result, assessing the availability and cost of ARVs, DAAs, and TB medications is critical since it may help improve the facility and eliminate the gap in society.

Furthermore, originator corporations no longer provide traditional price concessions to underdeveloped countries. Instead, they negotiate price reductions for antiretrovirals (ARVs) on an individual case basis. Developing nations are presently experiencing setbacks as they are once again charged exorbitant fees for the most recent treatments. In addition, there are continuing intellectual property conflicts in Bangladesh, Cambodia, Indonesia, and Malaysia, which are key manufacturers of low-cost antiretrovirals (ARVs), direct-acting antivirals (DAAs), and tuberculosis medications. It is critical to carefully assess and study the impact of voluntary actions implemented by businesses to increase access to these treatments. Antiretroviral treatments (ARVs), direct-acting antivirals (DAAs), and tuberculosis (TB) therapies are procured via a variety of channels, with the national government and the private sector doing most of the procurement. The private sector functions independently of the donor-sponsored market. As a result, additional strategies may be required to increase the availability of antiretroviral medications (ARVs), direct-acting antivirals (DAAs), and tuberculosis (TB) supplies, particularly at the point when patients seek medical assistance. Although existing drugs and projected future developments are available, there is a constant need to improve market functioning in order to improve patient's access to these medications. Market-based approaches are critical in addressing this need.

❖ Drug-drug Interactions between ARVs, DAAs and TB

Tuberculosis (TB) is the major cause of mortality in people living with HIV (PLHIV), reducing the risk by 26 times over a lifetime. People living with HIV (PLHIV) often get both antiretroviral (ARV) and anti-tuberculosis (TB) medications. Early antiretroviral therapy (ART) beginning during tuberculosis treatment increases survival in individuals with advanced HIV illness. New ARVs and TB medications have just been released, and worldwide recommendations have been revised.

This study, cited by Cerrone et al. (2021), outlines the medicine's dose. Rifamycins (rifampicin (RIF), rifabutin, and rifapentine) are important first-line anti-TB medications because of their excellent sterilizing properties. They also cause the majority of important drug-drug interactions with antiretrovirals. RIF stimulates the

hepatic phase I and phase II enzymes cytochrome P450 (CYP450) and uridine diphosphate glucuronosyltransferase 1A1, as well as the drug transporter P-glycoprotein (P-gp). The co-administration of antiretroviral medicines, which are substrates for these enzymes and transporters, significantly reduces their bioavailability. Here, we describe the PK interactions between rifamycins and anti-HIV medicines, as well as the suggested medication dose.

Table 1. Drug-drug interactions of Antiretrovirals with Rifampicin and Rifabutin as First-Line Anti-TB Drugs (Cerrone et al., 2021)

	Rifampicin		Rifabutin	
Antiretroviral	Effect	Dose Adjustment and Comments	Effect	Dose Adjustment and Comments
NNRTI				
NVP	↓↓NVP	Avoid concomitant use	↓RBT	Can be coadministered with RBT 300 mg once daily
EFV	↓/= EFV	EFV 600 mg can be coadministered without dose adjustments. Nonsignificant changes in EFV 400mg exposure in a small clinical PK study	↓RBT	Can be coadministered with RBT 450 mg once daily
RPV	↓↓RPV	Avoid concomitant use	↓RPV	Avoid concomitant use. When necessary, it can be coadministered with RPV 50 mg once daily with caution (ECG monitoring due to risk of QT prolongation)
ETR	↓↓ETR	Avoid concomitant use	↓ETR	It can be coadministered without dose adjustments.

				Limited data available
DOR	↓↓DOR	Avoid concomitant use	↓DOR	Can be coadministered with DOR 100 mg twice daily Limited data available derived only from PK studies
PI.				
LPV/r	↓↓LPV/r	Avoid concomitant use	↑RBT	It can be coadministered with RBT 150 mg once daily. Monitor closely due to potential increased RBT toxicity.
ATV/r	↓↓ATV/r		↑RBT	
DRV/r	↓↓DRV/r		↑RBT	
INSTI				
RAL	↓RAL	Can be coadministered with RAL 400 or 800 mg twice daily Avoid RAL 1200 mg once-daily dose	= RAL	Can be coadministered with RBT 300 mg once daily, RAL standard dose
EVG/c	↓↓EVG/c	Avoid concomitant use	↓EVG/c ↑RBT	Avoid concomitant use
DTG	↓DTG	Can be coadministered with DTG 50 mg twice daily	= DTG	Can be coadministered with RBT 300 mg once daily
BIC	↓↓BIC	Avoid concomitant use	↓BIC	Avoid concomitant use No data available
NRTI				
TDF, ABC, 3TC, FTC	=TDF =ABC =3TC =FTC	Can be coadministered without dose adjustments	=TDF =ABC =3TC =FTC	Can be coadministered without dose adjustments

TAF	↓↓TAF	Co-administration with TAF 25 mg once daily resulted in nonsignificant changes in intracellular tenofovir diphosphate exposure in a healthy volunteer PK study	↓TAF	Avoid concomitant use until further data is available
CCR5 Receptor Antagonists				
MVC	↓↓MVC	Can be coadministered with MVC 600 mg twice daily	↓MVC	Can be coadministered without dose adjustments

NNRTIs, non-nucleoside reverse transcriptase inhibitors; NVP, nevirapine; EFV, efavirenz; RPV, rilpivirine; ETR, etravirine; DOR, doravirine; PIs, protease inhibitors; LPV, lopinavir; ATV, atazanavir, DRV, darunavir;/r, ritonavir; cobi, cobicistat; INSTIs, integrase inhibitors; RAL, raltegravir; EVG, elvitegravir; DTG, dolutegravir; BIC, bictegravir; NRTIs, nucleoside reverse transcriptase inhibitors; TDF, tenofovir disoproxil fumarate; ABC, abacavir; 3TC, lamivudine; FTC, emtricitabine; TAF, tenofovir alafenamide; MVC, maraviroc; PK, pharmacokinetic; RBT, rifabutin

In addition, the recommendation of the drug interaction has covered the second-line anti-drugs. Most agents used in conventional DR-TB treatment regimens have no major PK drug-drug interactions with ART. An exception is moxifloxacin, which was found in a population PK study to have higher clearance and lower concentrations in patients with HIV-associated TB on efavirenz, possibly due to the latter's induction of moxifloxacin metabolism via UDP-glucuronosyltransferase (UGT). The clinical relevance of this is unknown, and no dose adjustments are currently recommended. Table 2 addresses the drug-drug interactions in the second line.

Table 2. Drug-drug Interaction with Bedaquiline.

Antiretroviral	Effect on Bedaquiline		Dose Adjustment and Comments
NNRTI			
EFV	↓↓ BDQ	Average steady-state concentrations were reduced by 52% (model-based prediction)	Risk of subtherapeutic BDQ concentrations and treatment failure: do not coadminister

NVP	= BDQ	A nonsignificant increase in average steady-state concentrations of BDQ (9%) and a decrease (5%) in M2 metabolite (PK model). Nonsignificant changes in BDQ AUC in clinical PK study.	Can be coadministered without dose adjustments
RPV	= BDQ	Not studied, but clinically relevant DDIs are not expected	Can be coadministered without dose adjustment
PI			
LPV/r	↑BDQ	3- and 2-fold increases in average steady-state concentrations of BDQ and M2 metabolite, respectively (model-based) 55 62% increased BDQ AUC in clinical DDI study	Avoid concomitant use when possible. Implement more frequent ECG monitoring for QT prolongation if used together.
Other PIs (ATV/r, DRV/r)	↑BDQ	Not studied; increased BDQ exposures expected	Avoid concomitant use when possible. Implement more frequent ECG monitoring for QT prolongation if used together.
INSTI			
DTG RAL	= BDQ	Not studied, but clinically relevant DDI not expected	Can be coadministered without dose adjustment
EVG/cobi	↑BDQ	Not studied; may result in increased BDQ concentrations	Avoid due to the potential risk of cardiac toxicity. Implement more frequent ECG monitoring for QT prolongation if used together.
NRTI			

TDF, ABC, 3TC, FTC	= BDQ	clinically significant DDIs not expected	Can be coadministered without dose adjustment
CCR5 receptor antagonists			
MVC	= BDQ	Not studied; clinically significant DDIs not expected	Can be coadministered without dose adjustment

NNRTIs, non-nucleoside reverse transcriptase inhibitors; NVP, nevirapine; EFV, efavirenz; RPV, rilpivirine; PIs, protease inhibitors; LPV, lopinavir; ATV, atazanavir, DRV, darunavir; INSTIs, integrase inhibitors; RAL, raltegravir; EVG, elvitegravir; cobi, cobicistat;/r, ritonavir-boosted; DTG, dolutegravir; NRTI, nucleoside reverse transcriptase inhibitors; TDF, tenofovir disoproxil fumarate; ABC, abacavir; 3TC, lamivudine; FTC, emtricitabine; TAF, tenofovir alafenamide; DDIs, drug-drug interactions;

The WHO guidelines for first-, second-, and third-line ART in adults, adolescents, pregnant women, and children in 2017 describe regimens in Table 3.

Table 3. The WHO guidelines for First-, Second-, and Third-Line ART in Adults, Adolescents, Pregnant Women, and Children in 2017.

Population	First-line regimens	Second-line regimens	Third-line regimens (alternative regimens)
Adults and adolescents (>10 years)	2 NRTIs+EFV	2 NRTIs+ATV/r or LPV/r[a]	DRV/r[b] + DTG[c] (or RAL) ± 1-2 NRTIs
		2 NRTI + DRV/r[b]	
	2 NRTIs+DTG	2 NRTIs+ATV/r or LPV/r	DRV/r[b]+ 2 NRTIs ± NNRTI
		2 NRTI + DRV/r	Optimize regimen using genotype profile.
Pregnant or breastfeeding women	2 NRTIs + EFV	2 NRTIs + ATV/r or LPV/r[a]	DRV/r[b] + DTG[c] (or RAL) ± 1-2 NRTIs
		2 NRTI + DRV/r[b]	
Children (0-10 years)	2 NRTI + LPV/r	If less than three years: 2 NRTIs + RAL[d]	RAL (or DTG)[f] + 2 NRTIs DRV/r[g] + 2 NRTIs DRV/r[g] + RAL (or DTG)[f] ± 1-2 NRTIs
		If older than three years: 2 NRTIs + EFV or RAL	
	2 NRTI + EFV	2 NRTIs + ATV/r[e] or LPV/r	

[a] RAL + LPV/r can be used an alternative second-line regimen in adult and adolescents.

[b] In PI-experienced patients, the recommended DRV/r dose should be 600 mg/100mg twice daily

[c] Safety and efficacy data on the use of DTG in adolescents younger than 12 years and pregnant women are not yet available.

[d] If RAL is not available, no change is recommended unless in the presence of advanced clinical disease progression of lack of adherence, specifically because of poor palability of LPV/r. In this case, switching to a second-line NVP-based regimen should be considered. Based on approval of the use of EFV in children less than 3 years of age, an EFV-based regimen could be considered as an alternative. However, more data are needed to inform how best to use EFV in this population.

[e] ATV/r can be used an alternative to LPV/r in children older than 3 months of age. However, the limited availability of suitable formulations for children younger than 6 years of age, the lack of an FDC and the need for separate administration of RTV booster should be considered when choosing this regimen.

[f] RAL can be used in children failing PI-based second-line treatment when DTG is not available and when RAL has not been not used in previous regimen. DTG is currently approved only for children 12 years and older; however, studies are ongoing to determine dosing in younger children, and approval for lower age groups is expected in the near future.

[g] DRV/r should not be used in children younger than 3 years of age.

3TC lamivudine, ABC abacavir, ATV atazanavir, AZT zidovudine, DTG dolutegravir, EFV efavirenz, FTC emtricitabine, LPV lopinavir, NRTI nucleoside reverse-transcriptase inhibitpr, NVP nevirapine, PI protease inhibitor, r or RTV ritonavir, RAL raltegravir.

It encourages national programs to create policies for second and third-line ART. Third-line regimens must comprise novel medications with a low risk of cross-resistance to previously used regimens, such as INSTIs, second-generation NNRTIs, and PIs. Furthermore, patients who fail a second-line treatment and have no new ARV medication alternatives should remain on a tolerated regimen.

METHODOLOGY

❖ Overview of Methodology

This report is based on modest quantitative research that carried out the survey. This included document evaluations and key responses. The APN+ offered financial assistance for data collection in four countries: Bangladesh, Cambodia, Indonesia, and Malaysia. There are four key informants, one from each nation, and at least 50 key respondents from each country to complete the questionnaire. The 50 key

respondents were chosen using a purposive selection approach to provide a valid and accurate sample. People Living with HIV (PLHIV) from heterosexual and LGBTQ+ populations who use ARVs, DAAs, and TB medications are eligible to participate.

❖ Document Review Through Desk Review

The document evaluation comprised published reports, guidelines, strategy papers, and policy documents related to literature reviews and survey questionnaires. This report uses keywords to perform the survey questionnaire. The keywords are derived from a variety of credible sources. The keywords of accessibility to medication are 1) availability, 2) affordability, and 3) quality (WHO, 2001; Aidsfonds, 2024).

WHO Implementation of Accessibility to Medication for National Drug Policy Establishment (2001);

Accessibility refers to the ease with which people may get and utilize healthcare services or treatments. It takes into account geographical closeness, transportation, infrastructure, and social constraints. In the context of HIV, hepatitis and tuberculosis treatments, accessibility refers to the ease with which these medications may be obtained and used, taking into account both physical and non-physical impediments, with three keywords, such as:

Availability is the existence of healthcare services, resources, or drugs in a certain region or system. In the context of HIV, Hepatitis, and tuberculosis medicines, it indicates the physical presence of these medications inside healthcare institutions or pharmacies.

Affordability refers to the financial feasibility of accessing healthcare services and pharmaceuticals. In the case of HIV, hepatitis, and tuberculosis treatments, it refers to the expense of these medications in relation to the economic capability of people or the community.

Quality refers to the level of quality or superiority inherent in a product, service, or process. In the context of HIV, hepatitis and tuberculosis treatments, it includes traits like dependability, efficacy, safety, and consistency, which represent how well a product or service meets or exceeds user expectations and requirements.

❖ Development and Finalization of Data Collection

Data collection strategies were developed utilizing easily available, standardized quantitative questionnaire sets that included questions customized to the local area. The tools were submitted for assessment, comments, and suggestions before being validated and approved for use. In-country partners created a list of stakeholders, including primary receivers (PR), sub-recipients (SR), and Key Population Networks from Bangladesh, Cambodia, Indonesia, and Malaysia. The

surveys are translated into four languages: Bengali, Khmer, Bahasa Indonesia, and Melayu.

❖ Field Data Collection

Data collection in the field began from November 2023 to January 2024 through each key informant in each country. This key informant from the key population network of Bangladesh, Cambodia, Indonesia, and Malaysia disseminated the survey online. As aforementioned, the 50 key respondents were required to answer several questions pertaining to the ARVs, DAAs, and TB medicine provision in each country and the condition of the medicine subsidy supported by the government. This helped to develop an understanding of the current ARVs, DAAs, and TB medicine availability, accessibility and affordability for better improvement.

❖ Data Analysis and Finalization of Report

After data collection, the material was analyzed descriptively using SPSS. In terms of qualitative data, the material was organized and examined for relevance. The quantitative data proved the existing market for these drugs, while the qualitative data highlighted the social difficulties surrounding their accessibility. This data was compiled and presented to be given additional suggestions and information.

❖ Limitation

There were a few limitations to the evaluation. Due to time limits, it was not feasible to contact formal governments, including a small number of critical informants. Furthermore, due to the time constraints of this assessment, it is not a comprehensive report on the market and patent of ARVs, DAAs, and TB medicines for key population groups; however, it does capture a snapshot of the issues they face and makes some recommendations to address rights to accessibility, availability, and affordability in order to strengthen rights-based Universal Health Coverage (UHC). The matching program does not cover DAAs extensively; hence, further suggestions will be made to assist PLHIV in gaining larger access without facing prejudice and stigma.

RESULT

❖ Overview of the Context for Equity and Social Justice

Universal health coverage (UHC) is a key pillar in fostering social fairness and population health. According to the International Society for Equity in Health, "equity is the absence of systematic and potentially remediable differences in one or more

aspects of health across populations or population groups defined socially, economically, demographically, or geographically" (Starfield 2002). Equality in health services is founded on the premise that everyone has an equal right to receive health care. Equity goes a step further, addressing the reality that certain groups in each society have less access to health care than others and recommending methods to alleviate this disparity. Achieving equity in a health program entails effectively reaching individuals who are otherwise disadvantaged and less able than others to get health care.

The Declaration of Alma Ata, issued in 1978, signaled a significant transition from the individualistic biomedical paradigm of physician-centered health policy to community-centered care (Walt and Rifkin, 1990). The Declaration explicitly emphasized excellent, cheap, and accessible primary care as critical to achieving the right to health. Dr. Halfdan Mahler, then Secretary General of the World Health Organization (WHO), championed the humanitarian ideals of 'equity and social justice,' which culminated in the Declaration's lofty aim of 'Health for All' by 2000.

Continuously the situation of UHC in each country in this report can be summarized in Table 4.

Table 4. Summary of UHC Profile in Each Country

Characteristic	Group 1	Group 2	Group 3
Status of UHC Policies and Programs	Agenda setting, piloting new programs and developing new systems	Initial programs and systems are in place, and implementation is in progress; need further system development and capacity building to address the remaining uncovered population	Strong political leadership and citizen demand lead to new investments and UHC Policy reforms, systems and programs developed to meet new demands
Status of Health Coverage	Low population coverage at the early stage of UHC	A significant share of the population gains access to service financial protection, but population coverage is not yet universal, and coverage gaps in	Universal population coverage has been achieved, but the country is focusing on improving financial protection and the quality of services.

		access to services and financial protection remain.	
Countries	Bangladesh Cambodia	Indonesia	Malaysia

(Source: World Bank, 2014; ILO, 2021a; ILO, 2021b.)

This paper summarizes demographic statistics for all nations by gender, including age and income from Bangladesh, Cambodia, Indonesia, and Malaysia. Figure 1 depicts the genders of significant populations.

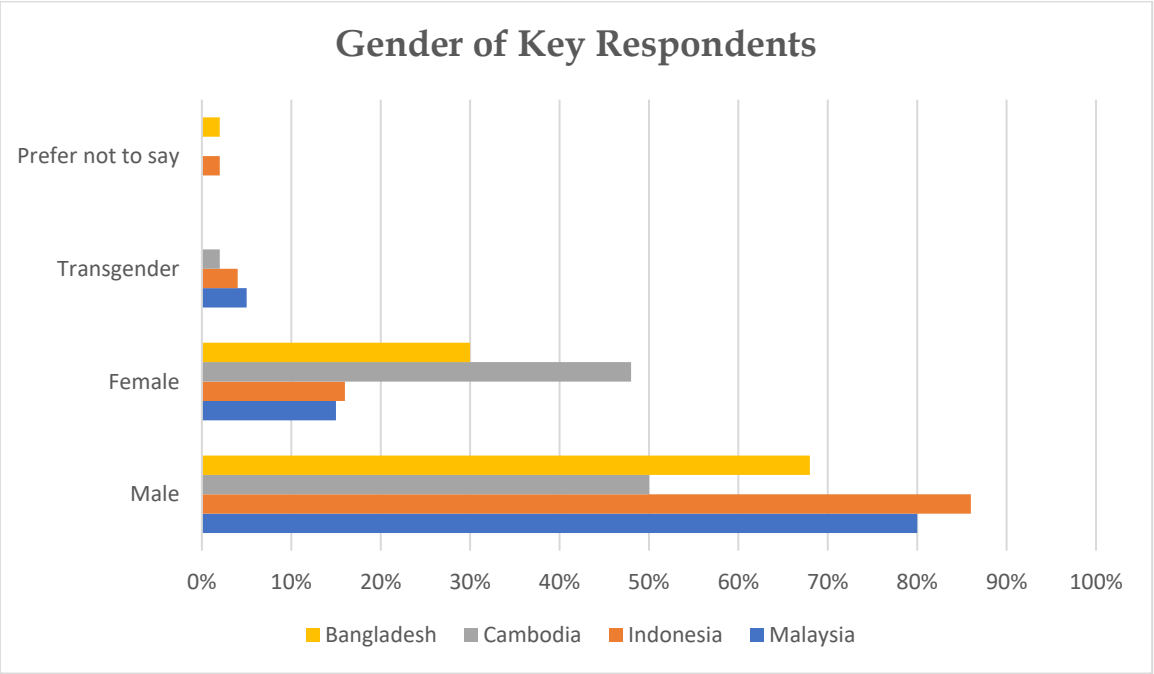


Figure 1. Gender of Key Respondents

Overall key respondents' age from all countries are male. Bangladesh's key respondents are 68% male, 30% female, and 2% transgender. In Cambodia, male key respondents account for 50%, while females account for 48% and 2% choose not to tell. Indonesia's key respondents are 86% male, 16% female, 4% transgender, and 2% choose not to say. In addition, 80 percent of Malaysian key respondents are men, 15 percent are females, and 5 percent are transgender. Continuously, the report describes the key population's age in Figure 2.

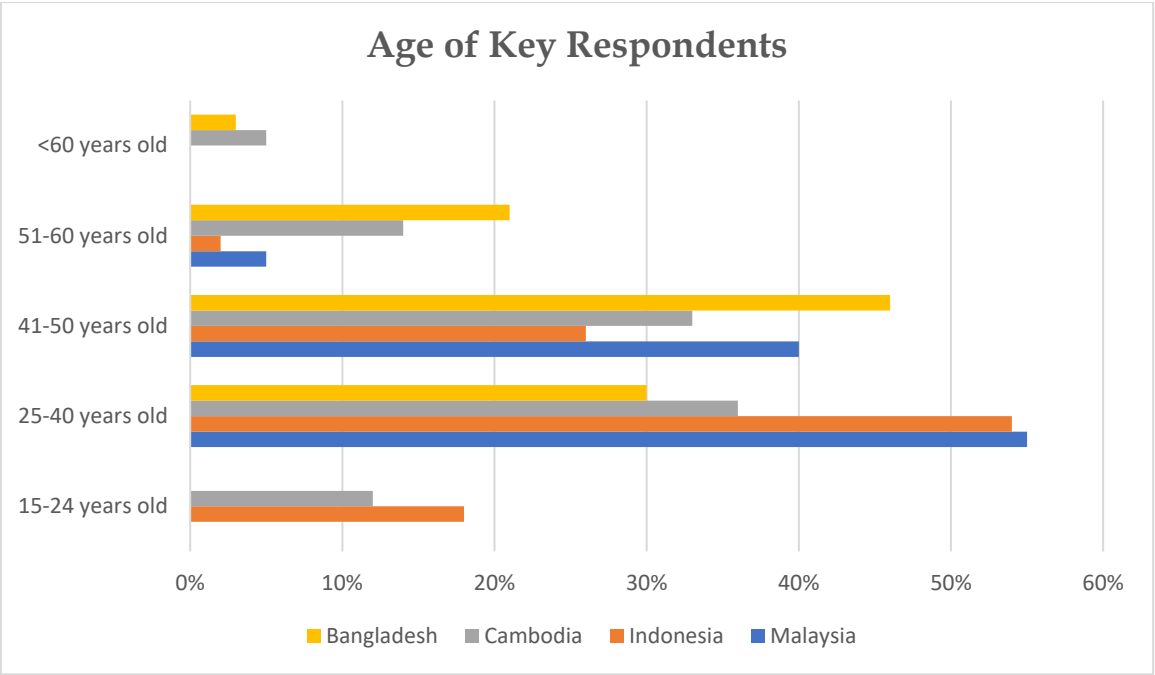


Figure 2. Age of Key Respondents

Overall, the key respondents' age from all countries are in the range age of 25 – 40 years old. According to this survey, Bangladesh's main responders vary in age from 25 to 40 years old (30%), 41 to 50 years old (46%), 51 to 60 years old (21%), and beyond 60 years old (3%). The age distribution of key respondents in Cambodia is as follows: 12 percent are between 15 and 24 years old, 36 percent are between 25 and 40 years old, 33 percent are between 41 and 50 years old, 14 percent are between 51 and 60 years old, and 5 percent are beyond 60. The age distribution of Indonesia's main responders is as follows: 18% are 15-24 years old, 54% are 25-40 years old, 26% are 21-50 years old, and 2% are 51-60 years old. Furthermore, the age distribution of Malaysian key responders is as follows: 55% are 25-40 years old, 40% are 41-50 years old, and 5% are 51-60 years old. The income of respondents is also described in Figure 3.

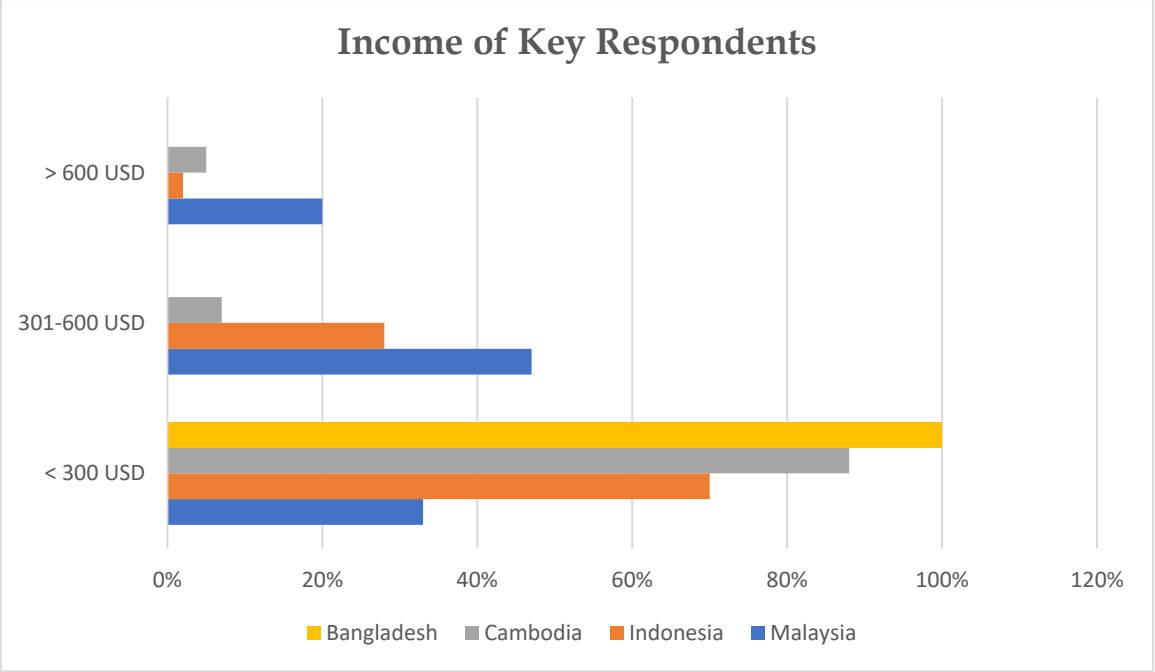


Figure 3. Income of Key Respondents

Overall, the major responders' incomes from all nations are less than 300 USD each month. In the instance of Bangladesh, the key respondents' income is 100 percent for income of less than $300 per month. In Cambodia, 88 percent of key respondents' income is less than 300 USD, 7 percent is between 301 and 600 USD, and 5 percent is more than 600 USD. In the Indonesia case study, 70% of key respondents had an income of less than 300 USD, 28% had an income of 300 to 600 USD, and 2% had an income of more than 600 USD. Furthermore, Malaysian key respondents' income includes 33 percent with less than 300 USD, 47 percent with between 301 and 600 USD, and 20 percent with more than 600 USD.

In the next section, the report elaborates on the availability, accessibility, and affordability of ARVs, DAAs, and TB medicine in each country.

❖ Availability, Accessibility, and Affordability of ARVs, DAAs, and TB Medicine in Bangladesh

As previously said, Bangladesh's demographics comprise three kinds of gender key respondents: the majority are male, female, and transgender, with a dominating age range of 41-50 and a total income of less than 300 USD. In reality, all respondents consume just ARVs, and 21 percent of important respondents use both ARVs and TB treatment, as seen in Figure 4.

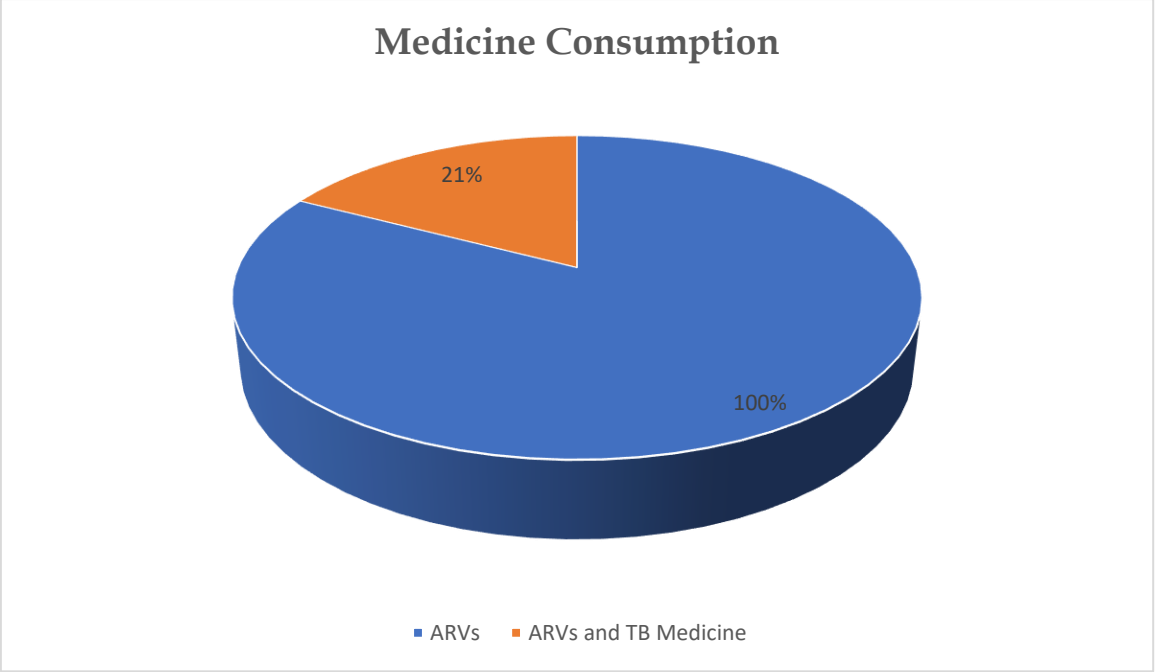


Figure 4. Bangladesh of Key Medicine Consumption

In addition, the key respondents elaborate more on their medicine consumption each time, as described in Figure 5.

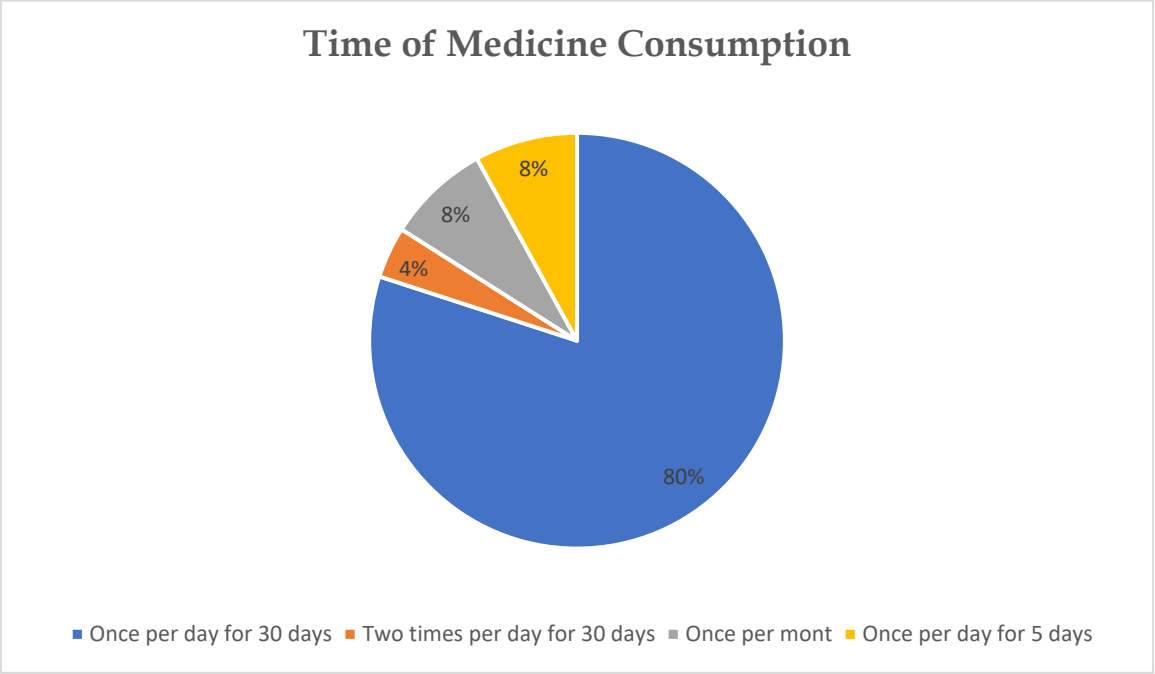


Figure 4. Time of Medicine Consumption in Bangladesh

In the Bangladesh case study, 80% of individuals take at least once a day for 30 days, 4% take twice a day for 30 years, and 8% take once a month and once a day for five days. In fact, almost 4% of important responders used the medication once daily for 13 years and one year, respectively.

Universal health coverage (UHC) is encouraged to cover the need for medicine inclusively. Eighty percent of key respondents mentioned government provides free drugs, while 20 percent of them disagree with providing free drugs by the government. In fact, the key respondents elaborate on the list of subsidies and non-subsidized medicines, including the availability in the Bangladeshi market in Table 5.

Table 5. Type of Medicine Available and Subsidized and Non-Subsidized by Government in Bangladeshi Market

Type of Medicine	Government Subsidy	Non-Government Subsidy	Uncertain availability in the market
Abacavir 600mg	✓	-	-
2 FDC	✓	-	-
4 FDC	✓	-	✓
Angilock 50mg	✓	-	✓
Atova 10mg	✓	-	✓
Avonza: TDF + 3TC + EFV 400 mg	✓	-	-
Cap, Omeprazole 20mg	✓	-	✓
Cap. Seclo 20mg	✓	-	-
Dolutegrivir 150mg	✓	-	-
Lamivudine 300mg,	✓	-	-
Monas 10mg	-	✓	✓
Nasal Drop- Antazol	✓	-	✓
Osertil 50mg	✓	-	-
Paracitamal 500mg	✓	-	✓
Pyrovit Omeprazol 20mg	-	✓	-
Seclo 20mg	-	✓	✓
Tab. Anclog 75mg,	✓	-	-
Tab. Calcium	-	✓	✓
Tab. Clofenac 50mg	-	✓	✓
Tab. Comet 500mg	✓	-	✓
Tab. Fenadin	✓	-	✓
Tab. Napa	✓	-	-
Tab. Osartil 50mg	✓	-	✓
Tab. Vitabion	-	✓	✓
Tenofovir	✓	-	-

Table 5 reveals that various non-subsidy drugs are available in Bangladesh, including Monas 10mg, paracetamol 500 mg, Pyrovit Omeprazol 20mg, Tab. Calcium, and Tab. Clofenac 50mg, and Tab. Vitabion. Significant responders said that several ARV and tuberculosis medications are accessible in the Bangladeshi market, including Monas 10 mg, Pyrovit Omeprazole 20 mg, Paracitamal 500 mg, Calcium, and dolutegravir. Figure 5 depicts the number of key responders taking the drug based on the kind provided.

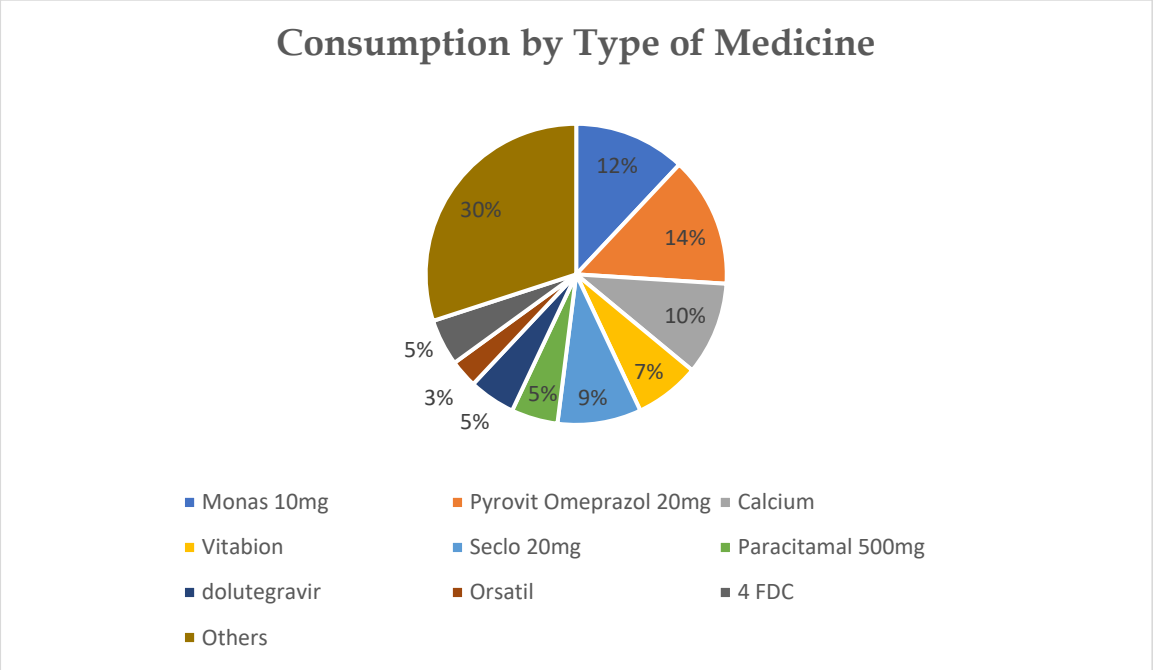


Figure 5. Consumption by Type of Medicine in Bangladesh

The popular medicines for consumption in the Bangladeshi market are Pryrovit Omeprazole 20 mg for 14 percent, Monas 10 mg for 12 percent, Calcium for 10 percent, Seclo 20 mg for 9 percent, Vitabion for 7 percent, Paracitamal, Dolutegravir, and 4 FDC for 5 percent respectively, Orsatil for 3 percent and other types for 30 percent. In fact, the most non-subsidized medicines are also the most consumed medicines in Bangladesh, which is mostly non-subsidized medicine from the government, and the price is around 1 to 2 dollars per medicine per pack. With this pricing, 12.5 percent of key respondents believed the drugs were extremely reasonable, 16.7 percent felt very affordable, 58% felt somewhat affordable, 8.3 percent felt not affordable, and 4.2 percent were unsure, as shown in Figure 6.

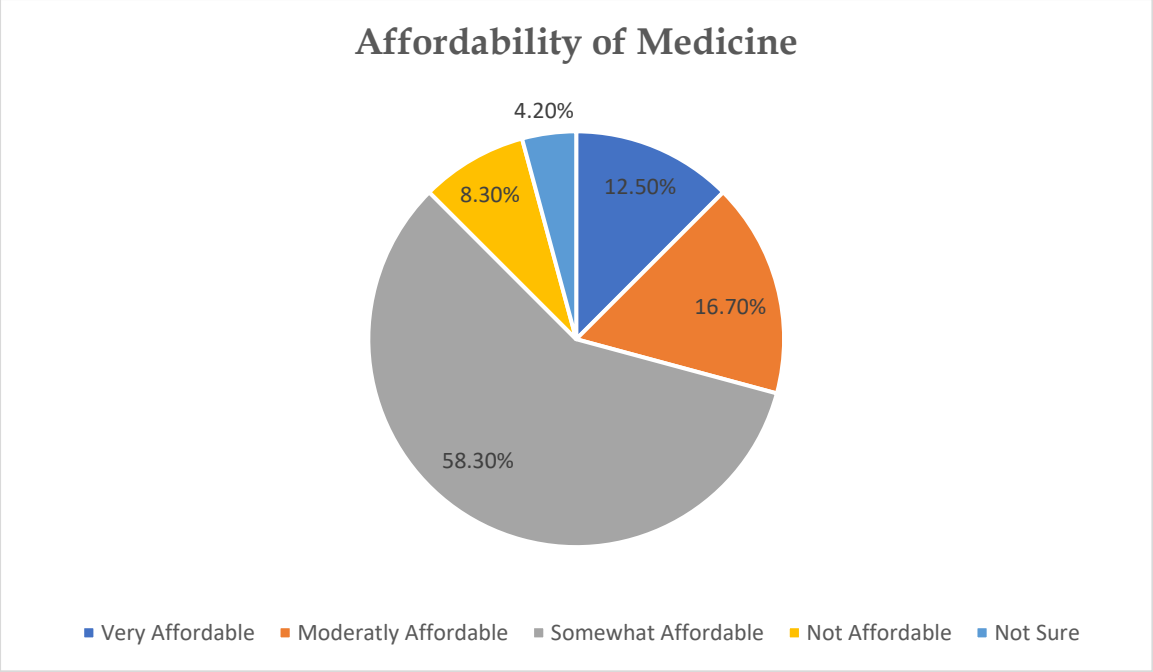


Figure 6. Affordability of Medicine in the Bangladeshi Market

Furthermore, significant respondents expressed their desire for completely free medication, an adequate supply of medicines in government hospitals, and the government to take suitable pharmaceutical measures, including the Bangladeshi key population hope that the medicine can be produced in the county. As a result, Bangladesh's case study might infer that the supply of medication is unpredictable, particularly given the government's lack of subsidies and the fact that the core population consumes the majority of it. It raises additional questions about the quality of access to these medications. In reality, with an income of less than 300 USD, the important populations experience the cost of medications in neutral circumstances.

❖ Availability, Accessibility, and Affordability of ARVs, DAAs, and TB Medicine in Cambodia

Similarly to Bangladesh, Cambodia's demographics comprise three kinds of gender key respondents: the majority are female, male and transgender, with a dominating age range of 25-40 and the majority of a total income of less than 300 USD. In reality, all respondents consume just ARVs 100 percent, and 17 percent of important respondents use both ARVs and TB treatment, as seen in Figure 7.

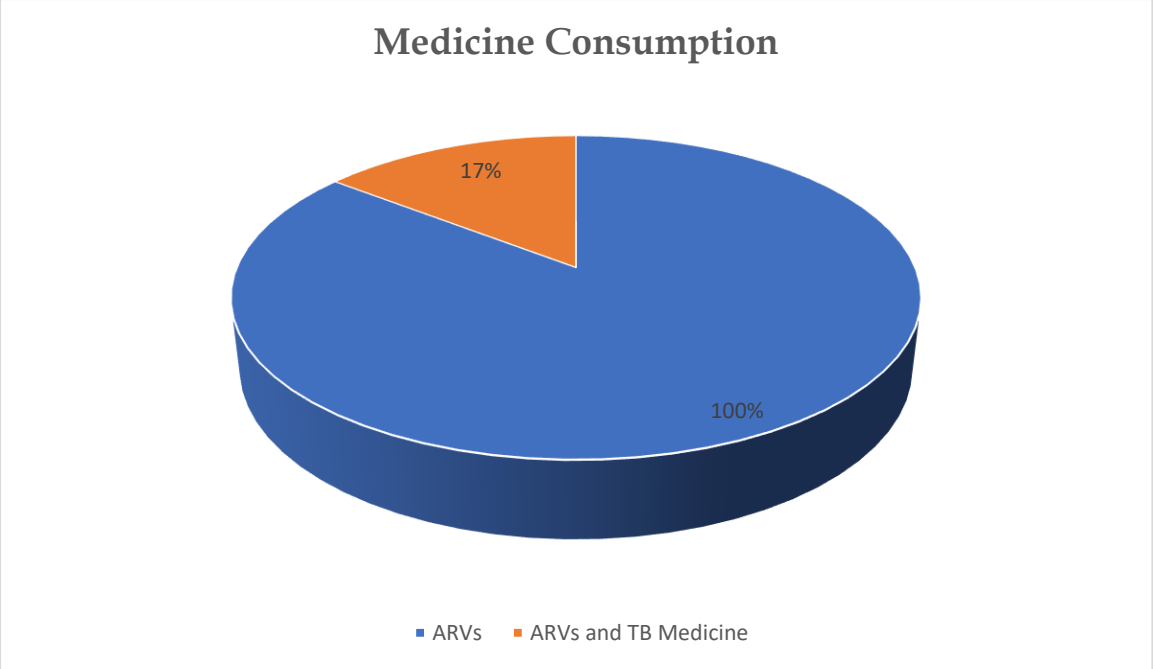


Figure 7. Cambodia of Key Medicine Consumption

In addition, the key respondents elaborate more on their medicine consumption each time, as described in Figure 8.

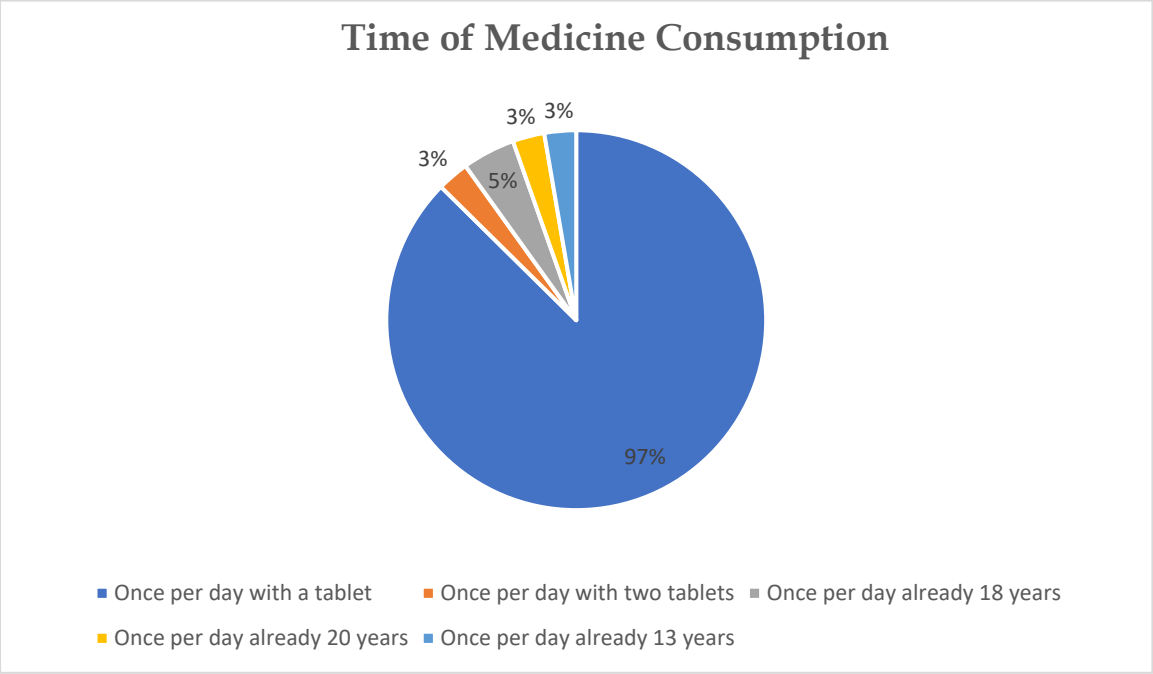


Figure 8. Time of Medicine Consumption in Cambodia

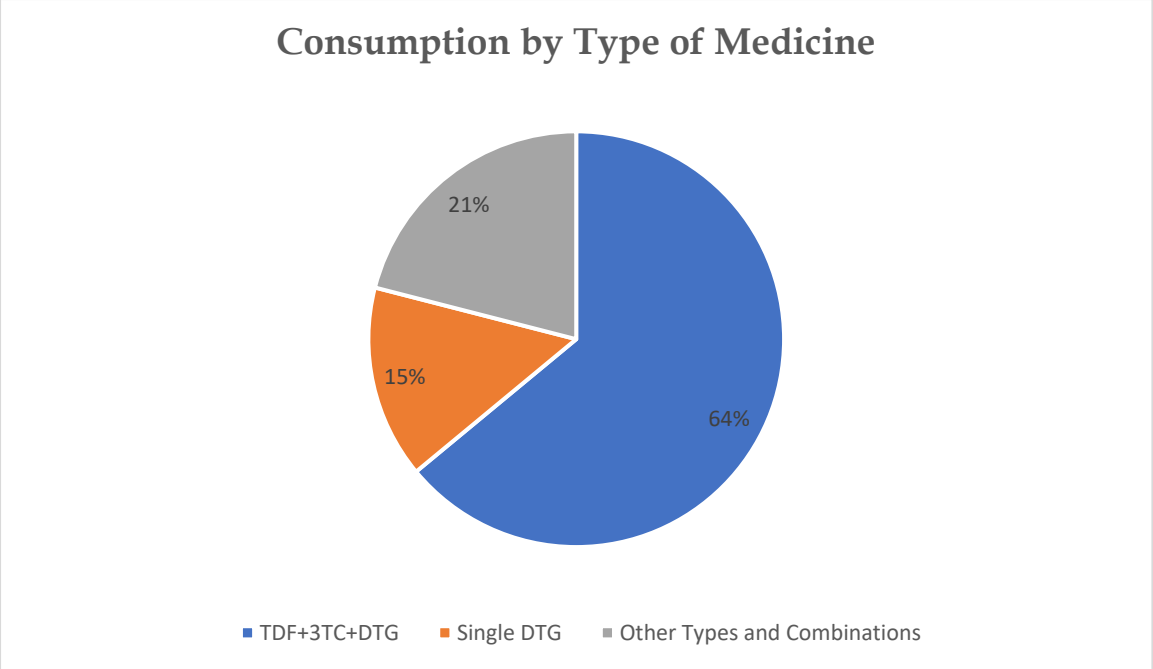
In the Cambodia example study, 97% of people take at least one pill each day, with barely 3% taking two. In fact, 5% of crucial respondents used the prescription once daily for 18 years, while 3% of essential respondents took it once daily for 13 years and more than 20 years, respectively.

To attain Universal Health Coverage (UHC), it is advised that drugs be available on the market for all requirements. In Cambodia, 100 percent of key responders said the government supports the drugs. However, a large responder said that the drug might cost between 70 and 80 USD each year. Table 6 presents a list of government-subsidized pharmaceuticals in the Cambodian market.

Table 6. Type of Medicine Available and Subsidized by Government in Cambodian Market

Type of Medicine	Government Subsidy	Uncertain availability in the market
ABC	✓	-
Atazanavir	✓	✓
DTG	✓	✓
EFV	✓	-
Lamivudine	✓	-
TDF	✓	-
TDF +3TC+ DTG	✓	✓
Tenofovir	✓	-

Table 6 shows that unclear availability medications include Atazanavir, DTG, and a combination of TDF+3TC+DTG. Almost all-important responders ingested the combo of TDF+3TC+DTG (64 percent). Fifteen percent of key responders used a single DTG tablet, while 21 percent took ABC, Atazanavir, Lamivudine, Tenofovir, a combo of TDF+3TC+EFV, and Atazanavir+Tenotovir. Figure 9 displays the number of key responders taking the medicine according to the kind offered.



In Cambodia, significant responders highlighted the historical and current viability of government-subsidized medication. Figure 10 shows that 57.1 percent of key respondents believe the drugs are very affordable, 14.3 percent believe the medicines are moderately affordable, and 2.4 percent believe medicines are somewhat affordable and simultaneously not sure. In this case, important responders state that regenerating soft infrastructure, such as government and health departments, is being addressed to close the gap in drug availability.

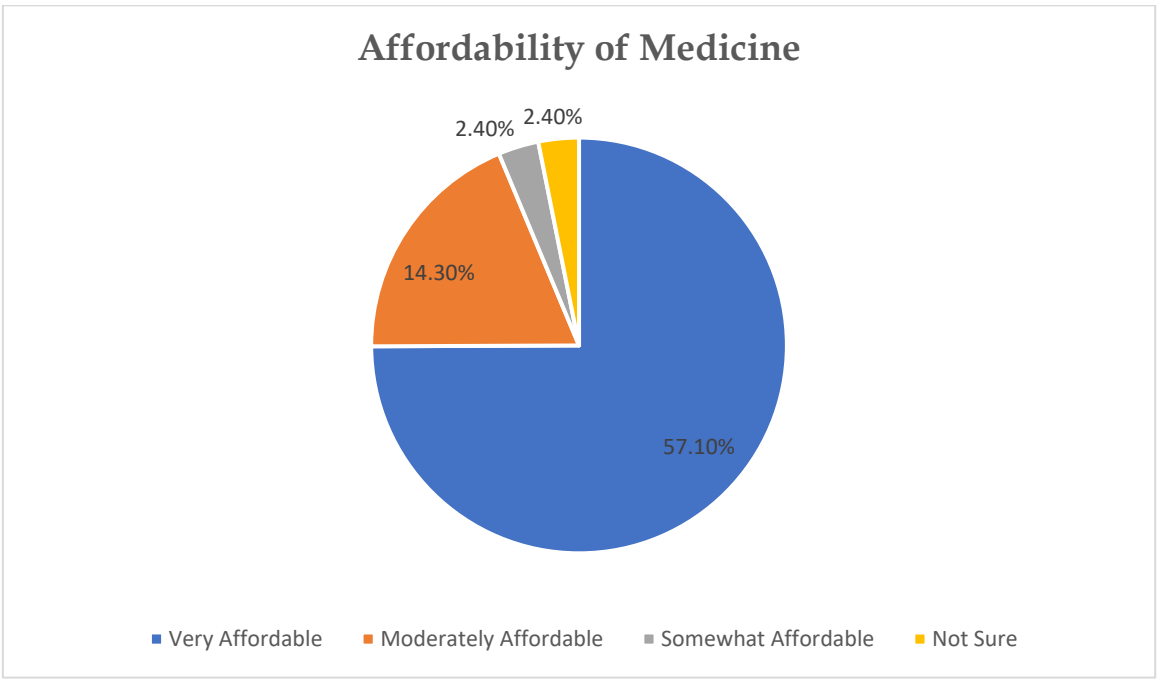


Figure 10. Medicine Feasibility in Cambodia

As a consequence, the government safeguards Cambodia's critical population as part of the UNAIDS 90-90-90 objective. The Cambodian government has shown serious management by subsidizing ARV and TB medications in the nation.

❖ Availability, Accessibility, and Affordability of ARVs, DAAs, and TB Medicine in Indonesia

As previously stated, Indonesia's demographics include three types of gender key respondents: male, female, and transgender. The majority are between the ages of 25 and 40 and have a total income of less than USD 300. In reality, all respondents consume just ARVs, and 22 percent of important respondents take both ARVs and DAAs, as shown in Figure 11.

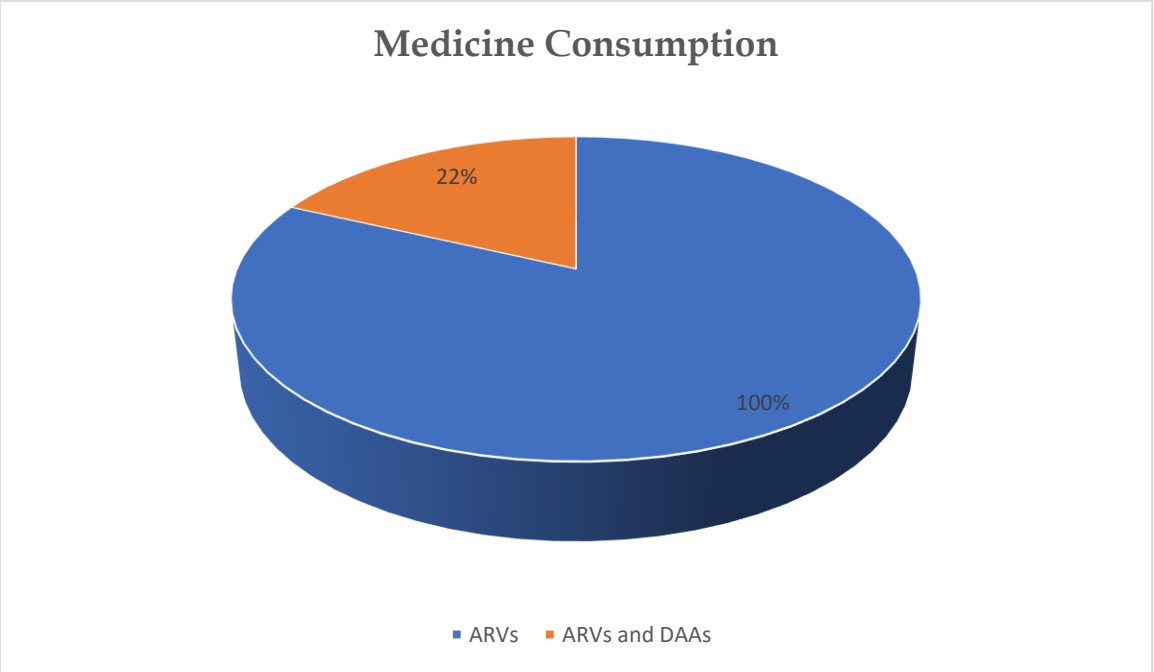


Figure 11. Medicine Consumption in Indonesia

In addition, the key respondents elaborate more on their medicine consumption each time, as described in Figure 12.

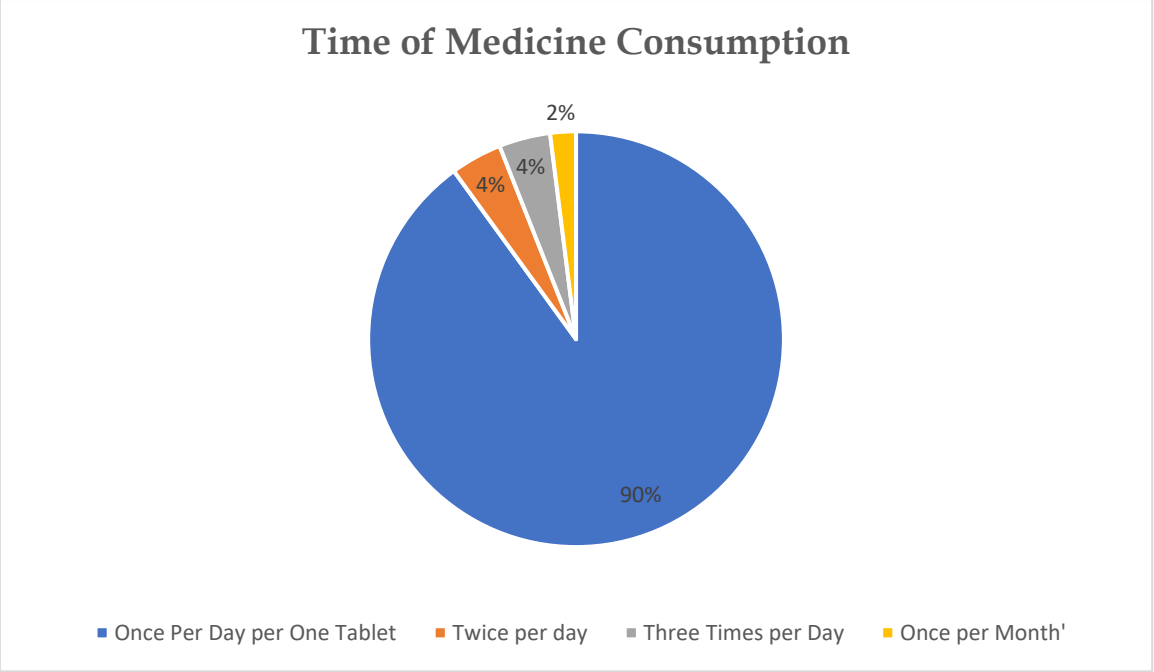


Figure 12. Time of Medicine Consumption in Indonesia

Figure 12 shows that 90% of key respondents consume every day, taking 1 to 2 pills per day, 4% consume twice and three times per day, and 2% consume once a month. Some significant respondents said that they must take this drug for the remainder of their lives, and one respondent has already been taking it for at least four years.

According to the literature study, Indonesia's government has always strived for comprehensive Universal Health Coverage (UHC) in order to meet the UNAIDS targets of 95-95-95. In Indonesia, 82% of key respondents stated that the government subsidized the medications, while 18% said the government did not support the treatment. Table 7 lists the medications available in the Indonesian market.

Table 7. The List of Pharmaceuticals in the Indonesian Market

Type of Medicine	Government Subsidy	Non-Subsidy	Uncertain availability in the market
Abacavir	✓	-	-
Acriptega	✓	-	-
Alprazolam	-	✓	✓
Aluvia,	✓	-	-
Dakla & Sofos	-	✓	✓
Dolutegravir sodium	✓	-	-
Duviral	✓	-	✓
Efavirenz	✓	-	✓
Lamivudine	✓	-	✓

MyHep	✓	-	✓
Nevirapine (neviral)	✓	-	-
SUBOXONE	-	✓	✓
TDF +3TC+ DTG (TLD)	✓	-	✓
Tenofovir	✓	-	-
Tenofovir, Lamivudine, Efaviren (TLE)	✓	-	-

Table 7 lists the medicines accessible in the Indonesian market, the majority of which are supported by the government. However, the Indonesian government does not promote Alpazolam, Dacla & Sofos, or Subuxone, and their supply is questionable. Following that, several government-subsidized drugs, such as Duviral, Efaviren, MyHep, and TLD, have questionable availability. Furthermore, 52 percent of key respondents ingested TLD (TDF+3TC+DTG), 19 percent consumed TLE, 10 percent consumed Subuxone, 6 percent took Dakla & Sufos, and 13 percent used other sorts. Figure 13 depicts the consumption of medication according to the type.

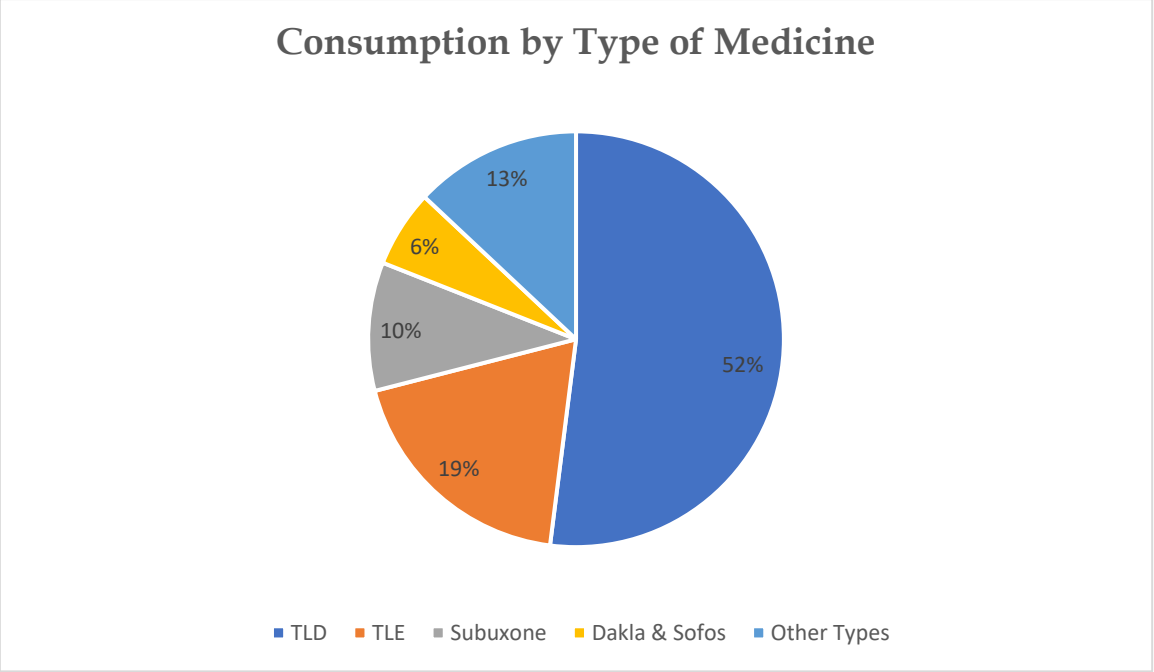


Figure 13. Consumption by Type of Medicine in Indonesia

Aside from the availability of drugs, they claimed that the prices ranged from $1 per pill to $100 per box. In terms of cost, 42 percent of Indonesian key respondents thought it was fairly inexpensive, 34 percent thought it was extremely affordable, 12 percent thought it was somewhat affordable, 2 percent thought it was not cheap, and 10 percent were unsure. Figure 14 depicts a visual representation of affordability.

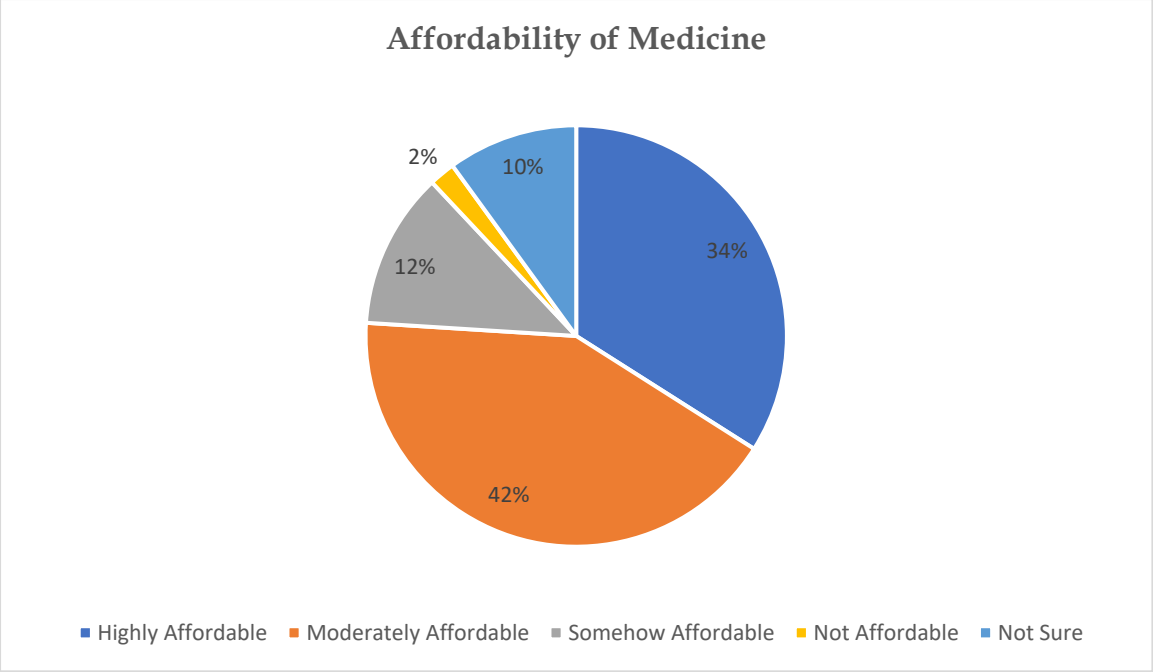


Figure 14. Affordability of Medicine in Indonesia

Furthermore, significant respondents thought that the supply of ARV treatment should always be manageable, particularly given the large variety of drugs accessible in clinics and pharmacies. Like Bangladesh, the main populace expects that medication may be manufactured in the nation. As a consequence, unlike Bangladesh and Cambodia, Indonesia's Key Population is dominated by ARV and DAA users or hepatitis patients. Through this condition, Indonesia will continue to meet the UHC inclusiveness objective.

❖ Availability, Accessibility, and Affordability of ARVs, DAAs, and TB Medicine in Malaysia

As previously stated, Malaysian demographics include two types of gender key respondents: male and female, with one of the key respondents claiming to be part of the LGBTQ+ community. The majority are between the ages of 25 and 40 and have a total income of between 301-600 USD. In fact, all respondents consume just ARVs, and 20 percent of important respondents take both ARVs and TB medicine, as shown in Figure 15.

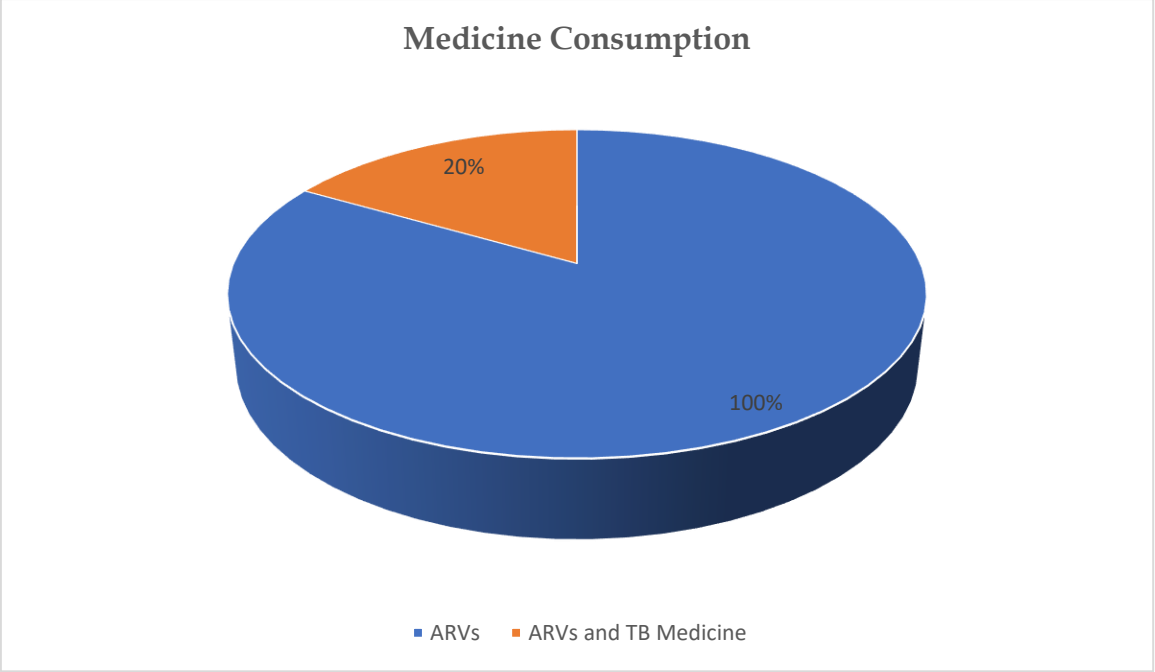


Figure 15. Medicine Consumption in Malaysia

In addition, the key respondents elaborate more on their medicine consumption each time, as described in Figure 16.

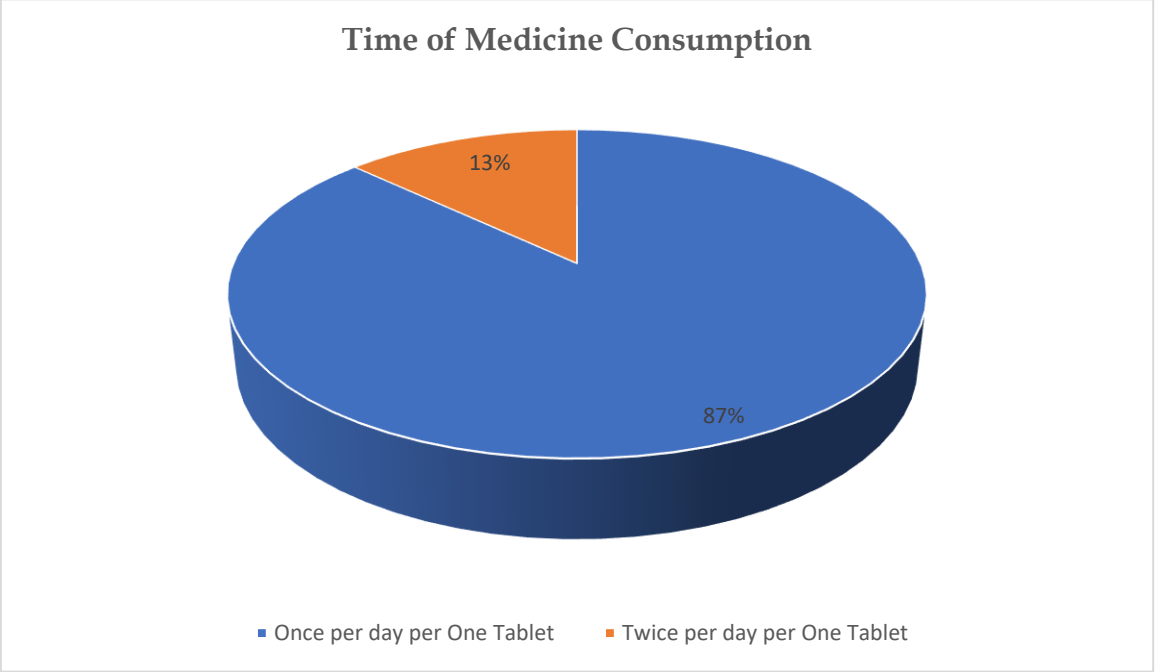


Figure 16. Time of Medicine Consumption in Malaysia

Figure 16 shows that 87 percent of key respondents take a tablet of medicine once per day, while 13 percent of them take a tablet of medicine twice per day. Some key respondents have consumed the medicine since 2016 and also for nearly ten years.

Similar to other countries, the key respondents will consume the medicine for a long time.

According to the literature study, Malaysia's government has always strived for comprehensive Universal Health Coverage (UHC) in order to meet the UNAIDS targets of 95-95-95 similar to Indonesia. In Malaysia, 100 percent of key respondents stated that the government subsidized the medications. Table 8 lists the medications available in the Malaysian market.

Table 8. The List of Pharmaceuticals in the Malaysian Market

Type of Medicine	Government Subsidy	Uncertain availability in the market
ABC	✓	-
DOLUTEGRAVIR	✓	-
Efamat	✓	-
Efavirenz	✓	-
Emtricitabine,	✓	-
Isoniazid (75mg)	✓	-
Limuvudine	✓	-
LPV/r	✓	-
Neveripe	✓	-
Pyridoxine (10mg)	✓	-
Rifampicin (150mg)	✓	-
sodium fusidate	✓	-
TDF + 3TC + EFV 400 mg	✓	-
Tenof-EM	✓	-
Tenofovir	✓	-
Zidovudine	✓	-

Table 8 displays the availability of medicines in the Malaysian market. The government supports all drugs and says that the drugs are always accessible when needed. However, only 2 percent of key respondents mentioned that somehow, the Efavirenz 200mg, LPV/r and ABC are uncertainly available. In Malaysia, 26 percent of key respondents use the combo of Tenof-Em and Efavirenz. Tenof-EM+Efamat, TLD, and Tenof-Em + Dolutegravir followed with 13 percent each, and other varieties with 22 percent. Figure 17 displays the consumption of medications by kind.

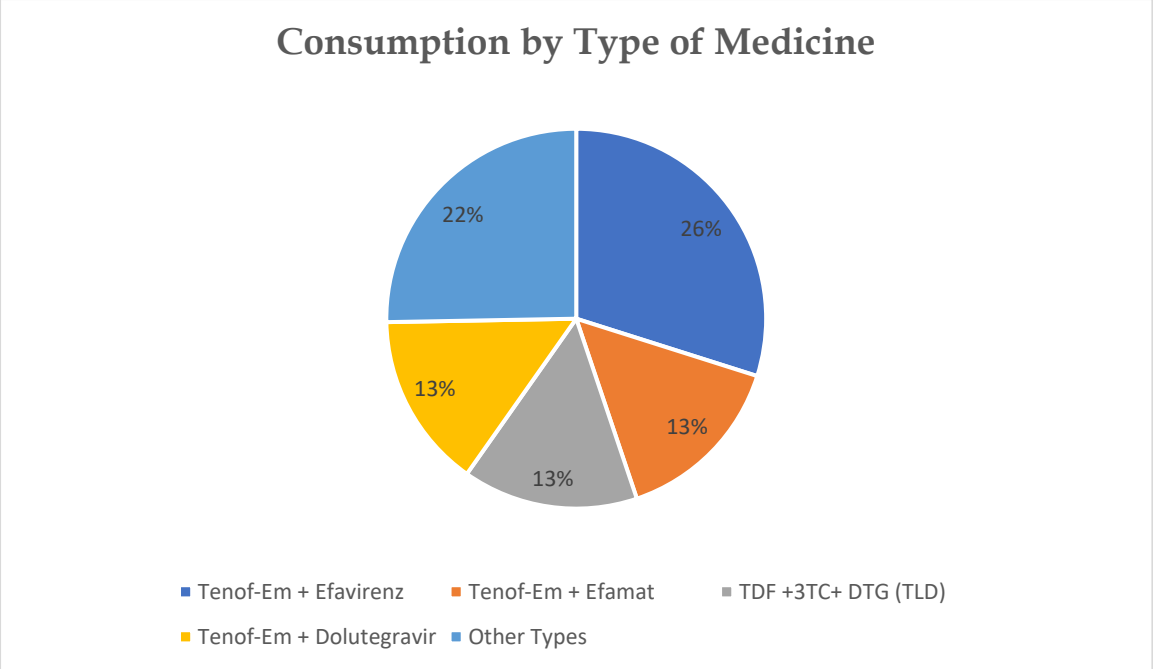


Figure 18. Consumption by Type of Medicine in Malaysia

Because of the government's complete backing, 70% of Malaysians feel that medication is very inexpensive, 20% fairly affordable, and 10% slightly affordable. Figure 19 shows a graphic depiction of affordability.

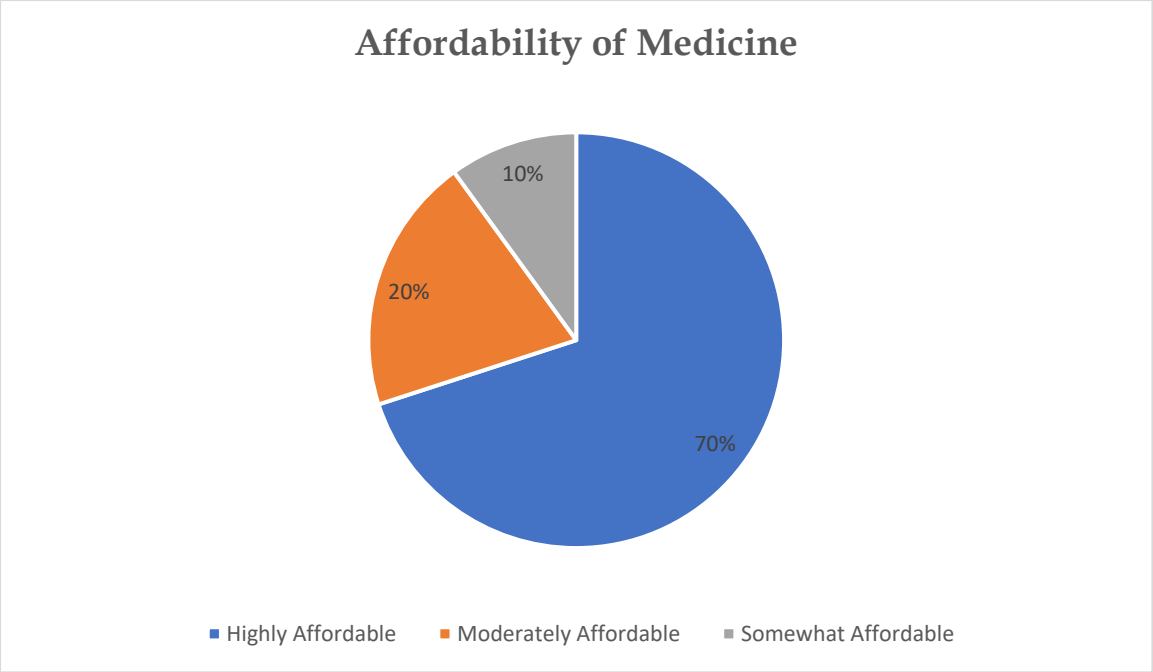


Figure 19. Affordability of Medicine in Malaysia

Furthermore, a considerable number of respondents said that technology should be integrated into the healthcare system. Some of them want the government

to establish a healthcare internet delivery business via government subsidiaries. Free delivery may help with our everyday expenditures. Because of their poor self-esteem, some ARV patients are unable to obtain suitable occupations with a steady source of income. Furthermore, many vital drugs must be broadly patented in order for them to be distributed by multiple vendors. Aside from that, it is important to promote and educate people about linked disorders by various methods. The need to educate about WHO-recommended drugs is also a crucial aspect of being an advocate. As a consequence, Malaysia has already met the minimum need for UHC; nevertheless, to attain quality and ease of access, soft infrastructure must be updated and scaled up using technology.

Overall, each country has tried to provide ARVs, DAAs and TB medicine inclusively for all who need them. With the infographic described above, the availability and affordability levels have been described in the case of each country. With most income obtained by key respondents less than 300 USD per month, the affordability condition is in the level of very affordable in Malaysia, moderately affordable in Indonesia and somewhat affordable in Bangladesh. Furthermore, availability circumstances differ by nation, as detailed in Annex 1 for Bangladesh, Annex 2 for Indonesia, and Annex 3 for Malaysia.

EVALUATION

❖ Evaluation of ARVs, DAAs, and TB Medicine Availability

According to the data studied, the governments of Bangladesh and Indonesia supply more than 80% of drugs, while Cambodia and Malaysia provide 100% of prescriptions. In reality, non-subsidy medicine has not been offered on the market in Bangladesh or Indonesia, despite the availability of subsidized medication in both countries. As a consequence, availability remains an issue, particularly in Bangladesh, Cambodia, and Indonesia.

In the instance of Bangladesh, where ARVs and TB drugs are the most often used in this case study, it has been acknowledged that the government has achieved tremendous success in improving ARV access, particularly for persons living with HIV/AIDS. However, difficulties such as inadequate availability or stockouts in remote regions continue. Although the DAAs drug has not been developed in this situation, according to Udompap, Tanwadee, and Gani in 2020, chronic hepatitis B therapy in Bangladesh only reaches less than 1% of the population. Surprisingly, Bangladesh has filed generic DAAs such as DCV, SOF, SOF+DCV, SOF+LDV, and SOF+VEL. There is a contradictory scenario regarding availability in relation to

Hepatitis situations. This scenario may be further analyzed to grasp the actual conditions better. TB drugs, including ARVs, are widely accessible in the nation via government-run health institutions and non-governmental organizations (NGOs). However, stockouts, particularly of second-line medications, have been observed in certain places, affecting treatment results.

The most often used drugs in Cambodia are ARVs and TB, according to the case study. The government has made ARVs available free of charge at public health institutions, leading to high treatment coverage rates as the country's commitment to achieving the 90-90-90 target of UNAIDS. In reality, via its national HIV/AIDS program, it has made significant progress in ensuring the long-term, universal provision of ARV. Cambodian DAAs, like those in Bangladesh, have had difficulties, particularly with regard to hepatitis C. In Cambodia, over 36% of hepatitis infections occur in rural areas (MoH, 2017). In rural Cambodia, there is a district-based health system that provides basic health care via tiny primary care health facilities, with referral hospitals offering tertiary care. Nursing professionals offer the majority of care in health facilities (Zhang et al., 2021), which makes it challenging to reach marginalized populations. In addition, the price of DAAs remains high, impacting treatment services. Furthermore, TB treatment is one of the most widely used drugs in the nation and is subsidized by the government; nonetheless, inadequate supplies or stockouts provide difficulty in terms of availability, including the limited types of medicine in Cambodia. As a result, in Cambodia, the rare supply or stockouts associated with health and drug policy implementation and management must be solved along with the upgraded types of drug-resistant ARVs, DAAs, and TB.

Unlike Bangladesh, Cambodia, and Malaysia, Indonesia's most popular drugs are ARVs and DAAs. With about 80% of subsidized drugs, Indonesia has made significant efforts to meet UNAIDS' 95-95-95 objective. As a result, the government continues to provide ARV drugs that are widely available in the market. However, Indonesia continues to experience issues in guaranteeing the consistent availability of ARVs in the market, particularly in distant and disadvantaged regions. Stockouts and supply chain disruptions are widespread, jeopardizing treatment continuity and compliance. DAAs, notably for Hepatitis C, are often associated with high prices. The commitment to support different initiatives, notably those for Hepatitis C, does not meet the aim of reducing the number of patients (Scrutton et al., 2018). Although TB treatment is not completely covered in this case study, it is the biggest cause of mortality from a single infectious agent, surpassing HIV/AIDS. In reality, the National Health Insurance (BPJS) does not cover TB treatment expenditures (MoH, 2022). As a result, the availability or stockout of TB medications and treatment services in Indonesia continues to be a concern that must be addressed.

According to the analysis, 100% of drugs are government-supported, and in the case of this research, the two most used medicines are ARVs and TB treatments. Malaysia has a well-established HIV/AIDS treatment program, which meets UNAIDS' 95-95-95 objective. However, underprivileged communities, such as refugees and drug users, continue to face access barriers. DAAs for Hepatitis C, like the case report from Indonesia, are expensive when compared to other ARVs and TB medications. Furthermore, the government has made significant efforts to guarantee that its national health program pays the costs. TB medications are offered via the national TB control program, and treatment is given for free at public health institutions. Malaysia has a strong supply chain structure that reduces stockouts and ensures consistent availability of TB medications associated with innovative technology to reach patients throughout Malaysia.

Evaluation on Availability

Bangladesh:

ARV medicines have been hindered by a low availability of supplies, particularly in rural locations.

DAA medicines, including DCV, SOF, LDV, and VEL, are registered in the nation; nonetheless, fewer than one percent of the population receives hepatitis therapy.

TB medicine in second-line medicines is restricted in certain places, affecting treatment success.

Cambodia

ARV drugs are not generally accessible throughout the country, especially in rural areas.

DAA drugs are costly, and Hepatitis C therapy is difficult to get for underserved people owing to insufficient services.

TB medications availability is unpredictable, and they must be improved to enable access to newer drug-resistant TB.

Indonesia

ARV drugs are inconsistently accessible on the market.

DAA drugs continue to be difficult to get because to high prices and the government's lack of commitment.

TB medications have been in short supply or have gone out of stock.

Malaysia

ARV medications continue to be inconsistently accessible on the market.

DAA drugs continue to be difficult to get because to high prices and government inaction.

TB medications have been in short supply or out of stock.

❖ Evaluation of ARVs, DAAs, and TB Medicine Affordability

According to the study in this report, the majority of key respondents believed that ARVs and TB drugs are "very affordable," with Malaysia leading at 70 percent, Cambodia at 57.1 percent, and Indonesia at 34 percent. This was followed by a level of "moderately affordable," with Indonesia dominating at 42 percent and Malaysia at 20 percent. The last judgment on affordability is "somewhat affordable," which is held by 58.3 percent of Bangladeshis and 12 percent of Indonesians.

In Bangladesh's case study, the government has supplied ARVs for free via the national program and donors from the Global Fund to Fight AIDS, Tuberculosis, and Malaria (GFATM) (World Bank, 2012). As previously said, 12.5 percent of key respondents feel that drugs are extremely inexpensive, while 16.7 percent say they are fairly cheap, with the highest rate being somewhat affordable. However, it is thought that the government's efforts would make ARVs more accessible to consumers. In reality, the problem of hepatitis is not addressed in this research; the affordability of DAAs for hepatitis C remains a concern owing to their high cost. As previously stated, the combination of restricted availability and a lack of insurance coverage keeps DAA medication out of reach for many people. Similar to ARVs, TB drugs in Bangladesh are given by the government, making them inexpensive, costing between 1 and 2 USD for each pack.

The government of Cambodia supports the drugs mentioned above. It shows that 57.1 percent of key respondents consider drugs to be extremely inexpensive, with 14.3 percent believing they are somewhat reasonable. The ARVs were likewise free of charge. The government has made significant efforts to develop HIV/AIDS programs that are affordable to those living with HIV/AIDS. Furthermore, Cambodia continues to suffer from Hepatitis C management services and pharmaceutical access, including availability and pricing, including the high cost of the medications themselves and treatment services. The government also supports TB drugs via public health facilities in Cambodia, which contributes to high treatment affordability for TB patients, resulting in annual costs of roughly 70 to 80 USD.

In Indonesia's case study, 42 percent of key respondents say that drugs are moderately inexpensive, followed by 34 percent who think they are extremely affordable and 12 percent who think they are somewhat affordable. In terms of ARVs, the difficulty continues since the location in a remote region is difficult to access, and the supply chain is expensive, limiting affordability. In addition to DAAs, which are among the most often used drugs in this research, the affordability of DAAs for hepatitis C therapy is a key problem in Indonesia owing to high prices and limited insurance coverage. The absence of a comprehensive national program increases financial hurdles for patients. In reality, TB patients encounter issues that are not

covered by national health insurance. As a result, tuberculosis sufferers continue to face hefty treatment costs.

Malaysia's case study shows that 70% of key respondents believe drugs are extremely reasonable, while 20% believe they are moderately affordable. The government has backed such medications. Malaysia distributes ARVs for free at government clinics, guaranteeing that persons living with HIV/AIDS can afford them. Malaysia has made tremendous progress in increasing the affordability of DAAs for hepatitis C treatment via a government initiative that negotiates lower costs with pharmaceutical firms. However, out-of-pocket fees for diagnostic testing and related services may continue to be a financial barrier for certain patients. TB drugs are offered free of charge via public health facilities in Malaysia, making treatment more affordable for TB patients.

Overall, although ARVs and TB medications are typically inexpensive in Bangladesh, Cambodia, Indonesia, and Malaysia thanks to government-supported programs, the price of DAAs for hepatitis C therapy remains a major concern in these countries. Efforts to negotiate lower costs, improve insurance coverage, and minimize out-of-pocket payments are critical to increasing affordability and guaranteeing access to vital drugs for HIV, hepatitis, and TB. Advocacy for Universal Health Coverage is critical in resolving economic difficulties and fostering fair access to healthcare services.

Evaluation on Affordability

Bangladesh:

DAAs medicines have persisted in the high cost.

Cambodia

DAAs medicines have persisted in the high cost along with additional costs for other TB treatments and services.

Indonesia:

ARVs medicines cost vary, but supply chain logistic contribute to extra price.

DAAs medicines have persisted in the high cost along with additional costs for other TB treatments and services.

TB medicines is in the affordable cost; however, TB treatment takes expensive cost non-fully covered by National Health Insurance

Malaysia:

DAAs medicines are taking a lot of cost with financial burden for other related treatments.

❖ Evaluation of ARVs, DAAs, and TB Medicine Quality

Despite the fact that this research did not address important respondents' concerns about the quality of medications, this section discusses factors to consider when assessing the quality of ARVs, DAAS, and TB drugs in Bangladesh, Cambodia, Indonesia, and Malaysia. There are various considerations, including:

Certainly, evaluating the quality of antiretrovirals (ARVs), direct-acting antivirals (DAAs), and Tuberculosis (TB) drugs in Bangladesh, Cambodia, Indonesia, and Malaysia requires analyzing a variety of factors:

1. **Manufacturing Standards:** Determine if ARVs, DAAs, and TB medications in each nation are manufactured in facilities that follow Good Manufacturing Practices (GMP) guidelines. This guarantees the quality, safety, and effectiveness of drugs.

2. **Regulatory Oversight:** Evaluate each country's drug regulatory system and capabilities. Effective regulatory monitoring ensures that medications satisfy quality requirements and are safe to consume.

3. **Quality Control mechanisms:** Assess the existence and efficacy of quality control mechanisms across the supply chain, from manufacture to distribution. This involves determining the strength, purity, and stability of drugs.

4. **Drug Procurement Practices:** Assess the procurement procedures for ARVs, DAAs, and TB medications to ensure that quality takes precedence above price. Transparent procurement methods and supplier certifications help to get high-quality pharmaceuticals.

5. **Storage and Distribution**: Evaluate storage and distribution strategies to avoid drug deterioration or contamination. Proper storage conditions, including temperature management and packing integrity, are critical for preserving pharmaceutical quality.

6. **Adherence to Treatment standards:** Determine how closely healthcare practitioners follow national treatment standards for HIV, hepatitis, and TB. Following evidence-based guidelines ensures that patients are given suitable drugs of recognized quality.

7. **Monitoring and monitoring:** Evaluate pharmacovigilance and post-market monitoring methods to identify and manage medication-related adverse events or quality concerns. Timely reporting and response methods are critical for ensuring drug safety and effectiveness.

8. **Patient Feedback and Results:** Use patient feedback and treatment results as markers of drug quality. Monitoring patient experiences and treatment results aids in the identification of any difficulties with pharmaceutical efficacy or tolerability.

9. **International Standards and Collaborations**: Evaluate compliance with international quality standards and partnership with organizations like the World Health Organization (WHO) and the Global Fund. Participating in quality improvement programs and following international norms improves pharmaceutical quality and credibility.

10. **Public knowledge and Education**: Increase public knowledge and education on the significance of drug quality and adherence to treatment. Empowering patients with information about quality assurance and pharmaceutical safety encourages informed decision-making and treatment adherence.

Overall, assuring the quality of ARV, DAA, and TB drugs in Bangladesh, Cambodia, Indonesia, and Malaysia requires a multifaceted strategy that includes regulatory monitoring, quality control measures, adherence to treatment standards, and patient-centered care. Collaboration among stakeholders, including governments, regulatory agencies, healthcare providers, and patients, is critical for ensuring good drug quality and achieving Universal Health Coverage for persons living with HIV, hepatitis, and TB.

Our Recommendation in EPICS

Engaged. Involve in promoting awareness, adherence, and advocacy for access to medications and availability to foster ownership of health programs in order to attain the quality health.

Prioritized. Place utmost and significant emphasis on making availability, affordability and quality of ARVs, DAAs, and TB medicine for those in need widely.

Integrated. Determine the extent to which HIV, Hepatitis, and TB treatment are integrated within broader health care system leveraging existing infrastructure and resource to ensure availability, affordability and quality of ARVs, DAAs, and TB medicines.

Commitment. Essential political support given to maintain access to medications, availability, affordability and quality over the long term.

Sustained. Continuous and uninterrupted access to medications over time with ensuring financially accessible, and maintaining high standard if medications.

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ANNEX

Annex 1 List of Available Drugs in Bangladesh

DRUGS (Based on WHO consolidated guidelines 2021 and 2022)	Available in the Market	Remarks
Antiretroviral (ARV)		
Preferred first line for PLHIV adults and adolescents initiating ART: TDF + 3TC (or FTC) + DTG	Yes	Provided by Government
Alternative first-line for PLHIV adults and adolescents initiating ART: TDF + 3TC + EFV 400 mg	Yes	-
Preferred first line for PLHIV children initiating ART: ABC + 3TC + DTG	No	-
Alternative first-line for PLHIV children initiating ART: ABC + 3TC + LPV/r; TAF + 3TC (or FTC) + DTG	Yes	Provided by Government
Preferred first line for neonates: AZT (or ABC) + 3TC + RAL	No	-
Alternative first-line for neonates: AZT + 3TC + NVP	Yes	Provided by Government
Preferred second line for PLHIV adults and adolescents: Two NRTIs + (ATV/r or lopinavir/ritonavir (LPV/r))	Yes	Provided by Government
ARV drugs in PEP for adults and adolescents		
Single ARVs	**With Fix-Dose**	**Remarks**
Tenofovir (TDF)	300 mg once daily	-
Lamivudine (3TC)	150 mg twice daily or 300 mg once daily	-
Emtricitabine (FTC)	200 mg once daily	-
Lopinavir/ritonavir (LPV/r)	400 mg/100 mg twice daily or 800 mg/200 mg daily	-
Atazanivir/Ritonavir (ATV/r)	300 mg + 100 mg once daily	-

Raltegravir (RAL)	400 mg twice daily	-
Darunavir + Ritonavir (DRV/r)	800 mg + 100 mg once daily or 600 mg + 100 mg twice daily	-
Efavirenz (EFV)	600 mg once daily	-
Co-Trimoxazole Prophylaxis for Adults and Adolescence		
Co-Trimoxazole	960 mg daily	Provided by the government and available in the private market
Sulfamethoxazole	800 mg daily	Provided by the government and available in the private market
Trimethoprim	160 mg	Provided by the government and available in the private market
Tuberculosis (TB) Medicines		
Treatment of drug-susceptible TB using 4-month regimens (according to WHO Consolidated on Tuberculosis, 2022)		
Isoniazid	300 mg daily	Provided by the government and available in the private market
Rifapentine	1200 mg / 300 mg daily	Provided by the government and available in the private market
Moxifloxacin	-	Provided by the government and available in the private market
Pyarazinamide	30-40 mg/kg	

Ethambutol	-	Provided by the government and available in the private market
Streptomycin	-	Provided by the government and available in the private market
Treatment of drug-susceptible TB with People Living with HIV (according to WHO Consolidated on Tuberculosis, 2022)		
Rifampicin	600 mg/daily	-

Annex 2 List of Available Drugs in Cambodia

DRUGS (Based on WHO consolidated guidelines 2021 and 2022)	Available in the Market	Remarks
ARV drugs in PEP for adults and adolescents		
Single ARVs	**With Fix-Dose**	**Remarks**
Tenofovir (TDF)	300 mg once daily	Provided by the government
Lamivudine (3TC)	150 mg twice daily or 300 mg once daily	Provided by the government
Emtricitabine (FTC)	200 mg once daily	Provided by the government
Lopinavir/ritonavir (LPV/r)	400 mg/100 mg twice daily or 800 mg/200 mg daily	Provided by the government
Atazanivir/Ritonavir (ATV/r)	300 mg + 100 mg once daily	Provided by the government
Raltegravir (RAL)	400 mg twice daily	Provided by the government
Darunavir + Ritonavir (DRV/r)	800 mg + 100 mg once daily or 600 mg + 100 mg twice daily	Provided by the government
Efavirenz (EFV)	600 mg once daily	Provided by the government
Co-Trimoxazole Prophylaxis for Adults and Adolescence		
Co-Trimoxazole	960 mg daily	Provided by the government
Sulfamethoxazole	800 mg	Provided by the government

Trimethoprim	160 mg	Provided by the government
Tuberculosis (TB) Medicines		
Treatment of drug-susceptible TB using 4-month regimens (according to WHO Consolidated on Tuberculosis, 2022)		
Isoniazid	300 mg daily	Provided by the government
Rifapentine	1200 mg / 300 mg daily	Provided by the government
Moxifloxacin	-	Provided by the government
Pyrazinamide	30-40 mg/kg	Provided by the government
Treatment of drug-susceptible TB with People Living with HIV (according to WHO Consolidated on Tuberculosis, 2022)		
Rifampicin	600 mg/daily	Provided by the government

Annex 3 List of Available Drugs in Indonesia

Antiretroviral (ARVs)				
Type of Medicine	**With Fixed-Dose**	**Supported by G/P**	**Supplier**	**Price**
Preferred first line for PLHIV adults and adolescents initiating ART: TDF + 3TC (or FTC) + DTG	300mg once daily	G	-	-
Alternative first-line for PLHIV adults and adolescents initiating ART: TDF + 3TC + EFV 400 mg	600mg	G	-	-
Preferred first line for PLHIV children initiating ART: ABC + 3TC + DTG	-	G	-	-
Alternative first-line for PLHIV children initiating ART: **ABC + 3TC + LPV/r; TAF + 3TC (or FTC) + DTG**	-	G	-	-
Preferred first line for neonates: AZT (or ABC) + 3TC + RAL	-	G	-	-
NVP = Nevirapine	NVP for adults is phasing out in Indonesia as of January 2024 NVP will continue to be available for children	G	-	-
Preferred second line for PLHIV adults and adolescents: **Two NRTIs + (ATV/r or lopinavir/ritonavir (LPV/r))**		G	-	-

Preferred third line: DTG-base ART following the use of integrase inhibitors				
ARV drugs in PrEP for adults and adolescents	still on pilot, will be implemented in 2024		-	-
TDF = Tenofovir disoproxil fumarate (Generic)	-	G	-	-
FTC = Emtricitabine (Generic)	-	G	-	-
ARV drugs in PEP for adults and adolescents	-		-	-
Tenofovir (TDF) (Generic)	-	G	-	-
Lamivudine (3TC) (Generic)	-	G	-	-
Emtricitabine (FTC) (Generic)	-	G	-	-
Lopinavir/ritonavir (LPV/r) (Generic)	-	G	ABBOTT	Rp.4.960/tablet
Efavirenz (EFV) (Generic)	600mg	G	-	-
Tenofovir alafenamide (TAF) (Generic)	-	P	AMAROX	RP.2.688/tablet
Azidothymidine (AZT) (Generic)	-		-	-
Abacavir (ABC) (Generic)	-		-	-
Co-Trimoxazole Prophylaxis for Adults and Adolescence				
Co-trimoxazole (Generic)	-	G+P	PT.HOLI PHARMA	Rp.126/tablet
Sulfamethoxazole (Generic)	-	P	PT. Becton Dickinson Indonesia	Rp.551/tablet
Trimethoprim (Generic)	-	P	PT. Becton Dickinson Indonesia	Rp 537.906/pack
Direct-Acting Antiviral (DAA)				
Type of Medicine	**With Fixed-Dose**	**Supported by G/P**	**Supplier**	**Price**
SOF = Sofosbuvir **(Patented)**	-	G	AMAROX	Rp.11.505/tablet
DCV = Daclatasvir **(Patented)**	-	G	AMAROX	Rp.4.774

Tuberculosis (TB) Medicine				
Type of Medicine	**With Fixed-Dose**	**Supported by G/P**	**Supplier**	**Price**
Standard regimen for anti-TB treatment; first-line anti-TB for adults and children	TAKEN DAILY	-	-	-
Isoniazid (Generic)	5mg/kg body weight	G+P	PT. Holi Pharma	Rp.75/tablet
Rifampicin (Generic)	10mg/kg body weight	G+P	PT. Kimia Farma Tbk	Rp.2.394/tablet
Pyrazinamide (Generic)	25mg/kg body weight	G+P	PT. Holi Pharma	Rp.423/tablet
Ethambutol (Generic)	15mg/kg body weight	G+P	PT.Bernofarm	Rp.507/tablet
Streptomycin (Generic)	15mg/kg body weight	G+P	PT.Phapros Tbk	Rp..5.533/vial
Drug-resistant TB (DR-TB) treatment				
In patients with confirmed rifampicin-susceptible, isoniazid-resistant tuberculosis (Hr-TB), treatment with rifampicin, ethambutol, pyrazinamide and levofloxacin is recommended for six months.				
Rifampicin (Generic)		G	PT. Kimia Farma Tbk	Rp.2.394/tablet
Ethambutol (Generic)		G	PT.Bernofarm	Rp.507/tablet
Pyrazinamide (Generic)		G	PT. Holi Pharma	Rp.423/tablet
Levoflaxin		P	PT. Hexpharm Jaya Laboratories	Rp.373/tablet
Regimens for longer multi-drug resistant TB (MDR-TB) regimens: all three Group A agents and at least one Group B agent should be included to ensure that treatment starts with at least four TB agents likely to be effective and that at least three agents are included for the rest of the treatment after bedaquiline is stopped.3 If only one or two Group A agents are used, both Group B agents are to be included. If the regimen cannot be composed of agents from Groups A and B alone, Group C agents are added to complete it.				
Levofloxacin (Generic)	-	P	Pfizer	Rp.373/tablet
Moxifloxacin (Generic)	-	P	Dexa	Rp.42.498/bottle
Bedaquiline **(Patented)**	-	G+P	PT SOHO	Rp.34.400/tablet
Linezolid **(Patented)**	-	P	PT Anugrah Persada Semesta	Rp.377.360/package

Clofazimine (Generic)	-	G+P	PT Dexa Medica	Rp.473/tablet
Ethambutol (Generic)	-	G+P	PT.Bernofarm	Rp.507/tablet
Delamanid **(Patened)**	-	G+P	PT Otsuka	Rp.44.551/mg
Pyrazinamide (Generic)	-	G+P	PT. Holi Pharma	Rp.423/tablet
Imipenem–cilastatin or meropenem (Generic)	-	P	PT Bernofarm	Rp.155.440/vial
Amikacin (Generic)	-	G+P	PT Dexamedica	Rp.15.500/ampoule
Ethionamide or prothionamide (Generic)	-	G+P	PT Indofarma	Rp.511.377/package
p-aminosalicylic acid (Generic)	-	P	PT UBC MEDICAL INDONESIA	Rp.97.900/bag
Clavulanic acid	-	P	PT. Becton Dickinson Indonesia	Rp.529.780/cartridge
Treatment of drug-susceptible TB using 4-month regimens (according to WHO Consolidated on Tuberculosis, 2022)				
Isoniazid (Generic)	-	G+P	PT. Holi Pharma	Rp.75/tablet
Rifapentine (Generic)	-	G+P	PT Sampharindo	Rp.33.500/tablet
Moxifloxacin (Generic)	-	G+P	PT DEXA MEDICA	Rp.42.498/bottle
Pyarazinamide (Generic)	-	G+P	PT. Holi Pharma	Rp.423/tablet
Treatment of drug-susceptible TB with People Living with HIV (according to WHO Consolidated on Tuberculosis, 2022)				
Efavirenz (Generic)		G		
Rifampicin		G+P	PT. Kimia Farma Tbk	Rp.2.394/tablet

Annex 4 List of Available Drugs in Malaysia

Antiretroviral (ARVs)				
Type of Medicine	**With Fixed-Dose**	**Supported by G/P**	**Supplier**	**Price**
Preferred first line for PLHIV adults and adolescents initiating ART: TDF + 3TC (or FTC) + DTG TDF = Tenofovir disoproxil fumarate (Generic) 3TC = Lamivudine (**Generic and Patent**) FTC = Emtricitabine (Generic) DTG = Dolutegravir **(Generic and Patent)**	-	G	MYLAN	MYR 6.22 per tablet
Preferred first line for PLHIV adults and adolescents initiating ART: TDF+FTC	-	G+P	HETERO	-
Preferred first line for PLHIV adults and adolescents initiating ART: AZT + 3TC	-	G+P	GSK & YSP	MYR 0.17 per tablet
Preferred first line for PLHIV adults and adolescents initiating ART: AZT + 3TC	-	G+P	HETERO	MYR 3.67 pertablet
Alternative first-line for PLHIV adults and adolescents initiating ART: TDF + 3TC + EFV 400 mg EFV = Efavirenz (Generic)	600mg	G+P	HETERO & CIPLA	-
Preferred first line for PLHIV children initiating ART: ABC + 3TC + DTG ABC = Abacavir **(Patent)**	-	G	ViiV HEALTH	MYR 5.67 per tablet
Alternative first-line for PLHIV children initiating ART: **ABC + 3TC + LPV/r; TAF + 3TC (or FTC) + DTG** LPV = Lopinavir/Ritonavir **(Patent)**	-	G+P	-	-
Preferred first line for neonates: AZT (or ABC) + 3TC + RAL RAL= Raltegravir **(Patented)**	-	G	-	-

NVP = Nevirapine (Generic)	-	G+P	CIPLA	MYR 0.63 per tablet
Preferred second line for PLHIV adults and adolescents: Two NRTIs + (ATV/r or lopinavir/ritonavir (LPV/r))	-	G	-	MYR 17.69 per day
Preferred third line: DTG-base ART following the use of integrase inhibitors				
Second-line and third-line ARV drugs				
DRV/r = Darunavir	-	P	JESSON	-
ETV= Etravirine	-	-	-	-
RAL= Raltegravir **(Patented)**	-	P	MSD	-
ARV drugs in PrEP for adults and adolescents	-	-	-	-
TDF = Tenofovir disoproxil fumarate (Generic)	-	G+P	MYLAN	MYR 4.33 per tablet
FTC = Emtricitabine **(Generic and Patented)**	-	G	-	-
ARV drugs in PEP for adults and adolescent				
Tenofovir (TDF)	300 mg once daily	G+P	CIPLA	MYR 0.55 per tablet
Lamivudine (3TC)	150 mg twice once daily	G+P	ViiV Heath & YSL	MYR 0.34 per tablet
Emtricitabine (FTC)	200 mg once daily	G+P	-	-
Lopinavir/ritonavir (LPV/r)	400 mg/100 mg twice daily or 800 mg/200 mg daily	G	AbbVie	MYR 20.00 per tablet
Raltegravir (RAL)	400 mg twice daily	P	AMAROX	RP.2.688/tablet
Darunavir + Ritonavir (DRV/r)	800 mg + 100 mg once daily or 600 mg + 100 mg twice daily	p	JESSON	MYR 25.00 per tablet
Efavirenz (EFV)	600 mg once daily	G+P	Mylan	-
Co-Trimoxazole Prophylaxis for Adults and Adolescence				
Co-trimoxazole (Generic)	960 mg daily (2in 1)	G+P	-	-

Sulfamethoxazole (Generic)	800 mg	-	-	-
Trimethoprim (Generic)	160 mg	-	-	-
Direct-Acting Antiviral (DAA)				
SOF = Sofosbuvir (Generic)	400 mg	G	GILEAD & MYLAN	MYR 1.71 per tablet
DCV = Daclatasvir (Generic)	60 mg	G	MYLAN	MYR 9.52 per tablet
VEL = Velpatasvir (Generic)	SOF+VEL	G	MYLAN	MYR 1.71 per tablet
G = Glecaprevir	-	P	-	-
P = Pibrentasvir	GP	P	-	-
Tuberculosis (TB) Medicines				
Type of Medicine	**With Fixed-Dose**	**Supported by G/P**	**Supplier**	**Price**
Standard regimen for anti-TB treatment; first-line anti-TB for adults and children	IN FDC (4 IN 1), rifampicin 150mg+isoniazidv 75mg+pyrazinamide 400mg+ethambutol 275mg	G+P	LF MERCU SDN. BHD.	MYR 0.61 per tablet
Isoniazid (Generic)	75 mg	G+P	-	-
Rifampicin (Generic)	rifampicin 150 mg+isoniazid 75 mg	G+P	HANAN MEDICARE SDN. BHD.	MYR 0.54 per tablet
Pyrazinamide (Generic)	400 mg	P	-	-
Ethambutol (Generic)	275 mg	P	-	-
Regimens for longer multi-drug resistant TB (MDR-TB) regimens: all three Group A agents and at least one Group B agent should be included to ensure that treatment starts with at least four TB agents likely to be effective and that at least three agents are included for the rest of the treatment after bedaquiline is stopped.3 If only one or two Group A agents are used, both Group B agents are to be included. If the regimen cannot be composed of agents from Groups A and B alone, Group C agents are added to complete it.				
Moxifloxacin (Generic)	-	P	-	-

Bedaquiline **(Patented)**	100 mg	G+P	PHAMARNIAGA LOGISTICS	MYR 103.91
Linezolid	-	P	-	-
Clofazimine (Generic)	100 mg	G+P	HANAN MEDICARE SDN. BHD.	-
Ethambutol (Generic)	400 mg	G+P	DUOPHARMA	-
Imipenem–cilastatin or meropenem (Generic)	meropenem 1g injection	G+P	PRIMABUMI SDN. BHD.	-
Treatment of drug-susceptible TB using 4-month regimens (according to WHO Consolidated on Tuberculosis, 2022)				
Moxifloxacin (Generic)	400 mg	G+P	DUOPHARMA	-
Treatment of drug-susceptible TB with People Living with HIV (according to WHO Consolidated on Tuberculosis, 2022)				
Efavirenz (Generic)	600 mg	G+P	WIJA PHARMA SDN. BHD.	-
Rifampicin (Generic)	150 mg powder for injection.	G+P	TERAJU FARMA SDN. BHD.	MYR 147 per vial