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Vaccines, Immunization and Health Supply
Chain Management (EAC RCE-VIHSCM)**

**FACTORS THAT AFFECT THE COMMODITY SECURITY OF
ANTIRETROVIRAL DRUGS IN RWANDA: PROCUREMENT
PERSPECTIVES.**

Thesis submitted to the University of Rwanda, in partial fulfilment of the
requirements for the degree of Masters in Health Supply Chain Management (MSc HSCM)

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DECLARATION

I declare that this dissertation Factors that affect the commodity security of antiretroviral drugs in Rwanda: Procurement perspectives is my own and original work and it not has been submitted before at any academic institution for the award of any degree and all sources used or quoted have been cited and acknowledged as complete references.



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ABSTRACT

According to the World Health Organization (WHO), access to essential medicines has been described as one of the six building blocks of the health system and has been set (as priority for all citizens in the sustainable development goals (SDGs) to be attained by 2030. While HIV/AIDS is on global priority agenda, all people living with HIV (PLHIV) are deemed to consistently access to antiretroviral treatment. This requires strong strategies to ensure commodity security of antiviral drugs (ARV) so that PLHIV can obtain and use ARV whenever and wherever he or she needs it.

This descriptive and retrospective study aimed at describing the factors affecting the commodity security of antiretroviral drugs in Rwanda with procurement perspectives. Accordingly, procurement proceedings, level of dependency towards suppliers and suppliers' performance had been assessed to find areas needing improvements to attain the commodity security of ARVs.

Data were collected from procurement records for the period of January 2017 through December 2018, using MS Excel tools and analyzed to explore factors that affect the commodity security of antiretroviral drugs, in procurement perspectives.

We found that procurement proceedings are well performed, the lower number of available suppliers for antiretroviral drugs does not affect the availability of antiretroviral drugs. However, suppliers' performance especially in terms of timely deliveries was found not satisfactory as the timeliness compliance was noted at 29% and 38% in 2017 and 2018 respectively.

The procurement of antiretroviral drugs in Rwanda is well established following the public law, regulations and Global Fund guidelines. This is to ensure access to safe, effective, quality and affordable antiretroviral drugs in Rwanda, which with other components of the health systems can help in attaining the commodity security, and this can be a starting point to build a well-established health system countrywide. Nevertheless, improvement intervention is recommended in suppliers' performance to ensure orders fullness and timeliness.

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LIST OF ABBREVIATIONS

AIDS	Acquired Immunodeficiency syndrome
ART	Antiretroviral therapy
ARV	Antiretroviral
CIPS	Chartered Institute of Procurement and Supply
CPDS	Coordinated Procurement and Distribution System
EAC	East African Community
eLMIS	Electronic Logistics Management Information System
EU	European Union
GF	Global Fund
GHSC – PSM	Global Health Supply Chain – Procurement Supply Management
HIV	Human immunodeficiency virus
MOH	Rwanda Ministry of Health
MPPD	Medical Procurement and Production Division
PEPFAR	President’s Emergency Plan for AIDS Relief
PLHIV	People living with Human immunodeficiency virus
RBC	Rwanda Biomedical Center
SDG	Sustainable Development Goal
SRA	Stringent Regulatory Authority
UNAIDS	United Nations Programme on HIV/AIDS
USAID	United States Agency for International Development
USFDA	United States Foods and Drugs Authority
WHO	World Health Organization

CHAPTER 1. INTRODUCTION

1.1. Background

After the recognition of AIDS early in 1980s, the discovery of its treatment has started and later on 1997, it was introduced in Sub-Saharan countries (1). In Rwanda, the supply of those ARVs was facilitated by the government of Rwanda and partners including the Global Fund (GF) and United States Agency for International Development (USAID) since 2000s (2). Nevertheless, in many countries the access to ART has been reported to be compromised by many factors including high prices as the products were still under patent (3).

Commodity security is assimilated to commodity availability and in the context of antiretroviral therapy (ART), access to antiretroviral drugs is key due to the fact that ART has to be uninterrupted once treatment has been started. To attain this priority (access to medicine), we need to have required commodity when and where people need that commodity. People can start on commodity security to determine the strategic approaches to improve availability and access of health commodities, by integrating the distribution systems, healthcare services, financing systems and policies which can be a useful strategy to ensure commodity security, because there is a need of appropriate coordination in financing and logistics systems, health program management and other factors in place to ensure commodity security for any health product.

Policies, access, quality and rational use constitute a framework of commodity security and this framework has the sense because an effective supply chain alone cannot ensure the commodity security; each element of the health program, including supply chain must be seconded by a supportive policy environment, an adequate financial and human resources, a legal framework and an institutional environment sustaining and supporting the program.

1.2. Problem statement

Rwanda has made tremendous progress and committed to fight and control HIV/AIDS through comprehensive prevention, care delivery and treatment services. In so doing, the government makes sure the supply chain of ARV is consistently maintained for further commodity security in the treatment of HIV/AIDS countrywide. These efforts have involved setting up appropriate healthcare delivery systems, governance, funding and supply chain systems among others.

The supply chain management of ARV drugs has been under national coordinated procurement and distribution system (CPDS) involving the MOH and partners like GF and USAID for further increased availability of, and accessibility to the treatment and other health commodities related. However, when it comes to availability of drugs, many studies have found that procurement complications in many public settings affect significantly commodity security of drugs and Rwanda is not set free from the factors thereof. Those complications were reportedly recorded as suppliers' uncertainty, long delivery time, etc. (4,5). Thus, in order to keep ensuring commodity security for ARV in Rwanda there is a need to track and assess all bottlenecks in the supply chain of those commodities with emphasis to effective procurement, accurate forecasting, adequate financing and consistent distribution.

1.3. Study objectives

This study aims to describe the factors that affect the commodity security of the antiretroviral drugs by the procurement perspectives where specifically the objectives are:

1. To analyze the procurement proceedings for procurement of antiretroviral drugs
2. To assess the level of dependency towards the suppliers of antiretroviral drugs and product availability
3. To evaluate how the suppliers' performance influences the procurement of antiretroviral drugs [order completeness, timely delivery and supplier defect rate (quality of product) of the delivered products].

1.4. Significance, Scope and Definitions

Rwanda Biomedical Centre (RBC)/Medical Procurement and Production Division (MPPD) is the procuring entity responsible for antiretroviral drugs procurement. The latter being performed based on national laws and regulations, funders guidelines, it is not easy to get interested bidders during tendering processes, the available suppliers are in a limited number, their location elongates the reasonable lead times.

This research assesses the above factors linked to the procurement, on the influence of the commodity security of antiretroviral drugs in Rwanda. Thus, RBC/MPPD was selected as study location. The findings will be used to increase the commodity security of antiretroviral drugs by

improving procurement proceedings or processes, suppliers' availability and suppliers' performance management of antiretroviral drugs.

The choice of this topic was motivated by the fact that antiretroviral therapy needs antiretroviral drugs and it should be uninterrupted therapy, meaning patients must always have access on ARV drugs.

CHAPTER 2. LITERATURE REVIEW

This chapter aims at introducing and clarifying the study subject by providing definitions of key concepts, current situation of HIV/AIDS, place of ARV drugs in the success of ART, overview on general procurement and supply chain, Antiretroviral Drugs Supply Chain Management, Antiretroviral therapy, Antiretroviral drugs procurement.

According to Churchill and Iacobucci, the literature review depends on the problem to be addressed (6). Thus, in this study, through the review of studies carried out in the same field, the researcher took step to assess the factors affecting commodity security of antiretroviral drugs in Rwanda with procurement perspectives.

2.1 Definitions of key concepts

Antiretroviral drug means the medicine used in antiretroviral therapy.

Antiretroviral therapy means a combination of at least three antiretroviral drugs to maximally suppress the HIV virus and stop the progression of HIV disease.

Contract is a document indicating the agreement between the procuring entity and the successful bidder (7).

e-procurement is the use of electronic system, especially the internet, in conducting the procurement relationships with bidders (7).

Framework agreement is a document concluded between a procuring entity and one or more bidders indicating an arrangement which allows the purchaser to procure supplies that are needed continuously or repeatedly on an agreed price over a given period of time (7).

Procurement process is a series of steps from the quantification to contract management where a set of procedures is followed to determine what will be needed in terms of quantity, the methods to be used to acquire goods, suppliers selection, tendering and evaluation processes to end up with the contract awarding to successful bidders (which are suppliers) to execute contracts according to agreed terms.

Stringent Drug Regulatory Authority (SRA) means a regulatory authority which is a member of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).






WHO Prequalification Program means the program managed by WHO which prequalifies medicines that are considered to be acceptable for procurement by the United Nations and specialized agencies; and quality control laboratories for medicines.

2.2 Current situation of HIV/AIDS burden.

Approximatively in 2018, 37.9 million of people were living with HIV worldwide, where around 68% (25.7 million of people) were in Africa region; 23.3 million (62%) of those people were receiving the antiretroviral treatment (8).

The situation of HIV/AIDS in East Africa region is that Uganda has a highest national adult HIV prevalence (6.4% in 2005) in the East African Community (9). In Rwanda, the HIV prevalence has been sustained around 3% countrywide (10,11).

Summary of the global HIV epidemic (2018)

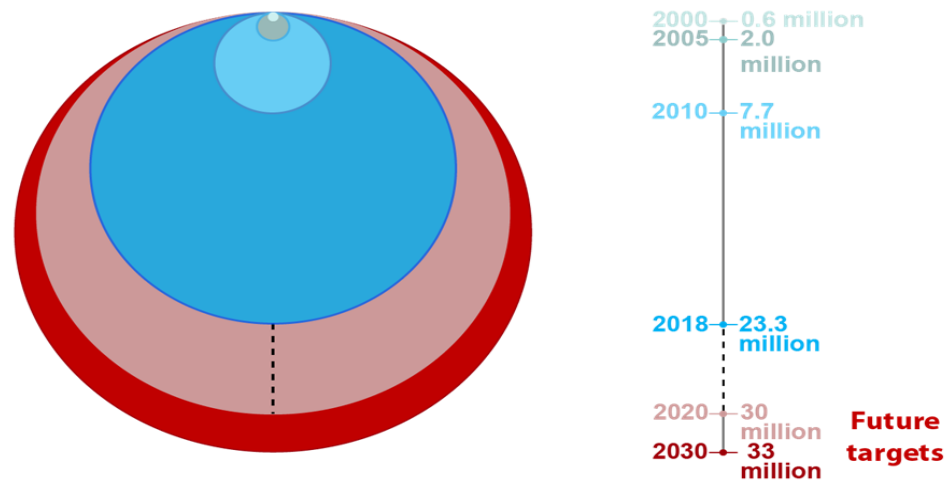
	People living with HIV in 2018	People newly infected with HIV in 2018	HIV-related deaths 2018
 Total	37.9 million [32.7 million – 44.0 million]	1.7 million [1.4 million – 2.3 million]	770 000 [570 000 – 1.1 million]
 Adults	36.2 million [31.3 million – 42.0 million]	1.6 million [1.2 million – 2.1 million]	670 000 [500 000 – 920 000]
 Women	18.8 million [16.4 million – 21.7 million]	–	–
 Men	17.4 million [14.8 million – 20.5 million]	–	–
 Children (<15 years)	1.7 million [1.3 million – 2.2 million]	160 000 [110 000 – 260 000]	100 000 [64 000 – 160 000]

Source: UNAIDS/WHO estimates



Figure 1. Summary of the Global HIV epidemic in 2018

Number of people receiving antiretroviral treatment



Source: UNAIDS/WHO estimates



Figure 2. 2018 ART coverage 2000 - 2030

2.3 Place of ARV drugs in the success of ART

As per the World Health Organization, standard antiretroviral therapy consists of a combination of at least three antiretroviral drugs to maximally suppress the HIV virus and stop the progression of HIV disease. This therapy, as a chronic treatment needs to be uninterrupted; thus, the antiretroviral drugs have to be always available in order to help the people living with HIV to receive them where and when they are needed. The World Health Organization defines the access to medicines to all citizen as a priority.

ART can also be defined as a combination of several antiretroviral drugs used to inhibit HIV replication in order to slow the progression of HIV disease to AIDS, leading to the improvement of clinical status and quality life of patients.

Focusing in the commodity security is cost effective for a given health program, improves impact of that program and of course, saves lives, but success is only possible and granted if commodity security is addressed early in the planning stages of implementation for a health program (5).

2.4 Antiretroviral therapy

The number of people living with HIV continues to increase globally, following the number of antiretroviral therapy's increase and their associated increase of life expectancy. Therefore, the need for effective and affordable antiretroviral drugs with few adverse effects will continue to rise and it is noted that the growth in the antiretroviral therapy coverage seen, has been due to the use of generic antiretroviral drugs (12).

Being of good health is very important because our health affects everything in our life. This the reason has been made a goal to ensure that everyone have a health coverage and access to medicines and vaccines. Therefore, the target has been set to achieve universal health coverage with financial risk protection, access to quality essential healthcare services and access to safe, effective, quality and affordable essential medicines and vaccines for all in order to end for example the epidemic of AIDS among others by 2030 (13).

Following the 2011 political declaration on HIV and AIDS establishing the targets and commitments taking 2015 as a deadline, the unite of diverse stakeholders in a common effort, established the post-2015 era to end HIV and AIDS by 2030 with the new ambitious but achievable targets: by 2020, (a) 90% of all people living with HIV will know their status, (b) 90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy and (c) 90% of all people receiving antiretroviral therapy will have viral suppression (14).

To improve the commodity security in Rwanda, the MOH, in collaboration with its partners, has worked on a number of key initiatives focusing on establishment of harmonized logistics management information systems and inventory management system (15).

In Rwanda, the reported coverage rate in 2013 was 82.7 of all HIV infected patients receiving treatment with ART services available in 93% health facilities countrywide (16). The proportion of patients per treatment lines is 95.9% and 4.1% respectively for adults and paediatrics with 95.87%, 4.1% and 0.04% for adults first, second and third line; and 89.09%, 10.83 and 0.08% for paediatrics first, second and third line (17).

In order to coordinate available resources, from various funding partners in supply chain for health commodities, including specific area like quantification and supply planning, procurement, storage, inventory control system and distribution, the government of Rwanda, through the

Ministry of Health, put in place a mechanism called Coordinated Procurement and Distribution System (CPDS) aiming to increase the availability of health services, including quality medicines and other related health commodities, as an interrupted supply of health commodities is required to ensure quality services at the service delivery point and such availability is to be threatened if adequate supply chain system is in place and different health programs are well coordinated (18).

2.5 Overview on general procurement and supply chain

There are many steps in the procurement process and efficient procedures have to be in place to manage them without considering what model used even for distribution system. These steps are: selecting most cost-effective supplies required for a given program (in case of health matters); to quantifying the needed supplies; potential suppliers' pre-selection; managing procurement and delivery; ensuring good quality of the supplies; and monitoring performance of suppliers and procurement system. Access of safe and effective drugs will not be possible in case of failure in any of the above areas.

Procurement cannot be considered simply as an act of buying but it is a complex set of elements designed to address an organization or institution's needs. These elements are: operational, business, information technology, safety and risk management, and legal systems. Even if different national procurement types have been established in developing countries, procuring essential medicines is carried out at central level (Central Medical Store (CMS) under responsibility of the Ministry of Health) and funded largely through public treasury, in partnership with international funding mechanisms. These public entities do not have always sufficient and adequate skills and strategies to efficiently carry out the procurement processes. In order to reduce costs, long lead times and stock shortage of commodity, and, overall, commodity insecurity, quantification has to be adequate, better choice in procurement methods to be used and appropriate tendering strategies must be put in place (19).

A procurement process to be effective, it has to respond to 6 rights: the right medicines in the right quantities, with recognized standards of quality, delivered in the place, in right time and at reasonable prices. Therefore, procurement brings together drugs quantification processes, defining quality standards of production, suppliers' selection, evaluating price quotations, and payment for the drugs. Procurement practices are applicable and useful in the logistics and supply chain

industry to support operational requirements of the company by focusing on how purchasing is done, how the product is flowed and received by the company from suppliers, establishing relationships with suppliers and managing the procurement process by identifying opportunities and managing internal operations (20). The optimization concept in today's procurement environment, is very important by minimizing costs during purchasing which leads to the best costs and value to its customers.

The Chartered Institute of Procurement and Supply (CIPS) in 2005 defined procurement as the business management function that ensures identification, sourcing, access and management of the external resources that an organisation needs or may need to fulfil its strategic objectives (21). Comparing procurement with purchasing from supply chain management perspective, procurement focuses on how supplies are flowing strategically from the purchasers and suppliers.

The procurement perspectives are mainly continuous supply: production has to be ensured by continuous material supply because its stoppage increased operational costs and exposed customers to shortage in supplies; minimizing inventory investment: maintaining supply continuity with minimum inventory investment is the goal of the modern procurement; quality improvement which increasing the customer s satisfaction and supplier development by locating, analyzing capabilities or developing suppliers for better continuous improvement.

Timely, reliable movement of health commodities and data up and down the supply chain: from the service delivery point (such as health facilities where health commodities are dispensed) to the higher levels and back are the characteristics of an effective supply chain. Indeed, data from the service delivery points are the most useful for decision making in supply chain management of regarding health commodities requirements (22).

2.6 Antiretroviral Drugs Supply Chain Management

The supply chain management, a mechanism which by which the drugs and others items are delivered to health facilities and procurement, process of ordering these drugs and other items, are critical processes required to move antiretroviral drugs from manufacturers to patients. Understanding the dynamics of these processes is important for the global health community, to ensure an efficient and full treatment of people living with HIV. The supply chain management is a way to coordinate a set of activities carried out to acquire goods and services from a defined

source and to be delivered to end consumer. These activities include procurement (sourcing the supplies), warehousing (where applicable) and distribution (logistics systems) to end consumer. Antiretroviral drugs supply chain each year worth more than one billion US Dollars, corresponding to over one hundred million packs moving worldwide from manufacturers to countries around the world in order to be served to millions of patients under antiretroviral therapy in different tens thousands of sites. Four key stakeholder groups are involved in the antiretroviral drugs supply chain: (i) manufacturers who develop and produce the products, (ii) beneficiaries who have responsibility to take care of patient treatment, (iii) funders or donors who finance operations and processes for getting products from manufacturers to beneficiaries and payments from donors to manufacturers; and (iv) operating agents who determine the technical specifications and quantity of antiretroviral and their projected route from manufacturer to recipient country (23).

2.7 Antiretroviral drugs procurement

Globally, the public procurement follows an established process where the principles are almost the same: ensuring the value for money, competition, transparency, equity and integrity; all in order to attain the six rights (right product, right quantity, right quality, right time, right place and right price). We can cite the case of the European Union where key principle in public procurement are: EU treaty – accountability – separation of duties – risk assessment – record keeping – training – conflict of interest – public financial procedures – codes of conduct – acceptance of bribes/gifts – collusive tendering (24).

The procurement processes are carried out by the RBC/MPPD following various steps: from the quantification and forecasting to contract management, where:

- a. The quantification, a process of determination of quantities and costs of needed commodities for a given health program, using appropriate and established tools of estimation, is a critical supply chain management activity linking information on commodities and services at facility level with program policies and plans at national level to ensure uninterrupted supply of health commodities (25). To come up with the forecasted needs the team used different tools (Quantimed® for ARVs) and the supply plans in different tools (Pipeline® tool for ARVs drugs) is elaborated for the fiscal year related to the quantification period.

In Rwanda, the quantification of antiretroviral drugs is conducted by the national quantification committee on the leadership of the Ministry of Health, through RBC and other MOH development partners, and follows various stages from initial planning activities to continuous process of review and update of the quantification and its results.

The quantification stages are (26):

- Preparatory activities: aiming to ensure that entire process of quantification happens effectively, in due timeline and with data required for each stage;
 - Data collection: prescribed by the preparatory activities, and data collected from various sources will inform the forecast and supply planning process;
 - Data analysis, validation and assumptions building: collected data are reviewed to ensure quality, then validated to be used as a basis to assumptions building, guiding the forecast and supply planning process;
 - Forecasting and supply plan generation: activity resulting to a forecasted consumption data and cost requirements and scheduling of shipments to ensure uninterrupted supply of commodities;
 - Report writing and dissemination: preparing and presenting documentation on agreed assumptions and results of the forecasting and supply planning activities, for decision making;
 - Routine stock status review: by analyzing data at central level to identify actions to be taken and ensuring that stock of commodities is at adequate levels;
 - Quarterly supply plan review: collect routinely, aggregate and analyze logistics management information system data to review and/or update shipments scheduling;
 - Implementation review by measuring performance of procuring entities to inform decision makers on problems faced during procurement; and
 - Quantification review: to appraise the accuracy of the forecast consumption data versus the actual consumption data to take appropriate action.
- b. The procurement of antiretroviral drugs started after receiving of the quantification report approved by the MOH, by two entities: RBC/PPD for Global Fund and USAID Global Health Supply Chain Program – Procurement and Supply Management Project for PEPFAR.

The initiation of the procurement processes is done based on the public procurement law and regulations and the Global Fund Quality Assurance Policy for pharmaceutical products to procure quality products from prequalified manufacturers in case of using GF budget.

The availability of health commodities is a key in success of any health program and the antiretroviral drugs are key in the success of the antiretroviral therapy. Thus, the latter requires an effective supply chain to ensure that antiretroviral drugs are available at all the times to avoid treatment interruptions. However, today the major challenge, is to maintain an uninterrupted supply of antiretroviral drugs which is critical to minimize an emergence of HIV drugs resistance, protect the health and well-being of patients and reach universal access goals (27). Investing in a commodity security approach for ensuring continuous product availability for health programs is cost effective, improves program impact, and saves lives. To be successfully possible, commodity security is to be addressed early in the planning stages of program implementation and scale up.

The procurement of antiretroviral drugs in Rwanda are performed through two ways: by RBC/MPPD, using the budget from GF (28) and by USAID GHSC-PSM Project, under PEPFAR budget.

The source of supply of antiretroviral drugs are the manufacturers prequalified by WHO and Stringent Regulatory Authorities, such United States Foods and Drugs Authority (USFDA). However, these manufacturers sometimes are in a limited number, leading to dependency for specific antiretroviral drugs, case of third line products.

CHAPTER 3. RESEARCH METHODOLOGY

The chapter outlines which methodology used in this research study. Information relating to research design, sampling methods, target population, and analysis of data have been given.

3.1 Research Design

This descriptive and retrospective study described the factors affecting the commodity security of antiretroviral drugs in Rwanda with procurement perspectives using procurement records for the period of January 2017 through December 2018.

3.2 Population Target

The target population of this study was 100% procurement records of ARV drugs procured throughout study period. The antiretroviral drugs used in Rwanda are determined based on the national standard treatment guidelines and the latest version was issued in 2016 (29), but with some amendments through circulars informing users changes in treatment and patients care (30,31). Thus, the national standard treatment guidelines have 2 main categories: adults and pediatrics and within these categories; there is first line, second and third line for adults and for pediatrics. There are also regimens and medicines per regimens where a total of 29 antiretroviral drugs is used in HIV care and treatment in Rwanda. However, since July 2017, the phaseout processes led to abandon progressively the use of some drugs under Nevirapine and Zidovudine regimen like Lamivudine/Zidovudine/Nevirapine (150/300/200) mg, Nevirapine 200mg and Zidovudine 10mg/mL syrup, and Tenofovir/Emtricitabine (300/200) mg used in pre-exposure prophylaxis, leading to the decrease of the number of antiretroviral drugs to 25.

The first line treatment is defined as a combination of antiretroviral molecules that is accepted as best for the initial treatment of HIV (naïve or newly enrolled patients), including ARV drugs which are safe, effective, and convenient for most PLHIV who have never taken ARVs before; while second line treatment is defining a combination of ARV drugs to which a patient switches in case treatment failure on 1st line is confirmed and lastly, third line treatment refers to treatment regimens for people who have failed first and second line and thus remaining with few or limited antiretroviral drug options.

The phaseout processes are due to the fact that the national standard treatment guidelines are dynamic; products can be entering while others being abandoned. The above information is summarized in the table of ARV used in Rwanda provided in Appendix A.

3.3. Study site

The data of our study were collected from Rwanda Medical Center / MPPD: in procurement unit, in quality assurance/quality control unit and from eLMIS.

The commodity security is a term defined as the availability of a given commodity to people in need when and where that commodity has to be used.

The national medical central store is the Rwanda Biomedical Centre (RBC)/ Medical Procurement and Production Division (MPPD), one of standalone divisions, ensuring that quality and cost-effective drugs and medical equipment are available for the population, it ensures equitable access of quality cost effective drugs and medical equipment, and procures world class quality pharmaceutical products, improves storage and distribution of medical commodities through a computerized management system, by its five units which are: Warehouse and Distribution, Quantification and Stock Monitoring, Sales and Marketing, Health commodities procurement and Medical Production.

The Rwanda Biomedical Centre (RBC) is one of the central level's entities in the health system's pyramidal structure in Rwanda, along with the national referral hospitals under the Ministry of Health; elaborating policies and strategies, ensuring monitoring and evaluation, capacity building and resource mobilization; organizing and coordinating the intermediary and peripheral levels of the health system, and providing them with administrative, technical and logistical support (32).

Rwanda Biomedical Centre, established by the law N° 54/2010 of 25/01/2011 establishing Rwanda Biomedical Centre (RBC) and determining its mission, organization and functioning (33), modified and completed by the law N° 48/2012 of 14/01/2013 (34), is a government institution under Ministry of Health, having the vision to become a Center of Excellence for the prosperity of the country, ensuring quality health service delivery, education and research and its mission is to promote quality affordable and sustainable health care services to the population through innovative and evidence-based interventions and practices guided by ethics and professionalism (35).

3.4. Study instruments and tools

Secondary data were obtained from tenders, framework agreements, purchase orders, acceptance reports for delivered products and quality reports of the analysis performed on sampled batches of received products.

To collect those data, data collection sheets and checklists, (Appendix B) were used.

3.3 Data analysis and interpretation

Both qualitative and quantitative data were analysed using Microsoft Excel and presented in tables as percentages.

The interpretation of findings based on the following:

- How procurement proceedings (policies and processes) related to procurement of antiretroviral drugs are compared to standards requirements:

Tender requirements/needs from the forecasting and supply planning, tendering based on the procurement law and Global Fund quality assurance guidelines, contract awarding based on the bidding document criteria and contract signature, contract management (purchase orders issuance, contract execution and reception of goods).

- The level of dependency of the suppliers for antiretroviral drugs:

Monitoring the level of dependency towards the suppliers over a time is a procurement key performance indicator against the number of suppliers because, relying on too few suppliers creates a high risk of dependency even if having too many suppliers increases the risk of dealing with unreliable suppliers.

- The supplier performance for the suppliers of antiretroviral drugs:

This is regarding the order completeness, the timely deliveries and supplier defect rate: the quality of the final product delivered from the suppliers.

The used data have been collected from the procurement proceedings (tenders performed in the studied period: from January 2017 to December 2018) of antiretroviral drugs; the contracts (framework agreements) between RBC/MPPD and suppliers of antiretroviral drugs, executed from January 2017 to December 2018; the purchase orders placed and performed under the above framework agreements from various suppliers within the above mentioned period.

For the analysis of procurement proceedings, the observed proceedings have been compared to the standards from the law, regulations and other guidelines to procure antiretroviral drugs as per the following:

- Tender requirements/needs from the forecasting and supply planning
- Tendering based on the procurement law and GF quality assurance guidelines
- Contract awarding based on the bidding document criteria and contract signature
- Purchase orders issuance
- Contract execution

Regarding the level of dependency of the supplies of antiretroviral drugs, the analysis was carried out on the number of the available suppliers (as prequalified manufacturers) to participate in procurement processes in order to obtain contracts of supplying antiretroviral drugs in Rwanda, using GF budget (as the source of funds passing through the national treasury).

For the suppliers performance, a set of parameters have been taken into consideration: order completeness, timely delivery and quality of products delivered during the period from January 2017 to December 2018; by analysing the purchase orders of antiretroviral drugs issued by RBC/MPPD, the reception (acceptance) reports of these purchase orders and the reports on the quality assessment performed on sampled batches of the delivered antiretroviral drugs over the studied period of time (from January 2017 to December 2018).

3.4 Ethics considerations

For purposes of research and ethics requirements, the research was approved by the Institutional Review Board of the College of Medicines and Health Sciences, University of Rwanda (CMHS IRB) approved research protocol on 19th July 2019 under approval notice N° 358/CMHS IRB/2019 and then the National Health Research Committee (NHRC) approved research protocol on 5th August 2019 under scientific review approval notice N° NHRC/2019/PROT/044.

3.5 Study limitations

The research was performed alongside uninterrupted daily tasks at work and consequently the time available was limited. In addition, lack of sufficient previous researches on this topic was a challenge for the performance of the research.

CHAPTER 4. RESULTS

4.1 Procurement proceedings

Considering the requirements on the procurement proceedings, things are well in place: procurements are initiated based on results from the quantification and forecasting exercise, leading to purchase what is needed and according to available funds; the law, regulations and guidelines are respected where restricted tendering (based on the fact that the goods to be procured are from known manufacturers) is used to procure antiretroviral drugs, as per the Global Fund guidelines recommending to purchase antiretroviral drugs from GF (WHO and SRA) prequalified manufacturers and then the contracts will be made upon carefully evaluations, according to tender criteria to purchase right products, leading easy contract execution and management.

The table below is summarizing how the recommended criteria are followed and complying to the reference set for the smooth procurement proceedings:

- Required products, quantities and related budget will be defined in the supply plan outcomes,
- Restricted tendering was used as procurement method following the public procurement law and GF (funder) quality assurance guidelines
- Lowest qualified bidder principle to ensure value for money is driving the contract award made based on bidding document criteria to establish contracts
- Once the contracts, based on unit prices, are established, purchase orders are issued according to shipments defined during supply planning and
- Contracts are executed according to agreed terms and conditions mainly, the delivery period and technical specifications.

Table 1. **Procurement proceedings performed both in 2017 and 2018.**

Recommended criteria/procurement proceeding	Reference	Tender 1 (2017)	Tender 2 (2018)
		Compliance	Compliance
Tender requirements/needs from the forecasting and supply planning	Supply plan outcomes	Complied	Complied
Tendering based on the procurement law and GF quality assurance guidelines	Restrict tendering method	Complied	Complied
Contract awarding based on the bidding document criteria and contract signature	Value for money (the lowest qualified bidder)	Complied	Complied
Purchase orders issuance	Planned shipments at unit price contracted	Complied	Complied
Contract execution	Delivery period and technical specifications	Complied	Complied

4.2 Level of dependency

On the number of prequalified (available) manufacturers for antiretroviral drugs (36), 7 products are having 3 or less prequalified manufacturers, but only 5 products were concerned with the tendering processes, with an average rate of participation in tendering processes of 47% in 2017 (as indicated in the table 2 below), decreasing in 2018 up to 33% (as indicated in the tables 3 below). Products with more than 3 prequalified manufacturers had the average rate of participation in tendering processes of 24% and 39% respectively in 2017 and 2018 as per the tables 4 and 5 below. During the period from January 2017 to December 2018, no stock out recorded at the central level (RBC/MPPD) for all antiretroviral drugs managed at this level of supply chain management and the aforesaid information are summarized in the tables 6 and 7 respectively entitled participation in tendering process and recorded stock out in 2017 and participation in tendering process and recorded stock out in 2018.

Table 2. Participation in tendering process in 2017: products having 3 or less available prequalified manufacturers.

	Number of GF prequalified manufacturers (= A)	Suppliers participated	
		2017 (=B)	[100*(A/B)]
Atazanavir/Ritonavir 300/100mg, Box of 30 tabs	3	1	33%
Etravirine 100mg, Box of 120 tabs	1	1	100%
Lamivudine 150mg + Zidovudine 300mg, Box of 60 tabs	3	3	100%
Lopinavir/Ritonavir 80/20mg/mL, Box of 5 bottles of 60mL	2	0	0%
Raltegravir 400mg, Box of 60 tabs	2	0	0%
Average participation rate			47%

Table 3. Participation in tendering process in 2018: products having 3 or less available prequalified manufacturers.

	Number of GF prequalified manufacturers (= A)	Suppliers participated	
		2018 (=B)	[100*(A/B)]
Abacavir 60mg + Lamivudine 30mg, Box of 60 tabs	3	1	33%
Etravirine 100mg, Box of 120 tabs	1	1	100%

Lopinavir/Ritonavir 80/20mg/mL, Box of 5 bottles of 60mL	2	0	0%
Nevirapine 10mg/mL Syrup, Bottle of 240mL	3	1	33%
Raltegravir 400mg, Box of 60 tabs	2	0	0%
Average participation rate			33%

Table 4. **Participation in tendering process in 2017: products having more than 3 available prequalified manufacturers.**

	Number of GF prequalified manufacturers (= A)	Suppliers participated	
		2017 (=B)	[100*(A/B)]
Abacavir 20mg/mL Syrup, Bottle of 240mL	4	1	25%
Abacavir 600mg + Lamivudine 300mg, Box of 30 tabs	6	3	50%
Atazanavir 150mg, Box of 60 tabs	5	0	0%
Atazanavir 200mg, Box of 60 tabs	4	0	0%
Darunavir 600mg, Box of 60 tabs	6	2	33%
Efavirenz 200mg, Box of 90 tabs	7	1	14%
Efavirenz 50mg, Box of 30 tabs	4	0	0%
Efavirenz 600mg, Box of 30 tabs	15	3	20%
Lamivudine 150mg + Nevirapine 200mg + Zidovudine 300mg, Box of 60 tabs	7	3	43%

Lamivudine 10mg/mL Syrup, Bottle of 240mL	15	1	7%
Lamivudine 30mg + Zidovudine 60mg, Box of 60 tabs	6	2	33%
Tenofovir 300mg + Lamivudine 300mg + Efavirenz 600mg, Box of 30 tabs	5	3	60%
Lopinavir/Ritonavir 100/25mg, Box of 60 tabs	4	1	25%
Lopinavir 200mg + Ritonavir 50mg, Box of 120 tabs	5	1	20%
Nevirapine 200mg, Box of 60 tabs	13	3	23%
Tenofovir 300mg + Lamivudine 300mg, Box of 30 tabs	9	3	33%
Tenofovir 300mg, Box of 30 tabs	11	2	18%
		Average participation rate	24%

Table 5. **Participation in tendering process in 2018: products having more than 3 available prequalified manufacturers.**

	Number of GF prequalified manufacturers (= A)	Suppliers participated	
		2018 (=B)	[100*(A/B)]
Atazanavir 150mg, Box of 60 tabs	5	1	20%
Atazanavir 200mg, Box of 60 tabs	4	1	25%
Dolutegravir 50mg, Box of 30 tabs	4	4	100%
Efavirenz 50mg, Box of 30 tabs	4	1	25%

Ritonavir 100mg, Box of 60 tabs	4	1	25%
Tenofovir/Emtricitabine 300/200mg, Box of 30 tabs	10	3	30%
Tenofovir/Lamivudine/Dolutegravir 300/300/50mg, Box of 30 tabs	5	3	60%
Zidovudine 10mg/mL Syrup, Bottle of 240mL	7	2	29%
	Average participation rate		33%

Table 6. Participation in tendering process and recorded stock out in 2017.

	Number of GF prequalified manufacturers (= A)	Suppliers participated		Stock out (in days)
		2017 (=B)	% [100*(A/B)]	2017
Abacavir 20mg/mL Syrup, Bottle of 240mL	4	1	25%	0
Abacavir 600mg + Lamivudine 300mg, Box of 30 tabs	6	3	50%	0
Atazanavir 150mg, Box of 60 tabs	5	0	0%	0
Atazanavir 200mg, Box of 60 tabs	4	0	0%	0
Atazanavir/Ritonavir 300/100mg, Box of 30 tabs	3	1	33%	0
Darunavir 600mg, Box of 60 tabs	6	2	33%	0
Efavirenz 200mg, Box of 90 tabs	7	1	14%	0
Efavirenz 50mg, Box of 30 tabs	4	0	0%	0
Efavirenz 600mg, Box of 30 tabs	15	3	20%	0
Etravirine 100mg, Box of 120 tabs	1	1	100%	0
Lamivudine 150mg + Nevirapine 200mg + Zidovudine 300mg, Box of 60 tabs	7	3	43%	0
Lamivudine 150mg + Zidovudine 300mg, Box of 60 tabs	3	3	100%	0
Lamivudine 10mg/mL Syrup, Bottle of 240mL	15	1	7%	0

Lamivudine 30mg + Zidovudine 60mg, Box of 60 tabs	6	2	33%	0
Tenofovir 300mg + Lamivudine 300mg + Efavirenz 600mg, Box of 30 tabs	5	3	60%	0
Lopinavir/Ritonavir 80/20mg/mL, Box of 5 bottles of 60mL	2	0	0%	0
Lopinavir/Ritonavir 100/25mg, Box of 60 tabs	4	1	25%	0
Lopinavir 200mg + Ritonavir 50mg, Box of 120 tabs	5	1	20%	0
Nevirapine 200mg, Box of 60 tabs	13	3	23%	0
Raltegravir 400mg, Box of 60 tabs	2	0	0%	0
Tenofovir 300mg + Lamivudine 300mg, Box of 30 tabs	9	3	33%	0
Tenofovir 300mg, Box of 30 tabs	11	2	18%	0

Table 7. Participation in tendering process and recorded stock out in 2018.

	Number of GF prequalified manufacturers (= A)	Suppliers participated		Stock out (in days)
		2018 (=B)	% [100*(A/B)]	2018
Abacavir 20mg/mL Syrup, Bottle of 240mL	4	N/A	N/A	0
Abacavir 60mg + Lamivudine 30mg, Box of 60 tabs	3	1	33%	0
Abacavir 600mg + Lamivudine 300mg, Box of 30 tabs	6	N/A	N/A	0
Atazanavir 150mg, Box of 60 tabs	5	1	20%	0

Atazanavir 200mg, Box of 60 tabs	4	1	25%	0
Atazanavir/Ritonavir 300/100mg, Box of 30 tabs	3	N/A	N/A	0
Darunavir 600mg, Box of 60 tabs	6	N/A	N/A	0
Dolutegravir 50mg, Box of 30 tabs	4	4	100%	0
Efavirenz 200mg, Box of 90 tabs	7	N/A	N/A	0
Efavirenz 50mg, Box of 30 tabs	4	1	25%	0
Efavirenz 600mg, Box of 30 tabs	15	N/A	N/A	0
Etravirine 100mg, Box of 120 tabs	1	1	100%	0
Lamivudine 150mg + Nevirapine 200mg + Zidovudine 300mg, Box of 60 tabs	7	N/A	N/A	0
Lamivudine 150mg + Zidovudine 300mg, Box of 60 tabs	3	N/A	N/A	0
Lamivudine 10mg/mL Syrup, Bottle of 240mL	15	N/A	N/A	0
Lamivudine 30mg + Zidovudine 60mg, Box of 60 tabs	6	N/A	N/A	0
Tenofovir 300mg + Lamivudine 300mg + Efavirenz 600mg, Box of 30 tabs	5	N/A	N/A	0
Lopinavir/Ritonavir 80/20mg/mL, Box of 5 bottles of 60mL	2	0	0%	0
Lopinavir/Ritonavir 100/25mg, Box of 60 tabs	4	N/A	N/A	0
Lopinavir 200mg + Ritonavir 50mg, Box of 120 tabs	5	N/A	N/A	0
Nevirapine 10mg/mL Syrup, Bottle of 240mL	3	1	33%	0
Nevirapine 200mg, Box of 60 tabs	13	N/A	N/A	0
Raltegravir 400mg, Box of 60 tabs	2	0	0%	0
Ritonavir 100mg, Box of 60 tabs	4	1	25%	0

Tenofovir 300mg + Lamivudine 300mg, Box of 30 tabs	9	N/A	N/A	0
Tenofovir/Emtricitabine 300/200mg, Box of 30 tabs	10	3	30%	0
Tenofovir 300mg, Box of 30 tabs	11	N/A	N/A	0
Tenofovir/Lamivudine/Dolutegravir 300/300/50mg, Box of 30 tabs	5	3	60%	0
Zidovudine 10mg/mL Syrup, Bottle of 240mL	7	2	29%	0

* **N/A (Not applicable):** means that the product had not been in the tendering process because there was in ongoing framework agreement.

4.3 Suppliers' performance

A total of 55 purchase orders have been issued during the period from January 2017 to December 2018: 30 in 2017 and 25 in 2018; for 23 out of 29 antiretroviral drugs used for HIV/AIDS care and treatment in Rwanda. However, in 2017, there was one drug not ordered by RBC/MPPD but also one drug not ordered in 2018 even if it was not the same drugs as in 2017. The reason that a product is not ordered while there is a related framework agreement is the stock level countrywide (15).

4.3.1 Order fullness

Regarding the fullness in delivery of the purchase orders, in 2017, only 3 drugs have not fully delivered; the order fullness average is 86% and this number was 81% in 2018, representing 3 drugs, the same number as in 2017 but not for the same drugs.

Table 8. **Order fullness in 2017**

	2017		
	Number of orders in total	Number of orders fully delivered	%
Abacavir 20mg/mL Syrup, Bottle of 240mL	1	1	100%
Abacavir 600mg + Lamivudine 300mg, Box of 30 tabs	1	0	0%
Atazanavir 150mg, Box of 60 tabs	2	2	100%
Atazanavir 200mg, Box of 60 tabs	2	2	100%
Atazanavir/Ritonavir 300/100mg, Box of 30 tabs	3	3	100%
Darunavir 600mg, Box of 60 tabs	1	1	100%
Efavirenz 200mg, Box of 90 tabs	3	3	100%
Efavirenz 50mg, Box of 30 tabs	1	1	100%
Efavirenz 600mg, Box of 30 tabs	1	1	100%
Etravirine 100mg, Box of 120 tabs	3	3	100%
Lamivudine 150mg + Nevirapine 200mg + Zidovudine 300mg, Box of 60 tabs	1	0	0%

Lamivudine 150mg + Zidovudine 300mg, Box of 60 tabs	2	2	100%
Lamivudine 10mg/mL Syrup, Bottle of 240mL	2	2	100%
Lamivudine 30mg + Zidovudine 60mg, Box of 60 tabs	1	1	100%
Tenofovir 300mg + Lamivudine 300mg + Efavirenz 600mg, Box of 30 tabs	1	1	100%
Lopinavir/Ritonavir 80/20mg/mL, Box of 5 bottles of 60mL	1	1	100%
Lopinavir/Ritonavir 100/25mg, Box of 60 tabs	1	1	100%
Lopinavir 200mg + Ritonavir 50mg, Box of 120 tabs	1	1	100%
Nevirapine 200mg, Box of 60 tabs	1	0	0%
Raltegravir 400mg, Box of 60 tabs	2	2	100%
Tenofovir 300mg + Lamivudine 300mg, Box of 30 tabs	1	1	100%
Tenofovir 300mg, Box of 30 tabs	1	1	100%
Total number of orders	33*	Average of fullness	86%

*The difference between the total number of purchase orders in the text (30) and the number in the table (33) came from the fact that a purchase order can contain more than one product.

Table 9. Order fullness in 2018

	2018		
	Number of orders in total	Number of orders fully delivered	%
Abacavir 20mg/mL Syrup, Bottle of 240mL	2	2	100%
Abacavir 600mg + Lamivudine 300mg, Box of 30 tabs	1	0	0%

Atazanavir 200mg, Box of 60 tabs	1	1	100%
Atazanavir/Ritonavir 300/100mg, Box of 30 tabs	1	1	100%
Darunavir 600mg, Box of 60 tabs	2	2	100%
Efavirenz 200mg, Box of 90 tabs	2	2	100%
Efavirenz 50mg, Box of 30 tabs	3	3	100%
Efavirenz 600mg, Box of 30 tabs	1	1	100%
Etravirine 100mg, Box of 120 tabs	1	0	0%
Lamivudine 150mg + Nevirapine 200mg + Zidovudine 300mg, Box of 60 tabs	1	0	0%
Lamivudine 10mg/mL Syrup, Bottle of 240mL	2	1	50%
Lamivudine 30mg + Zidovudine 60mg, Box of 60 tabs	2	2	100%
Tenofovir 300mg + Lamivudine 300mg + Efavirenz 600mg, Box of 30 tabs	1	1	100%
Lopinavir/Ritonavir 100/25mg, Box of 60 tabs	1	1	100%
Lopinavir 200mg + Ritonavir 50mg, Box of 120 tabs	1	1	100%
Nevirapine 10mg/mL Syrup, Bottle of 240mL	1	1	100%
Nevirapine 200mg, Box of 60 tabs	1	1	100%
Raltegravir 400mg, Box of 60 tabs	1	1	100%
Tenofovir 300mg + Lamivudine 300mg, Box of 30 tabs	1	1	100%
Tenofovir 300mg, Box of 30 tabs	3	2	67%
Total number of orders	29*	Average of fullness	81%

*The difference between the total number of purchase orders in the text (25) and the number in the table (29) came from the fact that one product can have more than one purchase order.

4.3.2 Timeliness in delivery

The deliveries of the purchase orders have been made timely only for 8 drugs (issued in 10 purchase orders) in 2017 corresponding to an average of 29% while there were 9 drugs (totalizing 16 purchase orders) timely delivered in 2018, which is an average of 38%.

Table 10. Order timeliness in 2017

	2017		
	Number of orders in total	Number of orders timely delivered	%
Abacavir 20mg/mL Syrup, Bottle of 240mL	1	0	0%
Abacavir 600mg + Lamivudine 300mg, Box of 30 tabs	1	1	100%
Atazanavir 150mg, Box of 60 tabs	2	0	0%
Atazanavir 200mg, Box of 60 tabs	2	1	50%
Atazanavir/Ritonavir 300/100mg, Box of 30 tabs	3	2	67%
Darunavir 600mg, Box of 60 tabs	1	0	0%
Efavirenz 200mg, Box of 90 tabs	3	0	0%
Efavirenz 50mg, Box of 30 tabs	1	0	0%
Efavirenz 600mg, Box of 30 tabs	1	0	0%
Etravirine 100mg, Box of 120 tabs	3	2	67%
Lamivudine 150mg + Nevirapine 200mg + Zidovudine 300mg, Box of 60 tabs	1	0	0%
Lamivudine 150mg + Zidovudine 300mg, Box of 60 tabs	2	0	0%
Lamivudine 10mg/mL Syrup, Bottle of 240mL	2	0	0%
Lamivudine 30mg + Zidovudine 60mg, Box of 60 tabs	1	1	100%
Tenofovir 300mg + Lamivudine 300mg + Efavirenz 600mg, Box of 30 tabs	1	0	0%

Lopinavir/Ritonavir 80/20mg/mL, Box of 5 bottles of 60mL	1	1	100%
Lopinavir/Ritonavir 100/25mg, Box of 60 tabs	1	1	100%
Lopinavir 200mg + Ritonavir 50mg, Box of 120 tabs	1	0	0%
Nevirapine 200mg, Box of 60 tabs	1	0	0%
Raltegravir 400mg, Box of 60 tabs	2	1	50%
Tenofovir 300mg + Lamivudine 300mg, Box of 30 tabs	1	0	0%
Tenofovir 300mg, Box of 30 tabs	1	0	0%
	33	10	29%

Table 11. Order timeliness in 2018

	2018		
	Number of orders in total	Number of orders timely delivered	%
Abacavir 20mg/mL Syrup, Bottle of 240mL	2	0	0%
Abacavir 600mg + Lamivudine 300mg, Box of 30 tabs	1	0	0%
Atazanavir 200mg, Box of 60 tabs	1	0	0%
Atazanavir/Ritonavir 300/100mg, Box of 30 tabs	1	0	0%
Darunavir 600mg, Box of 60 tabs	2	2	100%
Efavirenz 200mg, Box of 90 tabs	2	1	50%
Efavirenz 50mg, Box of 30 tabs	3	2	67%
Efavirenz 600mg, Box of 30 tabs	1	0	0%
Etravirine 100mg, Box of 120 tabs	1	1	100%
Lamivudine 150mg + Nevirapine 200mg + Zidovudine 300mg, Box of 60 tabs	1	0	0%

Lamivudine 10mg/mL Syrup, Bottle of 240mL	2	2	100%
Lamivudine 30mg + Zidovudine 60mg, Box of 60 tabs	2	0	0%
Tenofovir 300mg + Lamivudine 300mg + Efavirenz 600mg, Box of 30 tabs	1	0	0%
Lopinavir/Ritonavir 100/25mg, Box of 60 tabs	1	1	100%
Lopinavir 200mg + Ritonavir 50mg, Box of 120 tabs	1	1	100%
Nevirapine 10mg/mL Syrup, Bottle of 240mL	1	0	0%
Nevirapine 200mg, Box of 60 tabs	1	0	0%
Raltegravir 400mg, Box of 60 tabs	1	1	100%
Tenofovir 300mg + Lamivudine 300mg, Box of 30 tabs	1	0	0%
Tenofovir 300mg, Box of 30 tabs	3	1	33%
	29	12	38%

The order timeliness rate was found to be very low during the period of this research and there is a need to take action by strengthening suppliers' performance. The table below shows the comparison of both 2017 and 2018 order timeliness per product.

Table 12. Comparison of 2017 and 2018 order timeliness.

	2017			2018		
	Number of orders in total	Number of orders timely delivered	%	Number of orders in total	Number of orders timely delivered	%
Abacavir 20mg/mL Syrup, Bottle of 240mL	1	0	0%	2	0	0%
Abacavir 600mg+Lamivudine 300mg, Box of 30 tabs	1	1	100%	1	0	0%
Atazanavir 150mg, Box of 60 tabs	2	0	0%			N/A
Atazanavir 200mg, Box of 60 tabs	2	1	50%	1	0	0%
Atazanavir/Ritonavir 300/100mg, Box of 30 tabs	3	2	67%	1	0	0%
Darunavir 600mg, Box of 60 tabs	1	0	0%	2	2	100%
Efavirenz 200mg, Box of 90 tabs	3	0	0%	2	1	50%
Efavirenz 50mg, Box of 30 tabs	1	0	0%	3	2	67%
Efavirenz 600mg, Box of 30 tabs	1	0	0%	1	0	0%
Etravirine 100mg, Box of 120 tabs	3	2	67%	1	1	100%
Lamivudine 150mg+Nevirapine 200mg+Zidovudine 300mg, Box of 60 tabs	1	0	0%	1	0	0%
Lamivudine 150mg+Zidovudine 300mg, Box of 60 tabs	2	0	0%			N/A
Lamivudine 10mg/mL Syrup, Bottle of 240mL	2	0	0%	2	2	100%

Lamivudine 30mg+Zidovudine 60mg, Box of 60 tabs	1	1	100%	2	0	0%
Tenofovir 300mg+Lamivudine 300mg+Efavirenz 600mg, Box of 30 tabs	1	0	0%	1	0	0%
Lopinavir/Ritonavir 80/20mg/mL, Box of 5 bottles of 60mL	1	1	100%			N/A
Lopinavir/Ritonavir 100/25mg, Box of 60 tabs	1	1	100%	1	1	100%
Lopinavir 200mg + Ritonavir 50mg, Box of 120 tabs	1	0	0%	1	1	100%
Nevirapine 10mg/mL Syrup, Bottle of 240mL			N/A	1	0	0%
Nevirapine 200mg, Box of 60 tabs	1	0	0%	1	0	0%
Raltegravir 400mg, Box of 60 tabs	2	1	50%	1	1	100%
Tenofovir 300mg+Lamivudine 300mg, Box of 30 tabs	1	0	0%	1	0	0%
Tenofovir 300mg, Box of 30 tabs	1	0	0%	3	1	33%

*N/A (Not applicable) means that there was no order for related product in the period in question.

4.3.3 Quality in delivered products

The analysis performed by the quality control/quality assurance unit on the delivered drugs in 2017 concerned 11 drugs and 15 drugs in 2018, and all sampled batches found complying to analyzed parameters which are: identification, uniformity of mass, assay, related substances, total aerobic microbial count, total combined yeasts/molds count and specified microorganism tests.

CHAPTER 5. ANALYSIS AND DISCUSSIONS

5.1 Procurement proceedings

Concerning the procurement proceedings, there was a compliance in all stages. However, there was a limited number of participants in tendering processes, even if the GF guidelines recommending the WHO/SRA prequalified manufacturers, the registered manufacturers are still few, linked to the new procurement system (e-procurement system) starting to be implemented in Rwanda by July 2016. In addition, efforts have to be put in forecasting, supply planning, inventory management systems and contract management in order to maintain even do better in commodity security of antiretroviral drugs.

5.2 Level of dependency

During the research, there was no recorded stock out in eLMIS for the period from January 2017 to December 2018 but this was due to the fact that the stock out in the system is defined as no quantity of a given product in the stock while, based on the inventory control system at MPPD level, the stock out means that there is less quantity than minimum stock level or nothing, where the minimum stock level is 6 months of stock (15).

Before this research, the thinking was that the limited number of available prequalified manufacturers for a certain products can lead to the dependency of the purchaser against the suppliers, but findings shown that this was not the case; and the justification is that other factors in place in the supply chain systems worked well to absorb that.

5.3 Suppliers' performance

The purchase orders were issued based on the supply plan from the exercise of quantification and forecasting to define the quantity to be ordered and this is made based on the level of stock at all supply chain management levels (central, regional (district pharmacies) and health facilities). Also, the purchase orders issuance considered framework agreements in place per delivery periods and not per products and/or supplier. There, one product can be on one or more purchase orders.

Based on the above and following the findings during the research, we found that not all antiretroviral drugs had been ordered during the studied period, a given product could be on more than one purchase order. This helped to maintain the efficient inventory management at all levels and ensuring the products availability.

The orders fullness is depending on various factors such as the volume of the purchase orders: if the ordered quantity was approaching the batch size, there is a chance to get the full quantity delivered or, if it is a product mostly used (case of antiretroviral drugs used in first line), that product is produced frequently without threat to not be sold from the manufacturer. But also, having an accurate supply planning facilitated the production schedule on manufacturers' side to attain the reliable supply chain. However, the transportation means affected the fullness where there are damaged quantities during delivery leading to the orders not fully delivered in term of quantity. The purchase orders not fully delivered in 2017 were for most the products ordered once and not frequently used because of the phaseout planning to shift for other products.

The timeliness in delivery of the purchase orders found in this research presented a low rate (29% in 2017 and 38% in 2018) and the reasons are the suppliers' location, the transportation mode used, following the volume of the ordered quantity.

CHAPTER 6. CONCLUSION AND RECOMMENDATIONS

The procurement proceedings are well performed, the lower number of available suppliers of antiretroviral drugs does not affect the availability of antiretroviral drugs in term of dependency towards the suppliers and there is a way go regarding the suppliers' performance especially in terms of timely deliveries, where the average rate of timeliness was 29% and 38% respectively in 2017 and 2018.

The procurement of antiretroviral drugs in Rwanda is well established following the public law, regulations and Global Fund guidelines to ensure access to safe, effective, quality and affordable antiretroviral drugs in Rwanda, which with other components of the health systems can help in attaining the commodity security, and this can be a starting point to build a well-established and stronger health supply chain management for health commodities countrywide.

Based on the findings, the following are the recommendations:

1. With limitation in time and financial resources, other deep researches have to be done covering long period of time and on all commodity security components: policies, access, quality and rational use of medicines, human and financial resources.
2. Establishing and conducting suppliers' performance as one of the best practices to ensure orders fullness and timeliness.
3. Another area to be explored is the use of e-procurement system versus manual system in order to establish the link between the participation rate in tendering processes following the low number of e-procurement system registered companies (prequalified manufacturers of ARV drugs).

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APPENDICES

Appendix A. List of antiretroviral drugs used in HIV care and treatment in Rwanda

#	Product Description	Adult formulations			Pediatric formulations	
		First Line	Second Line	Third Line	First Line	Second Line
1	Abacavir 20mg/mL Syrup, Bottle of 240mL				Yes	
2	Abacavir 60mg+Lamivudine 30mg, Box of 60 tabs				Yes	Yes
3	Abacavir 600mg+Lamivudine 300mg, Box of 30 tabs	Yes	Yes		Yes	Yes
4	Atazanavir 150mg, Box of 60 tabs				Yes	Yes
5	Atazanavir 200mg, Box of 60 tabs				Yes	Yes
6	Atazanavir/Ritonavir 300/100mg, Box of 30 tabs	Yes	Yes	Yes	Yes	Yes
7	Darunavir 600mg, Box of 60 tabs			Yes		
8	Dolutegravir 50mg, Box of 30 tabs	Yes			Yes	
9	Efavirenz 200mg, Box of 90 tabs				Yes	
10	Efavirenz 50mg, Box of 30 tabs				Yes	
11	Efavirenz 600mg, Box of 30 tabs	Yes			Yes	
12	Etravirine 100mg, Box of 120 tabs			Yes		
13	Lamivudine 150mg+Zidovudine 300mg, Box of 60 tabs		Yes	Yes	Yes	Yes
14	Lamivudine 10mg/mL Syrup, Bottle of 240mL				Yes	
15	Lamivudine 30mg+Zidovudine 60mg, Box of 60 tabs					Yes

16	Tenofovir 300mg+Lamivudine 300mg + Efavirenz 600mg, Box of 30 tabs	Yes			Yes	
17	Lopinavir/Ritonavir 80/20mg/mL, Box of 5 bottles of 60mL				Yes	
18	Lopinavir/Ritonavir 100/25mg, Box of 60 tabs				Yes	Yes
19	Lopinavir 200mg+Ritonavir 50mg, Box of 120 tabs	Yes	Yes		Yes	Yes
20	Nevirapine 10mg/mL Syrup, Bottle of 240mL				Yes	
21	Raltegravir 400mg, Box of 60 tabs			Yes		
22	Ritonavir 100mg, Box of 60 tabs			Yes	Yes	Yes
23	Tenofovir 300mg+Lamivudine 300mg, Box of 30 tabs	Yes	Yes	Yes	Yes	
24	Tenofovir 300mg, Box of 30 tabs		Yes			
25	Tenofovir/Lamivudine/Dolutegravir 300/300/50mg, Box of 30 tabs	Yes			Yes	

Appendix B. DATA COLLECTION TOOLS

1. Procurement proceedings

		Tender 1 (2017)	Tender 2 (2018)
Recommended criteria/procurement proceeding	Reference	Compliance	Compliance
Tender requirements/needs from the forecasting and supply planning	Supply plan outcomes		
Tendering based on the procurement law and GF quality assurance guidelines	Restrict tendering method		
Contract awarding based on the bidding document criteria and contract signature	Value for money (the lowest qualified bidder)		
Purchase orders issuance	Planned shipments at unit price contracted		
Contract execution	Delivery period and technical specifications		

2. Level of dependency

	Number of GF prequalified manufacturers	Suppliers participated		Stock out (in days)	
		2017	2018	2017	2018
Abacavir 20mg/mL Syrup, Bottle of 240mL					
Abacavir 60mg + Lamivudine 30mg, Box of 60 tabs					
Abacavir 600mg + Lamivudine 300mg, Box of 30 tabs					
Atazanavir 150mg, Box of 60 tabs					
Atazanavir 200mg, Box of 60 tabs					

Atazanavir/Ritonavir 300/100mg, Box of 30 tabs					
Darunavir 600mg, Box of 60 tabs					
Dolutegravir 50mg, Box of 30 tabs					
Efavirenz 200mg, Box of 90 tabs					
Efavirenz 50mg, Box of 30 tabs					
Efavirenz 600mg, Box of 30 tabs					
Etravirine 100mg, Box of 120 tabs					
Lamivudine 150mg + Nevirapine 200mg + Zidovudine 300mg, Box of 60 tabs					
Lamivudine 30mg + Nevirapine 50mg + Zidovudine 60mg, Box of 60 tabs					
Lamivudine 150mg + Zidovudine 300mg, Box of 60 tabs					
Lamivudine 10mg/mL Syrup, Bottle of 240mL					
Lamivudine 30mg + Zidovudine 60mg, Box of 60 tabs					
Tenofovir 300mg + Lamivudine 300mg + Efavirenz 600mg, Box of 30 tabs					
Lopinavir/Ritonavir 80/20mg/mL, Box of 5 bottles of 60mL					
Lopinavir/Ritonavir 100/25mg, Box of 60 tabs					
Lopinavir 200mg + Ritonavir 50mg, Box of 120 tabs					
Nevirapine 10mg/mL Syrup, Bottle of 240mL					
Nevirapine 200mg, Box of 60 tabs					
Raltegravir 400mg, Box of 60 tabs					
Ritonavir 100mg, Box of 60 tabs					
Tenofovir 300mg + Lamivudine 300mg, Box of 30 tabs					
Tenofovir/Emtricitabine 300/200mg, Box of 30 tabs					
Tenofovir 300mg, Box of 30 tabs					
Tenofovir/Lamivudine/Dolutegravir 300/300/50mg, Box of 30 tabs					

Zidovudine 10mg/mL Syrup, Bottle of 240mL					
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3. Suppliers performance

	2017				2018			
	Number of orders in total	Number of orders fully delivered	Number of orders timely delivered	Number of orders delivered with quality issues	Number of orders in total	Number of orders fully delivered	Number of orders timely delivered	Number of orders delivered with quality issues
Abacavir 20mg/mL Syrup, Bottle of 240mL								
Abacavir 60mg + Lamivudine 30mg, Box of 60 tabs								
Abacavir 600mg + Lamivudine 300mg, Box of 30 tabs								
Atazanavir 150mg, Box of 60 tabs								
Atazanavir 200mg, Box of 60 tabs								
Atazanavir/Ritonavir 300/100mg, Box of 30 tabs								
Darunavir 600mg, Box of 60 tabs								
Dolutegravir 50mg, Box of 30 tabs								
Efavirenz 200mg, Box of 90 tabs								
Efavirenz 50mg, Box of 30 tabs								
Efavirenz 600mg, Box of 30 tabs								
Etravirine 100mg, Box of 120 tabs								
Lamivudine 150mg + Nevirapine 200mg + Zidovudine 300mg, Box of 60 tabs								

Lamivudine 30mg + Nevirapine 50mg + Zidovudine 60mg, Box of 60 tabs								
Lamivudine 150mg + Zidovudine 300mg, Box of 60 tabs								
Lamivudine 10mg/mL Syrup, Bottle of 240mL								
Lamivudine 30mg + Zidovudine 60mg, Box of 60 tabs								
Tenofovir 300mg + Lamivudine 300mg + Efavirenz 600mg, Box of 30 tabs								
Lopinavir/Ritonavir 80/20mg/mL, Box of 5 bottles of 60mL								
Lopinavir/Ritonavir 100/25mg, Box of 60 tabs								
Lopinavir 200mg + Ritonavir 50mg, Box of 120 tabs								
Nevirapine 10mg/mL Syrup, Bottle of 240mL								
Nevirapine 200mg, Box of 60 tabs								
Raltegravir 400mg, Box of 60 tabs								
Ritonavir 100mg, Box of 60 tabs								
Tenofovir 300mg + Lamivudine 300mg, Box of 30 tabs								
Tenofovir/Emtricitabine 300/200mg, Box of 30 tabs								
Tenofovir 300mg, Box of 30 tabs								
Tenofovir/Lamivudine/Dolutegravir 300/300/50mg, Box of 30 tabs								
Zidovudine 10mg/mL Syrup, Bottle of 240mL								

Appendix C. CMHS IRB APPROVAL NOTICE



UNIVERSITY of
RWANDA

COLLEGE OF MEDICINE AND HEALTH SCIENCES
DIRECTORATE OF RESEARCH & INNOVATION

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 19th/07/2019

NTIBARIGERA Roger
School Of Medicine and Pharmacy, CMHS, UR

Approval Notice: No 358/CMHS IRB/2019

Your Project Title "*Factors That Affect Commodity Security for Antiretroviral Drugs in Rwanda; Procurement Perspectives*" has been evaluated by CMHS Institutional Review Board.

Name of Members	Institute	Involved in the decision		
		Yes	No (Reason)	
			Absent	Withdrawn from the proceeding
Prof Kato J. Njunwa	UR-CMHS	X		
Prof Jean Bosco Gahutu	UR-CMHS	X		
Dr Brenda Asimwe-Katoera	UR-CMHS	X		
Prof Ntaganira Joseph	UR-CMHS	X		
Dr Tumusiime K. David	UR-CMHS	X		
Dr Kayunga N. Egide	UR-CMHS	X		
Mr Kanyoni Maurice	UR-CMHS		X	
Prof Munyanshongore Cyprien	UR-CMHS	X		
Mrs Ruzindana Landrine	Kicukiro district		X	
Dr Gisboma Darius	UR-CMHS	X		
Dr Donatilla Mukamana	UR-CMHS			X
Prof Kyamanywa Patrick	UR-CMHS		X	
Prof Condo Umutesi Jeannine	UR-CMHS		X	
Dr Nyirazinyoye Laetitia	UR-CMHS	X		
Dr Nkeramihigo Emmanuel	UR-CMHS		X	
Sr Maliboli Marie Josee	CHUK	X		
Dr Mudenge Charles	Centre Psycho-Social	X		

After reviewing your protocol during the IRB meeting of where quorum was met and revisions made on the advice of the CMHS IRB submitted on 19th July 2019, **Approval has been granted to your study.**

Please note that approval of the protocol and consent form is valid for **12 months.**

You are responsible for fulfilling the following requirements:

1. Changes, amendments, and addenda to the protocol or consent form must be submitted to the committee for review and approval, prior to activation of the changes.
2. Only approved consent forms are to be used in the enrolment of participants.
3. All consent forms signed by subjects should be retained on file. The IRB may conduct audits of all study records, and consent documentation may be part of such audits.
4. A continuing review application must be submitted to the IRB in a timely fashion and before expiry of this approval
5. Failure to submit a continuing review application will result in termination of the study
6. Notify the IRB committee once the study is finished

Sincerely,

Date of Approval: The 19th July 2019

Expiration date: The 19th July 2020



Professor GAHUMANA Jean Bosco
Chairperson Institutional Review Board,
College of Medicine and Health Sciences, UR

Cc:

- Principal College of Medicine and Health Sciences, UR
- University Director of Research and Postgraduate Studies, UR

Appendix D. NHRC SCIENTIFIC REVIEW APPROVAL NOTICE

Republic of Rwanda



MINISTRY OF HEALTH

National Health Research Committee
Ref: NHRC/2019/PROT/044

To: **Roger NTIBARIGERA**
Principal Investigator

Scientific Review Approval Notice

With reference to your request for approval of the Research Protocol entitled; **"Factors that affect commodity security of antiretroviral drugs in Rwanda: Procurement perspectives ."**; We are pleased to inform you that, following a thorough review and critical analysis of your proposal (NHRC/2019/PROT/044), your Research Protocol has been approved by National Health Research Committee.

However,

- 1) Changes amendments on approach and methodology must be submitted to the NHRC for review and approval to validate the changes.
- 2) Submission to NHRC of final results is mandatory
- 3) Failure to fulfill the above requirements will result in termination of study

Once again National Health Research Committee appreciates your interest in research and requests you to submit this proposal to the National Ethics Committee (NEC) and then share a copy of the approval letter from them.

Your final approval reference number is **NHRC/2019/PROT/044**.

Sincerely,

A handwritten signature in black ink, appearing to be 'Pfaiff Uwaliraye'.

Dr. Pfaiff UWALIRAYE
Chairperson of NHRC

Date: 05/03/19